

# Capsaicinoids Enhance Metabolic Rate – An Open Label Study

<b>Submission date</b> 08/12/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 15/12/2016	<b>Overall study status</b> Completed	
<b>Last Edited</b> 31/07/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### Background and study aims

Obesity is a growing problem worldwide. The main reason that people become obese is thought to be due to over-eating and/or not exercising enough. It has also been found that some people with obesity have a lower metabolism than healthy people. Capsaicinoids are a type of chemical which are found in members of the capsicum family of plants (chilies). There is evidence to suggest that capsaicinoids may play a role in metabolism (the breakdown of food and drink into energy). The aim of this study is to look at the effect of capsaicinoids on metabolism for weight management.

### Who can participate?

Healthy adults who have a sedentary or lightly active lifestyle.

### What does the study involve?

Participants are randomly allocated to one of two groups who receive two treatments in a random order, with one week of no treatment in between. The first treatment involved receiving 100mg Capsimax (Capsaicinoids 2 mg) with a meal. The second treatment involves receiving a placebo (dummy drug) with a meal. Before and then 1, 2 and 3 hours after consuming the meal, participants have their metabolic rate calculated using specialized equipment and their heart rate measured. In addition, participants are asked to rate their appetite and interest in eating after 3 hours.

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

Participants benefit from learning about their own energy expenditure (metabolism). There are no known risks involved with participating.

### Where is the study run from?

Arizona State University (USA)

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

January 2016 to March 2017

Who is funding the study?  
OmniActive Health Technologies Ltd. (India)

Who is the main contact?  
Dr Vijaya Juturu  
v.juturu@omniactives.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Vijaya Juturu

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
STUDY00004264

## Study information

**Scientific Title**  
Capsaicinoids Enhance Metabolic Rate Using a Novel Metabolic Tracker Breezing Device – An Open Label Study

**Study objectives**  
The digestion of the meal induce energy expenditure processes that produces heat, increases heart rate due to higher blood circulation, and increases oxygen consumption and carbon dioxide production. The latter is measured via breath analysis and a measurement named metabolic rate or energy expenditure.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Arizona State University- Enterprise and Development IRB, 28/04/2016

**Study design**

Single blind acute placebo-controlled crossover open label study

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

School

**Study type(s)**

Prevention

**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**

Metabolism

**Interventions**

Participants are randomised to one of two groups who receive two treatments in a random order.

Group 1: Participants receive 100 mg Capsimax (Capsaicinoids 2 mg) once a day with a meal single administration..

Group 2: Participants receive a placebo (corn starch) once a day with a meal single administration.

After each treatment period, participants undergo one week wash-out before starting the other treatment.

The Breezing® device evaluates people's energy expenditure (EE) by detecting the rate of oxygen consumption and carbon dioxide generation in breath. It is based on a flow meter for flow detection and a chemical sensing cartridge, which used a cell-phone camera for optical detection. The device is 6.0 oz. (170 g), and 1.8 in × 2.1 in × 4.8 in (4.7 cm × 5.4 cm × 12.3 cm), and connects wirelessly to an iOS/Android mobile device, via Bluetooth®. A QR code with pre-calibrated sensor information is applied on the single-use sensor cartridge, which can be scanned and recognized by the mobile application.

During each measurement, participants breathed through a disposable mouthpiece connected to the Breezing® device for about 1-2 minutes until a total of 6L exhaled breath were measured by the flow meter. The data received on the mobile device is processed and displayed on the application. According to Weir equation, RQ, VO<sub>2</sub> and VCO<sub>2</sub>, the energy expenditure is

determined. The participants will be provided with meal including a non-caloric, decaf drink and certain amount of Thomas Plain Bagel and 1/3 less fat Philadelphia cream cheese based on their REE level. The ratio of calorie intake to their REE value was 0.35 for 14 participants and 0.25 for 25 participants. In the meantime, the participants will be served with either a Capsaicinoids pill or a placebo pill. After finishing the meal/pill, the participants' metabolic rate will be measured at 1, 2, and 3 hours .

### **Intervention Type**

Supplement

### **Primary outcome measure**

Resting Energy Expenditure (Metabolic rate) is measured using breezing equipment (indirect calorimetry) at baseline, 1 hour, 2 hours and 3 hours and data calculated for 24 hours (overall average  $\Delta$ REE%).

$\Delta$ REE:  $REE_i - REE_0$

$\Delta$ REE (%) :  $[(REE_i - REE_0)/REE_0] * 100\%$

### **Secondary outcome measures**

1. Heart rate measured using i-phone apps and blood pressure are measured using with sphygmomanometer at baseline and after 3 hours
2. Appetite and interest on food intake is measured using a visual analogue scale (0-100 scale) at baseline and at 3 hours

### **Overall study start date**

01/05/2016

### **Completion date**

15/12/2016

## **Eligibility**

### **Key inclusion criteria**

1. English-speaking
2. Adult participants (18 – 80 years old)
3. Sedentary or lightly active lifestyle
4. Able to consent and perform the necessary tests for the study

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

Healthy volunteer

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

**Target number of participants**

40 subjects Crossover trial

**Key exclusion criteria**

1. Food allergy or sensitive to gluten
2. Under treatment for chronic conditions/disease such as cancer, burns or obstructive pulmonary diseases

**Date of first enrolment**

10/05/2016

**Date of final enrolment**

30/06/2016

**Locations****Countries of recruitment**

United States of America

**Study participating centre****Arizona State University**

Center of Bioelectronics and Biosensors

Biodesign Institute

Tempe AZ

United States of America

85281

**Sponsor information****Organisation**

OmniActive Health Technologies Ltd.

**Sponsor details**

Phoenix House, T- 8, A Wing

462 Senapati Bapat Marg, Lower Parel

Mumbai

India

400 013

**Sponsor type**

Industry

**Website**

<http://omniactives.com/>

ROR

<https://ror.org/03fxrgb29>

## Funder(s)

### Funder type

Industry

### Funder Name

OmniActive Health Technologies

### Alternative Name(s)

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

United States of America

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

### Intention to publish date

31/12/2017

### 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 Erica Forzani ([eforzani@asu.edu](mailto:eforzani@asu.edu)) or Dr Vijaya Juturu ([v.juturu@omniactives.com](mailto:v.juturu@omniactives.com)).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	12/06/2017		Yes	No