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Combination of specialist treatment and psychosocial intervention in women after a cardiac event

Submission date	Recruitment status	[_] Prospectively registered
07/11/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/12/2008	Circulatory System	

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

N/A

Study information

Scientific Title
Combination of specialist treatment and psychosocial intervention in women after a cardiac event: a randomised controlled trial

Acronym
HFH

Study objectives
Combined intervention of specialist treatment and psychosocial rehabilitation specifically tailored for women's needs improves prognosis and psychosocial functioning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Karolinska Institute (Karolinska Institutet), approve on 20/07/1995 (ref: 196/94)

Study design
Open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting

Interventions
The participants were randomly assigned (randomisation ratio 1:1) to the following two groups:

Intervention group: A combination of the following two interventions:
1. Specialist treatment (cardiologist) as opposed to usual care
2. A 1-year intervention consisting of a psychosocial rehabilitation based on cognitive-behavioural therapy principles tailored to women's needs (20 x 2-hour sessions)

Control group: Usual care only.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patients were followed-up for the following primary outcomes for 6.5 years on average through Swedish health care registers:
1. Mortality
2. Non-fatal myocardial infarction

Secondary outcome measures
Psychosocial functioning, assessed by the following questionnaires:
1. Beck Depression Inventory
2. Mastricht Questionnaire measuring vital exhaustion
3. Daily Stress Behaviour Questionnaire
4. Availability of Social Integration
5. Availability of Attachment

All secondary outcomes were assessed at the following four timepoints:
T1: At baseline (6-8 weeks after randomisation)
T2: After 10 weeks i.e. after 10 intervention sessions
T3: After 1 year (end of intervention)
T4: At 1-2 year follow-up measurement

Overall study start date
21/08/1996

Completion date
31/01/2000

Eligibility

Key inclusion criteria
1. Women aged <=75 years
2. Those who had either acute myocardial infarction, percutaneous coronary intervention or coronary artery bypass grafting

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
250

Key exclusion criteria
1. Women >75 years of age
2. Those not communicating in the Swedish language
3. Those who participated in other research studies
4. Those who did not belong to the hospital catchment area
5. Those who had serious co-morbidity that would preclude taking part in the 1-year intervention programme, such as malignancy or psychiatric disease

Date of first enrolment
21/08/1996

Date of final enrolment
31/01/2000

Locations

Countries of recruitment
Sweden

Study participating centre
Norrbacka level 6
Stockholm
Sweden
17176

Sponsor information

Organisation
Public Health Committee/ EXPO-95 (Sweden)

Sponsor details
Norrbacka level 8
Karolinska University Hospital
Stockholm
Sweden
17177

Sponsor type
Government

Website
http://www.karolinska.se

ROR
https://ror.org/00m8d6786

Funder(s)

Funder type
Government

Funder Name
EXPO-95/ Public Health Committee, Stockholm County Council (Sweden)

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	01/03/2008		Yes	No