Jan 17, 2020

Prospective life-style intervention in a CVD risk cohort

PLOS One

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1 Works for me dx.doi.org/10.17504/protocols.io.4wrgxd6

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ABSTRACT

Abstract

The high CVD-risk population (2504 patients; 1096 males and 1408 females) were treated with a 4-week comprehensive life-style program with follow-ups at 6 month and 11/2 year or 1 year and after 5 year. The present cox regression concern risk factors for mortality after 18 years with stratification for sex and for smoking habits. Traditional risk factors for CVD was included in the regression to study all-cause, CVD- and Cancer mortality.

Laboratory analysis and methods are described in addition to performance of tests for physical function (maximal predictive cycle ergometer test; VO_2 max), blood pressure in supine position (3 times/week) and anthropometry (BMI, kg/m^2) are reported in medical records. The intervention program and information from questionnaires, including data for assessing smoking habits are included in the present extended section for methods to assure reproducibility. The staff at the center consisted of physical therapists, nurses, dietitians and physicians to substantiate a high level of clinical registrations. The purpose was, besides implementation of rehabilitation, to assess therapies for individual patients.

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0227692

THIS PROTOCOL ACCOMPANIES THE FOLLOWING PUBLICATION

Håglin L, Törnkvist B, Bäckman L (2020) Obesity, smoking habits, and serum phosphate levels predicts mortality after life-style intervention. PLoS ONE 15(1): e0227692. doi: 10.1371/journal.pone.0227692

ATTACHMENTS

Stepwise protocol 190628.docx

GUIDELINES

Ethical consideration

The Ethical Committee of North Sweden at the University of Umeå, Sweden, approved the protocol in November 22, 2006 (Dnr 05-177M). The study has been registered as a sub study to the Lifestyle intervention trial (no. ISRCTN79355192). Hospital, Umeå, Sweden. Oral informed consent was obtained from the participants of this study.

The data collection was controlled by professional staff and according to official guidelines.

SAFETY WARNINGS

Not applicable

BEFORE STARTING

Handling of equipments for clinical assessments were ensured and managed on a regular basis.

1 **The population in VHEC.**

The patients had a clinical and biochemical assessed diagnosis and were referred from primary care and hospitals in the county (64%, hypertension; 20%, type 2 diabetes; and 55%, BMI >30 (kg/m2). The diagnosis was re-assessed and confirmed by the physician at the health care center. In addition to the main diagnosis, about half of the patients had a second subsidiary diagnosis, and the prevalence of multiple risk factors resembling metabolic syndrome was high. A second subsidiary diagnosis was never type 2 diabetes, chronic kidney disease (CKD), or coronary heart disease (CHD). About 90 % of the patient population with diabetes mellitus had Type 2 diabetes.The material (calculated from registrations of body weight) comprised 2504 consecutive patients admitted to a 4-week full-time patient education scheme during 1984 - 1996, aimed at their mastering of hypertension, diabetes mellitus (DM), ischemic heart disease or hyperlipidemia. Half a year or one year after the program, the activities were repeated during a four-day revisit to the center. After the residential period, the patients were expected to practice their in-home program in their habitual environment. Patients admitted between 1984 and 1987 (groups 1 ± 29, n.818) were invited to a follow-up after 6 months and again at 11/2 year. Patients admitted during the years 1987 ± 1996 (groups >29, n.1805) were followed up after 1 y.

2 **Setting and staff.**

Vindeln Health Education Centre, Vindeln is in the North of Sweden, 55 km west of Umeå, in the County of Västerbotten. Vindeln Patient Education Centre was administrated by primary health care (PHC).The study is prospective and includes a high-risk cohort for CVD. Biochemical, physical and lifestyle/social factors were studied in a cohort of 2504 patients (1096 men and 1408 women), all of whom were at high risk of contracting CVD. Eight new groups of patients (each group with n=30) were admitted each year from 1984 to 1995. They all arrived the same day (Monday, 1st week) to the Centre and stayed for nearly 4 weeks (Thursday ± Friday, 4th week), i.e. for 24 days. At admittance, the participants completed a lifestyle questionnaire that included questions about smoking habits at time of admittance.The staff included, the dietician, a physician, two nurses, three physiotherapists, a housekeeper, all of whom were available for consultations and guidance during the whole period.

3 **Program activities.**

The design of the program was derived from a broad eclectic theoretical foundation (Matarezzo et al 1984). In this framework, the development of a capable and safe environment within which the patients could tackle their health problems was considered to be especially important; an environment enabling the patients to develop a deeper sense of connection and community, a safe place to let go of their emotional defenses, freeing them from the constraints and pressures of their home environments. Theory and evidence-based principles of learning and behavioral or lifestyle change as synthesized and reflected in the Precede–Proceed (Sjöström et al 1999). Model of health promotion planning was applied (Kaati et al 2006). Lectures, demonstrations and group discussions, with or without a supervisor, took place daily. Most of the time, however, was filled with practical sessions, such as meal preparations and physical exercise.The diet was a diabetes diet that included salt restrictions and moderate calorie restrictions. In accordance with Nordic nutrition recommendations, breakfast provided 25% of a person's daily energy intake, 30% at lunch and dinner, and 15% between meals (Nordic Nutrition Recommendations 1980). The recommended portion sizes amounted to 1600-1800 kcal/day for overweight individuals. Use of alcohol was not permitted and smokers were strongly encouraged to quit smoking.Physical training of moderate intensity was scheduled for 2 h/day. Half an hour a day was devoted to autogenous relaxation. Towards the end of the residential period, patients prepared (with the support of the staff) a plan or contract for further improvement after they return home. The overall goal was to motivate and empower the patients to deal with their own health problems. The patients were taught in one large group about health-related issues (e.g. cooking, meal planning, tobacco, ways of coping with stress and body image) and encouraged to take part in health-promoting exercise (e.g. walking, swimming). This theoretical and physical training occupied 53 h during the 4-week period. Furthermore, varying time of individual guidance was given by a physiotherapist, a dietitian, a nurse and a physician during the period. The individual guidance was `problem- and individual-oriented' for each patient.

4 **Blood sampling and analysis.**

Blood samples were drawn in the fasting state in the morning from all patients at the start of the program and at the final day of the four-week rehabilitation. Centrifugation of blood samples was performed by the nurse at the health center. Serum and plasma were sent to Department of Clinical Chemistry, University Hospital, Umeå, Sweden within 24 hours. During these years (1984-1996), serum dominated over plasma for routine variables. Analysis of hormones and enzymes required EDTA or heparin-plasma and this was collected when requested for. Serum samples were analyzed according to the standard routines developed at the Department of Clinical Chemistry, University Hospital, Umeå, Sweden. Blood and urine tests were recorded on the second day after arriving and each consecutive week using a standardized routine. Average time between first and last measurements was 23 days.

5 **Biochemical analysis.**
Serum cholesterol (S-Chol) was determined using an enzymatic method (Boehringer Mannheim Diagnostica, Mannheim, Germany) on either Hitachi 705 or Hitachi 717.Serum triglycerides (S-TG) were determined using enzymatic methods (Boehringer Mannheim Diagnostica, Mannheim, Germany) on Hitachi 717. Serum urate (S-Urate) was determined using an enzymatic Uricase method (Boehringer Mannheim Diagnostica, Mannheim, Germany) on Hitachi 705 or Hitachi 717.Serum calcium (S-Ca) was determined using a complexometric method from Boehringer Mannheim on SMA II (Technicon) and on Hitachi 717 (after 1989).Up until 1989. Corrected calcium was adjusted for albumin (S-Calcium, total + 0.01 x (39-s-albumin).Serum phosphate (S-P) was determined using an ammonium-molybdate method (Boehringer Mannheim Diagnostica, Mannheim, Germany) on a Boehringer Mannheim (SMA II Technicon) and on Hitachi 717 (after 1989).Plasma albumin were analyzed using Vitros ALB Slides on an Ortho Vitros 5.1 FS analyzer.Reference values;Serum Cholesterol 31-50 years of age 3.3-6.9 mmol/L and >50 3.9-7.8 mmol/L.Serum Triglycerides adults < 2.6 mmol/L.Corrected P-Ca >18 year 2.15-2.50Serum phosphate for males >50 years 0.75-1.40 mmol/L and for females 0.80-1.50 mmol/L.Albumin 40-70 years 36-45 g/L and >70 years 34-45

6 **Other tests and analyses.**
Presence of glucose, albumin and ketones in urine was measured by dipstick by the nurse at the center. The glucose tolerance test OGTT with glucose measurements at fasting condition, before the glucose intake and after 2 hours was performed by the nurse at the center and included all patients admitted for rehabilitation. B-glucose was analyzed on capillary blood taken at the center and was used for insulin dosage, diet and physical activity recommendations. Serum magnesium (S-Mg) was determined using the atom absorption technique; after 1989, serum magnesium was determined using a calorimetrically complex method with reagents from Boehring Mannheim on Hitachi 717. Serum glucose (S-Glu) was determined using a hexokinase method (Boehringer Mannheim Diagnostica, Mannheim, Germany) on either Hitachi 717 or Hitachi 911. Serum creatinine was analyzed by Jaffé method with dialysis on a SMAII (Technicon) before 1989; thereafter and up to 1996, serum creatinine was analyzed by an enzymatic creatinine PAP (BM) method on a Hitachi 717 analyzer (BM).

7 **Anthropometry and physical assessments.**
The mean and standard deviation for BMI at baseline, in the cohort studied, are 31.2±5.4 (30.7±5.0 for males and 31.5±5.7 for females) with the following quartiles: males 27.3; 30.2; 33.2; females 27.7; 31.0; 37.4.On the second day after being admitted to the VHE center, systolic blood pressure (SBP; mmHg), body weight (kg), height (cm), and body mass index (BMI; kg/m2) were recorded. Blood pressure was determined using a semi-automatic machine, operated by the same trained nurse throughout the study period. Patients rested for 5 minutes before measurements in the horizontal position. Systolic and diastolic blood pressure was measured two times a week on every patient. Blood pressure and resting pulse were measured with the patient in a supine position and after five minutes of rest.Patients were tested using a cycle ergometer test the day they arrived and during the last residential week. Oxygen uptake was estimated using the linear relationship between heart rate, workload, and oxygen uptake and by using age adjusted gender-specific tables (Åstrand 1976). The test-cycle was made by Monark. Heart rate was measured using a Cardiomix Cardiometer 275.

8 **Documentations and communications.**
Results from measurements and assessments at time of admittance, and at end of the rehabilitation period was included in the patient's data journal. The medical secretary took the main part of the work with registrations of assessments and medical measurements. When indicated from these results and the need of therapeutically changes the physician at the place was consulted for advice and for therapeutically changes. The nurse, physician, dietitian and physiotherapist had regular meetings concerning the planning of practical and theoretical lessons.

9 **Questionnaires.**
At admittance, the participants completed a lifestyle questionnaire that included questionsabout smoking habits – former smoker, smoker or non-smoker – at time of admittance. Education level, social and work-related questions together with questions on spare time physical activity was included in these questionnaires. Assessments of psychological condition and individual problem-oriented subjects was registered by a professional team at the center.