UNIVERSITY OF SOUTHAMPTON

FACULTY OF HEALTH SCIENCES

A Feasibility and Acceptability Study and a Qualitative Process Evaluation of a Coping Intervention for Recurrent Miscarriage

by

Sarah Louise Bailey

Thesis for the degree of Doctor of Philosophy

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ABSTRACT

FACULTY OF HEALTH SCIENCES

Nursing

Thesis for the degree of Doctor of Philosophy

A FEASIBILITY AND ACCEPTABILITY STUDY AND QUALITATIVE PROCESS EVALUATION OF A COPING INTERVENTION FOR RECURRENT MISCARRIAGE

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Background: Recurrent miscarriage is diagnosed when a woman has had three or more consecutive miscarriages. Increased levels of distress and anxiety are common during the early stages of any subsequent pregnancies, as women affected by this condition wait for confirmation that their pregnancy is ongoing. This can pose a significant threat to their psychological well-being, however only limited support and therapy are available. The Positive Reappraisal Coping Intervention (PRCI) is a novel self-administered supportive technique that has been shown to be effective in patients awaiting the outcome of fertility treatment.

Study objectives: The primary objective of this study was to assess the feasibility of running a future definitive study to test the effectiveness of the PRCI in improving quality of life in the difficult waiting period that women with previous miscarriage endure before an ongoing pregnancy can be confirmed.

Methodology: A two-centre randomised controlled trial feasibility study and qualitative process evaluation recruited seventy-six participants. Forty-seven of these were randomised at the point of a positive pregnancy test in to one of two study groups. The PRCI intervention group received the PRCI card and weekly questionnaires to assess their psychological well-being during the waiting period of their new pregnancy. The non-intervention group completed the same weekly questionnaires. The qualitative process evaluation employed semi-structured interviews (n=14) to address relevant aspects of the study objectives.

Feasibility findings: Data suggest that successful recruitment to a future definitive study investigating a coping intervention for recurrent miscarriage is possible and that there is an appropriate and sizeable patient population willing to take part. The study participants demonstrated a positive attitude to using the PRCI, finding it an acceptable and practical intervention to use during the challenging waiting period of a new pregnancy. Results are encouraging and demonstrate that use of the PRCI was popular and conveyed some benefits to participants. An effectiveness RCT is warranted, however with some modification to take into account feasibility findings including varying recruitment rates between study sites, the reactive effect of Weekly Record Keeping data collection questionnaire and the adaptation of the use of the PRCI.

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DECLARATION OF AUTHORSHIP

I, SARAH BAILEY .....

declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

A FEASIBILITY AND ACCEPTABILITY STUDY AND A QUALITATIVE PROCESS EVALUATION OF A COPING INTERVENTION FOR RECURRENT MISCARRIAGE

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Definitions and Abbreviations

DRK: Daily Record Keeping Form

EPL: Early Pregnancy Loss

EPU: Early Pregnancy Unit

ERPC: Evacuation Retained Products of Conception

GP: General Practitioner

HADS: Hospital Anxiety Depression Score

IVF: In Vitro Fertilisation

MRC: Medical Research Council

NHS: National Health Service

NICE: National Institute for Health, Care and Excellence

NIHR: National Institute Health Research

PPI: Patient Public Involvement

PRCI: Positive Reappraisal Coping Intervention

PTSD: Post Traumatic Stress Disorder

RCOG: Royal College of Obstetricians and Gynaecologists

RCT: Randomised Controlled Trial

SMOM: Surgical Management of Miscarriage

WRK: Weekly Record Keeping Form

Chapter 1: Introduction

1.1 Background

This thesis is submitted in consideration of the degree of Doctor of Philosophy. It presents the findings of a feasibility study that is the first step in a programme of research concerned with improving the psychological well-being for women affected by recurrent miscarriage during the early stages of a new pregnancy when they are waiting to see if their pregnancy will continue. Previous studies have indicated that this 'waiting period' is associated with high levels of anxiety and distress for the affected woman (Ockhuijsen et al. 2013a; Ockhuijsen 2014; Ockhuijsen et al. 2014c; Ockhuijsen et al. 2015), yet there is limited support and therapy available to support them and many are left to cope alone with managing these distressing emotions. The Positive Reappraisal Coping Intervention (PRCI) is a novel self-administered supportive technique, based on the principles of positive reappraisal and has been shown to be effective at promoting positive feelings and sustaining the ability to cope in a similar group of patients who experience a similar 'waiting period,' namely fertility patients, awaiting the outcome of in vitro fertilisation (IVF) treatment (Lancastle and Boivin 2008; Ockhuijsen et al. 2014a, b). It comprises of an explanatory leaflet describing positive reappraisal coping and its potential benefits as well as 10 statements printed on a laminated card that users read at least twice a day to stimulate the use of this form of coping (Appendix A). For women who have experienced recurrent miscarriage the waiting period in the early stages of a new pregnancy shares many characteristics and stress factors with the waiting period fertility patients experience after in vitro fertilisation (IVF) suggesting that the PRCI may also provide a potentially valuable supportive intervention for this patient group.

The primary objective of this feasibility study is to establish the viability of conducting a future multi-centre randomised controlled trial to definitively test the effectiveness of the PRCI in improving quality of life in the difficult waiting period which women with previous recurrent miscarriage endure before an ongoing pregnancy can be confirmed.

The aim of this introductory chapter is to summarise the purpose and nature of this research study. Firstly, it will outline the condition of recurrent miscarriage and describe the potential distressing psychological challenges facing those women affected. Secondly it will review the growing focus on the importance of feasibility and pilot studies, establishing what constitutes a 'feasibility study,' exploring the methodology that can be used in this type of study and discuss the setting of appropriate feasibility objectives, in addition to outlining the significant role that

qualitative process evaluations play within feasibility studies. The chapter will begin with a personal reflection on miscarriage and describe where the focus for this piece of research originated from.

1.2 A personal reflection on miscarriage

I am an experienced health care professional whose philosophy of practice has been shaped by extensive clinical experiences, working as a nurse, midwife and health visitor, mainly within the arena of women's health. Whilst working as a midwife during the 1990s I had personal experience of suffering a miscarriage. The physical care I received from clinicians was excellent however, little psychological support was offered. This personal experience of miscarriage compelled me to try and change this apparent neglect of the psycho-social aspects of miscarriage; I set up a local support group for women who had experienced miscarriage and became an active member of the maternity bereavement group lobbying for improved local support and care provision for women who had experienced miscarriage.

My career trajectory continued and after several years working as a midwife and then a health visitor, I returned to work in the arena of reproductive health, working as a clinical research nurse on obstetric and gynaecological studies. The role involved working on various reproductive health research studies, but I spent significant periods of my time working with women who had experienced recurrent miscarriage as I was the lead research nurse for a multi-centre study concerned with developing medical interventions for this condition, called the PROMISE study (Coomarasamy et al. 2015). Working with this patient population re-kindled my interest in this clinical area and whilst working on this study it became apparent that a particularly stressful time for women affected by recurrent miscarriage is during the early stages of any subsequent pregnancy; these women were terrified that they would miscarry again. Anxiety levels increased acutely as women faced this unsettling and challenging period of uncertainty about the outcome of their pregnancy. As the pregnancy progressed and the women moved past the first trimester (the first twelve weeks of their pregnancy) they became more confident that the pregnancy would continue to a successful outcome and anxiety levels decreased. The patients I cared for whilst working as a research nurse on the PROMISE study (Coomarasamy et al. 2015) expressed their need for psychological support during the first weeks of their new pregnancy. However, when efforts were made to source support for them, I established that little or no therapeutic support was available for them and the majority of these women affected by recurrent miscarriage were left to cope alone with their worry and anxiety. Furthermore, as I reviewed the literature

regarding recurrent miscarriage with the aim to find out more about this distressing time period it became apparent that the majority of previous research had investigated the provision of psychological support during the immediate aftermath of a miscarriage and the evidence base around the provision of supportive care during the early stages of a new pregnancy was extremely limited.

It is this experience of caring for women affected by recurrent miscarriage, and of being part of a wider research team developing and improving treatment, care and support for women with reproductive health issues, including recurrent miscarriage, which inspired this piece of research. It was evident that there was a gap in the provision of supportive psychological care for women who suffered recurrent miscarriage and I felt compelled to try and address this by aiming to establish a method of providing appropriate and effective support mechanisms for this patient group.

1.3 What is recurrent miscarriage?

Recurrent miscarriage is defined by the Royal College of Obstetricians and Gynaecologists (RCOG) as arising when a woman suffers three or more consecutive miscarriages and affects approximately 1% of all women trying to conceive (RCOG 2011). It is an extremely distressing condition and even after thorough investigation aetiological causes can be found in only 50% of cases (Clifford et al. 1997) and the cause is frequently elusive or multi-factorial (Branch et al. 2010). This can lead to intense frustration for the affected woman and her health care team as there is currently extremely limited treatment or therapy that can be offered. Because of the absence of an effective treatment, current research into recurrent miscarriage tends to focus on establishing a greater understanding of the potential causes and the development of effective medical interventions to treat the condition. Only a limited number of studies are investigating the development of supportive paradigms to help support and sustain the psychological well-being of women affected by recurrent miscarriage. These are discussed in Chapter 2 of this thesis which reviews the relevant literature to this study.

1.4 The psychological effects of recurrent miscarriage

For women affected by recurrent miscarriage, it is an extremely distressing and traumatic condition. It represents far more than just another loss of pregnancy, evoking feelings surrounding a lost baby, a lost future child and a lost motherhood (Ockhuijsen et al. 2014c). Feelings of grief and depression are common (Rowsell et al. 2001; Cumming et al. 2007; Lok and

Neugebauer 2007) and other studies have suggested that both single and recurrent miscarriage can cause the affected woman a 'significant physical and psychological challenge' (Callander et al. 2007) posing a substantial threat to their psychological wellbeing (Magee et al. 2003). Yet despite these potential grieving responses, women who experience miscarriage tend not to receive the same level of psychosocial support afforded to people experiencing other types of bereavement (Simmons et al. 2006) and the majority are left to cope alone with their grief and upset.

Although multiple studies have investigated emotional morbidity in women in the time period after miscarriage (Craig et al. 2002; Swanson et al. 2009; Musters et al. 2013) and previous studies have indicated that increased levels of anxiety and depression are often experienced by women with a history of reproductive loss during subsequent pregnancies (Magee et al. 2003; Lok and Neugebauer 2007), there is limited research about the feelings experienced by women who have suffered recurrent miscarriage specifically during the early stages of a subsequent pregnancy.

Ockhuijsen et al. (2013a) concluded that for recurrent miscarriage patients, the waiting period in a new pregnancy, between a positive pregnancy test and confirmation that their pregnancy is ongoing, can be a particularly stressful time. Affected women are anxious and extremely worried that they may experience yet another miscarriage. Correspondingly personal clinical experience caring for women affected by recurrent miscarriage suggests this is one of the most stressful times for these patients as the psychological strain for the affected woman often increases substantially as any excitement brought about by a positive pregnancy test is often overshadowed by the fear and despair that another miscarriage will occur. This period of uncertainty causes significant levels of anxiety and stress which can impact on all aspects of the affected woman’s life by placing physical, psychological and social demands on them. Indeed, some women will elect not to become pregnant again at all rather than face this upsetting and challenging period of uncertainty. This stressful and difficult situation is further compounded by the fact that the woman has no capacity to control or accurately predict the outcome of the pregnancy and she literally has to wait and see what will happen.

However, despite the potential psychological reactions that are triggered by the uncertainty of the outcome of their new pregnancy, the majority of women affected by recurrent miscarriage receive little or no therapeutic psychological support during this waiting period and are left to cope alone with their anxiety and distress. This appears to be mainly because of a lack of resources within the National Health Service (NHS) as existing psychological supportive interventions are labour intensive and expensive to provide. Furthermore, the need for this support is often urgent (as anxiety levels rise immediately after a positive pregnancy test) and it is

often difficult for health care providers to mobilise and provide support quickly enough. One of the key advantages of the PRCI approach is that it is convenient for patients and easily deliverable at negligible cost and a previous study demonstrated that despite the fact that the intervention is self-administered, with minimal contact from a health professional, the intervention was still positively evaluated by the women who used it (Lancastle and Boivin 2008).

Previous studies have reviewed the use of interventions to alleviate distress in the period immediately following miscarriage (Nikcevic et al. 1998; Rowsell et al. 2001) but there is limited evidence relating to the effectiveness of support during the initial waiting period of a subsequent pregnancy following recurrent miscarriage or the way in which such support should be delivered. However, a recent study has identified that the coping strategies utilised by women with recurrent miscarriage during the early waiting stages of a new pregnancy are likely to be amenable to the PRCI, concluding that the next step is to assess the value of the PRCI in women with recurrent miscarriage in a RCT (Ockhuijsen et al. 2013a). The Medical Research Council (MRC) framework for the development of complex interventions highlights the importance of modelling and refining an intervention and assessing its feasibility before carrying out a definitive large scale RCT (Craig et al. 2008). This study is the next stage in the process, laying the foundation for a definitive study to assess the effectiveness of the PRCI in women who experience recurrent miscarriage.

1.5 The importance of feasibility

A fundamental part of any feasibility study is to determine whether it is possible to deliver the study successfully and to establish whether the study 'can work' (Bowen et al. 2009). As such, their main purpose is to increase the likelihood of the success of interventions in a subsequent large-scale study and to help justify the investment of finances and time in this future study (Charlesworth et al. 2013).

Planning an intervention takes creativity and innovation (Tickle-Degnen 2013) and this is particularly the case when the planned intervention is aimed to address such a multifaceted problem as recurrent miscarriage. This condition has the potential to affect all aspects of the affected woman's life by placing physical, psychological and social demands on them. If all of these demands are to be considered, then the planning and development of an intervention designed to improve the psychological wellbeing of this patient group is a necessarily complex process.

The MRC's new guidance on developing and evaluating complex interventions (Craig et al. 2013) proposes that the feasibility and piloting stage of a study is vital preparatory work and should include the testing of study procedures for their acceptability, estimating recruitment and retention rates of study participants and the calculation of appropriate sample sizes. The guidance goes on to suggest that difficulties with acceptability, compliance, delivery of the intervention and recruitment and retention can be anticipated by effective feasibility or piloting work, thus enabling any problems to be assessed and addressed prior to a large scale outcome evaluation such as an RCT. Correspondingly a review by O'Cathain et al. (2015, p.1), considers the impact of feasibility studies and proposes that the feasibility phase prior to an RCT helps to ensure the success of a large scale definitive study by maximising the likelihood of researchers evaluating 'the optimum intervention using the most appropriate and efficient recruitment practices and trial design.' The review concludes that it is important to explore uncertainties in the trial design to enable researchers to address any problems and improve the intervention or conduct of the trial.

1.5.1 What constitutes a feasibility study?

Although much of the literature regarding the theory around feasibility and pilot studies uses the terms interchangeably, the National Institute for Health Research (NIHR) online glossary offers a useful definition of feasibility studies and pilot studies as two separate entities. Feasibility studies are described as a piece of research done before a main study in order to answer the question 'can this study be done?' A feasibility study will estimate the major parameters which are needed to design the main definitive study (NIHR 2016). Correspondingly, Lancaster (2015) proposes that this type of study focuses on understanding any areas of uncertainty which need to be addressed in preparation for a future large-scale definitive study. The NIHR glossary describes a pilot study specifically as a smaller version of the main study and it differs from a feasibility study in that it resembles the main study in design in most aspects, including the selected primary outcome measures. As such, a pilot study is described by the NIHR glossary as one that focuses on the processes of the main study such as recruitment, randomisation, treatment and follow-up ensuring that all these processes run efficiently. Furthermore, a pilot study is often the first phase of a substantive study and data collected during this pilot phase may contribute to the final analysis. Conversely the MRC guidance for developing and evaluating complex interventions makes no clear distinction between feasibility and pilot studies suggesting that the feasibility and piloting stage of a study includes the need to test procedures for their acceptability, recruitment and retention rate and sample size calculation (Craig et al. 2013). However, this guidance also

stresses the importance of the need for a pilot/feasibility study in addressing the main uncertainties of a study.

It seems that despite the concise guidance issued by the NIHR, the language used to describe the preliminary stages of a large-scale definitive study remains inconsistent with the terms feasibility study and pilot study often being used interchangeably. Recent work with a consortium from the Consolidated Standards of Reporting Trials (CONSORT) group, aimed to develop guidelines for reporting feasibility and pilot studies and also to give consideration to the construction of a definition as to what constitutes a feasibility and pilot study (Lancaster 2015). However, these recently published recommendations (Eldridge et al. 2016), in fact, made no distinction between pilot and feasibility studies and this will be discussed in greater detail in Chapter 4. Until a widely agreed acceptance of standardised conclusive definitions is reached, then the significant factor that connects this synonymous use of the terms 'feasibility study' and 'pilot study' appears to be that both types of study addresses the uncertainties of a study design and lay the foundation for a future definitive RCT.

1.5.2 Methods and approaches taken in feasibility studies

Feasibility studies are able to utilise a variety of methods and although some feasibility studies employ quantitative methods only, it is becoming increasingly common for qualitative or mixed methods to be used (O'Cathain et al. 2015). Similarly the MRC new guidance for developing and evaluating complex interventions (Craig et al. 2013) highlights the fact that it is likely that a mixture of methods will be needed to fully assess the feasibility of running a definitive RCT of a complex intervention.

Qualitative research can be an effective strategy to address key uncertainties prior to a definitive trial (O'Cathain et al. 2015), however the utilising of qualitative methodology within feasibility studies remains a developing area. O'Cathain et al. (2015) goes on to suggest that despite its potential value, there is little guidance on how to maximise the input of qualitative research into feasibility studies.

One of the objectives of this feasibility study was to increase the understanding of the function and acceptability of the Positive Reappraisal Coping Intervention (PRCI). It was envisaged that by utilising both quantitative and qualitative methods in this study, a complete and more considered assessment of the feasibility of employing the PRCI in a future trial could be made and that the planned qualitative component of this study would help to achieve this by increasing the understanding of participants' experience of using the intervention.

1.5.3 Setting objectives of the feasibility study

Feasibility studies lay the foundation for future RCTs by providing the insights necessary to justify and plan the definitive study (Lancaster et al. 2004). The investigative work that takes place in feasibility studies is therefore important preparatory work and vital to help ensure successful implementation of future definitive RCTs. One of the key purposes of a feasibility study is to ensure that study implementation is both possible and practical and to reduce threats to the validity of the main study's outcome (Tickle-Degnen 2013). Furthermore the feasibility stage of a trial is unique as it often leads to ongoing adjustment and adaptation in the original study design (O'Cathain et al. 2015) and therefore it is essential that these studies possess a clear list of well-defined aims and objectives to promote early methodological rigour. In a recent editorial Lancaster (2015, p.2) stresses the significance of setting appropriate and clearly expressed objectives when conducting a pilot or feasibility study, highlighting the importance of ensuring that these objectives should differ from those of the future definitive study and 'stipulate the issues of uncertainty to be addressed.' The overall objective of a feasibility study and one supported by emerging methodological literature is that feasibility and pilot studies should be addressed specifically to descriptively assess the feasibility and validity of the future definitive study plan (Tickle-Degnen 2013). Objectives for conducting feasibility and pilot studies should be different from the future definitive study. This type of study is not designed (or statistically powered) to assess the effectiveness of the intervention being investigated and this should be one of the main objectives of the future RCT (Lancaster 2015).

Recent years have seen an increase in publications reviewing the justification for defining a study as a feasibility or pilot study, explicitly in terms of its content and objectives (Lancaster et al. 2004; Arain et al. 2010; Thabane et al. 2010; Lancaster 2015). Specifically Lancaster et al. (2004) describe recommendations for good practice when designing feasibility type studies and outlines a list of legitimate objectives which will add methodological rigour to any feasibility study. This guidance lists the legitimate objectives of a feasibility/pilot study as: sample size calculation; assessing the integrity of the study protocol; the testing of data collection methods such as questionnaires; the testing of randomisation; recruitment and consent procedures and the examination of the acceptability of the intervention. Furthermore, the guidance issued by Lancaster et al (2004) provides a useful and detailed framework when considering and setting the objectives for a feasibility study and this suggested structure will be utilised in this feasibility study of a coping intervention for recurrent miscarriage.

1.6 Chapter Summary

This chapter has summarised the purpose and nature of this research study, highlighting the importance and purpose of feasibility studies and detailing an overview of the condition of recurrent miscarriage. Importantly it has determined that this extremely distressing condition can have a significant negative effect on the psychological well-being of those affected not only during the immediate aftermath of a miscarriage but also during the 'waiting period' of a new pregnancy.

This piece of research is both timely and topical, investigating an issue which causes distress and anxiety to the women affected by recurrent miscarriage and one which is proving a challenge to the health care professionals caring for them. This study aims to add valuable information to the body of evidence relating to how women who have suffered recurrent miscarriage experience the waiting period of a new pregnancy. In addition, the evaluation of the acceptability and feasibility of the PRCI and the key elements of study design, will inform any necessary refinements or adaptations to the intervention, in order to tailor it to fit the needs of this client group.

If the PRCI proves to be an acceptable and useful intervention to help women affected by recurrent miscarriage manage their anxiety during the early stages of any new pregnancy, then this model of care has the potential to be made more widely available within the NHS, both locally and nationally as an effective, low cost, safe and easily deliverable intervention to provide much needed support to this vulnerable patient population.

Chapter 2: Reviewing the Literature

2.1 Introduction

A fundamental part of the research process is the comprehensive and critical evaluation of the existing evidence relating to the subject being investigated. This review of the literature in a systematic way enables the researcher to locate, appraise and synthesise the best available evidence concerning a specific research question (Boland et al. 2013). The aim of the following literature review is to complete a comprehensive overview of the subject area whereby general themes are highlighted and reviewed. This is followed by an in-depth synthesis of the available evidence, bringing together the present state of related literature and identifying gaps in the evidence base. The findings inform the justification for conducting this piece of research and support the proposed study aims and objectives.

The subject area of this research study is complex and multi-faceted and involves a range of paradigms including the clinical and psychological care of women experiencing miscarriage, waiting periods and the theoretical concept of coping and positive reappraisal. To ensure all of the relevant literature which informed this research study was identified and appraised, the scope of the review is purposely wide. It initially examines the broad evidence base relating to the physiological and psychological aspects of miscarriage as this enables the context of the research to be established. This is followed by a specific focus on recurrent miscarriage, the distinct condition that this research is concerned with. Thirdly, the evidence on the 'medical waiting period' and the waiting period experienced during the early stages of a new pregnancy by those women who have suffered recurrent miscarriage is reviewed in order to identify and substantiate the psychological significance of this waiting time period. Finally the theories and research addressing the psychological principles of coping, positive reappraisal and the development of the PRCI (Lancastle and Boivin 2008) are explored and examined. The aim of reviewing the literature in this systematic order is to illustrate how the relevant clinical, psychological and theoretical principles which underpin this research study come together to inform and justify the development of the research topic and its specific objectives.

2.2 Literature Search Strategy

The available literature was reviewed in a systematic way in order to identify the over-arching associated themes surrounding the proposed research as illustrated in Figure 1. Because the subject area included a range of concepts including clinical and psychological care and theoretical contexts, it was necessary to ensure that the literature review encompassed these. As such, a series of medical, clinical and psychological databases were searched comprising of CINAHL, MEDLINE (EBSCO), the Cochrane Library, PsycINFO, AMED, Scopus, Web of Science and EMBASE. Research literature on the medical aspects of miscarriage and recurrent miscarriage was searched initially, along with the associated terms and MeSH terms which included habitual abortion, successive abortion, repeated pregnancy loss and recurrent abortion followed by the combined terms of miscarriage and depression and miscarriage and grief. The psychological theories and principles were then searched within the databases and these consisted of the search terms coping, positive reappraisal, the PRCI and the 'waiting period.' The Boolean operators AND and OR were used to combine the research evidence regarding the medical phenomenon of recurrent miscarriage with the psychological aspects to further refine the search. Appendix B gives details of the databases searched, date accessed, search terms used and 'hits' obtained.

Figure 1: Conceptual map to illustrate range and order of literature review themes.

In addition to the review of the literature outlined above, a hand search of the journal *Human Reproduction* and the BioMed Central Open Access journal *Women's Health* was undertaken to

identify any further relevant evidence. These publications were specifically chosen to hand search as the database search yielded numerous results from these journals on relevant evidence. There were also some serendipitous findings of pertinent literature including those identified from cross-referencing the articles identified in the systematic database search. In addition, research evidence and findings were generated through personal communications with other researchers working in the field of recurrent miscarriage.

The initial database search generated over one thousand 'hits.' A degree of pragmatism and practicality was used in the choice of literature regarding these themes retrieved for closer analysis. Although the selection process was influenced by the applicability and relevance of the evidence to the research study, the validity and rigour of methodology used and the strength of study findings, it was also largely influenced by prior reading of the subject area and to a lesser degree date of publication.

The aim of reviewing the literature relating to physiological and psychological aspects of miscarriage was to enable the context of the research topic to be established, as it was anticipated that this literature would most accurately be able to inform and set the background of the research study within present practice and service delivery. Literature was selected to be included in the review if it provided evidence of the physical and psychological effects of miscarriage and how this fitted within current care recommendations. Similarly, titles and abstracts referring to recurrent miscarriage were reviewed and retrieved if they provided evidence of the distinct disease entity of recurrent miscarriage. The literature on the psychological impact of recurrent miscarriage provided a particularly valuable source of data to help develop this research study and justify its need. The database search of evidence on the medical waiting period, the waiting period of a new pregnancy following recurrent miscarriage and the psychological concepts and principles of coping and positive reappraisal that underpin the development of the PRCI, yielded far fewer results. Consequently all the available evidence pertaining to these subjects was reviewed, irrespective of date of publication, indeed the theory of the psychological principles of stress, coping and positive appraisal outlined in pioneering work by Lazarus and Folkman (1984) still forms the basis of contemporary research within this area and remains extremely relevant.

This sifting and review of the literature initially identified over 100 papers and publications (Table 1), which were retrieved where possible in hard copies for closer inspection and critical review. During the duration of this study, additional hard copies of publications were retrieved as new papers and research were published.

Literature review theme	**Articles retrieved and reviewed for relevance**
Miscarriage Physiological Psychological	Combined n=37
Recurrent miscarriage Physiological Psychological	Combined n=28
Medical waiting time	n=11
Emotions in new pregnancy following miscarriage	n=10
Waiting time in new pregnancy following recurrent miscarriage	n=3
Positive Reappraisal Coping and appraisal PRCI	 n=19 n=4
Total	n=111

Table 1: Overview of topics and initial number of articles retrieved for review.

Each retrieved journal article was thoroughly read and evaluated. The focus of critical appraisal of these articles was an evaluation of the type of publication, purpose, method, sample, key findings/recommendations and main themes and this information was recorded (Appendix C). This record provided a useful 'aide memoire' and helped to identify how the relevant clinical, psychological and theoretical principles which underpin this research study converge. Due to the number of publications identified in this review, not all papers are examined and detailed in depth in this chapter. However, the remainder of this chapter examines those that made the most appropriate and substantial contribution to the supporting evidence base to this research study. Furthermore, the literature was reviewed under the sub-themes of miscarriage, recurrent

miscarriage, medical waiting times, the waiting time of a new pregnancy following recurrent miscarriage, the theory of coping and positive reappraisal and the PRCI.

2.3 Miscarriage

Following a positive pregnancy test, the normal expectation of most women is that the pregnancy will result in the birth of a healthy term infant. Unfortunately, this is not always the case with approximately 15% of all recognised pregnancies ending in miscarriage. There is a considerable variation in incidence of miscarriage according to maternal age (Larsen et al. 2013), ranging from an incidence rate of 10% in women who are aged between 20 and 24 and rising to 51% in women aged 40-45 years of age (Andersen et al. 2000).

Miscarriage has been described as a global health issue (Murphy and Merrell 2009) and the most common adverse outcome of pregnancy (Simmons et al. 2006), so commonplace that it has been estimated that at least 25% - 50% of all women will experience at least one spontaneous miscarriage during their child bearing years (Rai and Regan 2006).

A miscarriage is the early and unanticipated termination of a pregnancy and is defined as the spontaneous loss of a pregnancy before the fetus reaches viability, as such this includes all pregnancy losses from conception up until 24 weeks of gestation (RCOG 2011). Approximately 75% of all spontaneous miscarriages occur during the first trimester of pregnancy (the first three months), normally as a result of fetal chromosomal abnormalities and are generally termed early miscarriages. The incidence of second trimester miscarriages (which can occur up to 24 weeks gestation) is much lower and these are routinely referred to as late miscarriages.

Although the term miscarriage describes any spontaneous demise of a pregnancy which occurs before the fetus reaches viability (ESHRE 2017) there is some controversy regarding the terminology amongst health professionals used to describe early miscarriage. Larsen et al. (2013) highlights the revised terminology introduced by the European Society of Human Reproduction and Embryology (ESHRE) that suggests that a pregnancy loss that occurs after a positive urinary pregnancy test or raised serum b-hCG but before ultrasound verification, should be defined as a biochemical loss. These pregnancy losses generally occur at a very early gestation, normally before 6 weeks. Once the existence of an intrauterine pregnancy has been confirmed by ultrasound scan or histological evidence, then the term clinical miscarriage should be used. Clearly it is paramount that definitions of stages of miscarriage are adequately described and adhered to

in order to make meaningful comparisons between scientific studies (Kolte et al. 2015a), however personal clinical experience suggests that this 'labelling' of biochemical miscarriages and clinical miscarriages can confuse women and add to their distress. Many women question whether a biochemical miscarriage is a 'proper' miscarriage. What is evident is that miscarriage is a common and distressing complication of early pregnancy whatever gestation it occurs at and whether it meets the terminology of a biochemical pregnancy or a clinical miscarriage, indeed ESHRE (2017) stress the importance of using clear and sensitive language when discussing miscarriages with those affected. For the purpose of this research and thesis, the term miscarriage refers to any pregnancy loss occurring after a positive urinary pregnancy test and therefore includes biochemical pregnancy losses and clinical miscarriages.

Miscarriages are classified according to their presentation. A 'complete miscarriage' occurs when the complete products of conception are passed spontaneously and in an 'incomplete miscarriage,' the products of conception are only partially expelled and the rest retained in the uterus. Both types of miscarriage can result in varying degrees of pain and vaginal bleeding for the affected woman. The third classification of miscarriage is often referred to as a 'missed miscarriage,' 'silent miscarriage' or 'missed abortion' whereby the fetus is no longer viable but has not yet been expelled from the uterus. As there are no visible or physical signs that the pregnancy has ended, this type of miscarriage is often undiagnosed until the woman attends for her first trimester scan at approximately 12 weeks of pregnancy. Other related terms include 'threatened miscarriage,' which is another term to describe any vaginal bleeding in early pregnancy and 'inevitable miscarriage' whereby a pelvic examination indicates that the woman's cervix is open and her body is in the process of expelling the pregnancy.

Management of the miscarriage will depend on the category and classification of the miscarriage in addition to the woman's physical condition and symptoms. Although referral for medical and physical treatment is not always a requirement following miscarriage, the optimal management of women with symptoms of miscarriage commonly involves referral to an Early Pregnancy Unit (EPU) for ultrasound confirmation that the pregnancy is either ongoing or has ended. Medical or surgical intervention is often required and accounts for over 50,000 hospital admissions annually in the United Kingdom (NICE 2012). The National Institute of Health and Care Excellence (NICE) ectopic pregnancy and miscarriage guideline outlines the recommendations and best practice advice for the diagnosis and initial management strategies for women who are experiencing miscarriage (NICE 2012). Following a confirmed diagnosis of miscarriage, the recommended first line management plan is expectant management whereby no medical interventions are given and

time is allowed to elapse to wait for the products of conception to pass spontaneously and of their own accord. In cases where a woman's condition is compromised or expectant management is not acceptable to her then medical or surgical intervention may be recommended. Medical management involves the administration of drugs, normally Misoprostol which is a synthetic prostaglandin used to induce abortions or start labour. This is administered either vaginally or orally to induce uterine contractions and aid expulsion of the retained products of conception. In surgical management, previously referred to as evacuation of retained products of conception (ERPC), but now more commonly referred to as surgical management of miscarriage (SMOM), a general anaesthetic is required and a surgical curettage performed to empty the uterus. In some EPUs manual vacuum aspiration of the retained products of conception under local anaesthetic is offered as an alternative to surgical management under general anaesthetic.

As miscarriage is such a common phenomenon, experienced by so many women, some consider it to be without long term consequences and it has been suggested that the psychological morbidity associated with miscarriage can sometimes be 'overlooked' by health care professionals (Kong et al. 2010). Certainly there appears to be a less defined and developed body of evidence surrounding the psychological management of miscarriage (Murphy 2012). However, there has been an increasing awareness of the emotional impact of miscarriage and the potential for adverse psychological consequences for women who are affected and their partners. Paradoxically although miscarriage is a fairly common event, women who are affected by it are often unprepared and adverse psychological repercussions and sequelae are common. The majority of women experience miscarriage as the loss of a baby to whom they have already developed a close attachment (Neugebauer and Ritsher 2005) and following a miscarriage women often experience a deep sense of loss for their pregnancy. Numerous studies have investigated emotional morbidity in women in the period after miscarriage, concluding that women's emotions at this time are frequently typified by feelings of sadness, guilt and emptiness (Jansson and Adolfsson 2011). Many other studies have used diagnostic tools to measure symptoms of grief, depression and anxiety in the time period after miscarriage (Cecil and Leslie 1993; Prettyman et al. 1993; Beutel et al. 1995; Lee et al. 1997; Nikcevic et al. 1999; Neugebauer and Ritsher 2005; Cumming et al. 2007; Lok and Neugebauer 2007). These studies concluded that feelings of grief following a miscarriage can be as great as the loss of any loved one (Lok and Neugebauer 2007) and appear equal to those following the loss of children, spouses and other relatives, with approximately 40% of women reporting symptoms of grief in the period shortly after miscarriage (Beutel et al. 1995). A study by Neugebauer and Ritsher (2005) investigated the symptoms of grief in the six months following miscarriage using the perinatal bereavement scale

and concluded that approximately 20% of women were 'grief stricken' at six to eight weeks and again at six months after their miscarriage. Grief following miscarriage has been described as unique (Maker and Ogden 2003) because it is frequently coupled with guilt that a woman has 'failed' in her attempt to have a healthy pregnancy and an assumption that miscarriage was a consequence of her actions (Adolfsson et al. 2004). Despite these potential grieving responses and the untold anguish that miscarriage can cause, women who experience it tend not to receive the same level of psychosocial support afforded to people experiencing other types of bereavement (Simmons et al. 2006). This maybe because miscarriage is still one of those taboo subjects which few people are willing to discuss and a lack of understanding by society and health professionals alike regarding the grief and distress which can be caused by miscarriage.

Approximately 20-55% of women experience an increase in depressive symptoms in the period immediately following miscarriage (Neugebauer 2003) and at six to eight weeks post pregnancy loss are likely to be more depressed on average than a comparable group of women who have not experienced miscarriage (Neugebauer and Ritsher 2005). Brier (2004) suggests that given the suddenness, unanticipated nature and often traumatic physical symptoms of miscarriage (e.g. bleeding and pain), it is not surprising that feelings of anxiety following miscarriage are commonly reported. The anxiety is normally centred on the pregnancy loss, with an increased risk of obsessive compulsive disorders and post traumatic disorders, however anxiety symptoms diminish considerably within six months (Brier 2004). Correspondingly, Lok and Neugebauer (2007) propose that anxiety symptoms generally focus on pregnancy-related issues and are frequently characterised by increased levels of somatic complaints. A prospective longitudinal study by Nikcevic et al. (1999) emphasised that women who had recently suffered a miscarriage experienced concerns about the possible causes of their miscarriage and the risk of re-occurrence for subsequent pregnancies.

Throughout the time span of this research study, there has been an ever-increasing awareness of the emotional impact of miscarriage resulting in an increase in media coverage of the subject and the publication of significant research findings regarding this. One noteworthy piece of research which has been published recently aimed to investigate the type and severity of emotional distress in women who had experienced miscarriage or ectopic pregnancy, compared to a control group with ongoing pregnancies (Farren et al. 2016). This pilot study used validated instruments to assess mental well-being after early pregnancy loss (EPL). Significantly, the study proposed that a large number of women who experienced EPL fulfilled the diagnostic criteria for probable post-traumatic stress disorder (PTSD) and that the resulting psychological symptoms (in particular PTSD) persisted for at least three months following pregnancy loss. The study concluded that if

the findings of this study were supported by a large-scale study, then consideration should be given screening all women who experience EPL for emotional distress and symptoms of PTSD. Furthermore, in order to better direct the limited resources available in this area of care, attention should be paid to assessing how to predict those women most at risk of severe emotional distress.

Current and ongoing literature and research illustrates the potential challenge posed by miscarriage to the psychosocial wellbeing of those affected. However previous research has suggested that culture is an important element in shaping grief reactions (Cowles 1996; Hutti et al. 2015) and therefore it is necessary to consider the influence of cultural and religious diversities, how these might impact on the experience of miscarriage for women and how this might affect their subsequent coping and grieving. Indeed there are many ambiguities surrounding the event of miscarriage as it a unique type of loss (Frost et al. 2007), with uncertainties around when the death of the fetus occurred, what exactly has been lost and when the actual miscarriage occur (in the case of a missed miscarriage). All of these ambiguities can be affected by cultural issues.

Whilst the evidence base regarding culture and its effect on general grief reactions appears to be extensive, studies and research specifically investigating the effects of miscarriage cross-culturally are limited. The majority of existing studies which explore culture in relation to pregnancy loss focus on late pregnancy loss, stillbirth and neonatal death rather than miscarriage. Few studies specifically focus on the effect of culture and religion on the experience of miscarriage and no studies from the UK were identified. Two South African studies published in the Journal of Psychosomatic Obstetrics and Gynaecology over twenty years ago (Chalmers and Meyer 1992a, b) did explore a cross-cultural view of the psychosocial management of miscarriage and a cross-cultural view of the emotional experience of miscarriage. The studies investigated the emotional differences experienced after a miscarriage in 106 women of White, Asian, African and mixed culture and suggested that all of these groups of women experienced difficulty around the loss of their pregnancy and that cultural differences did influence the experiences and reactions of the women. The studies concluded that Asian women and women with a mixed culture background experienced the most difficulty in expressing their feelings compared to the other ethnic groups and African women expressed more emotional reactions than all other groups. The research identified a unique cultural difference proposing that without exception, all the African women expressed a ‘feeling’ that something was wrong with their pregnancy before the onset of miscarriage symptoms and this was absent in women from other groups. The authors suggest that this may indicate a greater subjective awareness of bodily processes in the African women and a

greater reliance on physiological and biological explanations by women from a Western culture. However, the sub-sample sizes were small in this study and therefore interpretations need to be made with some caution.

A qualitative study by Van and Meleis (2003) explored the coping strategies of African American women following all types of involuntary pregnancy losses including miscarriages, ectopic pregnancies and still births. The study concluded that women affected by pregnancy loss believed that by deliberately connecting with their spiritual and religious beliefs and practices they could help to develop self-help strategies to help them cope with their loss. Most of the participants in the study reported that religious and spiritual activities were important to their lives and helped them deal with any traumatic events they experienced including pregnancy loss.

Further writings and research around culture and miscarriage are evident in some anthropological texts. Certainly the anthropological approach which places an emphasis on the cultural interpretation of meanings and ritual practices (Layne 1990) adds a different and important dimension to understanding the psychosocial effects of miscarriage.

In her book 'The Anthropology of Pregnancy Loss. Comparative Studies in Miscarriage, Stillbirth and Neonatal Death,' Cecil (1996) asks the question how much influence does culture have on a mother's reaction to pregnancy loss? The key anthropological question appears to be at what stage is the developing fetus attributed human status and how does this affect the mother's reactions to the loss of the baby? The text provides contemporary and historical accounts and insight into the management and experience of pregnancy loss from diverse cultures and regions such as rural Northern India, urban America, Papua New Guinea, South Africa and Northern Ireland. However once again, apart from a chapter exploring the South African study mentioned previously, the text mainly focuses on experiences around stillbirth and perinatal loss.

Work by the American feminist anthropologist, Linda Layne (1990), explores and focuses on the participants of pregnancy loss support groups. She argues that although the majority of those attending the support groups are white middle class, and therefore do not represent 'American society' as a whole, it is these women who are vocal and organised who hold the potential for significantly altering the way miscarriage and stillbirth is viewed by American society. Her work identifies several recurrent themes observed within the support group participants. They include the angst of an incomplete rite of passage, the struggle of defining the embryo, fetus or neonate as a 'child' and oneself as a 'parent,' the search for and acknowledgement of a seemingly unexplainable event and the link between changing attitudes to birth, death and personhood. Layne (1990) concludes that miscarriage should be acknowledged as a legitimate social problem

and argues that this will encourage institutions to modify and improve the care given to women (and men) who experience pregnancy loss.

Anthropological researchers in the UK are trying to address the gap in academic social science literature regarding miscarriage and ongoing work led by Susie Kilshaw (Principal Research Fellow), a leading expert on the anthropology of miscarriage and pregnancy loss, based at University College London, is exploring a focused and anthropological contemporary look at the issue of miscarriage. Personal communication with Kilshaw has confirmed that she is currently in the process of co-editing a book which will explore aspects around miscarriage from the perspective of a multi-disciplinary team including anthropologists, medical clinicians, lay people and specialist nurses. In addition, she is currently conducting fieldwork and research comparing miscarriage experiences in Qatari and British women. Although Kilshaw's research is still ongoing her research team's work aims to direct findings towards improving women's lives by informing the services which help and support women who are affected by miscarriage and pregnancy loss. Furthermore, research participants in both the UK and Qatar expressed a real desire to help other women as they felt that they had suffered through miscarriage and felt it was a poorly understood phenomenon (Kilshaw et al. 2016).

For many women religious beliefs provide a useful framework to help them understand the meaning of their loss (Layne 1997) and major religions appear to offer specialised and distinctive advice on pregnancy loss including miscarriage. This guidance is freely available to all and can be easily accessed online. For example, the Jewish community provide a guide for Jewish parents on miscarriages, stillbirths and neonatal deaths (United-Synagogue n.d), however Jewish law makes a clear distinction between a fetus under twenty-one weeks gestation and more developed foetuses. There is no formal mourning in the case of a miscarriage occurring before twenty-one weeks gestation, but the guidance recognises that couples who have experienced this should take time to heal both physically and emotionally. The Christian faith reassures its followers that their God has compassion for those who experience a miscarriage and Christians should have faith in the 'glorious hope' of seeing their child again (Got Questions Ministries n.d). Any unborn child is 'one of His children as their God knows us whilst still in the womb' (Got Questions Ministries n.d). Practical advice from the Christian community includes encouraging those affected by pregnancy loss to take time to grieve, take comfort from their family and friends, name their baby and acknowledge it was a unique individual and to remember the baby.

During difficult times such as miscarriage, followers of the Muslim faith strive to take comfort and solace through their religious beliefs (Arshad et al. 2004). Muslim followers believe that all

children are innocent and upon death, the soul of the child (including those lost as a miscarriage or stillbirth) will ascend directly to paradise. Arshad et al. (2004 p. 484) state that when a baby dies there is great reward for its parents in the '*Hereafter'* and that the children who have died await their parents at the gates of paradise, adding that the Prophet Muhammad said that '*even the miscarried fetus will drag its mother towards Jannat (paradise) if she exercised patience in the hope of requiring reward.*'

Despite the complexities surrounding culture and religion on miscarriage, the evidence base regarding this highly sensitive area is extremely limited. Indeed, an expert review by Van Den Akker (2011) explored the psychological and social consequences of miscarriages and concluded that further research is needed to determine the influences of culture, traditions and religion on coping with miscarriage. What is clear, however, is that the limited research in this area does suggest that culture and religion can significantly affect how individuals cope with and grieve for their miscarriages. As such, whilst health professionals should not make assumptions about an individual's culture and religious beliefs there is an obvious need for more cultural awareness when developing health policy which addresses the needs of women affected by miscarriage.

In summary, despite the high incidence rate of early miscarriage, for many women it is a profound life event often accompanied by feelings of a lost expectancy, emptiness, sadness, guilt, grief, depression, anxiety and concerns regarding the outcome of any subsequent pregnancies. The current emphasis on 'medical management' of miscarriage may lead to a neglect of psychologically important issues. The grief experienced by women is often compounded by the fact that the miscarriage consists not only of a lost pregnancy and future childhood, but also a lost motherhood. Unfortunately, some women experience recurrent miscarriages and therefore face and experience these difficult feelings and anxieties repeatedly.

2.4 Recurrent miscarriage

Recurrent miscarriage is defined by most clinicians as the loss of three or more consecutive pregnancies and the condition occurs in proximately 1% of those women trying to conceive (RCOG 2011) . Its prevalence is therefore significantly lower than sporadic miscarriage (Larsen et al. 2013). This repeated and unintentional loss of pregnancy has been described as a distinct disease entity (Rai and Regan 2006; Christiansen et al. 2008; Larsen et al. 2013) given that the observed incidence of recurrent miscarriage is much higher than would be expected to occur by chance alone. It has been suggested that the causes are multi-factorial and might include parental chromosomal abnormalities, maternal thrombophilia, immune dysfunction and endocrine

disorders. However, a recent paper by Larsen et al. (2013) highlighted the fact that none of these conditions are specific to recurrent miscarriage or always associated with it and explores the new and emerging insights into the possible mechanisms behind recurrent miscarriage. It comments that the significant advance in the progress in the areas of cytogenetics and immunogenetics in recent years has led to a more comprehensive understanding of implantation and maternal-fetal interactions. This in turn has created new opportunities for research into the possible causes of prevention and treatment of recurrent miscarriage. New avenues for research have opened up and comprehensive research programmes continue to explore the role of aetiological lifestyle factors such as smoking, obesity, alcohol and caffeine consumption in recurrent miscarriage. Other research is investigating the role of immunological dysregulation in pregnancy, changes in sperm DNA integrity and the function of the decidualised endometrium acting as a biosensor to embryo quality (suggesting that if this is disrupted it may lead to the implantation of embryos which are destined to miscarry) in recurrent miscarriage (Larsen et al. 2013). A number of national and international clinical trials are currently in progress to investigate the development of medical interventions to treat this condition.

The RCOG Green-top guidelines (RCOG 2011) assembled available evidence in order to provide guidance on the recommended treatment and investigation of recurrent miscarriage. However, given our current incomplete understanding of the phenomenon of recurrent miscarriage, and despite ongoing comprehensive research programmes into aetiology and treatments, the causes of recurrent miscarriage remain elusive. Indeed, even after thorough investigation a significant proportion of cases remain unexplained with no underlying pathology or cause identified. This alongside the fact that there is currently only extremely limited medical treatment or therapy for recurrent miscarriage leads to intense frustration for the women experiencing recurrent miscarriage and the health care team caring for her.

Whilst the loss of any desired pregnancy ending in miscarriage is a profound and negative life event, for women who face the repeated loss of much wanted pregnancies it is an extremely distressing condition and can be both physically and emotionally traumatising. One of the most difficult time periods for women affected by recurrent miscarriage is the early stages of any new pregnancy, normally the first twelve weeks whilst they wait for confirmation by ultrasound scan that their pregnancy is ongoing and viable. Instead of experiencing this period as a time of ‘joyful anticipation’ (Hutti et al. 2015), they are filled with increased worry and anxiety that they will miscarry again. The psychological strain for couples who have experienced recurrent miscarriage often increases substantially as any excitement brought about by a positive pregnancy test is overshadowed by the fear and despair that they will suffer yet another miscarriage. This period of

anxiety and stress can impact on all aspects of their life, including relationships, work and daily living activities and the stressful and difficult situation is further compounded by the fact that the woman has no capacity to control or accurately predict the outcome of the pregnancy.

A recent cross-sectional study (Kolte et al. 2015b) concluded that increased levels of psychological stress and major depression are significantly more common among women with recurrent pregnancy loss compared to women trying to conceive who had not experienced this. Furthermore, other studies investigating emotional morbidity in women in the time period following miscarriage have indicated that increased levels of anxiety and depression are often experienced by women with a history of reproductive loss during subsequent pregnancies (Craig et al. 2002; Côté-Arsenault 2007; Swanson et al. 2009; Musters et al. 2013). However, research data on the psychological morbidity associated with the difficult waiting period during a subsequent pregnancy when the woman waits to see whether the pregnancy will again end in miscarriage or not, is limited, and therefore this area is a key focus of this study. Only three publications (Ockhuijsen et al. 2013a; Ockhuijsen et al. 2014c; Ockhuijsen et al. 2015) were identified which explicitly explored the thoughts and emotions of women during the waiting period of a new pregnancy following miscarriage and these proved to be a valuable source of information for this research study. It is evident that the experience of recurrent miscarriage frequently results in a period of 'marked stress reaction' (Liddell et al. 1991) when the woman becomes pregnant again, specifically during the 'waiting period' between a positive pregnancy test and confirmation that the pregnancy is on-going. Indeed, some women will elect not to conceive at all rather than repeatedly face this period of troubling uncertainty.

2.5 The medical waiting period

Medical waiting periods have been defined as the period of time in which patients wait for medical test results, results which could be potentially threatening to their well-being (Boivin and Lancastle 2010), and as such they often involve a stressful period of waiting. The phenomenon of the medical waiting period has been studied amongst a range of patient groups including women waiting for genetic information (Phelps et al. 2006; Phelps et al. 2013), women waiting for a breast cancer diagnosis (Drageset and Lindstrøm 2005), patients waiting for gastro-intestinal endoscopy investigations (Parker and Kennedy 2010), and the waiting period during fertility treatment between embryo transfer and pregnancy test (Lancastle and Boivin 2008). Osuna (1985) proposes that psychological stress reactions are present and build from the start of any waiting period: anticipation of loss leads to further anxiety and potential psychological distress.

Lazarus and Folkman (1984) explored and identified characteristics which make a situation stressful and significantly these are particularly applicable to medical waiting periods. Most medical waiting periods involve waiting for an outcome which could have adverse outcomes or consequences, the patient has little or no control over the outcome of the waiting period and the waiting period provides little 'objective information to accurately gauge the likelihood of positive or negative outcomes' (Boivin and Lancastle 2010). The results of the tests are unknown and unpredictable which in turn lead to increased levels of uncertainty that are difficult to cope with. Portnoy (2010) suggests that the medical waiting period can be a psychologically stressful time as the person prepares themselves for what could be negative information. Indeed comparisons have been made to the fact that just as the body prepares itself for an impact before a collision, people psychologically brace themselves for bad news as a protective mechanism (Carroll et al. 2006). It appears that one of the most stressful things about a medical waiting period is the uncertainty of not knowing the outcome. According to Lancastle and Boivin (2008) people prefer to know what is going to happen, especially if the anticipated event is likely to be unpleasant. This is because this knowledge enables the person to engage in anticipatory coping which might offset the psychological consequences of the event (Lazarus and Folkman 1984). A further study by Boivin and Lancastle (2010) aimed to document the psychological processes (such as anxiety, depression, positive affect and coping) that unfold during such waiting periods, in particular the waiting period between fertility treatment and a pregnancy test to ascertain whether the treatment has been successful. This study used a Daily Record Keeping (DRK) form to investigate emotional reactions during the two-week medical waiting period in fertility treatment. It established that anxiety gradually increased to the day of the pregnancy test then decreased precipitously after the results were known. In contrast feelings of depression increased more gradually during the waiting period and remained elevated during the follow-up period. The authors explain that anxiety reflects anticipatory emotions (tense, nervous, worried), whereas the depressive symptoms reflected outcome emotions (sadness and disappointment). The researchers concluded that medical waiting periods have a distinct emotional signature with a clearly defined emotional trajectory but a less differentiated coping pattern, suggesting that this is why the medical waiting period is so demanding and challenging to those affected.

For women who have experienced recurrent miscarriage, the waiting period between a positive pregnancy test and confirmation that their pregnancy is viable and ongoing shares many characteristics with a medical waiting period, with similar anticipatory emotions and outcomes that are unpredictable and over which they have no control. Significantly women affected by

recurrent miscarriage experience increased anxiety, worry and acute uncertainty about the outcome of the waiting period of any subsequent pregnancy.

2.6 The 'waiting period' of a new pregnancy following recurrent miscarriage

The body of evidence which specifically examines the waiting period experienced by women who have suffered recurrent miscarriage during a subsequent pregnancy is small but growing. Recent findings from a qualitative focus group study (Ockhuijsen et al. 2013a), for example, provide insight into the coping styles and experiences of women who have suffered miscarriages, focusing on the initial waiting period (weeks 1-12) of a subsequent pregnancy. Differences were found in the way women with single or recurrent miscarriages appraised and assessed the waiting period. Those who had experienced just one miscarriage assessed the waiting period of a subsequent pregnancy as a benign period and as a challenge rather than as a period of threat or harm. Conversely, women with a history of recurrent miscarriage were unsure how to assess the waiting period of a new pregnancy and felt extremely uncertain about the pregnancy outcome, proposing that this uncertainty grew after each miscarriage. Women who had experienced recurrent miscarriage lacked confidence about future outcomes (a successful pregnancy) and their perceptions and coping were orientated towards potential failure. The coping strategies utilised in both groups were most commonly emotion-focused, and included avoidance, seeking social support, distraction and positive reappraisal. However, the main difference between those women who had experienced just one miscarriage and those who had suffered recurrent miscarriage was the reason for using these coping strategies. Women with just one miscarriage tried to cope by doing things differently than they had in their failed pregnancy and the authors give an example of a woman who avoided sporting activities in her first pregnancy in which she miscarried, so ran a marathon in her second successful pregnancy. Conversely, women who had experienced recurrent miscarriage utilised coping strategies to 'brace for the future', as a means of attempting to control their emotions and future emotions as much as possible to prepare for the 'worst outcome' (Ockhuijsen et al. 2013a). This involved anticipating the negative feelings that would be caused by a further miscarriage, for example avoiding daydreaming about their baby.

A further study by Ockhuijsen et al. (2014c) investigated the challenges experienced by women who had suffered miscarriages, exploring how they responded to the loss of a previous pregnancy and experienced the uncertainties of early waiting period of a subsequent pregnancy. During the women's first pregnancy (prior to their miscarriages occurring) they reported that their

experience of early pregnancy was very positive, a time when they fantasized about their unborn child and planned for its future. Their first miscarriage came as a surprise to them. However, feelings became mixed in early pregnancy after one or more miscarriages as although positive feelings emerged in the immediate period of a new pregnancy, very quickly these became mixed with negative feelings, in turn leading to uncertainty. The more miscarriages a woman had suffered, the more negative she felt, so much so that many felt no positivity at all in the immediate period after the start of a subsequent pregnancy. According to Ockhuijsen et al. (2014c), women who had experienced multiple miscarriages searched for ways to gain a sense of control during the early stages of a new pregnancy as a way of responding to the mixed feelings they experienced. They attempted to do this, for example, by employing a variety of tactics to assist them, including observing and controlling strategies. Women in the study closely monitored pregnancy symptoms such as nausea, breast tenderness and tiredness, considering these symptoms as an indicator of an ongoing pregnancy whereas infrequent or unstable signs and symptoms of pregnancy led to an increased feeling of uncertainty. Women made lifestyle adaptations in an attempt to control their bodies, including improving nutrition, avoiding strenuous exercise, taking rest and relaxing holidays with all activities focused on achieving an ongoing pregnancy. This study also highlighted the notion of bracing as a self-protective mechanism which women who had previously experienced miscarriage used to control emotions. Bracing strategies included not thinking about a future with their unborn child, living in the 'here and now,' stalling any thoughts about their pregnancy, restricting and controlling any social support and attempting to avoid any bonding or attachment with the fetus.

Behaviours similar to 'bracing for the worst' (Ockhuijsen et al. 2013a; Ockhuijsen et al. 2014c) have been reported in other studies which investigated pregnancy after previous perinatal loss, including 'holding back emotions' (Côté-Arsenault and Dombeck 2001) and 'emotional cushioning' (Cote-Arsenault and Donato 2011). Emotional cushioning is described as a unique self-protective mechanism which women who have experienced previous pregnancy loss utilise to help cope with the anxiety, uncertainty and vulnerability they experience in subsequent pregnancies. For women affected by previous pregnancy loss 'pregnancy does not equal baby,' and emotional cushioning involves 'compartmentalising the pregnancy and avoiding its emotional aspects for as long as possible' (Cote-Arsenault and Donato 2011).

A Swedish study aimed to explore how women who had experienced one or more miscarriages managed their feelings and emotions when they became pregnant again (Andersson et al. 2012). A total of 16 women took part in qualitative interviews. Although some participants included in the study had only experienced one previous miscarriage, the findings provide useful information

and add to the limited available body of evidence about the feelings and emotions experienced in pregnancy following miscarriage. In this study, thoughts of worry, concern and apprehension that they would miscarry again were generated at the actual moment of realisation that they were pregnant again, following a positive pregnancy test. These feelings were accompanied by a marked sense of isolation. Women described the need to distance themselves from the pregnancy, focus on their pregnancy symptoms (for example nausea and tender breasts) to reassure themselves that everything was normal, search for confirmation of their pregnancy (by therapeutic confirmation with ultrasound scans and the seeking of information from books and the internet that their pregnancy was viable) and for professional and social support. The study concluded that the mixed emotions generated by their new pregnancy were often too complex for the women to manage on their own. The researchers stressed the importance of professional support in managing and alleviating feelings of worry and apprehension.

A study by Musters et al. (2013) aimed to quantify supportive care preferences in women with recurrent miscarriage. The researchers concluded that women preferred a plan for the first trimester of a subsequent pregnancy which involved seeing a doctor, and reassurance from ultrasounds, and they stressed the importance of 'soft skills' from health care professionals (such as showing understanding, listening skills and respect towards the women's miscarriages). The RCOG green top guideline (RCOG 2011) details the investigation, treatment and care of women with unexplained recurrent miscarriage and concludes that those affected have an excellent prognosis for future pregnancy outcome (approximately 75%) if offered supportive care alone.

Although limited, the available body of evidence on the waiting period experienced by women during a new period following recurrent miscarriage provides a strong insight into their experiences and thoughts at this time. Feelings of worry, apprehension, uncertainty, isolation and vulnerability are often coupled with an overwhelming fear that they will miscarry again. Despite this and evidence on the benefits of supportive care, many women who have experienced recurrent miscarriage are not provided with any therapeutic or professional support and are often left to cope alone with their anxiety and distress. This is mainly because current supportive interventions for this group are labour intensive and expensive to provide. As support is often required urgently, health services may struggle to provide support quickly enough. There is therefore a need to explore alternative support systems and strategies for use by women affected by recurrent miscarriage during the stressful waiting period of a subsequent pregnancy. Ideally, such a strategy would need to be easy to provide in a timely manner, effective in sustaining coping abilities during the waiting time period, cost effective and a useful adjunct to existing supportive strategies or therapeutic interventions. To understand how such a strategy could

sustain coping abilities during the stressful and distressing waiting period of a new pregnancy following recurrent miscarriage it is necessary to explore in detail the theoretical underpinning of the coping process.

2.7 The Theory of Coping and Positive Reappraisal

The pioneering work of Richard Lazarus (1966), outlined in his book 'Psychological Stress and the Coping Framework,' provided the basis of contemporary research around the concept of coping. Previous research had focused on the pathology of coping but Lazarus was the first to present a 'contextual approach to stress and coping' (Folkman and Moskowitz 2004), exploring the varying range of cognitive and behavioural responses which people use to manage stress and address the problem that is causing the stress. Significantly this work set a new course in research investigating the concept of coping and it began to emerge as a distinct area of psychological inquiry during the 1970s and 1980s (Coelho et al. 1974; Moos and Tsu 1977; Lazarus and Folkman 1984; Folkman and Lazarus 1985).

Simply put, coping has to do with how people manage life conditions and events which are stressful to them (Lazarus 1999). Correspondingly, the concept of coping is described by Lazarus and Folkman (1984) in their formative text which explored stress, appraisal and coping, as the psychological process by which a person struggles to manage the psychological stress that they are experiencing, proposing that stress is an inevitable aspect of everyday life. They go on to suggest that what makes the difference in human functioning is how people cope with the stress they experience. Significantly, they describe coping as a process by which an individual manages the demands of the 'person-environment relationship' (Lazarus and Folkman 1984) which has been appraised as stressful and the emotions which are generated as a result of this. The process is a dynamic one that is characterised by change, whereby a person makes continuous appraisals and reappraisals of the stress they are experiencing. As such, stress is a dynamic two-way process whereby the stressors are produced by the environment, but the individual finds the way to deal with the stressors.

Folkman and Moskowitz (2004) offer a similar definition of coping, describing it as the thoughts and behaviours which individuals use to manage the demands of a situation that has been appraised as stressful. Similarly, they too describe coping as a process which is initiated as a response to an individual's appraisal that important goals have been 'harmed, lost or threatened' (Folkman and Moskowitz 2004) and a process which is strongly associated with managing emotions and particularly distress as a result of the stressful situation.

The coping process described by Lazarus and Folkman (1984) proposes that cognitive appraisal is used as an evaluative process to determine why and to what extent a situation is perceived as stressful. It is a two-component process consisting of primary and secondary appraisal. In primary appraisal the individual assesses whether an encounter or event is irrelevant, benign-positive or stressful. Folkman and Lazarus (1985) describe an irrelevant encounter as having no significance for the person's well-being and therefore the person has no stake in its outcome and in a benign-positive event only a good outcome is signalled. However, a stressful appraisal is typified by threat, challenge or harm-loss, whereby threat refers to the potential for harm or loss, challenge refers to the potential for growth or gain and harm-loss refers to injury already done (Folkman and Lazarus 1985). Each of these appraisals is coped with differently.

Situations that are appraised as stressful (threat, challenge or harm) necessitate coping to regulate the distress they cause and utilise emotion-focused coping. Emotion-focused coping is used more commonly when stressful encounters or events are appraised as unchangeable (Folkman and Lazarus 1985) and something to be endured. Problem-focused coping involves confronting and seeking solutions to the situation or event causing the distress and this type of coping is used more commonly when the event or encounter has been appraised as changeable. These coping processes lead in turn to an event outcome which may lead to a favourable resolution, an unfavourable resolution or a lack of resolution (Folkman 1997). Furthermore, throughout the process of appraisal and coping, outcome emotions are generated; a favourable event outcome is likely to achieve a positive outcome and a conclusion of coping activity, conversely an unsatisfactory outcome such as an unfavourable or lack of resolution often leads to distress and the need for additional coping (Folkman 1997). The coping cycle then begins again with an appraisal of the event.

Secondary appraisal is concerned with the person evaluating their coping resources and options. It refers to a cognitive-evaluative process which focuses on establishing what can be done about the stressful situation and consists mainly of an evaluation of coping options, especially when there has been a primary appraisal of harm, threat or challenge (Lazarus 1999). Lazarus (1999) goes on to suggest that because threat or challenge is focused on the future, on what may happen, then the individual is often in a state of uncertainty because they have no definite idea of what will actually happen. Significantly, threat or challenge can occur simultaneously in the same situation, however, one or the other usually dominates. Lazarus (1999) emphasises that 'secondary appraisal' is not a less important process than 'primary appraisal' and summarises this by proposing that primary appraisal is an evaluation of whether an event or situation is worthy of attention and mobilisation, whereas secondary appraisal is focused on what can be done. He

further proposes that the differences between the appraisal processes are not about timing but rather the content of the appraisal and that there is an active interplay between the two appraisal processes in that the processes operate interdependently. If the demands of the situation exceed the level of coping resources then the individual affected is likely to experience psychological, physiological and behavioural responses to the stress that they are experiencing (Lazarus and Folkman 1984).

During chronic stress a meaning-based coping can be utilised which supports a more positive appraisal of the stressful situation (Folkman and Moskowitz 2000) - positive reappraisal coping. Lazarus and Folkman (1984) refer to this cognitive form of emotion-focused coping as a cognitive effort to change the meaning of a situation to something more positive. Positive reappraisal is an active coping strategy (Folkman 1997) which can be described as an effort to control the meaning of a problem by giving attention to the positive aspects of a situation. Folkman and Moskowitz (2000) define it as a cognitive strategy used to re-frame a situation into a more positive light (seeing a glass half full as opposed to half empty) and Garland et al. (2009) describe positive reappraisal as an adaptive process by which 'stressful events are construed as benign, valuable or beneficial.' In summary, positive reappraisal means choosing to take account of the positive as well as the negative aspects of a situation and appreciating that even the most challenging and difficult situations have some positive elements. Lancastle and Boivin (2008) make suggestions that some of the positive examples and benefits of a negative situation may include recognising that relationships have become closer as a result of the situation, appreciating the support or kindness shown by others during a challenging time, or evaluating one's circumstances more positively by comparing the situation with those who are in even more difficult situations.

This functional role of positive emotions within the context of stressful events was explored over thirty-five years ago when Lazarus et al. (1980) hypothesized that even under stressful conditions, when negative emotions are prevalent then positive emotions may provide some psychological respite and sustain efforts to cope. More recently Folkman and Moskowitz (2004) suggested that positive affect can co-exist with distress and that coping processes which generate and sustain positive affect during chronic stress involve meaning. They go on to propose that although negative affect is normally associated with stress, empirical evidence supports the function of positive affect.

An influential study by Folkman (1997) explored how positive psychological states could be present even when a person was suffering severe stress. The longitudinal study investigated the coping processes of partners caring for their terminally ill partners, dying from AIDS-related illnesses and established the co-occurrence of positive and negative psychological states in the

midst of enduring profoundly stressful situations. The study highlighted important implications for understanding the coping process, namely that four types of coping processes were associated with positive psychological states during caregiving and bereavement: positive reappraisal, problem-focused coping, spiritual beliefs and practices and infusing ordinary events with positive meaning. All of these types of coping involve the activation of beliefs, values or goals which help to define the positive significance of events (Folkman 1997). Prior to Folkman's research, theories of coping had concentrated on reducing distress felt as a result of the situation (Lazarus and Folkman 1984; Miller 1987; Moos and Schaefer 1993) and presumed that any positive emotion in coping and stress was usually associated with the 'cessation of an aversive condition' (Folkman 1997) and the relief associated with it. Significantly, Folkman's study concluded that even when the aversive condition persisted and did not cease, then persistent positive states existed, suggesting that the coping processes that generate positive psychological states help sustain renewed problem and emotion focused coping. Folkman goes on to suggest that the model of coping by Lazarus and Folkman (1984), should be modified to accommodate positive psychological states that can sustain coping even in the midst of chronic and sustained stress (see Figures 2 and 3 below).

Figure 2: Modified theoretical model of coping process: Original model (Folkman 1997)

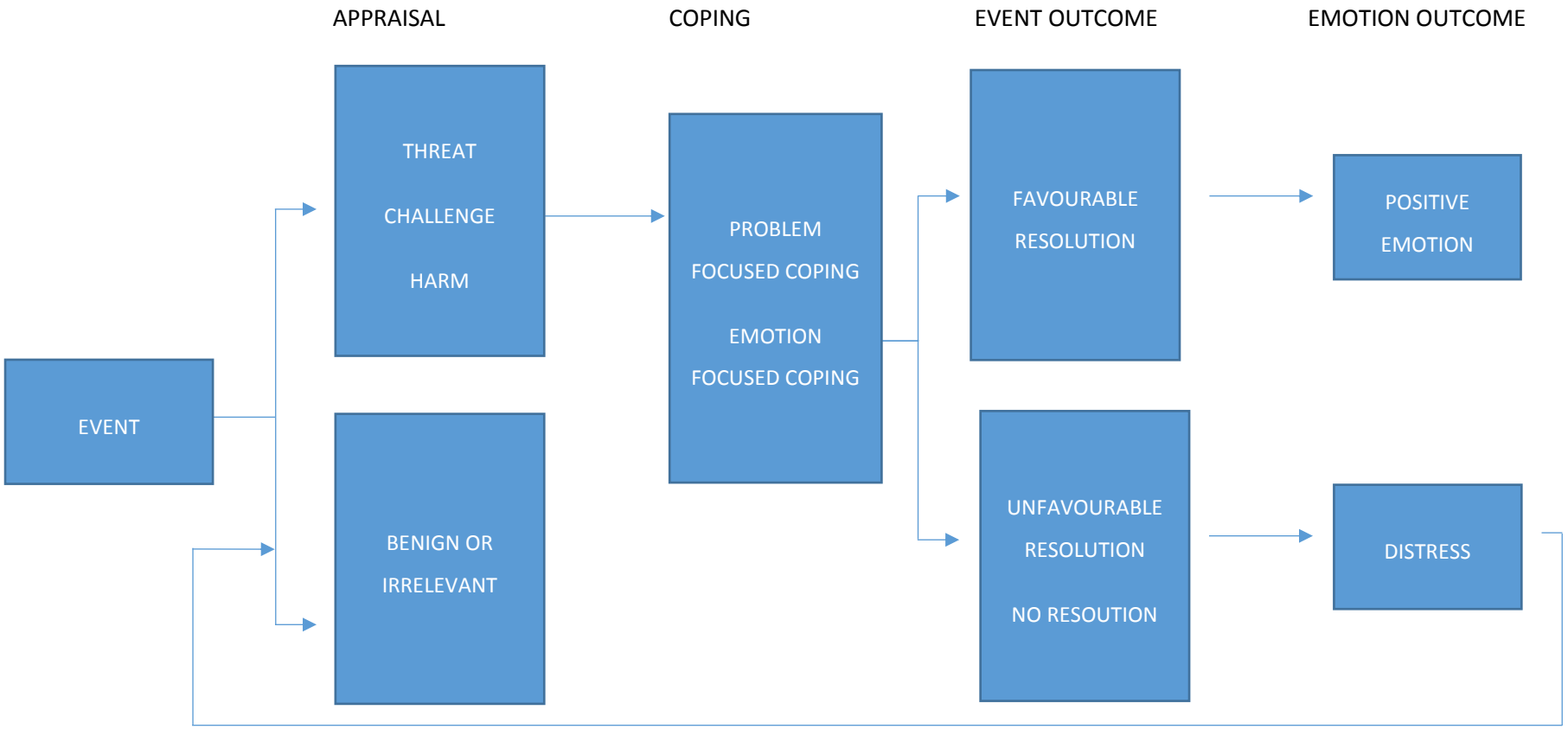
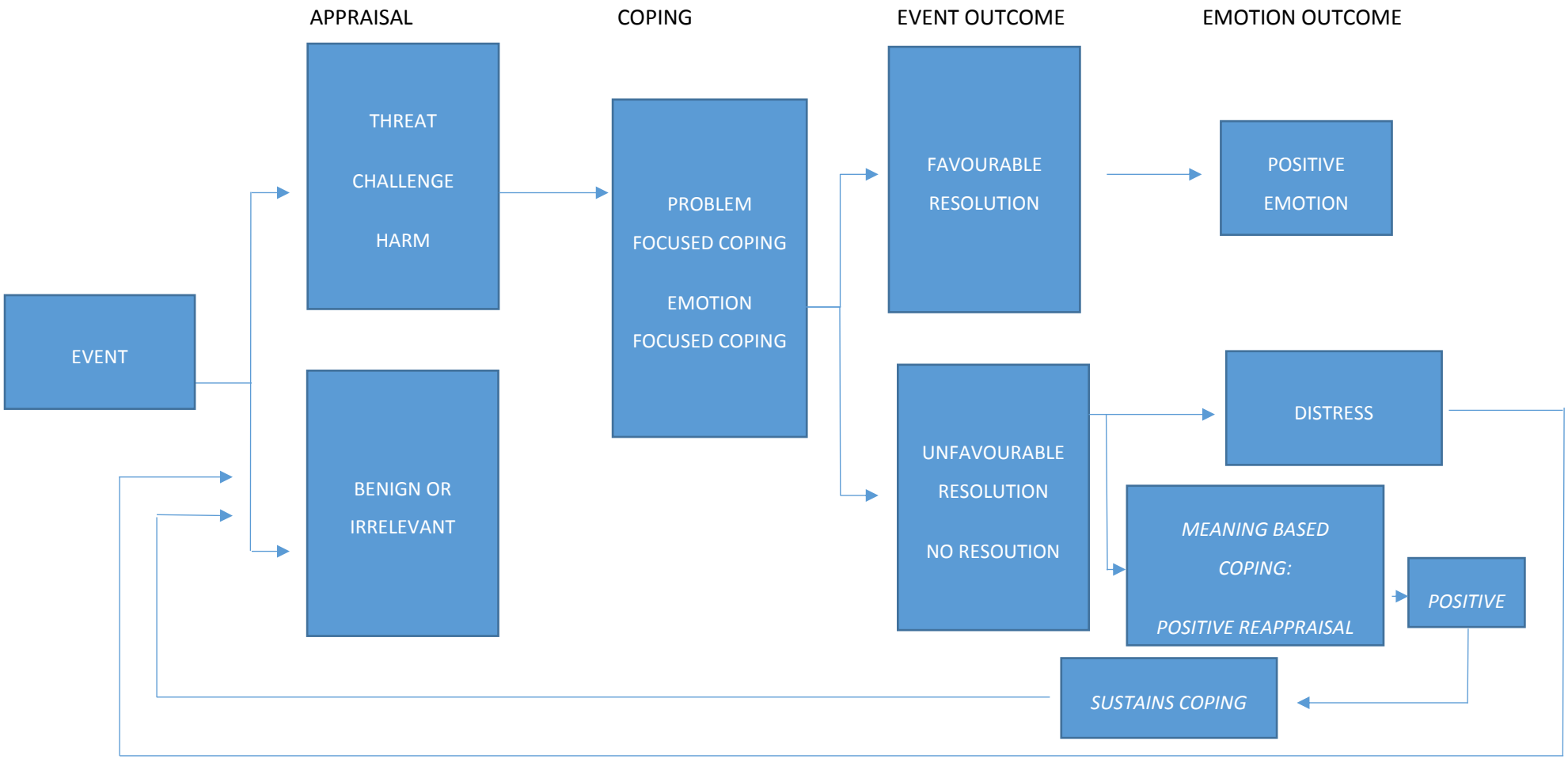


Figure 3: Modified theoretical model of coping process: Modified model (Folkman 1997)



In addition to Folkman's (1997) research investigating the coping processes of partners caring for their terminally ill partners, previous studies have also demonstrated that positive reappraisal has been successful at reducing stress levels for many other patient populations who are facing periods of sustained stress. These include those suffering from breast cancer (Manne et al. 2009), myocardial infarction (Santavirta et al. 2001) and brain injury (Moore and Stambrook 1992). Indeed, positive reappraisal appears particularly useful when the stressful situation includes an uncontrollable and unpredictable outcome. More contemporary studies have examined the use of positive reappraisal as a means of promoting coping in older adults with chronic physical illness (Nowlan et al. 2015) and in parents of children with autistic spectrum disorders (Rayan and Ahmad 2016). Both of these recent studies concluded that positive reappraisal can promote quality of life and emotional wellbeing in a stressful situation.

The reviewed evidence suggests that positive reappraisal is a useful and valuable coping strategy which can be a useful tool to help sustain coping processes during stressful periods of uncertainty. For women affected by recurrent miscarriage the waiting period of a new pregnancy brings with it a stressful period of uncertainty with an uncontrollable and unpredictable outcome. The psychological strain experienced by the woman and her partner can increase substantially as any excitement brought about by a positive pregnancy test is very quickly overshadowed by fear and anxiety that they will miscarry again. The affected woman has no ability to affect the outcome of the situation, nor is she able to predict the outcome and the difficult and challenging waiting time of a new pregnancy is something she has to endure. Meaning based coping, such as positive reappraisal, may provide some respite from the prolonged and unrelenting stress that these women experience and sustain their ability to cope with this stressful waiting time.

The Positive Reappraisal Coping Intervention (Lancastle and Boivin 2008) was developed as a short self-help card for use in medical waiting periods and found to be particularly effective when sustained coping efforts were required and therefore may provide a useful and effective self-administered strategy to women who have experienced recurrent miscarriage.

2.8 The Positive Reappraisal Coping intervention

In recent years a theoretically derived, short coping intervention, based on the concept of positive reappraisal, has been developed, originally for use during the time period in which women wait for the results of their pregnancy test following fertility treatment (Lancastle and Boivin 2008). This intervention, called the PRCI (Appendix A) was designed to promote positive reappraisal coping during the waiting period between embryo transfer (IVF) and a pregnancy test and aimed to encourage the positive re-evaluation of the situation and its meaning for the patient. Patients

were given a simple, pocket-sized card listing statements which were designed to prompt or promote positive reappraisal efforts and in addition to the PRCI women received a leaflet explaining the rationale behind positive reappraisal (Appendix D). This study (Lancastle and Boivin 2008) was designed and conducted by colleagues as part of a wider programme of developing support for women at critical points of complex pregnancies. It concluded that participants found the PRCI acceptable and beneficial in terms of supporting positive feelings during the IVF waiting period, and sustained their efforts to cope. The intervention was favourably evaluated by participants, who found it to be an acceptable intervention during the waiting period prior to the pregnancy test. Indeed, many of the participants were reluctant to discontinue the use of the PRCI. Evidence on the use of positive reappraisal see (Tedlie Moskowitz et al. 1996; Folkman 1997; Manne et al. 2009) suggests that this type of effort to redefine a challenging and difficult situation in a more positive way, could have benefits for emotional well-being during a range of different demanding life-events (Lancastle and Boivin 2008).

One of the key advantages of the PRCI approach is that it is convenient for patients and is easily deliverable at negligible cost. It is comprised of an explanatory leaflet describing positive reappraisal coping and its potential benefits as well as ten statements printed on a laminated card that users read at least twice a day to stimulate the use of this form of coping. Since use of the PRCI does not require clinic or hospital attendance or the direct involvement of a carer or health professional, it is very low cost. Lancastle and Boivin (2008) demonstrated that despite the fact that the women in their study had minimal contact with clinical or research staff during the waiting period, the intervention was still positively evaluated.

For women who have experienced recurrent miscarriage, the waiting period in the early stages of pregnancy shares many characteristics and stress factors with the waiting period after fertility treatment. Both waiting periods include outcomes which are unpredictable, outcomes over which the woman has no control and a waiting period which lasts several weeks. Both groups of patients may experience an increase in anxiety and worry and acute uncertainty about the outcome of this waiting period. Significantly, the psychological strain experienced by both groups and their partners is compounded by concerns and doubts about their ability to achieve a successful pregnancy, the possibility of a future child and their ability to become parents. The two groups of women share closely analogous experiences, and similarities between the characteristics and stress factors experienced in the two types of waiting period suggest that the PRCI is a potentially valuable as well as cost-effective intervention for women during the initial waiting period of a new pregnancy.

A focus group study (Ockhuijsen et al. 2013a) investigated how women with single or recurrent miscarriage cope during the waiting period of a new pregnancy and aimed to determine whether the PRCI could be used for women with recurrent miscarriage. Women were asked their opinion about the usefulness of the PRCI and many were of the opinion that the PRCI would be practical and applicable. Specifically, women with a single miscarriage did not want to use this or indeed any intervention, whereas women with recurrent miscarriage did. The study concluded that coping interventions targeting reappraisal of the stressful waiting period could be beneficial and that a form of the PRCI, specifically designed for waiting periods in recurrent miscarriage maybe indicated. More recently in a convergent parallel mixed method study, Ockhuijsen et al. (2015) explored the use of the PRCI by pregnant women who had a history of miscarriage. Twelve women participated in the study, but only five of these had been affected by recurrent miscarriage and therefore the study provided limited evidence on the use and acceptability of the PRCI by women who had experienced three or more miscarriages. However, the study did propose that although clear written instructions were given about the use of the PRCI, women adapted the use of the PRCI to suit their individual circumstances. These circumstances were based on the intensity of the emotions they were experiencing and their judgement on the effect of the PRCI. The study concluded that the PRCI could be offered to pregnant women with a history of miscarriage when they are experiencing uncertainty and loss of control in a new pregnancy, but that more research is necessary to assess the effect of the PRCI on this population. Given that only five of the research participants in this study (Ockhuijsen et al. 2015) had experienced recurrent miscarriage (three or more miscarriages), the feasibility study reported here is the next important step in assessing whether the PRCI can improve and sustain coping during the waiting period of a new pregnancy following recurrent miscarriage.

2.9 Quality of evidence

The complex and multi-faceted subject area of recurrent miscarriage requires the review of a wide breadth of work to ensure that all relevant literature which informed the study was identified and appraised. As expected, qualitative research makes up the majority of the literature reviewed which varied in its relevance and depth of analysis. However, the review also included randomised controlled trials, systematic reviews, guidelines and editorials.

A methodological limitation with many of the qualitative papers reviewed was that they commonly investigated the experiences of women who had suffered a variety of types of pregnancy loss. This included single miscarriage, recurrent miscarriage, still birth and neonatal death. Care was taken, however, not to generalise the results between single miscarriage/late pregnancy loss and multiple miscarriage and the available literature still provided a good source

of relevant data in addition to assisting in the identification of gaps in the evidence, which in turn helped with justification of the need for this study.

There appeared to be a better defined and developed body of evidence surrounding the physical management of recurrent miscarriage than the psychological management. However, within this literature there was some contradiction around the definition of recurrent miscarriage and the recommendations for the physical care of women affected by this condition depending upon the country of publication. With this in mind the UK guidance and recommendations regarding the care of women experiencing miscarriage (RCOG 2011; NICE 2012) was adhered to when considering and reviewing the physical management of this condition. A more international view was taken when reviewing literature regarding the psychological management of this patient group, with a significant number of relevant and valuable studies having been conducted in the Netherlands (Musters et al. 2013; Ockhuijsen et al. 2013a; Ockhuijsen et al. 2014c; Kolte et al. 2015b; Ockhuijsen et al. 2015), Scandinavia (Adolfsson et al. 2004; Jansson and Adolfsson 2011; Andersson et al. 2012) and the USA (Côte-Arsenault and Marshall 2000; Côté-Arsenault 2007; Cote-Arsenault and Donato 2011).

The majority of studies reviewed here explored the concept of psychological distress during pregnancy as a whole following recurrent miscarriage (Craig et al. 2002; Côté-Arsenault 2007; Swanson et al. 2009; Andersson et al. 2012; Musters et al. 2013), collecting data from the whole pregnancy at a single time point. They missed focusing on a time in the pregnancy that was likely to be particularly stressful and anxiety provoking, namely the first trimester. Studies which specifically explored the experiences and emotions of women during the waiting period of a new pregnancy following miscarriage were lacking. Only three papers were identified (Ockhuijsen et al. 2013a; Ockhuijsen et al. 2014c; Ockhuijsen et al. 2015) and these provided a particularly valuable source of information for this study. Although they were conducted using small samples, these qualitative studies consisting of a focus group study and a face-to-face interview study, explored in detail the coping strategies adopted by women with recurrent miscarriage as they wait for confirmation their pregnancy is ongoing. Furthermore, the comprehensive insight these studies provided about the experiences and emotions of woman affected by recurrent miscarriage and their amenability to the use of the PRCI, contributed significantly to this growing area of research and helped lay the foundation for this current study.

Another valuable source of information for this study was the pioneering work of Richard Lazarus and Susan Folkman (Lazarus and Folkman 1984; Folkman and Lazarus 1985; Folkman 1997) which although in some cases was originally published over thirty years ago still forms the basis of contemporary research into the psychological principles of stress, coping and positive appraisal

and remains extremely relevant. The founding evidence base provided by Lazarus and Folkman assisted considerably in the development of this study by generating a more comprehensive understanding of the complex psychological concept of the coping process and the role of positive reappraisal.

2.10 Study aim and objectives

Evidence from the review of the literature indicates that the PRCI may provide an acceptable, effective and cost effective intervention to help women who have experienced recurrent miscarriage sustain their ability to cope during the waiting period of a subsequent pregnancy. In light of this the main aim of this research study was therefore:

- To establish the feasibility and acceptability of performing future exploratory and definitive trials to determine the effectiveness of the PRCI in women who have experienced recurrent miscarriage and are awaiting the outcome of a subsequent pregnancy.

The study had the following specific objectives:

- To establish how suitable and acceptable the PRCI was for participants, including the observed and perceived impact, benefits and disadvantages;
- To establish how acceptable the proposed research methods were to the participants, including recruitment, randomisation, outcomes measures used, and methods of follow-up;
- To establish recruitment and retention rates to inform planning for a possible future multi-centre trial of the PRCI with this population;
- To establish if any refinement or adaptation of the PRCI or its guidance is necessary

2.11 Chapter summary

The aim of this literature review was to complete an initial overview of the available evidence on recurrent miscarriage and the waiting period of a subsequent pregnancy, identifying general themes and performing an in-depth synthesis of the available evidence base. As a result, relevant literature regarding the background, incidence, investigation and treatment of this specific disease entity was identified, and significantly, the profound effect of recurrent miscarriage on women who experience it has been established. Recurrent miscarriage is an extremely distressing condition and even after thorough investigation aetiological causes can be found in only 50% of cases. Frequently the cause is elusive or multi-factorial leading to intense frustration for the

affected woman and her health care team, as there is currently no effective treatment or therapy which can be offered. In order to address this condition appropriately and effectively, there is a need to develop a greater understanding of the causes, treatment and effects. Current research into recurrent miscarriage focuses on aetiology and the development of medical interventions to treat the condition. Other studies have reviewed the use of interventions to alleviate distress in the period immediately following miscarriage, but there is insufficient evidence relating to the effectiveness of support during the initial waiting period of a subsequent pregnancy or the way in which such support should be delivered.

This literature review has highlighted the potential value of the PRCI as a coping strategy to help women who have experienced recurrent miscarriage feel more positive and sustain their efforts to cope during the waiting period of a new pregnancy. Previous studies have indicated that this waiting period is associated with high levels of anxiety and distress for the affected woman, but a period of time when there is limited support and therapy available, mainly due to restrictions in resources of current health care service provision. This study is therefore an important step in a growing programme of research concerned with improving psychological well-being for women affected by recurrent miscarriage during the early stages of a new pregnancy.

Chapter 3: Methodology and Methods

3.1 Introduction

The choice of study design is one of the most important considerations of the research process as it impacts on all other stages (Lacey 2015). Selection of the appropriate approach can assist in ensuring credibility, objectivity and transparency of a research study and provide a useful framework for promoting rigorous, diligent and methodical research techniques. Therefore, the aim of this chapter is to present a concise and comprehensive overview of the selected study design and methodology utilised to address the specific aims and objectives of this research study and to justify and provide a rationale for this choice of approach.

3.2 Study Design

There were two main components to this feasibility study:

1. A two-centre randomised controlled feasibility study to test establish the viability of conducting a multi-centre RCT to test the hypothesis that the PRCI can improve the psychological well-being of women who have experienced recurrent miscarriage during the initial waiting period (1-12 weeks) of a subsequent pregnancy. This component of the study addresses the following key research questions:
    - How feasible and acceptable are the proposed methods of recruitment, randomisation, intervention and follow-up?
    - Is it possible to achieve acceptable recruitment and retention rates within each centre, taking into account defined inclusion/exclusion criteria?
    - Are the proposed study questionnaires and data collection methods appropriate?
    - Are the study time points for questionnaires and use of PRCI appropriate?
    - Is there a preliminary indication of an effect of the PRCI?
2. A qualitative process evaluation aims to explore in-depth women's subjective experience of the study intervention and research methods (including recruitment and randomisation strategies, study outcome measures and study time points) in order to provide information to refine the study intervention or any other aspects of research design (if required).

3.3 The Intervention

The PRCI (Appendix A) is a theoretically derived, short coping intervention, based on the concept of positive reappraisal with proven reliability and validity (Lancastle and Boivin 2008). It aims to promote positive re-evaluation of a challenging situation and consists of a small card containing 10 positive reappraisal statements which aim to encourage users to redefine the waiting period of a new pregnancy following repeated pregnancy loss more positively. An accompanying leaflet (Appendix D) provides concise guidance on the use of the PRCI. Specifically, participants were encouraged to read the PRCI at least twice a day, in the morning and in the evening, and any other time of day they felt the need. When reading the statements, the women were invited to consider and think about how each statement related to them personally. They were advised that thinking about the positive aspects of a difficult situation did not mean pretending that 'everything was wonderful' when they did not think it was, or ignoring the negative aspects of a difficult situation, but taking account of the positive aspects alongside the more negative aspects of the situation. The positive aspects of the waiting period would differ depending on personal circumstances, and the leaflet gave examples, for example focusing on the support and kindness friends and family were showing during their difficulties or how their relationship with their partner has strengthened because of the shared experience. The statements on the card were general and did not refer to any one specific positive aspect, as individual users had very different ideas about what was or was not positive. The participants were encouraged to put the small card in a purse or pocket so that they were able to remind themselves of the positive reappraisal techniques wherever and whenever they felt the need. The accompanying leaflet advised that the positive reappraisal technique could feel strange at first, but that the technique became easier the more it was practised.

3.4 Study Population

The study population consisted of patients attending the Recurrent Miscarriage Clinic and the Early Pregnancy Unit at two regional hospitals in the South of England, Site A and Site B.

3.5 Access and identification of participants

Discussion with the clinical teams in Site A and B and analysis of patient flow data through these centres established that there was a sizeable and suitable population who would meet the requirements for this study. Site A had a weekly Recurrent Miscarriage Clinic through which potential participants were identified. Although Site B did not have a Recurrent Miscarriage Clinic, access to potential participants at this site was negotiated with the Early Pregnancy Unit in this

hospital. The nurse in charge of this unit agreed to act as a gatekeeper for this study by identifying potential participants. However, it was anticipated that although there was a suitable population, the actual number of women who met the requirements for this study would potentially be less than in Site A which is a regional referral centre for recurrent miscarriage. In both units the clinical team members caring for recurrent miscarriage patients were asked to inform potential participants about the study and distribute the study Patient Information Sheet (PIS) (Appendix E). If the patient expressed an interest in taking part in the study, then they were asked if they would be willing to meet with the researcher and discuss the study in fuller depth.

3.6 Inclusion / Exclusion Criteria

Provided the potential participants were over eighteen years of age and able to give written consent to take part in the study, all women who attended the Recurrent Miscarriage Clinic in Site A and the Early Pregnancy Unit in Site B (providing they had a history of recurrent miscarriage) were eligible to participate in the study. However, exclusion criteria included if the woman was unable to speak English well enough to understand study materials and if the woman required fertility treatment to achieve a pregnancy.

Inclusion Criteria	**Exclusion Criteria**
Aged 18 or over	Unable to speak English well enough to understand study materials
Experienced 3 or more miscarriages	Fertility patient requiring treatment to achieve a pregnancy
Willing and able to provide written consent	

Table 2: Study inclusion and exclusion criteria

3.7 Study sample

3.7.1 Randomised controlled feasibility study

The sample size was not determined by a power calculation. The size of this feasibility study was determined by more pragmatic considerations. The referral rate for recurrent miscarriage patients was reviewed for both study sites, in addition to taking into account the existing patient population who were being seen in the Recurrent Miscarriage Clinic as part of follow up care. In Site A, a regional referral centre for recurrent miscarriage patients, general practitioner (GP) referral figures to the Recurrent Miscarriage clinic were reviewed for the year 2012-2013 and seventy-five women were referred during this time period. In Site B, an Early Pregnancy Unit (EPU), patients were referred by their GP or able to self-refer for assessment of early pregnancy complications. Unfortunately, specific quantitative metrics for the annual referral rate of recurrent miscarriage patients to this unit were not available therefore the researcher relied on estimates given by the EPU staff. Staff estimated that at least five eligible participants would be seen on average per month in Site B.

Having reviewed referral numbers and patient flow through the two study sites, it was estimated that approximately five eligible women would attend appointments in each centre each month. It was anticipated that a recruitment rate of 60% (conservative compared to other studies in this population) would yield a total of six patients a month to this study (three from each centre) over a recruitment period of one year.

The study sample consisted of two groups: the intervention group (Group 1) received the PRCI and study questionnaires in addition to the current recommended care pathway for RM patients. The control group (Group 2) received study questionnaires in addition to the current recommended care pathway for recurrent miscarriage patients. Initially it was envisaged that a maximum of 25 patients would be recruited to each arm over a twelve-month period, although one of the aims of this study was to investigate the actual time lag from recruitment (when the woman has experienced their most recent miscarriage) to randomisation (when participants inform the study team that they have had a positive pregnancy test). However previous research had indicated that this time period is likely to be relatively short, as many women who experience recurrent miscarriage become pregnant again quickly and have a short ‘time-to-pregnancy’ (Salker et al. 2010). Two of the aims of this study, however, were to investigate the actual recruitment rate to this study and the time lag from recruitment to randomisation and the outcome of this will be discussed in Chapter 4.

3.7.2 Qualitative process evaluation

Participants were selected purposively from those who had previously taken part in the RCT component of this study. Purposive sampling involves the selection of participants on the basis of certain criteria relevant to the research (Holloway and Wheeler 2010). This method of sampling is commonly used in qualitative research (Patton 2002) and is a means of collecting perspectives from as diverse a group as possible, which is particularly important when trying to understand whether an intervention is acceptable to a population. Therefore, for this qualitative component selection characteristics considered in the purposive sampling method included previous study group (control or intervention), ongoing pregnancy or miscarriage, ethnicity of participant, education level of participant and clinically important demographics such as age, comorbidity/ medical conditions and previous live births. It was envisaged that consideration of these characteristics would ensure that the views of varied participants were represented.

In practice, the majority of researchers aim for an initial sample size that is considered adequate and of a sufficient size to provide data which is detailed enough to answer the research questions (Hunt and Lathlean 2015), or in this case perform the process evaluation of this study. Therefore, in this study it was anticipated that a maximum of 20 participants would be interviewed as it was likely a sample of this size would provide sufficient data to identify key issues and themes.

Actual recruitment numbers for both the feasibility RCT and the qualitative process evaluation are presented in Chapter 4.

3.8 Recruitment and Randomisation

3.8.1 Randomised controlled feasibility study

3.8.1.1 Recruitment

The recruitment process for this study was completed in a manner which aimed to minimise the possibility of coercion or undue influence.

Potential participants were given initial information about the study in the form of a Patient Information Sheet (Appendix E) by their clinical care team (doctor, nurse specialist or nurse) when they attended the Recurrent Miscarriage Clinic or the Early Pregnancy Unit (EPU). The clinical care team asked the potential participant if they would be willing to speak to the researcher and find out more about the study. If the potential participant was agreeable, then a meeting was arranged at a convenient time and location to discuss the study in more detail with the researcher and ask any questions they may have (this may have been a telephone conversation if it suited

the potential participant better). Whilst potential participants were free to take as much time as they wished to consider their participation in the study they were asked to consent to taking part in the study prior to becoming pregnant. Once the participant had come to a decision to take part in the study then a face to face meeting between themselves and the researcher took place to sign the study consent form (Appendices F and G). If the researcher was absent, then a research midwife trained in taking consent for research studies and who was on the delegation log of the study took consent.

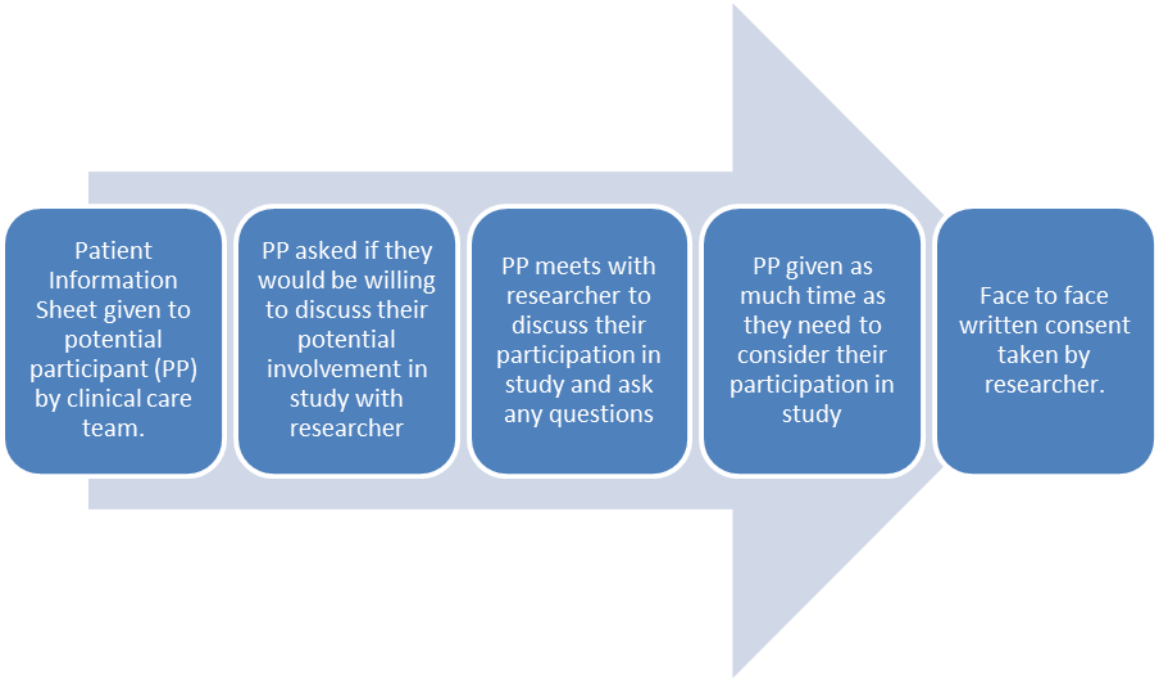


Figure 4: Diagram to show step-by-step consent process to RCT feasibility study

3.8.1.2 Randomisation

After consent the research participants were asked to notify the researcher as soon as possible after a positive pregnancy test either by telephone or email in order to enable randomisation, the aim being to achieve randomisation the same day or as soon after as possible. The researcher's contact details were provided to the participant on recruitment to the study.

Randomisation into one of the two study groups was carried out by the study statistician using an independent computerised randomisation system with a randomly sized block design with block sizes of 2, 4 and 6. The study population was stratified for those receiving concurrent medical treatment for recurrent miscarriage, those women with underlying medical conditions which were causative of recurrent miscarriage and number of previous miscarriages.

Participants were randomised into one of the two study groups. Participants allocated to the intervention group (Group 1) were asked to use the PRCI and received a weekly questionnaire assessment from the date of a positive pregnancy test until twelve weeks of pregnancy. The control group (Group 2) received a weekly questionnaire assessment from the date of a positive pregnancy test until 12 weeks of pregnancy. All study materials including the study questionnaires and the PRCI were posted to the participant at randomisation. If a participant experienced a further miscarriage during the study period, they were asked to notify the researcher and then exited the study. However, data from any completed questionnaires was included in the data analysis irrespective of whether the woman had an ongoing pregnancy or experienced another miscarriage before twelve weeks of pregnancy.

All participants were requested to return the completed questionnaires by post on a monthly basis and were provided with pre-paid envelopes addressed to the researcher.

3.8.2 Qualitative process evaluation

3.8.2.1 Recruitment

Participants became eligible to take part in the second qualitative component of the study once they had completed the first part of the RCT study. This included participants who had reached twelve weeks of pregnancy and had completed the use of the PRCI and weekly questionnaire assessment, or in the case of the control group, weekly questionnaire assessment and also those who had experienced another miscarriage. If a participant experienced a further miscarriage then they were still eligible to participate in the qualitative process evaluation component of the study, but care was taken to leave a suitable time period to elapse, before being approached and invited to take part in an interview. Participants were asked to indicate on the consent form for the RCT feasibility component of this study (Appendices F and G) whether they would be willing to be invited to take part in the qualitative component of the study. All participants who signed the consent form indicated that they were willing to be contacted.

Potential participants to the qualitative interview were then selected purposively from the cohort of patients who indicated a willingness to be contacted with regards to taking part in this part of the study. Potential participants received a PIS (Appendix H) which provided details of what their involvement in this part of the study would entail and they were given as much time as they wished to consider their participation. If they agreed to take part, then informed consent was taken by the researcher (Appendix I).

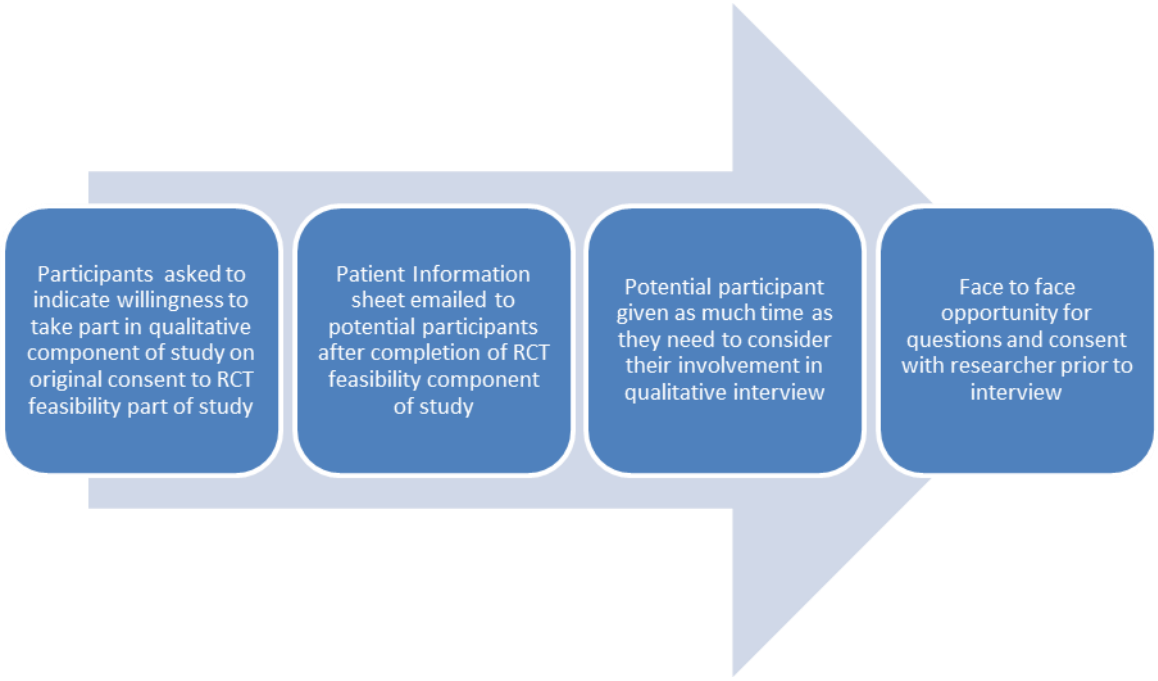


Figure 5: Diagram to show step-by-step consent process to qualitative process evaluation

3.9 Data collection

3.9.1 Feasibility RCT

3.9.1.1 Materials

3.9.1.1.1 Pre-intervention demographic questionnaire

Understanding the characteristics of a population is crucial when assessing whether an intervention is effective. This information helps to expand the knowledge of a study (Connelly 2013) and to ensure that the sample is representative of the population, aids replication in any future study and assists the detection of bias (Morse 2008). The pre-intervention questionnaire (Appendix J) was specifically designed for use in this study to capture relevant information. The information collected included demographic information (such as age and educational status), medical/psychological history (to identify any co-morbidities associated with recurrent miscarriage), gynaecological and reproductive history (fertility history, dates and number of live births and miscarriages) and the length of time the woman had been trying to have a successful pregnancy. It was envisaged that this information would lead to a comprehensive understanding of the characteristics of the study sample.

3.9.1.1.2 Outcome Measures

The Hospital Anxiety Depression Scale (HADS) (Zigmond and Snaith 1983) and the Weekly Record Keeping Form (a modified version of the Daily Record Keeping Form) (Boivin and Takefman 1995), were identified as primary outcome measures for this study. They had been used successfully in previous studies to evaluate the use of the PRCI (Lancastle and Boivin 2008; Ockhuijsen et al. 2013b; Ockhuijsen et al. 2014a), however, one of the feasibility objectives of this study was to assess the suitability of these questionnaires as outcome measures. The questionnaires assessed the psychological well-being in both study groups at specific time points during the early stages of a subsequent pregnancy. These study time points consisted of the day of a positive pregnancy test (or as soon after as possible) and then at weekly intervals until the woman was twelve weeks pregnant or experienced a further miscarriage.

For the purpose of this study the waiting period was defined as the time period from a positive pregnancy test until twelve weeks of pregnancy. This was because an early pregnancy ultrasound scan is normally performed at approximately twelve weeks gestation as part of routine antenatal care throughout the UK. Furthermore, extensive clinical experience caring for this group of women suggests that although anxiety levels in this patient group can remain elevated after this time period, they will generally start to decrease once the woman has seen a viable pregnancy at their ultrasound scan and as their pregnancy moves in to the second trimester.

3.9.1.1.3 Hospital Anxiety Depression Scale (Zigmond and Snaith 1983)

The HADS, devised over 30 years ago by Zigmond and Snaith (Appendix K), was specifically developed to measure anxiety and depression in a general medical population of patients. It is now commonly used by both clinicians and researchers alike as a tool for assessing the levels of anxiety and depression a person is experiencing. Stern (2014) suggests that this popularity may be due in part to its simplicity, ease of use and speed (taking approximately 2-5 minutes to complete).

The HADS has been shown to be a valid measure of the severity of anxiety and depression and is one of the tools recommended by NICE to be used to assist in the diagnosis of these conditions (National Institute for Health and Care Excellence 2011). Furthermore the scale has been validated in many languages, countries and settings including general practice and community settings (Stern 2014).

Whilst the HADS is a useful tool to aid initial diagnosis of anxiety and/or depression in an individual, significantly it can also prove valuable to help evaluate changes in a patient's emotional state over a period of time (Zigmond and Snaith 1983). As such, utilising the HADS as

an outcome measure in this study made it possible to monitor any changes in the anxiety and depression of the research participants throughout the initial waiting period of a new pregnancy following recurrent miscarriage.

The HADS questionnaire consists of 14 items (seven questions for anxiety and seven questions for depression) and are rated on a four-point Likert scale. Although the anxiety and depression scores are interspersed within the questionnaire, they should be scored separately; the total score is the sum of the 14 items, and the subscale score is the sum of the respective seven items. The scores on each subscale are interpreted in ranges 0–7 (normal), 8–10 (mild), 11–14 (moderate) and 15–21 (severe) – (seeTable 3)

HADS score	
For both scales, scores of less than 7 indicate non-cases	
8-10	Mild
11-14	Moderate
15-21	Severe
Note: Score anxiety and depression separately	

Table 3: To illustrate association between HADS score and severity level of anxiety and depression (Stern 2014)

3.9.1.1.4 Daily Record Keeping Form (Boivin and Takefman 1995)

The DRK was originally developed as a method of making daily assessments to measure the levels of emotional, physical and behavioural reactions during fertility treatment (Boivin and Takefman 1995). Previous and ongoing research at this time with fertility patients had demonstrated that one of the most stressful periods of treatment recalled by this patient group was the period of time following fertility treatment when the woman was waiting to see if her treatment had been successful (Boivin 1997). Boivin (1997), a specialist fertility psychologist, concluded that her previous research suggested that it was not the type of fertility treatment that was important in predicting stress levels, but in particular the period spent waiting to discover whether treatment had been successful or not. The DRK was therefore specifically developed to measure and explore the emotional reactions across the stages of fertility treatment as no measure previously existed

which was sensitive to the types of reaction women might experience during treatment or the changes in reaction across the treatment cycle.

During the development of the DRK, various versions were tested in studies with fertility patients (Boivin and Takefman 1995, 1996; Lancastle 2006) with any necessary revisions and refinements made. Validity for the DRK was established by demonstrating that it was sensitive to the expected emotional and physical changes and reactions during cycles of fertility treatment (Boivin and Takefman 1996; Boivin 1997) and acceptability and feasibility measurements confirmed that the DRK was a feasible measure to implement in the context of IVF treatment (Boivin 1997). Furthermore, women who used the daily record keeping form during IVF treatment found the daily monitoring procedure to be acceptable and easy to use (Lancastle 2006).

The final version of the DRK comprises of 46 possible reactions to the IVF waiting period. Users of the DRK are asked to indicate if they have experienced an emotion or reaction (for example happy, sad, anxious) and to what extent they have felt that way in the previous 24 hours. The emotions and reactions are rated on a scale from 0-3 (higher scores representing more intense emotion) and correlate with the positive and negative emotion subscales that (Folkman and Lazarus 1985) suggested were the emotional counterparts of an appraisal of a particular situation. Negative emotions include threat (for example anxious, nervous, tense and worried) and harm emotions (for example disappointed, sad and discouraged). Positive emotions include challenge emotions (for example confident, encouraged and positive) and benefit emotions (for example content and happy).

The DRK has been used to rate daily emotions, physical symptoms, reactions and appraisals in multiple fertility studies (Boivin and Takefman 1995, 1996; de Klerk et al. 2008) during the waiting period (between treatment and a pregnancy test to assess whether the treatment has been successful) on a daily basis. More recently the DRK has been used in research studies in conjunction with the PRCI to monitor the intervention's effects on psychological well-being of fertility patients during the waiting period of their fertility treatment (Lancastle and Boivin 2008; Ockhuijsen et al. 2013b; Ockhuijsen et al. 2014b) .

For the purpose of this study changes were made to the wording of the DRK to reflect the fact that this study is concerned with the waiting period of a new pregnancy following recurrent miscarriage as opposed to the waiting period following IVF. For example, Section 4 in the original DRK is entitled 'Ways of coping with fertility problems.' This section title was changed to 'Ways of thinking about waiting for my twelve-week scan' in the DRK used in this study. The changes were approved by the original DRK's authors, Professor Jacky Boivin and Dr. Deborah Lancastle who were satisfied that these changes would not affect the validity of the questionnaire.

Due to the burden of daily monitoring and potential reactivity the DRK (Ockhuijsen 2014), the form was used only at weekly intervals during this study. As such, to avoid confusion for research participants the questionnaire was re-titled the 'WRK' (Weekly Record Keeping form) for the duration of the study (Appendices L and M).

3.9.2 Qualitative process evaluation

Data were collected face-to-face, during semi-structured interviews that took place at a convenient place and time for the participant. Participants were given the choice of attending the hospital for the interview or the researcher visiting the participant at home.

Interviews are one of the most commonly utilised data collection methods within qualitative research and one classic text on interviewing has described them as conversations with purpose (Webb and Webb 1932). Furthermore (Tod 2015) proposes that interviews are able to generate rich data which reflect the perspective of the participants, also stating that this method of data collection is particularly useful when the research focus is a sensitive area.

The interviews followed a topic guide (see Appendix N) in order to help ensure the 'right degree of consistency' (Arthur et al. 2014) in data collection, however this still enabled the necessary flexibility to ensure the exploration of detail that was pertinent to each participant. As such, the topic guide was not intended to be prescriptive but steered the general form of the data collection. The topic guide for this study was developed and based upon the study aims, a review of current literature and discussion with Patient Public Involvement (PPI) representatives and the study supervisory team.

The interviews were scheduled to last for between thirty and sixty minutes and were audio recorded and then transcribed verbatim.

3.10 Data analysis

3.10.1 Feasibility RCT

Descriptive statistics were used to explore the feasibility of the study procedures (numbers of eligible women, recruitment and retention rates and missing data) for each centre. Psychological well-being measures (the HADS and the WRK) were summarised and changes over the time course of the study examined informally by study statistics and graphical displays. The relationship between physical symptoms, psychological well-being, appraisals and coping were explored, again through informal methods, such as graphical displays.

The aim of a feasibility study is to focus on methodological issues rather than outcomes or effect of the intervention (Bugge et al. 2013), furthermore this type of study is not designed or powered to assess the effectiveness of an intervention and this should be the objective of a future definitive study (Lancaster 2015). McGrath (2013) suggests that given that feasibility studies are under-powered with small sample sizes, then it is only possible to use their results to generate beliefs that there will be a trend towards significance and it is this trend will provide support for a larger study. Correspondingly Thabane et al. (2010) propose that feasibility studies should provide only preliminary evidence on the clinical efficacy of an intervention. Hypothesis testing and tests of treatment effectiveness should not be an objective of a feasibility study and instead emphasis should be placed on confidence interval estimation (Lancaster 2015).

Careful consideration was given to how to statistically assess any indication of effect size between the control and intervention group in this feasibility study. The above papers suggest that the main objective should not be to test treatment effectiveness, but rather to provide preliminary evidence on any trend towards significance. As such a decision was made to make an informal assessment of an indication of any effect or impact of the PRCI, using descriptive statistics and graphical displays to compare and contrast the psychological measurement scores within the control and intervention groups. These preliminary results and their potential impact will be discussed further in Chapter 6 – Impact of the Intervention.

3.10.2 Qualitative process evaluation

The aim of the qualitative interview component of the study was to focus on the process evaluation aspects of the study.

The Medical Research Council (MRC) describe a process evaluation as a method of exploring the way in which a study intervention is implemented, suggesting that it also provides important information about how or why an intervention fails, has unexpected consequences or, if successful, how its effect can be optimised (Moore et al. 2015). Process evaluations are therefore now being seen as an integral and important part of the development of complex interventions. Indeed, the MRC have recently developed concise guidance and a suggested framework for conducting and reporting process evaluation studies (Moore et al. 2015) which emphasises the relationship between implementation, mechanism and context of an intervention. Significantly the framework suggests that the focus of the process evaluation will vary according to the stage at which it is conducted, further proposing that at the feasibility and piloting stage of an intervention, a process evaluation can play a vital role in understanding the feasibility of the intervention and optimising its design and evaluation (Moore et al. 2015). As such, the

information gained from the qualitative process evaluation in this feasibility study provides a useful and important extension to the quantitative feasibility findings by providing increased insight into the acceptability of the PRCI in this patient group and a better understanding of any necessary refinements or adaptations to the intervention, which may be required before a definitive RCT.

The aim of qualitative analysis is to unravel the plethora of data, make sense of the phenomena which are under investigation (Parahoo 2014) and transform data into findings (Patton 2002). Previous papers have criticized the large amounts of data generated in qualitative health care research and suggested the analytical procedures utilised to explore the data lack clarity and transparency (Murphy et al. 1998; Andersson et al. 2012). One of the key challenges of qualitative analysis is constructing a framework to assist in the communication of what it is the data reveals (Patton 2002). Therefore, an important consideration in this qualitative process evaluation was to select a method to aid analysis of the data that ensured the process was clear, organised, rigorous and defendable.

Numerous traditions, theoretical guidelines, approaches, frameworks and procedures are available to support the analysis of qualitative evaluative data in a systematic and transparent way (Patton 2002; Thomas 2006; Spencer et al. 2014b). However Patton (2002) stresses that the application of these guidelines and procedures requires judgement and creativity acknowledging that each qualitative study is unique and selection of an appropriate approach should also depend on the skills and insights of the inquirer. With this in mind, careful consideration was given to selecting the most fitting approach to assist with the analysis of the process evaluation data from this feasibility study.

In inductive analysis, findings emerge out of the data (Patton 2002) without the restraints of structured methodologies (Thomas 2006) and it involves the determining of patterns, themes and categories within the data. Thomas (2006 p238) proposes that a five-step general inductive approach provides a 'straight forward approach for deriving findings in the context of focused evaluation questions' and although he suggests that this strategy is apparent in much qualitative analysis (for example, Dey 1993; Bryman and Burgess 1994), his paper explicitly describes the key features of this approach and outlines a set of procedures to assist with analysis. The general inductive approach described by Thomas (2006) is cited in over 900 recent papers.

Given the nature of the evaluative data generated in this process evaluation component of this feasibility study, this visible and systematic approach was selected as an appropriate method to facilitate transparent and robust analysis. The process of analysis will be explored and examined in detail in Chapter 5 – Qualitative Process Evaluation: Analysis and Findings.

In order to further promote integrity and reliability during the data analysis process, other strategies were introduced:

- Field notes were written immediately after the interview and a reflective diary maintained, aiming to reduce the potential for the researcher's values, beliefs and pre-conceptions to influence subsequent findings (Polit and Hungler 1997).
- Other members of the research supervision team were asked to examine parts of the transcripts to compare their perceptions of the interview data with the researcher's interpretation.

3.11 Ethical considerations

Health care research is complex and ethical implications present at every stage of the research process (Parahoo 2014). If the rights and safety of research participants are to be respected and maintained, then there needs to be careful consideration of the ethical aspects of any study at all stages of the research process. Although it is not always easy to prioritise ethical issues in health care (Iphofen 2005) , Johnson and Long (2006) identify that the main ethical issues which require diligence and planning in research studies include the informed consent process, the maintenance of confidentiality and the need to respect research participants, responding to their vulnerability. This research study was developed and planned with these main ethical issues in mind.

3.11.1 Ethical Approval

Ethical approval for the study was obtained from the National Research Ethics Service (NRES) local committee in October 2013. Approval for the study was given at the first committee meeting, however the panel did request further clarification on whether the qualitative interviews would be structured or not, and asked for reassurance that potential participants would not be asked to agree to take part in the study after their initial appointment. Clarification was given that the interviews would be semi structured and a topic guide was submitted to the Ethics committee for approval and the board was reassured that potential participants would be given as much time as they needed to decide if they wished to take part in the study.

There were some ethical issues which needed specific consideration in view of the sensitive nature of the research. These included informed consent, support of the participants, support of the researcher and confidentiality and anonymity.

3.11.2 Informed Consent

The principles of the International Council on Harmonisation (ICH) described in the Guide to Good Clinical Practice (GCP) guidelines (NIHR CRN Workforce Development 2011) highlight the need to ensure that freely given informed consent is obtained from every subject prior to clinical trial participation. It also refers to the fact that the rights, safety and well-being of study participants should be the most important consideration and prevail over all over interests of science and society. This guidance was adhered to in the study. Potential participants were identified by their clinician and asked if they would be interested in finding out more about the study. They were given detailed written information regarding the study in the form of a Participant Information Sheet and invited to discuss the study in greater detail if they wished with the researcher or one of the research midwives who worked on the study giving them the opportunity to ask any questions. The potential participants were given as much time as they needed to consider their involvement in the study and reminded that their participation in the study was voluntary and they were free to withdraw at any time without their health care being affected.

3.11.3 Support for Research Participants

This research involved a potentially vulnerable patient group who had all experienced recurrent miscarriage. Care was taken from the outset to ensure their health and wellbeing. The Participant Information Sheet included the contact information of the Miscarriage Association, the national support group for women who have experienced miscarriage (see Appendix E).

Previous studies have demonstrated that women using the PRCI strongly recommend its use to others (Lancastle and Boivin 2008) and that women who had experienced miscarriage did not report any negative experiences from using the PRCI (Ockhuijsen et al. 2013a). In light of this any negative effects regarding the safety and wellbeing of study participants due to the specific use of the PRCI were not anticipated. Nevertheless, participants were being asked to complete questionnaires and participate in interviews at a time when their anxiety levels were likely to be raised, namely during the early stages of a subsequent pregnancy and potentially after a miscarriage. Responding to the vulnerability of a client group has been identified as one of the main ethical issues in health care research (Johnson and Long 2006) and participants in this study were reminded of the voluntary nature of their participation in the study and the option of withdrawing at any stage.

Care was taken to ensure that if a participant agreed to take part in a qualitative interview, then this was arranged at a time and location convenient to the woman. It was important that the interview took place in a quiet and private place where the risk of interruption was minimal and

the interviewee felt at ease. The locations normally suggested by the researcher were at the hospital, in a private clinic room or at the participant's home. The interview was undertaken in a sensitive manner and if the participant showed any sign of distress or fatigue, then they were offered the option of suspending the interview while they recovered or resuming at a later date. Some of the women became tearful during the interview as they recounted their feelings and experiences. However, no participant wished to suspend the interview and in all cases participants indicated that they wanted to continue sharing their story, often adding that they found it helpful to be able to discuss these experiences.

Prior to the interview, support mechanisms were discussed with the participants including who would be at home to provide support if required and who they had to discuss their feelings with. They were reminded of the Miscarriage Association contact details in case further specialist support was required.

Significantly, although this study was investigating a sensitive subject with a potentially vulnerable group, previous personal experience of researching sensitive topics in the area of reproductive health suggests that women seem to appreciate the opportunity to contribute to a personally relevant field of investigation. Indeed, every participant in the study has highlighted the importance of helping other women who were in their situation.

3.11.4 Confidentiality and Anonymity

This study was designed and conducted to meet the requirements of the Data Protection Act (1998) and the Caldicott Principles (1997). Individual participant information obtained as a result of this study is confidential and each participant was allocated a unique study number at recruitment. All study materials were anonymised, except for the consent form, and only linked to participants by the personal code number assigned upon entry to the study. All coded hard data such as questionnaires were held securely in a filing cabinet in a locked office on NHS property. Only the research team had access to the cabinet and the master-list that links personal code numbers with identifying information. Anonymised coded data stored on the computer were password protected and stored on a university computer.

3.12 Chapter summary

This chapter has detailed the selected study design and methodology used in this RCT feasibility study and process evaluation, outlining the study population, the recruitment and randomisation methods and the data collection and analysis methods. Given the sensitive nature of this research area and the potential vulnerability of the study population, attention has also been given to the

ethical considerations of this study. The theoretical background to feasibility studies and qualitative process evaluations, which was discussed in Chapter 1, provided the justification for and rationale behind the approach and methodology in this feasibility study of a coping intervention for recurrent miscarriage.

Chapter 4: Quantitative Feasibility Findings (Study Processes)

4.1 Introduction

This chapter will present the quantitative feasibility findings. These specifically reviewed the study processes involved in the recruitment process, the randomisation process, the study outcome measures and the use of the study intervention.

The initial section of this chapter seeks to clarify the background and theoretical perspectives surrounding the reporting of feasibility studies by reviewing and exploring the emerging literature on the subject. It aims to establish how the setting of appropriate study objectives can assist in promoting the scientific rigour of a feasibility study and thus ensure effective and applicable reporting. This in turn will help set out a framework, which is consistent with the current recommendations for reporting feasibility studies, within which to present the findings of this feasibility study.

The second section of this chapter will utilise the suggested framework to present the quantitative feasibility findings from this study. It will assess whether the methodological approaches selected in this study are robust and achievable and address the issues of feasibility around each of the study processes.

4.2 Background

A feasibility study is described by the NIHR glossary as a piece of research done before a main study in order to answer the question, 'can it be done?' and to estimate the important parameters which are needed to design a main study (NIHR 2011). It is therefore intended to guide the planning of a large scale intervention by exploring the uncertainties in trial design and its main purpose is to increase the likelihood of success of the intervention in a large scale study and to help justify the investment of finances and time in a future study (Charlesworth et al. 2013). Feasibility studies are therefore essential components of planning and preparing for a large-scale randomised controlled trial (Thabane et al. 2016) and are often a pre-requisite before research grants can be secured from major funding bodies.

Despite the noted significance of feasibility studies, it is only in recent years that this type of study has received attention in scientific research training (Thabane et al. 2010). Of late there has been

an emergence of methodological literature which specifically focuses on the significance, management and the methodological theory which underpins feasibility type studies (Lancaster et al. 2004; Thabane et al. 2010; Shanyinde et al. 2011; Charlesworth et al. 2013; Hoddinott 2015; Lancaster 2015; Thabane et al. 2016). Furthermore, in the past feasibility studies have been described as the 'black box' or 'Cinderella' of complex intervention trial design with many scientific journals reluctant to publish the findings of such studies (Hoddinott 2015). However, this too is changing with the protocols and findings of more feasibility studies being published in notable journals such as BMJ Open. Indeed, the protocol for this feasibility study was published in BMJ Open in June 2015 (Appendix O). Significantly a new open access journal, 'Pilot and Feasibility Studies' began publishing in 2015 and focuses specifically on pilot and feasibility studies which are in preparation for randomised controlled trials (Lancaster 2015).

Thabane et al. (2010) propose that one reason for the lack of publication of feasibility studies in the past is due to the way that the results were presented, in that the authors incorrectly focused more on the statistical significance of the intervention rather than addressing the issues of feasibility. They go on to suggest that in the past feasibility projects were frequently poorly designed in that no clear feasibility objectives were set, no clear analytic plans were made and significantly no clear criteria for measuring the success of feasibility were formulated. Furthermore Eldridge et al. (2013) propose that this failure by researchers to understand the purpose of feasibility studies and therefore answer and address important questions at the feasibility stage can result in less efficient definitive trials testing and less effective interventions.

Lancaster et al. (2004) discuss the importance of ensuring methodological rigour is maintained in a feasibility study, proposing that evidence of this would improve the chance of publication. In a more recent publication (Lancaster 2015) goes on to suggest that a significant area of concern in previously published feasibility studies has been around the setting of inappropriate objectives for conducting a feasibility study and that one way to ensure that the study embraces a feasibility methodological focus and is scientifically valid is for the study to possess appropriate feasibility aims and objectives. Rather than focus on the effectiveness of an intervention (which feasibility studies are not designed or statistically powered to do), objectives for a feasibility study must 'stipulate the issues of uncertainties to be addressed' (Lancaster 2015). The setting of appropriate feasibility objectives provides a methodological framework within which to set the study, measure the success of feasibility and importantly to assist in the effective reporting of scientifically valid results.

A list of recommendations for good practice in relation to the design of feasibility studies was first published in 2004 (Lancaster et al. 2004) and it outlined seven evidence-based key objectives

which, if adhered to, would improve the scientific rigour of a feasibility study and aid the interpretation of its results. The seven objectives consisted of the need:

1. To test the integrity of the study protocol for the future trial
2. To gain initial estimates for future sample size calculation
3. To test data collection forms and questionnaires
4. To test the randomisation procedure
5. To estimate recruitment and consent rates
6. To determine the acceptability of the intervention
7. To select the most appropriate outcome measure.

A more recently published tutorial by Thabane et al. (2010) also noted the importance of setting clear criteria to assess the success of a feasibility study. These criteria should be based on the primary feasibility objectives as it is these which provide the basis for interpreting the results and determining whether it is feasible to continue on to a main study. Pointedly the tutorial by Thabane et al. (2010) proposes that, in general, the outcome of a feasibility type study should conclude with one of the following recommendations:

1. *Stop* – main study not feasible
2. *Continue but modify protocol* – feasible with modifications
3. *Continue without modifications but monitor closely* – feasible with close monitoring
4. *Continue without modifications* – feasible as is

Despite the increase in methodological guidance for feasibility studies from authors such as Lancaster et al. (2004) and Thabane et al. (2010), other research seems to suggest that this type of study still experiences poor publication rates, a lack of clarity in objectives and methodological focus (Eldridge et al. 2013) and poor reporting of findings. Indeed a study by Shanyinde et al. (2011) which reviewed published pilot and feasibility trials concluded that the large majority of studies which were meant to be addressing feasibility most commonly focused on efficacy (therapeutic effect) and failed to primarily address the necessary methodological issues preparatory to planning a subsequent large scale study.

In summary, it appears that despite the important part feasibility studies have to play in ensuring that the methodological approach taken in the main study is robust and achievable, many still fail to address key feasibility objectives and to discuss and address the issues of uncertainty that might affect the planning of a subsequent definitive study.

Many prominent authors on the subject of feasibility share the view that the intention for further work is often left far too vague in the reporting of feasibility studies (Lancaster et al. 2004; Bugge et al. 2013; Lancaster 2015; Eldridge et al. 2016). This type of study frequently appears to lack any clear criteria for measuring the success of the feasibility study and no clear analytical plans to review the study. One possible example of a framework to assist in the decision-making process around feasibility studies is offered by Bugge et al. (2013). Their research provides a comprehensive example of a feasibility study of a complex intervention to aid pelvic organ prolapse but the authors also discuss the need for researchers to respond to feasibility study findings in the correct manner so that problems identified within the feasibility stage have appropriate solutions. The paper puts forward the ADePT process (A process for Decision-making after Pilot and feasibility Trials) as a way to enable this. The authors describe this process as possessing three steps: a decision about the type of problem, the identification of solutions and a systematic appraisal of the identified solutions (Bugge et al. 2013). The process can therefore be utilised to help categorize and appraise problems and uncertainties arising from a feasibility study and improve the transparency of the decision-making processes as a result of the study.

Other than Bugge et al. (2013) there has previously been limited guidance available on how to best report feasibility studies, resulting in major inadequacies in the reporting of pilot and feasibility studies. With this lack of guidance in mind, a consortium of national specialists in feasibility and pilot studies have recently developed Consolidated Standards of Reporting Trials (CONSORT) extension guidelines which provide specific guidance on the reporting of pilot and feasibility studies (Eldridge et al. 2016). The motivation to develop this extension to the CONSORT statement was primarily due to an increase in the number of studies described as pilot or feasibility, but also the fact that a significant number of these published studies had identified weaknesses in their conduct and reporting (Eldridge et al. 2016).

The original CONSORT statement was initially published in 1996 (Schulz et al. 2011) and was last updated in 2010 (Schulz et al. 2011). The main aim of CONSORT is to offer an evidence-based minimum set of recommendations for reporting trials (CONSORT 2010), aiming to improve the transparency and quality of the reporting of RCTs (Eldridge et al. 2016). The CONSORT statement is endorsed by numerous prominent medical journals and previous research has demonstrated that utilisation of the statement has led to an improvement in the quality of the reporting of RCTs (Turner et al. 2011)

Interestingly the recent extension to the CONSORT statement (Eldridge et al. 2016) makes no distinction between pilot and feasibility randomised trials, suggesting that it is not possible to define the terms pilot and feasibility study in a mutually exclusive way, which fits with current use

within the research community. However, work done in parallel to the CONSORT extension has designed a conceptual framework to assist in the definition of feasibility and pilot studies (Eldridge et al. 2016). It concluded that researchers view feasibility as an over-arching concept, stating that all studies done in preparation for a main study should be referred to as a feasibility study. Pilot studies are a sub-set of a feasibility study which ask the same questions about feasibility (whether the future trial can be done?) but also have a particular design feature whereby part or all of the future RCT is conducted on a smaller scale (Eldridge et al. 2016). For ease and succinctness, the recent CONSORT extension uses the term 'pilot trial' in its statement. However, it sets no restrictions on the terminology used to describe this type of study and gives examples of other terms which can be used (for example pilot RCT, pilot study, randomised pilot study, feasibility study, feasibility RCT, randomised feasibility).

In order to promote methodological rigour and ensure an accurate and appropriate feasibility assessment is made, this chapter will utilise the CONSORT checklist guide to ensure all of these elements are included in the findings from this feasibility study of a coping intervention for recurrent miscarriage. However, the previous work of Lancaster et al. (2004) also provides a specific and practical framework to assist with this by highlighting the importance of having a clear list of aims and objectives to promote methodological rigour and study validity. Lancaster et al. (2004) propose that the following evidence based key objectives should be present in a feasibility study. They include:

- The recruitment process
- The consent process
- The randomisation procedure
- The study data collection forms/questionnaires
- The acceptability of the intervention to study participants
- A formal sample size calculation for a future definitive study

The next component of this chapter will present the findings of this feasibility study of a coping intervention for recurrent miscarriage. Each of the following sections will address one of the aspects of feasibility outlined by (Lancaster et al. 2004), utilising this as a framework to assist in the reporting of this feasibility study. Furthermore, rigorous attention will be paid to the recent CONSORT extension guidance for reporting pilot and feasibility studies.

A Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Figure 6) illustrates the flow of participants through each stage of this feasibility randomised controlled trial of a coping intervention for recurrent miscarriage for the duration of the study. The numbers shown

represent the combined total from both research sites A and B, specific numbers from each individual site will be explored and discussed at a later point in this chapter.

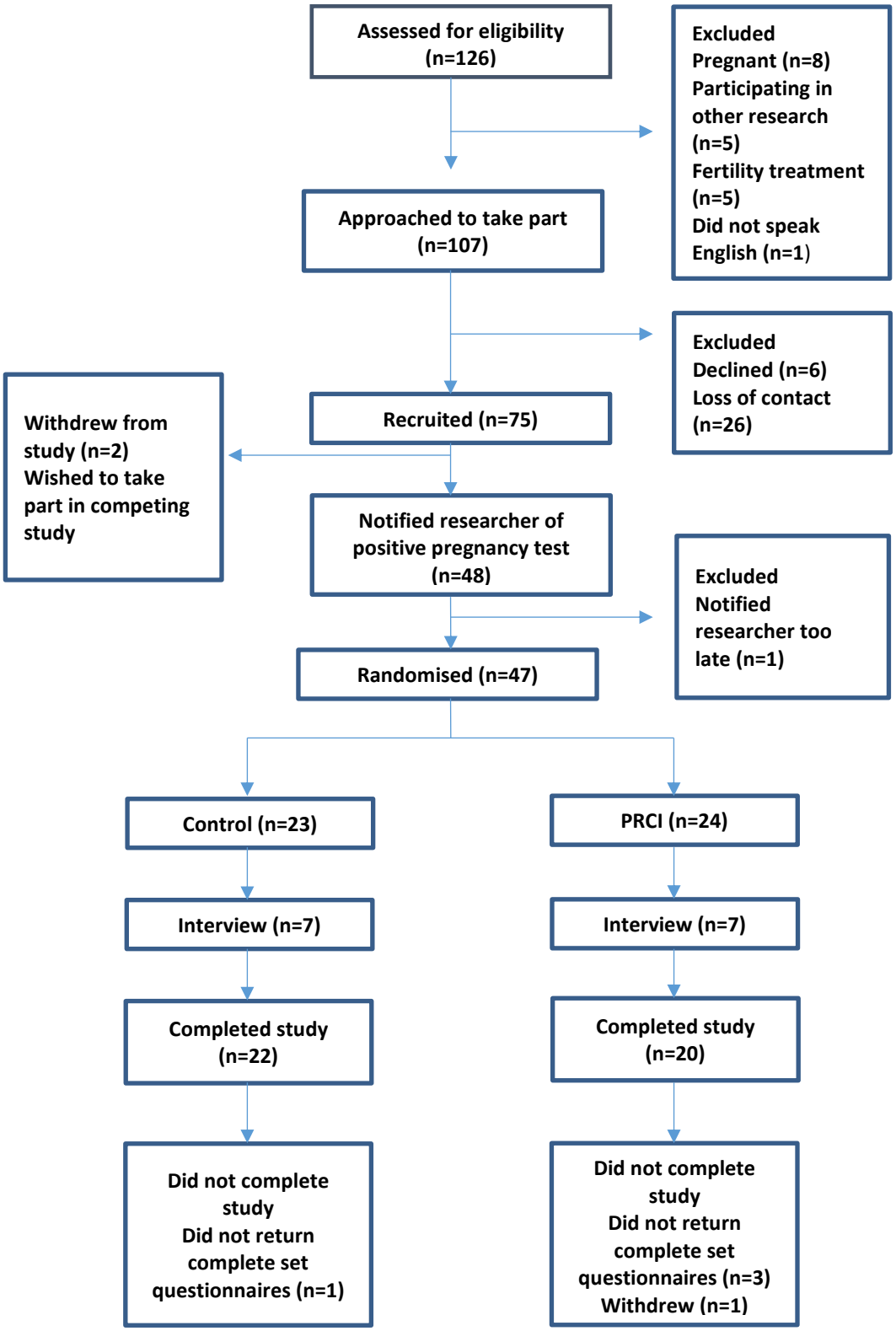


Figure 6: Study CONSORT flow diagram

4.3 The recruitment process

The recruitment target for this study was set during the planning stage of this study. In order to establish how many recurrent miscarriage patients would be seen on average per month that were likely to fit the eligibility criteria for taking part in this feasibility, the clinical teams in the two selected planned study sites were contacted and asked to analyse the flow of recurrent miscarriage patients through their units during the last twelve months.

In Site A, a regional referral centre for recurrent miscarriage patients, general practitioner (GP) referral figures to the Recurrent Miscarriage Clinic were reviewed for the year 2012-2013. Seventy-five women were referred during that time period. In addition, there was an existing patient population who were being seen in the Recurrent Miscarriage Clinic as part of follow-up care and these were also taken into account. It was estimated that approximately five eligible participants would be seen on average per month in Site A.

In Site B, an EPU, patients are referred by their GP or able to self-refer for assessment of early pregnancy complications. Specific quantitative metrics for the annual referral rate of recurrent miscarriage patients to this unit were not available therefore the researcher relied on estimates given by the EPU staff. Staff estimated that approximately five eligible participants would be seen on average per month in Site B.

Having determined that approximately five eligible potential participants would be seen in each study site each month a recruitment rate of 60% (conservative compared to other studies in this population) would yield a total of six patients a month to this study (3 from each centre). Therefore, a recruitment target of three participants per month from each of the two study sites was set over a twelve-month time period.

All women who attended their appointment at the Recurrent Miscarriage Clinic in Site A or the EPU in Site B and met the inclusion criteria, which included women aged eighteen years or older (no upper age limit) and those who had experienced three or more miscarriages, were eligible to take part in the study. Potential participants were considered ineligible to take part in this feasibility study if their English language skills were limited (as study materials were only available in the English language and the participants needed to be able to understand the study materials and potentially be able to take part in a qualitative interview), if they were already pregnant when they attended their out-patient appointment (the ‘waiting period’ of their new pregnancy had already begun) and those who were already participating in other competing recurrent miscarriage research studies. Patients who required fertility treatment were also excluded from recruitment to this study as they had already experienced a ‘waiting period’ in between fertility

treatment and a pregnancy test to confirm if their treatment had been successful, and this could potentially affect the 'waiting period' they would experience during the early stages of a new pregnancy.

In Site A, potential study participants were screened for eligibility to take part in this feasibility study by their clinical health care providers when they attended the Recurrent Miscarriage Clinic. The purpose of this clinic is to offer women dedicated care by clinicians who specialise in the care of recurrent miscarriage patients and investigations are initiated as recommended by national guidelines (RCOG 2011). Referral to this clinic is by the GP following a third miscarriage, so by the time women attend the clinic appointment a time period of at least six weeks has elapsed since their most recent miscarriage.

The researcher, who was based in Site A, recorded the number of eligible patients seen in the Recurrent Miscarriage Clinic during the recruitment period and the reasons why patients were considered ineligible and excluded from the recruitment process (see Table 4).

Reason for ineligibility	**Number**
Language barriers – unable to speak English	1
Already pregnant when attended appointment	8
Participating in competing research study	5
Awaiting fertility treatment	5

Table 4: Reasons why patients considered ineligible to take part in study Site A

In Site B, potential participants were screened for their eligibility to take part in this feasibility study when they attend the EPU. Patients attending this unit were either self-referred or referred by their GP and the majority of patients attending this unit were doing so at the time of their miscarriage or in the time period immediately afterwards. This unit is an early pregnancy assessment unit and does not specialise in the care of recurrent miscarriage patients.

In Site B, the clinical care team were briefed on recruitment procedures and agreed to record the total number of eligible patients seen and the reasons for ineligibility. Compliance with this was poor. Discussions were pursued with the clinical staff to encourage them to record these data, however the 'screening log' was not completed and as a result data on the proportion of patients who were approached and either declined to participate or not eligible are not available.

Successfully screened potential participants in both study sites were provided with study information in the form of the Patient Information Sheet (PIS) for the study (see Appendix E). Potential participants were given the option of contacting the researcher themselves if they were interested in taking part in the study (contact details were listed on PIS) or their permission was sought for the researcher to contact them either by telephone or email to discuss their potential involvement in the study. If a potential participant gave permission for the researcher to contact them to enquire about their potential involvement in the study, then a maximum of two attempts was made to contact them to avoid undue pressure.

Total number of potential participants who received PIS	107
No. of potential participants who failed to notify researcher of decision whether to take part in study	15
No. of potential participants researcher was unable to contact to enquire about their decision to take part in study	11
Declined to take part in study	6
Agreed to participate in study	75

Table 5: Total number of participants who received PIS between 17/01/14 and 31/03/16

Six potential participants who received the PIS declined taking part in this feasibility study. Table 6 (below) illustrates the reasons potential participants gave when they chose not to take part in the study.

Reason for decline	**Number of declines**
Wished to take part in competing study	1
Not wanting to take part in clinical research	2
No reason given	3

Table 6: Reasons for declining to take part in study in Site A

Once a potential participant had agreed to take part in the study, formal written consent to take part in the study was obtained during a face-to-face meeting between the researcher and the participant.

The original protocol for this feasibility study set a recruitment target of fifty participants within twelve months. However, randomisation rates for this study during the first six months were lower than anticipated and it became evident that it would be necessary to increase the recruitment target if the randomisation target of fifty participants was to be achieved (the issue of randomisation rates is discussed more fully in the next section of this chapter). A substantial amendment in February 2015 was approved by the ethics committee and enabled the researcher to increase the recruitment target to up to eighty participants. The reason for requesting this amendment was with a view that randomisation rates would increase if there was a larger sample size of recruited participants. In an attempt to reach the increased combined recruitment target of eighty and to account for the unsatisfactory recruitment rate in Site B, the recruitment time period was extended until 31/03/2016.

During the recruitment period (04/02/2014 – 31/03/2016) a total of seventy-five participants were recruited to this study. Sixty-eight of these were from Site A. The start of recruitment in Site B was delayed to allow for local research and development departmental approval in that site. Eight participants were recruited from Site B between 12/06/2014 to 31/03/2016. The table below illustrates the monthly recruitment rates in both study sites during the interim findings recruitment time period.

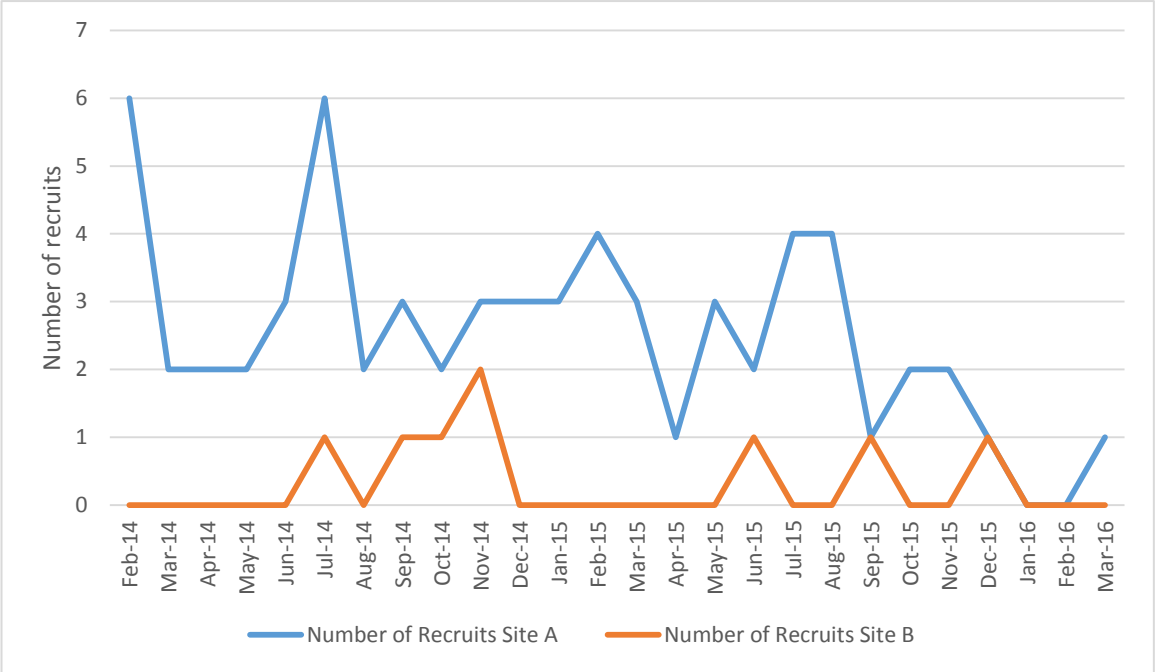


Figure 7: Comparison of the number of monthly recruits in site A and Site B (February 2014 - March 2016

4.4 Comments on feasibility and acceptability of recruitment processes

During the planning stage of this feasibility study efforts were made to robustly establish accurate estimates of the number of potential participants and recruitments seen per month in each study site. This was done by an 'unconditional approach' (Carter 2004; Carter et al. 2005) whereby referral trends at each of the two selected study sites were reviewed in order to create a study wide estimate of the recruitment rate over a specific time period. In Site A, GP referral numbers from the past year were scrutinised, in Site B this metric was not available and the researcher relied on estimates of how many referrals they received to their unit each month. Carter (2004) proposes that the obvious limitation to this approach is that there is no mechanism in place to account for known sources of variation in this rate and adds that experience has shown the actual recruitment period is often longer than planned even when tangible efforts have been made to estimate the recruitment rate. In Site A, the estimated recruitment rate was accurately reflected in the actual recruitment rate. However, there was marked discrepancy between estimated recruitment rate and the actual recruitment rate in Site B. Whilst the 'unconditional approach' described by Carter et al. (2005) to estimating recruitment rates was simple to implement, the actual recruitment rates achieved in this study site fell below expectations. A more refined process to estimating site specific recruitment rates would allow for a more accurate assessment in a future definitive study.

Sixty-eight of the seventy-five participants were recruited from Site A. The contrast with the lower than expected level of recruitment achieved from Site B indicates the importance of carefully screening and selecting potential study sites, and in particular of establishing a robust on-site presence of either researchers or effective, skilled collaborators.

Site A is a research active, regional referral centre for recurrent miscarriage patients with a robust system in place for caring for this patient group. As patients are referred to the clinic by their general practitioner (GP) following a third miscarriage, by the time they attend the clinic appointment a time period of at least six weeks has normally elapsed since their miscarriage. There is a named clinical nurse and consultant who specialise in caring for this patient group and work closely together to coordinate their care and organise investigations. Significantly Site A has an integrated clinical academic team, the researchers have strong links with the clinical care team and clinical research is a fundamental and integral part of patient care in the Recurrent Miscarriage Clinic.

In contrast the Early Pregnancy Unit in Site B is a self-referral/GP referral unit for women experiencing early pregnancy problems including miscarriage. This is not specifically a referral unit for the care and investigation of recurrent miscarriage patients, nor is there a named clinician (nurse or doctor) responsible for coordinating the care of this patient group or a combined clinical academic team. Patients attended the unit during the immediate time period around experiencing their miscarriage, a time when they were likely to be extremely distressed by their condition, and this fact may have acted as a local barrier to recruitment and adversely affected the numbers of patients screened for eligibility and subsequently recruited. The clinical care team caring for women during this time may have understandably been reluctant to prioritise or consider whether patients fitted the eligibility criteria for this study at a time of personal distress, resulting in low screening numbers and a low number of recruits.

Although the host hospital in which Site B is situated is a research active institution, research activity within the EPU prior to this study was minimal and research interest and commitment to this feasibility study amongst some clinical staff appeared low. The lack of engagement with this feasibility study became particularly apparent when the researcher attended a site visit to launch the study with the consultant clinical care team responsible for providing care to patients attending the Early Pregnancy Unit. There were poor levels of ‘buy in’ to this research study from the medical clinicians who would be responsible for identifying potential participants. Many of the clinicians present voiced their reluctance to engage with the study, expressing concerns about the value of nurse-led research, the potential impact of a ‘psychological’ intervention as opposed to a ‘medical’ intervention and a feasibility study that did not formally assess the efficacy of the

intervention being investigated. Clinicians were informed of the importance of running a feasibility study prior to a large-scale definitive study and the potential value of the PRCI, but this information was not well received.

An anonymised excerpt from my field note diary (see below) reflects and summarizes some of the difficulties encountered during this meeting. The decision to share the diary extract was made following in-depth discussion with academic supervisors. It was felt that sharing of the excerpt is justified because it provides insights into the feasibility elements of motivating clinicians to participate in a multi-centre study that is addressing a non-medical intervention.

The launch meeting did not go well! I was asked to give a short presentation to the group on my study and what I required from the staff in that Site. Those attending included consultants, registrar level doctors, medical students and midwifery managers. I began by giving a brief introduction to the background of the study, describing the overwhelming levels of anxiety that women who have experienced recurrent miscarriage feel when they become pregnant again. One consultant in particular responded to this information in a very rude and confrontational manner, laughing when I described the emotions these women felt when they became pregnant, implying we should be focusing on finding a medical solution for the problem. He asked what the point of such a study was which was looking at feasibility not even testing an intervention. Despite answering with what I thought was very accurate answers, focusing on the purpose of a feasibility study and how it lays the foundation for future definitive studies, he continued to point out that he thought the research had no value and wanted further justification for running it ….. He also made reference to the 'limited' value of nurse led research. He clearly did not understand the concept of a feasibility study and continued to ask me for justification of this study in a confrontational manner. Other clinicians present seemed to agree with his comments, the consultant's registrar joining in particularly with questions about the point of the study and another consultant voicing concerns over what the study was hoping to achieve ……. Throughout the meeting no one voiced any particular interest in my proposed study and some present appeared not to be listening and were looking at mobile phones. I was prepared to be questioned about the study but was shocked by the attitude of some of those present ……. No one appeared to realise how uncomfortable I was feeling during the meeting or made any effort to offer any positive support ……. there appeared to be a real lack of interest in the study and the value of my research. After the meeting one of the midwifery managers who was present came up to me and thanked me for the presentation I had given and apologised for the consultant's inappropriate questioning and attitude towards me……

Efforts were made to provide the research infrastructure necessary to support the study and assist busy clinical staff in Site B with the research process. The researcher was in possession of an NHS research passport and able to recruit at Site B and in addition on-site Clinical Research Network (CRN) midwives were made available to support this study, offer advice and help at the screening and recruiting stage. Significantly, the research team in this unit were not seen as an integral part of the clinical team caring for this patient population as in study Site A and there were no clinical academic links. Although willing to help with the identification of eligible participants, ward staff described research as 'something else to do' in what was a very busy unit and research was seen as an 'add on' to clinical care rather than an integrated part of it.

Given the more successful recruitment strategies in Site A, the findings of this feasibility study suggest that the presence of site specific barriers and facilitators to recruitment have affected

screening and recruitment rates across the two study sites. It is important that consideration is given to these when planning a future definitive study of the PRCI. Indeed Hubbard et al. (2015) propose that an awareness of the site specific barriers in the recruitment pathway for a study will assist researchers to develop strategies to address common recruitment barriers and promote recruitment facilitators when planning a future definitive study.

In summary recruitment in Site A appears to have met expectations. Recruitment was successful and the original targets were exceeded. In contrast, screening and recruitment numbers in Site B fell well below the expected number and despite an extended recruitment period and the provision of research infrastructure support systems recruitment proved difficult. Staff in Site B who were collaborating with recruitment were provided with log sheets to record the number of participants screened however completion of these was poor and it is therefore difficult to determine whether failure to achieve anticipated recruitment targets was due to lack of eligible patients, or to other factors.

The influencing recruitment factors between the two study sites are illustrated in the below table.

Site A	**Site B**
Regional referral unit for recurrent miscarriage	Non-specialist unit
Named clinical lead responsible for care of RM patients	No named clinical lead for care of RM patients
Potential participants attending clinic in weeks / months following miscarriage	Potential participants attending clinic at time of miscarriage
Researcher on site	No on-site researcher
Combined clinical academic teams providing care to RM patients	Clinical teams providing care to RM patients

Table 7: Factors underlying different recruitment rates in the two study sites

Newington and Metcalfe (2014) outline some of the factors which can be influential on recruitment rates in research, including the nature of the research, the characteristics of the participants, the characteristics of the recruiter and the clinical/research infrastructure of the study site(s). The findings of this study suggest that it is the two latter factors, which have been most influential on the recruitment in this feasibility study. Interestingly the characteristics of the

recruiter (the fact that she was on-site) and the infrastructure have acted as facilitators to successful recruitment in Site A and appeared to have acted as recruitment barriers in Site B demonstrating the importance of considering recruitment issues on a site-by-site basis. Hubbard et al. (2015) suggest that the recruitment stage of a study is best conceived as a whole system with inter-related discrete stages and processes, and that a feasibility study can be particularly useful to 'pinpoint' recruitment pathway barriers within this process. Although it has been difficult to address the site-specific barriers present in Site B for the duration of this feasibility study it has been possible to identify some of them. This in turn has helped to develop a more comprehensive understanding of the recruitment stages and processes on a site-specific basis for this study, providing valuable information for planning a subsequent definitive study.

The reasons for the success or failure of a study recruitment strategy appear to be multi-faceted and the diverse and often complicated issues around the recruitment to this study will be discussed in greater depth in Chapter 7. However, evidence suggests that successful recruitment to a future definitive study investigating a coping intervention for recurrent miscarriage is possible and significantly that there is an appropriate and sizeable patient population willing to take part. Indeed, a significant feasibility consideration is that only a small percentage of screened patients who were given the Patient Information Sheet declined taking part in the study (5.8%) suggesting that women with recurrent miscarriage were willing to be recruited to this study. Data from the qualitative process evaluation provide further insights into this aspect of the study and will be addressed in Chapter 5.

4.5 Randomisation

The NIHR glossary (NIHR 2016) describes randomisation as a process that involves the assigning of research participants into different study groups without taking any similarities or differences between them into account. The purpose of randomisation is to eliminate any possible biases that might lead to 'systematic differences' between the treatment/study groups (Altman 1991) and it is therefore an essential component of randomised controlled trials. Correspondingly, Gebski et al. (2002) propose that this allocation of participants to specific treatment groups in a random fashion helps to ensure that each randomised study group is as alike as possible ensuring that similar levels of risk factors are present in each group and group characteristics are rendered comparable. If the selected randomisation process in a study is to be efficient and effective then it should not be possible to predict in advance which study group a research participant will be assigned to. Furthermore, the research participant will have an equal chance of being in any of the randomised study groups and therefore the same chance of receiving a particular study intervention or treatment.

4.5.1 Randomisation procedures

Prior to agreeing to take part in this study potential participants were provided with a Participant Information Sheet (PIS) (see Appendix E) which contained the information that the study included a randomised controlled component. The PIS advised that study participants would be randomly allocated to one of two study groups by a computer and that they would have an equal chance of being in either of these groups.

It is common for clinical research studies to randomise participants to a treatment/intervention group as soon as they are recruited to the study. However, in this study there was a necessary delay between recruitment and randomisation as women were recruited to the study before they were pregnant and only randomised to a study group when they had received a positive pregnancy test. Therefore, following consent, participants were asked to notify the researcher as soon as possible after a positive pregnancy test either by telephone or email in order to enable randomisation. The aim was to achieve randomisation on the same day as being notified of a positive pregnancy test or as soon after as possible.

Once the researcher had been notified of a positive pregnancy test, a randomisation sheet was completed (Appendix P) and emailed to the study statistician. The study statistician randomised participants into one of the two study groups using an independent computerised randomisation system with a randomly-sized block design with block sizes of 2, 4 and 6. The study sample was stratified for age, those receiving concurrent treatment for recurrent miscarriage, those with underlying medical conditions which are causative of recurrent miscarriage, and number of previous miscarriages.

The two study groups consisted of:

- The intervention group (Group 1) who were asked to use the Positive Reappraisal Coping Intervention (PRCI) and complete weekly questionnaire assessments to monitor their psychological wellbeing from the date of a positive pregnancy test until twelve weeks of pregnancy
- The control group (Group 2) who were asked to complete weekly questionnaire assessments during the same time period.

Following randomisation into study group 1 or 2 the researcher posted out the necessary study materials (questionnaires and PRCI) to the participant by first class mail.

Between 04/02/2014 and 31/03/2016 a combined site total of 47 participants (62.6% of participants who had consented to join the study) informed the researcher that they had had a positive pregnancy test and were randomised to one of the study groups (Site A n=43 Site B n=4).

4.6 Comments on feasibility and acceptability of the randomisation process

An important aspect of feasibility addressed in this study is the willingness of participants to be randomised and the acceptability of the randomisation process. Indeed research suggests that potential participants often fail to understand both the concept of randomisation and the actual term (Featherstone and Donovan 2002; Kerr et al. 2004) and many are taken by surprise when they are informed about random allocation (Kerr et al. 2004). It was important to establish whether potential participants were willing and happy to take part in a study which involved an element of randomisation, and once they had joined the study, to evaluate their experience of this aspect of the research process.

This Patient Information Sheet (Appendix E) outlined clearly that for the purpose of feasibility testing participants would be randomly allocated by a computer to one of the two study groups. It also informed them that they had an equal chance of being in either of the groups. This information was repeated verbally by the researcher before a participant signed the consent form.

Findings suggested that study participants did show a willingness to be randomised into intervention or control study group. Certainly, no potential participants declined to take part in the study because of the issue of randomisation. A small number of participants verbally expressed some disappointment when they were not allocated to the PRCI study group at the point of randomisation, but were still keen to continue with the study and be a part of the control group. However, it is acknowledged that this may have been because these participants would still receive some study materials in the form of questionnaires to complete. Data from the qualitative process evaluation have informed and added to the understanding of how acceptable the notion of randomisation was to the study participants and will be presented in Chapter 5.

The literature review for this study suggested that the lag time between recruitment (when the woman has experienced her most recent miscarriage) and randomisation (when the study participant informs the researcher of a positive pregnancy test) was likely to be relatively short. Many women who experience recurrent miscarriage become pregnant very quickly and easily and have a short time-to-pregnancy (Salker et al. 2010). However, one of the aims of this feasibility study was to investigate the time lag from recruitment to randomisation as this is an important factor to consider when planning a future definitive study. Between 04/02/2014 and 31/03/2016 75 participants joined the study, 47 of whom notified the researcher of a positive pregnancy test. Figure 8 (below) shows the range in number of months between recruitment and a positive

pregnancy test of the 47 randomised participants, 34 (72.3%) of whom became pregnant within the first 6 months of trying for a pregnancy.

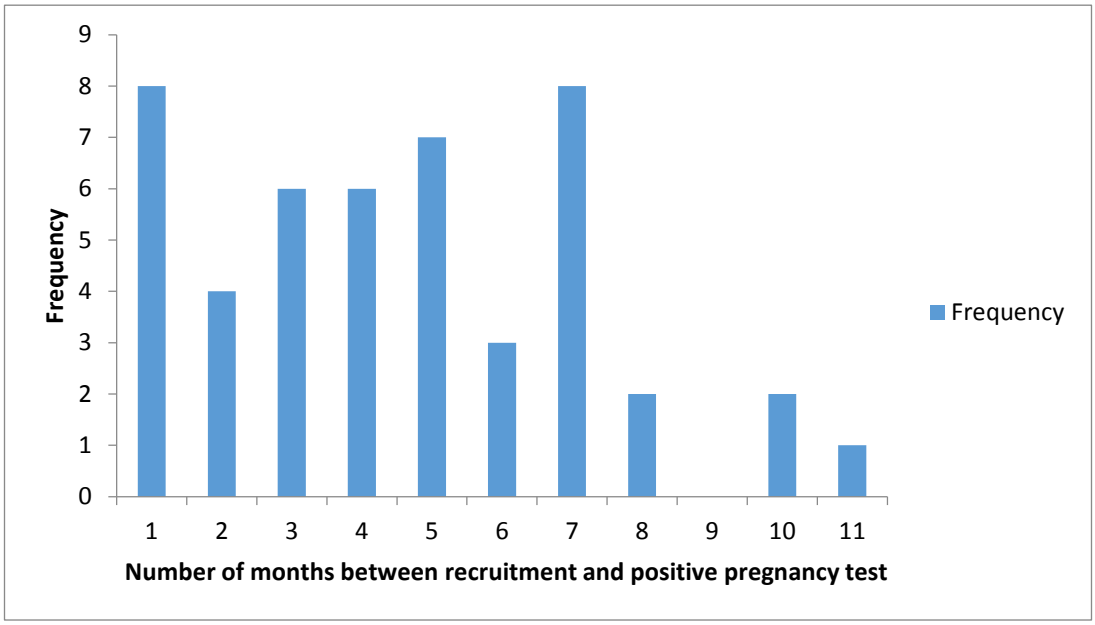


Figure 8: Histogram to illustrate the range of number of months between recruitment and a positive pregnancy test of 47 randomised participants

The original study protocol set a recruitment and randomisation target of 50 participants. As the study progressed it became clear that a recruitment target of 50 was unlikely to lead to randomisation of all 50 participants. Not all women who agreed to participate in the study would become pregnant, some would delay a new pregnancy whilst they had investigations to exclude potential causes for their recurrent miscarriages, some chose to delay pregnancy because they were unsure if they were able to cope with the emotional strains of becoming pregnant again, and others experienced fertility problems. The combined randomisation rate for both research sites during the recruitment time period 01/02/2014 and 31/03/2016 was 47 (62.6% of all recruited participants). In Site A, 43 (64%) of the 67 participants recruited notified the researcher of a positive pregnancy test and were randomised between 01/02/2014 and 31/03/2016. In Site B, 4 (50%) of the 8 recruited notified the researcher of a positive pregnancy test and were randomised between 12/06/2014 and 31/03/2016. The chart below (Figure 9) below shows the comparison of recruitment/randomisation rates for the two study sites.

Figure 9: Chart to show comparison of recruitment/randomisation rates in two study sites

A further aspect of feasibility to consider is the size of sample required to ensure an adequate randomisation rate. The total number of participants recruited to this study is 75, 47 of whom have had a positive pregnancy test and were randomised to study group. This equates to a current combined randomisation rate of 62.6%. The proportion of participants who proceeded to randomisation is slightly greater than in a recently published multi-centre study which was a randomised controlled trial of the use of a medical intervention (progesterone therapy) in women with recurrent miscarriage (Coomarasamy et al. 2016). This study had a similar study design in that recurrent miscarriage patients were recruited to the study before they were pregnant and randomised at the point of a positive pregnancy test to receive progesterone supplementation or placebo. A total of 1568 women were recruited to the trial and 836 of these were randomised, equivalent to a 53% randomisation rate. Although it is acknowledged that randomisation rates will vary between studies, it is likely that a future definitive study with this patient population and a similar study design would yield a comparable randomisation rate and therefore should include a recruitment target that is at least twice the randomisation target.

A small number of participants who had given consent to take part in the study in Site A, failed to notify the researcher of a positive pregnancy test (n=4). The research team became aware of this information serendipitously and were informed of these ongoing pregnancies by clinical colleagues in Site A. It was not possible to randomise these participants and they were deemed lost to study follow up. Unfortunately, the reason for these participants failing to notify the researcher is unknown. Possible reasons for this may include the fact that they no longer wished to be part of the study, had lost the contact details of the researcher or had forgotten that they were part of the study. If the latter two reasons were the cause of failing to notify the researcher of a positive pregnancy test then more regular contact between the researcher and the participant during the time lag between recruitment and randomisation (which could be several

months) might help to remind participants that they are taking part in the study. To address this, a future study might include regular contact between the researcher and the participant, either via email or text between recruitment and randomisation. This possibility was explored in the qualitative process evaluation.

Participants were asked to inform the researcher of a positive pregnancy test as soon as possible after it had taken place to facilitate randomisation. Findings indicate that all of the randomised participants notified the researcher within 48 hours of a positive pregnancy test. However, one participant was excluded from randomisation completely as she did not notify the researcher until she had completed twelve weeks of pregnancy, stating that she was convinced she would miscarry before that point and therefore did not want to 'bother' the researcher.

Once a participant had informed the researcher of a positive pregnancy test the process of initiating randomisation and allocation to a study group appeared to work smoothly. The randomisation sheet (Appendix P) was quick and easy to complete and provided all the information the study statistician required to complete randomisation. Following randomisation, the sheet was returned to the researcher with details of which group the participant had been assigned to. The study statistician has confirmed that the computerised randomisation system worked well and efficiently.

Envelopes containing the study materials for the intervention and control groups were prepared in advance. This ensured that collating the study paperwork was a straightforward process as the researcher or a member of her team only needed to select the appropriate envelope depending on the group the participant was randomised to, record the participant's identification number on the questionnaires and address and post the envelope to the participant. This process worked well and envelopes containing study materials were posted to the participant within 24 to 48 hours of her notifying the researcher of a positive pregnancy test.

In summary, the findings of this feasibility study suggest that the processes for achieving randomisation worked smoothly for the research team and that study participants found, both the concept and process of randomisation acceptable. The findings have highlighted that any future study would need to carefully consider the number of study participants it would be necessary to recruit in order to achieve an adequate randomisation rate. Interview data from the qualitative process evaluation will add significantly to the feasibility and acceptability assessment of the randomisation processes used in this study and these will be presented in Chapter 5 of this thesis.

4.7 Data Collection Questionnaires

Lancaster et al (2004) suggest that the testing of data collection forms or questionnaires is a fundamental part of any feasibility study but that this is particularly important when the questionnaires are being self-completed by the participant. This is because it is important to establish in the feasibility stage of the study that the study questionnaires are 'comprehensive and appropriate, and that the questions are well defined, clearly understood and presented in a consistent manner' (Lancaster et al 2004). As such, the aim of the feasibility study is to assess whether the research participants are able to understand what it is that the study questionnaires are asking them, that the study participants are able to complete them and that the questionnaires are providing the researchers with the information they require. The questionnaires selected for use in this feasibility study are the Pre-Intervention Demographic Questionnaire, the HADS (Zigmond and Snaith 1983) and the DRK Form (Boivin and Takefman 1995).

4.7.1 Pre-Intervention Demographic Questionnaire

This questionnaire was specifically designed for use in this study to capture and compare relevant information in the control and intervention group. This included demographic information (such as age and educational status), medical / psychological history (to identify any co-morbidities associated with recurrent miscarriage), gynaecological and reproductive history (fertility history, dates and number of live births and miscarriages) and the time period the woman has been trying to have a successful pregnancy.
The study participants self-completed this questionnaire at the time of consent.

4.7.2 Hospital Anxiety and Depression Score (Zigmond and Snaith 1983)

The HADS is a self-report questionnaire. It was specifically developed to measure anxiety and depression and is commonly used by clinicians to determine the levels a patient is experiencing. It has been shown to be a valid measure of the severity of anxiety and depression and as well as assessing for this it can prove useful to evaluate changes in a patient's emotional state (Zigmond and Snaith 1983). The HADS consists of 14 items (7 items for each of the subscales relating to anxiety and depression) and rated on a four-point Likert scale. The total score is the sum of the 14 items, and the subscale score is the sum of the respective seven items. The scores on each subscale are interpreted in ranges 0–7 (normal), 8–10 (mild), 11–14 (moderate) and 15–21 (severe).

Study participants in both study groups were asked to complete this HADS at weekly intervals from a positive pregnancy test (i.e. immediately post randomisation to the study) until twelve weeks of pregnancy (or until the pregnancy ended in the event of a further miscarriage). The objective of this questionnaire is to assess the woman's psychological well-being during this time.

4.7.3 Daily Record Keeping Form (Boivin and Takefman 1995)

The DRK form was originally developed for daily assessments to measure the levels of emotional, physical and behavioural reactions during fertility treatment (Boivin and Takefman 1995). It has been reported to be sensitive to changes in emotional (Boivin and Lancastle 2010) and physical reactions (Boivin and Takefman 1995) during the waiting period prior to a pregnancy test after fertility treatment.

Previous research has shown that some women used the DRK as an intervention itself and consequently experienced a positive or negative effect of rating their daily emotions (Ockhuijsen 2014; Ockhuijsen et al. 2015). Therefore, due to the potential reactivity of the DRK and the potential burden of daily monitoring, research participants were asked to complete the questionnaire at weekly intervals during this feasibility study (i.e. from a positive pregnancy test until twelve-weeks or until miscarriage if this occurs before twelve-weeks). To avoid confusion for research participants, it was referred to as the Weekly Record Keeping (WRK) form.

The wording of the original DRK was adapted for this study by the use of terminology referring to the waiting period of a new pregnancy following recurrent miscarriage, specifically waiting for the twelve week scan which would confirm if the pregnancy was ongoing. For example the section entitled 'Ways of coping with fertility problems' in the original DRK was changed to 'Ways of coping with waiting for my twelve-week scan' in the WRK for this study. Similarly the section entitled 'Ways of thinking about fertility problems' in the original DRK was changed to 'Ways of thinking about my twelve-week scan' in the WRK for this study.

Two versions of the WRK were used in this feasibility study. The initial version (Version 1, Appendix L) was used between February 2014 and January 2015 and 19 (40.4%) of randomised participants used this version. However at this point it became clear that an error during translation from the Dutch version of the form into English had meant that some words had been interpreted incorrectly and the section of the questionnaire which explored ways of thinking about the waiting period had been omitted. The final and corrected version of the form (Version 2, Appendix M) was used from January 2015 following submission of a substantial amendment to NHS Ethics to approve the revised questionnaire. 21 (59.6%) of randomised participants used this version.

4.8 Comments on feasibility of study questionnaires

4.8.1 Pre-Intervention Demographic Questionnaire

This questionnaire is a 16-item self-report questionnaire that was specifically designed to determine the characteristics of the study population (see Appendix J). Participants were asked to complete the form at the time of recruitment.

Seventy-four of the seventy-five participants (98.6%) completed the form. One participant preferred to complete the form at home after recruitment and although a stamped envelope was provided the form was not returned.

A comprehensive review of the completed forms suggest that participants completed all questions with minimal missing data. Questions were answered in an appropriate way and completed correctly suggesting that the questionnaire was easy to use for the participant and that there were no general comprehension difficulties in participant understanding of the questionnaire.

However, although the participants were asked to complete the form independently, the researcher was present at the time and observed that some participants did ask for clarification about one question in particular i.e. 'How long have you been trying for a baby with your partner?' Participants appeared to be confused about how to interpret this question. There was uncertainty about whether it referred to the period since their last miscarriage or the overall period they had been attempting to conceive and experiencing miscarriages. Although the questionnaire was specifically designed for this study, it was adapted from a previously used demographic questionnaire used in a fertility study. The question will be reviewed and amended, if required, for use in any future definitive study of the PRCI.

In conclusion, with the exception of the point noted above, findings suggest that the pre-intervention demographic questionnaire provides appropriate and accurate baseline information about sample characteristics. Table 8 (below), presents and compares the baseline information and sample characteristics of the intervention and control groups.

Table 8: Baseline characteristics of recruited and randomised participants

	Recruited Participants (n=75)	**PRCI group (n=24)**	**Control group (n=23)**
Mean age (range)	33.53 (19-44)	31.79 (20-42)	33.91 (19-42)
Ethnic Group n (%)			
White British	69 (92)	21 (87.5)	23 (100)
Chinese	1 (1.3)	0	0
Other	4 (5.3)	3 (12.5)	0
Missing Data	1 (1.3)	0	0
Level of Education n (%)			
None	2 (2.7)	0	1 (4.3)
GCSE / O Levels	17 (22.7)	4 (16.7)	5 (21.7)
A Levels	4 (5.3)	3 (12.5)	1 (4.3)
Higher Degree	37 (49.3)	15 (62.5)	12 (52.2)
Other	14 (18.7)	2 (8.3)	4 (17.4)
Missing data	1 (1.3)	0	0
Number of previous miscarriages n (%)			
3	29 (38.7)	10 (41.7)	9 (39.1)
4	30 (40)	7 (29.2)	12 (52.2)
5	5 (6.7)	3 (12.5)	1 (4.3)
6	3 (4)	1 (4.2)	1 (4.3)
7	3 (4)	2 (8.3)	0
8	1 (1.3)	0	0
9	2 (2.7)	0	0
10	1 (1.3)	1 (4.2)	0
Missing data	1 (1.3)	0	0
Already have child with partner n (%)			
Yes	34 (45.3)	11 (45.8)	11 (47.8)
No	40 (53.3)	13 (54.2)	12 (52.2)
Missing data	1 (1.3)	0	0
Diagnosed medical reason for miscarriages n (%)			
Yes	9 (12)	3 (12.5)	1 (4.3)
No	65 (86.7)	21 (87.5)	22 (95.7)
Missing data	1 (1.3)	0	0
Seen counsellor for problems related to miscarriages n (%)			
Yes	5 (6.7)	3 (12.5)	2 (8.7)
No	66 (88)	19 (79.2)	21 (91.3)
Missing data	4 (5.3)	2 (8.3)	0

4.8.2 The Hospital Anxiety and Depression Scale

This validated questionnaire (Zigmond and Snaith 1983) was selected as an outcome measure for this feasibility study as previous research which explored the use of the PRCI in other patient populations had also utilised it successfully as a measure of general anxiety and depression (Ockhuijsen et al. 2013b; Ockhuijsen 2014; Ockhuijsen et al. 2014a, b). Moreover, previous research has concluded that the HADS performs well in assessing the symptom severity and cases of anxiety disorders and depression in both psychiatric patients and in the general population (Bjelland et al. 2002).

Study participants were asked to complete the questionnaire (see Appendix K) on eight occasions at weekly time points from a positive pregnancy test (usually around four weeks of pregnancy) up until twelve weeks of pregnancy (but to discontinue its use if they experienced a further miscarriage). Study findings suggest that there were no identified difficulties with comprehension of the questionnaire wording or scoring. All returned questionnaires were completed correctly, there were no missing data and the forms were completed according to the guidance.

Analysis of qualitative data from interviews undertaken in the process evaluation is presented in Chapter 5 and adds to the understanding of how study participants used and reacted to the HADS. It also explores whether participants would have preferred a different mode of administration of questionnaires to the postal method used and whether the questionnaire was perceived to address relevant aspects of experience during the waiting period under investigation. Furthermore, Chapter 6 of this document will assess the impact of the intervention and will explore in more detail the data produced by the HADS, using descriptive statistics to analyse whether the data behaved in a predictable way and assess the anxiety and depression scores between control and intervention group.

4.8.3 Weekly Record Keeping Form

This questionnaire (Appendix L and M) was selected as an outcome measure for this feasibility study as it had been previously used to successfully rate positive and negative emotions during ‘waiting periods’ in related studies assessing the use of the PRCI (Boivin and Takefman 1995; Lancastle and Boivin 2008; Ockhuijsen et al. 2013b; Ockhuijsen 2014; Ockhuijsen et al. 2014b). The WRK was originally developed to be used daily to record positive and negative emotions experienced by women receiving fertility treatment during the waiting period following in vitro fertilisation. It was adapted for use in this study to assess emotional reactions to the waiting period experienced by women with recurrent miscarriages between a positive pregnancy test and a 12-week ultra- sound scan to confirm that the pregnancy was ongoing. Although words and

phrases were changed to better reflect the waiting period experienced by recurrent miscarriage patients, the format of the questionnaire was not changed. An important aim of the feasibility study is to assess the effectiveness and acceptability of the adapted questionnaire, including any strengths or limitations linked to changes in wording and the change to weekly rather than daily completion.

Participants were asked to complete the questionnaire weekly up until the 12th week of pregnancy (but to discontinue its use if they experienced a further miscarriage). Whilst the study findings suggest that overall participants completed the questionnaire as requested, there are indications that at least one participant did not fully understand the instructions. Participants were asked to rate their experience of the emotional and physical symptoms listed in the WRK using the scale provided, however, one participant used 'ticks' to indicate if she had experienced a particular symptom.

As the study progressed and analysis of the questionnaires commenced, other issues were highlighted about the instructions provided on how to rate the different items. The instructions provided by the original authors indicate that the score relates not to the intensity of the symptom, but to the impact the symptom had on their ability to perform daily tasks. Analysis of completed WRK forms suggests, however, that it was not possible to rate positive emotions (e.g. 'happy,' 'hopeful,' 'encouraged,' and 'optimistic') in an appropriate way, as the rating scale descriptors reflected different levels of negative impact. For example if a participant was feeling 'happy' and rated this emotional symptom with a score of 3, then the rating scale on the questionnaire suggested that this symptom was having 'a markedly negative effect on how well they were performing their daily tasks during the previous week.'

Another possible criticism of the way in which the WRK is presented is that the response options instruct participants to leave the score box 'blank' if that emotional or physical symptom has not been experienced. Although the researcher may interpret a 'blank' score box as meaning that the participant has not experienced that symptom, it may be that this is in fact 'missing data' and the participant had failed to answer that question. The International Conference on Harmonisation (ICH) of technical requirements for registration of pharmaceuticals for human use states that 'missing values should be distinguishable from the value zero or characteristic absent' (Smith and Heywood 2002, p 35). This issue needs to be addressed in any future study using the WRK and feasibility assessment of the use of this questionnaire suggests that careful consideration needs to be given to ensuring that it is possible to distinguish between missing data and the absence of any emotional or physical symptoms.

It is anticipated that qualitative feedback from the process evaluation interviews, where participants commented on the relevance and appropriateness of the WRK, their understanding of the measure and whether they would add or make changes to it, will add significantly to the feasibility assessment of the WRK as a study outcome measure. Indeed, despite the problems noted above with regards to scoring / rating the positive emotions listed on the WRK, qualitative evidence from the interviews suggests that the participants actually found the WRK a supportive and helpful questionnaire. Chapter 5 explores these findings in greater depth and presents the data from the qualitative process evaluation. Furthermore, a key feasibility aspect is to ensure any selected study outcome measures are able to accurately determine the impact/effect of an intervention, therefore Chapter 6, will explore the quantitative data generated by the WRK and assess its strengths and limitations in terms of measuring the effect size of the PRCI on psychological wellbeing.

4.9 The PRCI

The Positive Reappraisal Coping Intervention (PRCI) is a theoretically derived, short coping intervention, based on the concept of positive reappraisal (Lancastle and Boivin 2008). The intervention aims to promote positive re-evaluation of a challenging situation and consists of a small card containing 10 positive reappraisal statements which aim to encourage users to redefine the waiting period of a new pregnancy following repeated pregnancy loss more positively (Appendix A). An accompanying leaflet (Appendix D) provides concise guidance on the use of the PRCI.

The PRCI was developed specifically for use by fertility patients. It was recognised that the waiting period between In Vitro Fertilisation (IVF) and a pregnancy test, with the associated uncertainty about the success of the treatment, was a particularly stressful time mainly because distress and 'intrusive cognitions' about the implications of the result could reduce quality of life (Lancastle and Boivin 2008). A feasibility study of the coping intervention investigated whether the card would encourage fertility patients who were waiting for a pregnancy test to redefine the waiting period more positively (Lancastle and Boivin 2008). The study concluded that women waiting for an IVF pregnancy test found the PRCI to be acceptable in that they described it as being helpful and suitable, sustaining their ability to cope and feel more positive during the challenging waiting time between fertility treatment and a pregnancy test.

Study participants who were randomised to the intervention group were asked to read the PRCI at least twice a day, in the morning and in the evening, and any other time of day they felt the need and record how often they had used it on the WRK.

4.10 Comments on feasibility and acceptability of the PRCI

Lancaster et al. (2004) suggest that it is sensible to determine the acceptability of an intervention in a feasibility study as in some cases an intervention may not appeal to all patients. Certainly previous studies have shown that this is especially likely to be the case if the intervention has known side effects or is difficult to administer (Ross McGill et al. 2000) as in the case of medical device or drug studies.

Although previous studies had shown no known negative side effects of the PRCI (Lancastle and Boivin 2008; Ockhuijsen et al. 2013b; Ockhuijsen et al. 2014a, b) there was a potential that despite being given concise guidance on its use, participants would find this self-administered intervention challenging to use. The essence of positive reappraisal coping is that it 'sustains the coping process through increasing positive mood, via cognitive processing' (Lancastle and Boivin 2008) and participants may find this concept difficult to understand, and be sceptical about whether this self-managed intervention could help them feel more positive. Recurrent miscarriage patients frequently experience overwhelming anxiety and despair when they become pregnant again as they are worried they will miscarry again. Some women may have questioned the value of using a 'self-help' card based on the principle of positive reappraisal to help them manage the extreme levels of anxiety and worry they were experiencing. The Patient Information Sheet (PIS) (Appendix E) introduced the concept of positive reappraisal and it was discussed in greater depth at the time of consent. No potential participants expressed concerns or declined taking part in the study as a result of the intervention being tested and all seemed amenable to the concept of using the PRCI.

Participants who were randomised to the intervention group were asked to use the PRCI at least twice a day and to record how often they actually used it during the previous week when they completed the Weekly Record Keeping questionnaire (see Appendices L and M). One part of assessing the feasibility and acceptability of the PRCI is investigating how often study participants used the intervention. Simple statistical analysis was used to determine this.

The bar chart below (Figure 10) illustrates the average number of times per day participants read and reflected on the PRCI (less than twice a day, twice a day or more than twice a day) during the eight weeks of its use (Weeks 4-12 of pregnancy).

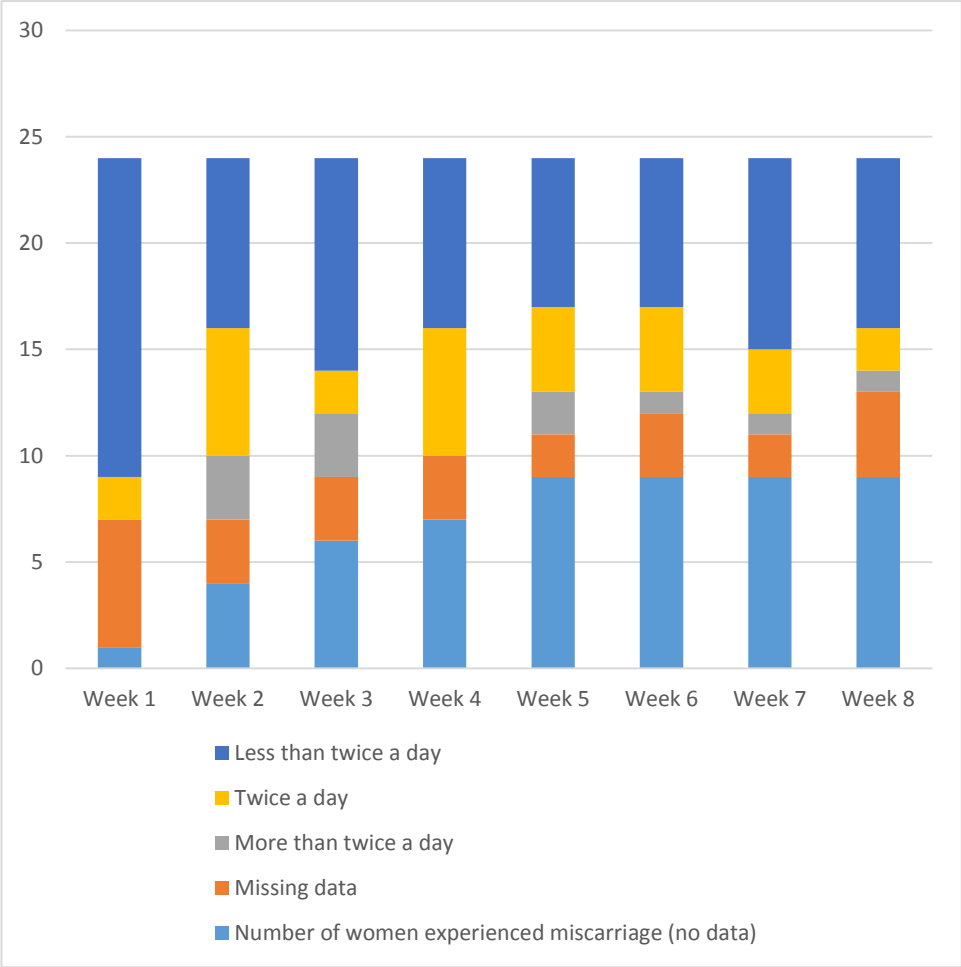


Figure 10: Chart to show how often participants used the PRCI during its eight weeks of use

Participants were requested to complete the WRK for the first time on the day they received it however because study questionnaires and the PRCI were sent out in the same envelope after randomisation it would not have been possible to have used the PRCI in the preceding week. Yet two participants recorded they had used it twice a day in the previous week, indicating some potential ambiguity about this question on the WRK and highlighting the need to address this before its use in any future study.

Answers on the WRK indicated that all women used the PRCI but there was some variation in the frequency of its use as illustrated in the above table. Individual usage varied greatly and qualitative feedback from the process evaluations added significantly to the understanding of the participants' perceptions of the PRCI. They were asked to reflect on the format of the card, how easy or difficult they found it to use, the frequency with which they used it and whether they would recommend its use to others. Participants were also asked to make an informal assessment of whether they thought use of the intervention had had any effect on their psychological well-being during its use.

The selected intervention for this study was the PRCI and the potential it had to promote positive feelings and sustain coping ability during the waiting period of a new pregnancy following recurrent miscarriage. However, it became clear during the early stages of data collection that some participants wanted to use the engagement between themselves and the researcher as a secondary support intervention. The researcher received numerous telephone calls and emails requesting support and seeking reassurance with regards to anxieties participants were experiencing about the well-being of their pregnancy. This issue was perhaps exacerbated by the fact that the researcher was also a clinician who specialised in the area of recurrent miscarriage and known to the study participants in Site A. As previous studies have suggested that professional support and 'tender loving care' can have a positive impact on psychological well-being and improve pregnancy outcome in this patient group (Stray-Pederson and Stray-Pederson 1984; Clifford et al. 1997) there was a need to minimise the risk of the researcher's engagement acting as an intervention itself. Any additional support offered by the researcher could potentially impact upon the participant's use and experience of using the PRCI and therefore steps were taken to try and reduce this risk. A substantial amendment via NHS Ethics approved changes to the study consent form and a section was added informing participants that the researcher would be unable to provide additional support or clinical advice (see Appendix G). In addition a study specific email address was developed and participants were provided with this contact email in case of queries about the research study as opposed to the researcher's personal NHS email address. The 'out of office' facility for this email informed participants that if they had a question about the research study then a member of the research team would get back to them, however if they needed clinical advice or support then they were advised to contact their GP. These two simple steps significantly reduced the request for clinical advice and support from the researcher.

One of the key objectives of this feasibility study was to evaluate the acceptability of the PRCI amongst recurrent miscarriage patients during the early stages of a new pregnancy. The findings presented in this chapter suggest that the participants' willingness to take part in the study and their general compliance in using the PRCI is an encouraging sign that these women might be receptive to this intervention. A final and more informed feasibility assessment of the acceptability of the PRCI will be made in Chapter 7 of this thesis.

4.11 Chapter summary

The initial section of this chapter clarified the background and theoretical perspectives regarding the reporting of feasibility studies and established that the setting of appropriate study objectives can assist in promoting the scientific rigour of a feasibility study and help to ensure effective and applicable reporting. These theoretical perspectives were outlined to enable the setting of specific

feasibility objectives for this feasibility study of a coping intervention for recurrent miscarriage thus providing a useful framework to aid presentation of the main findings in an appropriate and rigorous manner.

The second section of this chapter focused on exploring and assessing the significance of the findings for each of these specific feasibility objectives (the recruitment process, the randomisation process and the acceptability and appropriateness of the selected study outcome measures and the PRCI). The quantitative data presented in this chapter has provided information about the practical feasibility aspects of the study processes, however, it gives only limited insight into the participant's involvement in the study and their view of the selected study processes and the intervention, the PRCI. Findings from the qualitative process evaluation component of this study significantly enhance the understanding of the participant's perception of participating in this feasibility study of a coping intervention for recurrent miscarriage and these are presented in Chapter 5. This supports the Medical Research Council guidance for developing and evaluating complex interventions (Craig et al. 2013), which emphasises the fact that a mixture of both quantitative and qualitative methods are generally needed to fully assess the feasibility of running a definitive RCT of a complex intervention, such as the PRCI, highlighting the value of the process evaluation component of this feasibility study.

Chapter 5: Qualitative Process Evaluation: Analysis and Feasibility Findings

5.1 Introduction

Chapter 5 presents the analysis and findings from the qualitative process evaluation element of this feasibility study.

This component of the study aims to add to the findings presented in Chapter 4 that specifically considered the quantitative feasibility findings of the study processes employed in this study. It aims to explore in-depth, women's experience of their participation in the study (including recruitment strategies, randomisation strategies, study intervention, study time points, study outcome measures and research methods).

The initial section of this chapter explores and outlines the process of data analysis utilised in this study, whilst the second section presents the findings.

5.2 Process of analysis

A general inductive approach (Thomas 2006) was selected as a method to enable the systematic, transparent and robust analysis of the data from the qualitative process evaluation. The main analytic strategy of this approach is to establish the core meanings evident in the text, which are relevant to the evaluation (or research) objectives. Justification for this choice of approach is described in Chapter 3, section 3.10.2. The five steps of the process of inductive coding were utilised as a framework to facilitate data analysis (Figure 11).

The intended outcome of this process is to identify a small number of summary categories which encapsulate (in the researcher's view) the key themes identified in the raw data which are assessed to be the most significant, given the objectives of the evaluative piece of research (Thomas 2006).

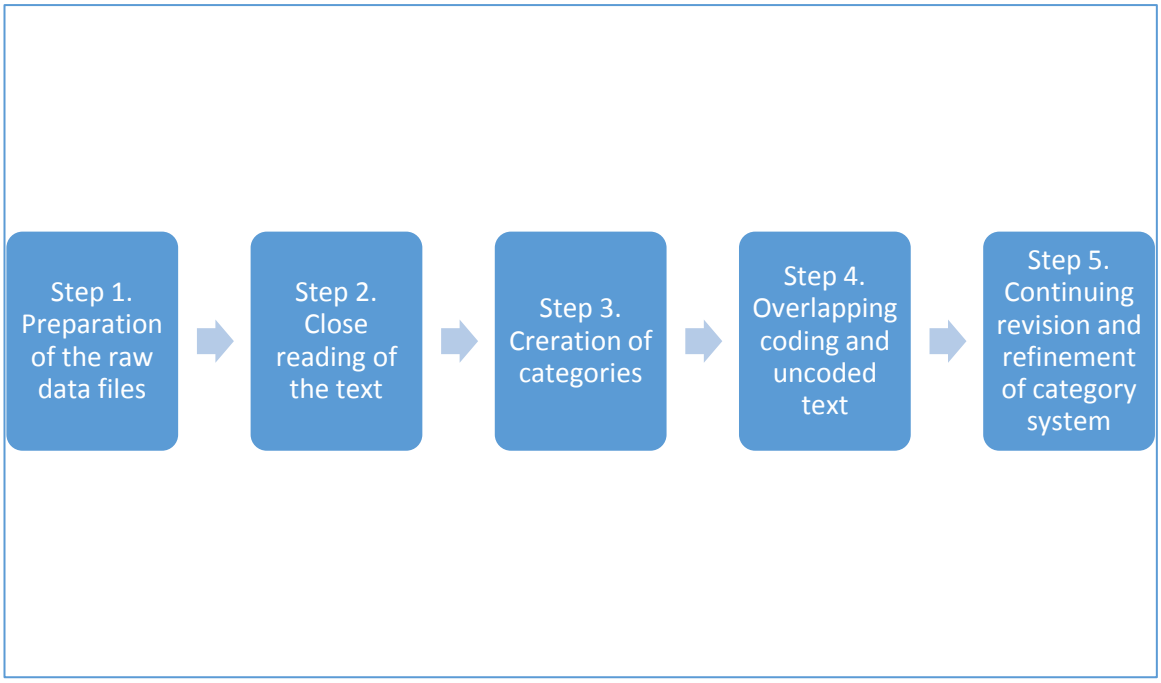


Figure 11: Flow chart to illustrate five steps of inductive coding

5.2.1 Step 1. Preparation of raw data files:

Data from the 14 qualitative interviews were transcribed verbatim in to a common format using a transcription service. Although manual transcription by the researcher allows the opportunity to commence the process of immersion in the data (Lathlean 2015), a transcription service was used in this study mainly due to time constraints, however the transcriptions were thoroughly checked by the researcher for accuracy. The process of data immersion began in the Step 2 of the inductive coding process.

Electronic and hard copies of the transcripts are stored securely and are available to view on request. An example of one of the complete transcripts can be seen in Appendix Q.

5.2.2 Step 2. Close reading of the text:

The interview transcripts were initially read, whilst simultaneously listening to the original interview recordings. This ensured that the latent content and nuances (for example pauses in conversation, voice patterns) of the audio recordings were not lost. Any notes from the reflective field diary kept during the interview stage of this research study were also reviewed. Transcripts were then read and re-read until the contents of each interview became familiar. This enabled the identification of issues of interest which were recurrent across the complete data set and which were relevant to the research objectives (Spencer et al. 2014a), as well as developing an understanding of the key themes and experiences (Thomas 2006).

5.2.3 Step 3. Creation of categories

Having developed a familiarisation with the interview texts by repeated reading, the next stage of the inductive coding process, necessitated the identification and definition of initial themes or categories within the data which were most relevant to the identified research objectives.

Categorisation and classification of themes / codes is an integral part of thematic qualitative analysis and is used in many different analytic traditions (for example grounded theory and content analysis) and involves the unearthing, discovering, interpretation and reporting of patterns within the data (Spencer et al. 2014a). Specifically, Thomas (2006) describes this component of the general inductive process as the development of upper-level categories (which are likely to be more general and based on the evaluation aims) and lower level categories (which are more specific and arise from readings of the raw data). In the inductive coding process, these categories are frequently generated from the actual phrases used by the research participants in the interview text.

Although it is possible to use specialist software to assist and speed up the coding process in studies where there are copious amounts of text data, in this study a decision was made to manually generate and group categories together. This was because the amount of text data in this study was manageable and significantly, the manual process of coding and categorisation could be used as a method to aid full immersion in the data.

The initial task in the categorisation process was to code each transcript in turn. The interview texts were read again and headings and notes were written alongside the text to describe every aspect of the content. The original coded interview texts are available on request, however an example of a coded section of text exploring the participant's views of completing the questionnaires is presented below in Figure 12.

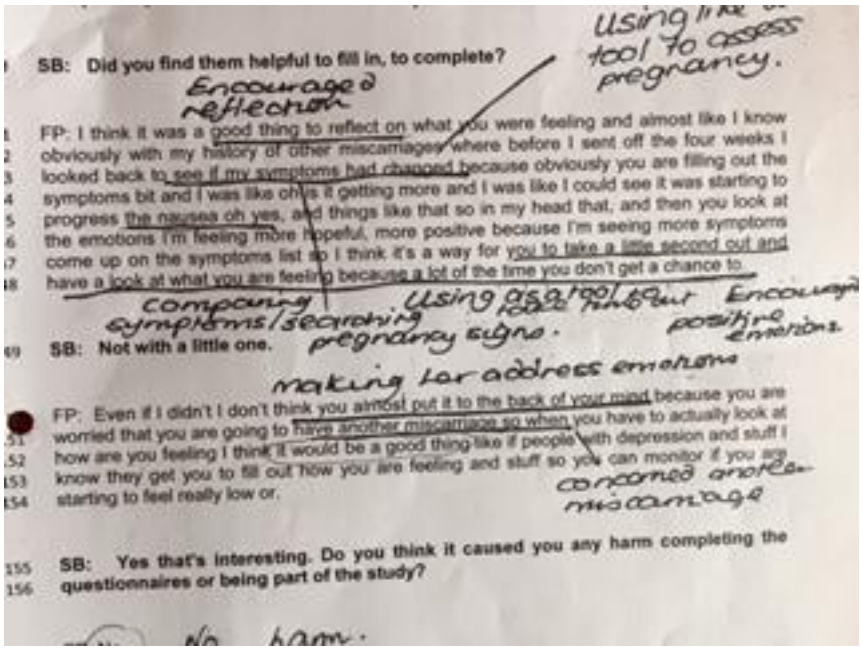


Figure 12: Example from coded transcript

This familiarisation stage in the data analysis process resulted in the generation of 502 initial categories (Figure 13) and these were mostly developed from utilising the participant's own words from the interview text. An excel spreadsheet was developed to list each of these categories / themes (Appendix R).

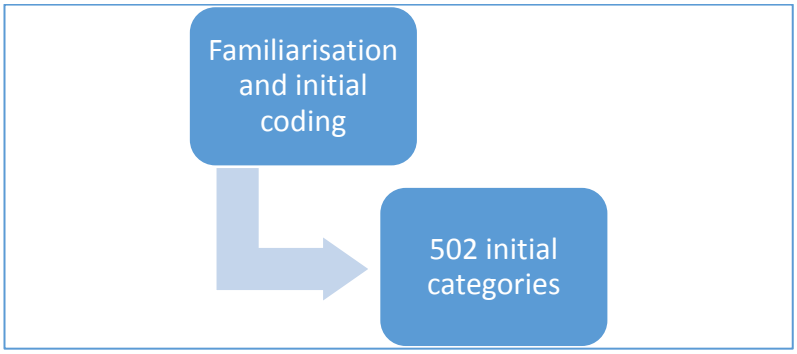


Figure 13: Diagram to show development of initial categories

Upper level categories were then generated to meet the outcomes of the process evaluation and these included the exploration of participants' subjective experiences of taking part in the research study (for example recruitment process, randomisation process, study time points, study outcome measures and the intervention itself the PRCI). However, other lower level categories also emerged and were recurrent across the data. Although they did not meet the evaluative objectives of the study, they were nonetheless important findings, which added to the understanding of women's experience of taking part in the study. Twenty upper level and twelve lower level categories were identified (Figure 14).

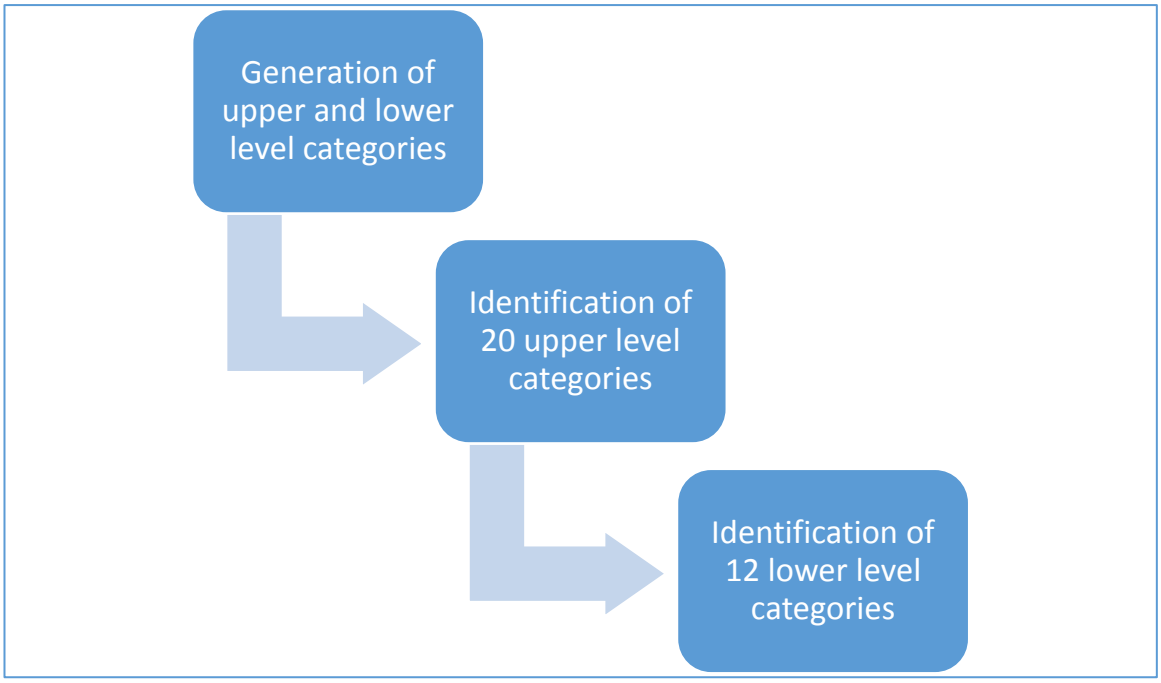


Figure 14: Figure to show identification of upper and lower level categories

5.2.4 Step 4. Overlapping coding and uncoded text

Thomas (2006) notes that it is quite possible that any segment of the transcription data may be coded in to more than one category. Furthermore, because of a lack of relevance to the evaluative objectives, then some of the text might not be assigned to any category at all.

Recurrent miscarriage is a highly emotive subject and during the qualitative interviews, participants were keen to share their personal reflections on their thoughts, feelings and experiences during the waiting period of a new pregnancy. It had not been anticipated that participants would impart such copious amounts of rich interview data. Given that the purpose of this qualitative process evaluation was to explore participants' experiences of their involvement in the study, careful consideration was given to whether or how to code text which did not meet this study objective. In addition, a decision was necessary to establish how interview data, which did not meet the process evaluation objectives, should be used. Agreement to participate in a research study entails 'gifting' that experience to the researcher as data (Iphofen 2005), as such I felt it was my ethical and professional responsibility to reproduce the knowledge and experiences that the participants had shared with me.

A discussion with academic supervisors ensued in which we discussed how to manage these 'extra' data. The primary study objectives were reviewed and, after careful consideration, a decision was made that this PhD thesis should specifically focus on the interview data which were relevant to the evaluative objectives (i.e. those data that explored women's subjective experience

of participating in the study). Analysis of the data that focus on the participants' emotions and 'lived experiences' during the waiting period will form the basis of post-doctoral study.

The format of the semi- structured interview utilised in this study resulted in 'well-ordered data' (Spencer et al. 2014a p.282), whereby the process evaluation questions were addressed at the beginning of the interview and participants shared their personal lived experiences of the waiting period in the latter part. As such, the structure of the interviews enabled differentiation between the evaluative data of the first section of the interview transcripts and the 'extra' data in the second section. For the purpose of this thesis, coding for upper and lower level categories was limited to the initial sections of each interview transcript which addressed process evaluation questions.

5.2.5 Step 5. Continuing revision and refinement of category system

In this component of the general inductive process, core themes or essences of categories are conveyed (Thomas 2006) often with the use of appropriate quotations from the original interview data. In addition, categories are combined or linked under a superordinate heading, when meanings are similar.

In this stage of the data analysis, refinement of the categories was achieved by carefully and manually grouping together categories with apparent similar meanings. This was initially done by myself, but validation of the superordinate categories was attained during discussion with academic supervisors. Discussion with the Patient Public Involvement (PPI) representatives for my study, whereby interview data was shared with them and their opinion sought on the themes within it, also helped to establish and validate categories. In total, six superordinate categories were generated and these consisted of:

1. Participation in research
2. Study outcome measures
3. Study intervention
4. 'Hope for the best but expect the worst'
5. Coping and validation
6. Perception of need

The aim of the general inductive approach for analysing qualitative evaluation data is to create a small number of final summary categories (Thomas 2006). To achieve this, the superordinate categories are again combined and linked to generate summary categories. These final summary categories should, in the evaluators view, encapsulate the key aspects of the themes identified in

the raw data and are assessed to be the most notable themes, given the evaluation objectives of the study (Thomas 2006).

Further discussion and dialogue with supervisors enabled and confirmed the development of the final summary categories for this study. The two final summary categories consist of:

1. Study processes
2. Managing expectation

Table 9 (below) illustrates how the 32 upper and lower level categories were linked and combined to generate superordinate categories and two final summary categories, utilising the general inductive coding process for this study.

	SUPERORDINATE CATEGORIES	SUMMARY CATEGORIES
UPPER LEVEL CATEGORIES		
Reflections on taking part in research Ad hoc reflections on taking part in study The patient information sheet Randomisation Informing researcher of positive pregnancy test Contact / communication with researcher	Participation in research	Study processes
Frequency of completing questionnaires Understanding of questionnaires Positive reflections on completing questionnaires Negative reflections on completing questionnaires Sensitivity of questionnaires Ad hoc reflections on use of questionnaires Practicality of completing / returning questionnaires	Study outcome measures	
First impression of PRCI Frequency of use of PRCI Practicality of use of PRCI Positive reflections on use of PRCI Negative reflections of use of PRCI Long term use of PRCI Other reflections on using PRCI	Study intervention	
LOWER LEVEL CATEGORIES		
Feelings and experiences Social isolation Anxiety Fear Expect the worst Tempting fate	Hope for the best but expect the worst	Managing expectations
The waiting period Length of waiting period Other reflections / activities waiting period Effect of waiting on relationships	Coping and validation	
Health professional support / care during waiting period Reassurance ultrasound scans	Perception of need	

Table 9: Table to show classification of upper, lower, superordinate and final summary categories identified and generated in the inductive coding process

5.3 Assessing validity of the analysis process

Qualitative research has been criticized in the past for being subjective, anecdotal, lacking in generalisability and subject to researcher bias (Cope 2014). Evidence of reliability and validity in qualitative research methods is therefore important (Amankwaa 2016) as these concepts will promote the transparency, trustworthiness and credibility of the conduct of the study. Trustworthiness refers to the degree of confidence in data, interpretation and methods used to ensure the quality of a study (Polit and Beck 2014) and the most common measures utilised to assess the trustworthiness of qualitative research are those described by Lincoln and Guba (1985), credibility, transferability, dependability and confirmability.

Table 10 (below), presents some of the criteria that can be utilised to demonstrate aspects of trustworthiness in qualitative data and gives examples from this qualitative process evaluation.

	DEFINITION	EXAMPLES OF CRITERIA WITHIN THIS RESEARCH STUDY TO DEMONSTRATE ASPECTS OF TRUSTWORTHINESS
CREDIBILITY	Confidence in the 'truth' of the findings.	This study was conducted using standard procedures typically used in qualitative research, specifically face-to-face interviews and thematic analysis of data. Qualitative interviews were audio recorded and initial coding is available for checking. Audio transcriptions were checked repeatedly and findings discussed with supervisors, demonstrating the iterative process and questioning of the data.
TRANSFERABILITY	Demonstrating that the findings have applicability in other contexts	The findings of this qualitative study are specific to the women who participated in this study. However, this study's transferability is supported throughout this thesis with a rich, detailed description of the context, location, and the people studied. It is transparent in the methods of data analysis utilised as described in Chapter 5.
DEPENDABILITY	Demonstrating that the findings are consistent and could be repeated	All processes used within this study are reported in detail in Chapter 3, 'Methods and Methodology'. This would enable a future researcher to repeat the work, although given the study represents the individual views and reflections of study participants from this particular study, it may not necessarily gain the same results.
CONFIRMABILITY	The degree of neutrality or the extent to which the findings of the study are shaped by the research participants and not by researcher bias, motivation or interest	Chapter 7, the 'Discussion' chapter of this thesis addresses reflexivity, acknowledging some of the shortcomings in the selected methods utilised in this study and their potential effects.

Table 10: Table to show assessment and demonstration of trustworthiness of qualitative data

5.4 Findings

The main objective of the qualitative interviews was to focus on the process evaluation aspects of the study by exploring the participants' subjective experiences of the study process, study outcome measures and study intervention. This information combined with the quantitative feasibility findings for this study provides vital preparatory work for a future definitive study of the Positive Reappraisal Coping Intervention (PRCI) by establishing the acceptability of study procedures and methods, in turn helping to determine whether any study refinements are necessary. In total 14 qualitative interviews were carried out, seven of these were with participants in the intervention (PRCI) group and seven with participants from the control group. At the time of the interview, eight of the interviewees had ongoing pregnancies and six had already miscarried.

Two summary categories (or main themes) arose from the higher, lower and superordinate categories following the process of inductive coding in this study. These two summary categories consisted of 'study processes' and 'managing expectations' and will constitute a framework within which to present the findings of this qualitative process evaluation.

5.4.1 Study Processes

The 'study processes' summary category was shaped by participants' subjective views and experiences of taking part in the research (for example the acceptability of recruitment / randomisation strategies, study literature, study time points, outcome measures and the PRCI). As such, this term encompassed the upper level and superordinate categories (i.e. participation in research, study outcome measures and study intervention) in the data, which had met the evaluative objectives of the process evaluation. Significantly, this summary category provides evidence of the participants' views of taking part in this research study and identified study factors which they perceived worked well and those that needed some refinement.

5.4.1.1 Participation in research

Previous personal experience of researching sensitive topics in the area of reproductive health had suggested that women affected by health problems such as recurrent miscarriage, seemed willing to participate in research and appreciated the opportunity to contribute to a personally relevant field of investigation. Furthermore, a recent multi-centre clinical trial investigating the medical treatment of recurrent miscarriage (Coomarasamy et al. 2016) exceeded the planned recruitment target suggesting this patient group was indeed willing to take part in research. However, one of the important feasibility objectives of this study was to assess whether sufficient

numbers of women affected by recurrent miscarriage would be willing to participate in this research study.

Without exception, all 14 women who took part in the qualitative interview reported a positive mental attitude to taking part in research and were willing to participate in this particular study. This reflects the quantitative feasibility findings that had demonstrate that only six potential participants out of the 107 invited to take part in the study, declined the opportunity to participate. Indeed, one of the participants had read about this research study on the Miscarriage Association website and actively sought referral to the hospital it was being conducted in so she could take part.

Women reported that they felt 'happy' with the way they were approached and invited to take part in the research and that this occurred whilst attending the Recurrent Miscarriage Clinic in Site A or the Early Pregnancy Unit in Site B. The respondents referred to the fact that this was an important area of research and they were keen to do anything that would help, furthermore three of them had previously taken part in clinical research projects investigating recurrent miscarriage (N.B. participant code refers to study identification code used on study materials):

> *I'm more than happy to take part in this* (research) *since I've been through miscarriages in the past (Participant SO047, line 43)*
>
> *I felt positive and happy that I was asked* (to take part) *(Participant SO056, line 20)*
>
> *I'm always delighted to take part in things like that because it helps find out new stuff (Participant SO016, line 62)*
>
> *I was very happy to participate, I think it's very important and I think that the topic of research is very important (Participant SO064, line 41)*

Significantly, findings suggested that this group of women were altruistic, keen and willing to take part in research that would help other women, even if it did not help them personally. Moreover, participating in the research appeared to give the women and their pregnancy a purpose:

> *It* (the research) *helps me through the pregnancy and especially the early days to know that there is another reason for it and if it goes wrong then there was a purpose still for doing it (Participant SO015, line 33)*
>
> *I wanted to be part of something …. And if I was able to help people in the future I was quite positive about that (Participant SO056, line 22).*

One participant even referred to the fact that being invited to take part in the research study had given her a purpose and a reason to 'move forward' in her life following her miscarriage,

potentially indicating that the research process itself acted as an intervention or motivation to improve psychological well-being:

> *….it was nice to actually move on. I think it actually helped me a bit in my transition from the previous miscarriage, because that had gone on for so long (Participant SO052, line 46)*

Similarly, another described the positive affect she experienced as a result of participating in research:

> *I think the whole being part of, knowing that you are part of a study has made a difference to me massively (Participant SO061, line 381)*

In the standard care pathway for recurrent miscarriage patients in Site A, the majority of contact between the woman and the recurrent miscarriage clinic takes place during the investigation phase. Once any potential cause of the miscarriages has been excluded, then the patient is normally discharged from the clinic and encouraged to try for a pregnancy again. As such, communication and involvement with the recurrent miscarriage service is limited during this time, which in itself can add to the isolation the woman experiences during the early stages of a new pregnancy. I was keen to investigate whether one of the reasons women were willing to participate in the study was because it would maintain their links with the recurrent miscarriage service. In response to this question several of the interviewees confirmed that although the main reason they took part in the study was indeed altruistic, having contact with me, a health professional who specialised in the care of recurrent miscarriage was seen as an added bonus to participating in the study:

> *Because I felt more linked with here* (recurrent miscarriage clinic) *by being part of the research (Participant SO002, line 174)*

> *I knew I had a link of someone to go to, rather than just being left. It's a really long duration of time to be left (Participant 031, line 390)*

The fact that these narratives appear to suggest that the additional contact of a researcher who was also a clinical specialist in the area of recurrent miscarriage affected their decision to participate in the study raises important issues when considering the internal validity and feasibility aspects of this study. The implications of the involvement of a health professional known to the participants in the study processes (for example recruitment) will be discussed in detail in Chapter 7 of this thesis.

Once a participant was positively screened for eligibility to take part in this study, their first interface with the study materials / processes was the Patient Information Sheet (PIS) (Appendix

E). The aim of the PIS is to help to ensure that all those who are invited to take part in the research study have been adequately informed about the aim of the study and their potential involvement in it (Health Research Authority 2017). As such, it is a vital source of information to potential participants and supports the consent process. The information provided in the PIS must therefore be clear and understandable and contain sufficient information about the study to aid the potential participant's decision-making process as to whether they wish to take part in the study. One of the evaluative objectives of the interviews was to assess the participants view on the PIS in order to evaluate whether any refinements were necessary.

All fourteen interviewed participants identified that the PIS clearly outlined the study aims and objectives and what their involvement in the research project would entail. There were no suggestions made for improvements and participants were brief and to the point that the PIS was satisfactory as it stands:

> *I think it gave me everything that I needed. I can't think of anything that I would have added (Participant PO003, line 48)*
>
> *I thought it was really clear (Participant SO064, line 45)*
>
> *The information sheet was very thorough. It explained everything comprehensively (Participant SO056, line 38)*

This component of the feasibility study was an RCT, which is particularly valued for its ability to rigorously test the effectiveness of treatment and interventions (Nelson et al. 2015). The advantage of the RCT relies on its distinguishing feature: randomisation or random assignment of participants to the experimental and the comparison treatment groups (Sidani et al. 2017). Sidani et al. (2017) propose that the advantages of randomization are compromised when participants express non-acceptance or unwillingness to be randomized to the treatments under evaluation. Because this study was offering the use of a new intervention (with no apparent detrimental side effects), I was concerned that in this study the opposite might be true, that potential participants might express unwillingness to be randomised to the non- intervention group (that is the group that did not receive the PRCI). I was therefore keen to ask participants about their views on the acceptability of taking part in a study in which they might be allocated to the control group and therefore not receive the PRCI.

All respondents noted that they had understood the notion of randomisation as described in the PIS, however two interview participants who had been in the control group voiced some disappointment that they had not received the PRCI:

> *I was disappointed, I wanted to try something …. But someone always has to be in that group so that's fine. I just wanted to help. (Participant SO044, line 100)*

> *I mean I wanted the card and I was disappointed that I didn't get in that group, but I get the point of it all and I know how it works (SO064, line 64)*

Significantly, the fact that this study included an element of randomisation had not affected the participants' willingness to take part in the research, however when considering recruitment to any future definitive study of the PRCI, the readiness of potential participants to be randomised to a control or intervention group remains an important consideration.

Information on positive reappraisal is freely available on the internet, so participants who had been randomised to the control group and therefore not received the PRCI, were asked if they had been tempted to research the notion of positive reappraisal and use it anyway. All of those asked stated that this was not something they had thought of doing:

> *I have to be completely honest and say it never even crossed my mind (Participant SO003, line 123)*

Study participants were asked to notify the researcher as soon as possible after a positive pregnancy test to enable randomisation to take place. Therefore, the interview respondents were invited to share their views on the feasibility of doing this. In particular, I wanted to ascertain whether contacting the researcher by telephone and /or email had been practical and without delays and because the aim was to randomise as soon after a positive pregnancy test as possible, how quickly participants had done this.

All fourteen participants reported that the practicality of contacting the research team had been straightforward. When asked whether they found it easier to contact the research team to notify them of a positive pregnancy test by telephone or email, the majority of the interviewees preferred email contact, this appeared a more practical method for them to use. As one interviewee stated:

> *It wasn't a problem at all* (contacting the research team). *I think because I was at work most days as well it was a lot easier by email (SO047, line 78)*

During the interviews, the participants were asked how long it took them to contact the research team to inform them of a positive pregnancy test. All fourteen of the interviewees notified the team within two days (sometimes waiting until the next working day) and the vast majority emailed on the day of their positive pregnancy test:

> *We did the test on the Friday and I contacted you on the Monday, so it was within a couple of days (Participant SO044, line 87)*

In summary, findings from the superordinate category 'participation in research,' demonstrated that patients with recurrent miscarriages showed a willingness to engage with and participate in this study, consistently exhibiting altruistic qualities, wishing to help other women who experienced recurrent miscarriage. They described the recruitment and randomisation process as acceptable, the PIS as being informative and expressed satisfaction with the practicality of making contact with the research team. However, some of the participants recruited from Site A, suggested that the additional contact of a researcher, who they also knew as a clinical specialist in the area of recurrent miscarriage, did influence their decision to take part in this research. This apparent threat to the internal validity of this study merits further discussion in Chapter 7, when the key feasibility objectives and findings of this study will be discussed in detail.

5.4.1.2 Study outcome measures

The study outcome measures selected for this study consisted of the Hospital Anxiety Depression Scale (HADS) (Zigmond and Snaith 1983) and the Weekly Record Keeping (WRK) form (Boivin and Takefman 1996) (Appendix K, L and M). A description of these questionnaires and the rationale for selecting them is outlined in Chapter 3, section 3.9.1.1.

A fundamental part of any feasibility study is the testing of the data collection forms and questionnaires (Lancaster et al. 2004). This is particularly important when the questionnaires are to be self-completed by the research participant because, prior to any definitive study, it is necessary to establish they are comprehensive, understood and easy to complete. Furthermore, it is important to establish that the selected study outcome measures are in fact providing researchers with the information they require. Therefore, one of the important feasibility objectives for the qualitative process evaluation interview was to establish interviewees views on the use of the selected study outcome measures. In particular, attention was paid to the acceptability of the frequency of completing questionnaires, the ease of completing and comprehensibility of the questionnaires and the practicality of returning the questionnaires to the researcher and any individual reflections on the use of them.

When the participants were asked whether they had been willing to complete the questionnaires on a weekly basis, in all cases, they reported this was acceptable and not an onerous task:

> *I think it was good* (weekly completion)*, it was just about right (Participant SO001, line 63)*

In one case, the participant stated that she would have been happy to complete the questionnaire on a daily basis. When asked to comment on whether she felt completion of the questionnaires on a weekly basis was acceptable to her she remarked:

> *Maybe not enough, maybe twice a week (Participant SO031, line 417)*

Another interviewee commented that she felt completing the form on a daily basis would allow for more accurate reflections of the emotions experienced during the waiting period as these fluctuated day by day:

> *You are commenting on how you felt during the week but some days everything was so positive, I was fine and I'm like this is fine and then literally the next day you are like I've lost it. So I don't know if it captures that rollercoaster you are on (Participant SO003, lie 82)*

Furthermore in response to being asked about weekly completion of the questionnaire, the majority of interviewees expanded on their response to this question by indicating that they had in fact utilised this as a method to divide the waiting time up in to individual weeks and therefore shorter milestones. The women would often look forward to completing the questionnaire, setting a fixed day and time to complete them, taking time out to do so and ostensibly taking comfort from the fact that they had achieved another week of their pregnancy. These findings suggest that the research process itself may have had a positive effect on the waiting period in that as well as using the questionnaires as intended to measure emotions, the participants also used them as a weekly monitoring system:

> *Thursdays were when I did the questionnaires and that kind of got me in the middle of the week. So I do feel it was possibly the best time and I think at that stage of the pregnancy things are weekly. I was being scanned weekly ….. so these questionnaires fitted in with that quite well (SO044, line 116)*

> *I think it actually helped me being weekly, because then in my head it's like that's another week that I've completed. So it did actually help me going through it on a weekly basis (Participant SO047, line 100)*

> *I did them regularly. I finish work on a Wednesday and I always did them on a Wednesday and it was a good time for me because I wouldn't have any distractions, come straight home, didn't have my son because he was at school. So I'd do them on a Wednesday (Participant SO061, line 184)*

Instructions for completing both the HADS and the WRK were included on the actual questionnaire. Further guidance on the frequency of completion and practical information on how

to return them was either given in an email or in a telephone call between myself and the research participant. The majority of the interviewees commented on the fact that they had found these instructions sufficient:

> *They* (the questionnaires) *were very easy and very self-explanatory (Participant 044, line 106)*

However, two participants explained that more comprehensive guidance or a cover letter containing more explicit instructions on the practicalities of completing the questionnaires would have been useful:

> *….you are just pregnant and there's a lot of emotions going round …maybe put in an idiots guide to this is what you need to do, fill out this form, because I think even on the questionnaires it does have a little brief description of what you are doing*, *but I almost expected an idiots guide in there as well (Participant SO016, line 109)*

> *Well I was like what am I supposed to do? …. There were some bits that I didn't know, did I have to fill it out or could I just choose what I was filling out? (Participant SO016, line 87)*

The overall response to completing the HADS questionnaire (Appendix K) was very positive. Although one of the interviewees suggested that she would have liked to have space to elaborate on the tick box answers of the HADS, none of the interviewees identified any difficulty with comprehension of the wording or scoring of this measure. Although another respondent commented that the HADS was not pregnancy specific enough, all agreed this questionnaire was appropriate for use in their situation and straightforward to complete. This confirmed previous validation of the HADS as a reliable instrument to measure anxiety and depression in earlier fertility studies investigating the use of the PRCI (Ockhuijsen et al. 2013b; Ockhuijsen 2014; Ockhuijsen et al. 2014b).

When asked to comment on the ease of completing the WRK (Appendix L and M), the majority of the interviewees commented that they had found this questionnaire easy to complete. However, three of the interviewees highlighted issues regarding their understanding of how to rate / score the different items on the WRK. The scoring system on this questionnaire asks users to score the impact the emotional or physical symptom has had on their ability to perform daily tasks, but the score does not relate to the intensity of the symptom. As such, it became apparent during the study, that the rating scale was not appropriate for scoring the positive emotional symptoms such as 'happy,' 'encouraged' and 'optimistic about pregnancy.' For example if a participant was feeling 'happy' and rated this emotional symptom with a score of 3, then the rating scale on the questionnaire suggested that this symptom was having a 'markedly negative effect on how well

they were performing their daily tasks during the previous week.' This made it impossible for participants to accurately score the positive emotions on the WRK.

> *It* (the WRK) *just stumped me completely and I was like this is quite confusing, I'm not going to be able to do this. I think I ended up thinking well I'll just put 2, it was like the in-between one, but then I thought well I just can't accept that so I contacted you for clarification (Participant 056, line 93)*

> *I did find it really difficult because emotion-wise you've got the really positive things in there mixed in with these real deep things and you are asking me to grade it on the same scale. I found the scoring a little bit tricky (Participant SO061, line 173)*

Clearly, this apparent flaw with the rating system of the WRK has implications for future studies using this measure and this will be discussed in detail in Chapter 7. However, in their accounts of how they actually scored the positive emotional symptoms on the WRK questionnaire, it appears that some respondents may have chosen to rate these emotions by scoring the intensity with which they felt it, rather than the degree to which it had a negative impact it had on their ability to perform daily task:

> *I scored it as intensity rather than positivity or negativity (SO064, line 133)*

> *The way I interpreted it, I said well I assume it's a three-point scale, so three must be I'm really amazingly happy, two was okay, one was yes it's touching the end and zero was I never actually felt it. (Participant SO052, line 144)*

> *If I was happy then I would give it a score (Participant SO061, line 173)*

Overall, the interviewees shared numerous positive reflections on the use of the questionnaires. Furthermore, participants appeared to adapt the questionnaires as a form of intervention, suggesting the research process itself may have promoted psychological well-being by providing the questionnaires. The self-adaptation of the questionnaires into an intervention and source of support, appeared to focus on two main themes. Study participants used the questionnaires as a tool to aid reflection on the emotions they were experiencing during the difficult waiting period and utilised the weekly completion of them as a method of monitoring the pregnancy's progression.

When using the questionnaires as a tool to aid reflection, respondents referred to the fact that the actual process of completing the questionnaires encouraged them to take time out from their day to day activities to reflect on the plethora of challenging emotions they were experiencing at that time. This in turn encouraged an awareness of these emotions, anxieties and feelings, helping

them to rationalise them and giving back a little control in a situation where the women had no control over the outcome.

> *I think it was a good thing to reflect on how you were feeling …. I think it's a way for you to take a little second out and have a look at what you are feeling, because a lot of time you don't get a chance to (Participant SO016, line 141)*

> *It's not like you are not thinking about it* (the pregnancy) *because you struggle to think about anything else, but it does help you to rationalise your feelings a bit…. It does help you to get control of yourself a little bit (Participant SO003, line 95)*

> *It* (the questionnaires) *would pull me back in-line (Participant SO031, line 419)*

> *I think it helped me to feel a bit more in control of it all (Participant SO002, line 83)*

The physical effort of writing and completing questionnaires proved supportive. One respondent reported:

> *I found them helpful in the way that you could just 'dump' on them …. Sort of like when people tell you if you've got problems to write them down and it just gets it out of your head (Participant SO028, line 134)*

Significantly, three of the interviewees even specifically remarked on the fact that the questionnaires promoted positive reappraisal, something the Positive Reappraisal Coping Intervention (PRCI) was designed to do:

> *They just reminded me of especially thinking about the positive things, they just reminded me of actually yes this has been a good week! (Participant SO056, line 146)*

> *Reading the questionnaires made me think a little bit more positive, so that was probably the day I felt more positive about it, when I was filling it in. Even though you had the card* (PRCI) *throughout the week, the questionnaire was probably what made you come around a bit more (Participant SO031, line 425)*

> *It* (the questionnaires) *made me think positively about the pregnancy (Participant SO015, line 87)*

There was a sense among all interviewees that one of the benefits of completing the weekly questionnaires was that as the pregnancy continued, they were able to look back over the completed questionnaires and monitor the progress of their pregnancy:

> *It helped me get through the week, because every time I filled out a new one I'm like 'well I've just completed a week' and then I'd look at the last ones and the symptoms have*

changed and the second questionnaire I have filled out seems to be more positive than the last one where I put everything as negative (Participant SO047, line109)

You kind of assess how you are doing. I felt as though each week I could see the highs and lows. I could get a sense of highs and lows and then especially when it started to get more positive towards the end you felt like you were making progress (Participant PO003, line 101)

Specifically the WRK enabled women to monitor their symptoms of pregnancy and seemingly participants saw this as a useful function of the questionnaires and an added benefit:

When you looked at the symptoms of pregnancy it was kind of like, oh yes I've got that. So that bit was reassuring in itself (Participant SO015, line 104)

I looked back to see if my symptoms had changed because obviously you are filling out the symptoms bit. And I was like oh it is getting more and I could see it was starting to progress – the nausea ….and then you look at the emotions and I'm feeling more hopeful, more positive because I'm seeing more of the symptoms (Participant SO016, line 143)

Conversely, one interviewee commented that the WRK made her much more aware of the physical symptoms of pregnancy and any fluctuating symptoms added to her anxiety:

When you talk about symptoms that was a bit tricky actually because obviously in the early stage I had extreme nausea and then of course as soon as it drops off, it's like oh what does that mean? Is that a bad thing? .... It did make me more aware of the symptoms (Participant SO061, line 193)

Another apparently positive effect of the questionnaires was that participants indicated that they felt less anxious as a result of completing the questionnaires. Specifically three of the interviewees indicated the questionnaires helped them to feel normal, because if they were being asked about the worry and extreme anxiety they were experiencing, then this was a normal consequence of the situation they were in:

It made me feel a bit normal that someone was asking me because I don't feel normal (Participant SO044, line 48)

Even if you just feel like other people are feeling the same way, I think that helps you with anxiety (Participant SO002, line 83)

When I thought I was feeling quite bad …. When I was filling it in was like oh well I'm in the average zone, so that's alright! (Participant SO028, line 128)

Comments regarding the use of the questionnaires were mostly positive, with a minority of negative reflections on their use. These negative reflections mainly focused on the fact, as mentioned previously, that a small number of participants would have liked space in the questionnaires to elaborate on their answers. However, one participant saw the fact that only tick box answers were required as an advantage, commenting:

> *You didn't have to open up too much (Participant SO028, line 143)*

Another interviewee proposed that she found some sections of the questionnaires vague and not specific enough to monitor the emotional upset she was experiencing because of the new pregnancy. She was concerned her answers were misleading because of other life pressures:

> *I was in a hideous place at work and felt tense and wound up the entire time, but I knew that a lot of that would have happened whether I was pregnant or not, so it wasn't very specific….I felt like my answers would have been more helpful to you if the questions had been more specifically to do with pregnancy after miscarriage rather than just general (Participant SO064, line 97)*

Clearly, an important and fundamental feasibility aspect of this study was to assess whether the selected study outcome measures were acceptable to the research participants and not upsetting in any way. As such, during the interviews, respondents were specifically asked to indicate whether they felt the questionnaires had been insensitive in any way. In response to this question, all interviewees expressed that the questionnaires had been sensitive to their situation and not added to any emotional distress they experienced during the waiting time of their new pregnancy.

During their involvement in the study, following randomisation, participants had received hard copy questionnaires in the post and been provided with a stamped addressed envelope to return them to the researcher. Interviewees were asked to comment on the practicality of this, whether this had been an acceptable and practical method to receive and return the completed questionnaires. Whilst a minority of interviewees remarked that the option of receiving, completing and returning questionnaires via an on-line, electronic system might be useful, all of the participants commented that they had found the completion of hard copy questionnaires and the postal system utilised in this study easy and convenient:

> *I prefer doing them by post and hand …. I think I prefer that (Participant SO002, line 102)*

> *It was a lot easier to post them because you can just shove them in the envelope on the school run. Easy! (Participant SO16, line 168)*

The study participants received the set of questionnaires in two batches. At randomisation, they were posted questionnaires for the first four weeks along with a stamped addressed envelope for return. A second batch of four sets was sent out one week before they were required. Chapter 4, which explored the quantitative feasibility findings of this study established that the return rate of questionnaires was excellent. Interestingly however, one interviewee commented that once she had returned the first batch of questionnaires she was disappointed that she couldn't look back over them to monitor the progress of her pregnancy:

> *I did the first batch then sent them off to you ….. and I remember doing the next lot and I was like, I can't look back on what I've done before! Because what I used to do is complete them and then I'd just have a look to see how I was progressing, just like my own little research (Participant SO052, line 188)*

This particular interviewee would have preferred to return all of the completed questionnaires back together as this would have enabled her to reflect back on her answers and monitor her progress.

This section, which has detailed the findings from the 'study outcome measure' superordinate category, suggests that, on the whole, the interviews provided evidence that the research participants had found the frequency of completing the questionnaires and the ease and practicality of receiving and returning the hard copy questionnaires acceptable. However, interviewees highlighted problems with the rating/scoring system of the WRK and some participants felt that the instructions accompanying the questionnaires should have been more explicit. Although one interviewee felt that the HADS was not specific to pregnancy related anxiety, there was also a consensus amongst the other interviewees that the questionnaires had been an appropriate way of reflecting their emotions and experiences.

Significantly, participants reported feeling a positive effect as a result of completing the questionnaires on their psychological well-being that appeared to be independent from use of the PRCI. Participants indicated that they placed high value on the use of the questionnaire; it had provided them with a method of monitoring the progress of their pregnancy, a method of monitoring their emotions and pregnancy symptoms and aided reflection encouraging an awareness and rationalisation of the challenging emotions that they were experiencing. These important feasibility findings merit further discussion and will be explored in detail in Chapter 7.

5.4.1.3 Study Intervention

The PRCI (Appendix A) is a short coping intervention, based on the concept of reappraisal which aims to promote positive re-evaluation of a challenging situation (see Chapters 2,3 and 4 for

background on this intervention). As part of a feasibility study it is necessary to establish the acceptability of the selected intervention, as in some cases an intervention may not appeal to all patients (Lancaster et al. 2004) . The aim of the interviews in the qualitative process evaluation interviews was to add to the quantitative feasibility findings outlined in Chapter 4 by asking participants about their views and opinions on the use of the PRCI. They were specifically asked to comment on the practicalities of using the intervention and to share some insight in to their personal reflections of using it.

The actual PRCI consists of a simple, small laminated card containing 10 positive reappraisal statements and this was posted to the research participant after being randomised to the intervention group. First impressions and initial reactions to the intervention were, on the whole, negative and questioning of how this simple card was going to help them manage the anxiety and coping abilities during the stressful waiting period:

> *I thought gosh this is a bit nuts! (Participant SO061, line 241)*
>
> *My first impressions were it was a lot simpler than I expected (Participant PO003, line 140)*
>
> *When I first saw it I actually thought it was a bit awkward. I thought how am I going to use this to make myself feel better or remind myself to stay positive? (Participant SO047, line 147)*

Despite the initial reactions to the PRCI, there was a positive attitude and willingness to engage with this research and participants appeared agreeable to persist with the intervention:

> *When I actually sat down and really thought about each one* (the statements on the PRCI) *very carefully, it made sense and it helped me to really think about those things (Participant PO003, line 139)*
>
> *So at the beginning I didn't use it as much, but then as the pregnancy started progressing and I started reading it on a daily basis, it started staying in my head more and it just used to remind me to stay positive because I didn't have that from anywhere else (Participant 047, line 149)*
>
> *It was only as I had little worries and issues and I started to look at the card, I thought well actually yes this does help me to think more positively (Participant 056, line 170)*

The written guidance which accompanied the PRCI (Appendix D) requested that participants read the card twice daily throughout the waiting period. During the interviews, respondents were asked to comment on the frequency with which they had used the PRCI. The frequency of use varied considerably. Some interviewees used the card more frequently at the beginning:

Well at the beginning I was trying to do it twice a day but then I then I think I moved to …. Trying to look at it every evening (Participant SO001, line 105)

It was between five to six times a week to start with and then it went down so I was only using it twice (Participant SO056, line 203)

Conversely, another respondent commented that she used the PRCI more as the pregnancy continued and she became more familiar with the card and concept of positive reappraisal:

At the beginning I'd look at it once here and there and sometimes I wouldn't remember that I had this card to help me but later on I did …. I started using it 3 or 4 times a day as the pregnancy started progressing (Participant SO047, line 158)

Ostensibly, however, it appears that participants individualised how often they used the PRCI and made it a technique, which was personal to them, utilising the card at time points when their anxiety levels were most elevated:

Last thing before I go to bed was always a real worry time for me so I would make sure that I read that at least once, sometimes a couple of times …. So what I ended up with was a very personal technique to me, but it helped to keep repeating it (Participant PO003, line 155)

I found it helpful in respect of if I was getting a bit wobbly, if that's the best word to use. I would get the card and go right well actually that's good isn't it (Participant 061, line 246)

It would suddenly be five am every morning that I was waking up in a complete panic, that's the only way I can describe it, so the card, then I would have a cup of tea, sit and read and think right OK just calm down (SO0031, line 492)

Interviewees were asked about the practicality of carrying the PRCI card with them. In fact, the majority of the respondents had preferred to leave the card at home in a safe place where they could access it on their return:

I would leave it here (at home), *but I knew that when I got back from work that when I had my quiet time, I could sit and read it (Participant SO061, line 261)*

Whilst one participant did suggest that a credit card sized PRCI would make it easier to carry around, another transposed the PRCI on to her mobile telephone so that she had with her whenever she wanted to use it:

So for each of the ten points (on the PRCI), *what I ended up doing is because I have my phone with me all the time, is I wrote out the statements in my notes on my phone (Participant PO003, line 142)*

This particular interviewee wrote further notes on to her smartphone to adapt and individualise the PRCI to suit her. She added personal statements under the headings of the ten items on the PRCI and commented that whilst the PRCI gave her good guidance on positive reappraisal techniques, it helped her to expand on these and make them personal to her. She would then read the personal statements, adding to them when and as necessary, rather than read the PRCI.

A key aspect of intervention evaluation is to ensure that the intervention is delivered consistently across participants (Ockhuijsen et al. 2014b). As such, the guidance sheet for the PRCI (Appendix D) gave clear written instructions on the use of the PRCI, recommending that users read the card at least twice a day (morning and evening) or more frequently if required and that they carry it with them throughout the day so it was available to use anytime. However, the qualitative findings from this study provide evidence which demonstrates that participants modified the written guidance they received by individualising the use of the PRCI to suit their situation. Some participants read the PRCI more frequently than twice a day and others used it much less than this. Furthermore, findings indicated that participants did not always carry the card with them, choosing instead to leave the card at home or even adapting the card to use via their smart phone, highlighting the need to consider the present format of the PRCI and assess whether it is appropriate to update this hard copy format to a smartphone application.

Previous studies of the PRCI (Ockhuijsen 2014; Ockhuijsen et al. 2015) demonstrated similar findings, proposing that adaptation of the PRCI was based on judgement regarding the effect of the PRCI, whether users felt the effort to use the instrument to be worthwhile or not and the intensity of the emotions being experienced. For example, women who were experiencing negative emotions were motivated to read the PRCI more frequently. However, the key feasibility message here is the need to consider implementation fidelity of the intervention in a future trial, whereby procedures are considered as to how the intervention implementation will be monitored during its delivery to study participants (Spillane et al. 2007). This will be further discussed in Chapter 7.

Positive reappraisal and positive thinking was a completely new concept to some of the participants, this appeared to be a cultural effect:

> *For people like me who come from a different part of the world, and I have a very different mentality and positive thinking is not what I was brought up with …. Where I'm coming from we look very negatively at life (Participant SO001, line 123)*

However, the majority of the interviewees had previously heard of the concept of positive reappraisal and informally tried to use it, but not in such a structured or therapeutic way as the technique suggested by the PRCI. The PRCI appeared to formalise a positive reappraisal of the

challenging situation they were in, encouraging the users to take time to validate the positives in their lives, alongside the negative:

> *I would actually look at it* (PRCI) *sometimes, even if I wasn't feeling like it, just so I could hone in and focus on those emotions (Participant SO061, line 257)*

> *I think the card* (PRCI) *was a really good guidance and it then helped you to think around that…. I would not have organised my thoughts in any kind of way like this especially positively (Participant PO003, line 161)*

Despite initial reservations regarding the use of the PRCI, without exception, all of the interviewees offered varied and extremely candid positive perspectives on the use of this intervention.

There was consensus amongst all interviewees that the PRCI had promoted a positive re-evaluation of the situation:

> *Seeing things positively …. And that was really just re-affirming to myself that I could do this. Women were meant to have babies (Participant PO003, line 198)*

In particular, positive reappraisal appeared to encourage an appreciation of aspects of their lives that had been neglected and forgotten, often lost in the overwhelming feelings of worry and anxiety they had experienced as a consequence of their new pregnancy. When asked to give an example of this, one interviewee commented:

> *It sounds silly but I completely fell in love with my daughter again, like all over again …. I suddenly looked at her again and thought I've forgotten about you (Participant SO031, line 539)*

Others commented that positive reappraisal had given them a renewed appreciation of the everyday things in their lives:

> *…. a bubble bath to relax, a massage because I have a friend that does massage, a walk with my husband and the dog, seeing my friends (PO003, line 176)*

> *I'd think right I'm going to have a nice bath and I'm going to put some music on and I'm going to have a bit of 'me time' because I think with everything going on you forget about yourself (Participant SO061, line333)*

During the waiting period of a new pregnancy, women who have experienced recurrent miscarriages face a plethora of worries and anxieties, as they are anxious and concerned they will experience a further miscarriage. The PRCI appeared to have a role in helping the women to

rationalise their situation and the thoughts and anxieties they were experiencing, thereby sustaining their ability to cope with the situation in which they found themselves:

> *I think the main thing was just rationalising my thoughts. So when I was thinking oh this is going to go wrong, it just made me sit back and when I went through each part of it* (the PRCI) *…. There were certain bits I focused on and I was like yes think about something positive for the day or show some emotions and basically that's what it was, a kind of re-grouping in my head and saying yes I can deal with this, I can move forward (Participant SO056, line 238)*

> *In the morning when ping at 4 am you wake up and your mind goes then there's no going back to sleep. It's the oh what if what if? So some of the time I'd go and get it* (the PRCI) *at that time in the morning because it would just relieve a bit of that anxiety, and although I might not have gone back to sleep, it's just that rationalising (Participant SO031, line 482)*

Many of the interviewees highlighted the fact that one of the most distressing things about the early waiting period of a new pregnancy was the lack of control they had over the situation in which they found themselves. One interviewee suggested that one of the benefits of the PRCI was that it helped them feel more in control of the situation:

> *I didn't feel in control of things ….I felt a bit all over the place in my first trimester; one minute I was up and then I was down and I was just a bit all over the place, so to be honest I think that the card did help me at times (Participant SO047, line 210)*

Women who have experienced recurrent miscarriage face acute uncertainty about the outcomes of their new pregnancy. One of the factors that adds to the challenging nature of the waiting period of a new pregnancy is the fact that they are facing an outcome which is unpredictable and one over which they have no control. As such, frequently these women spend significant amounts of time worrying and ruminating over the potential outcomes of their pregnancy. Several respondents indicated that the PRCI had helped them to cope better with the protracted length of the waiting period by encouraging them to take a day at a time:

> *But actually it really did work and maybe not all the points, but the ones that really made it for me was the think of something positive today and that was probably the biggest one for me, was just trying to find something every day and not looking at next week or two weeks or three weeks. Let's just focus on today and let's get through today and tomorrow will be another day (Participant SO031, line 581)*

> *I felt every single day was going really slowly and I wanted the next day and the next week to come just to get past that waiting period. But when I used to read the card it used to*

> *take my mind off things at least for a couple of hours or a half a day and it used to help me get through each day. It came to a point where I started looking at it three to four times a day and I think it would just push me to get through each day one at a time (Participant SO047, line 241)*

This particular participant (SO047) was keen to stress how the card had helped her get through the waiting period and its accompanying emotions of uncertainty and worry. She describes the isolation she felt as a result of her situation and the lack of a confidante to whom she could express her emotions. The PRCI appeared to meet this need:

> *Nobody really knew what I was going through, so I think it was positive in that sense, because even though it was just a card, it was like my best friend that was helping me get through every single day and get through my weeks of feeling upset at times. And also with my husband, sometimes we had a little awkwardness where he wouldn't really understand what I was feeling so I'd feel like the card was there for me …. It was just a card but I felt like it was there for me (Participant SO047, line 190)*

There were mixed accounts of whether the PRCI actually helped or reduced the anxiety and worry the participants were experiencing. Some interviewees expressed the belief that it had really helped alleviate their anxiety:

> *It just made me feel less anxious and made me change how my mind worked really rather than just feeling like everything was crashing down or feeling very negative (Participant SO056, line 248)*

Another interviewee commented that rather than reduce the anxiety she was experiencing, the PRCI sustained her ability to cope with these feelings:

> *I think it didn't necessarily reduce my anxiety but it did definitely help me cope with anxious feelings and although it didn't reduce anxiety it made me think more positively so there was still a lot of highs and lows but more highs than I would have had had I not had the technique (Participant PO003, line 279)*

The PRCI also appeared to have a positive effect on other aspects of the users' lives. In particular, several of the interviewees referred to the fact that utilising the PRCI had improved their relationship with their partner by encouraging conversation with them enabling them to share their concerns and emotions:

> *It helped me with my relationship because at the beginning of my pregnancy it was really hard for my husband as well and I think he didn't quite understand (Participant SO047, line 164)*

> *I ended up having a lot more contact with my husband. We'd talk things through whereas previously I would have just tried to deal with everything myself (Participant SO056, line 184)*

Interviewees all agreed that the PRCI provided them with a practical tool to promote positive reappraisal of a situation and this in turn was proving to be useful in all aspects of their life. One woman suggested that the statements on the PRCI could be applied to life in general, commenting:

> *I think they are quite generic statements which you can apply to life and definitely they are kind of little mantras almost (Participant SO 061, line 366)*

> *So I think for me it was very good learning just generally for life skills ….. it's a wonderful skill to have (Participant SO001, line 135)*

Others suggested that they would continue to utilise the positive reappraisal techniques they had learnt as a result of the PRCI:

> *I could probably do with one for day-to-day life quite frankly …. I'll probably dig it out the glove box and use it again! (Participant SO031, line 568)*

The interviewees gave very few negative reflections on the use of the PRCI. One participant commented that when she first started using the PRCI, she didn't like being reminded of the situation she was in, but this settled as she got used to the concept of the PRCI and positive reappraisal:

> *At the beginning I did think well it doesn't really need to remind me of how I'm feeling throughout the day, or at my work, or things like that. But then later on it became a part of me I thought this was really helpful (Participant SO047, line 217)*

Similarly, another woman reflected that she preferred to leave the card at home as work was a good distraction for her and if she took it to work it might encourage her to think about the pregnancy more:

> *I did think about taking it to work …. And I just thought by having at work maybe that would then make me think about things more (Participant SO061, line 262)*

Overall, these qualitative findings suggest that participants' general compliance in using the PRCI was good and their reflections on the tool were extremely positive. Importantly none of the interviewees reported any negative effect from using the PRCI, indeed quite the opposite with numerous examples given in the interviews on the encouraging effects of positive reappraisal and the intervention:

I think one of the things is you can perceive the twelve week wait differently and I thought well I've got a lot of strength since things have happened. I think I'm the strongest that I've ever been. So I think it made, regardless of the outcome, it made me a stronger person (Participant SO061, line 349)

I truly believe that it helped me, so I think I would definitely carry on using it (Participant PO003, line 238)

When summarising this section which has reviewed the superordinate category of 'study intervention,' it appears that despite mixed initial impressions of the PRCI, the participants persisted with its use and demonstrated a positive attitude to using the card, finding it an acceptable, practical intervention to use during the stressful waiting period of a new pregnancy. The women were able to give numerous positive examples of using the intervention, describing how it sustained their ability to cope during the uncertainty of the waiting time, however, there were mixed accounts of whether it actually reduced their anxiety levels. Significantly, there were very few negative comments about its use. One key finding was that participants modified the advice they had been with provided with about how frequently they should use the PRCI, adapting this guidance to suit their needs. Furthermore, many chose not to carry the intervention with them as advised in the guidance sheet (Appendix D), another participant reported adapting the intervention so as it was available on their smart phone. Issues around adaptation of the PRCI raises questions about the fidelity of the intervention. This is an important feasibility finding and merits further detailed discussion in Chapter 7 where consideration will be given how the intervention will be implemented in a future study and what would be permissible in terms of modifying /changing the PRCI or its guidance.

5.4.2 Managing expectations

The semi-structured topic guide (Appendix N) utilised during the interviews for this study, was designed to enable interviewees to expand on their answers to the process evaluation questions. This facilitated discussion around the interviewees' personal reflections on the waiting period of a new pregnancy following recurrent miscarriage, encouraging the women to share a personal insight into the thoughts and feelings they had experienced during this challenging time. The 'managing expectations' summary category was therefore shaped by the recurrent themes running through the process evaluation component of the interview. Although the data in this 'managing expectations' summary category did not meet the evaluative objectives of this study, they did provide valuable insight in to the lived experience of the waiting period, offering importance evidence to support the need for an intervention, such as the PRCI, to promote psychological well-being for women affected by recurrent miscarriage.

The lower level categories and superordinate categories which make up the summary category of 'managing expectations' can be seen in Table 9.

5.4.2.1 Hope for the best but expect the worst

The experience of recurrent miscarriage frequently results in a period of 'marked stress reaction' (Liddell et al. 1991) when the woman becomes pregnant again as she faces a significant period of uncertainty until confirmation by ultrasound scan that her pregnancy is ongoing. This uncertainty frequently generates a state of fear and anxiety and a plethora of mixed emotions for the affected woman as she worries if she will experience yet another miscarriage.

For those women not affected by recurrent miscarriage, a positive pregnancy test is a time of celebration and happiness. However, for women who have faced repeated pregnancy losses, a positive pregnancy test marks the onset of a period of uncertainty and anxiety as they wait for confirmation that their pregnancy is ongoing. Many of the interviewees referred to the time of the positive pregnancy test and the accompanying onset of worry and emotional turmoil:

> *You may have a slight moment of excitement, but we've had so many positive pregnancy tests that I say to my husband I'm pregnant and he goes oh right. Because it's not a joyous moment like on the advert where the woman is like woohoo I'm two weeks pregnant. It doesn't feel like that at all, it feels like here we go we're just getting on the rollercoaster again (Participant SO003, line 134)*

> *There was no excitement and the fact that I didn't do the test for two weeks after I was late, I just didn't want to know. There was no excitement at all, it's just complete anxiety of here we go again, it's going to go wrong again (Participant 031, line 187)*

The experience of recurrent miscarriages meant that these women no longer rejoiced at a positive pregnancy test, indeed the feelings it induced were in stark contrast to those they had previously experienced in their first pregnancy. Many of the respondents reflected back on this, and remarked that they had been naïve thinking all would go well. One interviewee commented:

> *I consider normal the person who was pregnant for the first time in the little bubble, the naïve person walking around. I don't think I'll ever be that person again. It's changed me (Participant SO044, line 151)*

Another respondent reflected:

> *I remember that first pregnancy and I had no inkling at the fact that things could go wrong and I was just so naïve ….it's just not like that when you've lost one, two, three, four, five, it just isn't (Participant SO064, line 194)*

Surprisingly, one of the interviewees even commented that because of her personal experience of recurrent miscarriage, the news of other people's pregnancies increased her anxiety levels as she worried about the outcome of their pregnancy:

> *And every time I see or hear someone else is pregnant, I think oh God. I don't feel happy for them because I know what can happen. It's* (recurrent miscarriage) *opened up a whole new world to me and it's not very nice (Participant SO044, line 164)*

Without exception, all of the interviewees gave extremely candid examples of the turmoil of emotions they had experienced during the waiting period:

> *Sometimes you will be happy, sometimes you will be sad, sometimes you will be angry. To me it always feels like a fire has been put out inside you, so you can smile, do whatever you want to do, but your eyes just feel blank (Participant SO028, line 17)*

The majority of the interviewees referred to the significant levels of anxiety and worry they experienced during the waiting period. This was often overwhelming, affecting every aspect of their life and an emotion that they were unable to escape from or forget:

> *The amount of anxiety was tremendous (Participant SO001, line190)*

> *I was really anxious. I wasn't sleeping properly, you worry about everything you eat, everything you drink. You just criticize and analyse everything you do all day long, all night long …. Being anxious makes you anxious so it's a real vicious circle (Participant SO044, line 131)*

> *It's* (the anxiety) *completely life consuming for me …. It's just like a big black cloud over a time that should be really exciting (Participant SO031, line 191)*

> *You are just worried about it the whole time …. It (*pregnancy*) will never be an enjoyable experience, it will just be an anxious time (Participant SO015, line 166)*

Accompanying the extreme levels of anxiety and worry, several of the interviewees described emotions of fear and even terror at the situation they were in and the potential outcome of their pregnancy:

> *I'm just scared about everything (Participant SO044, line 156)*

> *The more you know what can go wrong, it becomes even more frightening …. It is terrifying really, literally terrifying and that is how I feel (Participant SO031, line 400)*

For women who have not faced the ordeal of recurrent miscarriage, the early weeks of a new pregnancy is a time filled with hope, looking forward to the birth of their unborn child and

imagining a future with them. The comments and reflections of the interviewees suggest that things are very different for those who have suffered repeated pregnancy loss. Instead of experiencing a time period full of 'joyful anticipation' (Hutti et al. 2015) the participants reflected on the early stages of a new pregnancy as a time where they suppressed any hope of a successful pregnancy, fully expecting another miscarriage to occur:

> *You won't let yourself believe that it will be alright (SO028, line 61)*

> *And I just came to the conclusion that the kindest thing I could do for myself was not to hope, because if you hope and then it goes that you lose more …. I tried really, really hard not to, I felt that literally that was the only thing that was in my control, the amount I let myself hope …. Hope just feels utterly naïve now (SO064, line 180)*

Previous research has demonstrated that women with a past-history of repeated pregnancy losses utilise coping strategies to 'brace for the future,' (Ockhuijsen 2103) by anticipating the negative feelings which would be caused by a further miscarriage and avoiding any day-dreaming about a future with their child. Correspondingly, interviewees in this study appeared to suggest that the suppression of hope and avoidance of thinking about a future with their unborn child, seemed to be linked with the notion of self-preservation/protection; by attempting to prepare for the worst outcome (i.e. a miscarriage) they would not be as upset when another miscarriage occurred:

> *I think its self-preservation because of what I've gone through …. It's almost like you can't let yourself dream this might happen after wanting something for so long (Participant SO052, line 470)*

> *I need to be real…. I prepare for the worst but hope for the best and that's almost like a protective shield around me that if I go into anything thinking something bad and it's something good, then I'm better off (Participant SO044, line 189)*

> *It would be lovely to hope and I guess I'm losing out on some of that happiness by not doing that, but it feels like a more practical approach. Really the only thing I can do for myself actually is to protect myself (Participant SO64, line 246)*

Many of the interviewees gave examples of what they considered irrational behaviours and thoughts about what might have caused their previous miscarriages. The women appeared to understand that the thoughts they experienced were not logical, or rational causes of miscarriage, but they were unable to stop thinking in that way. Two of the women gave specific examples:

> *So I wasn't mowing the grass because I've got it in my head that one of my miscarriages I'd mowed the lawn and if I hadn't mowed the lawn, I wouldn't have miscarried, but I know that's not relevant in my head (Participant SO016, line 181)*

> *I worried because I had lots of baths the first three times, I've not had one bath since I got pregnant (Participant SO44, line 135)*

Unsurprisingly, a common theme running through the interviews was that many of the women mentioned that they were reluctant to tell friends and family of their new pregnancy, certain that there was no point because during the ensuing weeks they would only have to tell them they had experienced a further miscarriage. Other interviewees commented that although they knew it was irrational, they were hesitant to tell people about their new pregnancy because that in itself would tempt fate or 'jinx' the pregnancy:

> *…. You don't want to tell your friends* (about your pregnancy)*. Going back to the stupidity of how you think is if you tell someone then you are going to miscarry, I can't remember what the word is. Superstition. Yes tempting fate, superstition. (Participant SO028, line 111)*

> *I haven't wanted to tell anybody. Because I almost felt like I was jinxing myself (Participant SO044, line 347)*

The superordinate category of 'hope for the best but expect the worst' has established that the women who took part in this study suppressed any hope of a successful outcome to their new pregnancy. They fully expected another miscarriage to occur and anticipated the upset this would bring. As such, in an effort to protect themselves from this distress they tried to prepare for the worst outcome (i.e. a further miscarriage) and avoided any future thinking about life with their baby. Instead of experiencing the early stages of their new pregnancy as a time of hope and excitement, the waiting time was a time of anxiety and despair as the women worried about the potential outcome of their pregnancy.

5.4.2.2 Coping and validation

For the purpose of this study the waiting period of a new pregnancy was defined as the time period from a positive pregnancy test until twelve weeks of pregnancy. This time period was decided on as an early pregnancy ultrasound scan is normally performed at approximately twelve weeks gestation as part of routine antenatal care throughout the United Kingdom. Furthermore, extensive clinical experience caring for this group of women suggests that although anxiety levels in this patient group can remain elevated after this time period, they will generally start to

decrease once the woman has seen a viable pregnancy at their ultrasound scan and as their pregnancy moves in to the second trimester.

Chapter 2 of this thesis highlighted the fact that there is only limited research evidence available on the waiting period of a new pregnancy following recurrent miscarriage and what time-period it consists of. Therefore, the participants were asked to comment on what they considered the duration of the waiting period. Several of the interviewees made the point that the waiting time of a new pregnancy is individual and based on previous experiences of when they had suffered previous miscarriages:

> *I don't know if twelve weeks was relevant to me …. I also know that just based on my other previous miscarriages that actually eight weeks was the key point I had never got to in this journey (Participant SO052, line 153)*

> *If I got to nine weeks and things were still positive then I might let in a tiny bit of hope and at twelve weeks I knew the chances of anything going wrong dropped drastically and particularly for me because it goes wrong in the early days for me. So that was my mind, if I get to twelve to fourteen weeks then I can start actually thinking about the future (SO064, line 235)*

However, there appeared to be a general consensus amongst the women that that the first twelve weeks of the pregnancy was the time period associated with extreme levels of uncertainty and anxiety. One interviewee commented:

> *Obviously I had the milestones of where I had miscarriages before so those are my personal milestones. So that was five and a half weeks, eight weeks and ten, so those were my milestones but twelve weeks is obviously the general one ….. twelve weeks is the right time frame (Participant SO056, line 111)*

Whatever the length of the waiting time, interviewees describe it as a time of mixed emotions and high stress levels as they persistently ruminated upon the potential outcomes of their pregnancy:

> *Pretty stressful, anxious, worried, joyful every emotion going …. I've got to fourteen weeks in the journey, so yes its been very up and down, a rollercoaster (Participant SO052, line 10)*

> *During that period your whole life is on hold just waiting …. It really is horrendous. You are just waiting constantly, I'm waiting for it to go wrong …. And you make yourself ill almost during that time (Participant SO015, line 158)*

> *It* (the waiting period) *has been really difficult. I get a lot of weird dreams as well, that I'm miscarrying and things like that and I think it's because it's just playing in the back of my head (Participant SO047, line 28)*

Furthermore, it appears that, without exception, all of the interviewees made reference to the fact that the waiting period of a new pregnancy following recurrent miscarriage was a time period that they managed on a daily basis and one which they had to endure:

> *Every single day was going really slowly and I wanted the next day and the next week to come just to get past that waiting period (Participant SO047, line 241)*

> *We just have to live one day at a time, deal with this bit, speak to you, see what happens next …. It's a very long and lonely time (Participant SO061, line 68)*

> *It is so difficult to get through because it's all consuming, you can't think of anything else really …. During that period your life is on hold just waiting (Participant SO015, line 133)*

The interviewees were able to give many examples of the coping strategies they personally employed to help them manage the uncertainty of the waiting period and the challenging emotions it brought with it.

Commonly the women reported utilising distraction techniques, trying to avoid thinking about the pregnancy:

> *I have short-term distraction coping mechanisms where I clean…. I'll clean all the windows or I'll go on a massive thing of washing everything (Participant SO044, line 329)*

> *I've got a dog now so I concentrate on that, I try not to think about it (Participant SO028, line 38)*

Other interviewees reported that work had helped them both by providing them with a distraction but also by helping to promote some normality during the stressful waiting period:

> *I'm a bit of a career girl so I actually went in to work because that was the best thing for me to do, just keep life normal (Participant SO031, line 33)*

One participant suggested that she managed her emotions by trying not to think about the pregnancy and blocking out all thoughts about it. When asked if anything helped her anxiety during the waiting time, she replied:

> *Well I guess blocking it out in a way and trying not to think about it (Participant SO015, line 140)*

Frequently the interviewees reported using observing strategies and a hypervigilance to closely monitor their pregnancy symptoms, considering signs such as nausea and breast tenderness as indicators of an ongoing pregnancy. Any fluctuation in these pregnancy symptoms increased the women's feelings of uncertainty and caused added distress to the women:

> *You feel completely out of control and you have no idea what is happening inside you and you are constantly monitoring your pregnancy symptoms, constantly. Do I feel the same as yesterday? Are my boobs still sore? Do I need to go to the loo more often, or am I just drinking more? And you are constantly questioning every single twinge you feel, you are dying to get morning sickness so that you know you are pregnant. It's all consuming (Participant SO003, line 149)*

One of the most common signs of miscarriage is the onset of vaginal bleeding or spotting. Many were so convinced that they were going to experience another miscarriage, that a frequent theme discussed by nearly all of the interviewees was the need to visit the toilet excessively and repeatedly to check if they had started spotting or bleeding. This could often amount to numerous visits to the toilet in a period of one hour. The women considered vaginal bleeding or spotting as symptoms of an imminent miscarriage and were anticipating this and waiting for it to start:

> *Every time you go to the toilet you are looking for blood, for it to start (Participant SO015, line 127)*
>
> *Knicker checking is a big obsession (Participant SO016, line 238)*
>
> *Going to the toilet when I don't need to go to the loo, sitting back at my desk thinking oh shall I just check one more time (Participant SO031, line 445)*
>
> *I was always very pleased to have sore boobs …. I was always boob checking and checking when I'd been to the loo. That's constant and that still happens, I can't get out of that, the checking thing … knicker checking (Participant 056, line 344)*

In a previous study, Ockhuijsen et al. (2013a) had also described how women with repeated miscarriages used observing strategies to monitor their pregnancy symptoms, so these findings were not surprising. When pregnancy symptoms were more intense then the woman felt more certain of an ongoing pregnancy. However, it is normal for pregnancy symptoms to fluctuate day-to-day or even hour-to-hour and changing symptoms caused the women added distress and worry.

A common theme amongst the interview texts was that the women commented that their partners / husbands did not really understand how they were feeling during the waiting period

and often suggested that they carry on with life as normal and try and forget about the pregnancy:

> *I think he thinks I should just forget about the fact that we've just found out we're pregnant and just carry on and just see what happens and stop worrying about it (Participant SO003, line 279)*

However, this did not appear to have an adverse effect on their relationship. Only one participant alluded to the fact that this lack of understanding had added to her upset at the situation:

> *With my husband sometimes we had a little awkwardness where he wouldn't really understand what I was feeling (Participant SO047, line 194)*

It appeared important to those interviewees who already had an older child to try to ensure that family life and relationships remained stable, wishing to protect their child from the stress they were experiencing. Indeed some interviewees expressed the belief that already having a child who needed looking after appeared to act as a moderating factor to the extremes of anxiety experienced by some interviewees:

> *For us with our daughter we've always tried to make it so it doesn't have an impact on family life and sometimes I was worrying about that, so we'd always make a point then to do something on a Sunday if I felt I'd had a particularly bad week (Participant SO052, line 205)*

> *In the evening when I got home I just had a complete flood of tears and breakdown about it but then having my little girl, who is three, she gets upset because if Mummy is upset which is actually in hindsight quite a good thing. Because actually life continues and she needs to be looked after and if I didn't have her it might be quite different (Participant SO031, line 40)*

To summarise the superordinate category of 'coping and validation' interviewees expressed that the actual length of the waiting time of a new pregnancy varied between women. This depended upon the point in gestation when they had suffered previous miscarriages, however, most felt that they worried more about a further miscarriage during the first twelve weeks of a new pregnancy. All agreed that the waiting time was a period they had to endure and manage on a day-to-day basis, using coping strategies to manage the uncertainty they felt. The women were hyper-vigilant in monitoring their pregnancy symptoms and any fluctuation in these caused them added distress and anxiety. They also referred to the fact that already having a child acted as a moderator to the anxiety they were feeling.

5.4.2.3 Perception of need

This superordinate category of 'perception of need' presents the participants' thoughts and views on the level of care they actually received from health professionals during the waiting period of their pregnancy and their perceptions of the level of care they would like to receive.

In a pioneering piece of work Bradshaw (1972) presented a taxonomy of social need in which he acknowledged that the concept of need was both complex and imprecise, furthermore he emphasised the fact that need was relative and, as such, needs identified by professionals often differed to those felt by the individual. Certainly, a recurrent theme in the interviews for this research study was a sense amongst interviewees that current health service provision for recurrent miscarriage patients during the waiting period was both limited and unsupportive and demonstrated a lack of understanding of the women's needs during this challenging time.

For many women with recurrent miscarriage the first health professional they would contact for support and advice about their new pregnancy would be their General Practitioner (GP). Whilst the degree of support offered by GPs varied individually, several of the interviewees spoke of their dissatisfaction at the lack of support and understanding shown to them by their GP:

> *You are left to get on with it and there's no offer or any counselling or anything or any support at all …. The GP doesn't really do a lot (Participant SO105, line 37)*

> *Why is nobody listening to me?.... You've got no pain and no blood you are fine, that's what the GP would say just go home (Participant SO031, line 499)*

> *Even my GP has been rubbish if I'm honest (Participant SO052, line 74)*

Another interviewee commented on the importance of the personal attitudes of the health professionals she had contact with, noting the value of an empathetic stance in the professionals caring for her:

> *In terms of the health professionals …. Some of the people I find quite short, quite well not rude, but very professional. I get the professional line but then there are some others…. who I've seen over time and they've got it, they are very sympathetic (Participant SO052, line 67)*

In general, the participants referred to the fact that contact with a health professional during the uncertainty of the waiting period was very important. They understood that their involvement would not make a difference to the outcome of the pregnancy, but it would have made a positive difference to this challenging time, helping them feel more supported and being able to share

their concerns with a professional. When asked to comment further on this one interviewee seemed to sum this up by commenting:

> *I think it just proves that they care and I think if you feel cared about then that makes all the difference (SO061, line 114)*

During the interview, respondents were asked to comment on what, if anything, had made the waiting period easier to cope with. In response to this, several of the interviewees referred to the value of reassurance ultrasound scans:

> *I think the scans help (Participant SO002, line 168)*

Despite this the value of reassurance scan there was a common acknowledgement amongst the interviewees that although they found ultra sound scans reassuring, this was also associated with worry about the potential outcome:

> *When we had a scan, just before a scan then I would tend to have a little wobble about things, a worry, because scans to us are a two-edged sword (Participant SO061, line 268)*

The availability and arrangement of scans is not standardised and often varies between individual cases, GPs and hospitals and the interviewees frequently commented that it was not always easy to persuade a health professional to organise this for you:

> *You have one at seven (weeks) and then I mean I had to push for anything after that which I think is awful. I don't think I should have to push because it's so reassuring to have those scans (Participant SO064, line 150)*

> *And it annoys me that you don't automatically get the early scan, I don't think that's fair. We are lucky enough that I can just go and pay for it but there are other people who can't and then it's the wait because twelve weeks …. It is the longest time (participant SO015, line 44)*

Interestingly, although many of the interviewees reported that a reassurance scan was helpful when asked to comment further on this, three of the interviewees who were having regular scans, suggested that it only reassured them in the immediate aftermath of the scan. They described their anxiety like a wave which dropped once they had had a positive scan, but then built again towards the next scan appointment:

> *I was having my scans on a Monday, so it made me think about my anxiety more like a wave. Monday mornings it was really high and I would go for the scan and I would be elated everything was ok and it would come down …. I was counting as soon as I walked*

> *out of the hospital after having the scan, I would count down six days to go (Participant SO44, line 113)*

> *I can't tell you how much they really helped. I did find I get to like a week in between and that would be probably be my lowest point because I was like I've gone from the euphoria of the previous scan to oh my god, what am I going to get? And my husband used to say the night before I was the worst person to be in the house with …. I'd be saying it's going to be really bad news and every time I went for a scan I was in floods of tears (Participant SO052, line 163)*

Despite this wave of anxiety produced by regular scanning, it seemed the reassurance provided by the scan was still seen as valuable with one interviewee commenting:

> *If I had a choice between having them or not having them I would want them, I don't think I could have got to twelve weeks being quite as sane (Participant SO052, line 176)*

To summarise, the 'perception of need' superordinate category explored how participants viewed the care they had received from health professionals during the waiting period of a new pregnancy. In general, they expressed that the care they had received was limited and unsupportive, demonstrating a lack of understanding of their needs at this time. When they did receive support and empathetic care from a health professional, then it had a positive impact on how they were feeling. All participants referred to the value of reassurance ultrasound scans.

5.5 Chapter summary

The first section of this chapter presented a detailed account of the process of analysis of the qualitative process evaluation data for this study, utilising the General Inductive Approach (Thomas 2006). This process culminated in the creation of two summary categories, namely 'study processes' and 'managing expectations.'

The second section presented the qualitative findings of the process evaluation under the headings of the two summary categories. Findings presented in the first summary category, 'study processes,' explored in-depth, women's experience of their participation in the study (including recruitment strategies, randomisation strategies, study intervention, study time points, study outcome measures and research methods), addressing the evaluative objectives of this study.

The 'managing expectations' summary category presented the qualitative findings that did not meet the evaluative objectives of the study. Participants gave extremely candid personal insights into the lived experience of the waiting period, in turn providing validation and additional

evidence to support the need for an intervention to promote psychological well-being for women affected by recurrent miscarriage during the early stages of a subsequent pregnancy.

The process evaluation has highlighted a number of key feasibility issues that merit further discussion and these will be considered alongside the quantitative feasibility results in Chapter 7 of this thesis where a comprehensive feasibility and acceptability assessment of the PRCI and the planning of any future definitive study to test its effectiveness, will be explored in detail.

Chapter 6: Effect of intervention

6.1 Introduction

A feasibility study is not designed to assess the effectiveness of the intervention under investigation (Lancaster 2015). As such, this study was not statistically powered to formally calculate the effectiveness of the Positive Reappraisal Coping Intervention (PRCI) at improving the psychological well-being of women during the waiting stages of a new pregnancy following recurrent miscarriage. However, the comprehensive quantitative and qualitative data generated in this study have made it possible to make an assessment of an indication of the effect and impact of the PRCI. This chapter will utilise descriptive statistics and graphical displays to compare and contrast the psychological measurement scores within the control and intervention groups to present preliminary evidence to support the development of a future definitive study of the PRCI.

6.2 Factors affecting data quality and quantity

6.2.1 Statistical power

The aim of this study was to test the methodological and logistical components of the study design; it was not designed or statistically powered to detect modest effects of the PRCI in the recurrent miscarriage patient population. Therefore, the objective of the statistical testing and descriptive statistics in this chapter is to discover if there are any associations between the study variables or any indication of effect of the PRCI on the psychological wellbeing of the participants, and to generate data that could inform the power calculation for a definitive clinical study. Significantly, given the fact this is a feasibility study with no formal power calculation the findings presented in this chapter should be read and interpreted with caution.

6.2.2 Variations in participant numbers

This study employed two data collection questionnaires, the HADS (Appendix K) (Zigmond and Snaith 1983) and the WRK (Appendix L and M) (Boivin and Takefman 1995). Participants were invited to complete these measures at eight different time points during this study, namely at randomisation (approximately four weeks of pregnancy) and then at weekly intervals from weeks five to twelve of pregnancy.

At the point of a positive pregnancy test, forty-seven participants were randomised to one of two study groups. Group 1, the intervention group, received the PRCI and questionnaires (n=24) and Group 2, the control group, received questionnaires only (n=23). However, a complicating factor when reviewing the data was that the number of participants (and therefore completed questionnaires) decreased throughout the data collection period as some of the participants experienced a further miscarriage and therefore ceased completing the study questionnaires.

The figure below illustrates the total number of participants completing questionnaires at each weekly time point during the data collection period, demonstrating the reducing numbers of participants in each study group by the end of the data collection period. Apart from one case, where a participant assigned to the intervention (PRCI) group withdrew from the study at the point of randomisation, the reduction in number of participants was consistently due to the occurrence of miscarriage.

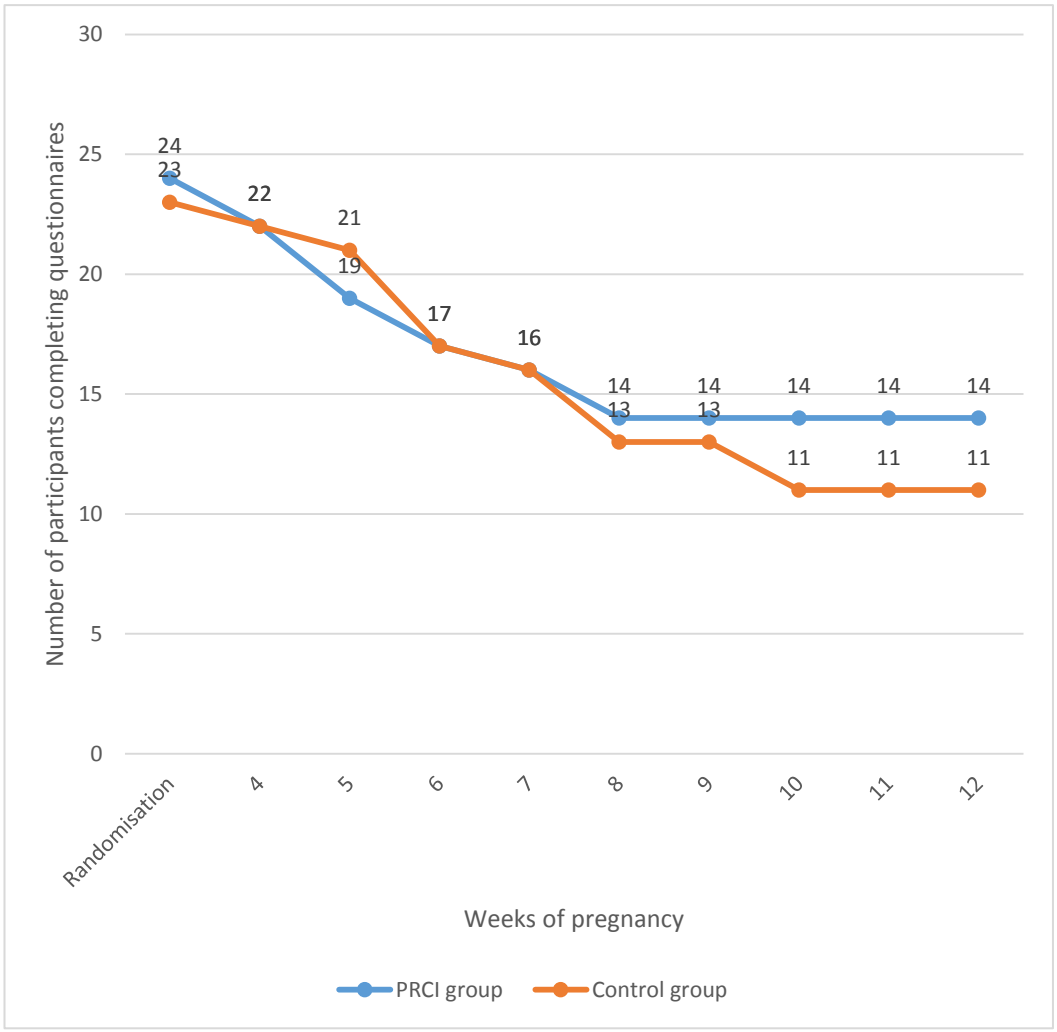


Figure 15: Line chart to show reducing number of participants completing questionnaire over data collection period

6.3 The Weekly Record Keeping Form

The WRK form used as a study outcome measure in this study was adapted from the Daily Record Keeping Form (DRK) that was originally developed as a method of making *daily* assessments to measure the levels of emotional, physical and behavioural reactions during fertility treatment (Boivin and Takefman 1995). Although earlier studies have investigated the validity and reliability of the DRK with fertility patients (Boivin and Takefman 1996; Boivin 1997; Lancastle 2006) it has not been used previously on a weekly basis with recurrent miscarriage patients, as in this study. Furthermore, for the purpose of this study, changes were made to the wording of the DRK to reflect the fact that this study is concerned with the waiting period of a new pregnancy following recurrent miscarriage as opposed to the waiting period following in IVF (see Chapter 3, section 3.9.1.1.4 for details).

The findings of this feasibility study and qualitative process evaluation identified several factors that complicated the interpretation of data generated by the WRK questionnaire and this impacted on the ability to review these for any indication of effect of the PRCI:

1. Two versions of the WRK were used in this study (Appendix L and M) (Chapter 4, section 4.7.3 explains reasons for this) and although there was some commonality between the two versions, there were also important differences in the items and wording on the questionnaire. This resulted in limited data from each version due to the divided small sample sizes with 19 randomised participants (40.4%) using Version 1 of the WRK and 21 randomised participants (59.6%) using Version 2. These small sample sizes decreased further in size during the data collection period, as many participants experienced a further miscarriage and discontinued completion of the study questionnaires (see Figure 15).
2. Problems were highlighted with the rating system of the positive emotions on the WRK, therefore data was only available for the negative emotions (see Chapter 4, section 4.8.3 for details).

Although Ockhuijsen (2014) had successfully performed quantitative analysis on the frequency and mean scores of the complete DRK data set, the quantitative data obtained in this study proved complex and difficult to interpret, mainly because only partial data sets were available as explained above. In addition, the WRK is a measure of emotional reactions (Boivin 1997) and whilst it enables the development of the surrogate markers of anxiety and depression , it is not a validated method of quantifying degrees of anxiety and depression. As such, following in-depth discussion with the study supervisors and statistician, a decision was made to omit the quantitative emotional symptom ratings from the WRK in this study, focusing instead on the

quantitative data generated by the well-validated HADS questionnaire (qualitative process evaluation findings, however, evaluated both the WRK and HADS).

6.4 The Hospital Anxiety Depression Scale

The HADS (Zigmond and Snaith 1983) is a well-established measure of anxiety and depression, well accepted by patients with no apparent difficulty with comprehension (Fitzpatrick et al. 2009). The HADS data generated in this study reflected this, being of excellent quality with questionnaires completed correctly and in full.

The IBM SPSS Statistics Package 24 was utilised to perform statistical analysis of the HADS scores, whereby quantitative data from this questionnaire were obtained by calculating frequencies and means for anxiety and depression scores for each case.

6.4.1 General anxiety

A state of anxiety reflects the anticipatory emotions (for example tense, nervous, worry) (Boivin and Lancastle 2010). For recurrent miscarriage patients, it was anticipated that anxiety emotions would decrease in intensity during the waiting period of a new pregnancy (up until twelve weeks) as the risk of miscarriage diminished. Indeed, extensive clinical experience caring for this patient group suggests that although anxiety levels during the waiting period of a new pregnancy can remain elevated, levels generally do start to decrease throughout this time, as the women pass the gestation period of their previous miscarriages. As such, it was expected that analysis of the anxiety level scores would reflect this and indicate a gradual decrease in anxiety scores as the pregnancy progressed towards twelve weeks.

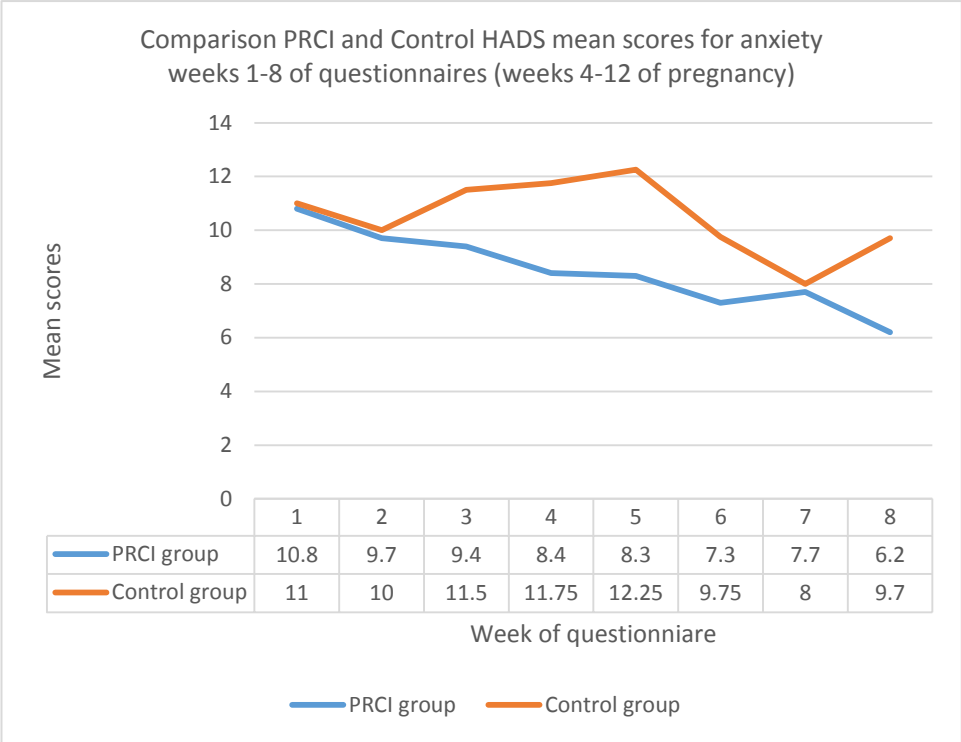


Figure 16: Line graph to show mean weekly anxiety scores for both study groups (see Chapter 3, section 3.9.1.1.3 for details of scoring HADS questionnaire)

Interestingly, there were differences in the anxiety level pattern between the intervention and control group (Figure 16). The PRCI group shows a smooth, overall downward trend (reducing anxiety levels) as pregnancies progress, reflecting the expectation that anxiety scores would decrease on a weekly basis throughout the waiting period. However, the anxiety scores for the control group were more variable with peaks and troughs over the eight weeks of questionnaires. There was an increase in anxiety levels at week five of the questionnaire (week eight of pregnancy), perhaps explained by the fact that miscarriages frequently occur around this gestation and for many women eight weeks represents a milestone in their pregnancy. Furthermore, as the pregnancy progresses to this stage, the woman may begin to emotionally invest in the pregnancy, so her anxiety levels will increase as she becomes more aware of her growing feelings towards the developing pregnancy and the grief she would feel if a further miscarriage occurred.

There was an indication that anxiety scores were lower in the PRCI group. This was unexpected, as although one previous study has demonstrated a lower anxiety level in women who used the PRCI during the fertility waiting period (Ockhuijsen et al. 2014a), it concluded that the effects of the PRCI on anxiety levels, were attenuated when combined with daily monitoring of the emotions (by the DRK) used in that study. Correspondingly, findings from the qualitative process evaluation in this feasibility study (see Chapter 5, section 5.4.1.2), identified that several study

participants suggested that their anxiety levels were indeed reduced as a result of completing the study questionnaires, some even stating that they had found the study questionnaires more useful at improving psychological well-being than the PRCI. Although another previous study of the PRCI showed that the use of the PRCI did not significantly reduce anxiety level during fertility waiting periods (Ockhuijsen et al. 2014b), these findings raise the question of the potential impact of the selected study measures and this issue will be explored in detail in the Chapter 7 of this thesis, the discussion chapter.

However, one possible reason for seeing reduced anxiety levels in the PRCI group in this study with recurrent miscarriage patients, could be that the participants were a 'high risk' sample, whereby they were at high risk of experiencing anxiety because of their past history of recurrent miscarriages. Indeed, a study which investigated whether women with miscarriage thought the PRCI would be useful and applicable to them concluded that women with only one past miscarriage did not see the need for such a coping tool, where as those women with recurrent miscarriage did (Ockhuijsen et al. 2013a), suggesting a 'higher risk' patient population. As such, the intervention might be most useful for those women needing to deploy coping effort, because their available current coping levels are not sufficient to match the perceived threat (i.e. another miscarriage), resulting in greater levels of anxiety.

This study did stratify for number of previous miscarriages (those who had experienced three miscarriages and those who had experienced more than three). These findings are important for future definitive studies of the PRCI because they highlight the importance of stratifying the study sample by threat severity, the hypothesis being that the greatest benefit of promoting a coping intervention is for participants experiencing the highest threat level.

Comparing the results and findings from the quantitative analysis and the qualitative process evaluation, two divergent findings emerged regarding the impact of the intervention on anxiety levels. Whilst graphical presentation of the HADS indicated a reduced anxiety level in the intervention group, in the interviews, women gave mixed accounts of whether the PRCI actually helped or reduced the anxiety and worry they were experiencing. Some interviewees expressed the belief that it had really helped alleviate their anxiety but others commented that rather than reduce the levels of anxiety they were experiencing, the PRCI sustained their ability to cope with these feelings. A larger RCT of the PRCI could provide confirmation or otherwise of these conclusions and investigate the potential beneficial effects of the intervention on anxiety levels.

6.4.2 General depression

Previous studies have established that whereas anxiety levels will decrease precipitously once the outcome of a waiting period is known (for example in this case the pregnancy is ongoing), feelings of depression increase more gradually during this time and remain elevated for the follow-up period (Boivin and Lancastle 2010). Depressive symptoms reflect the outcome emotions (such as sadness and disappointment) (Boivin and Lancastle 2010). This expected pattern was not reflected in the depression scores of either the PRCI or control group (Figure 17).

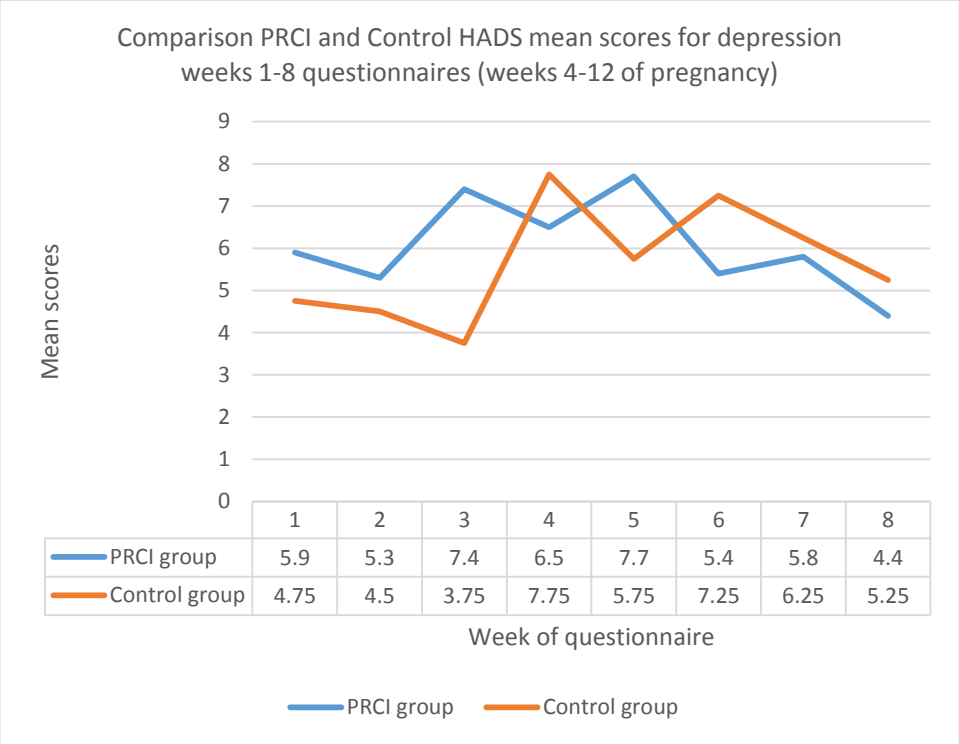


Figure 17: Line graph to show the mean weekly depression scores for both study groups

There was no obvious trend in the depression scores as recorded by the HADS during the waiting period. This result was unsurprising as previous studies of the PRCI in fertility patients have found that the intervention had no effect on depression levels (Ockhuijsen et al. 2014a, b). Furthermore, Lazarus and Folkman (1984) propose that whilst anxiety is future-orientated, depressive symptoms are associated with perceived or actual outcomes of imminent events, suggesting that depressive symptoms would become more apparent in this patient group should a further miscarriage occur. Certainly, the participants did not refer to symptoms or feelings of depression in the qualitative interviews

6.5 Coping

The findings from the qualitative process evaluation reflected previous studies of the PRCI, indicating that the PRCI sustained the participants' ability to cope with the stressful situation they found themselves in (Ockhuijsen 2014; Ockhuijsen et al. 2014b). The only quantitative measure of coping this study utilised was a small section (Part 4) of the WRK (Appendices L and M). The form was designed to assess seven coping strategies: distraction, problem-focused coping, acceptance, relaxation, wishful thinking, emotional expression and positive reappraisal coping (Lancastle 2006) and women were asked to rate the degree to which they had thought in this way to the reactions listed below on a scale of 0-3 (whereby 0=never, 1=rarely, 2=sometimes and 3=frequently). The scores can be added together and represent the total coping effort. A higher score indicates more effort was put into the act of coping with the situation:

1. 'I turned my attention away from the problem by thinking about other things or doing some activity' – Distraction
2. 'I made a plan of action and followed it' - Problem-focused coping
3. 'I accepted there was nothing I could do' – Acceptance
4. 'I did something with the implicit intention of relaxing' – Relaxation
5. 'I wished the situation would go away or somehow be over' – Wishful-thinking
6. 'I expressed my emotion' – Emotional expression
7. 'I tried to make the most of the situation' – Positive reappraisal coping.

Study participants were requested to complete the WRK questionnaire on eight occasions, at weekly intervals from week four to twelve of pregnancy.

Apart from the omission of the distraction coping strategy in Version 2 of the WRK ('I turned my attention away from the problem by thinking about other things or doing some activity'), there was commonality between the two versions of the WRK used in this study. Mean scores were therefore generated for the six coping strategies which were common to both versions of the questionnaires. Figures 18 and 19 illustrate and compare the coping strategies utilised by study participants in the intervention and control group.

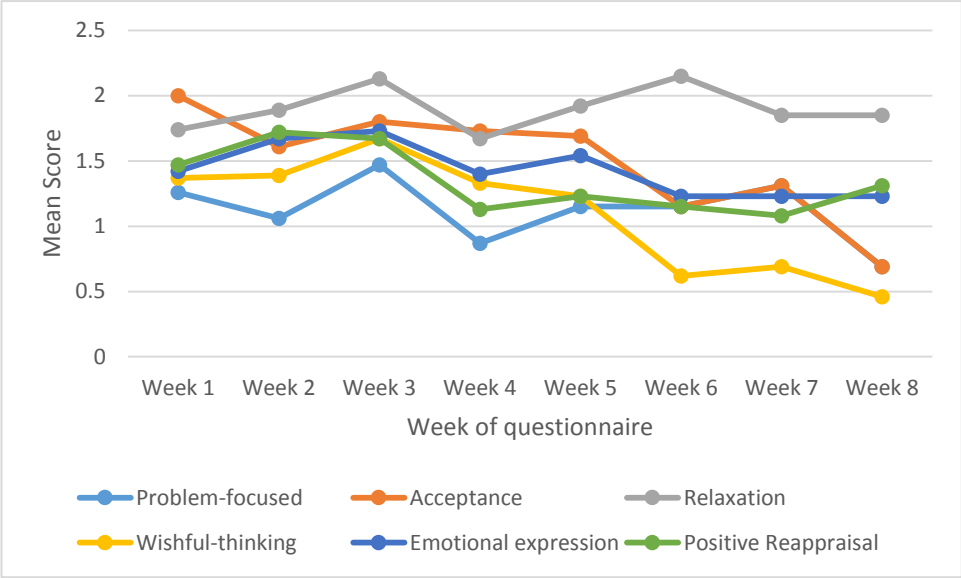


Figure 18: Line graph to show mean scores of coping strategies week 1-8 questionnaires (weeks 4-12 pregnancy) - Intervention group

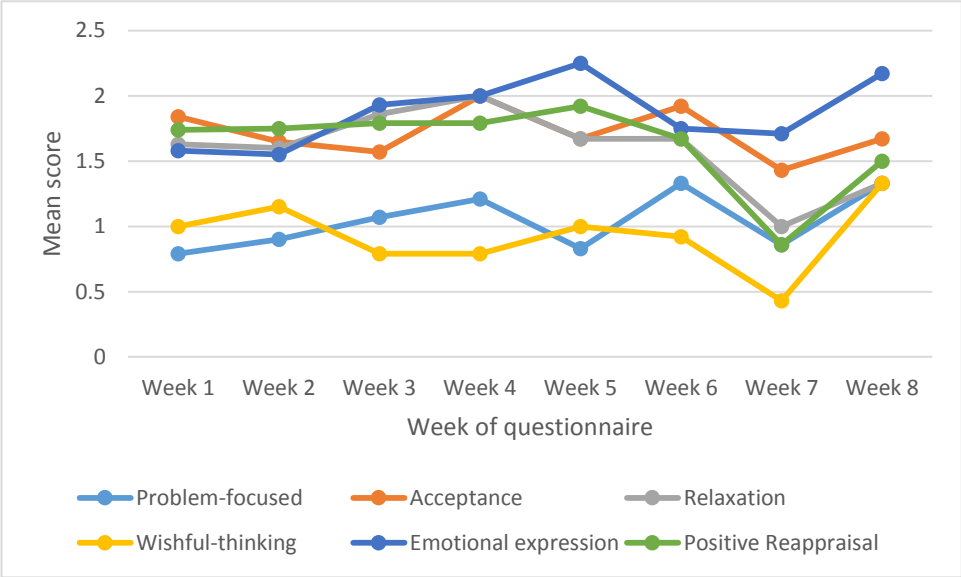


Figure 19: Line graph to show mean scores of coping strategies week 1-8 questionnaires (weeks 4-12 of pregnancy) - Control group

The most common coping strategy used by women in the PRCI group was relaxation, whereas, in the control group, the participants most commonly utilised emotional expression. In both groups, the least frequently used coping strategies were wishful-thinking and problem-focused coping.

The PRCI card was designed to promote positive reappraisal coping and in the qualitative process evaluation, without exception, when asked directly, all of the interviewees who had used the PRCI gave varied and candid positive perspectives on the use of the intervention and examples of how

the card had promoted positive reappraisal of the challenging situation they were in. Although only one question on the WRK assessed positive reappraisal coping, quantitative findings offered no evidence of increased use of positive reappraisal coping in the PRCI group and was, in fact, at odds with the qualitative data. The weekly mean score of positive reappraisal coping in the control group was consistently higher during the data collection period, apart from 'Week 7' of the questionnaires, suggesting that the control group used this method of coping more than the intervention group (Figure 20).

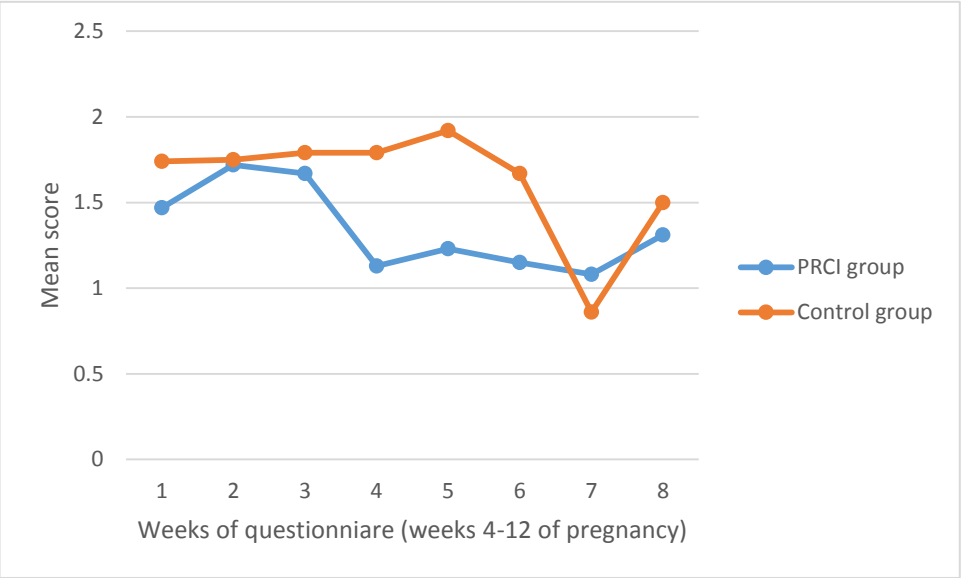


Figure 20: Line graph to show comparison of mean scores between PRCI and control groups for positive reappraisal coping weeks 1-8 questionnaires (week 4-12 of pregnancy)

The limited quantitative data on coping generated by this study are difficult to interpret and at odds with the qualitative data offered in the process evaluation interviews. This suggests a need to develop a deeper understanding of the coping strategies utilised by this group of women during the stressful waiting period of a new pregnancy and how the PRCI affects this. A future definitive RCT of the PRCI should consider the use of alternative measures of coping and potential study outcome measures for a future study will be discussed further in Chapter 7 of this thesis.

6.6 Assessment of impact of intervention on ongoing pregnancy rate

There is limited contemporary research that investigates the link between the provision of psychological support and pregnancy outcome in women with recurrent miscarriage. However, a frequently quoted piece of research suggests that there is an increased pregnancy success rate observed in women with recurrent miscarriage who receive counselling and psychological support during subsequent pregnancies (Stray-Pederson and Stray-Pederson 1984). Ongoing pregnancy rates in the study sample were recorded at each study time point up until twelve weeks of

pregnancy, and the graph below (Figure 21) presents the number of continuing pregnancies for each week in the intervention and control groups.

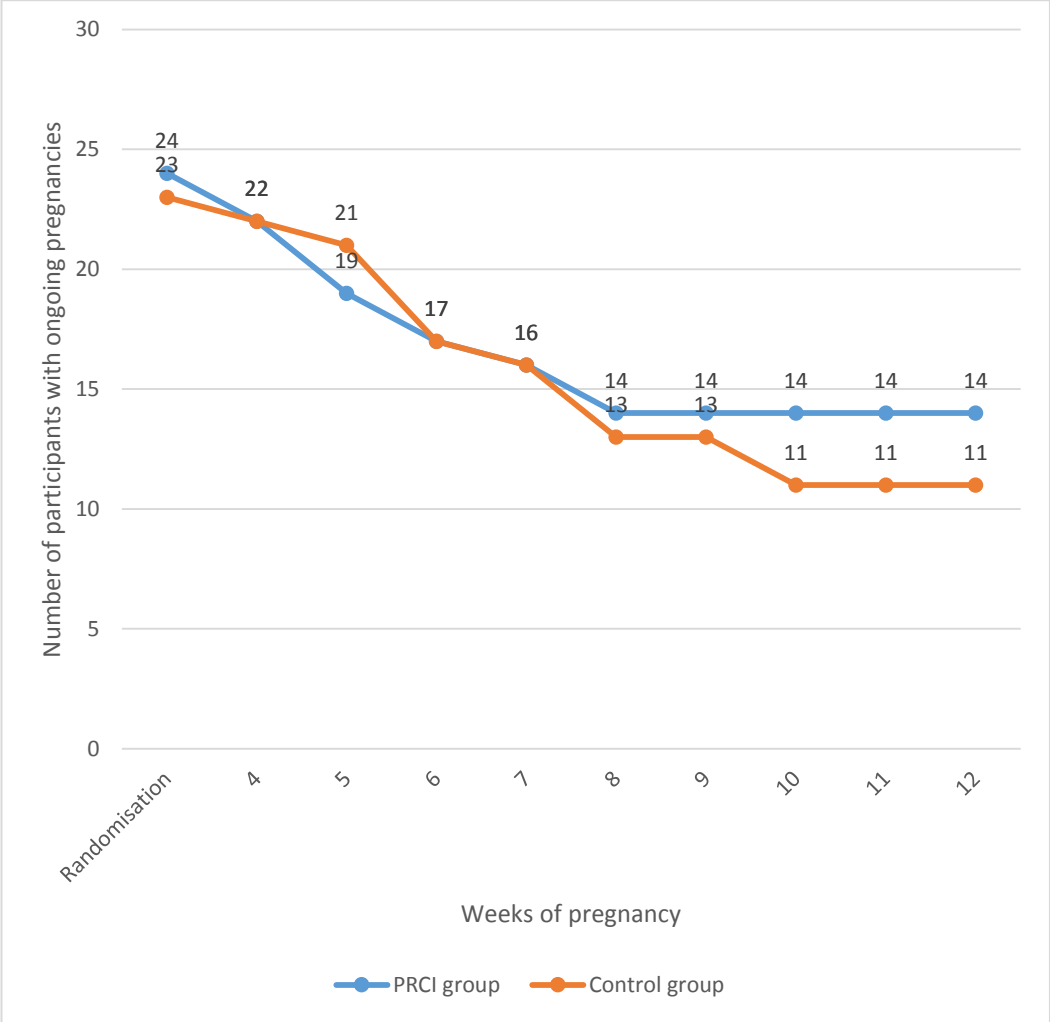


Figure 21: Line chart to compare weekly ongoing pregnancy rates in control and intervention groups

This above graph does indeed suggest that there is a difference in the number of continuing pregnancies in the two groups, but given the small numbers in the intervention and control groups it may be that there are other variables which account for the observed effect.

However, these data indicate that pregnancy outcome has merit as a study outcome measure in a future study of the PRCI, as does the notion of prolonging the data collection period to allow for monitoring of final pregnancy outcome/birth details. In their much cited study, Stray-Pederson and Stray-Pederson (1984) provided evidence of improved pregnancy outcome alongside the provision of supportive care. Since then research pertaining to the value of psychological support on pregnancy outcome in recurrent miscarriage patients has been sparse and any future study of this kind would add valuable evidence to this important area of research.

6.7 Chapter Summary

This chapter has considered the effect of the PRCI, by comparing and contrasting the psychological measurement scores within the control and intervention groups, presenting preliminary evidence to support the development of a future definitive study of the PRCI.

The first section of this chapter explored the factors which affected the data quality and quantity generated in this study; the study was not statistically powered to formally calculate the effectiveness of the PRCI and the number of participants (and therefore number of completed study outcome measures) decreased throughout the data collection period, due to the occurrence of miscarriage.

The quantitative data generated by the WRK, proved complex and difficult to interpret. However, the complete data generated by the HADS questionnaire showed differences in the anxiety levels between the PRCI and control groups with an indication that anxiety scores were lower in the intervention group. However, there was no obvious trend in the depression scores as recorded by the HADS. The most common coping strategy utilised by participants in the PRCI group was relaxation and in the control group, the participants most commonly utilised emotional expression and although the PRCI was designed to promote positive reappraisal coping, findings suggested that the control group used this method of coping more than the intervention group.

The chapter concluded by indicating that pregnancy outcome has merit as a study outcome measure in a future definitive study of the PRCI.

Chapter 7: Discussion and Conclusions

7.1 Introduction

The combined results from this feasibility randomised controlled trial (RCT) and qualitative process evaluation that were presented in Chapters 4, 5 and 6 highlight a number of elements pertinent to feasibility that merit further discussion and exploration. This chapter considers and develops these findings, drawing on additional literature to help develop a clear and concise understanding of the key feasibility aspects of this study and an increased awareness of the lived experiences of women affected by recurrent miscarriage.

Reflexivity is commonly understood as an awareness of the influence the researcher has on the subject being studies and people involved in it (Gilgun 2008) and is a major strategy for quality control within research as it encourages an understanding of how the characteristics and experiences of the researcher impacted on the research (Berger 2015). As such, this final chapter also provides the opportunity to utilise reflexivity to consider and appraise the involvement and influence of the researcher's position and the affect this may have had on the research process and study outcome in this feasibility study. Rather than be a separate concept within this chapter, reflexivity will be an integral component to the discussion.

The work of Lancaster et al. (2004) provides a specific and practical structure (see Chapter 4, section 4.2) to assist with the reporting of feasibility studies and this will be utilised as a framework to assist this discussion chapter, with each of the following sections addressing key aspects of feasibility. In addition, attention will be paid to the recent CONSORT extension for reporting pilot and feasibility studies (Eldridge et al. 2016).

The chapter closes with a personal reflection, written from a clinical perspective, on implications for practice of using the PRCI and recommendations for future research.

7.2 The recruitment process

Recruitment to RCTs is a 'perennial problem' (Hubbard et al. 2015). A commonly reported difficulty is that achieving the expected recruitment target it is more problematic than expected or it takes longer to attain than anticipated (Francis et al. 2006). A failure to recruit sufficient numbers to a research study is one of the main reasons for abandoning trials early (Ross et al. 1999), indeed, published reviews of publicly funded UK trials have established that between 45-69% fail to recruit successfully to target (Brennan et al. 2015). As such, one of the most crucial

aspects of a feasibility study is an assessment of the recruitment process. This aspect will have direct impact on planning recruitment strategies, such as determining the length of recruitment period, in a future definitive study (Lancaster et al. 2004).

In general, the evidence from this feasibility study suggests that successful recruitment to a future definitive study investigating a coping intervention for recurrent miscarriage is indeed possible and significantly, that there is an appropriate and sizeable patient population willing to take part. However, before recommendations can be made with regards to the suggested recruitment strategies for a future definitive study of the PRCI, the feasibility findings presented in Chapters 4 and 5 of this thesis highlighted several recruitment process issues which merit further discussion. These include the questions:

- Can we more accurately predict recruitment rates to a multi-centre RCT of the PRCI?
- What are the barriers to recruitment?
- Does having a researcher, who recurrent miscarriage patients had seen as a specialist clinician, have an effect on their willingness to participate in this study?

7.2.1 Predicting recruitment to a multi-centre RCT of the PRCI

RCTs are seen as the 'gold standard' research design when evaluating the effectiveness of health care interventions (Odgaard-Jensen 2015). Adequate participant recruitment is therefore vital to the successful conduct of a clinical trial (Carter et al. 2005) and RCTs which fail to recruit sufficient numbers of participants, may not produce reliable evidence (Hubbard et al. 2015).

Significant efforts were made during the planning stage of this study, to robustly establish an accurate estimate of the potential recruitment rate in Sites A and B of this study (see Chapter 4, section 4.3 for details). Clinicians in both study sites were asked to review their referral rate for recurrent miscarriage patients in the previous year. Having reviewed this, both site investigators estimated that they would be able to recruit three participants per month to this study, over a recruitment period of one year. Although the actual recruitment rate accurately reflected the estimated recruitment rate in Site A, feasibility findings demonstrated that there was a marked discrepancy between the estimated and actual recruitment rate in Site B. In total, Site A recruited 68 participants during a two-year recruitment period and Site B recruited just eight participants during a 21-month recruitment period (the recruitment period was extended to increase recruitment from Site A).

Chapter 4 of this thesis, set out some of the underlying factors that might account for the differing recruitment rates in Site A and B (see Section 4.3, Table 7). However, one of the reasons for below

expectation recruitment rate in Site B that warrants further discussion and consideration, may be the approach taken to estimating participant recruitment.

Adequate participant recruitment rates are vital to the successful conduct of a clinical trial and projected rates are often over-estimated (Carter et al. 2005), as in Site B in this study. However, estimating rates of participant recruitment is not a straightforward process (Barnard et al. 2010), furthermore inaccurate estimation of recruitment rates can have a significant impact on the planning, execution and funding of clinical trials, especially when a feasibility study, such as this, is aiming to lay the foundation for a successful future definitive study of the intervention.

In this feasibility study, both sites employed an 'unconditional approach' (Carter et al. 2005) to estimating recruitment rates, whereby referral trends were reviewed in order to create a study wide estimate of recruitment rates over a specific time period. Whilst the unconditional approach utilised in this feasibility study was simple to implement, it is clear to see that the actual number of participant recruits in Site B and the time-period it took to recruit them was not consistent with the trial assumptions (see Figure 22).

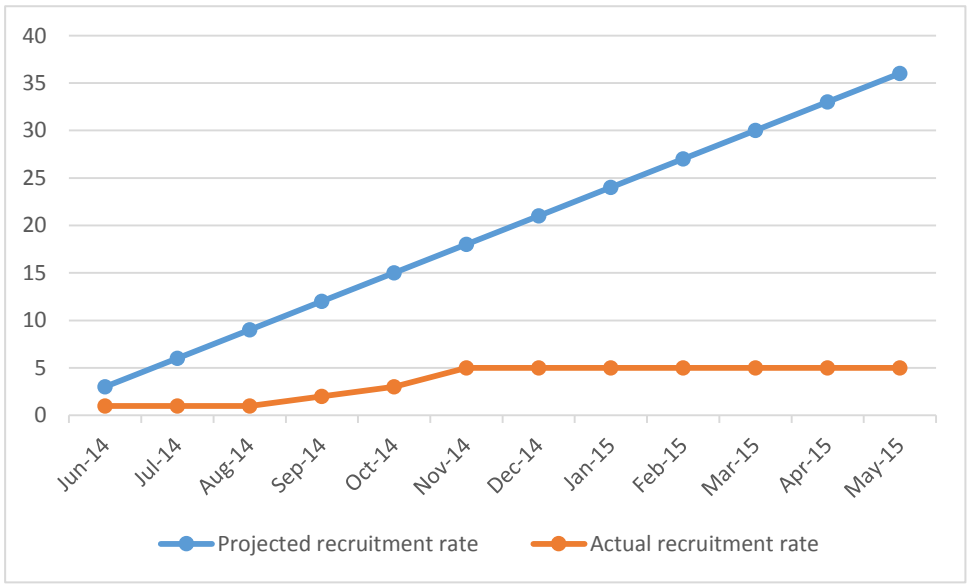


Figure 22: Line graph to show difference between predicted and actual recruitment rate in Site B in 12-month recruitment period

The unconditional approach is the most common method adopted to estimate predicted recruitment numbers and timescales for research studies. However, Barnard et al. (2010) makes a valid point, suggesting that it is unrealistic to suggest that all planned centres in a multi-centre RCT, will start recruiting to their maximum capacity on day one as this approach suggests. Correspondingly, in an earlier study, Carter (2004) argues that utilising the historical mean for the projected recruitment period, as in the unconditional approach, fails to account for the variation

in rate as the study progresses. Consequently, this can lead to an inaccurate assessment being made of a particular site's recruitment rate and the time-period necessary to achieve this.

Carter et al. (2005) describe other approaches to estimating recruitment to a clinical trial. In the context of a multi-centre study, it can be useful to elicit information from each of the planned clinical centres by a formal questionnaire, enquiring about factors such as the number of cases seen for a targeted condition, a list of any competing studies and a summary of the site's success at meeting previous recruitment expectations with this condition. The questionnaire can then be used to plan an initial estimate of the recruitment rate for each potential study centre.

A more accurate estimate of recruitment and accrual period is also possible when additional prior information is included in to the 'unconditional' model (Carter et al. 2005). The 'conditional' model for estimating clinical trial accrual periods (Carter et al. 2005), allows for the expected recruitment in any given month to vary, depending on other conditions in the study, such as how many centres are available to recruit (Barnard et al. 2010). For example, if Site A is capable of recruiting 20 participants per month, but additional smaller sites are only capable of recruiting 10 participants per month, then the time point at which Site A begins active recruitment will greatly affect the study's recruitment rate. As such, the 'conditional' model enables a more accurate assessment of the accrual period as a whole, taking in to consideration, the rates at which individual sites recruit and the length of time in which they will actively recruit.

Other, more complex models for predicting recruitment to multi-centre clinical trials are available including the Poisson process (Carter 2004) and the Bayesian model (Abbas et al. 2007). Although these models show promise for use in terms of the accuracy of their recruitment prediction, they have an associated complexity in their use. Indeed, in a systematic review of models to predict recruitment to multi-centre trials, Barnard et al. (2010) propose that given that there was very little difference in prediction between the 'Poisson' and 'conditional' models, the comparative simplicity of the conditional model makes it more attractive, especially as usability of the model is an important consideration.

The feasibility findings regarding the discrepancy between the differing recruitment rates in Site A and B, suggest that a more refined process to estimating site-specific recruitment rates is necessary to allow for a more accurate assessment of how realistic a particular study-site recruitment target is. Therefore, the simplicity of the conditional model, alongside a formal questionnaire to elicit recruitment information from potential sites, indicates that these methods might provide a more appropriate and accurate technique for predicting recruitment rates and accrual periods in a future definitive study of the PRCI.

7.2.2 Barriers to recruitment

Assessing the accuracy of predicted recruitment rates should not be the only recruitment strategy explored by a feasibility study. Indeed, if little effort is expended in understanding other barriers and facilitators to recruitment, then any definitive trial may still encounter recruitment problems (Hubbard et al. 2015).

Kaur et al. (2012) present an evidence-based list of potential factors that can affect recruitment to a trial. The factors can be categorised in terms of relating to the trial, site, patient, clinical team, information and consent and the study team. Chapter 4, Section 4.4, of this thesis, highlighted that one of the factors that acted as a barrier to recruitment in this feasibility study was the poor level of engagement of the clinical team in Site B. This became particularly apparent when the researcher attended a site visit to launch the study with the consultant clinical care team responsible for providing care to patients attending the Early Pregnancy Unit. There were poor levels of 'buy in' to this research study from the medical clinicians who would be responsible for identifying potential participants. Many of the clinicians present voiced their reluctance to engage with the study, expressing concerns about the value of nurse-led research, the potential impact of a 'psychological' intervention as opposed to a 'medical' intervention and a feasibility study that did not formally assess the efficacy of the intervention being investigated. This poses two main questions:

- Why were clinicians reluctant to engage with this research?
- How is it possible to motivate clinicians in a multi-centre study that addresses a non-medical intervention?

The engagement of clinicians with the research process is fundamental to the recruitment success of a clinical trial. Indeed, recruitment is an interactional activity (Donovan et al. 2014), normally initiated between the potential participant and their clinician, whereby the clinician establishes whether their patient is eligible for a study and importantly whether they are interested in taking part in research or finding out more about the study. Whilst research nurses may takeover research related activities, once a potential participant has confirmed their interest to participate in a clinical trial, this initial conversation between the clinician and their patient, where preliminary information about a particular trial is given, is vital to the recruitment process.

A systematic review of three bibliographic databases from 1986 to 1996 by Ross et al. (1999) identified 78 papers which reported the barriers to recruitment of clinicians and patients to RCTs. It proposed that clinician barriers included time constraints, lack of staff, lack of training, worry about the impact on the doctor-patient relationship, concern for patient, loss of professional

autonomy, difficulty with the consent procedure, lack of rewards and recognition and an insufficiently interesting research question. Correspondingly, a study by Bugge et al. (2013) acknowledged the importance of clinicians in the recruitment process of a research study, paying particular attention to understanding clinician-level factors that acted as barriers to recruitment. This study concluded that these barriers included lack of time, lack of research experience and training, concerns about the impact of the trial on the doctor-patient relationship and concerns about the extra burden on patients.

Chapter 4, Section 4.4 of this thesis highlighted and identified some of the organisational difficulties that affected recruitment rate to this feasibility study in Site B and offered possible explanations of why this variability in recruitment was apparent across the two sites. These included the fact that in Site B, there were fewer participants than expected, a lack of on-site researcher and no named clinical lead for recurrent miscarriage patients. In addition, because recruitment was taking place on the Early Pregnancy Unit (EPU) and not in a specialist recurrent miscarriage out-patient clinic, patients were being seen at the time of their miscarriage. However, the chapter omitted to consider in any depth, the clinician/clinical barriers that affected recruitment to this study. Furthermore, although when it became apparent during the course of this feasibility study, that recruitment rates were lower than anticipated in Site B, consideration was given to rectifying organisational factors that might improve recruitment rates (for example by increasing research nurse availability to help with recruitment), less consideration was given to the clinical factors that might have been influencing recruitment. Interestingly, in a recent study, Skea et al. (2017) makes the point that studies which have focused on barriers to trial recruitment, have previously tended to highlight problems associated with organisational factors such as the importance of building a research culture and ensuring adequate research resources are available. However, the study goes on to suggest that when considering barriers to recruitment, it is important to explore the notion of how trial burden or trial 'work' (Skea et al. 2017) can have an effect on recruiting clinicians. Similarly, Donovan et al. (2014) make the point that whilst recruiters to clinical trials commonly identify organisational barriers to recruitment, they are seemingly unaware of their own influences as clinicians on the recruitment process, particularly when the research topic clashed with their clinical judgement and when the intervention didn't fit their own preference.

A significant effort was made to engage clinical colleagues in Site B at the onset of the study, which involved the researcher attending a site visit launch and presenting background information about the study. The medical clinicians who attended the meeting were responsible for providing routine care to women attending the EPU, and whilst they were not directly related to the trial, they were nonetheless, important facilitators to recruitment. Unfortunately, these

clinicians proved difficult to engage with even at this early stage of the study as the diary extract from the researcher's field diary demonstrates (see Chapter 4, Section 4.4). The challenging feedback from the clinicians attending this meeting suggested that, ostensibly, they may not have understood or accepted, the research value of this feasibility study and the non-medical focus of this study appeared not to have fitted with their preferences for research.

As with many trials, recruitment to this feasibility study, proved more difficult than anticipated at the outset of the study. The process of recruitment is a fragile process and the overt/covert, witting/unwittingly influences of recruiters can have a significant impact on the success or failure of recruitment to clinical trials (Donovan et al. 2014). Furthermore, recruitment barriers and facilitators can vary between study sites due to the differing and varying internal and external forces that affect clinicians locally (Kaur et al. 2012).

The key feasibility finding is that the recruitment strategy in Site A was very successful; essentially the process was robust and worked well. However, in Site B, as a result of the views of clinicians, access to potential participants, may in effect, have been blocked. This study has highlighted the fact that in order to make an accurate feasibility assessment of the recruitment process, then consideration should be given not only to the organisational barriers, but also to the clinical/clinician barriers to recruitment. Whereas, organisational barriers are sometimes easier to 'fix,' the complexity of clinical barriers often prove extremely difficult to rectify, if they are not identified in the planning stages of the research process. Certainly, in this study, the researcher, had not fully anticipated or comprehended the nature of the clinical barriers in Site B and the apparent lack of interest and non-engagement of medical clinicians in Site B with this non-medical intervention study. Whilst highlighting these findings maybe 'contextually sensitive' (Skea et al. 2017 p.7), this is an important feasibility finding and emphasises the need to consider the broader processes of recruiting participants when planning recruitment sites in a multi-centre study.

7.2.3 Does having a researcher, who recurrent miscarriage patients had seen as a specialist clinician, have an effect on their willingness to participate in this study?

The first recruitment encounter in to a clinical trial normally takes place between the patient and the recruiting clinician (Tomlin et al. 2012). During this consultation, preliminary trial information is given verbally and sometimes in the form of a Patient Information Sheet, and the patient is invited to participate. In this feasibility study, potential participants were given initial information about the study by their clinical care team (doctor, specialist nurse or nurse) when they attended the Recurrent Miscarriage Clinic or EPU. The clinical care team asked the potential participant if they would be willing to speak to the researcher and find out more about the study and if the

potential participant was agreeable, then a meeting was arranged at a convenient time and location to discuss the study in more detail with the researcher.

Previous studies have highlighted some of the ethical dilemmas associated with the potential conflict between the roles of clinicians, who are both a care provider and researcher recruiting to clinical trials. Indeed a recent study which aimed to understand more about recruitment to RCTs, emphasised that intellectual and emotional challenges can arise when combining research with clinical roles (Elliot et al. 2017). Other studies have reported on the ethical dilemmas of recruitment when there is a potential conflict of the clinician/researcher roles. These include the potential misuse of confidential information obtained within a therapeutic relationship for recruitment purposes (Habiba and Evans 2002), the risk of professional preferences being mediated through interactions with patients (Bower et al. 2005), the focus of the consultation being shifted away from the patient to research (Wilson et al. 2015) and the risk of coercion as patients may feel pressured into entering a trial to please their clinician (Spiro 1975; Wilson et al. 2008).

In Site A of this feasibility study, the recruiting clinician was already known to potential participants in the capacity of a specialist clinician in recurrent miscarriage, prior to them being invited to participate in the study. The recruitment rate in this site, exceeded the original recruitment target. Furthermore, only very few of the patients invited to participate in this study, declined. This poses two main ethical considerations regarding recruitment to this study in Site A, where the recruiting researcher was also the clinician, which merit further discussion and exploration:

- Did participants feel pressured to take part in the research study because they found it difficult to decline their clinician's invitation to participate?
- Was the willingness of potential participants in Site A, influenced by the fact that they knew the researcher as an expert clinician in recurrent miscarriage and therefore perceived her to be sympathetic to their situation and knowledgeable about potentially helpful resources for support?

When patients are recruited / consented to research studies by a clinician they regularly see, then there is a potential risk that they might feel uncomfortable refusing participation, as they may feel dependent on their clinician's goodwill for their ongoing care (Wilson et al. 2015). In addition, even when potential participants are willing to take part in a study, there is a risk that they feel pressured to agree to participate without taking adequate time to consider their involvement and discuss their participation in the study with others (for example their friends, family or GP).

Combined clinician/researcher roles might increase the risk that patients would feel pressured to participate studies. Patients might feel uncomfortable declining participation, for fear of 'offending' the researcher, because of the potentially dependent nature of their relationship with them as a clinician.

Whilst the risk of coercion by a clinician, albeit unintentional at times, is a very valid ethical concern, undue pressure was not placed on potential participants to take part in this feasibility study. Potential participants were encouraged to take as much time as they needed to consider their participation in the study and discuss their potential involvement with friends, family or even their GP. Interestingly, Wilson et al. (2008) makes the point that rather than feeling pressurised to participate in research, many patients may, in fact, feel reassured when invited to participate by their physician and it should not be assumed that the patient will necessarily be pressured. Indeed, successful recruitment to an RCT often relies on the development of a positive relationship between the researcher and the patient. When the researcher is already known to the potential participant as a clinician, this trusting relationship is sometimes already present. The important factor is to ensure that potential participants are invited to take part in the study in an ethical manner.

It is also important to consider whether the participants' relationship with the researcher in Site A and their willingness to participate in this feasibility study was affected by the fact that they already knew her as a clinician who was responsible for providing and coordinating their care in the Recurrent Miscarriage Clinic. Rather than feel coerced in to participating in the study they were actually very willing to participate because they valued and respected her professional expertise. Indeed, in an article that addresses the importance of addressing reflexivity on the researcher's position, Berger (2015) suggests that the status of the researcher can impact the research because respondents may be more willing to participate and share their experiences with a researcher whom they perceive as sympathetic to their situation.

The qualitative process evaluation of this thesis (Chapter 5) suggests that this patient group perceived that current health service provision for them, especially during the waiting period of a new pregnancy, was both limited and unsupportive and demonstrated a lack of understanding of their needs during this challenging time. At the point of a positive pregnancy test, recurrent miscarriage patients experienced an acute onset of anxiety, as they were extremely concerned about the well-being of their pregnancy and fully expected a further miscarriage to occur. Therefore, the women reported an imperative need for reassurance and support from a health professional with regards to their concerns about their pregnancy. The most accessible health professional available to them was the GP. However, qualitative findings show that they failed to

offer the intensity and level of psychological support that the women wished to receive, often trivialising their concerns and levels of anxiety. Furthermore, the only support available from secondary care services such as the EPU, was sporadic and inconsistent and mainly consisted of the offer of one reassurance scan. Moreover, the availability of this often depended on the member of staff they spoke to and the work load of the extremely busy scan departments.
In Site A, the opportunity to participate in this research provided participants with access to a researcher who was also a clinician who specialised in recurrent miscarriage. This poses the question of whether the decision to participate in this study was influenced by the fact that the potential participants knew the researcher was also a clinician who they had seen in a clinical capacity. Indeed, as part of the research, participants were asked to contact the researcher at the time of a positive pregnancy test, often the catalyst to extreme levels of anxiety, to enable randomisation. Potential participants may have been under the misconception that participating in the research would provide them with additional and easily accessible support from a health professional, during the stressful waiting period of any subsequent pregnancy.

Several studies have investigated whether offering incentives, such as financial inducements, for participants impacts on study recruitment rate (Bentley and Thacker 2004; Halpern S 2004; Free et al. 2010). However, there appears to be no available evidence base that specifically considers whether the potential opportunity of accessing extra support from a researcher in their dual role as a clinician, acts as an incentive to participate in a research study and influences the research participation decision-making processes.

Of course, it maybe that this incentive is specific to this particular study and the condition of recurrent miscarriage, given the apparent unmet need and lack of psychological support for this distinct patient population.

Certainly, during the initial recruitment period of this study it became apparent that some study participants wished to use the engagement between themselves and the researcher as an extra support mechanism, reflecting the level of need of recurrent miscarriage patients. The researcher received numerous telephone calls and emails requesting support and seeking reassurance about study participants' anxieties regarding the well-being of their pregnancy. The fact that the researcher was also a clinician who specialised in the area of recurrent miscarriages and was known to study participants in Site A in this capacity, is likely to have exacerbated this situation. Indeed, the researcher did not receive any additional support requests from participants in Site B.

The selected intervention for this study was the PRCI and the potential it had to promote positive feelings and sustain coping ability during the waiting period of a new pregnancy following recurrent miscarriage. As previous studies have suggested that professional support and 'tender

loving care' can have a positive impact on psychological well-being and improve pregnancy outcome in this patient group (Stray-Pederson and Stray-Pederson 1984; Clifford et al. 1997) there was a need to minimise the risk of the researcher's engagement acting as an intervention itself. Any additional support offered by the researcher could potentially impact upon the participant's use and experience of using the PRCI. Therefore, steps were taken to try and reduce this risk:

- When potential participants were invited to participate in the study they were strongly advised that taking part in the study would not lead to the provision of additional clinical support
- A substantial amendment made changes to the study consent form (see Appendix G) and a section was added informing participants that the researcher would be unable to provide additional support or clinical advice.
- A study specific email address was developed and participants were provided with this contact email in case of queries about the research study. Previously the researcher's personal NHS email address and telephone number had been provided. The 'out of office' facility for this email informed participants that if they had a question about the research study then a member of the research team would get back to them. If they needed clinical advice or support then they were advised to contact their GP.

Whilst the introduction of these steps significantly reduced the request for clinical advice and support from the researcher, qualitative findings suggest that the additional contact of a researcher who was also a clinical specialist in the area of recurrent miscarriage still affected potential participants' decision to participate in the study. Indeed, this 'extra' contact and potential supplementary support mechanism, was seen by some study participants, as an added bonus to participating in the study (See Chapter 5, Section 5.4.1.1 for details). The interview narratives appear to provide evidence that this may have influenced the participation decision-making process, which in turn, raises important issues when considering the internal validity aspects of this study. As such, given the apparent particular unmet psychological needs of this patient population, a future definitive study of the PRCI should carefully consider the ethical implications of having a recruiting researcher who is also a specialist clinician known to potential participants and what steps can be taken to limit any influence this might have on the research participation decision-making process.

7.2.4 Feasibility assessment of recruitment process

In summary, the evidence from this feasibility study does indeed suggest that successful recruitment to a future definitive study investigating a coping intervention for recurrent miscarriage is possible and significantly, that there is an appropriate and sizeable patient population willing to take part. Importantly, however, the discussion chapter has reflected on some of the broader processes of recruitment and offered valuable insight into the complexity of recruitment issues, including the importance of ensuring integrity of the recruitment approach and the impact of having a researcher who is also known as a clinician to potential participants.

Table 11 identifies the key organisational, clinical and ethical recruitment considerations highlighted by this feasibility study. These could be used to inform site selection and recruitment strategies in any future multi-centre definitive study of the PRCI.

Organisational considerations	Utilisation of a robust strategies to ensure accurate assessment of expected recruitment rates in each study site
	Selected sites should have robust systems in place for the care of recurrent miscarriage patients (ideally regional referral centres) as these sites are likely to provide a substantial and willing patient population from which to recruit from.
	Patient care pathways in which clinical research is fully integrated
	Visible on site research nurse / midwife teams to assist with recruitment and coordination of the study
	Positive research infrastructure in place with on-site collaborators who will facilitate and support study recruitment
Clinical considerations	A visible on-site research champion in each study centre who is committed to promoting recruitment and pushing forward the study to successful completion
	A clinical team with proven engagement in non-medical interventions
Ethical considerations	Consent training should be in place to ensure clinicians and physicians are able to assess whether or not a patient's consent is valid (un-coerced and informed)
	An awareness and understanding of the potential impact of having a clinician/researcher recruiting to the study

Table 11: Table to show organisational, clinical and ethical recruitment considerations for a future multi-centre RCT of PRCI

7.3 Randomisation

An essential component of an RCT is to ensure that the research participant will have an equal chance of being in any of the randomised study groups and therefore the same chance of receiving a particular study intervention. Furthermore, randomisation ensures that each study group is as alike as possible, making sure that similar levels of risk factors are present in each group and group characteristics are rendered comparable (Gebski et al. 2002). Therefore, one of the key feasibility objectives of this study was to test the randomisation procedure utilised and to

assess that it was both efficient and effective. This included evaluating the practicalities of the actual randomisation procedure and assessing the willingness of study participants to participate in a randomised trial.

The quantitative feasibility findings of this study (Chapter 4) established that the processes for achieving randomisation worked smoothly for both the research team and study participants. Findings from the qualitative process evaluation (Chapter 5) support these findings. Moreover, it also highlighted the fact that participants showed a willingness to participate in an RCT and an understanding of the need to have an intervention and a control group, even when they knew there was a possibility that they might not receive the PRCI. The randomised groups were of equal size and well balanced for stratification variables.

7.3.1 Feasibility assessment of randomisation process

In conclusion, the combined quantitative and qualitative feasibility findings from this study indicate that the randomisation processes selected in this study were successful and worked smoothly and effectively. It is recommended that any future definitive multi-centre RCT of the PRCI should adopt similar randomisation processes, ensuring that number of previous miscarriages remains one of the stratification variables. However, given the likely increased sample size, it may be more appropriate to utilise a specialist Clinical Trials Unit to perform and manage the actual randomisation process.

7.4 Data collection questionnaires

The testing of data collection forms/questionnaires is fundamental to a feasibility study (Lancaster et al. 2004) and this is particularly important when the questionnaires are being self-completed by the participant. It is important to establish in the feasibility stage of the study that the study questionnaires are 'comprehensive and appropriate, and that the questions are well defined, clearly understood and presented in a consistent manner' (Lancaster et al 2004). Data collection procedures should ensure that the participants have enough time and capacity to complete study questionnaires and that it does not create a burden for them (Tickle-Degnen 2013). Importantly from a validity point of view, it is necessary to ensure that the selected questionnaires are the most appropriate data collection methods and provide researchers with the information they require.

The questionnaires used in this feasibility study consisted of the; Pre-Intervention Demographic Questionnaire (Appendix J), the HADS (Zigmond and Snaith 1983) (Appendix K) and the WRK Form (Boivin and Takefman 1995) (Appendix L and M). The HADS and WRK were selected as they had

been used in previous studies of the PRCI to measure emotions experienced. The quantitative feasibility findings (Chapter 4, section 4.7.1, 4.7.2 and 4.7.3) enabled an assessment of the practical aspects of the study measures/questionnaires, such as comprehensibility, completion rates and mode of administration. The qualitative process evaluation (Chapter 5, section 5.4.1.2) aimed to investigate in greater depth, participants' individual reflections on completing the questionnaires, adding considerably to the understanding of how participants used and reacted to the study questionnaires.

The feasibility assessment of the data collection assessments utilised in this study identified two main feasibility issues that warrant further exploration and consideration in this discussion chapter.

- Dialogue with participants during the qualitative interviews highlighted an internal validity issue, whereby participants adapted the WRK questionnaire and used it as a self-monitoring intervention, experiencing positive effects as a result.
- The PRCI is designed to promote positive reappraisal coping yet the selected study questionnaires provided only minimal quantitative data on the coping strategies utilised by participants in this study suggesting that a future RCT of the PRCI should consider the use of alternative/additional measures of coping.

7.4.1 Use of the WRK as a self-monitoring intervention

Qualitative interviews with participants highlighted a major feasibility and internal validity issue regarding the usage of the study questionnaires, focusing in particular on the use of the WRK. This questionnaire was intended as an instrument to measure emotional and physical symptoms during the study time-period however, many participants reported adapting the questionnaire and using it as a self-monitoring intervention and may have perceived or experienced a positive effect as a result of weekly rating of the emotional and physical symptoms listed on the WRK.

Self-monitoring refers to a term when the assessment procedure involves data collection by the client (Korotitsch and Nelson-Gray 1999) and is a method of measuring subjective experience and includes the 'recording of experience in the moment' (Craske and Tsao 1999 p.467), providing users with continuous and immediate feedback of their situation (Bornstein et al. 1986). It is well established as an assessment tool, and it has been shown to be an effective intervention strategy (Brown et al. 2014) with therapeutic effects due in part to the reactive effects of the self-monitoring activity (Korotitsch and Nelson-Gray 1999). Correspondingly, McCarthy et al. (2015) propose that assessment reactivity refers to changes in participant experiences that are triggered

by the actual assessment process therefore, assessing behaviour may be an intervention in itself resulting in therapeutic consequences.

In this feasibility study, the WRK provided study participants with an opportunity to spend time reflecting on the physical and emotional symptoms they were experiencing during the waiting period of their new pregnancy. Participants reported that this encouraged an awareness of the emotions, anxieties and feelings they were experiencing, helping them to rationalise them and giving back a little control in a situation where the women felt they had little control over the outcome. There was a sense among all interviewees that one of the benefits of completing the weekly questionnaires was that as the pregnancy continued, they were able to look back over the completed questionnaires and monitor the physical and emotional symptoms of pregnancy they were experiencing. This also provided the women with an overview of the progress of their pregnancy to date, almost a reflective diary. Another apparently positive effect of the questionnaires was that participants indicated that they felt less anxious because of completing the questionnaires and several of the interviewees even specifically remarked on the fact that the questionnaires promoted positive reappraisal, something the PRCI was designed to do. Negative reactivity effects from using the WRK in this study were minimal and mainly caused by apparent fluctuations in the physical symptoms of pregnancy (for example, a reduction in nausea).

The self-monitoring and reactivity effect of the WRK was not altogether surprising. A previous study which first investigated the use of the PRCI as a self-help coping intervention in women with miscarriage(s) (Ockhuijsen et al. 2015) also highlighted the potential reactivity effects of the WRK questionnaire concluding that women experienced a positive or negative effect as a result of rating their emotions, physical symptoms, appraisal and coping. In this previous study, participants were asked to complete the WRK on a *daily* basis therefore the questionnaire was referred to as the Daily Record Keeping form (DRK), but the format of the questionnaire was ostensibly the same as in this feasibility study (see Chapter 4, section 4.7.3 for details). Ockhuijsen et al. (2015) concluded that any future RCT of the PRCI in which the DRK was utilised as a study questionnaire, should take in to account the potential positive or negative impact its daily use might have. Careful consideration was given to this during the planning of this feasibility study and therefore, due to the potential reactivity of the DRK participants were asked to complete the questionnaire at weekly intervals during this feasibility study and to avoid confusion it was referred to as the Weekly Record Keeping (WRK) form.

The fundamental issue here appears to be the repeated use of the WRK (daily or weekly), enabling it to act as a self-monitoring technique. From an internal validity point of view, any PRCI benefits may be due to an interaction between the monitoring and the PRCI, rather than the PRCI

itself. Indeed, a study by Korotitsch and Nelson-Gray (1999) that explored the concept of self-monitoring research in assessment and treatment proposed that the reactive effects of self-monitoring may make an adjunctive contribution to the beneficial treatment effects when used alongside other interventions.

Certainly, the reactivity effects of the WRK may have been magnified by the fact that some of the specific properties of this questionnaire and its repeated use addressed some of the explicit needs of women with recurrent miscarriage. The qualitative interviews gave a broader and deeper understanding of this issue, highlighting the emotional turmoil experienced by women during the waiting period of a new pregnancy, the lack of control they had over the situation and significantly, a persistent hypervigilance of monitoring pregnancy symptoms such as nausea, breast tenderness and tiredness, all of which were items requiring rating on the WRK. Furthermore, the study participants referred to the difficulty of coping with the protracted length of the waiting period and many indicated that the weekly use of the WRK had helped them to divide the waiting time up in to individual weeks with shorter milestones. The women would often look forward to completing the questionnaire, setting a fixed day and time to complete them, taking time out to do so and ostensibly taking comfort from the fact that they had achieved another week of their pregnancy. In summary, the WRK appeared to offer the women a tangible method of self-monitoring the challenging situation they were in, offering them continuous feedback and therapeutic value.

The PRCI was designed to help women re-interpret the demands of the waiting period in a more positive way (Ockhuijsen et al. 2014b) and the aim of the WRK in this feasibility study was to measure treatment specific reactions to using this by capturing the intervention's weekly effects. However, it seems evident that the weekly monitoring and associated reactivity to the WRK in itself have had an impact on the reporting of emotional and physical symptoms/reactions. A future definitive study of the PRCI would need to pay careful consideration to how to disentangle this 'methodological artefact' (Ockhuijsen 2014) and the effects of the PRCI to ensure the internal validity of any future study. A possible alternative study design may be the use of a 2 x 2 factorial design study. This would allow an assessment to be made of the individual contribution of the PRCI and WRK, but also measure any interactive effect they may have.

7.4.2 The need for additional data collection questionnaires to assess coping

The aim of study questionnaires is to allow for the collection of research data in a systematic and standardised way (Jones and Rattray 2015). Much of the literature that explores the purpose of feasibility studies highlights the need to focus on the practical aspects of the data collection

questionnaires in a study. This includes the need to assess aspects such as comprehensibility of the questionnaires, completion rate and drop out and any potential burden to participants. However, study data collection measures are there to perform a specific purpose and therefore a further fundamental feasibility aspect is to assess whether the selected questionnaires provide the necessary data to answer the research question.

One of the specific objectives of this feasibility study was to establish how suitable and acceptable the PRCI was for participants, including the observed and perceived impact, benefits and disadvantages. Findings from the qualitative process evaluation component of this feasibility study, reflected previous studies of the PRCI, indicating that the PRCI sustained the participants' ability to cope with the stressful situation they found themselves in (Ockhuijsen 2014; Ockhuijsen et al. 2014b). However, the only quantitative measure of coping assessed by the study questionnaires was a small section (Part 4) of the WRK (see Appendices L and M). Furthermore, only one specific question on the WRK assessed positive reappraisal coping and this single question provided no evidence of increased use of positive reappraisal coping in the PRCI group and was, in fact, at odds with the qualitative data. Indeed, the weekly mean score of positive reappraisal coping in the control group was consistently higher during the data collection period, apart from 'Week 7' of the questionnaires, suggesting that the control group used this method of coping more than the intervention group (Figure 20, page 164).

The outcome measures evaluated in this study appeared to have limited scope to measure the coping strategies used by participants. Given that the aim of the PRCI is to help women interpret the demands of the waiting period in a more positive way (Ockhuijsen et al. 2014b) by promoting positive reappraisal coping, then a future definitive study of the PRCI would need to utilise a more valid and reliable measure of coping. This, in turn would generate more comprehensive data on coping strategies necessary if levels/strategies of coping were identified as the primary outcome measure of a definitive PRCI study. The introduction of additional measures of coping would allow for a more accurate assessment of the coping strategies utilised by this group of women during the stressful waiting period of a new pregnancy and of what, if any effect the PRCI has on this.

Coping is defined as the thoughts and behaviours used to manage the internal and external demands of situations that are designed to be stressful (Folkman and Moskowitz 2004). It is a complicated process that unfolds in the context of a situation or condition that is appraised as personally significant and as taxing or exceeding an individual's resources for coping (Lazarus and Folkman 1984). Because coping is such a complex concept, influenced by numerous conceptual issues then the measurement of coping levels is complicated (Schwarzer and Schwarzer 1996). Correspondingly, Chesney et al. (2006) propose that one of the major challenges in coping

research is the measurement of change in coping. Numerous coping measurements were reviewed in an attempt to assess which would best measure utilised coping strategies and specifically evaluate positive reappraisal in a definitive study of the PRCI in women with recurrent miscarriage. These included the Coping Self-efficacy Scale (Chesney et al. 2006), the Coping Strategies Questionnaire (Rosenstiel and Keefe 1983), the COPE Inventory (Carver et al. 1989), Ways of Coping Questionnaire (Folkman and Lazarus 1985). Detailed discussion with Professor Jacky Boivin (Professor of Psychology, Cardiff University and author of the PRCI) ensured expert input from a psychologist to aid the selection of the most appropriate measure of coping. Following review and discussion it was decided that a future definitive study of the PRCI should introduce an additional quantitative measure of coping to determine the potential impact, benefits and disadvantages of the PRCI for women with recurrent miscarriage and their coping strategies. The Ways of Coping Questionnaire (Folkman and Lazarus 1985) is a validated coping measure that has been used in multiple studies to investigate the components and determinants of coping, is theoretically consistent with the PRCI and has the following advantages:

- It identifies the processes individuals use in coping with stressful situations
- Is easily understood and can be completed in approximately ten minutes
- Has been used successfully as a data collection method in previous studies investigating coping in fertility patients (Lancastle and Boivin 2005) and studies investigating the use of the PRCI (Ockhuijsen 2014)
- Includes a subscale to specifically measure positive reappraisal coping

7.4.3 Feasibility assessment of selected study questionnaires

In summary, one of the specific objectives of this study was to assess the feasibility and acceptability of the selected quantitative study data collection methods; the pre-intervention demographic questionnaire, the HADS and the WRK. This included an evaluation of their comprehensibility to study participants, the identification of any signs that they were burdensome to participants and significantly an assessment of whether these selected data collection methods provided researchers with the information they would require to make an accurate assessment of the effects and impact of the PRCI in a future definitive study.

The feasibility findings presented in Chapter 4 (Sections 4.8.1, 4.8.2, 4.8.3) highlighted the quantitative feasibility findings of the study questionnaires. The pre-intervention demographic questionnaire provided acceptable and accurate levels of baseline information on the demographical detail of participants and the HADS generated excellent quality data and proved a useful an accurate measure of anxiety and depression. Some issues were highlighted around the

rating scale of the WRK and these would need addressing before it could be used as a data collection method in a future study of the PRCI.

The discussion chapter has reflected on some of the unexpected issues around the selected study questionnaires and data collection methods that became apparent throughout the study period. A future trial of the PRCI would potentially need to consider the use of an alternative study design to control for the effect of the WRK and introduce an additional measure of coping such as the Ways of Coping Questionnaire (Folkman and Lazarus 1985)

7.5 Acceptability of the intervention

Acceptability has become an important consideration in the design, evaluation and implementation of healthcare interventions (Sekhon et al. 2017). Successful implementation of an intervention, such as the PRCI, depends on the acceptability of the intervention to the recipients. Therefore a key aspect of feasibility is the need to assess the acceptability of the intervention amongst the population in which it is intended for use as if an intervention is considered acceptable then patients are more likely to adhere to treatment (Sekhon et al. 2017) . Indeed, Lancaster et al. (2004) stress that it is sensible to determine the acceptability of an intervention in a feasibility study as in some cases an intervention may not appeal to all patients. Certainly, there was a concern at the outset of this study that women with recurrent miscarriage may find the concept of positive reappraisal difficult to understand and be sceptical of the value of using a self-managed intervention, given the extreme levels of anxiety and emotional turmoil they experienced during the waiting period of a new pregnancy. As such, one of the main objectives of this feasibility study was to assess to what extent the PRCI was judged by women as suitable and functional to address their psychological needs and practical and serviceable to use.

In general, the quantitative findings from this feasibility study suggest that participants' amenability to take part in the study and general compliance in using the PRCI is an encouraging sign that women with recurrent miscarriage might be receptive to this intervention. Furthermore, the evidence generated by the qualitative process evaluation demonstrated that despite mixed initial impressions of the PRCI, the study participants persisted with its use and demonstrated a positive attitude to using the card. Women found the PRCI an acceptable and practical intervention to use during the stressful waiting period of a new pregnancy, giving numerous positive examples of how it had sustained their ability to cope during this challenging time, with reassuringly, few negative comments about its use.

However, although willingness and compliance in using the intervention give an indication that the PRCI and trial processes were acceptable to participants, the matter of adherence to the

intervention and its guidance is one particular acceptability issue that merits further discussion. Indeed, a key aspect of intervention evaluation is to ensure that the intervention is delivered consistently across participants (Ockhuijsen et al. 2014b). As such, the guidance sheet for the PRCI (Appendix D) gave clear written instructions on the use of the PRCI, recommending that users read the card at least twice a day (morning and evening) or more frequently if required and that they carry it with them throughout the day so it was available to use anytime. A key finding from both the quantitative and qualitative data for this study was that participants modified the advice provided to them about frequency of use of the PRCI, reducing the overall time spent using the PRCI and decreasing or increasing the number of times per day they read the card, adapting this guidance to suit their needs. Participants appeared to base this adaptation on their judgement and perception of the intensity of the emotions (e.g. anxiety, fear and uncertainty) they were experiencing and their assessment of the effect of the intervention on these challenging emotions. For example, some participants elected to utilise the card at time points when their anxiety levels were most elevated, often using the card more frequently at the beginning of the waiting period and decreasing use as their pregnancy continued and they began to feel more confident that the pregnancy would continue and their levels of anxiety reduced. Others increased the use of the PRCI throughout the waiting period as they became familiar with both the card but also the process of positive reappraisal. Some participants chose to use the PRCI simply as a method of aiming to manage acute anxiety episodes. Furthermore, whilst the guidance accompanying the card advised women to use the PRCI twice a day, but to carry the card with them so as they could use it more often if they felt the need, many chose to leave the intervention at home. One participant transposed the PRCI on to her smart phone, adding personal statements under the headings of the ten items on the PRCI, reading the personal statements and adding to them when necessary, applying positive reappraisal in her own way, rather than reading the PRCI. Interestingly, there was a general view among the participants that rather than adapting the PRCI guidance, they were modifying and personalising the use of the PRCI to suit their individual needs.

This finding was not altogether surprising as previous studies that first explored the use of the PRCI with women who had experienced miscarriage(s) (Ockhuijsen 2014; Ockhuijsen et al. 2014b; Ockhuijsen et al. 2015) demonstrated similar adaptations to the PRCI guidance. These studies also concluded that adaptation of the PRCI was based on judgement regarding the effect of the PRCI, whether users felt the effort to use the instrument to be worthwhile or not and on the intensity of the emotions being experienced. Ockhuijsen et al. (2015) proposed that this form of self-adaptation of the PRCI may occur because of how women evaluate their coping resources, suggesting that this is consistent with the stress and coping theory of Lazarus and Folkman (1984)

and other functional approaches to coping. People's emotions are influenced by their secondary appraisal of the situation. This involves the evaluation of the coping resources available to them, their options for coping with a situation, and an assessment of how likely is it that a particular coping strategy will accomplish what it is supposed to do and whether it is likely to be effective. Ockhuijsen et al. (2015) suggest that when women are given the option of using positive reappraisal as a coping strategy, in the form of the PRCI, then they evaluate the likelihood that it will be effective and whether they can apply it effectively. This evaluative process necessitates an appraisal of perceived self-efficacy, which refers to an individual's self-belief in his or her capacity and confidence to successfully accomplish a task and produce a favourable outcome (Akhtar 2008). Self-efficacy beliefs determine the goals individuals set for themselves, how much effort they expend in achieving them and how long they persevere at a task (Bandura 1997). Ockhuijsen et al. (2015) propose that when a woman feels capable of using positive reappraisal and judges the PRCI as effective, then she will continue to utilise the intervention and, as a result, there is an increased sense of self-efficacy. Furthermore, she concludes that this increased sense of self-efficacy in their ability to use the PRCI effectively, encourages them to modify associated skills (e.g. using the PRCI in their own way) and/or increase the use of actions (e.g. using the PRCI more often) (Ockhuijsen et al. 2015).

Perhaps the key feasibility aspect concerning self-adaptation of the PRCI is the need to consider how treatment fidelity could be accurately monitored to ensure consistent implementation of the PRCI in a future definitive multi-centre study, or indeed, if this is necessary?

Complex interventions have been described as health service interventions that are not drugs or surgical procedures, but have many active potential ingredients (Oakley et al. 2006). Correspondingly, the Medical Research Council suggest that complex interventions are usually described as those interventions which contain several interactive components that have other characteristics or evaluators such as the number of variability in outcomes of the intervention or the number and difficulty in behaviours required by those receiving the intervention (Craig et al. 2008). Certainly, the PRCI has many interactive elements, in as much as it was designed to be flexible in its use and open to individual interpretation, resulting in some variability in how it is used and its outcomes. Because of the often flexible and individualised nature of complex interventions, Spillane et al. (2007) observe that problems of documenting and replicating the intervention are likely and this in turn makes it difficult to monitor fidelity to the intervention. Whilst it is argued by some that RCTs of complex interventions must strive to consistently implement the same intervention by standardising its content and delivery (Hawe et al. 2004), more recently there has been a recognition that complex intervention modelling and planning should expect and capture the dynamics of adaptation of the intervention (Greenwood-Lee et al.

2016). Greenwood-Lee et al. (2016) argue that complexity is linked to interventions in two ways. Firstly, due to the properties and multiple components of the intervention itself and secondly as a property of the system into which the intervention is implemented. This second point highlights the fact that interventions (complex in themselves or not) are embedded within diverse, complex adaptive systems comprised of intelligent agents (e.g. policy maker or patient) who modify their behaviour (including any actions which are required to implement the intervention) in an effort to improve outcomes relative to their own standpoint and purposes. As such, even though an intervention may be intended to take a particular form or have a specific outcome, a degree of adaptation may occur in both its implementation and impact as a result of the dynamic human actions and interactions involved in the process of change brought about by the intervention (Greenwood-Lee et al. 2016). Clearly, the combined quantitative and qualitative data from this feasibility study suggests that participants responded to the PRCI and its guidance in very different ways, personalising its use to best suit their diverse needs, reflecting the suggestions of Greenwood-Lee et al. (2016) that the adaptive behaviour of intervention users can affect the form and implementation of the intervention itself.

The issue of adaptation of the PRCI, in this and previous studies, and how this would potentially effect treatment fidelity, has been discussed with the authors of the PRCI, Professor Jacky Boivin (Professor of Health Psychology, University of Cardiff) and Dr Deborah Lancastle (Principle Lecturer in Psychology, University of South Wales). Personal communication with the authors has confirmed that the PRCI was not designed to be used prescriptively, rather it was developed to promote a form of coping (i.e. positive reappraisal) which is known to be useful in unpredictable and uncontrollable situations like the waiting time of a new pregnancy following recurrent miscarriage. The ten items listed on the PRCI refer to general ways of achieving positive reappraisal and as such, it is about encouraging engagement with the principles of positive reappraisal. The authors stress that what is important is that people engage with process of positive reappraisal and because people will engage with the PRCI differently, then the outcome of the engagement is also likely to differ.

The findings from this study have shown that there are a large number of individual different variables in both the use, interpretation and effects of the PRCI. For example, one person might read the card only once, but it may resonate with her and she keeps the PRCI statements firmly lodged in her memory. The next person may read the card twice a day as requested and start to think differently as a result, but it is a slow process to learn the skill of positive reappraisal. Another person may read it twice a day as requested, like a ‘tick box’ exercise, but avoid thinking about the concept of positive reappraisal at all, perhaps because it is too far out of her comfort zone and something she has no intention of thinking about. There are many different variants of

how women might use and interpret the PRCI, but in terms of broad metrics, simply reading the card does not mean that the person is engaging with positive reappraisal. Indeed, the person who just reads the card once, but its statements resonate with her immediately, maybe engaging with positive reappraisal coping most of all.

It appears that in this feasibility study 'engagement' and 'intervention fidelity' refer to far more than twice daily reading the PRCI and compliance with the guidelines for use. Given that it is a self-help intervention involving thinking and personal interpretation, it is difficult to measure, control or have insight into how participants precisely used it and this maybe a limitation of the intervention and of this feasibility study.

The only quantitative measures of use of the PRCI in the current feasibility study was on the WRK questionnaire (Appendix M). Positive reappraisal assessment items on this questionnaire consisted of the items, 'I tried to make the most of the situation' (Part 4) and 'waiting for the twelve week scan could have a positive impact' (Part 5). Part 6 of the WRK asked participants to record how often they had read the PRCI card. Although the qualitative process evaluation added to the understanding of acceptability of the PRCI, it could have expanded assessment of the intervention by asking participants in more detail about how and in what ways they tried to positively reappraise the situation (if at all) and about whether they felt that their coping strategies had improved as a result of the PRCI.

Treatment fidelity is an important concept when considering the methodological strategy used to monitor and assess the reliability and validity of an intervention. However, because the aim of the PRCI was to encourage women to engage with positive reappraisal and was open to individual interpretation, rather than be prescriptive in its approach, then it is far too simplistic to assess engagement and acceptability with the PRCI by asking the question did participants use and read the PRCI as they were advised. A future definitive study of the PRCI should consider how to better monitor engagement with the concept of positive reappraisal and place greater emphasis on the use of other methods of evaluating the intervention. This use of other treatment fidelity methods or procedures to monitor the use, adaptation and acceptability of the PRCI, improving the validity and reliability of the intervention could include the use of:

- 'Proxy' measures of PRCI effect uses such as such as measuring changes in coping strategies and changes in other psychological variables (e.g. anxiety levels)
- Use of participant diaries to better monitor usage of the PRCI
- Qualitative interviews with participants to explore in-depth positive reappraisal coping as a result of using the PRCI

- Focus groups with study participants and research teams to provide a forum for discussion of the intervention

7.5.1 Feasibility assessment of acceptability of the intervention

The assessment of the acceptability of healthcare interventions appears to be a complex concept in itself. Indeed a recent review of how the acceptability of healthcare interventions are defined, theorised and assessed concludes that acceptability appears to be a multi-faceted construct, represented by seven component constructs consisting of affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy (Sekhon et al. 2017). This section of the discussion chapter aimed to consider some of the constructs of acceptability and, in particular, the unique challenges of assessing acceptability and adherence to the use of the PRCI. Successful implementation of an intervention relies on the acceptability of the intervention to recipients because if an intervention is acceptable, then patients are more likely to adhere to treatment recommendations and benefit from improved outcomes (Sekhon et al. 2017). A future definitive study of the PRCI would need to consider how to better assess engagement with the intervention. However, overall, the combined quantitative and qualitative evidence from this feasibility study does indeed suggest that women with recurrent miscarriage would find the use of the self-managed PRCI, an acceptable method of promoting psychological well-being during the challenging waiting period of a new pregnancy.

7.6 Summary of findings and final recommendations for a future study of the PRCI

A feasibility study should set clear criteria to assess its success (Thabane et al. 2010) and these should be based on the primary feasibility objectives of the study as it is these which provide the basis for interpreting the results and determining whether it is feasible to continue on to a main study.

This feasibility study had two main components. A two-centre randomised controlled feasibility study to establish the viability of conducting a multi-centre RCT and test the hypothesis that the PRCI can improve the psychological well-being of women who have experienced recurrent miscarriage during the initial waiting period (1-12 weeks) of a subsequent pregnancy. This component of the study aimed to address the following key research questions:

- How feasible and acceptable were the proposed methods of recruitment, randomisation, intervention and follow-up?

- Was it possible to achieve acceptable recruitment and retention rates within each centre, taking into account defined inclusion/exclusion criteria?
- Were the proposed study questionnaires and data collection methods appropriate?
- Were the study time points for questionnaires and use of PRCI appropriate?
- Was there a preliminary indication of an effect of the PRCI?

The second component, a qualitative process evaluation aimed to explore in-depth women's subjective experience of the study intervention and research methods (including recruitment and randomisation strategies, study outcome measures and study time points) in order to provide information to refine the study intervention or any other aspects of research design (if required).

Recent publications concerned with ensuring appropriate reporting of feasibility and pilot studies (Shanyinde et al. 2011; Bugge et al. 2013) offer a useful analytic framework for applying methodological issues when assessing feasibility research. The below table summarises the key feasibility findings of this study against methodological issues for feasibility research.

Methodological issues	**Findings**	**Evidence *(Section in thesis)***
1. Were women with recurrent miscarriage willing to participate in research?	Recurrent miscarriage patients showed a positive mental attitude to participating in this research	Women reported they were altruistic, keen and willing to take part in research that would help other women, even if it did not help them personally *(Section 5.4.1.1)*
2. What factors influenced eligibility and what proportion of those approached were eligible?	Ineligibility to participate was mainly due to the fact that the patient was already pregnant, receiving fertility treatment or already participating in another research study	126 potential participants were screened for eligibility. 107 of these were eligible *(Section 4.3)*
3. Was recruitment successful?	Recruitment in Site A successful, but fell below expectations in Site B	Total of 75 participants recruited (47 in Site A, 8 in Site B) *(Section 4.3/4.4)*
4. Did eligible participants consent?	Good conversion from eligibility to consent	Only 6 women declined invitation to participate in study. Main reason for lack of conversion was loss of contact between giving study information and participants confirming they wished to participate *(Section 4.3)*
5. Were participants willing to be randomised to control or intervention group and did they find the randomisation process acceptable?	Participants found the concept and process of randomisation acceptable.	Combined randomisation rate for both sites 62.6%. The fact that this study included an element of randomisation did not affect the participants' willingness to take part in the research *(Sections 4.6/5.4.1.1)*

Methodological issues	Findings	Evidence *(Section in thesis)*
6. Were participants successfully randomised and did randomisation yield equality in groups?	Randomisation processes worked very well	Equal sized groups. Well balanced stratification. Study highlighted need to consider the number of study participants it would be necessary to recruit in order to achieve an adequate randomisation rate - suggest should include a recruitment target that is at least twice the randomisation target. *(Section 4.6)*
7. Did participant's use the intervention	Good adherence to overall use of PRCI, but frequency and mode of use differed to specific intervention recommendations	Participants reported consistent but varying use of the PRCI on the WRK questionnaire. Participants adapted PRCI use to suit their individual *(Sections 4.9/5.4.1.3/7.5)*
8. Was the intervention acceptable to the participants?	Participants demonstrated a positive mental attitude to using the PRCI	Only one participant withdrew after randomisation to intervention. Participants reported they found the PRCI an acceptable, practical intervention to use during the stressful waiting period of a new pregnancy *(Sections 4.9/5.4.1.3)*
9. Were study data collection questionnaires completed?	There were excellent completion rates of all questionnaires. Participants reported they were happy with returning questionnaires by post	Only 4 randomised participants (out of 47) did not return questionnaires *(Sections 4.4/4.7)*
10. Were the questionnaires understandable to the participants?	Participants showed good understanding of the pre-intervention demographic questionnaire and the HADS and these were completed accurately. Issues were raised on the use of the WRK	Pre-intervention demographic questionnaire and HADS completed accurately and in full. The study highlighted issues with the rating scale on the WRK (did not allow for the scoring of positive emotions) and confusion over whether a blank score box equated to a zero score or missing data *(Sections 4.8.1/4.8.2/4.8.3/5.4.1.2/6.3/6.4)*
11. Did the questionnaires provide the researchers with the data they required?	Data generated by the study questionnaires were appropriate and valuable. However, limited data were generated that specifically assessed coping and coping strategies	Because of the lack of data generated by the questionnaires which specifically assessed coping, it was not possible to fully assess the effect of the PRCI on coping mechanisms and strategies *(Sections 6.3/6.5/7.4.2)*
12. Was study retention good?	Retention rates good	Out of the 47 randomised participants, 42 completed the study *(Section 4.2)*
13. Were the logistics of running a multicentre study assessed?	Varying recruitment rates in two study sites	Differing recruitment success in Site A and B highlighted issues around recruitment barriers in different sites which would need consideration in future definitive study *(Sections 4.3/4.4/7.2.1/7.2.2)*

Methodological issues	Findings	Evidence *(Section in thesis)*
14. Did all the components of the protocol work together?	Protocol components had excellent synergy	No difficulties were identified in the various research processes employed in this study or in the researcher's ability to implement them. For example, following recruitment, the randomisation process worked well and the participant's care moved forward to the appropriate trial arm *(Whole thesis)*

Table 12: Table to show summary of findings against methodological issues for feasibility research (based on Shandyinde et al 2011 and Bugge et al 2013)

The primary aim of a feasibility study is to answer the question, 'can it be done?' This study has successfully gained knowledge about the feasibility aspects of conducting a future multi-centre definitive study to determine the effects of the PRCI on the psychological well-being of women with recurrent miscarriage during the challenging waiting period of a new pregnancy. Overall, the data from this study provide conclusive evidence of the need for an intervention such as the PRCI to address the psychological needs of women during this stressful time. Feasibility findings suggest that a definitive study of the PRCI to test the hypothesis that the PRCI can improve the psychological well-being of women who have experienced recurrent miscarriage during the initial waiting period of a new pregnancy is indeed possible and likely to 'work.' It ascertained that the components of the protocol worked well together, that there was a sizeable and appropriate patient population willing to participate in this study and importantly that participants engaged with the PRCI and found it an acceptable intervention to use. These results are encouraging and demonstrate that use of the PRCI was popular with conveyed benefit to participants. However, it has identified several relevant feasibility issues that require further consideration and exploration prior to progressing to a main trial.

The final feasibility recommendation is that an effectiveness RCT of the PRCI is possible but with some modifications in order to take into account the following specific issues:

- The introduction of strategies to ensure robust estimates of potential participants in each study site
- The need to pay careful consideration to potential barriers and facilitators to recruitment in potential study sites
- How to more accurately monitor use of the intervention
- The introduction of additional study outcome measures to assess coping strategies
- The self-monitoring action of the WRK questionnaire

7.7 Strengths and Limitations of Study

This feasibility study addresses a novel area of research not previously investigated. It provides feasibility data to lay the foundation for a future definitive study to test the effectiveness of the PRCI to improve psychological well-being of women with recurrent miscarriage during the waiting period of a new pregnancy. The study has two main strengths: it used both quantitative and qualitative data collection methods enabling a more complete and considered assessment of the feasibility of employing the PRCI in a future trial by increasing the understanding of participants' subjective experience of using the intervention. Indeed feasibility study methodological literature advises the use of qualitative process evaluation alongside quantitative measures (Craig et al. 2013). Importantly, the qualitative process evaluation highlighted feasibility issues that were not apparent in the quantitative data, such as the self-monitoring effect of the WRK and the adaptation of the intervention. A second key strength of this study was the active involvement of a Patient Public Involvement (PPI) advisory team who offered advice and support from the initial planning stage of this study, advising on study processes and progress including the design of the PIS, recruitment, analysis and dissemination stages. In addition to helping to ensure the quality and relevance of a research study (INVOLVE 2012), the PPI team helped to shape this feasibility study ensuring study processes were acceptable and sensitive to women with recurrent miscarriage contributing to the overall successful study processes.

Discussing the limitations of a study helps to provide a better context for understanding the importance of its findings, and in the case of a feasibility study, it is useful to distinguish between limitations that can be overcome in a definitive RCT and those that cannot (Eldridge et al. 2016). The unequal sample sizes from the two study sites in this feasibility study might be considered a study limitation. However, given that the aim of this study was to assess feasibility not treatment effect of the PRCI, then this 'limitation' did not affect findings in this study, but highlighted an issue that would need to be overcome in a future study in order to help ensure generalisability of the data. The majority of participants who took part in this study were of a white British ethnicity, mainly due to the location of the study sites in the South of England. This was a limitation of the study as views of participants from black and ethnic minority women were under-represented. A more varied ethnicity study sample, particularly in the qualitative process evaluation may have provided a more diverse and richer insight into the cultural effects of recurrent miscarriage, adding to the limited body of evidence that explores the cultural effects and priorities on recurrent miscarriage.

7.8 Personal reflections and implications for practice

This PhD and associated research study was inspired by a personal desire to improve the provision of supportive care to women with recurrent miscarriage, particularly during the early waiting stages of a new pregnancy. My current role, working as a clinical academic nurse with recurrent miscarriage patients, gives me first-hand experience of the rewarding, but sometimes challenging demands of ensuring that this vulnerable group of patients receive the level of care they deserve. Therefore, when considering the implications for practice of this feasibility study and the potential impact of the PRCI on the care of women with recurrent miscarriage, it is important and necessary to reflect on my extensive clinical experience of working with women with this patient group. This clinical perspective helps to address the reality of how and when the findings and implications of this research study are translatable into clinical practice.

Women primarily attend Recurrent Miscarriage Clinics to seek investigations to ascertain the cause of their miscarriages and to receive the input of clinical experts to try to reduce the risk of further pregnancy losses. Women's expectations are that investigations will identify the cause of their miscarriages and that a treatment option will be available to enable them to have a successful pregnancy. However, previous research suggests that even after thorough investigation aetiological causes for recurrent miscarriages can only be found in 50% of cases (Clifford et al. 1997) and, as a clinician experienced with working with this patient group, I would argue that an identifiable cause for recurrent miscarriages is actually found in far fewer cases than this. When investigations are unable to determine a cause for a woman's miscarriages, then the only available option for clinicians is to advise women to try for another pregnancy, as statistically the woman's chances of having a successful pregnancy in the future are extremely good. However, the prospect of embarking on a new pregnancy is a big decision for some couples and many feel anxious about their ability to cope with the uncertainty of the waiting period of a new pregnancy. Indeed, some will even elect not to conceive again at all, rather than repeatedly face a waiting time filled with troubling uncertainty.

The objectives of this research study were grounded in the day-to-day issues that affect recurrent miscarriage patients. It aimed to address the reality of patient care and a gap in care for this patient group that I had identified in my role as a clinician. When no cause for recurrent miscarriages can be found, patients often feel 'let down,' disappointed and frustrated by the lack of care options available to them and unprepared to face the uncertainty of trying for another pregnancy. This situation is equally frustrating for the clinicians who care for recurrent miscarriage patients as, of course, they want to be able to offer women an explanation for their miscarriages, in addition to an effective treatment option. Whilst some women take comfort from

the fact that no cause has been identified for their miscarriages, the reality is that many women often leave the Recurrent Miscarriage Clinic feeling that they lack anything tangible or concrete to help them manage the uncertainty of trying to conceive again and the early waiting period of a new pregnancy.

The key aim from the outset of this study was to try to address this gap in care and offer women with recurrent miscarriage increased emotional support to help them manage the uncertainty they might feel when they embarked on another pregnancy. This feasibility study provided the opportunity to explore new ways of providing this support, specifically the PRCI. This novel self-administered coping intervention had the potential to be able to provide an intervention that was convenient to patients and easily deliverable at negligible cost to the NHS. Furthermore, a previous fertility study had demonstrated that despite the fact that the intervention was self-administered, with minimal contact from a health professional, the intervention was still effective and positively evaluated by the women who used it (Lancastle and Boivin 2008). Importantly, when investigations into miscarriages are unable to identify an aetiological cause, then the PRCI would offer patients something tangible to take away from the recurrent miscarriage clinic, potentially easing the dissatisfaction and frustration of both women and clinicians when no treatment option is available. Certainly, this feasibility study has illustrated that the PRCI might provide women with a tool to help them cope with the uncertainty of the waiting period of a new pregnancy. Participants were positive about engaging with the intervention, receptive to its use and, although this feasibility study was not intended to measure effect, use of the PRCI did appear to convey benefit to participants.

The final feasibility assessment of this study (Section 7.6) suggested that in academic terms, with some modifications in trial design, an effectiveness RCT of the PRCI is both possible and justified. However, this section of the thesis gives me the opportunity to reflect personally on the implications of this study on clinical practice and write from my perspective as a clinician. As a clinician, I want to be able to address the gap in supportive care for recurrent miscarriage patients at this current point in time, not in several years when the results of a definitive study of the PRCI are available. Applying for funding to run a definitive study to test the effectiveness of the PRCI is time consuming; furthermore, definitive multi-centre RCTs are expensive. From a clinical perspective, therefore, some consideration should be given to the question of whether the substantial investment of finances and time can be defended given the positive findings of this study and the relatively low requirement for evidence of efficacy to justify the introduction of the PRCI as cost-effective, non-invasive intervention with no clear downside. As a clinical academic, this standpoint causes me a dilemma and my clinical and academic perspectives are slightly at odds with each other.

My clinical perspective possesses a more pragmatic and practical point of view and is of the opinion that the encouraging findings from this study suggest that the PRCI has the potential to have a positive impact on the psychological well-being of women with recurrent miscarriage during the waiting stages of a new pregnancy. Given that study participants did not report any negative experiences associated with the use of the intervention, then the PRCI could already provide women with a visible and quantifiable tool to help them manage their emotional anxiety, negating the need for further research to determine the effectiveness of the intervention. Although a future multi-centre definitive study of the PRCI would provide conclusive evidence to validate its use as a supportive intervention for women with recurrent miscarriages the positive evidence generated in this research study suggests that this model of care already has the potential to be made more widely available.

The role of a clinical academic is not always straight forward, indeed this section of the thesis has reflected on how clinical and academic perspectives can sometimes conflict. However, a key focus of the role of a clinical academic is to contribute to a research rich environment leading the way towards achieving excellence in patient outcome and health care (AUKUH 2016). At the heart of this is the provision of excellent patient care. Significantly, this feasibility study has highlighted the need to improve the provision of supportive care to recurrent miscarriage patients and the importance of providing this patient group with tangible support methods to help them manage the uncertainty of the waiting period of a new pregnancy. The PRCI has the potential to help address this need by providing an effective, easily deliverable intervention, offering a useful and quantifiable adjunct to supportive care. However, the intervention will not negate the need for clinicians to ensure that the service they offer is responsive to women's psychological needs as well as their physical their needs during the challenging waiting time of a new pregnancy.

7.9 Future directions and research

The findings from this feasibility study suggest that women with recurrent miscarriage are in great need of psychological support during the early waiting period of a new pregnancy and that they are likely to be amenable to using the PRCI as a self-help intervention to sustain their ability to cope during this challenging time. Study participants found the PRCI practical and feasible. It appeared to convey positive benefits in terms of emotional well-being and was never experienced as a negative intervention.

This study highlights a number of areas that may warrant further investigation to facilitate the development of a sound knowledge base to support the use of the PRCI in women with recurrent miscarriage and to promote a deeper understanding of the 'lived' experience of the waiting

period of a new pregnancy following repeated pregnancy losses. Furthermore, the qualitative findings of the study emphasise the far-reaching emotional consequences of recurrent miscarriage on not only the woman, but also her partner. Future directions and recommendations include:

- The analysis and dissemination of the supplementary 'extra' data generated in the qualitative interviews of this study that focus on the participants' emotions and 'lived experiences' during the waiting period. These data will add significantly to the limited evidence base that explores the waiting period of a new pregnancy following recurrent miscarriage
- Secondary analysis of the qualitative data generated by this study would allow greater understanding of how the PRCI appears to generate resilience in its users. This, in turn, would help determine how to better measure resilience during the waiting period in future PRCI trials. A substantial amendment to the Ethics approval for this study in October 2017 granted permission for the qualitative data from this study to be shared with the School of Psychology, University of Cardiff and secondary analysis will begin shortly.
- Further research into the need for emotional support following recurrent miscarriage should involve and focus on the needs of partners. Indeed, it is highly likely that they too have invested greatly in becoming a parent (Magee et al. 2003) and as a result are vulnerable to the distress of recurrent miscarriages. The views and perceptions of partners could provide a valuable and useful adjunct to understanding more about the impact of recurrent miscarriage in addition to determining the need for supportive therapy for partners of women with recurrent miscarriage.

7.10 Concluding remarks

This study contributes to a small but growing body of evidence that explores the needs and provision of psychological support to women during the difficult waiting period of a new pregnancy following recurrent miscarriage and offers new and previously unexplored insights in to this challenging time. The study set out to assess the feasibility and acceptability of an RCT of the PRCI, a novel self-help intervention based on the principles of positive reappraisal, for use by women with recurrent miscarriage. Whilst the study successfully met its original objective determining that an effectiveness RCT of the PRCI is possible, it also highlighted the specific feasibility issues that would need consideration in the planning of a definitive study of the PRCI, drawing attention to the sometimes complex modifications that would be necessary to the study methods and methodology. Significantly, the study raises the important question of whether a

future definitive multicentre RCT of the PRCI is justified given the substantial investment of finances and time this would require. Balanced against this is the fact that there is a current gap in care and a lack of available therapeutic support to this patient group. This feasibility study identified that study participants engaged with the PRCI, were receptive to its use and appeared to convey benefits from its use with no apparent downside. Furthermore, the cost of the PRCI is negligible in terms of both resources and finances. The demand for healthcare continues to grow and the NHS is challenged to provide high quality, effective health care within limited resources. With that in mind, the evidence generated in this study suggests that this model of care already has the potential to be made more widely available as a safe, low cost, convenient and easily deliverable intervention to provide much needed support to a vulnerable patient population. Given the lack of therapeutic support available for this patient group, the low cost of the PRCI, the apparent conveyed benefits of the intervention and lack of downsides, balanced against the financial cost and the necessary complexity of a future study, my final recommendation is that a future definitive RCT to test the effect of the PRCI is not warranted. Instead, future PRCI research should focus on generating a greater perception and understanding of how the intervention produces resilience in its users, why and how individuals adapt its use to suit their coping styles and whether it is possible to identify individuals who would be more receptive to this type of coping intervention.

Now this study is complete and dissemination of findings is underway, other clinicians who are involved in the care of recurrent miscarriage patients have confirmed both their enthusiasm and willingness to introduce the use of the PRCI as part of their clinical care. There is a general recognition amongst many clinicians that based on the positive and favourable findings of this study, the PRCI has the potential to offer women affected by recurrent miscarriage a tangible tool to help them manage the uncertainty of the early waiting period of a new pregnancy, providing a novel, cost effective care option with no apparent downside. Having completed this PhD study, I have now taken the decision in my personal clinical practice to invite patients with recurrent miscarriage to use the PRCI during the early waiting stages of any subsequent pregnancies. Furthermore, discussions are currently underway with Professor Jacky Boivin (University of Cardiff), the author of the PRCI, about the logistics and practicalities of making the intervention more widely available within the NHS.

In addition to establishing feasibility findings, this study denotes the thoughts and perceptions of women with recurrent miscarriage and represents a challenge to both clinicians and service providers to develop a recurrent miscarriage service that reflects these views and needs. This condition has the potential to cause serious psychological effects including grief, anxiety and depression, and these emotional symptoms can affect every aspect of a woman's life. As such,

recurrent miscarriage is much more than just a medical condition; its consequences are much more far-reaching than this and the provision of supportive care should be central to the management of women who experience this distressing and frustrating condition. The majority of current research into recurrent miscarriage focuses on determining aetiology and the testing of medical interventions to treat this condition. However, despite a comprehensive and extensive programme of research associated with colossal financial investment, effective treatment for recurrent miscarriage remains elusive. Until effective treatment is available, then this study has highlighted the importance of providing supportive care to women with recurrent miscarriage and identified a need to refocus current care provision so that it is more responsive to women's psychological needs.

Specifically, this study has evidenced the fact that for many women with recurrent miscarriage, the waiting period of a new pregnancy is a time of great uncertainty and emotional turmoil and one in which they are likely to require therapeutic emotional support. Current NHS policy emphasises the need to consult with, and involve patients and service users in planning care, ensuring there is a focus on responding to what matters to them (Department of Health 2012; NHS England 2017). Within this context, those responsible for planning the provision of care for recurrent miscarriage patients cannot ignore the views of service users who have expressed the need for supportive care, particularly identifying that they would like to receive improved levels of emotional support during the difficult and challenging waiting stages of a new pregnancy.

Appendix A The Positive Reappraisal Coping Intervention

Positive Reappraisal Coping Items

During this experience I will:

1. Try to do something that makes me feel positive

2. See things positively

3. Look on the bright side of things

4. Make the best of the situation

5. Try to think more about the positive things in my life

6. Focus on the positive aspects of the situation

7. Find something good in what is happening

8. Try to do something that is meaningful

9. Focus on the benefits and not just the difficulties

10. Learn from the experience

Appendix B Matrix to show details of databases searched in literature review

Appendix B Matrix to show details of databases searched in literature review

Electronic databases searched via university library (16/2/16)	Miscarriage	Recurrent miscarriage* (RM)	Habitual abortion (HA)	Successive abortion (SA)	Repeated pregnancy loss (RPL)	Recurrent abortion (RA)	Miscarriage + grief	Miscarriage and depression
CINAHL	1379	138	221	0	4	68	30	93
MEDLINE (EBSCO)	6955	1232	5870	10	1245	1346	32	178
Cochrane Library	103	11	0	0	0	0	0	0
PschINFO	896	19	15	0	0	14	42	148
AMED	34	2	3	0	0	3	0	13
Scopus	11425	2724	5878	234	785	8418	218	328
Web of Science	9770	3205	599	117	573	3623	213	282
Embase	10986	2364	1213	1	80	6186	2	302

Electronic databases searched via university library (16/2/16)	Coping	Positive reappraisal	Positive reappraisal coping intervention (PRCI)	Waiting period	Coping AND positive reappraisal	Positive reappraisal AND waiting period
CINAHL	32525	144	3	313	117	1
MEDLINE (EBSCO)	32248	256	7	1882	172	5
Cochrane Library	0	0	0	0	0	0
PschINFO	67050	463	4	633	338	0
AMED	2065	13	0	33	12	0
Scopus	80402	1040	81	9562	321	4
Web of Science	103087	907	65	6943	250	5
Embase	60314	247	6	2050	206	6

Appendix B: Matrix to show details of databases searched in literature review

Electronic databases searched via university library (16/2/16)	RM or HA or RPL or RA and coping	RM or AH or RPL or RA and positive reappraisal	RM or AH or RPL or RA and PRCI	RM or AH or RPL or RA and waiting period
CINAHL	2	1	1	1
MEDLINE (EBSCO)	5	1	1	1
Cochrane Library	0	0	0	0
PschINFO	4	0	0	0
AMED	4	0	0	0
Scopus	10	1	1	4
Web of Science	16	1	1	4
Embase	7	1	1	2

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Subject - Miscarriage					
Adolfsson et al (2004)	Sweden	To uncover lived experience of miscarriage	Interviews - general-interview approach	13 women who had experienced miscarriages less than 16/40	When a miscarriage occurs, womenpercive this as a child.they feel guilt that they are the cause of the miscarriage and experience profound grief
Abboud and Liamputtong (2005)	Australia	To examine the experience of miscarriage	Indepth qualitative interviews	6 women and their partners	Paper focuses on the coping strategies, social support and satisfaction with health care among the women and their partners. Factors such as treatment by medical personnel and family and friends were identified as either helping or hindering the experience. Coping with pregnancy loss depends on individual women and their partners, as each couple has different ways of dealing with it. However, a good support network and positive contacts with health care professionals also impact on how well the women and their partners are able to cope with the loss. This needs to be recognized when providing care to women who have experienced a miscarriage so that sensitive health care can be achieved.
Andersen et al (2000)	UK	To estimate the association between maternal age and pregnancy loss	Prospective register linkage study	634272 women and 1221546 pregnancy outcomes	High maternal age (late 3os or older)a significant risk factor for spontaneous abortion, irrespective of parity or previous number of miscarriages
Andersson et al (2012)	Sweden	To investigate how women with one or more miscarriages manage their feelings when they become pregnant again	Individual qualitative interviews	16 women	Generally women manage their emotions by themselves. They do not feel they get the support they need form maternity staff and rely on support from friends, family and partners to manage their emotions

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Beutel et al (1995)	Germany	To review the rates of grief and depression following miscarriage and differentiate between the two	Longtitudinal study, questionnaire assessment	125 women who had experienced miscarriage with 125 age-matched controls	Immediately after the miscarriage, the average anxiety and depression scores were elevated when compared with 80 pregnant and 125 age-matched community controls. Twenty percent of the patients who had miscarried showed a grief reaction, 12% showed a depressive reaction, and 20% responded with a combined depressive and grief reaction. The remaining women (48%) reported no changes in their emotional reactions. As predicted, longer-lasting psychological, social, and health status changes followed the initial depressive, but not the grief reactions. Depressive reactions were predicted by a history of previous depression, a lack of social resources, and an ambivalent attitude to the lost fetus. The grief measures were reliable and made it possible to discriminate between grief and depression.
Brier (2004)	USA	To determine if anxiety is elevated after miscarriage	Search of databases medline and psychinfo	Limited literature found. 7 studies reviewed	A significant percentage of women experience elevated levels of anxiety after a miscarriage up until about 6 months post-miscarriage, and they are at increased risk for obsessive-compulsive and posttraumatic stress disorder. Conclusions: Practitioners, as part of routine care after a miscarriage, should screen for signs of anxiety as well as depression. The stress is likely to appreciably lessen over the next 6 months.

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Cameron and Penney (2005)	UK	To evaluate whether inappropriate early pregnancy terminology is being used in Scottish gynaecology care	A case note review and a patient survey assessed usage of four inappropriate terms ('abortion', 'blighted ovum', 'incompetent cervix' and 'pregnancy failure')	1259patient records and 648 patient survey in 18 Scottish hospitals providing care to women with early pregnancy loss.	Women reported hearing 'abortion' in 4.2% of hospital episodes (95% CI 2.9-6.0), but the term was used in 9.9% (95% CI 8.4-11.7) of hospital records. In order to meet national recommendations on terminology for pregnancy loss, clinicians should not only say 'miscarriage' but also write it.
Cecil and Leslie (1993)	UK	To assess provision of support, information and anxiety levels post miscarriage	4 interviews over 6 month time period	50 women	State and trait anxiety measures indicated that this was not a particularly anxious sample of women with respect to trait anxiety, but that state anxiety was raised by the miscarriage and declined in the months thereafter. This study has implications for the professional and informal social support of women who suffer miscarriage.
Cordell and Thomas (1997)	USA	To expand understanding of concept of grief parents endure after suffering loss of baby	Review of experiences at perinatal support group	Not known	Examined theories of grief and demonstarted unique characteristics of parental grief.
Cumming et al (2007)	UK	To identify the trajectories of anxiety and depression in women and in their partners over 13 months after miscarriage.	A prospective study with follow-up at 6 and 13 months after miscarriage	Complete data from 273 women and 133 men	Early pregnancy loss represents a significant emotional burden for women, and to some extent to men, especially with regards to anxiety.

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Fertl et al (2009)	Germany	To assess the current level of pregnancy-related fear and state anxiety in pregnant women who experienced prior miscarriages and to explore the impact of higher levels of anxiety during the first trimester on the following course and outcome of the pregnancy	Questionnaire assessment including the STAI-state scale and other various instruments	143 women who had previously experienced miscarriage and three independent control groups	Women with prior miscarriage had higher levels of pregnancy-related fear and state anxiety during the first trimester. The level of anxiety differed between pregnant women with a single as compared to those with recurrent miscarriage. Early pregnancy-related fear significantly correlated with complications during pregnancy and delivery
Gurber-Epstein et al (2009)	Israel	To understand and give voice to the woman who has experienced miscarriage	Qualitative interviews	19 women who had experienced one miscarriage	Five themes were revealed--the greater the joy, the more painful the crash; the nature and intensity of the loss; sources of support; life after the miscarriage; and recommendations to professionals. The experience of miscarriage was found to be grounded in the meaning of being a woman, as the loss of the pregnancy undermines the women's basic belief in their fertility and as a result threatens their meaning and role as women.

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Jansson and Adolfsson (2011)	Sweden	To apply Swanson's Middle Range Caring Theory to the follow-up visit with a midwife for Swedish women who have suffered early miscarriage or received care for late missed miscarriage in pregnancy week 18 - 20.	Qualitative interviews	25 women 4 weeks after they had experienced miscarriage and 13 interviews with nurses and midwives who care for women with miscarriages	Each woman described her personal experience of miscarriage in the relative terms of a human experience. The midwives and nurses described their experiences with women who received care for missed miscarriage. The interviews included information about the treatment provided by the caregivers during the period afterward of the diagnosis. The caregiver attitude was formed from Swanson's caring categories: "Maintaining belief", "knowing", "being with", "doing for", "enabling". Given the proper care after a miscarriage every woman has the power within herself to improve their wellbeing.
Kolte et al (2015)	Denmark	Is the prevalence of psychological stree and moderate / severe depression higher for women with recurrent pregnancy loss than pregnancy planners trying to conceive naturally?	Cross-sectional study	Compared 301 women with recurrent miscarriage to 1813 attempting to conceive who had not experienced recurrent miscarriage	Both psychological stress and major depression are significantly more common among women with recurrent pregnancy loss than in those trying to conceive naturally

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Kong et al (2010)	Australia	To assess health care professionals' and patients' attitudes towards the psychological impact of miscarriage	A prospective, cross-sectional study	1269 were health care professionals and 1519 were pregnant women or their spouses	Health care professionals were less aware of the psychological impact of miscarriage compared with postnatal depression (91.9 vs 98.4%, P = 0.02). Furthermore, they believed that the psychological impact of miscarriage was less than that of postnatal depression (79.9 vs 88.9%, P < 0.001). However, more patients believed that psychological impact after miscarriage can seriously affect women (59.0 vs for health care professionals 38.3%, P < 0.001). A higher proportion of patients compared with health care professionals (85.2 vs 74.3%, P < 0.001) believed that routine psychological support should be provided after miscarriage, but few agreed that primary health professionals were the most suitable people to provide this care although most health care professionals thought this to be appropriate (9.1 vs 59.7%, P < 0.001).
Lee and Slade (1996)	USA	To consider the psychological implications of miscarriage and follow-up care	Literature review	Not stated	Previous research has identified grief as a feature of postmiscarriage distress, but trauma associated with the process of miscarriage has been neglected. Despite the recognized impact, there is dissatisfaction with professional emotional care, and there is no routine follow-up. There have been no controlled intervention studies with women who miscarry during early pregnancy, although anecdotal evidence suggests beneficial effects. Such studied have concentrated on loss, but perhaps future research should consider the whole experience of miscarriage. An intervention derived from trauma research has been suggested as a possible strategy for facilitating emotional adjustment and preventing longer term negative responses

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Lee et al (1997)	Hong Kong	The aim of this study was to measure the prevalence of psychiatric morbidity following miscarriage among Chinese women in Hong Kong	Interviews	150 women six weeks after miscarriage	Chinese women in Hong Kong have a lower rate of psychiatric morbidity after a miscarriage.
Lok and Neugebauer (2007)	Hong Kong / USA	To investigate the risk of significant and enduring psychological consequences of miscarriage			
Maker and Ogden (2003)	UK	To explore the experience of miscarriage	Indepth qualitative interviews	Heterogenous sample of 13 women	Rather than being a trigger to psychological morbidity a miscarriage should be conceptualised as a process involving the stages of turmoil,adjustment and resolution.Miscarriage could also be considered a pivotal point in the lives of many women resulting in the reassessment of both their past and future experiences.
Murphy and Merrell (2009)	UK	To explore women's experiences of having an early miscarriage in a hospital gynaecological unit.	Qualitative , ethnographic study	8 women who had experienced miscarriage and sixteen health professionals	Three clear phases emerged in the women's experience of miscarriage and hospital admission; first signs and confirmation, losing the baby and the aftermath. These were interpreted as being components of a process of transition. The hospital admission emerged as vital in these early phases in which the importance of nurses and other health professionals providing sensitive, engaged care to meet the emotional and physical needs of the woman was identified.
Murphy et al (2012)	UK	To review the evidence on whether follow-up affects the psychological well-being of women with miscarriage	Cochrane systematic review	Six studies involving 1001 women were included.	Evidence is insufficient to demonstrate that psychological support such as counselling is effective post-miscarriage. Further trials should be good quality, adequately-powered using standardised interventions and outcome measures at specific time points. The economic implications and women's satisfaction with psychological follow-up should also be explored in any future study.

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Neugebauer (2003)	USA	To investigate psychiatric symptoms following pregancy loss	Interviews	A cohort of 114 women 6 weeks after miscarriage, compared with a cohort of 318 women not recently pregnant	Women first seen at their 6- to 8-week post miscarriage gynecologic visit are likely to be more depressed on average than otherwise comparable women who have not experienced a recent reproductive loss. Factors that moderate the impact of miscarriage may vary with time since loss. Enhanced recognition of the implications of study design for research inferences may help bring greater clarify and uniformity to findings from future investigations
Neugebauer and Ritsher (2005)	USA	To examine the frequency of symptoms of depression and of yearning (grief), in the six months following miscarriage, with grief assessed using the Perinatal Bereavement Scale	Telephone interviews	304 women	Approximately 20% of women were grief-stricken at six to eight weeks and again at six months after loss. The prognostic significance of grief symptoms soon after miscarriage and an examination of whether treatments for these feelings are efficacious or warranted, merit further study
National Institute for Health and Care Excellence (2012)	UK	Provides evidence-based guidance on managing ectopic pregnancy and guidance	Guidelines	NA	NA

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Nikcevic et al (1999)	UK	To determine whether knowledge of the possible cause of miscarriage reduces women's long term psychological distress	Prospective longtitudinal study	143 participants divided into two groups according to whether the cause was identified or not for their miscarriage.	In women with a missed miscarriage, identification of the cause of fetal loss reduces the feelings of self-blame
Nikevic et al (2007)	UK	To measure the impact of medical and psychological interventions on women's distress after early miscarriage	Prospective study	Intervention group of 66 women who received additional psychological counselling after miscarriage compared to control group of 61	Psychological counselling, in addition to medical investigations and consultation, is beneficial in reducing women's distress after miscarriage. However, absence of an identifiable cause of miscarriage led to the maintenance of the initial anxiety levels, which should have otherwise decreased with time
Prettyman et al (1994)	UK	To assess psychological morbidity after miscarriage and during following 12 weeks	Questionnaire study	69 women	Significantly more anxiety cases at week 12 among thse women whose pregnancies were unplanned

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STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
RCOG (2011)	UK	The investigation and treatment of couples with recurrent first-trimester and second-trimester miscarriage	NA	NA	NA
Rowlands and Lee (2009)	Australia	To compare social and health correlates of miscarriage	Longtitudinal study	998 women who had experienced a miscariage compared with 8083 who had never reproted one	Strongest correlates of miscarriage among young women are those associated with preparing for, or experiencing, motherhood, and it may be that these factors rather than the miscarriage itself explain any excess of mental health problems in this population
Simmons et al (2006)	UK	To study in detail narrative accpounts of miscarriage	National survey of women's reproductive history	172 deatailed narriatives examined	Findings suggest that women do not experience miscarriage as a routine complication; medicalisation is both resisted and desired; and, for some women, more support and information is needed to assist their search for meaning.

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Smith et al (2006)	UK	To assess the social and personal impact of different management methods (expectant, medical and surgical) on women's experience of first trimester miscarriage	Qualitative interviews and focus groups	72 interviews and 47 participants included in focus groups	Women's experiences and beliefs vary widely and their preferences need to be considered in their early miscarriage management. The three methods have different benefits and problems from the women's point of view. Competence and caring from professionals are especially important
Swanson et al (2009)	USA	To examine the effects of three couples focused interventions and a control condition on women and men's resolution of depression and grief during the first year after miscarriage.	RCT comparing treatment groups	341 couples	Nurse care which involved three counselling sessions had the greatest positive impact on couple's resolution of grief and depression.
Sejourne et al (2009)	France	To implement and to examine the effectiveness a psychological support intervention drawing from three clinical techniques (support, psychoeducation, Cognitive-Behavioural Therapy) for women who have suffered a spontaneous abortion	Questionnaire study	134 women (66 control group, 68 intervention group)	In terms of prevention, a brief early single-session psychological intervention appears to be a particularly pertinent, efficacious and cost-effective method for addressing psychological distress following miscarriage.
Subject - Recurrent miscarriage					
Al-Otaibi et al (2013)	Saudi Arabia	To determine the effect of supportive care therapy for women with RM on their anxiety level and early pregnancy outcome	Quasi experimental research design	17 participants	Supportive care therapy is effective in the management of unexplained recurrent miscarriage and promote early pregnancy outcome

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Callender et al (2007)	UK	To investigate the relationship between counterfactual thinking, distress, future plans and search for meaning following recurrent miscarriage.	Questionnaire and thought listing tasks	62 participants	Findings indicated a positive association between upward counterfactual thoughts and anxiety. Contrary to predictions, there was no relationship between counterfactual thinking and positive outcome
Craig et al (2002)	UK	To assess, depression, anxiety and general health in women who had suffered recurrent miscarriage	Questionnaire study	81 participants	33 of patients could be classified as depressed with 9.9 of women being moderately depressed and 7.4 suffering from severe depression. Twenty-one percent of patients had levels of anxiety that were equal or higher to a typical psychiatric outpatient population. Neither age, cigarette consumption, alcohol intake, previous live birth, number of miscarriages, lateness of miscarriage nor length of time since last miscarriage were found to affect the degree of psychiatric morbidity. These findings add to the understanding of the degree to which recurrent miscarriage can affect mental health.
Kaandorp et al (2014)	The Netherlands	To investigate time to conception in a cohort of women with unexplained recurrent miscarriage	Nested prospective cohort study	251 participants	Time to conception in women diagnosed with unexplained RM appears to be comparable with time to conception in healthy fertile women, as reported in the literature. The interesting finding that women with Factor V Leiden mutation have a significant shorter time to conception may suggest a favourable embryo implantation process

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Kolte et al (2014)	Denmark	To investigate whether non-visualized pregnancy losses (biochemical pregnancy loss and failed pregnancy of unknown location combined) in the reproductive history of women with unexplained recurrent miscarriage (RM) negatively associated with the chance of live birth in a subsequent pregnancy	Retrospective cohort study	587 participants	We show that a prior non-visualized pregnancy loss has a negative prognostic impact on subsequent live birth and is thus clinically significant.
Larsen et al (2013)	Denmark	To review new and emerging theories about the mechanisms behind sporadic and recurrent miscarriage.	Review	NA	New insights into the mechanisms behind miscarriage offer the prospect of novel effective interventions that may prevent this distressing condition
Li et al (2012)	UK	To examine the relationship between stress and recurrent miscarriage (RM) and the impact of stress on establishment of pregnancy	Clinical trial	45 patients	There was a little association between psychological stress measurements and biochemical stress measurements. These results suggest that stress is a risk factor of RM. Within women with RM, moderate stress appears to be associated with improved pregnancy outcome
Liddell et al (1991)	New Zealand	To compare emotional support with standars care after miscarriage in women with RM	Qualitative questionnaire	51 women	Emotional support seems to be important in the prevention of unexplained recurrent miscarriage, giving results as good as any currently accepted therapy
Lund et al (2012)	Denmark	To establish a method of estimating the proportion of women with a subsequent live birth after a well-defined time period in an open cohort of women referred to a tertiary recurrent miscarriage clinic.	Descriptive cohort study	987 women	Approximately two thirds of women with recurrent miscarriage referred to a tertiary center succeed in having at least one live birth within 5 years after their first consultation

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Magee et al (2003)	UK	To examine psychological factors that might predict variations in distress in women with recurrent miscarrage	Questionnaire study	61 women	Levels of distress were associated with being over0invested in becoming a parent relative to other life roles and goals and having more negative child-related positive thoughts about the future
Mason (2010)	UK	Opinion piece on recurrent miscarriage specialist nurse	NA	NA	NA
Musters et al (2012)	The Netherlands	To quantify the supportive care preferences and identify women's characteristics that are associated with a higher or lower need for supportive care in women with RM	Questionaire study	171 participants	Women with RM preferred a plan for the first trimester that involved one doctor, ultrasounds and the exercise of soft skills, like showing understanding, listening skills, awareness of obstetrical history and respect towards the patient and their miscarriage, by the health care professionals. In the event of a miscarriage, women prefer aftercare
Orlando and Coulam (2014)	USA	To confirm or refute that superfertility is assocaited with RM	Retrospective review of clinical histories	201 participants	Recurrent pregnancy loss is associated with superfertility in 32%, immunologic risk factors in 30% and a 20% frequency of chromosomally abnormal pregnancy losses
American Society of Reproductive Medicine (2013)	USA	Define terms associated with RM	NA	NA	NA
Cordle and Prettyman (1994)	UK	To assess the psychological wellbeing of women 12 weeks and 2 years after their miscarriage	Questionnaire study	65 participants	There were no significant differences between rates of anxiety and depression ‘caseness’ at week 12 and 2-year follow-up. An association was found between lack of support from partner and clinically significant levels of anxiety as assessed on the HAD Scale

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Quenby (2010)	UK	To review limited available evidence which indicates that the wide use of empirical treatments for RM has led to minimal benefit for both patients and health care providers.	NA	NA	Article designed to enhance critical thinking and improve clinical skills in an area with extensive and contradictory literature.
Rai and Regan (2006)	UK	Seminar paper reviewing RM	NA	NA	Research has emphasised the importance of RM in the range of reproductive failure linking subfertility and late pregnancy complications. This has enabled the rejection of practice based on anecdotal evidence in favour of evidence-based management
Royal College of Obstetricians and Gynaecologists (2011)	UK	Guideline on the investigation and treatment of couples with recurrent first-trimester and second-tri mester miscarriage	NA	NA	NA
Rowsell et al (2001)	UK	To investigate the psychological impact of recurrent miscarriage, and ways in which intervention at a pre-pregnancy counselling clinic (PPCC) influences psychological adaptation	Questionnaire study	37 participants	No evidence was found to support the hypothesis that those given a medical explanation following intervention would show a greater reduction in levels of psychological distress than those who were not given such an explanation
Sapra et al (2014)	USA	To investigate whether time to pregnancy is similar across successive pregnancy attempts among women experiencing pregnancy loss	Longitudinal investigation of a population-based environment study.	70 couples	Time to pregnancy in women experiencing early pregnancy losses may trend towards longer subsequent attempts.
Sotirios et al (2012)	UK	An investigation and explaination of two different types of recurrent miscarriage	NA	NA	NA

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Serrano and Lima (2006)	Portugal	To describe the consequences of recurrent pregnancy loss for the couple's relationship, and explore gender differences in attitudes and grief intensity toward this kind of reproductive failure.	Questionnaire study	30 couples	Results showed that men do grieve, but less intensely than their partners. Although the couple's relationship seemed to not be adversely affected by recurrent miscarriage, couples described sexual changes after those events. Grief was related to the quality of communication in the couple for women, and to the quality of sex life for men
Sugiura-Ogasawara et al (2015)	Japan	To investigate whether congenital uterine anomalies have a negative impact on reproductive outcome in recurrent-miscarriage couples	Prospective study of couples with two or more miscarriages and a congenital uterine abnormality	170 patients	Surgery showed no benefit in patients with a bicornuate uterus for having a baby, but tended to decrease the preterm birth rate and the low birth weight. The possibility that surgery has benefits for having a baby in patients with a septate uterus suffering recurrent miscarriage could not be excluded
Sugiura-Ogasawara et al (2014)	Japan	Discussion paper regarding investigation of RM	NA	NA	NA
Subject -Medical waiting time					
Bennett et al (2007)	UK	To evaluate the effectiveness of a distraction-based coping leaflet in reducing distress in women undergoing genetic risk assessment for breast/ovarian cancer	RCT to receive intervention or normal care	162 women	The intervention offers a low-cost effective coping intervention, which could be integrated into existing services with minimal disruption and may also be appropriate for other periods of waiting and uncertainty.

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Carroll et al (2006)	USA	Discussion paper. Although subjective optimism is generally regarded as adaptive, people show a sharp decline in optimism when they anticipate self-relevant feedback in the near future. The authors propose that a shift in reponse can reflect a response to new information or an attempt to brace for undesired outcomes. Both explanations represent a response to an adaptive need to prepare for uncertain states of the world.	NA	NA	NA
Drageset and Lindstrom (2005)	Norway	To examine the relationships between demographic characteristics, social support, anxiety, coping and defence among women with possible breast cancer.	Survey	117 women	Social support was positively related to instrumental-oriented coping and emotion-focused coping, unrelated to cognitive defence and defensive hostility. Educational level was positively related to instrumental-oriented coping. Educational level, employment and marital status were negatively related to cognitive defence. Educational level was the most important contributor to social support. Attachment and education were the most important contributors to instrumentaloriented coping, with education as the strongest predictor.

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Folkman and Greer (2000)	USA	Aim of paper encourage researchers and clinicians to give as much attention to the development and maintenance of psychological well-being in the face of serious illness as they do to the etiology and treatment of psychiatric symptoms	NA	NA	This article describes a theoretical framework for the discussion of psychological well-being during serious illness. Then, this framework is used to define variables that research indicates contribute specifically to psychological well-being during serious illness, and finally, based on theory and research, a therapeutic program is described for patients with serious illness.
Boivin and Lancastle (2010)	UK	The aim of the study was to document the course of anxiety, depression, positive affect and coping during the waiting period before a pregnancy test result in fertility treatment.	Questionnaire study using DRK	61 women undergoing IVF	The predominant emotions in the waiting stage were a combination of positive affect and anxiety symptoms versus depression. From the pregnancy test day onwards, the predominant emotion was depression. There was a significant increase in coping activity between the stimulation and waiting stages, with variable effects across coping strategies. It was concluded that whilst medical waiting periods have a clearly defined emotional trajectory, the coping pattern is less differentiated. This may explain why waiting for medical test results is so demanding. Healthcare professionals can assist their patients by facilitating coping strategies that better fit the demands of the waiting period and by offering support once outcomes are known

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Lancastle and Boivin 2008	UK	The aim of this feasibility study was to establish whether a novel brief coping intervention (positive reappraisal coping intervention, PRCI) card that encouraged women waiting for an IVF pregnancy test to redefine the waiting period more positively would be acceptable and practical in this context.	RCT	55 women	PRCI was feasible in the IVF context and was perceived as an acceptable intervention to help minimize the strain of waiting for pregnancy test results during fertility treatment but future research needs to evaluate the full benefits of PRCI against routine care during the waiting period.
Ockhuijsen et al (2013)	The Netherlands	To investigate the effects of a Positive Reappraisal Coping Intervention (PRCI) on psychological well-being of women waiting for the outcome of their fertility treatment cycle	Three-armed RCT	372 women	Positive reappraisal is one of the few ways of coping that has been shown to be associated with increased wellbeing during unpredictable and uncontrollable situations like medical waiting periods. A simple evidence based self-help intervention could facilitate coping during this common medical situation.
Osuna (1985)	UK	It is generally accepted that after having to wait for certain amount of time, anxiety and stress start to build up in an individual, due to both the sense of waste and the uncertainty involved in a waiting situation. This paper provides a theoretical basis for analysing this building up process as it occurs during the waiting period.	NA	NA	NA

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Parker and Kennedy (2010)	UK	Lower gastro-intestinal endoscopy is a common investigative procedure which can be distressing. The extent of this distress is not known, nor have the predictive factors been identified. The aim of the present study was to identify to what extent it is distressing, what factors might predict distress in this population and to identify coping strategies that may mediate such distress	Cross-sectional survey	301 patients	Patients were found to be significantly more anxious than the general population but not more depressed. Coping strategies of self-blame and self-distraction, threat appraisals of endoscopy procedure and control appraisals of results, low optimism, presence of symptoms, low social support, and gender were found to account for 56.3% variance in anxiety. Longer times on the waiting list increased the degree to which the procedure was appraised as a threat. High levels of distress are evident in this population.
Phelps et al (2013)	UK	To evaluate the effectiveness of a self-help coping intervention in reducing intrusive negative thoughts while waiting for cancer genetic risk information	RCT-Control group received standard information. The intervention group also received self-help coping leaflet.	1958 new referrals for cancer genetic risk assessment	Findings that the intervention both reduced distress in those with moderate levels of distress and had no adverse effects following notification of cancer genetic risk suggest that this simple intervention can be implemented across a range of oncology settings involving periods of waiting and uncertainty. The intervention may also reduce the number of individuals dropping out of cancer genetic risk assessment or screening. However, those with clinically high levels of psychological distress are likely to require a more intensive psychological intervention

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Portnoy (2010)	USA	To examine how 'bracing' for a medical test result, impacts cognitive processing as well as recall of information delivered during this period	Factorial design	150 students tested for deficiency in fictitious saliva biomarker	Delivering critical information to patients after administrering a test and immediately before giving results may not be optimal
Subject - Emotions in new pregnancy following previous pregnancy loss					
Andersson et al (2012)	Sweden	To investigate how women who have experienced one or more miscarriages manage their feelings when they become pregnant again	Qualitative interviews	16 women	Generally speaking, women manage their emotions by themselves. They feel isolated with their worries and concerns, and they are in need of the support provided from their intimate circle of friends and family as well as from the staff of the maternity health care ward. Unfortunately, the women do not feel that they get the support they need from the staff, instead they have to rely on their friends, family and partners to help them manage their emotions
Bicking et al (2015)	USA	To investigate whether women with a history of multiple miscarriages are at risk of pregnancy-related anxiety and utilise greater health care services.	Retrospective survey	2854 women	Women with a history of multiple miscarriages may be more likely to smoke and may demonstrate increased health care utilization during a subsequent pregnancy
Côté-Arsenault et al (2001)	USA	To determine specific emotions and concerns of women who are pregnant following perinatal loss	Postal survey	73 women	Women are skeptical about pregnancy with mixed emotions. The most common emotions are 'anxiety,' 'nervous' and scared

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Côté-Arsenault et al (2011)	USA	To describe the consequences of recurrent pregnancy loss for the couple's relationship, and explore gender differences in attitudes and grief intensity toward this kind of reproductive failure.	Questionnaire study	63 women	The majority of women experienced some degree of emotional cushioning. Clinicians should recognise the prevalence of this
Côté-Arsenault et al (2011)	USA	To describe women's experiences of pregnancy after loss and their long term effects of perinatal loss	Qualitative focus groups	21 women in 3 focus groups	Women had many common concerns in response to perinatal loss and subsequent pregnancies. Variations were not linked to number of losses or gestational age of loss. Effects can be potentially lifelong
Geller et al (2004)	USA	A review to summarise the research literature regarding anxiety following miscarriage	Literature review	NA	Considered research which had reviewed anxiety following miscarriage - concluded more large scale research needed to accurately assess
Gong et al (2013)	China	To investigate the influence of pregnancy loss on anxiety and depression in a subsequent pregnancy	Questionnaire study	20 308 women	Women with a history of miscarriage experienced significant anxiety and depression in their next pregnancy. A short inter-pregnancy and the first trimester are risk factors for adverse mental health

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Fertl et al (2009)	Germany	To assess the current level of pregnancy-related fear and state anxiety in pregnant women who experienced prior miscarriages and to explore the impact of higher levels of anxiety during the first trimester on the following course and outcome of the pregnancy	Questionnaire study	143 women	This study suggests that miscarriages may lead to higher levels of pregnancy-related fear and state anxiety. In particular, pregnancy-related fear may have a negative impact on the course of pregnancy and delivery. Thus, interventions to reduce pregnancy-related fear are highly recommended
O'Leary (2004)	USA	To examine grief following perinatal loss and the impact this has on subsequent pregnancy and child	Literature review	NA	Need to be more research on the impact of infant loss and how parent s cope in a subsequent pregnancy and how this effects their parenting of any fututе child
Subject - Waiting time in a new pregnancy following RM					
Ockhuijsen et al (2013)	The Netherlands	To increase understanding of how women with one or more miscarriages experience waiting period of a new pregnancy and assess their perception of positive reappraisal	Focus groups	9 women	Although all women felt that a positive reappraisal coping intervention would be practical and applicable during the waiting period, only women with recurrent miscarriage actually wanted to use the intervention
Ockhuijsen et al (2014)	The Netherlands	To explore how women experience miscarriage, conception and the early waiting period of a new pregnancy	Qualitative interviews	24 women	Analysis resulted in an over-arching theme, 'balancing between loss of control and searching for control.'
Subject - Coping and appraisal					

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Boivin and Lancastle (2010)	UK	To document the course of anxiety, depression, positive affect and coping during the waiting period before a pregnancy test result in fertility treatment. Using a daily record-keeping chart designed for fertility treatment	Questionnaire study	61 women	It was concluded that whilst medical waiting periods have a clearly defined emotional trajectory, the coping pattern is less differentiated. This may explain why waiting for medical test results is so demanding. Healthcare professionals can assist their patients by facilitating coping strategies that better fit the demands of the waiting period and by offering support once outcomes are known.
Côté-Arsenault et al (2007)	USA	To test Lazarus' theory of stress, coping, and emotions in this population, and to understand the patterns of threat appraisal, coping, and emotional states of women across pregnancy after perinatal loss	Longtitudinal study	82 women	Women find pregnancy after loss stressful and a **threat**, and this **appraisal** remains across pregnancy. Because pregnancy anxiety is common, and highest in early pregnancy, providers should address worries and fears with all women early in pregnancy after perinatal loss. Interventions must be tested in future studies.
Folkman and Moskowitz (2000)	USA	Reviews findings about the co-occurrence of positive affect with negative affect during chronic stress	Review	NA	The theme of affect and emotion in the stress process has been dominated by discussions of negative affect and other adverse outcomes. Positive affect and other positive outcomes have been given much less consideration. Psychologists need to understand more clearly the adaptaional significance of positive affect in the midst of stress

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Folkman et al (2004)	USA	To review the history of contemporary coping research with adults	Review	NA	Discuss three primary challenges for coping researchers (measurement, nomenclature, and effectiveness), and highlight recent developments in coping theory and research that hold promise for the field, including previously unaddressed aspects of coping, new measurement approaches, and focus on positive affective outcomes
Garland et al (2009)	USA	Propose a hypothetical causal model that argues for the role of mindfulness in positive reappraisal coping. Positive reappraisal is a critical component of meaning-based coping that enables individuals to adapt successfully to stressful life events. Mindfulness, as a metacognitive form of awareness, involves the process of decentering, a shifting of cognitive sets that enables alternate appraisals of life events	Review	NA	Review summarises by suggesting the implications for clinical practice, suggesting how mindfulness-based integrative medicine interventions can be designed to support adaptive coping processes.
Lancastle and Boivin (2005)	UK	To examine the unique and shared predictive power of psychological variables on reproductive physical health	Questionnaire study	97 women	This research contributes to evidence suggesting that the health benefits of dispositional optimism are due to its shared variance with neuroticism.
Lazarus and Folkman (1984)	USA	Book - Stress, Appraisal and Coping	NA	NA	NA

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Manne et al (2009)	USA	To evaluate the role of cognitive and social processing in partner psychological adaptation to early stage breast cancer, evaluating both main and moderator effect models	Questionnaire study with partners on 3 occasions - shortly after diagnosis and at 9 and 18 months post diagnosis	253 partners of women with breast cancer	Results indicate several cognitive-social processes directly predict partner distress. However, moderator effect models in which the effects of partners' processing depends upon whether these efforts result in changes in perceptions of the cancer experience may add to the understanding of partners' adaptation to cancer.
Moore and Stambrooke (1992)	Canada	To categorise coping strategies in male patients with brain injuries	Cluster analytic techniques	53 males with brain injuries	A cluster characterized by comparatively higher use of self-controlling and positive reappraisal coping strategies and lower external locus of control was associated with significantly lower mood disturbance and physical difficulties and a trend to be less depressed.
Moskowitz et al (1996)	USA	To examine the contextual effects of caregiving and bereavement on coping and the association between coping and positive and negative mood during the five months leading up to their partner's death and the five months following their partner's death in a cohort of human immunodeficiency virus positive (HIV+) and HIV negative (HIV-) caregiving partners of men with AIDS	Prospective study		Participants used more problem-focused types of coping and more cognitive escape avoidance during caregiving than during bereavement. Six of the eight types of coping that were assessed were associated with negative mood, controlling for prior negative mood. These associations differed as a function of context (caregiving versus bereavemenO. Five types of coping were associated with positive mood, controlling for prior positive mood. HIV serostatus did not affect the relation between coping and mood

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Ockhuijsen et al (2013)	The Netherlands	To understand how women with single or recurrent miscarriages cope during the waiting periods after miscarriage - waiting for pregnancy or waiting for pregnancy confirmation - and to investigate their perception of a 'positive reappraisal' coping intervention designed for these waiting periods	Qualitative study with focus groups	2 focus groups with 9 women in each	Coping interventions targeting reappraisal of the waiting period stressor situation could help women to cope as they wait for a subsequent pregnancy to be confirmed as ongoing. Coping interventions may need to be tailored, but before any strategy is introduced, further study is needed to identify the most appropriate approach.
Park and Folkman (1997)	USA	To elaborate the critical dimensions of meaning as it relates to stressful life events and conditions, (b) to extend the transactional model of stress and coping to include these dimensions, and (c) to provide a framework for understanding current research and directions for future research within this extended model.	NA	NA	A framework for understanding diverse conceptual and operational definitions of meaning by distinguishing 2 levels of meaning, termed global meaning and situational meaning is presnted. The authors then use this framework to review and synthesize the literature on the functions of meaning in the coping process and propose a definition of meaning making that highlights the critical role of reappraisal. The authors specify the roles of attributions throughout the coping process and discuss implications for future research.

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Santavirta et al (2001)	Finland	The aim of this study was (1) to determine the coping strategies employed by spouses of patients with acute myocardial infarction in the early phase of the crisis, (2) to define the role of age, gender, health perception, time since infarction, spouses' fears, and negative life events in the choice of coping strategies applied, and (3) to test the effect of coping strategies on physical and psychological strain.	Questionnaire study	57 spouses (47 female and 10 male)	The researchers found that age, negative life event during the last 12 months, time since infarction, and the spouse's fears influenced the choice of strategies. In the early stage of the crisis, positive reappraisal seems to be a strategy that increased physical strain. Spouses' need for social support in the early stage of the crisis is a factor for health care providers to bear in mind. Besides giving information, empathy, and understanding, health care personnel can try to assist spouses in their efforts to reappraise their situation
Skinner and Zimmer-Gembeck (2007)	USA	To integrate 44 studies reporting age differences or changes in coping from infancy through adolescence into a developmental framework of coping. .	Review	44 studies	The framework outlines a systems perspective in which, as regulatory subsystems are integrated, general mechanisms of coping accumulate developmentally, suggesting multiple directions for future research
Stone and Neale (1984)	USA	To develop a new measure of coping with daily problems was developed for use in longitudinal studies with repeated assessments.	Questionnaire study	120 married individuals	Development of a new measure of coping

Appendix C Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Tennen et al (2000)	USA	To link current theory, research and practice of coping and the value of daily monitoring	Review	NA	Review concluded that daily process research offers fresh opportunities to link psychological theory, research, and practice.
Subject - The PRCI					
Lancastle and Boivin (2008)	UK	To establish whether a novel brief coping intervention (positive reappraisal coping intervention, PRCI) card that encouraged women waiting for an IVF pregnancy test to redefine the waiting period more positively would be acceptable and practical in this context	55 women	Mixed method	PRCI was feasible in the IVF context and was perceived as an acceptable intervention to help minimize the strain of waiting for pregnancy test results during fertility treatment. Future research needs to evaluate the full benefits of PRCI against routine care during the waiting period.
Ockhuijsen et al (2013)	The Netherlands	To investigate the effects of a Positive Reappraisal Coping Intervention (PRCI) on psychological well-being of women waiting for the outcome of their fertility treatment cycle	372 women	3-armed RCT	Positive reappraisal is one of the few ways of coping that has been shown to be associated with increased wellbeing during unpredictable and uncontrollable situations like medical waiting periods. A simple evidence based self-help intervention, such as the PRCI, could facilitate coping during this common medical situation

Appendix C: Matrix to show details of hard copy articles retrieved after initial literature review

STUDY	COUNTRY	QUESTION/AIM	DESIGN AND DATA COLLECTION	SAMPLE	KEY FINDINGS
Ockhuijsen et al (2014)	The Netherlands	To investigate whether use of a positive reappraisal coping intervention (PRCI) alone following IVF embryo transfer influence anxiety, the depression and treatment outcome when compared with its use combined with monitoring emotions, monitoring emotions alone or no intervention?	110 women	Mixed method	Woman using the PRCI alone had significantly lower anxiety levels at Day 10 of the waiting period and 6 weeks after the start of the waiting period but also a significantly higher clinical pregnancy rate compared with the other three groups

Appendix D Positive Reappraisal Coping Intervention guidance leaflet

Coping with the 'waiting period' in your next pregnancy, following recurrent miscarriage

When you have experienced recurrent miscarriage and you become pregnant again, you may find yourself worrying that the same thing is going to happen again. The 'waiting period' between a positive pregnancy test and a scan confirming that the pregnancy is ongoing at about 12 weeks pregnant, can be a particularly stressful time. You may find that this intense focus on whether the pregnancy will continue makes you feel nervous and worried. Women often ask us for suggestions about how to deal with these intrusive and persistent thoughts. This leaflet describes a technique you can use to manage your worries during this waiting period.

The Positive Reappraisal Technique

All situations involve some good aspects and some bad aspects and the aspects we pay attention to often determines how good or bad we feel.

Thinking more about the positive aspects of a difficult situation and dwelling less on problems or uncertainties about the future helps people feel better. This is especially true during the challenges of the waiting period of a new pregnancy following recurrent miscarriage, when there is not much a person can do to influence the outcome of the pregnancy.

The positive reappraisal technique can help you manage your worries by encouraging you to think positively about the situation you are currently experiencing. In the context of recurrent miscarriage, the positive reappraisal technique involves actively thinking about any positive aspects to come out of your experience of recurrent miscarriage.

Thinking about the positive aspects of a difficult situation does not mean pretending that everything is wonderful when you do not feel it is, or thinking that you will definitely have a successful pregnancy when you feel unsure or ignoring all the negative aspects of a difficult situation. What it *does* mean is choosing to take account of good aspects alongside the more negative aspects of the situation. And reminding yourself that even very challenging situations have some positive elements. Taking the positive aspects into account will help you feel better during the waiting period of your new pregnancy.

The positive aspects of the waiting period will differ depending on your personal circumstances. Some people might focus on appreciating the support or kindness that friends or family have shown them during their miscarriages. Others might think about the ways in which their relationship with their partner is stronger now because of the shared experience. These are the

sorts of benefits that women going through recurrent miscarriage have shared with us in the past. You may be able to think of other examples that are personally important to you.

What do you consider to be some of the positive aspects of this situation?

To help people use the positive reappraisal technique we designed a card that contains ten different ways of thinking positively. The statements are general and do not refer to any one specific positive aspect because we know that different people will have different ideas about what is or isn't positive. This small card can be put in a purse or a pocket so you can remind yourself of the positive reappraisal techniques wherever and whenever you feel the need.

You should read the statements and think about how each statement applies to you personally. For example, what could you do to make yourself feel positive? What do you feel you have learnt from this experience? Think about the parts of your experience of recurrent miscarriages that have led to something positive or some benefit, or that help you to carry on even when the situation gets really difficult.

We suggest you read the card twice a day, once in the morning and once at night, and then any other time you feel the need.

As with any new way of thinking and behaving, it can take time for the positive reappraisal technique to become second nature. Thinking differently can feel strange and unnatural at first. However, practice will help so try and persevere. You should find the technique easier the more you practice it and you should then find that you are not dwelling so much on thoughts that worry and upset you.

Appendix E Patient Information Sheet for Main Study

Participant Information Sheet (Main Study)

Study Title

A Feasibility and Acceptability Study and a Qualitative Evaluation of a Coping Intervention for Women with Recurrent Miscarriage

Short Title: Feasibility of a Coping Intervention for Recurrent Miscarriage

Invitation Paragraph

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

We are investigating whether a simple self-help intervention can be used to help women who have previously had three or more miscarriages to cope with anxiety in early pregnancy and whether it would be useful to undertake a large scale study.

- Part 1 of this information sheet tells you the purpose of the study and what will happen to you if you take part.
- Part 2 of this information sheet gives you more detailed information on how the study will be conducted.

Part 1

What is the purpose of this study?

We have developed a simple intervention, the Positive Reappraisal Coping Intervention (PRCI), a sort of self-help card, to help women cope with difficult waiting periods. It was first used in fertility treatment to help women who might be feeling anxious during the period after fertility treatment when they are waiting to see if their treatment has been successful. The main aim of this research is to see whether this coping strategy might also be helpful for women who have suffered recurrent miscarriage. We understand that you may experience a similar period of anxiety during the early stages of any subsequent pregnancies following recurrent miscarriage, particularly during the waiting period between a positive pregnancy test and your routine scan at approximately 12 weeks gestation. We want to find out if you find the intervention acceptable and/or useful, and whether you think that the questionnaires we have chosen to assess any anxiety, you may or may not experience, are appropriate and easy to use. In the future, we would like to undertake a more detailed larger scale study, to see whether this coping strategy helps women cope with this difficult period.

The secondary aim of this study is to develop a deeper understanding of women's feelings and experiences during this 'waiting time,' throughout the early stages of a new pregnancy following recurrent miscarriage.

Why have I been invited to take part?

You have been invited to take part because you have a history of recurrent miscarriages.

Do I have to take part?

No. It is up to you to decide whether or not to take part. You can take as much time as you need to decide if you wish to take part in this research study and you will not be asked to agree to take part at your initial hospital appointment. 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 without giving a reason. A decision to withdraw at any time or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

The study will require your participation for up to approximately eight weeks from the time of a positive pregnancy test. You are still free to withdraw at any time. If you decide to take part in the study you will be asked to sign a consent form and to complete a background information form. Once you have done this, you don't need to do anything else until you become pregnant (and have a positive urine pregnancy test). Once this happens, we want you to let the research team know, by telephone, as soon as possible. You will probably be about 4 weeks pregnant (4 weeks from last menstrual period) at this time.

The research team will send you some short questionnaires via email (or paper copies through the post if this is easier for you) and you will be asked to complete these as soon as possible after your positive pregnancy test. The questionnaires will ask you about your feelings, day to day activities and any physical symptoms you may be experiencing. These should take no more than about 30 minutes. So that we can understand how your feelings change, you will be asked to repeat these questionnaires on a weekly basis up until you are approximately 12 weeks pregnant (the research team will explain when to do these) and to return them in the stamped addressed envelopes provided. We hope your pregnancy will progress well this time, but should you unfortunately experience another miscarriage we would like you to notify the research team.

This study is designed as a randomised controlled trial. This means that if you participate, you will be randomly allocated to either of two groups. If allocated to group 1, you will be asked to complete questionnaires on a weekly basis from a positive pregnancy test until 12 weeks of pregnancy, but in addition you will be asked to use the Positive Reappraisal Coping Intervention (a sort of self-help card) during this time period. If allocated to group 2, you will be asked to complete questionnaires on a weekly basis from a positive pregnancy test until 12 weeks of pregnancy. You will be allocated to these groups by a computer which has no other information about you, i.e. by chance. You will have a 50% chance of being in either group and you will be put into a group at the time of a positive pregnancy test.

We would also like to find out more about the feelings and anxieties women may experience during the early stages of a new pregnancy following recurrent miscarriage and so would like to interview a small number of women who agree to take part in this study once they have completed the use of the questionnaires and/or the self- help card. You will be given a separate information sheet about that part of the study.

What will I have to do?

If you decide to take part in the study you should carry on with life as normally as possible. There are no lifestyle restrictions if you choose to participate. You will, however, be asked to notify the research team when you have a positive pregnancy test, to complete questionnaires on a weekly basis (the research team will explain when to do these), and to use the coping intervention daily from the day you have a positive pregnancy test until 12 weeks of continuing pregnancy, if you are assigned to that treatment group.

What is the intervention being tested?

The coping intervention being tested is called the Positive Reappraisal Coping Intervention (the PRCI). 'Positive reappraisal' is a coping intervention which involves taking into account the good aspects of a situation, alongside the more negative aspects. It does not mean pretending that everything is wonderful when you do not feel it is or mean ignoring all the negative aspects of a situation. What it does mean is that even in the most difficult and challenging situations, there are some positive elements. Positive aspects will differ depending on your personal experiences but examples of this might be recognising that relationships have become closer as a result of the

situation or appreciating the kindness shown by someone to you when you have been upset or worried.

The PRCI consists of a small card listing 10 statements which aim to encourage a positive reappraisal of the situation. It was originally developed to be used in fertility treatment to help women cope with any anxiety they might feel during the time period between their treatment and a pregnancy test or scan to confirm if this had been successful. Because women who have experienced recurrent miscarriage may go through a similar waiting period of anxiety during the early stages of a subsequent, new pregnancy, it is hoped that the PRCI may be a useful coping intervention to help women cope with any anxiety they may be feeling at this time.

What are the possible disadvantages of taking part?

It is unlikely that there are any disadvantages to you from taking part in this study, although there is a possibility that completing the questionnaires could trigger thoughts or feelings which could be distressing to you. However a previous study has showed that women who had suffered from recurrent miscarriage did not report any negative experiences from using the PRCI.

If you experience any upset or want to talk more about your miscarriages, we would suggest that you contact your GP, the clinical team caring for you at the hospital or the Miscarriage Association, the national UK support group for those affected by miscarriages on 01924 200799 or http://www.miscarriageassociation.org.uk/

What are the possible advantages of taking part?

We cannot promise that the study will help you personally, but the information we get from the study may help women who are experiencing recurrent miscarriage in the future.

What if there is a problem?

Any complaint about the way you have been dealt with in the study or any possible harm you might suffer will be addressed. The detailed information on this is given in
Part 2 of this information sheet.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1 of the information sheet.
If the information in Part 1 has interested you and you are considering participating, please read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available?

Sometimes we get new information about the subject being studied. If this happens, we will tell you and discuss whether you should continue in the study. If you decide not to carry on, we will make arrangements for your care to continue. If you decide to continue in the study we may ask you to sign an agreement outlining the discussion.

What will happen if I do not want to carry on with the study?

If you decide to take part and then change your mind you are free to withdraw at any time without giving a reason and your treatment will not be affected in any way.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions (their names and contact details can be found on the front of this information sheet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital (……..) or you can contact the Patient Advice Liaison Service (PALS) on ……..

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the course of this study will be kept strictly confidential and any information that is used outside the hospital will have your name and address removed so you cannot be recognised. Occasionally study data maybe looked at by authorised people to check that the study is being carried out correctly, but apart from this only the research team will have access to your data.

Involvement of your General Practitioner

If you agree we will inform your General Practitioner of your participation in the study.

What will happen to the results of the research study?

Once the study has finished the results will be reviewed and the results will be published in a medical journal and maybe presented and discussed at national/international meetings. You will not be identified in any publication as a result of this study.

Who is organising and funding the research?

This study is being organised by the …… This PhD research study has been funded by the National Institute of Health Research (via the Department of Health) and is being conducted in the …..Hospital and the ……..Hospital.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Hampshire B (south Central) Ethics Committee.

Contact for further information

If you have any questions or require any further information about the study, please feel free to contact the Chief Investigator (…….).

If you decide to take part in the study you will be given a copy of the information sheet and the signed consent form to keep.

Thank you for taking the time to read this sheet and for considering to take part in this study.

Appendix F Consent Form for Main Feasibility Study (Version 1)

INFORMED CONSENT FORM

Study Title: A Feasibility and Acceptability Study and a Qualitative Evaluation of a Coping Intervention for Women with Recurrent Miscarriage

Short title: Feasibility of a Coping Intervention for Recurrent Miscarriage

Principal Investigator: Sarah Bailey

REC approval number:

Participant ID:

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet (Version ..... dated DD/MM/YYYY) for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my medical care or legal rights being affected. ☐
3. I agree to take part in this study which will require me to use the Positive Reappraisal Coping Intervention (if I am assigned to that group) and to complete the study questionnaires as requested. ☐
4. I understand that my medical notes will be looked at by members of the research team, and by regulatory bodies auditing research practice. ☐
5. I agree to my GP being informed of my participation in the study ☐
6. I give consent for the research team to contact me when I have finished using the intervention/ questionnaires to enquire whether I would be willing to take part in a face to face interview ☐
7. I voluntarily agree to take part in this study ☐

.....	.....	.....
NAME OF PATIENT	DATE	SIGNATURE

.....	.....	.....
INVESTIGATOR	DATE	SIGNATURE

.....	.....	.....
NAME OF WITNESS	DATE	SIGNATURE

(if applicable)

You will be given a copy of the Patient Information Sheet and a copy of the signed Informed Consent Form to keep for your records.

Appendix G Consent Form for Main Feasibility study (Version 2)

INFORMED CONSENT FORM

Study Title: A Feasibility and Acceptability Study and a Qualitative Evaluation of a Coping Intervention for Women with Recurrent Miscarriage

Short title: Feasibility of a Coping Intervention for Recurrent Miscarriage

Principal Investigator: Sarah Bailey

REC approval number:

Participant ID:

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet (Version ..... dated DD/MM/YYYY) for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my medical care or legal rights being affected. ☐
3. I agree to take part in this study which will require me to use the Positive Reappraisal Coping Intervention (if I am assigned to that group) and to complete the study questionnaires as requested. ☐
4. I understand that participation in the study will not give me access to further additional care over and above what is routinely offered, and specifically that the researcher Sarah Bailey will not be able to provide additional clinical advice or support. Should clinical advice be required, I will be directed to contact my GP or a member of my current health care team. ☐
5. I understand that my medical notes will be looked at by members of the research team, and by regulatory bodies auditing research practice. ☐
6. I agree to my GP being informed of my participation in the study ☐
7. I give consent for the research team to contact me when I have finished using the intervention/ questionnaires to enquire whether I would be willing to take part in a face to face interview ☐
8. I voluntarily agree to take part in this study ☐

.....	.....	.....
NAME OF PATIENT	DATE	SIGNATURE

.....	.....	.....
INVESTIGATOR	DATE	SIGNATURE

.....	.....	.....
NAME OF WITNESS	DATE	SIGNATURE

(if applicable)

You will be given a copy of the Patient Information Sheet and a copy of the signed Informed Consent Form to keep for your records.

Appendix H Patient Information Sheet for Interview

Participant Information Sheet (Interview)

Study Title

A Feasibility and Acceptability Study and a Qualitative Evaluation of a Coping Intervention for Women with Recurrent Miscarriage

Short Title: Feasibility of a Coping Intervention for Recurrent Miscarriage

Invitation Paragraph

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

We are investigating whether a simple self-help intervention can be used to help women who have previously had three or more miscarriages to cope with anxiety in early pregnancy and whether it would be useful to undertake a large scale study. We also want to develop a deeper understanding of women's feelings and experiences during this 'waiting time,' throughout the early stages of a new pregnancy following recurrent miscarriage.

- Part 1 of this information sheet tells you the purpose of the study and what will happen to you if you take part.
- Part 2 of this information sheet gives you more detailed information on how the study will be conducted.

Part 1

What is the purpose of this study?

We have developed a simple intervention, the Positive Reappraisal Coping Intervention, a sort of self-help card, to help women cope with difficult waiting periods. It was first used in fertility treatment to help women who might be feeling anxious during the period after fertility treatment when they are waiting to see if it has been successful. The main aim of this research is to see whether this coping strategy might also be helpful for women who have suffered recurrent miscarriage. We understand that you may experience a similar period of anxiety during the early stages of any subsequent pregnancies following recurrent miscarriage, particularly during the waiting period between a positive pregnancy test and your scan. We want to find out if you find the intervention acceptable and useful and whether you think that the questionnaires we have chosen to assess any anxiety you may experience are appropriate. In the future, we would like to undertake a more detailed larger scale study, to see whether this coping strategy helps women cope with this difficult period.

The secondary aim of this study is to develop a deeper understanding of women's feelings and experiences during this 'waiting time,' throughout the early stages of a new pregnancy following recurrent miscarriage.

Why have I been invited to take part?

You have been invited to take part because you have a history of recurrent miscarriages and because you have already volunteered to take part in another part of this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. 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 without giving a reason. A decision to withdraw at any time or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

This part of the study will require you to participate in a face to face interview with the researcher. The interview will take place at a time and place convenient to you and is likely to last approximately 1 hour. Before the interview the researcher will explain the study and give you an opportunity to ask questions, you would then be asked to sign a consent form agreeing to take part in the study.

During an earlier phase of the study some of you may have used the coping intervention and completed questionnaires or may have just completed the questionnaires. During the interview we will ask you about how you found using the questionnaires and the coping intervention (if you used it). We also want to find out from women, who have suffered recurrent miscarriage, how they experience the 'waiting period' of a new pregnancy, what your thoughts and feelings are during this time, so you will also be asked about that.

We will ask your permission to audio tape the interview as we want to ensure an accurate record of the views and experiences you share. After the interview the audiotape would be listened to by the researchers and the information on it written on to a computer.

What will I have to do?

If you decide to take part in the study you should carry on life as normally as possible. There are no lifestyle restrictions if you choose to participate. Once you have finished using the questionnaires / Positive Reappraisal Coping Intervention, you will be contacted, by telephone, to ask if you are willing to take part in an interview within two weeks (by approximately 14 weeks of pregnancy). If

you are willing to take part then an interview will be arranged at a date, time and location convenient to you.

We hope your pregnancy will progress well this time, but should you unfortunately experience another miscarriage, we may still like to contact you to see if you would be willing to take part in an interview, as hearing about your thoughts and experiences will be very important and valuable to us. However, taking part in this study is completely voluntary and you are able to decline taking part in the interview part of the study at any point.

What are the possible disadvantages of taking part?

It is unlikely that there are any disadvantages to you from taking part in this study, although there is a possibility that during the interview memories and thoughts could be triggered which could be distressing to you. Should this occur, the interview will be stopped and either concluded or, if you prefer, resumed at a later date.

If you experience any upset or want to talk more about your miscarriages, we would suggest that you contact your GP, the clinical team caring for you at the hospital or the Miscarriage Association, the national UK support group for those affected by miscarriages on 01924 200799 or http://www.miscarriageassociation.org.uk/

What are the possible advantages of taking part?

We cannot promise that the study will help you personally, but the information we get from the study may help women who are experiencing recurrent miscarriage in the future.

What if there is a problem?

Any complaint about the way you have been dealt with in the study or any possible harm you might suffer will be addressed. The detailed information on this is given in

Part 2 of this information sheet.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1 of the information sheet.

If the information in Part 1 has interested you and you are considering participating, please read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available?

Sometimes we get new information about the subject being studied. If this happens, we will tell you and discuss whether you should continue in the study. If you decide not to carry on, we will make arrangements for your care to continue. If you decide to continue in the study we may ask you to sign an agreement outlining the discussion.

What will happen if I do not want to carry on with the study?

If you decide to take part and then change your mind you are free to withdraw at any time without giving a reason and your treatment will not be affected in any way.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions (their names and contact details can be found on the front of this information sheet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital (*******) or you can contact the Patient Advice Liaison Service (PALS) on *******.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the course of this study will be kept strictly confidential and any information that is used outside the hospital will have your name and address removed so you cannot be recognised. The audio recordings will be saved securely on a password protected computer, no identifying information will be stored with it.

Occasionally study data maybe looked at by authorised people to check that the study is being carried out correctly, but apart from this only the research team will have access to your data.

Involvement of your General Practitioner

If you agree we will inform your General Practitioner of your participation in the study.

What will happen to the results of the research study?

Once the study has finished the results will be reviewed and the results will be published in a medical journal and maybe presented and discussed at national/international meetings. You will not be identified in any publication as a result of this study.

Who is organising and funding the research?

This study is being organised by the ****** University Hospital and the University of ******. This PhD research study has been funded by the National Institute of Health Research (via the Department of Health) and is being conducted in the ****** Hospital and the ****** Hospital.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by ****** Ethics Committee.

Contact for further information

If you have any questions or require any further information about the study, please feel free to contact the Chief Investigator (Sarah Bailey ******).

If you decide to take part in the study you will be given a copy of the information sheet and the signed consent form to keep.

Thank you for taking the time to read this sheet and for considering to take part in this study.

Appendix I Consent Form for Interview

INFORMED CONSENT FORM (Interview)

Study Title: A Feasibility and Acceptability Study and a Qualitative Evaluation of a Coping Intervention for Women with Recurrent Miscarriage

Short title: Feasibility of a Coping Intervention for Recurrent Miscarriage

Principal Investigator: Sarah Bailey

REC approval number:

Participant ID:

PLEASE INITIAL THE BOXES IF YOU AGREE WITH EACH SECTION:

1. I have read the information sheet (Version ..... dated DD/MM/YYYY) for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my medical care or legal rights being affected. ☐
3. I agree to take part in this study which will require me to take part in a face to face interview with the researcher at a time and place convenient to me. ☐
4. I agree to the audio-recording of the interview ☐
5. I agree to written extracts of the interview being used for conference presentations and/or publications following the removal of any identifying characteristics ☐
6. I understand that my medical notes will be looked at by members of the research team, and by regulatory bodies auditing research practice. ☐
7. I agree to my GP being informed of my participation in the study ☐
8. I voluntarily agree to take part in this study ☐

.....	.....	.....
NAME OF PATIENT	DATE	SIGNATURE
.....	.....	.....
INVESTIGATOR	DATE	SIGNATURE
.....	.....	.....
NAME OF WITNESS (if applicable)	DATE	SIGNATURE

You will be given a copy of the Patient Information Sheet and a copy of the signed Informed Consent Form to keep for your records.

Appendix J Pre-Intervention Questionnaire

A Feasibility Study of a Randomised controlled Trial of a Coping intervention for Women with Recurrent Miscarriage

PRE INTERVENTION ASSESSMENT

Study Identification number:

A. Background information:

1. How old are you? .....

2. What type of work do you do? .....

3. What is your highest educational qualification?
*Please tick **one** box*

No qualification ☐

GCSE or O level ☐

A level or similar ☐

Higher education or similar ☐

Other, please specify .....

4. How would you describe your ethnic group?
*Please tick **one** box*

White	☐	Pakistani	☐
Black – Caribbean	☐	Bangladeshi	☐
Black – African	☐	Chinese	☐
Black – Other	☐	Other	☐
Indian	☐		

5. What is your relationship status?

Married	☐	Single	☐	Cohabiting	☐
Partner, not living together	☐	Civil partnership	☐	Widowed	☐
Divorced	☐	Separated	☐	Other	☐

6. (a) Have you and your partner had any children together? (Including adopted children) *Please circle the appropriate answer* Yes / No

If yes: How many? _____

(b) Do you have any children from a previous relationship? *Please circle the appropriate answer* Yes / No

If yes: How many? _____

(c) Does your partner have any children from a previous relationship? *Please circle the appropriate answer* Yes / No

If yes: How many? _____

B. Medical History:

6. Do you have any medical problems? (E.g., diabetes, high blood pressure, asthma). Do these cause physical symptoms? What sort of symptoms do you experience?

_____
_____
_____
_____
_____

8. Do you have any current mental health problems, or have you experienced any mental health problems in the past? (e.g., depression, anxiety). *Please give details below.*

_____
_____
_____
_____
_____

9. Are you currently receiving any psychological treatment (e.g., counselling) or medication (e.g., anti-depressants) to help you with these mental health difficulties? *Please give details below.*

_____
_____
_____
_____
_____

7. Have you ever seen a counsellor or psychologist for a problem related to recurrent miscarriages? *Please circle the appropriate answer* Yes / No

B. Recurrent miscarriage history:

1. How long have you been trying to have a baby with your partner? .....

2. Have any medical tests you have had given a reason for your miscarriages? If yes, please give details below.

---

3. How many miscarriages have you had? .....

4. Overall, how well do you feel you have been coping with the strains of recurrent miscarriage?

Please circle the appropriate number

(*not very well*) 1 2 3 4 5 (*very well*)

3. What do you personally think your chances are of having a successful pregnancy?

Please circle the appropriate number or write it here .....

(not at all) 0 10 20 30 40 50 60 70 80 90 100% *(excellent)*

4. How much control do you think/feel you have over the outcome of your pregnancy?

Please circle the appropriate number or write it here .....

(No control) 0 10 20 30 40 50 60 70 80 90 100% *(Complete control)*

Appendix K Hospital Anxiety Depression Scale

Patient ID -

Date of completing questionnaire-

Hospital Anxiety and Depression Scale (HADS)

Please read every sentence and place an 'X' on the answer that best describes how you have been feeling in the last week. You do not have to think too much to answer. In this questionnaire spontaneous answers are more important.

1	**I feel tense or 'wound up':**	
	Most of the time	
	A lot of the time	
	From time to time, occasionally	
	Not at all	

2	**I still enjoy the things I used to enjoy:**	
	Definitely as much	
	Not quite so much	
	Only a little	
	Hardly at all	

3	**I get a sort of frightened feeling as if something awful is going to happen:**	
	Very definitely and quite badly	
	Yes, but not too badly	
	A little, but it doesn't worry me	
	Not at all	

4	**I can laugh and see the funny side of things:**	
	As much as I always could	
	Not quite so much now	
	Definitely not so much now	
	Not at all	

5	**Worrying thought go through my mind:**	
	A great deal of the time	
	A lot of the time	
	From time to time, but not too often	
	Only occasionally	

6	**I feel cheerful:**	
	Not at all	
	Not often	
	Sometimes	
	Most of the time	

7	**I can sit at ease and feel relaxed:**	
	Definitely	
	Usually	
	Not often	
	Not at all	

8	**I feel as if I am slowed down:**	
	Nearly all the time	
	Very often	
	Sometimes	
	Not at all	

9	**I get a sort of frightened feeling like 'butterflies' in the stomach:**	
	Not at all	
	Occasionally	

	Quite often	
	Very often	

10	**I have lost interest in my appearance:**	
	Definitely	
	I don't take as much care as I should	
	I may not take quite as much care	
	I take just as much care as ever	

11	**I feel restless as I have to be on the move:**	
	Very much indeed	
	Quite a lot	
	Not very much	
	Not at all	

12	**I look forward with enjoyment to things:**	
	As much as I ever did	
	Rather less than I used to	
	Definitely less than I used to	
	Hardy at all	

13	**I get sudden feelings of panic:**	
	Very often indeed	
	Quite often	
	Not very often	
	Not at all	

14	**I can enjoy a good book or radio or TV programme:**	
	Often	
	Sometimes	
	Not often	

Appendix K: Hospital Anxiety Depression Scale

	Very seldom	

Reference: Zigmond and Snaith (1983)

Appendix L WRK (Version 1)

Weekly Record Keeping Chart – Group 1
Part 1
(Please see instructions for completing this chart overleaf)

Study ID ……

Date……

Method of scoring

Part 2 and 3

☐ None: Leave the box free if you have not felt this emotion or symptom

1 Mild: if you have experienced the emotion or symptom but it has not affected your daily activities

2 Moderate: if you have experienced the emotion or symptom but it has on only had a moderate effect on your daily activities activites

3 Serious: if the emotion or symptom has clearly interfered with you carrying out your daily tasks

Part 4

☐ None: leave this box free if this description does not describe how you have reacted to the situation

1 Rarely: if you have rarely thought in this way in reaction to the situation.

2 Sometimes: if you occasionally have thought this way in reaction to the situation

3 Frequently: if you have regularly thought this way in reaction to the situation.

Date	
Part 2	
Nervous	
Positive	
Relieved	
Sad	
Hopeful	
Trusting	
Disappointed	
Happy	
Discouraged	
Worried	
Unsure	
Satisfied	
Anxious	
Reluctant	
Fulfilled	
Doubtful	
Insecure	
Encouraged	
Angry	
Uneasy	
Optimistic about pregnancy	
Pessimistic about pregnancy	
Part 3	
Sensitive breasts	
Pain or tightness in the breasts	
Menstrual cramps	
Shortness of breath	
Muscle tension	
Perspiring	
Nausea	
Stomach pain	
Tiredness	
Cold hand or feet	
Palpitations	

Part 4	
I made an action plan and followed it	
I realised that there is nothing I can do about the situation	
I have done something aimed to help me relax	
I wished that this situation would disappear or end	
I expressed my emotions	
I tried to make the most of the situation	

Please indicate in the box below if you have had a scan to assess your pregnancy in the last week and if so what the outcome was.

Date of scan: Results of scan:

How often you have used the Positive Reappraisal Coping Intervention Card during the last week? (Please indicate by circling the appropriate answer in the box below)

Twice a day More than twice a day Less than twice a day

Instructions for completing the chart.

You are asked to complete this form on a weekly basis. Please try to complete it on the same day each week at the same time. The research team will advise you when to do this.

Part 1:

Complete the date.

Part 2 and 3:

Lists of different emotional (part 2) and physical symptoms (part 3) which you may experience during the early part of your pregnancy are outlined in the largest table. Please complete this form on a weekly basis as requested by the research team. Each time you complete the form you should give a score which reflects to what extent you feel that emotion or physical symptom. Please try to do this at the same time of day; before you go to sleep, and consider to what extent you have felt each symptom the past 24 hours.

Part 4:

A list of different ways of reacting or coping with the waiting period of your pregnancy are described in this section. When you complete the form you should give a score which reflects to what extent you have dealt with the situation in the ways described in this table.

Appendix M WRK (Version 2)

Weekly Record Keeping Chart – Group 1

STUDY ID -

RATING SCALE

Parts 2 and 3

☐ Not at all: leave the box blank if you have not experienced this symptom this week

1 Mild: if you have experienced the symptom this week, but it hasn't interfered with your daily activities

2 Moderate: If you have experienced the symptom this week and it has interfered to some degree with daily activities

3 Severe: if this symptom has had a markedly negative effect on how well you have performed your daily tasks during the last week

Part 4 and 5 (see over page)

☐ None: leave this box free if this description does not describe how you have reacted to the situation during the last week

1 Rarely: if you have rarely thought in this way in reaction to the situation during the last week

2 Sometimes: if you occasionally have thought this way in reaction to a situation during the last week

3 Frequently: if you have regularly thought this way in reaction to the situation during the last week.

NB further instructions to help you complete the form can be found overleaf

PART 1	
Date	
PART 2: EMOTIONAL SYMPTOMS	
Nervous	
Positive	
Relieved	
Sad	
Hopeful	
Confident	
Disappointed	
Happy	
Discouraged	
Anxious	
Unsure	
Content	
Tense	
Hesitant	
Fulfilled	
Doubtful	
Uncertain	
Encouraged	
Angry	
Worried	
Optimistic: pregnancy	
Pessimistic: pregnancy	
PART 3: PHYSICAL SYMPTOMS	
Breast tenderness	
Chest pain / tightness	
Menstrual cramps	
Shortness of breath	
Muscle tension	
Sweatiness	
Nausea	
Stomach pain	
Fatigue / tiredness	
Cold hands / feet	
Racing heart	
Spotting	

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PART 4: WAYS OF COPING WITH WAITING FOR MY TWELVE WEEK SCAN	
I turned my attention away from the problem by thinking about other things or doing some activity	
I made a plan of action and followed it	
I accepted there was nothing I could do	
I did something with the implicit intention of relaxing	
I wished the situation would go away or somehow be over with	
I expressed my emotions	
I tried to make the most of the situation	
PART 5: WAYS OF THINKING ABOUT WAITING FOR MY TWELVE WEEK SCAN	
I perceive that waiting for the scan is stressful	
I can control what happens during this waiting period	
The waiting period could have a negative impact on me	
I have what it takes to cope	
Waiting for the twelve week scan could have a positive effect on me	
PART 6: USE OF THE POSITIVE REAPPRAISAL COPING INTERVENTION (PRCI)	
How often have you used the PRCI coping card during the last week? Please state number of times	
PART 7: SCANS	
Please indicate if you have had a scan in the last week to assess your pregnancy	YES
	NO
If you had a scan please indicate in the box below what the outcome was.	

INSTRUCTIONS TO HELP YOU COMPLETE THE FORM

You are asked to complete this form on a weekly basis. Please try to complete it on the same day each week, at the same time.

PART 1: State the date when you completed the form

PART 2 and 3: The different emotional (part 2) and physical (part 3) symptoms you may experience during the first few weeks of your pregnancy when you are waiting to have your pregnancy confirmed (i.e., the twelve week scan) are listed. On a weekly basis, you should rate the extent to which you experienced each one of these physical and emotional symptoms, averaging over the last 7 days.

PART 4 and 5: These sections list the different ways of coping with and thinking about the first few weeks when you are waiting to have your pregnancy confirmed. On a weekly basis, you should rate the extent to which you have used the strategies listed (Part 4) to cope with waiting for the twelve week scan or thought about (Part 5) the twelve week scan in this way.

PART 6: Please indicate how often you have used the PRCI during the last week.

PART 7: Please indicate if you have had a scan to assess your pregnancy during the last week.

Appendix N Topic Guide

Project Title: A Feasibility and Acceptability Study and a Qualitative Process Evaluation of a Coping Intervention for Women with Recurrent Miscarriage

Topic Guide

The aim of this topic guide is to provide a loose structure and a guide of sample questions which may be asked to steer the discussion and promote the exploration of the participant's personal experiences of being part of this study and their reflections on feelings and experiences during the early 'waiting period' of their pregnancy. These are sample questions, and can be modified or expanded according to the particular concerns of the participant. As such, whilst it is envisaged that this topic guide forms the basis of the interview promoting the systematic and uniform exploration of relevant issues (Arthur and Nazroo 2003), care will be taken to be sensitive to the concerns of the participant enabling and encouraging them to explore what is significant to them.

Objectives:

- To explore how acceptable the research participants found the recruitment, randomisation, intervention and follow-up methods for the study.
- To explore how appropriate and usable the research participants found the study questionnaires and data collection methods.
- To explore whether research participants found the study time points for completion of questionnaires and use of Positive Reappraisal Coping Intervention (PRCI) card appropriate.
- To gather reflections on any preliminary effect of the PRCI card.
- To develop an understanding of the experiences, feelings and needs of women who have experienced recurrent miscarriages during the early stages of any subsequent pregnancy.

Introduction:

- Introduce myself, summarise the study and thank participants for taking part.
- Ascertain participant is comfortable to begin the interview
- Remind participant that their confidentiality will be maintained
- Remind participant that they are able to discontinue the interview at any time.

Topics and Sample Questions

Present Circumstances:

- How have things been over the last few weeks?

Invitation to take part in and recruitment to the study:

- Did this take place in an acceptable and informative way?
- Did you understand the purpose of the study?

Randomisation:

- How soon after a positive pregnancy test did you contact the researcher to let her know?
- Was it easy to contact her?
- Would you have preferred to have contacted her by telephone, text or email?

Study questionnaires:

Completing questionnaires

- How easy and convenient (or difficult) was it to complete the questionnaires?
- Did you understand them and what they were asking you to do?

- What do you feel about the frequency you were asked to complete the questionnaires? (i.e. once a week)
- Did you find completing the questionnaires upsetting or insensitive in anyway?
- Were the questionnaires helpful (or unhelpful) in anyway?

Return of questionnaires

- How easy and convenient was it to return the questionnaires monthly in the pre-paid envelope?
- Would you have preferred to use other methods of completing the questionnaires e.g email / online survey / text?

The PRCI:

Frequency of use

- How often did you use the PRCI card?
- When did you use the PRCI card?
- Did you use it the same time every day?
- Did you carry the card with you?

Ease / difficulty of use

- How easy or difficult did you find using the PRCI card? In what way?
- Did it become easier or more difficult to use over time?

Positive Reappraisal

- Were there any aspects of the PRCI that you found helpful (or unhelpful) in anyway?
- Do you think you might continue to use positive reappraisal to help you in other ways during your life?
- Would you recommend the use of the PRCI card to other women in your situation?
- How would you sum up your experience of using the PRCI card?

Experiences / feelings during waiting period of the pregnancy:

Feelings and personal reflections

- What were your feelings during the waiting period?
- How would you describe a 'good' day? How would you describe a 'difficult' day?
- What kind of things did you do if you felt anxious or worried?
- Was there anything that helped you during this time?
- Was there anything that made things worse during this time?
- Do you think there was anything which would have made a difference to how you were feeling?

Family and friends

- I'd like to ask you about your family and friends…
- How do you think they were feeling during this time?
- Were your family and friends able to support you in anyway? Can you give some examples of how they did this?
- How easy was it for them to understand how you were feeling during this time?

Closing the interview:

- Are there any other issues you wish to talk over which haven't been discussed today?
- Thank the participant for taking part.
- Confirm that the participant has contact details in case of any further queries.

References

Arthur, S., Nazroo, J., 2003. Designing fieldwork strategies and materials In: Ritchie, J., Lewis J (eds) *Qualitative Research Practice: A Guide for Social Science Students and Researchers*, Sage: London

Appendix O Study protocol article published British Medical Journal (open)

Open Access Protocol

BMJ Open

A feasibility study for a randomised controlled trial of the Positive Reappraisal Coping Intervention, a novel supportive technique for recurrent miscarriage

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ABSTRACT

Introduction: Recurrent miscarriage (RM) is diagnosed when a woman has had three or more miscarriages. Increased levels of distress and anxiety are common during the waiting period of any subsequent pregnancies, posing a significant threat to psychological well-being. However, only limited support and therapy are available for these women, and many are left to cope alone. The Positive Reappraisal Coping Intervention (PRCI) is a novel self-administered supportive technique which has been shown to be effective in patients awaiting the outcome of in vitro fertilisation treatment. The primary objective of this study is to assess the feasibility and effectiveness of the PRCI in improving quality of life in the difficult waiting period which women with previous RM endure before an ongoing pregnancy can be confirmed.

Methods and analysis: A randomised controlled trial (RCT) feasibility study will establish the viability of conducting a multicentre RCT to definitively test the effects of the PRCI on the psychological well-being of women who have experienced RM during the initial waiting period of a subsequent pregnancy. A second component consists of a qualitative process evaluation exploring the initial experience of pregnancy following repeated miscarriages. Participants (n=50) will be randomised into one of two groups. The PRCI intervention group will receive the PRCI card and weekly questionnaires to assess their psychological well-being during the waiting period of their new pregnancy. The non-intervention group will be asked to complete the same weekly questionnaires. The qualitative process analysis will employ semistructured interviews (n=20) to address relevant aspects of the study objectives.

Ethics and dissemination: Ethics approval has been obtained from the National Research Ethics Service Committee South Central—Hampshire A. Participating centres have given National Health Service R&D approval. Study findings will be disseminated through peer reviewed journals, national and international conferences and lay user groups.

Trial registration number: ISRCTN43571276. This study was registered with the ISRCTN 18/02/2014 following adoption onto the United Kingdom Clinical Research Network (UKCRN) portfolio. Recruitment of the first participant occurred 04/02/2014.

Strengths and limitations of this study

- This study will test a validated tool in a randomised controlled trial providing essential feasibility information to inform a definitive fully powered study.
- Addresses a novel area of research not previously investigated.
- This mixed-method study uses participant qualitative interviews to supplement feasibility data providing additional insight into how women experience the waiting period of a new pregnancy following recurrent miscarriage.
- Feasibility study not powered for a definitive study.

BACKGROUND

Miscarriage is the most common adverse outcome of pregnancy[1] and recurrent miscarriage (RM), defined as the loss of three or more consecutive pregnancies,[2] affects approximately 1% of women. RM is a distressing and traumatic condition, representing more than a loss of a pregnancy; it evokes feelings surrounding a lost baby, a lost future child and a lost motherhood.[3] Feelings of grief and depression are common[4–6] and previous studies have suggested that single and RM can cause the affected woman a 'significant physical and psychological challenge'[7] posing a considerable threat to psychological well-being.[8] Despite these potential grieving responses, women who experience miscarriage tend not to receive the same level of

psychosocial support afforded to people experiencing other types of bereavement.[1]

Studies investigating emotional morbidity in women in the time period following miscarriage[9–11] have indicated that increased levels of anxiety and depression are often experienced by women with a history of reproductive loss during subsequent pregnancies.[4 8] However, research data pertaining to the psychological morbidity associated with the difficult period in a subsequent pregnancy as the woman waits to see whether the pregnancy will again end in miscarriage or not, is scarce. The experience of RM frequently results in a period of 'marked stress reaction'[12] when the woman becomes pregnant again, specifically during the 'waiting period' between a positive pregnancy test and confirmation that the pregnancy is ongoing. Indeed, some women will elect not to conceive at all rather than repeatedly face this period of troubling uncertainty.

The medical waiting period

Waiting periods have been defined as the period of time in which patients are waiting for medical test results which could be potentially threatening to their well-being.[13] The medical waiting period can be a psychologically stressful time[14] and Osuna[15] proposes that during the waiting period a psychological reaction can occur whereby anticipation of loss leads to anxiety and potential psychological distress. The medical waiting period has been studied among a range of patient groups including women waiting for genetic information,[16] women waiting for a breast cancer diagnosis,[17] patients waiting for gastrointestinal endoscopy investigations,[18] and the waiting period during fertility treatment between embryo transfer (in vitro fertilisation, IVF) and pregnancy test.[19] A further study by Boivin and Lancastle[13] has shown that medical waiting periods have a distinct emotional signature.

The waiting period of a new pregnancy

In the context of a pregnancy after RM, the waiting period refers to the first 12 weeks of a pregnancy when women wait for ultrasound confirmation that their pregnancy is ongoing. This can be a particularly stressful and anxious time as the worry for the affected woman and her partner often increases substantially. Any excitement brought about by a positive pregnancy test is often overshadowed by the fear and despair that they will suffer yet another miscarriage. Once the woman has reached 12 weeks of pregnancy and an ultrasound scan has confirmed this, the chance of progression to term is around 95% and this reassurance is likely to make her feel more confident in her continuing pregnancy, and will experience less anxiety and distress.

There is a small but growing body of research concerning the waiting period experienced by women who have suffered RM. Recent evidence from a qualitative focus group study,[3] for example, provides insight into the coping styles and experiences of women who have suffered miscarriages, focusing on the initial waiting period (eg, weeks 1–12) of a subsequent pregnancy. Differences were found in the way women with one miscarriage and women with RMs appraised and assessed the waiting period, but the coping strategies utilised in both groups were similar. These were most commonly emotion focused, and included avoidance, the seeking of social support, distraction and the utilisation of positive appraisal.

Positive reappraisal and the positive reappraisal coping intervention

Positive reappraisal coping is an active strategy[20 21] which aims to reduce the emotional morbidity of a stressful period by focusing on the positive aspects of a situation. Positive reappraisal means choosing to take account of good aspects alongside the negative aspects of a situation, appreciating that even the most challenging difficult situations will have some positive elements.[19]

Previous studies have identified that positive reappraisal has been successful at reducing stress levels for many patient populations including those suffering from breast cancer,[22] myocardial infarction[23] and brain injury,[24] and in caregivers whose partners were terminally ill with AIDS.[25] In recent years, a theoretically derived, short, coping, intervention based on the concept of positive reappraisal has been developed, initially for use during the time period in which women wait for the results of their pregnancy test following fertility treatment.[19] This intervention, called the Positive Reappraisal Coping Intervention (PRCI) was designed to stimulate positive reappraisal coping during the waiting period between IVF and a pregnancy test and aimed to encourage the consideration of positive aspects of the situation and its meaning for the patient. The study[19] concluded that the women favourably evaluated the PRCI and found it acceptable and beneficial in terms of supporting positive feelings during the IVF waiting period, and sustaining their efforts to cope.

One of the key advantages of the PRCI approach is that it is convenient for patients and is easily deliverable at negligible cost. It comprises of an explanatory leaflet describing positive reappraisal coping and its potential benefits as well as 10 statements printed on a laminated card that users read at least twice a day to stimulate the use of this form of coping. Since use of the PRCI does not require clinic or hospital attendance or the direct involvement of a carer or health professional, it is very low in cost. Lancastle and Boivin[19] demonstrated that despite the fact that the women had minimal contact with clinical or research staff during the waiting period, the intervention was still positively evaluated.

For women who have experienced RM, the waiting period in the early stages of pregnancy shares many characteristics and stress factors with the waiting period after fertility treatment. Both waiting periods include outcomes which are unpredictable, outcomes over which the

woman has no control, and a waiting period which lasts several weeks. Both groups of patients may experience an increase in anxiety and worry and acute uncertainty about the outcome of this waiting period. Significantly, the psychological strain experienced by both groups and their partners is compounded by concerns and doubts about their ability to carry a successful pregnancy, a future child and their ability to become parents. The two groups of women share closely analogous experiences, and similarities between the characteristics and stress factors experienced in the two types of waiting period suggest that the PRCI is potentially valuable as well as cost-effective intervention for women during the initial waiting period of a new pregnancy. This proposed randomised controlled trial (RCT) feasibility and acceptability study of the intervention is the next step in assessing the suitability of the PRCI as a coping intervention for women who have experienced RM.

PLAN OF INVESTIGATION

Study design

A mixed-method, two-centre, randomised controlled feasibility study aims to establish the viability of conducting a multicentre RCT to definitively test the effects of the PRCI on the psychological well-being of women who have experienced RM during the initial waiting period (1–12 weeks) of a subsequent pregnancy. Part 1 of this study will address how acceptable the proposed methods of recruitment and randomisation are: whether it is possible to achieve acceptable recruitment and retention rates; whether the proposed data collection methods are appropriate; whether the study time-points are appropriate; and whether there is any preliminary effect of the PRCI.

Part 2 of the study consists of a qualitative process evaluation which aims to explore women's subjective experiences of the study intervention and research methods (including study outcome measures), provide information to refine the study intervention (if required), and to strengthen in-depth understanding of the initial experience of pregnancy following repeated miscarriages.

Intervention

The PRCI consists of an explanatory leaflet and a small card containing 10 positive reappraisal statements that aim to encourage users to redefine the waiting period more positively. The leaflet provides concise guidance on the use of the PRCI. Specifically, women are encouraged to read the PRCI at least twice a day, in the morning and in the evening, and any other time of day they feel the need. When reading the statements, women are instructed to consider and think about how each statement relates to them personally. They are advised that thinking about the positive aspects of a difficult situation does not mean pretending that 'everything is wonderful' when they do not think it is, or ignoring the negative aspects of a difficult situation, but taking account of the positive aspects alongside the more negative aspects of the situation. The positive aspects of the waiting period will differ depending on personal circumstances, and the leaflet gives examples (eg, focusing on the support and kindness friends and family have shown during their difficulties or how their relationship with their partner has strengthened because of the shared experience).

The statements on the card are general and do not refer to any one specific positive aspect, as individual users will have very different ideas about what is or is not positive. The women will be encouraged to put the small card in a purse or pocket so that they are able to remind themselves of the positive reappraisal techniques wherever and whenever they feel the need. The leaflet advises that the positive reappraisal technique can feel strange at first, but that the technique becomes easier the more it is practiced.

Target population

The study population will consist of patients attending the Recurrent Miscarriage Clinic and the Early Pregnancy Unit at two regional hospitals in the south of England. Women who have experienced three or more miscarriages will be invited to participate, as this population is at greater risk of high levels of anxiety and distress, as described previously.

Inclusion and exclusion criteria

Inclusion criteria will be: women with three or more miscarriages, women aged >18 years, and those who are willing and able to give written consent. Women will be excluded from this study if they do not speak English well enough to understand and complete study materials. This criterion is in place because the study materials (including PRCI) are not currently available in translation.

Feasibility RCT study

Proposed sample size and sampling strategy

Since this is a feasibility study which will indicate treatment effect for the design of a definitive study, the sample size is not determined by a power calculation.

The study sample will consist of two groups: the intervention group will receive the PRCI in addition to the current recommended care pathway, and the control group will follow the current recommended care pathway. A maximum of 25 patients will be recruited to each of the treatment arms over a 12-month period. There will be a lag time from recruitment (when the women experience their most recent miscarriage) to randomisation (when the participants inform the study team that they have a positive pregnancy test). This period, however, is likely to be relatively short, as many women who experience RM become pregnant quickly and have a short 'time-to-pregnancy',[26] despite difficulty carrying the pregnancy to term. Two of the aims of this

study, however, are to investigate patient flow for an actual recruitment rate to this study and the time lag from recruitment to randomisation.

Recruitment and randomisation

Potential participants will be given information about the study by their clinical care team when they attend the Recurrent Miscarriage Clinic or Early Pregnancy Unit and are invited to take part. If they agree, participants will be asked to consent to take part in the study prior to becoming pregnant. Informed consent will be obtained by the researcher or research midwife assigned to the study. The participants will be invited to contact the researcher as soon as possible after a positive pregnancy test to enable randomisation, the aim being to achieve randomisation the same day or as soon after as possible. A card with the researcher's contact details will be provided. Randomisation into one of the two study groups will be carried out by the study statistician using an independent computerised randomisation system with a randomly sized block design with block sizes of 2, 4 and 6. The study population will be stratified for those receiving concurrent treatment for RM, those with underlying medical conditions which are causative of RM, and number of previous miscarriages.

Participants will be randomised into one of the two study groups. The intervention group will be asked to use the PRCI and receive a weekly questionnaire assessment from the date of a positive pregnancy test until 12 weeks of pregnancy. The PRCI will be sent to the participant at randomisation. The control group will receive a weekly questionnaire assessment from the date of a positive pregnancy test until 12 weeks of pregnancy.

If a participant experiences a further miscarriage during the study period, they will be asked to notify the researcher. Questionnaire data from women who experience another miscarriage before 12 weeks of pregnancy analysis will be included in the data analysis.

Questionnaires will be returned by post to the research team monthly in prepaid envelopes.

For the purposes of this study, the waiting time period has been defined as the period from a positive pregnancy test until 12 weeks of pregnancy. An early pregnancy ultrasound scan is normally performed at approximately 12 weeks gestation, as part of routine antenatal care throughout the UK.

Materials

Preintervention demographic questionnaire

This questionnaire will be used to obtain demographic information (eg, age, educational status), medical conditions (eg, comorbidity associated with RM), gynaecological history (eg, fertility history) and reproductive history (eg, live births and dates and number of miscarriages) in order to appraise the clinical characteristics of study participants.

The following questionnaires will be completed from randomisation, that is, on the day of a positive pregnancy test and then at weekly intervals until the woman is 12 weeks pregnant:

Hospital Anxiety Depression Score (HADS):[27] This questionnaire is commonly used by clinicians to determine the levels of anxiety and depression a patient is experiencing. The HADS consists of 14 items (7 items for each of the subscales relating to anxiety and depression) and rated on a four-point Likert scale; the total score is the sum of the 14 items, and the subscale score is the sum of the respective seven items. The scores on each subscale are interpreted in ranges 0–7 (normal), 8–10 (mild), 11–14 (moderate) and 15–21 (severe).

The Daily Record Keeping Form (DRK)[28] will be used to assess emotions, appraisals, coping and physical symptoms experienced during the waiting period. The original measure was developed for daily assessments, but due to the burden of daily monitoring and potential reactivity as reported in prior research using the PRCI tool[29] the DRK will be used only at weekly intervals in the current study. To avoid confusion for research participants it will be called the 'Weekly Record Keeping Form' for the duration of the study. The DRK has been shown to be sensitive to changes in emotional[13] and physical reactions[28] during the waiting period prior to a pregnancy test.

Data analysis

Descriptive statistics with CIs will be used to explore the feasibility of the study procedures (numbers of eligible women, recruitment and retention rates, missing data) for each centre. Psychological well-being measures and the DRK will be summarised, and changes over the time course of the study examined descriptively. The relationship between physical symptoms, psychological well-being, appraisals and coping will also be explored descriptively using methods such as graphical displays. An assessment of any indication of an intervention effect will be made, but this will be viewed with caution given that this is a feasibility study. The variation of the psychological measurements within the control group will be used to inform power calculations for a future RCT, should this be warranted.

Qualitative process evaluation

The qualitative process evaluation will employ semistructured interviews using a topic guide to address relevant aspects of study objectives.

Proposed sample size and sampling strategy

Participants will be selected purposively, based on study group, that is, control or intervention, ongoing pregnancy or miscarriage, and clinically important demographics including age, comorbidity/medical conditions and previous live births. This method of sampling is commonly used in qualitative research[30] and is a means of collecting perspectives from as diverse a group as possible, which is particularly important when trying to

understand whether an intervention is acceptable to a population.

Sample sizes in qualitative studies vary[31] and tend to aim for data saturation, that is, that point at which no new information is found, as the ideal. In this study, in which the aim is to study participants' experience of study processes, rather than the development of explanatory theory, a maximum of 20 participants will be interviewed unless saturation is deemed to be achieved before this point, as it is likely a sample of this size will provide sufficient data to identify key issues and themes.

Data collection

Data will be collected using face-to-face, semistructured interviews and will take place at a location convenient for the participant. All the interviews will be performed by SB. Interviews will follow a topic guide which will be developed based on the study aims, a previous PRCI evaluation tool, a review of current literature, and discussion with Patient Public Involvement representatives and the supervisory team. The interview will last no longer than 60 min and will be audio-recorded and transcribed verbatim.

Participants will be eligible for interview once they reach 12 weeks of pregnancy and have completed the use of the PRCI and weekly questionnaire assessment, or in the case of the control group, weekly questionnaire assessment. If a participant experiences a further miscarriage they may still be approached for interview, but care will be taken to allow a suitable time period to elapse before this is arranged.

Data analysis

The aim of qualitative analysis is to unravel the plethora of data and make sense of the phenomena under investigation. Most qualitative approaches involve some degree of thematic analysis, and although thematic analysis can be as simple or complex as the research study demands, it is a more complicated process than merely coding and categorising data, and requires the researcher to ask more complex questions such as how the codes relate to each other.[32] Therefore, in order to promote and facilitate a more systematic and robust analysis of the interview data and to aid in its presentation, the transcripts will be subjected to a thematic analysis using the framework approach.[33] This approach was developed specifically to meet information needs and to provide outcomes or recommendations, and offers a highly visible and systematic approach to data analysis, showing very clearly how findings are derived from the data. It allows for both an inductive and exploratory approach, as other forms of qualitative analysis do, so that the integrity of individual accounts is preserved, but is also designed to facilitate analysis of specific concepts and issues that are particularly important to address, as in the proposed process evaluation.[34]

In order to further promote integrity and reliability during the data analysis process, other strategies will be introduced. Field notes will be written immediately after the interview and a reflective diary maintained, aiming to reduce the potential for the researcher's values, beliefs and preconceptions to influence subsequent findings.[35] Coding and analysis of the qualitative data will be completed by the researcher. In order to monitor and limit subjectivity, two members of the research supervision team will examine parts of the transcripts to compare their perceptions of the interview data and analysis with the researcher's interpretation.

DISCUSSION

RM is an extremely distressing condition. Even after thorough investigation, aetiological causes can be found in only 50% of cases.[2] Frequently, the cause is elusive or multifactorial,[36] leading to intense frustration for the affected woman and her healthcare team, as there is currently no effective treatment or therapy which can be offered. In order to address this condition appropriately and effectively, there is a need to develop a greater understanding of the causes, treatment and effects of RM. Current research into RM focuses on aetiology and the development of medical interventions to treat the condition. Other studies have reviewed the use of interventions to alleviate distress in the period immediately following miscarriage[5 37] but there is insufficient evidence relating to the effectiveness of support during the initial waiting period of a subsequent pregnancy[3] or the way in which such support should be delivered. This study is the first step in a programme of research concerned with improving psychological well-being for women affected by RM during the early stages of a new pregnancy; a waiting period which previous studies have indicated is associated with high levels of anxiety and distress for the affected woman, but a time period when there is limited support and therapy available. As such, it is envisaged that this research will both enhance and complement ongoing studies within a wider programme of research into the care and management of women who experience RMs.

This study is both timely and topical, investigating an issue which causes distress and anxiety to women affected by RM, and one which is proving a challenge to the healthcare professionals caring for them. The study will add valuable information to the body of evidence relating to how women who have suffered RM experience the waiting period of a new pregnancy. Additionally, the evaluation of the acceptability and feasibility of the PRCI will explore and identify how women who have experienced RM utilise this type of self-administered tool. If the PRCI proves to be an acceptable and valuable intervention then this model of care has the potential to be made more widely available within the National Health Service, both locally and nationally, as an effective, low cost, convenient, safe and

easily deliverable intervention. The primary objective of this study, which lays the foundation for possible future trials, is to complete a necessary preliminary stage in the process of testing the effectiveness of the PRCI in improving quality of life for women in the initial 12 weeks of pregnancy following repeated miscarriages. The PRCI has the potential to provide a low-cost intervention to provide much needed support to a vulnerable patient population.

Ethical considerations

This research will involve a potentially vulnerable patient group that has experienced RM. Care will be taken from the outset to ensure the health and well-being of the research participants, and they will be reminded that their participation is entirely voluntary and that they are free to withdraw at any time without their healthcare being affected. Potential participants will be given as much time as they need to decide whether they wish to take part in the study, and appropriate informed consent procedures will be adhered to.

Previous studies have demonstrated that women using the PRCI, strongly recommend its use to others,[19] and that women who had experienced miscarriage did not report any negative experiences from using the PRCI.[3] As such, any negative effects regarding the safety and well-being of participants in this study due to the specific use of the PRCI are not anticipated. Qualitative interviews will be arranged at a convenient time and location for the participant and will be conducted in a sensitive manner. If the participant shows any sign of fatigue or distress, then the interview will be stopped and either concluded, or agreement sought to resume at a later date.

Although this study is investigating a sensitive subject with a potentially vulnerable group, previous experience of researching sensitive topics in reproductive health suggests that women appreciate the opportunity to contribute to an important and personally relevant field of investigation.

Trial management and monitoring

Trial management meetings will be held every 6 weeks between the researcher and the supervisory team to discuss study progress. Additionally, a steering group consisting of the researcher, the academic supervisors and the two members of the patient and public representative team will meet six monthly to scrutinise and review progress of the research. Financial management of the study will be overseen by the Research and Development Finance Manager, University Hospital Southampton.

Dissemination

Study findings will be disseminated to study participants and through peer reviewed journals/publications, and national and international conference presentations. The Miscarriage Association has agreed to disseminate and publish study findings to the public and lay groups through their website.

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Contributors SB contributed to the design of the study, was responsible for obtaining the ethical approval and drafted the manuscript. NM, CB, JB and YC contributed to the design of the study. IR planned the statistical analysis. NM, CB, JB and YC are scientific reviewers for the study. All authors have read, revised and approved the final manuscript.

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Appendix P Randomisation sheet

A Feasibility and Acceptability Study and a Qualitative Evaluation of a Coping Intervention for Women with Recurrent Miscarriage

Randomisation Sheet

PARTICIPANT ID	
DATE AND TIME OF CONTACT WITH RESEARCH OFFICE TO CONFIRM POSITIVE PREGNANCY TEST	
AGE OF PARTICIPANT	
NUMBER OF PREVIOUS MISCARRIAGES	
PARTICIPANT TAKING ANY TREATMENT FOR RECURRENT MISCARRIAGES? e.g heparin, progesterone, steroids	Answer yes or no
PARTICIPANT HAS A DIAGNOSIS OF CAUSE OF RECURRENT MISCARRIAGES? e.g thrombophillia	Answer yes or no

Please complete above table and email to Dr ****** (statistician)

Appendix Q Example of complete interview transcript

SB: Thank you for letting me come to your house. So today I just want to ask you a little bit about how you found being part of my study, anything you thought would have made it better or any things that were good and also then we'll move to asking you a bit around your feelings of how you felt during that early stages of your pregnancy. Now before we start I'm delighted that this pregnancy is going really well and you are about 21 weeks now so we're looking forward to the beginning of September. You look very well actually.

FP (Female participant): Thank you.

SB: So, after a bumpy start things are going really well for you so that's just excellent. Now the first bit I want to concentrate on the study so I first met you when you came to the recurrent miscarriage clinic and you'd been referred there by your GP and remind me how many miscarriages you'd had?

FP: That was my third but not consecutive. I had one, then had my son and then had two.

SB: OK. You came to us to see if there were any investigations we could do and we had a long chat and then it was while you were at that appointment I saw you as your clinician and then I said would you be interested in finding out about any research and you took the, as I remember you took the information sheet home and had a good read of it.

FP: Yes.

SB: When I told you about the study were you surprised to be asked about taking part in research?

FP: Yes, because it's not something that people generally talk about and it hadn't up until that point been in the press or anything like that and previous to that nobody like professional wise seemed to want to do any follow up on anything so I was really shocked but excited at the same time because I thought well this is good.

SB: Were you happy being asked are you interested in research would you mind taking this away and having a read about, did you think that was a bit too pushy or were you quite happy?

FP: No I just thought I'm a big believer that things happen for a reason and I was meant to bump into you for a reason, it was almost like it was meant to be that we had that that appointment and you were there at the same time and I'm a big believer then taking that forward.

SB: Good, excellent.

FP: Yes, definitely.

SB: When you had the information sheet which spoke about the study did you understand the purpose of the study what we were trying to do? Was that clear or could it have been clearer?

FP: Yes, no it was clear. I think the thing that was obviously was in my mind is that I would only ever be part of the study if I was with this successful pregnancy and I think you've got one or two things there, as much as I was happy to take part in the study there was a kind of a sort of a pain if you like and there was like that well my views won't actually be any good because this may not happen again and

that's where we were at the time and it happened in June so we saw you in August so it was still very raw for us.

SB: Yes, I remember.

FP: With everything going on so yes met at a very emotional time.

SB: Did you believe me when I said the odds are in your favour?

FP: I did and I didn't. I thought at the time that's probably maybe a standard thing that was said to most women to allay their fears but we were just embarking on that journey and for us it was that first step of maybe not getting the answers that we wanted but we're getting some answers.

SB: I understand that entirely. So then I saw you and you agreed to take part in the study and you kindly signed the consent form and then the next thing I said to you was when you are pregnant you need to let me know as soon as possible. It wasn't that long before you let me know I don't think. I can't remember I'm afraid.

FP: So we saw you obviously in the August and I think we were signed off in November and then I found out I was expecting in the January. It was very early days when I messaged you because I had that insecurity if you like of I don't know what to do and I know in the back of my head I thought I'm only going to get support if I open my mouth but at the same time I was scared to to acknowledge what was going on just in case something happened so it was kind of realising that if I spoke to somebody then it was all going to become real and I think that's the difficulty with things especially I think just given what's happened in the past. Once you acknowledge that test whatever it is you are then committing to that pregnancy aren't you.

SB: How did you feel when you did that positive pregnancy test?

FP: Oh just very mixed emotions, very happy I've never seen two blue lines come up that quick before and then it was like what do I do now and then that trepidation, I think that's the right word, because both my husband and I we both said the same we can't get excited we just have to live one day at a time, deal with this bit, speak to you, see what happens next but it was that kind of that in my head it was like oh I've got this test now and I might not get tested until 12 weeks so there was that, already there was that creeping in that doubt, what happens if something goes wrong, yes very difficult.

SB: So you let me know quite quickly after a positive test.

FP: Yes, I think I was less than six weeks so I must have been about five weeks.

SB: Did you do the test as soon as you missed a period or?

FP: Yes, I knew I was only late only in respect of when I had the two D&C's back in June since then I've been very regular and when I went over that time which I only knew because it was my son's birthday and that's the only reason because I hadn't been tracking I was like wow this is a bit odd because up until this point I've been really regular so I thought I'd just leave it a few days and that's when I thought well I can't leave it anymore because this could well be a pregnancy much to my disbelief, so I was literally probably just over five weeks when I contacted you.

SB: Now for you there wasn't much time between when you signed up to the study and when you notified me you'd had a positive pregnancy test but for some ladies it takes longer than that and I've been thinking about during that time should I contact the women maybe every few weeks or every couple of months just to send them an email to remind them they're on the

study and is there anything I could do. How do you think people would feel about that or do you think I'm best just to leave it?

FP: I think what's quite nice, I think you did message me before that point and that then it's the little things that make the difference, it just proves that actually although technically I was signed off as of November it still meant that you cared about what was happening in that meantime because mentally obviously that's a lot to take in isn't it, everything is fine, there's no reason why it shouldn't happen, go away as Dr C said you'll be back here before you know it for a good reason so that was that. I thought that contact was really useful, it made me feel quite positive about.

SB: Oh that's interesting.

FP: Whereas I can maybe see that other people would see it as just leave me alone I need to get on with things but me personally I think the longer you'd have left that I would have kind of maybe got disinterested with the study when we got to that point but I think because you had that little chat, that message, that made all the difference to me.

SB: That's really useful to know because it's something I've been thinking maybe I should make that a more standardised contact but that's useful I will think about that.

FP: I think miscarriage in general, sorry just to side track here.

SB: No please carry on.

FP: I think when I had my first miscarriage and second miscarriage once you are told you've had a miscarriage and you are told to go home and then that's that it's a very long and lonely time and the doctors they haven't got the time to phone up or whatever but to me that would make the difference. I could have gone mentally

really downhill in that space of time, luckily I've got a strong character so I can get myself out of it but I can imagine other ladies who have got other stuff going on that might have been the straw that broke the camel's back.

SB: So that contact from maybe a health professional is.

FP: Really important.

SB: Really important.

FP: I think it just proves that they care and I think if you feel cared about then that makes all the difference.

SB: I think so.

FP: Outlook wise.

SB: Yes, I think so. So you were able to contact me by telephone or email and it was quite easy to get hold of me as the researcher you were quite happy with that?

FP: Yes, absolutely.

SB: When you were on the study I'd said to you and it was said on the consent form I'm not able to offer any extra support because obviously what we were trying to do was look at the study and the intervention. Did you understand that?

FP: Yes, I think I was like sometimes it was blurred lines a little bit in respect of it's like you've got this far and then you think when you say you couldn't offer anything further it was, I didn't actually fully understand that.

SB: No because there were blurred lines for me as well.

FP: Yes, and I think that is just because you've found this person or professional that suddenly take an interest and then you just want to ask them so many things, you've got so many questions, I mean I'd spoken to you about Professor Q which was totally on a tangent to be fair, I mean it was still linked with the subject but I was like can she tell me that, I thought well I'm going to ask her anyway and if she can she can and if she can't she can't, and low and behold she's part of the massive study research that I just, you know, but yes I think it was a little bit, I suppose because of the type of person that I am I give myself to everyone and it's very difficult I think.

SB: It was difficult for me too but unfortunately that's the nature of research really.

FP: But I can imagine because how emotive that subject is when I broke down in your office a few times that for anybody on the other side of that you wouldn't be human if you wouldn't be emotionally moved maybe by that.

SB: Yes of course, I understand that.

FP: So I totally get that but equally when you said oh I can't do this test I understood that was fine, if we wanted to do that we'd have to do that privately and there was that kind of if there was anything I asked you would come back and whether it could happen or not happen at least I knew.

SB: OK. Then you were put in the group to use the intervention and have the questionnaires.

FP: Yes.

SB: Now the questionnaires there were two of them if you remember and I meant to bring some copies with me but I forgot. One was something called the Hospital Anxiety Depression School, that was a tick box where it said in the last week I've felt like I can relax all the time, similar questions to that, did you find that one straight forward or difficult or did it, no answer that question first?

FP: I'm just trying to think.

SB: It was a while ago I realise.

FP: I did struggle I must admit when I first got the questions I did struggle because I was like right OK so can I say, I think sometimes you just want to put your own little comment in there and you could, I think you could comment I think on that one. Could you? I can't remember.

SB: I think the HADS was a bit more.

FP: Specific wasn't it.

SB: It was just a tick box like a multiple choice one.

FP: I think any type of question is difficult because sometimes there's all these options but sometimes there are other things that you want to put down there that aren't there and sometimes the grading especially on the other one was a bit tricky.

SB: That's what I want to ask you about that scoring system.

FP: I found that difficult.

SB: Because it's come to light that the scoring wasn't that easy. It was a questionnaire I used because it's been used on a similar study. It was a while ago and I appreciate that you might not be able to remember but I wanted to ask you about the scoring because it said leave the box blank if you've not had this symptom, 1 – mild; 2 – moderate; 3 – severe, but some of the boxes were things like happy, positive. So what did you do then, how did you take it, did you maybe just leave it?

FP: If I was happy then I would give it a score, I did find it really difficult because I thought you've got emotion-wise you've got the really positive things in there mixed in with these real deep things and you are asking me to grade it on the same scale. I found the scoring a little bit tricky.

SB: You weren't the only one.

FP: I've done questionnaires and I've designed questionnaires in the past myself of research when I did my teaching bits and pieces so I get that but I did think. I don't know what actually I meant to put because I know you weren't meant to think too much about it either so yes I did struggle a little bit.

SB: What about the frequency of use once a week, was that OK with you? The questionnaires.

FP: I did them regularly, I finish work on a Wednesday and I always do them on Wednesday and it was a good time for me because I wouldn't have any distractions, come straight home, didn't have my son because he was at school so I'd do them on a Wednesday.

SB: Did you find completing, were the comments sensitive or insensitive in any way, was there anything that offended you?

FP: No there was nothing.

SB: Or upset you about them?

FP: No there was nothing derogatory on them or worrying on there it was just, sometimes it was a bit vague, some of the boxes were a bit vague to be honest and it was like oh OK. I did find things like you know when you talk about the symptoms that was a bit tricky actually because obviously early stage I had extreme nausea and then of course as soon as it drops off it's like oh what does that mean, is that a bad thing and of course in the past.

SB: Did you think the questionnaire made you more anxious because that made you think?

FP: Made me aware of symptoms.

SB: Oh gosh I'm not feeling sick or for some people maybe my breasts aren't so tender anymore.

FP: Or tiredness or whatever, yes it made me more aware, it made me look and think oh wow I've had this extreme nausea which I did they had to put me on sickness tablets because of it because I wasn't even keeping down fluids and then it was like oh and then the next week so maybe I don't know whenever it was I didn't feel so bad but that's natural because you can get peaks and troughs and things.

SB: Did that worry you?

FP: A little, and then I was like but you've got to look at it from the whole perspective, OK so you haven't had the extreme sickness but you have had bad back pain or this, that and the other. It did make me more aware of the symptoms, yes.

SB: Were the questionnaires helpful or unhelpful in any way?

FP: I thought they were helpful in respect of I felt that I was giving back, so all through the process I felt that my input however messy it is or whatever it is it's an input isn't it, it's going to eventually go to something else that's going to help and by doing it every week it gave me that little focus about well actually I don't have to worry about this every day, I can just focus on it one day a week where I sit down and do my questionnaires because that's what I would do I wouldn't tend to then think the rest of the week oh I haven't had this or I haven't done this, I'd just think right I'm going to do my questionnaires. To me it was a positive thing and I would just sit down in a positive way and do them.

SB: Did it help you pass the time do you think then? Is that what you are saying or not really?

FP: I think just by having them again it was part of that showing that you care, I know it's daft it was like well actually you are part of a study it's showing that you care again and so for me if you were happy to do that then I was happy to put my end of the bargain in.

SB: Your feedback is very valuable so the comments and so on and very, very valuable.

FP: Did it help pass the time? I found the time difficult but to be honest I was so ill I didn't really get a lot of time to think about the time because I had that extreme nausea and then I got really ill with.

SB: Oh you had your sinusitis didn't you?

FP: Yes, I had sinusitis.

SB: And your little boy was ill.

FP: He had chicken pox, so to be honest it was a nice distraction, it was like right I'm going to sit down Wednesday do my other questionnaires and then get them sent off.

SB: You were happy how we did that that you had them in the post to return. Would you have preferred it online?

FP: No I quite like the fact that it's in the post, I mean I could have done it online to be fair and sent it off to you but I quite like the fact that I had to sit and then I would have my card as well, my positive reappraisal, and do it so for me that was fine.

SB: So I asked you to use the positive reappraisal coping intervention card – what did you think when you first saw it?

FP: I thought gosh this is a bit nuts. That's my honest answer but I kind of get it, it's kind of thinking very differently about things, is there another way to think because in the past I've done CBT so I get that there is always another way to think about things it's not necessarily doom and gloom there are other reasons

why you could be feeling so hideous and it's not necessarily because the pregnancy is not successful as I've proven like now, so yes I found that helpful in respect of if I was getting a bit wobbly, if that's the best word to use, I would get the card and go right well actually that's good isn't it and some of the statements I'd say well actually that's a good sign isn't it. I was always told I'm sure was it Dr C said to me the worse you feel the better and then when I went to QA and I had my first scan, very early scan at 6 weeks she said if you feel hideous that's really good as far as we're concerned because it proves that everything is going to baby and everything is being taken away from you. I was like brilliant that's good, but it takes a long time for that to sink in.

SB: It does. How often did you use the card because I asked you to use it twice a day but you may have used it less you may have used it more? You implied then that maybe if you were feeling worried you might get it out and have a look.

FP: Yes, I think in the early stages those first few weeks those 6-9 weeks I used it quite a lot. I wouldn't say twice a day I would say at least once a day and I would actually look at it sometimes even if I wasn't feeling like that just so that I could hone in and focus on those emotions.

SB: Did you carry it with you or leave it here?

FP: I would leave it here but I knew that when I got back from work that when I'd had my quiet time that I could sit and read it and I thought that was important. I did think about taking it to work but to be honest work has always been a great distraction for me anyway, I've got very little time to think about things at work and I just thought by having it at work maybe that would then make me think about things more so I thought well I'll leave it at home and then when I get back from work I've got it there for me to look at.

SB: So did you use it roughly the same time every day then?

FP: Yes pretty much and then if I was having a wobble I think as and when we had a scan just before a scan then I would tend to have a little wobble about things, a worry, because scans to us are a two-edged sword, on one hand they are very happy with everything successful pregnancies on the other hand we've been in to scan rooms before and we've had treatments, investigations and also been told this isn't a viable, so it's very difficult.

SB: Did your anxiety increase as you got nearer to your scans?

FP: Yes, definitely because it's all that fear of the unknown isn't it even though you know it's one or the other, there's not a middle ground is there, yes.

SB: Often it seems and agree or disagree that some ladies suggest the worst thing is the not knowing.

FP: Yes, I'd agree with that.

SB: Because if we could say to someone yes this is going to work or no this isn't going to work at the start it would be awful but you.

FP: You could kind of get your head around that.

SB: But I don't know, it's the uncertainty because I guess I don't know how your emotions would move, would they go from positive to negative?

FP: We've had three miscarriages, so the first miscarriage was 10/11 weeks and I think that one we'd put our heart and soul into because it was our first ever experience of pregnancy and we had to go quite long if you like before we had that

conclusive well actually there's just a sac and that's that really. Me personally the longer you invest in a pregnancy the harder it is so last year when we went to 13 weeks and potentially we've gone through all that, we've still gone through the sickness, still had all that, so for me you can't even compare pregnancy to pregnancy they are all very different. Had we of known, we had a holiday booked I think when I was about 7/8 weeks, had we known then then yes that would have changed the thought processes that we were having on holiday, the behaviours obviously, you are reticent to do anything because you are pregnant but had we known then we could have maybe gone on holiday and actually enjoyed our holiday a bit more. So yes it wouldn't have changed the outcome we still would have been sad absolutely but I think the longer you invest in a pregnancy the harder it is.

SB: I think you are right.

FP: The less time that you've got to, so I had one the year before last and that was eight weeks so literally you could have just called it a late period and a little bit more. That wasn't so bad at eight weeks even though the timing of it was Mother's Day which wasn't exactly brilliant. It's weird isn't it? I think last year hit us harder because we'd got over that 12-week stage, we had literally had our scan ready to be booked in for the 13 weeks and yes it was really, really difficult and obviously anybody that goes over that time even more I can imagine you are just putting your heart and soul because me personally you invest as soon as you see those two blue lines and that's that really.

SB: It's an expectancy isn't it?

FP: Yes, and the fear of the unknown is the worst because if you know it's not viable from an early stage yes it's difficult but at least you've got time then to get your head straight, to get sorted and maybe get the treatment that you actually need or support or whatever it is because I think that both times on my first and second we were just kind of oh well it's just one of those things, it's very common, it's this, that and the other and neither time did I get investigation, follow-up or

anything like that. Then last year came and obviously a very different outcome of having to have the operation this time, yes very difficult and I think more so because we had two operations in the space of three weeks so you kind of come to terms with things and then you then realise actually there are still problems and you've got to go back in. Unfortunately, when you look at statistics I was one of those statistics, I was one of the one in 300 or whatever and at the time you just don't pay much notice to it do you or the 1 in 3 or is it 1 in 4.

SB: It must have been hard for you.

FP: Yes, it was really difficult.

SB: It must have been very hard for you.

FP: But if it hadn't have happened then we wouldn't have ended up with you guys and we wouldn't be here.

SB: You might well be. So how easy or difficult was it to use the card?

FP: Really easy.

SB: What the card was, as you know, trying to encourage you to do was to say well this is a rubbish situation you are in but even in a rubbish situation something positive can happen every day and often because of the situation you are in and what we wanted you to do was maybe look at those positive things as well so do you have any examples of positive things you might have looked at or thought about? Can you remember any?

FP: Yes, I deliberately because I think did you say do something different or something like that, so I would deliberately have a nice bath like I'd constantly have a shower and then I'd think right I'm going to have a nice bath and I'm going to put music on and I'm going to have a bit of me time because I think with everything going on you forget about yourself.

SB: Would you have done that had you not had the card to remind you do you think?

FP: I've had more baths recently because I just think actually I need to take time out for me since what happened and more so with the card, yes I did more so with the card. I would do things like I would turn the telly off and sit there and I'd read and I'd get absorbed in a book rather than just when I've done my housework sometimes I put the telly on and I get absorbed into that so I deliberately try and do other things.

SB: I know it's a difficult thing to answer because you don't know how you would have been without the card but do you think it made you think about things differently?

FP: I think it just, I'm just trying to think really, I think if I was having a wobble then it was good to have that card because then I could get it out and think well actually this is like my CBT from before, I think what is another way of thinking about this. I found that I think one of the things is can you perceive the 12 week wait any differently and I thought well actually I've got a lot of strength since things have happened, I think probably I'm the strongest that I've ever been so I think it's made, regardless of the outcome it made me a stronger person so I think that was quite important.

SB: Do you think it became easier to use over time or do you think it was quite straight forward from the beginning?

FP: Yes, I think it was quite straight forward just to pick it up and run with it.

SB: Were there any aspects of it you found unhelpful or helpful at all?

FP: No, I just think in general I'm quite a proactive person anyway and I don't dwell, I try not to anyway, and for me it was just useful to know that it was there, that you cared and that if I was feeling low then I could go to the card at any time not just when I was having a wobble.

SB: Do you think you'd use it in the future?

FP: I think the statements are quite generic.

SB: They are.

FP: They can be applied to life and I've often, my husband is very well how else can you think about this, there are other ways that you can think about bits and pieces not just with miscarriage because obviously with that happening that can then impede on other aspects of your life so I think they are quite generic statements which you can apply to life and definitely they are kind of little mantras almost.

SB: Would you recommend it's use to anybody else?

FP: Yes, absolutely.

SB: In any situation or with miscarriage in particular?

FP: Anything really but I think especially with miscarriage I think if a lady has got that and she knows and she's doing the questionnaires or whatever it is it's just helpful in the fact that she thinks well actually I'm taking some time out for myself now and I can do this differently, I don't have to be thinking the next 12 weeks are going to be like torture and it be in my case that I was so ill that I didn't get much time to think but yes I think it would definitely help other ladies.

SB: In this study we're not testing the effectiveness of it we're just thinking would it be viable and useful but if I asked you to say did it have any positive effects on you or any negative effects on you would you have anything to say about that or do you think it made a difference in any way?

FP: Yes, I think the whole being part of, knowing that you are part of a study has made a difference to me massively which is why when you said about meeting up and doing this bit I was really quite keen because I thought well actually it's going to help isn't it.

SB: Yes it will help.

FP: And not initially but long term that research collectively is going to help other people.

SB: I hope so.

FP: And I think I just got a little positive from that and I think it made me feel positive about doing the study whereas sometimes I receive questionnaires in the past and I've thought it's a bit laborious, I didn't fully invest in it but I felt like I fully invested in this. The difference is I wanted to fully invest because it's something that has personally affected me whereas other things that I've received not so, you pay lip service to don't you.

SB: So it was almost more being part of the study that was helpful to you, that someone was thinking about how you were feeling?

FP: Yes, as opposed to the actual card itself.

SB: Yes, that's fair comment, that's excellent. So now if it's OK I just want to take you back to some of your feelings you felt around when you were first pregnant this time because what I've looked at quite extensively in looking at the literature around is how women feel. Now there is a lot written about how women feel in the immediate aftermath of a miscarriage, there is a fair bit written about how women feel in general in pregnancy when they've experienced pregnancy losses before, there is very little written about how they feel in that waiting time that's the time I'm interested in between a positive test and around 12-weeks of the pregnancy when you don't know which way it's going to go really. So I just wanted to ask you, I know you've touched on some of those feelings, but how you felt on the whole during that waiting time - you were obviously poorly?

FP: Yes, I had extreme nausea so that was obviously really difficult in itself. I found it really difficult in respect of you obviously don't want to tell too many people, I had a few confidants that I would talk to about bits and pieces but we didn't go public at all until quite late on actually, it was well after 13 weeks that we went public. I would have good days and bad days really emotion wise because I was again invested in the pregnancy like you do when you get the test but kind of scared to at the same time. Because of how quickly it happened as well it's almost like one minute we're in hospital and the next minute this is happening it's like life overtook, it made me, I didn't have a lot of time to think I think that's the thing, I mean I would have days where I thought please God let this be OK and then I would have other days where I'd think wow this is all good sign and the fact that when I was really ill when I had my sinusitis I was really ill and they said take

paracetamol every four hours, I was really reticent to take anything because of previous bits and pieces and I remember just that reassurance when I had to go into our local midwife team and they did a little listen in and the first thing she said was don't be alarmed if we don't hear anything straight away baby is very small and the next minute she was like oh there you go can you hear it? And I'd have really low times because of illness and then I'd have quite highs where I'd think oh wow I heard the heartbeat whereas I've been to the midwife team before and we've had a listen in and they've heard nothing and then that's meant something totally different. So it's very difficult because if that hadn't happened then it does make you think very differently, you can't just go out and you want to tell people of course you do but it makes you very private, very keep yourself to yourself and it was very hard to get excited about any of it to be honest.

SB: Really?

FP: Yes. Even we had a scan at 6 weeks, we had a scan at 9 weeks and every time we've come out of the scan room we go OK that's good but we wouldn't get the champagne out or anything like that we just didn't, I think it's very, very difficult. I can't even, it's trying to put it into words it's really difficult.

SB: It is hard yes.

FP: It's really difficult. It's not in a doom and gloom kind of way either, it's not in a pessimistic way it's in a well this has happened to us three times so for us it's like it's affected our life three times miscarriage so there is a possibility that it could affect our lives again and you don't want to fully invest in something if you think that the outcome could be, so that's why I think and I'm trying to find the words but I.

SB: You're doing very well. Did you let yourself daydream about the pregnancy and the birth of the baby and your future?

FP: It's weird actually even up to this point I can't envisage any further than the next appointment or the next midwife or the next, I have occasionally I might think of my son and his little now because it's a girl, his little sister running around but it's very hard to visualise whereas I think when we found with our son where we'd had the miscarriage before we kind of yes I can imagine that we thought about things a lot more but it's very difficult.

SB: Do you talk to your husband about the pregnancy or between the two of you so that's safe, you would talk to him?

FP: Yes.

SB: But to other people you sort of?

FP: Yes, I'll give you an example of when that was at its strongest is obviously just after the operation I wouldn't talk to anyone apart from my husband because I thought you are the only one that knows what I'm going through, you are the only one that was in that room and heard those words and had to have all that treatment, you are the only one that gets it. Anybody else would say yes, yes I understand what you are going through and I think it's the same when we found out I was pregnant yes I know there are loads of people that have been pregnant and that but I just wouldn't want them to come up and go oh that's amazing, which it is its fantastic news but it's so difficult to get that excited to share their excitement as well when what's happened has happened. Actually when we told my parents even they were the same and they were like well that's really great whereas before they were like oh that's fantastic, new addition to the family, so even my experience has now filtered down into their.

SB: How did you feel about when they said well that's great but?

FP: I kind of get it because we're the same, my husband and I are exactly the same we had our 20 week scan this week and again we came out and we were like well we're going to have a little girl and then that was that, it's like it's all calmed down again because it just, it's one day at a time, that's how we live one day at a time, that's how we have lived since June and I don't think that's a bad thing because we are appreciating that emotions can change from day to day and we're not naïve in the fact that life can throw little curve balls as well so we have to deal with those as well one day rather than think about the birth we think about little hurdles, so my next hurdle is I've got a midwife appointment in a couple of weeks so I'll be about 24 weeks when I see her and then another little hurdle then will be when I get my paperwork and I have to make it official at work because they do know obviously but that's another little hurdle. I try not to think too far ahead because I think I get overwhelmed with things. If I think about last year we found out I was pregnant in the March/April time and by June everything was very different and we already at that point we were looking ahead and we were thinking wow we're in the 12 weeks now this is fantastic, we're planning names, bits and pieces – we didn't do any of that this time.

SB: Do you find yourself looking back to this time last year rather than looking forward?

FP: Yes, sometimes I look back in a positive way and sometimes I go gosh look how different our life is and I do it in a positive, I don't look back and go oh god this time last year.

SB: That's good.

FP: Yes, I look back and I think we've come a long way in a year, a lot has happened since last year and I'm very thankful that, I'm going to dread saying this but without last year happening I wouldn't be where I am now because we could very well be in a very different position.

SB: That's a positive thing to say.

FP: Yes.

SB: That's a really positive thing to say.

FP: Which I wouldn't have said.

SB: About an uncomfortable and upsetting time.

FP: I wouldn't have said that last year, I wouldn't have said that when I saw you in August.

SB: No I know you wouldn't.

FP: And I wouldn't have even said that in November, I think December was probably our closure when we acknowledged our losses properly rather than just papering over the cracks. We sent some balloons off.

SB: Did you? That's nice.

FP: Yes, we did three balloons because very poignant and after that life became a lot easier. It's just something that helped us really and we involved our son. I think always before we've kept him out of things, we involved him and just said, he'd asked me one day, sorry this is side tracking a bit.

SB: No it's interesting.

FP: But he'd asked me he said mummy where are the other babies, now he didn't know about me being pregnant or anything on any of the occasions and I was open and honest and I think that's the best way to be with a young child and because it has been part of our life and it is technically part of his and I just said there were babies but they weren't strong enough and typical kid reaction he said but I was mummy wasn't I? And I said yes you were a fighter and he went oh a bit like Captain America, and I went yes exactly like Captain America and he went so where are the babies now and I said they are in the sky I said they're in heaven and I said that's where they are they are looking down and making sure we're all OK. Even though they weren't physically like that but to me their spirits in everything and our son because he was involved he then said we should set some balloons off mummy.

SB: Did he?

FP: Yes.

SB: Where has he seen that?

FP: My niece had a still birth the year before so maybe that's kind of but he just said we should do some balloons because he said they are in the sky so the balloons, interestingly when we set the balloons off he turned around and said they'll never be lonely mummy because we tied them all together, they'll always be together won't they. And it was that day, and it's interesting actually because that was a poignant day see we did the balloons and our son was fully involved and that was the day we just thought I think it was that closure on what had been a really difficult six months or whatever and from then life was very different, life was very different. I remember going into his school that day we did the balloons to pick him up after I'd never won a raffle or anything and we'd entered and of all the days to win we won that day and I think it was a little sign and then ever since then I've just felt actually we are being looked after, there's a reason why last year happened and I can see why now.

SB: You do seem in a different place to where you were, I can see that. So you've got lots to look forwards to.

FP: Yes, so that's my son's perspective.

SB: I think that's probably the right perspective bless him. Just one more thing I wanted to ask you about because this is something that's come up when I've been talking to ladies – what do you think about social media when you are pregnant with scan pictures and baby bumps? How do you find that? Do you have Facebook?

FP: Yes I do and I've recently come off it actually. I have a real, it's not even hatred that's the wrong word, I really don't feel it's appropriate to be putting stuff like that out there. Now that is probably because of my experiences and also having someone that's trying to get pregnant or repeated miscarriage to then have that in your face it's really difficult. When we found out with our son we didn't put anything on social media until he was born, until he was in my arms because I always remember the caveat at the bottom of the letter, low risk doesn't mean no risk, and the same caveat with this one, low risk doesn't mean no risk, and that's not to say I'm ashamed or anything like that it's just to say we're very private people, we didn't feel it's appropriate to be putting all that stuff out there. Once you put it out there then you've got to tell everybody if it doesn't go the way you want it to go and that's really difficult. However, we did use social media last year as a way when we lost, when we had to go into hospital because quite a few people knew and rather than having to talk to people individually I thought if we get it out there as a oner then everybody knows at the same time, it negates me then having to do individual chats and I wasn't in a good place. We've also used it because we are quite involved with the Miscarriage Association rather than doing Christmas cards last year we did donations so we said we are going to do a donation to Miscarriage Association so then I would upload just the card that I

received back from them as a thank you just so that people rather than them sending us cards we wanted people to acknowledge that we're not sending cards this year but the money that we're going to use to send you the cards on the postage we're going to give to the Miscarriage Association, we're going to give back. So I think that's important and it was nice to be involved with the Miscarriage Association and obviously doing Great South they were going to be and they will be next year when I do the run because I am going to do it next year, they are a big reason why I'm doing the run so I still massively want to be part of them. But I've come off it at the moment just because I just think it's easier because quite a few people know and it negates them putting stuff on there. It's weird it's like I don't want them to know but I do want them to know but I personally think and my husband will back me up here scan pictures, bumps, not appropriate on there. I don't know why; I think it's probably because of what's happened. I'd love to be able to do it but maybe I think it's tempting fate and I just think it's very private, a scan, I would never take a child to a scan.

SB: You are not allowed to in [name of hospital] now.

FP: I think because it means two different things, when you've got that child in the room if it doesn't go the way it's meant to go you've then got to explain to that child who is an emotional sponge especially our son he's very emotional like me and my husband and then you've got to sit down and go through all that. I just don't think it's appropriate and I can see that. I went to QA the other day and gosh there were loads of kids and obviously there were kids in pushchairs but there were loads of kids going in for their scans and I just thought I don't think it's appropriate.

SB: Yes, we've just stopped it for practical reasons and for what you said that sometimes scans aren't good and it's difficult but also for practical reasons.

FP: If you've got a child in a waiting room if you are somebody that has had a miscarriage and you are in a scan room and you are waiting to go for a scan to

have confirmation of a miscarriage and you've got another child in that room in the waiting area that's really difficult. What I found really difficult at [name of hospital].

SB: I know what you're going to say.

FP: Is a big sign so we're sat in the waiting room and there are loads of people there, big sign please give up your seat for expectant mothers and I found that the biggest.

SB: Do you know what I've not even noticed that.

FP: I find that the biggest urgh, I can't tell you how.

SB: Because I want to be an expectant mother.

FP: Yes.

SB: I'll go and look at that.

FP: I found that really difficult because I thought oh.

SB: I didn't know you were going to say that I thought you were going to say this shows having a mixture of pregnant women it's not ideal but I shall look at that this afternoon.

FP: My husband and I had a laugh about it in the end and we went yes, it is a little bit, can you imagine if we all had our little speech bubbles you'd be saying get me

out of here now and somebody else would be saying oh we're looking forward to our first child and all of that sort of stuff but we did find that a little bit cruel. We knew it wasn't done deliberately it was just our positioning when we are waiting for the obviously because we went for the 2D didn't we and then we had the 3D down there but it's in that waiting room.

SB: I think what it's for it's for the men that sit down and take a.

FP: Yes, or the families.

SB: Yes the children, that's what it's for, what it could actually be better for a patient.

FP: It's really difficult.

SB: I'm going to go and look at that.

FP: Technically I was in that position not a few months before and I found that really oh but that's probably because my head wasn't in the right space. I'd say I'm quite strong anyway but I'd say maybe somebody else might look at it and be quite offended by that.

SB: That's really interesting, I'll go and have a look later.

FP: But we did have a laugh about it in the end because you could have little bubbles going get me out of here and where you are waiting as well you've got the picture machine haven't you where you can get your pictures and as people are coming out its life, I get that but it's really difficult especially when you are first in there and everyone has got their bumps. Interestingly when I went to QA everyone has got their Bounty packs but I didn't want to broadcast it because I thought there might be other people in there that are waiting for a scan for another reason so I

put mine deliberately in a bag but that's just the way I think, I try and think about other people how difficult that might be for them and I've done that with every single appointment but everyone else has got their Bounty pack and their bumps on show which is fine because it's life but I used to think 9 times out of 10 there is going to be somebody else in that room for another reason and not a good reason so.

SB: That's very interesting, I shall take that away and think about that. I don't know what I can do but I will think about it.

FP: It's just never been brought to anyone's attention but it's probably because emotionally I was like.

SB: Yes but what we should be doing is respecting everybody's emotions and we are a women's hospital we're not just a maternity hospital, so we are seeing women like you, we are seeing women with infertility that can't get pregnant and I'm very aware of that. I went down the other day and on the table in the waiting room there was one of the most recent actresses to have a baby, how I got my pre-pregnancy figure back in two weeks, and I did pick it up and say I don't think that's appropriate in the infertility waiting room but you can't get rid of everything but you can be respectful as much as you can and sensitive.

FP: I think the trouble is when you've gone through a loss or you are trying it then highlights everything in your mind, we call it the law of attraction things like that are then attracted to you which you wouldn't necessarily normally be attracted to. My analogy is when I started running is I never noticed runners before as soon as I started running I'm looking at all the gear, the trainers and I seemed to see a running community whereas before if we go back to the pregnancy and the miscarriage and that I never would have been, that sign probably wouldn't have

even bothered me and any literature wouldn't have bothered me but yes you are right I think the setting, when you went to the sub-waiting room you had to wait for yourself and Dr C that was fine because you kind of had all sorts of things in there didn't you but it was the waiting room where you have the scan.

SB: And down by ultrasound.

FP: Which again that is there for many different reasons isn't it but we did find that particularly challenging at times.

SB: Yes I'll think about that; I'll bring that to someone's attention when the time is right. OK, one more question because I've taken up too much of your time.

FP: No it's absolutely fine.

SB: When you were going through that early stage and it was obviously you were in a different place so you coped with it very well but was there anything that would have made a difference to how you were feeling during that time that would have made it better?

FP: I don't honestly know to be honest, I just felt hideous sort of side effect wise. I don't know if I made you aware but when I had the first scan at six weeks they suggested that although there was no evidence with me personally that I should take aspirin that I should take a high strength folic acid and a progesterone pessary and it was all like well like Dr C had never said this and I know she maybe alluded to it but she didn't think that was a massive factor in so obviously all of those medications are not going to necessarily agree with you are they especially when you are someone that doesn't take things anyway so I think I was just too ill to kind of really get too worried about anything I was just concentrating on trying to get better the whole time.

SB: OK. Well is there anything else you'd like to say at all before I turn the tape recorder off that we've not covered that you think we should have?

FP: I think we've pretty much covered a lot of ground I think it's fantastic that this is now being looked at, it's sad that for me my miscarriages started in 2009 and it's obviously taken to this year for things to really go global shall we say because there's a lot of press about miscarriages now, there's a lot more talk about it people don't seem to, it doesn't seem to be as taboo maybe that's because of our experience last year in going properly public and I think more things like this should happen for more ladies that maybe earlier intervention even after one miscarriage might just make all the difference. I know the law is three miscarriages concurrent, I didn't have three miscarriages concurrent but maybe if somebody had taken the time and spoken to me more in depth at the second one maybe things could have been very different at an earlier stage. Who knows. To be fobbed off and to be told it's just one of those things for some ladies it isn't just one of those things there's medically reasons why. For us obviously it was an unknown because it all turned out that all our tests were fine so there's no rhyme or reason but I think if people show that they care early on maybe at the first miscarriage there's help and support there not just given a leaflet for the Miscarriage Association kind of you've got to get on with it that could be the difference with someone then suffering depression or getting on with their life. I think that's really important.

SB: It's that personal care.

FP: Why is it the more miscarriages you have it holds more weight every miscarriage you go through is just as difficult you've still got to rebuild your life, you've still got to carry on, why is it that one is any less important than three or four or however many I think. Miscarriage is miscarriage and emotionally it affects you every single time.

SB: OK. I'll turn it off now. Thank you.

END

Appendix R Matrix to show listed initial categories from interview analysis

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
S16														
Questionnaire -daunting to work out what to do	x													
PIS - understood no drug	x													
Positive attitude to taking part in study	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Confirmed understanding of PIS	x	x	x	x	x	x			x				x	x
Communication difficulties - rang wrong number	x													
Prompt contact from researcher	x		x						x			x	x	
Easy to contact researcher	x	x	x	x	x	x	x	x	x			x	x	x
Not clear of instructions how to complete questionnaires	x													
Problem solved how to complete questionnaires	x		x	x							x	x	x	
Needed space without interruptions	x											x		
Questionnaires gave time to think	x	x					x	x		x	x	x		x
Overthinking things	x													
Wanted to complete correctly	x		x	x	x		x			x	x	x	x	
Would have liked guidance	x													
Wanted an idiots guide	x													
Lots of emotions going round	x				x		x	x	x			x	x	
Preferred to put in numbers	x													
HADS not so relevant	x												x	
Liked WRK relating to symptoms and emotions	x								x		x			
HADS limiting	x						x				x		x	
Literally interpreted questionnaire	x													
Followed 'rules' of completing questionnaire	x		x	x	x		x			x				x
Liked flexibility of WRK	x	x												
Happy with completing once a week	x	x	x	x	x	x	x		x		x	x	x	x
Willing to have completed every day	x				x									

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Completing questionnaires helped her to reflect on feelings - good thing	x						x			x	x	x		x
Looked back over questionnaires as a 'tool' to assess pregnancy	x	x	x							x	x			
Questionnaire completion gave timeout	x	x						x				x		x
Searched for changes in pregnancy symptoms and emotions	x	x	x					x	x		x			
Put pregnancy to back of mind because worried about another miscarriage	x													
Questionnaires made her address her emotions	x						x	x		x	x	x		
No harm from questionnaires	x	x	x	x	x	x		x		x	x	x	x	x
Not upsetting	x	x	x	x		x		x		x	x	x	x	x
Easy return of questionnaires via post	x	x	x	x	x	x	x	x		x	x	x	x	x
Easier to post	x		x	x								x		
Understood notion of randomisation and happy with this	x								x	x	x		x	
S47														
Aware of reputation of institution		x												
Altruistic reason to take part- might help somebody else		x					x	x		x	x	x	x	
Confidentiality important		x												
Don't have to face a lot of people		x												
Initial reaction keen to be part of research		x		x								x	x	x
Considered PIS carefully before agreeing to take part		x									x			
Understood research might not help personally		x						x		x				

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Study made more sense as time went on		x												
Knew she was pregnant before test		x												
Let researcher know within 1 hour		x												
Contact by email convenient		x	x	x	x	x	x	x	x	x			x	x
Contacting researcher extra thing to do		x												
Not hard to complete questionnaires		x	x	x	x	x	x	x	x	x				
Easy to understand		x		x	x	x	x	x	x	x				
Completing on weekly basis showed progression of pregnancy		x	x				x							
Passed time in weeks		x					x		x			x		
Found questionnaires weird initially		x												
Bit repetative		x		x										
Appreciated looking back and comparing with previous weeks		x	x							x	x			
Liked seeing scores getting more positive		x	x								x			x
More positive after scan when everything ok		x							x	x				
Sometimes upset when did questionnaires- when I remembered previous pregnancies		x												
Don't think its ever going to be positive outcome		x					x	x		x				
Always thinking about previous miscarriages - won't ever go out of my head		x			x			x	x					
Paper copies easier		x		x								x		
Initially thought PRCI awkward		x												
How is this going to make me feel better?		x						x			x			
Didn't use much at beginning		x												
As pregnancy progressed used on daily basis		x	x											

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Aquired skill - got easier		x	x									x		
Reminded me to stay positive		x						x			x	x		x
Use few times a day		x												x
Carried in hand bag		x												
Work a distraction from pregnancy		x						x		x		x		
Helped in other aspects of life		x	x											x
Helped with relationship with husband		x												x
Difficult not to think about pregnancy		x						x						
Helped to stay positive and calm		x						x						
Still uses PRCI now		x												x
Prefers to hear something positive from another person		x												
Difficult to understand card could help		x						x			x	x		
Isolated - nobody knew what I was going through		x						x		x				
Even though just a card was my best friend		x												
Helped me get through every single day		x												
Card was their for me - didn't have to explain myself.		x												
Card took her at face value		x												
Didn’t help with anxiety (PRCI)		x	x									x		x
Encouraged to be more positive		x	x	x				x				x		x
Worrying isn't going to help		x						x						
Encouraged to take a positve stance		x	x					x				x		x
Encouraged a positive mental attitude		x	x					x			x	x		x

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Lack of control during waiting period		x		x										x
Emotions all over the place		x					x	x						
Card gave some order		x												
Sometimes upsetting - PRCI made think about situation		x												
Became part of everyday life		x												
Became familiar		x	x	x										x
Would recommend PRCI		x	x	x				x				x		x
Hard to use in beginning and not helpful		x												
Became part of me		x												
PRCI took mind off things		x												
Instant relief from using		x												
PRCI encouraged to get through one day at a time		x						x						
Everyday of waiting time slow		x												
Wanted to get through waiting period		x												
S01														
Important area of research			x											
Contacted researcher within one day of positive test			x		x	x								
Shocked by speed of becoming pregnant			x											
Completing questionnaires learning process			x								x			
Worried by questionnaires			x											
Concerned would not do correctly			x											
Understood questionnaire guidance			x	x		x	x		x					
Constantly pessimistic			x					x	x	x			x	
WRK encouraged facing of emotions			x					x		x	x			
Negative outlook initially			x									x		
Scoring changed as pregnancy continued			x											x

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Questionnaires encouraged time out			x									x		x
Used as a tool to aid reflection			x					x						x
Would not use 'app' to complete questionnaires			x											
Used PRCI twice a day in beginning			x											
Used once in evening as pregnancy progressed			x											
Knew PRCI 'by heart'			x	x										x
Used at bed time			x											x
PRCI did not reduce anxiety			x									x		x
PRCI contained good messages			x											
Culture can adversely affect positive thinking			x											
Positive mental attitude new skill			x											
PRCI not specific to miscarriage			x											
PRCI easy to use			x					x				x		
Assumption that if you allow yourself to think positively something bad will happen			x											
Prior to this never considered PMA			x											
Personal tendency to catastrophize			x											
How do you make 'best of situation?'			x											
Personality can affect interpretation of card			x											
PRCI useful technique			x					x						x
Pos. thinking wonderful skill			x											
PRCI forced to consider positive thoughts			x											

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Tendency to focus on negative			x					x						
Tool for life'			x					x						x
Denied pregnancy			x					x		x				
Using PRCi 'eye opening' experience			x											
Saw everything in dark			x											
Numbness - not able to feel anything			x											
Anxiety levels tremendous			x					x		x				
Unsure whether PRCI helpful			x											
Awareness different women would experience PRCi differently			x											
PMA would cheer me up			x											
S02														
Quickly informed researcher of pos pregnancy test				x	x	x			x	x	x	x	x	x
Early stages - not that pregnant really				x										
Email contact with researcher easier with work				x	x				x					x
Wouldn’t let myself be excited				x			x	x						
Anxiety levels varied day to day				x	x		x	x						x
Valued reassurance of USS				x		x			x	x	x	x	x	
Some confliction in statement s questionnaires				x										
Questionnaires helped me think I was normal				x										
Reassurance other people must feel like this				x										
Had to think about answers to questions				x							x			
WRK - first time bit odd				x										
Questionnaires reduced anxiety levels				x				x		x				
Gave back some control (PRCI)				x										x
Needed reminder to use PRCI twice a day				x										

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Thought about sentences on card at other times				x										x
Tried to use morning and night				x										
Concern re outcome of pregnancy remains after waiting period				x				x						
Continues to use pos appraisal				x				x						x
Anxiety levels reduced with pos reppraisal				x				x						
PRCI practical tool				x										
S03														
More miscarriages, more you get used to it					x									
Keen to elaborate on answers WRK					x									
Important to report feelings honestly					x									
Emotions change one day to next					x		x	x						
Keen to complete daily to reflect better changes in emotions					x									
Emotional rollercoaster not accurately captured by weekly completion					x									
Persistently ruminating about pregnancy					x			x	x	x				
Struggle to think about anything else					x			x	x					
Questionnaires helped to rationalise feelings					x			x				x		
Gave back control					x									x
Questionnaires didn't make things worse than they were already					x									
Postal returns - something else to remember					x									

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Would prefer on-line facility to return study materials					x									x
Disappointed not to be randomised to intervention					x				x				x	
No temptation to use positive reappraisal anyway					x									
S15														
Added bonus of taking part in research gave access to health professional						x	x	x				x		
Wanted reassurance						x		x				x		
No support from GP						x		x		x				
Questionnaires quick to complete						x				x	x			
Questionnaires encouraged positve thinking						x		x		x	x	x		
Questionnaires made a positve difference to emotions						x	x	x		x	x			
Expression of gratitude for older child						x		x		x				
Doing something for me made me feel more positive						x						x		x
Limited time for myself						x						x		
Monitoring symptoms on WRK reassuring						x		x						
S28														
Time of emotional turmoil							x	x	x	x				
Hide your emotions from people							x							
Emotional rollercoaster							x	x		x				
Prepare for the worst							x	x	x	x			x	
Waiting for signs of miscarriage							x	x						
Unsuccessful attempts at trying to avoid thinking about pregnancy							x							
Concerns about pregnancy always present							x	x	x					
Envy - will never be that person happy about her pregnancy							x		x					
Assume will be bad news							x	x	x	x		x		

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Make changes to life to try and sustain pregnancy							x							x
Aware of illogical behaviour							x							
Bargain with yourself							x							
Lie to yourself about symptoms of miscarriage							x							
Relief when miscarries							x							
Nobody understands							x	x		x				
Lack of psychological support information - mainly medical							x							
Different for RM patients who already have a child							x							
Only people who understand are people in exactly same situation as you							x			x				
Journey big rollercoaster							x			x				
Superstitious - tempting fate if you tell someone about a positve test							x							
Telling HP doesn’t tempt fate							x							
Helps to share news of pregnancy with HP							x					x		
Questionnaires help to assess your emotions							x	x		x				
Liked being in 'average zone' - not as bad as you thought you were							x							
WRK hard to quantify scores - had to think about it							x					x		
Questionnaires helpful - 'dump on them'							x							
Questionnaires supportive - got me through the week							x							
Writing problems down gets them out your head							x							

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Liked limitation of questionnaire - didn't have to open up too much							x							
Free text space would enable to get thoughts down							x					x	x	
S31														
Delay notifying researcher of positive test as didn't want to confirm pregnancy								x						
Wanted to pretend not real								x						
Here we go again								x						
Complete anxiety								x		x				
Assume pregnancy will fail								x	x	x		x	x	
Level of worry life-consuming								x	x	x				
Big black cloud								x						
Horrible emotions								x						
Isolated - didn't want to go out								x						
PRCI encouraged meaningful activities								x						
Encouraged an appreciation of everyday								x						
Encouraged an appreciation of child already had								x						
Fell in love with daughter again								x						
Mind very busy worrying and ruminating								x	x	x				
Dislike of social media								x						
Keen to do any research that might help								x		x		x		
Saw research as an olive branch								x						
Having contact with researcher helped loneliness								x				x		
Sense of loneliness								x				x		
Petrified and terrified of new pregnancy								x						
Really helped knowing researcher was health professional								x				x		

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Would have preferred twice a week for questionnaires								x						
Questionnaires pulled me back in line								x						
Questionnaires rationalised situation								x						
Questionnaires encouraged positivity								x		x	x	x		
Questionnaires more useful / helpful than PRCI								x						
Encouraged you to contemplate								x		x				
Always thinking. Always worrying								x						
Questionnaires levelled out emotions								x						
Monitoring symptoms on WRK confirmed something not right								x						
Constant checking for pregnancy symptoms								x						
Used PRCI once a day								x						
Rationalised emotions								x						
Extreme worry affected sleep								x	x					
Used card when couldn't sleep								x						
PRCI did relieve some anxiety								x						
Worry worse when alone								x						
Mind talking all the time								x						
PRCI calmed thoughts								x						
Nobody listens to you								x						
Waiting time is a limbo land								x						
Worries about health of unborn babe								x						

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Anxiety re stillbirth								x						
Added worry whole new dimension								x						
Suggest credit card sized PRCI								x						x
Initial reflection on PRCI - stating the obvious								x						
PRCI reminded me of what was positive in life								x						x
Daughter was my positive								x						
PRCI patronising at first								x						
Picked out most salient points on PRCI								x						
S44														
Valued input of researcher									x					
Sought out research study									x	x				
Questionnaires self-exlanatory									x					
Anxiety like a wave									x					
Anxiety built before weekly scan									x	x				
Wanted reassurance USS daily									x					
Overwhelming worry									x	x				
Anxiety viscious circle									x					
Constant searching on internet									x					
Scared									x					
Don’t feel a normal person									x					
Worried about well-being of other peolple's pregnancies									x					
S52														
Taking part in research a good distraction										x				
Taking part in research helped move on from previous miscarriage										x				
Research a positive move										x		x		x

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Lack of understanding surrounding RM										x				
Online peer support valuable										x				
RM shocking										x				
Trusting professionals will find answers										x				
Silent society around RM										x				
Taboo										x				
Others don't know what to say										x				
Lack of empathy amongst health professionals										x				
Informed researcher within 2 days of positive pregnancy test										x				x
Previous participant of RM research										x			x	
GP unhelpful										x				
WRK interesting										x				
Responded to questions on questionnaires with gut reaction										x				
Realised not possible to score positive emotions on WRK										x	x	x	x	
Assumed WRK 3 point scale - 3 very happy or v unhappy										x		x		
Waiting period varies depending on previous experience										x			x	x
Questioned whether waiting period 12 weeks										x	x			
10 weeks critical point										x				x
8 weeks key point										x				
Constant uncertainty										x			x	
Lowest mood between scans										x				
Euphoria immediate period after scan										x				

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Worst person to be around										x				
Denial of pregnancy										x				
Beneficial to have continuity of care EPU										x				
USS maintained sanity										x				
Questionnaires quick to do										x	x			
Questionnaires encouraged thinking around situation										x	x	x		x
Missed questionnaires after 12 weeks										x				
Questionnaires felt like personal research										x				
Brought feelings to the surface										x				
Questionnaires good intervention to reduce anxiety										x				
Encouraged awareness of emotions										x		x		
Encouraged communication with husband about feelings										x				x
Questionnaires encouraged awareness of the impact of stress on family										x				
Increased stress levels affected all in family										x				
Unconserned re outcome of randomisation										x				
Sought view of others re taking part in research											x			
Used calendar reminders to keep in touch with researcher											x			
Woman should not be contacted by researcher during time between recruitment and pos test as may heighten women's anxiety about time to pregnancy											x			
? Detrimental to participant to receive contact from researcher when waiitng for pregnancy											x			
Indirect approach like a study newsletter softer approach to provide gentle reminder they are on study											x			
WRK all towards negative things											x		x	

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
WRK stumped me											x			
Scoring on WRK confusing											x	x		
WRK leant itself to all negative things											x		x	
Should be equal scores for pos and neg emotions											x			
Milestones to get through before 12 weeks											x			x
Awareness everyone has different timeframes											x			
HADS captured emotions well											x			
Preferred WRK											x			
HADS gave similar responses											x			
Questionnaires gave hope											x			
Questionnaires encouraged addressing of issues											x	x		x
Questionnaires promoted looking forward											x			
Being randomised 'full package'											x			
PRCI helped to voice concerns to others											x			x
PRCI encouraged 'opening up'											x			x
Used PRCI frequently at first when anxiety levels higher											x			x
Encouraged sharing of feelings with husband											x			x
Used PRCI on adhoc basis											x	x		x
Questioned coping abilities during waiting period											x			
Clear instructions how to use questionnaire											x			
Adapted instructions of use to suit individual											x			
Carried card around so accessible											x			

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
PRCI more useful at beginning of waiting period when anxiety levels higher											x	x		x
Used PRCI less as anxiety decreased											x	x		x
Expected the worst to happen											x	x		x
PRCI rationalised tjoughts											x			
Pick and chose statements on PRCI to utilise											x			x
Sustained ability to cope with waiting											x			x
Encouraged re-grouping of emotions											x			
PRCI reduced anxiety levels											x			
S61														
Shocked to be invited to take part in research												x		
Excited to take part in research												x		
Assumption pregnancy would fail												x		
Would views still be valuable if pregnancy failed												x		
Important that views would count												x		
Scared to acknowledge pregnancy												x		
Did not want to commit to pregnancy												x		
Positive pregnacy test caused trepidation												x		
Tried to take one day at a time												x		
Disbelief at positive test												x		
Suggestion that contact with participant between recruitment and randomisation would be beneficial												x		
Researcher cares about what happens to me												x		
Little things make a difference												x		
Contact between researcher and participant promotes positivity in participant												x		

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Risk of becoming disintersted in study if no contact												x		
Contact form health professional really important												x		
Need to know health professionals care												x		
Would have preferred verbal support from researcher												x		
So many questions about miscarriages wanted an answer to												x		
Awareness difficult for researcher not to be emotionally involved												x		
Wanted researcher to be point of contact for advice re miscarriages												x		
Keen to know what could and couldn't be dne with respect to miscarriages												x		
Struggled with questionnaires at first												x		
Questionnaires limiting												x		
Wanted to add free text to questionnaires												x	x	
Scoring system WRK difficult												x	x	
Negative emotions experienced are deep												x		
Questionnaires a bit vague												x	x	
Worried if physical symptoms decreased on questionnaire												x		
Unsure how to interpret changes in physical symptoms												x		
Helpful to complete questionnaires - giving back something to other women												x		
Approached completion of questionnaires in a positive way												x		x

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Questionnaires showed researcher cared												x		
Felt supported by being part of a research study												x		
Preferred to complete hard copy questionnaires												x		
PRCI - 'bit nuts'												x		
PRCI encouraged to look differently at situation												x		
Utilised PRCI more when anxious moments												x		x
Lack of belief that all progressing well with pregnancy												x		
Used PRCI on average once a day												x		
PRCI helped focus on emotions												x		x
Didn't want to use PRCI out of home situation as would encourage thinking about pregnancy												x		
Anxiety worse before a scan												x		
Uncertainty about outcome of USS added caused anxiety												x		
Fear of unknown is the worst thing												x		x
Longer you invest in a pregnancy harder miscarriage is												x		
Reticent to make plans when pregnant because of worry of miscarriage												x		
Invest in pregnancy as soon as pos test												x		
Description of personal expereince of miscarriage as a statistic												x		
PRCI gave 'me time'												x		x
As a result of PRCI deliberately tried to do things differently												x		x
PRCI alikened to CBT												x		
PRCI encouraged me to see myself differently												x		
PRCI helped me realise I've got strength to deal with situation												x		
Miscarriages have made me strongest I've ever been												x		

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Helped knowing could access PRCI if mood low												x		
PRCI statements could be applied to life in general												x		
PRCI statements little 'mantras'												x		
Would recommend PRCI to RM patients												x		x
Good knowing in the long term I've helped other people												x		
Fully invested in research study												x		
Being part of research study helped more than PRCI												x		
S64														
Previous research participant													x	
Hard not to talk myself in to hoping													x	
Lack of understanding re what a feasibility study is													x	
Disappointment not randomised to PRCI													x	
Felt less valued being in control group													x	
Questionnaires surprising - more detailed than expected													x	
Comparison made between HADS and EPDS													x	
Questions not appropriate to pregnancy													x	
In a hideous situation													x	
Concerned answers in questionniares misleading													x	
Other life events affecting answers to questions													x	
HADS didn't reflect anxieties around miscarriage/pregnancy													x	
WRK scored emotions as intensity felt													x	
Interpreted how to score WRK in own way													x	

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Felt had to be forceful to get scans													x	
Supplemented NHS USS with private USS													x	
Unable to believe anything except the worst													x	
Disbelief anybody has a successful pregnancy													x	
Policed emotions													x	
No hope													x	
Kindest thing not to hope													x	
P03														
More relaxed as weeks progress in pregnancy														x
Research fitted well with personal attitude														x
Expecting another miscarriage to occur														x
Hopes dashed even before scan														x
Felt encouraged PRCI had been trialled with similar patient group														x
No concerns being part of Site B cohort														x
Excited by positive pregnancy test														x
Determination to do best to help new pregnancy succeed														x
Questionnaires difficult to complete at first														x
HADs easily completed														x
WRK acquired skill														x
Preference to complete questionnaires at end of working week														x
Questionnaires rounded up week														x
Questionnaires encouraged inward focusing														x
Experienced worry														x
Positive emotions, time went quicker														x

Appendix R: Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
First impression of PRCI simpler than expected														x
PRCI made sense														x
Needed to think about PRCI														x
Copied PRCI on to phone so available at all times														x
Wrote answers to points on PRCI on phone														x
Noted down thoughts, feelings and things learnt from doing PRCI														x
Made PRCI a personal thing														x
Developed personal techniques / statements to encourage positive thinking as a result of PRCI														x
Used personal statements of positive things in life instead of PRCI														x
Bed time real worry time for me														x
Added personal statements as thought of them														x
Read PRCI and personal statements last thing at night														x
Very personal technique to me														x
Repetition of personal statements helped improve positive thoughts														x
PRCI good guidance of positive reappraisal														x
Need to expand PRCI statements by writing then down														x
Need to personalise PRCI to make most effective														x
Obsessive checking pregnancy symptoms														x

Appendix R Matrix to show listed initial categories from interview analysis

COMMENT	S16	S47	S01	S02	S03	S15	S28	S31	S44	S52	S56	S61	S64	P03
Positive reappraisal supportive in between visits to health professionals														x
Made a plan and stuck to it - gave back some control														x
Reaffirmation 'I can do this'														x
Women meant to have babies														x
Reliance on other therapies e.g. medicines, complimentary therapies														x
Attempt to prepare body to cope with new pregnancy														x
PRCI organised thoughts														x
Truly belief that PRCI helped														x
Transposed PRCI on to phone so accessible all the time														x
Guilt miscarriages caused by previous lifestyle choices														x
Made healthier lifestyle choices to improve chances of successful pregancy														x
Positive thinking helped come to terms with thoughts and worries														x
PRCI promoted ability to cope with waiting														x
Isolated - availability of someone to talk to limited														x
Completing questionnaires felt like talking to self - therapeutic														x

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