

Extended daily fasting (omission of breakfast) and regulation of energy balance

Submission date 30/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/11/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 12/03/2020	Condition category 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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BB/H008322/1

Study information

Scientific Title

Extended daily fasting, regulation of energy balance and associated health outcomes: a randomised single centre intervention study with two phases

Acronym

Bath Breakfast Project (BBP)

Study objectives

Primary hypothesis:

Extended daily fasting will cause a positive shift in energy balance relative to frequent breakfast consumption due to decreased spontaneous physical activity.

Secondary hypothesis:

Extended daily fasting will cause a change in energy balance regulatory hormones conducive of increased appetite and decreased spontaneous physical activity relative to frequent breakfast consumption, with a resultant impairment of glycaemic control and increased systemic inflammation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Health Service (NHS) South West 3 Research Ethics Committee (REC), 13/04/2010, ref: 10/H0106/13. Amendment approved on 11/08/2010

Study design

Interventional single-centre randomised study: phase I = cross-over, phase II = parallel group

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Can be found at <http://www.bath.ac.uk/health/research/breakfastproject.html>

Health condition(s) or problem(s) studied

Diet/inactivity/obesity-related diabetes and associated cardiovascular disease

Interventions

Intervention: 6-week daily consumption of breakfast (i.e. at least 2933 kJ before 11:00)

Control: 6-week daily omission of breakfast (i.e. 0 kJ until 12:00)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Alterations in energy balance between treatments (i.e. the culmination of resting metabolic rate, diet-induced thermogenesis and physical activity energy expenditure relative to dietary energy intake).

All measurements contributing to both the primary and secondary outcomes are made throughout two 8 hour lab visits during Phase I and then continuously throughout the first and sixth week of dietary intervention during Phase II.

Secondary outcome measures

Both the mechanistic data explaining how the intervention may have impacted on energy balance (i.e. appetite regulatory hormones, metabolic regulatory hormones and associated expression of key genes) and also the whole-body endpoints indicative of altered health status with each treatment (i.e. adiposity, glycaemic control and chronic lowgrade inflammation).

All measurements contributing to both the primary and secondary outcomes are made throughout two 8 hour lab visits during Phase I and then continuously throughout the first and sixth week of dietary intervention during Phase II.

Overall study start date

14/04/2010

Completion date

14/04/2013

Eligibility

Key inclusion criteria

1. Participants may be male or female (females may or may not be taking oral contraceptives but must maintain a record of menstrual cycle phase or contraceptive use prior to entry into the study)
2. Those within the specified age range (20 - 60 years)
3. Individuals with a body mass index between 20 - 24 kg/m² or above 30 kg/m²
4. Able and willing to safely comply with all study procedures
5. Able to provide written informed consent for participation whilst acknowledging their freedom to withdraw at any point during the study

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

70

Key exclusion criteria

1. Women who are known to be pregnant or who are intending to become pregnant over the course of the study
2. Women who are breast feeding
3. Participation in another clinical trial
4. Any reported use of substances which may pose undue personal risk to participants or introduce bias into the experiment
5. Any other condition or behaviour deemed either to pose undue personal risk to the participant or introduce bias into the experiment
6. Individuals with any known bleeding disorder
7. Individuals currently taking any medication known to act as an anticoagulant

Date of first enrolment

14/04/2010

Date of final enrolment

14/04/2013

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University of Bath

Bath

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BA2 7AY

Sponsor information**Organisation**

University of Bath (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.bath.ac.uk/>

ROR

<https://ror.org/002h8g185>

Funder(s)**Funder type**

Research council

Funder Name

Biotechnology and Biological Sciences Research Council (BBSRC) (UK) (ref: BB/H008322/1)

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**

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/07/2011		Yes	No
Results article	results	01/08/2014		Yes	No
Results article	results	01/03/2016		Yes	No
Results article	results	01/01/2018		Yes	No
Results article	substudy results	01/05/2019	12/03/2020	Yes	No
HRA research summary			28/06/2023	No	No