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.