A self-management application “pain-housekeeper” to control cancer pain: a randomized controlled trial study protocol[†]

Original article

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Received: 19 December 2019; Accepted: 17 January 2020; Published: 20 September 2020

Abstract: **Objective:** Pain is a prevalent and distressing symptom in patients with cancer which has a significant impact on patients' physical health, psychological well-being, and quality of life (QOL). Deficiency of pain care, inadequate pain communication, and reluctance toward pain medication contribute to the difficulties in improving the situation of patients with cancer pain. Fortunately, the integration of self-management and professional healthcare provides new opportunities for patients with cancer pain.

Methods: A two-arm randomized controlled trial will be conducted to assess the effectiveness of self-management application compared with routine care among patients with cancer pain. Based on Orem's self-care theory and Naylor's transitional care theory, cancer pain self-management application “Pain-housekeeper” was developed with dual client: patient client and medical client. A total of 120 patients with cancer pain are recruited from two university-affiliated tertiary public hospitals in China. They are randomly assigned to the control group and the intervention group. The patients in the control group get routine care while the patients in the intervention group get routine care and Pain-housekeeper App. The intervention is delivered by registered doctors, nurses, and postgraduate nursing students specialized in pain care. Effect measurements for both groups are carried out with questionnaires at baseline (T0), after 4 weeks (T1) and after 12 weeks (T2). The primary outcomes include pain condition, self-efficacy, and QOL. The secondary outcomes include pain medication adherence, satisfaction, anxiety, and depression. Compliance of data submission, economic evaluation, usage, and clinical data are also considered in the test. Data for the evaluation are gathered continuously during the study period.

Discussion: This article provides insight into the effectiveness of a theory-based self-management mobile application intervention delivered to patients with uncontrolled cancer pain. The results are used to help patients to improve cancer pain control, self-efficacy, and QOL.

Conclusions: The findings of this article provide evidence to support the implementation of an innovative and easily accessible intervention that enhances health outcomes.

Trial registration: ChiCTR: ChiCTR1800020295, Registered 22 December, 2018.

Keywords: cancer pain, self-management • application • pain condition • quality of life • self-efficacy • randomized controlled trial

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[†] This project was supported by the Xuzhou Science and Technology Plan Project (No. KC19223) and Natural Science Project of Xuzhou Medical University (No. 2018KJ07).

How to cite this article: Liu Q, Zhang XM, Liu PY, Wang YL, Wang YQ. A self-management application “pain-housekeeper” to control cancer pain: a randomized controlled trial study protocol. *Front Nurs.* 2020;3:257-268.

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1. Introduction

1.1. Background

International Association for the Study of Pain (IASP) defined pain as an experience associated with actual or potential tissue damage, including sensory, emotional, cognitive, and social components. Pain is a prevalent and distressing symptom described by patients during curative and palliative cancer care.¹ Evidence suggests approximately 53% of cancer patients have experienced pain. At the same time, 59% of cancer patients suffer from pain during treatment, and the incidence of pain in patients with advanced or metastatic cancers is 64%. Thirty-three percent of cured patients still have chronic pain related to cancer or treatment.² Pain is one of the most feared symptoms of patients, which greatly affects the patients' quality of life (QOL) and psychological well-being. Many studies have further confirmed the Saunders's concept of "total pain,"³ namely, cancer pain has a serious impact on the physical, mental, social, and emotional health of patients (Figure 1).

Effective pain management can not only improve the patients' overall QOL but also prolong life of cancer patients. As one of the effective supports for cancer treatment, self-management can strengthen patient's education and arouse the patient's initiative, make them have a deeper understanding of pain, then improve their compliance and change the outcomes of treatment.⁴

Self-management reflects its expected results and effectiveness by using self-efficacy, QOL, symptom management, and healthy behavior indicators.⁵ Mobile-based interventions often function to improve symptom status by engaging patients in the self-management of their disease, which is expected to be mediated partially by an enhanced sense of self-efficacy. However, the study of self-management in China is limited to overall symptom management of cancer patients, and a few studies have carried out on single symptom management, especially, cancer pain management.

Technology has created new media for the delivery of health interventions. Mobile phone applications (Apps), for instance, are now widely used among Chinese. In the field of health promotion, there are more than 3,000 mobile phone Apps, involving online consultation, health control, rehabilitation exercise, diet nutrition, and other aspects.⁶ Medical App can help to promote the formation of their healthy behavior and self-management ability.⁷ In mainland China, only a few randomized controlled trials (RCTs) have investigated the effectiveness of Apps among patients with breast cancer.^{8,9} To our knowledge, no RCTs have been conducted to evaluate the effects of App on patients with cancer pain. Moreover, Rosser reviewed 111 of the available pain Apps, 86% of which lack evidence and involvement of medical professionals in their development.¹⁰ The pain self-management App has been developed to address this gap. We previously set up

Figure 1. The influence of cancer pain on the patient's QOL.

a multi-disciplinary cooperation team, including oncologists, pain specialists, and medical informatics experts, to develop a multicomponent self-management App.

1.2. Theoretical framework

The Pain-housekeeper App was developed by incorporating Orem's self-care theory¹¹ and Naylor's transitional care theory.¹² Orem's theory is mainly about the maintenance of a dynamic balance between patients' needs and their self-care ability to promote rehabilitation and improve patients' living ability. Considering that patients with cancer pain need social support, health education, and self-management, we built an interactive platform, a knowledge database, and a self-assessment of questionnaire in the App. Another transitional care refers to the timely and effective transition of patients by medical staff from acute stage to subacute stage, and the patients can enjoy transitional care continually even after discharge.¹³ Based on the Naylor's transitional care theory, the Pain-housekeeper App presented with dual clients and is embedded in clinical practice to ensure patients can also get appropriate care after discharge. The main components of this App include interactive platform, pain management, pain medication, graphical feedback, risk alert, and professional healthcare support. The App was designed according to the needs of patients and medical staff. Prior to carrying out a main study, a semi-structured (15 doctors and nurses) and focus group (20 patients with cancer pain) interviews have conducted in a pilot study to confirm the feasibility of the App, which confirmed the feasibility of App in this population.

1.3. Objectives

The objective of the RCT is to evaluate the effectiveness of the self-management App "Pain-housekeeper" for patients with cancer pain in terms of improving the patients' pain control, self-efficacy, and QOL, and reducing pain condition, anxiety, and depression. A hypothesis proposed that the differences between the control group and intervention group at baseline (T0), after 4 weeks (T1) and after 12 weeks (T2) are (1) improved self-efficacy, QOL, and pain medication adherence, (2) reduced pain condition, anxiety, and depression, and (3) greater satisfaction with the health care received from the Pain-housekeeper App.

2. Methods

The study follows the SPIRIT 2013 Statement and the guidelines for the Standard Protocol of Clinical Trials.^{14,15} The study received the ethic approval from the participating hospital in China (XYFY2019-KL018).

2.1. Study design

A two-arm RCT is conducted to investigate the effectiveness of the self-management App "Pain-housekeeper" compared with routine care among patients with cancer pain. This study began recruiting participants in January 2019, and the following measures (T0, T1, and T2) are expected to be completed in December 2019. The Consolidated Standards of Reporting Trials (CONSORT) flowchart is presented in Figure 2.¹⁶

2.2. Eligibility

The inclusion criteria are as follows: (1) diagnosed with cancer by definite imaging and pathology; (2) at least 18 years old; (3) coping with uncontrolled moderate to severe cancer (treatment) pain which is defined as the numerical rating scale (NRS) score ≥ 4 ; (4) suffering from the pain for more than 2 weeks; (5) have access to the Internet with a mobile phone; (6) be cognitively and physically capable of participating; and (7) informed of the disease and voluntarily participated in the study. The exclusion criteria for patients are: patients (1) having a life expectancy less than 3 months; (2) having acute pain caused by surgical or traumatic operation; (3) with chronic non-cancer-related pain; and (4) with unclear consciousness and cognitive impairments. Besides, patients were excluded if they cannot continue to participate in the study due to physical condition during the treatment.

2.3. Sample size

The sample size was estimated by Eq. (1). Substituted into the calculation formula, 51 in each group. Considering invalid samples, the dropout rate was 15% to achieve a power of 0.80 at a 0.05 level of significance. Eventually, 120 patients with cancer pain are recruited in this study and equally divided into two groups.

$$n_1 = n_2 = 2 [Z_{\alpha/2} + Z_{\beta}]^2 \sigma^2 / \delta^2 \quad (1)$$

where n_1 and n_2 represent the intervention and control groups, respectively, α represents the probability of the first type of error: $\alpha = 0.05$ (a two-sided alpha of 0.05), β represents the probability of the second type of error: $\beta = 0.20$, σ is the combined standard deviation, and δ is the difference of two groups' average.

2.4. Recruitment

The patients are recruited in two university-affiliated tertiary public hospitals in the People's Republic of China. The medical staff introduce the Pain-housekeeper App to patients who meet the inclusion criteria and provide

Figure 2. CONSORT flowchart of the study adapted from Schulz et al.

the patients with the contact details of the postgraduate nursing students as a research assistant (RA). Patients who have contacted the RA are approached by the RA at the research unit to provide them with additional information regarding the Pain-housekeeper App and to answer any questions that they might have. Patients who verbally agree to participate are followed up to obtain their written consent. The enrollment period is expected to extend over 3 months. Survey data are collected at baseline (T0), intervention after 4 weeks (T1) and after 12 weeks (T2). In addition, to ensure activity and compliance, the patients are rewarded with a small gift (equal to RMB 20) for each questionnaire completed.

2.5. Sample and randomization

A total of 120 patients with cancer pain who meet the inclusion criteria and give informed consent of the study

are randomly allocated in a 1:1 ratio to either the intervention group or the control group. Procedures are as follows, in the order of admission, patients are numbered 001 to 120. Then, randomization is performed by a random number table method.¹⁷ According to the random number table to extract 120 random digits, the first 60 digits for the intervention group, the last 60 digits as a control group. If the intervention and the control groups are in the same ward, they need to be assigned to different rooms in coordination with the primary nurse and the bed doctor. The patients in the intervention group have access to the Pain-housekeeper App and receive routine care while undergoing treatment. The patients in the control group receive routine care during treatment. Blinding of patients, doctors, and nurses to group allocation is not possible due to the nature of the intervention. Data are analyzed after encryption, without recognition of original variables including name, bed number, and

group allocation. An independent RA stores the encryption key and reveals the original variables for each questionnaire completed in the study.

2.6. Intervention

2.6.1. Setting up the intervention group and training

The intervention group consisted of 10 medical staff, 3 nursing postgraduates, and 1 medical informatics postgraduate: 1 chief physician and 4 nurses from each hospital participate in the group, chief physician responsible for the consultation of relevant clinical knowledge. Nurses are required with more than 5 years of working experience and more than 2 years of working experience as responsible nurses. Nurses and nursing postgraduate students are responsible for the popularization of the Pain-housekeeper App. Besides, medical informatics postgraduate is in charge of technical assistance and background management. Members of the intervention group received training on pain-related and mobile health-related knowledge before implementing the intervention program.

2.6.2. Intervention plan based on App

During hospitalization, the members of the intervention group introduce the intervention plans to the patients and participate in ward rounds regularly. After discharge from hospital, patients were mainly managed by App and telephone to implement health management in a personalized way. Specific interventions are shown in Table 1.

2.6.3. Telephone follow-up

A telephone follow-up is conducted once a week. Two steps are addressed. First, solving the problems of

using the App. Second, urging patients to use Pain-housekeeper App and complete questionnaires in time. In addition, the patients can be informed by telephone to strengthen the use when the frequency of use is low demonstrated in background.

2.6.4. The cancer pain self-management application "Pain-housekeeper"

The Pain-housekeeper is a mobile phone App for Chinese people with cancer pain and was developed by a research team at the School of Nursing and Medical Informatics in the University of China. The Pain-housekeeper App aims to enhance patients' self-efficacy to promote their ability to manage the symptoms associated with cancer pain, thus improving their self-management ability and QOL.

The study has a fixed structure, which lasts approximately 12 weeks. Data from previous studies suggest that an 8-week online intervention is enough to produce changes. Thus, a 12-week intervention is considered sufficient to test the effectiveness of the App. A pamphlet has been developed to provide a standardized procedure for downloading the App from the mobile phone. The patient client of Pain-housekeeper App has six modules: (1) an interactive platform; (2) a pain diary; (3) a daily medication; (4) a pain follow-up; (5) a knowledge database, and (6) a self-assessment of questionnaire. These six modules are visually recognizable on the homepage of the Pain-housekeeper (Figure 3-A). The medical client includes two modules: (1) a patient management and (2) a message management. These two modules are visually recognizable on the homepage of the Pain-housekeeper App (Figure 3-B).

The interactive platform has two forums: An Ask-the-Expert forum and a Wardmate forum. In the Ask-the-Expert forum, medical staff (doctors and nurses)

Period	Intervention group	Control group
During hospitalization	- On admission, instruct the patients to download the Pain-housekeeper App and complete registration. Then, enter the main page to explain the use of relevant modules, and instruct patients to complete the baseline assessment in the App. - Routine treatment and care - Participate in health lectures regularly	- On admission, instruct patients to complete the baseline assessment on paper. - Routine treatment and care - Participate in health lectures regularly
One day before discharge	- Guide to discharge - Give notes on daily life - Guide drug use - Formulate intervention plan*	- Guide to discharge - Give notes on daily life - Guide drug use
After discharge	- Use Pain-housekeeper App for pain record, disease-related knowledge learning, etc. - Implement intervention plan formulated during hospitalization - Regular telephone follow-up	Regular telephone follow-up

Note: * Intervention plan includes routine care, social support (emotional support and material support), health education (patients and main caregivers), dietary nursing, and emergency management.

Table 1. Intervention plan for two groups of patients.

Figure 3. Screenshots of the home page: (A) the home page of patient client and (B) the home page of medical client.

respond to health-related questions posed by individuals from 8:00 am to 5:00 pm every day. Only the individual who posed the question and the medical staff at the medical client have access to the question and do response. In the Wardmate forum, patients are invited to discuss symptom management topics and to share information and experience. Patients with different stages of cancer pain, different ages and different socioeconomic statuses are interviewed and recorded to provide role models for wardmate with different needs.

A Pain Diary can be used to records pain intensity, pain interference, pain duration and location, side effects, and treatment strategies used by a valid and reliable seven-item questionnaire at any time and anywhere. To look back at the pain condition through the

day, patients are required to complete pain dairy each evening. When pain is reported, the App forms a chart. As a result, the doctors and nurses at the medical client can monitor and analyze the patients' situation and give a recommendation. If patients with new, persistent or severe pain, he/she can record and upload the data immediately. A Risk Alert within a Patient Management gives a message reminder, and colored risk flags are formed with a standardized algorithm with questions and answers, which supports medical staff in monitoring tasks. Red flags require immediate contact with patient, yellow flags ask to pay attention to, and green flags indicate everything is regular. In the situation, medical staff can send text messages and consult patients by phone. Besides, it also provides an overview of pain diaries created by patients to visualize pain progress and help medical staff make decision.

A Daily Medication includes the usage, dosage, and using time of medicine in each stage. This medicine is checked and confirmed by doctors and nurses. In addition, the intervention group evaluates the contents of pain diary and the patient's situation and updates the prescription to the medical client, the nurse will tell the usage, dosage, using time of medicine according to the doctor's prescriptions, and then update to the patient client. Reminders are built in the App to promote patients to take medicine on time. Body mass index (BMI) calculation is built in a goal setting. Patients can set their own diet and exercise goals according to the results of BMI and finally evaluate the implementation of the goals according to the actual situation. A knowledge database introduces the treatments of cancer and pain as well as new medical technologies, equipment, beneficial policy, and so on. The knowledge is provided or reviewed by the medical staff and is pushed 5–7 times a week to meet the patient's information needs. Finally, patients can go through a self-assessment of questionnaire to conduct self-assessment on pain conditions, self-efficacy, QOL, medication adherence, and so on.

Furthermore, technical assistance is available through message or telephone from 8:00 am to 5:00 pm every day. At other times, users can leave a message. A technical assistant will check messages and respond to the patients as soon as possible.

2.6.5. Comparison

The patients in both groups are given routine pain care and pain education from doctors and nurses during hospitalization. After discharge, patients will be given guidance of discharge and followed up by telephone (calls and send messages) once a week. Questions in doubt will be answered in detail when giving a call. Furthermore, we also check the patients' improvement and satisfaction.

The control group may freely use the mobile phone to search for information about cancer pain. However, they do not have access to the Pain-housekeeper App.

3. Results

3.1. Primary outcomes

3.1.1. *The Brief Pain Inventory*

This self-report questionnaire, formerly the Wisconsin Brief Pain Questionnaire,^{18,19} is a well-known measure of clinical pain and has shown sufficient reliability and validity. This questionnaire provides information about pain history, intensity, and location as well as the degree to which the pain interferes with daily activities, mood, and enjoyment of life. Scales (rated from 0 to 10) indicate the intensity of pain in general, at its worst, at its least, average pain, and pain “right now” over the past 24 h. A figure representing the body is provided for the patient to shade the area corresponding to his or her pain. Test-retest reliability for the Brief Pain Inventory (BPI) reveals correlations of 0.93 for the worst pain, 0.78 for usual pain, and 0.59 for pain now.

3.1.2. *Chronic Pain Self-efficacy Scale*

The scale was developed by American scholar Anderson in 1995,²⁰ and the Chinese version was revised by Haiyan He in 2008.²¹ There were 22 items in the revised scale, which were divided into three dimensions: self-efficacy for pain management, for physical function, and for coping with symptom. A 5-grade Likert positive score method was used. Scores (rated from 1 to 5) indicated that there was no assurance, 20–30% assurance, 50% assurance, 70–80% assurance, and >80% very assurance. The total score of the scale was between 22 and 110 scores. Higher total scores represent the stronger self-management efficacy of the patients. The Chinese version of Chronic Pain Self-efficacy Scale (CPSS) has good reliability and validity in the treatment of cancer pain. The Cronbach's alpha of total scale and three dimensions are 0.836–0.951.

3.1.3. *EORTC Quality of Life Questionnaire (EORTC-QLQ-C30 version 3)*

The 30-item core European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) version 3.0 is a cancer-specific quality-of-life questionnaire developed for repeated assessments within clinical trials. It was developed in a cross-cultural setting and is a valid and reliable instrument

for quality-of-life assessments in various cancer populations. It contains five functional scales (physical, cognitive, emotional, social, and role), a global quality-of-life scale, three symptom scales (pain, fatigue, and nausea/vomiting) and six single items (dyspnea, insomnia, loss of appetite, constipation, diarrhea, and financial difficulties). All scales and single items range in score from 0 to 100. A higher score on one of the functioning scales or the global quality-of-life scale represents a better QOL, whereas a higher score on the symptom scales or the single items indicates a higher level of symptoms.^{22,23} The study has shown the acceptable levels of reliability, validity, and sensitivity of the questionnaire.²²

3.2. Secondary outcomes

3.2.1. *Morisky Medication Adherence Scale*

Medication adherence is measured using the Morisky Medication Adherence Scale (MMAS-8).²⁴ It consists of eight items. The alternative answers to the first seven questions can be divided into two categories: yes or no. The fifth question is the reverse scoring question, which has different scoring standards for the two groups of subjects. In the test group, the answer yes is score 1, otherwise is 0. In the control group, there is only one answer: the answer yes is score 1, otherwise is 0. The answers to Question 8 were scored on five-point Likert scale that indicate never, occasionally, sometimes, often, and always. The total score of MMAS-8 was 8, less than score 6 indicate low adherence; scores 6 and 7 indicate moderate adherence; and score 8 indicates high adherence. The reliability and validity of the scale are good. It is a reliable tool for measuring the adherence to taking medicine.²⁵

3.2.2. *Hospital Anxiety and Depression Scale*

Anxiety and depression are assessed using the Hospital Anxiety and Depression Scale (HADS).²⁶ The HADS is a 14-item instrument assessing depression and anxiety in a medical setting. Higher total scores indicate greater distress. The original HADS has shown good reliability and validity in breast cancer survivors.²⁷ The HADS has been translated into Chinese and is widely used among the Chinese population with different types of health conditions. The Cronbach's alpha coefficients of the Chinese version of HADS are 0.806 and 0.724 for the anxiety and depression subscales, respectively.²⁸

3.2.3. *Satisfaction with care*

The patients' satisfaction are assessed with an 8-item checklist developed for this study. Questions include:

1) how easy to use the Pain-housekeeper App; 2) how useful was the pain diary in the App; 3) how appealing was the App to use; 4) how useful were the medication reminders; 5) how willing to use the App every day; 6) how easy to upload data through the App; 7) how responsive were medical staff to the patients' questions; and 8) how helpful was the App in coping with your pain? This question is rated on a five-point Likert scale, with 1 meaning "not at all" and 5 meaning "very much." For each subscale, higher scores indicate greater satisfaction.

3.3. Other outcomes

3.3.1. Compliance of data submission

The background management system can display the data recorded in patient client. Compliance is assessed by the number of submissions of pain diaries during the 12-week intervention. The criteria were as follows: actual submissions more than 80% of total submissions were recorded as every compliance, actual submissions less than 30% of total submissions were recorded as non-compliance, and the rest are deemed to partial compliance.

3.3.2. Usage data for the Pain-housekeeper

The App contains a background management system. The medical informatics postgraduate is responsible for the background management. Usage data include the frequency, duration of logins, information audit and processing, and the activity of each module of the Pain-housekeeper App was recorded and evaluated.

3.3.3. Economic evaluation

Cost-effectiveness analysis (CEA) is an advanced technology to evaluate the effect of medical services, which provides strong scientific evidence for the allocation of resources. The cost estimates refer to the requirements of Health Economics, which implies that all relevant medical and non-medical costs and effects are considered. The support intervention is expected to have improvements in pain intensity and quality-adjusted life years (QALYs).

3.3.4. Demographic and clinical data

The data collected include the patients' age, marital status, education level, employment status, exercise after illness, and main sources of medical expenses. Hospital provides disease-related information when a patient is recruited, such information includes cancer stage, types of pain, and the course of disease.

3.4. Data collection and control

Researchers explain to patients the purpose of the study and the specific methods of implementing the program to answer patients' questions about the study. Data are collected at various time points (baseline, 4 weeks and 12 weeks) as described in Table 2. To ensure the authenticity and validity of the survey, the following principles are to be noted: 1) researchers responsible for this matter should not guide the patients with any tendency, 2) the patients without reading ability or dysgraphia, the professional researchers should take the form of a question-and-answer to accurately convey the communication content, and 3) in the face of patients who were communicated by families, to ensure accurately that family members and patients are present at the same time, and each part of the narrative needs to be approved by the patients' nod.

Relevant experts are invited to review the built-in patient self-assessment questionnaires in App, revise and supplement the scale repeatedly to ensure the questionnaires are comprehensive, scientific, and feasible. When the researcher compiled the patients' self-assessment questionnaires, the completeness of the data was checked immediately. If missing items, the patients were interviewed face to face or by telephone to complete the questionnaire in time. After screening the questionnaires collected according to strict criteria, the researcher checks the errors, fills in the omissions, and logically checks the encoding and entry of the data before analyzing the data and then analyzes the valid questionnaires to ensure the accuracy of the input data.

Data collection	Baseline	4 weeks	12 weeks
BPI	X	X	X
CPSS	X	X	X
EORTC QLQ-C30 (version 3.0)	X	X	X
MMAS-8	X	X	X
HADS	X	X	X
Satisfaction with care			X
Compliance of data submission			X
Usage data for the Pain-housekeeper			X
Economic evaluation			X
Demographic and clinical data	X		

Note: BPI, Brief Pain Inventory; CPSS, Chronic Pain Self-efficacy Scale; MMAS-8, Morisky Medication Adherence Scale; HADS, Hospital Anxiety and Depression Scale.

Table 2. Data collection schedule: the table depicts the schedule for data collection.

3.5. Data analysis

After double entry of data in Epidata Entry (Epidata) version 3.1, all outcome measures are analyzed using the IBM Statistical Package for the Social Sciences (SPSS) version 22.0. An intention-to-treat analysis is adopted to manage missing data. Independent student *t*-tests and chi-square tests are performed to determine the comparability in baseline demographic and disease data between patients randomized to the intervention and control group. To evaluate the effect of the intervention across three time points of data collection (T0, T1, and T2), independent student *t*-tests and paired students *t*-test are used to analyze the difference between inter-group and intra-group. The independent student *t*-test is used to confirm how satisfied the intervention group with the care that they received after 12-week intervention. Differences in the economic evaluation are presented in an incremental cost-effectiveness ratio (ICER). The ICER represents the difference in mean costs of the intervention and control group in the numerator and the difference in mean effects of the intervention and control group in the denominator.

4. Discussion

In this RCT, we assess the effectiveness of using a self-management App “Pain-housekeeper” to support patients as they cope with the uncontrolled pain. The results of this study provide a better understanding of the Pain-housekeeper in reducing pain condition and the credibility of using an App to give intervention. Such results may help to advance research regarding the use of mobile-based self-management App to promote patients’ symptom control, thus improving patients’ self-efficacy and QOL. Moreover, App is proposed to be useful to improve access to and quality of care and has a cost-saving potential.^{29,30}

An advantage needs to be highlighted. The Pain-housekeeper App is designed and developed in collaboration with oncologists, pain specialists, and medical informatics experts, rather than directly handed over to software companies for design and development. Pain management is a long-term, systematic process. Medical care professionals are required to guide and participate in the development, design, and exchange of feedback and provide professional feedback and guidance in the later supervision and use. Most of the existing mobile Apps for patients with cancer pain lack the participation of medical professionals.^{31,32} Wallace and Dhingra reviewed 220 pain-related Apps and concluded that many of these Apps were created with less involvement from healthcare professionals.³³ Therefore, the new multi-disciplinary cooperation model greatly

improves the efficiency of research and practice and improves the methods of intervention. The contents of the study are more comprehensive, which can reduce the missing of data due to lack of cooperation among the subjects and technical difficulties with the hardware and software.

In addition, the intervention is different from previous attempts in its multicomponent and interactive approach. Complex interventions having several interacting components require a good theoretical understanding and the use of different outcome measures to evaluate underlying mechanisms. Quantitative and qualitative data collection is combined, and different outcomes related to cancer pain and self-management are measured.³⁴ While clinical effectiveness is of primary concern, the information from the process provides important in-depth insights into the success of the intervention to better interpret results and improve future implementation.^{35,36}

If the Pain-housekeeper is effective, it could be offered by healthcare professionals as part of the routine treatment to enhance health outcomes for patients with cancer pain who are undergoing treatment. This study suggests that a mobile phone pain App is reliable and valid in collecting remote data, is generally accepted and tolerated by patients with cancer pain, can be readily implemented in the clinic, and can be a viable platform to communicate daily pain conditions with medical staff. Furthermore, this study meets the requirements of the big data era development which realizes medical information resources sharing, makes clinical work more convenient and efficient, and provides new ideas and references for cancer pain care.

A challenging matter is the recruitment of patients with cancer pain.³⁷ When the study involves self-management of pain control, rather than health education, recruitment even require more efforts. Health professionals protect their patients because of high disease and symptom burden; patients mostly in need for these interventions often feel too ill or overwhelmed. Provision of information about the intervention and both advantages and disadvantages of study participation to healthcare professionals and patients is believed to increase enrollment.

5. Conclusions

While mobile technology cannot completely replace traditional face-to-face interactions with medical staff. Overall, this study offers support for the novel way to obtain clinical information through an App. The potential for reduced healthcare utilization among patients with cancer pain using mobile phone pain Apps will be explored in future trials. In addition, study outcomes

contribute to the understanding on interventions improving cancer pain using self-management App. The intervention could be base for other cancer-related health problems or for pain problems in other chronic-disease populations.

Ethics approval

This study was approved by the ethic committee of Affiliated Hospital of Xuzhou Medical University and Xuzhou

Tumor Hospital. Written informed consents from all the participants were obtained. Patients are assured that participation in this study is voluntary, and they can withdraw from the study at any point of time. The consent form is obtained, and all data are kept confidential and anonymous.

Conflicts of interest

All contributing authors declare no conflicts of interest.

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