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Development and evaluation of a WeChat-based life review programme for cancer patients : Protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020239
Article Type:	Protocol
Date Submitted by the Author:	24-Oct-2017
Complete List of Authors:	Zhang, Xiaoling; Fujian Medical University, School of Nursing Xiao, Huimin; Fujian Medical University, School of Nursing
Primary Subject Heading:	Nursing
Secondary Subject Heading:	Oncology, Mental health, Palliative care
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, ONCOLOGY, CHEMOTHERAPY

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Development and evaluation of a WeChat-based life review programme for cancer patients : Protocol for a randomized controlled trial

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Keywords: life review; cancer; nursing; psychological intervention; Internet

word count: 3391

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ABSTRACT

Introduction Cancer patients often suffer from considerable distress, which increases the risk of cancer mortality. Innovative and easily accessible psychological interventions for cancer patients are lacking. Some Internet-assisted psychological interventions have been demonstrated to efficiently mitigate psychological distress among cancer patients. However, the evidence of Internet-based life review programme tailed to cancer patients is scarce and its effects remain unclear. This study aims to develop a WeChat-based life review programme and evaluate its effects on psycho-spiritual well-being among cancer patients undergoing chemotherapy.

Methods and analysis A randomized controlled trial with repeated measures. Ninety-two cancer patients will be randomly allocated to either control group or experimental group who receives 6-week WeChat-based life review programme. The program was developed mainly based on Erikson's psychosocial development theory and Reed's self-transcendence theory. It provides synchronous and asynchronous communication for patients to review a life. The former is an e-life review interview guided by a facilitator on line. The latter is used to interact with patients before and after a life review interview through Memory Prompts, Review Extraction, Mind Space, and E-legacy products. Anxiety, depression, self-transcendence, meaning in life, and hope will be measured at baseline, immediately, three months, and six months after the programme.

Ethics and dissemination Ethics approval has been obtained from Biological and Medical Research Ethics Committee of Fujian Medical University (IRB Ref No: 2016/00020). The trial results will be published in a peer-reviewed journal.

Trial registration number This trial was registered on Chinese Clinical Trial Registry (ChiCTR-IOR-17011998)

Strengths and limitations of this study

- This is a pioneer study to develop a theory-based and WeChat-based life review programme tailored to cancer patients and test its effects in the context of China with a rigorous design.
- The innovative programme consists of E-life review interview, Memory Prompts, Review Extraction, Mind Space and E-legacy products, providing synchronous and asynchronous communication for patients to review a life.

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- WeChat-based life review programme may be an alternative approach to enhance patients' psycho-spiritual well-being and benefit more cancer patients.
- The programme is probably not suitable for illiterates, because they may encounter difficulty in viewing memory prompts and operating life review modules.

INTRODUCTION

Cancer is a life-threatening disease worldwide, and almost 1 of every 6 death cases is due to cancer.[1] In China, cancer is the leading cause of death, accounting for 27% of deaths among global cancer patients.[2] A meta-analysis has shown that 27% of the cancer mortality risk is associated with psycho-spiritual distress.[3] Psycho-spiritual distress such as anxiety, depression, and hopelessness is prevalent among cancer patients undergoing chemotherapy.[4] Approximately 32.5% to 75.7% of cancer patients experience psycho-spiritual distress, which is higher than normal population as well as patients with other disease.[5-7] The distress may greatly prolong hospitalization,[8] interfere with cancer treatment,[9] and lower rehabilitation of cancer patients.[3]

Life review is regarded as a psychological intervention in palliative care. It is a process of recalling, evaluating and integrating life experiences to facilitate the achievement of ego integrity at the final stage of life.[10] Cumulative evidence suggests that life review can relieve psychological distress and improve well-being among palliative patients, such as cancer individuals.[11-12] In life review process, reviewers express their thoughts on life experiences, retrieve better feelings of positive memories and release negative emotions of unpleasant events, which helps to alleviate psychological distress.[13-14] It also helps to clarify personal values, priorities and life meaning. During the process, reviewers are provided an opportunity to reaffirm their contributions and accomplishments, reconcile their failures and disappointments, and integrate their entire life into a more acceptable or meaningful one.[13,15-16] The integration of various life experiences is beneficial to ego integrity.

However, traditional face-to-face life review is not always available for cancer patients, especially those community-dwelling patients with advanced cancer suffering from psycho-spiritual well-being. Current life review is commonly undertaken in hospitals, palliative care units or other working places. It may conflict with patients' medical treatment or nursing care.

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Besides, facilitators often encounter barriers such as geographic distance and traffic problems when delivering life review in communities, particularly some areas with poor transportation. The barriers also pose challenges for those patients with deteriorating physical conditions to get access to life review intervention.

The Internet, an interconnected network beyond time and space may be potential to overcome the mentioned above barriers.[17] Statistics have reported that approximately 47% of population access to the Internet in 2016, and the figure is estimated to be over 50% in 2018. [18] People are more connected than ever with increased access across multiple devices at home availability, [19] which provides favorable conditions for the delivery of interventions. Research related to life review based on the Internet has been reported, with two studies focusing on older adults and one for cancer patients. In 2009, an e-health system called Butler Project had been constructed with the aim to facilitate optimal aging.[20] Preschl et al conducted life review therapy with computer supplements for depression using Butler Project System.[21] The intervention consisted of a face-to-face life review, and a computer part to induce positive emotions. This study was performed in the traditional face-to-face setting. Another study is a randomized controlled trial to test the efficacy of life review as online-guided self-help for adults. Life review intervention group received a self-help book to review their life, performed a well-being exercise on an audio-CD and sought support from researchers via e-mail. Though it addressed the issue of geographic distance, mail contact was not so timely to receive a reply. Wise et al designed a life review with online social networks for cancer patients.[22] The intervention combined a dignity-enhancing telephone interview, a text life story, and a self-directed website to share their story and establish social networks. Then a randomized controlled trial was performed to test its effects on distress and existential well-being among 68 advanced cancer patients.[23] The study explored patients' satisfaction with the life review process, social networking use patterns, and themes emerged from the life stories, but statistical results were lacking and the evidence to determine the efficacy remained inconclusive. Moreover, telephone interview failed to observe reviewers' non-verbal information such as facial expressions and body language. To our knowledge, there exists no life review programme completely based on the Internet tailed to cancer patients, particularly in China.

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WeChat is an instant application that spreads over 200 countries with more than 20 languages and covers 90% of mobile phones in China.[24] Up to June 2017, China had 751 million Internet users, with 724 million mobile netizens accounting for 96.3% of the total netizen population.[25] Due to its functions of synchronous and asynchronous communication, WeChat has been increasingly used in nursing education, and continuous nursing etc.[26-27] Given the popularity of the Internet and its promising application on psycho-interventions, we aimed to utilize WeChat platform to design a WeChat-based life review programme (WBLRP) and test its effects on psycho-spiritual well-being among cancer patients. We hypothesized that the WBLRP would have a significant difference in the mean scores of anxiety, depression, self-transcendence, meaning of life, and hope among cancer patients undergoing chemotherapy in experimental group compared with control group.

METHODS AND ANALYSIS

Study design

The study is a randomized controlled trial design, funded by National Nature Science Foundation of China, Fujian Provincial Natural Science Fund and Fujian Provincial Health and Family Planning Commission. The study design is consistent with the guidelines of Consolidated Standards of Reporting Trials (CONSORT)[28] and will follow CONSORT flow chart to show the flow of participants through each stage of a randomized controlled trial (Figure 1).

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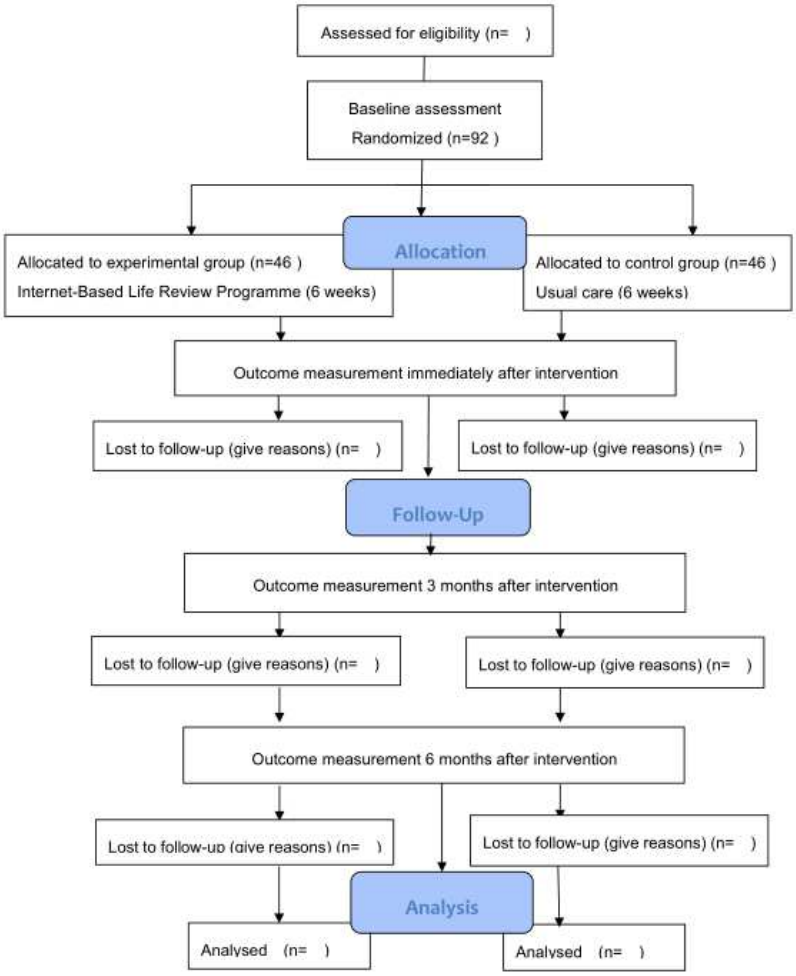

Fig. 1. Study flow chart based on consolidated standards of reporting trials (CONSORT) guidelines.

Participants

The participants will be recruited from medical oncology wards in a public hospital in China. The inclusion criteria for the participants are: (1) diagnosed with cancer and undergoing chemotherapy currently; (2) aged 18 years or above; (3) aware of their diagnosis and treatment; (4) able to access to the Internet via mobile phone. The exclusion criteria are: (1) currently taking anxiolytics and antidepressants; (2) receiving other psycho-therapeutic treatments; (3) having severe vision or hearing impairment, psychiatric disorders and indications of suicide.

Sample size determination

Sample size calculation is based on power analysis. Power analysis adopts a

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hypothesis-testing method to determine sample size according to pre-specified significance level and desired power level.[29] Assuming a two-tailed alpha of 0.05, a probability of 0.02 for beta error (80% power) and an effect size of 0.39 after calculating with respect to the same primary outcome measure (self-transcendence) according to the previous study,[30] 76 participants are required. We assume 20% drop out rate in this study, thus the total sample size is 92 participants.

Randomization, allocation concealment and blinding processes

This study will follow the process of randomization. Before randomization, a person who is not engaged in the subject recruitment and data collection will prepare a randomization list with 92 sets of numbers, either 0 (control group) or 1 (experimental group), using the computer software Research Randomizer (http://www.randomizer.org/). These 92 sets of numbers will be printed out separately and sealed in each envelope. After recruiting a participant, facilitator will open an envelope in sequence. The number written in the envelope will represent the group of that particular participant. In this study, group assignments do not bind to participants and the facilitator, but data collectors are bind in order to minimize measurement bias.

Intervention

Development of WBLRP

The WBLRP has been developed based on Erikson's psychosocial development theory, Reed's self-transcendence theory, literature review and our research team's previous studies. Erikson articulated that a healthily developing human should pass eight developmental stages from infancy to late adulthood.[31] At the final life stage, if individuals are able to overcome the development crisis, they will achieve ego integrity; otherwise, they will become preoccupied by despair, feel regrets, and fear death. Butler's life review is a systematic process that follows Erikson's lifespan stages and promotes life integration by recalling, evaluating and integrating positive and negative life experiences.[22] Based on Erikson's theory, the synchronous communication module aims to guide patients to review a whole life from childhood to the present on line. Self-transcendence is described as the expansion of personal boundaries that is influential in finding meaning and purpose in life including outward，inward，spirituality，and temporal.[32] It is an inherent quality in every human being, which can be a powerful coping strategy when one is faced with adversity.[33]

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Indeed, reviewing a life involves in every factor of self-transcendence. In order to enhance the effect of the WBLRP on self-transcendence, four asynchronous communication modules are designed including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products. For examples, Mind Space is designed to further unbosom patients' innermost feelings, beliefs and meaning in life after the life review interview. E-legacy Products help to integrate their past, present and the whole life. Moreover, literature review and our previous studies were also employed to enrich the programme. For example, the guiding questions for each life review section in the WBLRP were refined based on our previous studies.[34-35] The WBLRP has been validated by a panel of experts consisting of three life review researchers, three palliative care nurse specialists, two clinical oncology professors, one social worker, and one psychologist. The panelists evaluated the appropriateness and relevance about the content, the format, the frequency and duration of the programme, and provided comments based on their experience and knowledge. After the experts' validation, two cancer patients were recruited to test whether the content of the programme was understandable and acceptable.

Components of WBLRP

E-life review interview is an individual face-to-face interview with the function of video-call on WeChat. Four sections will be reviewed weekly over six weeks, including present life (cancer experience), adulthood, childhood and adolescence, and summary of life, which are ordered in a reserve sequence starting with the present and working backwards. Each section has its corresponding guiding questions. The duration of each life review interview ranges from 40 to 60 minutes up to patients' physical condition and willingness to talk. The first author will act as facilitator, who is a nursing postgraduate, a registered nurse, and has received approximately 50 hours of life review training. Both facilitator and patients can deliver the interview in their convenient time at any locations access to the Internet.

Memory Prompts Module contains various resources such as images, songs, videos, audio-picture books and guiding questions related to the content of each section. They will be presented to patients ahead of life review interviews in order to evoke their memories. For

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example, in Childhood and Adolescence Section, an audio picture book entitled the night birth opens the prelude of the review; images about house, study, game, labor and food display the life scene of that age; songs about childhood trigger the recollection of past life. Patients are encouraged to supplement other relevant resources (e.g. images, songs) according to their circumstances. Guiding questions are used to stimulate memories and help patients recall the important events of their life.

Review Extraction Module refers to a summary of meaningful events created by facilitator after each section, where patients can view the content and leave their comments. After each life review interview, facilitator will elicit some significant events with relevant images for patients. It aims to help patients clarify the trajectory of each life stage, relive life events and facilitate self-evaluation during life review intervals.

Mind Space Module provides an opportunity to express emotions, hand down wishes, or reveal their true feelings to any important one at that stage. For example, in Adulthood Section, patients can express thanks to family members or friends on Mind Space. The module allows patients to look inside themselves, re-consider and reflect on the relationship with others, and establish a sense of connection with surroundings beyond personal boundary.

E-legacy Products Module presents products of a family-tree, a life-line and an e-life review product, which can be preserved as spiritual memorials. The family-tree and life-line are created by patients under the guidance of facilitator during life review interview. E-life review product will be created by facilitator through selecting significant experiences, views on life, and words for their loved ones with additional elements of photos, songs or videos based on patients' preference.The products will be presented to patients in order to let them re-evaluate and integrate the life events, and finally, left as a legacy product. This module helps to promote the recollection of patients' family history and life experiences, as well as to integrate their past, present and the whole life.

Intervention procedure

Prior to the intervention, patients in experimental group will be guided to install WeChat, register an account, launch a video-call, browse the memory prompts of life review and operate

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each module on the life review platform. An operation pamphlet can be consulted on the platform as well. Before each session, patients can access to Memory Prompts Module to get an overview of current session. Subsequently, an e-life review interview is implemented, along with creating a family tree or a life-line. Both patients and facilitator can communicate in the virtual face-to-face setting with additional expression ways such as texts, stickers, or icons. After life review interview, they can get access to the 24-hour open asynchronous communication modules to relive and integrate the reviewed content, deliver feelings and e-legacy products, or supplement any content during life review intervals. Generally, each session follows the same process (More details see Table 1). When it approaches to the end of the intervention, facilitator will create a time-line recording life review process in which patients participate. To protect patients' privacy, life review platform can only be accessed with personal WeChat number and patients can decide which modules can be read by other people.

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Table 1 An overview of the WeChat-based life review programme

Session	Section	Asynchronous communication (Appreciate memory prompts before the interview)	Synchronous communication (Deliver the e-life review interview)	Asynchronous communication (Operate modules after the interview)
1	The present (from cancer diagnosis to present)	♦Images about hospital, ward,health-care staff; ♦Audio picture book--The fall of Freddie the leaf; ♦Video--Circulation of four seasons； ♦Guiding questions.	♦Review the present life;	♦Review Extraction: summarize events of this section; ♦Mind Space: hand down wishes to anyone who is important for you at this stage; ♦Supplement any content on this section.
2 & 3	Adulthood (≥18 years old)	♦Images about family, work, hobbies; ♦Audio picture book--love is a handful of thick honey; ♦Songs about family, work or love; ♦Video about family-tree; ♦Guiding questions.	♦Review the adulthood (including creating a family-tree) .	♦Review Extraction: summarize events of this section; ♦Mind Space: express thanks to family members or friends; ♦E-legacy product: display the family-tree; ♦Supplement any content on this section.

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4 & 5	Childhood and Adolescence (<18 years old)	♦Audio picture book--On the night you were born; ♦Images about house, study, game, labor,food; ♦Songs about childhood, playmate; ♦Video-- The Rhythm of Life; ♦Guiding questions.	♦Review the childhood and adolescence.	♦Review Extraction: summarize events of this section; ♦Mind Space: say something to any deceased relative who is important for you (e.g. grandparents) ; ♦Supplement any content on this section.
6	Summary of Life	♦E-life review product--My Life Story; ♦Images about life-line; ♦Guiding questions.	♦Summary important experience (including creating a life-line).	♦Mind Space: say something to the most important one in your life; ♦E-legacy products: display the life-line and e-life review product; ♦View a time-line of life review course; ♦Supplement any content on this section.

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Control

Patients randomly assigned to the control group will receive usual care focused on physical symptom management, medical consultations, and health education.

Outcome measures

Primary outcomes

Anxiety will be measured by Zung's self-rating anxiety scale (SAS).[36] The 20-item self-report scale is rated on 4-point score form 1 (a little of the time) to 4 (most of the time). The total score ranges from 20-80 with a higher score indicating a higher level of anxiety. It is widely used to quantify the level of anxiety, which has been proven to be reliable among cancer patients in China ($\alpha = 0.799$).[37]

Zung's self-rating depression scale (SDS) is useful to detect the level of depression.[38] The 4-point scale also consists of 20 items with a total score of 80. Good reliability has been shown with Cronbach's alpha 0.87.[39]

Self-transcendence will be measured by self-transcendence scale (STS).[32] It is a 15-item scale and each item is rated from '1= not at all ' to '4 =almost always'. The total score ranges from 15 to 60 calculated by adding all the individual items. The Chinese version scale has been validated with high reliability ($\alpha = 0.83$-0.87).[40]

Secondary outcomes

Meaning in life will be measured by the Meaning in Life Questionnaire (MLQ) developed by Steger.[41] It consists of 10 items measuring the presence of meaning and the search for meaning. Each item is rated on 7-point Likert from '1 = extremely disagree' to '7 = totally agree'. It has been shown good reliability with internal consistency values between 0.79 to 0.93.[42]

Herth hope Scale (HHS) will be used to assess the level of hope.[43] It is a 12-item scale divided into three dimensions including temporality and future, positive readiness and expectancy, and interconnectedness. Good validity and reliability have been reported among patient with lung cancer, with Cronbach's alpha value 0.87 and construct validity 0.85.[44]

Demographic and clinical data

Demographic data, including age, gender, race, marital status, level of education, level of

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income and cancer information will be collected using personal information form.

Data collection

Data will be collected by two research assistants at baseline, immediately, three months, and six months after the programme. They are blinded to group assignments and collect patients' demographic data, primary and secondary outcome variables. During the investigation, the assistants will ensure the confidential and voluntary nature of the study, then explain the requirements of each measure. Once patients encounter the difficulty in completing the questionnaires, assistants will help them through reading each item clearly, repeating the item if needed and recording the participants' responses accordingly.

Data analysis

Descriptive statistics will be used for sample characteristics. Parametric or non-parametric tests will be conducted to compare the baseline characteristics of two groups. A bivariate analysis using the Student's t test or the chi-square test will be performed, when the data are normally distributed that is determined by Normality tests. Otherwise, non-parametric tests such as the Wilcoxon test and the Mann-Whitney U test will be used. Repeated-measures analysis of variance will also be used to evaluate the effects of the life review programme.

Ethics

Ethics approval has been obtained from Biological and Medical Research Ethics Committee of Fujian Medical University (IRB Ref No: 2016/00020) in July 2017. This study will adhere to ethical standards for the whole procedure. Written informed consent will be signed by participants to assure that they voluntarily take part in this study, know about the details of the study including the purpose, the procedure, benefits and potential risk, the right to withdraw form study at any point without any negative consequences. All data collected from participants will be kept confidential and anonymous, exclusively for the research only.

DISCUSSION

Cancer patients often experience considerable distress due to the disease and chemotherapy.

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Effective psychological interventions such as life review are not always available to cancer patients due to geographic distance and traffic problems. Therefore, the proposed intervention protocol is to construct the WBLRP and test its effects in cancer patients undergoing chemotherapy, which is expected to overcome the obstacles and benefit more patients by improving their psycho-spiritual well-being and achieving a state of self-integration.

The effectiveness of WBLRP may attribute to its characteristics. First, WBLRP is a theory-based intervention tailed to cancer patients. Second, it is easily accessible for cancer patients. Third, five components of WBLRP play a vital role. E-life review interview allows patients to select a familiar environment to review their life, where they can feel safe and comfortable to reveal intimate, painful life experiences.[45] Memory prompts may help to wake up patients' memories and facilitate life review process. Previous studies have supported that they can trigger patients' recollection.[10,46] Review Extraction summarizes meaningful events of each stage to help patients relive life events during life review intervals. Relive life events on their own is part of the process of self-evaluation, which is important to the success of the life review.[47] Mind Space is an internal process, which can assist patients in finding meaning and purpose in life.[33] E-legacy products help patients integrate their whole life. The vivid e-life review product is convenient for patients to review and pass on from generation to generation. It may also play an important part in maintaining positive emotions for a period time.[35]

Some limitations are acknowledged in this study. Firstly, the programme is probably not suitable for illiterates, because they may encounter difficulty in viewing memory prompts and operating life review modules. Secondly, e-life review interview may lack human contact compared with face-to-face intervention. Fortunately, texts, emotion icons and other non-verbal information can be used to compensate this shortcoming.[48] Finally, some patients will probably drop the study during the six-month following up due to the progression of disease.

If the WBLRP was effective, it could be integrated into cancer routine care to enhance psycho-spiritual well-being of cancer patients. It may an alternative approach for nurses to deliver life review intervention to community-dwelling cancer patients. Additionally, this study could provide reference for nursing care utilizing the Internet and put forward a new idea for psychological rehabilitation. To the best of the researchers' knowledge, this is an innovative

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programme based on the theoretical framework to improve the psycho-spiritual well-being among cancer patients.

Acknowledgements

We would like to thank the experts for their kind help and insightful advice during the validation of this programme. We also would like to thank National Nature Science Foundation of China, Fujian Provincial Nature Science and Fujian Provincial Health and Family Planning Commission for providing fund for this study.

Contributors

HMX undertook the conception of the study, as well as critical revision of the manuscript and obtaining funding and supervision. XLZ mainly designed the study and drafted the manuscript. All authors have reviewed and approved the manuscript.

Competing interests

None declared.

Funding

This study is funded by National Nature Science Foundation of China [8140, 1863] , Fujian Provincial National Nature Science [2017J01814] and Fujian Provincial Health and Family Planning Commission [2017-CX-35].

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	P1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	P1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	P2-4
	2b	Specific objectives or hypotheses	P4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	P4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	No applicable
Participants	4a	Eligibility criteria for participants	P5
	4b	Settings and locations where the data were collected	P5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P6-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	P12-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No applicable
Sample size	7a	How sample size was determined	P5-6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	No applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	P6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	P6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	P6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	P6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	P6

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	No applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	P13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	No applicable
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	No applicable
	13b	For each group, losses and exclusions after randomisation, together with reasons	No applicable
Recruitment	14a	Dates defining the periods of recruitment and follow-up	No applicable
	14b	Why the trial ended or was stopped	No applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	No applicable
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	No applicable
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	No applicable
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	No applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	No applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	No applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	P13-15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	P13-15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	P13-15
Other information			
Registration	23	Registration number and name of trial registry	P1
Protocol	24	Where the full trial protocol can be accessed, if available	No applicable
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	P15

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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BMJ Open

Development and evaluation of a WeChat-based life review program for cancer patients : Protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020239.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Mar-2018
Complete List of Authors:	Zhang, Xiaoling; Fujian Medical University, School of Nursing Xiao, Huimin; Fujian Medical University, School of Nursing
Primary Subject Heading:	Nursing
Secondary Subject Heading:	Oncology, Mental health, Palliative care
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, ONCOLOGY, CHEMOTHERAPY, life review

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Development and evaluation of a WeChat-based life review program for cancer patients : Protocol for a randomized controlled trial

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Keywords: life review; cancer; nursing; psychological intervention; Internet.

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Development and evaluation of a WeChat-based life review program for cancer patients: Protocol for a randomized controlled trial

ABSTRACT

Introduction Cancer patients often suffer from considerable distress. Life review is a process of recalling, evaluating and integrating life experiences to alleviate a sense of despair and achieve self-integrity. Empirical data have supported the fact that life review is an effective psychological intervention, but it is not always accessible for cancer patients. There is little evidence of an Internet-based life review program tailored to cancer patients. This study aims to develop a WeChat-based life review program and evaluate its effects on the psycho-spiritual well-being of cancer patients undergoing chemotherapy.

Methods and analysis A randomized controlled trial with repeated measures will be used. Cancer patients will be randomly allocated to either a control group, or an experimental group that receives a six-week WeChat-based life review program. The program was mainly developed based on Erikson's psychosocial development theory and Reed's self-transcendence theory. It provides synchronous and asynchronous communication modes for patients to review their life. The former is real-time communication, providing an e-life review interview guided by a facilitator online. The latter is not simultaneously dialogic, used to interact with patients before and after a life review interview, through Memory Prompts, Review Extraction, Mind Space, and E-legacy products. Anxiety, depression, self-transcendence, meaning in life, and hope will be measured at baseline, immediately, three months, and six months after the program.

Ethics Ethics approval has been obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020). The trial results will be published in a peer-reviewed journal.

Trial registration number This trial was registered on the Chinese Clinical Trial Registry (ChiCTR-IOR-17011998)

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Strengths and limitations of this study

- This is a pioneer study to develop a theory-based WeChat-based life review program, tailored to cancer patients, and test its effects in the context of cancer patients in China with a rigorous design. The program may be an alternative approach to enhancing patients' psycho-spiritual well-being, and benefit more cancer patients.
- This program is probably not suitable for people with poor literacy skills, because they may encounter difficulties in viewing memory prompts and operating the life review modules.
- In this psychological research, it is not possible to blind all participants to the program, which may lead to the Hawthorne Effect.
- This study is a single-center randomized trial, and the findings may not be generalizable to all settings. A study with more rigorous design, with a multi-center, inter-disciplinary and transregional setting is necessary in the future.

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INTRODUCTION

Cancer is a life-threatening disease. By 2025, the number of people dying annually from cancer is expected to increase to 11.4 million from the 2015 figure of 8.8 million.[1] In China, cancer is the leading cause of death, accounting for 27% of deaths among global cancer patients.[2] Previous study has shown that 27% of the cancer mortality risk is associated with psycho-spiritual distress.[3] A meta-analysis has found a dose-response effect indicating that higher levels of psychological distress are linked with a 41% increased risk of cancer death.[4] Psycho-spiritual distress, such as anxiety, depression, and hopelessness is prevalent among cancer patients undergoing chemotherapy.[5] Approximately 32.5% to 75.7% of cancer patients experience psycho-spiritual distress, which is higher than in the normal population, as well as higher than in patients with other diseases.[6-8] Psycho-spiritual distress may greatly prolong cancer patient hospitalization rates,[9] interfere with cancer treatment,[10] lower rehabilitation effectiveness,[3] and be related to cancer mortality.[3-4]

Life review is regarded as a psychological intervention in palliative care. It is defined as a process of recalling, evaluating and integrating life experiences to facilitate the achievement of ego integrity.[11] Grounded by Erikson's psychosocial development theory, life review is structured with guiding questions to review each stage of life. Reviewing an entire life enables participants to revisit past experiences, retrieve better feelings of positive memories, and release negative emotions of unpleasant events.[12-13] It also helps to reaffirm their contributions and accomplishments, reconcile their failures and disappointments, and integrate their entire life into a more acceptable or meaningful whole.[12,14-15] Previous studies have explored a life review's effects on psychological distress (i.e. anxiety, depression),[16-17] spiritual well-being (i.e. meaning of life, hope) ,[18-19] and quality of life.[20-21] Various reviews have been conducted to synthesize these results, including systematic reviews[22-23] and meta-analysis.[24] The meta-analysis presented the cumulative evidence from well-designed clinical trials of life review's effect on cancer patients. It suggests that life review is potentially beneficial in palliative care, and can be integrated into typical cancer care to enhance patients' psycho-spiritual well-being. Life review is more feasible for cancer patients, compared to other psychological interventions, such as cognitive behavioral therapy (CBT) and meaning-centered psychotherapy (MCP). First, reviewing one's life is a naturally

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occurring, universal mental process in cancer patients in their final life stage.[25] However, they are sometimes frustrated and distorted by negative experiences. In a life review, a facilitator will guide patients to reconcile their disappointments. Second, CBT and MCP usually require participants who are capable of some level of activities of daily living. Instead, Ando et al. found that patients with deteriorating health or low functionality can still participate in a life review, even if they are lying in bed.[26] However, traditional face-to-face life review is not always available for advanced cancer patients suffering from psycho-spiritual distress. A systematic review pointed out that life review is commonly undertaken in hospitals, palliative care units or other working places. Some patients in such settings may lose the opportunity to participate in life review due to the time conflicts between life review and medical treatment or nursing care.[23] Furthermore, few patients dwelling in community can gain access to a life review intervention, because of geographic distance, traffic problems, and limited human resources.

E-Health, a recent health care practice supported by electronic processes and communication, may be a potential means of overcoming the above mentioned barriers.[27] Research related to online life review has been reported, with two studies focusing on older adults[28-29] and one study on cancer patients.[30] In 2009, an e-health system called the Butler Project was constructed, with the aim of facilitating optimal aging.[31] Preschl et al. conducted life review therapy with computer supplements for depression using the Butler Project System.[28] The intervention consisted of a face-to-face life review, and a computer component to induce positive emotions. This study was performed in a traditional face-to-face setting. Another study focusing on adults was a randomized controlled trial to test the efficacy of life review as online guided self-help.[29] The life review intervention group members received a self-help book to review their lives, performed a well-being exercise by following an audio-CD, and sought support from researchers via e-mail. Though it addressed the issue of geographic distance, e-mail contact was not so timely as to receive a reply. Wise et al. designed a life review for cancer patients that used online social networks.[30] The intervention combined a dignity-enhancing telephone interview, a text life story, and a self-directed website for patients to share their story and establish social networks. Then a randomized controlled trial was performed to test its effects on distress and existential well-being among 68 advanced cancer patients.[32] The study explored patients' satisfaction with the life

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review process, social networking use patterns, and themes emerging from their life stories; however, statistical results were lacking and the evidence to determine its efficacy remained inconclusive. Moreover, telephone interviews failed to observe reviewers' non-verbal information, such as facial expressions and body language. To our knowledge, there is no life review program tailored to cancer patients that is completely based on the Internet, particularly in China.

WeChat is a multi-function social networking application covering 90% of mobile phones in China and used in 200 countries with more than 20 languages,[33] which provides the functions of synchronous and asynchronous communication. Synchronous communication is a real-time communication between two or more individuals. Asynchronous communication permits a delay between the sender and receiver. The sender can transmit the data at any time, and the receiver can read it whenever he or she wants. WeChat users can interact asynchronously with each other through text messaging, voice messaging, video conferencing, and so on, and they can obtain information and browse resources from all kinds of WeChat platforms at any time. Due to its synchronous and asynchronous communication functions, WeChat has been increasingly used in nursing education and continuous nursing, as well as in other areas.[34-35] Given the popularity of WeChat, we aimed to design a WeChat-based life review program (WBLRP) and test its effects on psycho-spiritual well-being among cancer patients. We hypothesized that cancer patients undergoing chemotherapy who received the WBLRP would see a significant difference in their mean scores of anxiety, depression, self-transcendence, meaning of life, and hope, compared to the control group.

METHODS AND ANALYSIS

Study design

The study is a randomized controlled trial design, consistent with the guidelines of Standard Protocol Items: Recommendations For Interventional Trials (SPIRIT).[36] This study will follow the Consolidated Standards of Reporting Trials (CONSORT) flow chart to show the flow of participants through each stage of a randomized controlled trial [37](Figure 1).

Participants

The participants will be recruited from two oncology departments of a medical university

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affiliated hospital in Fujian province in China's southeast. It is a comprehensive hospital that has received a national service quality evaluation. Cancer types in oncology departments include colorectal cancer, gastric cancer, breast cancer, lung cancer, and others, with the exception of hematological and brain cancer, which are treated in other clinical departments. An average of 244 cancer patients in two oncology departments per month receive chemotherapy, and approximately 82% of these patients have access to the Internet at home. The inclusion criteria for the participants are: (1) diagnosed with stage III or IV cancer and currently undergoing chemotherapy; (2) aged 18 years or above; (3) aware of their diagnosis and treatment; (4) able to access to the Internet via multiple devices, such as a mobile phone. The exclusion criteria are: (1) currently taking anxiolytics or antidepressants; (2) receiving other psycho-therapeutic treatments; (3) experiencing verbal communication impairment or cognitive impairment, psychiatric disorders and indications of suicide; (4) severely disabled or the disease progressing rapidly (Karnofsky Performance Status, KPS<40%).

Sample size determination

Sample size calculation is based on power analysis. Power analysis adopts a hypothesis-testing method to determine sample size according to a pre-specified significance level and desired power level.[38] Assuming a two-tailed alpha of 0.05, a probability of 0.02 for beta error (80% power) and an effect size of 0.42 after calculating anxiety according to the previous study,[24] 64 participants are required. For depression (effect size 0.52) and self-transcendence (effect size 0.39),[24,39] the sample sizes are 30 and 76 respectively. According to the larger sample size, 76 patients are needed. Assuming a 20% dropout rate in this study, the total sample size is 92 participants.

Randomization, allocation concealment and blinding processes

This study will follow the process of randomization. Before randomization, a person who is not engaged in the subject recruitment and data collection will prepare a randomization list with 46 sets of numbers, either 0 (control group) or 1 (experimental group), using the computer software Research Randomizer (http://www.randomizer.org/). These 46 sets of numbers will be printed out separately and sealed in each envelope. After recruiting a participant, the facilitator will open an

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envelope in sequence. The number found in the envelope will represent the group of that particular participant. In this study, group assignments do not blind both participants and the facilitator, but blind data collectors in order to minimize measurement bias.

Intervention

Development of WBLRP

The WBLRP is an e-life review intervention for cancer patients reviewing their life in synchronous and asynchronous communication modes. The former is an e-life review interview; the latter are four life review modules, including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products. Based on Erikson's psychosocial development theory, an e-life review interview was developed to facilitate a life review going through each life stage online. Erikson articulates that a healthily developing human should pass eight developmental stages, from infancy to late adulthood.[40] At the final life stage, if individuals are able to overcome the development crisis, they will achieve ego integrity; otherwise, they will become preoccupied by despair, experience regrets, and fear death. Butler's life review interview is a systematic process that follows Erikson's lifespan stages and promotes life integration by recalling, evaluating and integrating positive and negative life experiences.[11] Thus, according to Erikson's theory, the synchronous communication mode aims to guide patients in reviewing their entire life online, from childhood to the present.

Based on Reed's self-transcendence theory, four life review modules, including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products were designed in the asynchronous communication mode. Self-transcendence is described as the expansion of personal boundaries that is influential in finding meaning and purpose in life including outward，inward，spirituality, and temporal.[41] It is an inherent quality in every human being, which can be a powerful coping strategy when one is faced with adversity.[42] Indeed, reviewing a life involves every factor of self-transcendence. In our program, the four life review modules are designed to enhance self-transcendence. For example, Mind Space is designed to further help patients reveal their innermost feelings, beliefs, and what is most meaningful in life, after the life review interview. E-legacy Products help patients integrate their past, present and their entire life.

Additionally, the guiding questions of the life review interview, and images and videos

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promoting patients' memories, were employed from our research team's previous studies for the WBLRP.[43-44]

Validation of WBLRP

The WBLRP has been validated by a panel of experts with a two-round Delphi survey. The panelists consisted of three life review researchers, three palliative care nurse specialists, two clinical oncology professors, one social worker, and one psychologist. All of them hold a Bachelor's degree or above, and have at least five years of work experience in their respective fields. The panelists evaluated the content's appropriateness and relevance, the program's format, frequency and duration, and provided comments based on their experience and knowledge. The Content Validity Index was calculated by the percentage of items rated as "relevant" or "very relevant". It was 90% in the first round. According to the experts' comments, eight guiding questions were adjusted, and two pictures were added. The Content Validity Index of the second round reached 100%. After the experts' validation, two cancer patients were recruited to test whether the WBLRP content was understandable and acceptable.

WBLRP Components

E-life review interview is an individual face-to-face interview with the function of video-call on WeChat. Four sections will be reviewed weekly over six weeks, including present life (cancer experience), adulthood, childhood and adolescence, and summary of life, which are ordered in a reserve sequence starting with the present and working backwards. Each section has its corresponding guiding questions. The duration of each life review interview ranges from 40 to 60 minutes, depending on the patient's physical condition and willingness to talk. The first author, a nursing postgraduate and registered nurse, who has received approximately 50 hours of life review training, will act as facilitator. Both facilitator and patients can conduct the interview at a convenient time, at any location with access to the Internet.

Memory Prompts Module contains various resources, such as images, songs, videos, audio-picture books and guiding questions related to the content of each section. They will be presented to patients ahead of the life review interviews in order to evoke their memories. For example, in the Childhood and Adolescence Section, an audio picture book entitled "On the Night

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You were Born" opens the prelude of the review; images about house, studies, games, labor and food display the life scenes of that age; songs about childhood trigger recollections of a person's past life. Patients are encouraged to supplement other relevant resources (e.g. images, songs) according to their circumstances. Guiding questions are used to stimulate memories and help patients recall the important events of their life.

Review Extraction Module refers to a summary of meaningful events created by the facilitator after each section, where patients can review the content and leave their comments. After each life review interview, the facilitator will elicit significant events with relevant images for patients to clarify the trajectory of each life stage, and facilitate self-evaluation during the life review intervals.

Mind Space Module provides patients with an opportunity to express their emotions, set down their wishes, or reveal their true feelings to those who are important to them. For example, in the Adulthood Section, patients can express thanks to family members or friends on Mind Space. This module allows patients to look inside themselves, reconsider and reflect on their relationship with others, and establish a sense of connection with their surroundings beyond personal boundaries.

E-legacy Products Module presents products of a family tree, a lifeline and an e-life review product, which can be preserved as spiritual memorials. The family tree and lifeline are created by patients under the facilitator's guidance during the life review interview. The e-life review product will be created by the facilitator through selecting significant experiences, views on life, and words for loved ones, with additional elements of photos, songs or videos based on patients' preferences. The products will be presented to patients in order to let them re-evaluate and integrate their life events, and finally, will be left as a legacy product. This module helps to promote the recollection of patients' family history and life experiences, as well as to integrate their past, present and entire life.

Intervention procedure and monitoring

Prior to the intervention, patients in the experimental group will be guided to install WeChat, register an account, launch a video-call, browse the memory prompts of life review, and operate

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each module on the WeChat platform. Additionally, an operation pamphlet can be consulted on the platform. Before each session, patients can access the Memory Prompts Module to obtain an overview of the current session. Subsequently, an e-life review interview is implemented, along with creating a family tree or a lifeline. Both patients and facilitator can communicate in a virtual face-to-face setting with additional instant messaging methods, including text message, voice message and emotion icons. After the life review interview, they can access the 24-hour open asynchronous communication modules to relive and integrate the reviewed content, deliver feelings and e-legacy products, or supplement any content during life review intervals. Generally, each session follows the same process (For more details, please see Table 1). When approaching the end of the intervention, the facilitator will create a timeline recording of the life review process that patients will participate in.

During the WBLRP, there will be ongoing monitoring of participants' physical condition, emotional status, response to guiding questions of the life review, and compliance with the intervention; as well as of the facilitator's life review skills. If participants experience negative emotions, a follow-up by a clinical psychologist is required. To protect patients' privacy, the life review WeChat platform can only be accessed with a personal WeChat number, and patients can decide which modules may be read by other people.

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Table 1 An overview of the WeChat-based life review program

Session	Section	Asynchronous communication (Appreciate memory prompts before the interview)	Synchronous communication (Deliver the e-life review interview)	Asynchronous communication (Operate modules after the interview)
1	The present (from cancer diagnosis to present)	♦Images about hospital, ward, health care staff; ♦Audio picture book--The Fall of Freddie the Leaf; ♦Video--Circulation of four seasons; ♦Guiding questions.	♦Review present life.	♦Review Extraction: summarize events in this section; ♦Mind Space: set down wishes for anyone who is important to you at this stage; ♦Supplement any content in this section.
2 & 3	Adulthood (≥18 years old)	♦Images of family, work, hobbies; ♦Audio picture book--Love is a Handful of thick Honey; ♦Songs about family, work or love; ♦Video of family tree; ♦Guiding questions.	♦Review adulthood (including creating a family tree).	♦Review Extraction: summarize events in this section; ♦Mind Space: express thanks to family members or friends; ♦E-legacy product: display the family tree; ♦Supplement any content in this section.

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4 & 5	Childhood and Adolescence (<18 years old)	♦Audio picture book--On the Night You were Born; ♦Images of house, studies, games, labor, food; ♦Songs about childhood, playmates; ♦Video-- The Rhythm of Life; ♦Guiding questions.	♦Review childhood and adolescence.	♦Review Extraction: summarize events in this section; ♦Mind Space: say something to any deceased relative who is important to you (e.g. grandparents) ; ♦Supplement any content in this section.
6	Summary of Life	♦E-life review product--My Life Story; ♦Images of lifeline; ♦Guiding questions.	♦Summary of important experiences (including creating a lifeline).	♦Mind Space: say something to the most important one in your life; ♦E-legacy products: display the lifeline and e-life review product; ♦View a timeline of life review course; ♦Supplement any content in this section.

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Comparison

The patients in both the experimental and control groups will receive usual care provided by the study hospital. Usual care involves personal care, medical care, health education, and emotional support. The control group may freely use the Internet to search for information. However, they will not have access to the WBLRP.

Outcome measures

Primary outcomes

Anxiety will be measured by Zung's self-rating anxiety scale (SAS).[45] The 20-item self-report scale is rated on 4-point score from 1 (seldom) to 4 (most of the time). The total score ranges from 20-80, and a score more than 50 indicates mild to moderate anxiety. It is widely used to quantify the level of anxiety, which has been proven to be reliable among cancer patients in China ($\alpha = 0.799$).[46]

Zung's self-rating depression scale (SDS) is useful to detect the level of depression.[47] The 4-point scale also consists of 20 items, with a total score of 80. A score of more than 53 can be rated as mildly depressed. Good reliability has been shown with Cronbach's alpha 0.87.[48]

Self-transcendence will be measured by the self-transcendence scale (STS).[41] It is a 15-item scale, and each item is rated from '1= not at all' to '4 =almost always'. The total score ranges from 15 to 60, calculated by adding all of the individual items. The Chinese version scale has been validated with high reliability ($\alpha = 0.83$-0.87).[49]

Secondary outcomes

Meaning in life will be measured by the Meaning in Life Questionnaire (MLQ) developed by Steger.[50] It consists of 10 items measuring the presence of meaning and the search for meaning. Each item is rated on 7-point Likert from '1 = extremely disagree' to '7 = totally agree'. It has been shown to have good reliability, with internal consistency values between 0.79 to 0.93.[51]

Herth Hope Scale (HHS) will be used to assess the level of hope.[52] It is a 12-item scale divided into three dimensions, including temporality and future, positive readiness and expectancy, and interconnectedness. Good validity and reliability have been reported among patients with lung cancer, with Cronbach's alpha value 0.87 and construct validity 0.85.[53]

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Other data

Demographic data, including age, gender, race, marital status, level of education, level of income and cancer information will be collected using a personal information form.

Patients' physical function will be evaluated with KPS. KPS measures palliative care patients' progressive decline in physical condition and exercise tolerance.[54] It grades a patient's general condition with an 11- point score system from 0 (death) to 100% (normal). A KPS of less than 40% means that the patient is severely disabled and that his/her disease is progressing rapidly. Thus, this study includes patients with KPS of more than 40%.

Patients' psychiatric condition will be checked from their medical records, and patients with a psychiatric diagnosis will be excluded from participating in this study. The indications of suicide will be measured by the Scale for Suicide Ideation (SSI).[55] SSI was developed in 1979 by Beck, quantifying intensity in suicide ideation. Its Chinese version scale has been validated with good reliability (α =0.87).[56] The scale has a total of 19 items, and the first five items are used to identify the level of suicidal desire. Five items are rated as no suicidal desire, mild and strong suicidal desire. Patients who rate the fourth or the fifth item as mild or strong suicidal desire will not participate in this study.

Data collection

Data will be collected by two research assistants at baseline, immediately, three months, and six months after the program. They are blinded to group assignments and collect patients' demographic data, primary and secondary outcome variables. During the investigation, the assistants will ensure the confidential and voluntary nature of the study, then explain the requirements of each measure. Once patients encounter difficulties in completing the questionnaire, assistants will help them by reading each item aloud, repeating the item if needed, and recording the participants' responses.

Data analysis

Descriptive statistics will be used for sample characteristics. Parametric or non-parametric tests will be conducted to compare the baseline characteristics of two groups. If the data collected are normally distributed, the Student's t-test or the chi-square test will be performed. Otherwise,

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non-parametric tests such as the Wilcoxon test and the Mann-Whitney U test will be used. Repeated-measures analysis of variance will also be used to analyze the effects of the life review program. The missing data will be replaced with the mean value for the continuous variables, and the median for the nominal and ordinal variables.

Patient and Public Involvement

Based on our previous studies and the needs of cancer patients, we put forward the research question. Before designing the WBLRP, a survey was conducted to know about the usage of WeChat in cancer patients and their preferences towards the program. On patients recruitment, the author will visit the potential participants introduced by physicians in Oncology departments, and invite them to join the study. Personal face-to-face interviews will be carried out to ensure that the patients meet all the inclusion and none of the exclusion criteria. Then, eligible patients will be provided with detailed information about the trial and have a chance to discuss procedures with our research team members before signing a consent. The written informed consent assure patients voluntarily take part in this study, know about the study details, including the purpose, procedure, benefits and potential risk, and their right to withdraw from the study at any point without any negative consequences. Thus, there is not the burden of the intervention assessed by patients themselves. In our study, public is not involved.

Ethics

Ethical approval has been obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020) in July 2017. This study will adhere to ethical standards for the entire procedure. All data collected from the participants will be kept confidential and anonymous, and will be used exclusively for this research only.

DISCUSSION

Cancer patients often suffer considerable distress from the disease and from chemotherapy, but they cannot always access effective psychological interventions such as life review, due to geographic distance and traffic problems. Therefore, the proposed intervention protocol is to

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construct the WBLRP and test its effects in cancer patients undergoing chemotherapy, which is expected to overcome these obstacles and benefit more patients by improving their psycho-spiritual well-being and achieving a state of self-integration.

The effectiveness of WBLRP may be attributed to its characteristics. First, WBLRP is a theory-based intervention tailored to cancer patients. Second, it is easily accessible for cancer patients. Third, five components of WBLRP play a vital role. E-life review interviews allow patients to select a familiar environment to review their life in, where they can feel safe and comfortable to reveal intimate, painful life experiences.[57] Memory prompts may help to awaken patients' memories and facilitate the life review process. Previous studies have supported that they can trigger patients' recollections.[58] Review Extraction summarizes meaningful events of each life stage to help patients relive life events and promote self-evaluation during life review intervals. Reliving life events on their own is part of the process of self-evaluation, which is important to the success of the life review.[59] Mind Space is an internal process, where patients can look inside themselves, and clarify their personal values, priorities and life meaning.[42] Our research team's previous studies found that cancer patients wish to reveal their true feelings that until that time had been unknown to others. This module provides an opportunity for patients to express themselves freely, reconsider their relationship with others, and establish a sense of connection with their surroundings, beyond their personal boundaries. E-legacy products not only help patients to appreciate their entire life again, but also to leave a personal legacy for their loved ones. The individual e-product is vivid and convenient for patients to review and pass on from generation to generation. It may also play an important part in maintaining positive emotions for a period of time.[23]

A number of limitations are acknowledged in this study. Firstly, the program is probably not suitable for people with poor literacy skills, because they may encounter difficulties in viewing memory prompts and operating the life review modules. Secondly, e-life review interviews may lack human contact, compared with face-to-face interventions. Fortunately, texts, emotion icons and other non-verbal information on WeChat can be used to compensate for this shortcoming.[60] Seen from the perspective of methodological limitations, one issue is a lack of blinding. When not blinded to psychological interventions, participants are prone to generate the Hawthorne Effect,

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and the facilitator may have expectations of the intervention group. However, it is difficult to blind participants and facilitators to treatments in psychological research. Another issue is a possible high drop-out rate. Some patients will probably drop out of the study during the six-month follow-up, due to the progression of the disease. Finally, this study is a single-center randomized trial, and the findings may not be generalizable to all settings. A study with a more rigorous design, with a multi-center, inter-disciplinary and transregional setting is necessary in the future.

If the WBLRP was effective, it could be integrated into routine cancer care to enhance the psycho-spiritual well-being of cancer patients. It may be an alternative approach for nurses to deliver a life review intervention to community-dwelling cancer patients. Additionally, this study could provide a reference for nursing care utilizing the Internet, and putting forward a new idea for psychological rehabilitation. To the best of the researchers' knowledge, this is an innovative program based on a theoretical framework to improve psycho-spiritual well-being among cancer patients.

Acknowledgements

We would like to thank the experts for their kind help and insightful advice, and thank the patient advisers in the validation of this program. We would also like to thank Fujian Provincial Nature Science and Fujian Provincial Health and Family Planning Commission for providing funding for this study.

Contributors

HMX undertook the conception of the study, conducted critical revision of the manuscript, and obtained funding and supervision. XLZ mainly designed the study and drafted the manuscript. Both authors have reviewed and approved the manuscript.

Competing interests

None declared.

Funding

This study is funded by Fujian Provincial National Nature Science [2017J01814] and Fujian

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Provincial Health and Family Planning Commission [2017-CX-35].

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Figure Legends. Figure. 1. Study flow chart based on CONSORT.

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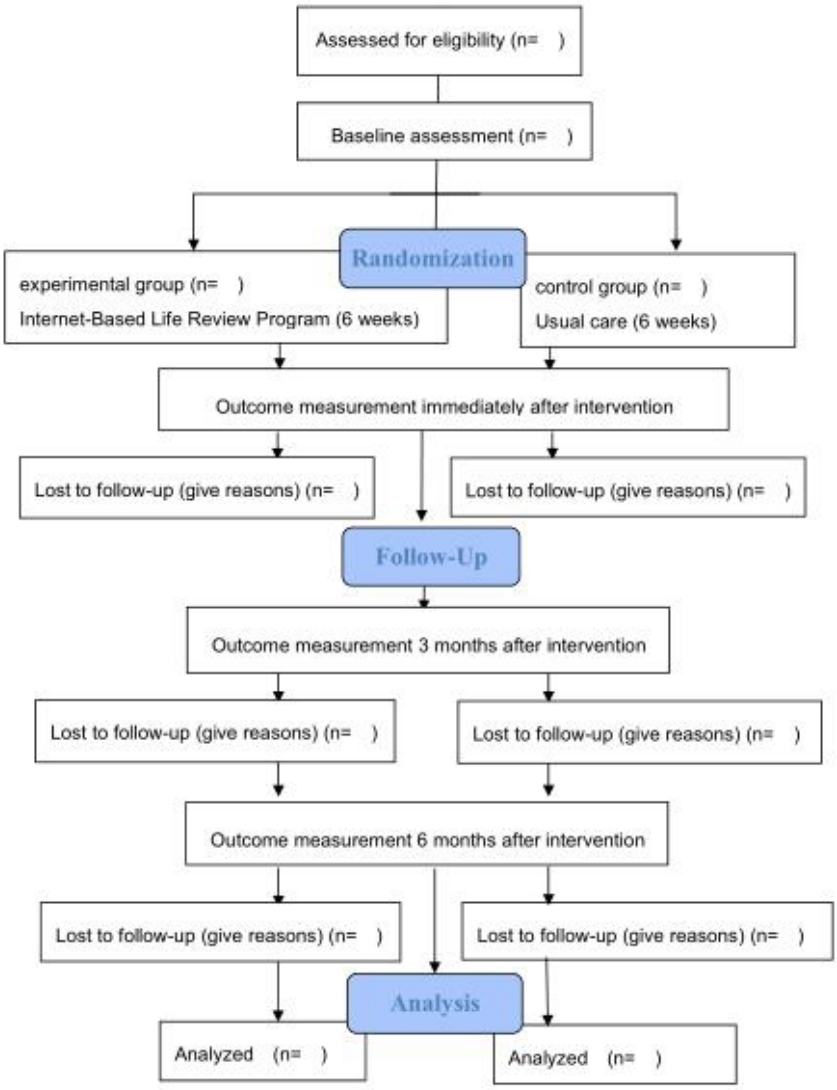

Legends. Figure. 1. Study flow chart based on CONSORT.

137x158mm (96 x 96 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item no	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions,and, if applicable, trial acronym	2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	18
Roles and	5a	Names, affiliations, and roles of protocol contributors	1

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Responsibility	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection,management, analysis, and interpretation of data; writing of the report;and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/a
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/a
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	15
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg,superiority, equivalence, noninferiority, exploratory)	6

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Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6-7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10-11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/a

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Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14-15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	6
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	16
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence	16a	Method of generating the allocation sequence (eg, computer-generation generated random numbers), and list of any factors for stratification.To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7-8

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Allocation concealment Mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7-8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found,	15

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		if not in the protocol	
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/a
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/a

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Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol.	15
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16

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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of Interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/a
Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for	N/a

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post-trial care		compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/a
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/a
Appendices			
No applicable	32	Model consent form and other related documentation given to participants and authorised surrogates	N/a
No applicable	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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BMJ Open

Development and evaluation of a WeChat-based life review program for cancer patients : Protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020239.R2
Article Type:	Protocol
Date Submitted by the Author:	08-May-2018
Complete List of Authors:	Zhang, Xiaoling; Fujian Medical University, School of Nursing Xiao, Huimin; Fujian Medical University, School of Nursing
Primary Subject Heading:	Nursing
Secondary Subject Heading:	Oncology, Mental health, Palliative care
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, ONCOLOGY, CHEMOTHERAPY, life review

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Development and evaluation of a WeChat-based life review program for cancer patients : Protocol for a randomized controlled trial

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Keywords: Internet; life review; cancer; nursing; psychological intervention .

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Development and evaluation of a WeChat-based life review program for cancer patients: Protocol for a randomized controlled trial

ABSTRACT

Introduction Cancer patients often suffer from considerable distress. Life review is a process of recalling, evaluating and integrating life experiences to alleviate a sense of despair and achieve self-integrity. Empirical data have supported the fact that life review is an effective psychological intervention, but it is not always accessible for cancer patients. There is little evidence of Internet-based life review programs tailored to cancer patients. This study aims to develop a WeChat-based life review program and evaluate its effects on the psychospiritual well-being of cancer patients undergoing chemotherapy.

Methods and analysis A randomized controlled trial with repeated measures will be used. Cancer patients will randomly be allocated either to a control group, or to an experimental group that receives a six-week WeChat-based life review program. The program was mainly developed based on Erikson's psychosocial development theory and Reed's self-transcendence theory. It provides synchronous and asynchronous communication modes for patients to review their life. The former is real-time communication, providing an e-life review interview guided by a facilitator online. The latter is not simultaneously dialogic, and is used to interact with patients before and after a life review interview, through Memory Prompts, Review Extraction, Mind Space, and E-legacy products. Anxiety, depression, self-transcendence, meaning in life, and hope will be measured at baseline, immediately, three months, and six months after the program.

Ethics and dissemination Ethics approval has been obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020). The trial results will be published in a peer-reviewed journal and presented at national and international conferences.

Trial registration number This trial was registered on the Chinese Clinical Trial Registry (ChiCTR-IOR-17011998).

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Strengths and limitations of this study

- This is a pioneer study to develop a theory-based WeChat-based life review program with a rigorous design, tailored to cancer patients, and to test its effects in the context of cancer patients in China. The program may be an alternative approach to enhancing patients' psychospiritual well-being, and has the potential to benefit more cancer patients.
- This program is likely not suitable for people with poor literacy skills, because they may encounter difficulties in viewing memory prompts and going through the life review modules.
- In this type of psychological research, it is not possible to blind all participants to the program, which may lead to the Hawthorne Effect.
- This study is a single-center randomized trial, and the findings may be not generalizable to all settings. Conducting another study with more rigorous design, with a multi-center, inter-disciplinary and transregional setting, will be necessary in the future.

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INTRODUCTION

Cancer is a life-threatening disease. By 2025, the number of people dying from cancer each year is expected to increase to 11.4 million, up from the 2015 figure of 8.8 million.[1] In China, cancer is the leading cause of death, accounting for 27% of deaths among cancer patients worldwide.[2] A previous study has shown that 27% of the cancer mortality risk is associated with psychospiritual distress.[3] A meta-analysis has found a dose-response effect, indicating that higher levels of psychological distress are linked to a 41% increased risk of cancer death.[4] Psychospiritual distress, such as anxiety, depression, and hopelessness, is prevalent among cancer patients undergoing chemotherapy.[5] Approximately 32.5% to 75.7% of cancer patients experience psychospiritual distress, which is higher than in the population as a whole, as well as higher than in patients with other diseases.[6-8] Psychospiritual distress may greatly prolong cancer patient hospitalization rates,[9] interfere with cancer treatment,[10] lower rehabilitation effectiveness,[3] and be related to cancer mortality.[3-4]

Life review is regarded as a psychological intervention in palliative care. It is defined as a process of recalling, evaluating and integrating life experiences to facilitate the achievement of ego integrity.[11] Grounded in Erikson's psychosocial development theory, life review is structured with guiding questions to assist participants in reviewing each life stage. Reviewing an entire life enables participants to revisit past experiences, retrieve happier feelings from positive memories, and release negative emotions lingering from unpleasant events.[12-13] It also helps them to reaffirm their contributions and accomplishments, reconcile their failures and disappointments, and integrate their entire life into a more acceptable or meaningful whole.[12,14-15] Previous studies have explored life review's effects on psychological distress (i.e. anxiety, depression),[16-17] spiritual well-being (i.e. meaning of life, hope),[18-19] and quality of life.[20-21] Various reviews have been conducted to synthesize these results, including systematic reviews[22-23] and meta-analysis.[24] The meta-analysis presented the cumulative evidence from well-designed clinical trials of a life review's effect on cancer patients. It suggests that doing a life review is potentially beneficial

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in palliative care, and can be integrated into typical cancer care to enhance patients' psychospiritual well-being. Life review is more feasible for cancer patients, compared to other psychological interventions, such as cognitive behavioral therapy (CBT) and meaning-centered psychotherapy (MCP). First, among cancer patients in the final life stage, reviewing one's life is a naturally occurring, universal mental process.[25] However, patients are sometimes frustrated, and their feelings can be distorted by negative experiences. In a formal life review, a facilitator will guide patients to reconcile their disappointments. Second, CBT and MCP usually require participants who are capable, at some level, of participating in the activities of daily living. However, Ando et al. found that patients with deteriorating health or low functionality can still participate in a life review, even when lying in bed.[26]

Traditional face-to-face life review is not always available for cancer patients suffering from psychospiritual distress. A systematic review pointed out that life review is commonly undertaken in hospitals, palliative care units or other health care institutions. Patients in such settings may lose the opportunity to participate in a life review due to time conflicts between the life review and medical treatment or nursing care.[23] Furthermore, few patients dwelling in community can gain access to a life review intervention, due to issues of geographic distance, traffic problems, and limited human resources.

E-health, a recent health care practice supported by electronic processes and communication, may be a potential means of overcoming the above-mentioned barriers.[27] Research related to online life review has been reported, with two studies focusing on older adults[28-29] and one study on cancer patients.[30] In 2009, an e-health system called the Butler Project was developed, with the aim of facilitating optimal aging.[31] Preschl et al. conducted life review therapy with computer supplements for depression using the Butler Project system.[28] The intervention consisted of a face-to-face life review, and a computer component to induce positive emotions. This study was performed in a traditional face-to-face setting. Another study, focusing on adults, was a randomized controlled trial to test the efficacy of life review as online

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guided self-help.[29] The life review intervention group members received a self-help book to review their lives, followed an audio-CD that guided them in performing a well-being exercise, and sought support from researchers via e-mail. Although this approach addressed the issue of geographic distance, e-mail contact was not immediate enough for the patients to receive a timely reply. Wise et al. designed a life review for cancer patients using online social networks.[30] The intervention combined a telephone interview, a text-formed life story, and a self-directed website for patients to share their personal story and establish social networks. Then a randomized controlled trial was performed to test the intervention's effects on distress and existential well-being among 68 advanced cancer patients.[32] The study explored patients' satisfaction with the life review process, social networking use patterns, and themes emerging from their life stories; however, statistical results were lacking, and the evidence to determine its efficacy remained inconclusive. Moreover, telephone interviews failed to allow the observation of participants' non-verbal information, such as facial expressions and body language. To our knowledge, there is no life review program tailored to cancer patients that is completely Internet-based, particularly in China.

WeChat is a multi-function social networking application covering 90% of mobile phones in China, in use in 200 countries and with more than 20 languages,[33] and providing the functions of synchronous and asynchronous communication. Synchronous communication is real-time communication between two or more individuals. Asynchronous communication permits a delay between sender and receiver. The sender can transmit data at any time, and the receiver can read it whenever he or she wants. WeChat users can interact asynchronously with each other through text messaging, voice messaging, video conferencing, and so on, and they can obtain information and browse resources from all kinds of WeChat platforms at any time. Due to its synchronous and asynchronous communication functions, WeChat has increasingly been used in nursing education and continuous nursing, as well as in other areas.[34-35] Given the popularity of WeChat, we aimed to design a WeChat-based

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life review program (WBLRP) and test its effects on psychospiritual well-being among cancer patients. We hypothesized that cancer patients undergoing chemotherapy who received the WBLRP would see a significant difference in their mean scores of anxiety, depression, self-transcendence, meaning of life and hope, compared to the control group.

METHODS AND ANALYSIS

Study design

The study is a randomized controlled trial design, consistent with the guidelines of Standard Protocol Items: Recommendations For Interventional Trials (SPIRIT).[36] This study will follow the Consolidated Standards of Reporting Trials (CONSORT) flow chart to show the flow of participants through each stage of a randomized controlled trial [37](Figure 1).

Participants

Participants will be recruited from two oncology departments of a medical university affiliated hospital in Fujian province in China's southeast. It is a comprehensive hospital that has received a national service quality evaluation. Cancer types in the oncology departments include colorectal, gastric, breast, lung, and others, with the exception of hematological and brain cancer, which are treated in other clinical departments. In the two oncology departments, an average of 244 cancer patients per month receive chemotherapy, and approximately 82% of these patients have access to the Internet at home. The inclusion criteria for the participants are: (1) diagnosed with Stage III or IV cancer and currently undergoing chemotherapy; (2) aged 18 years or above; (3) aware of their diagnosis and treatment; (4) able to access the Internet via multiple devices, for example, a mobile phone. The exclusion criteria are: (1) currently taking anxiolytics or antidepressants; (2) receiving other psychotherapeutic treatments; (3) experiencing verbal communication impairment or cognitive impairment, psychiatric disorders and indications of suicide; (4) severely disabled or the disease progressing rapidly (Karnofsky Performance Status, KPS<40%).

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Sample size determination

Sample size calculation is based on power analysis. Power analysis adopts a hypothesis-testing method to determine sample size according to a prespecified significance level and desired power level.[38] Assuming a two-tailed alpha of 0.05, a probability of 0.02 for beta error (80% power) and an effect size of 0.42 after calculating anxiety according to the previous study,[24] 64 participants are required. For depression (effect size 0.52) and self-transcendence (effect size 0.39),[24,39] the sample sizes are 30 and 76 respectively. According to the larger sample size, 76 patients are needed. Assuming a 20% dropout rate in this study, the total sample size is 92 participants.

Randomization, allocation concealment and blinding processes

This study will follow the process of randomization. Before randomization, a person who is not engaged in the subject recruitment and data collection will prepare a randomization list with 46 sets of numbers, either 0 (control group) or 1 (experimental group), using the computer software Research Randomizer (http://www.randomizer.org/). These 46 sets of numbers will be printed out separately and sealed in each envelope. After recruiting a participant, the facilitator will open an envelope in sequence. The number found in the envelope will represent the group of that particular participant. In this study, group assignments do not blind participants or the facilitator, but instead, they blind data collectors in order to minimize measurement bias.

Intervention

WBLRP Development

The WBLRP is an e-life review intervention for cancer patients reviewing their life in synchronous and asynchronous communication modes. The former is an e-life review interview; the latter are four life review modules, including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products. Based on Erikson's psychosocial

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development theory, an e-life review interview was developed to facilitate an online life review of each life stage. Erikson states that a healthily developing human should pass through eight developmental stages, from infancy to late adulthood.[40] At the final life stage, if individuals are able to overcome the developmental crisis, they will achieve ego integrity; otherwise, they will become preoccupied by despair, experience regrets, and fear death. Butler's life review interview is a systematic process that follows Erikson's lifespan stages and promotes life integration by recalling, evaluating and integrating positive and negative life experiences.[11] Thus, according to Erikson's theory, the synchronous communication mode aims to guide patients in reviewing their entire life online, from childhood to the present.

Based on Reed's self-transcendence theory, four life review modules, including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products, were designed in the asynchronous communication mode. Self-transcendence is described as the expansion of personal boundaries that is influential in finding meaning and purpose in life, including Outward, Inward, Spirituality, and Temporal.[41] It is an inherent quality in every human being, which can be a powerful coping strategy when one is faced with adversity.[42] Indeed, reviewing a life involves every factor of self-transcendence. In our program, the four life review modules are designed to enhance self-transcendence. For example, Mind Space is designed to further help patients reveal their innermost feelings, beliefs, and what is most meaningful in life, after the life review interview takes place. E-legacy Products help patients integrate their past, present, and their entire life.

Additionally, the guiding questions of the life review interview, and images and videos promoting patients' memories, were drawn from our research team's previous studies for the WBLRP.[43-44]

Validation of WBLRP

The WBLRP has been validated by a panel of experts with a two-round Delphi survey. The panelists consisted of three life review researchers, three palliative care nurse

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specialists, two clinical oncology professors, one social worker, and one psychologist. All hold a Bachelor's degree or above, and have at least five years of work experience in their respective fields. The panelists evaluated the content's appropriateness and relevance, the program's format, frequency and duration, and provided comments based on their experience and knowledge. The Content Validity Index was calculated by the percentage of items rated as "relevant" or "very relevant". It was 90.8% in the first round. According to the experts' comments, eight guiding questions were adjusted, and two pictures were added. The Content Validity Index of the second round reached 100%. After the experts' validation, two cancer patients were recruited to test whether the WBLRP content was understandable and acceptable.

WBLRP Components

E-life review interview is an individual face-to-face interview with the video-call function on WeChat. Four sections will be reviewed weekly over six weeks, including present life (cancer experience), adulthood, childhood and adolescence, and summary of life, which are ordered in a reserve sequence, starting with the present and working backwards. Each section has its corresponding guiding questions. The duration of each life review interview ranges from 40 to 60 minutes, depending on the patient's physical condition and willingness to talk. The first author, a nursing postgraduate and registered nurse, who has received approximately 50 hours of life review training, will act as facilitator. Both facilitator and patients can arrange for the interview to be conducted at a convenient time, at any location with access to the Internet.

Memory Prompts Module contains various resources, such as images, songs, videos, audio picture books and guiding questions related to the content of each section. They will be presented to patients ahead of the life review interviews in order to evoke their memories. For example, in the Childhood and Adolescence Section, an audio picture book entitled "On the Night You were Born" opens the prelude to the review. Images of home, studies, games, labor, and food, display the typical life scenes of that age, while songs about childhood trigger recollections of a person's past.

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Patients are encouraged to supplement with other relevant resources (e.g. images, songs) according to their individual circumstances. Guiding questions are used to stimulate memories and help patients recall the most important events of their life.

Review Extraction Module refers to a summary of meaningful events created by the facilitator after each section, where patients can review the content and leave their comments. After each life review interview, the facilitator will elicit significant events with relevant images, to help patients clarify the trajectory of each life stage and facilitate self-evaluation.

Mind Space Module provides patients with an opportunity to express their emotions, set down their wishes, or reveal their true feelings to those who are important to them. For example, in the Adulthood Section, patients can express their gratitude and thanks to family members or friends. This module allows patients to look within, reconsider and reflect on their relationships with others, and establish a sense of connection with their surroundings beyond personal boundaries.

E-legacy Products Module presents products of a family tree, a timeline of life and an e-life review product, which can be preserved as spiritual memorials. The family tree and a timeline of life are created by patients under the facilitator's guidance during the life review interview. The e-life review product will be created by the facilitator through selecting significant experiences, views on life, and words for loved ones, with additional elements consisting of photos, songs or videos, based on patients' preference. The products will be presented to patients in order to let them re-evaluate and integrate all of their life events, and finally, will serve as a legacy product. This module helps promote the recollection of patients' family history and their life experiences, as well as to integrate their past, present and their life as a whole.

Intervention procedure and monitoring

Prior to the intervention, patients in the experimental group will be guided to install WeChat, register an account, launch a video call, browse the memory prompts of the

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life review, and go through each module on the WeChat platform. Additionally, an operations brochure can be consulted. Before each session, patients can access the Memory Prompts Module to obtain an overview of the current session. Subsequently, an e-life review interview is arranged, along with creating a family tree or a timeline of their life. Both patients and facilitator can communicate in a virtual face-to-face setting with additional instant messaging methods available, including text message and voice message, as well as emotion icons. After the life review interview, patients can access the 24-hour open asynchronous communication modules to relive and integrate the reviewed content, express feelings and deliver e-legacy products, or supplement any content. Generally, each session follows the same process (For more details, please see Table 1). When approaching the end of the intervention, the facilitator will create a timeline recording of the life review process that patients will participate in.

During the WBLRP, there will be ongoing monitoring of participants' physical condition, emotional status, response to life review guiding questions, and compliance with the intervention; as well as ongoing monitoring of the facilitator's life review skills. If participants experience negative emotions, a follow-up by a clinical psychologist is required. To protect patient privacy, the life review WeChat platform can only be accessed with a personal WeChat number, and patients can decide which modules may be read by other people.

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Table 1 An overview of the WeChat-based life review program

Session	Section	Asynchronous communication (Appreciate memory prompts before the interview)	Synchronous communication (Deliver the e-life review interview)	Asynchronous communication (go through modules after the interview)
1	The present (from cancer diagnosis to present)	♦Images of hospital, ward, health care staff; ♦Audio picture book--The Fall of Freddie the Leaf; ♦Video--Circulation of four seasons; ♦Guiding questions.	♦Review present life.	♦Review Extraction: summarize events in this section; ♦Mind Space: set down wishes for anyone who is important to you at this stage; ♦Supplement any content in this section.
2 & 3	Adulthood (≥18 years old)	♦Images of family, work, hobbies; ♦Audio picture book--Love is a Handful of Thick Honey; ♦Songs about family, work or love; ♦Video of family tree; ♦Guiding questions.	♦Review adulthood (including creating a family tree).	♦Review Extraction: summarize events in this section; ♦Mind Space: express thanks to family members or friends; ♦E-legacy product: display the family tree; ♦Supplement any content in this section.

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4 & 5	Childhood and Adolescence (<18 years old)	♦Audio picture book--On the Night You were Born; ♦Images of house, studies, games, labor, food; ♦Songs about childhood, playmates; ♦Video--The Rhythm of Life; ♦Guiding questions.	♦Review childhood and adolescence.	♦Review Extraction: summarize events in this section; ♦Mind Space: say something to any deceased relative who is important to you (e.g. grandparents); ♦Supplement any content in this section.
6	Summary of Life	♦E-life review product--My Life Story; ♦Images of a timeline of life; ♦Guiding questions.	♦Summary of important experiences (including creating a timeline of life).	♦Mind Space: say something to the most important one in your life; ♦E-legacy products: display the a timeline of life and e-life review product; ♦View a timeline of life review course; ♦Supplement any content in this section.

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Comparison

The patients in both the experimental and control groups will receive the usual care provided by the study hospital. Usual care involves personal care, medical care, health education, and emotional support. The control group may freely use the Internet to search for information. However, they will not have access to the WBLRP.

Outcome measures

Primary outcomes

Anxiety will be measured by Zung's self-rating anxiety scale (SAS).[45] The 20-item self-report scale is rated on a 4-point score from 1 (seldom) to 4 (most of the time). The total score ranges from 20-80, and a score of more than 50 indicates mild to moderate anxiety. It is widely used to quantify the level of anxiety, which has been proven to be reliable among cancer patients in China ($\alpha = 0.799$).[46]

The Zung's self-rating depression scale (SDS) is useful to detect the level of depression.[47] The 4-point scale also consists of 20 items, with a total score of 80. A score of more than 53 can be rated as mildly depressed. Good reliability has been shown with Cronbach's alpha 0.87.[48]

Self-transcendence will be measured by the self-transcendence scale (STS).[41] It is a 15-item scale, and each item is rated from '1= not at all' to '4 =almost always'. The total score ranges from 15 to 60, calculated by adding all of the individual items. The Chinese version scale has been validated with high reliability ($\alpha = 0.83$-0.87).[49]

Secondary outcomes

Meaning in life will be measured by the Meaning in Life Questionnaire (MLQ) developed by Steger.[50] It consists of 10 items measuring the presence of meaning and the search for meaning. Each item is rated on a 7-point Likert scale from '1 = strongly disagree' to '7 = totally agree'. It has been shown to have good reliability, with internal consistency values between 0.79 to 0.93.[51]

The Herth Hope Scale (HHS) will be used to assess the level of hope.[52] This is a 12-item scale divided into three dimensions, including temporality and future,

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positive readiness and expectancy, and interconnectedness. Good validity and reliability have been reported among patients with lung cancer, with Cronbach's alpha value 0.87 and construct validity 0.85.[53]

Other data

Demographic data, including age, gender, race, marital status, level of education, level of income and cancer information, will be collected using a personal information form.

Patients' physical function will be evaluated with Karnofsky Performance Status(KPS), which measures palliative care patients' progressive decline in terms of physical condition and exercise tolerance.[54] It grades a patient's general condition with an 11-point score system from 0 (death) to 100% (normal). A KPS of less than 40% means the patient is severely disabled, and that his/her disease is progressing rapidly. Thus, this study includes patients with a KPS of more than 40%.

Patients' psychiatric condition will be checked from their medical records, and patients with a psychiatric diagnosis will be excluded from study participation. The indications of suicide will be measured by the Scale for Suicide Ideation (SSI).[55] SSI was developed in 1979 by Beck, quantifying intensity in suicide ideation. Its Chinese version scale has been validated with good reliability (α =0.87).[56] The scale has a total of 19 items, and the first five items are used to identify the level of suicidal desire. The five items are rated as follows: no suicidal desire, mild suicidal desire, and strong suicidal desire. Patients who rate the fourth or fifth item as mild or strong suicidal desire will not participate in this study.

Data collection

Data will be collected by two research assistants at baseline, and immediately, three months, and six months after the program. They are blinded to group assignments, and collect patients' demographic data, and primary and secondary outcome variables. During the investigation, the assistants will ensure the study's confidential and voluntary nature, and then explain the requirements of each measure. Once patients

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encounter difficulties in completing the questionnaire, assistants will help them by reading each item aloud, repeating the item if required, and recording the participant's responses.

Data analysis

Descriptive statistics will be used for sample characteristics. Parametric or non-parametric tests will be conducted to compare the baseline characteristics of two groups. If the data collected are normally distributed, the Student's t-test or the chi-square test will be performed. Otherwise, non-parametric tests, such as the Wilcoxon test and the Mann-Whitney U test, will be used. Repeated-measures analysis of variance will also be used to analyze the effects of the life review program. The missing data will be replaced with the mean value for the continuous variables, and the median for the nominal and ordinal variables.

Patient and public involvement

We developed the WBLRP based on our systematic review and on the needs of cancer patients. Then, a feasible study with five patients will be conducted to refine the WBLRP. Finally, a randomized controlled trial will be used to examine the effects of the WBLRP. Under the facilitator's guidance, patients will review their life during the WBLRP, and draw a family tree and a timeline of their life. The facilitator will also encourage patients to go through the life review modules after each WBLRP section, such as Content Extraction or Mind Space. At the end of the WBLRP, an e-life review product will be formulated by the facilitator, based on each patient's preferences. Generally, in our study, there is no burden of the intervention assessed by the patients themselves, and the public is not involved.

Ethics and dissemination

Ethical approval was obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020) in July 2017. This study will adhere to ethical standards for the entire procedure. All

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data collected from the participants will be kept confidential and anonymous, and will be used exclusively for this research only. Dissemination strategies may include a paper submission to a peer-reviewed journal, as well as a conference submission. Findings from this research will be used to propose a new idea for nursing care utilizing the Internet, and for psychological rehabilitation among cancer patients.

DISCUSSION

Cancer patients often suffer considerable distress from the disease and from chemotherapy, but they cannot always access effective psychological interventions such as life review, due to geographic distance and traffic issues. Therefore, the proposed intervention protocol is to construct the WBLRP and test its effects on cancer patients undergoing chemotherapy, which is expected to overcome these obstacles and benefit more patients, by improving their psychospiritual well-being, and allowing them to achieve a state of self-integration.

The effectiveness of WBLRP may be attributed to its characteristics. First, WBLRP is a theory-based intervention tailored to cancer patients. Second, it is easily accessible for cancer patients. Third, five components of WBLRP play a vital role. E-life review interviews allow patients to select a familiar environment to review their life in, where they can feel safe and comfortable in revealing intimate, and sometimes painful life experiences.[57] Memory prompts may help to awaken patients' memories and facilitate the life review process. Previous studies have found that memory prompts can trigger patients' recollections.[58] Review Extraction summarizes meaningful events in each life stage, to help patients relive life events and promote self-evaluation after life review interviews. Reliving life events on their own is part of the process of self-evaluation, which is important to the success of the life review.[59] Mind Space is an internal process, where patients can look inside themselves, and clarify their personal values, priorities and life meaning.[42] Our research team's previous studies found that cancer patients wish to reveal their true feelings, feelings that until that time they had not shared with others. This module provides an

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opportunity for patients to express themselves freely, reconsider their relationships with others and establish a sense of connection with their surroundings, beyond their personal boundaries. E-legacy products not only help patients to appreciate their entire life once again, but also to leave a personal legacy for their loved ones. The individual e-product is vivid and convenient for patients to review and then pass down, as a legacy handed from generation to generation. It may also play an important part in helping patients maintain positive emotions for a period of time.[23]

A number of limitations are acknowledged in this study. First, the program is probably not suitable for people with poor literacy skills, because they may encounter difficulties in viewing memory prompts and going through the life review modules. Second, e-life review interviews may lack human contact, compared to face-to-face interventions. Fortunately, texts, emotion icons and other non-verbal information on WeChat can be used to compensate for this shortcoming.[60] Third, seen from the perspective of methodological limitations, one issue is a lack of blinding. When not blinded to psychological interventions, participants are prone to generate the Hawthorne Effect, and the facilitator may have expectations of the intervention group. However, it is difficult to blind participants and facilitators to treatments in psychological research. Another issue is a potentially high dropout rate. Some patients will probably drop out of the study during the six-month follow-up, due to the progression of the disease. Finally, this study is a single-center randomized trial, and the findings may not be generalizable to all settings. Another study with a more rigorous design, with a multi-center, inter-disciplinary and transregional setting, will be necessary in the future.

If the WBLRP was effective, it could be integrated into routine cancer care to enhance the psychospiritual well-being of cancer patients. It may be an alternative approach for nurses to deliver a life review intervention to community-dwelling cancer patients. Additionally, this study could provide a reference for nursing care utilizing the Internet, and put forward a new idea for psychological rehabilitation. To the best of the researchers' knowledge, this is an innovative program based on a

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theoretical framework to improve psychospiritual well-being among cancer patients.

Acknowledgements

We would like to thank the experts for their kind help and insightful advice, and thank the patient advisers in the validation of this program. We would also like to thank Fujian Provincial Nature Science and Fujian Provincial Health and Family Planning Commission for providing funding for this study.

Contributors

HMX undertook the conception of the study, conducted critical revision of the manuscript, and obtained funding and supervision. XLZ mainly designed the study and drafted the manuscript. Both authors have reviewed and approved the manuscript.

Competing interests

None declared.

Funding

This study is funded by Fujian Provincial National Nature Science [2017J01814] and Fujian Provincial Health and Family Planning Commission [2017-CX-35].

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Figure Legends. Figure. 1. Study flow chart based on CONSORT.

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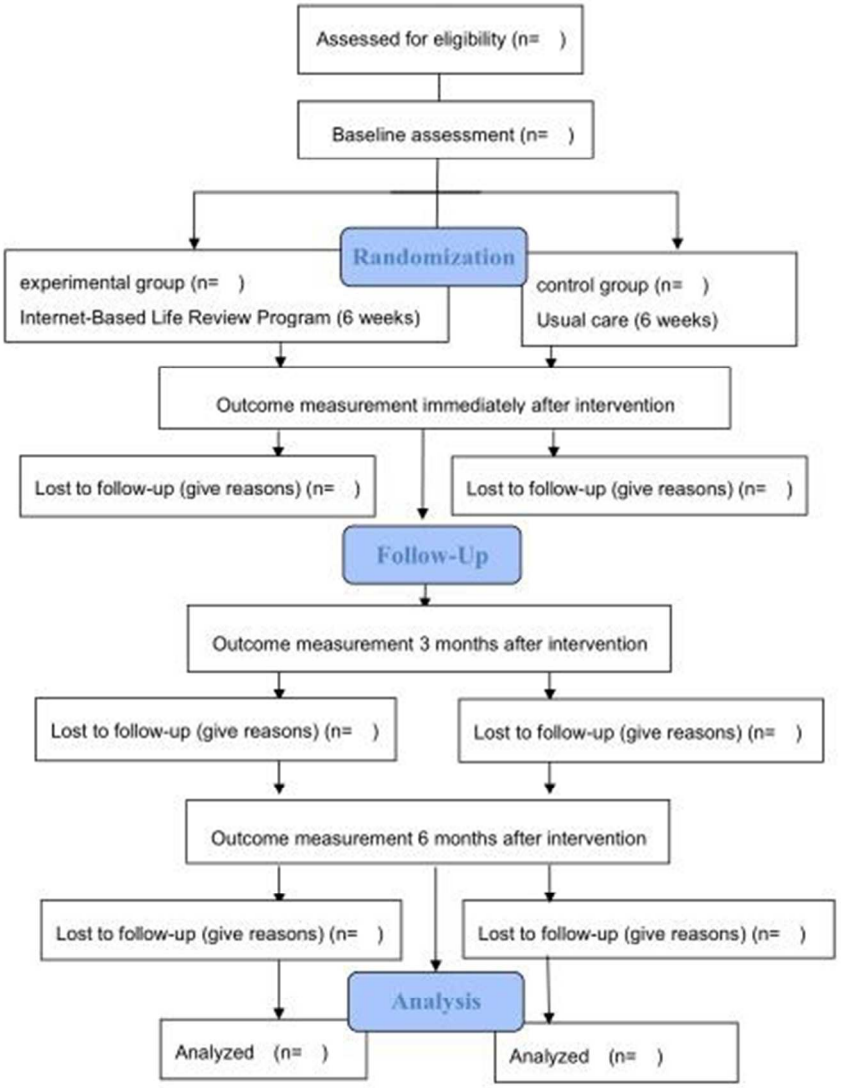

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137x158mm (96 x 96 DPI)

BMJ Open

Development and evaluation of a WeChat-based life review program for cancer patients : Protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020239.R3
Article Type:	Protocol
Date Submitted by the Author:	23-Jun-2018
Complete List of Authors:	Zhang, Xiaoling; Fujian Medical University, School of Nursing Xiao, Huimin; Fujian Medical University, School of Nursing
Primary Subject Heading:	Nursing
Secondary Subject Heading:	Oncology, Mental health, Palliative care
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, ONCOLOGY, CHEMOTHERAPY, life review

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Development and evaluation of a WeChat-based life review program for cancer patients : Protocol for a randomized controlled trial

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Keywords: Internet; life review; cancer; nursing; psychological intervention .

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Development and evaluation of a WeChat-based life review program for cancer patients: Protocol for a randomized controlled trial

ABSTRACT

Introduction Cancer patients often suffer from considerable distress. Life review is a process of recalling, evaluating and integrating life experiences to alleviate a sense of despair and achieve self-integrity. Empirical data have supported the fact that life review is an effective psychological intervention, but it is not always accessible for cancer patients. There is little evidence of Internet-based life review programs tailored to cancer patients. This study aims to develop a WeChat-based life review program and evaluate its effects on the psychospiritual well-being of cancer patients undergoing chemotherapy.

Methods and analysis A randomized controlled trial with repeated measures will be used. Cancer patients will randomly be allocated either to a control group, or to an experimental group that receives a six-week WeChat-based life review program. The program was mainly developed based on Erikson's psychosocial development theory and Reed's self-transcendence theory. It provides synchronous and asynchronous communication modes for patients to review their life. The former is real-time communication, providing an e-life review interview guided by a facilitator online. The latter is not simultaneously dialogic, and is used to interact with patients before and after a life review interview, through Memory Prompts, Review Extraction, Mind Space, and E-legacy products. Anxiety, depression, self-transcendence, meaning in life, and hope will be measured at baseline, immediately, three months, and six months after the program.

Ethics and dissemination Ethics approval has been obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020). The trial results will be published in a peer-reviewed journal and presented at national and international conferences.

Trial registration number This trial was registered on the Chinese Clinical Trial Registry (ChiCTR-IOR-17011998).

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Strengths and limitations of this study

- This is a pioneer study to develop a theory-based WeChat-based life review program with a rigorous design, tailored to cancer patients, and to test its effects in the context of cancer patients in China. The program may be an alternative approach to enhancing patients' psychospiritual well-being, and has the potential to benefit more cancer patients.
- This program is likely not suitable for people with poor literacy skills, because they may encounter difficulties in viewing memory prompts and going through the life review modules.
- In this type of psychological research, it is not possible to blind all participants to the program, which may lead to the Hawthorne Effect.
- This study is a single-center randomized trial, and the findings may be not generalizable to all settings. Conducting another study with more rigorous design, with a multi-center, inter-disciplinary and transregional setting, will be necessary in the future.

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INTRODUCTION

Cancer is a life-threatening disease. By 2025, the number of people dying from cancer each year is expected to increase to 11.4 million, up from the 2015 figure of 8.8 million.[1] In China, cancer is the leading cause of death, accounting for 27% of deaths among cancer patients worldwide.[2] A previous study has shown that 27% of the cancer mortality risk is associated with psychospiritual distress.[3] A meta-analysis has found a dose-response effect, indicating that higher levels of psychological distress are linked to a 41% increased risk of cancer death.[4] Psychospiritual distress, such as anxiety, depression, and hopelessness, is prevalent among cancer patients undergoing chemotherapy.[5] Approximately 32.5% to 75.7% of cancer patients experience psychospiritual distress, which is higher than in the population as a whole, as well as higher than in patients with other diseases.[6-8] Psychospiritual distress may greatly prolong cancer patient hospitalization rates,[9] interfere with cancer treatment,[10] lower rehabilitation effectiveness,[3] and be related to cancer mortality.[3-4]

Life review is regarded as a psychological intervention in palliative care. It is defined as a process of recalling, evaluating and integrating life experiences to facilitate the achievement of ego integrity.[11] Grounded in Erikson's psychosocial development theory, life review is structured with guiding questions to assist participants in reviewing each life stage. Reviewing an entire life enables participants to revisit past experiences, retrieve happier feelings from positive memories, and release negative emotions lingering from unpleasant events.[12-13] It also helps them to reaffirm their contributions and accomplishments, reconcile their failures and disappointments, and integrate their entire life into a more acceptable or meaningful whole.[12,14-15] Previous studies have explored life review's effects on psychological distress (i.e. anxiety, depression),[16-17] spiritual well-being (i.e. meaning of life, hope),[18-19] and quality of life.[20-21] Various reviews have been conducted to synthesize these results, including systematic reviews[22-23] and meta-analysis.[24] The meta-analysis presented the cumulative evidence from well-designed clinical trials of a life review's effect on cancer patients. It suggests that doing a life review is potentially beneficial

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in palliative care, and can be integrated into typical cancer care to enhance patients' psychospiritual well-being. Life review is more feasible for cancer patients, compared to other psychological interventions, such as cognitive behavioral therapy (CBT) and meaning-centered psychotherapy (MCP). First, among cancer patients in the final life stage, reviewing one's life is a naturally occurring, universal mental process.[25] However, patients are sometimes frustrated, and their feelings can be distorted by negative experiences. In a formal life review, a facilitator will guide patients to reconcile their disappointments. Second, CBT and MCP usually require participants who are capable, at some level, of participating in the activities of daily living. However, Ando et al. found that patients with deteriorating health or low functionality can still participate in a life review, even when lying in bed.[26]

Traditional face-to-face life review is not always available for cancer patients suffering from psychospiritual distress. A systematic review pointed out that life review is commonly undertaken in hospitals, palliative care units or other health care institutions. Patients in such settings may lose the opportunity to participate in a life review due to time conflicts between the life review and medical treatment or nursing care.[23] Furthermore, few patients dwelling in community can gain access to a life review intervention, due to issues of geographic distance, traffic problems, and limited human resources.

E-health, a recent health care practice supported by electronic processes and communication, may be a potential means of overcoming the above-mentioned barriers.[27] Research related to online life review has been reported, with two studies focusing on older adults[28-29] and one study on cancer patients.[30] In 2009, an e-health system called the Butler Project was developed, with the aim of facilitating optimal aging.[31] Preschl et al. conducted life review therapy with computer supplements for depression using the Butler Project system.[28] The intervention consisted of a face-to-face life review, and a computer component to induce positive emotions. This study was performed in a traditional face-to-face setting. Another study, focusing on adults, was a randomized controlled trial to test the efficacy of life review as online

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guided self-help.[29] The life review intervention group members received a self-help book to review their lives, followed an audio-CD that guided them in performing a well-being exercise, and sought support from researchers via e-mail. Although this approach addressed the issue of geographic distance, e-mail contact was not immediate enough for the patients to receive a timely reply. Wise et al. designed a life review for cancer patients using online social networks.[30] The intervention combined a telephone interview, a text-formed life story, and a self-directed website for patients to share their personal story and establish social networks. Then a randomized controlled trial was performed to test the intervention's effects on distress and existential well-being among 68 advanced cancer patients.[32] The study explored patients' satisfaction with the life review process, social networking use patterns, and themes emerging from their life stories; however, statistical results were lacking, and the evidence to determine its efficacy remained inconclusive. Moreover, telephone interviews failed to allow the observation of participants' non-verbal information, such as facial expressions and body language. To our knowledge, there is no life review program tailored to cancer patients that is completely Internet-based, particularly in China.

WeChat is a multi-function social networking application covering 90% of mobile phones in China, in use in 200 countries and with more than 20 languages,[33] and providing the functions of synchronous and asynchronous communication. Synchronous communication is real-time communication between two or more individuals. Asynchronous communication permits a delay between sender and receiver. The sender can transmit data at any time, and the receiver can read it whenever he or she wants. WeChat users can interact asynchronously with each other through text messaging, voice messaging, video conferencing, and so on, and they can obtain information and browse resources from all kinds of WeChat platforms at any time. Due to its synchronous and asynchronous communication functions, WeChat has increasingly been used in nursing education and continuous nursing, as well as in other areas.[34-35] Given the popularity of WeChat, we aimed to design a WeChat-based

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life review program (WBLRP) and test its effects on psychospiritual well-being among cancer patients. We hypothesized that cancer patients undergoing chemotherapy who received the WBLRP would see a significant difference in their mean scores of anxiety, depression, self-transcendence, meaning of life and hope, compared to the control group.

METHODS AND ANALYSIS

Study design

The study is a randomized controlled trial design, consistent with the guidelines of Standard Protocol Items: Recommendations For Interventional Trials (SPIRIT).[36] This study will follow the Consolidated Standards of Reporting Trials (CONSORT) flow chart to show the flow of participants through each stage of a randomized controlled trial [37](Figure 1).

Participants

Participants will be recruited from two oncology departments of a medical university affiliated hospital in Fujian province in China's southeast. It is a comprehensive hospital that has received a national service quality evaluation. Cancer types in the oncology departments include colorectal, gastric, breast, lung, and others, with the exception of hematological and brain cancer, which are treated in other clinical departments. In the two oncology departments, an average of 244 cancer patients per month receive chemotherapy, and approximately 82% of these patients have access to the Internet at home. The inclusion criteria for the participants are: (1) diagnosed with Stage III or IV cancer and currently undergoing chemotherapy; (2) aged 18 years or above; (3) aware of their diagnosis and treatment; (4) able to access the Internet via multiple devices, for example, a mobile phone. The exclusion criteria are: (1) currently taking anxiolytics or antidepressants; (2) receiving other psychotherapeutic treatments; (3) experiencing verbal communication impairment or cognitive impairment, psychiatric disorders and indications of suicide; (4) severely disabled or the disease progressing rapidly (Karnofsky Performance Status, KPS<40%).

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Sample size determination

Sample size calculation is based on power analysis. Power analysis adopts a hypothesis-testing method to determine sample size according to a prespecified significance level and desired power level.[38] Assuming a two-tailed alpha of 0.05, a probability of 0.02 for beta error (80% power) and an effect size of 0.42 after calculating anxiety according to the previous study,[24] 64 participants are required. For depression (effect size 0.52) and self-transcendence (effect size 0.39),[24,39] the sample sizes are 30 and 76 respectively. According to the larger sample size, 76 patients are needed. Assuming a 20% dropout rate in this study, the total sample size is 92 participants.

Randomization, allocation concealment and blinding processes

This study will follow the process of randomization. Before randomization, a person who is not engaged in the subject recruitment and data collection will prepare a randomization list with 46 sets of numbers, either 0 (control group) or 1 (experimental group), using the computer software Research Randomizer (http://www.randomizer.org/). These 46 sets of numbers will be printed out separately and sealed in each envelope. After recruiting a participant, the facilitator will open an envelope in sequence. The number found in the envelope will represent the group of that particular participant. In this study, group assignments do not blind participants or the facilitator, but instead, they blind data collectors in order to minimize measurement bias.

Intervention

WBLRP Development

The WBLRP is an e-life review intervention for cancer patients reviewing their life in synchronous and asynchronous communication modes. The former is an e-life review interview; the latter are four life review modules, including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products. Based on Erikson's psychosocial

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development theory, an e-life review interview was developed to facilitate an online life review of each life stage. Erikson states that a healthily developing human should pass through eight developmental stages, from infancy to late adulthood.[40] At the final life stage, if individuals are able to overcome the developmental crisis, they will achieve ego integrity; otherwise, they will become preoccupied by despair, experience regrets, and fear death. Butler's life review interview is a systematic process that follows Erikson's lifespan stages and promotes life integration by recalling, evaluating and integrating positive and negative life experiences.[11] Thus, according to Erikson's theory, the synchronous communication mode aims to guide patients in reviewing their entire life online, from childhood to the present.

Based on Reed's self-transcendence theory, four life review modules, including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products, were designed in the asynchronous communication mode. Self-transcendence is described as the expansion of personal boundaries that is influential in finding meaning and purpose in life, including Outward, Inward, Spirituality, and Temporal.[41] It is an inherent quality in every human being, which can be a powerful coping strategy when one is faced with adversity.[42] Indeed, reviewing a life involves every factor of self-transcendence. In our program, the four life review modules are designed to enhance self-transcendence. For example, Mind Space is designed to further help patients reveal their innermost feelings, beliefs, and what is most meaningful in life, after the life review interview takes place. E-legacy Products help patients integrate their past, present, and their entire life.

Additionally, the guiding questions of the life review interview, and images and videos promoting patients' memories, were drawn from our research team's previous studies for the WBLRP.[43-44]

Validation of WBLRP

The WBLRP has been validated by a panel of experts with a two-round Delphi survey. The panelists consisted of three life review researchers, three palliative care nurse

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specialists, two clinical oncology professors, one social worker, and one psychologist. All hold a Bachelor's degree or above, and have at least five years of work experience in their respective fields. The panelists evaluated the content's appropriateness and relevance, the program's format, frequency and duration, and provided comments based on their experience and knowledge. The Content Validity Index was calculated by the percentage of items rated as "relevant" or "very relevant". It was 90.8% in the first round. According to the experts' comments, eight guiding questions were adjusted, and two pictures were added. The Content Validity Index of the second round reached 100%. After the experts' validation, two cancer patients were recruited to test whether the WBLRP content was understandable and acceptable.

WBLRP Components

E-life review interview is an individual face-to-face interview with the video-call function on WeChat. Four sections will be reviewed weekly over six weeks, including present life (cancer experience), adulthood, childhood and adolescence, and summary of life, which are ordered in a reserve sequence, starting with the present and working backwards. Each section has its corresponding guiding questions. The duration of each life review interview ranges from 40 to 60 minutes, depending on the patient's physical condition and willingness to talk. The first author, a nursing postgraduate and registered nurse, who has received approximately 50 hours of life review training, will act as facilitator. Both facilitator and patients can arrange for the interview to be conducted at a convenient time, at any location with access to the Internet.

Memory Prompts Module contains various resources, such as images, songs, videos, audio picture books and guiding questions related to the content of each section. They will be presented to patients ahead of the life review interviews in order to evoke their memories. For example, in the Childhood and Adolescence Section, an audio picture book entitled "On the Night You were Born" opens the prelude to the review. Images of home, studies, games, labor, and food, display the typical life scenes of that age, while songs about childhood trigger recollections of a person's past.

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Patients are encouraged to supplement with other relevant resources (e.g. images, songs) according to their individual circumstances. Guiding questions are used to stimulate memories and help patients recall the most important events of their life.

Review Extraction Module refers to a summary of meaningful events created by the facilitator after each section, where patients can review the content and leave their comments. After each life review interview, the facilitator will elicit significant events with relevant images, to help patients clarify the trajectory of each life stage and facilitate self-evaluation.

Mind Space Module provides patients with an opportunity to express their emotions, set down their wishes, or reveal their true feelings to those who are important to them. For example, in the Adulthood Section, patients can express their gratitude and thanks to family members or friends. This module allows patients to look within, reconsider and reflect on their relationships with others, and establish a sense of connection with their surroundings beyond personal boundaries.

E-legacy Products Module presents products of a family tree, a timeline of life and an e-life review product, which can be preserved as spiritual memorials. The family tree and a timeline of life are created by patients under the facilitator's guidance during the life review interview. The e-life review product will be created by the facilitator through selecting significant experiences, views on life, and words for loved ones, with additional elements consisting of photos, songs or videos, based on patients' preference. The products will be presented to patients in order to let them re-evaluate and integrate all of their life events, and finally, will serve as a legacy product. This module helps promote the recollection of patients' family history and their life experiences, as well as to integrate their past, present and their life as a whole.

Intervention procedure and monitoring

Prior to the intervention, patients in the experimental group will be guided to install WeChat, register an account, launch a video call, browse the memory prompts of the

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life review, and go through each module on the WeChat platform. Additionally, an operations brochure can be consulted. Before each session, patients can access the Memory Prompts Module to obtain an overview of the current session. Subsequently, an e-life review interview is arranged, along with creating a family tree or a timeline of their life. Both patients and facilitator can communicate in a virtual face-to-face setting with additional instant messaging methods available, including text message and voice message, as well as emotion icons. After the life review interview, patients can access the 24-hour open asynchronous communication modules to relive and integrate the reviewed content, express feelings and deliver e-legacy products, or supplement any content. Generally, each session follows the same process (For more details, please see Table 1). When approaching the end of the intervention, the facilitator will create a timeline recording of the life review process that patients will participate in.

During the WBLRP, there will be ongoing monitoring of participants' physical condition, emotional status, response to life review guiding questions, and compliance with the intervention; as well as ongoing monitoring of the facilitator's life review skills. If participants experience negative emotions, a follow-up by a clinical psychologist is required. To protect patient privacy, the life review WeChat platform can only be accessed with a personal WeChat number, and patients can decide which modules may be read by other people.

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Table 1 An overview of the WeChat-based life review program

Session	Section	Asynchronous communication (Appreciate memory prompts before the interview)	Synchronous communication (Deliver the e-life review interview)	Asynchronous communication (go through modules after the interview)
1	The present (from cancer diagnosis to present)	♦Images of hospital, ward, health care staff; ♦Audio picture book--The Fall of Freddie the Leaf; ♦Video--Circulation of four seasons; ♦Guiding questions.	♦Review present life.	♦Review Extraction: summarize events in this section; ♦Mind Space: set down wishes for anyone who is important to you at this stage; ♦Supplement any content in this section.
2 & 3	Adulthood (≥18 years old)	♦Images of family, work, hobbies; ♦Audio picture book--Love is a Handful of Thick Honey; ♦Songs about family, work or love; ♦Video of family tree; ♦Guiding questions.	♦Review adulthood (including creating a family tree).	♦Review Extraction: summarize events in this section; ♦Mind Space: express thanks to family members or friends; ♦E-legacy product: display the family tree; ♦Supplement any content in this section.

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4 & 5	Childhood and Adolescence (<18 years old)	♦Audio picture book--On the Night You were Born; ♦Images of house, studies, games, labor, food; ♦Songs about childhood, playmates; ♦Video--The Rhythm of Life; ♦Guiding questions.	♦Review childhood and adolescence.	♦Review Extraction: summarize events in this section; ♦Mind Space: say something to any deceased relative who is important to you (e.g. grandparents); ♦Supplement any content in this section.
6	Summary of Life	♦E-life review product--My Life Story; ♦Images of a timeline of life; ♦Guiding questions.	♦Summary of important experiences (including creating a timeline of life).	♦Mind Space: say something to the most important one in your life; ♦E-legacy products: display the a timeline of life and e-life review product; ♦View a timeline of life review course; ♦Supplement any content in this section.

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Comparison

The patients in both the experimental and control groups will receive the usual care provided by the study hospital. Usual care involves personal care, medical care, health education, and emotional support. The control group may freely use the Internet to search for information. However, they will not have access to the WBLRP.

Outcome measures

Primary outcomes

Anxiety will be measured by Zung's self-rating anxiety scale (SAS).[45] The 20-item self-report scale is rated on a 4-point score from 1 (seldom) to 4 (most of the time). The total score ranges from 20-80, and a score of more than 50 indicates mild to moderate anxiety. It is widely used to quantify the level of anxiety, which has been proven to be reliable among cancer patients in China ($\alpha = 0.799$).[46]

The Zung's self-rating depression scale (SDS) is useful to detect the level of depression.[47] The 4-point scale also consists of 20 items, with a total score of 80. A score of more than 53 can be rated as mildly depressed. Good reliability has been shown with Cronbach's alpha 0.87.[48]

Self-transcendence will be measured by the self-transcendence scale (STS).[41] It is a 15-item scale, and each item is rated from '1= not at all' to '4 =almost always'. The total score ranges from 15 to 60, calculated by adding all of the individual items. The Chinese version scale has been validated with high reliability ($\alpha = 0.83$-0.87).[49]

Secondary outcomes

Meaning in life will be measured by the Meaning in Life Questionnaire (MLQ) developed by Steger.[50] It consists of 10 items measuring the presence of meaning and the search for meaning. Each item is rated on a 7-point Likert scale from '1 = strongly disagree' to '7 = totally agree'. It has been shown to have good reliability, with internal consistency values between 0.79 to 0.93.[51]

The Herth Hope Scale (HHS) will be used to assess the level of hope.[52] This is a 12-item scale divided into three dimensions, including temporality and future,

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positive readiness and expectancy, and interconnectedness. Good validity and reliability have been reported among patients with lung cancer, with Cronbach's alpha value 0.87 and construct validity 0.85.[53]

Other data

Demographic data, including age, gender, race, marital status, level of education, level of income and cancer information, will be collected using a personal information form.

Patients' physical function will be evaluated with Karnofsky Performance Status(KPS), which measures palliative care patients' progressive decline in terms of physical condition and exercise tolerance.[54] It grades a patient's general condition with an 11-point score system from 0 (death) to 100% (normal). A KPS of less than 40% means the patient is severely disabled, and that his/her disease is progressing rapidly. Thus, this study includes patients with a KPS of more than 40%.

Patients' psychiatric condition will be checked from their medical records, and patients with a psychiatric diagnosis will be excluded from study participation. The indications of suicide will be measured by the Scale for Suicide Ideation (SSI).[55] SSI was developed in 1979 by Beck, quantifying intensity in suicide ideation. Its Chinese version scale has been validated with good reliability (α =0.87).[56] The scale has a total of 19 items, and the first five items are used to identify the level of suicidal desire. The five items are rated as follows: no suicidal desire, mild suicidal desire, and strong suicidal desire. Patients who rate the fourth or fifth item as mild or strong suicidal desire will not participate in this study.

Data collection

Data will be collected by two research assistants at baseline, and immediately, three months, and six months after the program. They are blinded to group assignments, and collect patients' demographic data, and primary and secondary outcome variables. During the investigation, the assistants will ensure the study's confidential and voluntary nature, and then explain the requirements of each measure. Once patients

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encounter difficulties in completing the questionnaire, assistants will help them by reading each item aloud, repeating the item if required, and recording the participant's responses.

Data analysis

Descriptive statistics will be used for sample characteristics. Parametric or non-parametric tests will be conducted to compare the baseline characteristics of two groups. If the data collected are normally distributed, the Student's t-test or the chi-square test will be performed. Otherwise, non-parametric tests, such as the Wilcoxon test and the Mann-Whitney U test, will be used. Repeated-measures analysis of variance will also be used to analyze the effects of the life review program. The missing data will be replaced with the mean value for the continuous variables, and the median for the nominal and ordinal variables.

Patient involvement

When designing the program, a panel of experts and two patient advisers were invited to valid the WBLRP. During the program, patients will be asked to review their life, and draw a family tree and a timeline of their life. They will be encouraged to involve in Content Extraction and Mind Space after each session. At end of the WBLRP, a life review product will be given to each patient, in which record the patient's significant life events and experiences. No plans to disseminate the results of the RCT to the study participants.

Ethics and dissemination

Ethical approval was obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020) in July 2017. This study will adhere to ethical standards for the entire procedure. All data collected from the participants will be kept confidential and anonymous, and will be used exclusively for this research only. Dissemination strategies may include a paper submission to a peer-reviewed journal, as well as a conference submission.

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Findings from this research will be used to propose a new idea for nursing care utilizing the Internet, and for psychological rehabilitation among cancer patients.

DISCUSSION

Cancer patients often suffer considerable distress from the disease and from chemotherapy, but they cannot always access effective psychological interventions such as life review, due to geographic distance and traffic issues. Therefore, the proposed intervention protocol is to construct the WBLRP and test its effects on cancer patients undergoing chemotherapy, which is expected to overcome these obstacles and benefit more patients, by improving their psychospiritual well-being, and allowing them to achieve a state of self-integration.

The effectiveness of WBLRP may be attributed to its characteristics. First, WBLRP is a theory-based intervention tailored to cancer patients. Second, it is easily accessible for cancer patients. Third, five components of WBLRP play a vital role. E-life review interviews allow patients to select a familiar environment to review their life in, where they can feel safe and comfortable in revealing intimate, and sometimes painful life experiences.[57] Memory prompts may help to awaken patients' memories and facilitate the life review process. Previous studies have found that memory prompts can trigger patients' recollections.[58] Review Extraction summarizes meaningful events in each life stage, to help patients relive life events and promote self-evaluation after life review interviews. Reliving life events on their own is part of the process of self-evaluation, which is important to the success of the life review.[59] Mind Space is an internal process, where patients can look inside themselves, and clarify their personal values, priorities and life meaning.[42] Our research team's previous studies found that cancer patients wish to reveal their true feelings, feelings that until that time they had not shared with others. This module provides an opportunity for patients to express themselves freely, reconsider their relationships with others and establish a sense of connection with their surroundings, beyond their personal boundaries. E-legacy products not only help patients to appreciate their

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entire life once again, but also to leave a personal legacy for their loved ones. The individual e-product is vivid and convenient for patients to review and then pass down, as a legacy handed from generation to generation. It may also play an important part in helping patients maintain positive emotions for a period of time. [23]

A number of limitations are acknowledged in this study. First, the program is probably not suitable for people with poor literacy skills, because they may encounter difficulties in viewing memory prompts and going through the life review modules. Second, e-life review interviews may lack human contact, compared to face-to-face interventions. Fortunately, texts, emotion icons and other non-verbal information on WeChat can be used to compensate for this shortcoming.[60] Third, seen from the perspective of methodological limitations, one issue is a lack of blinding. When not blinded to psychological interventions, participants are prone to generate the Hawthorne Effect, and the facilitator may have expectations of the intervention group. However, it is difficult to blind participants and facilitators to treatments in psychological research. Another issue is a potentially high dropout rate. Some patients will probably drop out of the study during the six-month follow-up, due to the progression of the disease. Finally, this study is a single-center randomized trial, and the findings may not be generalizable to all settings. Another study with a more rigorous design, with a multi-center, inter-disciplinary and transregional setting, will be necessary in the future.

If the WBLRP was effective, it could be integrated into routine cancer care to enhance the psychospiritual well-being of cancer patients. It may be an alternative approach for nurses to deliver a life review intervention to community-dwelling cancer patients. Additionally, this study could provide a reference for nursing care utilizing the Internet, and put forward a new idea for psychological rehabilitation. To the best of the researchers' knowledge, this is an innovative program based on a theoretical framework to improve psychospiritual well-being among cancer patients.

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Acknowledgements

We would like to thank the experts for their kind help and insightful advice, and thank the patient advisers in the validation of this program. We would also like to thank Fujian Provincial Nature Science and Fujian Provincial Health Commission for providing funding for this study.

Contributors

HMX undertook the conception of the study, conducted critical revision of the manuscript, and obtained funding and supervision. XLZ mainly designed the study and drafted the manuscript. Both authors have reviewed and approved the manuscript.

Competing interests

None declared.

Funding

This study is funded by Fujian Provincial National Nature Science [2017J01814] and Fujian Provincial Health Commission [2017-CX-35].

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Figure Legends. Figure. 1. Study flow chart based on CONSORT.

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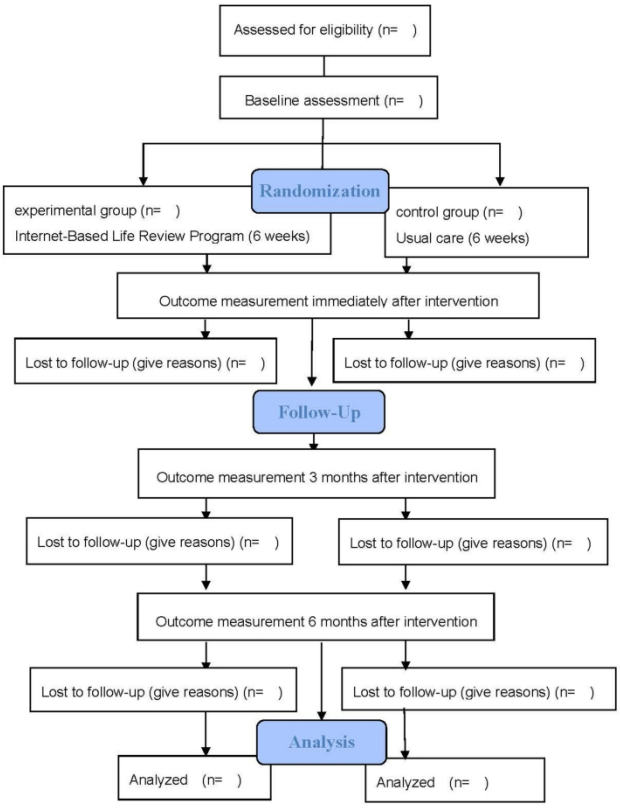

Study flow chart

210x297mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item no	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions,and, if applicable, trial acronym	2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	20
Roles and Responsibility	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection,management, analysis, and interpretation of data; writing of the report;and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/a
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the	N/a

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		trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-7
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg,superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g. drug dose change in response to harms, participant request, or improving/worsening disease)	N/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring	11-12

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		adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	15-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence	16a	Method of generating the allocation sequence (eg, computer-generation generated random numbers), and list of any factors for stratification.To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8

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Allocation concealment Mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16-17
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	17
Data	19	Plans for data entry, coding, security, and storage, including any	17

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management		related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/a
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/a
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol.	16-17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/a

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Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of Interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/a
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/a

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Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/a
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/a
Appendices			
No applicable	32	Model consent form and other related documentation given to participants and authorised surrogates	N/a
No applicable	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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BMJ Open

Development and evaluation of a WeChat-based life review program for cancer patients : Protocol for a randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020239.R4
Article Type:	Protocol
Date Submitted by the Author:	13-Aug-2018
Complete List of Authors:	Zhang, Xiaoling; Fujian Medical University, School of Nursing Xiao, Huimin; Fujian Medical University, School of Nursing
Primary Subject Heading:	Nursing
Secondary Subject Heading:	Oncology, Mental health, Palliative care
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, ONCOLOGY, CHEMOTHERAPY, life review

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Development and evaluation of a WeChat-based life review program for cancer patients: Protocol for a randomized controlled trial

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Keywords: Internet; life review; cancer; nursing; psychological intervention.

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Development and evaluation of a WeChat-based life review program for cancer patients: Protocol for a randomized controlled trial

ABSTRACT

Introduction Cancer patients often suffer from considerable distress. Life review is a process of recalling, evaluating and integrating life experiences to alleviate a sense of despair and achieve self-integrity. Empirical data have supported the fact that life review is an effective psychological intervention, but it is not always accessible to cancer patients. There is little evidence of Internet-based life review programs tailored to cancer patients. This study aims to develop a WeChat-based life review program and evaluate its effectiveness on the psychospiritual well-being of cancer patients undergoing chemotherapy.

Methods and analysis A single center, randomized, parallel group superiority design will be used. Cancer patients will be randomized, to either a control group, or to an experimental group receiving a six-week WeChat-based life review program. The program, which was mainly developed based on Erikson's psychosocial development theory and Reed's self-transcendence theory, provides synchronous and asynchronous communication modes for patients to review their life. The former is real-time communication, providing an e-life review interview guided by a facilitator online. The latter is not simultaneously dialogic, and is used to interact with patients before and after a life review interview through Memory Prompts, Review Extraction, Mind Space and E-legacy products. The primary outcomes include anxiety, depression and self-transcendence; and the secondary outcomes are meaning in life and hope. These will be measured at baseline, and immediately, three months, and six months after the program's conclusion.

Ethics and dissemination Ethics approval has been obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020). The trial results will be published in a peer-reviewed journal and presented at national and international conferences.

Trial registration number This trial was registered on the Chinese Clinical Trial

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Registry (ChiCTR-IOR-17011998).

Strengths and limitations of this study

- This is a pioneer study to develop and evaluate a theory-based WeChat-based life review program tailored to cancer patients with a randomized controlled trial.
- This program is likely unsuitable for people with poor literacy skills, because they may encounter difficulties in viewing the life review modules.
- In this type of psychological research, it is not possible to blind all participants to the program, which may lead to the Hawthorne Effect.
- This study is a single-center randomized trial, and the findings may not be generalizable to all settings. Further research, in a multi-center, inter-disciplinary and transregional setting, will be necessary.

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INTRODUCTION

Cancer is a life-threatening disease. By 2025, the number of people dying from cancer each year is expected to increase to 11.4 million, up from the 2015 figure of 8.8 million.[1] In China, cancer is the leading cause of death, accounting for 27% of deaths among cancer patients worldwide.[2] A previous study has shown that 27% of the cancer mortality risk is associated with psychospiritual distress.[3] A meta-analysis has found a dose-response effect, indicating that higher levels of psychological distress are linked to a 41% increased risk of cancer death.[4] Psychospiritual distress, such as anxiety, depression, and hopelessness, is prevalent among cancer patients undergoing chemotherapy.[5] Approximately 32.5% to 75.7% of cancer patients experience psychospiritual distress, which is higher than in the population as a whole, as well as higher than in patients with other diseases.[6-8] Psychospiritual distress may greatly prolong hospitalization rates,[9] interfere with cancer treatment,[10] lower rehabilitation effectiveness,[3] and be related to cancer mortality.[3-4]

Life review is regarded as a psychological intervention in palliative care. It is defined as a process of recalling, evaluating and integrating life experiences to facilitate the achievement of ego integrity.[11] Grounded in Erikson's psychosocial development theory, life review is structured with guiding questions to assist participants in reviewing each life stage. Reviewing an entire life enables participants to revisit past experiences, retrieve happy feelings from positive memories, and release negative emotions lingering from unpleasant events.[12-13] It also helps them to reaffirm their contributions and accomplishments, reconcile their failures and disappointments, and integrate their entire life into a more acceptable or meaningful whole.[12,14-15] Previous studies have explored life review's effectiveness on psychological distress (i.e. anxiety, depression),[16-17] spiritual well-being (i.e. meaning of life, hope),[18-19] and quality of life.[20-21] Various reviews have been conducted to synthesize these results, including systematic reviews[22-23] and meta-analysis.[24] The meta-analysis presented the cumulative evidence from well-designed clinical trials of a life review's effectiveness on cancer patients. It suggests that in palliative care,

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doing a life review could potentially be beneficial, and can be integrated into typical cancer care to enhance patients' psychospiritual well-being. Compared to other psychological interventions, such as cognitive behavioral therapy (CBT) and meaning-centered psychotherapy (MCP), a life review is more feasible for cancer patients to do. First, reviewing one's life is a naturally occurring, universal mental process among cancer patients in the final life stage.[25] However, patients are sometimes frustrated, and their feelings can be distorted by negative experiences. In a formal life review, a facilitator will guide patients to reconcile their disappointments. Second, CBT and MCP usually require participants who are capable, at some level, of participating in the activities of daily living. However, Ando et al. found that patients with deteriorating health or low functionality can still participate in a life review, even when lying in bed.[26]

Traditional face-to-face life review is not always available for cancer patients suffering from psychospiritual distress. A systematic review pointed out that life review is commonly undertaken in hospitals, palliative care units or other health care institutions. Patients in such settings may lose the opportunity to participate in a life review, due to time conflicts between the life review and medical treatment or nursing care.[23] Furthermore, few patients dwelling in community can easily access a life review intervention, due to issues of geographic distance, traffic problems, and limited human resources.

E-health, a recent health care practice supported by electronic processes and communication, may be a potential means of overcoming the above-mentioned barriers.[27] Research related to online life review has been reported, with two studies focusing on older adults[28-29] and one study on cancer patients.[30] In 2009, an e-health system called the Butler Project was developed, with the aim of facilitating optimal aging.[31] Using the Butler Project system, Preschl et al. conducted life review therapy for depressed older adults with computer supplements.[28] The intervention consisted of a face-to-face life review, and a computer component to induce positive emotions. This study was performed in a traditional face-to-face setting. Another study, focusing

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on adults, was a randomized controlled trial to test the effectiveness of life review as online-guided self-help.[29] The life review intervention group members received a self-help book to review their lives, followed by an audio-CD that guided them to perform a well-being exercise. Study participants sought support from researchers via e-mail. Although this approach addressed the issue of geographic distance, e-mail contact was not immediate enough for the patients to receive a timely reply. Wise et al. designed a life review for cancer patients using online social networks.[30] The intervention combined a telephone interview, a text-formed life story, and a self-directed website for patients to share their personal story and establish social networks. A randomized controlled trial was then performed to test the intervention's effectiveness on distress and existential well-being among 68 advanced cancer patients.[32] The study explored patients' satisfaction with the life review process, social networking use patterns, and themes emerging from their life stories; however, the evidence to determine its efficacy was inconclusive. Additionally, telephone interviews did not allow the researchers to observe non-verbal cues, such as patients' facial expressions and body language. To our knowledge, there is no life review program tailored to cancer patients that is completely Internet-based, particularly in China.

WeChat is a multi-function social networking application covering 90% of mobile phones in China. It is used in 200 countries, with more than 20 languages,[33] providing the functions of synchronous and asynchronous communication. Synchronous communication is real-time communication between two or more individuals. Asynchronous communication permits a delay between sender and receiver. The sender can transmit data at any time, and the receiver can read it whenever he or she wants. WeChat users can interact asynchronously with each other through text messaging, voice messaging, video conferencing and so on, and they can obtain information and browse resources from all kinds of WeChat platforms at any time. Due to its synchronous and asynchronous communication functions, WeChat has increasingly been used in nursing education and continuous nursing, as well as in

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other areas.[34-35]Therefore, we aimed to develop a WeChat-based life review program (WBLRP), and test the effectiveness of this program on psychospiritual well-being among cancer patients. We hypothesized that cancer patients undergoing chemotherapy who received the WBLRP would see a significant difference in their mean scores of anxiety, depression, self-transcendence, meaning of life and hope, compared to the control group.

METHODS AND ANALYSIS

Study design

The study is a single-center, randomized, parallel group superiority design, consistent with the guidelines of Standard Protocol Items: Recommendations For Interventional Trials (SPIRIT).[36] This study will follow the Consolidated Standards of Reporting Trials (CONSORT) flow chart to show the flow of participants through each stage of a randomized controlled trial [37](Figure 1).

Participants

Participants will be recruited from two oncology departments at a comprehensive medical university-affiliated hospital that has received a national service quality evaluation, in Fujian, southeast China. Cancer types treated in the oncology departments include colorectal, gastric, breast, lung and others, with the exception of hematological and brain cancer, which are treated in other clinical departments. In the two oncology departments, an average of 244 cancer patients per month receive chemotherapy, and approximately 82% of these patients have access to the Internet at home. The inclusion criteria for the participants are: (1) diagnosed with Stage III or IV cancer and currently undergoing chemotherapy; (2) aged 18 years or above; (3) aware of their diagnosis and treatment; and (4) able to access the Internet via multiple devices, for example, a mobile phone. The exclusion criteria are: (1) currently taking anxiolytics or antidepressants; (2) receiving other psychotherapeutic treatments; (3) experiencing verbal communication impairment or cognitive impairment, psychiatric disorders and indications of suicide; (4) severely disabled or the disease progressing

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rapidly (Karnofsky Performance Status, KPS<40%).

Sample size determination

Sample size calculation is based on power analysis. Power analysis adopts a hypothesis-testing method to determine sample size according to a prespecified significance level and desired power level.[38] Assuming a two-tailed alpha of 0.05, a probability of 0.02 for beta error (80% power) and an effect size of 0.42 after calculating anxiety according to the previous study,[24] 64 participants are required. For depression (effect size 0.52) and self-transcendence (effect size 0.39),[24,39] the sample sizes are 30 and 76 respectively. According to the larger sample size, 76 patients are needed. Assuming a 20% dropout rate in this study, the total sample size is 92 participants.

Randomization, allocation concealment and blinding processes

This study will follow the process of randomization. Before randomization, a person who is not engaged in the subject recruitment and data collection will prepare a randomization list with 46 sets of numbers, either 0 (control group) or 1 (experimental group), using the computer software Research Randomizer (http://www.randomizer.org/). These 46 sets of numbers will be printed separately and sealed in each envelope. After recruiting a participant, the facilitator will open an envelope in sequence. The number found in the envelope will represent the group that the particular participant belongs to. In this study, group assignments do not blind participants or the facilitator; instead, they blind data collectors in order to minimize measurement bias.

Intervention

WBLRP Development

The WBLRP is an e-life review intervention for cancer patients reviewing their life in synchronous and asynchronous communication modes. The former is an e-life review interview; the latter are four life review modules, including Memory Prompts, Review

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Extraction, Mind Space, and E-legacy Products. Based on Erikson's psychosocial development theory, an e-life review interview was developed to facilitate an online life review of each life stage. Erikson states that a healthily developing human should pass through eight developmental stages, from infancy to late adulthood.[40] If individuals are able to overcome the developmental crisis at the final life stage, they will achieve ego integrity; otherwise, they will become preoccupied by despair, experience regrets, and fear death. Butler's life review interview is a systematic process that follows Erikson's lifespan stages and promotes life integration by recalling, evaluating and integrating positive and negative life experiences.[11] Thus, according to Erikson's theory, the synchronous communication mode aims to guide patients in reviewing their entire life online, from childhood to the present.

Based on Reed's self-transcendence theory, four life review modules, including Memory Prompts, Review Extraction, Mind Space, and E-legacy Products, were designed in the asynchronous communication mode. Self-transcendence is described as the expansion of personal boundaries that is influential in finding meaning and purpose in life, including Outward, Inward, Spirituality, and Temporal.[41] It is an inherent quality in every human being, which can be a powerful coping strategy when one is faced with adversity.[42] Indeed, reviewing a life involves every factor of self-transcendence. In our program, the four life review modules are designed to enhance self-transcendence. For example, Mind Space is designed to further help patients reveal their innermost feelings, beliefs, and what they believe is most meaningful in life, after the life review interview takes place. E-legacy Products help patients integrate their past and present: their entire life as a whole.

Additionally, the guiding questions of the life review interview, and images and videos promoting patients' memories, were drawn from our research team's previous studies for the WBLRP.[43-44]

Validation of WBLRP

The WBLRP has been validated by a panel of experts with a two-round Delphi survey.

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The panelists consisted of three life review researchers, three palliative care nurse specialists, two clinical oncology professors, one social worker, and one psychologist. All hold a Bachelor's degree or above, and have at least five years of work experience in their respective fields. The panelists evaluated the content's appropriateness and relevance; the program's format, frequency and duration; and provided comments based on their experience and knowledge. The Content Validity Index was calculated by the percentage of items rated as "relevant" or "very relevant". It was 90.8% in the first round. According to the experts' comments, eight guiding questions were adjusted, and two images were added. The Content Validity Index of the second round reached 100%. After the experts' validation, two cancer patients were recruited to test whether the WBLRP content was understandable and acceptable.

WBLRP Components

E-life review interview is an individual face-to-face interview using the video-call function on WeChat. Four sections will be reviewed weekly over six weeks, including present life (cancer experience), adulthood, childhood and adolescence, and summary of life, ordered in a reserve sequence, starting with the present and working backwards. Each section has its corresponding guiding questions. The duration of each life review interview ranges from 40 to 60 minutes, depending on the patient's physical condition and willingness to talk. The first author, a nursing postgraduate and registered nurse, who has received approximately 50 hours of life review training, will act as facilitator. Both facilitator and patients can arrange for the interview to be conducted at a convenient time, at any location with access to the Internet.

Memory Prompts Module contains various resources, such as images, songs, videos, audio picture books and guiding questions related to the content of each section. These will be presented to patients ahead of the life review interviews, in order to evoke their memories. For example, in the Childhood and Adolescence Section, an audio picture book entitled, "On the Night You were Born" opens the prelude to the review. Images of home, studies, games, labor and food display the

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typical life scenes of that age, while songs about childhood trigger recollections of a person's past. Patients are encouraged to supplement with other relevant resources (e.g. images, songs) according to their individual circumstances. Guiding questions are used to stimulate memories and help patients recall the most important events of their life.

Review Extraction Module refers to a summary of meaningful events created by the facilitator after each section, where patients can review the content and leave their comments. After each life review interview, the facilitator will elicit significant events with relevant images, to help patients clarify the trajectory of each life stage and facilitate self-evaluation.

Mind Space Module provides patients with an opportunity to express their emotions, set down their wishes, or reveal their true feelings to those who are important to them. For example, in the Adulthood Section, patients can express their gratitude and thanks to family members or friends. This module allows patients to look within, reconsider and reflect on their relationships with others, and establish a sense of connection with their surroundings beyond their personal boundaries.

E-legacy Products Module presents the products of a family tree, a timeline of life and an e-life review product, which can be preserved as spiritual memorials. The family tree and timeline of life are created by patients under the facilitator's guidance, during the life review interview. The e-life review product will be created by the facilitator, who selects significant experiences, life views, and words for loved ones, along with additional elements such as photos, songs or videos, based on patients' preferences. The e-life review product will be presented to patients to help them re-evaluate and integrate all of their life events, and will ultimately serve as a legacy product. This module helps to promote patients' recollections of their family history and life experiences, as well as to integrate their past, present and their life as a whole.

Intervention procedure and monitoring

Prior to the intervention, patients in the experimental group will be guided to install

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WeChat, register an account, launch a video call, browse the life review's memory prompts, and operate each module on the WeChat platform. Additionally, a brochure can be consulted. Before each session, patients can access the Memory Prompts Module to obtain an overview of the current session. Subsequently, an appointment for an e-life review interview is arranged. The patients and facilitator can communicate in a virtual face-to-face setting, with additional instant messaging methods available, such as text message, voice message, and emotion icons. After the life review interview, patients can access the 24-hour open asynchronous communication modules to relive and integrate the reviewed content, express feelings and deliver e-legacy products, or supplement any content. Generally, each session follows the same process (For more details, please see Table 1). When approaching the end of the intervention, the facilitator will create a timeline recording of the life review process that patients will participate in.

During the WBLRP, there will be ongoing monitoring of participants' physical condition, emotional status, response to life review guiding questions, and compliance with the intervention; as well as ongoing monitoring of the facilitator's life review skills. If participants experience negative emotions, a follow-up by a clinical psychologist will be arranged. To protect patient privacy, the life review WeChat platform can only be accessed with a personal WeChat number, and patients can decide which modules may be read by other people.

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Table 1 An overview of the WeChat-based life review program

Session	Section	Asynchronous communication (Appreciate memory prompts before the interview)	Synchronous communication (Deliver the e-life review interview)	Asynchronous communication (go through modules after the interview)
1	The present (from cancer diagnosis to present)	♦Images of hospital, ward, health care staff; ♦Audio picture book--The Fall of Freddie the Leaf; ♦Video--Circulation of four seasons; ♦Guiding questions.	♦Review present life.	♦Review Extraction: summarize events in this section; ♦Mind Space: set down wishes for anyone who is important to you at this stage; ♦Supplement any content in this section.
2 & 3	Adulthood (≥18 years old)	♦Images of family, work, hobbies; ♦Audio picture book--Love is a Handful of Thick Honey; ♦Songs about family, work or love; ♦Video of family tree; ♦Guiding questions.	♦Review adulthood (including creating a family tree).	♦Review Extraction: summarize events in this section; ♦Mind Space: express thanks to family members or friends; ♦E-legacy product: display the family tree; ♦Supplement any content in this section.

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4 & 5	Childhood and Adolescence (<18 years old)	♦Audio picture book--On the Night You were Born; ♦Images of house, studies, games, labor, food; ♦Songs about childhood, playmates; ♦Video--The Rhythm of Life; ♦Guiding questions.	♦Review childhood and adolescence.	♦Review Extraction: summarize events in this section; ♦Mind Space: say something to any deceased relative who is important to you (e.g. grandparents); ♦Supplement any content in this section.
6	Summary of Life	♦E-life review product--My Life Story; ♦Images of a timeline of life; ♦Guiding questions.	♦Summary of important experiences (including creating a timeline of life).	♦Mind Space: say something to the most important person in your life; ♦E-legacy products: display the timeline of life and e-life review product; ♦View a timeline of life review course; ♦Supplement any content in this section.

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Comparison

The patients in both the experimental and control groups will receive the usual care provided by the study hospital. Usual care involves personal care, medical care, health education, and emotional support. The control group may freely use the Internet to search for information. However, they will not have access to the WBLRP.

Outcome measures

Primary outcomes

Anxiety will be measured using the Zung Self-Rating Anxiety Scale (SAS).[45] The 20-item self-report scale is rated on a 4-point score from 1 (seldom) to 4 (most of the time). The total score ranges from 20-80, with a score of more than 50 indicating mild to moderate anxiety. The scale is widely used to quantify anxiety levels, and has been proven to be reliable among cancer patients in China ($\alpha = 0.799$).[46]

The Zung Self-Rating Depression Scale (SDS) is useful for detecting depression levels.[47] This 4-point scale also consists of 20 items, with a total score of 80. Patients with a score of more than 53 can be rated as mildly depressed. Good reliability has been shown with Cronbach's alpha 0.87.[48]

Self-transcendence will be measured by the self-transcendence scale (STS),[41] a 15-item scale, with each item rated from '1= not at all' to '4 =almost always'. The total score ranges from 15 to 60, calculated by adding all of the individual items together. The Chinese version scale has been validated with high reliability (α = 0.83-0.87).[49]

Secondary outcomes

Meaning in life will be measured by the Meaning in Life Questionnaire (MLQ) developed by Steger.[50] It consists of 10 items measuring the presence of meaning and the search for meaning. Each item is rated on a 7-point Likert scale from '1 = strongly disagree' to '7 = totally agree'. It has been shown to have good reliability, with internal consistency values between 0.79 to 0.93.[51]

The Herth Hope Scale (HHS) will be used to assess the level of hope.[52] This is a

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12-item scale divided into three dimensions, including temporality and future, positive readiness and expectancy, and interconnectedness. Good validity and reliability have been reported among patients with lung cancer, with Cronbach's alpha value 0.87 and construct validity 0.85.[53]

Other data

Demographic data, including age, gender, race, marital status, level of education, level of income and cancer information, will be collected using a personal information form.

Patients' physical function will be evaluated with Karnofsky Performance Status (KPS), which measures palliative care patients' progressive decline in terms of physical condition and exercise tolerance.[54] It grades a patient's general condition with an 11-point scoring system from 0 (death) to 100% (normal). A KPS of less than 40% means the patient is severely disabled, and his/her disease is progressing rapidly. Thus, this study includes patients with a KPS of more than 40%.

Patients' psychiatric condition will be checked from their medical records, and patients with a psychiatric diagnosis will be excluded from study participation. The indications of suicide will be measured by the Scale for Suicide Ideation (SSI).[55] SSI was developed in 1979 by Beck, quantifying intensity in suicide ideation. Its Chinese version scale has been validated with good reliability (α =0.87).[56] The scale has a total of 19 items, and the first five items are used to identify the level of suicidal desire. The five items are rated as follows: no suicidal desire, mild suicidal desire, and strong suicidal desire. Patients who rate the fourth or fifth item as mild or strong suicidal desire will not participate in this study.

Data collection

Data will be collected by two research assistants at baseline, and immediately, three months, and six months after the program. The research assistants, who are blinded to group assignments, collect patients' demographic data, and primary and secondary outcome variables. During the investigation, the assistants will ensure the study's

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confidential and voluntary nature, and then explain the requirements of each measure. Once patients encounter difficulties in completing the questionnaires, assistants will help them by reading each item aloud, repeating the item if required, and recording the participant's responses.

Data analysis

Descriptive statistics will be used for sample characteristics. Parametric or non-parametric tests will be conducted to compare the baseline characteristics of the two groups. If the data collected are normally distributed, the Student's t-test or the Chi-square test will be performed. Otherwise, non-parametric tests, such as the Wilcoxon test and the Mann-Whitney U test, will be used. Repeated-measures analysis of variance will also be used to analyze the effectiveness of the life review program. The missing data will be handled using the multiple imputation method.

Data monitoring and interim analyses

Owing to a single-center trial design and short-term study duration, no data monitoring committee will be established and no interim analyses will be conducted.

Patient involvement

When designing the program, a panel of experts and two patient advisers were invited to validate the WBLRP. During the program, patients will be asked to review their life, and draw a family tree and a timeline of their life. After each session, they will be encouraged to involve in Content Extraction and Mind Space. At the end of the WBLRP, a life review product will be given to each patient, containing a record of the patient's significant life events and experiences. There are no plans to disseminate the RCT results to study participants.

Ethics and dissemination

Ethical approval was obtained from the Biological and Medical Research Ethics Committee of the corresponding author's university (IRB Ref No: 2016/00020) in July 2017. This study will adhere to ethical standards for the entire procedure. During

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participant recruitment, trained research assistants will visit potential participants and explain the study purpose, procedure, benefits and potential risk, and participants' right to withdraw from the study at any point without negative consequences.. Patients will have the opportunity to discuss relevant issues before signing the consent form. The data collected will be stored centrally and kept confidential and anonymous. The data analysis will be conducted by our research team. The investigators will have the capacity to request ancillary analyses three years after the trial completion. The data will be used exclusively for this research only.

Dissemination strategies may include a paper submission to a peer-reviewed journal, as well as a conference submission. The research findings will be used to propose a new idea for nursing care utilizing the Internet, and for psychological rehabilitation of cancer patients.

DISCUSSION

Cancer patients often suffer considerable distress from the disease and from chemotherapy, but cannot always access effective psychological interventions, such as life review, due to geographic distance and traffic issues. Therefore, the proposed intervention protocol is to construct the WBLRP and test its effectiveness on cancer patients undergoing chemotherapy. This is expected to overcome these obstacles and benefit more patients, by improving patients' psychospiritual well-being, and allowing them to achieve a state of self-integration.

The effectiveness of WBLRP may be attributed to its characteristics. First, WBLRP is a theory-based intervention tailored to cancer patients. Second, it is easily accessible to cancer patients. Third, five components of WBLRP play a vital role. E-life review interviews allow patients to select a familiar environment where they can review their life, and feel safe and comfortable while revealing intimate, and sometimes painful life experiences.[57] Memory prompts may help to awaken patients' memories and facilitate the life review process. Previous studies have found that memory prompts can trigger patients' recollections.[58] Review Extraction summarizes

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meaningful events in each life stage, to help patients relive life events and promote self-evaluation after the life review interviews. Reliving life events on their own is part of the process of self-evaluation, which is important to the success of the life review.[59] Mind Space is an internal process, where patients can look inside themselves, and clarify their personal values, priorities and life meaning.[42] Our research team's previous studies found that cancer patients wish to reveal their true feelings, which they had not previously shared with others. This module provides an opportunity for patients to express themselves freely, reconsider their relationships with others and establish a sense of connection with their surroundings, beyond their personal boundaries. E-legacy products not only help patients to appreciate their entire life once again, but also to leave a personal legacy for their loved ones. The individual e-product is vivid and convenient for patients to review and then pass down, as a legacy handed down from generation to generation. It may also play an important role in helping patients maintain positive emotions for a period of time.[23]

A number of limitations are acknowledged in this study. First, the program is likely unsuitable for people with poor literacy skills, because they may encounter difficulties in reading the memory prompts and operating the life review modules. Second, e-life review interviews may lack human contact, compared to face-to-face interventions. Fortunately, texts, emotion icons and other non-verbal information on WeChat can be used to compensate for this shortcoming.[60] Third, seen from the perspective of methodological limitations, one issue is a lack of blinding. When not blinded to psychological interventions, participants are prone to generate the Hawthorne Effect, and the facilitator may have expectations of the intervention group. However, it is difficult to blind participants and facilitators to treatments in psychological research. Another issue is a potentially high dropout rate. Some patients will probably drop out of the study during the six-month follow-up, due to the progression of the disease. Finally, this study is a single-center randomized trial, and the findings may not be generalizable to all settings. Another study with a more rigorous design, with a multi-center, inter-disciplinary and transregional setting, will

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be necessary in the future.

If the WBLRP is shown to be effective, it could be integrated into routine cancer care to enhance the psychospiritual well-being of cancer patients. It may be an alternative approach for nurses to deliver a life review intervention to community-dwelling cancer patients. Additionally, this study could provide a reference for nursing care utilizing the Internet, and put forward a new idea for psychological rehabilitation. To the best of the researchers' knowledge, this is an innovative program based on a theoretical framework to improve psychospiritual well-being among cancer patients.

Acknowledgements

We would like to thank the experts for their kind help and insightful advice, and thank the patient advisers in the validation of this program. We would also like to thank Fujian Provincial Nature Science and Fujian Provincial Health Commission for providing funding for this study.

Contributors

HMX undertook the conception of the study, conducted critical revision of the manuscript, and obtained funding and supervision. XLZ mainly designed the study and drafted the manuscript. Both authors have reviewed and approved the manuscript.

Competing interests

None declared.

Funding

This study is funded by Fujian Provincial National Nature Science [2017J01814] and Fujian Provincial Health Commission [2017-CX-35].

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Figure Legends. Figure. 1. Study flow chart based on CONSORT.

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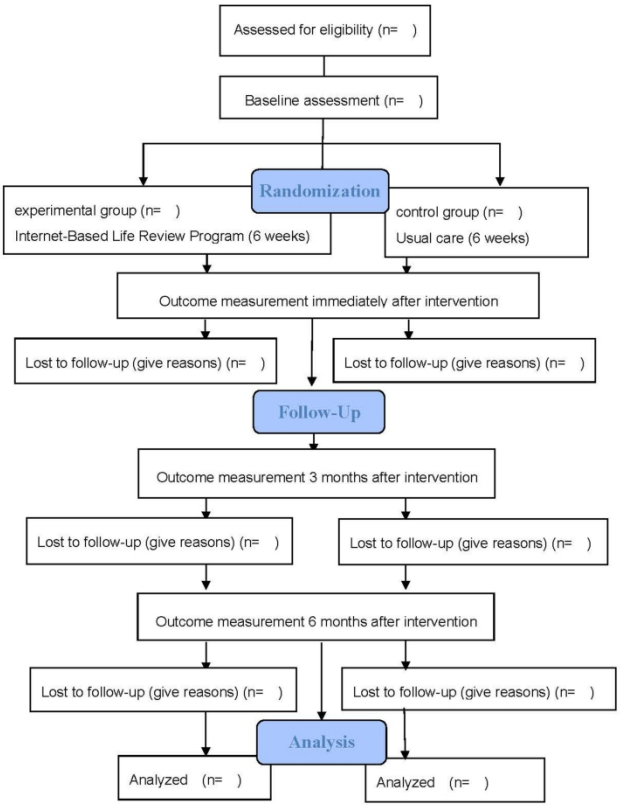

Study flow chart

210x297mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item no	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions,and, if applicable, trial acronym	2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	No applicable
Funding	4	Sources and types of financial, material, and other support	20
Roles and Responsibility	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection,management, analysis, and interpretation of data; writing of the report;and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	No applicable
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint	No applicable

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		adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-7
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg,superiority, equivalence, noninferiority, exploratory)	2,7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g. drug dose change in response to harms, participant request, or improving/worsening disease)	No applicable

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	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	No applicable
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	15-16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence	16a	Method of generating the allocation sequence (eg, computer-generation generated random numbers), and list of any factors for stratification.To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8

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Allocation concealment Mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	No applicable
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16-17
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	17
Data	19	Plans for data entry, coding, security, and storage, including any	17

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management		related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	No applicable
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol.	No applicable
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	No applicable
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	No applicable

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Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	No applicable
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	See attachment
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of Interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	No applicable

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Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	2，18
	31b	Authorship eligibility guidelines and any intended use of professional writers	No applicable
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	No applicable
Appendices			
	32	Model consent form and other related documentation given to participants and authorised surrogates	See attachment
	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	No applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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