

# The effect of a Chinese herbal formula on the quality of life and immune system of people who have asthma, a condition where the immune system overreacts to allergens or environmental stimuli and causes symptoms like cough, wheezing and shortness of breath

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| <b>Submission date</b><br>09/04/2025   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>12/04/2025 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>11/04/2025       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Asthma is a chronic inflammatory condition affecting the lower airways, characterized by symptoms such as coughing, wheezing, shortness of breath, and chest tightness. This condition significantly impacts quality of life and imposes substantial medical burdens.

In this study, we aimed to investigate if a Chinese herbal formula-BZYQT could be a complementary treatment for asthma by improving patients' quality of life and modulating their immunity.

### Who can participate?

Male and female patients aged 20 to 65 years with controlled or partly controlled asthma, diagnosed according to the Taiwan Asthma Guidelines (based on the 2009 GINA revision).

### What does the study involve?

Participants were randomly assigned in a 1:1 ratio to receive either oral medication of BZYQT or placebo for 12 weeks. They were scheduled for four visits to the outpatient clinic to assess quality of life questionnaire and blood sample collection.

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

The medication used may relieve symptoms of asthma and improve quality of life. Side effect may include dry mouth but without severe side effects.

### Where is the study run from?

The traditional Chinese medicine department of Taoyuan, Linkou and Taipei Chang Gung Memorial Hospital in Taiwan.

When is the study starting and how long is it expected to run for?  
November 2016 to December 2021

Who is funding the study?  
This work was supported by the Chang-Gung Medical Foundation (Taiwan) (grant number: CMRPG1G0091, CMRPG1G0092, CMRPG1G0093)

Who is the main contact?  
Prof. Sien-Hung Yang, dryang@mail.cgu.edu.tw

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

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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

Evaluation of Bu-Zhong-Yi-Qi-Tang (BZYQT) on quality of life and immune modulation in asthma patients: a randomized, double-blind, placebo-controlled pilot trial

### Study objectives

BZYQT improves asthma-related quality of life and modulates immune and inflammatory responses.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 10/11/2016, Medical Ethics and Human Clinical Trial Committee of Chang Gung Memorial Hospital (No. 123, Dinghu Rd., Guishan Dist., Taoyuan, 333008, Taiwan; +886-3-3196200 #3712; shihhua@cgmh.org.tw), ref: CGMH IRB No.201601139A3

### **Study design**

Multicentre interventional randomized double-blind placebo-controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital, Laboratory

### **Study type(s)**

Treatment, Safety, Efficacy

### **Participant information sheet**

No participant information sheet available

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

Treatment with a Chinese herbal formula for patients with asthma

### **Interventions**

Patients with asthma were randomly assigned to receive either BZYQT (oral, 12 grams per day) or placebo for 12 weeks.

Total duration of follow-up for all study arms: 16 weeks

Details of the randomisation process:

Eligible participants were randomly assigned to either the study or control group in a 1:1 ratio. Each participant was assigned a unique project number by the researchers. The randomization code list was generated using a permuted block randomization method by Chuang Song Zong Pharmaceutical Co., Ltd.. The manufacturer labeled the study capsules with identical appearances based on the randomization code list. Our hospital pharmacy then received these capsules, numbered consecutively and randomized as either BZYQT or placebo. The pharmacists dispensed the capsules to participants based on their project number.

### **Intervention Type**

Drug

### **Pharmaceutical study type(s)**

Pharmacodynamic

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Bu-Zhong-Yi-Qi-Tang (BZYQT)

**Primary outcome measure**

Quality of life, measured using the Asthma Quality of Life Questionnaire (AQLQ) at week 0 (before receiving BZYQT or placebo), week 6 (six weeks after starting BZYQT or placebo), week 12 (12 weeks after starting BZYQT or placebo, end of treatment), and week 16 (end of the trial)

**Secondary outcome measures**

1. Immune and inflammatory markers such as IgE, eosinophil counts, measured by blood sample at weeks 0,6,12, and 16
2. Asthma-related cytokines (IL-4, IL-5, IL-10, and IL-13), and inflammatory mediators (IL-8, LTC4, sICAM-1, and PGE2) measured by blood sample at weeks 0,6, and 12
3. Safety profiles, including CBC and liver and kidney function (ALT and creatinine), were also carried out at weeks 0,6,12, and 16

**Overall study start date**

01/01/2016

**Completion date**

31/12/2021

## **Eligibility**

**Key inclusion criteria**

1. Patients aged between 20 and 65 years with controlled or partly controlled asthma.
2. Diagnosed according to the Taiwan Asthma Guidelines (based on the 2009 GINA revision).
3. Participants were required to be capable of correctly performing pulmonary function tests (spirometry).

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

20 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

60

**Total final enrolment**

44

**Key exclusion criteria**

1. Patients currently undergoing treatment with oral or injectable corticosteroids, or other immunomodulatory agents.
2. Patients who had discontinued such medications within one month prior to the study.
3. Individuals with active infectious diseases, including pneumonia, sinusitis, or bronchitis.
4. Patients with dementia or other psychiatric disorders that could interfere with their ability to complete the required study questionnaires.
5. Individuals with a history of allergy to TCM, poor medication adherence, or a history of previous adverse reactions.
6. Patients with severe organ dysfunction, such as heart failure, liver failure, liver cirrhosis, or chronic kidney disease with an estimated glomerular filtration rate (eGFR) of less than 60 mL/min/1.73 m<sup>2</sup>.

**Date of first enrolment**

21/01/2019

**Date of final enrolment**

18/12/2021

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

Taiwan

**Study participating centre**

**Taoyuan Chang Gung Memorial Hospital**

No. 123, Dinghu Rd. Guishan Dist.

Taoyuan

Taiwan

333008

**Study participating centre**

**Linkou Chang Gung Memorial Hospital**

No.5, Fuxing St. Guishan Dist.

Taoyuan

Taiwan

333423

**Study participating centre**

**Taipei Chang Gung Memorial Hospital**  
No. 199, Dunhua N. Rd., Songshan Dist.  
Taipei  
Taiwan  
105406

## Sponsor information

### Organisation

Taoyuan Chang Gung Memorial Hospital

### Sponsor details

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ccyi@cgmh.org.tw

### Sponsor type

Hospital/treatment centre

### Website

[https://www.cgmh.org.tw/branch/branch\\_hel.htm](https://www.cgmh.org.tw/branch/branch_hel.htm)

### ROR

<https://ror.org/00fk9d670>

## Funder(s)

### Funder type

Charity

### Funder Name

Chang Gung Medical Foundation

### Alternative Name(s)

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

**Location**

Taiwan

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

31/12/2025

**Individual participant data (IPD) sharing plan**

The data that support the findings of this study are available from the corresponding author upon reasonable request.

[dryang@mail.cgu.edu.tw](mailto:dryang@mail.cgu.edu.tw)

**IPD sharing plan summary**

Available on request