CLINICAL RESEARCH CASE STUDY
Probiotics And Weight Management

Investigating the Effect of a Probiotic on Body Composition and Weight Management in Overweight Adults

Presented by:

atlantia
clinical trials

Executive Summary

Visceral adipose tissue accumulation is currently an important research target because of its connection to metabolic disturbances, cardiovascular disease and type 2 diabetes. This study illustrates how Atlantia designed and conducted a study to investigate the outcome of probiotics supplementation in body composition and weight management assessed through DXA scans.

The research clinic that the company owns and operates in Cork seemed a perfect fit to recruit overweight subjects within the sponsors expected timeline.

Challenges and Objectives

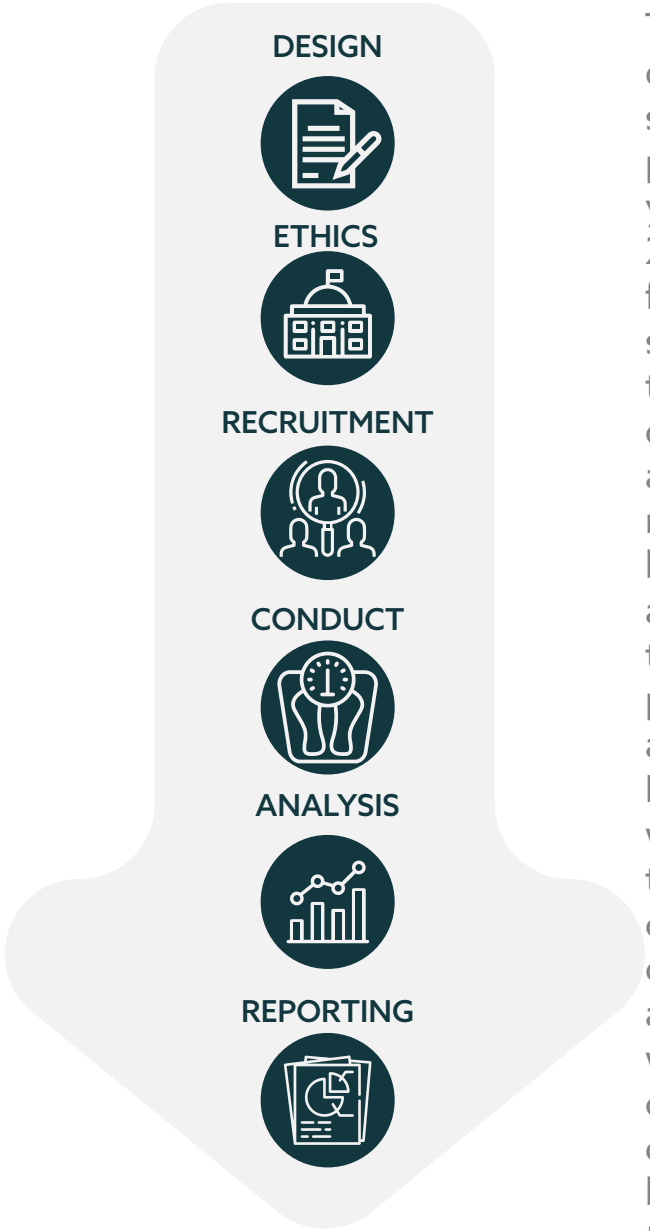
The rationale for the current study is to perform a follow-up randomized controlled trial to continue to build the evidence for this probiotic strain in the area of weight management. The sponsors needed a trusted partner able to access to the required study population, with enough expertise to design and conduct a gold-standard trial with probiotics to achieve the following objectives:

- To determine the effect of daily administration of a probiotic strain on Visceral Adipose Tissue (VAT), as well as on other secondary biomarkers and efficacy parameters.
- To determine the effect of a daily administration of a probiotic strain on faecal characteristics.

How Atlantia's Solution Helped

Atlantia's world-class team of nutritionists and research nurses worked closely with the Sponsors' researchers to design and deliver the study objectives. Ireland has one of the highest rates of obesity in Europe. The percentage of people who were classified as overweight or obese in 2015 was 60% (Irish Health Survey), and this has risen to 62% in 2017 (CSO). The research clinic that the company owns and operates in Cork seemed a perfect fit to recruit overweight subjects within the sponsors expected timeline. The company's expertise measuring VAT by DXA was a key factor on the conduction of this project.

About the Study



This study was a single-centre, randomised, double-blind, placebo-controlled, parallel study in overweight volunteers. The study population was aged between 25 and 65 years old with a body mass index between 25.0 to 29.9 Kg/m2, a waist-hip ratio of ≥0.91 for males and ≥0.81 for females, having a sedentary lifestyle (exercising less than 2 times per week). The participants should be outside the healthy parameters of visceral adipose tissue, defined as 762 cm3 for males and 256 cm3 for females, assessed by DXA scans. Other exclusion criteria were also considered. Participants were recruited through Atlantia's database, social media platforms, General Practitioners offices and advertisements in local media.

Participants who met the eligibility criteria were randomised (ratio 1:1) to one of the two treatment groups prior writing informed consent: a capsule containing the optimal dose as per the Sponsors pre-clinical results and placebo. Each eligible participant was assigned a randomisation number in chronological order, which corresponds to one of the two groups. The relationship between the randomisation number and the group assignment was unknown to the clinical research team, the sponsor, study site staff, or the participants.

The study involved visits over a 15-week period, per participant, including a run-in phase and the intervention period. Participants were instructed to consume one capsule per day, before breakfast for the duration of the study, they were retrained if their compliance was not suitable.

A fasting blood sample was collected at various visits. Additional plasma and serumwere stored at -80oC at Atlantia's facilities, for future exploratory analysis of inflammatory and satiety biomarkers. Participants were provided with a stool collection kit and instructions for collecting and storing at home. Participants returned the stool sample and they were stored at -80oC, for future exploratory analysis including sequencing, SCFA analysis and detection of the strain.

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Discuss your research program with our clinical trial experts:

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