

# A study to investigate the effect of probiotics in combination with fish oil on metabolic risk factors in overweight and obese subjects following caloric restriction diet

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<b>Registration date</b> 21/03/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/01/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Hypercholesterolaemia (high blood cholesterol) is one of the risk factors for cardiovascular (heart) disease. Probiotics are live bacteria and yeasts promoted as having various health benefits. There is a growing evidence that some probiotic organisms lower cholesterol and may contribute to disease prevention. This study assesses the effect of probiotics in combination with fish oil on blood lipids (fats) and other markers of cardiovascular risk in obese and overweight adults following a calorie restricted diet.

### Who can participate?

Overweight and obese adults aged 18 and over

### What does the study involve?

Participants are randomly allocated to take either probiotics in combination with fish oil or placebo (dummy) capsules for 12 weeks. All participants are on a calorie restricted diet for 8 weeks followed by their standard diet for 4 weeks. Participants provide blood samples and their body composition is measured at the start of the study and after 8 and 12 weeks. Participants also complete food and health diaries.

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

Participants who receive probiotics in combination with fish oil may benefit from the improvement of their lipid profile and reduction of metabolic risk factors. There are no known risks to participants. Participants with food allergy or intolerance to any of the product components are excluded.

### Where is the study run from?

Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry, Comenius University, Bratislava (Slovakia)

When is the study starting and how long is it expected to run for?  
May 2015 to April 2016

Who is funding the study?  
Cultech Ltd (UK)

Who is the mail contact?  
Assoc. Prof. Jana Muchova, PhD

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Jana Muchova

**ORCID ID**  
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**Contact details**  
Institute of Medical Chemistry Biochemistry and Clinical Biochemistry  
Medical School  
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81108

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
V1.0

## Study information

**Scientific Title**  
A study to investigate the effect of probiotics in combination with fish oil on metabolic risk factors in overweight and obese subjects following caloric restriction diet

**Acronym**  
ProWL

**Study objectives**

The study aims to investigate the impact of a probiotic and fish oil combination on lipid subfractions and cardiovascular risk factors in overweight and obese subjects following 8 weeks calorie restricted diet.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethical committee of Medical School, Comenius University in Bratislava, Slovakia, 14/04/2015

**Study design**

Randomised double-blind placebo-controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Probiotic and fish oil combination on lipid subfractions and cardiovascular risk factors

**Interventions**

Participants randomised to active or placebo group will be required to take two capsules twice a day for 12 weeks:

1. Active intervention: Lab4p probiotic consortium capsule (L. acidophilus CUL60, L. acidophilus CUL21, L. plantarum CUL66, B. bifidum CUL20 and B. lactis CUL34) at  $10 \times 10^{10}$  cfu per day and fish oil capsule containing 1 500 mg of a total omega 3 fatty acids per day
2. Placebo intervention: maltodextrin and sunflower oil capsules

All participants will be on a calorie restricted diet for 8 weeks followed by their standard diet for 4 weeks. Participants will provide venous blood samples and body composition measurements at baseline, 8 and 12 weeks. Participants will need to complete food and health diaries.

**Intervention Type**

Supplement

**Primary outcome measure**

1. Blood lipid profile (total cholesterol, LDL cholesterol, HDL, triacylglycerols), glucose, insulin and hsCRP levels are measured using the ADVIA 1800 Chemistry System at baseline, 8 and 12 weeks

2. HDL and LDL subfractions are determined using the Lipoprint® LDL and HDL systems at baseline, 8 and 12 weeks
3. Body composition measurements are determined using the InBody 230 at baseline, 8 and 12 weeks

### **Secondary outcome measures**

1. Systolic and diastolic blood pressure are measured using blood pressure monitor at baseline, 8 and 12 weeks
2. Markers of oxidative stress, hormones and vitamins are determined by HPLC or ELISA assays at baseline, 8 and 12 weeks

### **Overall study start date**

01/05/2015

### **Completion date**

01/04/2016

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged  $\geq 18$  years
2. BMI between 25 to 35 kg/m<sup>2</sup>
3. Participants are willing to give written informed consent
4. Participants who are willing to follow the caloric restricted diet for 8 weeks of the study period
5. Participants who are willing to avoid the use of other weight loss products during the study period
6. Participants who are willing to provide blood samples
7. Participants who are willing to avoid other probiotic, fish oil or oily fish use for the duration of the study

### **Participant type(s)**

Other

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

40 participants

### **Key exclusion criteria**

1. Participants who have BMI  $\leq 24.9$  kg/m<sup>2</sup> and  $\geq 36$  kg/m<sup>2</sup>
2. Participants who are unable/unwilling to give written informed consent
3. Participants who are not prepared to provide blood samples as required
4. Participants with known or suspected food allergy or intolerance to one of the intervention

products' components.

5. Participants who refuse to stop taking any probiotics supplements, dairy probiotic product (yoghurt with biocultures, Acidophilus milk, kefir, Actimel, Yakult, etc) and omega 3/fish oil supplements apart from the intervention products during the study period
6. Participants who have undergone bariatric surgery
7. Participants with three months of weight instability before study enrolment or known history of eating disorders (anorexia nervosa, bulimia nervosa)
8. Participants with diabetes mellitus 1st and 2nd type
9. Participants with personal history of severe chronic diseases (cancer, HIV, kidney failure, liver damage, diagnosed gastrointestinal disorders, arthritis, chronic respiratory failure, etc)
10. Pregnant or breastfeeding women or intending to become pregnant within next 3 months
11. Participants who had taken antibiotics within 4 weeks prior to enrolment
12. Participants with alcohol intakes > 14 units/week or 3 units/day
13. Participants fitted with any electronic implantable device (contraindicated for bioelectrical impedance analysis)

**Date of first enrolment**

08/09/2015

**Date of final enrolment**

30/09/2015

## **Locations**

**Countries of recruitment**

Slovakia

**Study participating centre**

**Comenius University**

Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry, Medical School  
Sasinkova 2  
Bratislava  
Slovakia  
81108

## **Sponsor information**

**Organisation**

Cultech Ltd

**Sponsor details**

Unit 2-3  
Christchurch Road  
Baglan Industrial Park

Port Talbot  
United Kingdom  
SA12 7BZ

**Sponsor type**  
Industry

**Website**  
<http://www.cultech.co.uk>

**ROR**  
<https://ror.org/00555bk04>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Cultech Ltd (UK)

## **Results and Publications**

**Publication and dissemination plan**  
Planned publication in a high-impact peer reviewed journal

**Intention to publish date**  
31/12/2019

**Individual participant data (IPD) sharing plan**  
The datasets generated during and/or analysed during the current study are/will be available upon request from Assoc. Prof. Jana Muchova, PhD

**IPD sharing plan summary**  
Available on request