

# The effect of a fishball meal with or without a soluble fibre (viscogum) on food intake and ratings of appetite

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 24/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/05/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Locust bean gum is a soluble fibre that increases food viscosity (making it thicker, for example, or less easy to pour). It takes a long time to be digested which means it has the potential to make people feel fuller and more satisfied for longer after eating a meal (increased satiety) without the need to provide more food with more calories. The effects of locust bean gum on satiety may be related to its effects (delay) on gastric emptying (the amount of time it takes for food to be taken from the stomach into the small intestine). We want to look at how locust bean gum (viscogum) added to a fishball meal might affect how much people eat of the meal, how quickly they eat it, how full they feel afterwards and how much they eat at their next meal.

### Who can participate?

Adult females aged between 18-55 that are either overweight or obese, with a body mass index (BMI) of 27.0 31.9.kg/m<sup>2</sup>.

### What does the study involve?

Participants are asked to attend two full testing days. For both days they eat a breakfast, a fixed lunch (the fishball meal) and a dinner of which they can eat as much as they like in the University of Liverpool's eating behaviour laboratory (Kissileff Laboratory). Each participant is randomly allocated to eat either a fishball meal with the viscogum added or a control fishball meal (which doesn't include the viscogum) on their first visit. They then have a break from the testing for a week (referred to as a wash out period) before coming back to the laboratory to eat their second meal. Participants who ate the fishball meal with the viscogum on their first visit are given the control fishball meal on their second visit and vice versa. Each participant is also asked to attend screening and testing sessions, which includes filling in a series of questionnaires and measuring their height and weight, before coming in for the two full testing days.

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

There are no direct benefits to participating but knowledge gained will help to better understand what kind of foods may help people control their weight. All the foods used in the study are either commonly available or specifically developed to be eaten from a combination of

commonly available foods with extensive food safety tests and are cooked in a conventional manner. Viscogum (guar gum) comes from the from the Carob plant, a natural source used in modern food processing. In the unlikely event of an emergency, The Kissileff Laboratory has dedicated first-aiders and an emergency procedure is in place should this be necessary.

Where is the study run from?

The Kissileff Laboratory in the University of Liverpool (UK)

Who is funding the study?

The University of Liverpool as part of the European Union funded Satiety Innovation (SATIN) Grant (UK)

Who is the main contact?

Dr. Joanne Harrold (harrold@liverpool.ac.uk)

Prof. Jason Halford (j.c.g.halford@liverpool.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

Scientific Title

Experimental study to investigate the acute effect of a fishball meal enriched with locust bean gum (Viscogum) on food intake and the experience of appetite

### **Study objectives**

To investigate the impact of a fishball meal with (experimental) or without (control) a soluble fibre (Viscogum) on food intake, feeding behaviour and experience of appetite in female volunteers with a BMI of 27-31.9 kg/m<sup>2</sup>

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Liverpool Committee of Research Ethics, 24/07/2014, ref: RETH000565

### **Study design**

Randomized crossover within subjects design with two conditions

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

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

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

Effects of a soluble fibre type on appetite to inform about future weight interventions/obesity

### **Interventions**

The study will involve 34 female participants attending the Kissileff Laboratory on two study day visits in which they will receive the active (viscogum guar gum) fishball meal for lunch on one day and a control (placebo) fishball meal on a separate day. Participation will include a 1-week wash out period between visits. All participants will undergo both conditions which will be randomized using a Latin Square design.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Current primary outcome measures as of 25/05/2017:

Changes in energy intake (weight (grams) and calories (kcal) consumed) after intake of a lunch containing either soluble fibre or no fibre. Specifically looking at dinner and evening snack intake.

Previous primary outcome measures:

To demonstrate:

1. Reductions in eating rate at a fixed load meal including consumption of viscogum containing fishballs in comparison to control (calculated as grams consumed per minute)
2. Reductions in caloric intake at a subsequent ad libitum meal following consumption of viscogum containing fishballs in comparison to control (measuring food intake - grams/calories consumed)
3. 24 hour reduction in caloric intake in ad-libitum meals following consumption of viscogum containing fishballs in comparison to control (measuring food intake - grams/calories consumed)

### **Secondary outcome measures**

Current outcome measures as of 25/05/2017:

1. Appetite (hunger, fullness, prospective intake, desire to eat) is measured using the visual analogue scale with measurements taken throughout the test day (hourly) and at pre- and post-meal as well as during the meal consumed (every 50g eaten) with a meal either containing a soluble fibre or containing no fibre.
2. Changes in meal duration of a fixed load meal including fibre containing fishballs compared to the control at the time of intake during the meal.
3. Changes in macronutrients intake and duration of a subsequent ad libitum meal following consumption of fibre containing fishballs compared to the control.

Previous secondary outcome measures:

To investigate:

1. Changes in within meal satiation during ingestion of viscogum containing fishballs compared to control using Visual Analogue Scale (VAS) appetite measures (hunger, fullness, prospective consumption, desire to eat)
2. Changes in meal duration of a fixed load meal including viscogum containing fishballs compared to control (measuring time of intake during the meal)
3. Changes in macronutrient intake and duration of a subsequent ad libitum meal following consumption of viscogum containing fishballs compared to control
4. Subjective experience of appetite and snack palatability using Visual Analogue Scale (VAS) measures

### **Overall study start date**

25/08/2014

### **Completion date**

01/01/2015

## **Eligibility**

### **Key inclusion criteria**

1. Participants having given written consent to take part in the study
2. Healthy female participants aged 18 to 55 years
3. BMI of 27.0 - 31.9 kg/m<sup>2</sup>
4. Not dieting within the last month or having lost a significant amount of weight over the

previous 6 months

5. Not increased physical activity levels in the past 2-4 weeks or intending to modify them during the study

6. Non-smokers

7. Able to eat most everyday foods

8. Consume fish products

9. Breakfast eaters

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

34

**Key exclusion criteria**

1. Those with significant health problems

2. BMI < 27.0 kg/m<sup>2</sup> or > 31.9 kg/m<sup>2</sup>

3. Participants who self-report dieting currently or within the last month or having lost a significant amount of weight over the previous 6 months

4. Volunteers who have significantly changed their physical activity patterns in the past 2-4 weeks or who intend to change them during the study

5. Gastrointestinal symptoms requiring treatment

6. Smokers or those who have recently ceased smoking (including electric cigarettes)

7. Participants receiving systemic or local treatment likely to interfere with evaluation of the study parameters

8. Pregnant or planning to become pregnant during the study; breast-feeding (self-reported)

9. Participants with a history of anaphylaxis (allergic reactions) to foods

10. Participants who work in the following areas: Nutrition, Dietetics, Food Research, Food Manufacturing or Supplements Industry

11. Participants currently adhering to any specific food avoidance diets such as Atkins, the South Beach diet or low Glycaemic Index (GI)

12. Participants who have had bariatric surgery for weight control or other reason

13. Non breakfast eaters

14. Post-menopausal participants

15. Those reporting a history of anaphylaxis to food, significant general food allergies or specific allergies to any of the study foods

16. Participants with abnormal eating behaviour

**Date of first enrolment**

25/08/2014

**Date of final enrolment**

01/01/2015

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**University of Liverpool,**

Psychological Sciences

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## **Sponsor information**

### **Organisation**

University of Liverpool (UK)

### **Sponsor details**

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### **Sponsor type**

University/education

### **Website**

<http://www.satin-satiety.eu/>

### **ROR**

<https://ror.org/04xs57h96>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

University of Liverpool as part of the European Union funded Satiety Innovation (SATIN) Grant (UK)

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a peer reviewed journal.

**Intention to publish date**

25/05/2019

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Jo Harrold ([harrold@liverpool.ac.uk](mailto:harrold@liverpool.ac.uk)) or Dr. Una Masic ([u.masic@liverpool.ac.uk](mailto:u.masic@liverpool.ac.uk)).

**IPD sharing plan summary**

Not provided at time of registration