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Lifestyle intervention trial: a multidisciplinary lifestyle modification programme

Submission date	Recruitment status	[_] Prospectively registered
17/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2009	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial of a multidisciplinary lifestyle modification programme to improve risk factors for stroke and cardiovascular disease in the short- and long-term

Acronym

VHC-intervention

Study objectives
1. A four week, life-style intervention program will improve risk factors for stroke and cardiovascular disease in the short- and long-term
2. A healthy diet and increased physical activity in addition to stress handling will increase survival in the long-term
3. The participants will have positive experiences from the individual guidance and the intervention which in turn will reduce morbidity and mortality risk by decreasing risk factor patterns

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Medical Faculty of Umeå University gave approval on the 22nd November 2006 (ref: 05-177M)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Risk factors for stroke and cardiovascular disease

Interventions
The education and rehabilitation program at Vindeln Health Centra (VHE-centre) has recently been described. A problem-based learning perspective was established and the responsibility of planning and execution of the activities was shared between patients and the staff, consisting of a doctor, nurse, physiotherapists, dietician, and other important supporters.

In total, 114 full-time hours, focusing on food preferences, selections, physical exercise, and stress management were provided during the first four weeks. The activities were repeated during a four-day revisit to the centre 6 or 12 months after the program. The study tried to establish functioning groups as a source to achieve changes and as a start for individual targets. The main focus was to combat risk of future stroke and CVD. The refresher course was used for repetition and revision of the "home program".

The randomised study took advantage of a mismatch between demands and supply of the multidisciplinary programme. Referrals from the county accumulated during the 4 - 6 weeks preceding the admittance dates. Proper referrals were determined by the team doctor and the clinical team at the centre. During seven rounds of admission in 1988 - 1989, 325 patients were properly referred to the programme. They outnumbered the available places. It was not feasible, with available knowledge, to rank the needs for this treatment by the type of risk factor or by the risk factor levels. Instead patients were listed with identity numbers (not names or referral forms) and the list was sent to one researcher (Thomas Svensson) who allocated the cases using

random numbers. When a patient allocated to treatment announced that he or she was prevented from coming, one more patient from the full list was randomised to be a case. Eventually 239 patients were randomly allocated to the programme, and 86 patients referred back to their doctor for usual care.

Signs of myocardial infarction (MI) and left ventricular hypertrophy (LVH) are important to include in the study of risk factors for CVD. Other pathological features were also noted (particularly if they had changed during the study period). A previous MI was diagnosed when, at the beginning of the study, there were electrocardiogram (ECG) signs corresponding to the Minnesota Code criteria: 1:1-2, 5:1-2, and 1:3+5:3, MI (ECGsp), coded as 2, and if less specific ECG criteria were found corresponding to Minnesota code 1:3, 5:3, 6:1-4, 7:1-3, 8:0-9, and 9:1-8 MI (ECGnonsp) coded as 1.

The occurrence of signs of a new MI during the study period, i.e, during a period of on average 5 years, as observed from the ECG recording at the end of the study, was diagnosed as a recent MI (ECGsp or ECGnonsp).

Changes in ECG signs after (A) compared with before (B) the intervention were obtained by subtracting the code values (B - A), resulting in a scale with the steps -2, -1, 0, 1, or 2. A negative value denotes diminishing and a positive value signs of a new or increasing signs of previous MI.

LVH was diagnosed when there was a high amplitude QRS complex, Minnesota Code criteria 3:1 and 3:3, or in combination with typical ST and T changes as in Minnesota Code criteria 4:1-4.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Survival analysis and ECG recordings
2. Dietary assessments before and after the four week intervention
3. Baseline to follow up after 6 months, 1 or 11/2 years and 5 years for stroke and CVD risk factors
4. Weight loss and improved VO2-max

Key secondary outcome(s))
1. Changes in risk factor levels including weight loss and all-cause and CVD mortality over short and long term
2. ECG-changes, with MI-signs calculations at baseline and after 5 years
3. Food selections at admittance and at one year follow up registered by a questionnaire developed for this study
4. Psycho-social status and stress related health behaviour evaluation from questionnaires
5. Death certificates to assure diagnosis related risk factor changes

Completion date
01/12/1996

Eligibility

Key inclusion criteria
1. All ages and both men and women
2. Remittance from primary health care or hospital doctors to target the components of a healthy lifestyle. The patients admitted to the centre in groups of 30 for a comprehensive activity
3. Able to take part in a four week long and organised program
4. The randomisation was performed after the inclusion of participants which eliminated the risk of selection bias. The outcomes from the intervention were assessed at baseline, after four weeks, sixth month and 11/2 year or one year and five years by the health care staff.
5. Sixty-four percent of the patients were hypertensive, 20% had type 2 diabetes mellitus, and 55% had a body mass index (BMI) greater than 30. In addition to the main diagnosis, around 50% had a second subsidiary diagnosis and exhibited a high number of risk factors associated with the insulin resistance syndrome.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/1994

Date of final enrolment
01/12/1996

Locations

Countries of recruitment
Sweden

Study participating centre
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Sponsor information

Organisation
Umeå University (Sweden)

ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Government

Funder Name
County Council of Västerbotten (Västerbottens läns landsting [VLL]) (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	principles of learning results:	01/05/1999		Yes	No
Results article	gender difference results:	01/06/2001		Yes	No
Results article	outcome results:	01/07/2006		Yes	No
Results article	mortality results:	01/09/2007		Yes	No