

Changes in procedures in the Inter99 study

In Inter99 the participants were divided into three groups: group A (high intensity group which was offered lifestyle consultation and participation in smoking cessation or diet-exercise groups), group B (low intensity group which was only offered lifestyle counselling and had to contact their own GP or e.g. an dietician or a smoking cessation group in a pharmacy, if they wanted further support), and group C (background population= the control group, which was not influenced).

The two-year follow-up changed to three-year follow-up

The original plan included a baseline study, a one-year follow-up, two-year follow-up and a five-year follow-up. The two-year follow-up was put off to a three-year follow-up. This was done due to logistic reasons (aiming at a constant participant flow to maintain a stable staff). Nothing in the literature indicated that the effect of the intervention would be different if there was a follow-up after three years instead of after two years.

New random sample of group C at five-year follow-up

A random sample was drawn from group C. These persons were followed by questionnaires at baseline, at one-year, after three years and after five years, independent of responses to the first questionnaire. In addition to that, a new random sample of group C was drawn at five-year follow-up and received a questionnaire. This random sample overlapped the original random sample.

30-year-olds invited as well

Originally, all 35-, 40-, 45-, 50- and 60-year-old persons were selected. To make the study comparable with previous studies in the research centre, it was subsequently chosen to draw a group of 30-year-olds. This was decided August 10, 1999.

Changes in the smoking intervention

At baseline all daily smokers in the high intensity group A were offered participation in a smoking cessation group (if motivated to quit) or a smoking reduction group (if reluctant to smoking cessation). The smoking reduction groups were dropped after one year (i.e. participants at one-year follow-up were not offered smoking reduction groups), as very few of the participants were interested in them. There were no changes in the offer of free nicotine products during the study. Zyban, however, came as a new smoking cessation product and was introduced in the study January 18, 2001.

Absolute risk

Originally, a calculation of a five-year absolute risk of ischemic cardio vascular disease was based on the actual age. As this caused very low values, it was decided – after 280 participants (after about 1 month) – to change the absolute risk to a ten-year risk and to change all participants age to 60 years. Cut-points were calculated in order to identify persons in the upper quintile. These were calculated using MONICA data. As we expected a decrease in the incidence of cardiovascular disease over time, the plan was to make an interim-analysis after the first participants to see if we identified the desired 20 % of the valid cut-points. This was effected after 1,549 participants and it appeared that a small adjustment downwards had to be made (this was expected due to the declining incidence in cardiovascular disease). Hereby 52 participants were identified and classified as high risk among the first 1,549 participants. Going through the records it appeared that 30 participants were already classified as high risk due to isolated risk factors. The last 22 were contacted by the person who had given the lifestyle counselling in order to be have a new counselling and be offered

participation in a lifestyle group. In this way we caught the persons among the first 280 participants who were not identified as high risk persons, using the new definition used in the rest of the study.

Body Mass Index

In the beginning diet and physical activity was discussed with everyone with a BMI above 25. As the majority had a BMI above 25 the limit was changed to BMI above 28 from April 13, 1999. As far as concerns limit values for being offered participation in diet and exercise groups, the limit value was above 31 in BMI in the beginning of the study. This was changed to 30 in December 1999.

Blood pressure

In the beginning we offered a control re-measurement to all participants with a blood pressure above 140 mmHg, but this was given up after some months. Instead participants with a systolic blood pressure above 140mmHG or a diastolic blood pressure above 90 mmHg were asked to contact their GP/have their blood pressure measured next time they attended the GP. This accomplished series of complaints from the GPs. However, we did not change the cut-off value of the blood pressure when we referred to the GP. Participants with systolic blood pressure above 160 were offered participation in diet and exercise groups and if the blood pressure did not decrease, we advised medical treatment by the GP. Participants with systolic blood pressure above 200 mmHG with symptoms or with diastolic blood pressure above 120 mmHg with symptoms were immediately referred to a medical department. There were no changes in these procedures throughout the period.

Cholesterol

In the beginning all participants with cholesterol above 5.5 mmol/l were referred to their GP. With a level above 7.5mmol/l they were offered participation in a diet and exercise group. In December 1999 we changed the lower limit to 6.0 mmol/l and later to 6.5 mmol/l, due to complaints from the GPs.

Blood glucose

Cut-points for blood glucose have not changed throughout the period. All persons with IGT have been offered intervention.

Heart disease: familiar occurrence and own previous ischemic heart disease

The definition of familiar occurrence of coronary heart disease was: biological mother or sister, who has had an AMI (or by pass surgery) before the age of 60, or a biological father or brother who has had an AMI (or by pass surgery) before the age of 55. Familiar occurrence of coronary heart disease was not clearly defined in the first couple of weeks. As far as concerns own previous cardiovascular disease it was emphasized that it was *ischemic* heart disease.

The intervention

There were no major changes in the counselling given to smokers, or in the smoking cessation groups. The diet and physical activity recommendations changed somewhat over time and in the diet and exercise groups some changes were made - as described in other documents. All staff-members probably improved their counselling skills as time passed by.

Participants in group A versus B

Participants in group B with increased risk of CVD had generally a longer consultation than

participants in group A. This was due to the fact that participants in group A were offered participations in groups, while group B did not receive this opportunity. It was estimated that the staff used about 10 minutes more in average on the high risk participants in group B who needed lifestyle counselling compared with participants in group A. There is no time registration of this.

Change of address

In summer 2003 we moved from the southern part of the hospital to our present residence in the northern part of the hospital.

Behavioural theories

Charlotte Hartvig, a clinical dietician, wrote a document about theories of change of behavioural, pedagogic considerations and didactic before start of the project. Stages of change were used during the whole period, but the Health Believe Model was used more in the beginning and later the Social Cognitive Theory was implemented.

Staff

Staffs were unchanged from baseline to beginning of five-year follow-up, except that a dietician was replaced November 30, 1999. Moreover, the person being responsible for the diabetes part (Dr Charlotte Glümer) moved back to Steno Diabetes Centre January 1, 2000 (but took care of the diabetes and IGT participants henceforth). Major replacement of staff occurred shortly after the start of the five-year follow-up.

Questionnaires

Questions on psychological reactions to screening started with participant no 9,259 on February 9, 2000. The questionnaires were hereafter sent to the remaining part of the participants in the baseline study. Allergy questions together with questions on diet, alcohol and physical activity were added to the questionnaire. These extra questionnaires were distributed at baseline from February 3, 2000.

Diet questionnaires

The same diet questionnaires were used at baseline and at one-year follow-up. At three-year follow-up questions on intake of soft drinks were added to the questionnaire.