# The Positive Reappraisal Coping Intervention: a supportive intervention for recurrent miscarriage

## Introduction

Recurrent miscarriage (RM) is currently defined as the loss of three or more pregnancies within the UK (RCOG 2011) and the early stages of a new pregnancy, when confirmation by ultrasound scan of an ongoing and viable pregnancy is awaited, represent a particularly challenging period for women affected by this condition. Previous studies have indicated that this waiting period is associated with high levels of distress due to the anxiety of possibly experiencing a further miscarriage (Ockhuijsen et al. 2013a; Ockhuijsen et al. 2014c; Ockhuijsen et al. 2015). However, limited support and counselling is available during this difficult period and many are left to manage these distressing emotions without coping support. While some women seek frequent confirmation of viability by ultrasound scans, this approach is not feasible in most clinical settings, and appears to be of limited efficacy in reducing anxiety (Bailey et al. 2019). An alternative approach may be to provide the woman with tools that can help her cope with this period.

The Positive Reappraisal Coping Intervention (PRCI) is a novel self-administered supportive technique, based on the principles of positive reappraisal. It 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, in addition to 10 positive reappraisal statements that users read at least twice a day to stimulate this form of coping (Figure 1). For women who have experienced RM the waiting period in the early stages of a new pregnancy shares many characteristics (unpredictable, uncontrollable, immense personal significance) with the waiting period fertility patients experience after IVF, suggesting that the PRCI may also provide a potentially valuable supportive intervention for this patient group.

The essence of positive reappraisal coping is that it ‘sustains the coping process through increasing positive mood, via cognitive processing’ (Lancastle and Boivin 2008). In view of the overwhelming anxiety and despair women with RM can experience during the early stages of a new pregnancy, then they might find this concept difficult to understand and be sceptical about whether the PRCI, a self-managed intervention, could make them feel more positive. Therefore, to assess the potential value of the PRCI as a means of improving the psychological well-being, a study was designed to assess the acceptability of the intervention and the feasibility of conducting a future large scale randomised controlled trial (RCT).

A fundamental aim of a feasibility study is to determine whether it is possible to successfully deliver a study in the proposed context (Bowen et al. 2009). A review of feasibility studies concluded that that the feasibility phase prior to a RCT helps to maximise the likelihood of researchers evaluating the optimum intervention utilising the most appropriate and proficient recruitment processes and trial design (O'Cathain et al. 2015). Feasibility studies, therefore, play an important role in establishing appropriate study design to support successful study completion. The primary objective of this study was therefore to establish the feasibility and acceptability of performing future exploratory and definitive trials to determine the effectiveness of the PRCI in improving the psychological well-being of women who have experienced RM during the initial waiting period (1-12 weeks) of a subsequent pregnancy.

## Methods

### Study Design

Between …. and ….., women with a history of RM were recruited to participate in this two-centred RCT. The key research questions to be addressed were:

* How feasible and acceptable were the proposed methods of recruitment, randomisaton, 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 any preliminary indication of an effect of the PRCI?

A second component of the study was a qualitative process evaluation (QPE) that aimed to explore in depth women’s subjective experience of the study intervention and research methods to provide information to refine any aspects of the research design (if appropriate). The methods have been respectively published elsewhere (Bailey et al. 2015; Bailey et al. 2019)

### The Intervention

The PRCI (Figure 1) is a theoretically derived and short coping intervention, based on the concept of positive reappraisal with proven reliability and validity (Lancastle and Boivin 2008; Ockhuijsen et al. 2013b; Ockhuijsen 2014; Domar et al. 2015). It aims to promote positive re-evaluation of a challenging situation and consists of a small card containing 10 positive reappraisal statements that encourage users to redefine the waiting period more positively. An accompanying leaflet provides concise guidance on the use of the PRCI. Specifically participants are encouraged to read the card at least twice a day, in the morning and the evening and any other time they feel the need. Guidance also advises 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 the situation, but taking account of the positive aspects alongside the more negative. The guidance was adapted for the present study to refer to the waiting period of a new pregnancy following repeated pregnancy loss.

### Study Population

The study population consisted of patients attending the Recurrent Miscarriage Clinic (RMC) and the Early Pregnancy Unit (EPU) at two tertiary referral hospitals in the United Kingdom. Site A operated a weekly RMC through which potential participants were identified. In Site B, access to potential participants was achieved through the site’s EPU.

### Inclusion / Exclusion Criteria

All women who attended the RMC in Site A and the EPU in Site B (providing they had experienced three or more miscarriages) were eligible to participate. Exclusion criteria included if the woman was unable to speak English well enough to understand the study materials, required fertility treatment to achieve a pregnancy, was less than 18 years of age or unable to provide written consent to take part in the study.

### Study Sample

Since this was a feasibility study aimed at indicating treatment effect for the design of a definitive study, the sample size was not determined by a power calculation. Instead, more pragmatic considerations were used around feasible recruitment figures and referral rates for RM patients for both study sites. It was estimated that the two study sites would yield a total of six patients a month (three from each centre) over a recruitment period of one year. The aim was to randomise 50 participants within this time.

In the QPE participants were selected purposively from those who had previously taken part in the RCT component of the study. Characteristics considered in the purposive sampling method included previous study group (intervention or control), ongoing pregnancy or miscarriage, ethnicity of participant, age and number of previous live births.

### Recruitment and Randomisation

Potential eligible participants were provided with information about the study in the form of a Patient Information Sheet (PIS) by their clinical care team, when they attended the RMC or the EPU. If patients were interested in finding out more about the study, then a meeting was arranged to discuss the study in more detail with the researcher. Although 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 participation prior to becoming pregnant.

After providing consent the research participants were asked to notify the researcher of a positive pregnancy test as soon as possible after in order to enable randomisation, the aim being to achieve randomisation on the same day or as soon after as possible.

Randomisation into the two study groups was carried out 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 that were causative of recurrent miscarriage and number of previous miscarriages. The PRCI group were asked to use the intervention and received a weekly questionnaire assessment from the date of a positive pregnancy test until twelve weeks of pregnancy. The control group received the same weekly questionnaire assessment from the date of a positive pregnancy test until 12 weeks of pregnancy, but not the PRCI. 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. Questionnaire data from women who experienced another miscarriage before twelve weeks of pregnancy was included in the data analysis as for those whose pregnancies continued.

Participants became eligible to take part in the QPE once they 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. If a participant experienced a further miscarriage they were still approached and invited to take part in an interview, but care was taken to leave a suitable time period to elapse before this was arranged. Participants indicated on the consent form of the RCT feasibility component of this study whether they would be willing to be invited to take part in the qualitative interviews. Potential participants for the qualitative interview were then selected purposively from the cohort of patients who indicated a willingness to participate.

### Data Collection

##### Pre intervention demographic questionnaire

This questionnaire was specifically designed for use in this study to capture relevant baseline demographic information including age, level of education, medical and psychological history (to identify any co-morbidities associated with RM), gynaecological and reproductive history (fertility history, dates and number of live births and miscarriages) and the time period the woman had been trying to achieve a successful pregnancy.

##### Outcome Measures

To assess psychological well-being in women in each study group, two validated outcome measure questionnaires, the Hospital Anxiety Depression Scale (HADS) (Zigmond and Snaith 1983) and the Daily Record Keeping Form (Boivin and Takefman 1995) were used at specific time points. Time points commenced on the day of a positive pregnancy test (or as soon after as possible) and then at weekly intervals until the woman either reported a further miscarriage or reached 12 weeks gestation when ongoing viability is associated with a greater than 95% chance (Tong et al. 2008) of reaching live birth.

###### Hospital Anxiety Depression Scale

###### The HADS and associated questionnaire has been shown to be a valid measure of the severity of anxiety and depression and of changes in a patient’s emotional state (Zigmond and Snaith 1983).

The questionnaire consists of 14 items (seven questions for anxiety and seven for depression) and are rated on a four-point Likert scale. The anxiety and depression scores are interspersed within the questionnaire, but are scored separately and are interpreted in ranges 0-7 (normal), 8-10 (mild), 11-14 (moderate) and 15-21 (severe).

###### Daily Record Keeping Form (Boivin and Takefman 1995)

The Daily Record Keeping Form (DRK) was used to assess the emotions, appraisals, coping and physical symptoms experienced during the waiting period. The original measure was developed to assess these elements during the waiting period prior to a pregnancy test after fertility treatment (Boivin and Takefman 1995; Boivin and Lancastle 2010).

To adapt the DRK for use in this study, a number of relevant words and phrases were changed to better reflect the waiting period experienced by RM patients. However, the overall format of the questionnaire was not amended. Furthermore o reduce the burden of daily monitoring and potential reactivity identified in previous studies (Ockhuijsen 2014), the DRK was completed only at weekly intervals. To avoid confusion for research participants it was called the ‘Weekly Record Keeping Form’ for the duration of the study.

Process evaluations play a vital role in understanding the feasibility of an intervention and optimising its design and evaluation (Moore et al. 2015). In the QPE, data was collected using face-to-face, semi-structured interviews that took place at a convenient place and time for the participant. The interviews followed a topic guide to steer the general form of data collection and this 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.

### Data analysis

Descriptive statistics were 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 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. An informal assessment of any indication of intervention effect was considered, however the purpose of this study was not hypothesis testing but feasibility and acceptability.

QPE interviews were audio recorded and then transcribed verbatim and data analysed utilising the general inductive approach (Thomas 2006). The main analytic strategy of this approach was to establish the core meanings evident in the text, which were relevant to the evaluation (or research) objectives.

Although findings from the quantitative and qualitative analyses are presented concurrently in this paper, fuller details of the qualitative methodology and findings are reported elsewhere (Bailey et al. 2015; Bailey et al. 2019)

### Patient and Public Involvement

A Patient and Public Involvement (PPI) advisory group supported this research and met on a regular basis for the duration of this study. The group were involved with the design of the study and commented on any potential burden of participating in the study from a patient’s perspective. The group were involved with data interpretation, and at the end of the study commented on the findings and contributed to the dissemination plan.

## Results

### Recruitment-related feasibility outcomes

126 women were assessed for eligibility across the two study sites, 19 did not meet the eligibility criteria. Of the 107 women approached to participate in the study, 6 (5.6%) declined to participate, there was lost contact with 26 (24.2%) women who failed to notify the researcher of their decision to take part in the study or the researcher was unable to contact. A total of 75 participants were recruited to the study, 68 (90.6%) of these were from Site A where recruitment targets were exceeded. In contrast, in Site B, screening and recruitment numbers fell well below the expected number and despite an extended recruitment period and the provision of research infrastructure support systems, recruitment proved difficult. Participant recruitment and flow through the study and reasons for exclusions are outlined in the CONSORT diagram in Figure 2.

All 14 women who participated in the QPE reported a positive attitude to taking part in the research and felt comfortable with the way they were approached and invited to participate in the research study. They commented that they considered this an important area of research and findings suggest that this group of women were altruistic, keen and willing to participate in research that would help women in a similar situation to themselves, even if it did not help them personally – see Box 1.

Box 1 – Qualitative views on recruitment and study participation

*I was very happy to participate, I think it’s very important and I think that the topic of the research is very important (S64)*

*I wanted to be part of something … and if I was able to help people in the future I was quite positive about that (S56)*

#### Sample characteristics

The baseline demographic characteristics of the recruited and randomised participants are shown in Table 1.

### Randomisation- related feasibility outcomes

Between February 2014 and March 2016 a combined site total of 47 participants (62.6% of participants who had consented to join the study) informed the researcher of a positive pregnancy test and were randomised to one of the two study groups. Participants were asked to inform the researcher of a positive pregnancy test as soon as possible to facilitate randomisation. All participants notified the researcher within 48 hours, although one participant was excluded from randomisation, as she did not notify the researcher until she had completed 12 weeks of pregnancy. The process of initiating randomisation and allocation to study group appeared to work smoothly and the study statistician confirmed that the computerised randomisation system worked efficiently. After randomisation, study materials (study questionnaires and PRCI if allocated) for the control and intervention group were posted to the woman within 24 -48 hours of her notifying the researcher of a positive pregnancy test. Study participants found, both the concept and process of randomisation acceptable.

In the QPE all respondents noted that they had understood the notion of randomisation as described in the PIS. Two interview participants who were randomised to the control group voiced some disappointment that they had not received the study intervention. However, the fact that this study included an element of randomisation did not affect participant’s willingness to participate in the study (Box 2).

Box 2 – Qualitative views on the randomisation process

*I mean I wanted the card and I was disappointed that I didn’t get that group, but I get the point of it all and I know how it works (S44)*

*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 (S44)*

### Study questionnaires – related feasibility outcomes

#### Pre-Intervention Demographic Questionnaire

Study participants completed this form at the time of recruitment. 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. Figure 3 presents and compares the baseline information and sample characteristics of the intervention and control groups.

#### The Hospital Anxiety Depression Scale (Zigmond and Snaith 1983)

Study participants were asked to complete the questionnaire on eight occasions at weekly time points from a positive pregnancy test (normally around 4 weeks of pregnancy) until 12 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. Questionnaires were provided in a paper format and participants were asked to return them in a prepaid envelope. Returned questionnaires were all completed correctly, there were no missing data and the forms were completed according to guidance.

#### Weekly Record Keeping Form (Boivin and Takefman 1995)

Participants were requested to complete this questionnaire weekly, alongside the HADS, up until 12 weeks of pregnancy (but to discontinue if they experienced a further miscarriage). Whilst the study findings suggest that overall participants completed the questionnaire as requested there were some problems noted regarding rating of the positive emotions listed on the WRK. The scoring system on this questionnaire asked users to rate the impact of the emotional or physical reactions they had on their ability to perform daily tasks, however, the response scale did not relate to the intensity of these reactions. Analysis of the completed WRK forms suggested that the response scale was not appropriate for rating the positive emotional reactions such as ‘happy,’ ‘hopeful,’ ‘encouraged’ and ‘optimistic’ in an applicable way. For example, the highest score on the response scale was 3, described as a ‘markedly negative effect on how well they were performing their daily tasks.’ This made it impossible for participants to accurately rate the positive emotions (e.g. happy) on the WRK.

Despite this apparent flaw with the rating system of the WRK, qualitative evidence from the interviews suggests that participants actually found the WRK a helpful and supportive questionnaire and interpreted the upper core of 3 as an intensity rating (i.e., experienced to high degree).

Overall, the interviewees in the QPE shared numerous positive reflections on the use of the questionnaires that appeared to be independent from the use of the PRCI. In addition, participants appeared to view the questionnaires as a form of intervention, suggesting that completion of the questionnaires may have promoted psychological wellbeing. The self-adaptation of the questionnaires into an intervention and source of support appeared to focus on two main areas. Study participants used the questionnaires as a tool to help reflect on the difficult emotions they were experiencing during the waiting period, encouraging an awareness of their emotions, anxieties and feelings, and utilised the weekly completion of them as a method of monitoring the pregnancy’s progression (Box 3).

Box 3 – Qualitative views on the study outcome measures

*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 a problem to write it down and it just gets it out of your head (S28)*

*The questionnaires 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 (S47)*

#### The intervention – related feasibility outcomes

### Intervention –related feasibility outcomes

Previous studies had shown no negative side effects of the PRCI (Lancastle and Boivin 2008; Ockhuijsen et al. 2013b; Ockhuijsen et al. 2014b). Despite this, it was important in this study to determine the acceptability of the intervention for use by women with RM as there was a potential that participants would find the use of this self-administered intervention unacceptable. The study PIS introduced the concept of positive reappraisal and participants were given the opportunity to ask questions about it at the time of consent. No potential participants expressed concerns or declined taking part in the study as a result of a positive coping intervention being tested and all seemed amenable to the idea of using the PRCI.

Participants who received the PRCI were asked to read and reflect upon it at least twice a day and to record how often they actually used it during the previous week when they completed the WRK. An important aspect of assessing the feasibility and acceptability of the intervention was to determine frequency of use of the intervention and descriptive statistics were used to show its use. Answers on the WRK indicated that all women used the PRCI but there was some variation in the frequency of its uses as illustrated in the Figure 4.

Figure 4 Frequency of using PRCI during eight weeks of study use (weeks 4-12 of pregnancy).

Qualitative feedback from the QPE added significantly to understanding the participants’ perceptions of the PRCI. During the interview they were asked to comment on the practicalities of using the intervention and to share their personal reflections of using it.

First impressions and initial reactions to the PRCI were, on the whole, questioning of how such a simple intervention was going to help them manage their anxiety. However, despite initial reaction there was a positive attitude and willingness to engage and participants appeared agreeable to persist with the intervention (Box 4).

Box 4 – Qualitative views on the intervention

*When I first saw it I actually thought it was a bit awkward. I thought how am going to use this to make myself feel better or remind myself to stay positive? (S47)*

*When I actually sat down and really thought about each one* (the statements on the PRCI) *very carefully, it made sense and it really helped me to think about those things (P3)*

Respondents were asked to comment on the frequency with which they had used the PRCI. This varied considerably with some interviewees stating that they used the card more at the beginning of the waiting period and others suggesting they used it more as the pregnancy continued as they became more familiar with the intervention and concept of positive reappraisal. However, participants individualised how often they used the PRCI frequently utilising the intervention at time points when their anxiety levels were most elevated.

Box 5 – Qualitative views on the frequency of use of intervention

*It would suddenly be five am every morning that I was waking up in complete panic, that’s the only way I can describe it, then I would have a cup of tea and sit and read the card and think right OK just calm down (S31)*

*Last thing before I go to bed was always a real worry time for me so I would make sure that I read it at least once, sometimes a couple of times …. So what I ended up with was a technique very personal to me (P3)*

Despite initial reservations regarding the use of the PRCI, without exception, all of the interviewees offered varied and candid positive perspectives on the use of the intervention. There was a consensus that the PRCI promoted a positive re-evaluation of the waiting period and that it encouraged an appreciation of the positive aspects of their lives and a renewed appreciation of the everyday things in their life. These positive aspects had often been forgotten and lost within the overwhelming feelings of anxiety experienced about the new pregnancy.

There were mixed accounts of whether the PRCI actually helped or reduced the anxiety the participants were experiencing. Some women expressed the belief that it had really helped to alleviate their worry and others suggested that intervention sustained their ability to cope with the continued anxiety during the waiting period (Box 5).

Box 5 – Qualitative views on psychological impact of intervention

*It just made me feel less anxious and made me change how my mind worked really rather than feeling like everything was crashing down (S56)*

*It didn’t necessarily reduce my anxiety but it did definitely help me cope with the 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 … I truly believed it helped me (P3)*

*Actually it really did work, maybe not all the points, but the ones that really made it for me was the think of something positive today … 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 tomorrow will be another day (S31)*

This study was not statistically powered to formally calculate the effectiveness of the PRCI at improving psychological well-being of women during the waiting stages of a new pregnancy following RM. However, the quantitative and qualitative data did make it possible to assess some of the impact of the intervention on measures to be used in a future RCT. Descriptive statistics and graphical displays compared and contrasted the psychological measurement anxiety scores within the control and intervention groups to generate data to help inform the power calculation for a definitive clinical study of the PRCI.

Figure 5 : Mean weekly HADS anxiety scores for PRCI and control groups.

There were differences in the HADS anxiety level pattern between the intervention and control group as demonstrated in Figure 5. 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 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 HADS 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 IVF 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 identified that several study participants suggested that their anxiety levels were indeed reduced as a result of completing the study questionnaires. Although another previous study of the PRCI showed that the use of the PRCI did not significantly reduce anxiety level during miscarriage waiting periods (Ockhuijsen et al. 2014b). One possible reason for the reduced anxiety levels in the PRCI group in this study with RM patients, could be that the participants were a psychologically vulnerable sample due to their past history of RM. In a qualitative study of women with miscarriage determining views of the usefulness of the PRCI 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 the intervention might be more acceptable to a ‘higher risk’ patient population. As such, the PRCI might be most useful for those women needing to deploy coping effort, because their available current coping resources are not sufficient to match the perceived threat (i.e. another miscarriage), resulting in greater levels of anxiety.

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 and summarising findings when assessing feasibility research. Figure 6 summarises the key feasibility findings of this study against the methodological issues for feasibility research.

## Discussion

The results of this RCT feasibility and acceptability study highlight a number of areas pertinent to feasibility that require further exploration. The work of Lancaster et al. (2004) provides a specific and practical structure to assist with the reporting of feasibility studies as does the recent CONSORT extension for reporting pilot and feasibility studies (Eldridge et al. 2016). Each of the following sections address key aspects of feasibility highlighted in these works.

### The recruitment process

In general, the evidence from this feasibility study suggests that successful recruitment to a future definitive study investigating the use of the PRCI with women with RM is possible and that there is an appropriate and sizeable population willing to participate, but recruitment can vary between sites.

Possible explanations to explain the variability in recruitment across the two study sites included the fact that in Site B, there were fewer participants than expected, a lack of on-site researcher to act as a champion to promote the research study and no named clinical lead for RM patients. In addition, because recruitment was taking place on the EPU and not in a specialist RM out-patient clinic, patients were being seen at the time of their miscarriage. This may have affected clinical staff’s decision whether to invite potential participants to take part in the study, especially if they were distressed about their miscarriage during the consultation.

As with many trials, recruitment to this feasibility study in Site B, proved more difficult than anticipated at the outset of the study and this study has highlighted the need to consider recruitment issues on a site-by-site basis. However, this study has enabled a more comprehensive understanding of some of the facilitators and barriers to recruitment and identified that consideration should be given not only to the organisational barriers, but also to the health professional barriers to recruitment that can vary between study sites. This is an important feasibility finding and emphasises the need to consider the broader processes of recruiting participants when planning recruitment sites in a future definitive multi-centre study of the PRCI.

### 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. 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 QPE highlighted a major feasibility and internal validity issue, focusing particularly on the WRK. This questionnaire was intended as an instrument to measure emotional and physical reactions during the study time-period. However, many participants reported using the questionnaire 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 reactions 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 it provides the user with continuous and immediate feedback of their situation (Bornstein et al. 1986). It has been shown to have therapeutic effects due in part to the reactive effects of the self-monitoring activity (Korotitsch and Nelson-Gray 1999).

In this feasibility study, the WRK provided study participants with an opportunity to spend time reflecting on the physical and emotional reactions 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.

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) also highlighted the potential reactivity effects of the WRK questionnaire. Specifically it concluded that women could experience a positive or negative effect as a result of rating their emotions, physical symptoms, appraisal and coping (Ockhuijsen 2014) .

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) exploring 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.

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 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. Ockhuijsen et al. (2014a) showed that when the PRCI is used alone it demonstrates greater benefits than when combined with monitoring (on quantitative measures).

### The intervention

Acceptability has become an important consideration in the design, evaluation and implementation of health care interventions (Sekhon et al. 2017). Successful implementation of an intervention, such as the PRCI, depends on the acceptability of the intervention to the recipients. 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 RM 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 be 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 RM might be receptive to this intervention. However, a key finding showed 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. Interestingly, there was a general view among the participants that rather than adapting the PRCI guidance, they were 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. 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? It could be that allowing women to individualise their use of the PRCI would be the best guidance to provide.

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. Although the QPE 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. Previous quantitative research does show that using the guidance as provided to participants in the present study does increase ability to use positive reappraisal coping as measured by another unrelated measure (Domar et al. 2015). However, more in-depth understanding of how the PRCI sustains coping could be a target for future research.

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 may be 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 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

### Strengths and limitations of the study

This study addresses a novel area of research not previously investigated, as it focuses specifically on the early stages of a new pregnancy in women who have experienced recurrent miscarriage. 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 RM during the waiting period of a new pregnancy. The study has two main strengths: it used a mixed method approach, 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. Importantly, the QPE 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.

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. 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 QPE may have provided a more diverse and richer insight into the cultural effects of RM.

### Conclusion

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 RM. The study set out to assess the feasibility and acceptability of running a definitive RCT investigating the use of the PRCI by women with RM. The study successfully met its original objective determining that an effectiveness RCT of the PRCI is possible; however, it also highlighted the specific feasibility issues (specifically around recruitment and study outcome measures) that require consideration in the planning of a definitive study.

The study identified that study participants engaged with the PRCI, were receptive to it 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 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. The demand for healthcare continues to grow and the NHS is challenged to provide high quality, effective care within limited resources. Recent NHS policy advocates the need to ensure health services are designed around patients on a more sustainable footing (NHS England 2017). With that in mind, evidence generated in this study suggests that this model of care might already have 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. The next stage in this programme of research plans to build on the findings of this feasibility study, investigating the use of technical innovation strategies to develop and deliver a supportive package of care, of which the PRCI will be an important component, to support the psychological wellbeing of women with RM.

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**Excluded**

**Pregnant (n=8)**

**Participating in other research (n=5)**

**Fertility treatment (n=5)**

**Did not speak English (n=1**)

**Assessed for eligibility (n=126)**

**Approached to take part (n=107)**

**Excluded**

**Declined (n=6)**

**Loss of contact (n=26)**

**Withdrew from study (n=2)**

**Wished to take part in competing study**

**Recruited (n=75)**

**Notified researcher of positive pregnancy test (n=48)**

**Excluded**

**Notified researcher too late (n=1)**

**Randomised (n=47)**

**PRCI (n=24)**

**Control (n=23)**

**Interview (n=7)**

**Interview (n=7)**

**Completed study (n=20)**

**Completed study (n=22)**

**Did not complete study**

**Did not return complete set questionnaires (n=3)**

**Withdrew (n=1)**

**Did not complete study**

**Did not return complete set questionnaires (n=1)**

Figure 6: Study CONSORT flow diagram

|  |  |  |  |
| --- | --- | --- | --- |
|   | **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 |

| **Methodological issues** | **Findings**  | **Evidence**  |
| --- | --- | --- |
| 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  |
| 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 |
| 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) |
| 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  |
| 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  |
| 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. |
| 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 needs |
| 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  |
| 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  |
| 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  |
| 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  |
| 12. Was study retention good? | Retention rates good | Out of the 47 randomised participants, 42 completed the study  |
| 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  |
| 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  |