

# Personalized management of functional gastrointestinal disorders in Anhui, China

<b>Submission date</b> 17/06/2021	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/07/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/10/2021	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Miss Mengsha Tang  
mengshatang@sina.com

## Contact information

### Type(s)

Public

### Contact name

Miss Mengsha Tang

### ORCID ID

<https://orcid.org/0000-0002-7108-5000>

### Contact details

Anhui Medical University  
81 Meishan Road  
Hefei  
China  
230032  
+86 (0)551 65116395  
mengshatang@sina.com

### Type(s)

Scientific

### Contact name

Miss Mengsha Tang

### ORCID ID

<https://orcid.org/0000-0002-7108-5000>

### Contact details

Anhui Medical University  
81 Meishan Road  
Hefei  
China  
230032  
+86 (0)551 65116395  
mengshatang@sina.com

## Additional identifiers

## **Clinical Trials Information System (CTIS)**

Nil known

## **ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

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

## **Study type(s)**

Quality of life

## **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(s)**

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

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

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

70 years

**Sex**

All

**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

Hefei

China

230601

**Sponsor information**

**Organisation**

Anhui Provincial Center for Disease Control and Prevention

**ROR**

<https://ror.org/03ddz1316>

**Funder(s)****Funder type**

Government

**Funder Name**

Anhui Provincial Center for Disease Control and Prevention

**Results and Publications****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