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Waste the Waist: Pilot study for a randomised controlled trial of a pragmatic, primary care based intervention to support lifestyle change in the management of high cardiovascular risk

Submission date
14/02/2012

Recruitment status
No longer recruiting

Registration date
14/02/2012

Overall study status
Completed

Last Edited
05/12/2017

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
9846

Study information

Scientific Title
Waste the Waist: Pilot study for a randomised controlled trial of a pragmatic, primary care based intervention to support lifestyle change in the management of high cardiovascular risk

Acronym
Waste the Waist

Study objectives
Primary Care Trusts in England need to commission services to promote healthy diet and physical activity for thousands of people who will be identified with high cardiovascular (CV) risk by the NHS Health Checks programme. The aim is to pilot, prior to a full trial evaluation, a practical, state-of-the-art intervention to promote healthy diet and physical activity for people with high cardiovascular risk, which has been adapted for use in UK primary care.
The pilot aims to:
1. Assess recruitment, intervention concordance, study retention and measures-completion rates
2. Assess the acceptability of the intervention to participants
3. Assess the acceptability and feasibility of recruitment, measurement, randomisation and intervention delivery procedures which would be used in a future pragmatic randomised controlled trial
4. Estimate the resources and costs needed to deliver the intervention and conduct a full trial
5. Estimate the standard deviation of continuous outcomes (e.g. changes in participants weight).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Cardiovascular disease

Interventions
The sample size is calculated to provide realistic estimates (and confidence intervals (CIs)) for the recruitment and study completion rates. The resulting sample size will also allow realistic estimates of the intervention concordance rate and provide an ample pool of patients for qualitative sampling. From recent UK-based trials of interventions to support dietary /physical activity change in high CV risk populations,33-35 it is estimated that 25-40% of those contact

Waste the waist
The intervention group will receive the Waste the Waist intervention in local community venues (e.g. community halls). The intervention encourages increased physical activity and weight loss (by changing intake of total and saturated fat increasing fibre and other dietary changes). Targets will be set by participants, but the health benefits of 5% weight loss and of 150 mins per week of moderate (or 100 mins vigorous) activity will be presented and suggested as minimum long-term targets for heal.

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Recruitment rate measured at baseline

Secondary outcome measures
1. All measures proposed for the main trial (e.g. weight) will be taken and variance explored at 0, 4, and 12 months
2. Intervention concordance (the proportion attending >=4 of the 7 sessions) measured at 8 months
3. Study completion rate measure at 12 months

Overall study start date
16/03/2011

Completion date
30/08/2011

Eligibility

Key inclusion criteria
1. Aged 40-74
2. BMI 30 or more (27.5 for S. Asians, if ethnicity is known)

3. A ten year cardiovascular risk score of 20% or more (calculated using either the Framingham or QRISK method)
4. IGT - Impaired glucose tolerance (2 hour glucose on IGT test of 7.8 to 11.0 mmol/l)
5. IFG - Impaired fasting plasma glucose (6.1 to 6.9mmol/l.)
6. Male and female participants

If recruitment proves difficult using the above criteria, we will search practice databases for people with higher risk obesity, defined as having a Body Mass Index of 30 or more plus either hypertension, hypercholesterolemia, family history of diabetes or heart disease, history of gestational diabetes, or polycystic ovary syndrome.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 100

Key exclusion criteria
1. People with existing heart disease or type 2 diabetes
2. People who are currently pregnant
3. People currently using weight loss drugs (which will interfere with planned measures) 4. People not fluent in English
5. Anyone who, in their GPs opinion, has other conditions that would prevent engagement with the programme (including terminal illness, major mental health problems, communication difficulties requiring translation)

Date of first enrolment
16/03/2011

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

The Department for Health
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
Bath and North East Somerset Primary Care Trust (UK)

Sponsor details
Bath & North East Somerset NHS Trust Headquarters
St Martin's Hospital
Clara Cross Lane
Bath
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United Kingdom
BA2 5RP
+44 (0)1225 831800
info@banes-pct.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.banes.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme (UK)

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	01/05/2012		Yes	No
Results article	results	16/01/2015		Yes	No