

**Citation:**

Kochar J, Djousse L, Gaziano JM. Breakfast cereals and risk of type 2 diabetes in the Physician's Health Study I. *Obesity*. 2007; 15 (12): 3,039-3,044.

**PubMed ID:** [18198313](#)

**Study Design:**

Prospective cohort study

**Class:**

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

**Research Design and Implementation Rating:**

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To explore prospectively the association between cold breakfast cereal consumption and incidence of diabetes mellitus among US male physicians.

**Inclusion Criteria:**

- US male physicians in the Physicians' Health Study I
- Detailed description of the study has been published previously.

**Exclusion Criteria:**

- Participants excluded due to missing information on baseline cereals (N=17), prevalent diabetes mellitus (N=460) or missing covariates (N=403)
- For whole-grain vs. refined grain analyses, 3,882 additional subjects were excluded for failing to specify brand of cereal.

**Description of Study Protocol:****Recruitment**

The study used data from the Physicians' Health Study I, which was a randomized, double-blind, placebo-controlled trial to study the effects of low-dose aspirin and  $\beta$ -carotene for the primary prevention of cardiovascular disease and cancer among US male physicians.

**Design**

Prospective cohort study.

**Blinding Used**

Physicians' Health Study was double-blind.

### **Statistical Analysis**

- Since the distribution of total, refined and whole-grain cereals was skewed to the right, quintiles were not used to categorize cereal consumption
- Adjacent categories were grouped to allow a sufficient number of person-times per category and to maintain a gradient of exposure
- Each subject was classified into one of the following categories: Rarely or never, less than or equal to one, two to six and seven or more servings per week
- Person-time of follow-up was calculated from baseline until the first occurrence of diabetes mellitus, death or date of receipt of last follow-up questionnaire
- Incidence rate of diabetes mellitus was calculated by dividing the number of cases by the corresponding person-time
- Cox proportional hazard models were used to compute multivariable, adjusted hazard ratios with corresponding 95% CI
- Fully adjusted model included age, smoking, alcohol consumption, vegetable consumption, use of multivitamins and physical activity
- Main analysis was repeated using updated cereal consumption at 24, 48, 72, 96 and 120 months using pooled logistic regression.

### **Data Collection Summary:**

#### **Timing of Measurements**

Subjects completed annual follow-up questionnaires over a mean follow-up of 19.1 years. Initial assessment of cereal intake occurred during enrollment during 1981 to 1983, and also obtained at 18 weeks, and 24, 48, 72, 96 and 120 months after randomization.

#### **Dependent Variables**

Incident of diabetes mellitus was ascertained through follow-up questionnaires.

#### **Independent Variables**

- Consumption of breakfast cereals was estimated using an abbreviated food questionnaire
- Participants were asked to report average consumption of cold breakfast cereals (one cup) during the past year
- Possible response categories included rarely or never, one to three per month, once a week, two to four a week, two to four a week, five to six a week, daily and two or more times daily
- Breakfast cereals that contain at least 25% of oat or bran were classified as whole grain.

#### **Control Variables**

- Age
- Cigarette smoking
- Height, weight, BMI
- Physical activity
- Vegetable consumption
- Alcohol intake
- Hypertension
- Use of multivitamins.

## Description of Actual Data Sample:

- *Initial N*: Original trial randomized 22,071 subjects. 480 participants were excluded due to:
  - Missing information on baseline cereals (N=17)
  - Prevalent diabetes mellitus (N=460)
  - Missing covariates (N=403)
- *Attrition (final N)*: 21,152 male physicians in current analysis. For whole-grain vs. refined grain analyses, 3,882 additional subjects were excluded for failing to specify brand of cereal
- *Age*: Mean age of 53.6±9.4 years (range 39.7 to 85.9 years) during initial assessment of cereal intake
- *Location*: United States.

## Summary of Results:

### Hazard Ratios (95% Confidence Intervals) for Diabetes Mellitus According to Breakfast Cereal Intake

Cereal Intake (Servings per Week)	Cases	Hazard Ratio (95% CI) for Age-adjusted Model	Hazard Ratio (95% CI) for Model 1	Hazard Ratio (95% CI) for Model 1 plus BMI
<b>0</b>	767	1.0	1.0	1.0
<b>1 or less</b>	478	0.86 (0.76 to 0.96)	0.89 (0.79 to 1.00)	0.83 (0.79 to 0.93)
<b>2 to 6</b>	425	0.70 (0.62 to 0.79)	0.76 (0.67 to 0.86)	0.76 (0.67 to 0.86)
<b>7 or more</b>	288	0.58 (0.51 to 0.67)	0.63 (0.55 to 0.72)	0.69 (0.60 to 0.79)
<b>P for linear trend</b>		<0.0001	<0.0001	<0.0001

Model 1: Adjusted for age, smoking, vitamin intake, alcohol consumption, vegetable consumption, and physical activity.

### Other Findings

- During mean 19.1 years of follow-up, 1,958 cases of diabetes mellitus occurred
- Higher intake of breakfast cereals was associated with older age, increased physical activity, higher consumption of vegetables and lower prevalence of current smoking, current alcohol drinking, and hypertension
- The crude incidence rates of diabetes mellitus were 57.7, 53.8, 43.2 and 35.4 cases per 10,000 person-years for people reporting breakfast cereal intake of zero, one or less, two to six or seven or more servings per week, respectively
- Additional adjustments had only a modest influence on the hazard ratios, with a 37% lower risk of diabetes mellitus among people consuming seven or more servings per week of breakfast cereals compared with those who did not consume breakfast cereals

- In secondary analyses, the inverse association between cereal intake and diabetes mellitus was stronger with whole-grain than refined cereals
- Using updated cereal information over time did not alter the conclusions: Age-adjusted relative risks of diabetes mellitus were 1.0 (reference), 1.01 (95% CI 0.85 to 1.21), 0.82 (95% CI 0.68 to 0.98) and 0.63 (95% CI 0.55 to 0.72) from the lowest to the highest category of breakfast cereal consumption, respectively (P for trend <0.0001).

### Author Conclusion:

In conclusion, our data show an inverse association between breakfast cereals and diabetes mellitus and such association was more evident and stronger with whole-grain cereals. If confirmed by other studies, a higher intake of whole-grain breakfast cereals in particular, along with other healthy lifestyle measures, might help reduce the risk of diabetes mellitus.

### Reviewer Comments:

- *Original recruitment methods were not described*
- *Long follow-up period of 19.1 years*
- *Only looked at cold cereals, not hot cereals (such as oatmeal) for assessment of whole-grain intake*
- *Diagnosis of diabetes mellitus was somewhat unclear; physicians were not receiving annual physicals.*

*Authors note the following limitations:*

- *Simple food questionnaire for collection of dietary information resulted in not controlling for total energy intake and other nutrients such as fiber and magnesium*
- *Possibility of inaccurate reporting due to self-reported data*
- *Sample consists of highly educated male physicians who may have different behaviors than the general population limits generalizability of findings*
- *It is possible that those on a healthy diet are more likely to maintain other healthy lifestyle measures*
- *Possibility of underreporting of diabetes, but this would only underestimate the effect*
- *Residual confounding or confounding by unmeasured factors could explain the findings.*

### 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) | N/A |
| 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)	N/A

### Validity Questions

<b>1.</b>	<b>Was the research question clearly stated?</b>	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
<b>2.</b>	<b>Was the selection of study subjects/patients free from bias?</b>	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?	No
<b>3.</b>	<b>Were study groups comparable?</b>	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.)	N/A
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?	Yes
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
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	<b>Yes</b>
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
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	<b>Yes</b>
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
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?	Yes
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
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?</b>	<b>Yes</b>
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
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?	N/A
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
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
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	<b>No</b>
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?	No
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?	No
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	<b>Yes</b>
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)?	N/A
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
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	<b>Yes</b>
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	<b>Yes</b>

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes