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The Impact of Support Group Membership on Social Support, Psychological Morbidity and Quality of Life in Patients with Cardiac Syndrome X

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Recruitment status
No longer recruiting

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28/09/2007

Overall study status
Completed

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18/01/2012

Condition category
Circulatory System

[_] Prospectively registered
[_] 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

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Secondary identifying numbers
N0201188118

Study information

Scientific Title

Study objectives
The Impact of Support Group Membership on Social Support, Psychological Morbidity and Quality of Life in Patients with Cardiac Syndrome X.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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: Cardiac syndrome X

Interventions
The study is designed as a randomised case-control trial. Patients will be randomly assigned to 12 monthly support group meetings or usual care control. Usual care is defined as continuing to attend all normal GP, consultant or clinic appointments without additional study intervention. All potential participants (see Subjects below) will receive a letter briefly outlining the study along with how and why they have been contacted to participate. All patients will also be sent an information sheet containing a detailed description of the study, a brief questionnaire confirming eligibility and a freepost envelope. Participants will be requested to complete the questionnaire and return it in the enclosed freepost envelope if they are interested in taking part.

Once a potential participant has expressed an interest in taking part in the study and their eligibility is confirmed, patients will attend a study visit. All study visits will take place in a quiet, private room on a one-to-one basis, where the project will be fully explained and any questions answered. All aspects of the support group will be described in detail, including the considerable commitment required to participate in such a program. The nature of the usual care arm of the study will also be fully explained. Patients will be advised that their GP will be informed of their participation in the trial at their request. All participants will give written informed consent using the consent form approved by the Royal Brompton & Harefield NHS Trust Ethics Committee.

Following consent, patients will be randomly assigned to either 12 monthly support group meetings or usual care control for the same 12 month period. Randomisation will be performed using identical opaque brown sealed envelopes containing an equal number of paper strips marked Support Group or Usual Care. The envelopes will be shuffled in front of the patient, who will then be asked to pick one from the pile. The patient will open the envelope themselves to discover their group assignment.

Following randomisation, all participants will be guided through and asked to complete a study questionnaire (see Questionnaire section below), exploring their current quality of life, anxiety, depression, social support and social contact, along with health recourse utilisation over the previous two years. All participants will be requested to complete the same questionnaire after six and twelve months of support group participation or usual care. Support group participants will receive the additional questionnaires during the group meeting to complete at home and return in a 'freepost' envelope provided. Usual care control group members will receive and return the six and twelve month questionnaires by post using the 'freepost' envelope provided.

The support group will consist of 12 monthly group meetings. The groups will be comprised of no more than 20 patients, in order to provide a supportive environment small enough to encourage full interaction, in line with current support group recommendations (1). Groups will be held at both the Royal Brompton and Harefield sites in order to reflect the geographical location of the majority of our patient population. Groups will run for approximately 90 minutes at a time and day most suitable to the majority of the participants.

At the first group meeting, the support group goals, aims and ethic will be explained in detail, allowing plenty of time for input from the group. The monthly meetings will be designed to reflect the needs of the participants involved. Participants will be asked to indicate what they hope to get out of the support group, what topics they would like to learn more about, or what activities they would like to undertake, thus empowering the participants with a sense of group ownership and responsibility. It is envisaged that guest speakers will address the group on associated topics every other month, with the interim meetings providing and opportunity for discussion, reflection and support. Presentations from guest speakers will include:
1. An overview of Syndrome X given by Prof Peter Collins, a recognised expert in the field
2. The importance of physical activity and exercise, given by a Harefield Hospital physiotherapist experienced in exercising patients with Syndrome X
3. Learning to relax to avoid pain, given by Dr Nasim Kanji, a practitioner of Autogenic Training
4. Ask an expert forum with Dr John Stevenson, a gynaecologist and authority in hormone replacement therapy and Syndrome X
5. Other guest speaker and topics for discussion will be motivated by the participants interests.

Support group ethic. In order to promote an atmosphere of tolerance, understanding and mutual respect, in line with other long-established support groups (The Wellington ME / Chronic

Fatigue Syndrome Support Group, Wellington, New Zealand), the following ethic will be applied to the Syndrome X group:
1. Confidentiality - whatever is said in the meeting room stays in the room
2. Respect other peoples views and beliefs - remember everyone is different what works for one person may or may not necessarily work for another.
3. One person speaks at a time - common courtesy and politeness
4. Participants can reveal as much or as little as they feel comfortable with
5. A question and answer session will always follow any presentation by a guest speaker If the participant has any complaints or suggestions about the way the meeting or group is run, they should contact the group leader (EA)
6. If the participant wants to suggest a guest speaker or specific topic, they should talk to the group leader (EA)
This ethic will be introduced to the participants during the first meeting and reinforced throughout the duration of the support group.

Syndrome X patients with chest pain, a positive exercise ECG stress-test for myocardial ischaemia and angiographically smooth coronary arteries who have expressed an interest in participating in any previous research study will be invited to participate in the study. This number totals approximately 200 patients, all of whom will be approached to participate by post. Further Syndrome X patients will be approached from the Womens Heart Clinic at the Royal Brompton & Harefield NHS Trust (London, United Kingdom). The Womens Heart Clinic is a specialised clinic for Syndrome X patients run by Prof. Peter Collins. All patients with Syndrome X will be invited to participate in the study, regardless of gender or additional illness.

The Health Anxiety Questionnaire (2) (HAQ) has been developed using the cognitive behavioural model of anxiety (3), which divides health anxiety into two parts: development and maintenance. The HAQ is split into four sub-scales that focus on: health worry preoccupation; fear of illness and death; reassurance seeking behaviour and interference with life. Developed and validated in medical, psychiatric and healthy volunteers (2), the 22 questions have a four-point Likert scale response format.

The Hospital Anxiety and Depression Scale (4) (HADS) measures clinically significant anxiety and depression in general medical patients. The 14-item questionnaire is split in to two sub-scales (anxiety and depression) using a four-point Likert scales response format. Anxiety and depression scales have also been combined to create a total score (5). The scale has been validated with both outpatients and inpatients (6), along with NCCP patients (7).

The SF-36 (8) is a general health questionnaire divided into different aspects of quality of life: physical role limitation, emotional role limitation, physical functioning, pain, general health and energy. The SF-36 is a commonly used tool in quality of life research and has previously been used with Cardiac Syndrome X patients (9).

A demographic information scale (10) will be used to assess social interaction by recording the patients living circumstances, frequency of contact with friends and relatives and size of social network. This measure investigates the frequency contact with adults, both outside and within the normal household, differentiating between friends and family along with identifying any specific confidant. The four reported levels represent the following frequencies of social contact: 1) every day; 2) three times per week; 3) once a week; or 4) once a month.

The ENRICHD Social Support Instrument (ESSI) (11) was developed for use with post acute MI patients. The seven item scale assesses four key attributes of social support: emotional, instrumental, informational and appraisal. The ESSI has also been validated among cardiac patients undergoing angioplasty (12).

The York Angina Beliefs (13) is designed to uncover the patients beliefs and possible misconceptions regarding chest pain symptoms and dyspnoea. Inaccurate health beliefs can drastically influence behaviour, leading in inactivity and reinforced illness perceptions. The York Angina Beliefs Scale has been designed for use in both the clinical and research environment.

Participants will also be asked about any known family history of CHD, their current medications, hospitalisations and clinical consults relating to Syndrome X over the past two years, along with their current level of physical activity.

The data will be analysed using one-way ANOVA, paired and independent Students t-tests, Pearsons Correlation and ANCOVA to determine between group effects while controlling for baseline variation; overall comparisons of categorical data will be performed using Chi-square test. Statistical significance level is set at $p<0.05$. In order to ensure a minimum 80% power, data from a previous large-scale cross-sectional study (14) has been employed to establish the necessary sample size using the standard calculation and normogram (15). The following assumptions were made for all the power calculations: 5% significance level, 80% power to detect a difference between groups, randomisation to the two groups in equal proportions. From the previous data (14) using these parameters, it has been calculated that a total sample size of 60 (30 patients in each group) would determine the impact of support group participation on psychological morbidity, health beliefs, quality of life and health resource utilisation in patients with Cardiac Syndrome X.

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performance of the ENRICHD Social Support Instrument in cardiac patients. Health Qual Life Outcomes 2004; 2(1):24.
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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Measures of psychological well being: quality of life, anxiety, depression, health anxiety, social support and health beliefs

Secondary outcome measures
Health resource utilisation (GP visits, hospital outpatient and inpatient care, medication use)

Overall study start date
31/10/2006

Completion date
31/01/2008

Eligibility

Key inclusion criteria
All patients must fulfill the exact criteria for Cardiac Syndrome X:
1. The triad of angina pectoris
2. A positive exercise ECG for myocardial ischaemia
3. Angiographically smooth coronary arteries.

In order to be as inclusive as possible and to involve a typically representative sample of patients with Syndrome X, patients will be invited to participate regardless of gender, concurrent illness, symptom severity or frequency.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
1. The inability to commit to participating in the support group on the designated day or for fewer than 6 sessions
2. The inability to complete the study questionnaires, therefore a poor understanding of written English
3. Ongoing uncontrolled psychiatric illness (disruption, domination or non-participation within the group)
4. Unwillingness or inability to give written informed consent
5. Participation in a concurrent research study

Date of first enrolment
31/10/2006

Date of final enrolment
31/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College School of Medicine NHLI
London
United Kingdom
SW3 6LY

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Royal Brompton and Harefield NHS Trust

Funder Name
No External Funding

Funder Name
NHS R&D Support Funding

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?
Results article	results	01/02/2011		Yes	No