

# The effect of chickpea structures on glucose response and appetite regulation

<b>Submission date</b> 22/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/06/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A number of reports globally demonstrate the rates of obesity and type 2 diabetes continue to increase. It highlights the importance of the maintenance of an energy balance and glucose homeostasis. Chickpeas are high in resistant starches and protein, and these nutrients have been shown to stimulate gut hormone secretion that could regulate glucose homeostasis. Therefore, this study aims to investigate the impact of different chickpea tissue-structures on gut hormone secretion, thus explaining the chickpeas' influences on glucose control and satiety reported in previous studies. This project will improve understanding of the relationship among food structure ranging in processing, nutrient bioavailability and chickpea-induced release of gut hormone.

### Who can participate?

People aged 18 – 65 years with a BMI of 18 – 30 kg/m<sup>2</sup>

### What does the study involve?

This study is to test the physiological effects of three chickpea-based meals that differ in processing and microstructures. This is a randomised crossover study therefore every participant will receive the same treatments.

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

**Benefits:** Taking part in the study will provide no direct benefit for you. The information that we get from this study will help us to better understand normal appetite regulation and may help us to better treat future patients who suffer from obesity. If any of the screening questionnaires or blood tests reveal any medical problems (e.g. diabetes, kidney or liver problems), your GP will be informed so that they can coordinate your further care, arrange any further tests, and refer you on to Hospital Doctors if necessary.

**Risks:** The diets consumed over the course of the study are common food items and dietary supplements. They are generally not found to be linked to any serious side effects.

Insertion of the cannula into participants' arms on each of the study visits may cause minor discomfort or superficial bruising. Serious risks associated with the insertion of the entonetric tubes are very rare and almost negligible. These risks include bleeding, perforation or damage to the base of the skull. Minor discomfort of the back of the throat does occur in the majority of

patients and may result transiently in a sore mouth, thirst, swallowing difficulties or hoarseness. The fluoroscopy procedure will expose participants to a small dose of radiation. The mean effective dose from each nasogastric tube procedure is equivalent to 2.8 months of natural background radiation (the same amount as you would be exposed to walking around outside) and would increase the risk of inducing cancer by 0.0025% (or 1 in 40,000). The minimum number of fluoroscopy procedures that will be conducted is 3. The maximum number of fluoroscopy procedures that will be conducted is 6.

Where is the study run from?

Imperial College NIHR/Wellcome Trust Imperial Clinical Research Facility, Hammersmith Hospital, UK

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

July 2019 to August 2024

Who is funding the study?

1. Biotechnology and Biological Sciences Research Council, UK
2. National Institute for Health Research (NIHR), UK

Who is the main contact?

Dr Mingzhu Cai (public)

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## Contact information

### Type(s)

Public

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

256533

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

6, IRAS 256533, CPMS 42519

**Study information****Scientific Title**

Determining the effect of chickpea tissue-structures on metabolic responses, satiety regulation and gut content along the entire gastrointestinal tract on healthy participants

**Study objectives**

Micro-structures of chickpea that are more resistant to digestion can improve glucose response and prolong appetite.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 31/07/2019, London-Camden and Kings-Cross Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0) 20 7104 8222; nrescommittee.london-camdenandkingscross@nhs.net), ref: 19/LO/0962

**Study design**

Single-centre randomised crossover nutritional-intervention study

**Primary study design**

Interventional

## **Secondary study design**

Randomised cross over trial

## **Study setting(s)**

Hospital

## **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**

Digestion in healthy participants

## **Interventions**

This study consists of one 4-day study visit and three 3-day study visits. At least one week's gap is needed. The 4-day study visit will mainly look at the upper gastro-intestine (GI) while the 3-day ones will look at the lower GI.

During each study visit, chickpeas-based meals in different structures (broken cells, intact cells, and cell clusters) will be served to participants. Then the physiological responses will be investigated:

Bloods will be taken to measure the post-prandial glucose, insulin, gut hormone and metabolites; Guts samples will be taken through a nasoenteric tube to monitor the digestive behaviours and structures breakdown; VAS will be conducted to measure subjective appetite; Urine and stool samples will be collected to measure the metabolites.

Randomisation is conducted using the website of sealed envelope: <https://www.sealedenvelope.com/>

## **Intervention Type**

Other

## **Primary outcome measure**

Appetite-regulating gut hormones measured using RIA assay in the intestinal contents that will be collected through a nasoenteric tube at 0, 60, 120, 180, 240, 300, 420, 480 min at each study day

## **Secondary outcome measures**

1. Circulating concentrations of glucose, insulin, and metabolites measured using ci8200 analyser enzymatic method, RIA assay, and GC-MS respectively at 0, 60, 120, 180, 240, 300, 420, 480 min at each study day
2. Subjective measures of appetite, as assessed by Visual Analogue Scales (VAS) at 0, 60, 120, 180, 240, 300, 420, 480 min at each study day
3. Energy intake as determined by an ad libitum meal at 240 min at each study day

## **Overall study start date**

01/07/2019

**Completion date**

30/08/2024

## **Eligibility**

**Key inclusion criteria**

1. Age between 18 - 65 years (inclusive)
2. Body mass index (BMI) of 18-30 kg/m<sup>2</sup>
3. Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

15

**Total final enrolment**

13

**Key exclusion criteria**

1. Abnormal ECG
2. Screening blood results outside of normal reference values
3. Weight change of  $\geq 5$ kg in the preceding 2 months
4. Current smokers
5. History of substance abuse and/or excess alcohol intake • Pregnancy • Diabetes • Cardiovascular disease
6. Cancer
7. Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
8. Kidney disease
9. Liver disease
10. Pancreatitis
11. Started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation and hormonal balance, including anti-inflammatory drugs or steroids,

antibiotics, androgens, phenytoin, erythromycin or thyroid hormones

12. Participation in a research study in the 12 week period prior to entering this study

13. Any blood donation within the 12 week period prior to entering this study

**Date of first enrolment**

11/02/2020

**Date of final enrolment**

27/04/2022

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Imperial College NIHR/Wellcome Trust Imperial Clinical Research Facility**

Hammersmith Hospital

Du Cane Rd

Shepherd's Bush

London

United Kingdom

W12 0NN

## **Sponsor information**

**Organisation**

Imperial College London

**Sponsor details**

Joint Research Compliance Office

Imperial College London and Imperial College Healthcare NHS Trust

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+44 (0)207 594 1872

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**Sponsor type**

University/education

**Website**

<http://www3.imperial.ac.uk/>

**ROR**

<https://ror.org/041kmwe10>

## **Funder(s)**

**Funder type**

Research council

**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**

Current publication and dissemination plan as of 16/08/2023:

Some preliminary results have been published in a PhD thesis. Final results will be published in 1-2 open-access scientific journals.

Previous publication and dissemination plan:

The study results will be published in a PhD thesis and 1-2 scientific papers in peer-reviewed journals.

**Intention to publish date**

31/12/2024

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

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.

**IPD sharing plan summary**

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version v7	13/09/2019	11/02/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Thesis results</a>		01/08/2022	10/08/2023	No	No
<a href="#">Results article</a>		20/06/2025	24/06/2025	Yes	No