



Original Article

The development and evaluation of a web-based complex intervention: The caring for couples coping with colorectal cancer “4Cs: CRC” program

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ABSTRACT

Objective: This article aims to systematically present the completed process of developing and evaluating a web-based complex intervention called ‘Caring for Couples Coping with Colorectal Cancer “4Cs: CRC” program’; summarize the findings of this integrated supportive program; and provide valuable experience and suggestions for future interventions.

Methods: The integrated 4Cs: CRC program was guided by the Medical Research Council (MRC) framework, which has widely been used to develop and evaluate complex interventions. Three stages were completed for the program development, namely: (1) developing a complex intervention; (2) assessing feasibility; and (3) evaluating the complex intervention.

Results: Based on a series of interactive studies and a dyadic theoretical framework, the 4Cs: CRC program was developed into an integrated supportive six-week program that includes five weekly web-based interventions, as well as three biweekly face-to-face sessions. In particular, an online platform was designed to provide web-based interventions for couples facing colorectal cancer (CRC). Both the pilot study and qualitative process evaluation showed the program's preliminary feasibility, acceptability, and effectiveness.

Conclusions: Under the guidance of the MRC framework, the 4Cs: CRC program was developed based on multiple interacting components. The program was initially proven to be feasible, acceptable, and effective at supporting CRC couples in mainland China, but requires further improvements according to the qualitative process evaluation results. More importantly, a full-scale randomized controlled trial is required to further explore the program's effectiveness in a wider population.

Introduction

Colorectal cancer (CRC) is the second most common cancer in the world.¹ With CRC diagnosis and treatment, patients often experience both physical and mental issues, including pain, sexual dysfunction, and depression.^{2,3} Spouses of cancer patients, as the primary caregivers, also face multiple challenges, including a heavy caregiving burden, lack of knowledge, and role conflicts.^{3,4} Over time, both partners tended to report similar and poorer cancer adaptation results, such as lower marital satisfaction and worse quality of life, than before.^{4,5} Moreover, patient adaptation is not only affected by their own coping behavior, but also by their spouse's behavior and adaptation, and vice versa.^{5,6} Therefore, as couples face CRC, it can be considered a dyadic process, suggesting it is important to treat CRC couples as dyads.⁷

Based on the fact that for couples, the CRC-related stress and

adaptation process is multifaceted and interactive, complex couples-based interventions are required to support CRC patient-spouse dyads.^{2,3,5} Complex interventions refer to interventions composed of multiple interacting components, which have standardized intervention functions and procedures.^{8–10} A wide variety of complex interventions has been carried out in the healthcare field.⁹ After a series of complex processes (eg, iterative phases with qualitative and quantitative methods) to explore the active intervention components, mechanism of action, and range of intervention effects, researchers can gradually develop well-designed and more effective healthcare programs.^{9,11,12}

In recent years, couples-based interventions have widely been used to support cancer couples, most of which successfully improved cancer adaptation.^{13–16} However, some studies have shown that interventions delivered through traditional face-to-face methods may place an additional time and travel burden onto cancer couples.^{16,17} With the

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development and widespread adoption of mobile devices, particularly smartphones, mobile health (m-health) has become deeply integrated into our lives, and has even changed the way we seek medical information.^{18,19} Web-based m-health has been used in psychosocial intervention research to deliver medical information and health services to patients and their families.^{17,20,21} Web-based interventions enable participants to obtain credible information at their convenience, which increases the flexibility of interventions, helps reduce participant time and travel burden, and further increases intervention recruitment and retention rates.^{20–22} In addition, web-based interventions are private and confidential,^{21,22} particularly for those with intimacy issues (eg, sexual dysfunction), who may prefer online consultations and appointments, to better protect their privacy.²² Furthermore, some studies have proved that web-based interventions are cost-effective, feasible, and acceptable in improving the quality of life of patients and their families.^{20,23} Based on the above reasons, it is necessary to develop web-based complex couples interventions to better support CRC couples in their journey of coping with the disease as dyads.

Consequently, a web-based complex intervention designed to support CRC couples, that is, the Caring for Couples Coping with Colorectal Cancer (4Cs: CRC) program, was developed by our research team. Based on the completed process, we gradually determined a more effective intervention program for CRC couples. The aims of this article are to:

1. Systematically present the completed process of developing and evaluating the 4Cs: CRC program;
2. Summarize the findings of this integrated supportive program;
3. Provide valuable experience and suggestions for future interventions.

Methods

The integrated 4Cs: CRC program was guided by the Medical Research Council (MRC) framework, which has widely been used to help researchers develop and evaluate complex interventions.^{9,10} Four phases for a complex intervention were identified by the MRC, namely development, feasibility and piloting, evaluation, and implementation.^{9,24} The development phase, involving identifying existing evidence, determining a theory, and modelling process and outcomes, is the basis for a complex intervention. Pilot studies are the key to assisting researchers in determining an intervention's preliminary feasibility and effectiveness. And process evaluations can help researchers recognize possible factors that could influence the intervention implementation. This article reports on the first three completed 4Cs: CRC program phases, including development, piloting, and evaluation. As shown in Table 1, based on the MRC's framework, we outlined the first three key steps to developing and evaluating a complex intervention, as well as the corresponding elements taken to develop the 4Cs: CRC program. All research procedures were approved by the Research Ethics Committee of Jiangnan University and the Affiliated Hospital of Jiangnan University (JNU20200312IRB09 and JNU20200731RB01).

Results

According to the MRC framework and relevant study literature, the following content presents the development of the 4Cs: CRC program from these three aspects: (1) developing a complex intervention; (2) assessing feasibility; and (3) evaluating the complex intervention. All study literature related to the development of this program has been published in a variety of journals. This section re-illustrates and summarizes the main findings of previous work to help us systematically understand the completed development process of the 4Cs: CRC program.

Developing a complex intervention

Identifying existing evidence, identifying a theory, and modelling process and outcomes are three steps in developing a complex intervention.

Table 1

The Key Steps to Developing and Evaluating a Complex Intervention According to the Medical Research Council (MRC) and the Corresponding Elements in Developing the Caring for Couples Coping with Colorectal Cancer (4Cs: CRC) Program.

Steps in the MRC framework	Steps taken to develop the 4Cs: CRC program
Developing a complex intervention	
Identifying existing evidence	<ul style="list-style-type: none"> √Conducting a face-to-face couples-based intervention for Chinese couples with advanced cancer, namely, the Caring for Couples Coping with Cancer (4Cs) program √Conducting qualitative and quantitative studies to explore the situation of Chinese couples living with colorectal cancer (CRC) √Conducting a literature review to systematically summarize the communication needs of cancer patients and their caregivers √Conducting a literature review to summarize the relevant aspects of dyadic web-based interventions that support cancer patients and their caregivers
Identifying a theory	√Identifying a preliminary Live with Love Conceptual Framework (P-LLCF) for CRC couple dyads
Modelling process and outcomes	√Developing and presenting related content of the web-based 4Cs: CRC program
Assessing feasibility	√Conducting a pilot study to examine the feasibility of the integrated web-based 4Cs: CRC program for Chinese CRC couples
Evaluating a complex intervention	√Conducting a qualitative study to assess the process of the pilot web-based 4Cs: CRC program

MRC, Medical Research Council; 4Cs: CRC, Caring for Couples Coping with Colorectal Cancer; 4Cs, Caring for Couples Coping with Cancer; CRC, Colorectal Cancer; P-LLCF, preliminary Live with Love Conceptual Framework

Identifying existing evidence

Identifying existing evidence based on preliminary studies and literature reviews is the first step in developing a complex intervention.^{9,10}

Our previous intervention program, called “Caring for Couples Coping with Cancer (4Cs)” has provided a methodological base for the 4Cs: CRC program. The 4Cs program, the first such program of its kind in mainland China, was based on a series of scientific studies to support cancer couples coping with the disease as dyads using traditional face-to-face group sessions and a guidebook.^{10,25} We reported that the 4Cs program recruitment and retention rates were 86.7% and 78.6%, respectively, comparable to rates seen in other similar interventions.²⁵ The program was found to significantly improve most outcome variables for cancer couples, including self-efficacy, dyadic coping, couples' communication, quality of life, and psychological adjustment.²⁵ It can be seen that the 4Cs program was acceptable, feasible, and effective in supporting cancer couples coping with the disease together. However, we also discovered some program limitations that should be studied further.^{25,26} For example, the traditional face-to-face delivery method reduced flexibility in terms of time and place, which may increase the burden on cancer couples and researchers alike. Thus, more flexible delivery formats (eg, m-health) are required, to reduce barriers to completing such programs. The heterogeneity of the study population dealing with different types of cancer could have influenced the intervention effectiveness, reminding us that we need to focus on couples facing a specific type of cancer, for example, CRC couples. Considering these needs, a new web-based 4Cs: CRC program was proposed to better support CRC couples coping with the disease as dyads.

To provide scientific evidence for the development of the web-based 4Cs: CRC program, we conducted qualitative and quantitative CRC couples-based studies exploring CRC couples' characteristics,^{27,28} a literature review identifying cancer patient and caregiver communication needs,²⁹ and a critical literature review summarizing specific aspects (eg, intervention content and intervention results) of existing cancer patient-caregiver dyadic web-based interventions.³⁰

Specifically, in the qualitative study, both partners in a couple confirmed the importance of the support and sharing they received from their partner as part of their positive adaptation to the various challenges (eg, insufficient communication, lack of care knowledge, role conflicts, and financial burden) they faced in their journey of coping with CRC.²⁷ The quantitative study results supported the dyadic interdependence of cancer patients and their spouses in terms of quality of life, benefit finding, anxiety, and depression.²⁸ The findings of these two studies call for the development of couples-based dyadic interventions to support CRC couple dyads.^{27,28} Furthermore, a literature review that systematically summarized the communication needs of cancer patients and their caregivers, found that most cancer patients and caregivers expect more opportunities to communicate with health professionals, and their specific communication content needs vary according to disease stage and treatment.²⁹ This required healthcare professionals to develop interventions based on the specific needs and preferences of cancer patients and their caregivers.²⁹ Another critical literature review, based on existing cancer patient-caregiver dyadic web-based interventions, concluded that future interventions should be multi-component, including information support, communication and support, skills building, and psychoeducation.³⁰ This review determined the satisfaction with, and feasibility, acceptability, and positive effects of web-based programs. However, it also found that due to the limitations of online delivery (eg, a lack of personalization and participant difficulties in using electronic devices), interventions delivered through a combination of online and traditional face-to-face methods may be more effective in supporting cancer couples through this process.³⁰

Identifying a theory

In a systematic review of psychosocial interventions for couples coping with cancer, Badr et al. pointed out that dyadic couples interventions based on individual-level theoretical frameworks may be hindered in terms of implementation.¹⁶ To strengthen the program feasibility, a dyadic theoretical framework called “preliminary Live with Love Conceptual Framework (P-LLCF),” specifically proposed to support cancer couples as dyads, was identified as the theory for developing the 4Cs: CRC program.^{26,31} The concepts, statements, and theories it contains have been proven to be applicable to cancer couples by a mixed-methods study.³² Furthermore, the 4Cs program results further support the rationality and feasibility of using the P-LLCF to design complex supportive interventions.^{25,33} The P-LLCF encompasses three interacting cancer couple dyadic domains: Event situation, dyadic mediators, and caregiver-patient dyads.³¹ As shown in [Supplementary File 1, Figure S1](#), event situation, that is, the contextual factors and stressors encountered by cancer couples, is located at the bottom of the framework as the driving force for cancer couples' coping. Dyadic mediators, located above the event situation, aim to balance or mitigate stressors. As for caregiver-patient dyads, these consist of dyadic appraisal, dyadic coping, and dyadic adjustment/outcomes, directly or indirectly influenced by the event situation and dyadic mediators. All elements contained in the framework interact and work together to achieve positive dyadic outcomes for cancer couples, which is the P-LLCF's central goal.

Modelling process and outcomes

In this step, the ‘Caring for Couples Coping with Colorectal Cancer “4Cs: CRC” Program’ and an online education platform were developed based on the P-LLCF. The literature review of cancer patient-caregiver dyadic web-based interventions³⁰ also served as a guide for modelling the intervention process and outcomes.

Main content of the 4Cs: CRC program. This program, which lasts six weeks, includes five weekly web-based interventions and three biweekly face-to-face sessions. Combining the three domains of the P-LLCF (Event situation, dyadic mediators, and caregiver-patient dyads) with the results summarized in the literature review, the 4Cs: CRC program includes

the following content: psychoeducation, supportive information, online chatting, and skills training.^{26,30} In particular, psychoeducation consists of five components, following the domains in the P-LLCF, specifically primary stressors (part 1); secondary stressors (part 2); dyadic coping (part 3); dyadic appraisal (part 4); and dyadic mediator (part 5).

Online platform. An online education platform was developed based on existing research and the P-LLCF to deliver web-based interventions. As [supplementary file 2, Figure S2](#) shows, the online platform contains six modules: Dyadic learning sessions, health information, cancer news, online support, sharing circle, and personal center. The dyadic learning sessions, focusing on the above five psychoeducation components, aims to provide specific psychological education, information, and strategies on how couples can cope with CRC as a unit. Moreover, couples will be reminded by weekly phone messages to participate in the weekly dyadic learning sessions. It should be noted that dyadic learning sessions is the online platform's core module. Detailed content from the dyadic learning sessions is presented in [Table 2](#). Health information is designed to offer cancer couples information on CRC, symptom management, care, treatment, and a healthy lifestyle ([Table 3](#)). Cancer news provides the latest official cancer news for CRC couples. Meanwhile, participants may consult the researchers on issues related to the disease, personal concerns, or the 4Cs: CRC program at any time through the online support. In the sharing circle, participants can share their personal insights on valuable topics with other users. The personal center includes such things as online questionnaires, homework, and written reminders.

Face-to-face sessions. Face-to-face sessions are delivered in weeks 2, 4, and 6. Each session lasts 60–90 min. The main content of the face-to-face sessions is intended to encourage CRC couples to review the online course content from the previous two weeks, to practice online learning strategies, and to discuss the homework. The last face-to-face session reviews the overall program's main content.

Outcome measures. Based on the “4Cs” program, multiple tools are adopted by the “4Cs: CRC” program to evaluate couples' outcomes.²⁶ Self-efficacy, as the dyadic mediator, will be assessed by the cancer behavior inventory. Couples' cancer-related communication (dyadic appraisal) will be evaluated by the cancer-related communication problems within the couples scale. Furthermore, how couples cope with stress as dyads (dyadic coping) will be examined by the dyadic coping inventory. Quality of life, benefit finding, anxiety and depression, and marital satisfaction (dyadic outcomes) will be measured by the medical outcomes study 12-item short form and European Organization for Research and Treatment of Cancer quality of life-CR29 (EORTC QLQ-CR29), the benefit-finding scale, the hospital anxiety and depression scale, and the revised dyadic adjustment scale, respectively. All outcome measurement tools used in the “4Cs: CRC” program have been determined by other studies to be reliable and valid.^{10,34–41} These outcome measures will be taken at baseline (T0), immediately after the last intervention (T1), three months after the program (T2), and six months after the program (T3). In addition, participants' basic information (eg, demographic information) will be collected at baseline. It is noteworthy that participants can choose to complete these questionnaires online or on paper, according to their preference.

Assessing feasibility

MRC has recommended that pilot studies be conducted to identify key uncertainties (eg, recruitment and retention rates) during the implementation of a complex intervention.⁹ From October 2019 to January 2020, a single-group (pre-post) pilot study was conducted to examine the feasibility, acceptability, and initial results (T0 and T1) of the “4Cs: CRC” program in mainland China. Consistent with the content introduced in

Table 2
Detailed Information on Online Dyadic Learning Sessions.

Domains title	Contents	Multiple components
Primary stressors Take care of your spouse with cancer	Assisting with medical care - Helping with medications - Dealing with common symptoms - Going with your loved one to medical visits Helping with daily life - Assisting with eating and drinking - Use of special equipment Providing emotional support - Taking care of your spouse's emotions - Relaxation activity: Slow rhythmic breathing (video) √/Homework - Discuss in this session what aspects benefit your situation.	Information Psycho-education Skills-building
Secondary stressors Adapt to your role as a patient–caregiver	Self-cognition - Cognitive restructuring - Looking for the positive Self-care - Understanding your feelings - Caring for your body - Make time for yourself - Relaxation Activity: progressive muscle relaxation (video) √/Homework - Writing down three positive things you have seen or experienced every day, and sharing with your partner for at least 7 days.	Information Psycho-education Skills-building
Dyadic coping Mutual support and coping together	Positive facing - Finding meaning in illness/caregiving - Finding new meaning in your life after cancer - Relaxation activity: meditation (video) Active coping - Setting your priorities - Dyadic coping strategies and working as a team - Problem-solving skills Proper help - Learning to ask others for help √/Homework - Share with your partner how each of you is coping; discuss choices you can make together.	Information Psycho-education Skills-building
Dyadic appraisal Effective and genuine communication	Learning to communicate with your partner - Caregiver–patient congruence - Sharing stress with your spouse - Understanding your Partner's inner world - To be a good listener Improving dyadic communication skills - Bringing up difficult topics with your loved one - Appreciating your partner - Making a date with your partner - Finding ways to get close to each other √/Homework - Partner-assisted communication and emotional disclosure - Written emotional disclosure for 15–20 min a day over 3–4 days	Information Psycho-education
Dyadic mediator Rebuild confidence and return to society	Enhancing your sense of self-efficacy - Sense of self-efficacy - Provides positive feedback to spouse Caring for your relationships - Your relationship with the person you are caring for - Involving children - Your relationships with family and friends √/Homework	Information Psycho-education

Table 2 (continued).

Domains title	Contents	Multiple components
	- List 10 positive qualities you see in your partner, and brainstorm about the strengths you share as a couple to cope with cancer.	

Table 3
Contents of Healthy Information Module.

Category	Contents
Common knowledge of colorectal cancer	Incidence Risk factors General symptoms Propagation mode Screening methods Prevention
Common symptom management	Diarrhea Constipation Pain Nausea and vomiting Appetite changes Hair loss Infection Fatigue Sleep disturbance
Essential self-care nursing skills-buildings	Ostomy care Ostomy complications Venous duct care
Healthy lifestyle after cancer	Diet food and nutrition Exercise Sexual changes
Managing your emotions	Reducing stress Keeping hope Coping with fear Coping with loneliness

“Modelling process and outcomes,” the pilot study provided online and face-to-face supportive sessions for Chinese CRC couples within a six-week period.²⁶ The pilot study’s feasibility was examined by recruitment and retention rates. The pilot study’s acceptability was evaluated using intervention completion rate, open-ended questions, and a post-intervention assessment questionnaire adapted from the USE (Usefulness, satisfaction, and ease of use) scale, which includes items on usefulness, ease of use, and satisfaction (Table 4 for detailed information).⁴² Further, the aforementioned outcome measures were used to assess the initial results of this pilot intervention, whose details have been previously reported.²⁶ As a result, 20 couples facing CRC completed the entire program. The recruitment, retention, and completion rates were 70.6%, 83.3%, and 85.0%, respectively. Most participants were very pleased with the program’s usefulness in increasing their knowledge and ability to cope with cancer, the ease of use of the online platform, and the satisfactory intervention content and delivery format. Moreover, the preliminary general intervention effect sizes were small to medium.²⁶

Evaluating the complex intervention

Researchers can realize facilitating or hindering mechanisms/factors associated with implementation and outcome variables by evaluating the intervention process, which will provide a basis for larger-scale studies.^{9,43} To comprehensively evaluate the “4Cs: CRC” program, a semi-structured face-to-face qualitative process evaluation was conducted on CRC couples and intervention facilitators who had participated in the feasibility study, to explore their feelings and experience with the program implementation.⁴⁴ Couples revealed that this new blended method of combining face-to-face sessions with an online platform not only brought them closer to the facilitators, but also freed them from time and space constraints when consulting on personal issues. These were all

Table 4

Post-intervention Assessment Questionnaire Adapted From USE (Usefulness, Satisfaction, and Ease of Use) Scale.

Category
Usefulness
The content of program is useful
The online platform is convenient for me and saves me time when I use it
The online platform includes important information I want
Ease of use
The online platform is easy to use
I found what I was looking for quickly and easily
The online content is easy to understand and follow
Satisfaction
I am satisfied with the intervention content
I am satisfied with the delivery format (combination of online and in-person delivery)
I would recommend it to someone else
The program has
Increased my knowledge about colorectal cancer
Improved my ability to cope with cancer with partner together

Items were rated on a seven-point Likert type scale, 1 = strongly disagree, and 7 = strongly agree.

factors that increased their motivation and adherence to the program. Almost all couples were thankful for the 4Cs: CRC program, which provided an official cancer learning platform, and created a supportive environment for mutual support and open communication between themselves and their partner. Moreover, most couples affirmed the program's positive impacts on improving their self-confidence, communication, dyadic coping, and adaptation to CRC. In the qualitative process evaluation, influencing factors, challenges, and valuable suggestions for program improvement were also identified. Cancer couples' ability to use a smartphone and their views on the program in terms of intervention content, delivery, and significance may be the key to encouraging them to successfully complete the entire program. For facilitators, on the other hand, flexible handling of emergencies, control of the intervention process, and the integration of participants' personal characteristics were the main challenges in the implementation process. Importantly, couples suggested that updating online courses more frequently, providing more detailed dietary information, and adding more images to the online content could make the program more attractive.⁴⁴

Discussion

According to the MRC framework, this article systematically presents the completed development process of our web-based complex intervention program, 4Cs: CRC. Based on the results and findings of a series of studies undertaken in the development of this program, this article provides reliable methodological experience and a basis for researchers to develop more feasible and effective dyadic cancer couples-based interventions.

The 4Cs: CRC program was developed based on a series of interactive studies and a dyadic theoretical framework. These interactive studies, including preliminary studies and literature reviews, were the best available evidence to systematically ensure the rationality of the program content and methods.¹⁰ The dyadic theoretical framework P-LLCF, specifically proposed to support cancer couples as dyads, improved the applicability of the 4Cs: CRC program supporting CRC couples. It can be seen that the 4Cs: CRC program is feasible, acceptable, and effective.

The recruitment, retention, and completion rates of the 4Cs: CRC program were comparable to or even higher than those of other similar cancer couples-based interventions.²⁶ This shows that this novel blended intervention delivery model combining online and face-to-face delivery formats is indeed feasible and acceptable to CRC couples. The online platform is both a cost-effective and time-effective intervention delivery method.^{21,45} For cancer couples who are struggling with treatment-related expenses and live far away from a clinic, online

delivery methods provide access to free and convenient treatment options.²¹ Thus, cancer couples may be more disposed to participate in online interventions. Meanwhile, a certain amount of face-to-face interaction is still necessary.^{30,46} Face-to-face delivery can bring participants closer to facilitators, create suitable conditions for training couples in communication and a variety of skills, and strengthen couples' adherence to an intervention.^{14,47,48} The significant recruitment, retention, and completion rates of the 4Cs: CRC program may verify the advantages of blended delivery by simultaneously enhancing participants' willingness to complete and adhere, to an intervention. Future interventions could combine more emerging technologies (eg, websites and social applications) with traditional face-to-face delivery formats, to increase intervention, feasibility, and acceptability.

CRC couples reported improvements in their self-efficacy, communication, dyadic coping, and adaptation to CRC after participating in the pilot 4Cs: CRC program, in line with the results of other interventions for cancer patients and their spouses.^{13,25} The effectiveness of this pilot intervention reaffirmed the appropriateness and applicability of the P-LLCF, reminding us that more interventions aimed at supporting cancer couples can be developed under the guidance of the P-LLCF. In addition, it is worth noting that the online dyadic learning sessions module content was designed according to each domain described in the P-LLCF.²⁶ Thus, researchers should be aware of the significance of a theoretical framework that not only helps them understand relevant study concepts, but also guides research development.⁴⁹

The results of the qualitative process evaluation provide important evidence for developing a more effective intervention program for couples facing CRC. Based on the qualitative process evaluation findings, facilitators need to explain the program to couples and provide detailed instructions on how to use the online platform, to ensure that couples can successfully join the program.³⁰ On the other hand, there is a need for a more attractive online platform that updates courses more frequently, provides more detailed dietary information, and adds more images to the online content. Notably, the qualitative evaluation study found that not only participants, but also facilitators, encountered a variety of challenges during the intervention process. During interventions, participants are more likely to express themselves and ask additional questions that need to be answered, creating challenges for facilitators beyond their regularly scheduled duties.⁴⁴ We suggest that facilitators should receive diverse training courses (eg, role play and group exercises) before the intervention commences, to help them respond more flexibly to emergencies and achieve the intervention goals more effectively.^{14,44} Researchers can consider these recommendations for the successful implementation of future web-based interventions.

Although both the pilot study and the qualitative process evaluation showed the preliminary feasibility and effectiveness of the 4Cs: CRC program, there were still some factors that made it impossible for us to conclusively determine the program's effects. First, this pilot study lacked a control group. Some factors outside of the study may have affected the intervention results, making it difficult for us to draw a clear conclusion about the program's effectiveness. Second, the pilot intervention sample size was small, so it might not be possible to generalize the study findings to a wider population. Moreover, the single-group pilot study did not have sufficient evidence to determine whether the blended intervention is superior in supporting CRC couples, compared to nonblended face-to-face and nonblended web-based interventions. Researchers have stated that studies are required to evaluate the effectiveness of different delivery methods in the same population within one specific randomized controlled trial (RCT).^{50,51} In particular, Sethi et al. emphasized the need for four-arm RCTs that comprehensively compare blended interventions with face-to-face intervention alone, online intervention alone, and usual care.⁵² To further determine the effectiveness of the 4Cs: CRC program and determine the most successful delivery method for supporting CRC couples, we are currently conducting a large full-scale RCT consisting of three experimental groups and one control group. CRC couples who meet the eligibility criteria will be randomly assigned to one of the following

four delivery methods: (1) traditional face-to-face sessions, (2) online platform-based sessions, (3) the 4Cs: CRC program combining face-to-face delivery and an online platform, or (4) usual care. It should be noted that the content and dosage of the three experimental groups is consistent.

Limitations

This study had some limitations. Given that the web-based complex 4Cs: CRC program was only tested in a small-sample pilot study, we are unable to draw a clear conclusion at this point as to whether the program would be feasible, acceptable, and effective for a wider population. A large full-scale RCT is underway to further evaluate the program's effectiveness. In addition, the web-based complex 4Cs: CRC program was only carried out in mainland China, therefore, the generalizability of the results may be affected by individual cultural backgrounds.

Clinical implications

Despite these limitations, our detailed description of the complex program development and evaluation process will enable further replication studies and disseminate valuable experience for future research. In particular, the development process and preliminary results of the 4Cs: CRC program will provide healthcare professionals with ideas on how to implement feasible and 4Cs: CRC effective interventions for cancer couples. Healthcare professionals can develop more complex intervention studies in accordance with the MRC framework, and integrate more emerging technologies with traditional face-to-face methods to increase the feasibility, acceptability, and effectiveness of cancer couples-based dyadic interventions.

Conclusions

Under the guidance of the MRC framework, the 4Cs: CRC program was developed based on multiple interacting components, including preliminary research, literature reviews, and a specific theoretical framework. A pilot study verified the initial feasibility, acceptability, and effectiveness of the program in supporting couples dealing with CRC in mainland China. However, the program needs to be improved further according to the findings of the qualitative process evaluation. Importantly, a full-scale RCT is required to explore the effectiveness of the 4Cs: CRC program in a wider population. This detailed description of the program development process will enable further replication studies according to the comprehensive guidelines in the MRC framework. Moreover, the program development process and preliminary results can provide healthcare professionals with ideas on how to implement feasible and effective interventions for cancer couple dyads coping with the disease.

Authors' contributions

Meizhen Chen: Conceptualization, methodology, investigation, writing—original draft. **Jiali Gong:** Investigation, writing—original draft. **Qian Cao:** Investigation, writing—original draft. **Qiuping Li:** Writing—review and editing, supervision. All authors read the final draft of this manuscript and approve its submission for publication.

Declaration of competing interest

None declared.

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Appendix A. Supplementary data

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