



Oxford Cambridge and RSA

For issue on or after: 25 April 2022

Level 3 Cambridge Technical in Applied Science

05874 Unit 23: Scientific research techniques

Pre-release material

**To prepare candidates for the examination taken on
Thursday 16 June 2022 – Afternoon**

Please write clearly in black ink.

Centre number

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Candidate number

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First name(s)

Last name

Date of birth

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INSTRUCTIONS

- **Seven** days before the exam, hand in this booklet to your teacher. This booklet will be given back to you at the start of the exam.
- Do **not** take any notes into the exam.
- At the end of the exam, hand in this booklet with your exam paper.

INFORMATION

- This document has **8** pages.

Source A

Adapted from 'Associations of fats and carbohydrate intake with cardiovascular disease and mortality in 18 countries from five continents'.

A prospective cohort study (The Lancet - [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)32252-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32252-3/fulltext))

Summary

Background

The relationship between macronutrients in the human diet, and cardiovascular disease and mortality is controversial. Most available data are from European and North American populations where nutrition excess is more likely, so their applicability to other populations is unclear.

Methods

The Prospective Urban Rural Epidemiology (PURE) study is a large, epidemiological prospective cohort study of individuals aged 35–70 years (enrolled between Jan 1, 2003, and March 31, 2013) in 18 countries with a median follow-up of 7.4 years (range 5.3–9.3). Dietary intake of 135,335 individuals was recorded using validated food frequency questionnaires. The primary outcomes were total mortality and major cardiovascular events (fatal cardiovascular disease, non-fatal myocardial infarction, stroke, and heart failure). Secondary outcomes were all myocardial infarctions, stroke, cardiovascular disease mortality, and non-cardiovascular disease mortality. Participants were categorised using the quintile of nutrient intake (carbohydrate, fats, and protein) based on the percentage of energy provided by the nutrients. We assessed the associations between consumption of carbohydrate, total fat, and each type of fat, with cardiovascular disease and total mortality.

Findings

During follow-up, we documented 5796 deaths and 4784 major cardiovascular disease events. Higher carbohydrate intake was associated with an increased risk of total mortality (highest [quintile 5] vs lowest quintile [quintile 1] category), but not with the risk of cardiovascular disease or cardiovascular disease mortality. Intake of total fat and each type of fat was associated with lower risk of total mortality (quintile 5 vs quintile 1). Higher saturated fat intake was associated with lower risk of stroke (quintile 5 vs quintile 1). Total fat, and saturated and unsaturated fats were not significantly associated with risk of myocardial infarction or cardiovascular disease mortality.

Interpretation

High carbohydrate intake was associated with higher risk of total mortality, whereas total fat and individual types of fat were related to lower total mortality. Total fat and types of fat were not associated with cardiovascular disease, myocardial infarction, or cardiovascular disease mortality, whereas saturated fat had an inverse association with stroke. Global dietary guidelines should be reconsidered in light of these findings.

Further information

A world-renowned cardiologist: THE DIETARY GUIDELINES ARE A LIE! Salim Yusuf full speech 2017 <https://www.youtube.com/watch?v=RwGteseHyas>

Let's revisit the consensus on fat, carbs and health <https://www.newscientist.com/article/mg23030772-000-unhealthy-advice/>

Prospective Cohort Study https://en.wikipedia.org/wiki/Prospective_cohort_study

Relative validation of a food frequency questionnaire to estimate food intake in an adult population <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5404419/>

Source B

Adapted from ‘Fat and politics – Nina Teicholz on how the Seven Countries Study influenced dietary policy’ (By Benedict Jephcote, Diabetes Digital Media - <https://www.diabetes.co.uk/in-depth/fat-politics-nina-teicholz-seven-countries-study-dietary-policy/>)

The idea that saturated fat is bad is beginning to be questioned as more and more research is being published showing it to be no worse than unsaturated fat. So why do people still believe saturated fat needs to be limited?

Nina Teicholz, an investigative journalist, explains that the bad name that saturated fat has carried, for half a century now, dates back to a ground-breaking, but flawed, research study. The Seven Countries Study was the first multi-country epidemiological study. It was the first study to gather data in a number of countries to look for patterns of behaviour that affect health. It came at a time when heart disease was becoming a significant problem in America as apparently healthy men were dying in middle-age of heart disease. This was a relatively new phenomenon as at the start of the 20th century, very few people fell victim of heart disease.

The author of the Seven Countries Study was Ancel Keys. He had been informed that in Italy heart disease was not a problem. To find out more, Keys started to study the diet and lives of people in Italy. This set in motion Keys’ notion that diet and cholesterol were key factors in heart disease. Keys presented his findings and conclusions at a congress in Amsterdam in 1952.

In 1955, the US President suffered a heart attack. Heart disease had penetrated to the very top of America. The next year, with funding from the US Public Health Service, Keys started the long process of collecting data for the seven countries of Finland, Greece, Italy, Japan, Netherlands, USA and Yugoslavia.

Fighting against fat

Whilst the study was underway, Keys wrote a book, with his wife Margaret, entitled ‘Eat Well and Stay Well’ (1959). The book soon became a bestseller and laid out the clear message that saturated fat leads to high cholesterol, which leads to heart disease. This was his ‘diet-heart hypothesis’. It was a simple answer to the serious problem of heart disease that America was facing at the time. In 1961, the American Heart Association (AHA) put the diet heart hypothesis at the centre of their first dietary guidelines which stated that diets should be low in saturated fat to protect against heart disease.

Politics

As heart disease continued to dominate as the leading cause of death in the USA, the government was keen to implement action to tackle the problem. They were “willing to cut corners with the science” as Nina puts it.

Before the Seven Countries Study was published in 1978, the government was using the idea that fat, and in particular saturated fat, was the cause of heart disease to guide their dietary policy. In 1977, the first set of dietary goals was published, which included a target to have 55-60% of calories coming from carbohydrate and to ensure a maximum of 30% of calories came from fat. The first ever ‘Dietary Guidelines for Americans’ brochure appeared in 1980, which provided food choice guidance for people in seven steps. In 1983 the UK adopted similar guidelines with a recommendation to eat a low-fat and higher carbohydrate diet.

Whilst Keys became a star of the health industry, he and his colleagues held a lot of power over the way in which research was funded. Researchers struggled to get funding if their views differed from that of Keys, and, as Nina points out, if you weren’t on the cholesterol bandwagon, essentially “you couldn’t be a scientist”. The dietary goals and guidelines were questioned by many scientists but by 1986 the critics had been completely shut out and silenced.

Fundamental flaws

The Seven Countries Study was ground-breaking in its scope and vision; however, it had its weak points. One key problem was that Keys had designed his study partly to gather new insights, but also to present his cholesterol theory as being true. So, he picked specific areas of countries to study that would support his hypothesis. One of the areas chosen was the Greek island of Crete, which he visited three times, spending a week gathering data each time. Keys knew that the people of Crete had very high life expectancy and followed a typical Mediterranean diet.

In researching the study, Nina noted that a lot of the data had been fudged. For example, one of the weeks in which Keys visited Crete was during Lent. The people of Crete were Christian Orthodox and this meant that, during Lent, the island's population was observing Lent by not eating any meat or dairy. Whilst Keys noted that this fact had little effect on the outcome, researchers who have retrospectively reviewed the data note that Lent would have made an enormous difference on the data gathered. As Nina notes, this was just one of many errors that appeared throughout the study.

An uncomfortable truth

The decision to lower saturated fat intake and increase carbohydrate intake did see a drop in rates of heart disease, but Nina states that when studies were carried out to compare a cholesterol-lowering diet with a standard American diet, no overall change in death rates was observed. For example the Los Angeles Veterans' Study of 1969, published by the AHA, showed that whilst a low-saturated fat, cholesterol-lowering diet reduced incidence of heart disease, rates of cancer and other causes of death went up.

Another study which showed similar effects was the Minnesota Coronary Experiment. This study, also from the 1960s, was never published because the results had shown that people with the lowest cholesterol levels were actually twice as likely to die as those with the highest cholesterol.

The US National Institutes of Health had a series of expert panels which considered the problem but didn't know how to resolve it, so the problem was allowed to persist unresolved. Ancel Keys' legacy is one that has helped to reduce heart disease from its height in the 1950s to 1970s but in its wake, we have seen increases in cancer and diabetes rates.

If there are messages to take from this, perhaps they are that:

- we should ensure researchers are given the chance to question and check whether guidelines are working
- we should not attempt to set dietary recommendations in stone when the research behind those recommendations are built on sand.

Further information

Nina Teicholz at TEDxEast: The Big Fat Surprise https://www.youtube.com/watch?list=PLNBI0fXTwqh1VojYoiS81YkrT4EE6Qxl_&time_continue=5&v=1CHGiid6N9Q

The Seven Countries Study <https://www.sevencountriesstudy.com/>

Research notes:

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