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Effectiveness of Acceptance Commitment Therapy for Head and Neck Cancer Patients with Body Image Distress in China: A Study Protocol for Randomized Controlled Trial

Wenjie Xu[1†], Lina Xiang[2†], Shuman Wang[1], Yu Zhu[1], Mimi Zheng[3], Hongwei Wan[1*]

[1]Department of Nursing, Shanghai Proton and Heavy Ion Center, Fudan University Cancer Hospital; Shanghai Key Laboratory of Radiation Oncology (20dz2261000); and Shanghai Engineering Research Center of Proton and Heavy Ion Radiation Therapy, China.

[2]School of Nursing, Fudan University, Shanghai, China.

[3]Department of Nursing, Zhongshan Hospital, Fudan University, Shanghai, China.

[†] Wenjie Xu and Lina Xiang should be considered joint first author

*Corresponding author: Hongwei Wan, PhD

Email: hong_whw@aliyun.com

Address: Shanghai Proton and Heavy Ion Center, 4365 Kangxin Rd, Pudong New Area, Shanghai 201321, China

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ABSTRACT

Introduction

The head and neck comprise vital organs and are apparent human body parts. When affected by cancer, this area can impact appearance, normal functions like eating and speech, and social interactions, leading to body image distress and threatening mental health and quality of life. Acceptance and commitment therapy have shown effectiveness in improving body image distress in groups such as breast cancer patients. This study aims to apply this therapy to intervene in head and neck cancer patients, aiming to improve body image distress and promote better psychological well-being.

Methods and analysis

This is a prospective, parallel-group, randomized controlled trial. 54 head and neck cancer patients will be randomized into interventional or control groups. The interventional will receive a 3-week, six-session, group-based acceptance and commitment intervention program, while the control group will receive treatment as usual. The primary outcome is cancer-related body image distress, and secondary outcomes are head and neck cancer-related body image distress, psychological flexibility, coping style, and psychological distress. These indicators will be measured at baseline, upon intervention completion, and again 1-month after conclusion.

Ethics and dissemination

The trial has received approval from the Institutional Review Board of Shanghai Proton and Heavy Ion Hospital (2308-67-02). The study results will be shared through peer-reviewed journals and conferences.

Trial registration number

Chinese Clinical Trial Registry ChiCTR2300077863.

Strengths and limitations of this study

- It enriches the intervention system of body image distress in head and neck cancer patients and expands the application scope of acceptance commitment therapy.

- The application of acceptance commitment therapy to head and neck cancer patients enables patients to actively accept the changes in physical appearance and function brought about by disease or treatment, reduces experiential avoidance, improves body image disorder, and promotes patients' psychological health.
- This study represents a single-center randomized trial; therefore, its findings may not readily apply to all settings. Further research in a multi-center, interdisciplinary, and transregional context will be imperative.
- The selection of patients needed more consistency regarding the duration of illness and disease stage. Future studies should take this into account, as the cancer experience of patients can significantly differ based on their duration and stage of disease.

INTRODUCTION

Head and neck cancer (HNC) is a series of malignant tumors that occur from the base of the skull to the supraclavicular and anterior cervical regions, including cancers of the oral cavity, salivary glands, pharynx, larynx, and sinuses.[1] The head and neck are vital for controlling physiologic functions such as breathing, swallowing, chewing, and expression and are apparent body parts.[2] HNC and its treatment not only affect sensory functions such as smell, taste, hearing, vision, and facial pain but also damage the patient's appearance and body image,[3] which further may negatively bias the patient's cognitive, emotional, or behavioral responses to their own body, resulting in social withdrawal and impaired emotional expression.[4-7] When severe, these impairments have significant adverse effects on psychosocial well-being and physical function and result in body image distress (BID). BID is characterized by a self-perceived, displeasing change in appearance and function and the resultant psychosocial distress.[8-10]

BID is common among HNC survivors because of the visible nature of the head and neck and its association with personal identity and communication. BID occurred in up to 75% of patients with head and neck cancer,[9] and the incidence even reached 87% in patients undergoing radiation therapy.[11] Most patients perceive themselves as physically incomplete and less attractive and are bothered by toxic side effects of radiotherapy, such as dry mouth, mucositis, and difficulty in swallowing or chewing,[11] and also report loss of appetite, rapid weight loss, and significant changes in body shape due to combination chemotherapy or targeted therapy, which in turn exacerbate psychological suffering.[12, 13] Moreover, BID has adverse psychological effects on head and neck tumor patients, such as self-denial, low self-esteem, social isolation, and depression. These not only seriously affect the patient's ability to cope with the tumor, treatment, and physical symptoms but also negatively affect their physical and mental health and quality of life.[6, 9, 14-16]

There are three intervention programs for improving BID: cosmetic rehabilitation instruction, mental health education, and cognitive-behavioral therapy.

Cosmetic rehabilitation instruction is the provision of makeup training or instruction to patients. Previous cosmetic rehabilitation instruction for oral cancer patients who underwent flap graft reconstruction found that patients' appearance appraisal, depression, social fear, and anxiety changed significantly over time. Still, the improvement of BID between the two groups before and after the intervention was not significant.[17, 18] An intervention using a mental health education manual for oral cancer patients found substantial improvements in the experimental group's BID and quality of life levels.[19] However, it is often challenging to develop a structured intervention program, but it is more difficult to replicate and further extend. A cognitive-behavioral therapy study conducted based on a telecinema approach found that the improvement of BID in the experimental group was 6.6 times higher than that in the control group after 1-months of intervention, and the level of improvement was clinically significant.[20] However, their application needs to be further validated due to the small number of such studies and small sample sizes.

It is worth mentioning that a growing number of studies have found acceptance commitment therapy (ACT) to have potential applications in improving BID.[21-23] ACT has been shown to have significant results for BID due to weight, size, height, skin color, and other aspects of the body.[24] Recent studies have found that ACT-based group psychological interventions can significantly improve BID in postoperative breast cancer patients,[21] and are effective in enhancing psychological flexibility and reducing BID due to body image issues in patients with eating disorders.[22] To address the lack of effective treatment options for BID in head and neck cancer patients, we designed a single-site randomized clinical trial (RCT) to evaluate the acceptability of ACT and its preliminary efficacy in reducing BID among HNC patients relative to the usual care (UC) group condition, as well as refine the trial infrastructure in preparation for a multisite RCT.

METHODS

Design

This study will follow a two-arm, parallel-design, randomized controlled trial

conducted among head and neck cancer patients. This study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) flow chart (see Fig. 1).[25] The SPIRIT Checklist is available as a supplementary document (see Additional File 1).[26] Eligible patients who consent to participate will be randomly assigned to the intervention or control groups. The intervention program comprises a total of 6 themes and spans three weeks. The primary outcome, cancer-related body image distress, and secondary outcomes, including HNC-related BID, psychological flexibility, coping style, and psychological distress will be evaluated at three-time points: baseline, post-intervention, and 1-month postintervention. The assessment timeline is visually depicted in Table 1. The study will begin in February 2024 and is expected to be completed by October 2024.

Study setting

The study will be conducted at the Shanghai Proton and Heavy Ion Center, the first medical institution in China to have both proton and heavy ion technologies. As of May 8, 2023, a cumulative total of 5,648 patients have received treatment and have been discharged from the hospital, demonstrating an average annual growth rate of 20 percent.

Recruitment

Participants were recruited in February 2024 at the Shanghai Specialized Hospital of Oncology. Recruitment will be conducted through various channels, including public advertisements (e.g., posters, flyers) and mobilization meetings (inform potential participants about the risks associated with BID, as well as 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, randomization procedures, potential risks, anticipated benefits, the assurance of data confidentiality, and an explanation of their rights as subjects. Upon agreement, participants will provide written informed consent. They will be informed that they can withdraw from

the study without impacting their treatment.

Participants

The study population will consist of head and neck cancer patients with no evidence of disease, 18 years of age or older, of all sexes, with cancer-related BID. The inclusion criteria for participants are as follows: (a) in patients diagnosed with head and neck tumors, including oral cavity, pharynx, larynx, nose/paranasal sinuses, carcinoma of a significant or minor salivary gland, or cutaneous malignancy of the face or neck, (b) age > 18 years at the time of screening, (c) possessed knowledge of the diagnosis, (d) fluent in Mandarin, (e) willingness to be randomized to either ACT or UC and (f) BIS score > 10. 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; the rationale for excluding these patients is that the intervention of this study may be therapeutically insufficient, (c) individuals currently taking psychiatric medications or engage in other comparable psychological interventions, and (d) those with appearance deficits or severe physical dysfunction before the diagnosis of head and neck cancer.

Sample size

The sample size was determined using Power Analysis and Sample Size Software (PASS, V.21.0.3) and calculations revealed that 44 patients were required to detect a standardized effect of 0.78 for the primary end point of change from baseline to 1-month postintervention in the Body Image Scale scores based on the 2-sample t test with 2-sided $\alpha = 0.1$. Accounting for an estimated dropout rate of 20%, a minimum of 54 subjects needed to be recruited for the study.

Randomization and blinding

The study will use block randomization with four block sizes and a 1:1 allocation ratio. A random sequence will be generated using the computer software Study Randomizer (https://www.studyrandomizer.com/) by a graduate student not involved in recruitment, intervention, or data collection. The grouping scheme for each block will be placed sequentially in four small opaque sealed envelopes, numbered from 1

to 4. These envelopes will then be uniformly placed in a large envelope labeled with the corresponding block number. All envelopes will be kept individually throughout the study. The allocation sequence will be generated before the recruitment phase begins to minimize selection bias. After enrolling eligible patients, another researcher will sequentially open the envelopes to obtain grouping information for allocation concealment. Data collectors and analysts must be aware of the grouping information to maintain blinding.

Intervention: acceptance commitment therapy

The intervention group's patients will receive the Acceptance and Commitment intervention program. Previous studies showed that scheduled six sessions in ACT have a significant intervention effect.[21, 22] Considering a patient's hospital stay of approximately 45 days, we will schedule six sessions spread across one month. This approach significantly increased scheduling flexibility and reduced the risk of patients missing the program due to conflicting treatment and intervention schedules.

ACT is a cognitive-behavioral therapy theory and practice based on the Relational Frame Theory (RFT) of human language and cognition and the philosophy of functional contextualism, which includes six aspects: acceptance, cognitive dissociation, living in the present moment, taking oneself as a view, values, and commitment to action.[27] In the intervention group, patients will engage in a 3-week, 6-session The Acceptance and Commitment Intervention Program conducted twice a week, lasting 2 hours per session. Each session introduces participants to distinct themes, such as 'acceptance,' 'defusion,' 'Being Present,' 'self-as-context,' 'values,' and 'committed action.' These processes are interrelated and support each other in increasing psychological flexibility. Each session comprises 10 minutes of didactics, followed by 10 minutes of mindfulness meditation and 40 minutes of experiential exercises, and concludes with a 60-minute group discussion. Each experiential exercise will be introduced as a game or visualization. During the discussion phase, the interventionist will pose guiding questions tailored to each patient's result of the exercise, aiming to accomplish the objectives of each topic. The group will be co-led by two group psychotherapists trained in acceptance and commitment therapy and a

master's student in nursing psychology. Each closed group will comprise approximately 8 participants. During the trial, participants in the experimental group will receive two timely reminders and notifications from their charge nurse before each group activity: one a day in advance and another two hours before the scheduled start time.

Control group: usual care

Patients will receive standard care during their hospitalization, which includes nutritional support, rehabilitative care, and routine psychosocial support. This regular psychological care includes systematic mental health assessments conducted by nurses. Trained nurses provide non-specific psychological support, such as empathetic interactions, encouragement, and opportunities for patients to express their thoughts and feelings if needed.

Intervention fidelity

Audio will be recorded from all group sessions to evaluate the effectiveness of intervention implementation. An expert with a medical and psychology background will randomly select 20% of the tapes for review to assess the intervention program's implementation. Adherence to the study protocol will be attending at least five sessions, closely monitored and documented by the interventionist. Instances of absence or withdrawal will be reported, along with reasons provided to gauge participant adherence to therapeutic interventions.

Data collection

A graduate nursing student trained in systematic research will evaluate intervention outcomes for eligible participants. Sociodemographic variables will be collected at baseline, including demographic data and disease-related characteristics. Additionally, five psychosocial variables—cancer-related body image distress, head and neck cancer-related body image distress, psychological flexibility, coping style, and psychological distress—will be assessed at three-time points: baseline, post-intervention, and 1-month post-intervention. Baseline and post-intervention data collection will be face-to-face, while the 1-month post-intervention data collection will be conducted via an online questionnaire. Both the control and intervention

groups will undergo reassessment at the same intervals.

Outcome measures

Sociodemographic and disease-related variables

A concise sociodemographic questionnaire will be administered at the baseline to assess various demographic characteristics, including age, gender, body mass index, marital status, education level, religion, employment status, marital status, and per capita monthly income. Information about disease-related characteristics, such as site, stage, time since cancer diagnosis, and medical treatment, will also be collected.

Primary outcome: cancer-related BID

The cancer-related body image distress of participants will be assessed using the Chinese version of the Body Image Scale (BIS).[28] The scale comprises three dimensions, affective, cognitive, and behavioral, with ten items, and is scored on a 4-point Likert scale, with a total score of 0-30, with higher scores indicating higher levels of cancer-related BID, and is primarily used to assess the affective, cognitive and emotional aspects of the patient's body image as a result of the cancer or its treatment over seven days.[29] The Cronbach's α coefficient is reported to be 0.801.[28]

Secondary outcomes

Head and neck cancer-related BID

Head and neck cancer-related BID will be assessed using IMAGE-HN (Inventory to Measure and Assess imaGe disturbancE–Head and Neck),[30] licensed, culturally adapted, and translated into Chinese. The IMAGE-HN score ranges from 0 to 84, with higher scores indicating worse head and neck cancer-related BID.[30] We included both the Body Image Scale and IMAGE-HN as outcome measures for the time of trial design; the Body Image Scale was the most widely used measure of BID among head and neck cancer patients,[31] with a known cutoff score indicating clinically significant BID.[32] However, it was developed and validated in a mixed population of cancer patients, predominantly breast cancer, lacking content validity for head and neck cancer patients.[31] In contrast, IMAGE-HN had better content validity for BID among HNC patients but had only recently been validated.[30]

Coping style

Coping style of participants will be assessed using the Chinese version of the Simplified Coping Style Questionnaire (SCSQ).[33] The scale comprises two dimensions, positive coping (1-12 items) and negative coping (13-20 items), with a total of 20 items used to measure individuals' coping styles when they encounter difficulties or frustrations. Each item is scored on a 0-3 scale, with higher scores on positive coping, indicating that the respondent is more inclined to adopt an upbeat coping style, and higher scores on negative coping, meaning that the respondent is more willing to adopt a negative coping style. The Cronbach's α coefficient is reported to be 0.90.[33]

Psychological flexibility

The psychological flexibility will be assessed using the Chinese version of the Acceptance and Action Questionnaire Second Edition (AAQ-II). The scale comprises seven items on a 7-point scale, with each entry scoring 1 - 7 points, and the range of scores is between 7 and 49. Higher scores indicate higher levels of empirical avoidance and lower psychological flexibility. The Cronbach's alpha coefficient for the scale was 0.88, and the retest reliability was 0.80.[34]

Psychological distress

Psychological distress will be assessed using the Distress Thermometer (DT), which employs a scale ranging from 0 to 10 to measure the degree of distress.[35] A score of 0 indicates no psychological distress, while a score of 10 indicates extreme distress. Higher scores indicate more severe distress.

Qualitative data

This study will gather qualitative data through interviews one week after the intervention concludes. The aim is to gather insights into participants' subjective experiences and identify potential areas for improvement in future programs. All interviews will be audio-recorded and transcribed verbatim.

Data analysis

The efficacy analytic population will include all eligible, randomized, evaluable patients. Statistical analysis will be conducted by an independent examiner using IBM SPSS Statistics version 26.0. Two-sided statistical testing will be performed, with P <

0.05 considered statistically significant, and 90% confidence intervals will be reported for point estimates.

All analyses will follow an intention-to-treat approach, addressing missing data from dropouts using the multiple imputation method. Descriptive statistics will characterize the cohort and intervention acceptability, fidelity, and adherence. A descriptive analysis of sociodemographic and disease-related variables in HNC patients will be conducted. Means and standard deviations will be used for variables with a normal distribution, and medians and interquartile ranges for those with a non-normal distribution. Categorical variables will be analyzed using frequencies and percentages. The baseline characteristics of the two groups will be compared using parametric or non-parametric tests. Student's t-test or the $\chi 2$ test will be used for normally distributed data and non-parametric tests such as the Wilcoxon test and Mann-Whitney U test for non-normally distributed data.

A mixed-effects model will assess the intervention effects on primary and secondary outcome indicators. Additionally, intervention effects between groups for each variable will be evaluated pre- and post-intervention and two months before and after the intervention through an analysis of covariance (ANCOVA). Each ANOVA model will include covariates such as corresponding baseline scores and demographic variables significantly associated with pre-and post-intervention scores. Waterfall plots will illustrate the change in BIS and IMAGE-HN scores for each patient from baseline to 1-month post-intervention.

Data management, monitoring and confidentiality

The current nonpharmacological intervention, aligning with ethical principles, aims to benefit participants without causing harm, minimizing the likelihood of adverse effects. Therefore, establishing a Data Monitoring Safety Board seems unnecessary. Participant identification numbers exclusively identify all collected data for confidentiality. Paper records, including consent forms and questionnaire data, will be securely stored. Audio recordings will be stored on a secure cloud server and safeguarded on a dedicated laptop. The first, second, and final authors will primarily manage the trial dataset, granting access to all authors as needed.

Adverse events

Throughout the study, we will meticulously document anticipated and unanticipated adverse events. Although we do not expect serious adverse events, if an unexpected serious adverse event occurs (e.g., risk of suicide), participants can seek guidance and support from a specialist within the study team. Any significant adverse events will be promptly reported to the Institutional Review Board of Shanghai Proton and Heavy Ion Hospital.

Ethics and dissemination

The ethical committee of Shanghai Proton Heavy Ion Hospital has approved the entire study design (2308-67-02) 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 master degree 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

This study aimed to improve BID in patients with HNC through ACT-based experiential exercises and open-ended discussions in a group. Reviewing research in this area reveals that due to the numerous adverse effects of BID, some researchers have attempted to develop intervention programs to improve BID in cancer patients from cognitive, emotional, and behavioral perspectives. Among these, intervention strategies based on cognitive-behavioral therapy are the most common. As the "third wave" of cognitive-behavioral therapy,[36] the role of acceptance and commitment therapy in improving BID in patients with HNC is noteworthy.

In the context of the causes of BID in patients with HNC, ACT has unique advantages over other intervention strategies. On the one hand, ACT does not treat any thought or feeling as abnormal, but rather the tendency to cognitively integrate and experience avoidance as problematic thinking responses. During the intervention, ACT does not directly change the individual's perception and evaluation of his or her appearance but instead develops skills and values related to appearance or negative

self-evaluation to reduce the impact on behavior.[37] On the other hand, ACT interventions contain a combination of treatment modules that attempt to modify the effects of maladjustment, and modular treatments have the benefits of standardization and the ability to provide individualized therapies based on theory and empirical evidence.

In addition, Group Psychology Therapy, the group psychological intervention approach selected for this study, is potentially more valuable than individual psychotherapy. It is an approach that brings members together for a common goal and allows group members to gain a greater sense of experience and access to authentic contextual support through interpersonal interactions, emotional support, and emotional and thought connections within the group.[38, 39] Group-based ACT takes advantage of the efficacy factors of group therapy to improve members' cognition, emotions, and behaviors. Studies have also shown that research studies on participation and attrition in group therapy have found that group cognitive behavioral therapy is superior to other forms of group therapy, with higher member participation and lower attrition.[40, 41] Overall, the design aspects of this study are scientifically sound and feasible.

Finally, this study evaluates both quantitative and qualitative data through interviews. Gathering information on participants' subjective experiences will inform areas for improvement in future programs. The focus is on opportunities to continue the program beyond the project's duration. We are committed to creating a comprehensive brochure that is accessible in specialized oncology hospitals and public hospitals and offers vital support to individuals dealing with HNC.

Author Contributions

WJX and HWW made significant contributions to the research methodology design and the development of the overall research objectives. WJX, LNX, and SMW 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.

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Competing interests: None declared.

Patient consent: Obtained.

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

Conflicts of interest

None of the authors had any conflict of interest in this study.

Availability of data and materials

Data are not made available because this paper is a protocol publication.

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Figure 1 CONSORT flow chart of the study

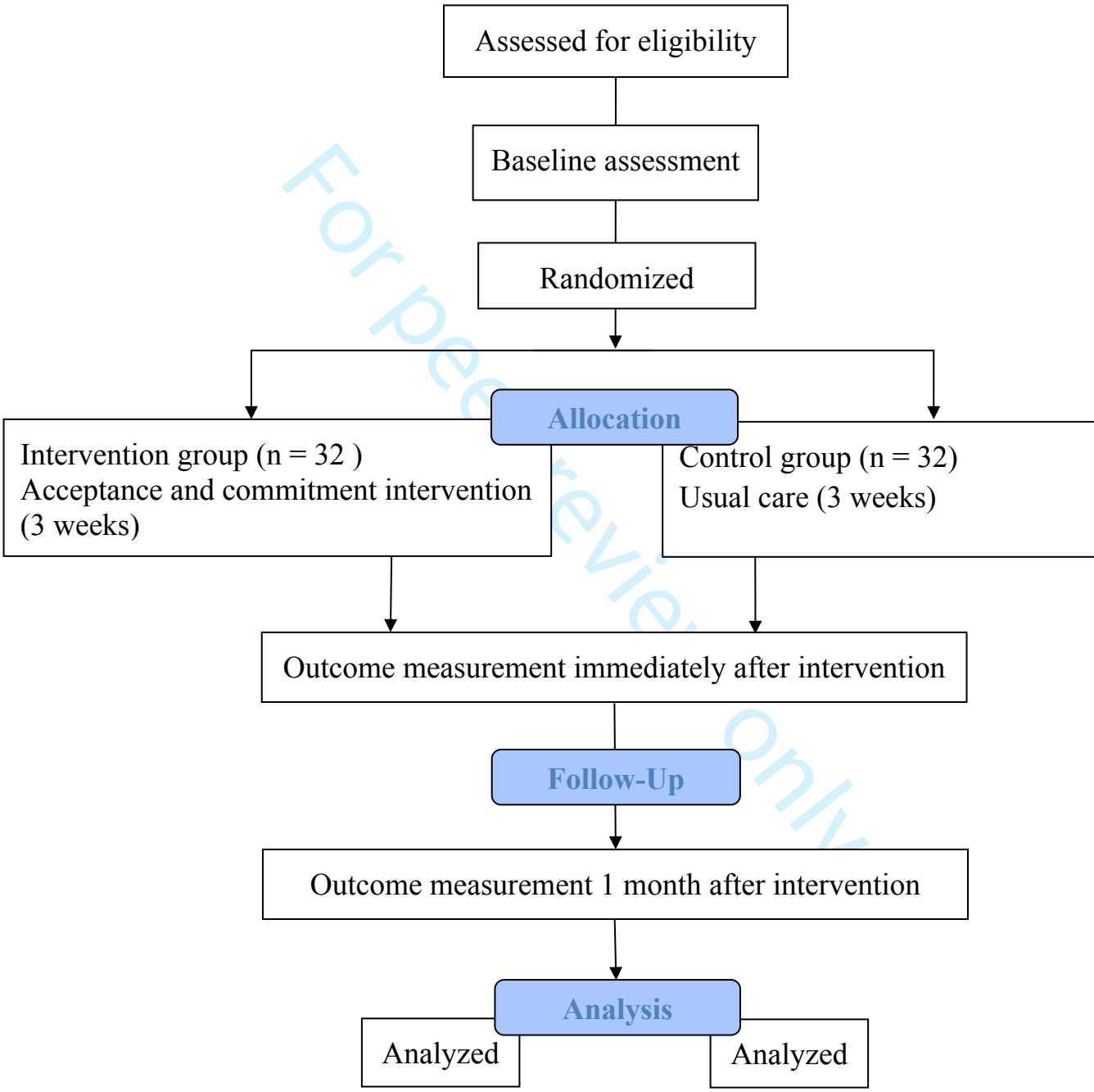

Table 1 The schedule of trial enrolment, interventions and assessments

	Pre screen	Baseline (t_0)	Allocation	3 weeks intervention	At immediately post-intervention (t_1)	1 month after intervention (t_2)
Informed Consent						
Review study eligibility	×					
Informed consent	×					
Study Procedures						
Randomization			×			
Demographics		×				
Clinical and oncologic history		×				
Intervention Administration						
ACT or UC				×		
Efficacy Evaluation						
Body Image Scale	×				×	×
IMAGE-HN		×			×	×
AAQ-II		×			×	×
SCSQ		×			×	×
DT		×			×	×
Other Evaluations						
Intervention fidelity				×		
Patient adherence				×		

Acronyms: ACT, Acceptance Commitment Therapy; UC, Usual Care; IMAGE-HN, The Inventory to Measure and Assess imaGe disturbance-Head and Neck; AAQ-II, The Acceptance and Action Questionnaire Second Edition; SCSQ, Simplified Coping Style Questionnaire; DT, Distress Thermometer.

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

Section/item	Item No	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2	4
	2b	All items from the World Health Organization Trial Registration Data Set	2	4
Protocol version	3	Date and version identifier	1	N/A
Funding	4	Sources and types of financial, material, and other support	15	2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1	N/A
	5b	Name and contact information for the trial sponsor	N/A	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	15	2
	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)	12	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	ALL
	6b	Explanation for choice of comparators	4-5	N/A
Objectives	7	Specific objectives or hypotheses	5	2

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)	5	2
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	2
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	1
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-9	2-3,1-2
	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	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9	3
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9	3
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	10-111	ALL
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	1
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	2
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6	3
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	7-8	3
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	3

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6,7	3,3
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8	3
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	7-8	3
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	9	4
	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	9	4
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	12	4
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	12	1-3
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12	1-3
	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)	12	1
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	12	4
	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	4
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	13	3
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	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)	6	3
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	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	12	4
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22	N/A
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	13	3
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	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	13	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	13	3
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13	3
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Avaliable in Chinese upon request	
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	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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Effectiveness of Acceptance Commitment Therapy for Head and Neck Cancer Patients with Body Image Distress in China: A Study Protocol for Randomized Controlled Trial

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Keywords:	Randomized Controlled Trial, Psychosocial Intervention, Head & neck tumours < ONCOLOGY

Effectiveness of Acceptance Commitment Therapy for Head and Neck Cancer Patients with Body Image Distress in China: A Study Protocol for Randomized Controlled Trial

Wenjie Xu[1†], Lina Xiang[2†], Shuman Wang[1], Yu Zhu[1], Mimi Zheng[3], Hongwei Wan[1*]

[1]Department of Nursing, Shanghai Proton and Heavy Ion Center, Fudan University Cancer Hospital; Shanghai Key Laboratory of Radiation Oncology; and Shanghai Engineering Research Center of Proton and Heavy Ion Radiation Therapy, China.

[2]School of Nursing, Fudan University, Shanghai, China.

[3]Department of Nursing, Zhongshan Hospital, Fudan University, Shanghai, China.

[†] Wenjie Xu and Lina Xiang contributed equally to this paper

*Corresponding: Hongwei Wan, PhD

Email: hong_whw@aliyun.com

Address: Shanghai Proton and Heavy Ion Center, 4365 Kangxin Rd, Pudong New Area, Shanghai, China

ABSTRACT

Introduction

The head and neck comprise vital organs and are apparent human body parts. tumors here impair physical and sensory functions as well as appearance and social interactions, leading to body image distress (BID) and threatening mental health and quality of life. Acceptance and commitment therapy (ACT) have shown effectiveness in improving body image distress in groups such as breast cancer patients. This study aims to apply this therapy to intervene in head and neck cancer patients, aiming to improve BID and promote better psychological well-being.

Methods and analysis

This study is a prospective, parallel-group, randomized controlled trial. A total of 64 head and neck cancer (HNC) patients will be allocated to either an intervention group or a control group. The intervention group will engage in a 3-week, six-session group-based acceptance and commitment therapy program, while the control group will receive standard treatment. The primary outcome is cancer-related BID, and secondary outcomes are head and neck cancer-related BID, psychological flexibility, coping style, and psychological distress. These indicators will be measured at baseline, post-intervention, and 1 month following the intervention's completion.

Ethics and dissemination

The trial has received approval from the Institutional Review Board of Shanghai Proton and Heavy Ion Hospital (2308-67-02). The study results will be shared through peer-reviewed journals and conferences.

Trial registration number

Chinese Clinical Trial Registry ChiCTR2300077863.

Keywords: head and neck cancer; acceptance commitment therapy; body image distress; protocol; randomized controlled trial

Strengths and limitations of this study

- This Randomized controlled trial will be the first to evaluate the effectiveness of ACT on improvement of HNC-related body image distress.
- The ACT has no side effects with strong potential for benefit for the mental health of patients with cancer.
- Recruitment relies on the patient's willingness to participate, which may generate a portion of the selection bias.
- Study results are based on the Patient-Reported Outcome Measurement Tool, which is subjective to a certain extent.
- This study represents a single-center randomized trial, so further research in a multi-center, interdisciplinary, and transregional context will be imperative.

INTRODUCTION

Head and neck cancer is a series of malignant tumors that occur from the base of the skull to the supraclavicular and anterior cervical regions, including cancers of the oral cavity, salivary glands, pharynx, larynx, and sinuses.[1] The head and neck area contain vital organs for controlling physiologic functions such as breathing, swallowing, chewing, and expression and are apparent body parts.[2] HNC and its treatment not only affect sensory functions such as smell, taste, hearing, vision, and facial pain but also damage the patient's appearance and body image,[3] which further may negatively bias the patient's cognitive, emotional, or behavioral responses to their own body.[4-7] When severe, these impairments have significant adverse effects on psychosocial well-being and physical function and result in body image distress. BID is characterized by a self-perceived, displeasing change in appearance and function and the resultant is psychological distress.[8-10]

BID is common among HNC survivors because of the visible nature of the head and neck and its association with personal identity and communication. An estimated 75% of HNC survivors express concerns about their body image,[9] with up to 28% experiencing significant BID.[11, 12] Owing to the differences between individuals, especially from different cultural contexts, BID can occur at every moment of a patient's treatment and recovery period. Most patients perceive themselves as physically incomplete and less attractive and are bothered by toxic side effects of radiotherapy, such as dry mouth, mucositis, and difficulty in swallowing or chewing,[12] and also report loss of appetite, rapid weight loss, and significant changes in body shape due to combination chemotherapy or targeted therapy, which in turn exacerbate psychological suffering.[13, 14] Moreover, BID has adverse psychological effects on head and neck tumor patients, such as self-denial, low self-esteem, social isolation, and depression. These not only seriously affect the patient's ability to cope with the tumor, treatment, and physical symptoms but also negatively affect their physical and mental health and quality of life.[6, 9, 15-17]

There are three intervention programs for improving BID: cosmetic

rehabilitation instruction, mental health education, and cognitive-behavioral therapy. Previous cosmetic rehabilitation instruction for oral cancer patients who underwent flap graft reconstruction found that the improvement of BID between the two groups before and after the intervention was not significant.[18, 19] An intervention using a mental health education manual for oral cancer patients found substantial improvements in the experimental group's BID and quality of life levels.[20] However, it is often challenging to develop a structured intervention program and it is more difficult to replicate and further extend. A cognitive-behavioral therapy study, with 44 patients, found that BID was significantly improved in the experimental group after 1-months of intervention.[21] However, their application needs to be further validated due to the small number of such studies and small sample sizes.

It is worth mentioning that a growing number of studies have found acceptance commitment therapy (ACT) to have potential applications in improving BID.[22-24] ACT has been described as the third wave of cognitive-behavioral therapy. ACT is a cognitive-behavioral therapy theory and practice based on the Relational Frame Theory (RFT) of human language and cognition and the philosophy of functional contextualism, which includes six aspects: acceptance, cognitive dissociation, living in the present moment, taking oneself as a view, values, and commitment to action.[25] ACT has been shown to have significant results for BID due to weight, size, height, skin color, and other aspects of the body.[26] Recent studies have found that ACT-based group psychological interventions can significantly improve BID in postoperative breast cancer patients,[22] and are effective in enhancing psychological flexibility and reducing BID due to body image issues in patients with eating disorders.[23] To address the lack of effective treatment options for BID in head and neck cancer patients, we designed a single-site randomized clinical trial (RCT) to evaluate the acceptability of ACT and its preliminary efficacy relative to the usual care (UC) group condition, as well as refine the trial infrastructure in preparation for a multisite RCT.

METHODS

Design

This research employs a two-arm, parallel-design, randomized controlled trial among head and neck cancer patients, adhering to the CONSORT guidelines as illustrated in Figure 1.[27] The SPIRIT Checklist is provided as a supplementary document (Additional File 1).[28] Consenting eligible patients will be randomized to either the intervention or control group. The intervention consists of a 3-week program with 6 thematic modules. The primary outcome, cancer-related body image distress, and secondary outcomes, including HNC-related BID, psychological flexibility, coping style, and psychological distress will be evaluated at three-time points: baseline, post-intervention, and 1-month postintervention. The assessment timeline is visually depicted in Table 1. The study will begin in February 2024 and is expected to be completed by October 2024.

Table 1 The schedule of trial enrolment, interventions and assessments

	Pre screen	Baseline (t_0)	Allocation	3 weeks intervention	At immediately post-intervention (t_1)	1 month after intervention (t_2)
Informed Consent						
Review study eligibility	×					
Informed consent	×					
Study Procedures						
Randomization			×			
Demographics		×				
Clinical and oncologic history		×				
Intervention Administration						
ACT or UC				×		
Efficacy Evaluation						
Body Image Scale	×				×	×
IMAGE-HN		×			×	×
AAQ-II		×			×	×
SCSQ		×			×	×
DT		×			×	×
Other Evaluations						
Intervention fidelity				×		
Patient adherence				×		

Acronyms: ACT, Acceptance Commitment Therapy; UC, Usual Care; IMAGE-HN, The Inventory to Measure and Assess imaGe disturbance-Head and Neck; AAQ-II, The Acceptance and Action Questionnaire Second Edition; SCSQ, Simplified Coping Style Questionnaire; DT, Distress Thermometer.

Study setting

The study will be conducted at the Shanghai Proton and Heavy Ion Center, the first medical institution in China to have both proton and heavy ion technologies. As of May 8, 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 percent.

Recruitment

Participants were enrolled at the Shanghai Proton and Heavy Ion Center in February 2024. Recruitment strategies included public advertisements such as posters and flyers, as well as informational sessions to explain the risks related to BID and the project's goals and benefits. Eligible participants who voluntarily agreed to take part were briefed by the research team on the study's objectives, procedures, interventions, assessments, randomization process, potential risks, and benefits. They were assured of confidentiality and informed of their rights, including the right to withdraw consent at any time without affecting their medical care. After receiving this comprehensive information, participants provided written informed consent. They were reassured that participation was voluntary and that withdrawal from the study would not influence their treatment in any way.

Participants

The study population will consist of head and neck cancer patients with 18 years of age or older, of all sexes, with cancer-related BID. The inclusion criteria for participants are as follows: (a) in patients diagnosed with head and neck tumors, including oral cavity, pharynx, larynx, nose/paranasal sinuses, carcinoma of a significant or minor salivary gland, or cutaneous malignancy of the face or neck, (b) age > 18 years at the time of screening, (c) possessed knowledge of the diagnosis, (d) fluent in Mandarin, (e) willingness to be randomized to either ACT or UC and (f) BIS

score > 10. The exclusion criteria are as follows: (a) individuals diagnosed by a specialist as being in the acute phase of the disease or experiencing severe hepatic, renal, or cardiopulmonary impairment, (b) those diagnosed by a specialist with severe mental disorders or significant cognitive deficits; the rationale for excluding these patients is that the intervention of this study may be therapeutically insufficient, (c) individuals currently taking psychiatric medications or engage in other comparable psychological interventions, and (d) those with appearance deficits or severe physical dysfunction before the diagnosis of head and neck cancer.

Sample size

The sample size was determined using Power Analysis and Sample Size Software (PASS, V.21.0.3) and calculations revealed that 54 patients were required to detect a standardized effect of 0.78 for the primary end-point of change from baseline to 1-month postintervention in the Body Image Scale scores based on the 2-sample t-test with 2-sided $\alpha = 0.1$.[29] Accounting for an estimated dropout rate of 20%, a minimum of 64 subjects needed to be recruited for the study.

Randomization and blinding

The study employs a block randomization method with varying block sizes, maintaining a 1:1 allocation ratio. The randomization sequence will be generated by a graduate student unaffiliated with recruitment, intervention, or data processes, using the Study Randomizer software. The assignment scheme for each block is meticulously placed in sequentially numbered, opaque, sealed envelopes, ranging from 1 to 4. These are then uniformly housed within a larger envelope, marked with the respective block number. Individual storage of all envelopes will be maintained throughout the study duration. To reduce selection bias, the allocation sequence is generated prior to the commencement of the recruitment phase. Upon enrollment of eligible patients, a designated researcher will open the envelopes in sequence to reveal group allocation details, ensuring allocation concealment. It is imperative that data collectors and analysts remain uninformed of the grouping to preserve the study's blinding integrity.

Intervention: acceptance commitment therapy

The intervention group's patients will receive the Acceptance and Commitment intervention program. Previous studies showed that scheduled six sessions in ACT have a significant intervention effect.[22, 23] Considering a patient's hospital stay of approximately 45 days, we will schedule six sessions spread across one month. This approach significantly increased scheduling flexibility and reduced the risk of patients missing the program due to conflicting treatment and intervention schedules.

In the intervention group, patients will participate in a 3-week Acceptance and Commitment Intervention Program, with sessions held twice weekly for a total of 6 sessions. Each session, lasting 2 hours, delves into key themes such as acceptance, diffusion, presence, self-as-context, values, and committed action—interconnected processes that bolster psychological flexibility. The structure of each session includes a 10-minute educational segment, a 10-minute mindfulness meditation, and a 40-minute experiential exercise, typically presented as a game or visualization. This is followed by a 60-minute group discussion where the interventionist uses tailored questions to explore each patient's experience and achieve the session's goals. The program is co-facilitated by two psychotherapists skilled in acceptance and commitment therapy, along with a master's student in nursing psychology. Groups are kept small, with about 8 participants each, to ensure personalized attention. To ensure attendance and engagement, participants in the intervention group will receive two reminders from their charge nurse for each session: one 24 hours in advance and another two hours prior to the session's start.

Control group: usual care

During hospitalization, patients will receive standard care encompassing nutritional support, rehabilitative services, and routine psychosocial assistance. Our regular psychological care involves systematic mental health evaluations by our nursing staff. These nurses, trained to provide non-specific psychological support, engage with patients through empathetic communication, encouragement, and by offering a safe space for patients to share their thoughts and emotions as needed.

Intervention fidelity

All group sessions will be audio-recorded to assess the effectiveness of the

intervention. A medical and psychology expert will randomly sample 20% of the recordings for evaluation, ensuring the intervention program is properly implemented. Study protocol adherence is defined as attending a minimum of five sessions, which will be closely monitored and meticulously documented by the interventionist. Any absences or withdrawals, along with their reasons, will be meticulously recorded to measure participant engagement with the therapeutic process.

Data collection

A graduate nursing student will assess the intervention's outcomes for eligible participants. At baseline, a comprehensive set of sociodemographic variables will be gathered, encompassing demographic details and disease-specific traits. Furthermore, five key psychosocial variables—cancer-related body image distress, head and neck cancer-specific body image distress, psychological flexibility, coping style, and psychological distress—will be evaluated at three distinct time points: baseline, immediately after the intervention, and one month post-intervention. Initial and post-intervention data will be collected through face-to-face interviews, while the one-month follow-up will utilize an online questionnaire for convenience. Participants in both the control and intervention groups will be reassessed at equivalent time intervals to ensure a standardized evaluation process.

Outcome measures

Sociodemographic and disease-related variables

A concise sociodemographic questionnaire will be administered at the baseline to assess various demographic characteristics, including age, gender, body mass index, marital status, education level, religion, employment status, marital status, and per capita monthly income. Information about disease-related characteristics, such as site, stage, time since cancer diagnosis, and medical treatment, will also be collected.

Primary outcome: cancer-related BID

The cancer-related body image distress of participants will be assessed using the Chinese version of the Body Image Scale (BIS). The scale comprises three dimensions, affective, cognitive, and behavioral, with ten items, and is scored on a 4-point Likert scale, with a total score of 0-30, with higher scores indicating higher

levels of cancer-related BID, and is primarily used to assess the affective, cognitive and emotional aspects of the patient's body image as a result of the cancer or its treatment over seven days.[31] The Cronbach's α coefficient is reported to be 0.91.[32]

Secondary outcomes

Head and neck cancer-related BID

Head and neck cancer-related BID will be assessed using IMAGE-HN (Inventory to Measure and Assess imaGe disturbancE–Head and Neck),[33] licensed, culturally adapted, and translated into Chinese. The IMAGE-HN score ranges from 0 to 84, with higher scores indicating worse head and neck cancer-related BID.[33] We included both the Body Image Scale and IMAGE-HN as outcome measures for the time of trial design; the Body Image Scale was the most widely used measure of BID among head and neck cancer patients,[34] with a known cutoff score indicating clinically significant BID.[35, 36] However, it was developed and validated in a mixed population of cancer patients, predominantly breast cancer, lacking content validity for head and neck cancer patients.[34] In contrast, IMAGE-HN had better content validity for BID among HNC patients but had only recently been validated.[33]

Coping style

Coping style of participants will be assessed using the Chinese version of the Simplified Coping Style Questionnaire (SCSQ).[37] The scale comprises two dimensions, positive coping (1-12 items) and negative coping (13-20 items), with a total of 20 items used to measure individuals' coping styles when they encounter difficulties or frustrations. Each item is scored on a 0-3 scale, with higher scores on positive coping, indicating that the respondent is more inclined to adopt an upbeat coping style, and higher scores on negative coping, meaning that the respondent is more willing to adopt a negative coping style. The Cronbach's α coefficient is reported to be 0.90.[37]

Psychological flexibility

The psychological flexibility will be assessed using the Chinese version of the Acceptance and Action Questionnaire Second Edition (AAQ-II). The scale comprises seven items on a 7-point scale, with each entry scoring 1 - 7 points, and the range of

scores is between 7 and 49. Higher scores indicate higher levels of empirical avoidance and lower psychological flexibility. The Cronbach's alpha coefficient for the scale was 0.84, and the retest reliability was 0.81.[38]

Psychological distress

Psychological distress will be assessed using the Distress Thermometer (DT), which employs a scale ranging from 0 to 10 to measure the degree of distress.[40] A score of 0 indicates no psychological distress, while a score of 10 indicates extreme distress. Higher scores indicate more severe distress.

Qualitative data

This study will gather qualitative data through interviews one week after the intervention concludes (Table 2). The aim is to gather insights into participants' subjective experiences and identify potential areas for improvement in future programs. All interviews will be audio-recorded and transcribed verbatim.

Table 2 Interview guide

What was your experience of the intervention?
What aspects of ACT did you find most useful? Can you describe some examples of what ACT helped you with?
What do you think about the sessions of the intervention (content, format, therapists, homework and environment)?
Do you feel like you have changed after participating in the ACT? About BID?
What challenges were experienced during participation in ACT?
What are your suggestions on the intervention? What could be improved?
How do you apply the knowledge you have gained in the ACT in your daily life?

Data analysis

The efficacy analytic population will include all eligible, randomized, evaluable patients. Statistical analysis will be conducted by an independent examiner using IBM SPSS Statistics version 26.0. Two-sided statistical testing will be performed, with $P < 0.05$ considered statistically significant, and 90% confidence intervals will be reported

for point estimates.

All analyses will follow an intention-to-treat approach, addressing missing data from dropouts using the multiple imputation method. Descriptive statistics will characterize the cohort and intervention acceptability, fidelity, and adherence. A descriptive analysis of sociodemographic and disease-related variables in HNC patients will be conducted. Means and standard deviations will be used for variables with a normal distribution, and medians and interquartile ranges for those with a non-normal distribution. Categorical variables will be analyzed using frequencies and percentages. The baseline characteristics of the two groups will be compared using parametric or non-parametric tests. Student's t-test or the $\chi 2$ test will be used for normally distributed data and non-parametric tests such as the Wilcoxon test and Mann-Whitney U test for non-normally distributed data.

A mixed-effects model will assess the intervention effects on primary and secondary outcome indicators. Additionally, intervention effects between groups for each variable will be evaluated pre- and post-intervention and two months before and after the intervention through an analysis of covariance (ANCOVA). Each ANOVA model will include covariates such as corresponding baseline scores and demographic variables significantly associated with pre-and post-intervention scores. Waterfall plots will illustrate the change in BIS and IMAGE-HN scores for each patient from baseline to 1-month post-intervention.

Data management, monitoring and confidentiality

The current nonpharmacological intervention, aligning with ethical principles, aims to benefit participants without causing harm, minimizing the likelihood of adverse effects. Therefore, establishing a Data Monitoring Safety Board seems unnecessary. Participant identification numbers exclusively identify all collected data for confidentiality. Paper records, including consent forms and questionnaire data, will be securely stored. Audio recordings will be stored on a secure cloud server and safeguarded on a dedicated laptop. The first, second, and final authors will primarily manage the trial dataset, granting access to all authors as needed.

Adverse events

Throughout the study, we will meticulously document both anticipated and unanticipated adverse events. While we do not anticipate serious adverse events, should an unexpected serious adverse event arise—such as the risk of suicide—participants will have access to immediate guidance and support from a specialist on our study team. Any significant adverse events will be reported to the Institutional Review Board of the Shanghai Proton and Heavy Ion Hospital.

Ethics and dissemination

The ethical committee of Shanghai Proton Heavy Ion Hospital has approved the entire study design (2308-67-02) and the informed consent forms. In the case of any protocol amendments, the trial registration will be updated accordingly. The study's outcomes will be compiled into a master's thesis by the primary author and will then be submitted for publication in a peer-reviewed journal. Additionally, the findings aim to be presented at an appropriate conference, should the opportunity arise.

Patient and public involvement

None. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

DISCUSSION

This study aimed to improve BID in patients with HNC through ACT-based experiential exercises and open-ended discussions in a group. Reviewing research in this area reveals that due to the numerous adverse effects of BID, some researchers have attempted to develop intervention programs to improve BID in cancer patients from cognitive, emotional, and behavioral perspectives. Among these, intervention strategies based on cognitive-behavioral therapy are the most common. As the "third wave" of cognitive-behavioral therapy,[41] the role of acceptance and commitment therapy in improving BID in patients with HNC is noteworthy.

In the context of the causes of BID in patients with HNC, ACT has unique advantages over other intervention strategies. On the one hand, ACT does not treat any thought or feeling as abnormal, but rather the tendency to cognitively integrate

and experience avoidance as problematic thinking responses. During the intervention, ACT does not directly change the individual's perception and evaluation of his or her appearance but instead develops skills and values related to appearance or negative self-evaluation to reduce the impact on behavior.[42] On the other hand, ACT interventions contain a combination of treatment modules that attempt to modify the effects of maladjustment, and modular treatments have the benefits of standardization and the ability to provide individualized therapies based on theory and empirical evidence.

In addition, Group Psychology Therapy, the group psychological intervention approach selected for this study, is potentially more valuable than individual psychotherapy. It is an approach that brings members together for a common goal and allows group members to gain a greater sense of experience and access to authentic contextual support through interpersonal interactions, emotional support, and emotional and thought connections within the group.[43, 44] Group-based ACT takes advantage of the efficacy factors of group therapy to improve members' cognition, emotions, and behaviors. Studies have also shown that research studies on participation and attrition in group therapy have found that group cognitive behavioral therapy is superior to other forms of group therapy, with higher member participation and lower attrition.[45, 46] Overall, the design aspects of this study are scientifically sound and feasible.

Finally, this study evaluates both quantitative and qualitative data through interviews. Gathering information on participants' subjective experiences will inform areas for improvement in future programs. The focus is on opportunities to continue the program beyond the project's duration. We are committed to creating a comprehensive brochure that is accessible in specialized oncology hospitals and public hospitals and offers vital support to individuals dealing with HNC.

Author Contributions

WJX and HWW made significant contributions to the research methodology design and the development of the overall research objectives. HWW is the guarantor of this study. WJX, LNX, and SMW participated in drafting the manuscript and providing critical input for important ideas. All authors (WJX, LNX, SMW, MMZ, YZ and WHW) 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.

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Competing interests: None declared.

Patient consent: Obtained.

Conflicts of interest

None of the authors had any conflict of interest in this study.

Availability of data and materials

Data are not made available because this paper is a protocol publication.

Figure legend

Figure 1, CONSORT flow chart of the study.

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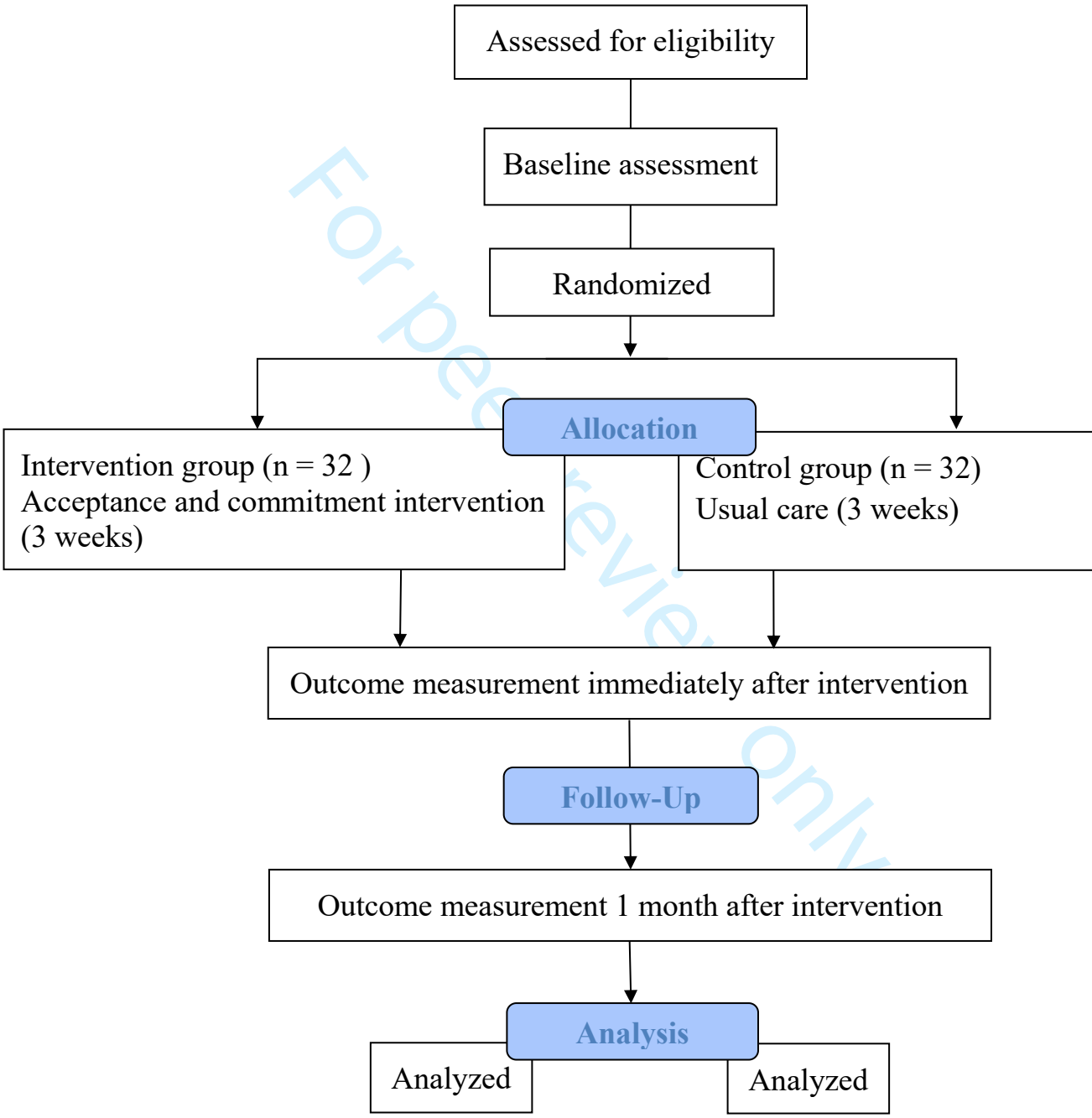
Figure 1 CONSORT flow chart of the study



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

Section/item	Item No	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2	4
	2b	All items from the World Health Organization Trial Registration Data Set	2	4
Protocol version	3	Date and version identifier	1	N/A
Funding	4	Sources and types of financial, material, and other support	16	2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1	N/A
	5b	Name and contact information for the trial sponsor	N/A	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	16	2
	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)	12	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	ALL
	6b	Explanation for choice of comparators	4-5	N/A
Objectives	7	Specific objectives or hypotheses	5	2

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	2
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	1
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	2
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9	1-2
	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	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10	1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10	1
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	10-11	4,1
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	1
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	2
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7	2
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	3
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	3

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8	3
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8	3
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8	3
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	10	2
	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	10	2
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	13	3
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	13	1-2
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13	1-2
	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)	13	1-2
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	13	3
	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	14	1
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	14	2
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	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)	7	2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	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	13	3
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22	N/A
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	13	3
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	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	13	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	13	3
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13	3
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Avaliable in Chinese upon request	
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	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.

BMJ Open

Effectiveness of Acceptance Commitment Therapy for Head and Neck Cancer Patients with Body Image Distress in China: A Study Protocol for Randomized Controlled Trial

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Keywords:	Randomized Controlled Trial, Psychosocial Intervention, Head & neck tumours < ONCOLOGY

Effectiveness of Acceptance Commitment Therapy for Head and Neck Cancer Patients with Body Image Distress in China: A Study Protocol for Randomized Controlled Trial

Wenjie Xu[1†], Lina Xiang[2†], Shuman Wang[1], Yu Zhu[1], Mimi Zheng[3], Hongwei Wan[1*]

[1]Department of Nursing, Shanghai Proton and Heavy Ion Center, Fudan University Cancer Hospital; Shanghai Key Laboratory of Radiation Oncology; and Shanghai Engineering Research Center of Proton and Heavy Ion Radiation Therapy, Shanghai, China.

[2]Department of Nursing, Mental Health Center, Shanghai Jiao Tong University School of Medicine; School of Nursing, Shanghai Jiao Tong University, Shanghai, China

[3]Department of Nursing, Zhongshan Hospital, Fudan University, Shanghai, China.

[†]Wenjie Xu and Lina Xiang contributed equally to this paper

*Corresponding: Hongwei Wan, PhD

Email: hong_whw@aliyun.com

Address: Shanghai Proton and Heavy Ion Center, 4365 Kangxin Rd, Pudong New Area, Shanghai, China

ABSTRACT

Introduction

The head and neck comprise vital organs and are apparent human body parts. tumors here impair physical and sensory functions as well as appearance and social interactions, leading to body image distress (BID) and threatening mental health and quality of life. Acceptance and commitment therapy (ACT) have shown effectiveness in improving body image distress in groups such as breast cancer patients. This study aims to apply this therapy to intervene in head and neck cancer patients, aiming to improve BID and promote better psychological well-being.

Methods and analysis

This study is a prospective, parallel-group, randomized controlled trial. A total of 64 head and neck cancer (HNC) patients will be allocated to either an intervention group or a control group. The intervention group will engage in a 3-week, six-session group-based acceptance and commitment therapy program, while the control group will receive standard treatment. The primary outcome is cancer-related BID, and secondary outcomes are head and neck cancer-related BID, psychological flexibility, coping style, and psychological distress. These indicators will be measured at baseline, post-intervention, and 1 month following the intervention's completion.

Ethics and dissemination

The trial has received approval from the Institutional Review Board of Shanghai Proton and Heavy Ion Hospital (2308-67-02). The study results will be shared through peer-reviewed journals and conferences.

Trial registration number

Chinese Clinical Trial Registry ChiCTR2300077863.

Keywords: head and neck cancer; acceptance commitment therapy; body image distress; protocol; randomized controlled trial

Strengths and limitations of this study

- The intervention was developed underpinned by the acceptance and commitment therapy model.
- Rigorous study methodology includes concealment of randomisation allocation and blinding of assessor to mitigate conscious and unconscious biases.
- Recruitment relies on the patient's willingness to participate, which may generate a portion of the selection bias.
- Study results are based on the Patient-Reported Outcome Measurement Tool, which is subjective to a certain extent.
- This study represents a single-center randomized trial, so findings may be dependent on local context.

INTRODUCTION

Head and neck cancer is a series of malignant tumors that occur from the base of the skull to the supraclavicular and anterior cervical regions, including cancers of the oral cavity, salivary glands, pharynx, larynx, and sinuses.[1] The head and neck area contain vital organs for controlling physiologic functions such as breathing, swallowing, chewing, and expression and are apparent body parts.[2] HNC and its treatment not only affect sensory functions such as smell, taste, hearing, vision, and facial pain but also damage the patient's appearance and body image,[3] which further may negatively bias the patient's cognitive, emotional, or behavioral responses to their own body.[4-7] When severe, these impairments have significant adverse effects on psychosocial well-being and physical function and result in body image distress. BID is characterized by a self-perceived, displeasing change in appearance and function and the resultant is psychological distress.[8-10]

BID is common among HNC survivors because of the visible nature of the head and neck and its association with personal identity and communication. An estimated 75% of HNC survivors express concerns about their body image,[9] with up to 28% experiencing significant BID.[11, 12] Owing to the differences between individuals, especially from different cultural contexts, BID can occur at every moment of a patient's treatment and recovery period. Most patients perceive themselves as physically incomplete and less attractive and are bothered by toxic side effects of radiotherapy, such as dry mouth, mucositis, and difficulty in swallowing or chewing,[12] and also report loss of appetite, rapid weight loss, and significant changes in body shape due to combination chemotherapy or targeted therapy, which in turn exacerbate psychological suffering.[13, 14] Moreover, BID has adverse psychological effects on head and neck tumor patients, such as self-denial, low self-esteem, social isolation, and depression. These not only seriously affect the patient's ability to cope with the tumor, treatment, and physical symptoms but also negatively affect their physical and mental health and quality of life.[6, 9, 15-17]

There are three intervention programs for improving BID: cosmetic

rehabilitation instruction, mental health education, and cognitive-behavioral therapy. Previous cosmetic rehabilitation instruction for oral cancer patients who underwent flap graft reconstruction found that the improvement of BID between the two groups before and after the intervention was not significant.[18, 19] An intervention using a mental health education manual for oral cancer patients found substantial improvements in the experimental group's BID and quality of life levels.[20] However, it is often challenging to develop a structured intervention program and it is more difficult to replicate and further extend. A cognitive-behavioral therapy study, with 44 patients, found that BID was significantly improved in the experimental group after 1-months of intervention.[21] However, their application needs to be further validated due to the small number of such studies and small sample sizes.

It is worth mentioning that a growing number of studies have found acceptance commitment therapy (ACT) to have potential applications in improving BID.[22-24] ACT has been described as the third wave of cognitive-behavioral therapy. ACT is a cognitive-behavioral therapy theory and practice based on the Relational Frame Theory (RFT) of human language and cognition and the philosophy of functional contextualism, which includes six aspects: acceptance, cognitive dissociation, living in the present moment, taking oneself as a view, values, and commitment to action.[25] ACT has been shown to have significant results for BID due to weight, size, height, skin color, and other aspects of the body.[26] Recent studies have found that ACT-based group psychological interventions can significantly improve BID in postoperative breast cancer patients,[22] and are effective in enhancing psychological flexibility and reducing BID due to body image issues in patients with eating disorders.[23] To address the lack of effective treatment options for BID in head and neck cancer patients, we designed a single-site randomized clinical trial (RCT) to evaluate the acceptability of ACT and its preliminary efficacy relative to the usual care (UC) group condition, as well as refine the trial infrastructure in preparation for a multisite RCT.

METHODS

Design

A two-arm, parallel design, randomized controlled trial will be implemented to investigate the effects of ACT for head and neck cancer patients.This study will adhere to the CONSORT guidelines as illustrated in Figure 1.[27] The SPIRIT Checklist is provided as a supplementary document (Additional File 1).[28] The study will begin in February 2024 and is expected to be completed by October 2024.

Study setting and participants

Participants will be recruited by using convenience sampling from the Shanghai Proton and Heavy Ion Center, the first medical institution in China to have both proton and heavy ion technologies.

The study population will consist of head and neck cancer patients with 18 years of age or older, of all sexes, with cancer-related BID. Eligible patients are (a) in patients diagnosed with head and neck tumors, including oral cavity, pharynx, larynx, nose/paranasal sinuses, carcinoma of a significant or minor salivary gland, or cutaneous malignancy of the face or neck, (b) age > 18 years at the time of screening, (c) possessed knowledge of the diagnosis, (d) fluent in Mandarin, (e) willingness to be randomized to either ACT or UC and (f) BIS score > 10. The exclusion criteria are as follows: (a) individuals diagnosed by a specialist as being in the acute phase of the disease or experiencing severe hepatic, renal, or cardiopulmonary impairment, (b) those diagnosed by a specialist with severe mental disorders or significant cognitive deficits; the rationale for excluding these patients is that the intervention of this study may be therapeutically insufficient, (c) individuals currently taking psychiatric medications or engage in other comparable psychological interventions, and (d) those with appearance deficits or severe physical dysfunction before the diagnosis of head and neck cancer.

Recruitment

Participants were enrolled at the Shanghai Proton and Heavy Ion Center in February 2024. Recruitment strategies included public advertisements such as posters and flyers, as well as informational sessions to explain the risks related to BID and the project's goals and benefits. A clinical nurse will then approach these individuals to assess their eligibility. Potential participants will receive information about the study and provide written informed consent within 48 hours. They were reassured that participation was voluntary and that withdrawal from the study would not influence their treatment in any way. After the participants approach the eligible assessment and provide written informed consent, a paper-based questionnaire will be provided to them to complete the baseline assessment.

Sample size

The sample size was determined using Power Analysis and Sample Size Software (PASS, V.21.0.3) and calculations revealed that 54 patients were required to detect a standardized effect of 0.78 for the primary end-point of change from baseline to 1-month postintervention in the Body Image Scale scores based on the 2-sample t-test with 2-sided $\alpha = 0.1$.[29] Accounting for an estimated dropout rate of 20%, a minimum of 64 subjects needed to be recruited for the study.

Randomization and blinding

The randomization process for this study will be conducted by an independent research assistant, who is not involved in the recruitment, enrollment, or treatment procedures. Participants will be assigned to either the intervention or control group in a 1:1 ratio through a random allocation method. This method will employ a permuted block design with block sizes of 4, facilitated by a computer-generated random sampling procedure using the Study Randomizer software. The allocation of participants will be communicated to interventionists via email, while participants will receive their group assignment through an opaque, sealed envelope containing a sequence number generated by the research assistant. Additionally, the allocation list

will be securely stored in an encrypted file on a password-protected computer to ensure confidentiality.

To minimize selection bias, the allocation sequence has been generated in advance of the recruitment phase. It is crucial that data collectors and analysts remain unaware of the group assignments to maintain the integrity of the study's blinding protocol. This precaution is essential to prevent any potential biases that could affect the study's outcomes and conclusions.

Interventions

Intervention group: ACT plus usual care

The intervention group's patients will receive the Acceptance and Commitment intervention program. Previous studies showed that scheduled six sessions in ACT have a significant intervention effect.[22, 23] Considering a patient's hospital stay of approximately 45 days, we will schedule six sessions spread across one month. Therefore, patients in the intervention group will participate in a 3-week Acceptance and Commitment Intervention Program, with sessions held twice weekly for a total of 6 sessions. Each session, lasting 2 hours, delves into key themes such as acceptance, diffusion, presence, self-as-context, values, and committed action—interconnected processes that bolster psychological flexibility. The structure of each session includes a 10-minute educational segment, a 10-minute mindfulness meditation, and a 40-minute experiential exercise, typically presented as a game or visualization. This is followed by a 60-minute group discussion where the interventionist uses tailored questions to explore each patient's experience and achieve the session's goals. The program is co-facilitated by two psychotherapists skilled in acceptance and commitment therapy, along with a master's student in nursing psychology. Groups are kept small, with about 8 participants each, to ensure personalized attention. To ensure attendance and engagement, participants in the intervention group will receive two reminders from their charge nurse for each session: one 24 hours in advance and another two hours prior to the session's start.

Control group: usual care

Participants randomized to the usual group will receive standard care, which entails the distribution of health education guidebooks and access to educational videos covering topics such as diet, exercise, and psychology. Moreover, this usual care will encompass routine psychosocial support, marked by attentive listening to patients' concerns and stories, and the establishment of communication channels aimed at providing guidance and facilitating emotional release.

Intervention fidelity

All intervention sessions will be systematically audiotaped and a subset of these recordings will be randomly selected by a medical and psychological expert for supervisory review. The purpose of this review is to provide constructive feedback to the interventionist, thereby refining their skills and ensuring the fidelity of the intervention delivery. This attendance will be closely monitored and meticulously recorded by the interventionist to ensure accurate tracking of participant engagement with the therapeutic process. Any instances of absences or withdrawals, along with their respective reasons, will be meticulously documented. This detailed record-keeping aims to gauge participant adherence to the therapeutic interventions.

Data collection

Data will be collected at baseline before randomisation (T0), postintervention (T1) and 1-month postintervention (T2) by completing by an independent assessor. Initial and post-intervention data will be collected through face-to-face interviews, while the one-month follow-up will utilize an online questionnaire for convenience. Participants in both the control and intervention groups will be reassessed at equivalent time intervals to ensure a standardized evaluation process. The assessment timeline is visually depicted in table 1.

Table 1 The schedule of trial enrolment, interventions and assessments

	Pre-screen	Baseline (t_0)	Allocation	3 weeks intervention	At immediately post-intervention (t_1)	1 month after intervention (t_2)
Informed Consent						
Review study eligibility	×					
Informed consent	×					
Study Procedures						
Randomization			×			
Demographics		×				
Clinical and oncologic history		×				
Intervention Administration						
ACT or UC				×		
Efficacy Evaluation						
Body Image Scale	×				×	×
IMAGE-HN		×			×	×
AAQ-II		×			×	×
SCSQ		×			×	×
DT		×			×	×
Other Evaluations						
Intervention fidelity				×		
Patient adherence				×		

Acronyms: ACT, Acceptance Commitment Therapy; UC, Usual Care; IMAGE-HN, The Inventory to Measure and Assess imaGe disturbance-Head and Neck; AAQ-II, The Acceptance and Action Questionnaire Second Edition; SCSQ, Simplified Coping Style Questionnaire; DT, Distress Thermometer.

Outcome measures

Sociodemographic and disease-related variables

A concise sociodemographic questionnaire will be administered at the baseline to assess various demographic characteristics, including age, gender, body mass index, marital status, education level, religion, employment status, marital status, and per capita monthly income. Information about disease-related characteristics, such as site, stage, time since cancer diagnosis, and medical treatment, will also be collected.

Primary outcome: cancer-related BID

The cancer-related body image distress of participants will be assessed using the

Chinese version of the Body Image Scale (BIS). The scale comprises three dimensions, affective, cognitive, and behavioral, with ten items, and is scored on a 4-point Likert scale, with a total score of 0-30, with higher scores indicating higher levels of cancer-related BID, and is primarily used to assess the affective, cognitive and emotional aspects of the patient's body image as a result of the cancer or its treatment over seven days.[30] The Cronbach's α coefficient is reported to be 0.91.[31]

Secondary outcomes

Head and neck cancer-related BID

Head and neck cancer-related BID will be assessed using IMAGE-HN (Inventory to Measure and Assess imaGe disturbancE–Head and Neck),[32] licensed, culturally adapted, and translated into Chinese. The IMAGE-HN score ranges from 0 to 84, with higher scores indicating worse head and neck cancer-related BID.[32] We included both the Body Image Scale and IMAGE-HN as outcome measures for the time of trial design; the Body Image Scale was the most widely used measure of BID among head and neck cancer patients,[33] with a known cutoff score indicating clinically significant BID.[34, 35] However, it was developed and validated in a mixed population of cancer patients, predominantly breast cancer, lacking content validity for head and neck cancer patients.[33] In contrast, IMAGE-HN had better content validity for BID among HNC patients but had only recently been validated.[32]

Coping style

Coping style of participants will be assessed using the Chinese version of the Simplified Coping Style Questionnaire (SCSQ).[36] The scale comprises two dimensions, positive coping (1-12 items) and negative coping (13-20 items), with a total of 20 items used to measure individuals' coping styles when they encounter difficulties or frustrations. Each item is scored on a 0-3 scale, with higher scores on positive coping, indicating that the respondent is more inclined to adopt an upbeat coping style, and higher scores on negative coping, meaning that the respondent is more willing to adopt a negative coping style. The Cronbach's α coefficient is

reported to be 0.90.[36]

Psychological flexibility

The psychological flexibility will be assessed using the Chinese version of the Acceptance and Action Questionnaire Second Edition (AAQ-II). The scale comprises seven items on a 7-point scale, with each entry scoring 1 - 7 points, and the range of scores is between 7 and 49. Higher scores indicate higher levels of empirical avoidance and lower psychological flexibility. The Cronbach's alpha coefficient for the scale was 0.84, and the retest reliability was 0.81.[37]

Psychological distress

Psychological distress will be assessed using the Distress Thermometer (DT), which employs a scale ranging from 0 to 10 to measure the degree of distress.[38] A score of 0 indicates no psychological distress, while a score of 10 indicates extreme distress. Higher scores indicate more severe distress.

Patient and public involvement

Patients will be first invited to participate in the main sessions of the study to ensure clarity and comprehension. After the intervention delivery, semistructured interviews will be carried out in participants in the intervention group (Table 2). The aim is to explore their experiences on the intervention's usefulness and acceptability and identify potential areas for improvement in future programs.

Table 2 Interview guide

What was your experience of the intervention?
What aspects of ACT did you find most useful? Can you describe some examples of what ACT helped you with?
What do you think about the sessions of the intervention (content, format, therapists, homework and environment)?

Do you feel like you have changed after participating in the ACT? About BID?
What challenges were experienced during participation in ACT?
What are your suggestions on the intervention? What could be improved?
How do you apply the knowledge you have gained in the ACT in your daily life?

Data management

Data collected in the study will be kept confidential and stored in locked filing cabinets and password-protected computers, which are open only to members of the research team. All collected data will be anonymized, identified solely by participant identification numbers that are unique to the study. Data will be destroyed 5 years after completing the study.

Data analysis

Statistical analysis will be conducted by an independent examiner using IBM SPSS Statistics version 26.0. Descriptive statistics will be used to calculate continuous data by mean and SD and categorical variables by frequency and percentage. Baseline differences between groups regarding sociodemographics and disease-related data will be examined using a t-test for continuous variables and $\chi 2$ test for categorical variables. A mixed-effects model will assess the intervention effects on primary and secondary outcome indicators. Additionally, intervention effects between groups for each variable will be evaluated pre- and post-intervention and two months before and after the intervention through an analysis of covariance (ANCOVA). Each ANOVA model will include covariates such as corresponding baseline scores and demographic variables significantly associated with pre-and post-intervention scores. Waterfall plots will illustrate the change in BIS and IMAGE-HN scores for each patient from baseline to 1-month post-intervention.

All data analysis will be performed according to the Intention-to-Treat principle, preserving the integrity of randomisation and minimise selection bias. Two-sided statistical testing will be performed, with $P < 0.05$ considered statistically significant,

and 90% confidence intervals will be reported for point estimates. NVIVO V.12 with content analysis using an inductive method will be used to explore the ACT experience in patients with advanced lung cancer and caregivers and indicate the intervention acceptability.

Ethics and dissemination

The ethical committee of Shanghai Proton Heavy Ion Hospital has approved the entire study design (2308-67-02) and the informed consent forms. The study conformed to the principles outlined in the Declaration of Helsinki. In the case of any protocol amendments, the trial registration will be updated accordingly. The findings will be compiled into a master's thesis by the primary author and disseminated in peerreviewed journals and through local or international conference presentations.

DISCUSSION

This study aimed to improve BID in patients with HNC through ACT-based experiential exercises and open-ended discussions in a group. Reviewing research in this area reveals that due to the numerous adverse effects of BID, some researchers have attempted to develop intervention programs to improve BID in cancer patients from cognitive, emotional, and behavioral perspectives. Among these, intervention strategies based on cognitive-behavioral therapy are the most common. As the "third wave" of cognitive-behavioral therapy,[39] the role of acceptance and commitment therapy in improving BID in patients with HNC is noteworthy.

In the context of the causes of BID in patients with HNC, ACT has unique advantages over other intervention strategies. On the one hand, ACT does not treat any thought or feeling as abnormal, but rather the tendency to cognitively integrate and experience avoidance as problematic thinking responses. During the intervention, ACT does not directly change the individual's perception and evaluation of his or her appearance but instead develops skills and values related to appearance or negative self-evaluation to reduce the impact on behavior.[40] On the other hand, ACT

interventions contain a combination of treatment modules that attempt to modify the effects of maladjustment, and modular treatments have the benefits of standardization and the ability to provide individualized therapies based on theory and empirical evidence.

In addition, Group Psychology Therapy, the group psychological intervention approach selected for this study, is potentially more valuable than individual psychotherapy. It is an approach that brings members together for a common goal and allows group members to gain a greater sense of experience and access to authentic contextual support through interpersonal interactions, emotional support, and emotional and thought connections within the group.[41, 42] Group-based ACT takes advantage of the efficacy factors of group therapy to improve members' cognition, emotions, and behaviors. Studies have also shown that research studies on participation and attrition in group therapy have found that group cognitive behavioral therapy is superior to other forms of group therapy, with higher member participation and lower attrition.[43, 44] Overall, the design aspects of this study are scientifically sound and feasible.

Finally, this Randomised controlled trial will be the first to evaluate the effectiveness of ACT on improvement of HNC-related body image distress. The results will provide a foundation for a intervention system for head and neck cancer patients with BID and offers vital support to quality of life for the patients.

Author Contributions

WJX and HWW contributed to the conception and design of the trial and acted as guarantors. WJX, LNX, and SMW participated in drafting the manuscript and providing critical input for important ideas. All authors (WJX, LNX, SMW, MMZ, YZ and WHW) 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.

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Competing interests: None declared.

Patient and public involvement

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

Patient consent: Obtained.

Conflicts of interest: None of the authors had any conflict of interest in this study.

Availability of data and materials

Data are not made available because this paper is a protocol publication.

Figure legend

Figure 1, CONSORT flow chart of the study.

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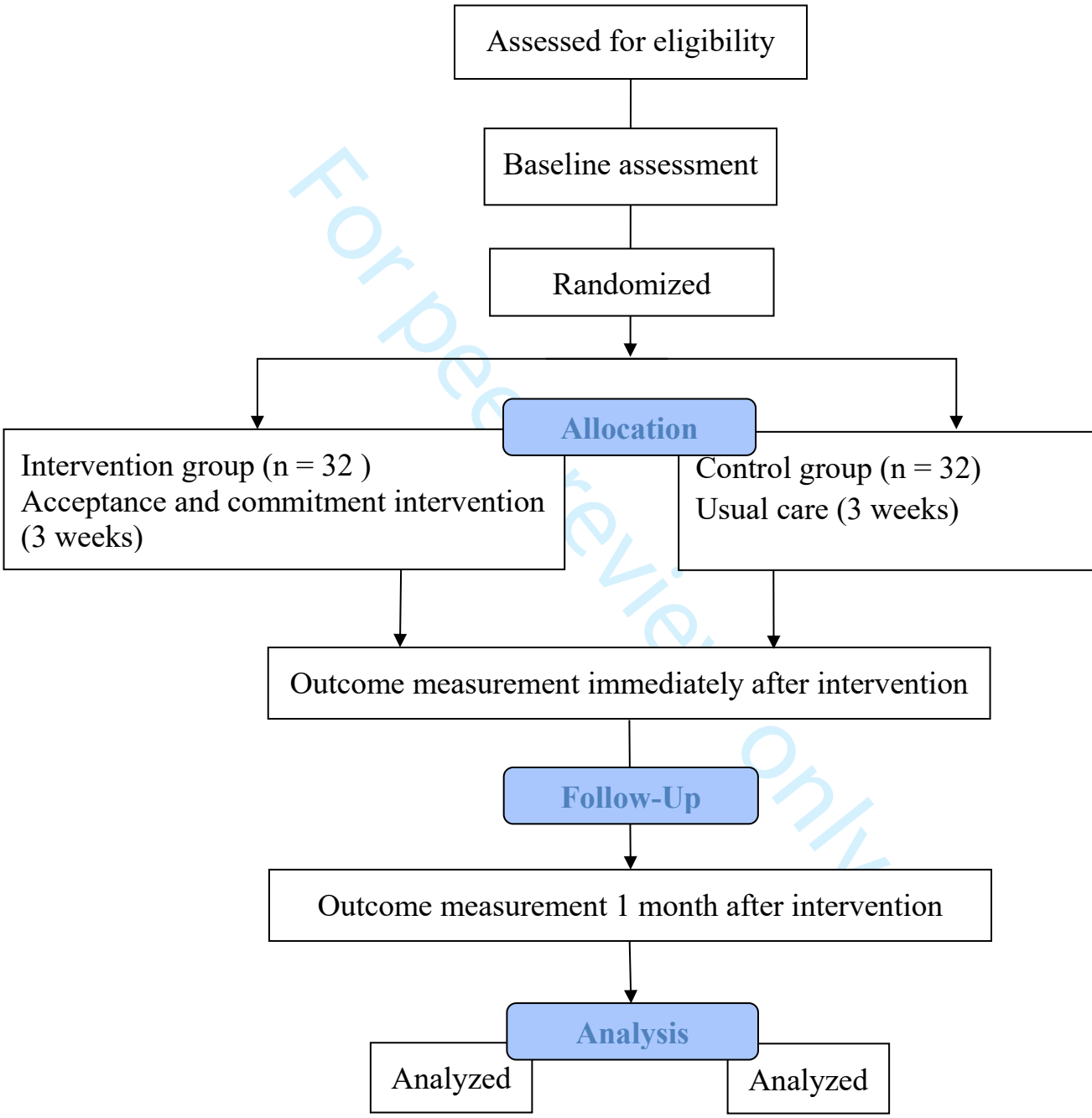
Figure 1 CONSORT flow chart of the study



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

Section/item	Item No	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2	4
	2b	All items from the World Health Organization Trial Registration Data Set	2	4
Protocol version	3	Date and version identifier	1	N/A
Funding	4	Sources and types of financial, material, and other support	16	2
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1	N/A
	5b	Name and contact information for the trial sponsor	N/A	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	16	2
	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)	12	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	ALL
	6b	Explanation for choice of comparators	4-5	N/A
Objectives	7	Specific objectives or hypotheses	5	2

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	2
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	1
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	2
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9	1-2
	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	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10	1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10	1
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	10-11	4,1
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	1
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	2
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7	2
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	3
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	3

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8	3
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8	3
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8	3
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	10	2
	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	10	2
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	13	3
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	13	1-2
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13	1-2
	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)	13	1-2
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	13	3
	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	14	1
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	14	2
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	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)	7	2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	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	13	3
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22	N/A
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	13	3
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	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	13	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	13	3
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	13	3
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Avaliable in Chinese upon request	
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	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.