INFORMATION SHEET

An examination into the effects of a probiotic and digestive enzyme combination (Weizy® and Poolzyme® MULTI) in adults experiencing self-reported digestive complaints: a randomised, double-blind, placebo-controlled trial

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Background

Digestive complaints such as stomach pain, bloating, reflux, nausea, constipation, or diarrhoea are experienced by a significant portion of adults. Probiotics are bacteria or yeasts that may have beneficial effects on gastrointestinal health. Digestive enzymes are produced in the body to help break down the foods we eat. There is some evidence that probiotics and digestive enzymes may help reduce troublesome digestive symptoms and improve gastrointestinal health. However, there are different types (species) of probiotics and digestive enzymes. This can influence their tolerability, safety, and efficacy. These ingredients are also often administered alone, rather than in combination. In this study, we are interested in examining whether supplementation with a combination of probiotics (Weizy®) and digestive enzymes (Poolzyme® MULTI) can help reduce digestive complaints in adults experiencing troublesome digestive symptoms.

This study will be conducted by Dr Adrian Lopresti and Dr Stephen Smith (Clinical Research Australia).

Information about the funding source and declaration of interests

This study is funded by Giellepi S.p.A, the company that produces the ingredients (Weizy® + Poolzyme® MULTI) that will be used in this study. However, this study is being independently managed by Clinical Research Australia (CRA) without external influence from the study sponsor.

What does participation involve? **(see study flow chart on page 2)**

This study will comprise several steps as outlined below:

Step 1: Completion of initial online screening

This questionnaire consists of approximately 30 questions and takes approximately 10 minutes to complete. It provides us with information relating to the eligibility criteria. If, based on the screening questionnaire results, you are assessed as 'likely' eligible, you will be contacted for a phone interview. Ineligible volunteers will be informed by email that they do not fulfil the eligibility criteria.

Step 2: Phone Interview for an assessment of eligibility

If you are potentially eligible to participate in the study, you will be interviewed by a researcher. The interview will be conducted over the phone (approx. 10 minutes). The purpose of this interview is to obtain relevant background information (e.g., medication use, current treatments, gastrointestinal symptoms, etc.) and assess other relevant eligibility criteria. We will also provide you with further details about the study. If you meet our eligibility criteria and agree to participate in the study, you will proceed to the next step.

Step 3: VISIT 1 (Day 0): Face-to-face assessment (approx. 30 mins)

During this visit, the following tasks will be completed:

1. Have your weight, height, and blood pressure measured
2. Complete questionnaires about your digestive symptoms and general wellbeing
3. Receive a 4-week supply of capsules containing Weizy® + Poolzyme® MULTI or a placebo

Step 4: (Day 1): Take your capsules

In this study, we will be using a randomised, double-blind, placebo-controlled design. This means half of the participants will be placed on capsules containing Weizy® + Poolzyme® MULTI, and the other half will be placed on placebo (dummy) capsules.

Neither you nor the investigator will know which group you have been placed in. This random placebo allocation is important for us to assess the true effects of the ingredients.

You will be required to ONE capsule with dinner and ONE with breakfast or lunch (whichever is the larger meal).

* Placebo involves providing a substance with no known treatment effects. In this case, the placebo will contain maltodextrin (a starchy powder).

It is extremely important that you take these capsules every day.

Step 5: (Days 1 to 28): Complete daily questionnaires

Every evening around 8pm, you will be sent a notification to your phone to complete a brief questionnaire. This will take less than one minute to complete and will ask about your bowel movements for the day, if you took your capsules, and the severity of your abdominal pain for the day.

Step 6: (Day 14): Complete questionnaire (approx. 5 to 10 mins)

At week 2, you will need to complete an online questionnaire assessing your digestive symptoms and general wellbeing. You will also complete questions that ask if you have been experiencing any adverse effects associated with the intake of your capsules, have experienced any illnesses/injuries, or have changed/started any new medications.

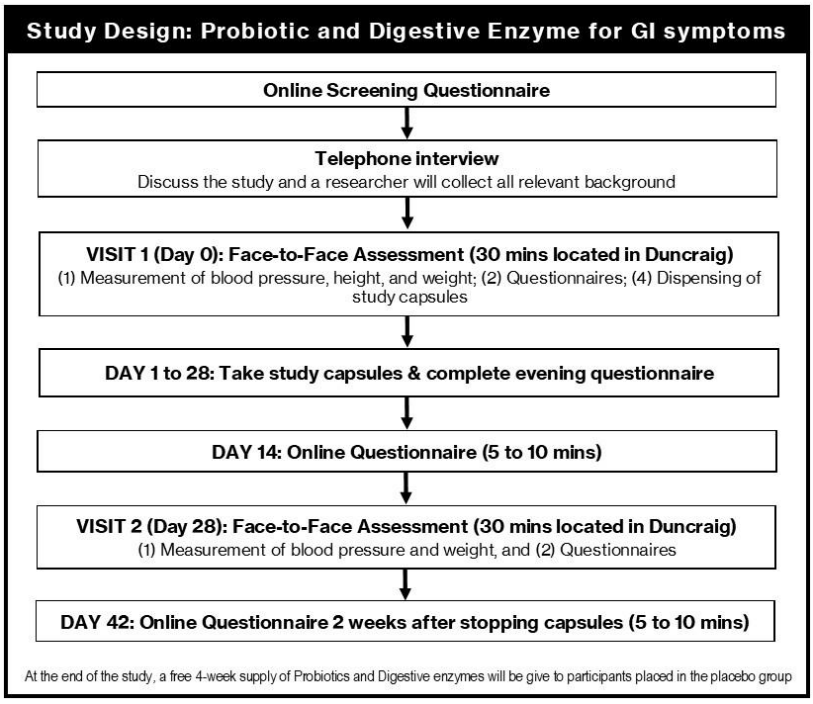
Step 7: VISIT 2 (Day 28): Face-to-face assessment (approx. 30 mins)

During this visit, the following tasks will be completed:

1. Have your weight and blood pressure measured
2. Complete questionnaires about your digestive symptoms and general wellbeing

Step 8: (Day 42): 2 Weeks after stopping capsules, complete questionnaire (approx. 5 to 10 mins)

Two weeks after you have stopped your capsules, you will be required to complete a final online questionnaire, which will ask about your digestive symptoms and general wellbeing since stopping the capsules.



Compensation for participating in this study

1. To compensate you for your travel costs and time associated with participating in this study, we will give you are $30 gift voucher on visits 1 and 2, and a $60 gift voucher when the final online questionnaire is completed at week 6.
2. At the end of the study, volunteers placed in the placebo group will be offered a free 4-week supply of digestive enzymes + probiotics capsules to try.

Criteria for inclusion/ exclusion in this study

To be included in the study, the following inclusion criteria must be met:

1. You are aged between 18 to 75 years
2. You have at least an 8-week history of experiencing gastrointestinal complaints such as recurrent abdominal pain, discomfort, or bloating associated with a change in the frequency of bowel movements, and/or a change in the appearance of your stool.
3. You consume at least 2 meals a day
4. You are a non-smoker
5. You have a BMI between 18 and 30 kg/m^2
6. You have no plan to commence new treatments for your gastrointestinal symptoms during the study
7. You understand and are willing and able to comply with all study procedures
8. You are willing to provide a personally signed and dated informed consent form detailing all pertinent aspects of the trial.

If any of the exclusion criteria below are met, you will not be suitable for participation in this study:

1. You have a history of major gastrointestinal surgery
2. In the last 3 months, you have experienced recent changes in your bowel habits, rectal bleeding, sudden weight loss, occult blood in your stool, anaemia, anal fissures, bleeding haemorrhoids, or have a significant family history of irritable bowel disease or gastrointestinal cancer.
3. You have a medical condition, which includes but is not limited to: active or a history of inflammatory bowel disease, diagnosis of gastroparesis, active/ongoing infection, uncontrolled diabetes mellitus, chronic renal failure, liver disease, cardiac disease, severe chronic obstructive pulmonary disease, significant neurological disease, cancer/ malignancy in the last 5 years, diagnosed lactose or fructose intolerance, you are immunocompromised or have a immunodeficiency syndrome of any kind.
4. You have been diagnosed with infectious gastroenteritis within 1 month before screening.
5. You have had a significant surgery over the last year that continues to affect your daily function, or have a surgery planned during the study period.
6. You have started a new treatment for digestive symptoms in the last 8 weeks.
7. You have used antibiotics, antifungals, antivirals, or antiparasitic medicines within 8 weeks before screening.
8. You currently, or in the last 3 months, take antipsychotic medications or systemic steroids.
9. You currently take the following medications more than three days a week: opiates, non-steroidal anti-inflammatory drugs, laxatives, anti-diarrhoeal, cholestyramine, colchicine, iron supplements, antispasmodics, or benzodiazepines.
10. You have changed your prescription medication in the last 4 weeks or expect to change it during the study
11. In the last 4 weeks, you have used supplements containing probiotics, prebiotics, or digestive enzymes, or expect to start these during the study period
12. In the last 4 weeks, you started or changed the dose of nutritional and/or herbal supplements that may impact treatment outcomes, or expect to change them during the study
13. In the last 8 weeks, you have made significant dietary or lifestyle changes that might affect gastrointestinal function, or expect to make changes during the study period
14. You consume more than 14 standard alcoholic drinks per week
15. You have a current or 12-month history of regular illicit drug use
16. You are pregnant, breastfeeding, or intend to fall pregnant during the study period
17. You have participated in another clinical trial in the last month

Voluntary participation and withdrawal from the study

It is important that you understand that your involvement in this study is voluntary. While we are grateful to have you participate, we respect your right to decline. There will be no consequences to you if you decide not to participate, and this will not affect any future treatment/service. If you decide to discontinue participation at any

time, you may do so without providing an explanation. If you withdraw, any assessments already conducted may continue to be used for analysis.

Please note that if you choose to commence a treatment to improve your digestive symptoms, or you require medical treatment for any other condition during the study, this may result in withdrawal from the study. Your health is the utmost priority, and your choice/need to commence new treatment before completing this study is respected and supported.

Your privacy

Your privacy is very important to us. Your participation in this study and any information provided will be treated in a confidential manner. Your name and identifying details will not be used in any publication arising out of the research. Following the study, the data will be kept in a de-identified format, in a locked cabinet in the office of the Investigator and will be held for statistical analysis for future publication. Re-identifying codes will be retained for 6 months in case this is needed and will then be destroyed.

Possible benefits

In previous studies, probiotics and digestive enzymes have been shown to help reduce troublesome digestive symptoms and improve gastrointestinal health. However, there are different types (species) of probiotics, and the composition of digestive enzymes varies. This can influence their tolerability, safety, and efficacy. These ingredients are also often administered in isolation, rather than in combination. If Weizy® + Poolzyme ® MULTI is found it be effective, it provides consumers with a supplement that has been demonstrated in a well-controlled clinical trial to be effective for people with gastrointestinal complaints.

Possible risks

Participation in this study carries little risk, and many measures will be in place to decrease the likelihood of potential risks. The probiotics and digestive enzymes used in the study are available over the counter in Europe. They have been shown to be well tolerated. Their safety has also been confirmed in previous clinical trials. However, mild adverse and typically transient gastrointestinal reactions are possible with probiotics, including gas, bloating, and diarrhoea.

What to do if you experience significant side effects

If you experience any significant illness, injuries, or side effects that have commenced since starting your tablets, please immediately contact Dr Adrian Lopresti or Dr Stephen Smith (contact details are below). You may be asked to stop participating in the study and to seek medical advice.

Dr Stephen Smith: Ph: 9448 7376 | Mob: 0412 813 518 | Email: steve@clinicalresearch.com.au

Dr Adrian Lopresti: Ph: 9448 7376 | Mob: 0411 969 797 | Email: adrian@clinicalresearch.com.au

Feedback on study results

It is estimated that the results of this study will be finalised in mid-2026. A summary of the results obtained from all participants in this study will be emailed to you when they have been published in a peer-reviewed journal (usually 6 to 12 months after the completion of the study).

Questions

If you would like to discuss any aspect of this study, please contact Dr Adrian Lopresti on 08 9448 7376.

We would like to thank you in advance for your assistance with this research project.

If you are interested in participating in this study, please contact Dr Adrian Lopresti on 9448 7376 or email adrian@clinicalresearch.com.au

This study has been approved by the National Institute of Integrative Medicine (NIIM) Human Research Ethics Committee (HREC) (Trial Reference Number: 0156E_2025). If you have any reservations or complaints about the ethical conduct of this research and wish to talk with an independent person, you may contact the NIIM Research Ethics Office (Tel. 03 9804 0646) or email hrec@niim.com.au). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.