ISRCTN49519227 https://doi.org/10.1186/ISRCTN49519227

Evaluation of lifestyle support programme for the reduction of cardiovascular risk in Stoke on Trent

Submission date	Recruitment status	[_] Prospectively registered
04/09/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/10/2018	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Zafar Iqbal

Contact details
NHS Stoke on Trent
Heron House
120 Grove Road
Fenton
Stoke on Trent
United Kingdom
ST4 4LX
+44 (0)1782 298130
zafar.iqbal@stoke.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial of additional lifestyle support for the reduction of cardiovascular disease (CVD) risk through primary care in Stoke on Trent

Study objectives
Additional lifestyle support will lead to an increased reduction in cardiovascular disease risk, as measured by the Framingham 10-year cardiovascular disease (CVD) risk estimate (systolic blood pressure version), compared with usual primary prevention care at 1 year. The study is powered (at 0.8) to detect an effect size of 0.3, assumes a cluster (general practice) effect (inter-cluster correlation coefficient) of .03 and that there will be 46 general practices in Stoke on Trent participating in the trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee, 25/03/2009, ref: 09/H1207/17

Study design
Prospective open-label individually randomised controlled trial clustered by general practice

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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 prevention through primary care

Interventions
1,840 participants in total will be recruited from 46 general practices (20 treatment and 20 control patients per practice).

Lifestyle support (treatment): The intervention will be 20 weeks, thereafter patients will be able to continue with individual support provided every 3 months for up to 1 year (if required). NHS Stoke on Trent has established a new community-based primary prevention/health improvement programme (Lifestyle Support programme) that is being rolled out across the City during 2008 /11. The Programme aims to identify and support people who are believed to be at high risk of developing cardiovascular disease and target those with diabetes and established heart disease. Those with an established cardiovascular risk >=20% identified by the practice's primary prevention component of the overall programme will be invited to meet with a lifestyle coach and be referred to free support for physical activity, weight and diet management, smoking cessation and motivational counselling as desired. Practices participating in the study will be supported by project support workers, working to the Primary Care Trust (PCT) protocol for the recruitment, allocation and treatment of patients.

Usual primary prevention care (control): Usual care allocated patients invited for screening will have their 10-year CVD risk calculated by an independent investigator to confirm eligibility for inclusion in the trial and will have undergone usual screening as part of the Practice's primary prevention programme (working to the agreed PCT protocol). These patients will receive usual care provided by the Practice (which may include treatment for blood pressure and/or cholesterol, smoking cessation, signposting to other services and/or lifestyle advice or intervention by the general practice team) but will not receive the additional external support for lifestyle change from the Lifestyle Support programme. These patients will be scheduled for a full repeat cardiovascular risk assessment at 1 year by the general practice team. After 1 year, these patients will be given opportunity to join the Lifestyle Support programme.

Staggered recruitment of general practices (from which individual patients will be randomised) will take place over 6 months. All patients will be followed up for 1 year after recruitment to the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Framingham 10-year CVD risk at 1 year after starting on the programme. This endpoint was chosen because it represents an all-round measure of the intervention's ability to achieve its objectives of informed clinical decision making as well as educating and motivating patients to address (and sustain changes to) modifiable multiple CVD risk factors and lifestyle.

Secondary outcome measures
Secondary outcomes will be measured to better understand the specific mechanisms by which the intervention did or did not help to achieve the primary endpoint.

1. Sustained progress with these lifestyle changes will be assessed at 6 months and 1 year by the following:
1.1. Weight (objectively measured for calculation of body mass index [BMI]) and waist circumference
1.2. Health-related quality of life using the SF-12® Health Survey
1.3. Physical activity
2. Changes in the following at 1 year:

2.1. Total cholesterol, high density lipoprotein (HDL) cholesterol
2.2. Systolic and diastolic blood pressure
2.3. Smoking habits
2.4. Diabetes and CVD status
3. Adherence (self-reported) with:
3.1. Anti-hypertensive therapy
3.2. Lipid-lowering therapy
3.3. Weight loss therapy
3.4. Physical activity recommendations
4. Proportions of patients achieving the following targets at 1 year:
4.1. Blood pressure goals of <140/90 mmHg
4.2. Cholesterol goals of TC <=5.0 mmol/l and TC/HDL-C ratio <=4.5

Overall study start date
01/09/2009

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Willingness to participate in either arm of the trial
2. Written informed consent
3. Aged between 35 and 74 years
4. Women highly unlikely to conceive over the course of the trial
5. Framingham 10-year CVD risk >=20%

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1,840

Key exclusion criteria
1. Documented history of cardiovascular disease
2. Documented history of diabetes mellitus or fasting glucose >6.9 mmol/l at screening
3. Physical or mental incapacity to participate in the programme (if offered)
4. Participation in other studies
5. Research site personnel
6. Patients whose language skills would not enable them to participate in treatment programmes
7. In addition, the following contra-indications to the physical activity component will apply:
7.1. Resting systolic blood pressure >180 mmHg or resting diastolic blood pressure >100 mmHg
7.2. Febrile illness or acute infection

7.3. Neuromuscular or rheumatoid conditions that are exacerbated by exercise
7.4. Patients who have had a major operation or joint surgery within the previous three months or are scheduled to undergo a major operation or joint surgery within three months of the recruitment date

Date of first enrolment
01/09/2009

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Stoke on Trent
Stoke on Trent
United Kingdom
ST4 4LX

Sponsor information

Organisation
NHS Stoke on Trent (UK)

Sponsor details
c/o Dr Giri Rajaratnam
Heron House
120 Grove Road
Fenton
Stoke on Trent
United Kingdom
ST4 4LX
+44 (0)1782 298145
giri.rajaratnam@stoke.nhs.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
NHS Stoke on Trent (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	01/07/2010		Yes	No
Results article	results	01/11/2012		Yes	No