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Effectiveness of meaning in life intervention programme in young and middle-aged cancer patients: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Diminished levels of meaning in life can have a range of detrimental effects on cancer patients, including heightened anxiety, depression, psychological distress, reduced quality of life and, in severe cases, even thoughts of suicide. Notably, young and middle-aged cancer patients often exhibit even lower levels of meaning in life compared with their counterparts in other age groups. The primary objective of this study is to formulate a meaning in life intervention programme and assess its efficacy in enhancing the meaning in life and other relevant indicators among young and middle-aged cancer patients.

Methods and analysis A prospective, parallel-group randomised controlled trial will be conducted. Eighty-eight young and middle-aged cancer patients will be randomised into either the intervention or control group. The intervention group will receive 4 week, six-session, group-based meaning in life intervention programme, while the control group will receive treatment as usual. The primary outcome is meaning in life, and secondary outcomes are post-traumatic growth and psychological distress. These indicators will be assessed at baseline, on completion of the intervention and again 2 months following its conclusion.

Ethics and dissemination The trial has received approval from the Institutional Review Board of Shanghai Proton and Heavy Ion Hospital (2202-53-04-2301A-2310B). The study results will be shared through peer-reviewed journals and conferences.

Trial registration number Chinese Clinical Trial Registry, ChiCTR2200060672.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Methodological rigour, encompassing practices such as concealed random allocation, blinded outcome assessment and the prospective registration, is expected to mitigate the risk of bias.
⇒ The intervention is theory-based and has been developed and refined based on previous research findings and qualitative data collected from young and middle-aged cancer patients.
⇒ Due to the nature of the psychological intervention, neither the participants nor the interventionists will be blinded.
⇒ Only the short-term follow-up effects for 2 months after the intervention will be studied.
⇒ One of the limitations of the study is that all outcomes will be measured through self-report.

INTRODUCTION

In 2020, approximately 19.3 million new cancer cases were reported.[1] Projections suggest that by 2040, global cancer cases will rise to 28.4 million, reflecting a substantial 47% increase compared with 2020.1 Notably, 23.7% of all newly diagnosed cancer cases occur in China.[2] As the world's largest developing country, China shoulders a substantial burden of cancer. As the number of cancer cases gradually increases, an expanding body of research reveals a concerning trend: the incidence of various types of cancers, including head and neck, colorectal, breast, pancreatic, kidney and uterine cancers, among others, is steadily rising among young-middle aged individuals.[3–5]

Young and middle-aged individuals often hold important familial and social roles,[5] and being diagnosed with cancer subjects them not only to physical discomfort but also to psychological distress and existential challenges. These challenges encompass an array of struggles, such as the inability to fulfil family roles, disruptions in the sequence of significant life events, difficulty in achieving life goals, uncertainty about the future and regrets concerning unfulfilled aspirations.[6] Additionally, compared with other age groups, they face greater challenges related to illness, life, work and financial pressures,[7 8] which may lead to a diminished sense of meaning in

life or even a complete loss of it.[9 10] Several studies have consistently confirmed that the level of meaning in life of young and middle-aged cancer patients is notably low or pessimistic.[11–13]

Emphasising the significance of meaning in life throughout their treatment, recovery and ongoing mental health maintenance proves to be immensely valuable.[14] The meaning in life plays a crucial role in alleviating anxiety, depression and distress, and nurturing a sense of meaning can significantly enhance the quality of life and overall physical and mental health.[15–17] Moreover, cancer patients often express the importance of seeking meaning and purpose in their lives.[18] Conversely, patients experiencing a diminished sense of meaning are prone to lower survival rates and higher suicide rates.[19 20] These findings underscore the imperative to intervene in the meaning in life for cancer patients, particularly young and middle-aged ones.

Meaning-centred psychotherapy is a psychotherapeutic intervention rooted in Frankl's logotherapy, specifically designed to cater to the psychological needs of advanced cancer patients.[21] It has been further adapted and applied across various cultural contexts and diverse populations.[22–29] In the initial stages, our group carefully revised the original meaning-centred group psychotherapy (MCGP), considering both Chinese culture and the specific characteristics of the target population. Subsequently, we conducted a randomised controlled trial and observed a positive impact on enhancing the meaning in life of Chinese cancer patients undergoing active treatment.[29] However, during the practical application and based on feedback from participants, we identified areas for improvement in the programme, including diversifying the presentation of themes to accommodate varying levels of insight among patients, ensuring participants are of similar age to optimise their engagement experience and better scheduling group sessions to reduce conflicts with treatment.[30]

Hence, the primary objective of this study is to formulate an intervention programme aimed at enriching the meaning in life. This endeavour was guided by the principles of logotherapy theory and built on the groundwork laid by the research team's prior experience. We hypothesise that a 4 week, 6-session meaning in life intervention programme will effectively improve the meaning in life, foster post-traumatic growth, and alleviate psychological distress among young and middle-aged cancer patients.

METHODS

Design

This two-arm, parallel-design randomised controlled trial among young and middle-aged cancer patients will follow the Consolidated Standards of Reporting Trials flow chart[31] (see figure 1). The SPIRIT checklist is available as a supplementary document[32] (online supplemental material 1). Eligible patients who consent to participate will be randomly assigned to either the intervention group or the control group. The intervention programme comprises a total of 6 themes and spans 4 weeks. The primary outcome, meaning in life and secondary outcomes, including post-traumatic growth and psychological distress, will be evaluated at three time points: baseline, post-intervention and 2 months post-intervention. The assessment timeline is visually depicted in figure 2. The study will commence in September 2023 and is expected to conclude by March 2024.

Study setting

This study will be conducted at the Shanghai Proton and Heavy Ion Centre, where proton and heavy ion radiation therapy are the primary treatment modalities. As of 8 May 2023, a cumulative total of 5648 patients have received treatment and have been discharged from the hospital, demonstrating an average annual growth rate of 20%.

Recruitment

Participants will be recruited from September 2023. Recruitment will be conducted through various channels, including public advertisements (eg, posters, flyers) and mobilisation meetings (inform potential participants about the risks associated with a low sense of meaning in life and the content and benefits of this project). Additionally, word-of-mouth dissemination by nurses about the project will be used to reach potential participants. Participants who meet the inclusion and exclusion criteria and voluntarily choose to participate will receive comprehensive information from the investigator. This information will cover the study's purpose, procedures, interventions, assessment details, randomisation procedures, potential risks, anticipated benefits, data confidentiality and an explanation of their rights as subjects. Upon agreement, participants will provide written informed consent (online supplemental material 1). They will be informed that they can withdraw from the study at any time without impacting their treatment.

Participants

The inclusion criteria for participants are as follows: (a) inpatients diagnosed with any type of solid tumour, (b) aged between 20 and 49 years, (c) aware of their diagnosis, (d) fluent in Mandarin and (e) voluntarily participated in this study by signing the informed consent form. The age range of 20–49 years was chosen based on the definition of early-onset cancer,[33] and research indicates that the meaning in life among cancer patients under 50 is often concerning.[11–13] The exclusion criteria are as follows: (a) individuals in the acute phase of the disease or experiencing severe hepatic, renal or cardiopulmonary impairment, (b) those with severe mental disorders or significant cognitive deficits and (c) individuals currently taking psychiatric medications or engaged in other psychological interventions.

Sample size

The sample size was determined using Power Analysis and Sample Size Software (PASS, V.15.0.5). Specifically,

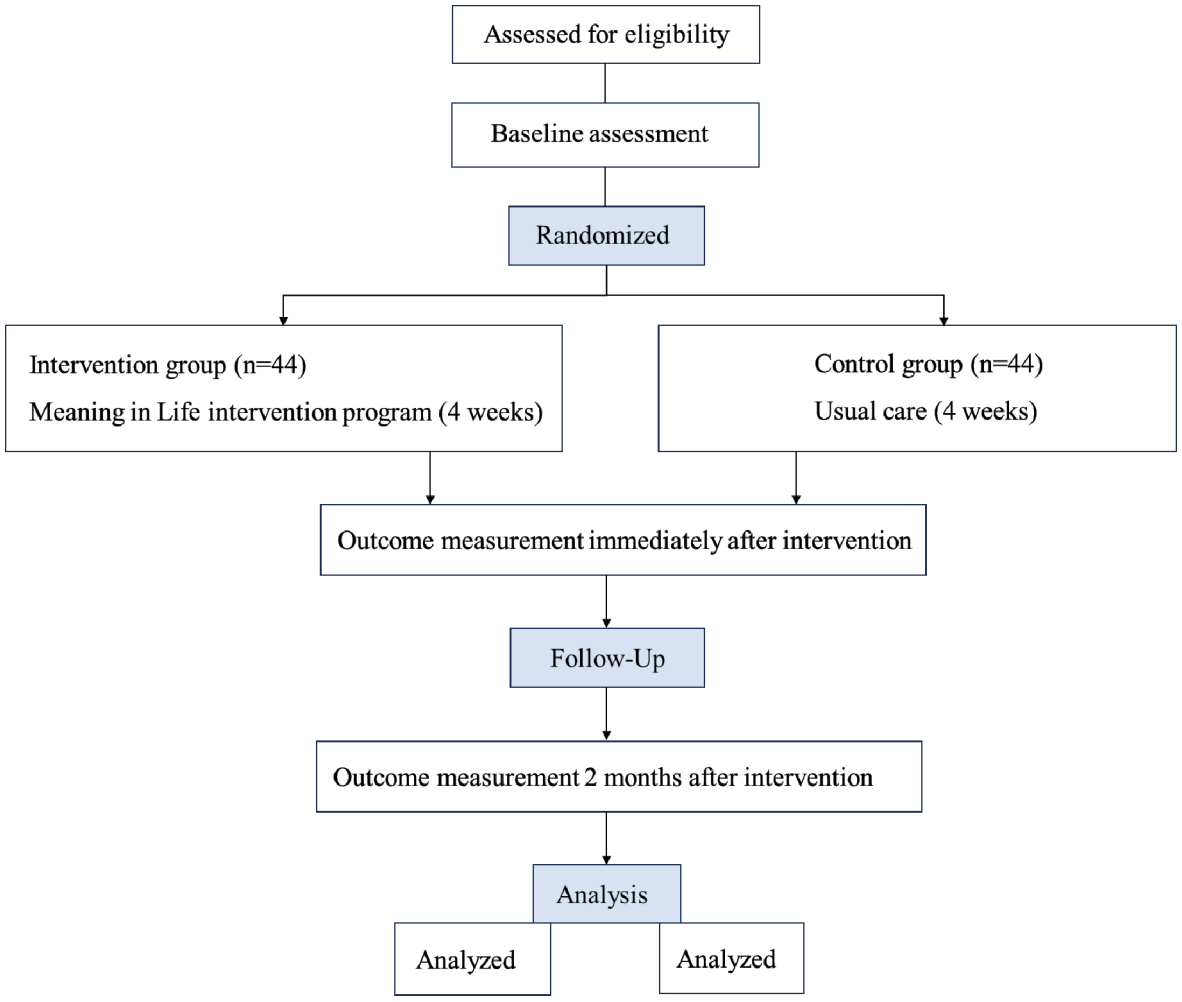

Figure 1 CONSORT flow chart of the study.

	STUDY PERIOD								
TIMEPOINT	**Enrolment**	**Baseline (t_0)**	**Allocation**	**4 weeks intervention (1-2 times per week)**				**At immediately post-intervention (t_1)**	**2 months after intervention (t_2)**
				Week 1 intervention	**Week 2 intervention**	**Week 3 intervention**	**Week 4 intervention**		
Eligibility screening	×								
Informed consent	×								
Allocation			×						
INTERVENTIONS:									
Meaning in life intervention program				×	×	×	×		
Usual care				×	×	×	×		
ASSESSMENTS:									
Sociodemographic and disease-related assessment		×							
PIL		×						×	×
DT		×						×	×
C-PTGI		×						×	×

Figure 2 The schedule of trial enrolment, interventions and assessments. C-PTGI, Chinese version of the Post-Traumatic Growth Inventory; DT, Distress Thermometer; PIL, Purpose in Life Test.

based on a two-sample t-test at a two-sided significance level of 0.05, the study is designed to achieve a power of 90% in detecting the anticipated effect. The sample size calculations are based on the primary outcome (meaning in life), using an effect size of 0.78 for the primary end point of change from baseline to post-intervention in the Purpose in Life Test (PIL), as evidenced in a previous study we conducted.[29] Consequently, a sample size of 72 participants is deemed necessary to detect this effect. Accounting for an estimated dropout rate of 20%, a minimum of 88 subjects needed to be recruited for the study.

Randomisation and blinding

The study will employ block randomisation with four block sizes and a 1:1 allocation ratio. The random sequence will be generated using the computer software Study Randomiser (https://www.studyrandomizer.com/) by a graduate student who is not involved in recruitment, intervention or data collection. The grouping scheme for each block will be sequentially placed in four small opaque sealed envelopes, each numbered from 1 to 4. Subsequently, these envelopes will be uniformly placed in a large envelope labelled with the corresponding block number. Throughout the study, all envelopes will be kept individually. To ensure minimal selection bias, the generation of the allocation sequence will be completed before the recruitment phase of the study begins. Upon enrolling patients who meet the inclusion criteria into this study, another researcher will sequentially open the envelopes to obtain grouping information for allocation concealment. To uphold blinding, data collectors and data analysts will remain unaware of the grouping information.

Intervention: meaning in life intervention programme

Cancer patients in the intervention group will receive the meaning in life intervention programme. Considering the duration of a patient's hospital stay, approximately 1 month, we have aligned the duration of the intervention programme accordingly. While many intervention programmes designed to improve the meaning in life for cancer patients typically have eight sessions, our practical experience has shown that balancing the requirement for eight sessions in 1 month with each patient's treatment schedule can be a challenge. A previous study showed that patients who fully participated in the intervention achieved greater improvements in their meaning in life compared with those who did not fully adhere to the intervention.[29] Hence, to enhance patient participation, we will opt to schedule six sessions spread across 1 month. This approach significantly increased scheduling flexibility and substantially reduced the risk of patients missing the programme due to conflicting treatment and intervention schedules.

The meaning in life intervention programme is grounded in logotherapy theory, drawing on insights from the MCGP and the book 'GUIDEPOSTS to MEANING: Discovering what really matters'.[34]" In the intervention group, patients will engage in a 4 week, 6-session meaning in life intervention programme, lasting 2 hours per session, conducted twice a week. Each session introduces participants to distinct themes, such as 'Value', 'Historical Sources of Meaning', 'Attitudinal Sources of Meaning', 'Free Choice and Responsibility', 'Creative Sources of Meaning' and 'Experiential Sources of Meaning' (online supplemental material 1). Each session comprises 10 min of didactics, followed by 10 min of mindfulness meditation and 40 min of experiential exercises, and concludes with a 60 min group discussion. Each experiential exercise will be introduced as a game or visualisation. During the discussion phase, the interventionist will pose guiding questions tailored to each patient's result from the exercise, aiming to accomplish the objectives of each topic. The group will be co-led by two group psychotherapists trained in meaning-centred therapy and a doctoral student in nursing psychology. Each closed group will comprise approximately 10 participants. During the trial, participants in the intervention group will receive two face-to-face reminders and notifications from their charge nurse before each group activity: one day in advance and another 2 hours prior to the scheduled start time.

Control group

Patients will receive standard care throughout their hospitalisation, including nutritional support, rehabilitative care and routine psychosocial care. This routine psychosocial care involved systematic mental health assessments conducted by nurses. If deemed necessary, trained nurses will provide non-specific psychological support, including empathetic interactions, encouragement and opportunities for patients to share their thoughts and feelings.

Intervention fidelity

The evaluation of intervention implementation effectiveness will involve recording audio from all group sessions. An expert with a background in both medicine and psychology will conduct a random selection of 20% of the tapes for reviewto assess the implementation of the intervention programme. Adherence to the study protocol will be defined as attending a minimum of five sessions, which will be closely monitored and documented by the interventionist. Any instances of the absence or withdrawal will be documented, and reasons will be provided. This process aims to gauge participant adherence to the therapeutic interventions.

Data collection

A graduate nursing student, equipped with training in systematic research, will assess the outcomes of the intervention for eligible participants. At baseline, sociodemographic and disease-related variables will be collected. Additionally, three psychosocial variables—meaning in life, post-traumatic growth and psychological distress—will be assessed at three time points: baseline, post-intervention and 2 months post-intervention. Both

the control and intervention groups will undergo reassessment at the same intervals. The baseline and post-intervention data collection will occur face-to-face, while the 2 month post-intervention data collection will be conducted online using Questionnaire Star.

Outcome measures

Sociodemographic and disease-related variables

A sociodemographic questionnaire will be distributed at the baseline to assess various demographic characteristics, including age, gender, marital status, educational level, religion, employment status, annual income, whether they have children, whether they have commercial insurance and the financial burden of treatment costs. Additionally, information related to the disease will be collected, such as cancer site, primary/recurrence, duration of illness, cancer stage, family history, presence of comorbidities, history of chemotherapy, history of surgery and other treatment histories.

Primary outcome: meaning in life

The PIL[35] was developed by Crumbaugh and others based on logotherapy and was later adapted into Chinese by Chinese scholars.[36] The participants' meaning in life will be assessed using the Chinese version of the PIL. This scale comprises 20 items, distributed across four dimensions: life purpose, life feeling, life value and life attitude. Each item is rated on a seven-point Likert scale, resulting in a total score range of 20 to 140. A higher score indicates a stronger sense of meaning and purpose in life. In our preliminary research on young and middle-aged cancer patients, the PIL demonstrated a good Cronbach's alpha coefficient of 0.869.[29]

Secondary outcomes

Post-traumatic growth

The Post-Traumatic Growth Inventory (PTGI)[37] was developed by Tedeschi and others and was later adapted into Chinese by Chinese scholars.[38] Post-traumatic growth will be assessed using the Chinese version of the Post-Traumatic Growth Inventory (C-PTGI). The scale consists of 20 items categorised into five adjusted dimensions: life perception, personal strength, new possibilities, relationships with others and self-transformation. It uses a six-point Likert scale, with scores ranging from 0 to 5 for each item and a total score ranging from 0 to 100. In our preliminary research on young and middle-aged cancer patients, the C-PTGI exhibited a strong Cronbach's alpha coefficient of 0.873.[29]

Psychological distress

The distress thermometer (DT)[39] was developed by Rosten *et al*. The Chinese version of the DT was translated by Chinese scholars and adjusted according to the actual conditions of Chinese cancer patients. Psychological distress will be assessed using the DT, where 0 indicates no psychological distress and 10 indicates extreme distress. The higher the score, the more severe the psychological stress. A DT of ≥4 indicates that the patient is experiencing clinically significant psychological distress and requires supportive services.[40]

Data analysis

An independent examiner will conduct the statistical analysis using IBM SPSS Statistics version 24.0 (IBM). All analyses will be carried out following an intention-to-treat approach. We will conduct a descriptive analysis of sociodemographic variables, disease-related variables, data missingness rates and all outcomes in young and middle-aged adults with cancer. For variables following a normal distribution, we will use means and SD; for those with non-normal distribution, medians and interquartile ranges (25th and 75th percentiles) will be employed. Categorical variables will be analysed through frequencies and percentages. Baseline characteristics of the two groups will be compared using either parametric or non-parametric tests. If the collected data follow a normal distribution, the analysis will involve Student's t-test or χ^2 test. In cases where the data do not meet normality assumptions, non-parametric tests such as the Wilcoxon test and Mann–Whitney U test will be employed.

A linear mixed model will be used to assess the impact of the intervention on primary and secondary outcome measures, including study group, time and the interaction between group and time as fixed effects, with participants as a random effect. Covariates integrated into the models encompass demographic variables that exhibit disparities between groups during baseline comparisons, along with those that exhibit a significant correlation with the pre- and post-intervention outcome indicator scores. Missing data will be addressed using multiple imputations with predictive mean matching,[41] and sensitivity analyses will also be conducted. The significance level will be established at $p<0.05$.

Data management, monitoring and confidentiality

As the current intervention is non-pharmacological and adheres to the ethical principle of benefiting participants without causing harm, the likelihood of adverse effects due to the intervention is low. Consequently, establishing a Data Monitoring Safety Board appears unnecessary. All collected data are exclusively identified by a participant identification number to uphold confidentiality. Paper records, including informed consent forms and questionnaire data, will be securely stored in a locked office filing cabinet. Furthermore, audio recordings will be stored on a secure cloud server and safeguarded on a dedicated laptop computer. The management of the final trial dataset will primarily be handled by the first, second and final authors. Nonetheless, all authors will have access to the dataset if needed. We do not have any intentions of publicly releasing the individual-level dataset or any statistical code.

Adverse events

Throughout the entire study duration, we will meticulously document both anticipated and unanticipated

adverse events. While we do not anticipate any serious adverse events, in the unlikely event of an unanticipated serious adverse occurrence (eg, a risk of suicide), all participants will have the opportunity to seek guidance and support from a specialist within the study team. Any notable adverse events will be promptly reported to the Institutional Review Board of Shanghai Proton and Heavy Ion Hospital.

Patient and public involvement

After implementing the MCGP with Chinese cancer patients, our research team conducted interviews with participants who had engaged in the programme. We incorporated the feedback and suggestions they offered into our current study, which encompassed the incorporation of positive thinking meditation exercises and the presentation of experiential exercises through gamification or visualisation techniques, among other enhancements.

ETHICS AND DISSEMINATION

The ethical committee of Shanghai Proton Heavy Ion Hospital has approved the entire study design (2202-53-04-2301A-2310B) and the informed consent forms. In the event of protocol changes, updates to trial registration information will be made accordingly. The results of this study will be included in a doctoral thesis by the lead author and subsequently submitted for publication in a peer-reviewed journal. If possible, the findings will also be presented at a relevant conference.

DISCUSSION

The purpose of this study is to aid young and middle-aged cancer patients during active treatment in discovering potential sources of meaning through experiential exercises and open-ended discussions. By effectively using these sources, the patients could enrich their meaning in life, empowering them to embrace life to the fullest even after their discharge from the hospital. The outcomes of this randomised controlled trial are expected to offer significant and novel insights into the positive influence of the meaning in life intervention program on the meaning in life of young and middle-aged cancer patients.

Research has revealed that the age of a cancer patient can exert a substantial influence on their meaning in life, leading to diverse experiences and perspectives on this matter among different age groups.[42] Patients within the same stage of life are more likely to connect and engage effectively in discussions and exchanges related to existential themes.[30] Therefore, the meaning in life intervention programme offers a supportive environment for young and middle-aged cancer patients, enabling them to delve deep into existential issues that cancer presents, alongside exploring the distinctive psychological challenges associated with their age group, such as concerns about future goals, careers and family. Moreover, this intervention holds particular significance for young and middle-aged cancer patients, as the programme fosters patients' awareness of avenues to find meaning, enabling them to not only embrace and adapt to their illness while navigating multiple roles but also offer them a renewed sense of purpose and direction.

After the completion of the current project, our final focus will be on sustaining such projects in the long term. We are fully dedicated to crafting a comprehensive brochure, with the aim of ensuring its accessibility not only in specialised oncology hospitals but also in public hospitals, thus providing indispensable support to individuals grappling with cancer.

This study is expected to have some limitations. First, this study represents a single-centre randomised trial, and therefore, its findings may not be readily applicable to all settings. Further research conducted in a multicentre, interdisciplinary and transregional context will be imperative. Second, considering the specificity and cost of treatment, the patients we recruit may be young and middle-aged cancer patients who meet the criteria for proton-carbon ion therapy and have higher incomes. This could potentially limit the generalisability of the study results. Finally, it should be noted that in our study, the control group receives standard care rather than an active control. The effectiveness of our intervention might be partly due to the non-specific effects of group therapy.

Contributors SMW and HWW made significant contributions to the research methodology design and the development of the overall research objectives. WJX, YZ and MMZ participated in drafting the manuscript and providing critical input for important ideas. All authors collectively contributed to the final version. Each author played a comprehensive role in the project and assumed public responsibility for relevant portions of the content. The guarantor of the study is SMW who accepts full responsibility for the finished work and/or the conduct of the study, had access to the data and controlled the decision to publish.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

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Overview of Meaning in Life Intervention Program

Session	Theme	Content
1	Value	● Didactics ● Mindfulness meditation ● Experiential exercises: Value Auction The objective of this exercise is to assist the patient in identifying and clarifying their values, while also recognizing the profound connection between values and meaning. ● Group discussions ● Homework Throughout the 4-week program, participants are encouraged to actively seek out moments, events, or situations that hold personal significance to them. They can capture these moments by taking photos with their cell phones and are invited to share them during the final session.
2	Historical Sources of Meaning	● Didactics ● Mindfulness meditation ● Experiential exercises: Impact Wheel Exercise The objective of this exercise is to assist patients in gaining awareness of the people, events,

		memories, experiences, values, and other aspects that have profoundly influenced their lives. Additionally, it aims to help them identify what they have achieved or learned in life that can be shared with others. ● Group discussions
3	Attitudinal Sources of Meaning	● Didactics ● Mindfulness meditation ● Experiential exercises: Mountain Range Exercise The objective of this exercise is to help the patient recollect how they navigated through previous challenging moments and experiences, while also fostering an understanding of the interplay between attitude and meaning. ● Group discussions
4	Free Choice and Responsibility	● Didactics ● Mindfulness meditation ● Experiential exercises: My Possibility The objective of this exercise is to enable each patient to directly experience the significance of freedom, choice, and responsibility in relation to the practical dilemmas they are currently confronting, and how these aspects are interconnected with the concept of meaning.

		● Group discussions
5	Creative Sources of Meaning	● Didactics ● Mindfulness meditation ● Experiential exercises: Time Pie Exercise The objective of this exercise is to encourage each patient to view their daily routine as a starting point for recognizing that creativity holds relevance not only to the individual but also to everyday tasks. It aims to assist the patient in finding meaning within these routines. ● Group discussions
6	Experiential Sources of Meaning	● Didactics ● Mindfulness meditation ● Experiential exercises: Share photos from your cell phone Experiences are inherently personal, and the objective of this exercise is to utilize photos from each individual's cell phone as a tool to facilitate patients in sharing meaningful moments and experiences from their lives. ● Share Homework for the first session ● Group discussions

临床研究受试者知情同意书

Informed Consent for Clinical Research Subjects

研究名称：意义中心团体心理干预方案对中青年肿瘤患者生命意义感的效果研究

研究单位：上海市质子重离子医院

主要研究者：万宏伟，朱毓，王姝曼

我们邀请您参加“意义中心团体心理干预方案对中青年肿瘤患者生命意义感的效果研究”的临床研究，本知情同意书提供给您一些信息，以帮助您更好的了解该研究并决定是否参加。请您仔细阅读，如有任何疑问请向负责该研究的研究者提出。

本研究已通过上海市质子重离子医院医学伦理委员会审查。该研究的实施将遵循 GCP 原则和赫尔辛基宣言。在研究过程中，如果出现研究方案的变更或改动，我们会及时通知您，您可以决定是否继续参加研究或退出。

研究背景：

肿瘤的诊断及治疗不仅会给患者的身体带来伤害，还会造成一系列心理困扰。其中，肿瘤患者生命意义感水平不容乐观，尤其是中青年肿瘤患者相比其他年龄段的人群需要承受更多对未来不确定感的担忧以及来自疾病、工作、生活及经济等方面的压力，因此，中青年肿瘤患者更容易陷入迷茫、无望、痛苦的困境，降低甚至丧失生命意义感。研究表明，体验到更多生命意义的患者比生命意义感低下的患者能更好的适应疾病，拥有更高的心理幸福感、更好的生活质量和更少的心理困扰，由此可见，生命意义感对中青年肿瘤患者临床和生存起到重要作用。目前，已经有多个国家的研究对意义中心团体心理干预方案进行应用。研究证据表明，该干预方法能有效减轻肿瘤患者的无意义感和无望感，改善患者负性情绪，并提高其生活质量，因此，本研究拟应用意义中心团体心理干预对中青年肿瘤粒子治疗患者进行干预效果评价，以期帮助其获得更多的生命意义感、减少心理痛苦以及促进创伤后成长。

研究目的：

本研究目的是评价意义中心团体心理干预方案对中青年肿瘤患者生命意义感的效果研究。我们希望本研究能够使中青年肿瘤粒子治疗患者获得更多的生命意义感、减少心理痛苦以及促进创伤后成长，在让粒子治疗肿瘤患者享受一流诊疗能力的同时，也能拥有更健康的心理状况。

研究过程：

我们会向您介绍本次研究目的、意义和完成过程，征得您的同意。如果您同意参加本

研究，您将被随机分配到干预组或对照组中的一组。如果被分配到干预组，您将会参与90min-120min/次、1-2 次/周，共 1 个月的团体心理干预，一般一次干预 10 人。干预方案包括 6 个主题，分别为价值、意义的历史来源、意义的态度性来源、自由选择与责任、意义的创造性来源以及意义的体验来源。干预共 6 次，每次干预围绕其中之一的主题进行教学、讨论和体验练习。如果被分配到对照组，您将会接受常规护理，包括营养支持、康复护理和常规社会心理护理。我们需要将参与意义中心团体心理干预的参与者和不参与该干预的参与者进行比较，因此，不参与该干预的参与者作为对照参加研究，对研究同样有重要贡献。

无论您被分配到哪个组，您都需要先进行一个约 15min 的调查，调查内容涉及个人基本信息以及目前的心理状况。我们将在您入组后**从开始干预直至干预结束以后的 2 个月**与您保持密切联系，并请您填写相关的问卷。

风险与不适：

一般情况下不会出现风险与不适，在研究过程中若您出现身体疲劳或者心理的不适，均可终止。

可能的受益：

您可以在研究过程中向研究者咨询心理相关问题，我们会及时为您解答。本研究为您提供一个可以表达情绪和情感安全的支持性环境，会帮助您增强意义感和目的感、优化应对方式。同时，您的参与可能会给未来遭受痛苦的患者带来益处。在此我们为您能够参与到研究，并为肿瘤心理所做出的贡献表示感谢！

保密性：如果您决定参加本项研究，您参加研究及在研究中的个人资料均属保密。您的身份不会被识别，可以识别您身份的信息将不会透露给研究小组以外的成员，除非获得您的许可。这项研究结果发表时，亦将不会披露您个人的任何资料。

受试者伤害赔偿：如果您因参加研究而直接导致的非预期损伤，将按照中国的法律法规进行经济补偿。

权利：您参加本研究是自愿的。您可以选择不参加研究，或在任何时候通知研究者要求退出研究，您的数据将不纳入研究结果，您的任何医疗待遇与权益不会因此而受到影响。

费用及报酬：参加该项研究不会额外增加您的医疗费用。

联系：您可随时了解与本研究有关的信息资料和研究进展，如果您对本研究有任何疑问或者顾虑，或您在研究过程中发生了任何不适与损伤，可向负责人——王姝曼咨询，联系电话：xxxxxx；在研究过程中，如果您有与自身权益相关的任何问题，可以联系本机构伦理

委员会办公室，联系电话：xxxxx。

知情同意声明

我已阅读了本知情同意书。

我有充足的时间并经过仔细考虑后自愿参加本临床研究。

我有机会提问而且所有问题均已得到解答。

我可以选择不参加本项研究，或者在任何时候通知研究者后退出，我的任何医疗待遇与权益不会因此而受到影响。

我同意在团体小组里录音。我的个人身份信息将会被保密。

如果我需要其他治疗，或者我没有遵守研究计划，或者发生了与研究相关的损伤或者有任何其他原因，研究者可以终止我继续参加本项研究。

同意参加本项研究并不意味着会向我支付任何报酬。

我将收到一份签过字的“知情同意书”副本。

我同意研究者收集并处理我的健康状况信息。

我同意国家监督部门、伦理委员会等有关部门，有必要时查阅我的健康状况信息。

受试者签名：

联系电话：

签字日期：

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	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 22
	5b	Name and contact information for the trial sponsor	N/A
	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	22
	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)	17-18
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	4-6

	6b	Explanation for choice of comparators	13
Objectives	7	Specific objectives or hypotheses	5-6
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	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)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-13
	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
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8, 14
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)	7-15, Figure2
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	8
Methods: Assignment of interventions (for controlled trials)			

Allocation: Sequence generation	16a	Method of generating the allocation sequence (eg, computer-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	8-9
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	8-9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8-9,14,16
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8-9
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	14-15
	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	14-15
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	17-18
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	16-17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-17

	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)	16-17
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. Alternatively, an explanation of why a DMC is not needed	17-18
	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	18
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	19
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)	19
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	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	17-18
Declaration of	28	Financial and other competing interests for principal investigators for the overall trial and each study	22

interests		site	
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	N/A
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	18-19
	31b	Authorship eligibility guidelines and any intended use of professional writers	18-19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Additional File 1
Biological specimens	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.