

# Metabolic effects of mustard

<b>Submission date</b> 03/07/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/08/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Increasing energy use (energy expenditure) is a way for overweight or obese people to lose weight. Mustard's pungent component AITC has the potential to increase energy expenditure and may have other beneficial effects on metabolism. The aim of this study is to investigate the effects of mustard on energy expenditure, glucose and fat utilization, body temperature, cold and hunger scores and blood values such as glucose.

### Who can participate?

Healthy volunteers aged 18 to 65

### What does the study involve?

Participants are studied on three different days. On each day they take either a spoon of mustard or capsulated mustard, or capsules with a placebo (dummy) mixture. At 30-minute intervals indirect calorimetry (a way to measure energy expenditure and fat and glucose utilization), cold/hunger scores and blood tests are performed. Temperature is measured continuously using a temperature monitoring pill. In between the measurements participants are allowed to read or watch TV but confined to bed. Blood samples are taken via an venous catheter (tube into a vein). Afterwards they eat a test meal during which appetite and food intake are measured.

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

There were no specific risks or benefits for the volunteers from participating in the study. Volunteers are reimbursed for travelling expenses and offered compensation for time spent participating.

### Where is the study run from?

University of Cambridge Metabolic Research Laboratories, Wellcome Trust-MRC, Institute of Metabolic Science, Addenbrooke's Hospital (UK)

### When is the study starting and how long is it expected to run for?

April 2012 to January 2014

Who is funding the study?

The trial was funded by grants from the NIHR, BRC Seed Fund, Marie Curie Fellowships, Wellcome Trust Fellowship, MRC, BHF and the BBSRC

Who is the main contact?

Dr M Langeveld

## Contact information

### Type(s)

Scientific

### Contact name

Dr Mirjam Langeveld

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Mustard1

## Study information

### Scientific Title

Metabolic effects of mustard allyl-isothiocyanate compared to placebo: a randomised cross over trial

### Study objectives

Ingestion of mustard (containing the active ingredient allyl-isothiocyanate (AITC) ) induces thermogenesis (primary outcome) and alters body temperature, cold and hunger sensations, plasma metabolic parameters and energy intake (secondary outcomes).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Cambridge Central East of England Research Ethics Committee, 22/03/2012, ref: 6/Q0108/84

**Study design**

Randomised cross over trial

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**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**

Overweight, obesity

**Interventions**

In this study with a crossover design, 10 healthy subjects were studied under temperature controlled conditions after an overnight fast. After the ingestion of capsulated mustard (10 grams) or unpackaged mustard (10 grams) or capsulated placebo mixture, measurements of energy expenditure, substrate oxidation, core temperature, cold and hunger scores and plasma parameters were repeated every 30 minutes during 150 minutes. Randomisation was done by flipping a coin by the investigator to decide between the administration of capsulated mustard or the administration of capsulated placebo mixture. Unpackaged mustard was given as final intervention since participants could not be blinded to this intervention. After the experiments were performed, energy intake was measured in a test meal using the universal eating monitor.

**Intervention Type**

Supplement

**Primary outcome measure**

Energy expenditure (thermogenesis), measured using by indirect calorimetry using a ventilated canopy respiratory gas exchange (GEM; GEMNutrition, Daresbury, UK) at baseline and 30, 60, 90, 120 and 150 minutes after the intervention

**Secondary outcome measures**

Measured at baseline and 30, 60, 90, 120 and 150 minutes after the intervention:

1. Core body temperature, measured using a temperature pill (VitalSense, Respironics, Bend, OR, USA)
2. Cold and hunger sensations, determined by asking the participant to rate the sensation of cold of the whole body and hands separately on a 1 to 10 scale, with ratings as following; 1 was rated as not at all cold and 10 was the coldest one had ever felt. Similarly for the degree of hunger, with ratings as: 1 for not hungry at all, and 10 was rated as the most hungry one had ever felt
3. Plasma metabolic parameters; blood samples taken via an indwelling venous catheter

3.1. Glucose measured using the Hexokinase method on a Siemens Dimension RXL AutoAnalyser, reagents and calibrators purchased from Siemens  
3.2. Non-esterified free fatty acids (NEFAs) measured using the Roche Free Fatty Acid kit  
3.3. Free thyroxin (FT4) measured by time-resolved fluorescence immunoassay on an AutoDELFIA analyser (Perkin Elmer) using kits from Perkin Elmer  
3.4. Cortisol measured by fluorescence immunoassay on the Siemens Centaur Autoanalyser  
4. Energy intake determined by using the Universal Eating Monitors (UEM)(The Sussex Meal Patterning System) during the test meal at 160 minutes after the intervention. Subjects ate a homogenous test meal (e.g. pasta) containing normal energy percent ratios (~30% carbohydrates, ~30% protein and ~40% fat). Test meal intake continuously monitored using the UEM equipment

**Overall study start date**

23/04/2012

**Completion date**

03/01/2014

## **Eligibility**

**Key inclusion criteria**

1. Healthy volunteers
2. Men and women
3. Non-smokers
4. Age between 17 and 65 years
5. No known medical conditions
6. Not taking any medications or supplements likely to influence energy expenditure

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

10

**Key exclusion criteria**

1. Known medical conditions
2. Using medication or supplements likely to influence energy expenditure or other metabolic parameters

**Date of first enrolment**

01/04/2012

**Date of final enrolment**

19/11/2013

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**University of Cambridge Metabolic Research Laboratories, Wellcome Trust-MRC, Institute of Metabolic Science, Addenbrookes Hospital**

Hills Road

Cambridge

United Kingdom

CB2 0QQ

# Sponsor information

## Organisation

Institute of Metabolic Science

## Sponsor details

Box 289

Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 0QQ

## Sponsor type

Research organisation

## ROR

<https://ror.org/0264dxb48>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

BRC Seed Fund

**Funder Name**

FP7 People: Marie-Curie Actions

**Alternative Name(s)**

PEOPLE - Specific Programme 'People' Implementing the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007 to 2013), FP7 Specific Programme 'People' Implementing the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007 to 2013), Specific Programme 'People' Implementing the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007 to 2013), FP7 Specific Programme 'People', Specific Programme 'People', FP7 People, FP7 People: Marie Skłodowska-Curie Actions, FP7-PEOPLE - Spezifisches Programm 'Menschen' zur Durchführung des Siebten Rahmenprogramms der Europäischen Gemeinschaft für Forschung, technologische Entwicklung und Demonstration (2007-2013), PEOPLE - Spezifisches Programm 'Menschen' zur Durchführung des Siebten Rahmenprogramms der Europäischen Gemeinschaft für Forschung, technologische Entwicklung und Demonstration (2007-2013), FP7 Spezifisches Programm 'Menschen' zur Durchführung des Siebten Rahmenprogramms der Europäischen Gemeinschaft für Forschung, technologische Entwicklung und Demonstration (2007-2013), Spezifisches Programm 'Menschen' zur Durchführung des Siebten Rahmenprogramms der Europäischen Gemeinschaft für Forschung, technologische Entwicklung und Demonstration (2007-2013), FP7 Spezifisches Programm 'Menschen', Spezifisches Programm 'Menschen', FP7-PEOPLE - Programa específico 'Personas' por el que se ejecuta el séptimo programa marco de la Comunidad Europea de acciones de investigación, desarrollo tecnológico y demostración (2007-2013), PEOPLE - Programa específico 'Personas' por el que se ejecuta el séptimo programa marco de la Comunidad Europea de acciones de investigación, desarrollo tecnológico y demostración (2007-2013), FP7- Programa específico 'Personas' por el que se ejecuta el séptimo programa marco de la Comunidad Europea de acciones de investigación, desarrollo tecnológico y demostración (2007-2013), Programa específico 'Personas' por el que se ejecuta el séptimo programa marco de la Comunidad Europea de acciones de investigación, desarrollo tecnológico y demostración (2007-2013), FP7 Programa específico 'Personas', Programa específico 'Personas', FP7-PEOPLE - Programme spécifique 'Personnes' mettant en œuvre le septième programme-cadre de la Communauté européenne

pour des activités de recherche, de développement technologique et de démonstration (2007-2013), PEOPLE - Programme spécifique 'Personnes' mettant en œuvre le septième programme-cadre de la Communauté européenne pour des activités de recherche, de développement technologique et de démonstration (2007-2013), FP7 - Programme spécifique 'Personnes' mettant en œuvre le septième programme-cadre de la Communauté européenne pour des activités de recherche, de développement technologique et de démonstration (2007-2013), Programme spécifique 'Personnes' mettant en œuvre le septième programme-cadre de la Communauté européenne pour des activités de recherche, de développement technologique et de démonstration (2007-2013), FP7 rogramme spécifique 'Personnes', Programma specifico 'Persone' che attua il settimo programma quadro della Comunità europea per le attività di ricerca, sviluppo tecnologico e dimostrazione (2007-2013), PEOPLE - Programma specifico 'Persone' che attua il settimo programma quadro della Comunità europea per le attività di ricerca, sviluppo tecnologico e dimostrazione (2007-2013), PF7 - Programma specifico 'Persone' che attua il settimo programma quadro della Comunità europea per le attività di ricerca, sviluppo tecnologico e dimostrazione (2007-2013), Programma specifico 'Persone' che attua il settimo programma quadro della Comunità europea per le attività di ricerca, sviluppo tecnologico e dimostrazione (2007-2013), PF7 Programma specifico 'Persone', FP7-PEOPLE - Program szczegółowego 'Ludzie', wdrażającego siódmy program ramowy Wspólnoty Europejskiej w zakresie badań, rozwoju technologicznego i demonstracji (2007–2013), PEOPLE - Program szczegółowego 'Ludzie', wdrażającego siódmy program ramowy Wspólnoty Europejskiej w zakresie badań, rozwoju technologicznego i demonstracji (2007–2013), PF7 Program szczegółowego 'Ludzie', wdrażającego siódmy program ramowy Wspólnoty Europejskiej w zakresie badań, rozwoju technologicznego i demonstracji (2007–2013), PF7 Program szczegółowego 'Ludzie', Program szczegółowego 'Ludzie', wdrażającego siódmy program ramowy Wspólnoty Europejskiej w zakresie badań, rozwoju technologicznego i demonstracji (2007–2013), Program szczegółowego 'Ludzie'

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location****Funder Name**

Wellcome Trust

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

International organizations

**Location**

United Kingdom

**Funder Name**

Medical Research Council

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

British Heart Foundation

**Alternative Name(s)**

the\_bhf, The British Heart Foundation, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

Biotechnology and Biological Sciences Research Council

**Alternative Name(s)**

UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom



# Results and Publications

## Publication and dissemination plan

The article describing the study results is currently submitted to a peer reviewed journal.

## Intention to publish date

01/10/2017

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as this was not outlined in the original study set up and application to the medical ethics committee. The original data will be held at the University of Cambridge Metabolic Research Laboratories, Wellcome Trust-MRC, Institute of Metabolic Science, Addenbrookes Hospital.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2017		Yes	No