The Effectiveness and Mechanism Study of Auricular Needling in Treating Cancer Induced Anorexia

Research programme

2016.05.01

Background of the study

Anorexia nervosa is a common clinical symptom in tumor patients. The incidence of anorexia ranges from 6% to 74% depending on the type of tumor and clinical stage. It is common in patients with gastrointestinal tumors and advanced tumors, and the incidence of anorexia in advanced patients receiving palliative care ranges from 25% to 45%, and in severe cases, it is accompanied by malnutrition, or even malignant fluid state. In some studies, anorexia is found in up to 80% of patients with advanced stage, among which gastric cancer patients account for about 60%. Once anorexia occurs in tumor patients, it not only affects the implementation of the treatment plan, increases the difficulty of treatment, and affects the quality of survival of patients, but also can lead to malignant tumor patients die of malnutrition and depletion, which affects the survival time of the patients, and becomes the direct cause of death of tumor patients. Therefore, an in-depth understanding of the characteristics of anorexia nervosa, associated factors, assessment tools and interventions is an important therapeutic need faced by patients with advanced tumors, and a key direction for oncology research. How to optimize the selection of interventions against anorexia nervosa and to explore its mechanism of action are also scientific problems that we TCM oncologists need to solve in clinical practice. At present, the treatment of anorexia nervosa includes medication, nutritional therapy and psychotherapy, etc., with different efficacy and outstanding problems. Among them, megestrol acetate, as a kind of progestin with anabolic effect, has the functions of promoting appetite, increasing body weight, and improving the quality of patient's survival, and it is the only approved drug for the treatment of anorexia nervosa with cancer, but the toxic side effects caused by it, such as stimulation of tumor growth, venous thrombosis, and water and sodium retention, should not be ignored. Chinese herbal medicine has some research results in the treatment targeting the improvement of appetite, but it is not well accepted abroad. Clinical significance is insufficient. By combining the study of ancient literature with modern research, our department has taken a new approach to propose a new idea of clinical treatment, intervening auricular acupuncture in the treatment of cancerous anorexia nervosa. In the preliminary clinical pre-test, the initial effect is satisfactory, auricular acupuncture treatment can significantly improve the patient's appetite, showing its simple, convenient, inexpensive, tested characteristics, safe and reliable, but the technology needs further verification, standardization and improvement. However, this technique needs to be further validated, standardized and improved. Auricular acupuncture, which is highly accepted in the West, lacks high-quality evidence-based clinical efficacy and mechanism studies, which affects the influence of auricular acupuncture and warrants in-depth research.

This research proposal is in response to the National Natural Science Foundation of China's top-level project (Project No. 81573958; Title:

Auricular Acupuncture for Clinically Advanced Tumor Patients' Appetite Intervention and Mechanism Research).

Research Objectives

To objectively evaluate the clinical efficacy of auricular acupuncture in improving the appetite of tumor patients, to verify and improve its technique, to determine the therapeutic points and treatment course, and to provide a strong evidence-based medical basis for auricular acupuncture intervention in tumor therapy. We will validate and improve its technique, determine the therapeutic points and treatment course, and provide a strong evidence-based

medical basis for the intervention of auricular acupuncture in the treatment of tumors.

Research content

1 Type of study design

This study used a randomized, parallel-controlled research method. Based on the principle of voluntary participation, baseline information was included and collected, random seeds were generated by the SAS 9.2 statistical software random seed generator, and in a ratio of 1:1, it was proposed to randomly assign 60 subjects meeting the inclusion criteria to the ear acupuncture group and the control group. Each group of 30 cases, statistical expert design, after the preparation of the randomization scheme, the control and implementation of the allocation by those who are not directly involved in the grouping.

2 Sample size setting

This study was an exploratory study, considering 30 cases in each group, totaling 60 patients.

3 Study population

Sixty patients with anorexia nervosa of malignant tumors of stage III and IV who attended outpatient clinics or were hospitalized in the Department of Oncology of Xiyuan Hospital of China Academy of Traditional Chinese Medicine from May 1, 2016 to October 31, 2017.

3.1 Diagnostic criteria

3.1.1 Western medical diagnostic criteria

There is no uniform diagnostic standard for anorexia nervosa. Referring to the "Diagnostic and therapeutic pathway of anorexia nervosa" of the Professional Committee of Tumor Nutrition and Supportive Therapy of the Chinese Anti-cancer Association, based on the "Symptom-based assessment table", we shall evaluate whether anorexia nervosa occurs in the patients who are clearly diagnosed with tumors and the degree of its occurrence. The patient is asked to answer all the questions in the scale. After the patients answered all the questions in the scale, the scores were evaluated, and the final score ≦ 24 points could be recognized as anorexia.

3.1.2 Criteria for Chinese medicine

Refer to the "Guidelines for Clinical Research on New Chinese Medicines" (2002) for the diagnosis of "Plankton", spleen and stomach weakness, and the Guidelines for Clinical Research on New Chinese Medicines for the Treatment of Spleen-Qi Deficiency (Diagnosis of Chinese Medicine Symptoms), and the National Standard of the People's Republic of China - Chinese Medicine Clinical Diagnosis and Treatment - Terminology and Symptoms (GB/T I6751.2-), which were formulated by the National Committee of the People's Republic of China. 1997) are formulated.

3.1.2.1 Evidence of spleen (stomach) deficiency

Primary symptom: poor appetite and dullness, abdominal distension after eating or in the afternoon, abnormal stools (loose, hard and then loose, loose and hard).

Secondary symptoms: fatigue and laziness, tiredness and weakness, light mouth and no thirst, lingering abdominal pain, nausea and vomiting, gastrointestinal distension, intestinal tinnitus, yellowish color, swelling, weakness in defecation, emaciation, pale tongue, fat tongue or teeth marks, thin white moss, weak pulse.

If there are two main symptoms, or one main symptom plus two secondary symptoms, it can be diagnosed as Spleen (Stomach) Deficiency.

3.1.2.2 Non-Spleen (Stomach) Deficiency Symptoms

Any other syndrome that does not meet the diagnostic criteria of Spleen (Stomach) Deficiency.

4 Selection and Withdrawal of Subjects

4.1 Inclusion criteria:

① Patients with malignant tumors diagnosed pathologically/cytologically and with stage III or IV disease;

① Patients with malignant tumors diagnosed by pathology/cytology, with stage III or IV disease;

① Patients with malignant tumors diagnosed by pathology/cytology, with disease stage III and IV;

③ Age 18 ~ 80 years old, gender is not limited; ④ KPS score ≧ 60 points;

⑤ The estimated survival period is more than 3 months;

⑥ Patients who voluntarily accept the treatment of this trial, with informed consent and good compliance.

4.2 Exclusion Criteria

① Those who do not meet the inclusion criteria;

① Those who do not meet the inclusion criteria; ② Those who have abnormalities in blood routine, liver and kidney function indexes more than twice;

Those with obvious eating disorders, gastrointestinal obstruction symptoms, heart disease and poor control of diabetes mellitus;

③ Those with obvious eating disorders, gastric obstruction symptoms, poor control of heart disease and diabetes mellitus;

⑤ Participating in other clinical studies;

⑤ Participants in other clinical studies; ⑥ Pregnant women, lactating women, psychiatric patients.

4.3 Withdrawal Criteria

Subjects may be withdrawn from this trial because of medical necessity in the opinion of the investigator, or because of the subject's own wishes. In all cases, the subject's results should be documented as much as possible, if possible.

Early withdrawal from the study may be considered by the patient and the investigator under the following circumstances:

4.3.1 Investigator-determined withdrawal

Withdrawal of a subject from a trial is a situation in which an enrolled subject becomes unfit to continue with the trial and the investigator decides that the case should be withdrawn from his or her trial.

① During the trial, the subject develops certain comorbidities, complications, or special physiological changes that make it inappropriate to continue the trial.

(ii) The case was mistakenly included because it did not meet the inclusion criteria.

(iii) During the trial, the subject's compliance is poor, affecting the validity and safety judgment.

(iv) The use of drugs not within the prescribed range affects the validity and safety judgment.

4.3.2 Self-withdrawal of subjects from the trial

According to the provisions of the informed consent, the subject has the right to withdraw from the trial in the middle of the trial, or the subject has not explicitly proposed to withdraw from the trial, but no longer accept the treatment and testing and lost visits, is also considered to be "withdrawing" (or "shedding"). As far as possible, the reasons for withdrawal should be

understood and documented. Regardless of the reason, a case record form should be kept for cases who drop out of the trial, and a full data set of efficacy and adverse events should be analyzed with the last test result carried forward as the final result.

4.3.3 Discontinuation Criteria

① Occurrence of serious adverse events, complications and specific physiological changes that make continuation of the study inappropriate;

② Death;

③ Revocation of the experiment by the competent administrative department, etc.

4.3.4 Disengagement measures and criteria

The investigator should assess the health status and progress of the subject during the treatment period, and the subject can be discharged from the study at any time when the following conditions occur

When the following conditions occur, the subject can be withdrawn from the experiment at any time, and the investigator should provide symptomatic treatment.

① When the subject experiences intolerable skin irritation or localized pain;

② Decrease of more than 40 points per week in the Kahl score.

③ Weight loss of more than 30% per week.

5 Implementation of the program

5.1 Grouping of cases

In this study, 60 subjects who met the inclusion criteria were randomly divided into the ear acupuncture group and the control group according to the principle of randomized parallel control. Each group consists of 30 cases.

5.2 Treatment program

5.2.1 Ear acupuncture group

Ear acupuncture treatment + conventional nutritional support and symptomatic treatment (refer to "Diagnostic and therapeutic path of anorexia nervosa" of tumor nutrition and supportive therapy committee of China Anti-Cancer Association).

Commonly used main points: Shenmen, stomach, spleen, subcortex.

Auxiliary points: Sanjiao, sympathetic, liver, small intestine.

Methods: Embed an earring needle and fix it with adhesive tape, press each point for about 2 minutes each time, 2-3 times a day, the pressure depends on the tolerance of the individual, alternating between the two ears, 2-3 times a week, 4 weeks of treatment, observation until 8 weeks.

5.2.2 Control group: Conventional nutritional support and symptomatic treatment.

During the treatment period, both groups can use supportive therapy reciprocally, if there are treatment-related adverse events, they should be handled separately, and the causes, history, symptoms and treatment measures should be recorded in detail. During the treatment period, both groups of cases could adopt the international standard protocol (Version 3.2014 NCCN) with or without standard chemotherapy or or without standard chemotherapy or radiation therapy.

6 Observation Indicators

6.1 General recording items

Name, gender, age, contact information, brief medical history, vital signs, physical examination, etc.

6.2 Diagnostic indicators

Tumor pathology, staging, symptom-based anorexia assessment, TCM evidence.

6.3 Main observational indexes: refer to the "Anorexia Diagnosis and Treatment Pathway" of the Professional Committee of Tumor Nutrition and Supportive Therapy of the Chinese Anti-Cancer Association.

① Symptom-based anorexia evaluation form: Appendix I.

② Simplified Appetite Scale: Appendix V.

6.4 Secondary observation indicators:

① Fatigue Symptoms Scale: Appendix III.

② Patient's expectation of acupuncture: Appendix II. Appendix II

Appetite level: VAS is a semi-quantitative assessment of the degree of anorexia nervosa. Drawing on the practice of foreign countries in the last century and the idea of VAS assessment for cancer pain in China, it is suggested that a 10 cm long travel scale with 10 scales on one side and "0" and "10" marks on the other side should be used. The scale has 10 marks on one side, with the "0" and "10" markings on both ends, with the "0" marking indicating a normal appetite and the "10" marking indicating an extreme aversion to food. When using the graduated side of the back to the patient, let the patient in the ruler marked on the degree of their desire for food on the corresponding position, the physician according to the position marked by the patient for its score, clinical evaluation to "0-2" is "normal appetite / basic normal eaters The clinical assessment is "0-2" as "normal appetite/basically normal eater", "3-5" as "mild anorexia", "6-8" as "moderate anorexia", and >8 as "anorexia". The score of "3-5" was classified as "mild anorexia", "6-8" as "moderate anorexia", and ">8" as "severe anorexia". The efficacy of the treatment was evaluated according to the change in appetite. Effective: improvement level greater than or equal to 1; stable: no change in level; ineffective: decrease in level.

④ Weight. Weight changes caused by factors other than fluid accumulation in the body cavity and swelling. Improvement: weight gain >2Kg and maintained for more than 4 weeks. Stable: weight gain or loss of ≤2Kg. deterioration: weight loss of >2Kg. 5.

⑤ Karnosky Score: Karnosky Physical Condition Score, refer to Appendix IV. Evaluation method: Comparison of scores before and after treatment. Significant effect: more than 20 points higher than before treatment; Effective: more than 10 points higher than before treatment; Stable: less than 10 points higher than before treatment or no change; Ineffective: decrease in weight after treatment compared with before treatment.

6.5 Provisions on the time point of follow-up

6.5.1 Data collection before enrollment

Medical record collection: fill in the baseline data according to the requirements of the CRF form;

Chinese medicine evidence: identify according to the Chinese medicine identification criteria and check the box on the CRF table;

Vital signs, physical examination;

blood, urine, stool routine, liver function, kidney function (within 2 weeks before enrollment);

Imaging examination: chest radiograph or chest CT, abdominal B ultrasound or abdominal or pelvic CT (within 1 month before enrollment).

6.5.2 Data collection at 2 weeks and 4 weeks of enrollment

Medical record collection: symptom-based anorexia assessment form, simplified appetite scale, fatigue symptom scale, appetite level, body weight, and Kahn's score according to the CRF form.

Therapeutic use of medications

TCM evidence: identify according to TCM identification criteria, check on the CRF form;

Vital signs, physical examination;

blood, urine, stool routine, liver function, kidney function (within 2 weeks);

6.5.3 Data collection 8 weeks after enrollment

Medical record collection: fill in the symptom-based anorexia assessment form, simplified appetite scale, fatigue symptom scale, appetite level, body weight, Kahn's score according to the requirements of CRF form.

Medication use for treatment

Tumor efficacy capture.

TCM evidence: identification according to TCM identification criteria, checked on the CRF form;

Vital signs, physical examination;

Blood, urine and stool routine, liver function, kidney function (within 2 weeks);

Imaging examination: chest radiograph or chest CT, abdominal B ultrasound or abdominal or pelvic CT (within 1 month).

7 Adverse events

7.1 Record of adverse events

During the clinical study, truthfully fill in the adverse event record form, record the occurrence time, severity, duration of the adverse event to take effective measures and regression.

7.2 Judgment of severity

Mild: usually transient and does not affect normal daily activities.

Moderate: considerable discomfort that interferes with normal daily activities.

Severe: unable to carry out normal daily activities.

7.3 Judgment of causality with drugs

Indicators of causal judgment for adverse event determination:

- Whether there is a reasonable sequential relationship between the time of initiation of the drug and the appearance of the suspected adverse event;
- Whether the suspected adverse event is consistent with the types of adverse events known for the drug;
- Whether the suspected adverse event can be explained by the effects of the combined drug, the patient's clinical condition, or the effects of other therapies;
- Whether the suspected adverse event resolved or abated after discontinuation or dosage reduction;
- Whether the same reaction recurred after re-exposure to the suspected drug.

Criteria for determining causality: based on the order of the above 5 judgment indicators

Judgment results	Judgment Indicators				
	1	2	3	4	5
Definitely relevant	+	+	--	+	+
Possibly related	+	+	--	+	?

Uncertain	+	+	±	±	?
Possibly not related	+	--	±	±	?
Definitely not	--	--	+	--	--

Explanation: + Affirmative, - Negative, ± Difficult to affirm or deny, ? Circumstances unknown.

Based on the table above, determine the relationship between the following 5 levels of adverse events and drugs

- Definitely related, 2 - possibly related, 3 - unable to determine, 4 - possibly unrelated, 5 - definitely unrelated.

The incidence of adverse events was calculated using the total number of cases 1+2+3 as the numerator and all the enrolled cases available for adverse event evaluation as the denominator.

7.4 Handling of adverse events

- Reporting method

Any adverse events, such as patients' subjective discomfort and abnormal laboratory tests, should be taken seriously and analyzed carefully. Any adverse events, such as subjective discomfort of the patient and abnormal laboratory tests, should be taken seriously, analyzed carefully, and immediate measures should be taken to protect the safety of the subjects.

- Handling procedure

Record in detail in CRF, and record its persistence, regression and disappearance as appropriate.

- Handling of serious adverse events

If any serious adverse event occurs, the investigator should not only give prompt treatment on site, but also report to the clinical trial unit in charge and the investigator within 24 hours. Within 24 hours, the investigator should report to the unit in charge of the clinical trial and the monitor of the clinical trial; and within 24 hours, the investigator should report in writing to the State Food and Drug Administration (SFDA). Within 24 hours, the investigator shall report in writing to the State Food and Drug Administration on the occurrence of the adverse event and its handling.

Treatment: When a patient has an emergency situation, the principal investigator of the study unit will do the appropriate treatment according to the drug and the symptoms presented, notify the clinical supervisor of the results of the treatment, and the investigator should record the treatment in detail, the results, and sign on the case report form.

- Follow-up of unrelieved adverse events

All adverse events should be followed up until properly resolved or stabilized. All adverse events with predominantly test values should be followed up with laboratory results until normal

8 Data management

The investigator loaded the data into the case report form in a timely, complete, correct, and legible manner based on the subjects' original observation records.

Supervisors monitored that the study was conducted in accordance with the study protocol. Confirm that all case report forms were completed correctly and consistent with the original data. In case of errors and omissions, the researcher was asked to make corrections in a timely manner. Corrections should be made in such a way that the original record is legible and the corrections should be signed and dated by the investigator.

After checking by the supervisor, the case report form will be verified and signed by the supervisor, and then sent to the Clinical Research Data Manager in a timely manner.

There should be a special record of the transmission of the completed case report form between the investigator, the supervisor and the data manager, with appropriate signatures on receipt, and the record should be kept appropriately.

The data manager will check the data again before data entry and notify the supervisor of any problems and ask the investigator to answer them. The exchange of questions and answers between them should be in the form of a questionnaire, which should be kept for reference.

The data manager should understand the content and coding of each item of the observation form before data entry, and record the coding work process in the coding book for preservation. Database naming should be standardized, easy to read and easy to find. And ensure its correctness, security and confidentiality.

The data entry clerk enters the data using secondary entry. Problems or unforeseen circumstances found during the entry process should be registered and reported in time so that the problems can be dealt with quickly. After the data entry is finished, some of the observation forms should be sampled to understand the quality of entry, and to analyze and deal with the existing problems.

The data manager should work together with the principal investigator to formulate the content of data range checking and logic checking according to the ranges and interrelationships of the values of each indicator in the case report form. The corresponding computer program should be prepared to control erroneous data entry before input, to find out the causes of errors and to correct them, and all the contents of errors and the results of modification should be recorded and properly preserved.

After completing data entry and verification as required, the original case report form should be filed and stored in the order of numbering and filled with a retrieval catalog, etc., to The original case report form should be filed and stored in a numbered order and filled with a search catalog for reference. Electronic data files include databases, examination procedures, analytical procedures,

analysis results, codebooks and description documents, etc., should be classified and stored with multiple backups on different disks or recording media for proper preservation. The electronic data files, including databases, inspection procedures, analytical procedures, analytical results, codebooks, and description files, should be kept in categories with multiple backups on different disks or recording media.

Appendix I.

Symptom-based assessment of anorexia

Please circle the answer you think is correct for each entry in the questionnaire below.

Entry	None	+	++	+++	++++
Good appetite	□0	□1	□2	□3	□4
Adequate food intake	□0	□1	□2	□3	□4
Worried about being	□0	□1	□2	□3	□4

overweight					
Most foods do not taste good to me	□4	□3	□2	□1	□0
Worried about losing weight	□4	□3	□2	□1	□0
Lack of interest in food when eating	□4	□3	□2	□1	□0
Difficult to eat rich or large amount of food	□4	□3	□2	□1	□0
Urged to eat by family and friends	□4	□3	□2	□1	□0
Vomiting	□4	□3	□2	□1	□0
Early satiety	□4	□3	□2	□1	□0
Pain in stomach and wrist	□4	□3	□2	□1	□0
Improving health	□0	□1	□2	□3	□4
Total Score					

After the patient answered all the questions in the table, the score was evaluated, and the final score ≦ 24 points, it can be recognized as anorexia nervosa.

Appendix II

Acupuncture Expectations Questionnaire

Every patient has different expectations about the efficacy of acupuncture. If you were to use the following sentences to describe how you feel about your disease/symptoms after a full course of acupuncture, how much would you agree? Please select the closest answer for each question.

	Totally disagree	Somewhat agree	Comparati vely agree	Generally agree	Totally agree
a. I will get much better	□	□	□	□	□
b. I can cope with my illness better	□	□	□	□	□
c. the symptoms of my illness will go away	□	□	□	□	□
d. I will have more energy than before	□	□	□	□	□

Appendix III

Fatigue Symptom Inventory(FSI)

This questionnaire is designed to find out your level of fatigue during treatment. Please circle the number that best describes your condition according to the following questions!

1. Please evaluate the extent to which you have felt most tired in the last 7 days.

0 1 2 3 4 5 6 7 8 9 10

Not at all I can feel

No fatigue Maximum fatigue

2. Please rate the least tired you have felt in the last 7 days?

0 1 2 3 4 5 6 7 8 9 10

Not at all I can feel

No fatigue Maximum fatigue

3. Please evaluate the average level of fatigue you have experienced in the last 7 days?

0 1 2 3 4 5 6 7 8 9 10

Not at all I can feel

No fatigue Maximum fatigue

4. Please rate your current level of fatigue?

0 1 2 3 4 5 6 7 8 9 10

Not at all I can feel

No fatigue Maximum fatigue

5. Please assess to what extent fatigue has affected your general activities in the last 7 days?

0 1 2 3 4 5 6 7 8 9 10

No effect Extreme effect

6. Please assess how much fatigue has affected your ability to bathe and dress yourself in the last 7 days?

0 1 2 3 4 5 6 7 8 9 10

No effect Extreme effect

7. Please assess how fatigue has affected your normal work activities (both outside work and at home) in the last 7 days.

0 1 2 3 4 5 6 7 8 9 10

No effect Extreme effect

8. Please assess how fatigue has affected your ability to concentrate in the last 7 days.

0 1 2 3 4 5 6 7 8 9 10

No effect Extreme effect

9. Please assess how fatigue has affected your relationships with others in the last 7 days?

0 1 2 3 4 5 6 7 8 9 10

No effect Extreme effect

10. Please assess how much fatigue has affected your enjoyment of life in the last 7 days?

0 1 2 3 4 5 6 7 8 9 10

No effect Extreme effect

11. Please assess how much fatigue has affected your mood in the last 7 days.

0 1 2 3 4 5 6 7 8 9 10

No effect Extreme effect

12. On how many of the last 7 days did you feel tired at any given moment?

0 1 2 3 4 5 6 7

Days Days

13. In the question above, how tired did you feel on average during the day?

0 1 2 3 4 5 6 7 8 9 10

No fatigue Feeling fatigued all day

14. In the last 7 days, which best describes your daily state of fatigue?

0	1	2	3	4
Not at all	Morning most	Afternoon most	Evening most	Tired every day

The questionnaire is divided into three parts, with questions 1-4 measuring the intensity of fatigue, including most fatigued, least fatigued, average fatigue, and currently fatigued; questions 5-11 measuring the extent to which fatigue interferes with quality of life; and questions 12-13 measuring the duration of fatigue (durations of fatigue). The questions measured the duration of fatigue, including the number of days fatigue occurs, the time of day; the scoring method, except for question 12, which measured the number of days fatigue occurs with 0-7, the other questions were 0-10 to indicate the presentation of symptoms of fatigue, with 0 representing no fatigue at all, and 10 representing the maximum amount of fatigue I can feel. 0 means no fatigue at all, and 10 means I can feel maximum fatigue. Only questions 5-11 can be summed up to represent the degree of interference with life, with a total score of 70 points; the higher the score, the higher the degree of interference of fatigue with life, and the other questions are scored individually to represent the degree of interference with the topic, with a total of 10 points for each question.

Appendix IV

Karnofsky Physical Condition Score:
This criterion was proposed by Karnosky of ECOG (Eastern Cooperative Oncology Group). Based on the patient's ability to Based on the patient's ability to perform normal activities, their condition, and their level of independence, the KPS recognizes the patient's health status as a total of 100 points, with a 10-point scale. The following table summarizes the criteria. See the table below:

☐1. normal, no signs and symptoms 100 points
☐2. able to perform normal activities with minor signs and symptoms 90 points
☐3. Barely able to perform normal activities with some signs or symptoms 80 points
☐4. Can take care of himself/herself, but cannot maintain normal life and work 70 points
☐5. Can take care of himself/herself mostly, but needs help occasionally 60 points
☐6. Needs care often 50 points
☐7. Cannot take care of himself/herself and needs special care and help 40 points
☐8. Severely unable to take care of themselves 30 points
☐9. Seriously ill and need to be hospitalized for active supportive treatment 20
☐10. Critically ill, close to death 10
☐11. Dead 0

Note: The higher the score, the better the health, the more tolerant of the side effects of treatment on the body, and therefore the more likely to receive complete treatment. The higher the score, the better the health, the more tolerant the treatment is of side effects, and therefore the more likely it is to be complete. The lower the score, the worse the health status, and below 60, many effective anti-tumor treatments cannot be administered. Anti-tumor treatments cannot be given if the score is below 60.

Appendix V

Simplified Appetite Scale (SNAQ)

For each entry in the questionnaire below, please circle the answer you think is correct and score it according to the following numerical intervals: a = 1, b = 2, c = 3, d = 4, e = 5. The sum of the scores for each entry constitutes the Simplified Nutritional Appetite Quotient (SNAQ) value. A value > ≤ 14 indicates that you are at significant risk of losing at least 5% of your body weight in the next six months.

1. My appetite

a. Very bad

b. Not good

c. Average

d. Good

e. very good

2. When I eat

a. after a few bites, I feel full.

b. one-third of the way through, I feel full.

c. I feel full after eating half of it. d. I feel full after eating a large portion of it.

d. I feel full after eating the majority of my meal.

e. I never feel full.

3. When I eat, I feel that the food tastes

a. very bad.

b. bad. c. good.

c. good. d. very good.

d. very good.

4. I usually eat

a. less than one meal a day.

b. Just one meal a day.

c. two times a day. d. three times a day.

d. Three times a day.

e. More than three meals per day.