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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 randomised controlled trial

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

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WX and LX contributed equally.

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For numbered affiliations see end of article.

Correspondence to
Hongwei Wan;
hong_whw@aliyun.com

ABSTRACT

Introduction The head and neck comprise vital organs and are apparent human body parts. Tumours 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 has shown effectiveness in improving BID in groups such as breast cancer patients. This study aims to apply this therapy to intervene in head and neck cancer (HNC) patients, aiming to improve BID and promote better psychological well-being.

Methods and analysis This study is a prospective, parallel-group, randomised controlled trial. A total of 64 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 programme, while the control group will receive standard treatment. The primary outcome is cancer-related BID, and secondary outcomes are HNC-related BID, psychological flexibility, coping style and psychological distress. These indicators will be measured at baseline, postintervention 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 ChiCTR2300077863.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The intervention was developed and 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-centre randomised trial, so findings may be dependent on local context.

INTRODUCTION

Head and neck cancer (HNC) is a series of malignant tumours 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 behavioural 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). BID is characterised 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 tumour 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 tumour, 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 programmes for improving BID: cosmetic rehabilitation instruction, mental health education and cognitive-behavioural 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 programme and it is more difficult to replicate and further extend. A cognitive-behavioural therapy study, with 44 patients, found that BID was significantly improved in the experimental group after 1 month 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-behavioural therapy. ACT is a cognitive-behavioural 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 colour 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 HNC patients, we designed a single-site randomised 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, randomised controlled trial will be implemented to investigate the effects of ACT for HNC patients. This study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines as illustrated in figure 1.[27] The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist is provided as a supplementary document (online supplemental 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 Centre, the first medical institution in China to have both proton and heavy ion technologies.

The study population will consist of HNC 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 tumours, 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 randomised to either ACT or UC and (f) Body Image Scale (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 HNC.

Recruitment

Participants will be recruited at the Shanghai Proton and Heavy Ion Center from 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 will be reassured that participation is 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.

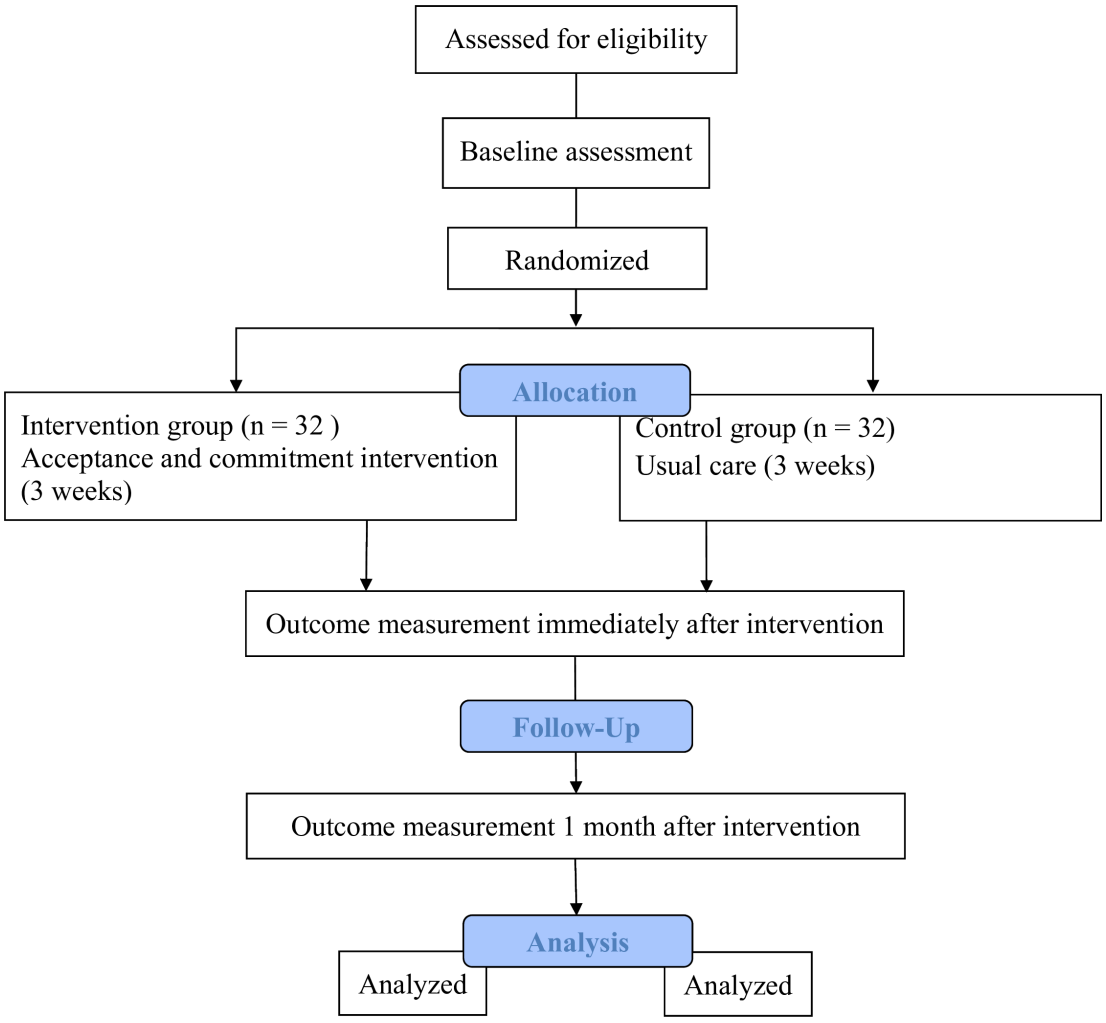

Figure 1 CONSORT flow chart of the study. CONSORT, Consolidated Standards of Reporting Trials.

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 standardised effect of 0.78 for the primary end-point of change from baseline to 1 month postintervention in the BIS scores based on the two-sample t-test with two-sided α=0.1.[29] Accounting for an estimated dropout rate of 20%, a minimum of 64 subjects needed to be recruited for the study.

Randomisation and blinding

The randomisation process for this study will be conducted by an independent research assistant, who is not involved in the recruitment, enrolment 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 minimise 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 programme. 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 1 month. Therefore, patients in the intervention group will participate in a 3 week Acceptance and Commitment Intervention Programme, with sessions held twice weekly for a total of six 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 min educational segment, a 10 min mindfulness meditation and a 40 min experiential exercise, typically presented as a game or visualisation. This is followed by a 60 min group discussion where the interventionist uses tailored questions to explore each patient's experience and achieve the session's goals. The programme is cofacilitated by two psychotherapists skilled in ACT, along with a master's student in nursing psychology. Groups are kept small, with about eight participants each, to ensure personalised 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 2 hours prior to the session's start.

Control group: usual care

Participants randomised 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 UC 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 (T_0), postintervention (T_1) and 1 month postintervention (T_2) by completing by an independent assessor. Initial and postintervention data will be collected through face-to-face interviews, while the 1 month follow-up will utilise an online questionnaire for convenience. Participants in both the control and intervention groups will be reassessed at equivalent time intervals to ensure a standardised evaluation process. The assessment timeline is visually depicted in table 1.

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 BID of participants will be assessed using the Chinese version of the BIS. The scale comprises three dimensions, affective, cognitive and behavioural, with 10 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 7 days.[30] Cronbach's α coefficient is reported to be 0.91.[31]

Secondary outcomes

Head and neck cancer-related BID

HNC-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 HNC-related BID.[32] We included both the BIS and IMAGE-HN as outcome measures for the time of trial design; the BIS was the most widely used measure of BID among HNC patients,[33] with a known cut-off score indicating clinically significant BID.[34] However, it was developed and validated in a mixed population of cancer patients, predominantly breast cancer, lacking content validity for HNC 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).[35] 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. Cronbach's α coefficient is reported to be 0.90.[35]

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

Table 1 The schedule of trial enrolment, interventions and assessments

	Prescreen	Baseline (t_0)	Allocation	3 weeks intervention	At immediately postintervention (t_1)	1 month after intervention (t_2)
Informed consent						
Review study eligibility	×					
Informed consent	×					
Study procedures						
Randomisation			×			
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				×		

AAQ-II, The Acceptance and Action Questionnaire Second Edition; ACT, acceptance commitment therapy; DT, Distress Thermometer; IMAGE-HN, The Inventory to Measure and Assess imaGe disturbance-Head and Neck; SCSQ, Simplified Coping Style Questionnaire; UC, usual care.

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. Cronbach's alpha coefficient for the scale was 0.84, and the retest reliability was 0.81.[36]

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.[37] 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 (box 1). The aim is to explore their experiences on the intervention's usefulness and acceptability and identify potential areas for improvement in future programmes.

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 anonymised, identified solely by participant identification numbers that are unique to the study. Data will be destroyed 5 years after completing the study.

Box 1 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?

ACT, acceptance and commitment therapy.

Data analysis

Statistical analysis will be conducted by an independent examiner using IBM SPSS Statistics V.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 χ^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 preintervention and postintervention and 2 months before and after the intervention through an analysis of covariance. Each analysis of variance model will include covariates such as corresponding baseline scores and demographic variables significantly associated with preintervention and postintervention scores. Waterfall plots will illustrate the change in BIS and IMAGE-HN scores for each patient from baseline to 1 month postintervention.

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% CIs 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 HNC 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 peer-reviewed 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 programmes to improve BID in cancer patients from cognitive, emotional and behavioural perspectives. Among these, intervention strategies based on cognitive-behavioural therapy are the most common. As the 'third wave' of cognitive-behavioural therapy,[38] the role of ACT 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 behaviour.[39] 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 standardisation and the ability to provide individualised 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.[40 41] Group-based ACT takes advantage of the efficacy factors of group therapy to improve members' cognition, emotions and behaviours. Studies have also shown that research studies on participation and attrition in group therapy have found that group cognitive behavioural therapy is superior to other forms of group therapy, with higher member participation and lower attrition.[42 43] 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 BID. The results will provide a foundation for a intervention system for HNC patients with BID and offers vital support to quality of life for the patients.

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

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Competing interests None declared.

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ORCID iDs
Wenjie Xu http://orcid.org/0000-0002-3956-4773
Shuman Wang http://orcid.org/0000-0001-9520-7722

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