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

Submission date	Recruitment status	[_] Prospectively registered
30/09/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/03/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
University of Bath
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
University of Bath (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, 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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
Protocol article	protocol	08/07/2011		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes