

Citation:

Lindström J, Peltonen M, Eriksson JG, Louheranta A, Fogelholm M, Uusitupa M, Tuomilehto J. High-fibre, low-fat diet predicts long-term weight loss and decreased type 2 diabetes risk: the Finnish Diabetes Prevention Study. *Diabetologia*. 2006;49(5):912-20.

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Study Design:

Randomized Controlled Trial

Class:

A - [Click here](#) for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

The aim of the present study was to investigate the association between dietary macronutrient composition and energy density with change in body weight and waist circumference and diabetes incidence in the Finnish Diabetes Prevention Study.

Inclusion Criteria:

- Middle-aged (40 - 64 years)
- Overweight (BMI > 25 kg/m²)
- Impaired glucose tolerance according to WHO 1985 criteria.

Exclusion Criteria:

- Individuals
 - not overweight
 - not middle-aged
 - not with impaired glucose tolerance

Description of Study Protocol:**Recruitment**

Participants in the Finnish Diabetes Prevention Study from 5 study centers.

Design: Randomized controlled trial

Blinding used (if applicable): Implied for laboratory measures

Intervention (if applicable)

- From the original design:
 - Control group: given general verbal and written health behavior information at baseline without specific individualized advice.
 - Intervention: intensive diet-exercise counseling with goals of: weight reduction of 5% or more; less than 30% of the daily energy intake from fat; less than 10% of the daily energy intake from saturated fat; fibre intake 15 g per 1000 kcal or more; and moderately intense physical activity 30 min per day or more. The duration of intervention ranged from less than 1 year up to 6 years, with median length of 4 years. Seven personal counseling sessions with the study nutritionist during the first year and every 3 months thereafter.

Statistical Analysis

- In all analyses of the present paper the two treatment groups were pooled, and the group assignment was used as a cofactor in the adjusted models.
- Weight and waist circumference change from baseline to year 3 was calculated by subtracting the value at year 0 from the value at year 3.
- The last-observation-carried-forward (LOCF) method was used in the calculations for those who were diagnosed with diabetes (n=53) or dropped out (n=18) before the 3-year visit.
- Analysis of covariance and χ^2 -tests were used to analyze the baseline and follow-up period differences between those who developed diabetes during the follow-up and those who did not. The ANCOVA adjusting for group assignment, age, VLCD-use as part of the intensive intervention (adjusted to 'not used'), physical activity at baseline and during the follow-up period, and baseline weight and nutrient intakes, was used to analyze the associations of quartiles of dietary intake during the follow-up with weight and waist circumference changes.
- Adjustment for the baseline intake of the nutrient in question was used to control for regression-to-the-mean effect, since those who report extreme intakes are, due to intra-individual variation, likely to report less extreme intakes at follow-up.
- Trends across the quartiles were analyzed by adding the quartile into the model as a continuous variable.
- The Cox model was used to calculate the hazard ratios (HRs) for developing diabetes between quartiles of dietary intake, with the lowest quartile as the reference category. These analyses were adjusted for group assignment, sex, age, physical activity at baseline and during the follow-up period, baseline weight, baseline nutrient intake, and the baseline 2-h post-challenge plasma glucose, and in further analyses, with the weight change from baseline to year 3.
- To clarify the combined effect of dietary fat E% and fibre density, participants were divided into low- (below median) and high- (above median) intake groups. Between these categories, ANCOVA was used to analyze effects on the weight reduction and the Cox model to analyze effects on diabetes risk.
- In all analyses $p < 0.05$ was considered statistically significant.

Data Collection Summary:

Timing of Measurements

- Years and time of year not given.
- Baseline and year 3 of intervention primary timepoints.

Dependent Variables

- Incidence of type 2 diabetes
- Weight and waist circumference change

Independent Variables

- Intensive diet and weight counseling
- Weight reduction of 5%
- Total fat intake of <30% of energy
- Saturated fat intake <10% of energy
- Moderate daily physical activity of 30 min/day
- Increased fiber intake to >15 g/1000 Cal

Control Variables

- A variety were used depending on the statistical analyses and included group assignment, age, VLCD-use, physical activity, baseline weight and nutrient intakes, sex, baseline 2-h post-challenge plasma glucose.

Description of Actual Data Sample:

Initial N: 522 men and women

Attrition (final N):

Individuals who did not participate in any annual follow-up visits by year 3 (n=15) or who had missing data on dietary intake at baseline (n=1) or during the follow-up (n=6) had to be excluded from the current analyses.

Age: 55±7 years

Ethnicity: Finnish

Other relevant demographics: not given

Medication and other biochemical measures

- Mean fasting plasma glucose 6.1±0.7 mmol/l
- Mean plasma glucose 2 h after glucose load was 8.9±1.5 mmol/l
- Cholesterol lowering drugs were used by 5% and blood pressure-lowering drugs by 29% of the participants.
- Family history of diabetes: 63% of the participants had at least one parent with diabetes.
- 5% were regular smokers.

Anthropometrics: BMI 31±4 kg/m²

Location: Finland

Summary of Results:

Key Findings

- After a mean follow-up of 4.1 years, 114 of the 550 participants had been diagnosed with diabetes. Those who developed diabetes were more obese at baseline, measured as weight,

BMI or waist circumference, and they had higher fasting and 2-h plasma glucose values (as shown in Table 1 of the article).

- The individuals who remained free of diabetes lost more weight and reduced their waist circumference more, also after adjustment for sex, group assignment and baseline value of obesity (BMI, weight or waist circumference), and they did not experience deterioration of glucose values during the first 3 years of the study.
- Subjects who were diagnosed with diabetes tended to consume a diet with lower carbohydrate and fibre content, and also higher in alcohol at baseline. The reported alcohol consumption (2-3 E%) was, however, low throughout the study.
- Among those who remained free of diabetes, E% of carbohydrates and fibre density increased further, and energy proportions of total, saturated and mono-unsaturated fat, and intake of cholesterol decreased compared with those who were diagnosed with diabetes during the study.
- In separate models, fibre density, fat E% and energy density of the diet during the follow-up were associated with weight reduction, after adjustment for group assignment, sex, physical activity, VLCD-use, baseline weight and baseline nutrient intake.
- Weight loss was related to an increase in the fibre (p for trend =0.001) and decrease in fat (p for trend=0.018) and energy density (p for trend=0.001).
- Fibre density of the diet was inversely associated with the change in waist circumference even after adjustment for weight change (p for trend=0.033).
- A total of 147 (29%) of the study subjects had lost 5% or more of their baseline weight at year 3. Fibre density, fat E%, saturated fat E%, and energy density were separately associated with sustained >5% weight reduction, after adjustments for potential confounders.
- The most significant dietary predictor for achieving large weight reduction was energy density, the multivariate adjusted odds ratio being 0.19 (95% CI 0.08-0.41) in the highest compared with the lowest quartile.
- After adjustment for potential confounders, higher fibre density (p for trend=0.01) and lower fat intake (p for trend=0.004) were associated with a reduced diabetes risk. When both fat and fibre were simultaneously entered into the same adjusted prediction model, due to multicollinearity (r=0.60) neither was a significant predictor for diabetes: the HR was 0.88 (95% CI 0.68-1.16) according to increasing fibre density quartile and 1.23 (95% CI 0.95-1.58) according to increasing fat E% quartile.
- The adjusted 3-year weight reduction among those whose diet was both low in fat and high in fibre was 3.1 kg (95% CI 2.3-3.9). Among the subjects whose diet was high in fat and low in fibre, weight reduction was significantly less at 0.7 kg (95% CI for weight change -1.7 to +0.1 kg). Compared with low-fat/high-fibre diet, the HR for diabetes was 1.98 (95% CI 0.98-4.02, p=0.06) in the low-fat/low fibre category, 2.68 (95% CI 1.40-5.10, p=0.003) in the high-fat/high-fibre category and 1.89 (95% CI 1.09-3.30, p=0.024) in the high-fat/low-fibre category (as shown in Figure 2 of the article).

Table 1. Characteristics of the study population at baseline and at 3 years (LOCF method) among those who developed diabetes and those who remained free of diabetes during the study (only significant differences shown)

	No Diabetes (n=386)	Diabetes (n=114)	p value
Weight (kg)			
Baseline	85±13	91±15	<0.001
Year 3	81±13	91±16	<0.001
BMI (kg/m ²)			

Baseline	30.8±4.4	32.3±4.6	0.001
Year 3	29.8±4.5	32.5±4.9	<0.001
Waist circumference (cm)			
Baseline	100±10	105±12	<0.001
Year 3	97±11	105±12	<0.001
Fasting plasma glucose (mmol/l)			
Baseline	6.0±0.7	6.5±0.9	<0.001
Year 3	6.0±0.6	7.1±1.0	<0.001
2-h plasma glucose (mmol/l)			
Baseline	8.8±1.5	9.4±1.4	<0.001
Year 3	8.1±1.9	11.6±2.6	<0.001

Author Conclusion:

Dietary fat and fibre intake are significant predictors of sustained weight reduction and progression to type 2 diabetes in high-risk subjects, even after adjustment for other risk factors.

Reviewer Comments:

Limitations as stated by authors:

- *The dietary intervention was planned to encourage an increase in dietary fibre and a decrease in fat intake, and it is possible that individuals who succeeded in weight reduction were more likely to report consuming 'the recommended diet'.*
- *All the models to investigate the effect of dietary composition were adjusted for physical activity at baseline and during the intervention, but some residual confounding might remain.*
- *The energy intakes calculated from the food records revealed that under-reporting had taken place. However, this may not be too problematic, because we calculated energy proportions of nutrients and not absolute amounts.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)

Yes

2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	Was the research question clearly stated?	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	Was the selection of study subjects/patients free from bias?	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study groups comparable?	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blinding used to prevent introduction of bias?	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcomes clearly defined and the measurements valid and reliable?	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration?	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due to study's funding or sponsorship unlikely?	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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