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BRRIDE 2 - Breast Risk Reduction Intermittent Diet Evaluation

Submission date	Recruitment status	[ ] Prospectively registered
08/01/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/01/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2020	Cancer	[ ] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/a-trial-looking-diet-women-family-history-breast-cancer-brride2

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18052

Study information

Scientific Title
A randomised controlled trial of the effect of intermittent energy restriction (IER) versus daily energy restriction (DER) on body fat stores and blood markers of cancer risk.

Acronym
BRRIDE 2

Study objectives
Hypothesis: Excess fat is important in the risk and development of breast cancer. Fat stored within the liver has an effect on the control of blood sugar levels (insulin resistance)this is an important mediator of breast cancer risk. Excess fat also causes changes in sex hormone levels, and chronic inflammation that are important in breast cancer risk.

Calorie restricted diets cause reductions in liver and abdominal fat and reduced insulin resistance and hence reduced cancer risk. Intermittent dieting is an increasingly popular method of dieting (2 day diet book, Harvie & Howell, Fast diet, Mosely & Spencer) which involves short spells of severe restriction and spells of normal intake. We have shown that intermittent dieting leads to a greater reduction in insulin resistance than daily dieting with comparable weight loss.

We hypothesise that an intermittent energy restricted diet will lead to a greater reduction in liver fat compared to a daily energy restricted diet. This study will define the effects of intermittent compared to standard daily dieting on markers of cancer risk (insulin resistance, markers of inflammation) and inform the value of intermittent energy restriction as a potential cancer risk reduction strategy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 20/08/2015, ref: 14/SC/1097

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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
Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

Interventions
1. Daily energy restriction, A daily 25% energy restricted Mediterranean diet (~1500kcal/day) for seven days/week which includes healthy fats, protein foods, low fat dairy, fruit and vegetables and high fibre carbohydrates and allows up to 10 units of alcohol per week
2. Intermittent energy restriction, a low carbohydrate energy restricted diet (600 kcal, <50g carbohydrate, 50 g protein day) for two consecutive days followed by an ~1900 kcal mediterranean type diet for the remaining five days of the week. Each of the two low carbohydrate 600 kcal energy restricted days includes; ~ 300g of lean protein foods e.g. lean meat, fish, eggs, tofu, quorn, textured vegetable protein, three portions of low fat dairy foods, five portions of low carbohydrate vegetables; one portion of low carbohydrate

Intervention Type
Other

Primary outcome measure
1. Image determined hepatic fat fraction and lipid types (MRS)
2. Insulin resistance using modelling of insulin, glucose and Cpeptide measurements during an Oral Glucose Tolerance Test (OGTT)

All measured at baseline and after following diet for 8 weeks.

Secondary outcome measures
1. Body mass and composition: total body fat, visceral and subcutaneous fat (MRS).
2. Intramyocellular fat fraction (MRS) a predictor of systemic insulin resistance
3. Pancreatic fat fraction and lipid types (MRS)
4. L3 skeletal muscle area using MR imaging – an indicator of sarcopenia and lean body mass
5. Markers of breast cancer risk. Inflammatory markers; IL6, adipokines: fasting adiponectin and leptin, IGF1
6. Fasting lipid profile. i.e. total low density lipoprotein (LDL) and high density lipoprotein (HDL) and triglceride linked to risk of breast cancer44 and cardiovascular disease
7. Resting energy expenditure (Fitmate GS portable desktop indirect calorimeter (Cosmed, Rome Italy) .
We will also assess simple clinic body fat and fat free mass (bioelectrical impedence;Tanita 180) and anthropometric measurements (waist, hip and bust circumference)

All measured at baseline and after following diet for 8 weeks.

Overall study start date
05/01/2015

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Family history of breast cancer (lifetime risk >1 in 6)
2. Premenopausal aged >30-45 years
3. Body mass index 30-45 kg/m2.
4. Nonsmoker
5. Sedentary (< 40 minutes moderate exercise per week)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 26; UK Sample Size: 26

Key exclusion criteria
1. Contradindication to MR imaging (e.g pacemaker, weight greater than 125kg)
2. Already successfully losing weight.
3. Pregnant or planning pregnancy over next 5 months
4. Currently Breast feeding
5. Eating disorder, depression or alcoholism
6. Alcohol intake greater than 10g of ethanol (10 units) per week
7. Comorbidity that affects liver fat stores i.e. NonAlcoholic Fatty Liver Disease, diabetes, viral hepatitis, fibrosis, Human Immunodeficiency Virus, coeliac disease
8. Drug use current or within the past 6 months affecting liver fat content i.e. insulin, oral contraceptives, tamoxifen, statins, amiodarone, methotrexate, corticosteroids
9. Previous or current history of cancer
10. Following an incompatible therapeutic diet

Date of first enrolment
05/01/2015

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of south Manchester
Genesis Prevention Centre

Wythenshawe Hospital
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Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Genesis Breast Cancer Prevention Appeal Ltd (UK)

Funder Name
Pancreatic Cancer UK

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No