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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
22/01/2020		[X] Protocol		
Registration date 11/02/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
24/06/2025	Digestive System			

#### 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 different 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 ensonetric 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) m.cai18@imperial.ac.uk Prof. Gary Frost (scientific) g.frost@imperial.ac.uk

# Contact information

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Public

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

256533

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

#### Study type(s)

Prevention

#### 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(s)

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

## Key secondary outcome(s))

- 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

65 years

#### Sex

Αll

#### Total final enrolment

13

#### Key exclusion criteria

- 1. Abnormal ECG
- 2. Screening blood results outside of normal reference values
- 3. Weight change of  $\geq$  5kg 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

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

#### **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, Biotechnology and Biological Sciences Research Council (BBSRC), BBSRC

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United Kingdom

# **Results and Publications**

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

The datasets generated during and/or analysed during the current study will be stored in a non-publically 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?
Results article		20/06/2025	24/06/2025	Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v7	13/09/2019	11/02/2020	No	No
Thesis results		01/08/2022	10/08/2023	No	No