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The SPHERE Study. Secondary prevention of heart disease in general practice: a randomised controlled trial of tailored practice and patient care plans with parallel qualitative, economic and policy analyses

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Registration date 28/02/2005	**Overall study status** Completed	
Last Edited 31/01/2018	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.spherestudy.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PR054/2001

Study information

Scientific Title
The SPHERE Study. Secondary prevention of heart disease in general practice: a randomised controlled trial of tailored practice and patient care plans with parallel qualitative, economic and policy analyses

Acronym
SPHERE

Study objectives
The aim of the SPHERE study is to design, implement and evaluate a multi-faceted intervention to improve the process of care and objective clinical outcomes for patients with established coronary heart disease in general practice in Ireland. The intervention runs over eighteen months and involves 960 patients from 48 practices across three study centres (Belfast, Dublin and Galway). Complex interventions focusing on altering human behaviour at organisational, practitioner and patient levels represent a challenge to randomised controlled trial research. This study employs both qualitative and quantitative evidence, adopting a phased approach to the development and evaluation of the intervention as recommended in the MRC Framework for the Development and Evaluation of RCTs for Complex Interventions to Improve Health (Medical Research Council, 2000). The SPHERE study is a cluster randomised controlled trial, with practice-level randomisation to intervention and control groups. Economic, policy and qualitative analyses will be carried out on data collected at baseline and 18-month follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committees of the Irish College of General Practitioners and Queen's University Belfast, April 2002

Study design
Practice level cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)

GP practice

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Coronary Heart Disease (CHD)

Interventions
INTERVENTION PRACTICES

Level 1: Tailored practice care plans.

1. Training for practice staff.
Training will be delivered independently in each of the three regional study centres. All trainers will adhere to a single training protocol to ensure standardised delivery of the training across centres. Training delivery will be planned and rehearsed jointly by all trainers using role-play and peer review techniques. In addition, the project manager will act as an observer during the first two training sessions in each centre and will provide feedback to trainers with a view to further standardizing the training.

1.1. First training session: Medication training.
GPs and practice nurses are invited to attend a ninety-minute training session on medication guidelines, delivered by the study GP in each region. This is an interactive session in which practice staff are invited to review and discuss the most recent medication prescribing guidelines for secondary prevention. The session uses case-based scenarios to enable the practitioners to reflect on their own practice. Practitioners are offered a summary sheet of prescribing guidelines and a summary prompt showing commonly used drugs and dosages within the various medication categories. If practices wish their practice nurse to make prescribing decisions the research nurse will help to prepare appropriate specific protocols.
The objectives of this session are:
1.1.1. To increase confidence and competence regarding prescribing and the secondary prevention of heart disease
1.1.2. To discuss the role of the Scottish Intercollegiate Guidelines Network (SIGN) guidelines and apply to real clinical situations
1.1.3. To explore practitioner attitudes to secondary prevention and to discuss points raised specifically by each practice
1.1.4. To address issues of patient adherence to medication

1.2. Second training session: Behaviour change training.
GPs and practice nurses are invited to attend a ninety-minute training session on facilitating patients with behaviour change, delivered by the research nurse in each region. This is an interactive session in which practice staff are invited to reflect on their views around lifestyle change and practice new techniques (through role play) to improve their ability to facilitate patients with behaviour change. Strategies to increase patient motivation are discussed, following guidelines from brief motivational interviewing literature. Additional techniques, based on principles of behaviour modification and social learning theory, include: setting small achievable goals, action planning, using prompts, self-monitoring, offering rewards, habit reinforcement, and relapse prevention.

The objectives of this session are:
1.2.1. To enable practitioners to develop skills based on leading behaviour change theories, which may help them with behaviour change consultations
1.2.2. To introduce the SPHERE patient-held booklet and the patient care plan (see Level 2 below)

2. Responding to individual practice needs.
Additional practice needs in relation to the delivery of preventive care for patients with established cardiovascular disease, as well as the day-to-day running of the study, are recorded on a tailored practice care plan and followed up by the SPHERE research nurse.

3. Ongoing support from the SPHERE research nurse.
The SPHERE research nurse maintains regular contact with the practices, and is easily contactable by phone if practice staff have any queries about SPHERE.

4. SPHERE newsletter.
Intervention practices receive a study newsletter which is published every four months. The newsletter contains the latest news and updates relating to the study.

Level 2: Tailored patient care plans.

1. Initial target setting consultations.
The first patient intervention consultation with the practice nurse takes place as soon as possible after baseline data collection, once training of practice staff has been completed. Blood pressure (BP) and body mass index (BMI) are measured, diet, smoking and exercise habits reviewed and the result of the baseline cholesterol assay discussed. The patient and nurse together identify areas of management which could be improved and the patient is invited to prioritise one particular aspect of their lifestyle for change. Possible ways of achieving targets reflecting optimal management (BP <140/90 mmHg, cholesterol <5 mmol/l, BMI <25, non-smoking, taking exercise for 30 minutes 5 days per week, eating fruit/vegetables daily and avoiding saturated fat intake, avoidance of stress) are identified. Plans for action are recorded on a personal care plan tailored for each patient and retained in the practice. The GP also sees the patient at this visit or at a further appointment within 2 weeks to determine if any change in medication is appropriate. A further follow up telephone call is made by the practice nurse to give support and address any questions 2 weeks later.

2. The patient-held booklet.
This booklet contains information on all the key risk factors for CHD. It is used by the practitioners in all initial target setting discussions with the patient and is given to the patient to be kept by them. The booklet can be referred to at subsequent consultations with the GP or practice nurse for consolidation of information relevant to secondary prevention and cardiovascular risk. There are 6 sections in the book:
2.1. Medications
2.2. Smoking
2.3. Exercise
2.4. Healthy eating
2.5. Stress
2.6. Community support
By providing a summary of lifestyle advice for secondary prevention of CHD, the booklet serves not only as an information resource for patients but also as a reference guide to help practitioners in their lifestyle-related consultations with patients.

3. Regular consultations with patients
Patients are invited to attend for an appointment with the GP/nurse every 4 months. At each visit a review of factors relating to targets and goals for optimal secondary prevention are made as appropriate. Routinely BP and BMI are checked and goals relating to diet, smoking and exercise habits are reviewed. Cholesterol is checked if it has been found to be raised at baseline, but if normal at baseline cholesterol is checked annually. Relevant measurements taken at each review visit are recorded and held in the practice and reviewed with the patient at subsequent review visits. Care which would be given according to current clinical guidelines will also be provided, as required.

CONTROL PRACTICES
Data are collected for patients in intervention and control practices in identical ways. In control practices, data are collected at baseline and 18-month follow-up. Otherwise, patients in control practices continue to receive health care as usual and the nature of this in each participating practice will be clearly described.

This research is being carried out jointly by:
Department of General Practice, National University of Ireland, Galway
Department of General Practice, Queen's University Belfast
Department of Public Health and Primary Care, Trinity College Dublin

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Blood pressure
2. Total cholesterol
3. Physical and mental health status: measured by the SF-12
4. Hospital readmissions

Secondary outcome measures
1. Process of care:
1.1. SPHERE visits
1.2. Total number of GP visits
1.3. Total number of hospital OPD visits
1.4 Recording of risk factors in GP records
2. Body Mass Index/Waist-Hip Ratio
3. Exercise: measured by Godin Leisure-Time Exercise Questionnaire
4. Smoking status
5. Diet: measured by Dietary Instrument for Nutrition Education (DINE), including question regarding portions of fresh fruit and vegetables
6. Adherence to medication: measured by MARS-5 (Medication Adherence Report Scale)

Overall study start date
01/01/2003

Completion date
30/06/2008

Eligibility

Key inclusion criteria
Patients with existing cardiovascular disease (defined as: documented myocardial infarction [MI], coronary artery bypass graft [CABG] or angioplasty, or a diagnosis of angina confirmed by exercise stress test, isotope test or coronary angiogram)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
960

Key exclusion criteria
Patients with significant mental or physical illness (based on the recorded judgement of practice staff), which is likely to impair capacity to change lifestyle behaviour or assimilate new information

Date of first enrolment
01/01/2003

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland
Galway
Ireland
-

Sponsor information

Organisation

Health Research Board (Ireland)

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Sponsor type
Government

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland) (ref: PR054/2001)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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?
Abstract results		01/07/2005		No	No
Protocol article	protocol	29/07/2005		Yes	No
Results article	results on the use of qualitative methods	18/07/2006		Yes	No
Results article	results on monitoring treatment fidelity	01/11/2007		Yes	No
Results article	results on recruitment and retention	19/06/2009		Yes	No
Results article	results	29/10/2009		Yes	No
Results article		21/11/2012		Yes	No
Results article	six year follow-up results	03/11/2015		Yes	No
Results article	results	01/12/2016		Yes	No