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Personalized management of functional gastrointestinal disorders in Anhui, China

Submission date
17/06/2021

Recruitment status
Recruiting

Registration date
12/07/2021

Overall study status
Ongoing

Last Edited
12/10/2021

Condition category
Digestive System

[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
Functional gastrointestinal disorders (FGIDs) can affect any part of the gastrointestinal (GI) tract, including the food pipe, stomach and intestines. They are disorders of function (how the GI tract works). Quality of life impairment and economic loss (both direct and indirect) because of FGIDs are huge. FGIDs have a long course and repeated symptoms, and so cause serious and enduring physical, psychological as well as sociological suffering. Personalized management of FGIDs (PM-FGIDs) aims to prevent and reduce the risk and harms of FGIDs through six behaviors, including:
1. Attending and responding to project communications
2. Changing unhealthy diet habits or practices
3. Reducing tobacco and alcohol consumption
4. Coping with psychological and sleep problems
5. Maintaining adequate physical exercise/activities
6. Using clinical examination and treatment
This study aims to test the effectiveness of PM-FGIDs and to identify key facilitators, barriers and corresponding strategies for the spread and implementation of PM-FGIDs.

Who can participate?
Patients aged 18-70 years with FGIDs at 26 general hospitals of Anhui province, China

What does the study involve?
Participants will either receive care-as-usual (CAU) or CAU plus PM-FGIDs over the study period. Participants' scores of overall treatment effect and data about their use of healthcare services, changes in the six behaviors, and quality of life will be measured using questionnaires at the start of the study and every 6 months for the following 5 years.

What are the possible benefits and risks of participating?
There are not thought to be any risks involved with participating in the study. A possible benefit could be that PM-FGIDs prevent and reduce the risk and harms of FGIDs.

Where is the study run from?
Anhui Provincial Center for Disease Control and Prevention (China)

When is the study starting and how long is it expected to run for?
November 2020 to October 2026

Who is funding the study?
Anhui Provincial Center for Disease Control and Prevention (China)

Who is the main contact?
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Contact information

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Public

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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
Personalized management of functional gastrointestinal disorders based on serial assessment and telemedicine in Anhui, China: a randomized controlled trial

Acronym
PM-FGIDs

Study objectives
1. Compared to those in the control condition, patients in the personalized management of functional gastrointestinal disorders (PM-FGIDs) intervention will demonstrate: higher scores on the overall treatment effect (OTE) of gastrointestinal symptoms and objective behaviors including project communications, healthy diet, physical activities, tobacco/alcohol consumption, psychological/sleep problems coping, and clinical examination/treatment.
2. Key facilitators, barriers and corresponding strategies for the spread and implementation of PM-FGIDs will be identified.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/07/2021, Anhui Medical University Biomedical Ethics Committee (Anhui Medical University, 81 Meishan Road, Hefei, Anhui, China; +86 0551-65161053; renzhenhua@ahmu.edu.cn), ref: 20210648.

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)

Quality of life

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

Health condition(s) or problem(s) studied
Functional gastrointestinal disorders

Interventions
This study adopts a cluster randomized controlled trial design involving 26 general hospitals in Anhui province, China. These hospitals are randomly assigned by a professional statistician outside the project team into equal intervention and control arms. The control group receives care-as-usual (CAU) while the intervention group receives CAU plus personalized management of functional gastrointestinal disorders (PM-FGIDs). Project evaluation applies to both the intervention and control groups using the same questionnaire and at the same time points, i.e., baseline and every 6 months after baseline. The trial design and implementation are overseen by a steering committee. Analysis and reporting of the trial strictly follows the CONSORT guidelines.

PM-FGIDs aims to prevent and reduce the risk and harms of FGIDs through six objective behaviors, including:
1. Attending and responding to project communications
2. Changing unhealthy diet habits or practices
3. Reducing tobacco and alcohol consumption
4. Coping with psychological and sleep problems
5. Maintaining adequate physical exercise/activities
6. Using clinical examination and treatment

The above objective behaviors are promoted through four interventions venues: supervised machine communication, daily education or reminder messages, quarterly signed feedback, and personal web account and pages. The design of these measures is guided by proven theories or strategies including system synergy, health belief model, social cognition theory, motivational interviewing, and computerized tailoring. Detailed intervention varies from patient to patient due to the personalized nature of the intervention.

Intervention Type
Behavioural

Primary outcome measure
The overall treatment effect (OTE) of gastrointestinal symptoms measured using a 7-point Likert scale (the question is “How have your gastrointestinal symptoms changed after treatment?”, and the answers include “much better”, “improvement”, “slight improvement”, “no change”, “slight deterioration”, “worse”, and “deteriorated”) at baseline and every 3 months after baseline for 5 years

Secondary outcome measures
Measured using structured questionnaires at baseline and every 6 months after baseline for 5 years:
1. Quality of life measured using EQ5D-5L
2. Participant’s utilization of health services measured using a self-designed patient assessment

questionnaire
3. Changes in the six objective behaviors measured using a self-designed patient assessment questionnaire

Overall study start date
01/11/2020

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Male and female patients
2. 18-70 years old
3. Diagnosed with FGIDs according to Rome IV diagnostic criteria
4. Able and willing, after informed consent, to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
2600

Key exclusion criteria
1. Serious mental illness, such as schizophrenia or dementia
2. History of gastrointestinal surgery, such as gastrectomy or colectomy
3. Serious or malignant disease confirmed by a clinician, such as kidney failure or tumor
4. Pregnancy or breastfeeding

Date of first enrolment
01/09/2021

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
China

Study participating centre
Anhui Provincial Center for Disease Control and Prevention
12560 Fanhua Road
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Sponsor information

Organisation
Anhui Provincial Center for Disease Control and Prevention

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Sponsor type
Government

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ROR
https://ror.org/03ddz1316

Funder(s)

Funder type
Government

Funder Name
Anhui Provincial Center for Disease Control and Prevention

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. No additional documents are available.

Intention to publish date
01/10/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date