The Partnership and Coping Enhancement Programme for couples undergoing in vitro fertilization treatment: the development of a complex intervention in China

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Abstract

Purpose Couples as dyads suffer from the diagnosis of infertility and related treatment. These couples commonly experience emotional and physical pain and tension in their marital lives. The purpose of this study is to report on the process of

Capsule According to MRC framework, the Partnership and Coping Enhancement Programme for couples undergoing IVF treatment was developed. The programme is couple-based, consisting of experience sharing, psychoeducation, meditation exercise, skill practise and supplemental written materials.

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developing a potentially feasible and effective complex intervention for couples undergoing in vitro fertilization treatment in China.

Methods The Medical Research Council (MRC) framework for developing and evaluating the complex intervention was adopted to guide the development of the Partnership and Coping Enhancement Programme (PCEP). In developing the PCEP, three steps were taken, namely, (1) identifying evidence by conducting literature reviews, a concept analysis and a qualitative study; (2) identifying/developing a theory—in this case, a preliminary Endurance with Partnership Conceptual Framework (P-EPCF) was proposed; and (3) modelling the process and outcomes of the PCEP.

Results The PCEP that was developed is targeted mainly at the domains of the partnership mediators of stress in the P-EPCF. It consists of two sections—partnership and coping—and will be delivered to infertile couples on the day of embryo transfer. The main focuses of the programme are to facilitate mutual sharing and support in infertile couples, and to improve their individual and dyadic coping strategies while undergoing IVF treatment, especially in the period when they are waiting for the results of a pregnancy test and after the disclosure of a negative treatment outcome. The programme is couple-based, consisting of experience sharing, psychoeducation, meditation exercise, skill practise and supplemental written materials.

Conclusions The Partnership and Coping Enhancement Programme (PCEP) for couples undergoing in vitro fertilization treatment was developed according to the guideline of the MRC framework. It is recommended that a pilot study be conducted to evaluate its feasibility and to model the process and outcomes of the programme.

Keywords Couple-based intervention · Coping · Infertility · In vitro fertilization · Marital benefit · Partnership · Psychological well-being

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Background

It is well recognized that couples as dyads suffer from the diagnosis of infertility and its treatment [1]. These couples experience emotional and physical pain and tension in their marital lives [1]. When the couples pursue IVF treatment, the intrusive procedures and the low rate of success (18.4–20.3 %) adds to their distress [2].

A systematic review has indicated that during the IVF cycle, women experience elevated levels of anxiety and depression before the treatment, and that these levels rise on the day of oocyte retrieval, the pre-post embryo transfer, and during the period of waiting for the pregnancy test [3]. Among infertile couples, the men also reported elevated levels of depression prior to treatment and even higher levels during the 2-week waiting period [3]. An unsuccessful IVF cycle tends to result in long-lasting psychological trauma for both spouses [3].

In terms of its impacts on the couple's relationship, studies have reported that infertile couples had a lower level of marital satisfaction than their fertile counterparts [4, 5]. A study conducted in China indicated that women seeking IVF treatment were more likely than fertile women to report that their marriage was unstable [6]. It was reported that infertile couples who had undergone treatment for over 2 years were less happy with their marriage than those in their first 2 years of treatment [7]. Study has also shown that a couple's relationship is affected by infertility and its related treatment, and that this is a major reason why couples terminate IVF treatment [8]. This calls for health professionals working with infertile couples to turn their attention to the marital functions of these couples.

A variety of psychosocial interventions, such as cognitive behavioural therapy [9–11], mind body intervention [12–14], counselling [15–18] and positive reappraisal coping therapy [19, 20], have been adopted to improve the mental health, pregnancy rates and marital function of couples who undergo IVF treatment. However, in a review of the literature, the effects of relevant interventions tested in randomized controlled trial studies could not be confirmed due to methodological or practical issues [21]. Also, although the couples suffered from the stressful experience as dyads, the men of infertile couples have been neglected in most of the studies (65 %) [21]. Therefore, it has been suggested that an evidence-based complex intervention be developed for both males and females of couples undergoing IVF treatment [21].

Complex interventions are usually described as interventions that consist of several independent or interacting components [22, 23] and in which the process and outcomes are modeled [24]. The Medical Research Council (MRC) provides guidance on the development and evaluation of complex interventions to improve health [23]. In following this guideline, the research team has conducted a series of interrelated studies since 2014 to identify the evidence, identify/

develop a framework, and develop a potentially effective and feasible intervention for couples undergoing IVF treatment. This paper presents the process by which the intervention was developed.

Method

The MRC framework was adopted to guide the development of this Partnership and Coping Enhancement Programme (PCEP) [22, 23]. Four stages are proposed in the framework, from development, feasibility/piloting and evaluation to the implementation of a complex intervention. The development stage includes three steps, namely, identifying the evidence base, identifying/developing a theory and modelling the process and outcomes [23]. This paper presents the first stage in the development of the complex intervention, PCEP. The studies conducted in each step according to the MRC framework are outlined in Table 1. Ethical approval for the qualitative study was obtained from the Human Subjects Ethics Subcommittee of The Hong Kong Polytechnic University. Permission for access was sought from the relevant hospital in Hangzhou, Zhejiang Province, China.

Results

The steps taken to develop the Partnership and Coping Enhancement Programme (PCEP) are presented here. The three steps are as follows: (1) identifying evidence by conducting reviews of the relevant literature and carrying out a concept analysis and a qualitative study; (2) identifying/developing a theory—in this case, putting forward a preliminary Endurance with Partnership Conceptual Framework (P-EPCF) for couples undergoing IVF treatment; and (3) modelling the process and outcomes of the PCEP. It should be noted that the literature reviews [1, 3, 21], the concept analysis [25] and the qualitative study [26] have been published, and that the preliminary Endurance with Partnership Conceptual Framework (P-EPCF) [27] has been developed and is under review for publication. The key findings of these reviews and the studies that contributed to the development of this complex intervention are recaptured and presented in this report.

The identified evidence

According to the MRC framework, the first step in developing a complex intervention is to identify the existing evidence through a series of literature reviews and to conduct a concept analysis and a qualitative study.

Table 1 The three steps to developing a complex intervention according to the MRC framework and the studies conducted to develop the Partnership and Coping Enhancement Programme (PCEP)

Steps in the MRC framework for developing a complex intervention	Studies conducted to develop the PCEP
Identifying the evidence base	<ul style="list-style-type: none"> -Three literature reviews related to infertile couple were conducted: <ul style="list-style-type: none"> • <i>The Effects of Psychosocial Interventions on the Mental Health, Pregnancy Rates, and Marital Function of In Vitro Fertilization Patients</i> • <i>Gender Differences in Emotional Reactions to In Vitro Fertilization Treatment</i> • <i>Gender Differences in Experiences with and Adjustments to Infertility.</i> -Concept analysis of partnership in couples undergoing infertility treatment -Preliminary qualitative study: the experiences of Chinese couples undergoing in vitro fertilization treatment
Identifying/developing a theory	<ul style="list-style-type: none"> -Proposing a preliminary Endurance with Partnership Conceptual Framework (P-EPCF) for couples undergoing IVF treatment
Modelling the process and outcomes	<ul style="list-style-type: none"> -Developing and presenting the related contents of the Partnership and Coping Enhancement Programme

Literature reviews

Three extensive reviews were conducted to obtain a better understanding of the couples' experiences with infertility [1] and IVF treatment [3] and to examine the effects of established randomized controlled studies of psychosocial interventions on patients/couples undergoing IVF treatment [21]. The findings of the reviews provide some valuable suggestions on developing interventions for couples undergoing IVF treatment.

The findings of the first review indicated that the females of infertile couples had more negative experiences than their male partners, while both females and males were subjected to a stressful married life [1]. For both men and women of infertile couples, support from one's partner was inversely related to stress [1]. The second review found that the periods prior to the pregnancy test and after the IVF failure in the IVF cycle were the most stressful time points for both men and women [3].

The third review, focusing on relevant psychosocial intervention studies, revealed that the effects of various interventions on levels of depression, anxiety, stress, pregnancy rates, and marital function could not be confirmed [21]. The review also found that only one study included the enhancement of marital satisfaction in the intervention. None of the studies examined the effects of interventions on the psychological distress of the couples after the disclosure of the outcome of the treatment. It is concluded that a complex intervention, based on sound evidence, is needed for couples seeking IVF treatment [1, 3, 21].

The three reviews provided some constructive suggestions and recommendations about the timing of interventions for infertile couples undergoing IVF treatment. First, the

interventions should target infertile couples at the dyad level instead of focusing only on women at the individual level, as both the men and women of infertile couples were affected by infertility and the IVF treatment [1, 3]. Second, the programme should be aimed at enhancing the psychological well-being and marital relationship of infertile couples, as they experienced emotional distress and a stressful married life as dyads [1, 3, 21]. Third, the intervention could focus on improving the couples' coping strategies and partner support, as it has been suggested that these are two important mediators of infertility-related stress [1]. Finally, the timing of the interventions should cover the period during which couples are awaiting the outcome of the IVF treatment, and also when a negative pregnancy result has been disclosed [3, 21].

An analysis of the concept of 'partnership' in couples undergoing infertility treatment

In order to obtain a better understanding of the dyadic dynamics of the couples' responses to infertility and its treatment, an analysis of the concept of partnership was conducted [25] using Rodger's evolutionary method [28].

Through this concept analysis, the attribute of 'partnership' in couples undergoing infertility treatment was identified as a process of joint hardship for infertile couples, which they endure through sharing, communication, and mutual support [25]. The antecedents are love and attraction for each other, agreement on treatment goals, and interpersonal skills. The consequences of 'partnership' are marital benefit and improvements in psychological status and quality of life [25].

The findings of this concept analysis also shed light on aspects that should be considered when developing the complex intervention, namely, (1) the intervention should focus on

the enhancement of partnership to facilitate the process of sharing, communication, and mutual support in couples; (2) the intervention should take into account factors that influence the partnership, such as a couple's love and attraction for each other and interpersonal skills; and (3) the outcomes of the intervention should assess partnership in terms of marital benefit and improvements in psychological well-being [25].

According to the results of this concept analysis, a middle-range model for partnership was proposed (Figure S1). This model, which depicts a number of variables and their relationships, serves as a bridge between practice and theory in the related field [29].

A qualitative study—the experience of Chinese couples undergoing IVF treatment

A qualitative descriptive approach was adopted in a study to explore the experiences of Chinese couples undergoing IVF treatment, especially their perceptions of the treatment process and the support between partners. A content analysis of the interviews revealed four themes related to the experience of infertile couples: the process of hardship, enduring hardship with a loving relationship, the partnership in couples and ambivalence towards social support [26].

Based on the findings, a model on the experiences of couples undergoing IVF treatment was put forward (Figure S2). In Figure S2, the IVF treatment is conceptualized as a process of hardship involving physical pain, emotional pain, the pain of the urgency and inflexibility of bearing a child, and disturbance of daily routines and work. The partnership in couples is described as involving sharing and the receipt of tangible support from one's partner, which will contribute to the psychological well-being and marital benefit of the couple. Some unfavourable aspects of partner support were also identified, including a lack of involvement or partnership on the part of the male partner, and a lack of emotional support for males. The couples feel ambivalent about receiving support from others, such as family members, friends, and health care providers, and support from others plays a limited role in the couples' efforts to cope with the hardship of infertility and its treatment [26].

The participants in the interviews expressed a need to receive psychological interventions as part of the fertility treatment. This qualitative study provided insights for health professionals on the impacts of the IVF treatment on infertile couples, on the development of a framework and on the development of a supportive programme for these couples.

The proposed theory

According to the MRC framework, the second step in developing an intervention is to identify or develop a conceptual framework [22]. As no existing framework specifically for infertile

couples undergoing IVF treatment could be identified in a review of the literature, a preliminary endurance with partnership conceptual framework (P-EPCF) was proposed [27].

The P-EPCF was developed on the basis of the biopsychosocial theory of infertility (BTI) [30], and on the established theory of dyadic coping [30], which present a comprehensive picture of how individuals experience and adjust to infertility, and dyadic coping, respectively. The P-EPCF was then extended to include the middle-range model for partnership [25], and the model for the experience of IVF couples emerged from the qualitative study [26].

The proposed P-EPCF involves four domains (Figure S3). At the bottom of the diagram, the domain of the impacts of infertility and stressors represents the origin of the event or phenomenon, which refers to the experience of couples undergoing IVF treatment. The three dimensions of the dyadic outcomes domain are situated at the top of the diagram, and are comprised of psychological well-being, marital function and biomedical outcome (pregnancy). In the middle of the diagram, the domains of the mediators of partnership and coping; and dyadic moderators, act as the pillars and buffers for the impacts of infertility and stressors. In particular, the partnership and coping mediators are the main focuses of the framework [27].

This conceptual framework presents a comprehensive picture of the process by which couples cope with IVF treatment and its outcomes. It provides theoretical guidance on the development of a complex intervention, by including information on the components and dyadic outcome measures of the intervention, and the possible confounding factors.

The developed 'Partnership and Coping Enhancement Programme (PCEP)'

Modelling process and outcomes is the third step in developing the intervention according to the MRC framework. In accordance with the proposed P-EPCF, a Partnership and Coping Enhancement Programme (PCEP) was developed for couples undergoing IVF treatment.

Essential components of the PCEP

The PCEP mainly targets the domain of the mediators of stress in the P-EPCF, including partnership support and dyadic coping. The essential components of this programme were developed based on a handbook for infertility counselling [31]. The PCEP consists of two sections: dyadic partnership and dyadic coping.

According to the P-EPCF, the partnership mediator involves sharing and providing support in partnership. The main focuses of the section on partnership are to facilitate sharing and mutual support between the partners of an infertile couple. The key contents are: (1) awareness of gender differences in psychological status; (2) awareness of the essential elements

in infertile couples' sharing; (3) the modification of undesirable sharing behaviours; (4) the facilitation of tangible support between partners; and (5) the development of skills for enhancing mutual support.

The key focuses of the session on dyadic coping are to improve the dyadic coping skills of infertile couples. The key elements are as follows: (1) understanding different coping strategies; (2) promoting stress-antagonistic activities; (3) promoting infertility-specific coping strategies; (3) enhancing positive dyadic coping; and (4) shying away from negative dyadic coping. Details are given in Table 2 and include the titles, main focuses, contents, delivery approaches and duration of the PCEP. The sources from which these elements were drawn are also included.

Intervention approaches

The approaches adopted in this programme are psychoeducation and skill training. Psychoeducation refers to the integration and synergism of the psychotherapy and education provided to individuals and their families, which are usually delivered by professionals [34]. The premise of this approach is that the knowledge, awareness and strategies that clients and their families receive and act upon will improve the clinical and psychological outcomes of those involved [34]. In this intervention, the primary focus of psychoeducation is on enhancing the awareness of gender differences in psychological reactions to infertility and treatment and the positive aspects and strategies of sharing, partnership, support and dyadic coping.

Skills training refers to 'the teaching of specific verbal and nonverbal behaviours and the practising of these behaviours' [35]. In this programme, skills training focuses on a variety of skills, including couple sharing, mutual support techniques, dyadic coping and positive coping techniques.

Distributed handout

Written materials containing the essential elements of the intervention programme will be distributed. They supplement the sessions and help infertile couples to reflect upon and reinforce the knowledge and strategies that have been delivered. In particular, it could remind the couples of the approaches that can be used to deal with psychological distress when the negative outcome of the treatment is disclosed.

Measurements

Based on the Preliminary Endurance with Partnership Conceptual Framework (P-EPCF), the expected dyadic outcome measures are psychological well-being (anxiety and depression) and marital benefits (marital satisfaction and marital adjustment). The partnership mediator and dyadic coping, and

the dyadic moderators, are also measures as independent variables and controlled factors, respectively. These variables will be assessed at three points: baseline (T0: pre-intervention), 10 days after the embryo transfer (T1: waiting period) and 1 month after the embryo transfer (T2: follow-up). The relationship between the measurements and the components of the P-EPCF are listed in Table 3.

Psychological well-being will be measured using the 14-item Hospital Anxiety and Depression Scale (HADS) [36]. The three-item Kansas Marital Satisfaction Scale (KMS) will be adopted to assess the level of marital satisfaction perceived by infertile couples [37]. The 14-item Revised Dyadic Adjustment Scale (RDAS) will be utilized to measure the marital adjustment of infertile couples [38]. The partnership mediator in infertile couples will be evaluated using the 18-item Infertility Partnership Scale (IPS) [39]. The two-item evaluation of the dyadic coping subscale of the Dyadic Coping Inventory (DCI) will be employed to assess infertile couples' global satisfaction with dyadic coping [40].

The couples' dyadic moderators will be measured using the self-reported Background Information Form (BIF) to solicit information on demographic characteristics (age, level of education, duration of marriage, religion) and treatment factors (duration of infertility treatment, infertility diagnosis, previous IVF treatment, current treatment type, number of fertilized embryos). Loving relationships and interpersonal skills will be assessed using the self-developed questions based on relevant literature. The clinical pregnancy outcomes will be confirmed through a medical chart review 35 days after the embryo transfer.

The female and male partner of infertile couples will complete the measurement forms separately at three time points. The questionnaires for Time 1 and Time 2 will be given in two forms: the printed and electronic version. The participants will be asked to return them through express mail, email or in person, when they come to the hospital for a pregnancy test at 12 days after the ET and for an ultrasonic check at 35 days after the ET. The nurses in the reproduction centre will give a detailed explanation of all of the instruments and assist those couples who are unable to complete the forms.

Discussion

This paper reported the process of developing a complex intervention for couples undergoing IVF treatment in China. As directed by the MRC framework, three steps for developing the Partnership and Coping Enhancement Programme (PCEP) were presented: identifying evidence, identifying/developing a theory and modelling the process and outcomes of the intervention [22, 23].

Table 2 Description of the partnership and coping enhancement programme

Title/main focus	Contents	Delivery and duration	Sources
1. Dyadic partnership: Facilitating infertile couples' sharing and mutual support.	<ul style="list-style-type: none"> -Awareness of gender differences in psychological status; • Gender differences in experiences with and adjustments to infertility; • Gender differences in the emotional reaction to IVF treatment. - Awareness of the essential elements in infertile couples' sharing; • Recognition of gender differences; • Soft self-disclosure; • Active listening; • Emotional validation; • Keeping a balance between the partners' need to share. -Modification of undesirable sharing behaviours; • Incongruence between the 'pursuer' and the 'distancer'; • Inadequate discussion; • Vague complaints; • Derogatory labels for the partner. -Facilitation of tangible support between partners; • Understanding different forms of support; • Being aware of the approaches and effects of tangible support. -Development of skills for enhancing mutual support. • Recognition of the stress of oneself and one's partner; • Assertive skills; • Empathic joining skills; • Emotional support for the male partner. -Understanding different coping strategies; • Emotion-focused coping; • Problem-focused coping; • Appraisal-focused coping. -Promoting stress-antagonistic activities; • Building up a personal repertoire of pleasant events; • Relaxation technique: meditation. -Promoting infertility-specific coping strategies; • During the embryo transfer: relaxation music, guided imagery; • During the 2-week waiting period and after the disclosure of a negative outcome <ul style="list-style-type: none"> • Stopping thoughts because of irrational fears; • Laughing more and looking for humour; • Positively appraising the experience of infertility and its treatment; • Having realistic expectations of the treatment outcome; • Sharing experiences in social media-based support groups; • Turning to nature for comfort. -Enhancing positive dyadic coping; • Supportive dyadic coping strategies; • Common dyadic coping strategies; • Delegated dyadic coping strategies. -Shying away from negative dyadic coping. • Hostile dyadic coping behaviours; • Ambivalent dyadic coping behaviours; • Superficial dyadic coping behaviours. 	<ul style="list-style-type: none"> -Sharing experiences: couples' experience with sharing and support during the treatment (5 min) -Psychoeducation (with illustrations and examples): (30 min) -Distribution of written supplemental materials; -Skills in sharing and practice: practise soft self-disclosure, active listening, emotional validation, empathic joining, and assertive skills (10 min); -Homework: practise and implement the effective skills of sharing and support. 	<ul style="list-style-type: none"> -Handbook for infertility counselling [32] -Literature reviews [1, 3] -Findings from the qualitative study on the experiences of Chinese couples undergoing IVF treatment [26]
2. Dyadic coping: Improving the individual and dyadic coping skills of infertile couples.		<ul style="list-style-type: none"> -Recalling experiences: couples' individual and dyadic coping strategies (5 min); -Psychoeducation (with illustrations); -Distribution of written supplemental materials; -Exercises: <ul style="list-style-type: none"> • Practise meditation, self-guided imagery (15 min); -Homework: <ul style="list-style-type: none"> • Practise positive dyadic coping skills with your partner. 	<ul style="list-style-type: none"> -Handbook for infertility counselling [31]; -Theory of dyadic coping [33]; -Literature review [21].

Table 3 Correlation between the measurements of the Partnership and Coping Enhancement Programme (PCEP) and components in the Preliminary Endurance with Partnership Conceptual Framework (P-EPCF)

Variables	Instruments	Correlation with components in P-EPCF
Dyadic outcomes		
Anxiety and depression	-The 14-item Hospital Anxiety and Depression Scale (HADS)	-Outcomes: psychological well-being
Marital satisfaction	-The 3-item Kansas Marital Satisfaction Scale (KMS)	-Outcomes: marital functions
Marital adjustment	-The 14-item Revised Dyadic Adjustment Scale (RDAS)	
Dyadic mediators		
Partnership	-The 18-item Infertility Partnership Scale (IPS)	-Partnership mediators: partnership in couples
Dyadic coping	-The 2-item evaluation of the dyadic coping subscale of the Dyadic Coping Inventory (DCI)	-Dyadic coping
Dyadic moderators		
Demographic and treatment factors	-The self-reported Background Information Form (self-developed)	-Dyadic moderators: personal factors
Loving relationship and interpersonal skills	-The 2-item Likert Scale (self-developed)	-Dyadic moderators: couple factors

The systematic approach in developing the complex intervention

According to the MRC framework, sound evidence and an appropriate theory should be adopted in developing interventions [23]. In the process of developing the PCEP, a series of literature reviews were conducted to identify gaps in evidence and research. Then, the preliminary Endurance with Partnership Conceptual Framework (P-EPCF) specific to couples undergoing IVF treatment was proposed, based on the findings of the reviews, the analysis of the key concept of *partnership* and the interviews with couples undergoing IVF treatment in a qualitative study. In the third step, the Partnership and Coping Enhancement Programme (PCEP) was developed, guided by the proposed P-EPCF. Therefore, it could be expected that the PCEP would be more acceptable and effective than programmes that are merely based on empirical or practical evidence [23].

The focuses of the complex intervention

The PCEP was designed to focus on the partnership mediators and dyadic coping of the infertile couples. According to the P-EPCF, these two variables could mediate the impacts of the infertility and stressors of infertile couples, moderated by dyadic moderators, and lead to improvements in the domain of dyadic outcomes, including in psychological well-being and marital benefits, and possibly to an enhanced pregnancy outcome.

The evidence has indicated the necessity for supportive interventions focusing on enhancing the partnership and coping strategies of infertile couples. When an undesirable partner relationship has been identified among couples seeking IVF

treatment [26], it has been reported that the marital relationship could be a protective factor for interfile couples across different stages of the IVF treatment [41], particularly for women with negative treatment outcomes [42].

The findings of the literature reviews have revealed that positive coping strategies are related to the psychological well-being of women undergoing IVF treatment [43, 44]. It has also been proposed that positive dyadic coping could reduce the stress for each partner and improve the functioning of the relationship of couples coping with stress [30, 45]. Therefore, it is theoretically and empirically supported that the focuses of this new complex intervention should include the enhancement of partnership in the couples, as well as the improvement of dyadic coping skills.

The components of the Partnership and Coping Enhancement Programme (PCEP)

After determining the focuses of the programme, its detailed components were developed on the basis of established empirical and theoretical evidence. As discussed, various sources were used when developing the PCEP.

First, the handbook for infertility counselling provides the basis for the guideline to facilitate the strategies of sharing and support in couples [32] and provides an introduction to different coping strategies and to infertility-specific coping strategies [46]. The soundness of these strategies has been confirmed by the clinical and empirical literature. Second, the key elements for improving dyadic coping were adapted from Bodenmann's dyadic coping theory, including the enhancement of positive dyadic coping strategies, the shying away from negative forms of dyadic coping and the promotion of stress-antagonistic activities [30].

Third, meaningful findings from the reviews of the literature have also been incorporated in the intervention. It has been proposed that the marital problems of infertile couples may arise due to gender differences in the couples' reaction to infertility and to incompatible perceptions of the problem of fertility [47, 48]. Thus, key results of the previous reviews on gender differences were included in the programme [1, 3] to enhance the understanding of the differences between couples. Last, the results of the qualitative study that was conducted to explore the experiences of Chinese couples with IVF treatment also contributed to the components of this programme [26]. This interview in the qualitative study has identified the essential elements of partnership and raised awareness of what constitutes an undesirable partnership in infertile couples. These were integrated into the PCEP to enhance the partnership of infertile couples.

The complete components of the PCEP were finally decided in a discussion meeting that was held by the research team, which consists of medical and nursing specialists from the ART centre, experts on women's health and a PhD nursing student specializing in infertility psychology. This programme will be further tested in a pilot/feasibility study.

Limitations

This complex intervention has its limitations. First, some difficult time points such as pretreatment and oocyte retrieval are not targeted since the intervention will be delivered on the day of the embryo transfer. However, because a huge disparity exists in the duration from ovarian stimulation to embryo transfer, due to different treatment protocols and the type of embryo transfer (frozen or fresh aspiration), the decision was made to focus only on the two most difficult periods for couples undergoing IVF treatment, namely the 2-week waiting period and the disclosure of the outcome of the treatment.

Another limitation is that the provision of treatment-related information has not been integrated into the complex intervention. This is because health information relating to the IVF treatment will be delivered by the staff from the study ART centre to all participants as part of their routine care. Only the psychosocial aspects of the infertile couples are considered in the intervention programme.

Recommendations for future research

According to the MRC framework, the following stages in developing a complex intervention are feasibility/piloting, evaluation, and the implementation of the programme. Thus, it is recommended that a pilot/feasibility study be conducted before the full-range randomized controlled trial (RCT) is implemented. The research methodology that will be adopted in the feasibility study is presented below, and it includes information on the following elements: the prospective trial design,

the prospective participants, the prospective study settings, the delivery of the intervention and assurance of the quality of the study.

Prospective trial design

A feasibility study on the effects of the Partnership and Coping Enhancement Programme (PCEP) will be conducted. The aims of that study will be to test the procedure, estimate recruitment/retention and determine the sample size of the programme, as well as to test the validity and reliability of the instruments.

The participants will be distributed to a PCEP group or to a routine care control group. Couples in both groups will receive three 30-min sessions of routine health education from the clinic on medical information during the IVF cycle, while the PCEP group will receive an additional face-to-face, couple-based session of PCEP on the day of the embryo transfer. The main focuses of the PCEP are dyadic partnership and dyadic coping, which are aimed at improving the psychological well-being and marital benefits of couples undergoing IVF treatment.

Prospective participants

The target population of the feasibility study will be infertile couples undergoing IVF/ICSI treatment cycles. The criteria for inclusion in this study will be the following: (1) Chinese adult married couples; (2) couples undergoing IVF/ICSI treatment; (3) couples who have no biological children; (4) couples who are able to speak Mandarin (the official language of China) or read in Chinese; (5) couples in which both partners have agreed to participate in the study. The exclusion criteria will be the following: (1) couples who have previously taken part in a psychosocial intervention; (2) couples who are currently taking part in other psychosocial interventions; (3) couples with male partners who are unable to provide support due to a serious physical illness; and (4) couples in which either partner has a psychiatric disorder for which he/she is receiving psychiatric medication or psychological treatment.

Prospective study settings

The study will be conducted in a reproductive centre at a provincial hospital in Hangzhou city, Zhejiang province, China. Couples who meet the criteria for eligibility will be approached in the reproductive centre on the day of the embryo transfer, when both the male and female halves of the infertile couples are required to come to the centre. An explanation of the purpose of the research and the details of the intervention will be given to the couples by the researcher. Couples who have signed the consent form will be included in the study.

Delivery of the intervention

The couples in the PCEP group will receive the 90-min programme on the morning of the day of the embryo transfer. This face-to-face intervention will be delivered by the researcher, who has received training in couple therapy. The session will be couple-based, consisting of the sharing of experiences, psychoeducation, meditation exercises, the practicing of skills and the handing out of supplemental written materials.

Ensuring the quality of the study

Strategies will be adopted to ensure the quality of the study. First, to ensure the fidelity of the treatment, the researcher will directly deliver the intervention in a uniform way according to the protocol. The contents of programme, the procedure of the exercise and the topic for recalling experiences will be written in detail.

In order to ensure that the researcher follows the study protocol, the fidelity evaluation will be conducted by a trained research assistant, who will not be involved in any other procedure of the study. The assistant will randomly attend ten of the interventions over the process of this study. The contents and duration of the intervention will be evaluated. A checklist will be used to evaluate the delivery of key features of the treatment. The duration of the intervention will be recorded to indicate the researcher's compliance with the time. The reasons for non-compliance will also be noted down for analysis. Furthermore, the intention-to-treat (ITT) approach will be employed to avoid detection bias.

Conclusion

This study reported on the process of developing the Partnership and Coping Enhancement Programme (PCEP) for couples undergoing in vitro fertilization treatment, which was guided by the MRC framework for developing and evaluating complex interventions. This was completed with sound evidence from three reviews of the relevant literature, an analysis of the key concept of partnership, the findings of a qualitative study on IVF couple dyads and a proposed preliminary Endurance with Partnership Conceptual Framework (P-EPCF). It is recommended that a pilot study be conducted to test the feasibility of the programme, and to model its process and outcomes.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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