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Study on novel treatment techniques for neurogenic gastrointestinal disorders utilizing the neuroendocrine axis and artificial intelligence technology

Submission date
19/02/2024

Recruitment status
Recruiting

Registration date
05/03/2024

Overall study status
Ongoing

Last Edited
05/03/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with neurosis may experience symptoms of stomach pain due to dysfunction of the autonomic nervous system, which can affect the digestive function of the gastrointestinal tract. Patients can take drugs that inhibit gastric acid secretion under the guidance of a doctor, such as omeprazole enteric-coated capsules and rabeprazole sodium enteric-coated tablets. They can also follow the doctor's advice to take gastric mucosal protective agents, such as sucralfate and bismuth potassium citrate. Neurosis can affect the digestive function of the gastrointestinal tract, causing food to accumulate in the stomach for a long time, leading to symptoms of bloating. Patients can take drugs that promote gastric motility under the guidance of a doctor, such as domperidone tablets and mosapride. They can also follow the doctor's advice to take drugs such as Jianwei Xiaoshi tablets and compound digestive enzyme tablets for treatment. Patients with neurosis may experience symptoms of reflex vomiting due to the regulation of the autonomic nervous system in the stomach. It is recommended that patients use drugs such as vitamin B6 and metoclopramide under the guidance of a doctor for treatment, or follow the doctor's advice to use drugs such as promethazine hydrochloride and chlorpromazine hydrochloride for treatment. In addition, patients with neurosis may also experience symptoms such as insomnia, anxiety, and palpitations. In the upcoming study, researchers will investigate the potential psychological treatment benefits of integrating physical music therapy into mental health interventions for patients with neurosis.

Who can participate?
Patients with neural digestive disease (intervention group) and patients with IBS-D (control group) aged between 16 and 88 years old

What does the study involve?
Participants will be randomly assigned to either a group receiving physical music therapy or a control group with no intervention. Those in the experimental group will receive music at the hospital and will continue listening at home while engaging in physical activities. Regular

communication with the hospital will facilitate monitoring of progress. The study, set to span six months, aims to assess changes in psychological well-being using surveys. By comparing outcomes between the two groups, researchers hope to gain insights into the effectiveness of physical music therapy on mental health. Ethical considerations will ensure participant confidentiality and voluntary participation.

What are the possible benefits and risks of participating?
This study has the potential to inform future therapeutic approaches and contribute to the understanding of music's role in mental well-being. There are no obvious side effects in the treatment, and there are no uninformed operations, especially no medical behaviors not approved by the Chinese government, mainly using non-invasive physical therapy.

Where is the study run from?
Chifeng Cancer Hospital (China)

When is the study starting and how long is it expected to run for?
December 2023 to February 2028

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Qin Yi, 2116228604@qq.com

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
Nil Known

Study information

Scientific Title
Research on new treatment methods for neurogenic gastrointestinal diseases based on neuroendocrine axis and artificial intelligence technology

Study objectives
Music can regulate human emotions and alleviate neurological symptoms in the gastrointestinal tract

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/02/2024, Ethics Committee of Chifeng Cancer Hospital (Chifeng Cancer Hospital in Hongshan District, Chifeng, 024000, China; +86 13030051220; ykmdphdsensorengineer@yksm.team), ref: 202401

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Preventing psychological illness in patients with neurogastroenteropathy

Interventions
Objective:
To investigate the efficacy of physical music therapy on psychological well-being compared to a control group without intervention.

Participants:
Participants will be divided into two groups: the experimental group receiving physical music therapy and the control group without any intervention. The sample will consist of patients seeking therapeutic support in the Hongshan District, Chifeng City, Inner Mongolia Autonomous Region, China.

Procedure:
Recruitment and Screening: Patients seeking therapy will be recruited and screened for eligibility based on predetermined criteria.
Group Allocation: Participants will be randomly assigned to either the experimental or control group.
Experimental Group: Participants in the experimental group will undergo physical music therapy. They will receive music at the hospital and will be provided with corresponding download addresses for home listening. The therapy will involve a combination of face-to-face sessions and online communication. Participants will listen to the music according to their needs and report their progress to the hospital every week.
Control Group: Participants in the control group will not receive any intervention and will continue with their usual routines.
Duration: The intervention will span over six months, with preliminary positioning for more than one month to assess clinical needs and suitability.
Outcome Measures: Psychological scales will be utilized to record changes in psychological well-being throughout the intervention period.
Data Collection: Data on psychological scales will be collected at regular intervals from both groups to analyze the effectiveness of physical music therapy.
Intervention Location: The intervention will primarily take place in the Hongshan District, Chifeng City, Inner Mongolia Autonomous Region, China. Additionally, music will be registered on Chinese music platforms with copyrights secured. Depending on the preliminary results, music will be promoted on online platforms.

Intervention Type
Behavioural

Primary outcome measure
Pain and related symptoms in irritable bowel syndrome (IBS) measured using the IBS-Symptom Severity Scale (IBS-SSS) from baseline monthly up to 6 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/12/2023

Completion date
19/02/2028

Eligibility

Key inclusion criteria
1. Free from genetic diseases
2. Patients with neural digestive disease, with no mental illness
3. Patients with IBS-D

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Upper age limit
88 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Diseases with obvious abnormalities in the auditory system

Date of first enrolment
03/04/2024

Date of final enrolment
04/12/2027

Locations

Countries of recruitment
China

Study participating centre
Chifeng Cancer Hospital
Chifeng City, Inner Mongolia Autonomous Region
Chifeng
China
024000

Sponsor information

Organisation
Chifeng Cancer Hospital

Sponsor details
Hongshan District, Chifeng City, Inner Mongolia Autonomous Region
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Sponsor type
Hospital/treatment centre

Website
http://www.cfxydefsyy.com/Html/Departments/Main/Index_139.html

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
19/02/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://pan.baidu.com/disk/main#/index).

Shared data types: Excel or Matlab data files
When and how long data is available: Permanent
What access standards will data be shared with: Scholars who have read relevant published literature
Including who to share with: Readers who have read the paper
What type of analysis to conduct: Quantitative analysis and machine learning analysis
Mechanism sharing: Sharing machine learning code and raw data
Have you obtained the consent of the participants: Yes
Comment on data anonymization: Anonymous
Any moral or legal restrictions: Comply with international and Chinese legal requirements
Any other comments: Allow comments

IPD sharing plan summary

Stored in publicly available repository