ISRCTN23276302 https://doi.org/10.1186/ISRCTN23276302

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

Submission date
08/06/2024

Recruitment status
No longer recruiting

Registration date
13/06/2024

Overall study status
Completed

Last Edited
14/08/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 α-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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 α-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. [20O-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*6=). 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 measure
Glucose metabolism of 18F-FDG measured using a single PET-CT scan at one time point

Secondary outcome measures
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

Overall study start date
01/05/2019

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 ≥ 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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
62

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

Sponsor details
Huashan Hospital affiliated with Fudan University
12 Middle Urumqi Road
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China
200040
+86 21 5288 9999
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Sponsor type
Hospital/treatment centre

Website
https://www.huashan.org.cn/hsdy

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, NKRDPC, 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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/07/2024

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?
Results article		12/08/2024	14/08/2024	Yes	No