

BRRIDE 2 - Breast Risk Reduction Intermittent Diet Evaluation

Submission date 08/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/08/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Contact details

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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 triglyceride 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 impedance; 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. Contradication 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
Southmoor Road
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation

University Hospital of South Manchester NHS Foundation Trust

Sponsor details

Southmoor Road
Wythenshawe
Manchester
England
United Kingdom
M23 9LT

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