

Development of A Nurse-Led Educational Intervention Program in Managing the Nutrition Impact Symptom Cluster in Patients with Nasopharyngeal Carcinoma following the Medical Research Council Framework

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ABSTRACT

Objective: This article aimed to report the experience of developing a complex nurse-led, theory-driven, and evidence-based educational intervention program intended to manage the nutrition impact symptom cluster experienced by patients with nasopharyngeal carcinoma (NPC) during radiotherapy, based on the Medical Research Council (MRC) framework. **Methods:** The “development” and “feasibility and piloting” phases of the MRC framework were used to guide the intervention development. The development phase included identifying the evidence base through a systematic review, exploring the relevant and guiding theory to enhance the effectiveness of the intervention and conducting a qualitative study to identify the intervention modelling. For the feasibility and piloting phase, we conducted a pilot study to examine the feasibility and estimate the effectiveness of the intervention. **Results:** The systematic review revealed that nurse-led educational interventions were used commonly for symptom cluster management, with promising effectiveness. The theoretical foundation was provided by the Theory of Unpleasant Symptoms, which indicates that an educational intervention can help patients

to manage symptom cluster by influencing psychological, situational, and physiological factors. The qualitative study further provided contents of the intervention based on the perspectives of NPC patients and health professionals. The resulting program involves a nurse-led, family caregiver involvement, educational intervention with two sessions that uses a booklet as a medium. The pilot study found that conducting the educational intervention program was feasible and it also had some favorable effects on managing the nutrition impact symptom cluster in NPC patients. **Conclusions:** The MRC framework provided a strong structure with which to develop a complex intervention for nutrition impact symptom cluster management through a theory-driven and evidence-based approach. The evaluation of the intervention, the delivery process and the mediation mechanism of change using a rigorous randomized controlled trial design is recommended.

Key words: Educational intervention, medical research council framework, nasopharyngeal carcinoma, nurse-led, radiotherapy, symptom clusters, symptom management

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Introduction

Compared with other cancers, nasopharyngeal carcinoma (NPC) is rare with an incidence rate of 1.5 per 100,000 in 2020.^[1] However, it shows an extremely unbalanced geographic distribution and is endemic in Southern China with an annual incidence of 15–20 cases per 100,000 reported, thus is known as “Cantonese cancer.”^[2,3] Radiotherapy (RT) alone or in combination with chemotherapy is the main treatment strategy for NPC,^[4] and modern therapeutic modalities have yielded improvements in tumor control. However, the symptoms frequently arise during treatment, and these remain a major concern for NPC patients.^[5] Among these, nutrition-related symptoms such as taste change, xerostomia, sticky saliva, sore throat, and anorexia are the most frequent and severe complaints.^[6] In addition, most of these symptoms escalate during week 3 of a 6- to 7-week RT regimen and continues to worsen throughout the treatment course.^[7] Accordingly, these symptoms may lead to treatment interruption, psychological distress, decreased functional status, and a poor quality of life (QOL).^[8–10] The timely identification and management of these symptoms are warranted to improve patients’ outcomes.^[11]

Ample evidence demonstrates that symptoms often occur in clusters, rather than in isolation, which may exacerbate the overall symptom experience.^[12–14] A symptom cluster is defined as two or more related symptoms that co-occur, form a stable group and are relatively independent of other clusters.^[15] Research on symptom clusters is regarded as cutting-edge science at an important frontier of symptom management during cancer care.^[16] Managing a symptom cluster as a whole, rather than treating single symptoms, could be more efficient and effective.^[14,17,18] A previous cross-sectional study ($n = 130$) conducted by our research team identified the nutrition impact symptom cluster experienced by NPC patients during RT.^[19] The six symptoms within this cluster include mouth/throat sore, difficulty swallowing/chewing, problem with mucus, problem with teeth or gums, problem with tasting food, and constipation. This symptom cluster has been rated by NPC patients as the most severe, and therefore, its management warrants the utmost importance.^[19]

Educational interventions are used broadly in cancer care to prepare patients by providing them with adequate knowledge and skills to perform self-care practices, with the aim of improving their psychological and physiological outcomes.^[20] Among these, nurse-led educational interventions intended to help patients manage their symptoms are feasible and effective.^[21] Nurses are usually the first clinicians to meet the patients and identify their needs in symptom management, and these professionals

thus play a key role in providing self-care information and teaching symptom management skills.^[22,23] However, most educational interventional studies on the management of nutrition-related symptoms experienced by NPC patients only targeted single symptoms.^[24]

To fill this research gap, we developed a nurse-led, theory-driven, and evidence-based educational intervention program for NPC patients, which aimed to help manage the nutrition impact symptom cluster. The intervention was developed following the guidance of the Medical Research Council (MRC) framework, a flexible and nonlinear approach to design a new and complex intervention process. The MRC framework was selected because the educational intervention program was complex and contained several interacting components, including behaviors, parameters of behaviors (e.g., frequency and timing), and methods of organizing and delivering those behaviors, such as the type of intervener, setting, and location.^[25] A systematic and scientific framework can enhance the effectiveness of such a complex intervention.

With this article, we aimed to disseminate our experience with the development of a complex educational intervention program intended to manage the nutrition impact symptom cluster experienced by NPC patients during RT, following the MRC framework. This article provides a useful reference by reporting the details of complex intervention development and also contributes to enhancing the current knowledge of nutrition impact symptom cluster management in NPC patients.

Methods

The MRC framework comprises four interconnected phases: “development,” “feasibility and piloting,” “evaluation,” and “implementation” of a complex intervention.^[25] This study adopted the first and second phases to guide the intervention development. The development phase of a complex intervention contains three steps: Identifying the evidence base, identifying/developing theory and modelling process and outcomes.^[25] First, we conducted a systematic review to identify the relevant and existing evidence base of psychoeducational intervention on managing symptom clusters. Second, we explored the relevant and guiding theory that would enhance the effectiveness of the intervention. Third, we modelled a complex intervention by identifying the components and their relationships and conducted a qualitative study to help define the relevant components. The purposes of the feasibility and piloting phase include: Testing procedures, estimating recruitment and retention, and determining sample size.^[25] Accordingly, we conducted a pilot study to

examine the feasibility and estimate the effectiveness of the intervention.

Results

Identifying the evidence base

To identify existing evidence regarding the effectiveness of psychoeducational intervention for managing symptom clusters in cancer patients, we performed a systematic review of eligible randomized controlled trials (RCTs) identified from the following six databases: CINAHL, MEDLINE, the British Nursing Index, Embase, PsycINFO, and the Cochrane Library. A total of 240 articles were identified, and four studies were ultimately included and analyzed.^[17,26-28] The methodological quality of most included studies was fair, although a small sample size and selection and detection biases were observed in some studies. The review suggested that psychoeducational intervention seemed to be effective for managing symptom clusters and improving functional performance in cancer patients. Patient education was the most commonly used type of psychoeducational intervention and yielded promising effects on symptom cluster management. Potentially useful intervention delivery strategies include provision by nurses in an individual format and during the active cancer treatment period. The review also revealed a research gap, namely that future large-scale and theory-driven research is needed to test the effectiveness of nurse-led educational interventions with respect to symptom clusters. Detailed information on this systematic review can be found in our previous publication.^[24]

Identifying/developing the theory

From our comprehensive literature review, we identified the Theory of Unpleasant Symptoms (TOUS) as the most commonly used theory and used this to guide our intervention. The TOUS was developed in 1995 and updated in 1997 by Lenz *et al.*, who advanced the theory from a purely linear model (unidirectional relationships among components) to a more interactive model that allowed the experience of multiple symptoms simultaneously.^[29,30] The TOUS has three major reciprocal components: Symptom experience, influencing factors, and functional performance. The central concept concerns symptoms, which can occur in isolation or, more often, in combination with others as clusters. Physiological, psychological, and situational factors comprise the three interrelated categories of factors that influence the symptom experience. The examples of physiological factors include normal systems, pathological problems, and nutritional adequacy. Psychological factors encompass the mental state or mood, degree of uncertainty, and level of knowledge. Situational factors

include the sociodemographic status, access to social support, and lifestyle behaviors. Functional performance is a consequence of the symptom experience, and includes physical functioning, activities of daily living, social activities, role performance, and cognitive performance. Besides, the TOUS developers recognized the QOL as another important outcome of the symptom experience and are exploring its position in the theory.^[11]

Overall, the TOUS asserts that three interrelated influencing factors affect the nature of the symptom experience, which in turn affects the functional performance and QOL. Our educational intervention was designed to exert influences on the three interrelated influencing factors described by the TOUS. Specifically, the intervention aims to provide self-care information that will affect psychological factors by increasing the patients' level of knowledge, reducing their uncertainty and improving their mood; to teach self-care skills that will influence situational factors such as oral hygiene maintenance and to provide dietary guidance to facilitate patients' nutritional intake and improve the physiological factor of nutritional status. The impact of the intervention on these three interrelated factors would be expected to generate better patient outcomes, including nutrition impact symptom cluster relief, a better functional performance, and an improved QOL. Figure 1 illustrates the analytical model that depicts the hypothetical relationships between the intervention and outcomes.

Modelling process and outcomes

A qualitative study of both NPC patients and health professionals was conducted to provide information about the intervention components and contents with respect to nutrition impact symptom cluster management. A descriptive qualitative study based on face-to-face semi-structured interviews was designed to explore the following four objectives: NPC patients' experiences with self-care while managing the nutrition impact symptom cluster; current clinical practice regarding symptom cluster management; barriers to symptom cluster management and

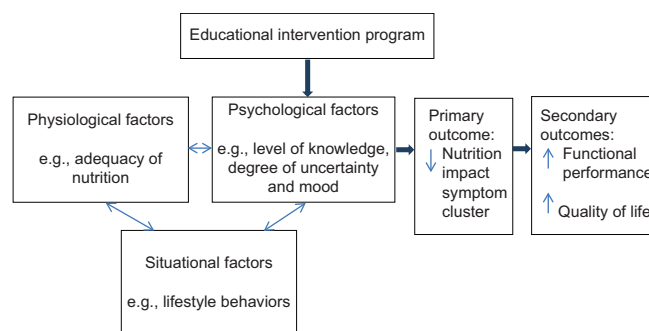


Figure 1: Analytical model depicting the hypothetical relationship between intervention and outcomes

strategies for improving symptom cluster management. Ethical approval was obtained in advance from the Survey and Behavioural Research Ethics Committee of the Chinese University of Hong Kong. Purposive sampling was used to select the participants who had experiences and ideas on the topic and were willing to discuss these with the researcher. All participants signed consent forms before data collection began. Twenty-five NPC patients undergoing RT and 16 health professionals, including 11 nurses and five doctors who worked in the NPC department of Sun Yat-sen University Cancer Center in southern China, participated in this qualitative study. Interview data were tape-recorded, transcribed verbatim and analyzed using content analysis. Table 1 summarizes the themes, sub-themes, and selected quotes from the perspectives of NPC patients and health professionals. NPC patients highlighted their unsatisfied needs regarding symptom cluster management information, despite their awareness of some pharmacological and nonpharmacological approaches. Problems with self-care practice including deficiencies in knowledge and skills, misconceptions and improper practices, and psychological burdens were reported. Health professionals also recommended enhancing patient education and providing psychological support to improve symptom cluster management. Barriers related to the health-care system, patients and family caregivers, and other people were identified in NPC patients' self-care of the nutrition impact symptom cluster.

The results indicated that the design of an educational intervention program should consider the following elements. First, the self-care knowledge and skills contents should encompass basic information about the nutrition impact symptom cluster, symptom preventive and management strategies, drug usage, oral care, dietary adjustments, and lifestyle modification. Traditional Chinese medicine-related self-care knowledge should also be provided. Psychological support can be embodied in the patient education process. Specifically, while delivering patient education, the intervener should listen to patients, clarify misconceptions, encourage self-care activities and above all, instil hope in the patient. Second, self-care knowledge can be delivered in a straightforward manner and demonstrations and return demonstrations can enable skill acquisition. Patients should be able to express their thoughts and raise questions freely throughout the intervention process. Third, a booklet should be designed to reinforce the patients' learning. This booklet should include large font, simple wording, and more pictures to improve readability. Fourth, reinforcement of the intervention before RT commencement is essential during RT. Fifth, inviting caregivers to participate in the intervention can

help to promote patients' self-management and relieve their psychological burdens. Sixth, nurses with adequate knowledge in the symptom management are recommended to deliver patient education. For health professionals, continuous education and training are also important for sustaining the clinical application of the educational intervention programme.

Nurse-led educational intervention and rationale for development

The nurse-led educational intervention, which is based on the development phase of the MRC framework, is a complex intervention that contains several interrelated components intended to address the symptom cluster as a whole. The design and delivery of the intervention are summarized in Table 2.

Intervention delivery

According to the systematic review and qualitative study, the intervention should be given in the week before the RT commencement and reinforced during week 3 of RT. Accordingly the intervention was designed to be delivered in two sessions over approximately 3 weeks. In this study, the first and second intervention sessions were estimated to have durations of 30 and 20 min, respectively. The delivery of the first intervention session within a week of RT commencement aimed to prevent symptoms, as patients would be unlikely to forget what they had learned in such a short time. According to the literature, the intervention should be reinforced in the middle of RT.^[31] Our qualitative study further suggested the importance of such a session during RT, as some patients would not treat their symptoms seriously until they became obvious. Week 3 was identified as the optimal choice, as symptoms begin to arise and continue to worsen at this point,^[7] and patients would therefore be most willing to learn self-care strategies that might reduce their distress. Accordingly, a reinforcing session at this time can be most effective.

Face-to-face individual education by nurses

The systematic review and qualitative study indicated that nurses are the most appropriate facilitator for delivering the educational intervention. Furthermore, an individual format was identified as more manageable because it could accommodate patients' different RT schedules. As mentioned earlier, the intervention was designed to be delivered in two sessions. The first session is delivered during the week before RT commencement. In this session, self-care information, such as the basic details of nutrition impact symptoms and preventive and management strategies, are introduced and self-care skills, such as toothbrushing and flossing, are demonstrated using a model of the mouth and other aids. A return demonstration is

Table 1: Self-care experiences and practice from the perspectives of NPC patients and health professionals

Themes	Sub-themes	Selected quotes
NPC patients		
Impact on eating	Dietary changes	"Regarding meat, I can only eat (meat) soup. Moreover, regarding chewing meat, I cannot swallow it. Without saliva, it feels dry when you chew it" (P20:128)
	Reasons for eating less	"I wanted to eat many kinds of food, but could not taste anything. Moreover, the throat sores make it hard to swallow. That's it" (P17:140)
Patients' self-care practice	Pharmacological approaches	"Doctors prescribed some oral sprays. I use (epidermal) growth factor once daily and I spray pain killer to mouth before eating" (P7:55)
	Nonpharmacological approaches	"Even if I cannot taste anything, I have to eat... So I only have one thought - that I must eat for my life. Former patients also told me this. Or the RT might be interrupted. That is to say, I have to eat even with my eyes closed. How to say... you don't want to eat at all if not for life" (P1:54)
The role of TCM	Believing in TCM	"After the completion of RT, I will use TCM to recuperate my body. Um, my next step is to recuperate my body by using TCM" (P11:262)
	Cultural remedy practice	"... I drink some herbal tea to clear away heat, such as honeysuckle, chrysanthemum, or ginseng tea" (P3:32 and 36)
	Confusion over dietary restrictions	"In our hometown (Jiangxi), finless eels cannot be eaten. However, here (in Guangdong) it is said (finless eel) can be eaten..." (P19:98)
Problems existing in patients' self-care practice	Deficient knowledge and skills	"I don't want to eat eggs, because I feel pain when chewing the hard and big eggs. I didn't eat egg custard, because I never thought of cooking eggs that way" (P23:44, 52, 48 and 50)
	Misconceptions and improper practices	"With regard to analgesics, I also know something. Your pain has to get to a certain level... you only take analgesics once you cannot bear the pain. I still have nine RT sessions to go. What if the analgesics have no effect when I get pain in the future?" (P13:105)
	Psychological burdens	"Usually, before I got sick, it was me who did all the housework. He (patient's husband) did not do (any housework). Now things have changed. So it creates a lot of trouble for him" (P5:182)
Information needs on self-care	Sources of information	"Some (of the self-care information) was given to me by the nurse, and some was got from books. My wife bought a cook book for preventing and fighting cancer in order to learn how to choose and prepare food and soup. She bought that book and followed it" (P4:50)
	Insufficient self-care information	"I think we patients have very limited (self-care) knowledge. (Health professionals should) teach patients how to prevent treatment-related distress step by step. I think (health professionals) should not wait and take action only when symptoms occur. It seems like you deserve this. It is real suffering" (P13:81)
	Need for more information	"... I know doctors and nurses are busy... Actually there are a lot of solutions... I think since they have so much experience... Actually if they are busy, they can... design some booklets..." (P13:81)
Health professionals		
Usual care of symptom management	Seeing a dentist before RT	"In our hospital, patients' teeth were cleaned before RT. If there were rotten teeth, they would be pulled out beforehand" (H5N:40)
	Conducting patient education	"... Upon signing the informed consent (of receiving RT), we will tell him (patient) about his disease, side effects of RT... what may possibly happen, there will be a weight loss,... and what he needs to do in term of (maintaining good) nutrition" (H15D:62)
	Prescribing relevant medicine	"We use some external medicine to promote the repair of the patient's mucous membrane, such as epidermal growth factor and vitamin B12 ...To relieve pain, we can prescribe analgesics for external and internal use. We also use antibiotics if necessary" (H8D:16)
	Nutritional support methods	"If the pain killer takes no effect ...or the patient loses will to eat, we still have other ways, including applying parenteral nutrition, nasogastric tube or percutaneous endoscopic gastrostomy" (H6D:32)
Health professionals' attitudes towards TCM	Holding a neutral position	"Basically, our attitude toward applying Chinese herbs during RT is: No support and no objection. Some symptoms, I think, are hard to deal with through Western medicine, while TCM might have some effect. With regard to relieving some symptoms like lack of appetite or dry mouth (TCM) might have some effect" (H11D:134,152 and 156)
	Having worries	"For TCM, I think during the treatment, it is better not to drink herbal medicine. I think it will increase patients' burden. I think every medicine has its side-effect, and herbal medicine might burden the liver" (H10D:138 and 140)
	Opposing too many dietary restrictions	"Actually all of us would tell (patients) that NPC disease involves very limited restrictions on food. Basically, there are not too many taboos regarding fresh food, as long as you do not eat spicy and stimulating food, and do not eat, um, pickled food. All of us would tell them this" (H1N:387)
Barriers to symptom management	Barriers related to the health care system	"Regarding booklets, after all, you have to think about the cost issue. If you deliver (booklets) to every patient, one on RT and one on chemotherapy, the cost would be higher (than posters)... Although booklets are superior to posters, everybody can have one to hand. But you have to consider where the budget comes from..." (H9N:96 and 98)
	Barriers related to patients	"Some patients cannot understand or communicate in Mandarin, for example people from Chaoshan. Those elderly aunts who live in rural areas cannot speak Mandarin, only dialects, so we can only invite their family members to meet and translate what I say to them" (H16N:119)
	Barriers related to family caregivers and other people	"Some family members who take care of patients very carefully may make fruit juice (for the patient). However, many of them are not necessarily that careful" (H8D:150)

Contd...

Table 1: Contd...

Themes	Sub-themes	Selected quotes
Recommendations for improving symptom management	Enhancing patient education	“Reinforce (self-care information) during RT when he meets problems... emphasize (self-care information) again. Usually, when you deliver (self-care information) to him for the first time, he might not get all the information at once” (H9N:52)
	Providing psychological support	“During RT and chemotherapy (patients are) definitely distressed. However, it would get better in the future if they hung in there. Symptoms would slowly go away. (We should) make patients feel that they still have a bright future, yes, not too dark. Some patients are in real pain and distressed” (H9N:98)
	Holding workshops for health professionals	“If health professionals undergo a comprehensive training, they might become more confident when conducting patient education at work, and patient compliance might be improved” (H15D:108)

NPC: Nasopharyngeal carcinoma; RT: Radiotherapy; TCM: Traditional Chinese medicine

Table 2: Design and delivery of the educational intervention program

Session	Timing	Duration (min)	Intervener	Format	Activity	Content	Participant	Medium
1 st session	In the week before RT begins	30	Nurse	Individual	Providing self-care information Teaching skills through demonstration and return demonstration Providing psychological support	Basic information on nutrition impact symptom cluster Symptom preventive and management strategies Drug usage Oral care Dietary adjustment Lifestyle modification	Patients accompanied by their caregivers	booklet
2 nd session	Week 3 of RT	20	Same as above	Same as above	Reviewing what has been taught Correcting misconceptions and improper use of skills Providing psychological support	Same as above	Same as above	Same as above

RT: Radiotherapy

then required from the patients. The second session is delivered in week 3 of RT. In this session, which is mainly for review and correction, patients are required to explain and demonstrate how they had practiced self-care during the previous 3 weeks. Misconceptions are clarified, and any improper use of skills is corrected. During both sessions, patients are encouraged to express their perceptions and feelings and raise questions at any time, and the researcher is expected to maintain a caring and optimistic demeanor.

Caregivers' involvement

The qualitative study indicated that family caregivers play an important role in NPC patients' self-management by assisting with the various aspects of the patients' daily lives (e.g., food preparation). However, the patients' self-management behavior is affected by their family caregivers' misunderstanding of the illness and lack of skills. Hence, it is important to include family caregivers in the intervention to improve their knowledge about the illness and self-care strategies. For patients, barriers to symptom control are usually related to language problems, an older age, a poor educational level or poor understanding. Accordingly, health professionals should invite family caregivers with better learning abilities to attend the patient education sessions. Family caregiver involvement can also help to relieve the patients' psychological burdens.^[32] Therefore, family caregivers are invited to accompany patients during the two intervention sessions.

Booklet as an essential component to facilitate education

As suggested by the modelling step, an educational booklet is strongly recommended to help patients absorb the self-care knowledge and skills.^[33] The contents of the booklet developed in this study were obtained through several routes. First, the above-described qualitative study on self-care experiences and practice based on the perspectives of NPC patients and health professionals provided the empirical evidence to support booklet development. Accordingly, the book covers three aspects of basic knowledge: An introduction of the nutrition impact symptom cluster, a discussion of mouth/throat symptoms and constipation and an explanation of self-care strategies, including drug usage, oral care, dietary adjustments and lifestyle modification. Second, we reviewed the internet resources of authoritative organizations, including the National Cancer Institute, the National Institute of Dental and Craniofacial Research and the Hong Kong Cancer Fund. Third, the researcher visited two facilities, the Department of Clinical Oncology at Hong Kong Prince of Wales Hospital and the Department of RT at Guangdong Provincial Hospital of Traditional Chinese Medicine, to seek more information about the protocol and clinical guidelines for nutrition impact symptom cluster management.

The qualitative study also provided suggestions for a booklet format and layout that would improve the patients' understanding. Accordingly, the information in

each section of our booklet is presented using headings and sub-headings, and font sizes of 18 points for headings, 16 for sub-headings, and 14 for the main text have been selected. The SimSun font style is used, in accordance with the preference of most Chinese people, and the line spacing is multiplied by 1.5. Bullets and numbering are used to improve readability and comprehensibility. Finally, colorful pictures related to the content are used to help convey the messages and make the booklet more appealing. In addition, several strategies have been used to improve the readability of the booklet. First, the language avoids the use of medical terms and jargon as far as possible. If these terms could not be avoided, explanations are provided in language comprehensible to the patients. Second, the sentences are clear, direct, short and written in a conversational style by adopting the active (rather than passive) voice and using the second person “you” to engage patients.

The booklet was validated by expert and patient reviews. An expert panel of three nurses and two doctors (average of 13.6 years of experience in the NPC department of the study hospital) was established to review the accuracy and content adequacy of the booklet and the appropriateness of the format and layout. Three patients were invited to evaluate the content and readability. All experts and patients confirmed the final version of the booklet.

The new educational intervention, which was developed according to the development phase of the MRC framework, is a nurse-led intervention with two sessions that aims to provide NPC patients with self-care knowledge and skills, includes family caregiver involvement and uses a booklet as a medium. By influencing psychological, situational and physiological factors, this intervention is expected to help NPC patients manage the symptom cluster as a whole, as indicated by the TOUS.

Feasibility and piloting

To examine the feasibility and estimate the effectiveness of the intervention, we conducted a pilot RCT with 40 NPC patients from Sun Yat-sen University Cancer Center being divided equally into the intervention and control groups. Except for usual care, the intervention group received the educational intervention program, compared with the control group. The study examined the outcomes before, during, and after RT, as well as evaluated the process of the intervention. The consent and attrition rate of the study was 95.2% and 5.0%, respectively, showing patients' willingness to participate and remain in the study. Further, the intervention was well-received by patients, indicated from their high levels of attention, interest and eagerness to learn, and satisfaction with the intervention. Thus, the educational intervention program was feasible. It was also found that the intervention had some favorable effects on

relieving the nutrition impact symptom cluster (Cohen's $d = -0.37$) and improving the physical (Cohen's $d = -0.15$) and head and neck cancer-specific (Cohen's $d = -0.05$) domains of QOL. Therefore, a future large-scale study is warranted to examine the effectiveness of the educational intervention program with an estimated sample size of 242. Details of this pilot study have been published online.^[34]

Discussion

In this study, a nurse-led, theory-driven and evidence-based complex educational intervention was developed based on the MRC framework. Our study supports the usefulness and feasibility of the MRC framework for guiding the development of an educational intervention for NPC patients. This article describes the design of our intervention and the operationalization of the framework for the development process. Our detailed description of the development process will enable further replication studies and provide guidance regarding the application of this framework in an interventional study. The educational intervention program also provides an approach and scientific evidence of managing symptom clusters in the symptom management of NPC patients.

The rigor and efficacy of the intervention was enhanced by using the development phase of the MRC framework. Our previous systematic review suggested that an intervention format involving the nurse-led delivery of patient education in an individual format and during the active treatment period would be a useful strategy. The TOUS provided a theoretical foundation and indicated the significant potential of our intervention to help NPC patients with nutrition impact symptom cluster management. The adoption of the MRC framework also enabled a strong relationship of the intervention with the target population and the practical environment. In this study, a preliminary qualitative study provided an empirical foundation by exploring the barriers and strategies encountered by the NPC patients and informing the educational contents with essential elements. Given the above steps, the nurse-led educational intervention is likely to address the interrelated psychological, situational and physiological factors, and enhance patients' outcomes by relieving the nutrition impact symptom cluster and improving the functional performance and QOL.

The feasibility and piloting phase also lays a foundation for future full-scale RCTs regarding the sample size, randomization, and data collection end-points. According to the effect size and attrition rate of the pilot study, the sample size for a full-scale study is estimated to be 242. Cluster randomization might be more appropriate to avoid possible contamination between the groups. In addition to

the baseline data collection, outcome evaluations should be conducted immediately and at a long-term follow-up after RT completion to examine the short- and long-term effectiveness of the intervention. Further, a process evaluation is recommended to be included to understand the intervention delivery process and the stakeholders' perspectives. Inversely, the outcome effectiveness and process evaluations can provide a comprehensive evaluation and implications of the promotion of the intervention design. Finally, possible mediators between the intervention and outcomes are needed to be examined in future.

This study had some limitations. The MRC framework is a nonlinear approach, and the intervention development might be revised after evaluation and implementation. Therefore, a full-scale study is needed to evaluate and promote the intervention in the future. Furthermore, the intervention was developed based on a qualitative study of patients and health professionals in Southern China; therefore, the generalizability of the program may be impacted by the different self-care experiences of patients in other areas.

Despite these limitations, this article reported the details of our educational intervention development process and thus can provide guidance for intervention development based on the MRC framework. We also explored NPC patients' and health professionals' perspectives on self-care with the intent to enrich scientific knowledge and evidence regarding symptom management for NPC patients during RT. The resulting nurse-led, theory-driven, and evidence-based educational intervention exhibits good potential for managing the NPC patients' symptom cluster and improving their functional performance and QOL.

Conclusions

The MRC framework provides a strong structure for developing a complex intervention to manage the nutrition impact symptom cluster based on a theory-driven and evidence-based approach. We recommend that this intervention be evaluated using a rigorous RCT design, and that the intervention delivery process and mediation mechanism of change be subjected to the analysis. This detailed description of the intervention development process will enable further replication studies according to the comprehensive guideline in the MRC framework. In addition, the intervention programme can inform clinicians about the novel approach to manage symptom clusters and has some reference value for refining usual care of conducting patient education in NPC patients' symptom management.

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Conflicts of interest

The corresponding author, Prof. Carmen W. H. Chan, is an editorial board member of *Asia-Pacific Journal of Oncology Nursing*. The article was subject to the journal's standard procedures, with peer review handled independently of Prof. Chan and their research groups.

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