A feasibility and acceptability study of the Positive Reappraisal Coping Intervention: a supportive intervention for women with recurrent pregnancy loss

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Contributors

SB contributed to the design of the study, was responsible for obtaining ethical approval, liaised with the PPI group and collected study data. NM, JB, YC and CB contributed to the design of the study. SB and EK-R coded and analysed interview transcripts. All authors were involved in the interpretation of data. SB wrote first draft of manuscript, all authors were involved in subsequent revision and all approved final manuscript.

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Abstract

Research Question

Is it feasible to perform a future definitive trial to determine the effectiveness of the Positive Reappraisal Coping Intervention (PRCI) in improving the psychological well-being of women with recurrent pregnancy loss (RPL) during the early stages of a new pregnancy?

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Design

This mixed method study aimed to establish the feasibility of conducting a multicentre randomised controlled trial (RCT) to definitively test the effects of the PRCI on the psychological well-being of women with RPL. Participants (n=75) were recruited to the study and at the point of a positive pregnancy test, 47 were randomised into two study groups. The intervention group received the PRCI and weekly questionnaire assessment (Hospital Anxiety Depression Scale and Weekly Record Keeping Form) to monitor psychological well-being, the control group received the same questionnaires. Nested within the RCT was a qualitative process evaluation (QPE) exploring participants' subjective experience of study methods and the intervention. The study was conducted over a two-year period between 2014 and 2016

Results

This study successfully gathered 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 RPL. Participants were receptive to its use and the intervention appeared to convey benefits with no apparent downside.

Conclusions

The study concluded that a definitive RCT of the PRCI is possible and that the 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.

Keywords

Recurrent pregnancy loss, Anxiety, Randomised controlled trial, Feasibility

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Introduction

Recurrent pregnancy loss (RPL) is currently defined as the loss of three or more pregnancies within the UK (RCOG 2011). However, other countries have adopted different definitions and the recently published European Society for Human Reproduction and Embryology (ESHRE) guideline suggests that RPL should be considered after the loss of two or more pregnancies (ESHRE 2017). 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 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 and 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 RPL 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 RPL can experience during the early stages of a new pregnancy, they might find this concept difficult to understand and be sceptical about whether the PRCI, a self-managed intervention, is able to make them feel more positive. Therefore, to assess the potential value of the PRCI as a means of improving 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).

Effective feasibility or piloting work can anticipate difficulties with acceptability, compliance, delivery of the intervention and recruitment and retention (Craig et al. 2013). Correspondingly, a recent review concluded that the feasibility phase prior to an 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). Much of the literature that examines the theory around such studies, use the terms feasibility and pilot studies interchangeably and the language used to describe the preliminary stages of a large-scale definitive study remains inconsistent. However, the significant factor that connects the synonymous use of the terms 'feasibility' and 'pilot' study appears to be that both types of study address the uncertainties of study design and lay the foundation for a future definitive 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). Feasibility studies, therefore, play an important role in establishing appropriate study design to support successful study completion and may provide an indication of likely efficacy of the intervention.

The primary objective of this study was 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 RPL during the initial waiting period (1-12 weeks) of a subsequent pregnancy.

Materials and Methods

Study Design

Between February 2014 and March 2016, women with a history of RPL were recruited to participate in this two-centred mixed method study incorporating an RCT and qualitative analysis in a triangulation design. This approach was selected as it was considered to provide a broader understanding (Cresswell 2015) of both the acceptability and the possible effect of the PRCI in this clinical context.

In order to support the study design and increase the validity of findings (Lancaster et al. 2004), the research questions to be addressed were articulated as follows:

- 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 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 study protocol and methodology employed in this qualitative element has been previously published elsewhere (Bailey et al. 2015)

The Intervention

The PRCI (Figure 1) is a theoretically derived and short coping intervention with proven reliability and validity, based on the concept of positive reappraisal (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. The guidance also advises that thinking about the positive aspects of a difficult situation does not mean pretending that 'everything is wonderful' when this is not the case, or ignoring the negative aspects of the situation, but taking account of positive aspects alongside the negative.

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 and In Site B, access to potential participants was achieved through the site's EPU. Review of referral rates prior to recruitment suggested that approximately five eligible women would be seen in each centre per month.

Inclusion / Exclusion Criteria

All women who attended the RMC in Site A and the EPU in Site B who 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

The PRCI has only been previously applied in the context of recurrent miscarriage in one study (Ockhuijsen et al. 2015). This did not yield effect size, therefore, no clinical data was available on which to base a power calculation for the current study. Indeed one of the aims of the present feasibility study was to generate data that could inform a power calculation. Therefore, more pragmatic considerations were used to determine a sample capable, for example, of showing likely rate of referral of participants and feasibility of recruiting adequate numbers in a future definitive trial. 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.

For entry in to 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 were intended to produce a heterogeneous sample, and therefore included previous study group (intervention or control), ongoing pregnancy or miscarriage, ethnicity of

participant, age and number of previous live births. Fourteen participants were recruited to the QPE at which point data saturation was achieved.

Recruitment and Randomisation

Eligible participants were given a Patient Information Sheet (PIS) containing study information, by their clinical care team, when they attended the RMC or the EPU. The information was given once they had completed their consultation. If patients were interested in finding out more about the study, a meeting was arranged for detailed discussion 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 in order to enable randomisation, the aim being to achieve randomisation on the same day as the positive pregnancy test or as soon as possible after this.

Randomisation into the two study groups (intervention and control) 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 women receiving concurrent medical treatment for RPL, those with underlying medical conditions that were causative of RPL 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 and were advised to discontinue completing study questionnaires after their miscarriage. Prior questionnaire data from women who experienced 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 if they reached twelve weeks of pregnancy, had used the PRCI and completed the weekly questionnaire assessment, or in the case of the control group, if they had completed weekly questionnaire assessments. If a participant experienced a further miscarriage, they were still approached and invited to take part in an interview. In all cases, the participant contacted the researcher directly to inform them of their miscarriage and it was at this point they were invited to participate in the QPE.

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. The aim of the purposive sampling was to ensure that perspectives were collected from as diverse a group as possible.

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 RPL), 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 as possible thereafter) 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) which 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

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 RPL patients. However, the overall format of the

questionnaire was not amended. Furthermore, to 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 determining the feasibility of an intervention and optimising its design and evaluation (Moore et al. 2015). In the QPE, data were collected using face-to-face, semi-structured interviews that took place at a convenient place and time for the participant. The interviews followed a guide to steer the general direction of data collection and this was developed and based upon the feasibility aims of the study, 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 processes (numbers of eligible women, recruitment and retention rates, missing data) for each centre. Scores from psychological well-being measures and data from the DRK were summarised and changes over the course of the study examined informally by study statistics and via graphical displays. The relationships between physical symptoms, psychological well-being 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, aiming to achieve transparency by maintaining memos, field notes and a reflective diary during the process. Two members of the research team completed the initial coding of the raw data and developed the initial themes and this was discussed with other members of the research team who examined the transcripts and were asked to compare their perceptions of the interview data. The data was 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 participation 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

The specific structure previously proposed for reporting findings of feasibility studies (Lancaster et al. 2004; Eldridge et al. 2016) was applied.

Recruitment-Related Feasibility Outcomes

In total, 126 women were assessed for eligibility to participate in the study across the two study sites, of whom 19 did not meet 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 either failed to notify the researcher whether they had decided to take part in the study or the researcher was unable to contact them. A total of 75 participants were recruited to the study, 67 (89.3%) of these were from Site A where recruitment targets were exceeded. In contrast, in Site B, the number of women identified as potential participants fell well below the expected number, with a marked discrepancy between the estimated and actual recruitment rate. Despite an extended recruitment period and the provision of research infrastructure support systems, recruitment remained difficult at this site.

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

Participant recruitment and flow through the study and reasons for exclusions are outlined in the CONSORT diagram in Figure 2. No data relating to the proportion of patients who were approached and declined to participate or were not eligible were available form Site B.

All 14 women who participated in the QPE (for sample characteristics see Table 2) 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. The participants 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).

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 randomised to one of the study groups notified the researcher within 48 hours. One participant was excluded from randomisation, as she did not notify the researcher of her pregnancy 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 groups were posted to the woman within 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 participants' willingness to participate in the study (see Box 2).

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.

The Hospital Anxiety Depression Scale

Study participants were asked to complete the questionnaire on eight occasions at weekly intervals 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

Participants were requested to complete this questionnaire weekly, alongside the HADS, until 12 weeks of pregnancy (but to discontinue if they experienced a further miscarriage).

Overall, participants found the WRK a helpful and supportive questionnaire and interviewees shared numerous positive reflections on the impact of the WRK that suggested an effect additional to any effect of the PRCI. Participants appeared to view the questionnaires as a form of intervention, suggesting that completion of the questionnaires may have promoted psychological well-being. 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 (see Box 3).

Intervention – related Feasibility Outcomes

It was important in this study to determine the acceptability of the intervention for use by women with RPL 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 regarding this at the time of consent. No potential participants expressed concerns or declined taking part in the study as a result of a 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 this. 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 Figure 3.

Qualitative feedback from the QPE contributed significantly to understanding the participants' perceptions of the PRCI. During the interview, women 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 suggested a degree of scepticism as to how such a simple intervention could help in the management of their anxiety. But, overall there was a positive attitude and willingness to engage and participants appeared agreeable to continue with the intervention (see Box 4).

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 (see Box 5).

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 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 the intervention sustained their ability to cope with the continued anxiety during the waiting period (see Box 6).

This study was not statistically powered to formally calculate the effectiveness of the PRCI in improving psychological well-being of women during the waiting stages of a new pregnancy following RPL. 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 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.

There were differences in HADS anxiety scores between the intervention and control group as shown in Figure 4. The PRCI group shows a smooth, overall downward trend (reducing anxiety levels) as pregnancies progress, indicating 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 a notable increase in anxiety levels at week five of the questionnaire (week eight of pregnancy).

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. Table 3, based on the work of Bugge et al. (2013) summarises the key feasibility findings of this study against the methodological issues for feasibility research.

Discussion

This study aimed to establish the feasibility and acceptability of conducting a multicentre RCT to test the effects of the PRCI on the psychological well-being of women with RPL. The results provide a number of insights pertinent to the successful design of such a study, and of the likely value of the PRCI in this clinical context.

The Recruitment Process

Successful recruitment to a future definitive study investigating the use of the PRCI with women with RPL is shown to be possible. There is an appropriate and sizeable population willing to participate. However, as with many trials, recruitment at an external site proved more difficult than anticipated at the outset of the study, despite both using the same study protocol. A number of facilitators and barriers to recruitment were identified.

Lack of an on-site researcher to act as a champion to promote the research study and no named clinical lead for RPL patients were likely to have contributed to the relative under recruitment at Site B. In addition, because recruitment was taking place on the EPU and not in a specialist RPL outpatient clinic, patients were informed about the study at the time of their miscarriage. This may have discouraged the staff from inviting participation. These findings highlight 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 validation of data collection forms / questionnaires is fundamental to a feasibility study (Lancaster et al. 2004) and this is particularly important when the questionnaires are completed by the participants themselves. This includes ensuring that the selected questionnaires are the most appropriate data collection methods and provide researchers with the information they require.

The QPE highlighted a significant 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 assessment procedures that involve data collection by the client (Korotitsch and Nelson-Gray 1999), and provides the user with continuous and immediate feedback on 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 this encouraged an awareness of the emotions, anxieties and feelings they were experiencing, helping them to rationalise them and giving back a some 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

Although previous studies had shown no detrimental side effects of the PRCI (Lancastle and Boivin 2008; Ockhuijsen et al. 2013b; Ockhuijsen et al. 2014b), establishing the acceptability of the intervention to women with RPL was an important consideration of this study. Indeed, Sekhon et al. (2017) proposes that determining acceptability has become an important consideration in the

design, evaluation and implementation of health care interventions. Successful implementation of an intervention, such as the PRCI, depends on the acceptability of the intervention to the recipients. Certainly, there was a concern at the outset of this study that women with RPL 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 experience 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' willingness 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.

Graphical presentation of the HADS scores (Figure 4) demonstrated a notable increase in anxiety levels at week five of the questionnaire (week eight of pregnancy). This may reflect the frequency of miscarriages occurring around this gestation, after which the likelihood of an ongoing pregnancy increases. As pregnancies progress to this stage, participants may have begun to emotionally invest in the pregnancy, and to anticipate anxiety of the grief that would accompany a further miscarriage at this stage.

The HADS showed reduced anxiety levels in the PRCI study group. While a previous study has demonstrated a lower anxiety level in women who used the PRCI during the IVF waiting period (Ockhuijsen et al. 2014a), the effects of the PRCI on anxiety levels, were attenuated when combined with daily monitoring of the emotions, which itself was found to have an impact. Consistent with this, the qualitative process evaluation suggested that anxiety levels were reduced as a result of completing the study questionnaires. These observed quantitative effects of the PRCI could be used to make a power calculation for a future study in which impact on anxiety is the primary endpoint.

Although a previous study of the PRCI during miscarriage waiting periods did not reveal any effect on anxiety (Ockhuijsen et al. 2014b) these participants had no history of recurrent pregnancy loss. In a qualitative study of the perceived usefulness of the PRCI, women with only one past miscarriage did not see the need for such a coping tool, whereas those women with recurrent miscarriage did (Ockhuijsen et al. 2013a). The PRCI might therefore be most useful in those 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.

Another key study finding was that participants modified the 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 guidance to suit their needs or preference. 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 times when their anxiety levels were most elevated, using the card more frequently at the beginning of the waiting period and decreasing when they came to feel more confident that the pregnancy would continue. Others increased the use of the PRCI throughout the waiting period as they became familiar with both the card and 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 observation, which has previously been described (Ockhuijsen 2014; Ockhuijsen et al. 2014b; Ockhuijsen et al. 2015) points to the need to consider how and whether fidelity should be accurately monitored to ensure consistent implementation of the PRCI in a future definitive multi-centre study. It could be that allowing women to individualise their use of the PRCI is likely to increase its effectiveness.

A further finding of this study is the large number of variables influencing 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, may be 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 may be a limitation of the intervention and of this feasibility study.

The only quantitative measures of use of the PRCI in the current feasibility study were in the WRK questionnaire. Although the QPE added to the understanding of acceptability of the PRCI, it could have extended 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.

A key strength of this study is that its development and protocol was guided by an active PPI advisory group and this ensured the patient's perspective was central to the study. Study limitations included the fact that the majority of participants who took part in this study were of White British ethnicity, mainly due to the location of the study sites in the South of England. A more varied ethnicity sample may have provided a more diverse and richer insight into the cultural effects of RM.

In conclusion, this study successfully met its original objective determining that an effectiveness RCT of the PRCI is possible; it also highlighted specific feasibility issues (for example around recruitment and study outcome measures) that require further consideration in the planning of a definitive study. However, 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 public health systems are challenged to provide high quality, effective care within limited resources. 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. Future research will focus on technically innovative strategies to develop and deliver a supportive package of care, of which the PRCI will be an important component, to support the psychological well-being of women with RPL.

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