GASTRO-AD® STUDY SUMMARY

Lallemand Health Ingredients

SUMMARY OF CLINICAL TRIAL

Fermented soy supplementation improves indicators of quality of life: a randomized, placebo-controlled, double-blind trial in adults experiencing heartburn.

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INTRODUCTION

The effect of Gastro-AD®, a fermented soy supplement, was examined on heartburn, gastrointestinal symptoms and heartburn-related quality of life indicators.

KEY FINDINGS

- Gastro-AD® may reduce heartburn frequency over time.
- Gastro-AD® may reduce the occurrence of diarrhea over time.
- Gastro-AD® may alleviate stomach bloating over time.
- Within 3 weeks Gastro-AD® contributed to an improved quality of life in people with acid reflux and heartburn symptoms.
- People with acid reflux and heartburn symptoms who took Gastro-AD® felt more comfortable taking their regular medications.
- Over time, those taking Gastro-AD® may be less afraid to consume their favorite foods and drinks due to expected acid reflux and heartburn symptoms.
- People taking Gastro-AD® were less afraid of overeating due to anticipated/expected acid reflux and heartburn symptoms.
- For those suffering from acid reflux and heartburn symptoms Gastro-AD® improved their ability to focus on work.
- Gastro-AD® intake allowed people with acid reflux and heartburn symptoms to better enjoy their after-meal activities.
- Gastro-AD® supported a calmer after-meal rest in people with acid reflux and heartburn symptoms.

METHODS

Study Design

A 5-week, randomized, double-blind, placebo-controlled, parallel-group study.

Study participants

Participants (18–60 years) were included if they experienced mild or moderate heartburn symptoms according to the Global Overall Symptom (GOS) questionnaire at least 2 days/week and used over-the-counter (OTC) products for heartburn, supplements, or dietary manipulation to relieve heartburn symptoms during the previous 3 months.

50 participants were included. 23 were provided with Gastro-AD® and 27 were provided with the placebo. Participants were selected based on inclusion/exclusion criteria between March and May 2019 in the state of Florida, U.S.A.

Procedures

Participants completed a 1-week baseline and on day 8, after confirmation of the inclusion/exclusion criteria, were randomized to receive either Gastro-AD® or placebo (maltodextrin) for 3 weeks, followed by a 1-week washout. The "baseline", "3 weeks supplementation" and "washout" were defined as 3 study periods.

A 3-week supply of orange-flavored supplements was provided in coded, identical packaging (9 x 1g opaque sachets/day).

- Participants were instructed to consume 1 sachet upon heartburn event and then record symptom intensity at 5, 15 and 30 min after administration.
- If this first sachet did not alleviate the heartburn symptoms completely, the participant could take another sachet and repeat the symptom reporting at 5, 15 and 30 min.
- If the heartburn symptoms persisted beyond the second 30 min period, participants could take a third sachet OR follow their regular, pre-study, routine with heartburn incidence (including consumption of an OTC heartburn medication).
- 9 sachets were provided, to treat up to 3 heartburn incidents per day.

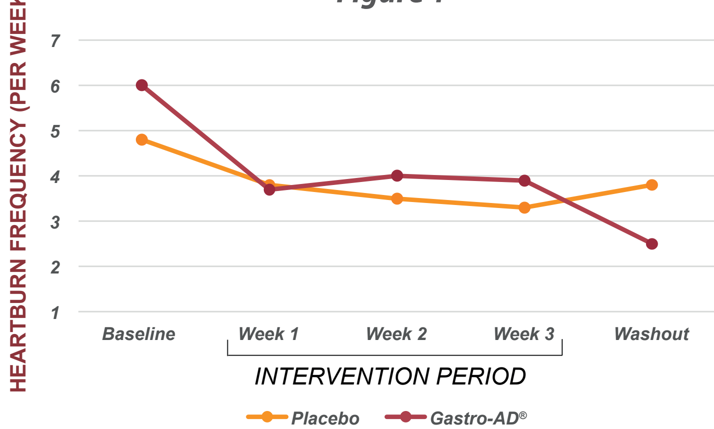
Participants recorded their use of study supplements and any OTC medication in booklets provided. They completed daily questionnaires regarding heartburn severity and frequency using a Likert-like scale (1 = no symptoms to 5 = severe discomfort).

Other secondary outcomes, including the Gastrointestinal Symptom Rating Scale (GSRS) (1-no discomfort to 7-very severe discomfort) and Gastroesophageal Reflux Disease Quality of Life Questionnaire (GERD-QOL) (4-strongly disagree to 0-strongly agree), were assessed during study visits at the end of each period.

RESULTS

Intake of study supplements during the intervention period was 15.3 ± 18.3 sachets/ participant for the Gastro-AD® group and 15.0 ± 11.2 sachets/participant for the placebo group. No differences were seen for OTC medication intake (Gastro-AD®: 0.4 ± 0.9; placebo: 0.6 ± 1.4 times/person).

Figure 1



Heartburn frequency by week is shown in Figure 1. No significant difference was seen for heartburn frequency from baseline between groups during the intervention period; however, Gastro-AD® significantly reduced heartburn frequency compared to the placebo during the washout period.

Gastrointestinal Symptom Rating Scale (GSRS)

There were significant differences between the Gastro-AD® and placebo groups, for the individual GSRS items, "Have you been bothered by diarrhea during the past week?" (Gastro-AD®: 0.3 ± 1.4 vs placebo: – 0.3 ± 1.2, $p < 0.05$) and "Has your stomach felt bloated during the past week?" (Gastro-AD®: 0.7 ± 1.7 vs placebo: 0.1 ± 1.3, $p < 0.05$), representing an improvement in the Gastro-AD® group.

Gastroesophageal Reflux Disease Quality of Life Questionnaire (GERD-QOL)

Figure 2 shows that there were significant differences favoring Gastro-AD® for the responses to the GERD-QOL items including:

a. "I found it inconvenient to have to take medications regularly because of acid reflux and heartburn symptoms" (– 1.0 ± 1.3 vs – 0.04 ± 1.8, $p < 0.05$).

b. "I was afraid to eat too much because of acid reflux and heartburn symptoms," (–1.4 ± 1.3 vs – 0.2 ± 1.7, $p < 0.05$).

c. "I was unable to focus on my work because of acid reflux and heartburn symptoms" (– 0.9 ± 1.6 vs – 0.3 ± 1.0, $p < 0.05$).

d. "Acid reflux and heartburn symptoms disturbed my after-meal activities or rest" (– 1.6 ± 1.5 vs – 0.7 ± 1.5, $p < 0.05$).

There were also significant differences favoring Gastro-AD® between baseline and washout for

- "Fear of eating favorite foods or drinks" (– 1.3 ± 1.6 vs – 0.4 ± 1.5, $p < 0.05$).
- "Disturbance of after-meal activities and rest" (– 1.6 ± 1.7 vs – 0.5 ± 1.6, $p < 0.05$).

Figure 2a: taking medication

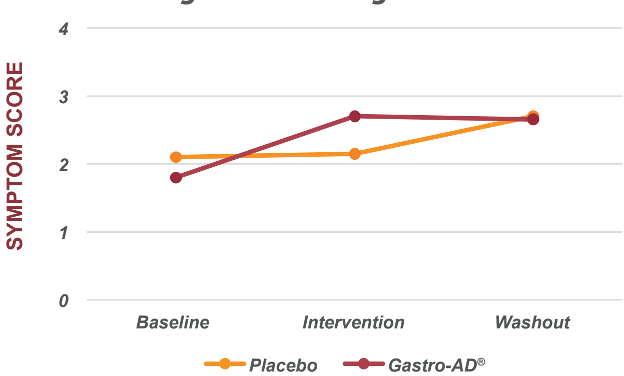


Figure 2b: eating too much

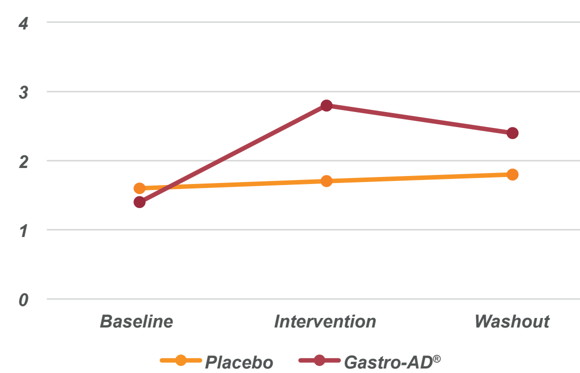


Figure 2c: focus on work

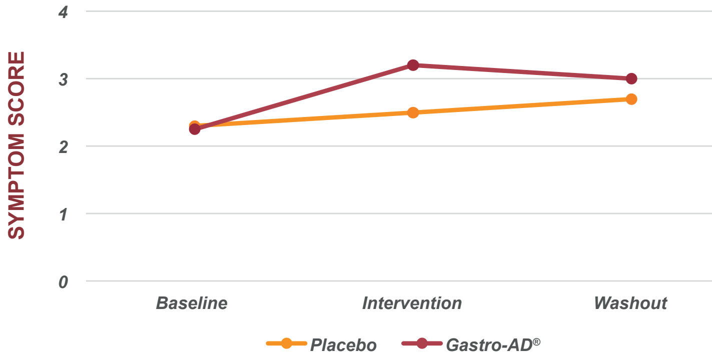
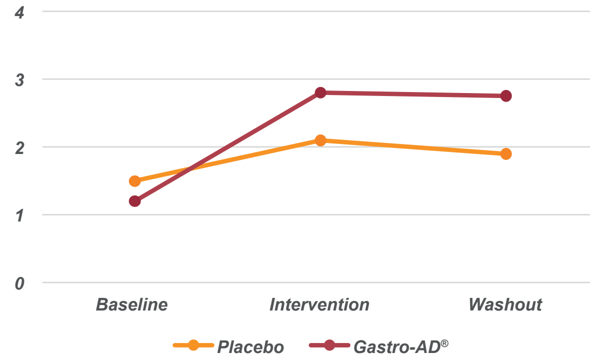


Figure 2d: activities & rest



DISCUSSION

In general, Gastro-AD® relieved heartburn symptoms in a similar way to the placebo. However, those participants receiving Gastro-AD® showed a reduction in heartburn frequency during washout and a downwards trend from baseline suggesting that there may be an effect of the fermented soy supplementation over time. It is possible that prophylactic administration of Gastro-AD®, perhaps daily, may decrease heartburn frequency over time by reducing inflammation due to the bioactive soy peptides produced by the Rosell-187 during the fermentation.

Individual quality of life items improved with Gastro-AD®. Although a reduction of heartburn frequency was observed only during washout period, enhancements of some aspects of quality of life - specifically less fear of eating and disruptions of work and activities - were reported during the supplementation period with fermented soy.

CONCLUSIONS

Overall, in individuals with mild to moderate heartburn, Gastro-AD® improved important indicators of heartburn-related quality of life and may have potential benefits for reducing heartburn frequency over time. Future research should examine whether reduction in heartburn frequency occurs with daily supplementation over time.

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