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Managing cardiovascular risk for people with severe mental illnesses. A clinical trial in primary care. (PRIMROSE)

Submission date
21/02/2013

Recruitment status
No longer recruiting

Registration date
25/02/2013

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with severe mental illnesses (SMI) die early from cardiovascular disease (CVD). They have increased CVD risk factors including abnormal lipids, diabetes, smoking and obesity. They make frequent contact with primary care, yet are less likely to be screened for risk factors or receive interventions such as statins. In this study, we aim to test the effectiveness of an intervention with GP practices working to reduce CVD risk in people with SMI. The intervention will include physical health reviews, prescription of medications such as statins and monitoring of adherence to recommended treatments.

Who can participate?
The study aims to recruit 350 patients from 70 GP practices across England. Patients with severe mental illnesses (Schizophrenia, Persistent Delusional Disorder, Schizoaffective Disorder or Bipolar Affective Disorder), aged 30-75 years with raised total cholesterol or HDL/total cholesterol ratio and one or more of the following risk factors will be able to take part: BMI greater than 30 kg/m2, current smoker, raised blood pressure or raised glucose levels, diagnosis of hypertension or diabetes.

What does the study involve?
All participants with SMI registered with GP practices in the trial will be screened for CVD risk factors. 70 general practices will be involved, 35 using the new intervention and 35 providing standard care. Over a period of one year, approximately 5 participants from each practice with raised cholesterol and one other risk factor will either receive the intervention or treatment as usual. The intervention will involve intensive management of CVD risk factors with fortnightly to monthly appointments to monitor progress with reducing cholesterol, prescription and adherence to statins and antihypertensive medication and signposting to services for weight management and smoking cessation where other CVD risk factors are detected. At the end of the study, we will establish whether practices trained in the intervention reduce CVD risk more than standard care practices.

What are the possible benefits and risks of participating?
Those in the intervention will receive help in reducing the risk of developing cardiovascular disease. The study will provide evidence on how to reduce cardiovascular disease risk for people with severe mental illness across the NHS. The main risk will be around the prescription of statins to people with severe mental illnesses. There is little research on the effectiveness of statins in people with severe mental illnesses, however statins have been found to be effective and safe in the general population. Any reported side effects will be closely monitored at monthly follow ups with the GP/practice nurse.

Where is the study run from?
The study is run by University College London in collaboration with Camden and Islington NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
Participant recruitment commenced in May 2014. Participants will be enrolled on the study for a maximum period of two years.

Who is funding the study?
National Institute for Health Research (NIHR).

Who is the main contact?
Miss Alexandra Burton
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Study website
https://www.ucl.ac.uk/primrose

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14015

Study information

Scientific Title
Prediction and management of cardiovascular risk for people with severe mental illnesses. A cluster randomised controlled trial in primary care (PRIMROSE)

Acronym
PRIMROSE

Study objectives
Current study hypothesis as of 01/09/2015:
The objective of the study is to test the effectiveness and cost effectiveness of a primary care led intervention to reduce cardiovascular risk in patients with severe mental illnesses.
The specific objectives are:
1. to establish the effectiveness of the intervention in reducing total cholesterol over a 12 month period compared with standard care
2. to determine the impact of the intervention on the following CVD risk factors: HBA1c, blood pressure, BMI, waist circumference, HDL cholesterol, total/HDL cholesterol ratio, 6 month smoking abstinence
3. to determine the impact of the intervention on the following behaviours: diet, exercise, alcohol intake
4. to determine the impact of the intervention on reducing CVD risk scores
5. to determine whether the intervention improves uptake of CVD Risk reducing medications (e. g. statins), adherence to statins and attendance at appointments
6. to establish the cost-effectiveness of the intervention considering the costs of the intervention itself and other direct health care costs alongside the outcomes,
7. to determine the effectiveness of the intervention on the number of hospital admissions, satisfaction with services, quality of life and mental health outcomes

Previous study hypothesis from 30/05/2013 to 01/09/2015:
The objective of the study is to test the effectiveness and cost effectiveness of a primary care led intervention to reduce cardiovascular risk in patients with severe mental illnesses.
The specific objectives are:
1. to establish the effectiveness of the intervention in reducing total cholesterol over a 12 month period compared with standard care
2. to determine the impact of the intervention on the following CVD risk factors: fasting glucose, blood pressure, BMI, waist circumference, HDL cholesterol, 3 month smoking abstinence
3. to determine the impact of the intervention on the following behaviours: diet, exercise, alcohol intake
4. to determine the impact of the intervention on reducing CVD risk scores
5. to determine whether the intervention improves uptake of CVD Risk reducing medications (e. g. statins), adherence to statins and attendance at appointments

6. to establish the cost-effectiveness of the intervention considering the costs of the intervention itself and other direct health care costs alongside the outcomes,
7. to determine the effectiveness of the intervention on the number of hospital admissions, patient satisfaction with services, quality of life and mental health outcomes

Original study hypothesis:
The objective of the study is to test the effectiveness and cost effectiveness of a primary care led intervention to reduce cardiovascular risk in patients with severe mental illnesses.
The specific objectives are:
1. to establish the effectiveness of the intervention in reducing total cholesterol and overall cardiovascular risk scores over a 12 month period compared with standard care
2. to determine the impact of the intervention on the following CVD risk factors: fasting glucose, blood pressure, BMI, waist circumference, HDL cholesterol, 3 month smoking abstinence
3. to determine whether the intervention improves uptake of statins, adherence to statins and attendance at appointments
4. to establish the cost-effectiveness of the intervention considering the costs of the intervention itself and other direct health care costs alongside the outcomes,
5. to determine the effectiveness of the intervention on the number of hospital admissions, patient satisfaction with services, quality of life and mental health outcomes

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14015

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - City Road & Hampstead, 10/01/2013, ref: 12/LO/1934

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

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 risk for people with severe mental illnesses

Interventions

Standard care

Primrose intervention, Practice led intensive CVD risk management service including:
1. Brief behavioural advice and support on diet, exercise and smoking
2. Referral to support services such as smoking cessation and weight management programmes
3. Prescription of statins and other pharmacological interventions such as nicotine replacement therapy
4. Monitoring of adherence to treatments and attendance at appointments and monitoring of progress made with goals and CVD risk targets

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 01/09/2015:
Total Cholesterol; Timepoint(s): Baseline, 6 and 12 months

Previous primary outcome measures from 30/05/2013 to 01/09/2015:
Total Cholesterol; Timepoint(s): Baseline, 3, 6 and 12 months

Original primary outcome measures:
CVD risk score; Timepoint(s): Baseline, 6 and 12 months

Secondary outcome measures
Current primary outcome measures as of 01/09/2015:
1. 10 year CVD risk scores
2. Changes in cardiovascular risk factors, including HBA1c, waist circumference, HDL cholesterol, BMI, blood pressure, total/HDL cholesterol ratio and smoking reduction and abstinence
3. Changes in exercise and diet
4. Changes in alcohol use
5. Adherence to the intervention, including attendance at services and appointments
6. Proportions accepting and continuing CVD risk reducing medications and interventions (e.g. statins, nicotine replacement therapy, bupropion)
7. Satisfaction with primary care services
8. All hospital admissions and health service use during the trial period.
9. Quality of life
10. Incremental costs of the intervention, from the perspective of the NHS and PSS
11. Cost-effectiveness of the intervention, measured in terms of the primary and secondary outcome measures, plus quality-adjusted life years (QALYs), estimated at one year and lifetime.
12. Psychiatric outcomes and wellbeing

Previous primary outcome measures from 30/05/2013 to 01/09/2015:
1. 10 year CVD risk scores
2. Changes in a multivariate outcome comprising of BMI, blood pressure and total cholesterol /HDL cholesterol ratio
3. Changes in cardiovascular risk factors, including HBA1c fasting glucose, waist circumference,

HDL cholesterol, smoking reduction and abstinence
4. Changes in exercise and diet
5. Changes in alcohol use
6. Adherence to the intervention, including attendance at services and appointments
7. Proportions accepting and continuing CVD risk reducing medications and interventions (e.g. statins, nicotine replacement therapy, bupropion)
8. Satisfaction with the intervention
9. All hospital admissions during the trial period.
10. Quality of life
11. Incremental costs of the intervention, from the perspective of the NHS and PSS
12. Cost-effectiveness of the intervention, measured in terms of the primary and secondary outcome measures, plus quality-adjusted life years (QALYs), estimated at one year and lifetime.
13. Psychiatric outcomes

Original secondary outcome measures:
Cholesterol; Timepoint(s): Baseline, 6 and 12 months

Overall study start date
01/10/2013

Completion date
31/08/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/09/2015:
1. GP patients with a computer diagnosis of severe mental illness (SMI), i.e. Schizophrenia, Persistent Delusional disorder, Schizoaffective disorder, Bipolar affective disorder
2. Raised total cholesterol of 5 mmol/l or more or total cholesterol/HDL ratio of 4 mmol/l or more AND one or more of the following risk factors:
2.1. BMI > 30 kg/m2
2.2. Current smoker
2.3. Blood pressure >140mm Hg systolic AND/OR >90 mm Hg diastolic on two or more consecutive occasions
2.4. HbA1c of 42- 47 mmol/mol (6.0-6.4%)
2.5 Diagnosis of hypertension
2.6 Diagnosis of diabetes
3. Male & Female; Upper Age Limit 75 years ; Lower Age Limit 30 years
4. Able to give written informed consent

Previous inclusion criteria from 30/05/2013 to 01/09/2015:
1. GP patients with a computer diagnosis of severe mental illness (SMI), i.e. Schizophrenia (ICD-10, F20), Persistent Delusional disorder (ICD-10, F22), Schizoaffective disorder (ICD-10, F25), Bipolar affective disorder (ICD-10, F31)
2. Raised total cholesterol over 5 mmol/l or total cholesterol/HDL ratio above 4 mmol/lAND one or more of the following risk factors:
2.1. BMI > 30 kg/m2
2.2. Current smoker
2.3. Blood pressure >140mm Hg systolic AND/OR >90 mm Hg diastolic on two or more consecutive occasions

2.4. HbA1c of 42- 47 mmol/mol (6.0-6.4%)
3. Male & Female; Upper Age Limit 75 years ; Lower Age Limit 30 years
4. Able to give written informed consent

Original inclusion criteria:
1. GP patients with a computer diagnosis of severe mental illness (SMI), i.e. Schizophrenia (ICD-10, F20), Persistent Delusional disorder (ICD-10, F22), Schizoaffective disorder (ICD-10, F25), Bipolar affective disorder (ICD-10, F31)
2. Raised total cholesterol over 5mmol/l or CVD 10 year risk score above 10%
3. Male & Female; Upper Age Limit 85 years ; Lower Age Limit 30 years
4. Able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 350; UK Sample Size: 350

Key exclusion criteria
1. Too acutely unwell defined as under acute psychiatric care
2. Primary diagnosis of an organic mental health problem and/or severe cognitive impairment
3. Life expectancy < 6 months
4. Pre-existing CVD

Added 01/09/2015:
5. Currently pregnant

Date of first enrolment
01/05/2014

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
B Wing, Maple House

149 Tottenham Court Road
London
United Kingdom
W1T 7NF

Study participating centre
80 participating GP practices
United Kingdom
-

Sponsor information

Organisation
Camden and Islington NHS Foundation Trust (UK)

Sponsor details
1st Floor
Bloomsbury Building
St Pancras Hospital
4 St Pancras Way
London
England
United Kingdom
NW1 0PE

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Central Commissioning Facility

Results and Publications

Publication and dissemination plan

The trial protocol will be submitted for publication in September 2015 to a peer-reviewed journal. The results of the trial will be submitted to a peer-reviewed journal. The paper(s) will present the results of the clinical and cost effectiveness analyses (possibly submitted as two papers).

Protocol: 31/10/2015
Clinical effectiveness analysis: 31/08/2017
Cost effectiveness analysis: 31/08/2017

Intention to publish date

31/08/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/02/2016		Yes	No
Results article	results	01/02/2018		Yes	No
HRA research summary			28/06/2023	No	No