

# Consumption of ancient grain flours as a new therapeutic option for irritable bowel syndrome

<b>Submission date</b> 24/04/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/12/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Climate change and its impact on food systems have renewed interest in sustainable crops like ancient grains, which offer environmental and nutritional benefits. Unlike modern cereals, ancient grains are less processed, more resilient to harsh conditions, and have a lower environmental footprint. Emerging evidence suggests that certain ancient grains, such as *Triticum monococcum* and Jermano wheat, may be better tolerated in individuals with irritable bowel syndrome (IBS) due to their lower fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP) content and improved digestibility. This study investigates the potential of these grains in developing a functional pasta to manage IBS symptoms.

### Who can participate?

Adult patients aged 18 years and over with a diagnosis of IBS

### What does the study involve?

Participants are randomly allocated to the intervention group or the control group. The intervention group receives a low-FODMAP diet that includes the functional pasta (80 g, 4 times per week) for 4 weeks. The control group receive a low-FODMAP diet that includes gluten-free pasta (80 g, 4 times per week) for 4 weeks. Gastrointestinal symptoms, mood disturbances and quality of life will be assessed using validated clinical questionnaires at the start and the end of the study.

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

The potential benefit is an improvement in IBS symptoms. There are no risks for participants.

### Where is the study run from?

University Magna Grecia (Italy)

### When is the study starting and how long is it expected to run for?

September 2022 to September 2024

Who is funding the study?  
University Magna Grecia (Italy)

Who is the main contact?  
Prof. Tiziana Montalcini, tmontalcini@unicz.it

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Tiziana Montalcini

### ORCID ID

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

279/2022/CE

## Study information

### Scientific Title

Ancient grain flours in IBS

### Acronym

AGORA-IBS

### Study objectives

The hypothesis is that the consumption of a functional pasta made from ancient grains will result in a significant reduction in symptom severity in patients with irritable bowel syndrome (IBS).

### Ethics approval required

Ethics approval required

## **Ethics approval(s)**

approved 15/09/2022, Ethics Committee Calabria Region Central Area Section (Comitato Etico Regione Calabria Sezione Area Centro) (A.O.U. Mater Domini in Via Tommaso Campanella, 115, Catanzaro, 88100, Italy; +39 (0)961 712 111; comitatoetico@hotmail.it), ref: 279/2022/CE

## **Study design**

Randomized open-label clinical trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Irritable bowel syndrome

## **Interventions**

Participants will be enrolled after providing written informed consent and will be randomly assigned (by computer-generated random numbers) in a 1:1 ratio to one of two treatment groups:

Group 1: Patients following a low-FODMAP diet including the functional pasta (80 g, 4 times per week).

Group 2: Patients following a low-FODMAP diet including gluten-free pasta (80 g, 4 times per week).

Participants will be assessed using validated clinical questionnaires evaluating gastrointestinal symptoms.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

Gastrointestinal symptoms measured using the Irritable Bowel Syndrome Symptom Severity Score (IBS-SSS) at baseline and after 4 weeks of treatment

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

The following secondary outcome measures are assessed at baseline and after 4 weeks of treatment:

1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
2. Quality of life measured using the SF-36 scale (IQOLA SF-36 Italian version 1.6)

## **Completion date**

17/09/2024

## **Eligibility**

### **Key inclusion criteria**

1. Age  $\geq$  18 years
2. Diagnosis of irritable bowel syndrome (IBS)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

42

**Key exclusion criteria**

1. Confirmed diagnosis of celiac disease or wheat allergy
2. Organic gastrointestinal disorders
3. Severe systemic conditions
4. Malnutrition
5. Psychiatric disorders
6. Adherence to specific dietary regimes
7. Pregnant or breastfeeding women

**Date of first enrolment**

17/03/2023

**Date of final enrolment**

26/07/2024

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

Italy

**Study participating centre**

Nutrition Unit of the "R.Dulbecco" Azienda University Hospital  
Viale Europa  
Campus Universitario S. Venuta  
Catanzaro

Italy  
88100

## Sponsor information

### Organisation

Magna Graecia University

### ROR

<https://ror.org/0530bdk91>

## Funder(s)

### Funder type

University/education

### Funder Name

Magna Graecia University

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Tiziana Montalcini, [tmontalcini@unicz.it](mailto:tmontalcini@unicz.it).

The IPD that underlie the results reported in the main publication (including baseline data, primary outcomes, and secondary outcomes) will be made available after de-identification. The data will be accessible beginning 6 months after publication and for up to 5 years by researchers who provide a methodologically sound proposal. Data will be shared in accordance with participant consent and applicable ethical guidelines. A data-sharing agreement may be required.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		19/12/2025	22/12/2025	Yes	No
<a href="#">Participant information sheet</a>	version 1.0	05/09/2022	29/04/2025	No	Yes