

Appendix 1. Low intensity intervention group (N=1,308).

Aim and randomisation

The purpose of the low intensity intervention group (labelled group B in previous papers (1)) was to investigate whether a less comprehensive lifestyle intervention, had a similar impact on lifestyle changes as a high-intensity intervention (labelled as group A).

Group B was not used for power calculations as regard the primary end-point (10 years incidence of IHD), but a power calculation was performed as regard change in lifestyle changes. With an expected participation rate of 70 %, it was calculated that a difference in smoking reduction of 10 % and a difference in reduction of cholesterol, systolic blood pressure, and weight of 5 % after one year between group A and B could be detected with a type 1 error of 0.05 and a 1-power of 0.20.

The intervention group (n=13,016) was randomised with the ratio 9:1 in each age and sex group into a group A (n=11,708) and group B (n=1,308). Randomisation was done by computer-generated random numbers, separately for each sex and age (30, 35, 40, 45, 50, 55, and 60 years) group.

Out of 1,308 persons invited to participate in the low intensity intervention 693 attended the clinic at baseline (53.0%).

The intervention

Persons in the low intensity intervention received the same questionnaires and health examinations as participants in the high intensity intervention group A. Their risk of IHD was also assessed in the same way, by use of the PRECARD[®] programme.

All participants were offered individual lifestyle counseling by a health professional. All participants were encouraged to a healthy lifestyle, based on their risk behavior and motivation to change a specific lifestyle. An individual counseling typically took about 15-45 min.

The only difference between participants in the low and high intensity intervention was that participants randomised to the low intensity intervention were not offered participation in group based counseling (table 1).

Table 1. Brief overview of activities in low intensity and high intensity groups

	Low intensity intervention group B	High intensity intervention group A
Questionnaires	✓	✓
Health examinations	✓	✓
Risk of IHD assessments	✓	✓

Individual lifestyle counseling	✓	✓
General practitioner informed about elevated values	✓	✓
Persons with elevated risk re-invited after 1 and 3 years	✓	✓
All participants re-invited after 5 years	✓	✓
Group-based lifestyle counseling		✓

Participants randomised to group B did not know that participants in group A were offered group based counselling.

If participants in the low intensity group had elevated risk of IHD due to their lifestyle they were encouraged to seek assistance. E.g. smokers were encouraged to quit and to contact local smoking cessation groups or the national quit-line. Also, persons with e.g. high blood pressure received a letter to their general practitioner and were encouraged to contact him/her for a new blood pressure measurement and eventual treatment.

Follow-up was exactly as in the high intensity group. Participants with high risk of IHD were re-invited for new risk assessment, health examination and individual counselling on lifestyle after one, three and five years. Again, the only difference was that those in group B were not offered group based counselling.

Participants at low risk of IHD received questionnaires only at one and three years follow-up and were re-invited for health examination and individual counselling after five years.

Effect of the low intensity intervention

Information from group B has been used in papers investigating changes in lifestyle and self-reported health in the first five years [2-7]. We found a higher impact on abstinence from smoking of the high intensity intervention A compared with the low intensity intervention B, but differences were not significant. For physical activity in men there were significant differences between high intensity intervention A and low intensity intervention B after five years but results were inconsistent and no firm conclusions could be drawn. At one-year follow-up group A had significantly increased the unsaturated/saturated fat ratio compared to group B and in men a

significantly greater decrease in saturated fat intake was found in group A compared to group B. At five-year follow-up group A had significantly increased the unsaturated/saturated fat ratio and the fish intake compared to group B.

10 year follow-up

End- point analyses were performed on high intensity intervention group A, as power calculations were based on this group. However, analyses including the whole intervention group (both group A and B) have been performed. This did not change results (HR (95% CI) for incident IHD = 1.03 (0.94-1.13); stroke = 0.98 (0.87-1.10); IHD + stroke = 1.01 (0.94-1.09) and death = 1.01 (0.93-1.10)).

Reference List

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