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Lifestyle change in individuals at risk of diabetes and heart disease

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/02/2014	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
N0203178114

Study information

Scientific Title

Study objectives
To see whether lifestyle behaviour changes (weight loss and increased physical activity) similar to those obtained in recent large Finnish and US studies can be achieved with a simplified lifestyle intervention in a UK primary care setting. The intervention will use motivational interviewing (a well established, patient-centered behaviour counselling technique), delivered by trained health promotion worker (not necessarily existing NHS staff).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval added as of 16/07/2007:
North & East Devon Local Research Ethics Committee, approved in 2005 (ref: 05/Q2102/40)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes and heart disease

Interventions
Please note that the amendments to the target number of participants and participants - inclusion criteria (both amended as of 12/10/2007) reflect errors in information provided at time of registration, not changes in protocol.

Interventions added as of 16/07/2007:
1. Intervention group: Motivational interviews (patient-centered behaviour counseling) delivered by trained health promotion worker
2. Control group: Information leaflets offering advice on healthy eating and the benefits of increased physical activity

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Proportion of people achieving specific targets for weight change and physical activity which have been shown to be beneficial in previous studies.

Secondary outcome measures
Secondary outcome measures added as of 16/07/2007:
1. The proportion of participants achieving 150 min moderate activity per week
2. Waist circumference
3. Achievement of dietary composition targets (<30% energy from fat [<10% energy from saturated fat], 15 g / 1000 kcal fibre), if sufficient food diary data returned

Overall study start date
30/11/2005

Completion date
20/02/2007

Eligibility

Key inclusion criteria
Inclusion criteria amended as of 12/10/2007:
1. Patients with a recorded BMI of 28 or more in the last 10 years
2. Age of 18 or more
3. Participants must be able to engage in at least moderate physical activity (e.g. no significant joint problems)
4. Participation will be restricted to those speaking English fluently, as the intervention is based on communication, and many of the measures are specifically validated for English speakers

Inclusion criteria provided at time of registration:
Identification of potential participants will be by computer searching of GP practice databases by NHS staff employed at the practice (e.g. practice nurse, clerical staff). This will generate a list of patients with a recorded BMI of 30 or more in the last 10 years, and age of 30 or more. A random selection of 420 patients will be identified by applying random numbers generated by the principal researcher. This list will be checked by the patient's GP for exclusion criteria. Participants must also be able to engage in at least moderate physical activity (e.g. no significant joint problems). Participation will be restricted to those speaking English fluently, as the intervention is based on communication, and many of the measures are specifically validated for English speakers. For pragmatic reasons it is not possible to pay for interpreters for this study, although this would be considered for a larger trial.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Not Specified

Target number of participants
Target number of participants amended as of 12/10/2007: 150 (141 participants were enrolled). Target number provided at time of registration: 420.

Key exclusion criteria
Existing diabetes or heart disease, or any other reason the GP thinks the patient is not suitable for the intervention (e.g. severe uncontrolled hypertension, dementia or mental illness preventing likely understanding of the intervention or of the research processes).

Date of first enrolment
30/11/2005

Date of final enrolment
20/02/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Devon Primary Care Trust (UK)

Sponsor details
Dean Clarke House
Southernhay East
Exeter
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EX1 1PQ

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Pam.deClive-Lowe@Exeter-PCT.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Government

Funder Name
Royal Devon and Exeter NHS Trust (UK)

Funder Name
Mid Devon Primary Care Research Group (UK)

Funder Name
NHS Research and Development Support Funding (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