

# The ShapeLine Study

The largest human study on the effect of probiotics on weight loss

Double-blind, randomised, placebo-controlled study (the gold standard of clinical trials)

220 healthy adults (BMI 25-35, waist circumference >89cm for women or >100cm for men) took one capsule per day for six months and **maintain normal diet and lifestyle**

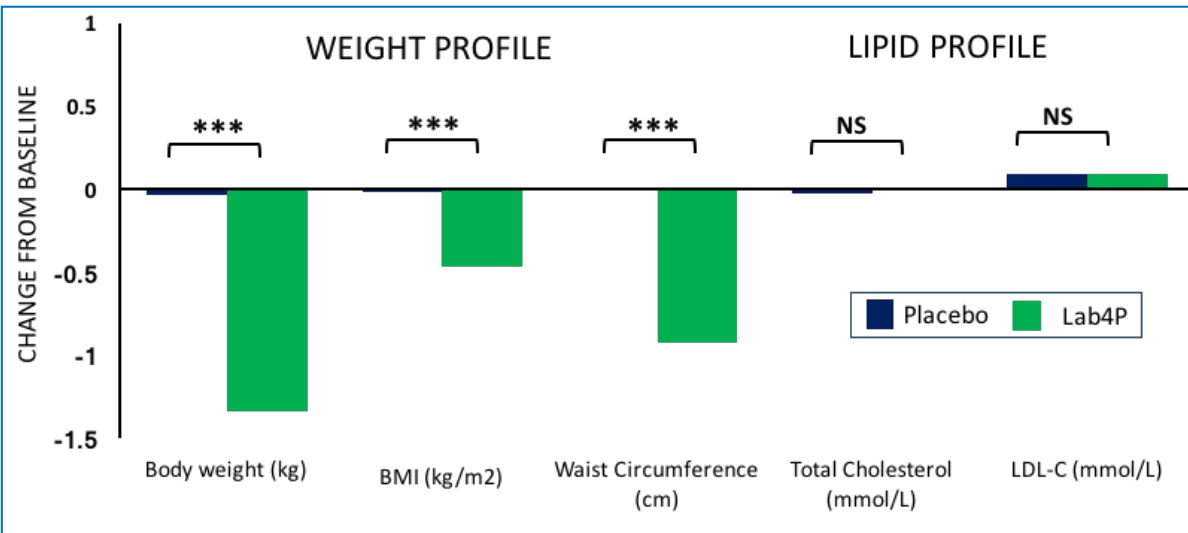
Active group (110) took the Lab4P probiotic consortium (Lab4 plus *Lactobacillus plantarum*)

Placebo group (110) took an identical looking inert capsule

After 6 months – ProVen ShapeLine group showed:

- **Reduction in a) weight (3lbs), b) waist circumference (1cm), c) BMI**
- **Reduction in upper respiratory tract infections, headaches and muscle pain**
- **Improvement in Quality of Life measures**

Study published in Scientific Reports on 6<sup>th</sup> March 2020 (<https://www.nature.com/articles/s41598-020-60991-7>)



## ShapeLine Study 2

Follow-up trial completed with sub-group of 70 healthy adults (BMI 25-29, age 45-65) over nine months

Focus on overweight people aged over 45 – the group that had the best results in the first study

Double-blind, randomised, placebo-controlled study – two groups of 35 (one probiotic, one placebo)

Research analysis and writing currently being completed – paper due to be published later in 2020

Initial results look to be even better than the first study

**OPEN** A randomised controlled study shows supplementation of overweight and obese adults with lactobacilli and bifidobacteria reduces bodyweight and improves well-being

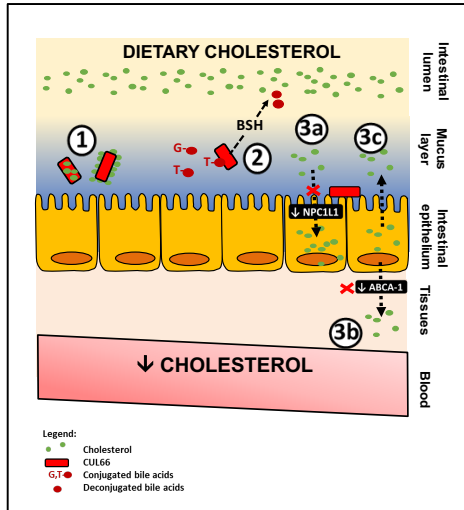
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In an exploratory, block-randomised, parallel, double-blind, single-centre, placebo-controlled superiority study (SR121262026, funded by Cultech Ltd), 220 Bulgarian participants (30 to 65 years old) with BMI 25–34 kg/m<sup>2</sup> received Lab4<sup>®</sup> probiotic (50 billion CFU) or a matched placebo for 6 months. Participants maintained their normal diet and lifestyle. Primary outcomes were changes in body weight, BMI, waist circumference (WC), waist-to-height ratio (WHR), blood pressure and plasma lipids. Secondary outcomes were changes in plasma C-reactive protein (CRP), the diversity of the faecal microbiota, quality of life (QoL) assessments and the incidence of upper respiratory tract infection (URTI). Significant between-group decreases in body weight (3.3 kg, p < 0.0001), BMI (0.045 kg/m<sup>2</sup>, p < 0.0001), WC (0.34 cm, p < 0.0001) and WHR (0.06, p < 0.0001) were in favour of the probiotic. Stratification identified greater body weight reductions in overweight subjects (1.88 kg, p < 0.0001) and in females (1.62 kg, p = 0.0005). Greatest weight losses were among probiotic hypercholesterolaemic participants (–2.29 kg, p < 0.0001) alongside a significant between-group reduction in small dense LDL-cholesterol (0.2 mmol/L, p = 0.0241). Improvements in QoL and the incidence rate ratio of URTI (0.60, p < 0.0001) were recorded for the probiotic group. No adverse events were recorded. Six months supplementation with Lab4P probiotic resulted in significant weight reduction and improved small dense low-density lipoprotein-cholesterol (sdLDL-C) profiles, QoL and URTI incidence outcomes in overweight/obese individuals.

World Health Organisation (WHO) global estimates indicate that 39% of adults are overweight and 13% are obese and trends suggest that levels will continue to rise as a result of current dietary habits and sedentary lifestyles<sup>1</sup>. The burden of obesity on primary healthcare providers is substantial and it is estimated that in England alone in 2015, excess body weight in women cost £2.2 billion in consultations and £1.9 billion for prescription medications<sup>2</sup>. One of the consequences of obesity is the increased incidence of Metabolic Syndrome (MetS) – an umbrella term used for a cluster of interrelated metabolic conditions linked with obesity including hypercholesterolaemia.

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## Lab4P proposed mechanism of action



### 1. CHOLESTEROL REMOVAL

Cholesterol is bound or metabolised by Lab4P and subsequently removed in faeces

### 2. BILE SALT HYDROLASE ACTIVITY

Deconjugation (modifying) of bile acids leads to their reduced re-absorption and places an increased demand on the liver to synthesize more bile acids from circulating cholesterol in blood to replenish intestinal bile acids lost in faeces

### 3. REDUCTION OF CHOLESTEROL TRANSPORT ACROSS THE INTESTINAL EPITHELIUM

**3a** reduction in the uptake of extracellular cholesterol and reduced expression of the NCP1L1 cholesterol transporter;

**3b** reduction in the efflux of intracellular cholesterol to the basolateral compartment (tissues) and reduced expression of the ABCA-1 cholesterol transporter;

**3c** no change on the intracellular cholesterol efflux back into the apical (intestinal lumen) compartment

## ShapeLine Case Study

Name: Ana Ivanov\*

Age: 56

Occupation: University Assistant Professor

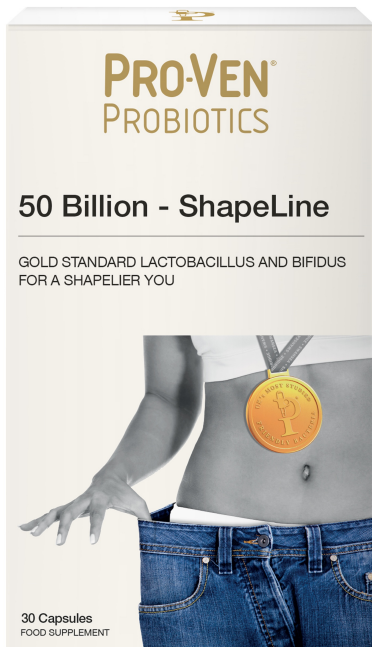
From: Sofia, Bulgaria

From 30 onwards I noticed a change in my weight; I found it more and more difficult to keep a healthy weight. In particular, I have become more prone to fat accumulation around the stomach and hip area. My current level of physical activity is around 1-3 hours per week – when I was younger increasing my level of exercise would help contribute to weight loss however as the years have passed, it has become increasingly difficult for me to lose weight through exercise.

Prior to ShapeLine, I hadn't tried any supplements or medicines to help with weight loss. I heard about ShapeLine through a friend who was participating in the study and decided to volunteer. My experience with ShapeLine has been very good, I noticed substantial weight loss after the 6 months of taking ShapeLine on a daily basis and haven't had any severe side effects. I lost a total of 5kg, clothes feel looser and have received a number of compliments from family members. As well as the weight loss I have noticed an increase in my energy levels, overall mood and I feel healthier.

I have maintained the weight loss achieved and will now definitely consider purchasing the supplement going forward. I would wholeheartedly recommend to my friends and relatives.

\*To get ethics approval for the study, names have had to remain anonymous



**50 Billion – ShapeLine** is a high-strength probiotic supplement that contains 33.5 billion Lab4 probiotics with 16.5 billion *Lactobacillus plantarum* (CUL66) per capsule - the exact level used in the ShapeLine clinical trial.

It is the first human microflora product that, when taken daily for 6 months at one capsule a day, has been shown to help support weight loss, reduce waist size and lower BMI.

Contains Lab4 probiotics, the most researched group of friendly bacteria in the UK, along with *Lactobacillus plantarum*, an additional strain of live bacteria, proven to reduce cholesterol (collectively known as Lab4P).

**50 Billion – ShapeLine** also contains nutrients to help support the immune system (vitamin C, vitamin D and zinc).

## 50 Billion - ShapeLine

### Nutritional Information

Serving Size:	1 Capsule	
Servings Per Pack:	30	
Amount Per Serving		%NRV*
Vitamin D	10µg	200%
Vitamin C	80mg	100%
Zinc	10mg	100%

### Lab4P Consortium

<i>Lactobacillus acidophilus</i> (CUL60)	33.5 billion viable cells	†
<i>Lactobacillus acidophilus</i> (CUL21)		†
<i>Bifidobacteria animalis subsp. lactis</i> (CUL34)		†
<i>Bifidobacteria bifidum</i> (CUL20)		†
<i>Lactobacillus plantarum</i> (CUL66)		†
	16.5 billion viable cells	