

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Staffan Ahnve

Contact details
Norrbacka level 6
Department of Public Health Sciences
Karolinska University Hospital
Stockholm
Sweden
17176
+46 8 737 38 97
Staffan.Ahnve@ki.se

Additional identifiers

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)

Primary study design

Interventional

Study design

Open-label randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Psychosocial functioning, assessed by the following questionnaires:

1. Beck Depression Inventory

2. Maastricht 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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR
<https://ror.org/00m8d6786>

Funder(s)

Funder type
Government

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

Results and Publications

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