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Effectiveness of spiritual interventions on psychological outcomes and quality of life among paediatric patients with cancer: a study protocol for a systematic review

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ABSTRACT

Introduction Cancer and its treatment affect children's physical, psychological and social well-being throughout the disease trajectory. Spiritual well-being is a fundamental dimension of people's overall health and is considered a source of strength to motivate patients to cope with and adapt to their disease. Appropriate spiritual interventions are important to mitigate the psychological impact of cancer on children, with an ultimate goal of improving their quality of life (QoL) throughout the treatment course. However, the overall effectiveness of spiritual interventions for paediatric patients with cancer remains unclear. This paper describes a protocol to systematically summarise the characteristics of studies related to existing spiritual interventions and synthesise their effectiveness on psychological outcomes and QoL among children with cancer.

Methods and analysis Ten databases will be searched to identify appropriate literature: MEDLINE, the Cochrane Central Register of Controlled Trials, EMBASE, CINAHL, PsycINFO, LILACS, OpenSIGLE, the Chinese Biomedical Literature Database, the Chinese Medical Current Contents and the Chinese National Knowledge Infrastructure. All randomised controlled trials that meet our inclusion criteria will be included. The primary outcome will be QoL as evaluated by self-reported measures. The secondary outcomes will be self-reported or objectively measured psychological outcomes, including anxiety and depression. Review Manager V.5.3 will be used to synthesise the data, calculate treatment effects, perform any subgroup analyses and assess the risk of bias in included studies.

Ethical and dissemination The results will be presented at international conferences and published in peer-reviewed journals. As no individual data will be involved in this review, ethical approval is not required.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This review will employ a systematic approach to assess the effectiveness of spiritual interventions on psychological outcomes and quality of life among children with cancer.
⇒ Two independent researchers will undertake the screening and selection of studies, as well as data extraction and management.
⇒ There may not be enough homogeneous studies to conduct a meta-analysis.
⇒ The high-quality trials may be deficient to generate convincing conclusions.
⇒ Clinical characteristics will confound the results if a subgroup analysis cannot be conducted.

INTRODUCTION

Description of the condition

Cancer is rare in children when compared with adults, with approximately 400 000 children and adolescents aged 0–19 years being diagnosed with cancer annually worldwide.[1] Despite cancer being relatively uncommon among children, it remains a leading cause of death for this population group, as approximately 100 000 children and adolescents are killed by cancer and associated complications every year.[2] The unpredictability of survival exposes children to the possibility of death and stimulates them to think about the meaning of cancer, the value of their existence and their purpose in life,[3 4] all of which are highly relevant to their spiritual well-being. According to the WHO, spiritual well-being is the fourth dimension of health, in addition to physical, psychological and social well-being.[5] Spiritual well-being is defined as a state of being where an individual is able to handle daily life issues in a way that leads to personal realisation of their full potential, meaning and purpose of life, and fulfilment from within.[6] Spiritual well-being is a fundamental dimension of people's overall health.[5] It is considered to be important for patients with cancer, including young patients,

because high spiritual well-being can heighten resistance to mental health crises through discovering meaning and ascertaining purpose in life, notwithstanding the possibility of death.[7 8] This is supported by mounting evidence that shows associations between high spiritual well-being and reduced depressive symptoms and lower anxiety among children with cancer along the disease trajectory.[9 10] Therefore, appropriate spiritual interventions are important to mitigate the psychological impact of cancer on children, with an ultimate goal of improving their quality of life (QoL) throughout the treatment course.[11 12]

Description of spiritual interventions

Spiritual intervention is considered an important aspect of holistic care and has been identified as a standard component that contributes to the well-being of children with cancer in the Care Project for Childhood Cancer.[13 14] Oh and Kim[15] noted that spiritual interventions are those that involve religious or existential aspects, such as finding meaning and purpose in life. A previous concept analysis revealed six important attributes relevant to spiritual interventions for children with cancer: (1) assessing spiritual needs, (2) assisting children to express feelings, (3) guiding children in strengthening relationships, (4) helping children to be remembered, (5) assisting children to find meaning and (6) aiding children to find hope.[16] Using this conceptual definition, spiritual interventions for children may include narrative therapy,[17] creative arts therapy,[18] meaning-focused meditation,[19] mindfulness-based interventions[20] and spiritually oriented psychotherapy.

How these interventions may work

Narrative therapy

Narrative therapy is a form of psychotherapy that aims to separate individuals from problematic narratives, and assist them to reinterpret their stories to identify underlying positive values.[21] For children with cancer, different techniques, such as externalisation (which focuses on creating distance between individuals and their problems) and deconstruction (which emphasises breaking down problems into smaller and manageable parts to avoid overgeneralisation of negative feelings) are used to facilitate the expression of feelings, losses and concerns in relation to their cancer experience.[17] In addition, the technique of restorying can be applied to assist children with cancer to consider alternative versions of their problems by looking for positive meaning in what they have gone through but were not previously aware of, thereby increasing their spiritual well-being.[22]

Creative arts therapy

In art therapy, children with cancer can express their cancer journey through art making, symbolise the meaning of their journey using different forms of art and creativity, and connect themselves to the world and the divine through the artistic processes, ultimately improving their spiritual well-being.[23 24] Common forms of creative arts therapy for children with cancer include music, drawing, poetry and journaling.[16 24]

Meaning-focused meditation and mindfulness-based interventions

The core belief of these two types of interventions emphasises staying in the present moment and slowing down inner thoughts that bombard our minds.[25] Through meditation or other mindfulness-related techniques, people are encouraged to create connections to something that is greater, vaster and deeper than the individual self.[26] Similarly, people are directed to pay attention to their body, breath and surroundings, and try to utter something good and meaningful that may or may not be related to religion.[25 26] Evidence shows that this process can help people become less agitated and build inner strengths (eg, love, compassion and forgiveness), and overcome negative experiences through long-term practice.[27]

Spiritually oriented psychotherapy

In addition to the aforementioned interventions, there are increasing numbers of individual-based and group-based psychotherapies that focus on the concepts of self-transcendence and meaning to improve spiritual well-being.[28 29] These psychotherapies usually involve various counselling techniques that stimulate children with cancer to think about different topics related to self-transcendence and meaning, helping them to experiences the expansion of self-boundaries and achieving a sense of peace.[30] Examples of these topics are trust, resort, meaning, purpose, faith, religious belief and thanksgiving.[11 31]

Why this review is important

Paediatric patients with cancer have unique spiritual concerns because of the high fatality and uncertainty of prognosis associated with cancer.[32 33] Spiritual interventions are important and necessary to address children's spiritual concerns, thereby enhancing their spiritual well-being along the disease trajectory. In turn, this improves their psychological outcomes and QoL. However, to date, there is a lack of conclusive evidence regarding the overall effectiveness of spiritual interventions for paediatric patients with cancer. To address the gap in existing literature, we will conduct a systematic review to systematically summarise the characteristics of studies related to existing spiritual interventions and synthesise their effectiveness on psychological outcomes and QoL in this population group.

Objectives

Our systematic review aims to (1) describe the details of spiritual interventions for children with cancer and (2) evaluate effectiveness of spiritual interventions on psychological outcomes and QoL among children with cancer.

METHODS AND ANALYSIS

This systematic review will start in January 2023, and the estimated end date is April 2023. The Preferred

Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement guidelines were used to guide the development of this systematic review protocol. The PRISMA-P checklist used to prepare this protocol is presented in online supplemental file 1.

Patient and public involvement

Due to the use of secondary data, no patients or the public will be directly involved in this study.

Criteria for considering studies for this review

Types of studies

We will include randomised trials that adopted any type of randomisation, including a parallel control and crossover designs. To be included, the randomised trials must also be published in the English or Chinese languages.

Types of participants

We will include all studies involving patients aged ≤18 years diagnosed with any type of cancer and at any point after their diagnosis. However, we will exclude studies that focused on paediatric cancer survivors.

Types of interventions

In this review, we will adopt the definition of spiritual interventions for children with cancer proposed in a previous study.[16] Namely, any intervention with an aim related to one or more of the identified attributes will be included: (1) assessing spiritual needs, (2) assisting children to express feelings, (3) guiding children in strengthening relationships, (4) helping children to be remembered, (5) assisting children to find meaning and (6) aiding children to find hope.[16]

Types of outcome measures

Primary outcome

QoL measured by self-reported measures.

Secondary outcomes

Psychological outcomes, including anxiety and depression, evaluated by self-reported or objective measures.

Search method for study identification

The search will be performed from 15 January 2023 to 15 February 2023. Ten databases will be searched to identify relevant trials for this systematic review: PubMed, the Cochrane Central Register of Controlled Trials, EMBASE, CINAHL, PsycINFO, LILACS, OpenSIGLE, the Chinese Biomedical Literature Database, the Chinese Medical Current Contents and the Chinese National Knowledge Infrastructure. Four relevant websites will also be searched: the WHO International Clinical Trials Registry Platform (www.who.int/ictrp/en), Current Controlled Trials (www.controlled-trials.com), CenterWatch (www.centerwatch.com) and ClinicalTrials. gov (www.clinicaltrials.gov). The subject heading index including Medical Subject Headings (MeSH) terms, Emtree terms and keywords will be identified. The Boolean operators 'AND' and 'OR' will be used to combine different search terms. All search terms will then be adapted and undertaken across all included databases and websites. No restriction regarding the publication date will be considered in the searching process. Although the focus of the review is on QoL and psychological outcomes, no reference to QoL and psychological outcomes will be included in the search term. This is to ensure that any relevant studies reporting on the broad range of psychological outcomes will not be missed by the electronic search. In addition, reference lists of relevant studies will be screened manually to further identify any eligible studies. The search strategy for the databases has been shown in online supplemental file 2.

Data collection and analysis

Selection of studies

Two reviewers (QL and KYH) will independently assess the eligibility of each study. EndNote, a bibliographic management software, will be used to store, organise and manage all of the references. Inclusion of trials in this systematic review will be decided unanimously by these two reviewers, with discrepancies resolved by a third reviewer (F-K-YW). The study selection flow will be presented in a PRISMA flow chart.[34]

Data extraction and management

Two researchers (QL and KYH) will separately extract the following information using data extraction forms developed by Cochrane.

1. Research characteristics:
   - Year of publication.
   - Journal name.
   - Title.
   - Authors' affiliations.
   - Sponsorship.
   - Study design.
   - Setting.
   - Country in which the trial was conducted.
2. Participants' information:
   - Eligibility criteria.
   - Demographic characteristics (including ethnicity, gender, age, educational level, socioeconomic background and religion).
   - Clinical characteristics (including type of cancer, cancer stage, age at diagnosis, time since diagnosis, recurrence history, treatment modality and comorbidities).
   - Number of participants in each study arm.
3. Randomisation, blinding and allocation concealment
   - Method of generating random sequences.
   - Method of allocation concealment.
   - Degree of blinding.
   - Any exclusion after randomisation.
4. Interventions
   - Types of interventions.
   - Frequency, duration, dose and format of interventions.
   - Details of the control group.
   - Adherence.

- Contamination and concurrent interventions.

5. Outcomes
   - Self-reported measures.
   - Objective data.
   - Follow-up time points.
6. Data analysis
   - Data analysis method.
   - Any selective outcome reporting.
   - Method of handling missing data.

Assessment of risk of bias in included studies

Two reviewers (QL and KYH) will independently assess the risk of bias in the included trials using the Cochrane Collaboration Risk of Bias tool.[35] This tool categorises the overall risk of study bias using seven domains: (1) sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcomes, (5) incomplete outcome data, (6) selective outcome reporting and (7) other sources of bias. Each domain will be rated in terms of high, low or unclear risk of bias. The criteria of overall risk-of-bias judgement are as follows: (1) low risk of bias: the trial is judged as low risk of bias if all of the domains are noted as low risk of bias; (2) some concerns: the trial is judged to raise some concerns in at least one domain for the result, but not to be at high risk of bias for any domain and (3) high risk of bias: The trial is judged to be at high risk of bias in at least one domain for the result or the trial is judged to have some concerns for multiple domains in a way that substantially lowers confidence in the result.[35] When disagreements arise, the opinion of a senior research team member (F-K-YW) will be sought. For each Risk of Bias domain and as an overall risk of bias judgement, the risk of bias assessment will be summarised and graphically presented.

Measurement of treatment effects

Review Manager V.5.3 will be used to conduct a meta-analysis. We will measure treatment effects using risk ratios (RRs) and the 95% CI for dichotomous outcomes. The range of possible values for RR will inform the interpretation of the effects and will be considered statistically significant if the 95% CI does not include 1.[36] RRs less than 1 indicate decreased likelihood of the stated outcome in the treatment group, while RRs greater than 1 indicate increased likelihood in the treatment group. Considering the expected variation in the measuring scales for continuous outcomes, the standardized mean difference (SMD) will be selected as a measure of the pooled data.[37] The Cohen's thresholds of 0.2, 0.5 and 0.8 will be used to classify the SMD as small, medium and big, respectively.

Units of analysis

Cluster randomisation

We will follow the guidelines set out in the Cochrane Handbook for the Systematic Review of Interventions for analysing cluster-randomised controlled trials. First, we will consider whether sufficient adjustment was made to account for clustering effects before estimating treatment effects. If adequate adjustment has not been made, we will extract the data and use a parallel control design to estimate treatment effects. Moreover, SEs will be adjusted to overcome clustering effects. If necessary, we will contact the authors to obtain information on the appropriate intraclass correlation coefficient (ICC). If we do not receive a response from the authors, the ICC will be estimated from existing databases or from studies included in this review. If this method fails to calculate the appropriate ICC, sensitivity analyses will be performed using a high ICC of 0.10, a medium ICC of 0.01 and a low ICC of 0.00. Review Manager V.5.3 will be used to combine estimates from cluster randomised controlled trials with estimates obtained from parallel controlled designs.[35]

Cross-over design

If a trial adopted a cross-over design, only data from the first period of the crossover trial will be used to avoid any possible carry over effect. If the trial did not report these data, we will contact the corresponding author. If we do not receive a response from the author, the trial will be excluded from our meta-analysis and its findings will be reported narratively.[35]

Missing data

We will treat missing or unclear data as described on the guidelines set out in the Cochrane Handbook for Systematic Reviews of Intervention. Specifically, we will contact the authors of the relevant articles to obtain the missing data. If this is unsuccessful, only the current data will be used for data analysis. The potential impact of missing data on the results will be addressed in the Discussion section of the report.

Assessment of heterogeneity

We will use I^2 tests conducted with Review Manager 5.3 to examine the statistical heterogeneity of included studies. The I^2 ranges from 0% (no heterogeneity) to 100% (the disparities between the effect sizes are entirely due to random variation). If the I^2 value is >75%, the included studies will be considered to have considerable heterogeneity and subgroup analyses will be performed as recommended in the Cochrane Handbook for Systematic Reviews of Interventions.

Assessment of reporting bias

The protocol will be strictly followed to minimise reporting bias. In addition, a funnel plot will be generated to facilitate the assessment of publication bias if we identify more than 10 trials. We will then apply the Egger's test to assess the symmetry of the funnel plot.[38]

Data synthesis

Study results and key characteristics, such as study design, sample size, risk of bias and sensitivity, will be presented in tables or graphs, thus facilitating the comparison of similarities and differences in design and results across studies. Data analysis will be performed using Review

Manager V.5.3 software. Data will be pooled for meta-analysis for included studies that are sufficiently homogeneous in terms of subjects, interventions and outcomes. A random-effects model will be used for all analyses. When the measurements are continuous data, the weighted mean difference with 95% CI will be used if same measurement tools were adopted. If different measurement tools were applied, the SMD with 95% CI will be used. When the outcomes are assessed as dichotomous data, the RR with 95% CI will be adopted.

Subgroup analysis

Given the nature of this review, we anticipate considerable heterogeneity among the included studies. To reduce heterogeneity, subgroup analyses will be conducted based on: (1) type of cancer, (2) cancer stage, (3) timing of the intervention, (4) intervention setting and (5) length of the intervention.

Sensitivity analysis

If necessary, sensitivity analyses will be performed to assess the robustness of the conclusions. The meta-analysis will be repeated, excluding each relevant study with high risk of bias, and incomplete results on a case-by-case basis, to reassess effect sizes.[37] If results are inconsistent, they will be discussed, and caution will be exercised in drawing conclusions.

Ethics and dissemination

Ethical approval is not required as this study does not involve personal data for patients. The results of this protocol will be published in a peer-reviewed journal.

Contributors QL: conceptualisation, methodology, writing—original draft, KYH: conceptualisation, methodology, supervision, data curation, writing—original draft, KKWL: conceptualisation, methodology, supervision, JMCH: revision, WL: conceptualisation, writing—revision, PM: methodology, writing—revision, HA-O: methodology, writing—revision, GMB: methodology, D-LL: methodology, writing—revision, S-S-YC: methodology, writing—revision, F-K-YW: conceptualisation, writing—revision.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	14
Support:			1
Sources	5a	Indicate sources of financial or other support for the review	
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	8
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8-9
Information sources	9	Describe all intended information sources (such as electronic databases,	9-10

		contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	9-10
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	10-12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	10-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	10-12
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	12
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	14
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	14-15
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	15
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	14
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Supplementary material

PubMed Search

#1	("pediatrics"[MeSH] OR "paediatric*" OR "pediatric*" OR "child"[MeSH] OR "Adolescent"[MeSH])
#2	("neoplasms"[MeSH] OR "cancer*")
#3	("Spirituality"[MeSH] OR "Spiritualism"[Mesh] OR "Spiritual Therapies"[Mesh] OR "spiritual*" OR "existential" OR "Religion"[MeSH] OR "narrative therapy" OR "Creative arts therapy" OR "Meditation" [MeSH] OR "Mindfulness")
#4	("randomized controlled trial" OR "randomized controlled trials as topic*" OR "controlled clinical trial")
#5	#1 AND #2 AND #3 AND #4

Embase Search

#1	'pediatrics'/exp OR 'child'/exp
#2	'malignant neoplasm'/exp OR cancer*:ti,ab OR neoplasm*:ti,ab
#3	'religion'/exp OR 'spiritual healing'/exp OR 'spiritual care'/exp OR spiritual*:ti,ab OR existential*:ti,ab OR narrative*:ti,ab OR 'creative arts therapy':ti,ab OR 'music therapy':ti,ab OR 'mindfulness meditation'/exp OR meditation:ti,ab OR mindfulness:ti,ab
#4	'randomized controlled trial (topic)'/exp OR 'controlled clinical trial (topic)'/exp
#5	#1 AND #2 AND #3 AND #4

CINAL Search via EBSCOhost

S1	(MH "Pediatrics+") OR (MH "Child+") OR (MH "Adolescence+")
S2	(MH "Neoplasms+") OR "cancer"
S3	(MH "Spiritual Healing+") OR (MH "Spiritual Care+") OR (MH "Spirituality+") OR "spiritual" OR (MH "Religion and Religions+") OR (MH "Narratives+") OR (MH "Storytelling+") OR (MH "Art Therapy") OR (MH "Nursing as an Art") OR "creative arts therapy" OR (MH "Art+") OR (MH "Meditation") OR (MH "Mindfulness")
S4	(MH "Randomized Controlled Trials+")
S5	S1 AND S2 AND S3 AND S4

Note: These search terms for the three databases will be adjusted to the other electronic databases, registers, and websites.