The Psychological Impact of Screening for Preeclampsia: A Qualitative Investigation

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Declaration

This thesis is a presentation of my original research work. Wherever contributions of others are involved, every effort is made to indicate this clearly, with due reference to the literature and acknowledgement of collaborative research and discussions.

An edited version of chapter 5 has been published in a peer-reviewed professional journal.

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ABSTRACT

Background: The screening test, to establish risk status for pre-term preeclampsia (PE), is a relatively recent medical advancement. Although the psychological impact of screening for various maternal conditions is well established, it is currently unknown as to the impact of screening for pre-term PE. PE is a condition which can affect not only the mother's health but also the health of her unborn child.

Aims: The primary aim of this thesis was to explore the psychological impact of screening for pre-term PE risk status, comparing the illness representations of women identified as high-risk with those identified as low-risk. The studies in this thesis also address how women reflect on their experiences of screening for pre-term PE, the factors that influenced them to take part, and how they would feel about participating in pre-term PE risk screening in the future. Finally, the studies in this thesis ran in conjunction with a medicated RCT, investigating the effects of aspirin versus a placebo in reducing pre-term PE incidence. This thesis also sought to establish the factors that influence participation or non-participation in the RCT.

Methods: This is a qualitative thesis; semi-structured interviews were conducted with high- and low-risk women, after they had been screened and found out their risk status. The interview template was informed by the Common-Sense Model of illness representations and transcripts were analysed using Template Analysis.

Results: The women who participated in these studies did not report experiencing any adverse psychological effects as a result of the screening process or finding out their risk status for pre-term PE. Women held positive views towards prenatal screening in general and also screening for pre-term

PE risk. Low-risk women felt reassured as results provided comfort. High-risk women were encouraged that they would receive appropriate medical care and be more aware themselves of signs or symptoms of PE. For those high-risk women invited to participate in a medicated RCT, women demonstrated good knowledge of the trial suggesting they made fully informed decisions. The main factor that influenced non-participation in the trial was negative attitudes towards taking medication during pregnancy and worries around potential side effects. Participants of the trial reported that their main reason for taking part was the close medical attention they would receive. They believed the extra medical awareness from the trial, and extra scan appointments, would be beneficial and reassuring, regardless of whether they were included in the active or placebo arm of the RCT.

Conclusions: The current research indicates that women did not, generally, experience adverse psychological effects from being screened or receiving their result for pre-term PE. This contributes and supports the previous research suggesting screening for pre-term PE risk should be recommended. This study also suggests that in order to increase uptake, in both medicated pregnancy RCTs and with aspirin for the prevention of pre-term PE, women would benefit from receiving more knowledge and understanding around the safety of taking such medications during pregnancy, from medical staff.

CHAPTER ONE
1 GENERAL INTRODUCTION

INTRODUCTION

The current research aims to investigate the psychological impact of screening for preeclampsia (PE) risk status. PE is a hypertensive disorder of pregnancy, which poses a significant risk to both maternal and fetal mortality and morbidity (Steegers, von Dadelszen, Duvekot, & Pijnenborg, 2010). Between 2% and 8% of pregnancies are affected by PE (Duley, 2009), with complications including placental insufficiency (WHO, 2011) and maternal organ dysfunction (Sibai, Dekker, & Kupferminc, 2005), as well as fetal growth impairment and low birth weight (Yu, Khourni, Onwudiwe, Spiliopoulos, & Nicolaides, 2008). Research has found that in cases where the condition is severe, with pre-term onset, the health outcomes are more adverse, compared to women who reach full term (Witlin, Saade, Mattar, & Sibai, 2000; Yu et al., 2008).

Although there are risk factors for PE, such as obesity, diabetes and chronic hypertension (WHO, 2011), the cause is not yet known (Steegers et al., 2010) and symptoms, such as increased blood pressure and protein in the urine, are often not immediately recognisable (Meher, & Duley, 2006). It has therefore been suggested that early identification of those at-risk of PE could result in improved pregnancy outcomes, through early diagnosis and thus prevention of serious complications (Poon, Kametas, Maiz, Akolekar, & Nicolaides, 2009).

A method through which women, at-risk of developing PE, could be identified is prenatal screening. Screening tests are conducted on healthy populations, with the aim of identifying individuals who may be at-risk of developing illnesses and diseases, and beginning preventative measures and treatments (Green, Hewison, Bekker, Bryant, & Cuckle, 2004).

Following extensive research, a screening technique has been developed with the ability to identify women, at 11-13 weeks gestation, as either high- or low-risk for developing pre-term PE (Akolekar, Syngelaki, Poon, Wright, & Nicolaides, 2012; Poon, Syngelaki, Akolekar, Lai, & Nicolaides, 2012). Risk status is established by combining maternal history and characteristics with biophysical and biochemical factors (Poon et al., 2012). The screening test for PE is, however, not diagnostic and can only indicate risk status for the likelihood of developing PE during pregnancy (Harris, Franck, Green, & Michie, 2014).

Screening for pre-term-PE risk status is considered as relatively innovative, and it is not yet offered routinely in the UK. Introduction of novel screening tests is endorsed in the UK if the benefits outweigh any physical and psychological harm (UK National Screening Committee (NSC), 2011; Gray, 1998). In the most recent review of recommendation of PE screening in pregnancy, by the UK National Screening Committee (UK NSC, 2011), a nationally managed screening programme for PE was not recommended. This was due to a lack of research regarding predictive tests and preventive treatments (UK, NSC, 2011).

Since that review was conducted, evidence has been found that the combination test of maternal characteristics, biophysical and biochemical markers, has found to be accurate in predicting early PE (occurring before 34 weeks gestation) risk status (95.3%), with a low false positive rate (10.9%; Poon et al., 2012). However, due to a lack of research in this area, the psychological impact of PE screening remains unclear. It is essential that the psychological effects of screening are explored and identified in order to endorse or discourage the use of PE screening. Concerns associated with the introduction of novel prenatal screening tests include whether being identified as screen-positive (high-risk) will increase women's distress in terms of elevations in anxiety, worry about the health of the baby and her own health, impact on mood and reduced quality of life generally (Marteau et al., 1993; Shickle & Chadwick, 1994; Gray, 1998). On the other hand, there could also be potential benefits; apart from the reassurance provided to those who

are identified as low-risk and the possibility of successful treatment in those identified as high-risk, there could also be additional benefits for the mother, and her unborn child, in terms of positive changes in maternal health behaviours (e.g. Griffiths, Rogers, & Moses, 1993; Nabhan & Faris, 2010).

Following the UK NSC review in 2011, research has also been on going to address the lack of preventive treatments available to those identified at risk, in particular the use of low-dose aspirin from <14 weeks gestation (Fetal Medicine Foundation, 2016). Previous research showed a reduction in pre-term PE when low-dose aspirin was administered before 16 weeks gestation and taken throughout the pregnancy, although results were limited due to small sample sizes in previous trials (Roberge et al., 2012). A large-scale multicentre trial (the ASPRE trial) has been underway since 2013 with the aim of examining the use of daily low-dose aspirin (compared to a placebo) on PE incidence, when taken from the first trimester, in women screened and identified as high-risk for pre-term PE (Fetal Medicine Foundation, 2016).

Research to date has identified various factors, which influence participation in RCTs during pregnancy. The role of risk (to both mother and foetus), the procedure and requirements of the trial, as well as the context and content of information given, seem to be significant motivating factors in trial participation (Kenyon, Dixon-Woods, Jackson, Windridge, & Pitchforth, 2006; Snowdon, Elbourne, & Garcia,, 2006; Tooher, Middleton, & Crowther, 2008; Smyth, Jacoby, & Elbourne, 2012; Oude Rengerink, Logtenber, Hooft, Bossuyt, & Mol, 2015). However, for some women these same factors (e.g. trial procedure, content of information, potential risk) have also been found to discourage participation in prenatal trials (Mohanna & Tunna, 1999). There remains a significant lack of research regarding the process of decision-making in expectant mothers who are offered a pharmacological intervention, when they are identified as being high-risk of a condition, such as PE.

Given the serious health threat pre-term PE poses to both mother and foetus, and taking into consideration recent developments in screening for PE risk status, it is necessary for research to be conducted to establish the psychological impact of participating in screening. Furthermore, investigating reasons for participation and non-participation in the ASPRE trial may provide insight into women's attitudes towards taking preventative medications during pregnancy.

1.1 THEORETICAL FRAMEWORK: THE COMMON-SENSE MODEL OF ILLNESS REPRESENTATIONS

Health psychology research, including influences on health behaviours and adherence to treatment, has become particularly prominent in recent decades (Hagger & Orbell, 2003). It has been identified that for health psychology research to appropriately inform practice, research should have theoretical foundations (Leventhal, 1970). A theoretical framework provides the context from which phenomena can be understood, clearly and efficiently (Price, Jhangiani, & Chiang, 2015). It also allows researchers to make predictions about behaviour and likely behavioural patterns (Price et al., 2015).

Various theoretical frameworks have been developed using cognitive, environmental and social factors to help explain and understand individuals' actions and behaviours to improve health or when faced with illness threats (Diefenbach & Leventhal, 1996; Hagger & Orbell, 2003). Several health behaviour models have been developed, including the Health Belief Model (Hochbaum, Rosenstock, & Kegels, 1952), the Theory of Reasoned Action/Planned Behaviour (Ajzen, 1991) and Social Cognitive Theory (Bandura, 1989). A further model is the Common Sense Model (CSM) of illness representations (also known as the Self-Regulation Model, but shall be referred to here as the CSM; Leventhal, Meyer, & Nerenz, 1980).

The HBM (Hochbaum, Rosenstock & Kegels, 1952) was originally developed to understand and predict health behaviours and has since been used with a

variety of populations including addiction and smoking cessation (Tong, Chen & Wu, 2019). The HBM initially consisted of a framework of five variables, through which health behaviours could be predicted: perceived severity, perceived susceptibility, cues to action, perceived benefits, and perceived barriers (Jones, Smith & Llewellyn, 2014). Although these simplified health constructs could be viewed as a strength of the model, the simplicity also opens it up to criticisms. The HBM does not explain potential relationships between the variables and so there is not a clear understanding of how or if they are related (Orji, Vassileva and Mandryk, 2012). The effect sizes reported for the variables as predictors of health behaviours have also been small, leading to researchers including and adapting the model, including adding new variables, although these are usually specific to the area of research (Orji, Vassileva and Mandryk, 2012).

In contrast, the CSM has a greater number of dimensions contributing to an overall picture of both cognitive and emotional illness representations (Hagger & Orbell, 2003; Leventhal, Myer & Nerenz, 1980). Addressing one of the potential weaknesses of the HBM, the CSM also suggests that individuals engage in parallel processing when faced with a health threat and identifies how the illness representations interlink (Diefenbach & Leventhal, 1996; see figure 1.1). The HBM can be criticised for emphasising the rational nature of illness beliefs and discounting the impact of emotion on decision making (McCaffery et al., 2014). The inclusion of both cognitive and emotional illness representations in the CSM is both novel and a strength of the theory (McBride, 2021). The parallel processing of both cognitive and affective pathways meant that the CSM was a more appropriate framework for the current research, rather than a model such as the HBM. It was expected that emotional illness representations would be evident and important as previous research has identified that women experience higher levels of anxiety when being screened for fetal conditions (Harris et al., 2012). Although levels of anxiety are not increased when screening takes place for maternal conditions, PE is a symbiotic condition and, therefore, a greater emotional response may be expected.

There have been some mixed findings in terms of the effectiveness of the CSM in predicting psychological and behavioural outcomes. For example, in a meta-analysis of 30 studies, Brandes and Mullan (2014) reported low-effect sizes and argues that this suggested weak relationships between CSM illness representations and adherence in chronically ill patients. However, such results address different research questions and concerns than the current study. The focus of the current study is not adherence to a particular treatment plan but to explore the psychological impact of screening for pre-term PE and to compare the illness representations of women identified as high- and low-risk. As Leventhal et al. (2016) state, predictive analyses are often linear and do not account for the complexity of interactions between illness representations which may result in low-effect sizes. It can be argued that the value of the CSM comes from its ability to help researchers to understand the complex relationships between illness representations and develop a greater understanding, particularly within a qualitative context (Leventhal et al., 2016).

In contrast to the findings of Brandes and Mullan (2014), an earlier meta-analysis concluded that predictable relationships between illness cognitions, coping and outcomes were valid (Hagger & Orbell, 2003). They also acknowledge limitations in studies where effect sizes were reported as low-to-moderate, as many studies use broad checklists to report coping styles. In terms of the current study, a deeper understanding is sought, given the symbiotic nature of pre-term PE and the associated risks. Using the CSM framework in a qualitative context, such as the current study, will reduce concerns associated with such limitations.

1.1.1 THE COMMON-SENSE MODEL OF ILLNESS REPRESENTATIONS

The CSM differs to other health behaviour models as it identifies an individual's perceptions of a health threat, both cognitively and emotionally,

also recognising that individuals appraise their beliefs, which subsequently impacts health behaviours and coping methods (Kucukarslan, 2012).

According to the CSM, upon receiving a health threat or diagnosis individuals form representations of their illness. These illness representations are formed by the perception and interpretation of different sources of information including previous knowledge of the illness (through culture and society), input from authoritative figures or significant others (e.g. doctors, family) and current illness experiences (symptoms, knowledge of coping methods and their effectiveness) (Diefenbach & Leventhal, 1996; Hagger & Orbell, 2003; Orbell, O'Sullivan, Parker, Steele, Campbell, & Weller, 2008). Leventhal, Meyer and Nerenz outlined the CSM of illness representations in their 1980 paper, after developing the model following their earlier research, investigating fear communication and distress control (e.g. Leventhal, 1970). Studies demonstrated that when individuals are exposed to a health-related fear message (low or high) as well as a second message, which facilitates the development of an action plan, they are more likely to engage in a recommended health behaviour than if they were presented with neither or a single message (e. g. Leventhal & Niles, 1965; Leventhal, Singer, & Jones, 1965). Research has since suggested that engaging in specific health behaviours is a result of a change in thinking about, or representation of, the health threat (Diefenbach & Leventhal, 1996).

From the data patterns that emerged from fear communication research and in the development of the CSM, Leventhal et al. (1980) identified the individual as an active problem solver (Diefenbach & Leventhal, 1996). The individual also engages in a system of parallel processing of health threats, dealing with the emotional reaction as well as the cognitive perceptions (see figure 1.1). After receiving a health threat an individual's illness representation will be activated; an individual will simultaneously have emotional, cognitive and behavioural responses (Leventhal, Leventhal, & Cameron, 2001). The subsequent coping behaviours then lead to appraisals of the individual's response. This process is then repeated in the opposite direction, so that outcome appraisals are revised, resulting in reconsideration

of the coping behaviours and possibly an alteration in the illness representation. The model is illustrated in figure 1.1.

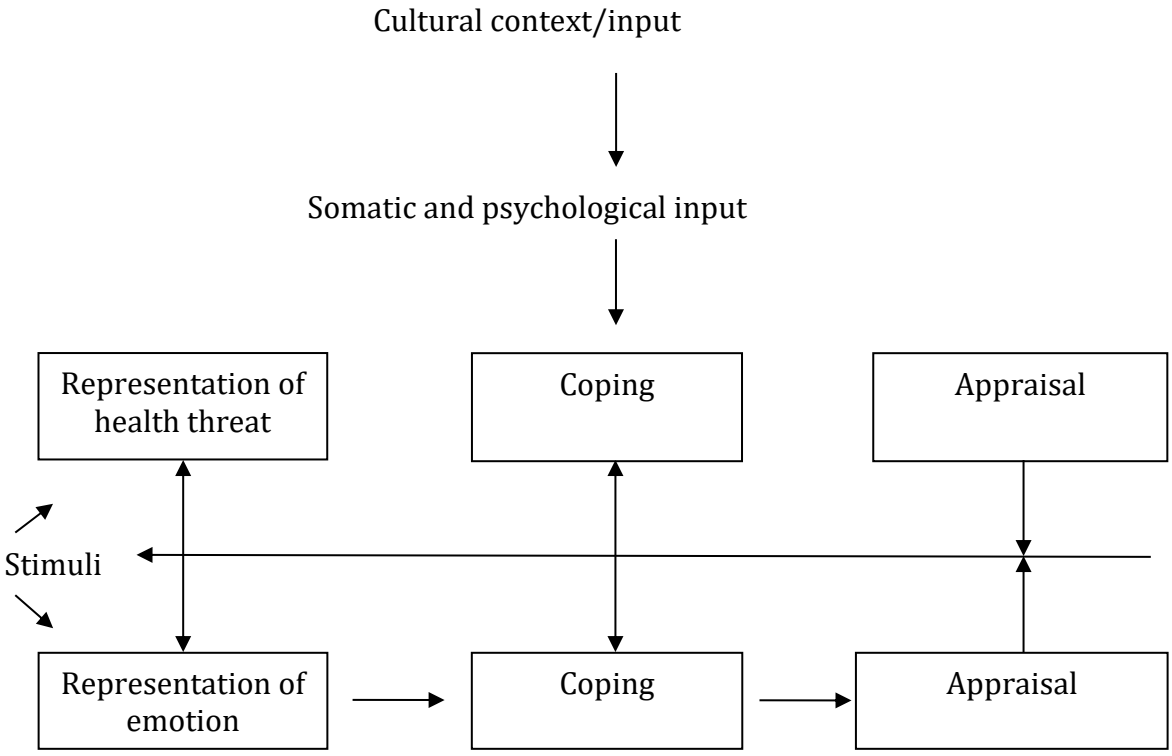

Figure 1.1 Leventhal's common-sense model of illness representations (taken from Diefenbach & Leventhal, 1996).

According to Diefenbach and Leventhal (1996) the parallel processing of cognitive and emotional responses occurs within two contexts: the individual, personal context and the social, cultural context. *The individual, personal context* refers to the impact of prior illness experiences or symptoms, as well as known family health history and genetic factors. Thus, when an individual is processing a health threat, they will do so within the context of their knowledge of their own health. *The social, cultural context* also influences illness representations; social etiquette and cultural expectations may affect the ways in which an individual reports or understands their symptoms. It has also been suggested that individuals are further influenced by social

interactions, after disclosing and discussing details of their symptoms with others (Diefenbach & Leventhal, 1996).

As well as the different contexts, which are relevant to the construction of illness representations, three 'rules' have been identified that apply to the CSM (Diefenbach & Leventhal, 1996): the symmetry rule, the stress-illness rule and the age-illness rule. These rules are used, by individuals facing a health threat, to identify symptoms and illnesses.

The symmetry rule is key to the development of illness representations (Leventhal, 1990). This rule suggests that the formation of illness representations is a two-level process: individuals perceive and interpret both concrete and abstract sources of information (Hagger & Orbell, 2003). For example, an individual will look for a specific illness which matches and can explain their symptoms (they will search semantic memory for abstract information), whilst the identification of an illness simultaneously prompts an individual to look for symptoms associated with the illness (based on concrete knowledge of an illness) (Hagger & Orbell, 2003). Symptoms give a concrete reflection of the state of the illness and individuals can base beliefs regarding how well/unwell they are on the presence of symptoms (Leventhal et al., 1980). Individuals may also disengage from treatment if their symptoms subside, or re-engage with treatment if symptoms reappear (Meyer, Leventhal, & Gutmann, 1985). The symptoms can, therefore, be an important factor in developing a coping strategy and treatment adherence.

The stress-illness rule dictates that symptoms are attributed to either a medical condition or stressful life events. An individual experiencing symptoms of illness, injury or disease would be attributed to a medical cause. However, when there are no obvious signs of disease or illness, an individual might attribute their symptoms to stressful life events (Cameron, Leventhal, & Leventhal, 1995). The stress-illness rule is, therefore, determined by the type of symptoms experienced.

The final rule, *the age-illness rule*, concerns whether the symptoms could be attributed to the natural aging process, or specific illness. It has been reported that symptoms that are familiar and gradual in onset, are attributed to aging

and so care or medical attention is not sought (Diefenbach & Leventhal, 1996). However, when symptoms occur suddenly individuals are more likely to seek professional, medical assistance (Prohaska, Keller, Leventhal, & Leventhal, 1987).

1.1.2 DIMENSIONS OF THE CSM

Data from qualitative interviews led to general agreement among researchers that illness representations can be logically ordered into different dimensions (Hagger & Orbell, 2003; Linz, Penrod, Leventhal, & Siverhus, 1982; Meyer et al., 1985). Initially the cognitive level of illness representations was originally categorised into four dimensions: identity, cause, consequence and timeline (Hagger & Orbell, 2003; Leventhal et al., 1980). The *identity* aspect relates to the labelling of an illness or health threat and any knowledge the individual has of their illness (Diefenbach & Leventhal, 1996). Upon the diagnosis, a patient may make statements where it is evident they embody the illness and related symptoms (Hagger & Orbell, 2003). *Cause* refers to the reason why the illness has occurred, which can be perceived as biological, emotional, environmental or psychological (Hagger & Orbell, 2003). Issues in researching the cause dimension can arise from factors which overlap, for example depression can be identified as emotional and psychological; the need for single item measures to establish cause has thus been emphasized in order to ensure causal items are illness-specific (Hagger & Orbell, 2003; Moss-Morris, Weinman, Petrie, Horne, Cameron, & Buick, 2002). In terms of the illness representation dimensions, *consequence* refers to the impact the illness could have on an individual's quality of life, ability to function or economic status (Diefenbach & Leventhal, 1996; Hagger & Orbell, 2003). *Timeline* is the dimension associated with an individual's beliefs regarding the time scale of both the overall illness and specific symptoms (Hagger & Orbell, 2003); generally, patients will project their expected timeframe on their illness, either acute (specific cause, short timeline), chronic (numerous causes, long timeline) or cyclic (recurrent cause, prolonged timeline) (Diefenbach & Leventhal, 1996; Lau & Hartman, 1983).

An individual's views of these dimensions will result in the overall illness representation. The process of interpreting these dimensions and the creation of the illness representations is multidirectional (Diefenbach & Leventhal, 1996). As an individual gathers more information regarding an illness or health threat their opinions of each representation may change. However, whilst the correlations between the dimensions have been found to be significant, research has found that there is not a conceptual overlap (Weinman et al., 1996). The illness representations also determine which coping methods are used, and similarly these will continually be evaluated and altered depending on the perceived identity, cause, consequence and timeline.

Cure/control was a fifth illness dimension proposed by Lau and Hartman (1983). They suggested that previous research had focused on chronic and severe illnesses and thus a possible cure dimension had been overlooked. Cure/control refers to the perceived ability to dictate the outcome of the illness and the perceived effectiveness of treatment (Diefenbach & Leventhal, 1996; Lau & Hartman, 1983). The five cognitive dimensions of illness representation have found to be validated within various clinical conditions, in studies using differing methodologies (e.g. Skelton & Croyle, 1991; Weinman, Petrie, Moss-Morris, & Horne, 1996).

In parallel to the cognitive level, an individual will also be experiencing a range of emotions (Diefenbach & Leventhal, 1996). Although not included in the original CSM, the emotional representations have been found to be as equally relevant and important to the model (Moss-Morris et al., 2002). Emotional reactions are elicited upon learning of symptoms, an illness or a health threat and continually throughout treatment and following coping mechanisms, and as a direct result of experiencing symptoms (e. g. flu symptoms may cause feelings of anger or annoyance as they disrupt day to day life). As shown in figure 1.1, the emotional and cognitive representations are interactive as well as parallel.

1.1.3 MEASURING THE CSM

Initially in-depth, semi-structured interviews were used to elicit and assess illness representations (Leventhal & Nerenz, 1985); this method was fruitful but time consuming and produced vast amounts of varying data (Weinman et al., 1996). Early attempts to produce quantitative questionnaires to elicit and understand illness representations (e.g. Lacroix, 1991; Prohaska, Leventhal, Leventhal, & Keller, 1985) were unsuccessful, generally because they were not theoretically derived and were not validated across different patient groups (Weinman et al., 1996). Thus Weinman et al. (1996) sought to develop an assessment questionnaire, based on the CSM, to understand illness representations, the consequences for coping and potential interventions, which could be flexible enough to use with various patient groups but remain psychometrically valid. The result was the Illness Perception Questionnaire (IPQ) (Weinman et al., 1996), which included items to specifically assess the five cognitive dimensions of illness representations. Although the IPQ was found to be psychometrically valid, with good internal consistency and test-retest reliability, Weinman et al. (1996) believed that a brief interview, focusing on the patient's ideas regarding the five dimensions, would be beneficial. This would only be if there were no time constraints and if the brief interview could take place directly before completing the IPQ. When tested they found the interview had a slight 'priming effect' and activated CSM-related illness schemata (Weinman et al., 1996). The IPQ has since been used with varying patient groups and across different illnesses, including heart disease (e.g. Cooper, Lloyd, Weinman, & Jackson, 1999), rheumatoid arthritis (e. g. Pimm & Weinman, 1998), cancer (e. g. Buick, 1997) and diabetes (e. g. Griva, Meyers, & Newman, 2000).

Research supports the relationships between the five cognitive dimensions, as well as links between illness representations and psychological outcomes, such as coping and adherence to treatment (Moss-Morris et al., 2002). However, it was identified that the subscales of the IPQ for cure/control and

timeline had internal consistency difficulties. The cure/control subscale had items loading on to two separate factors, regarding personal control and recommended treatment/advice control. The timeline subscale was found to have low internal consistency values and a need to asses more items, including cyclical beliefs (Moss-Morris et al., 2002). The emotional level responses that Leventhal et al. (1980) discussed in their original model had also been overlooked during the initial development of the IPQ and so Moss-Morris et al. (2002) wanted to rectify these issues in their revised illness perception questionnaire (IPQ-R).

In developing the IPQ-R, Moss-Morris et al. (2002) used factor analyses to separate the cure/control (personal and treatment) and timeline (acute, chronic and cyclical) subscales. A further goal of the IPQ-R was to assess the way in which a patient evaluates their illness representation as useful; this was termed illness *coherence* (Moss-Morris et al., 2002). The IPQ-R was recognised as improving the reliability of both the cure/control and timeline subscales, as well as strengthening the overall psychometric properties; simultaneously the IPQ-R supports the separation of the cognitive and emotional levels of the CSM. The authors emphasised the flexibility of the IPQ-R, encouraging future researchers to modify the assessment tool to suit particular populations (Moss-Morris et al., 2002).

More recently, further developments have been made to the IPQ and IPQ-R; Broadbent, Petrie, Main, & Weinman (2006) argued that both the IPQ and IPQ-R, although proven to be reliable and valid, were extremely long and could be improved for patients who are very ill or when time for assessment is limited. They developed a shorter questionnaire (9 items), which uses one question that summarises each subscale of the IPQ-R; five items assess the cognitive dimensions (timeline, consequences, personal control, treatment control, identity), two items assess emotional dimensions (concern and emotions), as well as one item to assess illness coherence and patients are asked to list the three most important factors to establish the cause dimension. As with its predecessors the Brief-IPQ has been found to have

good test-retest reliability and it was found to have good associations with the IPQ-R on all dimensions (Broadbent et al., 2006). Ultimately it was suggested that researchers should use the IPQ-R when seeking a detailed analysis of illness representations, with the Brief-IPQ being particularly useful in very ill or elderly populations where a longer questionnaire is not feasible.

1.1.4 THE CSM AND ILLNESS: PREVIOUS RESEARCH

To date, most research concerning illness representations has been conducted with ill populations (Hagger & Orbell, 2003); the conditions that have previously been investigated are also often chronic, such as chronic fatigue syndrome (e. g. Moss-Morris, Petrie, & Weinman, 1996), diabetes (e. g. Griva et al., 2000) and hypertension (e. g. Meyer, Leventhal, & Gutman, 1985). Chronic illnesses were identified as appropriate to study in relation to the impact of illness representations on behaviour for several reasons: patients are usually required to engage in long-term recommended behaviours, such as diet alteration and medication adherence, and they can often become major public health issues, when failure to adhere to recommended health behaviours results in increased morbidity and mortality rates (Meyer et al., 1985).

Hypertension is an example of a chronic illness of great research interest and importance (Meyer et al., 1985). An early study aimed to investigate whether hypertension patients develop illness representations in line with the CSM and if so, the impact these representations then have on their behaviours in response to their diagnosis (Meyer et al., 1985). Illness representations formed by hypertensive patients were found to be incoherent; few participants were able to identify connections between the causes, symptoms and physiological mechanisms of their illness. The authors suggested that participants developed such inaccurate models because the focus tended to be on their symptoms (and subsequent meanings) and the effectiveness of treatment (Meyer et al., 1985). Patients also did not tend to worry about the

cause of the illness until the immediate symptoms are alleviated and they were less concerned with the consequence of the illness as hypertension generally does not impact daily life (Meyer et al., 1985). Meyer et al. (1985) also state that many believe it is the responsibility of the doctor to understand the mechanisms of the illness and so patients are less inclined to do so themselves.

In 2003, a comprehensive meta-analysis of CSM research identified 57 quantitative studies, which investigated illness representations of participants suffering from 23 illnesses and conditions (Hagger & Orbell, 2003). The meta-analysis sought to examine the construct and discriminant validity of the illness representation dimensions of the CSM and investigate the relationships between illness representations, coping behaviours and illness outcomes. The results found that strong perceptions of illness identity were significantly, positively related to coping strategies, specifically avoidance and emotion expression. Similarly, perceptions of the illness as chronic, of serious consequences and highly symptomatic were also correlated with avoidance and emotion expression. Cognitive reappraisal, expressing emotion and problem-focused coping strategies were associated with perceived controllability of the illness. The meta-analysis also found that perceptions of the illness as curable/controllable were significantly, positively related to psychological well-being, social functioning and vitality, whilst also negatively related to psychological distress and disease state. The consequence, identity and timeline dimensions were negatively related to psychological well-being, social functioning and vitality. There was also significant support for the construct and validity of the cognitive illness representation dimensions, and the associated measures, including the IPQ and IPQ-R (Hagger & Orbell, 2003). Overall, Hagger & Orbell (2003) claim that participants are consistent in their development of illness representations, regardless of which illness they experience. It is suggested the CSM and illness representations remain valid across illnesses as it is based on cognitive theory. With the exception of the common cold (considered an acute illness; Lau, Bernard, & Hartman, 1989), the studies included in the meta-analysis

were chronic, symptomatic conditions. Hagger and Orbell (2003) identify this as a limitation, of their meta-analysis and the literature in general; up until this point there was a lack of research exploring illness representations with short-term conditions and at-risk populations.

Research has demonstrated that, within ill populations, the various dimensions of the CSM are valid and relationships are present between illness representations, coping behaviours and illness outcomes (Hagger & Orbell, 2003). However, increasingly research has begun to address healthy populations and those who may be at risk of illness (e.g. Cameron, 2008; Hilgart, Mercer, & Thirlaway, 2012).

1.1.5 THE CSM AND AT-RISK POPULATIONS

Whilst often applied to actual illness, the CSM can also be used in relation to health threatening information and potential risks. Screening for illness and health risks is an area where the CSM is particularly beneficial to understand how individuals think about their test results and possible conditions. In line with the CSM, it would be expected that following an abnormal screening result, regardless of what the screening was for, an individual will regard the information as threatening, and instinctive emotional reactions and coping responses will be activated (Orbell et al., 2008).

With technological and medical advances, in recent years it has become increasingly possible to screen individuals for a variety of potential illnesses and genetic risks (Senior, Marteau, & Peters, 1999). Screening is extremely beneficial in terms of early detection of illness and treatment (Bass et al., 2013) and for those who screening identifies as 'at-risk' of a condition, individuals are able to make changes to reduce their risk status (e.g. lifestyle changes and using medication; Cameron, Marteau, Brown, Klein, & Sherman, 2012). However, Cameron et al. (2012) note that behavioural changes as a result of risk status screening would be dependent on the extent to which an individual perceives the risk as significant and personal, as well as the extent

to which a change in behaviour could impact their risk status. This emphasises the importance of illness representations in the context of at-risk populations.

Research investigating illness representations in populations being screened for illnesses, or to determine their risk status, is important to encourage and facilitate behaviour change and reduce morbidity and mortality rates (Senior et al., 1999). Shiloh, Drori, Orr-Urteger, & Friedman (2009) wanted to explore whether being identified as at-risk for cancer, through a screening programme, would result in variations in the illness representations that were elicited. They hypothesised that those identified as at-risk due to different causes would also differ in their subjective representations regarding the degree and cause of risk. Shiloh et al. (2009) also predicted that the subjective representations would vary in their influence on levels of worry, health anxiety and self-assessed health. Three participant groups were included, based on the objective causes of an at-risk status (environmental, genetic and behavioural) as well as a control group with no recognised risk factor. Risk perceptions were measured using scaled questionnaires, whilst standardised questionnaires were used to measure illness attributions, worry and health anxiety. The results supported the prediction that being at an objectively increased risk for cancer is associated with increased perceived risk and causal attributions, which in turn is associated with health and anxiety and worry. There were no reported differences between the groups, which, Shiloh et al. (2009) claim, suggests that individuals use cognitive processes to avoid unnecessary stress and worry about potential health risks. They suggest that individuals adopt biased risk perceptions; however, this was not the case in the genetic group, who adopted a more 'realistic' acknowledgement of their risk. This finding highlights the importance of understanding cause representations of the CSM, particularly with under-researched populations. The limited nature of the quantitative design restricts the interpretations that can be made from these results. A further limitation of this study is that participants were not screened for their actual risk status and were instead chosen for their potential risk based on

genetic, environmental or behavioural factors. In order to better understand the range of individualised representations, further work needs to be done to explore the subjective ideas and beliefs. This study suggests that emotional and cognitive effects cannot be predicted or understood by risk status alone.

Illness representation research can also help health professionals understand patients' thought processes when deciding whether to participate in screening, and thus inform interventions to encourage uptake of screening (Sherman, Miller, Shaw, Cavanagh, & Sheinfeld Gorin, 2014). For example, a systematic review explored psychosocial approaches to participation in genetic risk assessment for breast cancer among African American women (Sherman et al., 2014). The review found that a combination of the CSM's cognitive and emotional representations influence the decision to participate in genetic screening for the BRAC1/2 genes, including knowledge about cancer genetics, fatalistic beliefs and perceiving themselves at high risk of developing breast cancer. Understanding these factors, in relation to specific health risks may enable researchers and practitioners to better predict those who may participate in screening or facilitate understanding of those who decline. The authors suggest that through identifying factors, which influence participation in screening, interventions can then be developed to target the decision-making within the relevant at-risk populations. However, the majority of studies included in the review recruited participants from clinics and hospitals where women paid for treatment, suggesting a certain level of income and possibly education. Therefore, questions remain regarding the generalisability of this research and whether they would be replicated in the general population. This study presents a further question as to how much intersectionality and background can impact and should be considered when exploring cognitive and affective representations.

Cognitive and emotional factors were also found to influence the decision-making process in an elderly population offered screening for bowel cancer (McCaffery et al., 2001). Semi-structured interviews took place with 60 individuals, aged 55-64 years, who had been offered a flexible sigmoidoscopy

screening to detect bowel cancer risk, but declined. The authors were interested in those who did not respond to the offer of screening (n=20), those who indicated they were definitely not interested (n=20) and those who stated they were probably not interested in screening (n=20). The results showed that perceived susceptibility to bowel cancer was an important factor for individuals deciding whether to engage in screening. Avoidance was also a predominant theme, whilst procedural barriers (including pain and embarrassment) and practical barriers (e. g. travel and time) were not regarded as significant in terms of decision-making (McCaffery et al., 2001). The authors analysed the results using a range of frameworks, including the CSM through which they interpreted the emotional and avoidance aspects of participants' accounts. The HBM was used to interpret the cognitive representations, such as perceived susceptibility. Again, the study provides an understanding of the decision-making process individual's go through when offered screening for illnesses, and the factors that influence their decision to decline, highlighting areas for potential interventions to focus on. However, a limitation of the study is the use of multiple theoretical frameworks to address their question. Using the CSM to address both the cognitive and affective representations would provide continuity in interpretations of the results. It may also provide an understanding of the complexities of the relationships between representations, as the CSM's parallel processing suggests.

In a study exploring the relationship between cognitive and emotional illness representations, in individuals with abnormal cancer screening results, it was found that cognitive representations accounted for significant variation in reported emotions (Hagger & Orbell, 2006). It was also found that emotional illness representations accounted for variation in emotional responses. The study included both men and women who received either abnormal cervical smears or abnormal colorectal cancer screening results. The IPQ-R (Moss-Morris et al., 2002), which is based on the CSM, was used to assess illness representations. The identity and consequence dimensions of the CSM were found to be significantly associated with variance in anxiety, as well as

identity and emotional representations. The authors suggest that illness representations elicited by screening may be related to a range of emotions, wider than the typically studied anxiety and worry. Emotions relevant to their populations included guilt and embarrassment, suggesting that researchers may need to widen their view of possible outcomes when considering the effects of illness representations. The results showed that although some illness representations were related to variance in emotion, others were not, for example, perceptions of control were not related to distress in the cervical screening group and in the colorectal group personal control was related to lower distress. The variation in results, amongst illness representations, highlights the importance of considering them individually whilst also acknowledging associations. However, the authors acknowledge a limitation of the study in that the cognitive and emotional representations were collected concurrently. It is possible that, the back-and-forth nature of the CSM and parallel processing of representations may not be accurately represented through a questionnaire design but also when both are collected simultaneously.

Studies which have applied the CSM framework to at-risk or potentially at-risk populations, have done so largely in a quantitative manner and often in conjunction with other theoretical models. The unique nature of health risks can highly impact both cognitive and affective illness representations, suggesting that results for one population may not be applicable to another.

1.2 PSYCHOLOGICAL IMPACT OF SCREENING

Predictive screening can be beneficial, allowing individuals the opportunity to take preventative behavioural measures before a condition or illness is present. However, such tests are unable to offer definitive answers whether the illness will occur or when (Claes et al., 2005). There is evidence that when emotional distress is triggered, following a screening result, it can have a negative impact on future health behaviours, such as continuing surveillance for the health issue (Lerman & Schwartz, 1993). It is also important,

therefore, for research to establish the emotional and cognitive consequences of screening results, as well as identifying the specific illness representations that are activated. There is evidence that individuals experience psychological side effects following screening, however, results are mixed and consequences seem to be illness-specific and not generalizable. For example, it has been found that illness-specific distress increases following a positive result, but state-anxiety and depression levels remained the same as prior to the screening (e.g. Meiser et al., 2002, studied patients at a genetic risk of cancer). Another study found that anxiety, depression and cancer-related distress increased following screening, but only in high-risk patients who chose to engage in preventative treatment (in this case a mastectomy; Lodder et al., 2002).

A 2011 review found that screening for illness did not have a significant impact on anxiety, depression or quality of life in the long-term (Collins, Lopez, & Marteau, 2011). Twelve studies were reviewed, all of which were RCTs where adults either went through screening or risk assessment processes, or they did not; all twelve studies also included at least one measure of participant-rated emotion. Of the reviewed studies, nine screened for disease (abdominal aortic aneurysms, type II diabetes, osteoporosis, colorectal cancer, ovarian cancer, peptic ulcer, prostate/lung/colorectal/ovarian cancer) and the remaining three assessed the risk of disease (lung cancer, coronary heart disease), with the emotional outcomes being depression, anxiety, quality of life and general distress. This review found no evidence that screening had an emotional impact, when assessed four weeks, or more, following the screening procedure. The authors suggest their results are in accordance with the CSM as individuals use cognitive strategies to reduce the likelihood of the health threat, and also actively engage in health behaviours to minimise the threat, both of which will positively impact the emotional experience following screening.

However, there are examples in the literature of research, which has found an increase in emotional distress following screening, and the issue of false-

positive results is also important. Research has shown that women who received a false-positive result for breast cancer reported lower quality of life scores and increased feelings of anxiety, an effect which lasted a year following the initial screening (van der Steeg, Keyzer-Dekker, De Vries, & Roukema, 2010). Variation in the research and the evidence indicating screening can trigger negative emotional responses suggests, therefore, that individuals should be fully aware not only of what the process of screening involves but have a complete knowledge of the possible consequences and side-effects (van der Steeg et al., 2010).

1.3 PSYCHOLOGICAL IMPACT OF PRENATAL SCREENING

Although research has been done investigating relationships between illness representations and the psychological impact of screening for illnesses, there is a shortage of literature exploring the effects of screening during pregnancy. Prenatal screening is generally carried out to establish if there is a health risk to the mother and foetus (e. g. with maternal conditions such as gestational diabetes and HIV), as well as to determine whether any abnormalities are present with the foetus (e. g. Down's syndrome, disabilities) (Harris, Franck, & Michie, 2012; Williams et al., 2005). In the UK, screening for fetal abnormalities is routine and offered to all pregnant women, with the method of screening dependent on the stage of pregnancy (NHS, 2014).

Screening for maternal health conditions, such as gestational diabetes, is generally dependent on the presence of risk factors (e. g. family history, body mass index over 30) (NHS, 2012). Screening for fetal abnormalities is offered to all pregnant women, however, there are ethical issues surrounding doing so and some women choose not to be screened (Williams et al., 2005). Thus research has been conducted to investigate how women come to a decision whether to be screened or not and what their experiences of screening are.

In an exploratory study, Williams et al. (2005) conducted semi-structured interviews with 14 women in their first trimester, who had taken part in

screening for Down's syndrome. A qualitative analysis of themes revealed that some women perceive their first ultrasound as their first opportunity to 'meet' their baby and also regard it as a significant event for their partner. The high quality images available enable the parents to see the baby as a 'real' person rather than an abstract idea, whilst for health professionals the images offer the opportunity to discover more complex fetal diagnoses. In terms of the decision-making process for women engaging in prenatal screening, it is noted that screening for specific abnormalities is generally conducted within a routine procedure that all women experience. As women look forward to their scan, it may be the case that they are less likely to think of or have a full understanding of potential negative consequences (Pilnick, Fraser, & James, 2004; van der Steeg et al., 2010). Williams et al. (2005) found this with only a small number in their sample.

Interviews revealed that women regarded the decision-making process as private but the majority of women had considered their moral values and how they would react to a positive test result; some noted that learning of any abnormalities at an early stage would enable an earlier termination. Women who declined to be screened stated their decision had been based on their moral values, that they didn't have the right to change the course of the pregnancy based on an adverse screening result. Ultimately the Williams et al. (2005) study demonstrates that some women take an active role and consider both their moral values and the realities associated with a positive screening result, although due to the small sample size their results are limited.

In the area of fetal medicine, as with other illness screenings, research has explored both the decision-making processes, as well as the psychological, emotional and behavioural effects of screening (although there is significantly less research in this area). In 2012, Harris et al. (2012) conducted a meta-analysis to establish the psychological effects of screening for maternal (18 studies) and fetal (33 studies, 4 reviews) conditions. It was found that women experienced increased anxiety levels following screening for fetal conditions, but not when they had been screened for maternal

conditions. Six studies found that anxiety levels increased further following a positive result, whilst anxiety levels of women who received negative results decreased significantly. In some cases it was reported that anxiety levels of women with a negative result reduced to lower than at pre-screen (Ekelin, Crang Svalenius, & Dykes, 2004; Larsson, Svalenius, Marsal, Ekelin, Nyberg, & Dykes, 2009). It is noted that although there is no evidence suggesting an emotional impact of screening for maternal conditions, many of the studies in that area used non-validated measures. Some studies demonstrated behavioural changes as a result of screening, both for maternal and fetal conditions (e.g. Griffiths, Rogers, & Moses, 1993; Nabhan & Faris, 2010), but methodological issues and a lack of evidence make it difficult to establish an accurate influence. The review found that screening, for maternal or fetal conditions, is associated with cognitive outcomes, including increased maternal responsibility, negative perceptions of their own health and decreased attachment following a positive result. Harris et al. (2012) recognise that the psychological effect of screening is not fully understood and further research needs to be done.

1.4 PREECLAMPSIA SCREENING AND THE CSM

Although some attempts have been made to establish the psychological effects of screening for maternal and fetal conditions, even less is understood about symbiotic conditions, which affect both mother and baby. An example of such a condition is PE, a condition that can develop during pregnancy and poses a significant risk to maternal mortality and morbidity (Steegers, von Dadelszen, Duvekot, & Pijnenborg, 2010). Previous research has found that in cases where the condition is severe, with early onset, requiring delivery before 37 weeks' gestation the health outcomes are more adverse, compared to those who reach full term (Witlin et al., 2000; Yu et al., 2008). It is important, therefore, to identify women who are at risk of PE, in order to monitor their condition and attempt to reduce its effects. A recent study (Akolekar et al., 2012) has confirmed the ability to screen pregnant women to establish their risk of PE. Using maternal history and characteristics,

uterine artery pulsatility index (PI), mean arterial pressure (MAP), maternal serum pregnancy associated plasma protein-A (PAPP-A) and placental growth factor (PIGF), at 11-13 weeks gestation women are able to be screened and identified as either high- or low-risk for PE. The primary purpose of the PE screening test is to observe those at-risk, as the condition is not currently present and therefore cannot yet be treated (Harris et al., 2014). The screening test for PE is not currently routine and has not yet been recommended by the UK National Screening Committee (2011). As a result, there is a significant lack of research regarding the effects of screening for PE, particularly within the theoretical framework of the CSM.

A 2014 study, however, did highlight this and was the first to explore the psychological impact of providing women with risk status for PE (Harris et al., 2014). In total ten high-risk and five low-risk women were interviewed within one month of being screened and finding out their PE risk status. The semi-structured interview included questions based on the cognitive and emotional dimensions of the CSM. It was found that low-risk women were reassured by their screening result and would accept screening for PE in potential future pregnancies; they also recognised that the screening result was a risk status and could still potentially go on to develop PE. High-risk women were categorised as 'data managers' or 'fear managers'; the characteristics of these two groups are shown in table 1.1.

Table 1.1 Characteristics of women identified as high-risk for PE, taken from Harris et al. (2014)

Fear managers	Data managers
Focus on the fetal consequences of PE	Focus on the maternal consequences of PE
High sense of external control	High sense of internal control
Low perception of risk	Low perception of risk
Coping strategies: threat minimization, avoidance	

	Coping strategies: information seeking, positive behaviour changes, cognitive reappraisal

Although the semi-structured interviews were based on the CSM, the analysis and results focused on the women's perception of risk and coping strategies, depending on which category they were in ('data managers' or 'fear managers'); women's responses to each CSM dimension were not explored in detail. The study (Harris et al., 2014) was exploratory and began the necessary investigative work on the psychological impact of screening for PE. However, the sample sizes were relatively small and research is needed on a larger scale; the authors also note that the participants were all well-educated and employed, suggesting the generalisability of the findings may be limited.

1.5 PARTICIPATION IN RANDOMISED CONTROLLED TRIALS

Following screening for the presence or risk status of an illness/condition, individuals may be offered the opportunity to participate in Randomised Controlled Trials (RCTs). The aim of an RCT is generally to evaluate new treatments or ways to manage conditions, which may have little or no empirical justification (Jenkins & Fallowfield, 2000). However, whilst participation in such trials is needed to further medical knowledge, often there are significant issues with recruitment, which can halt a trial entirely or cause delays, both of which cost time and money (Ross et al., 1999). A reduction of the sample size, if recruitment targets are not met, will also consequently affect the statistical power of a study (Ross et al, 1999). It is thus essential to understand the specific reasons why individuals chose to accept or decline participation to avoid such problems (McCann, Campbell, & Entwistle, 2010). By trying to establish a complete understanding of why individuals do or do not take part in RCTs, researchers can then target such issues and seek to improve uptake for participation (McCann et al., 2010).

Research exploring participation in randomised controlled trials (RCTs) has been conducted with a range of individuals, from those suffering from long-term illnesses, such as cancer (e.g. Jenkins & Fallowfield, 2000) and epilepsy (e.g. Canvin & Jacoby, 2006), to those who may be at-risk of a particular illness or condition (e.g. Infanti et al, 2014).

Participants provide a range of reasons why they do or do not want to take part in research, many of which are presented regardless of the specific illness or trial. For example, in a study exploring why patients accept or decline participation in a cancer RCT (Jenkins & Fallowfield, 2000), it was found that main reasons for participation included to benefit others (through contributing to research) and having trust in their medical professionals. Whilst reasons for not participating in the RCT included concern about being randomised during the trial and having a preference for their doctor to choose their treatment. A sense of altruism and furthering medical knowledge were also found to be important factors for individuals taking part in a trial comparing medical and surgical interventions for patients with gastro-oesophageal reflux disease (McCann et al., 2010). In terms of reasons for not participating, issues with randomisation were also found to be significant factors to patients who declined to take part in an RCT comparing standard surgery with conservative management of urinary tract symptoms related to benign prostatic disease (Featherstone & Donovan, 2002).

There have also been several reviews conducted, aiming to establish an overview of why individuals choose to participate or not, in RCTs (e.g. Frew et al, 2014; McDaid, Hodges, Fayter, Stirk, & Eastwood, 2006; Mills et al, 2006). An example of such review is that of Mills et al. (2006) who conducted a systematic review to establish the barriers to participation in cancer RCTs. Of the 33 studies that they examined (12 qualitative, 21 quantitative) significant barriers included concerns with the trial setting, unhappiness with randomisation and the presence of a placebo/no treatment group, discomfort with the research process in general, too complex protocols, concern about side effects, belief that trials are not appropriate for serious diseases, fear that participation would negatively effect relationship with physician and the

physician's attitude towards the trial. The authors note that the presence of several of these barriers across studies suggests that they are broadly applicable to potential participants of cancer RCTs.

Similar barriers to participation were also identified in a 1999 review (Ross et al, 1999). In this systematic review, 78 papers were examined to establish reasons why both clinicians and patients refuse to take part in RCTs for a range of conditions. The studies included in this review examined participation in a range of RCTs with various patient groups, such as cancer, smoking cessation, obstetrics, child health and mental health. Barriers to participation for clinicians included: time constraints; lack of staff and training; concern about the effect of participation on the relationship with patient; general concern for patient; loss of professional autonomy; difficulty with the consent procedure; lack of rewards and recognition; and the trial not being of personal interest to the clinician. In terms of barriers to participation for patients, reasons included: additional demands on the patient (extra procedures and appointments; travel costs); preferences for a particular treatment (or no treatment); worry about uncertainty of treatment/trial; and concerns regarding information and consent. The authors make subsequent suggestions for future research, such as ensuring the protocol is clear and understandable, as well as increased support for staff involved in the trial, and keeping the demands of the trial to a minimum for the sake of the patients involved. However, this review is limited due to it's vagueness as a result of looking across patient groups. This can be useful to provide an overview but the method is ultimately flawed; individuals suffering from illness or potential illness may also be experiencing a range of emotions and individual factors which can contribute to their decision-making regarding RCTs.

A focused and specific exploration of factors is especially necessary in areas where research is sparse. One such example of an under researched population in terms of RCT participation, is pregnant women. It is essential to conduct RCTs with this population, as they are particularly vulnerable and at-risk of infections and medical conditions such as gestational diabetes and PE. However, as Frew et al. (2014) state, they are typically underrepresented in

RCT research for fear that research could pose unnecessary risks to both the mother and foetus. Increasingly researchers are attempting to examine this patient group and conduct a variety of RCTs, but again an exploration of barriers to participation is needed to improve uptake. In a review, Frew et al. (2014) identified 86 studies investigating factors, which prevent or facilitate participation amongst pregnant women. Table 1.2 (below) shows the findings of Frew et al. (2014).

Table 1.2. Factors influencing recruitment and retention of pregnant women in clinical research

Recruitment	**Retention**
Socioecological factors: - Public scandals - Federal guidelines on recruitment of pregnant women - Institutional review board provisions - Liability issues	*Socioecological factors:* - Research budget constraints - Prevalence of longitudinal studies requiring follow-up
Community and social-level factors: - Provider study promotion (or lack thereof) - Provider-patient study recruitment networks - Clinic/study accessibility and affordability	*Community and social-level factors:* - Clinical accessibility - Strong relationship with study team - Social network and spouse influence

- Social network and spouse influence	
Individual-level factors:	*Individual-level factors:*
- Demographic factors - Time to participate - Pregnancy related health problems - Perceived research relevance - Fear	- Voucher-based incentives - Time to complete study - Pregnancy-related health issues - Demographic factors

These findings highlight the importance of addressing issues regarding the three different levels of recruitment. The results also provide a useful overview of themes as a starting point for future to explore.

1.6 OVERVIEW OF THE CURRENT STUDY

Chapter two details the qualitative methodology adopted throughout the subsequent studies. The method of template analysis is discussed as well as how the initial template for analysis was developed, including a priori themes based on the proposed interview schedule. Chapter two also details the pilot study that took place in order to refine the methodology and the changes that were made to both the interview schedules and the templates for analysis as a result.

Chapters three, four and five contain the empirical studies. Each chapter is based on the same data set and template analyses were used in each study; however, each chapter addresses a different research aim and question. For example, chapter three explores women's illness representations and emotional responses regarding their PE risk status. Although a quantitative study previously found no difference in self-reported anxiety in low- and high-risk women (Simone et al. 2015), this study aims to explore other emotional effects and responses women may experience as a result of their

risk status, within the framework of the CSM. This study sought to further the currently limited literature and explore these responses using a qualitative methodology to more fully report women's experiences.

The study detailed in chapter four aims to establish women's attitudes towards screening for pre-term PE and capture their reflections on the experience of being screened and finding out their risk status. To date, research has investigated the consequence of screening for various illnesses and conditions through pregnancy. PE is a symbiotic condition (that effects both mother and baby) that is particularly unique, yet it remains under-researched. This is largely as the screening test remains relatively new and is not routinely carried out. A focus study has been carried out to explore women's attitudes towards pre-term PE screening (Crombag et al., 2017), however, the women who were included had not been screened themselves. Therefore, the study in chapter four aims to expand the literature and explore the experiences of women who have been screened for pre-term PE risk status and the factors that influenced their participation in the screening.

Chapter five is the final empirical chapter and explores the factors influencing participation or non-participation in the ASPRE trial, amongst women who were identified as high-risk through PE screening. Participation in RCTs during pregnancy is complex and, as RCTs excluded pregnant women from participation prior to 1993 (Meshaka et al., 2017), their involvement is under-researched. Five studies were identified as trying to establish factors influencing participation and non-participation in medicated RCTs during pregnancy, however, none of these studies were with women identified as being high-risk for pre-term PE. This study is particularly significant as the results will inform clinicians as to the reasons why high-risk women did or did not decide to participate and explore their views around taking aspirin in particular. These factors will enable clinicians to address any concerns when advising or recommending aspirin

to women identified as high-risk, as well as offer understanding as to why some women decline.

The final chapter is a general discussion of the thesis. It outlines the key findings of each study and attempts to address some of the limitations of the thesis, as well as offer some future directions.

1.7 RESEARCH QUESTIONS

The current research aims to expand on the limited existing literature in this area and the primary aim of this thesis is to evaluate the psychological impact of screening for pre-term PE risk status.

Using a qualitative methodology this thesis also addresses the following research questions:

1. What are women's emotional responses to the risk status diagnosis following pre-term-PE screening? (Chapter three)
2. What are the illness representations of women identified as high-risk for pre-term PE? (Chapter three)
3. How do women reflect on their experiences of pre-term PE screening and what factors influenced them to take part? (Chapter four)
4. What are the factors that influence women's participation/non-participation in an RCT (i.e. the ASPRE trial)? (Chapter five)

CHAPTER TWO
2 DEVELOPING THE METHODOLOGY

2.1 RESEARCH DESIGN

2.1.1 EPISTEMOLOGICAL POSITION

The current thesis adopts a critical realist approach, using participants' experiences and perception of the world to explore the research aims. Critical realism does not favour particular methods but is instead used as a general methodological framework from which to explore the experience of participants (Fletcher, 2017; King & Brooks, 2016). The studies presented in the current thesis are concerned with presenting the lived experience of the participants, within the under-researched area of screening for pre-term PE risk status. Template analysis lends itself to a critical realist approach as it too is a general methodology and can be used from various philosophical stances (King & Brooks, 2016).

2.1.2 DEVELOPING THE METHOD

The overall aim of this thesis is to establish whether there is an emotional impact of screening for pre-term PE and explore women's illness representations, within the CSM framework, after receiving their risk status for developing pre-term PE. Qualitative interviews rather than quantitative questionnaires are more appropriate for these studies; as this is an under-researched area (Harris, Franck, & Michie, 2013), more in-depth explorations are being sought. Further interests include why women accept or decline screening for PE, and the factors influencing participation in an RCT throughout their pregnancy. By using semi-structured interviews women will be able to fully express their thoughts and feelings on these matters, producing a richer account than quantitative measures would allow. Qualitative research allows participants to express and articulate their thoughts and feelings, as well as how they experience the world around them

and the meaning people ascribe to their actions (McCluskey, Brooks, King & Burton, 2011a).

The semi-structured interviews for this thesis included questions to specifically address the research aims. Some questions were based on the components of the IPQ-R (adapted for this sample of pregnant women) to explore illness representations. This method of using semi-structured interviews, based on the IPQ-R, was successfully adopted in a study by McCluskey et al. (2011a), exploring the influence of significant others' illness perceptions on persistent back pain and work participation. The interview schedule included the same of similar questions to the IPQ-R subscales: identity, timeline (acute/chronic), timeline (cyclical), consequences of illness, personal control over illness, treatment control over illness, emotional representations, illness coherence and beliefs about causality. In the McCluskey et al. (2011a) study, as with the current thesis, template analysis was used due to the use of a priori themes to develop the coding template for data analysis. As semi-structured interviews were based on the dimensions of the IPQ-R, the a priori themes were the basis of the template. The researchers had also conducted a pilot study to develop their interview schedule and template (McCluskey, Brooks, King & Burton, 2011b). The initial template, from the pilot study, proved to be effective and their final template comprised of six (out of the initial nine) IPQ-R subscales and two additional themes (claimant as genuine and influence/impact on significant others). For data analysis McCluskey et al. (2011b) had at least two researchers carefully read and re-read the text in order to modify and finalise the template. The current study also adopted this method and also used the IPQ-R subscales as initial themes of both the interview schedule and template. By basing the semi-structured interviews on the IPQ-R, it will also enable it to be adapted for this population (pregnant women) for use in future quantitative studies.

2.1.3 TEMPLATE ANALYSIS

Interview transcripts throughout this thesis were analysed using template analysis. Template analysis refers to a group of techniques used to thematically analyse and organise data (King, 2004). It is a flexible approach, allowing researchers to adapt the method to their own requirements and those of various studies, whilst also being suitable with large data sets (King, 2004).

A stand-out feature of template analysis is the use of a priori themes; enabling the researcher to identify themes which are likely to occur in the data, and be important in terms of the research question, before actually beginning data analysis. In this case, the use of a priori themes is beneficial as the interview schedule was based on the constructs of the CSM and IPQ-R, suggesting that these were likely themes to emerge. Similarly, specific questions related to constructs of the CSM and IPQ-R, as well as, ultimately, the research aims were included in the interview schedule and could thus be predicted as a priori themes on the initial template. The template includes first level themes, which are the overarching themes; each theme can then be explored further through data analysis resulting in further themes, for example there are second-level themes, third-level themes and so on. Subsequent themes are still related the first level theme but provide a more specific viewpoint. However, the template is adaptable so that new themes can be added or existing a priori themes discarded or adapted depending on the subsequent analysis of the data set.

Template analysis is not welded to a particular epistemological position, but instead it is compatible with several (Brooks & King, 2012; King, 2004). Brooks and king (2012) note that template analysis is not compatible with methodologies concerned with how language is used in interactions, such as discourse analysis; however, this was not a focus or concern of the current studies. King (2004) suggests that template analysis is suitable for use with a range of sample sizes, but it is particularly compatible with larger sample sizes, where similar methodologies, such as Interpretative Phenomenological Analysis (IPA; Smith, 1996) are not. IPA was considered for the current thesis

and has some overlapping features with template analysis. For example, both methodologies are concerned with exploring the lived experiences of participants (Brooks & King, 2012; Smith 2004). As with template analysis, IPA is concerned with exploring the personal lived experiences of participants (Smith, 2004), however, IPA is suited to small numbers of participants (Smith, Flowers & Larkin, 2009; Tuffour, 2017). Researchers who have used IPA suggest the method allows for a more idiographic focus, but it was also noted that thirteen was a large sample for IPA, and such participant numbers had the potential to lead to data overload and overwhelm (Wagstaff et al., 2014). Due to the sample sizes intended for the current studies, IPA was not an appropriate analysis choice.

Other methods of analysis considered included Grounded Theory (Strauss & Corbin, 1990) and thematic analysis (Braun & Clarke, 2006). Grounded Theory, unlike IPA, is better suited for studies with larger samples (King, 2004). However, it relies on theoretical sampling and initially interviewing a small number of participants, before analysing data and then recruiting more participants to confirm/disconfirm the previous findings (Glaser & Strauss, 2017). Through this thesis I wanted to hear women's experiences and explore similarities and differences between those who were screened low-risk and high-risk, and then further between participants and decliners of the ASPRE trial. Data analysis was expected to take place following the interviews and not influence recruitment. Grounded Theory is therefore not appropriate for studies with pre-determined samples (Alhojailan, 2012), such as the present studies. Another technique considered was thematic analysis, which is regarded as flexible and would be suitable with a larger data set (Frith & Gleeson, 2004). Thematic analysis aligns with the aims of the present thesis as it allows a researcher to identify common themes running throughout the data (Joffe & Yardley, 2004). However, its flexibility and lack of structure can also be considered a disadvantage, particularly with larger samples, as it can lead to a lack of coherence and consistency when developing themes (Holloway & Todres, 2003). In contrast, template analysis is a method which offers some structure to manage themes but allows an exploration into

personal lived experiences, identifying common themes across or within participant groups and enabling researchers to focus on themes where the richest data is in relation to their specific question (Brooks & King, 2012). In particular, it is the use of a priori themes and the ability of template analysis to handle large data sets that makes this the most appropriate method of analysis, compared to others such as IPA, Grounded Theory and thematic analysis. It felt more appropriate to use a non-prescriptive analysis when exploring a relatively new area. A potential criticism of template analysis is that researchers can become too focused on their template, reluctant to modify it any way (King, 2004). In order to address this for the current thesis, the template modifications were agreed between the researcher and supervisors. It was also understood from the outset that the process of using a template was an iterative one, and changes were expected and welcomed in order to accurately reflect the individual views of participants. When using template analysis, there is also an understanding that there will be multiple themes, in various levels which represent how the researcher conceptualises the theme, rather than its perceived importance. However, researchers must be selective, choosing to focus on themes which are relevant and provide answers to the research question (King, 2004). Whilst this could be considered a weakness of the technique, the initial template exists in order to support the organisation of themes and analysis of the richest data relevant to the research question (Brooks & King, 2012). The template also lends itself to analysing the data as a group or team of researchers, as you are able to provide supporting, working definitions of the themes.

Template analysis is unique compared to previous methods mentioned due to the use of the template. The template and use of a priori themes were the main reasons template analysis was chosen and used for the current studies. Recruitment numbers were expected to be relatively high, for qualitative research, across multiple participant groups and so the organisation and structure offered by the template along with its flexibility resulted in it being the most appropriate method.

2.1.4 DEVELOPING THE INITIAL TEMPLATE

The initial template for the high-risk, participants of ASPRE group, consisted of a priori themes matching six subscales of the IPQ-R. The remaining thematic areas of the interview schedule mapped on to the template, these were: women's encounter with screening for PE, decision-making regarding screening, women's early encounter with high-risk status, decision-making regarding ASPRE trial, adherence and benefit of advanced knowledge of PE risk status early on in pregnancy/overall evaluation. Further lower-level themes were explored and identified during the analysis. Table 2.1 shows an example of how the initial template and interview schedule were linked.

Table 2.1. Extract from initial interview schedule and initial template

Interview schedule question	**Template first- and second-level themes**
Had you heard of PE before receiving the letter?	Women's encounter with screening for PE - Prior knowledge of PE
How much control in general do you feel you have over whether you will develop PE?	IPQ-R: control/cure - Beliefs concerning personal influence on the outcome
Thinking about when you were told…how did you react at the time? How did you feel?	IPQ-R emotional representations - Worry regarding high-risk status - Worry regarding developing PE

The initial template linked directly with the main questions from the interview schedule and were purposely broad, with few second-level themes

in order for the analysis to be driven by the data. The first-level themes used in the initial template are shown in Table 2.2.

Table 2.2. Initial template

First-level theme
1. Women's encounter with screening for PE
2. Decision-making regarding screening
3. Women's early encounter with high-risk status
4. IPQ-R: illness cause beliefs
5. IPQ-R: illness comprehension
6. IPQ-R: timeline
7. IPQ-R: consequence
8. IPQ-R: emotional representations
9. Decision-making regarding ASPRE trial
10. Adherence
11.IPQ-R: control/cure
12. Benefit of advanced knowledge of PE risk status early on in pregnancy/overall evaluation

2.2 PILOT STUDY

It was decided that an initial pilot study was to be conducted in order to develop and refine the methodology that would be the basis of the main studies in this thesis (Chapter three, Chapter four and Chapter five). The research team worked together to produce interview schedules, including questions relating to each aim of the thesis. The interview schedules were semi-structured, in order to give women, the space and freedom to express their own views and feelings about the screening but included enough questions to ensure that data would be provided to address the research aims. As the interview schedules included specific topics, it was decided that template analysis (King, 2004) would be the most appropriate method of data analysis. Template analysis is particularly appropriate for the current studies

as it can be used with large data sets, whilst also allowing individual voices and experiences to emerge. Template analysis is discussed further in section 2.3 of this chapter. It was predicted that for the current thesis at least ten individuals from each participant group (low-risk, high-risk participant of ASPRE, high-risk decliner of ASPRE) would need to be interviewed; the interview schedules were lengthy and comprehensive given the many and various aims of the thesis. Therefore, the researchers were aware there would be a vast data set to be analysed. A further advantage of template analysis is the use of a priori themes; this enables researchers to identify themes, which are likely to be present prior to data analysis, thus saving time and aiding organisation of the data. Given the semi-structured nature of the interview schedule, question topics then became the initial themes for data analysis. The templates are, however, flexible and adaptable to the data if new themes emerge and/or a priori ones are not relevant.

For the pilot study, women were recruited for the semi-structured interviews from a London hospital. The women had to be over 18 years old, have a single pregnancy and a live fetus at 11-14 weeks' gestation (the same criteria as to be screened for pre-term PE) in order to participate. They also had to have been offered screening for pre-term PE risk status and give consent for the study.

Before their first hospital visit at 11-14 weeks' gestation, women were sent information sheets, amongst other antenatal material, informing them about the research study regarding screening for pre-term PE risk. All women attending their first hospital visit at 11-14 weeks' gestation were offered screening to establish their risk status for PE. Results of the PE risk screening were available at the same appointment and women were told their result was either screen negative, i.e. low-risk for developing pre-term PE, or screen positive, i.e. high-risk for developing pre-term PE. Women identified as high-risk for pre-term PE were then offered counselling by the research doctor and then offered the opportunity to participate in the ASPRE trial. They could agree to participation in the ASPRE trial that day or take another day to

consider their decision. Women identified as high-risk for PE could only participate in the ASPRE trial if it was medically safe for them to do so.
High-risk women were approached as they attended antenatal scans at 34-37 weeks' gestation, or contacted after they had given birth. The women were informed that this research was concerned with exploring how they decided to take part in screening for pre-term PE, and subsequent participation in the ASPRE trial (if appropriate), as well as if and how their screening result affected their pregnancy.

Two research doctors, associated with the ASPRE trial, facilitated recruitment, for the present pilot study as the ASPRE study was already underway and they had developed a familiar relationship with the participants throughout their pregnancies. Women who agreed to participate were then followed up by the current researcher, and interviewed either face-to-face (n=7) or over the phone (n=3).

Women who were identified as low-risk were not included in this pilot study for several reasons; low-risk women did not have antenatal scans at 34-37 weeks' gestation and not had contact with the research doctors throughout their pregnancy, thus it would have been difficult to facilitate their recruitment. Also the focus of the present pilot study was to develop the template (and as a consequence the interview schedule), particularly in regards to women's illness perceptions of PE, within the CSM framework. It was thought that the time period since women found out their result combined with the low-risk outcome was unlikely to advance the template or interview schedule in this regard. The focus of recruiting low-risk women in the subsequent study was to elicit their attitudes towards and experiences of screening for pre-term PE. These views and feelings would be more fruitful when gathered near to finding out their risk status, which was not possible for the pilot study.

The total number of women who were interviewed for this pilot study was 11; however, one participant withdrew, resulting in ten participants'

interviews being analysed. Two women were decliners of screening; they had not been screened for pre-term PE risks status. The remaining eight participants had all been identified as high-risk of developing pre-term PE; three were decliners of the ASPRE trial and five were participants of the ASPRE trial.

Although no low-risk women were recruited for the pilot study, an additional interview schedule was developed. Low-risk women were omitted from the pilot study due to the time lapse since finding out their risk status. However, it was the intention to interview them in later studies as close to their screening as possible, to establish an accurate representation of their views. Again this is similar to the method of McCluskey et al. (2011b), who based their initial template on data from just the group of significant others; the claimant data was then analysed based on that template.

The interview schedules for the three groups of participants (decliners of screening, decliners of ASPRE and participants of ASPRE) were developed with the research team. Women who had declined screening for pre-term PE risk status were asked what they could recall about their first scan appointment and if they were aware of the screening for PE risk. The ASPRE trial was on-going at this stage, and so all women had been offered the screening. Further questions related to screening in pregnancy generally, as well as how they had come to make their decision to decline the screening test. They were also asked to reflect on their decisions and had the opportunity to discuss topics of their choice. See Appendix 7.3 to 7.6 for the interview schedule for each participant group.

Women who were identified as high-risk for PE but declined to participate in the ASPRE trial were asked questions regarding their decision to take part in the initial screening, as well as their opinions on prenatal screening in general. They were asked about their reactions to being told they were high-risk and subsequently how and why they decided against participating in the ASPRE trial.

For interviews with participants of ASPRE, the interview schedule included questions based on six of the IPQ-R dimensions (cause beliefs, illness comprehensibility, timeline, consequence, cure/control and emotional representations), as well as questions about their view on screening for pre-term PE risk and addressing their subsequent high-risk, for pre-term PE, status.

2.3 RESEARCH AIMS

The aims of the current study were as follows:

1. To establish the feasibility of conducting a semi-structured interview, based on the dimensions of the IPQ-R, to explore women's emotional responses to finding out their risk status for pre-term PE.
2. To produce an interview schedule and template for use with future studies to explore women's emotional responses and illness representations to PE risk, attitudes towards PE screening and factors influencing participation in a medicated RCT during pregnancy.

2.4 RESULTS OF THE PILOT STUDY

The initial template consisted of a priori themes relating to questions featured in the interviews (see Appendix 7.7 – initial pilot study template). As is customary with template analysis, themes and codes were adapted as and when needed, as dictated by the data. The pilot study provided rich data, enabling changes to be made to both the interview schedule and the template prior to the main studies commencing. Results of have, generally, not been analysed here, as the primary aim of the pilot study was to create, develop and try both the interview schedules and template with a pregnant sample. However, the main definitions of the first level themes of the template are provided to clarify which each theme is justified in being included in this version of the template.

2.4.1 PARTICIPANTS AND DECLINERS OF SCREENING FOR PRE-TERM PE RISK

These themes and codes explore women's reasons for accepting or declining to take part in the screening for PE.

1. Knowledge regarding PE

This first-level code refers to any knowledge the women had regarding PE and/or screening for pre-term PE risk status, prior to their 11-14 week scan. Identifying the source of any knowledge regarding PE is important because the research team aim to establish the extent of influence that the knowledge may potentially have on an individual's decision-making process. For example, a personal connection to PE is likely to produce stronger feelings and views than a vague awareness. Second-level codes further address the origin of the knowledge: personal history, family and friends, no particular awareness.

a. Personal history

This second-level code explores any personal connections women may have with PE, for example any previous symptoms or cases where PE occurred during previous pregnancies.

One high-risk woman had personally experienced PE in a previous pregnancy. She perceived the previous occurrence of PE as the reason why she was invited to take part in screening but stated that she "didn't mind taking part because…it needs more information why women have preeclampsia" (5, lines 64 – 65).

b. Family and friends

This second-level code concerns women who stated they had knowledge of PE through family or friends. Four high-risk women knew friends or family members, who had experienced PE in pregnancies:

> "My husband's…sister, had it at the late stages of her, with one of her children". 3, lines 50 – 52.

Two of these women also expressed knowledge of possible treatments and consequences of PE, from the experience of friends. One woman had a friend whose pregnancy was ultimately successful but was "placed on aspirin during their pregnancy" (1, lines 94 – 95). Whilst another participant recalled a close friend's experience in which the situation with PE was so severe that she delivered her baby by caesarean section at 23 weeks.

> "She was rushed into hospital at 23-weeks, she said she, her legs were too big, she couldn't see her feet they'd swollen that ridiculously…it was a terrifying risk and…she didn't have any more children because of this". 6, lines 103 – 115.

It is evident from the extract above that the participant is aware of the serious nature of PE and the effects it can have on the progress of the pregnancy.

c. No particular awareness

Some women reported no knowledge of PE, or a vague awareness; this second-level code encompasses these women and their responses.
Five of the ten women did not report knowing much or anything about PE prior to their 11-14 week scan appointment. Two women had not heard of PE, whilst the remaining three had some awareness; they had heard of the condition but did not know exactly what it was. Below is an example quotation from one of these women,

> "I think someone mentioned but it's not something, I thought it was something really common that happens in pregnancy". 2 lines 87 – 89.

A woman, who was a decliner of the screening, knew of PE "from general knowledge" (10, line 52) and her occupation, working for a medical organisation, although she reported to not know about PE "in depth" (10, line 56).

2. Attitude towards prenatal screening

This first-level code explores women's attitudes towards screening in pregnancy, in particular their personal feelings about the advantages and/or disadvantages of being screened. Two second-level codes emerged here: provides early information, and importance of research.

a. Provides early information

This second-level code explores women's ideas about the personal consequences of screening, and the idea that screening and finding out risk status for PE is beneficial, in terms of being able to potentially prevent problems or difficulties.

Seven women, across both participant groups, identified screening, during pregnancy as being personally beneficial for their wellbeing, and the wellbeing of the unborn baby. The perceived benefits were that screening could provide them and medical staff, with access to early information that something could be wrong, and therefore there would be a possibility to receive further advice or try to prevent any harm to the fetus. Participants of screening mentioned that screening could be reassuring, regardless if the results were negative or positive.

> "I think its good cause then you more or less get the opportunity to see if there's something wrong, or if something you can do to help, or prevent certain things, so I think that it's a good idea". 4, lines 93 – 96.

> "So it's reassuring to have, things you can cross off if you like, or things to, things to hold on to, if you've got 20 things to worry about and then one of them you know, is confirmed as a problem or confirmed as not a problem, I think that's a good thing because it gives you some rocks to hold on to". 6, lines 71 – 78.

In these extracts women express that provision of early information regarding the pregnancy is reassuring where no cause for concern is found but also, in cases where problems are identified, an opportunity to intervene early and in such a way prevent subsequent adverse outcomes. Due to the early reassurance from test results and subsequent options for early intervention, participants expressed generally positive views on screening in pregnancy.

Participants of screening also spoke specifically of the perceived benefits that came from finding out their risk status for PE. When offered the opportunity to reflect on screening for PE risk and knowing their risk status, high-risk women echoed previous sentiments regarding the importance of knowledge for prevention and raised awareness of possible problems. It is important to note that these comments are retrospective, rather than representative of their feelings and opinions at the time when they were offered screening.

3. Decision-making regarding participation in screening for pre-term PE risk

This first-level theme refers to the ways in which women decide to take part in screening or not, including the factors that can contribute to their decision. Second-level codes here are following doctor's advice, no harm evident in

taking part, screening as a routine procedure, screening for PE is not necessary, susceptibility and the role of significant others.

a. Following doctor's advice

The sense of normalcy regarding the screening for PE was also expressed through the belief that one would follow a doctor's recommendation in the hope of having "an easy pregnancy" (4, line 156).

b. No harm evident in taking part

Other factors, which proved to influence participation in screening for PE, included the non-invasive nature of the test.

> "It was an easy decision to make, erm you know again I think just because I think it's important to be a part of these things and [Int: umhm] it didn't really impact me [Int: yeah] physically erm in any way [Int: umhm] so you know so I didn't have a problem with doing it". 3, lines 125 – 130.

> "There is no harm in that [the screening] (Int: umhm), they were going to take my blood and, well take my blood pressure and erm they took the sample and erm yeah that was fine (Int: ok), I had no problem with that". 7, lines 90 – 93.

Such responses would suggest that women found the ease of involvement and the screening being conducted during the ultrasound appointment as convenient and this facilitated participation.

c. Screening seen as a routine procedure

In terms of deciding to participate in screening, participants of screening expressed beliefs that they thought the PE screening was part of the normal

procedure, and the easier option (compared to not being screened). In some cases, although women were aware of PE and the opportunity to be screened, they did not make an active decision prior to their appointment. Rather they went along with screening, regarding it as a routine task and did not give very much consideration to the decision.

> "I didn't really give it much thought [Int: Ok] I just thought ok [Int: umhm], so I went through the leaflet just for my own information". 1, lines 75 – 78.

> "I suppose I just thought it was part of the process you know [Int: umhm], part of what you do [Int: yeah] when you go for your scan". 3, lines 26 – 28.

> "I mean erm my sister and her husband are doctors and [Int: umhm] you know we had medical professionals in the family [Int: umhm] so you know, it just kind of feels like a normal thing to do really". 3, lines 71 – 74.

These examples suggest that some women did not engage in active decision-making, rather they participated in screening because it was offered to them, alongside other routine procedures. The women who participated in screening saw no disadvantage to taking part in screening for PE.

d. Screening for pre-term PE risk is not necessary

This second level code is concerned with women's beliefs that it is not necessary to screen for PE, particularly in comparison to other conditions.

One participant expressed her understanding that the symptoms of PE could be picked up on by midwives at her regular appointments. Furthermore, she reflected on her view that PE screening was not being provided routinely, therefore the legitimacy and necessity of the screening was questionable.

> "I thought well if other women aren't having it and their pregnancies are kind of going ok and they do test for it (Int: umhm) erm at your midwife appointment (Int: yeah) I, I you know, I probably don't have to go through that aspect of screening". 10, lines 190 – 194

The same participant also suggested that during the early stages of pregnancy, and throughout the first ultrasound appointment, there is a lot of information to digest and consider. PE and PE screening were considered, in this instance, less urgent and important, particularly in comparison to other conditions.

> "I wasn't too worried about knowing whether it was erm, whether I might have a disposition (Int: yeah) for it". 10, lines 100 – 101

> "I think probably the other screening's a bit more erm in a way can be a bit more, have a bit more of an impact on your life and your future life, rather than preeclampsia". 10, lines 218 – 221

e. Susceptibility

Further factors influencing participation included the self-perception of being 'at-risk' or not. For some participants, believing one was not at-risk seemed to encourage participation, since they perceived no threat from the screening and its potential result.

> "I thought that I wasn't in the high group of having preeclampsia, I never, ever thought about that so this is why I didn't have any concerns to be part of because I thought no, not me I'm fine". 2, lines 155 – 158.

In contrast, one high-risk participant who had previously experienced PE believed that she would be at-risk and wanted confirmation through the screening of her current risk status.

> "Because I already had it, yeah, and there's not enough information on why [Int: yeah] women do have it". 5, lines 80 – 82.

One participant of screening also expressed a self-perception of being at-risk for PE, due to her ethnic background.

> "I know it's really common among the ethnic min- ethnic groups so [Int: umhm] so there might be a possibility that I might be, I might fall under high risk". 1, lines 242 – 244.

f. The role of significant others

The opinion of significant others and a desire to partake in research were also factors contributing to participation in screening, for women who were participants of screening. Participants noted that they discussed their decision to be screened with family or significant others, none of whom objected to their decision.

2.4.2 HIGH-RISK WOMEN AND THE ASPRE TRIAL

This section of the template includes data from women identified as high-risk of pre-term PE and were either participants of the ASPRE trial or decliners of the ASPRE trial. The template analysis revealed three first-level codes, with associated sub-themes, which are shown below.

1. **Emotional impact of the high-risk results**

This first-level code concerns the emotional reactions that women experienced after finding out they were at high-risk for PE.

a. Negative

This second-level code refers to women who reported experiencing negative emotional responses upon learning of their high-risk status.

Five of the women described their shock and surprise as well as a sense of concern and nervousness at being told of their high-risk status. This is demonstrated in the following quotes,

> "I think at first it was a surprise and a shock, because to find out that I was in high-risk to be, to have preeclampsia, it's, it wasn't the best news ever". 2, lines 74 – 77.

> "I was obviously a bit nervous and scared because of some of the risks associated with having preeclampsia…it's not nice being told you are at high-risk". 3, lines 147 – 150.

> "It's a bit alarming because I think our friend nearly died of it". 6, lines 160 – 161.

b. No surprise

This second-level code concerns responses given by women who were not surprised by their high-risk status for PE. For example, one participant had expected the high-risk result (participant of the ASPRE trial), as she had previously experienced PE,

> "I wasn't shocked because it happened before [Int: umhm] so I knew that in my case they could be a chance that I have it again [Int: yeah, ok] yeah". 5, lines 178 – 180.

For this participant it seems that her perception of an elevated risk of PE had impacted on her emotional response to the news of her high-risk status.

One participant (decliner of the ASPRE trial) also reported not feeling shocked or surprised due to her personal belief that test itself was inaccurate. Whilst another woman (decliner of the ASPRE trial) could not recall how she felt at the time of hearing that she had been identified as high-risk. Again this highlights the varying emotional responses to the news of being high-risk and any consequences of emotional reactions.

2. Factors influencing participation and non-participation in the ASPRE trial

This first-level code refers to how women decided to participate, or not, in the ASPRE trial. The second-level codes that emerged from the data were meaning ascribed to the high-risk screening results, attitudes to aspirin/medication, trust in the doctor, extra care/support through taking part in research and attitudes to randomisation. Women reported these factors as having both a negative and positive impact on their decision to participate in ASPRE or not, thus both decliners and participants of ASPRE will be looked at within this first-level code.

a. Meanings given to the high-risk screening result

This second-level code concerns women's ideas of what being identified as high-risk means to them and how their ideas can influence participation in the ASPRE trial.

Whilst some of the women reported the news to be somewhat upsetting initially, it appears they developed ways of dealing with their feelings, dependant on the meanings they ascribed to their high-risk result.

For example, one woman reported developing a fairly pragmatic response, as demonstrated in the quote below.

> "I was scared at first but you know, prevention is better than cure". 1, lines 188 – 189.

One participant also spoke of the optimistic approach she developed, after the initial shock of being identified as high-risk. As demonstrated in the quote below, she appeared to take some comfort that the research available might have been able to further her understanding of PE and the support available to her.

> "I thought that maybe part of a research would be, help me to understand preeclampsia [Int: yeah] and get the support from here as well". 2, lines 77 – 79.

In this instance her thoughts appear to have shifted to thoughts of prevention and the possible benefits that arise from being involved in PE research.

b. Attitudes to aspirin/medication

This second-level code refers to how women's attitudes towards taking medication during pregnancy, and in some instances to aspirin, specifically, influenced their decision to participate/not participate in the ASPRE trial or not.

Three participants of the ASPRE trial reported being unconcerned about the possibility of taking aspirin throughout their pregnancy. These women seemed somewhat comforted by their belief that aspirin is a well-known drug, without side effects.

> "I knew that aspirin is for blood thinning [Int: umhm], you know so it wasn't that difficult for me to accept to take the aspirin but it's something as well so it might be a placebo [Int: yeah] or aspirin but, I know placebo means that some, there's nothing in there". 1, lines 330 – 334.

The two remaining participants of the ASPRE trial did not mention specifically being concerned about taking aspirin, but they were somewhat worried about taking tablets in general and having side effects. However, both of these women reported agreeing to the ASPRE trial regardless and were happy to take the tablets after they had not experienced any negative side effects.

> "I wasn't sure about taking the tablets at first but when I realised there's no, there wasn't no side effects nothing is going to happen to me so I thought yeah, might as well give it a go". 5, lines 67 – 70.

The participants of the ASPRE trial generally reported positive or neutral attitudes towards taking medication through pregnancy. Two out of the three decliners of the ASPRE trial reported taking medication on a daily basis throughout pregnancy, as a reason for declining the trial.

> "I just did not like the idea of having to ingest something like aspirin (Int: yeah) erm for the entirety of the rest of the pregnancy, it did not sit well with me". 7, lines 215 – 217.

> "I don't want to take anything, any drugs you know (Int: yeah) they want me to take part but it's hard for me so because of that I won't participate". 8, lines 87 – 89.

These two women did not discuss any possible benefits of being involved in the ASPRE trial or potentially taking aspirin, yet they also did not explicitly state any risks they associated with the trial or taking aspirin. Rather it was a general feeling of unease in regards to taking medication throughout pregnancy.

c. Trust in the doctor

This second-level code refers to how some women showed trust in their doctor's advice and expertise. These women felt that they placed their trust in the doctor and that this trust facilitated participation in the ASPRE trial. A common belief was that aspirin is safe to take because "they [the doctors] know what they are doing" (2, line 423 – 428).

> "I mean obviously there were lots of kind of leaflets and that sort of thing and I think the doctors, as I said were very good and you know they explained things and I think also they were always open if you did have any questions…so yeah I mean I felt comfortable doing the trial". 3, lines 350 – 357.

Some women reported feeling reassured by the medical professionals and this may have influenced their decision to participate in the ASPRE trial.
They also appeared to hold beliefs that the trial would be, if not beneficial, at least not harmful.

> "I just didn't want nothing to go wrong so I just thought there's no harm anyway cause from what the doctor was saying there's no harm in the trial, it doesn't affect the baby or nothing like that so I thought to myself why not try it". 4, line 383 – 387.

d. Extra care/support through taking part in research

This second-level code concerns the extra support women believed they would get as a result of participating in the ASPRE trial. The prospect of extra support seems to have somewhat encouraged participation in some cases.

e. Attitudes to randomisation

Randomisation was mentioned by one of the three decliners of ASPRE as the primary reason why she did not participate. This particular participant had a

close friend who had experienced PE as well as many personal issues with her previous pregnancies. As a result, she felt that participating in the trial and the possibility of being on the placebo was too great a risk. Thus rather than take part in ASPRE, this participant decided, in agreement with her partner to independently take aspirin throughout pregnancy.

> "I went to the chemist and bought some (Int: ok) erm the next, the very next day (Int: right) and started taking it that night… every single day, I didn't miss a single one". 6, lines 275 – 283.

This decliner of the ASPRE trial also spoke about their understanding that research was necessary and recognised the benefits they receive due to "all the research that's been done" (6, lines 306). She also acknowledged that this belief was contradictory to her declining to participate in the ASPRE trial. However, it was due to her personal circumstance and risks associated with her pregnancy that she declined.

3. Factors that could encourage participation in the ASPRE trial

The participant, who went on to take aspirin independently outside the trial throughout her pregnancy, stated that she would have been happy to participate in ASPRE if the trial was not randomised. She wanted a guarantee of taking aspirin, rather than the possibility of taking a placebo. In contrast, another decliner of the ASPRE trial stated that she would only consider taking part in the trial if she had started to show symptoms of PE. The third decliner of the ASPRE trial did not identify any potential factors that could have encouraged her participation in the ASPRE trial.

2.4.3 HIGH-RISK PARTICIPANTS OF ASPRE AND ILLNESS REPRESENTATIONS

This section includes data from participants who agreed to screening for PE, were identified as high-risk and subsequently agreed to participate in the

ASPRE trial. The first level codes here were all a priori, mapping on to the illness representations identified in the IPQ-R.

1. Illness cause beliefs

This first-level code refers to the reasons why participants believe their risk for PE was identified as high. Such causes can be perceived as biological, emotional, environmental or psychological. In this pilot study, the women gave a wide range of possible causes, mainly specific to their personal situations and backgrounds. The second-level themes are no specific cause, issues with the reproductive system, hereditary factors: high blood pressure in the family, ethnicity, stress during pregnancy and confusion regarding cause of PE.

a. No specific cause

Two of the women mentioned that they could not think of any specific reason why they would be at a high-risk for developing PE.

b. Issues with the reproductive system

One high-risk participant, who previously experienced PE, expressed a belief that her risk status for PE was linked to issues with her placenta. This belief was not shared by any of the other participants, presumably because they were not aware of or had not experienced any reproductive issues, which they felt correlated with PE.

c. Hereditary: high blood pressure in the family

Some high-risk participants expressed an element of surprise at their risk-status because high blood pressure and PE was not prevalent in their family. The lack of previous history of PE amongst family members appears to give the women a belief that they would be unlikely to develop PE. For example

one participant stated that she would expect that the risk-status for PE would be low "unless it more or less runs in your family" (4, line 283 – 287).

One participant, on reflection, acknowledged that high-blood pressure is common in her family, and therefore she may have a genetic predisposition as a result,

> "I think maybe genetic because of my family". 2, lines 253 – 270.

d. Ethnicity

One participant expressed a belief that her ethnic background could contribute to her high-risk status. She stated that PE is "really common among the ethnic…groups". 1, lines 242 – 245.

e. Stress during pregnancy

One participant discussed the possibility that environmental factors could have some influence over women's risk-status for PE.

> "I dunno maybe your environment or whatever you might be going through at that moment in time [Int: yeah] contributes to whatever develops in your pregnancy, so [Int: umhm] for me maybe it was like all that stress or whatever it was basically". 4, lines 184 - 199

She suggested that having a "smooth pregnancy from the beginning" (4, lines 280 – 287) could positively affect blood pressure levels and thus susceptibility to PE would decrease.

f. Confusion regarding the cause of pre-term PE

Two participants, one decliner of the ASPRE trial and one participant of the ASPRE trial, expressed a sense of confusion about the causes of PE and what could have contributed to their high-risk status, for example,

> "I understand the symptoms that you can have [Int: umhm] but erm understanding where it triggers from or why you get it, it's a bit confusing". 5, lines 219 – 221.

2. Illness coherence

In the CSM of illness representations, illness coherence refers to the ways in which a patient evaluates their illness representation as useful, whilst also assessing their level of understanding regarding their illness. Therefore, this first-level code refers to women's understanding of their at-risk status, in terms of how they understood their status and what the potential consequences were, as well as reflection on the usefulness of their illness representation.

All five participants of the ASPRE trial reported having an understanding of PE and what the consequences of their risk-status were for themselves and their unborn babies. Participants expressed knowledge of symptoms. High blood pressure was the main symptom identified as being an indicator of PE. The women were open in discussing the limitations to their knowledge but overall felt they had a good understanding of PE,

> "I'm not super expert but I can see the first signs". 2, lines 270 – 292.

Some of the women spoke explicitly about the possible outcomes if they were to develop PE, including the impact of PE on the growth and development on the baby and the potential for early delivery,

> "I knew that probably most likely the baby would, had to take out the baby earlier". 4, lines 231 – 236.

Through independent research or reading of the materials provided by their doctors, the women had some knowledge and awareness of the signs to be aware of and the consequences of PE.

3. Timeline

This first-level code refers to the time frame of PE risk-status and how long the women believed their high-risk status would last. The second-level codes here are duration of the high-risk status for PE and risk status in future pregnancies.

a. Duration of the high-risk status for pre-term PE

This second-level code concerns how long the women believe they would be considered as high-risk for PE, in their current pregnancy.

At the time of the interviews (34-37 weeks' gestation), three of the participants of the ASPRE trial expressed a belief that they would no longer be considered high-risk. From what they understood the high-risk status was present up until a certain point but by the later stage of pregnancy, if they had not developed PE they would be unlikely to do so and their risk status would not be high.

> "I don't think I'm still like a high high-risk to be honest". 4, lines 259 – 268.

> "I was told that if I didn't develop it at 20…was it 28 weeks or so…that I don't think I can have it with this pregnancy". 1, lines 229 – 235.

Despite holding this belief, one of the women suggested that she would still behave as if she definitely was still at high-risk, for example continuing to monitor her blood pressure until the end of the pregnancy.

One high-risk participant "assumed" (3, lines 230 – 234) that the high-risk status would be valid until the end of the pregnancy, whilst the final high-risk participant was unsure how long it would be relevant for. Overall there was a lack of clarity or understanding of how long the high-risk status would last.

b. Risk status in future pregnancies

This second-level code refers to women's beliefs regarding their risk status for PE in future pregnancies.

In terms of whether their current high-risk status would impact on any future susceptibility to PE, three of the five participants of the ASPRE trial stated that they would expect to be identified as high-risk for PE in a future pregnancy.

> "I suppose I'd go in with an expectation that there could…be problems". 3, lines 236 – 243.

The remaining two participants of the ASPRE trial expressed uncertainty about whether they would be high-risk in future, but also that they were hopeful that the high-risk status would not be relevant to them.

> "Maybe what I was going through from the start of the pregnancy cause my blood pressure to go a bit higher [Int: yeah] so I think maybe if you had a smooth pregnancy from the beginning you're less likely obviously to have high blood pressure, unless it more or less runs in your family or something like that basically". 4, lines 270 – 287.

4. Consequence

In accordance with the IPQ-R, this first-level code is concerned with the consequences of being identified as high-risk for PE. The second-level codes

are the impact of high-risk status on pregnancy and the impact of high-risk status on decision to have further pregnancies.

a. Impact of high-risk status in pregnancy

The five participants of the ASPRE trial reported perceptions of numerous consequences of their risk status for PE on their pregnancy. Three participants suggested that as a result of finding out their risk status for PE, they made changes to their lifestyle, taking precautionary measures in an attempt to control their risk status. In terms of diet changes, women reported reducing their salt intake as well as unhealthy, "junk food" (4, lines 341 – 355). Other 'healthy' lifestyle changes, such as: drinking more fluids; attempting to exercise; and actively monitoring weight in order to reduce the likelihood of high blood pressure were also reported.

The impact of being identified as high-risk was also demonstrated through the increased medical input women received, and in particular through attending more scans, which women found "reassuring" (3, line 250 – 262).

> "In some ways it's actually been a bit more comforting having more screening, more scans [Int: umhm], you know having that sort of continuous contact with the doctors". 3, lines 250 – 262.

> "In a way it's kind of like, it's a good thing [Int: umhm] because then obviously you get all these extra checks and everything else". 4, lines 289 – 299.

Two of the women also reported an increase in personal vigilance of their bodies and discussed monitoring themselves for potential symptoms of PE.

> "If I feel a bit swollen or if I feel that something's not gone right I do try to check my blood pressure". 2, lines 294 – 326.

> "You know the first thing you do is check that that's normal [Int: yeah] and isn't associated with potentially having any signs of preeclampsia". 3, lines 264 – 277.

This self-awareness of small changes in their body and monitoring themselves for potential symptoms appear to have been done for "peace of mind" (2, lines 294 – 326).

One participant reported actively avoiding stress as she felt this contributed to her risk status initially. She expressed a belief that further stress could potentially trigger PE onset.

> "I feel like if you're stressed your baby is stressed so I said to myself I don't want a complicated pregnancy". 4, lines 329 – 339.

None of the other participants reported avoiding stressful situations as a result of being high-risk, but also no others reported it as a putative cause. This could suggest a link between what women perceive to be the cause of their high-risk and then the actions they take to try and control it.

A further consequence of women finding out their risk status appears to have been that they decided to conduct further research on PE. Two women discussed the independent reading they had done in an attempt to "educate" (4, lines 204 – 208) themselves.

> "Obviously the first thing you do is go home and look on the internet". 3, lines 191 – 202.

These women engaged in such research and further reading as a direct consequence of being screened as high-risk for PE, in order to develop their knowledge and understanding of the condition.

b. Impact of high-risk status on decision to have further pregnancies

This second-level code explores how the experience of women being screened as high-risk for PE influences their ideas on whether they would want to have future pregnancies.

The impact of the high-risk status on the women, in terms of whether it would influence them having future pregnancies, appears to be varied, and dependant on individual circumstances. For example, only one of the women said that she would not have another pregnancy as a result of her high-risk status. This participant had PE in a previous pregnancy and described her experience as "off-putting" (5, lines 263 – 282).

> "I don't think I would go through it again because it's just too…it's too risky". 5, lines 263 – 282.

In contrast, those who had not developed PE, in this or any other pregnancy, reported that their current high-risk status would not prevent them from wanting future pregnancies. One participant reflected that her current risk status had been "well managed" (1, lines 244 – 256). This suggests that even if her risk-status were to be high again in future, she would not regard this as threatening or particularly problematic.

5. Emotional representations

This first-level code explores the emotional responses to being informed of their high-risk status. Upon finding out their high-risk status women reported various reactions. This is analysed through two second-level codes: significant initial negative emotional impact and absence of a significant negative emotional impact.

a. Significant initial negative emotional impact

This second-level code concerns women who reported a significant negative emotional impact of their high-risk status. Two participants of the ASPRE trial spoke of their fear and worry upon initially finding out their high-risk status, but the lessening of these emotions throughout the course of their pregnancy.

> "I was really scared because like the word preeclampsia…I was worried, and now that I can see that I'm not, getting to the stage and I feel that I've done everything I could". 2, lines 437 – 443.

> "As the time goes on and obviously you do the test and you get the results and from your scans, obviously it's been consistently good and nothing else had developed or nothing [Int: yeah] so it's kind of like made me less worried…more at peace". 4, lines 370 – 378.

From the women's responses it is evident that they did not feel that they had experienced any lasting effects from their initial emotional reactions, rather their high-risk status was something they had adjusted to. Their emotional reactions also seemed dependent on the events in their pregnancy; if everything was going relatively well they had no cause for increased concern.

b. Absence of a significant negative emotional impact

This second-level code explores the responses of women who reported more neutral feelings as a result of finding out their high-risk status, i.e. no particular surprise or concern. Generally, women who responded in this way did so as a result of pragmatic thinking and/or previous experience of PE.

One participant of the ASPRE trial reported the beneficial feelings as a result of knowing her risk status; she was reassured by the way her pregnancy was "under control" (1, lines 317 – 324). She reported actively trying to avoid feeling negative emotions "because being worried is going to trigger you know, like…more symptoms" (1, lines 317 – 324).

Another participant, who previously experienced PE, reported having an expectation for a high-risk status for PE, which resulted in her not being particularly surprised or worried.

> "I'm in the bracket already for preeclampsia [Int: umhm] I just haven't had the high blood pressure yet [Int: yeah] but I'm gonna have a small baby so I'm not, I'm not worried [Int: ok] cause I was fully prepared anyways". 5, lines 330 – 353.

6. Cure/control

This first–level code refers to the perceived ability to dictate the outcome of the situation and the control women feel can be exerted over their high-risk status and the potential to develop PE.

a. Beliefs concerning personal influence

This second-level code is concerned with the extent to which women believe they can personally influence the outcome of PE, and whether they can control if will develop it or not. Two participants of the ASPRE trial women expressed a belief that they had no personal control over their risk status or the development of PE.

> "I was a healthy person when I went into being told that I had high-risk of preeclampsia [Int: umhm] I didn't think that there was anything really that I could do to control it". 3, lines 387 – 398.

> **"**I just think that it's internally [Int: umhm] the situation, there's nothing I can really do". 5, lines 305 – 313.

The remaining three participants of the ASPRE trial expressed a perception of some personal control over their situation. The idea of personal control

centred on lifestyle factors. For example, eating habits were discussed, including exerting control via a healthy diet,

> "I know that I had a chance [to control] that it why I've tried to avoid the small things, even soy sauce which is really, really, rich in sodium [Int: yeah], so I think that yes, I think knowing, everything I did, I think it helped". 2, lines 554 – 567.

> "Have enough food intake, eat more veg and you know greens". 1, lines 375 – 394.

Women reported making dietary changes (eating more vegetables and reducing salt intake) in an attempt to control their high-risk status and prevent the development of PE.

Similarly ensuring they took enough rest when feeling tired was also reported as a potential lifestyle factor that could help them to control the situation.

> "I think personally if you like, if you don't have such a hectic life or a stressful life [Int: umhm] or a good diet or whatever it is basically [Int: umhm], I think you're less likely to have those issues to be honest". 4, lines 487 – 503.

Although these women did express some doubt that lifestyle factors alone could not prevent the onset of PE, the general feeling was that they had some potential benefit.

b. Beliefs concerning the influence of aspirin on the outcome

This second-level code refers to women's beliefs regarding the extent to which aspirin can control or prevent the onset of PE, in those who have been screened as high-risk. The women expressed various beliefs regarding the potential influence of aspirin on their risk of developing PE. None of the

participants perceived aspirin to be able to absolutely control the development of PE; they all had some doubts over its effectiveness.

One participant of the ASPRE trial discussed the potential benefits that could come from taking aspirin throughout pregnancy. She recognised that aspirin was not guaranteed to prevent PE or benefit their situation however it was noted "there's always a hope that it will do something" (3, lines 400 – 414).

One participant also reported a belief that the aspirin could have an element of control over the situation but also that lifestyle factors held some influence.

> "I can't say whether or not it's because my life 'isn't stressful that's why I never developed it or maybe cause the tablets helped to reduce [Int: yeah] it or stuff like that, but there's no harm in trying anyway". 4, lines 505 – 519.

Again the factors, which participants believed could contribute to the cause of PE or high-risk status, are relevant here. As the participant above (4) regarded stress as a cause of her high-risk status, she also inevitably felt that its presence could impact on the outcome, whilst also recognising that the aspirin could have some influence, i.e. perception of multiple influences.

Two participants seemed unsure of the effects of the aspirin, and also whether other factors, such as lifestyle, could influence the high-risk status.

> "I don't know if it's, if the aspirin was helping not develop, plus the lifestyle as well [Int: yeah] yeah. I'm not, I don't know how to answer this question". 2, lines 569 – 577.

> "I'm not too sure but like with my situation [Int: umhm] I don't know if the tablets are working or not". 5, lines 423 – 435.

This confusion regarding the influence of aspirin could be attributed to the amount that remains unknown about PE.

2.5 REVIEW OF METHODOLOGY

The pilot study, although relatively small, enabled the interview schedules to be tried and tested. As a result, questions, which did not yield relevant or rich data, were able to be removed from the schedule, whilst other questions were able to be adapted and improved. Following the pilot study, it was been decided that the IPQ-R dimensions of the interview schedule will be included in all interviews so as to attempt to compare the illness representations of high- and low-risk women.

Similarly, the pilot study provided an opportunity to use template analysis, a technique previously unfamiliar to the researcher, and confirm that it is the most suitable analysis for the requirements of these studies. With semi-structured interviews there is a potential to have an elaborate and extensive set of themes arise; however, matching the topics covered in the interview to the themes in the template enabled more efficient coding. The template was flexible enough to adapt to individual conversations, and changes to the schedules, but will provide a thorough basis from which to begin data analysis for future studies.

Several changes were made to the initial template, including the inclusion of more second- and third-level themes. The full template constructed following the pilot study can be found in Appendix 7.8. Some examples of changes made to the template following the study are shown in Table 2.3.

Table. 2.3

Initial template	**Post-pilot template**
First-level theme: decision-making regarding screening	*First-level theme:* decision-making regarding screening for PE *First-level theme:* thoughts regarding screening in pregnancy

Second-level themes: thoughts regarding screening in pregnancy, thoughts about screening for PE	
First-level theme: IPQ-R timeline	*First-level theme:* IPQ-R timeline Second-level themes: duration of the high-risk status for PE, risk status in future pregnancies
First-level theme: benefit of advanced knowledge of PE risk status early on in pregnancy/overall evaluation	*First-level theme:* utility of advanced knowledge of PE risk status early on in pregnancy/overall evaluation *Second-level theme:* knowledge is good *Third-level themes:* for prevention of problems, raised awareness to monitor early signs of problems

Several changes were also made to the interview schedule as a result of the pilot study. The most significant change was the addition of questions relating to the IPQ-R subscales to the low-risk interview schedule. It was decided that these would be added in order to provide comparison with the responses of high-risk women. The interview schedules for high-risk decliners and participants of the ASPRE trial were also merged so that they were all asked the same set of questions. The only difference was that women in the ASPRE trial were asked about how well they were remembering to take their tablets and how they felt about taking their tablets. The full interview schedules can be found in Appendix 7.9 and 7.10. For the high-risk women a further question was added regarding their perception of risk and how likely they felt it was that they would develop PE. A further question was added to the interview schedule to explore whether women (both high- and low-risk) would recommend screening for pre-term PE risk to other expectant mothers. Ultimately the pilot study enabled adaptations to both the interview

schedule and template which resulted in a clearer, more refined methodology for the future studies of this thesis.

Due to the wider constraints of the ASPRE trial, timing of the pilot study could not have been altered. However, throughout the study it became clear that the time lapse between when the present participants had been screened for pre-term PE and been given their risk status, and then interviewed was too long. Women were interviewed, as part of the pilot study, between 34 and 37 weeks' gestation or postpartum. Not only does this present the issue of a time and memory bias but 36 weeks' gestation is regarded as full term and, therefore, these women are almost past the point of which pre-term PE can occur. Similarly, those contacted postpartum may present altered views if they have experienced the full pregnancy and birth without developing PE. As the end result was a healthy pregnancy, it might have impacted the way in which they reflect on finding out about their risk status. In future studies interviews will aim to take place prior to 24 weeks' gestation; this will ensure that some time has passed, allowing women to accept their risk status but women should still be able to recall their conversations, decisions and feelings about their screening result.

CHAPTER THREE

3 WOMEN'S ILLNESS REPRESENTATIONS AND EMOTIONAL RESPONSES REGARDING PREECLAMPSIA RISK STATUS: A QUALITATIVE STUDY

3.1 ABSTRACT

Objective: The current study aimed to explore the cognitive and emotional illness representations of women, recently informed of their risk status for preeclampsia, following first-trimester screening. A further aim was to investigate the emotional impact of the screening results, for both low- and high-risk women.

Design: Cross-sectional interview study, using a semi-structured interview schedule, with questions relating to each cognitive and emotional illness representations, informed by the Common-Sense Model of illness representations. Specific questions also addressed any potential emotional consequences of the screening. Transcripts were analysed using Template Analysis.

Setting and participants: Women receiving prenatal care at two London National Health Service Trusts, who were offered screening for PE risk status during their nuchal scans, at 11-14 weeks gestation. In total 39 women were interviewed; 12 were identified as low-risk, and 27 were at high-risk of developing PE. Of the 27 high-risk women, 14 agreed to participate in the ASPRE RCT and 13 declined participation.

Findings: Illness representations were found to be complex and co-influential; for example, perceived cause can influence control and consequence. Women were more knowledgeable regarding the maternal health effects of preeclampsia and had a low perception of risk, regardless of their screening result. The emotional impact experienced following screening

was negligible, and in-line with what is expected when an individual receives a health threat.

Implications for practice: In order to address the limitations in women's knowledge regarding the fetal consequences of PE, healthcare professionals should attempt to increase awareness of the condition and the consequences of the screening test. Further research is needed to investigate how illness representations change during and post-pregnancy, and how they may influence future maternal behaviours and health choices.

3.2 INTRODUCTION

3.2.1 THE CSM

The Common-Sense Model of illness representations (CSM; Leventhal, Meyer, & Nerenz, 1980) is a theoretical framework, identifying the cognitive and emotional responses an individual generates after receiving an illness diagnosis or health threat. The illness representations are formed following the perception and interpretation of different sources of information, which are shaped by an individual's existing knowledge of the illness or health threat, as well as input from significant others and healthcare professionals (external stimuli) and their current or previous illness experiences and symptoms (internal stimuli; Hagger & Orbell, 2003).

Research has identified five cognitive illness representation dimensions: identity (the label given to the illness/health threat), cause (of the illness/health threat), consequence (impact on individual), timeline (when the illness will develop and for how long) and cure/control (the extent to which the illness/health threat can be cured or managed, personally or through treatment) (Lau & Hartman, 1983). Emotion and cognitive illness representations occur simultaneously.

Within the CSM framework, the individual receiving the health threat acts as an active problem solver (Diefenbach & Leventhal, 1996). Through the parallel processing system, an individual acknowledges a health threat,

activating their cognitive and emotional illness representations, which influence the reactions and behavioural response, including coping mechanisms. The individual will then appraise their response, the process will then be repeated in the opposite direction, with behaviours reappraised and illness representations altered as necessary; this is known as parallel processing (Leventhal et al., 1980; Moss-Morris et al., 2002; Meyer, Leventhal & Gutmann, 1985). Individuals have unique responses, dependant on their personal illness representations, which are influenced by their own experiences and previous knowledge (Weinmann Petrie, Moss-Morris, & Horne, 1996). Illness representations have also been found to be linked and influential through parallel processing (e.g. Leventhal, Weinman, Leventhal, & Phillips, 2008). See chapter 1 for a more detailed explanation of the CSM, its dimensions and parallel processing.

In early explorations of the CSM, semi-structured interviews and qualitative analyses were used to assess illness representations (Leventhal & Nerenz, 1985). This method was successful and provided the initial evidence for the CSM dimensions, yet it was acknowledged qualitative methods were time-consuming and would be difficult to replicate in some illness groups (Weinman et al., 1996).

Thus, a theoretically derived quantitative assessment was developed, in order to measure the cognitive illness representations, amongst various populations (the Illness Perception Questionnaire, IPQ, Weinman et al., 1996). The IPQ was subsequently revised twice: the revised IPQ (IPQ-R, Moss-Morris, Weinman, Petrie, Horne, Cameron, & Buick, 2002) extended the original scale and introduced an assessment of the emotional illness representation; the brief IPQ (Broadbent, Petrie, Main, & Weinman, 2006) consists of a reduced scale, assessing both cognitive and emotion illness representations, which is suitable for use with severely ill populations and on a large study scale. These quantitative assessments have been proven to elicit and assess illness representations within various ill and at-risk populations.

3.2.2 THE CSM AND CHRONIC ILLNESSES

Significant research has been conducted investigating the illness representations of individuals suffering with chronic illnesses, and the impact of these representations on health behaviours, medication adherence and health outcomes has been demonstrated across a variety of long-term conditions. Hagger and Orbell (2003) conducted a meta-analysis of 57 quantitative studies, examining the illness representations across 23 different illnesses and health threats, including psoriasis, diabetes, chronic fatigue syndrome and epilepsy. It was found that regardless of the illness or health threat, individuals were consistent in their development of illness representations. The meta-analysis also found that perceptions of health threat controllability and consequence influenced the coping mechanism used. The majority of studies featured in the Hagger and Orbell (2003) used the IPQ, IPQ-R, the Implicit Models of Illness Questionnaire (Turk, Rudy, & Salovey, 1986) or the Personal Models of Diabetes Interview (Hampson, Glasgow, & Toobert, 1990). These quantitative evaluations of illness representations are the most widely used and accepted in CSM research. However, as with the original CSM studies (e.g. Leventhal et al., 1980), semi-structured, qualitative interviews remain a valid and fruitful method to explore illness representations, particularly in under-researched populations. Research has suggested that the use of quantitative questionnaires, such as the IPQ and its variants, can often be inappropriate to explore illness representations of particular populations, which may alter, depending on treatment or screening tests available (Higbed & Fox, 2010). For example, when studying the illness representations of individuals with anorexia nervosa (AN), a qualitative method was deemed more appropriate as individuals suffering from AN are likely to have different health beliefs than those with a physical, symptomatic condition and so a quantitative assessment may not fully explore or explain their beliefs (Higbed & Fox, 2010). Similarly, Goodman, Morrissey, Graham and Bossingham (2005) argued that a qualitative method is better suited to illness populations who are under-represented in the CSM literature as it allows a deeper understanding of the participant's experiences, and so they used semi-

structured interviewing when investigating the illness representations of systemic lupus erythematosus. The original approach of using semi-structured interviews, based on the CSM dimensions, allows illness representations to be elicited and assessed in an exploratory manner.

3.2.3 THE CSM AND PREGNANCY

The majority of research conducted prior to the Hagger and Orbell meta-analysis was conducted with chronically ill, symptomatic populations. Increasingly the literature is attempting to assess and evaluate illness representations in healthy populations and individuals at-risk of illness (e.g. Cameron, 2008; Hilgart, Mercer, & Thirlaway, 2012). However, there is a lack of research investigating illness representations and screening during pregnancy.

The psychological effect of screening, for conditions, which affect both the foetus and the mother, has not yet been identified. One such condition is preeclampsia (PE); a hypertensive disorder of pregnancy, posing a significant risk to both maternal and fetal mortality and morbidity (Rolnik et al., 2017). PE affects between 2% and 8% of pregnancies (Duley, 2009) and complications can include maternal organ dysfunction (Sibai, Dekker, & Kupferminc, 2005), fetal growth complications (Yu, Khourni, Onwudiwe, Spiliopoulos, & Nicolaides, 2008) and placental insufficiency (WHO, 2011). Screening for PE is not currently endorsed by the UK National Screening Committee (NSC; 2011) due to a lack of research surrounding the psychological effects of current available screening tests and the lack of evidenced treatment available for those identified as high-risk.

The current screening test available to identify women as high- or low-risk for PE, involves combining maternal history and characteristics with biophysical and biochemical factors (Poon, Syngelaki, Akolekar, Lai, & Nicolaides, 2012). To date, there is limited research exploring the psychological effects of screening for PE risk status. In a qualitative study, using the State Trait Anxiety Inventory (STAI-S), no differences were found

in self-reported levels of anxiety between low- and high-risk women, screened for PE risk status in the first trimester (Simeone et al., 2015).

One study has attempted to provide more of an overview of the psychological impact of screening for PE (rather than anxiety alone as in Simeone et al., 2015), using the CSM of illness representations (Harris, Franck, Green, & Michie, 2014). The CSM is an appropriate theoretical framework, to explore the psychological impact of screening for PE, as it is a parallel processing model explaining how individuals react, cope and evaluate health risks (Harris et al., 2014). The model is able to explore the psychological impact through the emotional dimension, but also through the various cognitive elements, which thus give an overall explanation of the impact of screening for PE. Harris et al. (2014) used a qualitative method, conducting semi-structured interviews with 10 women identified as high-risk and 5 low-risk women. The interview guide included various questions concerning the CSM dimensions (identity, cause, coherence, control/cure, timeline, consequence, emotion) as well as women's perception of risk. Questions were included to elicit responses referring to the specific dimension of the CSM, for example a question within the emotion dimension was 'has your mood changed as a result of receiving the test result? If so, how?'

Harris et al. (2014) reported that low-risk women were reassured by their low-risk result, focusing more on the procedure of the screening test than their screen-negative result, whilst high-risk women were categorised as either danger managers or fear managers. Danger managers were concerned with the maternal consequences of PE, indicating high levels of internal control and subsequent behaviour changes, information seeking and cognitive reappraisal. In contrast, fear managers were more focused on the fetal consequences of PE, with a high sense of external control and the use of avoidance and threat minimisation coping strategies. Both high-risk groups were found to have low perception of risk, despite their screening results. Although Harris et al. (2014) included questions referring to each dimension of the CSM, they did not analyse them separately and so differences between low- and high-risk women for the individual dimensions have yet to be established. In order to thoroughly evaluate the psychological impact of

screening for PE, the dimensions should be examined independently, as well as together. This would increase the generalisability of the results and allow exploration of women's experiences not covered by quantitative investigations.

3.2.4 THE EMOTIONAL IMPACT OF SCREENING DURING PREGNANCY

In the area of fetal medicine, as with other illness screenings research has explored both the decision-making processes, as well as the psychological, emotional and behavioural effects of screening (although there is significantly less research in this area). In 2012, Harris et al. conducted a systematic literature review to establish the psychological effects of screening for maternal (18 studies) and fetal (33 studies, 4 reviews) conditions. It was found that women experienced increased anxiety levels following screening for fetal conditions, but not when they had been screened for maternal conditions. Six studies found that anxiety levels increased further following a positive result, whilst anxiety levels of women who received negative results decreased significantly. In some cases, it was reported that anxiety levels of women with a negative result reduced to lower than at pre-screen (Ekelin, Crang-Svalenius, & Dykes, 2004; Larsson, Svalenius, Marsal, Ekelin, Nyberg, & Dykes, 2009). It is noted that although there is no evidence suggesting emotional impact of screening for maternal conditions, many of the studies used non-validated measures. Some studies demonstrated behavioural changes as a result of screening, both for maternal and fetal conditions (e.g. Griffiths, Rogers, & Moses, 1993; Nabhan & Faris, 2010), but methodological issues and a lack of evidence make it difficult to establish the true influence. The review found that screening, for maternal or fetal conditions, is associated with cognitive outcomes, including increased maternal responsibility, negative perceptions of their own health and decreased attachment following a positive result. Harris et al., (2012) recognise that the psychological effect of screening is not fully understood and further research needs to be done.

3.2.5 OVERVIEW OF THE CURRENT STUDY

As the screening test for PE is not routine, there is little evidence of the psychological effects of finding out risk status for PE, following first-trimester screening. Simeone et al. (2015) used the State Trait Anxiety Inventory (STAI-S) with 255 women (135 low-risk and 120 high-risk) who took part in screening for PE risk status and found no significant differences between the groups. Of these women, 102 were followed longitudinally (in the second and third trimesters) but again no differences were found between the anxiety scores of low- and high-risk women. Whilst this large-scale study provides encouraging results, there are potentially other emotional effects women may experience as a result of screening for PE. The Common-sense model of illness representations (CSM) is a parallel processing model that states that individuals experience a range of emotional and cognitive reactions after learning of a health threat or illness (Diefenbach & Leventhal, 1996; see chapter 1). Emotional reactions are thought to continually develop during treatment, following the use of coping mechanisms, and as a direct result of experiencing condition-related symptoms. To date the psychological effects of screening for PE have only been explored, quantitatively and within the framework of the CSM, with a small sample (10 high-risk and 5 low-risk; Harris et al., 2014). It was found that there could potentially be positive and negative consequences following a PE screening result; women may increase or decrease their level of self-monitoring depending on their risk status. The interview schedule in the Harris et al. (2014) study did not, however, include questions or prompts to explore emotional reactions to screening results. Further qualitative research is necessary, therefore, to identify a potential range of emotional reactions women may experience.

The current study also seeks to build on the work of Harris et al. (2014), by reporting the similarities and/or differences between low- and high-risk women, in terms of their responses to CSM dimension-related questions. The current study will further expand on previous research by including and exploring the differences and similarities between two groups of high-risk

women: those participating in a clinical RCT aimed to reduce pre-term PE incidence, and those who declined participation in the RCT (the ASPRE trial). The current study will also aim to increase recruitment compared to the Harris et al. (2014) study.

3.2.6 RESEARCH AIMS

The current study aims to explore women's illness representations following a screening test for pre-term PE risk. A further aim is to explore the emotional responses of women following their screening test and result.

3.3 MATERIALS AND METHODS

3.3.1 DESIGN AND SETTING

Semi-structured interviews were conducted with women who had been identified as high-risk for PE, through screening, which took place at their 12 week nuchal scan appointments at two National Health Service hospitals in London, UK. The interviews were transcribed and analysed, using Template Analysis (King, 2012) to explore how low- and high-risk women differ in their emotional responses to PE screening results, as well as their illness representations.

3.3.2 SAMPLE

Women who underwent screening for pre-term-PE risk status were contacted, in person, via email/post or by telephone, by the researcher and invited to participate in the current qualitative study. In total 39 women agreed and were interviewed; 12 were identified as low-risk and 27 were identified as high-risk, with 14 participating in the ASPRE trial, and the remaining 13 were decliners of the trial. The mean age of low risk women was 32.4 years; the mean age of high-risk participants was 35.1 years, and 30.9 years for high-risk decliners. The mean gestation at time of interview was

21+3 weeks for low-risk women (range 15+1 to 33+5; SD = 6.14), 21+5 weeks for high-risk participants (range 16+6 to 28+3; SD = 4.19), and 26+3 weeks for high-risk decliners (range 14+6 to 36+6; SD = 6.41).

Table 3.1. Sample characteristics

	High-risk participants (14)		High-risk decliners (13)		Low-risk	
	N	%	N	%	N	%
Ethnicity						
Caucasian	9	64.29	7	53.85	9	75
Black	4	28.57	5	38.46	2	16.66
South Asian	1	7.14	1	7.69	1	8.33
Education						
Primary school	0	0	1	7.69	0	
A levels or equivalent	1	7.14	3	23.08	2	16.66
University degree	7	50.00	5	38.46	6	50.00
Postgraduate degree	6	42.86	4	30.77	4	33.33
Marital Status						
Living with partner	12	85.71	12	92.31	11	91.66
In a relationship but not living together	1	7.14	1	7.69	1	8.33
Single	1	7.14	0	0	0	
Pregnancy history						
Previous pregnancy	2	14.29	4	30.77	5	41.66
First pregnancy	12	85.71	9	69.23	7	58.33
Medical complications						
None	12	85.71	12	92.31	12	100
Asthma	2	14.29	0	0	0	0
Polycystic ovaries syndrome	0	0	1	7.69	0	0

3.3.3 PROCEDURE

Pregnant women attending for their 11-14-week ultrasound scan appointments were offered the opportunity to be screened for pre-term-PE risk status. Alongside appointment letters, women received information leaflets regarding the various screening tests that would be available at the 11-14 week ultrasound -scans. They were also given an information sheet on the day of their appointment, detailing the process in screening for PE risk status, before they were asked if they would like to participate in the screening.

Results of the pre-term-PE screening were available on the same day and women were identified as either screen negative, i.e. low-risk for developing pre-term-PE, or screen positive, i.e. high-risk of developing pre-term-PE. Those identified as high-risk were offered counselling by a research doctor and invited to participate in a medicated RCT, known as the ASPRE trial. Women were given information sheets regarding the ASPRE trial and had the opportunity to ask questions and speak further with the research doctor. High-risk women were given the option to decide the same day or take longer to consider, but participation in the trial could not begin after 14+6 weeks gestation.

In order to participate in the ASPRE trial, women had to be over 18 years old, have a single pregnancy and a live fetus at 11-14 weeks gestation, be screened as high-risk for PE and give written consent. The same inclusion criterion was used for the present study.

The researcher contacted women who had been screened high-risk for pre-term-PE risk status and invited them to participate in the interview study. Potential participants were sent an information sheet, via post or email, outlining the study and a reply form, allowing the women to give details of how and when they would like to be contacted, should they decide to participate. Women were given the opportunity to be interviewed at their

home, at the hospital, or via telephone. Where the interviews took place face to face, the researcher obtained written consent; verbal consent was obtained during telephone interviews. All participants were aware they had the right to decline answering questions if they were not comfortable and could terminate the interview or withdraw from the study, at any time, without giving reason and without subsequent influence on their antenatal care. All interviews were recorded on a dictaphone and transcribed.

3.3.4 SEMI-STRUCTURED INTERVIEWS

A semi-structured interview schedule was developed, based on a review of existing literature and previous pilot work. The interview schedule was designed to investigate how women responded emotionally to finding out their risk status for pre-term-PE and which illness representations were elicited upon finding out their result. Questions were included regarding the six cognitive dimensions of the CSM (coherence, identity, cause, timeline, consequence and cure/control) and the emotional responses that followed the PE screening result. The schedule was flexible and adaptable depending on women's answers, but also included prompts for the interviewer to encourage expansion of response.

3.3.5 ETHICAL CONSIDERATIONS

The local National Health Service research ethics committee gave ethics approval (ref: 14/LO/1238) for this study. Potential participants were given an information leaflet detailing the requirements of the study, as well as a period of at least 24 hours to consider participation. Prior to the interview commencing women were required to give consent. They were made aware that all participation was confidential; transcripts were shared with the research team but all identifiable information was removed.

3.3.6 ANALYTICAL METHODS

The interview transcripts were analysed using template analysis. Template analysis refers to a group of techniques used to thematically analyse and organise data (King, 2012). It was appropriate for use in the present study due to the exploratory nature of the data but also the use of a priori themes, common to template analysis. A priori themes enable the researcher to identify themes, which are likely to occur in the data and be of significant value to the research questions, before beginning data analysis. The template of themes is, therefore constructed before analysis begins (see Appendix 7.7), but it is flexible so that any themes, which are not present in the data, can be removed, and similarly themes, which emerge from the data, can be identified and included in the template. The initial template was created, based on pilot work and study aims, as well as arising from the interview schedule (see Appendix 7.8 and 7.9). For example, the question 'do you have any thoughts about why you got the result?' directly relates to the first-level theme in the initial template 'IPQ-R: illness cause beliefs'. The question was deliberately open so that women could express their views on the causes, and the data analysis led to further development of second- and third-level themes, found in Table 3.2. The template was developed throughout the process of data analysis and themes were added, modified or deleted from the template as necessary.

3.4 RESULTS

The template analysis identified eight first-level themes: coherence of PE risk status, identity, cause, timeline, consequence, control/cure, emotional impact of the low-risk results and emotional impact of the high-risk results. The full template of the first-level themes, and associated second- and third-level themes is shown in Table 1.

Throughout this results section all participants are referred to by number, rather than name. Where participant quotes are presented, the participant number, the participant group and the line numbers, corresponding to their transcript, follow them. The participant groups have been abbreviated as

follows: HR-PA (high-risk participants of ASPRE); HR-DA (high-risk decliners of ASPRE); LR (low-risk).

Table 3.2. Table of themes

First-level theme	Second-level theme	Third-level theme
1. Coherence of PE risk status	a. Understanding own PE risk status b. No clear understanding of own PE risk status c. Understanding of how PE risk status is calculated d. No clear understanding of how PE risk status is calculated	
2. Identity	a. Knowledge of PE b. Symptoms of PE c. Predictability of PE	 i. Predictable by medical staff ii. Predictable by self-monitoring iii. Unpredictable
3. Cause	a. Blood pressure b. General health c. Age d. Weight e. Measurements taken in the 12-week scan f. Confusion regarding cause of PE	i. Hereditary: high blood pressure or previous preeclampsia in the family ii. Previous personal high blood pressure

4. Timeline	a. Knowledge of timeline for PE	
	b. Duration of the 'high-risk' status for PE	i. Until the end of pregnancy ii. Not sure
	c. Risk status in future pregnancies	i. Probably yes ii. Probably (hopefully) not iii. Unknown
5. Consequence	a. Impact of high-risk status on pregnancy	i. Lifestyle change: eating healthily and exercising ii. Avoiding stress iii. Personal research on PE iv. Increased medical input (more scans) seen as reassuring v. Increased vigilance of symptoms e.g. blood pressure monitoring, checking for swelling vi. Increased awareness of potential problems during pregnancy vii. Absence of significant changes or impact
	b. Impact of high-risk status on decision to have further pregnancies	
6. Control/cure	a. Beliefs concerning personal influence	i. Perception of no personal control ii. Perception of (some) control through diet and exercise iii. Unsure
	b. Beliefs concerning the influence of aspirin on the outcome of PE	i. Belief that aspirin could be helpful in preventing PE ii. Not sure

7. Emotional impact of low-risk results	a. Reassured and relieved b. No memory of being informed of the results	
8. Emotional impact of the high-risk results	a. Negative emotional impact	
	b. Absence of a negative emotional impact	i. Absence of a surprise

1. Coherence of PE risk status

This first-level theme refers to the understanding that women had regarding their personal risk status for PE, following screening at their 12-week scanning appointment. This includes knowledge of how their risk status could influence their pregnancy and what the consequences of their risk status would be personally. Responses were separated into two second-level themes: 'understanding own PE risk status' and 'no clear understanding of own PE risk status'. Two further second-level themes refer to women's understanding of how their risk status was calculated at the 12-week scan: 'understanding of how PE risk status is calculated'; 'no clear understanding of how PE risk status is calculated'.

a. Understanding own PE risk status

The majority of women, in each participant group, reported a good understanding of their own risk status. In particular, the women were able to express knowledge that their risk status was an indicator of how likely they were to develop PE later in pregnancy but that the test was not diagnostic and thus they may or may not develop PE, regardless of being high- or low-risk at 12-weeks gestation. Eight of the 12 low-risk women demonstrated having good knowledge of their risk status, as well as 11 high-risk participants of ASPRE (out of 14) and 10 high-risk decliners of ASPRE (out of 13).

> "It's high-risk so it's not guaranteed you're going to get it or develop it erm but it gave me the chance to ask more about it, ask what to look out for and what I could do to minimise that risk as well, so it was a good chance to get all of the information and just like I say find out more about what it was". 23, HR-DA, lines 138-144.

> "I take that as you're either low risk or your high risk it's not, it doesn't mean anything other than it's a risk indicator, just like with

> any other screening it's, you come back as a low risk but it doesn't mean that everything will be fine, there is always the possibility, it's just that your risk is lower". 33, LR, lines 391-396.

> "It wasn't that I was going to have preeclampsia it was more that I was statistically in that category of people that did, and there's a big difference between those two things". 13, HR-PA, lines 244-249.

These responses are typical across all of the women with a good understanding of their PE risk status. Women identified as low-risk acknowledged that "obviously there is still a risk but it's a lower risk" (35, LR, line 307-308) than those women identified as high-risk.
Similarly, high-risk women (both participants and decliners of the ASPRE trial) expressed views that although they were at a higher chance of developing PE, it was not a "definitive thing" (18, HR-DA, lines 215-220).

b. No clear understanding of own PE risk status

In total, the responses of ten women (4 low-risk; 3 high-risk participants of ASPRE; 3 high-risk decliners of ASPRE), out of the 39 interviewed, suggested that they did not have a clear understanding of what their PE risk status meant for them personally. Those identified as high-risk expressed some confusion regarding what this actually meant:

> "I guess I'm just not quite sure like I said what the high risk actually means, is it guaranteed, is it not?" 9, HR-PA, lines 723-724.

> "The main thing is that I didn't understand the typical rate and what does high risk actually mean". 19, HR-DA, lines, 460-461.

> "She couldn't tell me if it was 80% risk or 20% and it was high so I guess more than 50%. I don't know what that means, high risk". 3, HR-PA, lines 706-708.

As these responses show, the women were unsure whether their risk status would mean they would develop PE, or what their risk status was in terms of a percentage. One of the low-risk women also expressed confusion regarding how long their risk status would last during the pregnancy:

> "What I don't know is when I came back as low risk, does it mean that I am low risk at the time or does it mean I am low risk all the way through to full term". 31, LR, lines 191-194.

Another low-risk woman stated that all she knew of her low-risk status was "that it was good, really" (29, LR, line 130). These extracts suggest that women were unclear as to whether their risk status was definitive and would last throughout pregnancy, or whether there was still a likelihood that they could develop PE.

c. Understanding of how PE risk status is calculated

This second-level theme includes responses from women who expressed some understanding of how their risk status was calculated. They were able to, consistently, identify two or more of the markers used to calculate risk status and recall some of the events of the nuchal scan that specifically related to PE screening. Twenty of the 39 women (3 low-risk; 10 high-risk participants of ASPRE; 7 high-risk decliners of ASPRE) demonstrated a good understanding of the screening process and how PE risk status was calculated.

Of the 14 high-risk participants of ASPRE, 10 had a good understanding of how risk status is calculated:

> "We went through the four types of, like family history, blood pressure, and I think is the blood flow to the baby something like that, and three out of four came up, and that is when I was told I'd be at a risk of getting preeclampsia later on". 11, HR-PA, lines 54-58.

> "Only, from what I can remember was the blood pressure and the flows in and out of the uterus and then they tested for a particular type of hormone which from previous research you have associated that with having preeclampsia". 7, HR-PA, lines 390-393.

> "They seem to do a lot of measurements so I think they measured it. I don't know if it was too high or too low. I guess the blood flow—I think she explained to me, actually. It's like the placenta may be had to do more effort to get the blood to the baby…that's how they identified it. Maybe the fact that it was also my first baby…I guess it put a lot of things together". 3, HR-PA, lines 587-600.

The high-risk participants of ASPRE generally reported that risk status was calculated by combining various measurements, taken during the nuchal scan, with blood pressure and the "bloods that I'd given" (6, HR-PA, line 212). This understanding was also shared by seven (out of 13) high-risk decliners of ASPRE:

> "Blood pressure and there's also something in my blood there were looking for I can't recall if that was hormones or proteins or something but erm, it was going to be that with a combination of the blood pressure I think". 19, HR-DA, 452-455.

> "I think it was a couple of markers in the blood, speed of blood flow through various different vessels. Plus, blood pressure, isn't it and age or something like that and BMI". 15, HR-DA, lines 147-149.

High-risk women were, overall, able to give a more detailed account of how PE risk status is calculated, in comparison to low-risk women, suggesting they had a better understanding of the procedure. However, three (out of 12) low-risk women did show some understanding of PE screening, reporting that risk status was calculated using a combination of "the blood pressure and the blood test" (30, LR, line 110), as well as measurements of the "blood flow" (32, LR, line 228) in the "placenta, from the scan" (28, LR, line 198).

d. No clear understanding of how PE risk status is calculated

This second-level theme includes extracts from interviews with women who did not have a clear understanding of how PE risk status was calculated. Responses in this theme mainly come from low-risk women (9 out of 12) and high-risk decliners of the ASPRE trial (6 out of 13). They reported some confusion as to how and why they were given their risk status:

> "I am a bit confused as to how I was diagnosed with being a high risk of preeclampsia". 17, HR-DA, lines 65-66.

> "They found something in the scan I think it was to do with I don't know, just something they seen in the scan, the gap between something and something like that but like I've got no family history, I've never had high blood pressure in my life, I'm young and healthy, so if anything I think I'll be fine". 20, HR-DA, lines 310-15.

> "I had assumed that it's based on your risk factors which again I'd assumed are similar for hypertension in obesity, poor diet and lack of exercise, etc. But, actually, as part of this trial I realised that it's clearly not quite the whole story, because there is something they can do about blood and actually I am not clear at all what that is". 37, LR, lines 270-276.

Some women were also unsure as to what part of the scan was relevant for the PE screening:

> "I can't remember which bit related to which bit". 36, LR, line 125.

> "I don't actually know what they did find out, so I'd be interested to know actually, yeah, so I don't remember going through it, I don't think I was aware of it". 38, LR, lines 197-200.

Due to the trial nature of the PE screening women were given participant information sheets, detailing the screening process; however, as these responses show, many of the women were unclear as to how the results were calculated, even after the screening had taken place. This was also the case with some of the high-risk participants of ASPRE, albeit a lower proportion of participants, compared with the two other groups (4 high-risk participants of ASPRE, out of 14).

> "Still don't 100% understand how that conclusion came about…once we understood what it was, I didn't really go into how they came to that conclusion". 10, HR-PA, lines 161-166.

> "I didn't know there was screening for it. I didn't know what the screening, was it actually to do with the blood test that they do. I don't even know that". 8, HR-PA, lines 134-136.

> "I don't think I absorbed it all when they did tell me, but it was a lot of information to take in at the time anyway…once the results came back and then they explained to me pretty much all over again erm what had contributed to that result and then it started to make a little bit more sense, don't ask me what it was because I don't remember all of it". 13, HR-PA, lines 164-171.

From the extracts above it is evident that some women, across all participant groups, are unclear about how PE risk status is calculated and the various reasons why they might be at-risk. This is despite being given the information sheets prior to the screening taking place.

2. Identity

This first-level theme is concerned with the identity component of the IPQ-R, which relates to the knowledge an individual has regarding their illness. For the purpose of the current study, 'identity' refers to the knowledge women have regarding PE, a condition they could potentially develop in pregnancy. The second-level themes are concerned with knowledge of PE, symptoms of PE and the predictability of PE.

a. Knowledge of PE

This second-level theme explores the general understanding of PE, held by some of the women interviewed. All 14 women who were identified as high-risk, and were participating in the ASPRE trial, had some understanding of PE. In total 36 out of the 39 women interviewed, had some accurate knowledge of what PE was, how it could potentially affect them and/or their unborn baby as well as the timeline of development for PE. Their responses are explored below: they have not been coded into further sub-themes as the consequences for mother and baby are inextricably linked. However, 'knowledge of timeline for PE development' has been included as a third-level theme.

Some women were able to provide a clear understanding of the illness, in regards to the symptoms and consequences of PE.

> "What I understand is that it can cause high blood pressure and protein in the urine, of the mother and at a higher risk you might have to be induced earlier". 11, HR-PA, lines 278-280.

> "It's a major cause of premature birth and that in really rare cases it can happen really too early so that you lose the baby and in rarer cases…it can be fatal for the mum as well as the baby. It was something serious". 3, HR-PA, lines 211-215.

> "Well, for me, I thought it was high blood pressure, protein in your urine, swelling and I know you can get bad headaches. And, you can fit and the baby can, you can die. For me I know it's a serious condition that can happen in pregnancy". 4, HR-PA, lines 446-450.

As these extracts show, women from all three participant groups were aware that PE was predominantly characterised by high blood pressure, which can affect both mother and unborn baby, and often result in premature delivery. Further to this, several of the high-risk participants of ASPRE were able to describe the possible consequences of PE in greater detail, for example:

> "I think it had to do, like the baby is probably going to be a bit small, em it could be because, yeah, something to do with the blood supply and yeah so basically the baby wouldn't get enough oxygen and enough nutrients, mainly enough oxygen to be able to grow fully, so it will be a small baby". 13, HR-PA, lines 404-409.

> "It seems that that problem you can't sort of find the only way to solve the problem is to give birth to the baby. But she was clear saying that depending on when it happened and all that. If it arrives and it's too early. They can try to maintain it like to make it last a bit and trigger the birth later when it's viable for the baby". 3, HR-PA, lines 467-472.

> "It is, I think, something to do with it not being safe to inside my body if I've got high blood pressure and so the need for the baby to, it leaves and be looked after not inside my body, it becomes that

> in later pregnancy, it becomes an issue. So the baby would have to come out earlier and be looked after in sort of the neonatal care unit". 6, HR-PA, lines 649-654.

As previously mentioned, all 14 women, who were high-risk risk participants of the ASPRE trial, displayed some knowledge and understanding of PE and its consequences. This is likely due to PE being particularly relevant to this group and the extra information they will have received as a result of being a participant of ASPRE.

Three women (two low-risk, one high-risk decliner of ASPRE) had little understanding of PE, or the various aspects of PE including it's symptoms, consequences and/or timeframe of development. Their partial knowledge differed on an individual basis. One of the low-risk participants knew that "you can get swelling" (29, LR, line 144) as a symptom of PE, she also acknowledged that she "didn't really know anything else" (29, LR, line 146). Another low-risk participant admitted that she does not "understand it technically" (36, LR, line 149) but that it concerns protein and that it causes "pressure on the body and pressure on the baby as well" (36, LR, lines 153-154).

Overall, this second-level theme demonstrates that women, across the participant groups, demonstrated good understanding of what PE is and how it could affect them. Women identified as low-risk, and high-risk women who were not participants of the ASPRE trial, had a less thorough understanding than those who participated in the ASPRE trial.

b. Symptoms of PE

Both low- and high-risk women were able to report common symptoms of PE, which they knew of due to personal experience or research, friends and family and/or information provided by medical staff. Women were able to accurately recall the most common symptoms of PE, including headaches,

high blood pressure, swelling/excessive weight gain, vision problems, nausea or vomiting, dizziness, proteinuria, and general pain. Women varied in the amount of detail given regarding symptoms, as well as how many symptoms they were able to identify; however, all 39 women interviewed were able to recall at least one symptom of PE. The extracts below are typical of the overall sample:

> "If you feel dizzy, if you have headaches, if you suddenly put on weight, so you feel swollen, erm if you have double vision, erm vomiting". 1, HR-PA, lines 220-222.

> "It's swelling, blurry vision, headaches, sick, pains in the chest". 25, HR-DA, lines 336-337.

> "You know your blood pressure would be quite high. Sometimes it can be dizziness or kind of not feeling well". 30, LR, lines 156-158.

> "Dizziness, swollen ankles, headaches, feeling faint, that's it, really". 35, LR, lines 347-348.

Further symptoms reported by women included bleeding, breathing difficulties, fatigue, cramps, fever, ringing in the ears and experiencing seizures.

c. Predictability of PE

This second-level theme refers to how predictable PE is, according to the women interviewed for this study. Their responses were coded into three third-level themes, that PE is: 'predictable by medical staff'; 'predictable by self-monitoring'; 'unpredictable'. This theme links with the previous second-level theme (symptoms of PE) as it is concerned with how predictable the symptoms are, and whether occurrence of these symptoms is automatically linked with PE development.

i. Predictable by medical staff

There was a general expression among high-risk women that medical staff could predict those at-risk of developing PE, through the screening that they had experienced themselves.

> "From the screening they were able to look for signs that it could happen, but I don't think they are able to completely predict, but they can certainly look for the risk factors". 2, HR-PA, lines 275-278.

> "Presumably it must be predictable, because you've got a screening test that is. But how accurate those screening tests are I don't know". 15, HR-DA, lines 490-492.

There was also a belief that medical staff would be able to identify some of the symptoms associated with PE, that women may not be able to identify at home, such as proteinuria and high blood pressure, as well as growth problems with the foetus. It was expected, by both low- and high-risk women, that such symptoms would be picked up on by medical staff at their scanning or midwife appointments:

> "That was my assumption about why you get tested quite frequently, because you might not know that you had it". 37, LR, lines 263-265.

> "Every time I go to any appointment I do a urine sample and they take my blood pressure…it's not like I am going months and months without being monitored if that makes sense". 8, HR-PA, lines 532-536.

> "I am hoping by being at the blood pressure clinic they will monitor and tell me if these things are happening". 16, HR-DA, lines 406-408.

It was commonly reported that the medical staff would be able to identify the development or occurrence of PE at regular appointments, regardless of whether the women themselves noticed symptoms associated with PE. As these responses show, women generally felt confident that PE development was predictable by medical staff.

ii. Predictable by self-monitoring

This third-level theme includes the responses of women who felt confident that the presence of PE would identified by self-monitoring. Some women reported that they would actively monitor themselves, looking for PE-specific symptoms:

> "I think that if a person's healthy then they'll be looking for things more". 26, HR-DA, lines 334-335.

> "I am checking more so that if preeclampsia starts the blood pressure will go up and maybe something else. And also I guess if something else happened, I can just go and check the blood pressure and the urine as well to get the confirmation it's happening. So, yes, I think it's, I can predict it now, because you can sort of see it developing". 3, HR-PA, lines 746-751.

Other women suggested that although they would not actively self-monitor, they were aware of the various symptoms of PE and would know to report these to medical staff to raise concerns.

> "I've been sort of not looking for them because I'm not worrying although I'm the kind of person that I'd always, if there was

> anything I felt that wasn't quite right I would mention it to the midwife". 19, HR-DA, lines 392-395.

> "A lot of them are things that you expect in pregnancy anyway so like swelling in your hands and feet, a lot of people will get that anyway erm and headaches and stuff but I think cause I'm, I've been told that I'm high-risk if it happened to me I'd probably just go and get it checked out rather than fobbing it off as just another symptom". 14, HR-PA, lines 351-358.

This third-level theme suggests that women are actively taking responsibility in monitoring PE symptoms, or at the very least being aware of which symptoms they should look out for. It also suggests that some women think PE is predictable by symptoms they can recognise at-home.

iii. Unpredictable

Six high-risk women (2 high-risk decliners of ASPRE; 4 high-risk participants of ASPRE) expressed the opinion that PE could be unpredictable in some cases, and that predictability can vary greatly between women.

> "I would say very unpredictable from what I've heard it can vary greatly between women and can come on very quickly with great severity with great warning, so I would say it's a very unpredictable thing in general". 21, HR-DA, lines 488-491.

> "I think it is a little bit but then I also think nobody kind of knows if I am going to get it". 9, HR-PA, lines 379-380.

> "I wouldn't have said it was predictable". 4, HR-PA, line 709.

Although the full sample of women were aware of the common symptoms of PE, the women in this third-level theme expressed beliefs that symptoms may

not be enough to predict PE. There is a suggestion, within these responses, that the common symptoms may not occur in every case of PE and thus the condition may not be predictable in every instance.

3. Cause

This second-level theme refers to the cause dimension of the CSM; specifically, the reasons why PE occurs during pregnancy, according to the women interviewed for the current study. There are five second-level themes which detail the various causes of PE, as well as a further second-level theme regarding the confusion some women experience regarding the cause of PE.

a. Blood pressure

Blood pressure was the most commonly reported cause of PE risk status, mentioned by 23 of the 39 women, from all participant groups; this second-level theme explores their ideas about why blood pressure could influence PE risk status. As women were informed that high blood pressure was a symptom of PE, they also understood this to be a cause of PE risk status.

Some women reported their high blood pressure, on the day of the screening, as the reason why they were identified as high-risk:

> "They just said I was high-risk, blood pressure was a bit high but I was just a bit agitated that day so I knew that my blood pressure would be a little bit high". 26, HR-DA, lines 241-243.

> "I was a bit rushed in when before they did my blood pressure that day so I didn't know if it was a very accurate reading in a sense like I think it might have been more accurate if they'd done it 20 minutes later". 18, HR-DA, lines 432-437.

The above responses suggest that some women feel their risk status may have been inaccurately calculated due to high blood pressure readings, which may be false-positives. Whilst low-risk women reported their normal blood pressure readings as the reason why they were identified as low-risk:

> "I guess because, touch wood I am relatively healthy and my blood pressure was okay". 39, LR, lines 201-202.

> "I think I've got quite good I think my blood pressure is quite low". 34, LR, lines 211-212.

This suggests, therefore, that women with high blood pressure, would likely not be identified as low-risk.

i. Hereditary: high blood pressure or previous preeclampsia in the family

Women, who were aware of high blood pressure in their immediate family members, cited this as a particular reason why they may have been identified as high-risk.

> "It's always that risk when a family member has high blood pressure". 10, HR-PA, lines 105-106.

> "The high blood pressure thing is obviously genetic and I am just thinking the only thing I can think of 'cause I don't know I don't think I particularly drank a lot or don't think I eat to badly can't think of anything else I could say 'oh that caused it'". 9, HR-PA, lines 487-491.

> "My mom has high blood pressure, my dad was born with an irregular heartbeat, so that was family history". 11, HR-PA, lines 147-148.

Using the same logic, low-risk women viewed their lack of hereditary high blood pressure as a reason why they were identified as low-risk:

> "I assumed that's…why I was low risk because my mum hadn't had it, neither of my sisters had it and the low blood pressure, so I just assumed that's why I was low-risk". 33, LR, lines 364-368.

> "No history in my family either. I just assumed that would mean you were low-risk". 37, LR, lines 350-351.

> "I think that [good health] can contribute and also maybe no family history of that. I feel it could contribute on the good side". 30, LR, lines 164-165.

Similarly, the occurrence or absence of PE in family members influenced women's opinions on whether they would develop the condition themselves:

> "I wondered if the fact that the mum of my boyfriend had it [PE], it could mean that it could affect the baby or not". 3, HR-PA, lines 560-562.

> "I don't think anything like that relates to me because my family history anything to do with preeclampsia is fine". 20, HR-DA, lines 337-339.

> "I felt it was inherited. I thought if it goes in your family there is a good chance that you could get it". 4, HR-PA, lines 519-520.

These responses suggest that women felt if high blood pressure or previous PE was evident in their immediate family, they too would be at-risk and may develop PE. In contrast, women with no family history of high blood pressure

or PE, felt this benefitted them and reduced the likelihood of them being at-risk or developing PE.

ii. Previous personal high blood pressure

Three high-risk women cited their personal previous high blood pressure as the main cause of their risk status.

> "I already have high blood pressure. I'd been warned from the very beginning that this is problem even before I got pregnant. I've always been warned that I might develop it. It wasn't really new information for me". 8, HR-PA, lines 85-88.

> "My own personal high blood pressure…I know it´s always been on high before". 2, HR-PA, lines 184-185.

> "I think it was to do with blood pressure. My blood pressure being high…quite often when I had it done as part of some of the regular tests, people go, uh, it's a bit higher than we would expect, but it's probably just because you rushed to the doctor's and so it's always explained away. I have had what was considered 'a bit higher than we'd expect' quite a few times". 16, HR-DA, lines 461-481.

As with the previous third-level theme, women have established a connection between high blood pressure and their risk status results; these women believe they were identified as high-risk for PE, at least partly, due to their personal previous high blood pressure, prior to getting pregnant.

b. General health

General health was reported by four women as contributing to PE risk status; there was an expectation that those with generally good health would be at

low-risk for PE, whilst those with poor health and fitness would likely be at a higher risk.

> "Well maybe because I'm not a very active, I don't exercise at all really, so I think that's the key thing that came into mind really, I'm quite young I don't think anyone in my family had it, so maybe it's because I'm lazy and don't exercise very much, even though I wouldn't say I'm over weight you know I could be lighter than I am, so I was thinking you know maybe if I'd exercise a bit more, maybe I wouldn't have come across as high risk". 19, HR-DA, lines 427-434.

> "Probably yeah just the combination of lifestyle factors". 2, HR-PA, line 186.

> "I guess because, touch wood I am relatively healthy". 39, LR, line 201.

The above responses suggest that some women believe there is a link between general health and PE, particularly that health can influence PE risk status.

c. Age

A further reported cause of being high-risk for PE, was age. These women classified themselves as being "older" (17, HR-DA, line 425) and thus hypothesised that this may place them at an increased risk of developing PE:

> "I guess, because I am older". 16, HR-DA, line 466.

> "I would say my age maybe being 36. Maybe that is considered quite old or older anyway". 17, HR-DA, lines 424-425.

> "I guess it's my age". 1, HR-PA, line 251.

> "Obviously I am 35 so I am in the later stages of when you might [be at-risk]". 7, HR-PA, lines 376-377.

Those identified as low-risk also acknowledged that being pregnant whilst young may have contributed to their risk status:

> "I guess because, touch wood, I am relatively health and my blood pressure was okay, my age maybe as well". 39, LR, lines 201-203.

> "I had assumed that it related to high blood pressure and therefore probably they did blood pressure and not being in the high-risk category of age". 36, LR, lines 165-167.

Age was regarded as influential on risk status for PE, and a possible contributing cause; women perceived being young as resulting in a low-risk status, whilst older mothers associated their age with being high-risk.

d. Weight

This second-level theme explores women's ideas about the influence of weight on PE risk status. Women expressed views that those who were overweight were likely to be at-risk, and those with a perceived healthy weight would be considered low-risk.

> "I thought maybe to do with my weight because I was overweight, I thought that might be, they haven't said that but I just wondered". 23, HR-DA, lines 334-336.

> "Well I know that my weight is an issue, that's one of the reasons I was high-risk". 10, HR-PA, lines 315-316.

> "I am not huge, but while I was doing my IVF I put on a bit of weight and I think my BMI had an impact on that [PE risk status]". 16, HR-DA, lines 466-468.

> "Now when I think of people that I've later found out have or had preeclampsia, so people like in my prenatal yoga class tend to be overweight people and so I assumed that that was part of the problem. I know I am not overweight. It's one of the reasons I am low risk". 37, LR, lines 352-357.

As these responses suggest, weight was considered by some women to be a cause of PE risk status; being overweight can contribute to a high-risk status, yet a healthy weight can reduce risk of PE.

e. Measurements taken in the 12-week scan

The various measurements taken during the 12-week scan were reported, by some women, to be a cause of their risk status for PE. Some women were unable to recall what the measurements referred to, whilst others believed they were concerned with "blood flow" (15, HR-DA, line 344). Responses in this second-level theme were from high-risk women who felt their at-risk status was partly caused by measurements taken during their 12-week scan.

> "I can't remember exactly what it is, but it's something they saw in the scan some sort of measurement they made while they were doing the scan that meant I could be high risk". 20, HR-DA, lines 332-335.

> "I'm getting confused with all the different things, some are placenta and the blood flow in the placenta and that was one of the factors". 14, HR-PA, lines 455-458.

> "They measured the flow to the baby, they said it was on the high side". 24, HR-DA, lines 387-388.

> "I think she said it was to do with one of the markers in my blood and the blood flow through one of the arteries, if I remember correctly. But like I said, it was quite a long time ago". 15, HR-DA, lines 343-345.

Although women were unsure what exactly was being measured during the 12-week scan, they appear confident that it was a contributing causal factor of identifying risk status.

f. Confusion regarding cause of PE

Through the interviews some women, from all sample groups, expressed an element of confusion as to what the cause of their risk status was. They were unable to identify any factors, which they perceived as contributing to their risk status.

> "Part of me is a little bit annoyed because I don't know the cause so I can´t fix it but part of me thinks then maybe it is not my fault, this is just a fluke, if it happens than it just happens". 9, HR-PA, lines 496-499.

> "It could be anything really and truly 'cause it has been, yeah, yeah it could be anything really and truly, I don't know". 24, HR-DA, lines 397-399.

> "I have no idea". 27, HR-DA, line 466.

> "I don't know…I can't explain it. I was not necessarily expecting it before". 3, HR-PA, lines 560-561.

> "Nothing that I can put my finger on and say, do you know what, actually if I cut that out then I probably wouldn't be triggering preeclampsia, so, no". 7, HR-PA, lines 383-385.

> "I don't really know what the risk factors would be". 29, LR, line 167.

> "I think, you, yeah, my initial thought was that it had predetermined destined be a, you know, to have a chance of it and then it could be brought on by being really, by kind of having more stress… but yeah, I don't really know what specifically might cause it". 38, LR, lines 356-362.

These responses suggest some women perceive their risk status to be unpredictable and are unsure as to the cause. There is a sense that no one factor, that they are aware of, could determine risk status.

4. Timeline

Within the framework of the CSM, timeline refers to an individual's beliefs regarding the timescale of an illness and its symptoms. This first-level theme is concerned with the women's beliefs regarding the timescale of their PE risk status. Responses have been coded into three second-level themes: 'knowledge of timeline for PE development', 'duration of the 'high-risk' status for PE' and 'risk status in future pregnancies'.

a. Knowledge of timeline for PE development

Women, in all participant groups, specifically demonstrated clear knowledge and understanding that PE would not develop until "later on in the pregnancy" (20, HR-DA, line 433).

> "I understand it's after the 20th week you may start seeing the symptoms if something intense didn't happen earlier on". 19, HR-DA, lines 339-341.

> "I know now that it's normally happens towards the end of your pregnancy rather than at 12, 13, 14 weeks". 31, LR, lines 137-139.

> "I think it's from 20 weeks". 14, HR-PA, line 323.

> "I think they said to me originally that you would develop after 22 weeks. You wouldn't develop it before then". 17, HR-DA, lines 521-523.

These extracts show that women were able to identify an accurate timeframe for the development of PE, and an understanding of when symptoms would be begin to appear. However, none of the women interviewed commented on the possibility of PE continuing or developing post-partum, or the consequences this may have.

b. Duration of the 'high-risk' status for PE

This second-level theme explores how long high-risk women feel their risk status will last, throughout their pregnancy. Their responses were further coded into two third-level themes; those who believed the high-risk status would last 'until the end of pregnancy' and those who were 'not sure' about the duration of their high-risk status.

i. Until the end of pregnancy

The responses in this third-level theme are from women who will consider themselves as having the high-risk status throughout the entirety of their pregnancy:

> "I don't think you could suddenly turn round and say you're not a risk anymore…how could it suddenly change". 23, HR-DA, lines 406-408.

> "I think I made, well I think, made the assumption that once you're in the box, you're in the box so it's for the duration of your pregnancy". 18, HR-DA, lines 517-519.

> "I thought just it was through your pregnancy. I thought once you had the baby that was the only way to clear the preeclampsia if you have got full preeclampsia I thought the only way was to have the baby". 4, HR-PA, lines 696-699.

> "I think I'll be high-risk 'til the end…'cause I don't think there's like, the factors aren't going to change so it's just whether I develop it or not". 14, HR-PA, lines 639-644.

> "I would say all the way through I'd say if it's on record that you have those tests down you're high risk it's a consideration that should be held throughout". 21, HR-DA, lines 481-483.

These women suggest that the factors which resulted in the high-risk status are not going to change during the pregnancy and so their risk status will not change. As a result, they will consider themselves to be at-risk throughout their pregnancy.

ii. Not sure

Other high-risk women expressed uncertainty regarding the timeline of their at-risk status; they are not sure whether their at-risk status will increase, decrease or stay the same during the pregnancy.

> "Well it gets higher towards the end, doesn't it? Well it could probably get lower, because it's originally based on what you see in that 12-week scan but things can change so I'm guessing they can revise it". 12, HR-PA, lines 484-493.

> "I think next time I could go for a scan and they could say everything is absolutely fine, things change all the time with what they see…your status changes all the time during pregnancy, so you just don't know, one minute they tell you this and the next the minute they say something else". 20, HR-DA, lines 418-426.

> "I don't know I read that it happens nearer the end of pregnancy but I don't know if my risk necessarily change or I don't know if I am risk now or it will stay the same risk it just doesn't show till later, erm no I don't know". 9, HR-PA, lines 653-656.

These women suggest that the timeline of the PE risk status is uncertain and unpredictable, and they themselves are unaware of how long the high-risk status can last for.

c. Risk status in future pregnancies

Women also discussed the long-term timeline of PE risk status and the possibility of receiving the same risk status in future pregnancies.

i. Probably yes

Over half of the women interviewed, who were identified as high-risk (14 out of 27), stated that they believed they would be categorised as high-risk again in future pregnancies. There was a consensus amongst these women that they would "assume" (9, HR-PA, line 698) that they would be high-risk in future pregnancies, but they were unable to give a definite reason as to why that would be the case.

> "I still would assume that I'd be the same…still the same make up, still the same body so". 23, HR-DA, lines 423-426.

> "Depending on the scans with the blood flow to the baby, then I guess I could have the same chance again, and obviously the family history will always be there, so yeah I think I could still have the chance of being high risk again". 11, HR-PA, lines 442-445.

> "I think I would be expected to be, yeah, because we've had that result now, I think if I was offered the screening again I would kind of expect that it would kind of be high". 19, HR-DA, 624-626.

> "I won't be surprised I guess, if nothing had changed in me, then I guess it's the same risk factors are still potentially there". 12, HR-PA, 525-527.

These responses suggest that women would consider themselves to be high-risk in future pregnancies because of their screening result from their current pregnancy.

ii. Probably (hopefully) not

Five high-risk women expressed an opinion that they would not expect to be high-risk in future pregnancies, or that they would strongly hope they would not be at-risk of PE.

> "I think it depends if I get it in this pregnancy, but if I don't then I wouldn't have thought so because I think the fact that it's my first time was one of the contributing factors". 18, HR-DA, lines 543-546.

> "I think if I didn't develop it this time then I probably wouldn't be high risk". 17, HR-DA, lines 555-556.

> "You just wish it's not going to happen. It feels like it's being greedy to try again…it seems like you don't have the risk all the time. It doesn't happen all the time". 3, HR-PA, lines 774-779.

These responses suggest that women's views regarding the future timeline of PE risk status are dependent on the outcome of their current pregnancy. They may hope or expect to be low-risk in future, but that may change if they go on to develop PE.

iii. Unknown

Ten women, of the overall sample, reported being uncertain over the future timeline of PE and likelihood of their risk status carrying over into future pregnancies. Some women expressed that they did not know enough about PE to be able to establish a timeline for risk status:

> "I don't know, I don't know how that works". 2, HR-PA, line 290.

> "I don't know. But I guess I would test again. Maybe I would wait for research". 3, HR-PA, lines 759-760.

> "I don't know. I think if age and hormones play a factor, I think I'd need to know which one of those things constitutes the bigger indication of it…but I think again, it would be out of my control, it's one of those things you would just have to get pregnant with another child and see what happens". 6, HR-PA, lines 1133-1142.

> "Again, it comes back to, did I get the high-risk results because it's my first pregnancy, and so would my body be more use to pregnancy the second or third or whatever it may be time around,

> or it's just the genetic risk I carry or the way my hormones, or you know my placenta just makes hormones at that level, therefore I'd be high risk every time, I really don't know". 21, HR-DA, lines 495-501.

> "I would assume that if I was okay in this pregnancy then I'd be okay in another pregnancy but maybe that wouldn't be the case. I don't really know enough about it…I suppose it would still be something that I could develop in another pregnancy". 29, LR, lines 260-265.

As these responses show, the likelihood of current risk status lasting, and being relevant to future pregnancies, was unknown; this was reportedly due to not knowing "how that works" (2, HR-PA, line 290) and the fact that "each pregnancy can be completely different" (30, LR, line 238).

5. Consequence

The 'consequence' illness representation relates to the impact that the PE risk status has had on the women. All responses within this first-level theme are from high-risk women; specifically, how they have been affected since finding out their screening result. Two second-level themes emerged during coding: 'impact of high-risk status on pregnancy' and 'impact of high-risk status on decision to have further pregnancies'.

a. Impact of high-risk status on pregnancy

This second-level theme explores how finding out about the high-risk status has affected women, in terms of behaviour and lifestyle changes, increased monitoring during pregnancy and greater awareness of potential problems, as well as the absence of any significant impact or changes. This is explored in the following third-level themes.

i. Lifestyle change: eating healthily and exercising

Ten high-risk women (out of 27) reported that, as a direct result of finding out their PE risk status, they had been trying to eat healthily and exercise throughout their pregnancy.

> "I've probably been a bit more careful what I'm eating and I know they said to avoid too much salt". 23, HR-DA, lines 238-239.

> "When I was told that I'd got a high risk of developing at, I sort of watched my diet a bit more…sort of monitored what I ate and everything. That sort of helps". 22, HR-DA, lines 36-43.

> "I can just remember thinking…well it's probably best to try and be as healthy as possible for my pregnancy to keep active and eat well in an attempt to stop this [PE] if it's going to happen, so I remember thinking that quite clearly". 21, HR-DA, lines 180-185.

> "Trying my best to stay healthy, eating properly, doing some exercise and juts trying to have a healthy pregnancy". 1, HR-PA, lines 274-275.

These women reported taking an active role in monitoring their diet and purposefully trying to improve it, with the aim of it having an impact on their PE risk status. As these responses suggest, women engaged in these actions as a result of finding out their PE risk status, thus it had a direct consequence on their lifestyle.

ii. Avoiding stress

This third-level theme includes responses from five high-risk women, who reported "trying not to stress" (11, HR-PA, line 360) or "not to worry too

much" (1, HR-PA, line 276), as "stressing out would make it worse" (22, HR-DA, line 418). One women stated that she had been "trying to stay as calm as possible" (24, HR-DA, line 283) since finding out about her high-risk status. The implication was that by avoiding stress, their situation regarding PE would not deteriorate.

iii. Personal research on PE

A further consequence of PE screening and finding out risk status was women conducting personal research on the condition and finding out as much as they felt necessary. Some of the women were unfamiliar with PE, prior to their screening appointment and so went away to look up more about the condition:

> "After that when I found out that I was high risk I went home and had like a look on the internet to find out about it". 2, HR-PA, lines 46-48.

> "Straight away I googled what preeclampsia was, so I knew exactly what it was, high blood pressure during pregnancy and what's the likelihood of you getting it, and I found out you can't get it until later on in the pregnancy anyway, yeah so I done more research". 20, HR-DA, lines 168-172.

Similarly, as a result of not knowing much about the condition, some women also felt motivated to find out about the signs and symptoms they should be aware of in relation to PE.

> "I did do a bit of research, which is when I found out things like, you know, if you got persistent headaches or vision problems and things like that, that you should go and get seen…I just looked at the practical side of it". 5, HR-PA, lines 381-387.

> "Sort of thinking in my head I'm going to go away and do some reading and you know make sure I'm very, very familiar with the signs and symptoms of developing [PE]". 21, HR-DA, lines 187-190.

For these women, learning more about PE and knowing what to expect, should the condition develop, was a personal choice, as a consequence of finding out that they were high-risk. There was a feeling amongst women that "it's better to be informed" (7, HR-PA, line 277).

iv. Increased medical input (more scans) seen as reassuring

Women who were high-risk for PE were monitored during their pregnancy in light of their risk status. As well as the usual monitoring for PE at midwifery and scan appointments, such as taking blood pressure readings and urine samples, women who were identified as high-risk and participants of the ASPRE trial were given extra scan appointments. These extra scan appointments were a consequence of their high-risk status:

> "I feel just more sort of reassured really that they are monitoring it a bit more closely…I guess that's the only impact on the pregnancy, in that respect is that I will get more scans and a bit more monitoring which I think is a good thing. I guess there is a positive impact on the pregnancy in some respects". 5, HR-PA, lines 726-734.

> "Now I've got extra appointments…I'm getting extra appointments and being checked up on". 14, HR-PA, lines 125-129.

In particular women reported feeling reassured by the extra medical input they were receiving:

> "I know it's there but at the moment I am kind of thinking everything is fine, because it's being monitored and so I don't need to worry about it. Whereas I think if I was just told I was high risk and doing nothing, it would be a constant worry like I would be constantly checking whatever I could check and stuff like that. Whereas the fact it's being managed is I think a good thing, definitely". 7, HR-PA, lines 768-775.

> "I've gone with the flow because I think it's good that I am looking at it that it's trying to help me. So I think, for me, it's a bit more of a relief because I think I get the extra scans". 4, HR-PA, lines 821-824.

This reassurance from the extra scans, and monitoring, was reported by seven (of the 14) high-risk participants of ASPRE, as being a beneficial consequence of PE screening and the high-risk status.

v. Increased vigilance of symptoms e.g. blood pressure monitoring, checking for swelling

This third-level theme refers to the impact the high-risk status had on women, in terms of being vigilant in looking for PE symptoms, and/or increasing awareness of PE symptoms. Out of the 27 high-risk women interviewed, 15 reported monitoring or checking themselves, specifically concerned with PE symptoms, such as high blood pressure and excessive swelling.

> "I've been monitoring my blood pressure, that's been fine, my weight is in normal limits and stuff, I've been doing the necessary and checking my feet". 26, HR-DA, lines 175-177.

> "They told me to do that from the 20th week they told me, you can check your blood pressure every week. You can do it in the

chemist. I said, okay, I am going to do that". 3, HR-PA, lines 190-193.

"If suddenly my feet swell up I wouldn't go oh that's normal in pregnancy cause for me it might be a risk, it might be a sign of something adverse…I know some of my friends feet swell up when they're pregnant, for them it's just a normal, normal thing to happen to them during pregnancy but it might be for me, I don't know yet but it'd be worth checking". 14, HR-PA, lines 369-378.

"Obviously, I would know the symptoms. If I start swelling up and then I would start getting worried and I would be speaking to my midwife and being, wanting to get checked over". 22, HR-DA, lines 450-453.

The responses within this third-level theme suggest that some women routinely thought of their high-risk status, in relation to checking for symptoms. Some women reported actively checking for PE-related symptoms, whilst others would raise concerns about symptoms as a result of being high-risk.

vi. Increased awareness of potential problems during pregnancy

A further consequence of screening for PE was women's increased awareness of potential problems that could occur during pregnancy, particularly as PE was a condition that many of the women had not heard of, or known much about, prior to the screening. One woman reported that her high-risk status opened her "eyes to the different things that could possibly happen" (24, HR-DA, lines 547-548), and that the result of the screening acted as "another little reminder…that things can go wrong" (12, HR-PA, lines 555-556) during pregnancy.

vii. Absence of significant changes or impact

Some women did not report the PE risk status as influencing their pregnancy, or behaviours, since the screening test. The primary reason for not making significant changes as a result of the high-risk status, was that women were already engaging in health-beneficial behaviours, for example:

> "I haven't deliberately modified anything that I've been eating with regards to the preeclampsia". 6, HR-PA, lines 846-847.

> "Not because I found out I was high-risk, maybe because I found out I was pregnant…I've tried to be healthy with what I eat". 15, HR-DA, lines 405-407.

> "I don't think I have [made changes] in terms of like my day-to-day, because I'm quite, I would say I'm quite active. I haven't stopped, I'm still working, still dropping my son to school and doing all those things". 26, HR-DA, lines 289-292.

These women were keeping active and healthy, as well as being vigilant for unusual symptoms, but this was not due to their high-risk status.

b. Impact of high-risk status on decision to have further pregnancies

This second-level theme explores the ways in which the high-risk status for PE, would likely influence women's decisions to have more pregnancies in future.

Thirteen high-risk women (both participants and decliners of the ASPRE trial) stated that their current risk status for PE would not impact their decision to have future pregnancies. Many of these responses could be considered as hypothetical, as there are several factors to take into

consideration when deciding to have a baby. However, for the women in this third-level theme, PE risk status would not be one of their deciding factors in future:

> "I don't think so, because I think the monitoring is very good and the fact it's been picked up very early is reassuring. I don't think that that factor alone would prevent me or influence my decision on whether to have a child". 5, HR-PA, lines 666-669.

> "No, I mean, we're not going to, but if this was my first child it wouldn't affect my decision, no". 6, HR-PA, lines 1147-1148.

Some women did acknowledge, however, that if they were to develop PE in their current pregnancy, and experience difficulties as a result, their opinions may change:

> "If it does all go wrong at the end I think that would affect what I thought about a second pregnancy". 9, HR-PA, lines 709-710.

> "It might be different if things get very complicated later on. It might change then. But at the moment, everything should be fine". 8, HR-PA, lines 565-567.

> "If I did go through an experience with preeclampsia in its worst way then I am guessing that that might affect my decision". 17, HR-DA, lines 563-564.

This suggests that high-risk status for PE is not enough on its own to impact women's decisions to have further pregnancies. The development of the condition later in pregnancy, and its associated complications, however, may have some degree of influence. This potential impact is dependent on the severity of the PE and the outcome of the pregnancy.

6. Control/cure

This first-level theme concerns the perception of control over the development of PE. During the interviews, women were asked about whether they believed PE could be prevented or controlled. Two second-level themes explore this further: 'beliefs concerning personal influence' and 'beliefs concerning the influence of aspirin on the outcome of PE'.

a. Beliefs concerning personal influence

This second-level theme includes women's responses about whether they believe they can exercise any personal control and prevent the development of PE. Women, across all participant groups, had mixed views, resulting in three third-level themes.

i. Perception of no personal control

Twenty women, out of the 39 interviewed, expressed beliefs that they had no personal control over the development of PE. There was a general feeling amongst these women that, as with several things during pregnancy, PE was unpredictable and almost predestined:

> "I kind of feel it´s already decided somehow I´m going to have it or not, so I feel it's out of my control really". 2, HR-PA, lines 158-160.

> "I don't think you've really got any control". 35, LR, line 376.

> "I don't really feel I have very much control over whether it will develop or not. I think it will just be one of those things that either happens or it doesn't". 5, HR-PA, lines 593-595.

Women also did not fully understand the factors that contribute to their risk status; this meant that they were unsure what action they could personally take to try and prevent PE. For example:

> "I suppose I am not sure what actually are the factors to increase it other than the fact that I already had high blood pressure which is not something I can control". 8, HR-PA, lines 402-404.

> "I felt that there wasn't anything you could do to reduce the risk in the way that you could reduce high blood pressure outside of pregnancy. So things like cutting down on salt or I guess increasing exercise or changing your diet wouldn't necessarily make a difference. That is what I understood". 16, HR-DA, lines 165-170.

> "It sort of feels like there's not an awful lot I can do about it given that it's based on a number of factors that are not in my control". 6, HR-PA, lines 334-336.

> "I don't think I've got any control at all, because I don't know what I did that made me get it". 27, HR-DA, lines 514-515.

This suggests that the development of PE is, perceived, to be caused by factors that women themselves are unable to control.

ii. Perception of (some) control through diet and exercise

This third-level theme features the responses of 17 women who believed, or at least hoped, they had some personal control over the development of PE. It was reported that general good health, as well as good diet and exercise could reduce the likelihood of developing PE.

> "I think if you're able to take care of yourself it's a case of if you know the implications and you know what you've got to do to kind

of reduce the outcome of having preeclampsia then if you keep on that path, eating right and so forth then you can reduce the risk". 26, HR-DA, lines 263-268.

"I do have a bit of control, because I do again, as I said with my diet and everything I try and look out for my, watch out for what I eat and sort of not stress myself out with my blood pressure. I feel like I do have control". 22, HR-DA, lines 426-429.

"I just kind of link the high blood pressure, what I see as the primary factor so I know there's some control over my blood pressure like medicine and obviously now I'm not drinking and stuff anyway erm like diet, so I see the control that I have over that I link that directly [with PE]". 14, HR-PA, lines 500-507.

"I think if you are keeping yourself as healthy as you can and I do think there is a lot that you can't control and it's just happening in your body…if it's 30% you can control it 70% it's your body, I guess, if that makes sense". 39, LR, lines 261-266.

"I think of anything that helps my general fitness has got to help any medical condition, so more kind of fruit and veg that I'm eating, it has to help overall even if it doesn't stop preeclampsia hopefully it will lessen the effects". 9, HR-PA, lines 588-592.

These extracts demonstrate women's hope that they can actively prevent the development of PE. Although at times they are unsure of the effects of improving general health, they are happy to do so "with the aim to maybe reduce the chances" (12, HR-PA, line 391) of PE occurring.

iii. Unsure

Two low-risk women reported being uncertain whether they could influence the development of PE:

> "To be honest, I don't know if I can control that". 28, LR, line 225.

> "I don't know exactly what causes it or how it can increase your risk factor or anything like that". 32, LR, lines 279-280.

Due to their low-risk status, these women did know enough about PE to be able to hypothesise about the level of control they have over the condition developing.

b. Beliefs concerning the influence of aspirin on the outcome of PE

The aim of the ASPRE trial was to establish whether administering aspirin, at 12-weeks, to women who were at-risk of developing PE, would prevent or lessen the effects of the condition. In this second-level theme, women's ideas about the possible impact of aspirin are explored. Women were found to either believe that aspirin could be helpful in preventing PE, or they felt unsure about the effects of aspirin.

i. Belief that aspirin could be helpful in preventing PE

In total, 14 women (both decliners and participants of the ASPRE trial) expressed beliefs that aspirin could be helpful and prevent the development of PE. Some women knew of the existing uses of aspirin, for heart conditions and to prevent blood clots, and thought this might have some correlation with PE:

> "I know aspirin helps thins the blood, so my Mum takes 75mils a day to help with her blood pressure so I'm aware that there are aspects of it that will help". 10, HR-PA, lines 403-405.

> "From what I understand it's like a blood thinner it's all about the placenta or something…I think it [aspirin] could [help] yeah". 14, HR-PA, lines 582-592.

> "I am guessing it's to do with thinning your blood in some ways. So, yes, obviously I would imagine that there is quite substantial evidence to point towards the fact that it does help. But obviously they haven't kind finalised it. I would say that, I am guessing it probably does help in preventing it". 17, HR-DA, lines 473-478.

Similarly, some women felt that the fact a large scale medical trial was being conducted, about the effects of aspirin on PE, suggested that aspirin was likely to help and have some benefit. For example:

> "On the basis that medical people are doing trial on it, so there must be some logic for the reasoning that aspirin is going to help". 9, HR-PA, lines 627-629.

> "I'm optimistic cause I feel like they wouldn't be conducting a massive trial unless there was enough evidence for it to be doing something so yeah I feel relatively confident that it could have an impact". 18, HR-DA, lines 472-476.

> "I suspect there wouldn't be a trial if someone didn't think that there was a reason. So, yes, I imagine it probably does. Aspirin is the wonder drug isn't it. It's used for so many things". 15, HR-DA, lines 424-427.

> "I hope it does. I presume from your research you've done, the initial results would say that it does help and that's why you are doing this wider thing. From you guys knowing more than me then I am fairly confident". 7, HR-PA, lines 516-520.

These responses suggest women were confidently optimistic that aspirin could, to some extent, control or benefit the development of PE during pregnancy. They based these beliefs on their existing knowledge of aspirin and the large-scale nature of the ASPRE trial.

ii. Not sure

The remaining 13 high-risk women felt unsure as to whether aspirin could be beneficial in preventing PE. Some felt they did not have enough knowledge to be able to speculate about the effects of aspirin:

> "As far as I'm concerned I don't know, I really don't know, I couldn't say". 20, HR-DA, lines 399-400.

> "I'm not sure because I didn't even know people could take aspirin if they had preeclampsia". 25, HR-DA, lines 439-440.

> "I'm not sure because it's still a trial, I'm not confident at the moment, I think I need firmer facts". 24, HR-DA, lines 420-421.

> "I really haven't got a clue, because I know aspirin to be a blood thinner but I don't know the connection between that and preeclampsia, I don't know what else aspirin does because it's not a medicine I've ever taken so I don't know much about it". 27, HR-DA, lines 570-575.

> "I'm not really one who takes paracetamol a lot anyway, so my opinion about aspirin and paracetamol and those type of medicines, because I don't normally use them, I try to just wait out the pain, so I don't really feel like it's going to do much difference anyway". 11, HR- PA, lines 383-387.

These responses suggest a lack of clear understanding about the medicinal properties of aspirin, in relation to PE. Therefore women did not know, or feel comfortable guessing the possible effects of aspirin on benefitting or controlling PE development.

7. Emotional impact of the low-risk results

This first-level theme encompasses the responses of women who were screened for PE and identified as low-risk. Specifically these responses reveal how the results affected the women emotionally. Women who were identified as low-risk generally fell in one of two categories: they were relieved with the low-risk result, or they could not remember being given the results of PE screening. These two categories, therefore, make up the second-level themes.

a. Reassured and relieved

Seven women did remember receiving their results for the PE screening, and reported feeling happy, relieved and pleased with the low-risk result. Specifically it was reported as lessening the worry felt by some women at this stage of their pregnancy.

> "Obviously it's a good thing, isn't it, because you don't want to be in the high risk, obviously and be more worried about that kind of stuff." 30, LR, lines 145-147.

> "It makes you more calm I would say. Because you know—I am always a bit worried when I go for a scan, because it doesn't matter which scan it is, if it's the first one, the second. I am somehow worried that they will find something wrong. I just want to go and see that everything is fine and then I can calm down." 28, LR, lines 209-214.

> "It was just reassurance yes." 36, LR, line 139.

Some women also reported feeling relieved but not surprised by the results, for example:

> "I guess pleased but not surprised." 37, LR, line 245.

> "I mean, obviously it's nice to know, but, to be honest, I didn't expect to be high risk anyway, because like I say, I don't really have any medical problems. So it wasn't something that I would anticipate anyway." 29, LR, lines 135-138.

The lack of shock reported appears to have contributed to lessening the emotional impact of the results. Overall these seven women who did remember being identified as low-risk reported a slight positive emotional impact.

b. No memory of being informed of results

The remaining five women identified as low-risk for PE could not recall being informed of the screening results and thus did not experience an emotional impact.

> "I don't remember being told that I was high risk or low risk, I don't remember being told what would happen as a result of it (Int: umhm), I still assume that I'm low risk (Int: umhm, yeah) but I don't remember actually being told that I was low risk." 33, LR, lines 144-148.

> "To be honest, that day was a long one. I am not sure if I remember. I don't think I remember if they told me or not, because there were so many tests done and I was kind, nobody mentioned anything high risk. I assumed everything was fine otherwise." 28, LR, lines 160-164.

> "If it was mentioned it definitely didn't stick in my head [Int: mhmm] and perhaps that's because I was really, it would have been pitched more as the downs results than anything else, and I guess that's the one I kind of mostly interested in knowing, [Int: mhmm] yeah, so yeah, it was all part of errr, it definitely wasn't like highlighted, I don't think, or I think I had remembered it." 38, LR, lines 241-247.

These women provide reasons why they may not remember being informed of the results, such as it being a long day and having taken part in testing for many conditions, and also suggest that there is less of a need to remember low-risk results as no further action is required, and no emotional impact is experienced.

8. Emotional impact of the high-risk results

This first-level theme is concerned with the emotional responses of women, when they were informed of their risk status for PE. Women's responses were coded as having a 'negative emotional impact' or the 'absence of a negative emotional impact'.

a. Negative emotional impact

This second-level theme includes responses from 14 high-risk women (9 participants of ASPRE; 5 decliners of ASPRE), who reported feelings of worry after being informed of their risk status for PE. In some cases, women felt concerned about their risk status when they first learnt of it but their worry lessened through the duration of the pregnancy:

> "It was something which was, me and my boyfriend at first were worried. I think now maybe I can judge for the feeling, I am ok. I think of it, but I am not obsessed with it". 3, HR-PA, lines 220-222.

> "It did at the beginning, yes, when they told me initially it did. And then it kind of receded a little bit into the background". 17, HR-DA, 624-626.

> "Only at the beginning I was really worried, and I was stressing about it a bit, erm but then after a couple of weeks…I think I just started to forget about it, so it didn't really bother me". 11, HR-PA, lines 464-468.

> "Overall, less worried there are some days where I'm quite worried, there's peaks and troughs on it, but no I think overall I kind of calmed down a bit now". 9, HR-PA, lines 730-732.

For others, feelings of worry persisted throughout their pregnancy, in anticipation of PE development:

> "It is something I am worrying about". 4, HR-PA, line 784.

> "It could just be normal pregnancy hormones but yeah it's just a bit, I don't want to say depressing cause I'm not depressed but just puts a dampener on things". 14, HR-PA, lines 685-688.

> "Until I reach that 37 [weeks], I'm going to be anxious a little bit". 27, HR-DA, line 798-797.

> "I mean, it has been playing on my mind a lot more, because I have been thinking about it and I have, I am worried about it, I'm not terrified yet bit I am worried about it". 6, HR-PA, lines 1153-1156.

For some women this worry was intensified due to the non-diagnostic nature of the screening test and the uncertainty of whether they would go on to develop pre-term-PE.

"I think em in the moment as well because the word high wasn't really explained to us in terms of and maybe this is because of the job I'm in as well, like I would have preferred some numbers, so for a particular woman is like 1 in whatever, but for you it's like one in another number, which when we pushed a little, actually you, he asked the question we were given some numbers but there was a bit of hesitation around it, so I don't think the person who was telling us didn't have numbers in mind, she had to think on the spot, so that definitely didn't help the situation." 19, HR-DA, lines 140-150.

"It was that in relation to the other ratios that I had heard that day that made me think, wow, this is something to really worry about." 17, HR-DA, lines 198-200.

"In my head I took that to mean oh God I'm probably going to get it, so I'm not sure that the high-risk you actually, I was given a statistical you know, that means one out of ten or whatever it may be will actually go on to get it…that's how I internalised the message that I'm probably going to get this and I was probably a bit worried after hearing it." 21, HR-DA, lines 170-177.

"To be honest it just felt like another thing to worry about…I don't know also if it is 50/50 or might not or might 80 percent likely to get it, or if I'm just a bit (Int: yeah) and if I get it it´s kind of an automatically an emergency scenario I just got so many, I don't really know what's what but I guess loads of these questions we don't know." 9, HR-PA, lines 211-219.

As these responses show, uncertainty regarding the likelihood of developing pre-term-PE contributed to the concern felt by some women when they were told of their high-risk status.

Despite reporting a slight negative emotional impact due to their high-risk status, none of these women stated that they would rather not know or that they regretted finding out their risk status. They expressed feeling some negative emotions as a result of being high-risk; however, there were no significant implications from this. The negative emotions experienced included worry, concern and some anxiousness. Overall, nine (out of 14) high-risk participants of ASPRE reported feeling some negative emotions, either immediately following the screening result or during their pregnancy. In comparison, only 5 (out of 13) high-risk decliners of ASPRE discussed feeling negative emotions after receiving their screening result.

b. Absence of a negative emotional impact

The remaining 13 high-risk women (5 participants of ASPRE; 8 decliners of ASPRE), did not report having feelings of significant worry. This was the case at the time of receiving their PE risk status, and throughout their pregnancy so far.

These women discussed feeling "pretty calm" (23, HR-D, line 465) about their high-risk status and not being "overly worried about it" (5, HR-PA, line 608).

> "It hasn't put a downer or an up on my pregnancy". 26, HR-DA, line 370.

> "I'm not worried about it… well my mood has certainly changed but I don't think it's got anything to do with the preeclampsia or being high risk yeah, not related to that at all". 12, HR-PA, lines 538-545.

> "I guess I don't [find PE worrying]. I guess it's one of those things…I am aware it's serious, but I'm also aware that it is something that like I live in the developed world in the 21st century it's probably going to be alright, even if I do get preeclampsia. I am

> really lucky. It's not a sort of something that makes me anxious at all". 15, HR-DA, lines 252-258.

> "It's not that it causes me worry, but it's, I do think about it". 27, HR-DA, lines 460-461.

The above responses suggest that women felt a general sense of calm regarding their high-risk status; they accepted their risk status and did not experience an emotional impact. Other women suggested that the reason for the absence of worry was because they had other things to be concerned with during the pregnancy; they perceived other things to be more important and worrying than PE risk status. For example:

> "I didn't have a massive reaction to it to be honest, there was so many bigger things to worry about in a sense like more definitive things about the baby's development and size so I was mainly just relieved that all of that was fine and erm the fact that there was a risk of that was kind of a tiny thing compared to all the rest of it". 18, HR-DA, lines 557-563.

> "I think I feel fine. Obviously there is some kind of worries. Talking to other people I know that are pregnant or have had babies recently, there is not that many people who are 100%. There is always some kind of little problem…I just feel fine". 8, HR-PA, lines 573-577.

> "You've got so many other concerns and things going on that you are trying to sort then it is just one of those other things. It doesn't stick out particularly as worse than any of the other kind of sort of potential problems of pregnancy". 16, HR-DA, lines 643-646.

> "I think because I've had it before it doesn't scare me whereas if it was something else, say they told me I'm high risk for diabetes, I don't know anything about diabetes". 27, HR-DA, lines 727-730.

Women had various potential and actual worries during their pregnancies, that to some, PE did not seem particularly concerning. They did not regard PE as a significant threat to their health or pregnancy and so were able to accept their risk status without worry.

i. Absence of a surprise

Seven women (four participants and three decliners of the ASPRE trial) claimed not to be surprised by their high-risk results, which lessened the emotional impact they experienced.

Five of these women were not surprised by their high-risk status due to previous health and pregnancy complications, which resulted in an expectation of being at-risk prior to receiving their results.

> "I had high blood pressure before…so it wasn't a big surprise that it came back high-risk for me." 9, HR-PA, lines 8-12.

> "I thought that's not great, but then I'm a bit old in reproductive terms, and it doesn't really surprise me I suppose." 12, HR-PA, lines 136-138.

> "When they told me I was at high-risk then I wasn't surprised because of my previous pregnancy." 22, HR-DA, lines 169-170.

> "I just remember saying that I don't need to have it [the PE screening test], because I already know but I still did it anyway, but I didn't really go into too much details." 27, HR-DA, lines 218-220.

> "I was a bit disheartened, if I am honest. I really didn't want to have to go through what I went through on my first one. But then it was still nicer to know that it could happen, but I was going to be helped and checked regular…that made me feel better." 4, HR-PA, lines 306-312.

These women, who expected to be at-risk, did not report particularly negative reactions to their results as they already had a sense of acceptance and expectations of the high-risk status.

The remaining two women, who did not report feeling particularly surprised by their result, had differing reasons for their reactions.
A high-risk decliner, reported that her sister had experienced PE and had "kind of been ok afterwards and her baby was ok afterwards" (18, HR-DA, lines196-197) so "it wasn't like a shock or anything, so…it was ok" (18, HR-DA, lines 197-198). Whilst the other high-risk participant stated that the PE result "got pushed to the side a little bit" (8, HR-PA, lines 228-229) as she was significantly concerned about also being at "high-risk of having a baby with Downs syndrome" (8, HR-PA, lines 224-225). In this situation the high-status for PE was less of a concern and a lower priority.

The lack of surprise appears to be dependent on personal situation and previous health complications, as demonstrated through the responses of these women. The sense of expectation seems to lower the emotional impact of these women, who already feel, in some ways, prepared and possibly with some prior knowledge of PE.

3.5 DISCUSSION

The current study explores the psychological impact of screening for PE, within the framework of the CSM. The seven themes identified, correlate with the illness representations of the CSM: coherence of PE risk status; identity;

cause; timeline; consequence; emotional representations during pregnancy; control/cure.

The current study found that when women are informed of their risk status for PE, they construct illness representations, which were interconnected and co-influential, supporting previous CSM research (e.g. Hagger & Orbell, 2003). Similar to the early CSM findings, these models are not well understood by individuals but the content of illness representations can influence behaviour and attitudes towards the condition (in this case PE) and potential treatments (Meyer et al., 1985).

The majority of participants in the current study generally demonstrated good knowledge and awareness of PE symptoms, irrespective of their risk status; 36 out of the 39 women were able to recall some details regarding the symptoms and consequences of PE. Women were aware that PE was a condition that could affect both mother and baby, with premature delivery a possible outcome of the condition. Women who were identified as high-risk had a more thorough understanding compared to low-risk women; this is expected, according to the CSM, as individuals facing a health threat are active problem solvers (Diefenbach & Leventhal, 1996). It corresponds with the CSM foundations that low-risk women may not take an interest or retain knowledge of conditions they have been screened for if they are not found to be at-risk, however, it is unusual for a high-risk individual to not engage with or understand their condition. This study only found one high-risk woman, out of 27, to have limited knowledge and understanding of PE, suggesting this was due to individual circumstances and not representative of the high-risk group.

Previous research has suggested that women screened for PE, can be identified as either danger managers, focused on maternal health, or fear managers, focused on fetal health (Harris et al., 2014). Although women in the current study demonstrated a more thorough illness identity for PE with maternal consequences, they were aware of the potential dangers for the

fetus. This study suggests, in contrast to Harris et al. (2014) that women may engage in changes in behaviour to mutually benefit maternal and fetal health. Several illness representations were found to be salient in relation to other CSM dimensions. For example, risk status for PE was found to have some impact on behavioural changes (consequences) dependent on the perceived cause and identity of the condition. The most commonly reported symptom of PE was high blood pressure; this knowledge of high blood pressure as a symptom resulted in women also reporting it as a cause of PE and a factor influencing lifestyle changes (e.g. diet, exercise, avoiding stress) specifically to reduce or maintain a 'healthy' blood pressure. Similarly, poor general health and being overweight were cited as possible causes of a high-risk status for PE (and PE development), which may influence reported behavioural consequences, such as altering diet and increasing exercise. This supports the findings of Harris et al. (2014), who stated that some women at high-risk for PE are data managers, who make behavioural changes to reduce their risk for PE.

A further correlation between illness representations was identified as perceptions of cause can impact consequences and the extent of control women feel they have over PE development. For those women who believed a high-risk status for PE was due to their age and/or physiological measurements (taken during the 12-week scan), behavioural changes are not necessary as they would not impact the perceived cause. This also limits the extent of control women perceive they have, if they cannot adapt behaviour to address the alleged cause, and supports previous CSM findings that a link exists between perceived illness causes and perceived beliefs about treatments (Leventhal et al., 2008).

The current study identified that some women who are high-risk for PE feel their actions can influence the development of PE. Some women reported a belief that behavioural changes (e.g. diet, exercise) could prevent PE development; their actions can control whether they develop the condition. In addition, women who perceived no personal control, did not change their behaviour and, therefore, reported fewer consequences from finding out their PE risk status. A further link between control and consequence was

found with women who participated in the ASPRE trial; they perceived aspirin to be a benefit in potentially reducing risk status and so took part, in the hope they would receive aspirin rather than placebo.

Although women showed a good understanding of PE, as a condition, generally they had poorer coherence of their own risk status and interpretation of their screening results for PE. Women expressed confusion over what 'high-risk' for PE meant for them personally; they were unsure how likely they were to develop PE. Over half of the women interviewed, a mixture of low- and high-risk, were unclear as to how their risk status was calculated; as all women were provided with this information prior to screening it can be inferred that women did not fully understand or retain this information.
Due to confusion with regards to the coherence of the high-risk status, women had conflicting beliefs about the timeline. Those who perceived the cause to be predetermined factors (such as age, physiological measurements etc.) and out of their control, believed that they would remain at high-risk until the end of their pregnancy, as the causal factors would not change. Others were unsure as to how long they would remain high-risk, due to ambiguity regarding cause and the influence of their behavioural changes made throughout the pregnancy. Similarly, women were conflicting in their opinions of their susceptibility to being high-risk for PE in future pregnancies; if perceived causal factors could be altered they may not be high-risk in future, otherwise they would likely remain at risk.

The identity illness representation was found to be influential over women's emotional responses, particularly for those who reported no negative impact of the screening result. Those who felt they had a good understanding of PE, its symptoms and consequences, reported feeling calm and confident that although high-risk, their pregnancy was not in danger; they knew the symptoms and so could be vigilant, seeking medical attention if necessary. Some women did not report feeling worries as they perceived PE to be less of a concern, compared to other prenatal conditions; this may suggest they do not have a complete understanding of the condition and its potential

consequences. Again this supports the finding by Harris et al. (2014) that high-risk women had a low perception of personal risk, despite their screening result.

Negative emotional experiences were identified in some women, including worry and concern, which fluctuated on an individual level. The length of time these emotions were experienced also varied. All women who took part in the current study maintained a belief that they would rather know their risk status, regardless of the associated worries and concerns. As a result of finding out risk status, those identified as at-risk were better informed of PE (when the identity illness representation of high-risk women was compared with low-risk), and generally aware and vigilant of PE symptoms. It can be expected, therefore, that these women were better prepared for PE as a result of screening; they were emotionally aware of potential problems that could occur in their pregnancy and aware of symptoms to look out for and monitor. However, as previously stated their low perception of risk (even when identified as high-risk) may have influenced the reported emotional impact.

Previous research has suggested that illness representations change over time (Meyer et al., 1985). However, as PE risk status can have one of two outcomes (women either develop it or they do not), women's illness representations are unlikely to change within the timeframe of the pregnancy, they do not engage with the reappraisal aspect of the parallel processing of illness representations during the pregnancy. They are unlikely to know if any treatment or behaviour change has altered their risk status, or prevented the development of PE, until after they have given birth. Similarly, the consequence illness representation is not fully understood; women reported their high-risk status as irrelevant to their decisions to have future pregnancies, however, they remarked there may be some influence on future decisions if they were to develop PE during this pregnancy. This suggests illness representations may change, and be reappraised, following the birth and dependent on whether the individual develops PE. Further research is needed to asses this and evaluate post-partum illness representations.

The current study aimed to build on the work of Harris et al. (2014), and contribute to the currently limited literature regarding the psychological effects of screening for PE in the first trimester. This research supports the previous research and suggests that women do not experience significant negative emotions following screening for PE. They are able to form illness representations, dependent on individual knowledge and backgrounds, which inform how they interpret their screening results and behave as a consequence. This study is limited in that women were interviewed at one time point during their pregnancy, and it is not possible to comment on how illness representations may change or develop throughout the course of the pregnancy, or post-partum. This work does, however, provide support that screening for PE is beneficial to those at high-risk, allowing women the opportunity to learn more about the condition and make appropriate decisions about behaviour changes.

To date there has not been a qualitative investigation of the psychological effects of screening for PE, in sample of this size, with both low and high-risk women. To the author's best knowledge, no previous research has explored the psychological effects of screening for PE in low-risk women. This study found that some women experienced no emotional impact as a result of screening as they could not recall being screened or being informed of their risk status. Women suggested they may not remember being screened or being informed of their results because low-risk outcomes require no further action, or that they had been overwhelmed with information and screening tests on the day. They did not report having an emotional reaction at the time of being screened for PE risk status. It should be noted that for these five women, it is not clear how well they understood the requirements and consequences of PE screening, however, as suggested by Mitchell (2003), women who agree with prenatal screening generally are often happy to consent to a variety of screening tests, even if they do not fully understand the process and result meanings. The remaining low-risk participants reported feeling reassured and relieved following the screening result. As with previous research (Jaques et al., 2004), these women engaged in the

prenatal screening for PE risk status, with the hope and expectation that they would be identified as low-risk. Their expectation of receiving a low-risk result meant that they were not surprised by the actual outcome; the screening confirmed their previous perception, regarding PE risk status, and so they reported feelings of happiness. For these low-risk women, PE screening resulted in a slight positive emotional impact. This was not particularly significant but did add to the reassurance felt by the low-risk result, and reduced the amount of worry that may have otherwise been experienced.

In the literature exploring the emotional impact of PE screening, Simeone et al. (2015) found that there were no differences in self-reported anxiety between low- and high-risk women. Yet Harris et al. (2014) concluded, following a small qualitative study, that there were potentially negative and positive emotional outcomes, following screening for PE. The current study findings reflects the previous literature, and suggests that women experience a range and absence of emotional consequences after screening for PE, depending on personal circumstances, previous knowledge of PE screening and concerns regarding other pregnancy-related conditions.

Of the 27 high-risk women interviewed for the current study, 13 reported experiencing some negative emotional impact upon receiving their results of the PE screening. In accordance with the CSM, a range of emotional experiences are to be expected following a health threat, such as being informed of a high-risk PE status (Diefenbach & Leventhal, 1996). Women reported feeling shocked, worried, concerned and upset after learning of their high-risk status. These women also expressed confusion regarding what their risk status meant for them personally and how statistically likely they were to develop PE, as well as concern over PE itself. Several women were unaware of PE, its symptoms and consequences, prior to taking part in screening; it is possible that some of their worry and concern, therefore, was a result of this lack of knowledge and understanding. In contrast, seven high-risk women reported a lack of surprise by their PE screening results; these women had previous health problems, some specifically related to high blood pressure, or knew of a family member or friend who had experienced PE. The personal

situations and previous experiences of these women seemed to influence their emotional response; they were already prepared for a high-risk result and so the emotional impact they experienced was minimal and reduced. Again, this suggests that the CSM is a useful framework in attempting to understand the emotional responses to screening for PE risk status; the model states that individual's previous experiences and health threats can shape responses to a new health threat (Diefenbach & Leventhal, 1996). Simeone et al. (2015) reported that following first-trimester screening for PE risk, there were no differences between low- and high-risk women, in terms of anxiety reported during the pregnancy. The remaining seven high-risk women, in the current study, support the results of Simeone et al. (2015) as they did not report either a positive or negative emotional impact. These participants cited several possible reasons why there was an absence of an emotional impact; they recognised the non-diagnostic nature of the screening, as well as the unpredictability around PE and its development. There was also a general feeling that PE was less of a concern, compared to other prenatal conditions being screened for on that day.

The current study supports the findings of Harris et al. (2014), who found that PE screening could result in both positive and negative emotional experiences, as well as Simeone et al. (2015) who reported no differences in anxiety experienced between low- and high-risk women. The current study builds upon this literature and highlights the heterogeneity of women's emotional responses following screening for PE risk status. As suggested through the CSM, women's individuality and previous life experiences can influence and shape their emotional responses to a health threat, such as PE.

3.6 CONCLUSION

This study found that women generate illness representations, which are complex, co-influential and that impact behaviour and actions during pregnancy, following screening for PE. Women appeared to be more knowledgeable on the maternal health effects of PE and the symptoms which they should be vigilant for. Women's coherence of their risk status was often

confused, as was their knowledge of the timeline for PE and their risk status. Although women experienced some worry and concern, this is as expected in-line with the previous CSM literature. Their concerns generally appear to be temporary and are alleviated when women learn more about the condition. These momentary worries, which occur immediately following receiving their screening result, could be limited further by trying to better educate pregnant women on the condition of PE. Further research is needed to establish how illness representations develop post-partum, depending on the outcome of the pregnancy.

Women generally have positive attitudes towards prenatal screening, which can encourage uptake in screening for conditions they are unfamiliar with, such as pre-term-PE. Women perceive prenatal screening to be of benefit to themselves and their unborn baby, as it can provide significant pregnancy-related information, in case anything is wrong and requires treatment or further action. If, however, prenatal screening shows that the pregnancy is healthy, women can take reassurance from this. Whilst some women agreed to screening as they were generally positive towards prenatal screening or perceived PE screening to be part of the usual procedure, other women reported being influenced to participate by having confidence and trust in the medical team and perceiving the screening to be harmless. Women tended to make the decision to be screened independently, although some did consult their significant others, and some were also motivated to be screened in order to advance medical knowledge and potentially help other women and babies in the future. Women identified as low-risk for PE reported either no emotional impact of the screening (as they could not remember taking part) or a positive impact, as they felt reassured by the results. High-risk women varied in their emotional response; some reported increased feelings of worry and concern, whilst others had already been prepared for the result and so were neither surprised nor particularly worried, and others recognised the unpredictability of PE and the non-diagnostic nature of the screening result. This study found that women generally support PE screening and experience no or minimal negative emotional effects following

the screening. However, in order to address some of the worries and concerns felt by high-risk women practitioners should seek to improve women's knowledge and understanding of PE and the possible consequences.

CHAPTER FOUR
4 AN EXPLORATION OF WOMEN'S ATTITUDES TOWARDS SCREENING FOR PRE-TERM PE RISK STATUS AND REFLECTING ON THE EXPERIENCE

4.1 ABSTRACT

Objective: A first-trimester prenatal screening test for pre-term PE risk status was introduced at two London hospitals. The current study aimed to explore women's attitudes towards pre-term PE screening, and identify factors, which influence uptake of pre-term PE screening. A further aim was to identify how women reflect on the experience of being screened and whether they would engage in screening again in any future pregnancies.

Design: Cross-sectional interview study, using a semi-structured interview schedule. Transcripts were analysed using Template Analysis.

Setting and participants: Women receiving prenatal care at two London National Health Service Trusts, who were offered screening for PE risk status during their ultrasound scans, at 11-14 weeks gestation. In total 39 women were interviewed; 12 were identified as low-risk, and 27 were at high-risk of developing PE. Of the 27 high-risk women, 14 agreed to participate in the ASPRE trial and 13 declined the ASPRE trial participation.

Findings: Women expressed positive attitudes towards prenatal screening in general and this extended to screening for PE risk status. Women agreed to participate in screening for pre-term PE, as they reported trust in the doctors and perceived the screening to be harmless to themselves and their unborn babies. The majority of women reported that they felt being screened was a benefit, they would want to be screened for pre-term PE risk in future pregnancies and would recommend the screening to others.

4.2 INTRODUCTION

Prenatal screening is generally carried out to establish if there is a health risk to the mother and foetus (e. g., with maternal conditions such as gestational diabetes and the human immunodeficiency virus (HIV)), as well as to determine whether any abnormalities are present with the foetus (e. g., Down's syndrome, disabilities) (Harris, Franck, & Michie, 2012; Williams et al., 2005). Screening for maternal health conditions, such as gestational diabetes, is generally dependent on the presence of risk factors (e. g. family history, body mass index over 30) (NHS, 2012). However, in the UK, screening for fetal abnormalities is routine and offered to all pregnant women, with the method of screening dependent on the gestation of the pregnancy (NHS, 2014).

Although research has been done investigating consequences of screening for a variety of illnesses and conditions, there is limited knowledge regarding the impact of screening for pre-term PE risk. As previously discussed, it is important to identify women who are at risk of PE, in order to monitor their condition and attempt to reduce its effects. Following extensive research, a screening technique has been developed with the ability to identify women, at 11-14 weeks gestation, as either high- or low-risk for developing preterm PE (Akolekar, Syngelaki, Poon, Wright, & Nicolaides, 2012; Poon, Syngelaki, Akolekar, Lai, & Nicolaides, 2012). Risk status is established by combining maternal history and characteristics with biophysical and biochemical factors (Poon et al., 2012).

The screening test for PE is, however, not diagnostic and can only indicate risk status for likelihood of developing pre-term PE during pregnancy (Harris et al., 2014). This can be regarded as a shift in screening intention; from screen-to-treat to screen-to-observe, which remains an under-investigated area (Harris, 2015).

Some women decline prenatal screening or express concerns prior to participating in screening due to potential ethical issues that could arise as a result of the screening, for example if the screening revealed potential difficulties they may consider terminating the pregnancy (Williams et al., 2005).

Women are involved in complex decision-making regarding prenatal screening, depending on the type of test offered, perceived attitudes of medical staff, the quality and type of information provided concerning the test, as well as women's personal beliefs and individual health (Jaques, Bell, Watson, & Halliday, 2004). Maternal attitudes towards screening have been found to be the most prevalent factor in the decision-making process; with over 95% of mothers reporting that they themselves had a strong influence over their final decision (Jaques et al., 2004). This highlights the importance of understanding women's attitudes and beliefs when they are considering prenatal screening and their experiences having done so.

Research in the area of PE screening is limited due to the recent development of the screening test; however, Crombag et al. (2017) used a focus group method, to explore the perceptions and preferences regarding screening for PE. A total of 45 pregnant women took part in the focus groups; they had not been screened for pre-term PE risk status. The majority of participants reported positive attitudes towards predictive screening models for PE, and perceived self-monitoring and increased monitoring by healthcare professionals as appropriate further action, if identified as high-risk. Crombag et al. (2017) also found that women expected a slight increase in prenatal anxiety as a result of PE screening, but that this did not deter them or affect their attitudes towards PE screening. According to the current literature women have a preference to find out their risk status, in order to feel a greater sense of control over their situation (Crombag et al., 2017; Harris, Franck, Green, & Michie, 2014).

Given the possible negative consequences of prenatal screening (e.g. increased anxiety during pregnancy is linked with pre-term birth; Ding et al., 2014), it is important to understand specific influences over women's attitudes and the decision to be screened. Understanding attitudes and experiences could impact future health behaviours throughout the pregnancy and how medical staff can approach treatment options (Crombag et al., 2017). Nicol (2007) suggested that due to social pressures and the medical environment where prenatal scanning takes place, women often comply with screening rather than making individual, informed choices. This links to the idea that women who agree with prenatal screening generally, will also do so for conditions where their knowledge and understanding (of both the processes and results meanings) is limited (Michie, Dormandy, & Marteau, 2003). It is important to establish that women are making informed decisions and understand the potential demands of the screening process.

Gottfredsdottir, Sandall, & Bjornsdottir (2009) interviewed ten couples regarding the influences on their decision-making for nuchal translucency screening, which can establish the risk for Down's syndrome. Through semi-structured interviews, it was found that the majority of mothers had not discussed their decisions with their partners prior to being screened, although acceptance of the screening was mutual. Mothers were primarily influenced by their own views and personal preference had the biggest influence on their decision, supporting the findings of Jacques et al. (2004). Hope and expectation were found to influence acceptance of screening, albeit differently for prospective fathers and mothers. This study found men accepted prenatal screening as a means of increasing control and reducing uncertainty, whilst women took part in screening, expecting screen negative results and reassurance of a healthy baby. However, this was a relatively small qualitative study, with 10 couples interviewed; each prospective mother and father was interviewed at 7-11 weeks gestation and again at 20-24 weeks gestation.

A systematic review of 32 studies, investigating factors influencing uptake of screening for Down's syndrome, found that women reported pressure from others, emotions and insufficient information about screening as the main factors they struggled with when making their decision (St-Jaques, Grenier, Charland, Forest, Rousseau, & Legare, 2008). Important factors that facilitated the decision-making were found to be confidence in the medical system, their own understanding of the screening and their personal values. Similarly, women who participated in screening for prenatal defects reported being influenced by healthcare professionals and friends (Jaques et al., 2004). This was in contrast to non-participants, who were influenced primarily by their own views and those of their partner.

It is important to establish the factors which influence women's decisions to be screened in order to ensure they are making informed choices and understand the screening procedures (Marteau, 1995). This has not yet been fully established within the literature regarding PE.

As the screening test for pre-term PE is relatively new, it is also important to investigate how women experience the test; whether they feel comfortable with it and perceive it to be beneficial. One way to establish this is to assess if women would repeat the experience and recommend it to other pregnant women.

4.2.1 RESEARCH AIMS

Whilst Chapter Three explored women's emotional experiences following receiving their screening result, the aim of the current study is to establish particular factors, which influence uptake of screening for pre-term PE risk status and explore women's attitudes to the PE screening. A further aim is to investigate whether women would take part in the screening again in any possible future pregnancies and recommend the screening process to other women.

4.3 MATERIALS AND METHODS

4.3.1 DESIGN AND SETTING

Semi-structured interviews were conducted with women who had been offered and took part in screening for PE risk, which took place at their 11-14 week ultrasound examination at two NHS hospitals in London, UK. The interviews were transcribed and analysed, using Template Analysis (King, 2012).

4.3.2 SAMPLE

The sample consisted of 39 women in total: 12 were identified as low-risk and 27 identified as high-risk. Of the high-risk participants, 14 were participants of the ASPRE trial and 13 were decliners of the ASPRE trial. Full participant details and a table of sample characteristics can be found in Chapter Three.

4.3.3 PROCEDURE

The qualitative study procedure is detailed in Chapter 3; the same inclusion applies here.

4.3.4 SEMI-STRUCTURED INTERVIEWS

A semi-structured interview schedule was developed, based on a review of existing literature and previous pilot work. The interview schedule was designed to investigate women's attitudes towards screening for pre-term PE risk, factors that influenced their decision to be screened and their experiences of participating in screening. Particular questions addressed whether women would want to be screened for pre-term PE risk in any future pregnancies, and whether they would recommend the process to others. The full interview schedule can be found in the Appendix; Appendix 7.8 for low-risk women and Appendix 7.9 for high-risk women.

The interview schedule included specific questions relating to the study's aims (for example, 'what do you think about screening in pregnancy generally?' and regarding screening 'what made you decide in that way?'). However, the semi-structured nature of this study enabled an exploration of the aims whilst also enabling women to openly reflect and discuss their experiences and feelings regarding screening generally and for pre-term PE risk.

4.3.5 ETHICAL CONSIDERATIONS

The local National Health Service research ethics committee gave ethics approval (ref: 14/LO/1238) for this study. Potential participants were given an information leaflet detailing the requirements of the study, as well as a period of at least 24 hours to consider participation. Prior to the interview commencing women were required to give consent. They were made aware that all participation was confidential; transcripts were shared with the research team but all identifiable information was removed.

4.3.6 ANALYTICAL METHODS

As detailed in Chapters Two and Three, the interview transcripts were analysed using template analysis (King, 2012).

An initial template was created based on the pilot study and data was analysed accordingly. The template produced as a result of the pilot study (see Table 4.1) was a guide to aide data analysis but during the analysis themes were added, removed or changed depending on the data. Consideration was given, in particular, to the theme titles; phrasing and wording was changed in order to remove ambiguity and effectively encapsulate the views of women within the themes. For example, the first-level theme 'utility of advanced knowledge of PE risk status early on in pregnancy/overall evaluation' was considered too be too lengthy and

ambiguous. The title evolved and became 'evaluation of PE screening' which more accurately and succinctly captures women's responses; the second-level themes ('benefit from PE screening' and 'no or little benefit from PE screening') again concisely reflect the data. Similarly, an a priori first-level theme was 'decision-making regarding screening for PE', which ultimately became 'factors influencing uptake of PE screening'. Through the data analysis it became clear that women often didn't feel as though they had spent time actively deciding to be screening but there were factors they considered and were able to articulate retrospectively.

4.4 RESULTS

Throughout this results section all participants are referred to by number, rather than name. Where participant quotes are presented, the participant number, the participant group and the line numbers, corresponding to their transcript, follow them. The participant groups have been abbreviated as follows: HR-PA (high-risk participants of ASPRE); HR-DA (high-risk decliners of ASPRE); LR (low-risk).

Table 4.1. Template of a priori themes, based on the pilot study

First-level theme	Second-level theme	Third-level theme
1. Thoughts regarding screening in pregnancy	a. Thoughts regarding screening in pregnancy in general	i. Positive: personal benefit through raised awareness of problems, receiving extra medical support ii. Positive: altruistic beliefs, e.g. through research help others
	b. Thoughts regarding screening for PE, before attending screening	i. "No paying attention", part of the process, a routine thing ii. Easiest option iii. Altruism: helping others
2. Decision-making regarding screening for PE	a. Participating in screening	i. Absence of 'active' decision-making ii. Active decision-making: influencing factors
	b. Non-participation in screening	
	c. Concerns about screening	
	d. The experience of the decision-making process	
3. Utility of advanced knowledge of PE risk status early on in pregnancy/overall evaluation	a. Knowledge is good	i. For prevention of problems ii. Raised awareness to monitor early signs of problems

Table 4.2. Template of themes

First-level theme	Second-level theme	Third-level theme
1. Attitudes towards prenatal screening	a. Screening offers early information	i. Screening offers an opportunity to engage in preventative behaviours
	b. Screening as a source of reassurance	i. The possibility of a screen positive result
2. Factors influencing uptake of PE screening	a. Trust in the doctors	
	b. 'Going along with it'	
	c. Absence of perceived harm	i. Screening for pre-term PE seen as a routine procedure
	d. The role of significant others	
	e. Taking part in order to help with research	
	f. Previous experience of PE	
3. Evaluation of PE screening	a. Benefit from PE screening	
	b. No or little benefit from PE screening	
4. Future PE screening	a. Would recommend to others	
	b. Would want to be screened in future pregnancies	

1. Attitudes towards prenatal screening

This first-level theme refers to the women's personal feelings and thoughts regarding prenatal screening in general. All participants, from across the three groups, reported positive attitudes towards prenatal screening, particularly when screening involved little risk to the foetus.
Two second-level themes were identified: provision of early information and source of reassurance and each will be explored in turn.

a. *Screening offers early information*

It was reported, by 29 out of the 39 women, that prenatal screening was beneficial in terms of the information it could provide during the early stages of pregnancy.

> "Yeah, any extra information you can get…I think it's probably nice to have all the information…I think I'd rather know everything and be prepared." 23, HR-DA, lines 34 – 39.

> "I think it's a great thing to do, I think it's always valuable to have as much information as possible…I think it's better to be armed with the knowledge." 6, HR-PAA, lines 34 – 39.

> "I think it is a good thing and I think, I tend to think especially when it comes to pregnancy people want some more, well, I like some, the more tests as possible the better." 34, LR, lines 33 – 38.

As demonstrated in these extracts, women in all participant groups valued any early information during pregnancy; more knowledge was seen as 'better'.

i. Screening offers an opportunity to engage in preventative behaviours

Some women spoke more specifically about why early information was regarded as beneficial; they discussed the opportunity that screening gives to take action to try and prevent or treat the problem.

> "I think why wouldn't you want to know, you'd want to know if you're at risk for anything, and maybe they can help you prevent things from happening, I think it's better to have it." 20, HR-DA, lines 51 – 53.

> "I also think that it would pick up problems earlier so you can get the treatments or get the additional care that you might need." 34, LR, lines 51 – 53.

> "If something might happen I like to know that I am, if I am more risk of it rather than less just so there are no major surprises…if there was something like diet I like to know so at least I can feel I can do something to help." 9, HR-PA, lines 49 -55.

As suggested throughout these responses, there was a perception amongst the women participants that negative results from screening tests would be likely to lead to closer monitoring or to be offered treatment procedures by the medical team, with the aim of helping the pregnancy and reducing the danger. Similarly in the last extract, this participant expressed a personal desire to make behavioural changes, if any changes were suggested as a consequence of screening, and for the benefit of her pregnancy.

Overall participants felt that getting information through screening was beneficial, and it helped them to be prepared, both personally and medically for any eventualities.

b. Screening as a Source of reassurance

Fifteen women expressed a positive attitude towards prenatal screening, due to the sense of relief and reassurance, which they felt upon receiving the screening results. Generally these women anticipated that everything would go well with their pregnancy, but prenatal screening was able to confirm this, thus leaving the women feeling reassured. This second-level theme encapsulates these responses.

> "I think it's a good thing, it makes you kind of relax a little bit more when you know everything is ok." 2, HR-PA, lines 18-19.

> "It was quite reassuring to kind of, I don't know, feel like they're checking for everything." 18, HR-DA, lines 28-30.

> "I guess until your first scan you don't know what's going on in your tummy, just hope all is developing correctly, so that was erm a relief…it was nice to see and to feel that something is going right here." 10, HR-PA, lines 32-40.

As these responses demonstrate, 'normal' results from prenatal screening tests helped the women to relax and feel more comfortable about their pregnancy. By taking part in the screening, the women participants aimed to find out if their baby was healthy and were reassured when the results were as they had hoped.

Women generally reported being open to prenatal screening tests generally, on the basis that they were perceived as not being harmful.

> "To be honest, I am quite happy to do screenings and blood tests and all that. I am quite comfortable with that. If they say it's now on offer, why say no, you know?" 30, LR, lines 65-67.

> "To be honest, I just said yes. It wasn't something I even gave much thought to…I just said to them, just go for it, because as far as I am

> concerned, the more I can find out, the more I am aware of the better for me." 31, LR, lines 55-61.

> "I think it's just my general attitude towards these things, is that of, you know, to, better to be scanned than not to be scanned for something…sort of be prepared for it and at least know what's going on than if it does ever happen." 13, HR-PA, lines 80-87.

The responses suggest that the women, across all participant groups, agreed to prenatal screening, including screening for pre-term PE risk, because they were either hopeful or expectant to be told they were having healthy pregnancies. These women were then reassured by the positive results that everything was going well.

i. The possibility of a screen positive result

Some women also mentioned the possibility of a screen positive result and how this might have impacted on their pregnancy.

> "I don't know what I would have decided if they had said there was a problem. Obviously that would have been a different conversation." 5, HR-PA, lines 27-28.

> "I suppose I don't know how I would react if I was given five days [to decide whether to be screened] then obviously you have a decision to make." 8, HR-PA, lines 73-75.

> "I guess later in pregnancy, it's hard because then it means coming up with decisions and things." 16, HR-DA, lines 48 – 50.

It is evident that women tried not to focus on possible negative outcomes from screening. They reported not knowing what decisions they would have made if any problems with the foetus had been found.

Overall, these participants tried not to consider the possibility of negative outcomes of any of the screening tests, and did not let this possibility influence their decision to be screened.

2. Factors influencing uptake of PE screening

The majority of women in the sample appear to have accepted participation in screening for pre-term PE quite happily. This first level theme highlights a number of factors that influenced their decision-making.

a. Trust in the doctors

This second-level theme emerged from the data as women discussed their lack of decision-making regarding PE screening. They felt they did not have to actively engage in a decision-making process, as they trusted the medical staff to be knowledgeable and confident concerning the screening methods.

> "It's a good hospital and it's very keen on research and, you know, it was one of those things where we just thought we'll just take the tests for whatever they think we should have." 6, HR-PA, lines 99-102.

> "I'm happy to be led by it…I'm definitely a person who responds well to being like, 'oh the hospital knows this is helpful to know', therefore finding out is a really good thing for you." 38, LR, lines 176 – 184.

In total, six women reported similar responses; these women were happy to agree with the doctor's advice, and the hospital's recommendation, to be screened. The strong reputation of the hospital, as research based, was also encouraging to these women and increased their trust in the doctors and their practices.

b. 'Going along with it'

Some women reported feeling, overall, that they had not made a conscious or considered decision to be screened for PE risk status. There were reports that the decision was "automatic" (23, HR-DA, line 95), for example

> "They asked me and I, I accepted" (1, HR-PA, line 44),

or that they do not remember a decision having to be made:

> "I think I didn't really know about it until after when they told me that I was high-risk so I hadn't known about the screening for it before then" (2, HR-PA, lines 66-68).

Women reported feeling overwhelmed with information, both prior to their appointment and on the day. Women received information packs when they booked their first scan appointment, which contained information about all the screening tests available as well as details of the nuchal scan. When women attended for their appointments this information was reiterated, verbally by the medical team and via the information leaflets, given on the day of the scan.

The volume of information, given to women, left them feeling overwhelmed or confused, and was thus a reason for not making a conscious decision to be screened for PE risk status. For example:

> "I have laterally found out it was supposed to be before the appointment, and it may have been before the appointment but because it came in with all the other leaflets, it was a bit confusing." 37, LR, lines 68-71.

> "Because there is so many things going on you are just like, okay. I probably could have done anything really." 16, HR-DA, lines 140-142.

> "I don't think other health concerns to myself or later on in pregnancy would have really sunk in at that point…it would be probably a bit too early for the information." 7, HR-PA, lines 695-700.

As these comments suggest, the screening taking place at a very early stage of pregnancy and the confusion regarding the details of the screening, result in the women not making an active decision to participate, rather they 'go along with' the screening. Although the screening information "was a bit confusing" (37, LR, line 71), women still took part in the screening; this may be for a number of reasons, already explored, such as trusting the doctors and perceiving that no harm would occur through participation in screening.

Another reason women gave for not making a considered decision was that they were open to different prenatal screening tests, again because these tests were perceived as not being harmful. This is explored in the second-level theme below, 'absence of perceived harm of participation'.

c. Absence of perceived harm

In regards to screening for PE, another factor found to influence uptake was the absence of harm perceived to be associated with the procedure of screening for pre-term PE risk.

> "Nothing seemed kind of detrimental to me." 18, HR-DA, lines 38-39.

> "I think it was an easy decision 'cause it doesn't have any risks." 14, HR-PA, lines 179-180.

> "As long as the screening wouldn't damage me or my baby, it was totally safe to do the screening, I would agree to it." 7, HR-PA, 70-71.

As seen in these extracts women believed that screening for PE was harmless, but the results were beneficial for the overall health of their pregnancy. Through the data it was evident that when the women believed that the screening procedure did not pose a risk to the fetus or to themselves, they tended to take the view 'why not' take part in screening:

> "I think really if I can be screened for anything I am happy to be screened, why not." 9, HR-PA, lines 113-114.

> "It wouldn't harm to just double check." 28, LR, line 119.

> "As long as it doesn't harm my baby I can do this kind of screening and it doesn't affect me like psychologically or anything like that." 28, LR, 125-128.

As the quotes above suggest, these women felt that they had nothing to lose from PE screening and it did not pose a threat to them. Women evidently took the risk associated with prenatal screening into consideration, but in the case of screening for PE, where there was no perceived risk, women were motivated to participate.

Some women did not actively decide to be screened; they either could not remember making the decision or automatically agreed. Women, who reported instinctively agreeing, did so because of their general positive attitudes towards prenatal screening and/or their belief that the screening was part of the routine process.

i. Screening for PE seen as a routine procedure

This third-level theme refers to the women's belief that screening for PE risk status was a routine prenatal screening procedure. Although screening for PE risk status was part of a research study (the ASPRE trial), it was combined

with the usual battery of tests; women were satisfied to go along with what they believed was routine:

> "It's my first baby, but I didn't know, I didn't know that it wasn't routine, I just assumed it was, I guess." 5, HR-PA, lines 219-221.

> "It seemed like the regular package of things that happen as part of your scanning…you would have to have actively said no, I don't want to be tested for that." 16, HR-DA, lines 64 – 71.

Not only did these women consider screening for PE as routine, but also the process of the test itself did not require an obvious additional procedure. Participating in the screening for pre-term PE included women giving an extra blood sample, although they already gave blood as part of the scan procedure. Some women noted this as a reason why the screening felt routine:

> "It was something you didn't need to do anything additional for, really, like had so much blood taken." 15, HR-DA, lines 96-97.

> "The bloods I thought was just part of the kind of process of em pregnancy 'cause I think that was the conversation I had at my very first midwives appointment, that I'd have the blood test, urine test, during the process so I didn't really pay much attention to that aspect of it." 10, HR-PA, lines 148-152.

> "It didn't feel like any other method that wasn't being done already." 38, LR, lines 204-205.

As these responses show, some women felt no immediate, additional actions were necessary to participate in the screening for PE and the process was merely part of the prenatal scanning routine. The autonomy of the screening

process may have removed the need to actively decide whether to participate in screening for PE.

d. The role of significant others

None of the women interviewed reported any conflict with significant others regarding their decision to be screened for pre-term PE. Some women stated that they informed or discussed the screening with their partner or family, on the day, at the scan appointment:

> "I do remember looking over to my partner to kind of, checked that you didn't have any hesitations about it, and then it was then an easy decision for me really." 19, HR-DA, lines 74-77.

> "Yeah I mentioned it to my husband…my husband was just like ok great." 38, LR, lines 215-222.

> "I mean the screening I think he was kind of on board he was sort of like, you know whatever we can screen for we should sort of thing." 13, HR-PA, lines 199-201.

These responses indicate that women did not deliberate at length with their significant others but that it was an easy and mutual decision to be screened. In contrast, there were some women who stated that they decided to be screened independently, and did not discuss their decision with significant others.

> "Yeah, I just decided by myself, happy to do it." 33, LR, lines 226-227.

> "I made the decision, I didn't check with him. He would be totally, he would be up for it too, always up for it." 39, LR, lines 140-141.

> "No, I think it was just…it wasn't like a discussion, it was offered and that was it." 27, HR-DA, lines 213-214.

These responses illustrate an overall heterogeneity in regard to the influence of significant others on women's decisions regarding screening for PE risk. Some women did consult family and friends, but already knowing they wanted to accept prenatal screening.

e. Taking part in order to help with research

Women also had altruistic motives for wanting to participate in the screening for pre-term PE, as it was part of a research study. Whilst this was not generally the primary consideration, the data does show it featured in the decision-making process.

> "I am also really pro being in research. That is quite a big motivator for me but yes it wasn't a difficult decision as to whether or not to have the screening." 15, HR-DA, lines 97-101.

> "Just to help with the research. It wasn't really for me being worried about getting it, it was just that if they want to find these things out then there is no reason for me not to help, really." 29, LR, 103-106.

> "We both agreed that it would be worth doing even if it wasn't high-risk if any kind of information for my bloods or whatever could help with research, but I thought that might be good for somebody else." 9, HR-PA, lines 179-183.

These women demonstrate a good understanding of how their participation in research screening may contribute to the wider perinatal and maternal medicine and health. They highlight an altruistic motivation and recognise that their participation in this medical research can improve knowledge and

may also contribute to medical treatment advancements, for conditions such as PE.

f. Previous experience of PE

Previous knowledge of PE, from friends and family, or from personal experience, was an influencing factor for eight women when deciding to participate in screening for PE. Some women had knowledge of PE, due to experiences in their previous pregnancies:

> "I think because of what I went through before, I was probably happy that I was going to find out and get checked out for it all…it's been good for me." 4, HR-PA, lines 274-278.

> "Obviously I just say, okay, because of what happened in my previous pregnancy, I didn't even have to think twice about it." 22, HR-DA, lines 93-95.

> "As soon as I knew I was pregnant, I knew that this might happen because it happened before…I went into the pregnancy knowing oh I might get preeclampsia again." 27, HR-DA, lines 74-79.

As demonstrated in these extracts, the decision to be screened for PE risk status was almost automatic in women who had previously experienced PE. It was evident that their knowledge of the condition motivated them to be screened, so that they were fully aware of their current risk status.

This could also be seen, to a lesser extent, in the responses of other women, who knew of family or friends who experienced PE.

> "When they asked about it yes, because obviously my mum suffered with it as well." 35, LR, lines 83-84.

> "I think at the time it was quite bad. She said she could have died. I don't really know much about it, to be honest… [Interviewer: was that a factor in you wanting to be screened…] a little bit, yes, because I didn't know how common it was or anything like that or what caused it." 29, LR, lines 47-57.

> "I think I probably expected the worst because of family history…I think the reason I agreed to do the blood tests because I probably expected the worst for me anyway." 21, HR-DA, lines 667-670.

For these women, the knowledge (or lack of knowledge) they had, as a result of the experiences of friends and family, contributed to their decision to be screened for PE risk status.

Similarly, some women perceived themselves to be high-risk, prior to screening, because of previous health issues. This is demonstrated in the following extracts:

> "Because I had high blood pressure before, I did kind of, had it in my mind that if I could be involved in it I'd like to be, just for peace of mind." 9, HR-PA, lines 8-11.

> "They said I would have a high-risk pregnancy anyhow but I've got a couple of fibroids in there, so I know there was going to be more to the pregnancy than just a normal pregnancy, so I kind of was open to whatever came next." 10, HR-PA, lines 45-49.

These women expressed a desire to be screened for PE due to their perception that their pregnancies were already high-risk.

3. Evaluation of PE screening

This first-level theme encompasses women's thoughts and feelings on the overall experience of screening for pre-term PE. Their responses were further coded into two second-level themes, those who expressed a belief there is 'benefit from PE screening' and those who perceived 'no or little benefit from PE screening'.

a. Benefit from PE screening

Both high- and low-risk women perceived screening for pre-term PE as beneficial; in total 35 women expressed these positive opinions during their interviews. Women who were identified as high-risk through screening felt that the screening gave them more opportunities to prepare (both mentally and physically) for the possibility of developing PE. All though this was less relevant to low-risk women during this pregnancy, they also recognised the potential benefit of being screened and as a result, being prepared.

> "I'd say it's important because you'd rather know the risks, I'd rather know if there was a potential risk and if there's anything I can do to avoid it so yeah I think it's benefitted us to know." 23, HR-DA, lines 26 – 30.

> "Well I wouldn't want to unknow it, yeah, it's always helpful to know, be prepared, as you can be." 12, HR-PA, lines 590 – 592.

> "I think, yes, I think it should, it's always good to know that there are certain risks where it might be kind of falling into a category of a certain risk. I think it's useful to know these things." 28, LR, lines 294 – 299.

b. No or little benefit from screening

Four women reported feeling that there was no or very little benefit from screening for pre-term PE risk. All of these women were identified as high-

risk and declined participation in the ASPRE trial. These women felt that the screening and high-risk results were made to feel fairly significant at the point of the nuchal scan, however, this juxtaposed with the lack of follow-up treatment offered. For these four women, the potential worry as a result of the high-risk status was more prominent and caused them to question whether it was worth finding out their risk status.

> "I can't really do anything about the risk status…in my situation that it's not something that was necessarily particularly helpful or unhelpful. But as I say, it was incidental. It was just something that happened along with all the other tests." 15, HR-DA, lines 541 – 549.

> "If this continues and I haven't got it, for me it would be a test that shows I'm high-risk that worried me and I didn't end up getting it so overall could have done without it, but if I go on to develop it I would feel more positive about it." 21, HR-DA, 604 – 608.

> "I'd rather be kept in the loop than not know at all but if it's not, I don't know, they [the medical staff] should be careful, if it's not really essential to say something, they shouldn't, they should mention it, but they shouldn't make such a big deal of it." 20, HR-DA, lines 514 – 520.

> "The only thing I worry about obviously because I am still part way through my pregnancy…is whether some of the screening, because subsequently I was told when I came to [the hospital] a couple of weeks ago that my risk of preeclampsia now is virtually zero. I think to be honest with you I found it quite upsetting when they told me that you are high-risk for preeclampsia and I got quite upset about that and started to worry. And then to be told a couple of weeks ago when I went for my scan because I was no longer a risk at all. But, obviously, great news. I wonder whether that screening at the beginning was necessary on one level I think. That is something I do worry about." 17, HR-DA, lines 22 – 34.

This second-level theme highlights the conflicting views some women feel regarding screening for pre-term PE. The induced worry that comes from receiving a high-risk screening result and the current lack of follow-up treatment contributed to these four women perceiving the screening to have little benefit.

4. Future PE screening

Women were asked their opinions on whether they would recommend screening for pre-term PE risk status to others, and whether hypothetically they would take part in the screening again, in any future pregnancies. Their responses were coded into two second-level themes: 'would recommend to others' and 'would want to be screened in future pregnancies'.

a. Would recommend to others

Thirty-seven of the women reported that they would recommend the screening process to others; this is despite not at all of these women perceiving the screening to be extremely beneficial.

> "I think it's good overall, I think some people might fret over it, but then people fret over everything don't they? Would you deny someone the opportunity to have that piece of extra knowledge to prepare for because it might potentially worry them? Probably not and anyways it's done more, become more understood generally in the public, everyone understands now about going for scans." 12, HR-PA, lines 597 – 605.

> "Yes, certainly. Assuming they [other people] want to know things about themselves and the development then yes, there doesn't seem a strong reason not to do it." 16, HR-DA, lines 783 – 785.

> "Generally, what you can get screened for, I'd say get it." 13, HR-PA, lines 873 – 874.

> "If you were offered [screening], it would make sense for…them to accept it. It would be up to them, really." 29, LR, lines 275 – 276.

Not all women gave specific reasons as to why they would recommend the screening, but many discussed their positive attitudes towards prenatal screening generally and their perception that there was no strong reason to not participate in prenatal screening.

b. Would want to be screened in future pregnancies

Thirty-six women expressed a desire or willingness to take part in screening for pre-term PE risk if they were to have another pregnancy in future.

> "I'd probably just, I think I just accept everything I am offered as long as I can take it." 15, HR-DA, lines 582 – 583.

> "Definitely. I think with the age it's always better to do more tests." 28, LR, lines 319 – 320.

> "Definitely. 100% yes. I do think it's a good, people need to know. I would want to know again." 4, HR-PA, lines 886 – 887.

> "I guess I probably always would want to take part in sort of screening anyway, to know my risk and to be aware if there is something that I could do or to just be aware, anyway that this is a possibility. So, yes, I would I think." 17, HR-DA, lines 591 – 594.

Based on their experiences in their current pregnancies, the majority of women interviewed reported that they would take part in screening for pre-

term PE in future. Again recurring reasons for this appear to be general positive attitudes towards prenatal screening.

4.5 DISCUSSION

This study provides insight into women's attitudes towards prenatal screening, the factors influencing participation in screening for PE risk status, and women's experiences of being screened for pre-term PE. Through semi-structured interviews and subsequent template analysis, four first-level themes were identified: attitudes towards screening in pregnancy; factors influencing uptake of PE screening; evaluation of PE screening; and future PE screening.

The women interviewed for this study reported positive feelings towards prenatal screening in general, regardless of their PE risk status. There was a consensus that women agreed to screening in the hope that there would not be any problems with their pregnancy, but at least if there were they would be picked up on at the screening and attended to accordingly. These findings are similar to those of Gottfredsdottir et al. (2009), who reported that women tend to be hopeful regarding prenatal screening and not expecting of any negative outcomes. The second-level themes then further highlight that the two reasons why women are positive about screening is due to the information and reassurance it can provide. Women perceived the extra information provided by screening as being important, not only for their own knowledge and awareness but for the medical team. They expressed beliefs that screen-positive results (i.e., high-risk for PE) could result in extra monitoring or treatments, which would be otherwise inaccessible. Positive attitudes were expressed regarding first-trimester screening, as early knowledge was perceived to result in earlier treatment and monitoring, and thus improved health outcomes. Reassurance was also highlighted as a significant theme; not only were women comforted by the screening results themselves, but they felt confident that the care they were receiving from the medical team was thorough. Participants were generally aware of the

possible negative psychological effects of screening, following a screen-positive result and the potential decisions they would have to make regarding treatments. Although these views were elucidated through the interviews, women evidently tried to avoid thinking of unwanted outcomes, reporting that they had not considered what decisions they would make. Instead women took part in prenatal screening to find out as much information about their baby and pregnancy as possible, as well as seek reassurance that their pregnancy was healthy. Despite some concerns about the potential results, women's attitudes towards prenatal screening were overwhelmingly positive.

Various factors were reported as influencing women's decisions to participate in screening for PE risk status. These reasons were reported under the second-level themes; trust in the doctors; 'going along with it'; absence of perceived harm; the role of significant others; taking part in order to help with research; previous experience of PE. These themes often overlapped as women cited more than one influence, whilst some appeared more prevalent or significant in the decision-making process. It is particularly evident that some women did not make a conscious decision to be screened for PE. Some women reported putting their trust in the medical staff and the hospital's recommendations, agreeing to participate in screening based on the strong reputation of the hospital. This raises questions as to how informed their decisions were; as Nicol (2007) suggested, it may be that in a medical setting, women may feel the need to comply rather than make independent, informed choices. Similarly some women described how they automatically accepted the PE screening, merely as they had been asked and did not know enough about it to say no. Six women, however, reported deciding to participate in screening for PE risk status in the expectation that they would receive advice or medical treatment, if they were found to be high-risk. These women expressed beliefs that 'someone will do something about it' (33, LR, lines 135-136) and that by finding out risk status they can try to 'protect' their baby and pregnancy. It is evident that these women had a good understanding of the screening process and the possible negative outcomes;

this understanding and trust in the healthcare team, acted as a motivator in the decision-making process. The vast amount of information provided to women prior to their first trimester scan was reportedly overwhelming and too much to process for some women. As reported by Michie et al. (2003), women who express positive attitudes towards screening generally, will agree to specific screening tests even if they have limited knowledge of the processes and result meaning. The positivity around prenatal screening in general seems likely to contribute to women's decision-making for PE screening; it is another test to (hopefully) confirm they have a healthy baby and pregnancy. This study found evidence to support this idea; women agreed to the PE screening despite knowing little about the condition itself or the details of what the screening involved.

This ease of acceptance of prenatal scans is likely partly due to the absence of perceived harm from taking part. Again, positive attitudes towards screening in general were reported, and women did not feel they would lose anything or be negatively affected by being screened. The absence of negatives is more crucial, in the decision-making process, than the presence of positives: "as long as it doesn't harm my baby, I can do this kind of screening and it doesn't affect me" (28, LR, lines 125-126). In regard to screening for PE risk status, several women expressed a belief that it was already a routine part of the first trimester testing. It was noted that the screening felt routine as no extra action needed to be taken, other than extra blood sample, but as this was being done anyway 'it seemed like the regular package of things that happen as part of your scanning' (16, HR-DA, lines 64-65). It is possible that the routine nature of the screening also contributed to the autonomy of the process and removed the need for women to actively consider and decide whether to participate.

This study found that women did not discuss, in great detail, the decision to be screened, with their significant others. Some reported making the decision independently, whilst others briefly conferred and mutually agreed. No women reported conflicting with their significant others regarding the

screening. This was also the case in the Gottfredsdottir et al. (2009) study, where some women had not discussed nuchal translucency screening with their partners and those who did mutually accepted. Similarly, this supports Jaques et al. (2004) who reported that expectant mothers themselves were the biggest influencers of their decision, rather than their partner or significant others.

A further reason that influenced pre-term PE screening uptake, albeit to a lesser extent, was the desire to help with research. Altruism was not found to be a significant motivation, however, some women expressed an understanding of how their participation can contribute and further medical knowledge. They also showed an appreciation of how previous research and women participating in research have contributed to the current state of maternal and perinatal health and that in also doing so they could further develop knowledge regarding PE.

This study demonstrates the complexities of deciding to be screened for PE in the first trimester. For some it is a considered decision with clear motivations, for others it is an automatic, almost default response to agree with the professional advice. Ultimately this study highlights the heterogeneity within women who are offered participation in screening for PE, as part of a research study.

Women with a family history or personal experience of PE, as well as high blood pressure, actively decided to participate in the screening. Both high- and low-risk women reported being particularly aware of their possible risk status and as a result were absolute in their desire to be screened. These women demonstrated a greater knowledge and understanding of preeclampsia and the potential risks, given their previous experiences.

This exploratory study has found there are various factors influencing women's decisions to participate in screening for PE risk status, with trust in doctors, the absence of perceived harm particularly significant. Overall women tend not to discuss their decision to be screened with significant

others, prior to it taking place and many women do not actively decide to be screened, instead they 'go along' with the process, with the perception that it is 'normal' to be screened for various conditions during pregnancy. This finding supports that of Jaques et al. (2004), who reported that 95% (of 737 participants) of women would make their final decision to be screened based on their own feelings and opinions. It is also in line with the results of Gottfredsdottir et al. (2009), who reported expectant mothers valued their own opinion regarding screening as the most important.

Thirty-five women, out of thirty-nine, reported feeling that screening for pre-term PE risk was beneficial. Low-risk women discussed the reassurance they felt from a screen negative result, but they also acknowledged that a screen positive result could enable women to feel more prepared for eventualities associated with pre-term PE. High-risk women expressed similar views; they felt the screening result made them more aware of what could happen during their pregnancy, and feel slightly more prepared. These results add concrete support to the hypothetical findings reported by Crombag et al. (2017); in that study women expressed positive attitudes towards a hypothetical screening test for pre-term PE, and suggested they would be prepared to experience some increases in anxiety and worry, due to the sense of control and feeling prepared that the result could provide.

The four women who felt the screening result was of little benefit, reasoned that it did not seem particularly serious and felt they had been informed too soon in their pregnancy. These women were experiencing healthy pregnancies, and so felt there was no need to worry about being high-risk, and potentially no need to for them to know about it.

Thirty-seven women reported that they would recommend the screening for pre-term PE to others, even some women who had not perceived it as beneficial. This suggests that women's positive attitudes towards prenatal screening generally are so robust that they are willing to recommend and encourage screening, even when the benefits of it aren't obvious. Similarly,

the majority of participants, both high- and low-risk would want to be screened for pre-term PE risk if they were to go to have future pregnancies.

4.5.1 LIMITATIONS

Although this study included similar sample sizes for each participant group, it is difficult to say that the findings for high-risk women would be generalizable to a whole population. It should be acknowledged that although the number of high-risk women who felt the screening was not beneficial was minimal, these views might be representative of a larger proportion in a bigger population. However, this study was intended as an exploration, as research in this area is currently limited, and results show that generally women had positive experiences with the screening process, regardless of their risk status.

4.6 CONCLUSION

Overall women identified as both high- and low-risk for pre-term PE responded well to the screening; they had positive attitudes towards the screening and recognised the benefits outweigh any potential concerns. These findings support the hypothesis reported by Crombag et al. (2017) that women are willing to engage with pre-natal screening due to the future benefits it may bring. However, these results go further than the Crombag et al. (2017) focus study group; the current findings are from women who participated in screening for pre-term PE risk status. The women who participated in the current study had to make definite decisions that would impact their pregnancy. Thus, the findings are also more robust than those of Crombag et al. (2017) whose study was hypothetical. The women who participated in this study were overwhelmingly clear that they found the screening to be beneficial, either preparing them mentally for the risks that lay ahead or serving as reassurance. General positive attitudes towards prenatal screening was found to be the biggest influence on screening uptake, and women, overall, claimed that they would both recommend screening to

other pregnant women and want to be screened again themselves, in any future pregnancies. This study found support for the screening process and suggests that women would engage and perceive the screening to be important in future.

CHAPTER FIVE
5 A QUALITATIVE INVESTIGATION OF FACTORS INFLUENCING PARTICIPATION AND NON-PARTICIPATION IN THE ASPRE TRIAL

5.1 ABSTRACT

Objective: To explore the factors that influence participation or non-participation, among women at high-risk of pre-term PE invited to a medicated RCT.

Design: Cross-sectional interview study, using a semi-structured interview schedule. Transcripts were analysed using Template Analysis.

Setting and participants: Women receiving prenatal care at two London National Health Service Trusts, who were offered screening for PE risk status during their antenatal scans, at 11-14 weeks gestation. Those identified as high-risk for pre-term PE were invited to participate in the ASPRE trial. In total 27 high-risk women were interviewed; 14 participants of the ASPRE trial and 13 decliners.

Findings: Women demonstrated having good knowledge and understanding of trial aims and procedures, regardless of being a participant or decliner of the trial. Those who agreed to participate in the ASPRE trial did so largely due to their own positive attitudes towards the potential benefits of aspirin and the extra care received through taking part in research. Main factors influencing non-participation were negative attitudes towards taking medication during pregnancy and concerns about possible side effects.

Implications for practice: The ASPRE trial has found that daily, low-dose aspirin is effective in reducing pre-term PE incidence. Healthcare professionals offering aspirin as a preventative treatment for pre-term PE, in high-risk women, should address and attempt to reverse women's beliefs regarding the dangers of taking medication during pregnancy. The current

study is also relevant to future researchers aiming to recruit pregnant samples to clinical RCTs.

5.2 INTRODUCTION

5.2.1 RECRUITMENT IN RCTS

RCTs are regarded as the most powerful research methodology; they provide unbiased accounts of the effectiveness of health treatments and technologies, which in turn guide clinical practice (Featherstone & Donovan, 2002; Locock & Smith, 2011; McDonald et al., 2006; Ross, Grant, Counsell, Gillespie, Russell, & Prescott, 1999). Their success hinders, largely, on meeting recruitment targets, of both patients and clinicians (McCann, Campbell, & Entwistle, 2010; Mills et al., 2006).

Issues with recruitment can result in smaller than intended sample sizes, and thus reduce the power and reliability of the RCT (McDonald et al., 2006; Ross et al., 1999). In a 2006 review (McDonald et al., 2006), of 114 trials (73 funded by the UK Medical Research Council and 41 by the Health Technologies Assessment Programme, conducted between 1994 and 2002), it was found that 38 achieved their original recruitment target, a further 42 studies revised their recruitment target, with 36 of these revising their target in a downward direction. In 14 (of the 114) trials enrolment was stopped early, with 11 of these cases due to poor recruitment. This review highlights the severity of recruitment difficulties for RCTs across various patient and clinician samples. It is important to identify and understand the barriers and facilitators to participation in RCTs in order to avoid recruitment issues and maximise the potential findings of the trials (McCann et al., 2010).

In order to achieve recruitment targets and improve the likely success of RCTs, it is important to understand why some individuals choose not to participate and identify any barriers, which obstruct participation. Reasons for non-participation in RCTs vary between illnesses and conditions, as well as trial requirements and procedures.

Participants provide a range of reasons why they do or do not want to take part in research, many of which are presented regardless of the specific illness or trial. For example, in a study exploring why patients accept or decline participation in a cancer RCT (Jenkins & Fallowfield, 2000), main reasons for participation included contributing to research and having trust in their medical professionals. Whilst reasons for non-participation included concern about randomisation and having a preference for their doctor to choose their treatment. A sense of altruism and furthering medical knowledge were also found to be important factors for individuals taking part in a trial comparing medical and surgical interventions for patients with gastro-oesophageal reflux disease (McCann et al., 2010). In terms of reasons for not participating, issues with randomisation were also found to be significant factors to patients who declined to take part in an RCT comparing standard surgery with conservative management of urinary tract symptoms related to benign prostatic disease (Featherstone & Donovan, 2002).

There have also been several reviews conducted, aiming to establish an overview of why individuals choose to participate or not, in RCTs (e.g. Frew et al, 2014; McDaid, Hodges, Fayter, Stirk, & Eastwood, 2006; Mills et al, 2006). An example of such review is that of Mills et al. (2006) who conducted a systematic review to establish the barriers to participation in cancer RCTs. Of the 33 studies that they examined (12 qualitative, 21 quantitative) significant barriers included concerns with the trial setting, unhappiness with randomisation and the presence of a placebo/no treatment group, discomfort with the research process in general, too complex protocols, concern about side effects, belief that trials are not appropriate for serious diseases, fear that participation would negatively effect relationship with physician and the physician's attitude towards the trial. The authors note that the presence of several of these barriers across studies suggests that they are broadly applicable to potential participants of cancer RCTs.

Similar barriers to participation were also identified in a 1999 review (Ross et al, 1999). In this systematic review, 78 papers were examined to establish reasons why both clinicians and patients refuse to take part in RCTs for a range of conditions. The studies included in this review used mixed methodologies and examined participation in a range of RCTs with various patient groups, such as cancer, smoking cessation, obstetrics, child health and mental health. In terms of barriers to participation for patients, reasons included additional demands on the patient (extra procedures and appointments; travel costs), preferences for a particular treatment (or no treatment), worry about uncertainty of treatment/trial and concerns regarding information and consent. The authors make subsequent suggestions for future research, such as ensuring the protocol is clear and understandable, as well as increased support for staff involved in the trial, and keeping the demands of the trial to a minimum for the sake of the patients involved. However, the review acknowledges that the primary purpose of many of the papers studied was to understand and describe patient decision-making rather than suggest practical methods to increase and facilitate RCT participation. The Ross et al. (1999) review is also limited as it looks across several patient groups. The majority of studies (38 out of 78) are concerned with cancer patients; however, it is likely that illness specific details influence RCT decision-making.

Whilst such reviews can be useful to provide an overview of the reasons why people accept or decline RCT participation, they may overlook the idiosyncratic explanations specific to patient groups. These illness specific explanations may be crucial to increase participation in RCTs and can be directly addressed, which is why a full understanding of various patient groups' reasons for participation and non-participation in RCTs is necessary.

5.2.2 UNDERSTANDING RANDOMISATION IN RCTS

It has also been established that it is important to ensure potential participants of RCTs are given sufficient information regarding the demands

and procedures of the trial and that they are fully understood by potential participants (Snowdon, Garcia, & Elbourne, 1997). It has been suggested that potential participants may not be accurate in their reasoning for participating in or declining trials if they do not fully understand trial information (Edwards, Lilford, Braunholtz, Jackson, Hewison, & Thornton, 1998). Previous research has found that randomisation is a barrier to participation for a small number of the sample. For example, in a study with 18 women exploring the reasons for non-participation in a RCT during pregnancy, assessing the effect of nifedipine on preventing preterm labour, it was found that randomisation influenced non-participation (Mohanna & Tunna, 1999). Women felt randomisation was unfair and meant they would be missing out on a potentially beneficial drug; through randomisation they perceived the placebo arm of the trial to being a lack of treatment. However, misunderstanding of trial methodology, and randomisation in particular, has also been found to be a facilitator to participation (Featherstone & Donovan, 2002). Despite being informed of the randomisation process patients may experience "therapeutic misconception" (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987). This occurs when individuals inaccurately assume that they will receive a trial drug, which is most likely to appease or improve their condition. Appelbaum et al. (1987) suggest that by maintaining a therapeutic misconception, patients may participate in trials with, and overlook, significant disadvantages. A qualitative study investigating parents' experiences of participating in a neonatal trial, found that parents did not have a clear understanding of trial randomisation (Snowdon et al., 1997). Although parents were aware that treatment was allocated randomly, some still had a belief that their child would receive the active treatment. This study took place with parents in emotionally heightened situations, where their newborn babies were critically ill (ultimately the trial involved 101 babies who survived and 84 who died). In such situations the importance of thoroughly understanding trial procedures and randomisation is vital and misunderstandings can cause ethical issues. It is important to establish that potential participants are fully aware of the trial demands and procedures in order to ensure accurate and ethical participation.

5.2.3 RECRUITMENT IN RCTS DURING PREGNANCY

A focused and specific exploration of factors influencing recruitment to RCTs is especially necessary in areas where research is sparse. One such example of an under researched population in terms of RCT participation and barriers, is pregnant women. Decision-making regarding participation in RCTs during pregnancy is complex; the mother must consider not only her own health but also that of her unborn baby, as well as the feelings of the father (Oude Rengerink, Logtenberg, Hooft, Bossuyt, & Mol, 2015; Meshaka, Jeffares, Sadrudin, Huisman, & Saravanan, 2016). Research in this area is insufficient, largely due to pregnant women being excluded from medical trials prior to 1993 (Meshaka et al., 2016). RCTs with pregnant populations are important to establish which interventions are successful, safe and can improve pregnancy outcomes on a widespread scale (Kenyon, Dixon-Woods, Jackson, Windridge, & Pitchforth, 2006; Meshaka et al., 2016).

5.2.4 REASONS FOR PARTICIPATION IN RCTS DURING PREGNANCY

There is currently limited research exploring factors that influence participation in RCTs during pregnancy. In a review of 16 papers, evaluating participant factors which influence recruitment in perinatal and neonatal trials, it was found that patient characteristics (altruism, attitudes towards research, cultural background, language barriers), the recruitment process and procedures (e.g. communication skills of recruiters, the timing and method of trial invitation), understanding of risk and the understanding of the research process and methodological issues (e.g. randomisation, placebos), were significant in influencing participation (Tooher et al., 2008).

Although the results of the Tooher et al. (2008) review are valuable for understanding influencing factors in RCT decision-making, of the studies included for review, only three involved women who had been invited to participate in medicated clinical trials during their pregnancy (Mohanna &

Tunna, 1999; Kenyon et al., 2006; Snowdon, Elbourne, & Garcia, 2006). The remaining studies focused on topics such as participation in non-medicated trials during pregnancy, willingness to participate in hypothetical research, parental consent in neonatal trials and fetal monitoring during labour (see Tooher et al., 2008 for full review).

In a RCT investigating the use of antibiotics to prolong pregnancy for those at risk of preterm labour, a qualitative interview study involving 20 women found that the main motivating factors for participation were the possibility of improved pregnancy outcomes, and to a lesser extent the desire to help other women and babies, through contribution to the research (Kenyon et al., 2006). Participation was also on the condition that the antibiotics involved in the RCT were risk free (Kenyon et al., 2006). The main limitation of this study was the time lapse between women deciding to participate in the RCT and taking part in the qualitative interviews. The study does not specifically state how long after interviews took place but the authors acknowledge it may be up to several years, which then introduces the possibility of memory bias. The qualitative interviews also took place after the results of the trial had been published and the women had received copies of the results. Again this may have negatively impacted women's responses, as they may be more likely to recall the trial favourably due any significant findings relating to their situations. For example, half of the women interviewed had ruptured fetal membranes at the time of the trial and the results of the RCT found that antibiotics for such women would lead to improved fetal outcomes. As one of the main reasons reported for participating in the trial was improved pregnancy outcomes, it is possible this may have been influenced by the RCT results already being available to the women. Interviewing women closer to the time when they decide to participate may provoke more accurate and unbiased responses.

A further RCT aimed to explore the effects of antenatal steroids on pregnancy outcomes, in women identified as high-risk for preterm birth. An accompanying qualitative study involving 16 women found that women's

perceptions of their risk status were significant in the decision making process (Snowdon et al., 2006). It was also found that the initial context of discussion regarding the trial, as well as concern for the baby were factors in the decision-making process. Of the 16 women interviewed, 13 reported perceiving the trial as carrying a high level of risk, although this may partly be due to the urgent nature of their situation when they were recruited. As some of the women had already been hospitalised at the time of their recruitment it is understandable their perception of risk was increased and in turn the perceived risk associated with the trial was also increased. However, this is a limitation of this study as it may not accurately reflect reasons why women participate in RCTs; reasons to participate in an RCT are likely to be different depending on the women's current situation and the immediate risk posed to herself and her unborn child.

Similar themes were present in the Qualitative Understanding of Trial Experience (QUOTE) study (Smyth, Jacoby, & Elbourne, 2012). The QUOTE study used interviews to assess pregnant women's decision-making and experiences of participating in a multicentre RCT (Magpie trial). The aim of the Magpie trial was to evaluate the use of prophylactic anticonvulsants with women with severe preeclampsia; the trial recruited 10,141 women from 33 countries. Forty women who participated in the Magpie trial were interviewed; interviews took place in accordance with trial follow-ups, with the mean time of interview being 3 years and 1 month after trial participation. The five main themes influencing and encouraging participation concerned the unpredictability of preeclampsia (and the possible severity of the condition), the quality of trial information received from medical professionals, the role and opinion of others (i.e. family and friends), the potential for personal benefit and improved pregnancy outcomes from trial participation, and the perception that participation was entirely voluntary and personal choice (Smyth et al., 2012). The suggestion that improved pregnancy outcomes influence trial participation is in line with previous research (Kenyon et al., 2006). However, this study is limited by the significant time lapse between deciding to participate and then recount the

decision-making processes; it is possible that memory bias influenced the results. A further limitation is the 'urgent' situation women were in at the time of being recruited to the trial; women were already in labour and suffering from PE. As with Snowdon et al. (2006) it is possible that these circumstances may have elicited different responses than if the women did not perceive any immediate danger or potential harm to themselves or the foetus.

To date, five studies have explored the factors influencing participation and non-participation in medicated RCTs during pregnancy, see Table 1 for a summary of their findings.

Table 5.1. Studies exploring factors influencing participation and non-participation in medicated RCTs during pregnancy (ordered by year of publication).

Study	*Description*	*Findings*
Mohanna & Tunna 1999	Semi-structured interviews with women who declined to participate in the PLANET trial, assessing the effect of nifedipine in preventing pre-term labour in high-risk women. (n=18) Responses were analysed using thematic content analysis.	Reasons for non-participation: risk limitation to the pregnancy; perceived susceptibility of preterm labour; negative attitudes towards the trial from medical staff; poor communication from medical staff regarding the trial; the possibility of being on the placebo arm of the trial.
Kenyon et al. 2006	Semi-structured interviews with women who participated in the ORACLE trial, using antibiotics to reduce occurrence or and risks associated with pre-term labour. (n=20) Constant comparison analysis was conducted.	Reasons for participation: the possibility of improved pregnancy outcomes; to help other women in similar situations; no risk in taking part, or minimal risk in comparison to premature birth.
Snowdon et al. 2006	Interviews with women who participated in the TEAMS trial, comparing repeat doses of antenatal steroids to single dose and placebo, in those at-risk of pre-term labour. (n=11) Interviews with women who participated in the ORACLE trial, assessing the use of antibiotics in reducing pre-term labour and associated risks. (n=5) Themes coded using Atlas-ti.	Reasons for participation: perception of a reduced risk of preterm labour through taking part.
Smyth et al. 2012	Interviews with women who had been recruited to the Magpie trial, using prophylactic anticonvulsants	Reasons for participation:

	versus placebo in women with severe preeclampsia, who had not given birth or were less than 24 hours postpartum. (n=40) Thematic analysis was conducted on responses.	severity and unpredictability of condition (i.e. preeclampsia); quality of trial information received; role of others in the decision-making process; personal benefit from trial participation; perception of voluntariness of joining; self-interest; altruism; trust in the medical staff.
Oude Regerink et al. 2015	Semi-structured interviews with women invited to participate in the Apostel I and Apostel II studies. Both trials examined the use of nifedipine versus placebo in reducing pre-term labour and neonatal morbidity. (n=3) Constant comparison analysis was conducted.	Reasons for participation: to reduce risks associated with preterm labour; interactions with and information provided by medical staff. Reasons for non-participation: Increased concern for pregnancy outcomes as a result of the trial drugs.

5.2.5 REASONS FOR NON-PARTICIPATION IN RCTS DURING PREGNANCY

A qualitative study investigating reasons why 18 women declined participation in a clinical trial (PLANET), exploring the use of nifedipine in preventing preterm labour, identified four significant themes (Mohanna & Tunna, 1999). Reasons for declining participation included limiting risk to the pregnancy by not taking part in the trial, their personal belief that they were not high-risk (despite their risk status) and thus the trial was not relevant to them, as well as perceived poor support and communication skills of medical staff involved with the trial and the placebo arm of the RCT. This study suffered from a low recruitment rate with only 18 women, out of 330 who declined participation in the PLANET trial, agreeing to participate in the qualitative study. As this study was exploratory in nature it still provides useful insight into the reasons why women may have declined participation. However, the results of the qualitative study may not reflect the whole population of women who declined to participate in the PLANET trial. The qualitative study also took place up to two years after women were invited to the trial; the results may therefore not be wholly accurate as they may be affected by memory bias. It is possible that the views of the women may have been affected by the outcome of their pregnancy, for example if their pregnancy did not end in preterm labour they may retrospectively perceive their risk status to have been lower thus justifying their decision to decline participation in the trial. It is likely that interviewing women closer to the time of their decision would provide a more accurate reflection of the reasons for non-participation in an RCT during pregnancy.

A further qualitative study was able to recruit one non-participant of a trial exploring the effectiveness of nifedipine versus placebo in reducing neonatal morbidity (Oude Rengerink et al., 2015). The main reason for non-participation was categorised as negative association or dislike of the intervention due to the potential harm it may have caused the baby. However, from the woman's response, given in this study, it is clear that this individual

also had a difficult pregnancy, suffering both physically and emotionally for the duration. This reason is therefore limited in its usefulness and representation as to why women decline participation in RCTs during pregnancy.

5.2.6 SUMMARY

Research to date has identified various factors, which influence participation in RCTs during pregnancy. The perception of risk (to both mother and foetus), the procedure and requirements of the trial, and the context and content of information given seem to be significant motivating factors in trial participation (Kenyon et al., 2006; Snowdon et al., 2006; Tooher et al., 2008; Smyth et al., 2012; Oude Rengerink et al., 2015). However, for some women these same factors (e.g. trial procedure, content of information, perceived risk) have also been found to discourage participation in perinatal trials (Mohanna & Tunna, 1999). Studies so far are limited due to small sample sizes and the large periods of time between making their decision to participate or not and being interviewed as to how and why they made their decision. There remains a significant lack of research regarding the process of decision-making in expectant mothers who are offered a pharmacological intervention, when they are identified as being high-risk of a condition, such as PE.

5.2.7 RESEARCH AIMS

In order to advance and expand upon the current knowledge regarding the PE screening test, it is vital to understand the decision-making processes and reasons why women decline or participate in the ASPRE trial (Rolnik et al., 2017). Specifically, in regards to the ASPRE trial, the reasons why high-risk women did or did not decide to take aspirin through their pregnancy will be beneficial for medical staff in deciding the best treatments for those at risk of pre-term PE.

The current study aims to investigate the influencing factors for accepting or declining participation in the ASPRE trial. This study also aims to address limitations of previous research and conduct interviews with women as soon as possible after making their decision to participate, or not, in the ASPRE trial.

5.3 MATERIALS AND METHODS

5.3.1 DESIGN AND SETTING

Semi-structured interviews were conducted with women who had been identified as high-risk for PE, through screening, which took place at their 11-14 week ultrasound examination at two NHS hospitals in London, UK. The interviews were transcribed and analysed, using Template Analysis (King, 2012).

5.3.2 SAMPLE

Women who underwent screening for PE risk status and were identified as high-risk were contacted, in person, via email/post or by telephone, by the researcher and invited to participate in the current qualitative study. In total 27 women at high-risk of pre-term PE were interviewed; 14 participants of the ASPRE trial, and 13 decliners of the trial. Sample characteristics can be found in Table 2. The mean age of participants was 35.1 years, and 30.9 years for decliners. The mean gestation at time of interview was 21+5 weeks for participants (range 16+6 to 28+3; SD = 4.19), and 26+3 weeks for decliners (range 14+6 to 36+6; SD = 6.41).

Table 5.2. Sample characteristics

	Participants (14)		Decliners (13)	
	N	%	N	%
Ethnicity				
Caucasian	9	64.29	7	53.85
Black	4	28.57	5	38.46
South Asian	1	7.14	1	7.69
Education				
Primary school	0	0	1	7.69
A levels or equivalent	1	7.14	3	23.08
University degree	7	50	5	38.46
Postgraduate degree	6	42.86	4	30.77
Marital Status				
Living with partner	12	85.71	12	92.31
In a relationship but not living together	1	7.14	1	7.69
Single	1	7.14	0	0
Pregnancy history				
Previous pregnancy	2	14.29	4	30.77
First pregnancy	12	85.71	9	69.23
Medical complications				
None	12	85.71	12	92.31
Asthma	2	14.29	0	0
Polycystic ovaries syndrome	0	0	1	7.69

5.3.3 PROCEDURE

Pregnant women attending for their 11-14 week ultrasound examination were offered the opportunity to be screened for preeclampsia risk status. Alongside appointment letters, women received information leaflets regarding the various screening tests that would be available during their first trimester ultrasound examination. They were also given an information sheet on the day of their appointment, detailing the process in screening for preeclampsia risk status, before they were asked if they would like to participate in the screening.

Results of the PE screening were available on the same day and women were identified as either screen negative, i.e. low-risk for developing pre-term PE, or screen positive, i.e. high-risk of developing pre-term PE. Those identified

as high-risk were offered counselling by a research doctor and invited to participate in the ASPRE trial. Women were given information sheets regarding the ASPRE trial and had the opportunity to ask questions and speak further with the research doctor. High-risk women were given the option to decide the same day or take longer to consider, but participation in the trial could not begin after 14+6 weeks gestation.

In order to participate in the ASPRE trial, women had to be over 18 years old, have a single pregnancy and a live foetus at 11-14 weeks gestation, be screened as high-risk for PE and give written consent. The same inclusion criteria were used for the present study.

The researcher contacted women who had been screened high-risk for PE risk status and invited them to participate in the interview study. Potential participants were sent an information sheet, via post or email, outlining the study and a reply form, allowing the women to give details of how and when they would like to be contacted, should they decide to participate. Women were given the opportunity to be interviewed at their home at the hospital or via telephone. Of the 27 women interviewed eight were interviewed at their home, 13 at the hospital and six via telephone. Where the interviews took place face to face, the researcher obtained written informed consent; verbal informed consent was obtained during telephone interviews. All participants were aware they had the right to decline answering questions if they were not comfortable and could terminate the interview or withdraw from the study, at any time, without giving reason and without subsequent influence on their antenatal care. All interviews were recorded on a dictaphone and transcribed.

5.3.4 SEMI-STRUCTURED INTERVIEWS

A semi-structured interview schedule was developed, based on a review of existing literature and previous pilot work. The interview schedule was designed to investigate women's knowledge and understanding of the ASPRE

trial's aims and procedures, as well as factors influencing their decision to participate, or not, in the trial. Where able to, women were invited to recall the information they had been verbally given by medical staff or read on the participant information sheets. The schedule was flexible and adaptable but also included prompts for the interviewer to encourage expansion of response. The topics covered in the interview schedule included: encountering screening; emotional impact of the high-risk result; decision-making regarding the ASPRE trial; identity of PE risk; perception of PE risk; cause beliefs; illness coherence; controllability/cure; timeline; emotional representations; consequence. See Appendix 6 for the full interview schedule.

5.3.5 ETHICAL CONSIDERATIONS

The local National Health Service research ethics committee gave ethics approval (ref: 14/LO/1238) for this study. Potential participants were given an information leaflet detailing the requirements of the study, as well as a period of at least 24 hours to consider participation. Prior to the interview commencing women were required to give written or verbal informed consent. They were made aware that all participation was confidential; transcripts were shared with the research team but all identifiable information was removed.

5.3.6 ANALYTICAL METHODS AND DEVELOPING THE TEMPLATE

The interview transcripts were analysed using template analysis. Template analysis refers to a group of techniques used to thematically analyse and organise data (King, 2012). It was appropriate for use in the present study due to the exploratory nature of the data but also the use of a priori themes, common to template analysis. A priori themes enable the researcher to identify themes, which are likely to occur in the data and be of significant value to the research questions, before beginning data analysis. The template of themes is therefore constructed before analysis begins, but it is flexible so that any themes, which are not present in the data, can be removed, and

similarly themes, which emerge from the data, can be identified and included in the template.

A template was developed, based on pilot work and the interview schedule, and this was used in the initial phase of analysis. This initial template is in Table 5.3 below. Themes emerging from the 27 interviews were added, removed or adapted throughout the data analysis, resulting in the final template in Table 5.4.

Through the process of data analysis it became clear that, in line with the aims of the study, factors influencing participation and non-participation in the ASPRE trial were significant themes. In the initial template 'factors influencing participation in the ASPRE trial' was a second-level theme but it was decided this should be a first-level theme, due to not only to its significance but also the number of second- and third-level themes it produced throughout the analysis. Similarly factors influencing non-participation was decided to be significant enough to warrant it being a first-level theme.

Adherence to the medication was included in the initial template but did not feature in the final template for this study. Women's responses regarding adherence to taking the medication was not found to have an impact on their decision to participate in or decline the ASPRE trial. However, their views of aspirin were explored as third-level themes under factors influencing participation or non-participation in the ASPRE trial.

The first-level theme in the initial template, decision-making regarding the ASPRE trial, was also removed. Through the data analysis it became evident that women's understanding of the trial and the factors influencing participation or non-participation, more accurately reflected the process of decision-making. Women's experiences of decision-making are thus captured in these new first-level themes.

5.4 RESULTS

The template analysis identified four first-level themes: knowledge and understanding of ASPRE trial aims and procedures, factors influencing participation in the ASPRE trial, factors influencing non-participation in the ASPRE trial, and factors influencing both participation and non-participation in the ASPRE trial. The full template of the first-level themes, and associated second- and third-level themes, can be found in Table 4.

Throughout this results section all participants are referred to by number, rather than name. Where participant quotes are presented, the participant number, the participant group and the line numbers, corresponding to their transcript, follow them. The participant groups have been abbreviated as follows: PA (participants of ASPRE); DA (decliners of ASPRE).

Table 5.3. Template of a priori themes, based on the pilot study

First-level theme	Second-level theme	Third-level theme
1. Decision-making regarding the ASPRE trial	a. The experience of the decision-making process	i. Easy decision to make ii. Ambivalent decision
	b. Factors influencing participation in the ASPRE trial	i. Attitude to aspirin: a known medication, not a concern, no side effects ii. Personal benefit of receiving extra care through taking part in research iii. Trust in doctor's advice and expertise iv. Altruism: importance of taking part in research v. Sufficient information and explanation vi. Views of significant others vii. Concerns regarding taking medications
	c. Concerns regarding participation in the ASPRE trial	
2. Adherence	a. Feelings towards taking the tablets	i. Importance for the baby ii. Integrated in routine vitamins (folic acid); not much thought given iii. Hatred towards taking the tablets iv. Acceptance due to absence of side effects
	b. Remembering to take the tablets	i. Easy as integrated into routine ii. Ambivalence towards tablets in general leading to missed tablets

Table 5.4. Template of themes

First-level theme	Second-level theme	Third-level theme
1. Knowledge and understanding of ASPRE trial aims and procedures	a. Good understanding b. No clear understanding	
2. Factors influencing participation in the ASPRE trial	a. Positive attitudes towards aspirin	i. Preference for taking active tablet ii. Lack of negative side effects associated with aspirin
	b. Placebo arm	
	c. Personal benefit from trial participation	
	d. Altruism	
	e. Satisfaction with the information received	
3. Factors influencing non-participation in the ASPRE trial	a. Negative attitudes towards medication during pregnancy	i. Precautionary medicine seen as unnecessary ii. Concerns about the safety of taking aspirin iii. Medical complications, past and present
	b. Placebo arm	i. Wanting a guarantee of taking aspirin ii. "You don't know what you are taking"
	c. Insufficient information about the trial	
4. Factors influencing both participation and non-participation in the ASPRE trial	a. Role of significant others	

1. Knowledge and understanding of ASPRE trial aims and procedures

This first-level theme captures women's knowledge and understanding of the ASPRE trial's aims and procedures; the majority of women (n=24) had a good understanding, compared to three women with inaccurate understanding of the trial's aims and procedures.

a. Good understanding

In this second-level theme both participants and decliners expressed a good knowledge of the trial's aims and procedures. Overall 24 women (13 participants and 11 decliners of the trial) remembered at least some of the key details regarding the aims, procedures and/or requirements of the ASPRE trial.

Women generally understood that the main aim of the ASPRE trial was to establish the effect of taking low-dose aspirin throughout pregnancy, on PE occurrence:

> "The idea was that they would be able to see if there was a link between taking the aspirin and reducing the preeclampsia." 10, PA, lines 185-187.

> "It's to look at whether women who have, who screen high-risk, whether taking daily aspirin will reduce the risk of getting preeclampsia." 15, DA, lines 201-203.

As these responses demonstrate, both groups of high-risk women were aware of the aim of the ASPRE trial. Some women also expressed knowledge and understanding of the trial's requirements and procedures, such as taking aspirin daily and attending more scan appointments at the hospital, as well as an understanding of the randomised nature of the trial.

> "Yeah so half the people take aspirin, 75mg and half the people take a placebo but you don't know what you're getting, it's like a double blind test and erm yeah how you get to go in like some, a couple of extra scans and they can see how you're going." 20, DA, lines 202-207.

> "Taking the tablets, they explained everything, the tablets some would be aspirin some would be like dummy, they wouldn't know, we wouldn't know and to take them every day and they gave me the diary and explained if I have any symptoms or anything just to write it down." 1, PA, lines 166-172.

> "You would have been randomised through the aspirin or placebo and you had to take, was it one tablet a day and I can't remember the exact duration but it would have been from that point and I think until 6 months." 21, DA, lines 196-199.

This second-level theme shows that 24 women, out of the 27, who were identified as high-risk for developing PE and informed about the ASPRE trial, understood the aims and procedures well.

b. No clear understanding

The remaining three women consisted of one participant and two decliners. These women did not have a clear understanding of the aims and requirements of the ASPRE trial:

> "They said to me that I would need to go in each week for an ECG I think it was and then I would just need to take these tablets and then they would see if they would work on like me and the other people that were taking part." 25, DA, lines 261-267.

> "It's to see psychologically as well and it helps you. I think she said to see like how you react psychologically to it. I think maybe that I am taking and maybe my body thinks the drugs are helping." 4, PA, lines 351-354.

These women failed to grasp or recall the key requirement of the trial, which was to take a tablet, either aspirin or a placebo, throughout pregnancy, with the aim of reducing the incidence of PE. Some of the misunderstanding came from a lack of understanding of the randomisation and use of placebo, and in one case a misunderstanding that the drug was paracetamol.

2. Factors influencing participation in the ASPRE trial

This first-level theme examines the different factors, which influenced and encouraged women to participate in the ASPRE trial. Thus all responses within this theme are from women who were identified, through screening, as high-risk for developing PE and also who had agreed to participate in the randomised ASPRE trial.
Women's responses were categorised into five second-level themes.

a. Positive attitudes towards aspirin

A significant and widely reported influence over trial participation was positive attitudes towards aspirin. Women generally felt reassured that aspirin was being used for the trial drug, because it was a medication they were familiar with and they were aware of its use for various conditions.

> "I know that there are, its being widely used, for so many years, we know there isn't really much of an effect, it's not teratogenic obviously and there doesn't seem to be a particular negative impact on the baby." 12, PA, lines 199-203.

> "The fact that aspirin is a drug that is well-known and taken for different reasons. In small doses it didn't seem like a high-risk thing to agree to as opposed to actually saying, I don't want to be involved." 7, PA, lines 190-194.

> "I knew it's aspirin or placebo, if it would've been a weird drug that I hadn't known about then it would be completely different, because I knew it is either aspirin or nothing, I thought it's fine." 2, PA, lines 119-122.

This positive attitude towards aspirin was, therefore, an enabling factor when women considered participation in the trial.

i. Preference for taking active tablet

Three high-risk participants of the trial stated a preference for taking the aspirin tablet during the trial.

> "It would be nice to know that I was on the aspirin if that's what's believed to obviously minimise the impact of it or avoid it happening. But I understand it's a trial so you need one in each side of the cap." 7, PA, lines 165-169.

> "I would have liked the confirmation that what I am taking is aspirin…if I've got a risk I want to try the thing that is going to lower that risk." 3, PA, lines 142-145.

As demonstrated through these extracts, the women recognised the need for randomisation in the trial and although they expressed a preference for the active drug, they did not choose to take aspirin every day, independent of the trial.

ii. Lack of negative side effects associated with aspirin

Another common factor influencing participation in the ASPRE trial was the perception that taking aspirin during pregnancy would not have adverse side effects. Nine high-risk participants of ASPRE reported that such perceptions contributed to their decision, for example:

> "I can't see any negative side effects on my side, so I thought I'm not losing anything." 2, PA, lines 114-116.

> "I think I was kind of concerned if taking an aspirin, a day could harm the baby. He reassured me that it couldn't do any harm to the baby. As soon as I knew that then it was fine." 8, PA, lines 308-310.

> "I did ask about the effects or side effects of having the real versus the opposite, the placebo, and was reassured that aspirin was something that was fine to give to pregnant women…I asked a lot about the risks before I signed up for it but again, it doesn't feel that that's a big risk." 6, PA, lines 432-438.

These responses showed that any initial concerns regarding the side effects of taking aspirin throughout pregnancy were alleviated after further discussion with the medical team. The perceived lack of side effects then acted as a motivating factor when deciding to participate in the ASPRE trial.

b. Placebo arm

Eight high-risk participants of the trial expressed positive attitudes towards randomisation; they were happy to take the active aspirin tablet or the placebo. They felt that aspirin was a safe drug to take during pregnancy, and that the placebo was effectively the same as not participating in the trial, and had no preference for either tablet.

> "I was really happy to take part in the trials. I didn't really see, obviously if it's a placebo then there is no, I am not better or worse off than I would have been anyway." 5, PA, lines 290-293.

> "I suppose because if I wasn't part of the trial I wouldn't be taking anything anyway. It's not really, I am kind of, I'm not losing out." 8, PA, lines 261-263.

> "It was fine because otherwise I wouldn't have had any treatment." 14, PA, lines 236-237.

These women recognised that declining participation in the ASPRE trial would have resulted in no treatment for their high-risk status. They seem to suggest therefore that being in the placebo branch of the trial would be no different to non-participation, from their point of view; whereas any benefit from being on the aspirin is a potential bonus, but not necessarily expected.

c. Personal benefit from trial participation

A reason, reported by 11 women, for agreeing to participate in the ASPRE trial was the extra support and medical care they would receive due to taking part in research. This second level theme explores how women perceived the extra care as beneficial.

These women specifically stated that by participating in the ASPRE trial, they felt they would be better monitored at existing scans and also receive extra scans and appointments, which they felt was reassuring and would result in overall better care.

> "Part of it was because I thought I might get increased monitoring myself." 9, PA, lines 262-263.

> "I thought in a way it's quite reassuring to know that I have extra scans and be monitored a bit more closely because of being in the trial, I find that reassuring." 2, PA, lines 125-128.

Several of these women also remarked that taking part in the trial and attending extra scan appointments, was the better option, when compared to non-participation.

> "I think I just went ahead with it because I thought it was the best option to take, because at least I'm being monitored regularly and now I would know everything rather than just waiting on some problems to occur." 11, PA, lines 219-222.

> "The alternative was not to take part and not to have the extra scans but still know I had this risk of preeclampsia and I don't, don't think that's a very good place to be, so it feels like it, it's the right thing to do." 6, PA, lines 627-630.

Through women's responses it is also evident that regardless of the effectiveness of the trial medication, the extra monitoring could also help identify other potential problems and result in a more informed, safer pregnancy.

> "The main reason, whether the aspirin works or not, the fact that I had been highlighted as high-risk and the fact that being part of the trial linked to extra monitoring and extra scans and things like that was the main reason. It was that actually I'd been identified as high-risk and it was going to help look out for it and also just generally, potentially other stuff. So us being scanned more regularly into the later stages of pregnancy that, that was kind of the benefit." 7, PA, lines 227-234.

d. Altruism

The idea of being able to help other women in future, by taking part in the trial, was seen as a beneficial consequence of participation and a further encouraging factor for 12 high-risk women.

> "I know it's really difficult to recruit and I am quite happy to kind of be part of a trial that might make it better in the future, which sounds quite altruistic. It didn't really, because as I say, it doesn't really impact on me particularly taking it, so I am quite happy to do it, and I might even benefit from it." 5, PA, lines 356-361.

> "I think if everyone started to say no to these things, you wouldn't really have a trial and you wouldn't, you wouldn't actually learn any more about preeclampsia or about treating it or anything like that, so I think it is actually important, I mean as long as it is safe, and there is enough evidence to show it is safe, I think it is actually important to, myself included, to participate in at least some kind of research that goes on in medical institutions, or else they always will just never get anywhere." 13, PA, lines 285-294.

As demonstrated through these extracts, some women who agreed to participate in the ASPRE trial believed that in doing so they would contribute to the medical knowledge regarding preeclampsia treatments. This idea of benefitting other people's pregnancies was both positive and motivating, particularly given the lack of perceived, intrusive and personal impact from the trial.

e. Satisfaction with the information received

This second-level theme refers to the satisfaction felt by some women regarding the information provided by the medical team and this positively impacted their decision to participate in the ASPRE trial.

> "I had a whole night to think about it, so we came back the next day, all our questions were answered by the doctor." 11, PA, lines 255-263.

Some women also reported feeling reassured by the information provided by the medical team, including contact details for the team in case of problems:

> "We did talk to the lady who told us about the trial and I sort of felt reassured when she told us some of the facts about it. She had a card where you can call somebody to talk about any side effects at all that you have." 6, PA, lines 443-446.

> "The doctor gave me all the contact details and things like that if I had any follow-up questions." 8, PA, lines 297-298.

The responses in this second-level theme suggest that the information from the medical team was an encouraging factor when opting to participate in the ASPRE trial.

3. Factors influencing non-participation in the ASPRE trial

This first-level theme explores the various factors influencing non-participation in the ASPRE trial, as reported by the high-risk decliners. All responses within this theme are from women identified as high-risk for developing preeclampsia but who then subsequently declined to participate in the ASPRE trial. There are three second-level themes addressing the reasons for non-participation, and each will be explored in turn: negative attitudes towards medication during pregnancy; placebo arm; insufficient information provided by medical team.

a. Negative attitudes towards medication during pregnancy

The main reason for declining participation in the ASPRE trial, which was discussed by 12 of the women, was negative attitudes towards taking

medication during pregnancy. This second-level theme included the most responses regarding why women declined to take part in the ASPRE trial, and highlighted a general unease amongst some of the women participants taking any kind of medication whilst pregnant.

> "I would be taking a drug that I wouldn't have otherwise taken. I spent quite a lot of time making sure I didn't eat cheese or red meat or anything like that. It seemed a bit strange when I'd read all the way through that I wasn't supposed to take aspirin, to start taking aspirin." 16, DA, lines 267-272.

> "I would prefer to stay natural. I take my multivitamins obviously, but I don't like to take medications." 22, DA, lines 232-233.

> "I didn't want to be taking any medication anyway if I don't have to, if they give me a choice you can take this or not take it, I'd rather not." 27, DA, lines 858-861.

As these extracts show, women expressed an overall negative attitude towards taking medication during pregnancy. This attitude was a response to the general medical advice that warns against taking medication during pregnancy.

Some women further explained the particular reasons as to why they had a negative attitude towards the trial medication; these are explored in the following third-level themes: precautionary medicine seen as unnecessary; concerns about the safety of taking aspirin; medical complications, past and present.

i. Precautionary medicine seen as unnecessary

From taking part in the screening, the women knew that they had been identified as high-risk for developing preeclampsia at a later stage in

pregnancy. However, as there was no guarantee that they would go on to develop preeclampsia, some women felt that taking trial medication was a precautionary measure that was unnecessary.

> "I don't think I would want to, really, no, because pills, I just don't like pills in general, especially if I've definitely not got it. I am at high-risk but I don't like to take things just to prevent something." 22, DA, lines 312-315.

> "I guess I was worried about taking additional drugs when I was working so hard at not taking paracetamol and not taking anything I didn't need to take." 16, DA, lines 274-277.

> "I don't want to be taking aspirin if I don't really need to." 21, DA, lines 280-281.

For some women it is evident that the non-diagnostic nature of the screening test resulted in a reluctance to take preventative medication. As some women were not particularly concerned by their screening results, they did not feel motivated to participate in the ASPRE trial.

ii. Concerns about the safety of taking aspirin

This third-level theme consists of responses from five women who indicated that their concerns about the safety of taking aspirin negatively influenced their decision to participate. Although they had been informed that side effects were unlikely and not harmful to the pregnancy, they remained concerned. For example:

> "I'd minimised what I had been taking in terms of drugs and paracetamol and stuff. I wasn't going to likely start taking aspirin in case there was any side effects." 16, DA, lines 243-246.

> "Yeah I was a bit, little bit uneasy about it erm but I dunno everyone kind of seemed to be saying there were no adverse effects." 18, DA, lines 313-315.

The suggestion, by these women, is that any possible side effects from taking aspirin were unnecessary and the women would rather avoid potential risks.

iii. Medical complications, past and present

Existing and previous medical complications and conditions influenced three women who declined participation in the trial. Some women were concerned that taking low dose aspirin in a daily basis would be detrimental, given their medical history, for example:

> "I think I thought that I would, but then, to be honest with you because my pregnancy is IVF, I was taking so many drugs up until that twelve week point that I just decided on reflection that actually I just didn't want to be taking more drugs every day and I was so looking forward to my twelve week point when I was stopping the cocktail of drugs that I was on in immunosuppressant therapy that I just, to be honest with you I just thought, I was looking forward to a time when I don't have to take any." 17, DA, lines 252-260.

> "I've got sickle cell disease there's other medications I take and I didn't want to be taking so much even though he said that the test you will, you might be on a placebo, you might be on a low dose aspirin, I just thought I'm already taking a lot I didn't really want to add another one." 27, DA, lines 187-192.

> "I can't take aspirin every day, because I've got another, I've got low platelets. So that's something that I can't do." 15, DA, lines 170-172.

As these extracts demonstrate, women did not want to take medication that wasn't absolutely necessary, as a result of previous or on-going medical conditions.

b. Placebo arm

i. Wanting a guarantee of taking aspirin

Four high-risk decliners specifically stated that if aspirin were effective in reducing the likelihood of developing preeclampsia, they would want the guarantee of taking it, rather than the possibility of taking the placebo.

> "If they had just have said to me that it was just aspirin I probably would have done it." 26, DA, lines 157-158.

> "If I'm high-risk and low dose aspirin would benefit me I would like to take low dose aspirin, whereas I might get the placebo, which means that it's pointless." 27, DA, lines 260-263.

> "It was mainly my sister I think I wanted to talk to…because she had it before and they just said you should have it, so yeah it kind of just convinced me to take it erm so yeah I think I made my decision maybe a day or so afterwards." 18, DA, lines 273-281.

Some women are speaking hypothetically here (e.g. participant 26) whilst others did go on to take aspirin throughout their pregnancy (e.g. participant 18). These women decided not to take part in the trial, as they were not guaranteed to be taking the aspirin.

i. "You don't know what you are taking"

Five women reported feeling uncomfortable with the randomised aspect of the trial. As well as having negative feelings towards the active trial drug, they

also did not like knowing exactly what medication they would be taking, and whether it would be the aspirin or placebo.

> "You don't know what you're taking as well, especially for your first pregnancy, I think like no why would you want to give yourself extra hassle, extra stress, it's just not worth it." 20, DA, lines 224-227.

> "I know I could have gotten the placebo but em, and I think that as well because also not knowing, 'cause when you go for your appointment with your midwife or anything had happened and I'd gone in the hospital, and they say are you taking any medication, to say well I could be but I don't know, that again is also quite difficult I think." 19, DA, lines 272-278.

As indicated through these responses, women appeared to feel as though the randomisation of the trial medication added another layer of stress and concern for them, particularly if something was to go wrong later in their pregnancy.

c. Insufficient information about the trial

Three women stated miscommunication and insufficient information provided about the trial as minor contributing factors for non-participation in the ASPRE trial.

> "She couldn't answer all of my questions, she probably wasn't expecting me to ask those kind of questions, and I think it would have been quite nice if she could have pointed me to something I could have read more to give more details." 19, DA, lines 238-242.

These women felt they didn't have all the information they wanted, which in turn contributed to their decision-making regarding the ASPRE trial.

4. Factors influencing both participation and non-participation in the ASPRE trial

One theme was reported as influencing both participation and non-participation in the ASPRE trial: the role of significant others. Through the interviews it was evident that significant others played a small role in the decision-making process, for both participants and decliners. Women sought reassurance from significant others but the majority reported making their initial decision independently, or jointly with their partner.

a. Role of significant others

Women who declined participation in the ASPRE trial appear to value the opinions of friends and family; ten women reported discussing the trial with their significant others. Some significant others were supportive of taking aspirin or happy to go with whatever decision the woman felt comfortable with, for example:

> "I did end up taking aspirin so I do take that now, it was based on discussing it with my sister and erm other members of my family who've had it, and it's actually quite common in my family, they both, they all kind of said that, well if so far and that the consultant agreed that there's no harm shown then you may as well take it." 18, DA, lines 238-244.

> "I suppose we were all in agreement to be honest, we all thought the same thing so they didn't influence it was just enhancing my decision." 24, DA, lines 196-198.

> "He [my husband] said just do whatever you think, so he didn't really have an opinion otherwise." 21, DA, lines 142-147.

Other women discussed how significant others were not supportive of trial participation, and disagreed with taking medication during pregnancy.

> "My partner was not happy about that as well. Again, he's a bit like that with the medication thing as well. He doesn't like to take medication especially when I am pregnant. We sort of made that decision together." 22, DA, lines 250-253.

> "I spoke about it with my mum and then my husband as well. We all just reached the same consensus that having already taken all of these drugs, you know, I just wanted a break." 17, DA, lines 313-316.

> "Yeah they were happy for me to be screened, it was more the treatment they weren't too happy with." 24, DA, lines 140-141.

Women appear to be encouraged and reassured by the support of significant others in regards to their decision to decline participation of the ASPRE trial.

In general, high-risk participants of the ASPRE trial also reported discussing participation with significant others, but that these discussions had little influence on their final decision.

> "He was there at the time. I said to him 'are you happy with it?' he said 'yes'." 5, PA, lines 334-335.

> "We both came very quickly to the same decision that was basically a no-brainer to be involved with." 7, PA, lines 208-210.

As shown through these responses, for those women who did discuss the decision with significant others, they did not perceive that their partner had a great impact on their decision, due to shared feelings and beliefs between them and their partner regarding the trial and taking the medication. As most

women did at least consult with significant others, it suggests that their opinions were valued.

However, one woman chose not to tell any significant others and made her decision independently.

> "I don't want to worry, because the only people I would tell about is my family and they would just fret anyway, so I just never told them." 12, PA, lines 221-223.

As with the decliners, participants were confident enough to make the initial decision independently but discussed their participation with significant others, once the decision had been made. Again this suggests they were seeking reassurance and confidence that they had made a 'good' decision. Only one high-risk participant chose not to tell any significant others, for fear of their worry influencing her own views of the decision and trial.

5.5 DISCUSSION

The use of RCTs to advance healthcare is now regarded as the 'gold standard' of treatment evaluation (McDonald et al., 2006). Recruitment remains a key factor in the success of RCTs and failure to meet recruitment targets and deadlines can result in statistically weaker results and poor reliability (McDonald et al., 2006; Ross et al., 1999). Previous research has focused on barriers and facilitators to trial participation in relation to various illnesses (Canvin & Jacoby, 2006, Mills et al., 2006, Infanti et al., 2014).

However, there is a dearth of research regarding the factors influencing participation and non-participation in medicated RCTs during pregnancy. The current study aimed to contribute to the limited literature examining the influences on participation and non-participation in medicated RCTs during pregnancy.

The majority of the women (24 out of 27) were able to recall at least some of the key details regarding aims, procedures and requirements of the trial. Three women (one PA and two DA) could not accurately recall the aims, procedures or requirements. This suggests that the majority of women were able to make considered, well-informed decisions regarding trial participation, with a good understanding of the possible consequences of trial participation and non-participation. This is an important factor when analysing recruitment into RCTs, as it reflects the accuracy of patients' justifications as to why they do or do not want to participate in RCTs. If participants or decliners of RCTs could not demonstrate a clear understanding of the trial, it would suggest their decision was based on inaccurate information and understanding (Snowdon et al., 1997). In the current study, given that 24 out of the 27 women interviewed showed a good understanding of the ASPRE trial, it can be inferred that the information provided was sufficient. No participants in the current study demonstrated "therapeutic misconception" (Appelbaum et al., 1987); all participants had a thorough understanding of randomisation and the placebo arm. It is possible that women in the present trial had relatively long periods of time in order to consider their decision and find out more information, contributing to their good understanding. This is in contrast to trials such as Snowdon et al. (1997), which were conducted under intense situations and required more immediate responses.

Several factors were reported as influencing participation and non-participation in the ASPRE trial, and one common theme was found between the two groups.

Five factors were identified as influencing trial participation: positive attitudes towards aspirin, placebo arm, personal benefit from trial participation, altruism and satisfaction with the information received.

The majority of participants of the ASPRE trial reported positive attitudes towards the trial drug, aspirin. Thirteen (of the 14) participants directly linked their positive attitude towards aspirin with their decision to

participate in the trial. The women felt reassured by the trial's use of aspirin, as it was a familiar drug, well known to the women for its uses in treating various conditions. Three participants expressed a preference for taking the aspirin during the trial, but recognised the necessity of randomisation in order to correctly evaluate the effects of aspirin on PE incidence. A preference for taking the active drug was found in two previous studies exploring RCT participation during pregnancy (Mohanna & Tunna, 1999; Smyth et al., 2012). Women tend to state a preference for the active drug, which they believe will be of benefit; this is also generally reported in non-pregnant samples (e.g. Mills, Donovan, Wade, Hamdy, Neal, & Lane, 2011). It has previously been suggested that clinician preference (expressed through the trial introduction) may be the cause of some women already being confident in the trial drug's benefits (Canvin & Jacoby, 2006; Smyth et al., 2012).

Women were also motivated to participate due to the lack of risk presented by taking aspirin during pregnancy; it was perceived that taking aspirin on daily basis would have no negative impacts on themselves or the baby. This was previously reported by Kenyon et al. (2006), who found that women's perceptions of the trial drug as low-risk, or risk free, was a motivating factor in trial participation. Similarly, Snowdon et al. (2006) identified that the level of risk women associate with trial drugs influences their decision to participate; they choose to participate if they perceive the trial drug as being low-risk. The results of the current study are in-line with this previous research, and suggest women's perceptions of risk associated with aspirin were influential in their decision to participate.

Another significant motivating factor for trial participation was the belief that women would personally benefit from taking part; 11 out of 14 women expressed this view. As well as taking part in the medicated aspect of the trial, women were also required to attend extra scans and were seen by the same medical team throughout their pregnancy. Women were encouraged by this extra monitoring and support that was available through trial participation, and reported feeling reassured as a result. Personal benefit from trial

participation has previously been reported as a motivating factor (Kenyon et al., 2006; Smyth et al., 2012). This study suggests that perceived trial benefits, other than taking the trial drug, further encourage women to participate in RCTs; for example, in the current study, women not only saw the possibility of taking aspirin as a benefit, but also the extra monitoring through additional antenatal scans. Some women expressed that extra monitoring was particularly important because of their 'high-risk' status, and they would feel reassured by additional appointments associated with the trial. Extra monitoring can alleviate worry as women know they will be assessed regularly and be made aware if their risk was to increase or become threatening to their pregnancy.

Women who chose to participate in the ASPRE trial were also comfortable with the placebo arm of the trial. They understood that randomisation was necessary in order to establish the accurate effects of aspirin. They also understood that if they were on the placebo they would not receive any potential benefits that would come from taking aspirin, however they would experience the extra monitoring that was only available due to trial participation. Rather than the placebo arm of the trial being an active encouraging factor in deciding to participate, it acts as a facilitator to participation as women were reassured that whichever branch they were on they would not be negatively affected.

Twelve participants reported being motivated, or influenced, to take part in the ASPRE trial, by the potential benefits to others, as well as themselves. These women expressed views that their participation would help on a wider scale, contributing to the medical knowledge regarding preeclampsia and its treatment, which would in turn benefit future mothers and babies. Altruism has been identified as a factor influencing trial as a prominent motivation to participate in a medicated RCT during pregnancy. The current results are similar to those of Kenyon et al. (2006), although to a lesser extent as altruism was not reported as a primary motivating factor here. In the current study, women expressed 'weak altruism' (Canvin & Jacoby, 2006; Edwards & Braunholtz, 2000); women communicated a desire to participate in order to help other women and contribute to medical knowledge, although this was

on the condition that the personal risk as a result of trial participation was perceived to be low. As with the Canvin and Jacoby (2006) study, none of the participants cited altruism as their sole motivation for participation; however, they gave a combination of reasons for participation, including those relating to self-interest and for the benefit of others thus demonstrating 'weak altruism'.

Satisfaction with trial information, provided by medical staff, was found to be important in influencing trial participation. Participants of the ASPRE trial reported receiving a good amount of high quality information regarding the trial, aims and procedures. They also felt confident and reassured by the availability and accessibility of medical staff, throughout their pregnancy, which encouraged them to participate in the RCT. Satisfaction with the level and quality of information provided has previously been found to be a contributing factor when deciding to participate in an RCT during pregnancy (Kenyon et al., 2006; Oude Rengerink et al., 2015; Smyth et al., 2012). When recruiting for clinical trials during pregnancy, this study supports existing literature suggesting that trial information should be clear, comprehensive and accessible for all potential participants.

In contrast, non-participation in the ASPRE trial was influenced by negative attitudes towards medication during pregnancy, the presence of a placebo arm and women feeling they had insufficient information regarding the trial.

Negative attitudes towards taking medication during pregnancy, were expressed by 12 of the 13 decliners of ASPRE. This was reported as the main reason for declining participation and women suggested taking aspirin was against general medical advice that women should avoid medication during pregnancy. In particular, some women felt uncomfortable with the idea of taking medication 'just in case' they may develop PE, or as a precaution based on risk status. These women perceived taking medication during pregnancy as a bigger risk than their status as being high-risk for developing PE. This finding is similar to that of Mohanna and Tunna (1999), who reported that

pregnant women decline trial participation in order to reduce potential risk posed by trial participation.

In addition, five decliners of the ASPRE trial reported having concerns about potential side effects of aspirin and this influenced their trial decision. Previous research is limited in exploring the factors influencing non-participation in medicated RCTs during pregnancy, however, a review of the literature in non-pregnant samples found that patients were concerned about the uncertainty of success of trial treatments (Ross et al., 1999). Similarly, pregnant women have previously demonstrated uncertainty about the effect of trial drugs on pregnancy outcomes (Oude Rengerink et al., 2015).

Some women were also discouraged to participate in the ASPRE trial by the presence of the placebo arm. Five women suggested that the placebo arm added extra, unnecessary worry; women felt concerned at the prospect of not knowing what medication they were taking and what the consequence of this would be if they were to attend hospital in an emergency situation. In contrast, some of the decliners of the ASPRE trial did so as they wanted the guarantee of taking aspirin to address their high-risk status; they took aspirin, daily, outside of the trial. They did not want to participate in the trial and risk being on the placebo, but instead wanted to be sure that they were taking the medication perceived to reduce their chances of developing preeclampsia. Again these results are supported by previous findings (Mohanna & Tunna, 1999).

Insufficient information, regarding the trial, was reported by three women as an influential in their decision to decline participation. Although this was not a primary factor, these women felt they still had unanswered questions following discussions with trial staff. This resulted in these women not feeling reassured and that they did not have enough information to feel confident about trial participation. As this was reported by so few of the women and not as their main reason for not participating in the trial, it is likely that these women did not feel comfortable with the demands of the trial and the

perceived lack of sufficient information was an 'extra' reason not to participate.

Women with pre-existing medical conditions reported this as a contributing factor influencing their non-participation in the ASPRE trial. They expressed concern in combining the trial medication with their current conditions, and again regarded participation as a source of unnecessary stress. They did not perceive the risk of preeclampsia to be more significant than their current conditions and did not believe that the trial would provide sufficient relief for their high-risk status.

Medical conditions and insufficient information were reported as secondary factors influencing non-participation in the ASPRE trial, by a small number of women. Of greater importance and influence in women's decision-making were negative attitudes towards taking medication during pregnancy, and specific concerns regarding side effects of the trial drug, aspirin.

Previous research has identified the role of significant others as important in the decision-making process (Mohanna & Tunna, 1999; Oude Rengerink et al., 2015; Smyth et al., 2012). In the current study, the role of significant others was also found to influence both participation and non-participation in the ASPRE trial. Although the majority of women in the current study reported making the decision independently, they did consider the opinions of significant others and sought reassurance from them following making their decision. The role of significant others can be considered a less important influential factor, and a woman in the present study went against her partner's wishes regarding trial participation, suggesting that it is pregnant women themselves and the opinions of pregnant women which are most important.

5.5.1 LIMITATIONS OF THE CURRENT STUDY AND FUTURE CONSIDERATIONS

The current study explored the factors influencing participation and non-participation in the ASPRE trial, in a small number of high-risk women in a two centres, in the UK. A limitation of the current study is the characteristics of the sample; participants were generally well educated, to at least A-level standard, in a relationship and/or living with their partner and Caucasian. The views of this sample, therefore, cannot, be considered generalisable to all pregnant women, offered RCTs during pregnancy.

The present study is also limited due to the moderate sample sizes obtained. As some of the contributing factors to decision-making were reported by only a few women, it is not possible to suggest they would be representative of pregnant women at high-risk of PE. Although the main reasons given for participation and non-participation were unanimous across participants and decliners, and supported by previous research, suggesting these could be considered more reliable and representative.

However, the current study supports and contributes to the existing, limited literature exploring barriers and facilitators to trial participation during pregnancy. The current study also addressed the issue of time, which was a limiting factor in some previous research; in this study all interviews took place whilst the women were still pregnant, relatively soon after having made their decision to participate or not in the ASPRE trial.

5.6 CONCLUSION

The majority of women demonstrated having good knowledge and understanding of the ASPRE trial's aims and procedures, suggesting they were able to make informed choices. Women who participated in the ASPRE trial had positive attitudes towards aspirin, as well as the extra monitoring they would receive as a result of the trial. Participants were also satisfied with the trial information provided by medical staff and were partly motivated to participate by a sense of weak altruism.

The main factor influencing non-participation was negative attitudes towards taking medication during pregnancy and specifically concerns regarding

potential side effects of aspirin. Some women who declined the trial also felt unsatisfied with information provided and were more concerned with pre-existing medical conditions, than their high-risk status for preeclampsia. Both participants and non-participants made their decision independently but considered and consulted with significant others after doing so. The most important factor influencing participation or non-participation was women's attitudes towards taking aspirin to reduce the likelihood of pre-term PE during pregnancy.

CHAPTER SIX
6 GENERAL DISCUSSION

6.1 EMOTIONAL RESPONSES AND ILLNESS REPRESENTATIONS OF HIGH-RISK WOMEN

One of the main aims of this thesis was to explore women's emotional responses following screening for pre-term PE; this was done through a semi-structured interview study (Chapter three). The findings of the current study suggest that women, who are informed of their risk status for pre-term PE, constructed illness representations that are co-influential and parallel. This finding is in line with previous research, exploring the CSM framework with a pregnant sample (e.g., Hagger & Orbell, 2003). Previous research found that illness representations influence behaviour and attitudes, even when CSM constructs are not well understood by individuals (Meyer et al., 1985), which the current research also supports. The findings presented in this thesis provide evidence for not only the parallel nature of the CSM but also the back-and-forth, adaptive nature of the illness representations, which can be influenced by each other. For example, Leventhal et al. (2008) presented evidence for a link between the cause and control dimensions and the current research also found that perceptions of the cause of PE can influence the extent women feel they can exert control over the development of PE. These beliefs subsequently influenced behaviour and consequence. These findings suggest links between previously known elements of the CSM, within the pregnant population, particularly in regard to screening. However, the current research found a weakness in the relationship between the identity and coherence representations. Although women generally had a good understanding of PE as a condition, their coherence of their personal risk status and interpretation of their results was poorer. This suggests that women should be given clear information as to what the screening process entails and what the potential outcomes may mean for them personally. This will help ensure

that informed consent is gained prior to screening but also that women will have a better understanding of what their risk status means.

The link between the cause and timeline representations, could not fully be explored due to the nature of the study design. Interviews took place at one time point during pregnancy, and so an exploration into the long-term illness representations could not be gathered. High-risk women were uncertain whether they would remain high-risk throughout their entire pregnancy, or in future pregnancies. There is some evidence to suggest that illness representations change and develop over time (e.g., Meyer et al., 1985) and so this has not been explored fully with the current sample. Future research into this area and establishing any changes to illness representations following birth would help generate understanding over a longer period. The consequence aspect may also depend on the outcome of the pregnancy, which may only be explored once the pregnancy is over.

Evidence was found to support the CSM, in that individuals faced with a health threat (in this case being high-risk) are more active problem solvers and have a better understanding of the illness identity (Diefenbach & Leventhal, 1996). This finding further supports the CSM as low-risk women were found to not have a particular interest in the condition or retain information related to it, following their low-risk result. The identity dimension of the CSM was also found to be particularly influential over women's emotional responses. This suggests it is important for women to have a good understanding of the condition they are being screened for and a strong understanding of the identity in order to minimise any emotional impacts. In terms of practical implications, this may mean women need quality medical advice and understanding when agreeing to screening or being given their result. Providing women with leaflets or clear access to information could improve their understanding and knowledge of PE and its symptoms.

This research replicates the finding by Harris et al. (2014) that women do not experience significant negative emotional effects following screening for PE. In line with the expectations of the CSM framework, a range of emotional responses can be expected following a health threat (Diefenbach & Leventhal, 1996). However, in the current study those fluctuations in emotional responses were not found to be significant or long-lasting. The current, larger sample adds to the finding of Harris et al. (2014) and contributes to the broader understanding of women's responses to screening for pre-term PE risk status, as well as providing further evidence for the CSM framework.

Several illness representations were found to correlate with others, for example cause and identity influenced consequence and the actions women would take following their screening result. This finding supports previous research by Harris et al. (2014) who concluded that women who were high-risk for PE were data managers and made behavioural changes based on their understanding of their risk. The current study expands on Harris et al. (2014) by exploring this and demonstrating this finding within a larger sample, although future work could seek to increase the diversity of the sample characteristics.

The current research contributes to literature exploring women's feelings and beliefs regarding prenatal screening. Findings confirm that screening for pre-term PE provides reassurance to both low- and high-risk women, giving high-risk women an opportunity to find out more about the condition, decide whether to make behavioural changes and be emotionally prepared for potential outcomes. This research uses a larger sample than previous studies and further expands the research base by including low-risk women, establishing an understanding of their illness representations. It also adds to previous research which found that women engage in screening during pregnancy, without having a complete understanding of the procedures or consequences (e.g., Mitchell, 2003) in the hope that they will be low-risk and thus reassured (e.g., Jacques et al., 2004).

Overall women expressed supportive, positive attitudes for screening for pre-term PE risk, and reported the potential benefits that come with finding out risk status outweigh any temporary worries.

6.2 WOMEN'S EXPERIENCES OF SCREENING FOR PRE-TERM PE

A further aim of this thesis was to investigate women's experiences of the screening process (Chapter four). Through semi-structured interviews, with both high- and low-risk women it was found that, overall, women have positive attitudes towards screening for pre-term PE risk status. This was the case regardless of risk status; those who were low-risk reported feeling reassured by their result, and high-risk women acknowledged the benefits of knowing their risk, and how it enabled them to feel more prepared. Women perceived first-trimester screening especially beneficial as it would result in increased monitoring by the medical team and, they hoped, would lead to better health outcomes. Women from both groups made reference to the fact that some women would be emotionally affected by the screening results, but generally they established that finding out risk status comes with more positive points than negative.

It was established that women tended to take up offers for screening because of their general positive attitudes towards prenatal screening. Many women expressed having trust in their doctors and the medical staff who care for them, they felt confident that they would not endorse a screening programme unless it was beneficial for the patient, thus interlinking with another second level theme 'absence of perceived harm'. Although many women did not make a conscious decision to be screened for pre-term PE risk, they all seemed happy that they had been screened and were aware of their risk status. This finding supports previous research in which women claimed they would be prepared to participate in screening for pre-term PE risk status (Crombag et al., 2017). However, it seeks to expand the finding of Cromberg et al. (2017) as they interviewed women about hypothetically participating in screening.

The current study provides concrete evidence to the screening literature, in support of the earlier hypothetical findings. The women in this study also reported that they would be happy to engage with the screening again in future pregnancies and would also recommend it to others.

Both low- and high-risk women interviewed for this thesis expressed positive attitudes towards screening, and particularly screening for pre-term PE risk status.

6.3 FACTORS INFLUENCING ASPRE TRIAL PARTICIPATION

The final aim of this thesis was to address the factors that influence women's participation in the ASPRE trial, following a screen positive result (Chapter five). The most influential factor in participating the ASPRE RCT was women's own personal, positive opinions about the potential of the trial. They reported feeling optimistic that if they were randomised to take the aspirin, it would be beneficial to their own pregnancy. However, women also reported that if they weren't taking the active drug then they would still be happy to participate. They identified further potential self-benefits from participation, such as feeling as though they were being more closely monitored and receiving extra scan appointments. High-risk participants of ASPRE did express some weak altruism as well; they reported that they were happy to participate in the trial and contribute to the medical research so that future women may have better outcomes.

A further contributing factor was that the trial drug was aspirin; women felt familiar and comfortable with the idea of taking is, as many other people do, every day. The perceived lack of risk associated with both the active and placebo arms of the trial motivated women to participate. This supports previous findings in the literature, where women's perceptions of drug risk influenced the likelihood of their participation (e.g., Kenyon et al., 2006; Snowdon et al., 2006). This finding adds to the literature and provides evidence specifically for women being screened for pre-term PE risk status.

The current study also found that women were motivated to take part in the RCT due to perceived benefits, aside from the drug arm of the trial. For example, women felt they were receiving increased monitoring and subsequently felt more reassured just from participating. This suggests that RCT researchers should be aware of extra benefits participants may receive and highlight these to potential participants, in order to aid recruitment.

In contrast the biggest influencing factor reported by decliners of the ASPRE trial was the potential of taking medication during pregnancy. It has been so engrained in society that women should not take medications during pregnancy that these women do not feel comfortable with it, even when it is being offered and administered by medical professionals. The ASPRE trial has since found that aspirin can reduce the incidence of pre-term PE (Rolnik et al. 2017), which suggests that more needs to be done to encourage women, identified at risk, to feel comfortable with the options available, to benefit not only maternal but fetal health and outcomes. The factors identified in this thesis could also be of use when considered other medicated RCTs during pregnancy; in order to encourage and facilitate participation the trial must be perceived as relatively harmless and with some benefit to the participant, and as this study suggests, using well known medication that potential participants are familiar with. Insufficient information was also reported as a factor for declining trial participation. This is something for RCT researchers to be aware of and focus on when planning recruitment as it has been explicitly highlighted as being important to the decision-making process, particularly by decliners of the trial.

6.4 REFLEXIONS

Throughout the recruitment and interview process, I, as the researcher, was not only aware of the power dynamics but the sensitive nature of the research. I approached interviews in a friendly manner and did my best to put women at ease, in order to create a safe space for them to share their

honest experiences. I tried to make clear boundaries between myself and the medical/ASPRE team involved in their care in order to foster trust and an understanding that their responses would be confidential and received without judgement. The openness and flexibility of the interview schedules also helped with this as women were able to talk freely about their experiences. I feel that my position as a female researcher enabled a bond to develop through the discussions and women seemed keen to tell their stories. This was particularly the case with high-risk women, who either previously experienced or knew of someone who had experienced PE, and their altruistic motivations for talking with me was evident. In contrast, with low-risk women it was often more difficult for them to share their experiences as their knowledge of a high-risk status was more limited. I found the prompts included on the interview schedule particularly relevant with low-risk women in order to fully explore their thoughts and experiences.

The process of transcribing and analysing the data enabled me to engage further with the participants of these studies. I felt that through using template analysis, I was able to be flexible and be led by the data and responses in front of me. I was apprehensive as I had not used template analysis previously, however, the process felt structured and manageable as the a priori themes guide the initial analysis.

6.5 LIMITATIONS

Although these qualitative studies had similar sample sizes for each group, it must be noted that these studies were intended to be exploratory and may not be generalizable to larger pregnant populations. These women had positive experiences with the screening test, however, that may not be the case for the majority of women; it would be difficult to establish as this study only involved a small number of the women who actually got screened.

A further limitation is the characteristics of the sample; participants were generally in relationships, well-educated and Caucasian and so again their

results are not representative of all pregnant women offered screening during pregnancy.

It would be beneficial to explore, with decliners of screening for pre-term PE risk, their reasons for doing so and whether these reasons differ based on individual screening tests. Decliners of screening may offer valuable insights into how practice can adapt to ensure women feel informed and confident in their decision-making.

The current research is also limited in that it provides insight into a snapshot of women's illness representations, during pregnancy, before any development of PE. To build and expand on current findings, research could be done with women following the end of their pregnancy, with both low- and high-risk women who developed or did not develop PE.

6.6 TEMPLATE ANALYSIS

Template analysis was chosen, above other methods, due to the structure offered by using a template and a priori themes (King, 2004), which helped not only manage the large data set but resulted in a more time efficient analysis. Using the template allowed the focus to remain on themes specific to the research questions and answer them as fully as possible. Template analysis involves coding all the data collected, and whilst the template helps to facilitate this, it can simultaneously be considered a weakness of the method as it results in data that is lost or unusable due to its perceived irrelevance to the research question. This was minimised as much as possible due to the focused interview schedules used, however, the very nature of semi-structured interviews allows for deviation and flexibility within the interview schedule.

A further weakness of template analysis is, what King (2004) calls, descriptive and interpretive coding. Descriptive coding involves the researcher using their own language to clarify or describe a theme, but

without explicitly or rigorously interpreting the data. This can result in a surface level analysis, where participants' responses are not fully explored, or where the researcher, knowingly or not, interprets and reports their own ideas disguised as their participants'. Whilst interpretive coding refers to researchers making links or jumps between ideas suggested by participants, and not being clear that they are doing so. For a researcher using template analysis, interpretive analysis is easily, often subconsciously done; after collecting, transcribing, and coding the data it is easy to presume what participants meant and create links between ideas on their behalf. This is where it becomes vitally important to establish inter-rater reliability within the research team. In an attempt to reduce the limitations posed by descriptive and interpretive coding, I created definitions of the themes and codes at each level of the hierarchy, and my supervisory team were involved in this process, as well as providing inter-rater reliability for the themes themselves. It is important for researchers to be held accountable, providing clear evidence from the data for any claims made. It is also the case that claims made should be tentative and relevant for the current population, at the time the data was collected.

King (2004) suggests that in some ways template analysis is similar to IPA, as it allows researchers to highlight important aspects of the lived experience of participants. However, there is also an acknowledgement that as the technique lacks a substantial amount of supporting literature that researchers may either produce a template that is too simplistic or too complex so that it becomes unmanageable (King, 2004). By using template analysis as part of a methodology that also uses semi-structured interviews, these concerns can somewhat be addressed as the template and interview schedule can be aligned and adapted as needed. A perceived weakness of template analysis and a significant difference between the method and others, is that template analysis does not lend itself to rigorous data coding and is dependent on the researcher. A method such as IPA allows for a more idiographic focus than template analysis, due to the small sample sizes needed, and consequently results in a rich data set (Wagstaff et al., 2014).

However, this in turn reduces its generalisability due to the more focused approach employed.

Exploring women's views around screening for PE risk status and reasons for participation in a pharmacological trial during pregnancy remain under researched areas. Recording their lived experiences and exploring similarities and differences between groups (e.g., low-risk and high-risk) by using template analysis has enabled an overview of understanding in this area. For the current thesis, a between, rather than within, case analysis was necessary, and template analysis facilitated this, although Brooks et al., (2015) acknowledge that to some this can be regarded as a limitation of the method. It could be argued that for studies using large sample sizes this is a necessary, or at least inevitable, limitation, although it is still important to acknowledge the 'loss of holistic understanding in relation to individual accounts' (p. 218; Brooks et al., 2015) as a consequence of using template analysis.

Alternatively, Brooks et al., (2015) suggest that template analysis does show depth of analysis, particularly in comparison to methods such as Framework Analysis, through the iterative process of coding and modifying the template which facilitates rigorous data analysis. However, the point at which this happens will differ between researchers and template analysis does not prescribe a certain number of template variations before the process is complete. The various levels of the template also allow researchers include a variety of themes, as the hierarchy of levels indicates the conceptualisation of themes and codes, rather than their importance (King, 2004). Through template analysis researchers are forced to explore how themes and codes interact and consider definitions and meanings behind them, as well as the extent to which the data truly represents the themes and codes. Consequently, template analysis does facilitate in-depth analysis but due to its flexibility and lack of prescriptive rules, this is dependent on the researchers and their willingness to fully engage with the analysis.

Ultimately, each method for qualitative analysis has strengths and weaknesses and these will vary depending on the context, research question and the sample required. Researchers are often faced with the decision of which method is the best fit. Template analysis was the most appropriate method for the circumstances of the current thesis. The main benefits of template analysis for the current thesis included the ability to use a template and develop a priori themes prior to beginning the data analysis, allowing the focus to remain on the concerns of the research questions throughout the analysis itself. The template also resulted in a time efficient analysis to take place of a large data set, giving the analysis structure and focus. However, limitations and weakness remain in terms of the depth of analysis that template analysis allowed on an individual case level.

6.7 FUTURE DIRECTIONS

Since these studies have been conducted, the ASPRE trial has found that low-dose aspirin, taken from the first trimester, does reduce the incidence of preeclampsia, in women identified as at high-risk (Rolnik et al., 2017). As the results in Chapter five demonstrate, the main reason for non-participation in the ASPRE trial was negative attitudes towards medication during pregnancy. These attitudes and beliefs that taking medication in pregnancy is dangerous or high-risk should, therefore, be addressed in order to encourage uptake of aspirin consumption in women identified as high-risk for preeclampsia. It has been routine practice for women to avoid taking medications in pregnancy; these views will need to be challenged and research successfully disseminated for women to feel comfortable taking aspirin if identified as high-risk. These results will be of particular interest to medical staff and researchers who are developing RCTs and preventative medications to be taken during pregnancy. PE should be discussed with medical staff at scan appointments or midwifery appointments, in order to open a discourse and inform pregnant women. Future researchers undertaking medicated RCTs with a pregnant sample should also consider the negative attitudes, towards medication during pregnancy, found in the current study in order to improve

understanding and awareness, which is likely to positively influence recruitment rates. The importance of good quality information in the decision-making process for RCTs should also be considered in order to boost recruitment.

In order to explore the generalisability of the current results, research should be undertaken with more diverse populations, with consideration given to various cultural impacts on decision-making, as well as race, relationship status and background (including education and socioeconomic status).

Exploring illness representations after birth and how or if they change would also provide insights into future decision-making. Within the framework of the CSM, it could be hypothesised that illness representations would change depending on the experience and outcome of birth. This is currently an unexplored area and would require a longitudinal study design to explore this fully.

The current research provides evidence and support for the parallel processing nature of the CSM, as well as the individual dimensions themselves. Consequently, the current findings could be used to adapt the IPQ-R for a pregnant population, and specifically for research regarding screening within a pregnant population.

6.8 CONCLUSIONS

The current thesis sought to contribute to a new area of undeveloped research. The findings of these studies show support that a screening test to determine risk status for pre-term PE should be recommended. Across the qualitative studies women did not experience any significant psychological effects. Overall the women in these studies displayed positive attitudes towards the screening test and were happy to participate in prenatal screening. Generally they were positive towards prenatal screening if they

perceived participation to be low-risk and had the potential to gain further knowledge to provide reassurance.

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8 APPENDICES

8.1: INFORMATION SHEET

King's College Hospital NHS
NHS Foundation Trust

Psychological Evaluation of Screening for Pre-eclampsia: Interview Study

Participant Information Sheet (version 2PSY, July 2014)

Tel [Redacted]
Fax: [Redacted]

What is the purpose of the study?
Thank you for considering taking part in this study, with which we aim to gain a better understanding of women's experiences of taking part in screening for pre-eclampsia. Screening for pre-eclampsia is not available routinely and prior to introducing this test on a larger scale it is important to understand why women take or not take part in the screening and for those who take part, what the low or high risk status means to them.

Why have I been chosen?
We are approaching you to take part in this interview study because you were invited to take part in pre-eclampsia screening and you either accepted or refused to take part.

Do I have to take part?
No. It is up to you whether or not to take part in the study. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the care you receive.

What does taking part in this study involve?
If you refused to take part in the screening for high blood pressure in pregnancy, we would be interested in talking to you to understand your reasons for not wishing to take part. Interviews will be conducted after your 11-13 week visit either at the hospital or at your home, whatever your preference is.

If you took part in the screening and screened either 'low-risk' or 'high-risk' we would like to find out what does this risk status means to you. In women who take part in the ASPRE trial we would like to hear how they decided to take part and how they experience their pregnancy. The interviews will be conducted at 11-13 weeks of pregnancy in low-risk women and at 20-32 weeks of pregnancy in high risk women, either at the hospital or at your home, wherever you would feel more comfortable,

The interviews will last approximately 20-50 minutes and will be tape-recorded. In cases where interview is conducted at a woman's home, two researchers will be in attendance. No one apart from myself, Zoe Dodd, and the principal psychologist, Dr Ana Nikcevic conducting the study, will have access to any of the recordings or to the transcribed interviews. All information collected during this study will be kept strictly confidential, will be kept on a password protected computer, and your name and address will be removed so that you cannot be recognised from it.

What will happen to the results of the study?

Once the study is complete, the results will be published in an academic journal. We may use your tape-recorded statements and provide them as participants' quotes in the academic publications. These quotes would be fully anonymised and no person will be identifiable from such quotes (for example, we may refer to a participant with a number e.g. participant number 10 or use a false name). Thus, you will not be identified in any report or publication. If you like, you will be able to find out the results of this study by contacting the study researchers Ms Zoe Dodd at [Redacted], or Dr Ana Nikcevic at [Redacted].

Who is organising and funding the research?
This study is funded by the Fetal Medicine Foundation.

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the London-Surrey Borders Research Ethics Committee.

If you have any questions or require any further information please contact the study researchers Ms Zoe Dodd at [Redacted], the chief investigator Dr Ana Nikcevic at [Redacted] or tel: [Redacted], or Dr Neil Gorman, ASPRE trial co-ordinator on [Redacted].

8.2: CONSENT FORM

King's College Hospital NHS
NHS Foundation Trust

Ki
ng's College Hospital NHS Foundation Trust
[Redacted]

Tel [Redacted]
Fax: [Redacted]

Participant Consent Form (July 2014 – Version 2PSY)

Please initial box

I confirm that I have read and understand the information sheet dated July 2014 (Version 2PSY) for the above study and have had the opportunity to ask questions and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I agree to participate in the interview study of women's experiences of screening for pre-eclampsia.
I agree to have the interviews tape-recorded.
I agree that my statements, as recorded in the interview, can be published in academic publications on condition that they are fully anonymous and that no person is identifiable from the published quotes.

Name of participant……..… Signature of participant……..

Date……..……..

Researcher…….. Signature……..……

Date……..……..

Witness…….. Signature……..……

Date……..……..

8.3: PILOT STUDY, INTERVIEW SCHEDULE FOR DECLINERS OF SCREENING

Introduction
Hi, thank you for agreeing to speak to me today and for taking part in the study.
I'll let you know a bit about myself first of all: I'm Zoe and I'm in the second of year of my PhD at Kingston University. I am fairly independent from the ASPRE trial and the goal of my research is to establish the psychological aspects of screening for preeclampsia. I am interested in understanding how women make a decision whether to take part in the screening or not, and if they are identified to be at high risk for preeclampsia, what that means to them and how they then decide to take part in the ASPRE trial. So I would like to speak to women like you and hear from them how they found the process of deciding to screen and any consequences.
Check consent form (if agreed to tape the session): Are you Ok with me tape recording our interview session? Do you have any concerns about that?
So how are things going with your pregnancy?
Warm up questions

- So, are you feeling comfortable here?
- How far along are you with your pregnancy now?
- Do you know if you're having a boy or girl?
- Do you have any other children? How old are they?

I'd like to start by talking about your first scan and deciding to be screened for preeclampsia…

1. So when you received your appointment letter for your first scan, were you also informed that at the same time as your usual scan you could be screened for preeclampsia?
2. Had you heard of preeclampsia before receiving the letter?
3. Did you know anyone, family or friends, who had experienced preeclampsia in pregnancy? How did their pregnancy go?
    - If so, did they receive treatment that you know of?
    - *If they have personal experience:*
      what was the outcome, did they receive treatment
    - Did your experience of PE, either your own or through your family and friends influence your decision about screening for PE?
4. What do you think about screening in pregnancy generally?
   Have you been screened for anything else, for example Downs's syndrome?
5. Did you discuss the letter and the opportunity to be screened with anyone close to you? E.g. partner or family?
    - Did they influence your decision about whether to take part in the screening?
    - Did you make up your own mind or decide together?
    - How did you decide?
    - Was it difficult to come to a joint decision?
6. Did you make a decision before the scan whether you wish to take part in the PE screening or not?
    - What made you decide in that way?
7. What were your main reasons for not wanting to be screened for PE?
8. Did you feel at the time that you were at a particular risk from preeclampsia? Why?
9. Did you realise at the time that screening for PE was offered as part of research and that it is not widely available?
    - Were you told what the screening would involve?
    - Did you have any concerns about the screening?
    - Any worries or anxieties? Did they impact on your decision to have a screening test?
10. Did you think at the time there was a need for such screening?

11. If you were to have other pregnancies in the future and offered screening for preeclampsia, would you decline again?
    - For the same reasons?
12. Is there anything that we have not covered that you'd like to talk about?

Thank you very much for your time. My contact details are on the participant information sheet if you need to get in touch.

8.4: PILOT STUDY, INTERVIEW SCHEDULE FOR LOW-RISK WOMEN

Introduction (as before)
Warm up questions

- So, are you feeling comfortable here?
- How far along are you with your pregnancy now?
- Do you know if you're having a boy or girl?
- Do you have any other children? How old are they?

I'd like to start by talking about your first scan and deciding to be screened for preeclampsia…

1. So when you received your appointment letter for your first scan, were you also informed that at the same time as your usual scan you could be screened for preeclampsia?
2. Had you heard of preeclampsia before receiving the letter?
3. Did you know anyone, family or friends, who had experienced preeclampsia in pregnancy? How did their pregnancy go?
    - If so, did they receive treatment that you know of?
    - *If they have personal experience:*
      what was the outcome, did they receive treatment
    - Did your experience of PE, either your own or through your family and friends influence your decision about screening for PE?
4. What do you think about screening in pregnancy generally?
   Have you been screened for anything else, for example Downs's syndrome?
5. Did you discuss the letter and the opportunity to be screened with anyone close to you? E.g. partner or family?
    - Did they influence your decision about whether to take part in the screening?
    - Did you make up your own mind or decide together?
    - How did you decide?
    - Was it difficult to come to a joint decision?
6. Did you make a decision before the scan whether you wish to take part in the PE screening or not?
    - What made you decide in that way?
7. What were your main reasons for wanting to be screened for PE?
8. Did you feel at the time that you were at a particular risk from preeclampsia? Why?
9. Did you realise at the time that screening for PE was offered as part of research and that it is not widely available?
    - Were you told what the screening would involve?
    - Did you have any concerns about the screening?
    - Any worries or anxieties? Did they impact on your decision to have a screening test?
10. Did you think at the time there was a need for such screening?

11. Thinking about when you were told that you were low-risk for developing preeclampsia, how did you feel?
12. Overall, do you feel that knowing your risk status regarding preeclampsia had been a useful piece of information during your pregnancy, or not?
13. Has taking part in the screening influenced in any way your experience of pregnancy?
14. Is there anything that we have not covered that you'd like to talk about?

Thank you very much for your time. My contact details are on the participant information sheet if you need to get in touch. I hope everything continues to go well with your pregnancy.

8.5: PILOT STUDY, INTERVIEW SCHEDULE FOR HIGH-RISK PARTICIPANTS OF ASPRE

Introduction (as before)
Warm up questions

- So, are you feeling comfortable here?
- How far along are you with your pregnancy now?
- Do you know if you're having a boy or girl?
- Do you have any other children? How old are they?

I'd like to start by talking about your first scan and deciding to be screened for preeclampsia…

1. So when you received your appointment letter for your first scan, were you also informed that at the same time as your usual scan you could be screened for preeclampsia?
2. Had you heard of preeclampsia before receiving the letter?
3. Did you know anyone, family or friends, who had experienced preeclampsia in pregnancy? How did their pregnancy go?
    - If so, did they receive treatment that you know of?
    - *If they have personal experience:*
      What was the outcome, did they receive treatment
    - Did your experience of PE, either your own or through your family and friends influence your decision about screening for PE?
4. What do you think about screening in pregnancy generally?
   Have you been screened for anything else, for example Downs's syndrome?
5. Did you discuss the letter and the opportunity to be screened with anyone close to you? E.g. partner or family?
    - Did they influence your decision about whether to take part in the screening?
    - Did you make up your own mind or decide together?
    - How did you decide?
    - Was it difficult to come to a joint decision?
6. Did you make a decision before the scan whether you wish to take part in the PE screening or not?
    - What made you decide in that way?
7. Did you feel at the time that you were at a particular risk from preeclampsia? Why?
8. Did you realise at the time that screening for PE was offered as part of research and that it is not widely available?
    - Were you told what the screening would involve?
    - Did you have any concerns about the screening?
    - Any worries or anxieties? Did they impact on your decision to have a screening test?
9. Did you think at the time there was a need for such screening?

Emotional impact

10. Thinking about when you were told that you were high risk for developing preeclampsia, can you remember who told you and where you were?
    - How did you receive the news? How did you react at the time?
    - How did you feel?

Decision making regarding the ASPRE trial, IPQ control/cure and adherence

11. Because you were identified as high-risk, you were invited to take part in the ASPRE trial.
    a. Can you remember what you were told about what was the aim of the trial?
    b. Were you told what the trial would involve?

c. Do you remember being told anything about randomisation? How did you understand that?
d. Did you have any other considerations as you were making the decision? For example, the opinion of your partner or contributing to medical science.

12. How did you make decision to take part (or not)? *(allow space so they can tell a story)*
Did you feel you had enough information at the time to make a decision?
- Were you able to ask all the questions you had?
- Did you have enough time to make a decision?

13. Did you have any concerns?
- Did you weigh up the risks and benefits of taking part?

14. Did you discuss your decision with anyone? E. g. your partner, other family members
- Did they influence your decision in any way?

15. What was your main reason for taking part in the trial?

IPQ-R emotional representations

15. How worried are you now about your high-risk status and about the possibility of developing preeclampsia?
- How have you been feeling about it?

IPQ-R cause beliefs

16. Do you have any thoughts about why you are at high risk for pre-eclampsia?
- What are the factors that you believe might have caused this?

IPQ-R illness coherence

17. Do you feel that you understand what preeclampsia is?
18. How do you understand the high-risk status?
- What is your understanding of this new for you? And for your baby?

19. Is there anything concerning your high-risk status for developing pre-eclampsia that has been puzzling to you?

IRQ-time line

20. How long do you think you will have this 'high-risk' status?
21. If you were to have other pregnancies, do you think you will have the high-risk status again? Will that influence your decision to have another pregnancy?

IRQ-Consequence

22. How has being identified as high risk impacted your experience of pregnancy, if at all?
- Do you think this will impact your pregnancy or experience of pregnancy?

23. Have you taken more notice of your body, compared to before being identified as high risk?
- Perhaps looking for any symptoms or signs that you might be developing pre-eclampsia?

24. Have you made any changes to your behaviour as a result of being high risk, or not?
25. Has being identified as high risk affected how your friends and family treat you?

IRQ-Controllability/cure

26. How much control in general do you feel you have over whether you will develop preeclampsia or not?
27. How have you been getting on with remembering to take the tablets regularly?
28. How much do you think the tablets you are taking can prevent the development of preeclampsia?
29. Overall, how do you feel about taking the tablets?
30. Overall, do you feel that knowing your risk status regarding preeclampsia had been a useful piece of information during your pregnancy, or not?
31. Has taking part in the screening influenced in any way your experience of pregnancy?

Closing
32. Is there anything that we have not covered that you'd like to talk about?

Thank you very much for your time. My contact details are on the participant information sheet if you need to get in touch. I hope everything continues to go well with your pregnancy.

8.6: PILOT STUDY, INTERVIEW SCHEDULE FOR HIGH-RISK DECLINERS OF ASPRE

Introduction (as before)
Warm up questions

- So, are you feeling comfortable here?
- How far along are you with your pregnancy now?
- Do you know if you're having a boy or girl?
- Do you have any other children? How old are they?

I'd like to start by talking about your first scan and deciding to be screened for preeclampsia…

1. So when you received your appointment letter for your first scan, were you also informed that at the same time as your usual scan you could be screened for preeclampsia?
2. Had you heard of preeclampsia before receiving the letter?
3. Did you know anyone, family or friends, who had experienced preeclampsia in pregnancy? How did their pregnancy go?
    - If so, did they receive treatment that you know of?
    - *If they have personal experience:* what was the outcome, did they receive treatment
    - Did your experience of PE, either your own or through your family and friends influence your decision about screening for PE?
4. What do you think about screening in pregnancy generally? Have you been screened for anything else, for example Downs's syndrome?
5. Did you discuss the letter and the opportunity to be screened with anyone close to you? E.g. partner or family?
    - Did they influence your decision about whether to take part in the screening?
    - Did you make up your own mind or decide together?
    - How did you decide?
    - Was it difficult to come to a joint decision?
6. Did you make a decision before the scan whether you wish to take part in the PE screening or not?
    - What made you decide in that way?
7. What were your main reasons for wanting to be screened for PE?
8. Did you feel at the time that you were at a particular risk from preeclampsia? Why?
9. Did you realise at the time that screening for PE was offered as part of research and that it is not widely available?
    - Were you told what the screening would involve?
    - Did you have any concerns about the screening?
    - Any worries or anxieties? Did they impact on your decision to have a screening test?
10. Did you think at the time there was a need for such screening?

Emotional impact

11. Thinking about when you were told that you were high risk for developing preeclampsia, can you remember who told you and where you were?
    - How did you receive the news? How did you react at the time?
    - How did you feel?

Decision making regarding the ASPRE trial, IPQ control/cure and adherence

12. Because you were identified as high-risk, you were invited to take part in the ASPRE trial.
    e. Can you remember what you were told about what was the aim of the trial?
    f. Were you told what the trial would involve?
    g. Do you remember being told anything about randomisation? How did you understand that?

h. Did you have any other considerations as you were making the decision? For example, the opinion of your partner or contributing to medical science.

13. How did you make decision to not take part? *(Allow space so they can tell a story)*

- Did you feel you had enough information at the time to make a decision?
- Were you able to ask all the questions you had?
- Did you have enough time to make a decision?

14. Did you have any concerns?
    - Did you weigh up the risks and benefits of taking part?
15. Did you discuss your decision with anyone? E. g. your partner, other family members
    - Did they influence your decision in any way?
16. What was your main reason for not taking part in the trial?

IPQ-R emotional representations

17. How worried are you now about your high-risk status and about the possibility of developing preeclampsia?
    - How have you been feeling about it?

IPQ-R cause beliefs

18. Do you have any thoughts about why you are at high risk for pre-eclampsia?
    - What are the factors that you believe might have caused this?

IPQ-R illness coherence

19. Do you feel that you understand what preeclampsia is?
20. How do you understand the high-risk status?
    - What is your understanding of this new for you? And for your baby?
21. Is there anything concerning your high-risk status for developing pre-eclampsia that has been puzzling to you?

IRQ-time line

22. How long do you think you will have this 'high-risk' status?
23. If you were to have other pregnancies, do you think you will have the high-risk status again? Will that influence your decision to have another pregnancy?

IRQ-Consequence

24. How has being identified as high risk impacted your experience of pregnancy, if at all?
    Do you think this will impact your pregnancy or experience of pregnancy?
25. Have you taken more notice of your body, compared to before being identified as high risk?
    Perhaps looking for any symptoms or signs that you might be developing pre-eclampsia?
26. Have you made any changes to your behaviour as a result of being high risk, or not?
27. Has being identified as high risk affected how your friends and family treat you?

IRQ-Controllability/cure

28. How much control in general do you feel you have over whether you will develop preeclampsia or not?
29. Overall, do you feel that knowing your risk status regarding preeclampsia had been a useful piece of information during your pregnancy, or not?
30. Has taking part in the screening influenced in any way your experience of pregnancy?

Closing

31. Is there anything that we have not covered that you'd like to talk about?

Thank you very much for your time. My contact details are on the participant information sheet if you need to get in touch. I hope everything continues to go well with your pregnancy.

8.7 INITIAL PILOT STUDY TEMPLATE

1. **Women's encounter with screening for PE**
    - **a.** Prior knowledge of PE
2. **Decision making regarding screening**
    - **a.** Thoughts regarding screening in pregnancy
    - **b.** Thoughts about screening for PE, before attending screening
    - **c.** The timing of deciding to be screened for PE
    - **d.** Thoughts about screening for PE, after attending screening
    - **e.** Influence of others
    - **f.** Perceived risk for PE
3. **Women's early encounter with high-risk status**
    - **a.** Being informed of high-risk status
    - **b.** Initial reaction
    - **c.** Thoughts
    - **d.** Feelings
4. **IPQ-R: illness cause beliefs**
    - **a.** Diet
    - **b.** Behaviour
    - **c.** Hereditary
5. **IPQ-R: illness comprehensibility**
    - **a.** Understanding PE
    - **b.** Understanding consequences of risk status for own health
    - **c.** Understanding consequences of risk status for baby's health
    - **d.** Confusion regarding risk status for PE
6. **IPQ-R: timeline**
    - **a.** PE duration through current pregnancy
    - **b.** Risk status in future pregnancies
    - **c.** Impact on decision to have further pregnancies
7. **IPQ-R: consequence**
    - **a.** Impact of high-risk status on pregnancy
    - **b.** Heightened awareness of symptoms during pregnancy
    - **c.** Behavioural changes as a result of high-risk status
    - **d.** Treatment by others as a consequence of high-risk status
8. **IPQ-R: emotional representations**
    - **a.** Worry regarding high-risk status
    - **b.** Worry regarding developing PE
9. **Decision-making regarding ASPRE trial**
    - **a.** The experience of the decision-making process
    - **b.** Concerns regarding participation in the ASPRE trial
    - **c.** Influence of others on decision-making process
    - **d.** Information provided regarding ASPRE trial
10. **Adherence**
    - **a.** Feelings towards taking the tablets
    - **b.** Remembering to take the tablets
11. **IPQ-R: Control/cure**
    - **a.** Beliefs concerning personal influence on the outcome
    - **b.** Beliefs concerning the influence of aspirin on the outcome

12. **Benefit of advanced knowledge of PE risk status early on in pregnancy/overall evaluation**

8.8 POST-PILOT STUDY TEMPLATE

Themes that were altered or added as a result of the pilot study are highlighted in yellow.

1. **Women's encounter with screening for PE**
    a. **Prior knowledge of PE**
        i. Yes
            - Friends & family
            - Previous pregnancy
        ii. No
2. **Thoughts regarding screening in pregnancy**
    a. **Thoughts regarding screening in pregnancy in general**
        i. Positive: personal benefit through raised awareness of problems, receiving extra medical support
        ii. Positive: altruistic beliefs e.g. through research help others
    b. **Thoughts regarding screening for PE, before attending screening**
        i. "No paying attention", part of the process, a routine thing
        ii. Easiest option
        iii. Altruism: helping others
3. **Decision-making regarding screening for PE**
    a. **Participating in screening**
        i. Absence of 'active' decision making
        ii. Active decision making: influencing factors
            - Influence of significant others
            - Perception of 'being at-risk'
            - Doctor's recommendation
            - No significant 'demand' of the screening process itself
            - Altruism: want to partake in research
    b. **Non-participating in screening**
    c. **Concerns about screening**
    d. **The experience of the decision-making process**
4. **Women's early encounter with high-risk status**
    a. **Emotional impact of the news**
    b. **Absence of emotional impact**
        i. Due to history of PE
5. **IPQ-R: Illness cause beliefs**
    a. **No specific cause**
    b. **Issue with reproductive system**
    c. **Diet**
    d. **Behaviour**
    e. **Hereditary: high blood pressure in the family**
    f. **Ethnicity**
    g. **Stress during pregnancy**
    h. **Confusion regarding cause of PE**
6. **IPQ-R: Illness coherence**
    a. **Understanding PE**
        i. Understanding consequences of risk status for own health
        ii. Understanding consequences of risk status for baby's health
    b. **Not understanding PE**
7. **IPQ-R: Timeline**
    a. **Duration of the 'high-risk' status for PE**
        i. Until a certain gestation
        ii. Until the end of pregnancy/delivery of the baby
        iii. Not sure
    b. **Risk status in future pregnancies**

i. Probably yes
ii. Probably (hopefully) not

8. **IPQ-R: Consequence**
   a. Impact of high-risk status on pregnancy
   - **a.** Life-style change: taking special care
     -Eating healthily (reduced salt intake, avoiding fried food, cooking at home)
     -Monitoring weight
   - **b.** Increased medical input (more scans): reassuring
   - **c.** Increased vigilance of symptoms e.g. blood pressure monitoring, checking for swelling
   - **d.** Avoiding stress
   - **e.** Significant others (worried and more protective)
   - **f.** Personal research on PE
   - **g.** Absence of significant changes/impact

   c. Impact of high-risk status on decision to have further pregnancies
   - **i.** No significant impact on decision re future pregnancies
   - **ii.** Significant negative impact (in the presence of other complications)

9. **IPQ-R: Emotional representations**
   - **a. Significant initial negative emotional impact**
   - **b. Absence of a significant negative emotional impact**

10. **Decision-making regarding ASPRE trial**
    - **a. The experience of the decision-making process**
      i. easy decision to make
      ii. ambivalent decision
    - **b. Factors influencing participation in ASPRE**
      i. Attitude to aspirin: a known medication, not a concern, no side effects
      ii. Personal benefit of receiving extra care through taking part in research
      iii. Trust in doctor's advice and expertise
      iv. Altruism: Importance of taking part in research
      v. Sufficient information and explanation
      vi. Views of significant others
      vii. Concerns regarding taking medications
    - c. **Concerns regarding participation in the ASPRE trial**

11. **Adherence**
    - **a. Feelings towards taking the tablets**
      i. Importance for the baby
      ii. Integrated in routine vitamins (folic acid); not much thought given
      iii. Hatred towards having to take the tablets
      iv. Acceptance due to absence of side effects
    - **b. Remembering to take the tablets**
      i. Easy as integrated into routine
      ii. Ambivalence towards tablets in general leading to missed tablets

12. **IPQ-R: Control/cure**
    - **a. Beliefs concerning personal influence**
      i. Perception of no personal control
      ii. Perception of (some) control
      - The role of life style factors
        a. Taking rest
        b. Eating habits (avoiding salt, eating greens)

      iii. Unsure
    - **b. Beliefs concerning the influence of aspirin on the outcome**
      i. The effect depends on the individual
      ii. Belief that aspirin could be helpful in preventing PE
      iii. Aspirin and life style factors interact to prevent PE
      iv. Not sure

13. **Utility of advanced knowledge of PE risk status early on in pregnancy/overall evaluation**
    a. Knowledge is good
        i. For prevention of problems
        ii. Raised awareness to monitor early signs of problems

8.9: INTERVIEW SCHEDULE FOR LOW-RISK WOMEN

Questions that were altered or added as a result of the pilot study are highlighted in yellow.

Introduction (as before)
Warm up questions

- So, are you feeling comfortable here?
- How far along are you with your pregnancy now?

Encountering screening
I'd like to start by talking about your first scan …

1. So when you received your appointment letter for your first scan, you were informed about various screening tests you will be having. Is that correct? Do you remember which screening tests you were told you will be having?
2. So, which screening tests did you have during your 11-13 weeks scan?
3. What do you think about screening in pregnancy generally?
4. Were you also informed that at the same time as your usual 11 week scan you could be screened for preeclampsia/high blood pressure *(use woman's term)*?
5. Had you heard of preeclampsia before receiving the letter/before the scan?
6. Did you know anyone, family or friends, who had experienced preeclampsia in pregnancy? How did their pregnancy go?
    - *If they have personal experience:*
      what was the outcome of that pregnancy?
        - Did your experience of PE, either your own or through your family and friends influence your decision about screening for PE?
7. Did you make a decision before the scan whether you wish to take part in the PE/high blood pressure in pregnancy screening or not?
    - What made you decide in that way? (let them say)
    - Was that…(x) the main reason for taking part in the screening? Any other reason?
8. Did you feel at the time that you were at a particular risk from preeclampsia? Why?
9. Did you think at the time there was a need for such screening?
10. Did you realise at the time that screening for PE was offered as part of research and that it is not widely available?
    - Were you told what the screening would involve?
    - Did you have any concerns about the screening?
    - Any worries or anxieties? Did they impact on your decision to have a screening test?

11. Did you discuss the letter and the opportunity to be screened with anyone close to you? E.g. partner or family?
    - Did they influence your decision about whether to take part in the screening?
    - Did you make up your own mind or decide together?
    - How did you decide?
    - Was it difficult to come to a joint decision?

Emotional impact of the low-risk screening result

12. Thinking about when you were told that you were at low risk for developing preeclampsia/high blood pressure, can you remember who told you?
    - What were you told?
    - What did you understand that to mean?
    - How did you feel about that?

Identity of PE risk

13. What do you understand by the word 'pre-eclampsia'?
14. What symptoms do you think are associated with PE?

Illness coherence

15. What do you know about the PE screening test?
    - Do you know how the test works/how they worked out your risk?
      If yes: ask how?
      If no: how do you think they worked out your risk?
16. Do you feel you are at risk of developing PE? How likely are you to develop it?
      Prompt: extremely, very, 50/50, unlikely, very unlikely
    - Do you know how it might affect you?
    - And your baby?

Cause beliefs

17. People often have their own theories about why they are at risk for a condition? Do you have any thoughts about why you got the result you got ie low risk for pre-eclampsia?

Controllability/cure

18. How much control do you feel you have over whether you will develop preeclampsia or not?
19. Is there anything YOU can do to reduce chances of developing PE in this pregnancy?
20. Have you made any changes to your behaviour, the things you do, in any way as a result of taking part in the screening? If yes, why?
21. Do you feel that, if found to work in this trial at preventing PE, aspirin is an acceptable medication to take in pregnancy or not? Would you take it if you were told to be at high-risk?
22. Overall, do you feel that knowing your risk status regarding preeclampsia had been a useful piece of information during your pregnancy, or not? Why?
24. Would you take part in the screening for PE in your next pregnancy?
25. Would you recommend it to other pregnant women?

Closing

26. Is there anything that we have not covered that you'd like to talk about?
Thank you very much for your time. My contact details are on the participant information sheet if you need to get in touch. I hope everything continues to go well with your pregnancy.

8.10: INTERVIEW SCHEDULE, HIGH-RISK WOMEN

Introduction (as before)
Warm up questions

- So, are you feeling comfortable here?
- How far along are you with your pregnancy now?

Encountering screening
I'd like to start by talking about your first scan …

1. So when you received your appointment letter for your first scan, you were informed about various screening tests you will be having. Is that correct? Do you remember which screening tests you were told you will be having?
2. So, which screening tests did you have during your 11-13 weeks scan?
3. What do you think about screening in pregnancy generally?
4. Were you also informed that at the same time as your usual 11 week scan you could be screened for preeclampsia/high blood pressure *(use woman's term)*
5. Had you heard of preeclampsia before receiving the letter/before the scan?
6. Did you know anyone, family or friends, who had experienced preeclampsia in pregnancy? How did their pregnancy go?
    - *If they have personal experience:*
      What was the outcome of that pregnancy?
        - Did your experience of PE, either your own or through your family and friends influence your decision about screening for PE?
7. Did you make a decision before the scan whether you wish to take part in the PE/high blood pressure in pregnancy screening or not?
    - What made you decide in that way
8. Did you feel at the time that you were at a particular risk from preeclampsia? Why
9. Did you think at the time there was a need for such screening?
10. Did you realise at the time that screening for PE was offered as part of research and that it is not widely available?
    - Were you told what the screening would involve?
    - Did you have any concerns about the screening?
    - Any worries or anxieties? Did they impact on your decision to have a screening test?
11. Did you discuss the letter and the opportunity to be screened with anyone close to you? E.g. partner or family?
    - Did they influence your decision about whether to take part in the screening?
    - Did you make up your own mind or decide together?
    - How did you decide?
    - Was it difficult to come to a joint decision?

Emotional impact of the high-risk screening result

12. Thinking about when you were told that you were at high risk for developing preeclampsia/high blood pressure, can you remember who told you?
    - What were you told?
    - What did you understand that to mean?
    - How did you receive the news? How did you react at the time?
    - How did you feel?

Decision making regarding the ASPRE trial

13. Because you were identified as high-risk, you were invited to take part in the ASPRE trial.
    - Can you remember what you were told about what was the aim of the trial? Can you tell me what you remember?
    - Were you told what the trial would involve? Can you tell me?

- Do you remember being told anything about randomisation? How did you understand that?
- Did you have any other considerations as you were making the decision? *Prompt:* For example, the opinion of your partner or perhaps wanting to contribute to the medical science?

12. How did you make decision to take part (or not)? *(allow space so they can tell a story)*
    Did you feel you had enough information at the time to make a decision?
    Prompt: Were you able to ask all the questions you had? Did you have enough time to make a decision?
13. Did you have any concerns?
14. Did you discuss your decision with anyone? E. g. your partner, other family members
    - Did they influence your decision in any way?
15. What was your main reason for taking part/declining to take part in the trial?

Identity of PE risk

16. What do you understand by the word 'pre-eclampsia'/high blood pressure in pregnancy (woman's term)?
17. What symptoms do you think are associated with PE?
18. Do you feel you are at risk of developing PE?
    - Do you know how it might affect you?
    - And your baby?

Perception of risk

19. How likely do you think you are to get PE? Why?
    Prompt: extremely, very, 50/50, unlikely, very unlikely

Cause beliefs

20. People often have their own theories about why they are at risk for a condition. Do you have any thoughts about why you got the result you got/are at high risk for pre-eclampsia?
    - What are the factors that you believe might have caused this?

Illness coherence

21. What do you know about the PE screening test?
    - Do you know how the test works/how they worked out your risk?
      If yes: ask how?
      If no: how do you think they worked out your risk?
22. Is there anything concerning your high-risk status for developing pre-eclampsia that has been puzzling to you/that you don't understand/that you would like to ask doctors about?

Controllability/cure

23. How much control do you feel you have over whether you will develop preeclampsia or not?
24. Is there anything YOU can do to reduce chances of developing PE in this pregnancy?
25. Have you made any changes to your behaviour, the things you do, in any way as a result of being told that you are at high risk, or not?

For women participants in the ASPRE only:

25a. How have you been getting on with remembering to take the tablets regularly?
25b. How do you feel about taking the tablets?

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26. How much do you believe that aspirin can prevent the development of preeclampsia?
    Prompt: extremely, very, 50/50, unlikely, very unlikely
27. Do you feel that, if found to work in this trial at preventing PE, aspirin is an acceptable medication to take in pregnancy or not?

Time line

28. Do you think your risk for PE will change as the pregnancy develops?
29. How long do you think the risk will last?
30. How predictable the onset of PE is?

31. If you were to have other pregnancies, do you think you will have the high-risk status again? Will that influence your decision to have another pregnancy?

Emotional representations

32. It has been (insert, one month) since you have been informed about the high-risk status? How do you feel about it now? Has your mood changed since as a result of receiving the screening test result? If so, how?

Consequence

33. How has being identified as high risk impacted your experience of pregnancy, if at all? And how has receiving the test result affected you more generally, if at all?
34. How would developing PE affect you?
35. Overall, do you feel that knowing your risk status regarding preeclampsia had been a useful piece of information during your pregnancy, or not?
36. Would you take part in the screening for PE in your next pregnancy?
37. Would you recommend it to other pregnant women?

Closing

38. Is there anything that we have not covered that you'd like to talk about?
Thank you very much for your time. My contact details are on the participant information sheet if you need to get in touch. I hope everything continues to go well with your pregnancy.

8.11: CHAPTER 3 TEMPLATE

Chapter 3
Differences between low- and high-risk women in terms of emotional impact of the results, and illness representations of the CSM

1. **Emotional impact of the low-risk results at the time of screening**
    - **a.** *Reassured and relieved*
    - **b.** *No emotional impact*
    - **c.** No memory of being informed of results

2. **Emotional impact of the high-risk results at the time of screening**
    - **a.** Negative emotional impact
    - **b.** Absence of a surprise
    - **c.** Absence of emotional impact

3. **Mood change since screening results**

4. **IPQ-R: Coherence of PE**
    - **a.** Understanding of PE
        - i. Understanding PE consequences for own health
        - ii. Understanding PE consequences for baby's health
        - iii. Knowledge of timeline for PE development
    - **b.** *No clear understanding of PE*

5. **IPQ-R: Coherence of PE risk status**
    - **a.** Understanding own PE risk status
    - **b.** No clear understanding of own PE risk status
    - **c.** Understanding of how PE risk status is calculated
    - **d.** No clear understanding of how PE risk status is calculated

6. **IPQ-R: Identity of PE**
    - **a.** Symptoms of PE
    - **b.** Predictability of PE
        - i. By medical staff
        - ii. By self-monitoring
        - iii. Unpredictable

7. **IPQ-R: Illness cause beliefs**
    - **g.** No specific cause
    - **h.** Diet
    - **i.** Blood pressure
        - i. Hereditary: high blood pressure or previous preeclampsia in the family
        - ii. Previous personal high blood pressure
    - **j.** Ethnicity
    - **k.** Stress during pregnancy
    - **l.** Previous pregnancies
    - **m.** Confusion regarding cause of PE
    - **n.** General health
    - **o.** Age
    - **p.** Smoking
    - **q.** Weight
    - **r.** Measurements taken in the 12-week scan
    - **s.** Medical issues
    - **t.** First pregnancy
    - **u.** *Combination of causes*

8. **IPQ-R: Timeline**

a.Duration of the 'high-risk' status for PE

iii. Until the end of pregnancy

iv. Not sure

b. Risk status in future pregnancies

iv. Probably yes

v. Probably (hopefully) not

vi. Unknown

9. IPQ-R: Consequence

a. Impact of high-risk status on pregnancy

i. Life-style change: taking special care

- Eating healthily *and exercising*
- Monitoring weight

ii. Avoiding stress

iii. Significant others (worried and more protective)

iv. Personal research on PE

v. Increased medical input (more scans) seen as reassuring

vi. Increased vigilance of symptoms e.g. blood pressure monitoring, checking for swelling

vii. Increased awareness of potential problems during pregnancy

viii. Learning about friends and family who have experienced PE, after screening

ix. Impact on birthing decisions

x. Absence of significant changes or impact

d. Impact of high-risk status on decision to have further pregnancies

i. No significant impact on decisions concerning future pregnancies

ii. Significant negative impact (in the presence of other complications)

10. IPQ-R: Emotional representations during pregnancy

c. Significant initial negative emotional impact

d. Absence of a significant negative emotional impact

i. Avoiding thinking about PE and risk status

ii. Trying to think positively

11. IPQ-R: Control/cure

c. Beliefs concerning personal influence

i. Perception of no personal control

ii. Perception of (some) control

- The role of diet and exercise

iii. Unsure

d. Beliefs concerning the influence of aspirin on the outcome

i. Belief that aspirin could be helpful in preventing PE

ii. Not sure

12. Adherence to ASPRE medication

a. Regularly remember to take medication

b. Forget to take medication

13. Attitude towards taking ASPRE medication

a. Positive

b. Negative

14. Acceptability of taking aspirin in pregnancy in regards to PE risk

a. Acceptable

i. Willing to take aspirin when PE symptoms occur

b. Uncomfortable with the prospect of taking aspirin

8.12: CHAPTER 4 TEMPLATE

Chapter 4; the woman's experience

1. **Utility of advanced knowledge of PE risk status**
    - **a.** "It's good to know"
    - **b.** Screening enables monitoring and better health outcomes
    - **c.** No particular need for PE screening
    - **d.** Less concerned about PE risk status compared to other conditions

2. **Evaluation of PE screening**
    - ***c.*** Benefit from PE screening
    - ***d.*** No or little benefit from PE screening

3. **Evaluation of scan process**

4. **Future PE screening**
    - ***e.*** Would recommend to others
    - ***f.*** Would not recommend to others
    - ***g.*** Would want to be screened in future pregnancies

5. **Things that are puzzling**

8.13: CHAPTER 5 TEMPLATE

Chapter 5
Decision making processes in women offered screening for PE risk status and subsequent decision making for women identified as high-risk and invited to take part in a medicated RCT

1. **Attitude to screening in pregnancy**
    a. Provides early information
    b. Importance of research
    c. Source of reassurance
    d. Screening can increase worry

2. **Knowledge of screening tests available**

3. **Awareness of PE screening, before it took place**

4. **Awareness of PE screening as part of research**

5. **Decision-making regarding participation in screening for PE**
    a. Having trust in the doctors
    b. No harm evident in taking part
    c. Screening for PE seen as a routine procedure
    d. Screening for PE seen as a straightforward procedure
    e. Self-perceptions of "being at-risk" (or not)
    f. The role of significant others
    g. Screening as part of research
    h. To increase awareness and begin preventative measures
    i. Dependent on the screening process
    j. Knowledge of PE
    k. Screening to get more information
    l. Getting screened to feel reassured
    m. No decision-making process
        i. "A lot of information to take in"

6. **Knowledge and understanding of ASPRE trial aims and procedures**
    a. Trial aims
        i. Good understanding
        ii. No clear understanding
    b. Requirements of the trial
    c. Knowledge of randomisation
    d. Knowledge of double-blind nature of trial

7. **Factors influencing participation/non-participation in the ASPRE trial**
    a.Meanings ascribed to the high-risk screening result
    b. Attitudes to medication
        i. Positive
        ii. Negative
        iii. Precautionary medicine seen as unnecessary
    c.Trust in the doctor
    d. Extra care and support through taking part in research
    e.Attitudes to randomisation
        i. Being advised to take aspirin
        ii. Wanting the guarantee of taking aspirin
    f. Side effects
    g.Altruistic attitudes
    h. Information provided by medical team
    i. Input from significant others
    j. Perception that participation was voluntary

k. Consulting previous research regarding the effects of aspirin on PE
l. Participation seen as low-risk
m. Time to consider participation
n. Previous experience of PE
o. Requirements of the trial
p. Other medical complications