

# Music therapy and music intervention for lung cancer patients who have a fear of cancer recurrence while undergoing diagnostic brain imaging

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<b>Registration date</b> 13/06/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/08/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cancer and psychiatric symptoms are associated. Fear of cancer recurrence (FCR) is the most common psychological problem for cancer survivors. Pharmacological interventions can help, but also have major drawbacks. Music therapy and music interventions are safe and practical complementary treatments. This study aims to investigate the effects of music therapy and music intervention in attenuating non-small cell lung cancer (NSCLC) patients' anxiety related to FCR.

### Who can participate?

NSCLC patients aged between 18 to 80 years old who have been diagnosed by a psychiatrist with mild to moderate anxiety and depression

### What does the study involve?

The study involves music therapeutical treatments before and after your diagnostic PET-CT examination. There will also be saliva collected and heart rate measurements and they will be asked psychology-related questions at regular intervals.

### What are the possible benefits and risks of participating?

The benefits are possible reductions in anxiety and stress during the procedure. Music therapy is considered safe and the measurements intended are not invasive. This means that there are no expected risks.

### Where is the study run from?

Qingpu Traditional Chinese Medicine Hospital

### When is the study starting and how long is it expected to run for?

May 2019 to October 2019

Who is funding the study?

1. National Key Research and Development Program of China
2. Huashan Hospital affiliated with Fudan University

Who is the main contact?

Dr. Kevin Thome, kevin\_thome@fudan.edu.cn

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Kevin Thome

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Development Project of Shanghai Peak Disciplines - Integrative Medicine and Western Medicine No. 20150407, National Natural Science Program of China No.81673916 and 81403148

## Study information

### Scientific Title

Music therapy and music intervention for NSCLC patients undergoing PET with fear of cancer recurrence

### Acronym

MTMINSCLC

### Study objectives

Music therapy and music intervention reduce fear of cancer recurrence in non-small cell lung carcinoma patients undergoing diagnostic PET-CT, as measured via: State-Trait Anxiety Inventory, heart rate, PET-scan, salivary cortisol, salivary  $\alpha$ -amylase.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 17/05/2019, Research Ethical Committee of Qingpu Traditional Chinese Hospital (Qingan road No. 95, Shanghai, 200040, China; +86 52888301; mbxdsk@163.com), ref: 2019BL0516011

## **Study design**

Interventional randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Reduction of fear of cancer recurrence in patients with non-small cell lung carcinoma undergoing diagnostic PET-CT

## **Interventions**

The study is an interventional study. NSCLC patients with a fear of cancer recurrence (FCR) will be randomly allocated to a music therapy and intervention group (Group 1, n = 31) and a control group who did not receive music therapy intervention (Group 2, n = 31). Patients' anxiety will be measured using the State-Trait Anxiety Inventory scores and heart rates. The primary outcome measure is assessed using PET scans. Secondary measures are salivary cortisol, salivary  $\alpha$ -amylase levels and heart rate. To control for selectivity bias, each participant will be randomly assigned a number using the online program RANDOM.org. All participants will then be randomly divided into Groups 1 or 2 using the online randomization program Research Randomizer.

For clarity, 'music intervention' is defined as a patient's exposure to music without a music therapist, and 'music therapy intervention' a patient's exposure to music with a music therapist.

Patients in Group 1 receive a music intervention and a music therapy intervention organized and conducted by a trained and experienced music therapist. The patients meet for two sessions, from Time -30 to Time 0 and from Time +30 to Time +60, for a total of 60 minutes. During the first session, before the PET examination, the subjects will be asked to restfully close their eyes and not talk in the waiting room to avoid interference with the brain's glucose metabolism. This first session involves a passive music intervention. Music therapists developed suitable music lists for patients based on age and educational level. For the music intervention, the music therapist selects 6 songs, 3 instrumental and 3 vocal songs, with slow rhythms and comfortable melodies. If the patient felt that the music was too noisy or made them feel uncomfortable the music therapist changed the music until the patient felt comfortable. Although the music therapist selected the music and was available for adjustments during the listening, there was no formal therapeutic involvement, which is why it is labeled as a music intervention.

During the second session, from Time +30 to Time +60, the music therapy intervention was carried out in individual sessions (one-on-one therapy) using a standardized plan of music intervention techniques. The subjects reclined halfway on a bed in a comfortable environment

and will be encouraged to listen to the music played in the first session for 15 min. After that, they discussed their responses such as images or feelings evoked by the music, the mood of the music, or associated memories. During the music therapy intervention sessions, the therapist provided encouraging responses to the subject's comments.

The Mandarin Chinese version of a shortened 6-item Dutch version of the State-Trait Anxiety Inventory (STAI) was used to assess patients' anxiety levels. It includes state anxiety, used to evaluate their feelings of apprehension, tension, nervousness, and worry. [200-14N] Therefore, for this study, the high-anxiety STAI threshold of 40 points for the 20-item STAI was converted to a threshold of 12 points for a 6-item STAI ( $40/20 \times 6 = 12$ ). STAI measurements will be taken six times before collecting salivary samples. At the same time, real-time monitored of the subjects' heart rate.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Glucose metabolism of 18F-FDG measured using a single PET-CT scan at one time point

### **Key secondary outcome(s)**

1. Salivary cortisol measured using radioimmunoassay with saliva collection 30 minutes before the PET scan, shortly before the PET scan, and then at 30, 60, 70 and 80 minutes after completion of the PET scan
2. Salivary alpha-amylase measured using radioimmunoassay with saliva collection 30 minutes before the PET scan, shortly before the PET scan, and then at 30, 60, 70 and 80 minutes after completion of the PET scan
3. Heart Rate measured using an ambulatory sphygmomanometer once at every saliva collection 30 minutes before the PET scan, shortly before the PET scan, and then at 30, 60, 70 and 80 minutes after completion of the PET scan
4. State-Trait Anxiety Inventory (STAI) measured using a questionnaire once at every saliva collection 30 minutes before the PET scan, shortly before the PET scan, and then at 30, 60, 70 and 80 minutes after completion of the PET scan

### **Completion date**

01/10/2019

## **Eligibility**

### **Key inclusion criteria**

1. Age range from 18 to 80 years old, regardless of gender
2. Patients who have been diagnosed with tumors through pathology or cytology and have received modern conventional medical treatment for tumors, including surgery, radiotherapy and chemotherapy, endocrine therapy, targeted therapy, immunotherapy, etc
3. Patient Karnofsky Functional State Scale KPS score  $\geq 80$  points
4. A psychiatrist diagnosed mild to moderate anxiety and depression patients through DSM-IV clinical diagnosis, with a score of 5-14 on the Generalized Anxiety Scale GAD-7 and a score of 5-14 on the Patient Health Questionnaire Depression Screening Scale PHQ-9
5. The patient has a certain level of emotional comprehension ability, clear language expression ability, can participate in intervention and management, has good compliance and signs an informed consent form

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

All

**Total final enrolment**

62

**Key exclusion criteria**

1. Age mismatch, tumor diagnostic criteria mismatch, KPS score<80, GAD-7 and PHQ-9 scores mismatch
2. Unstable vital signs or current physical condition unsuitable for participants
3. Patients with acute infectious diseases, acute myocardial infarction, acute cerebrovascular accident, autoimmune disease, severe digestive tract disease, severe liver and kidney dysfunction, hemorrhagic disease, bleeding tendency and other serious diseases of other systems
4. Those with poor compliance or limited cultural level who are unable to cooperate in completing intervention treatment plans
5. Those who are receiving other complementary and alternative therapies for treatment
6. Patients with severe depression, severe anxiety, or concomitant schizophrenia
7. Other individuals who are not suitable for inclusion, such as those with hearing impairment, memory impairment, strong suicidal ideation, or previous suicidal behavior

**Date of first enrolment**

20/05/2019

**Date of final enrolment**

01/09/2019

**Locations****Countries of recruitment**

China

**Study participating centre**

**Qingpu Traditional Chinese Medicine Hospital**  
Qingpu district, Qingan road number 95  
Shanghai  
China  
201799

## Sponsor information

### Organisation

Huashan Hospital

### ROR

<https://ror.org/05201qm87>

## Funder(s)

### Funder type

Government

### Funder Name

National Key Research and Development Program of China

### Alternative Name(s)

, National Basic Research Program of China (973 Program), Special Fund for the National Key Research and Development Plan, China National Key Research and Development Plan Project, National Key Research and Development of China, National Key Research and Development Program, National Key R&D Program of China, National Key R&D Programmes of China, China's National Key R&D Programmes, National Basic Research Program of China, 973 Program, National Program on Key Basic Research Project (973 Program), National Plan on Key Basic Research and Development, National Basic Research Program, NKRDP, NKPs

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

China

### Funder Name

Huashan Hospital

## Alternative Name(s)

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

China

# Results and Publications

## Individual participant data (IPD) sharing plan

1. The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository
2. The datasets generated during and/or analysed during the current study will be available upon request from Dr. Yijie Du, email: xdzy2004@163.com, wechat ID: sdzy2004

## IPD sharing plan summary

Stored in non-publicly available repository, Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		12/08/2024	14/08/2024	Yes	No