

Should dietary fat guidelines have been introduced?

Breckenridge

February 2017

Dr. Zoë Harcombe, Ph.D

Agenda

- The Dietary Fat Guidelines: When? What? Why?
- Did RCT evidence support the DFGs at the time?
- Did epidemiological evidence support the DFGs at the time?
- Does RCT evidence support them now?
- Does epidemiological evidence support them now?
- Other reviews of the evidence
- Conclusion
- Refs are on <http://www.zoeharcombe.com/phd-thesis/references/>

The Dietary Fat Guidelines

When?

- 1977 Dietary Goals for the USA
- 1980 Dietary Guidelines for Americans
- 1983 Proposals for nutritional guidelines for health education in Britain (NACNE)
- 1984 Diet & cardiovascular disease policy paper (COMA)
- We did a U-turn in our diet advice...

Refs 15, 16, 18, 248, 258

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The Dietary Fat Guidelines

What?

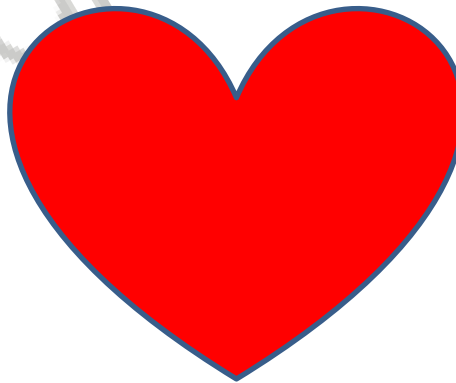
- **From:** “Farinaceous and vegetable foods are fattening, and saccharine matters are especially so.” (Tanner 1869 – page 213)
- **To:** “Base your meals on starchy foods.” (UK gov. 1984)
“The previous nutritional advice in the UK to limit the intake of all carbohydrates as a means of weight control now runs counter to current thinking ... The problem then becomes one of achieving both a reduction in **fat intake to 30% of total energy** and a fall in **saturated fatty acid intake to 10%.**”
- **Note:** We don't tell people to eat carbs because we know they're healthy...

Refs 244, 258

The Dietary Fat Guidelines

Why?

- 1950 US death rate 1.45% (1,446 per 100,000)
- Heart deaths 0.59% (589 per 100,000) OR
- Heart deaths = $589/1,446 = 40\%$



Refs 55-75

The Dietary Fat Guidelines

Why?

- "The evidence - both from experiments and from field surveys - indicates that cholesterol content, *per se*, of all natural diets has *no* significant effect on either the cholesterol level or the development of atherosclerosis in man." (Keys 1954)
- "Cholesterol occurs only in foods of animal origin" (Keys 1950)
- If cholesterol has no effect ...
- ... Foods of animal origin have no effect

Refs 98, 90, 100

RCT evidence at the time

Fat guidelines lacked solid scientific evidence, study concludes

the guardian

MailOnline

health

Meta-analysis

openheart Evidence from randomised controlled trials did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review and meta-analysis

Zoë Harcombe,¹ Julien S Baker,¹ Stephen Mark Cooper,² Bruce Davies,³ Nicholas Sculthorpe,¹ James J DiNicolantonio,⁴ Fergal Grace¹



Food fat

Official warr
flawed data

"Dietary advice does not merely need a review; it should not have been introduced."

This is the arresting conclusion made in a new review published in BMJ's [Open Heart](#) journal.

In this instance, the researchers are referring specifically to the fat recommendations in national dietary guidelines.

Functional food is a dynamic category. Wedge is growing quickly, debunking long-held beliefs. Beliefs like margarine is better than butter or that fat makes you fat.

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Turns out butter isn't so bad, researchers say. Photo / 123RF

healthy life.

By GILES SHELDRICK

PUBLISHED: 09:01, Thu 10 Feb 2016 | UPDATED: 10:48, Sat, Feb 28, 2015

RCT evidence at the time

Fat guidelines lacked solid scientific evidence, study concludes

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Vegetarian Dietary Patterns and the Risk of Colorectal Cancers

Turns out butter isn't so bad, researchers say. Photo / 123RF

healthy life.

By GILES SHELDRICK

PUBLISHED: 09:01, Thu 10 Feb 10, 2015 | UPDATED: 10:48, Sat, Feb 28, 2015

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RCT evidence at the time

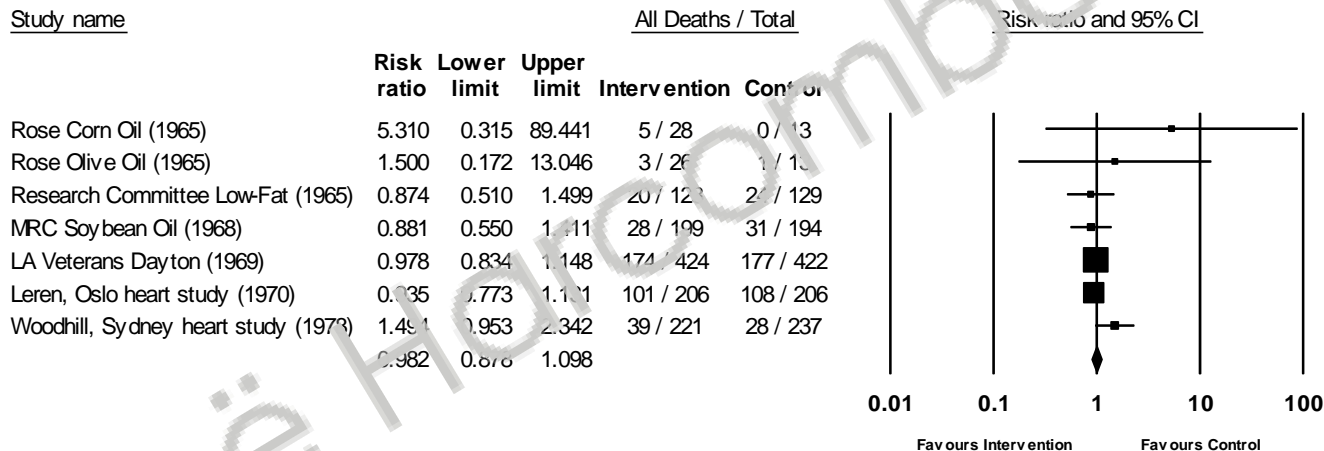
A Systematic Review & Meta-Analysis

Study	Men	Years	Diet
Rose Corn & Olive Oil (1965)	80 (S)	2	64g corn oil/day 58g olive oil/day
Research Committee low-fat diet (1965)	252 (S)	3	40g fat/day
MRC Soybean oil (1968)	393 (S)	3.4	85g soybean oil/day & many banned foods
LA Veterans (1969)	845 (S/P)	8	40% cals from fat 2/3 from veg oils
Leren Oslo (1970)	412 (S)	11	40% cals from fat 72% from soybean oil
Woodhill Sydney (1978)	458 (S)	5	10% sat fat (SFA)/15% poly vs. 14% sat/9% poly (PUFA)
TOTAL	2,467		S/P = Secondary/Primary

RCT evidence at the time

Forest Plot – All-cause mortality

Dietary Interventions & All Deaths



Meta Analysis is random effects method

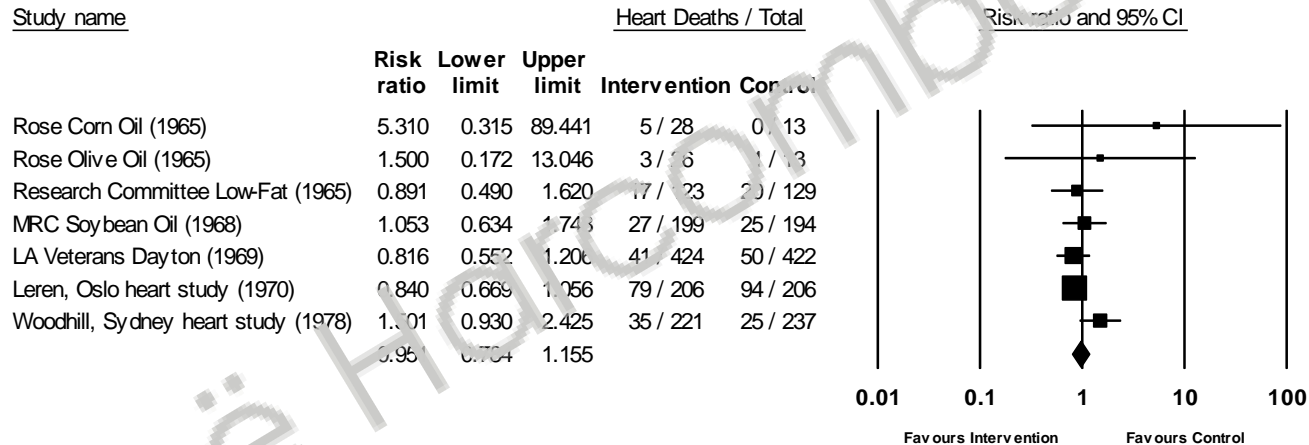
Refs 158, PhD Chapter 3

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RCT evidence at the time

Forest Plot – CHD deaths

Dietary Interventions & CHD Deaths



Meta Analysis random effects method

Refs 158, PhD Chapter 3

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RCT evidence at the time

Overall results

- The dietary guidelines introduced were 30% total fat & 10% sat fat.
- No RCT had tested government dietary fat recommendations before their introduction. (Woodhill tested 10% sat fat. Deaths 18% I vs. 12% C).
- 370 deaths from all-cause mortality in intervention & 369 in control (I & C). Risk ratio (RR) was 0.982 (95% CI 0.878 to 1.098) (death rate 30%).
- 207 & 215 deaths from CHD in the I & C respectively. RR was 0.951 (95% CI 0.784 to 1.155).
- Mean serum cholesterol levels decreased in both I & C groups. Reductions were significantly higher in intervention group; this did not result in significant differences in CHD or all-cause mortality.
- Recommendations were made for 276m people following 6 secondary studies of 2,467 men. Results lacked generalisability.
- No study recommended change.
- RCT evidence did not support the introduction of dietary fat guidelines.

Epidemiological evidence at the time



The screenshot shows the homepage of the British Journal of Sports Medicine. The header features the journal's name in large white text on a green background. Below this is a dark grey bar with the subtitle 'An international peer-reviewed journal of sport and exercise medicine'. A navigation bar contains links for 'Online First', 'Current issue', 'Archive', 'About the journal', and 'Submit a paper'. A secondary navigation bar includes 'Online First', 'Current issue', 'Archive', 'Supplements', 'eLetters', 'Topic collections', and 'BL'. A breadcrumb trail reads 'Home > Online First > Article'. The article title is 'Br J Sports Med doi:10.1136/bjsports-2016-096409'. Below the title is the word 'Review'. The main title of the article is 'Evidence from prospective cohort studies did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review'. The authors are listed as 'Zoë Harcombe¹, Julien S Baker¹, Bruce Davies²'.

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Br J Sports Med doi:10.1136/bjsports-2016-096409

Review

Evidence from prospective cohort studies did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review

Zoë Harcombe¹, Julien S Baker¹, Bruce Davies²

Epidemiological evidence at the time

A Systematic Review

Study	Men (age)	Years	Significant associations with CHD...		
			Chol.	Fat	Other
Western Electric Study (1963)	1,989 (40-55)	4	Y	Total N Sat N	Smoking/age of death of father/coffee
Seven Countries Study (1970)	12,770 (2% CHD) (40-59)	5	Y	Total N Sat Y	NO association with smoking/activity/weight
London bank & bus men (1977)	337 (30-67)	20	N	Total N Sat N/A	Smoking/Inverse with higher calorie intake
Framingham (1970 & 1981)	859 (45-64)	4	N/A	Total N Sat N	Inverse with higher calorie & higher alcohol intake
Honolulu (1974 & 1981)	7,272 (45-64)	6	N/A	Total N Sat N	Inverse with higher calorie & higher alcohol intake
Puerto Rico (1969 & 1981)	8,218 (45-64)	6	N/A	Total N Sat N	Inverse with higher calorie intake & rural living

Epidemiological evidence at the time

The Seven Countries Study

- 1970; 7 countries (Finland, Greece, Italy, Japan, Netherlands, USA & Yugoslavia); 16 cohorts; 12,770 men aged 40-59 in 1956
- 1) CHD tends to be related to cholesterol
- 2) Cholesterol tends to be related to sat fat
- 3) CHD is as closely related to sat fat as it is to cholesterol
- $r = 0.72$ for CHD deaths at 25 years & cholesterol at start ($0.52 = r^2$)
- $r = 0.96$ for CHD deaths & latitude ($0.92 = r^2$)

Epidemiological evidence at the time

Overall results

- 6 Prospective Cohort Studies; 31,445 male participants; 5 primary, 1 combined (SCS).
- None examined DGs.
- All-cause mortality was 1,521 deaths among 31,445 men (mean follow-up 7.5 yrs) = 4.84%
- CHD mortality was 360 deaths among 31,445 men = 1.14%.
- SCS death rate previous CHD 20.9%; no previous CHD 1%.
- None found any relationship with total fat; 1 found an inter-country association with saturated fat.
- Epidemiological evidence did not support the introduction of dietary fat guidelines.

RCT evidence currently available



openheart

An open access, peer reviewed, online-only journal dedicated to publishing research in all areas of cardiovascular medicine

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Open Heart 2016;3: doi:10.1136/openhrt-2016-000409

Meta-analysis

Original research article

Evidence from randomised controlled trials does not support current dietary fat guidelines: a systematic review and meta-analysis

Zoë Harcombe¹, Julien S Baker¹, James J DiNicolantonio², Fergal Grace¹ and Bruce Davies³

RCT evidence currently available

A Systematic Review & Meta-Analysis

Study (Table Part 1)	Men	Years	Diet
Rose Corn & Olive Oil (1965)	80 (S)	2	64g corn oil/day 58g olive oil/day
Research Committee low-fat diet (1965)	252 (S)	3	40g fat/day
MRC Soybean oil (1968)	393 (S)	3.4	85g soybean oil/day & many banned foods
LA Veterans (1969)	845 (S/P)	8	40% cals from fat 2/3 from veg oils
Leren Oslo (1973)	412 (S)	11	40% cals from fat 72% from soybean oil
Woodhill Sydney (1978)	458 (S)	5	10% sat fat (SFA)/15% poly vs. 14% sat/9% poly (PUFA)

S/P = Secondary/Primary

RCT evidence currently available

A Systematic Review & Meta-Analysis

Study (Table Part 2)	People	Years	Diet
DART Burr (1989) All men	2,033 (S)	2	Total fat 30% PUFA/SFA ratio = 1
Minnesota Coronary Survey Frantz (1989) - Men - Women	9,057 (P) 2,197/2,126 2,344/2,320	1	Ctrl: 39% cals fat (18% SFA; 5% PUFA; 16% MUFA) Int: 38% cals fat (9% SFA; 15% PUFA; 14% MUFA)
STARS Watts (1992) All men	55 (S)	3.25	27% cals fat (8-10% SFA; 8% PUFA)
WHI Howard (2006) All Women	48,835 (P/S)	8.1	20% cals fat; 7% cals SFA
TOTAL	62,421		

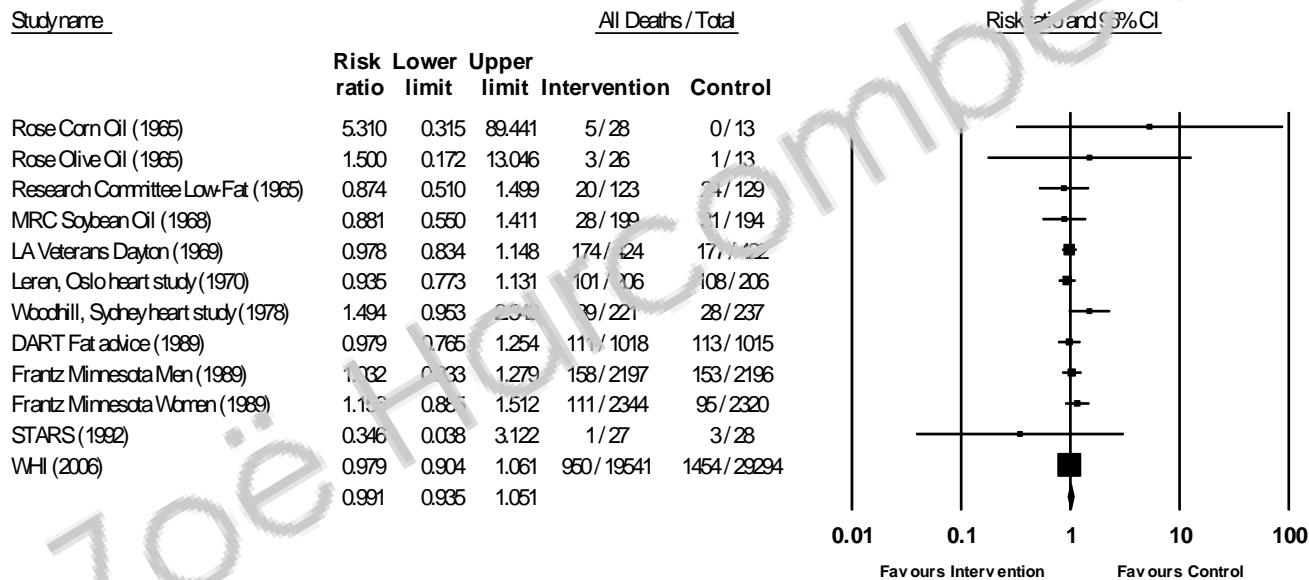
S/P = Secondary/Primary

PUFA/MUFA/SFA – poly/mono & sat fat

RCT evidence currently available

Forest Plot – All-cause mortality

Dietary Intervention & All Deaths

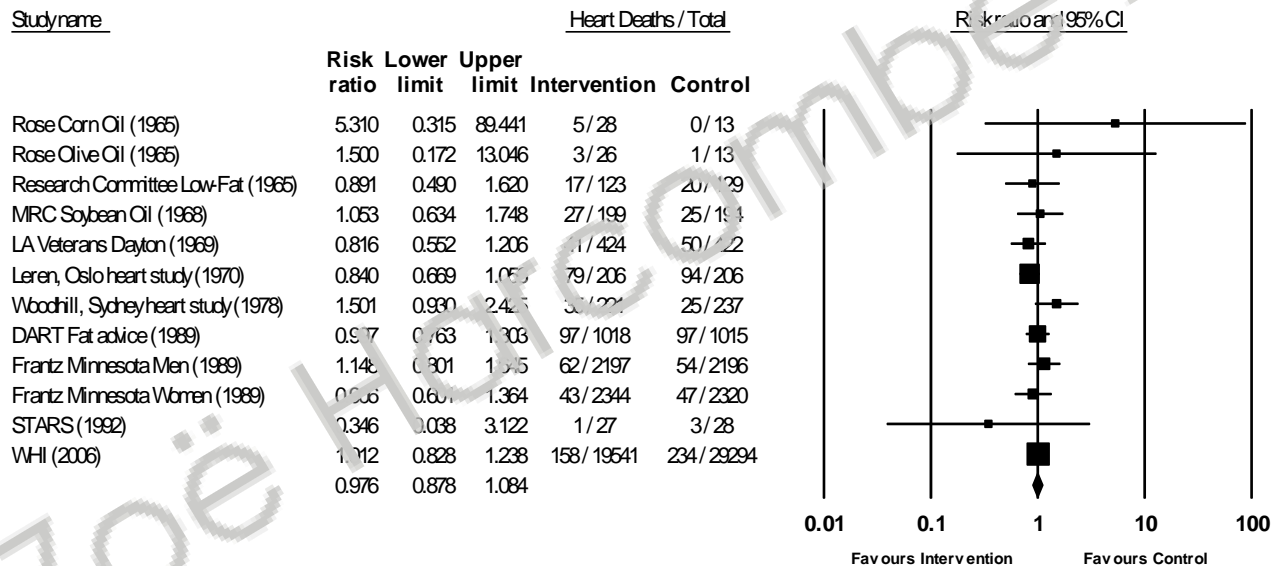


Meta Analysis random effects method

RCT evidence currently available

Forest Plot – CHD deaths

Dietary Intervention & CHD Deaths



Meta-Analysis random effects method

RCT evidence currently available

Overall results

- 10 RCTs; 62,421 participants; 8 M/1W/1 mixed; 7 secondary, 1 primary, 2 combined. 1 primary & mixed (Frantz).
- None examined DGs. Frantz & Woodhill tested 10% sat fat; DART tested 30% total fat; STARS tested 27% total/8-10% sat fat.
- All-cause mortality was 6.45% (I) and 6.06% (C). Risk ratio (RR) was 0.991 (95% CI 0.935 to 1.051).
- CHD mortality was 2.16% (I) and 1.80% (C). RR was 0.976 (95% CI 0.878 to 1.084).
- Mean serum cholesterol levels decreased in all but one of both I & C groups (DART control = +1.2%). Reductions were significantly higher in intervention group; this did not result in significant differences in CHD or all-cause mortality.
- RCT evidence does not support current dietary fat guidelines.

Epidemiological evidence now

British Journal of
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Review

Evidence from prospective cohort studies does not support current dietary fat guidelines: a systematic review and meta-analysis

Zoë Harcombe¹, Julien S Baker¹, Bruce Davies²

Epidemiological evidence now

A Systematic Review & Meta-Analysis

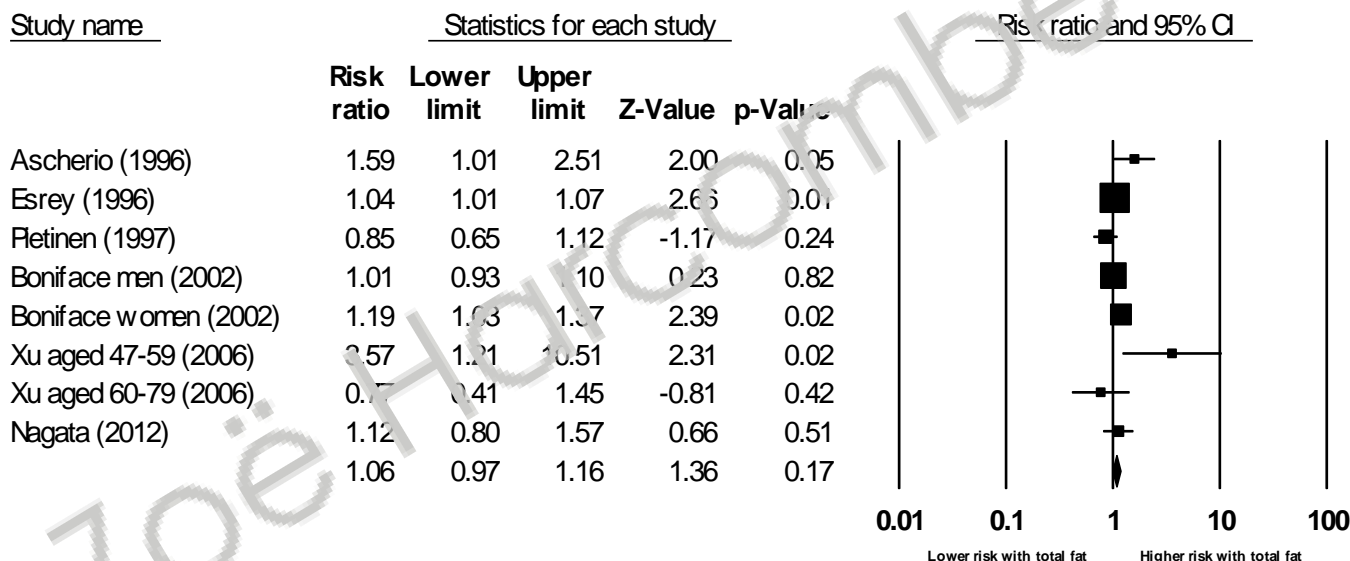
Study	Men/Women	Years	CHD-free	Total Fat/CHD	Sat Fat/CHD
Ireland Boston Kushi (1985)	1,001 M	20	N	No	No
US Health Profs Ascherio (1996)	43,757 M	6	Y	Yes	Yes
Lipid Research Esrey (1996)	2,353 M 2,193 W	12	Y	Yes	Yes
Finnish Cancer Pietinen (1997)	21,930 M	6.1	Y	No	Inverse
UK Health Survey Boniface (2002)	1,225 M 1,451 W	16	Y	M – No W – Yes	M – No W – Yes
Strong Heart (47-59) Xu (2006) (60-79)	646M/1,013W 405M/874W	7.2	Y	47-59 – Yes 60-79 – No	47-59 – Yes 60-79 – No
Japanese Nagata (2012)	12,953 M	16	Y	No	No

**Bradford
Hill!**

Epidemiological evidence now

Forest Plot – CHD mortality & Total fat

CHD deaths & Total Fat Risk Ratios

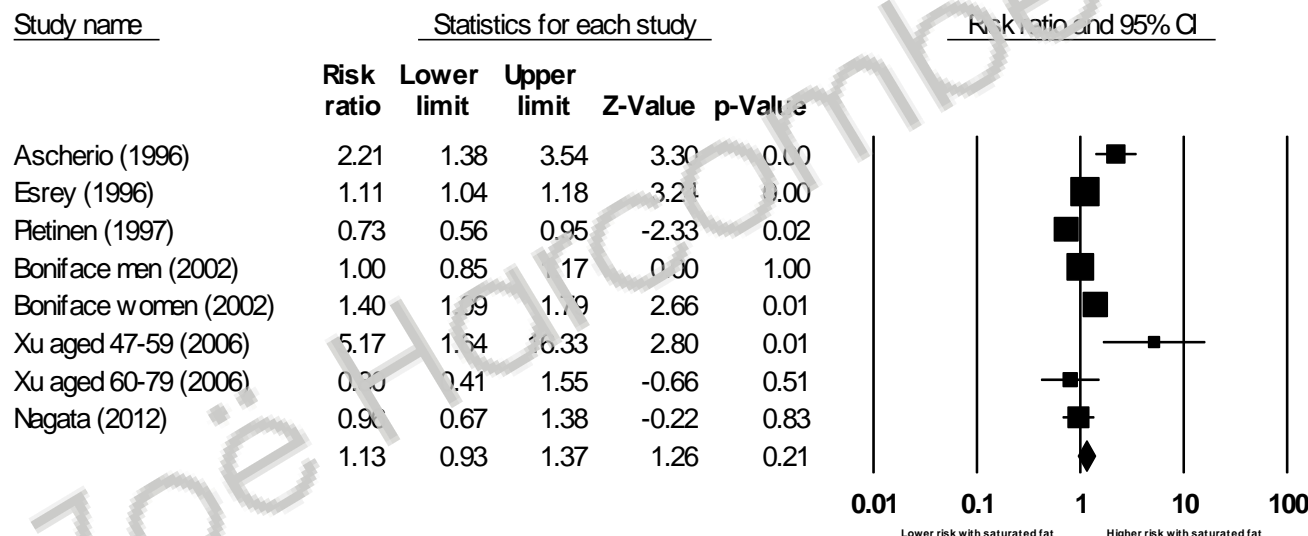


Meta Analysis random effects method

Epidemiological evidence now

Forest Plot – CHD mortality & Sat fat

CHD deaths & Saturated Fat Risk Ratios



Meta Analysis random effects method

Epidemiological evidence now

Overall results

- 7 Prospective Cohort Studies; 89,801 participants; 94% male; all but one (Kushi) excluded previous CHD (& this could not be used in MA).
- None examined DGs.
- Risk ratio (RR) for total fat & CHD deaths was 1.06 (95% CI 0.97 to 1.16). Not significant.
- Risk ratio (RR) for saturated fat & CHD deaths was 1.13 (95% CI 0.93 to 1.37). Not significant.
- Epidemiological evidence does not support current dietary fat guidelines.

Other reviews of the evidence

7 Systematic Reviews & Meta-Analyses (1/4)

Measure	Fat	Risk Ratio	Conclusion
Skeaff & Miller (2009). Prospective cohort studies & RCTs. 28 studies. 230,000 people			
CHD mortality	Total fat	0.94 [0.74, 1.18]	No sig difference
CHD events	Total fat	0.93 [0.84, 1.03]	No sig difference
Siri-Tarino (2010). Prospective cohort studies. 21 studies. 347,747 people			
CHD fatal & non	Sat fat (Extreme Quintiles)	1.07 [0.96, 1.19]	No sig difference
CVD fatal & non	Sat fat (Extreme quintiles)	1.00 [0.89, 1.11]	No sig difference
Mozaffarian, Micha & Wallace (2010). RCTs. 8 studies. 13,614 people			
CHD events	Replacing SFA with PUFA	0.81 [0.70-0.95]	Sig difference
Hooper (2011). RCTs. 21 studies. 71,790 people			
Total mortality	All RCTs	0.98 [0.93, 1.04]	No sig difference
	Modified fat	1.02 [0.88, 1.18]	No sig difference
	Reduced fat	0.97 [0.90, 1.04]	No sig difference
	Reduced & modified fat	0.97 [0.76, 1.23]	No sig difference

Other reviews of the evidence

7 Systematic Reviews & Meta-Analyses (2/4)

Measure	Fat	Risk Ratio	Conclusion
Hooper (2011). RCTs. 21 studies. 71,790 people (Cont'd)			
CVD mortality	All RCTs	0.94 [0.85, 1.04]	No sig difference
	Modified fat	0.92 [0.73, 1.15]	No sig difference
	Reduced fat	0.96 [0.82, 1.13]	No sig difference
	Reduced & modified fat	0.98 [0.76, 1.27]	No sig difference
CVD events	All RCTs	0.86 [0.77, 0.96]	Sig difference
	Modified fat	0.82 [0.66, 1.02]	No sig difference
	Reduced fat	0.97 [0.87, 1.08]	No sig difference
	Reduced & modified fat	0.77 [0.57, 1.03]	No sig difference
Chowdhury (2014). Prospective cohort studies & RCTs. 32 studies. 530,525 people			
Coronary disease (All top vs. bottom third)	Sat fat	1.02 [0.97, 1.07]	No sig difference
	Monounsaturated fat	0.99 [0.89, 1.09]	No sig difference
	Polyunsaturated fat	0.93 [0.84, 1.02]	No sig difference
	Trans fat	1.16 [1.06, 1.27]	Sig difference

Other reviews of the evidence

7 Systematic Reviews & Meta-Analyses (3/4)

Measure	Fat	Risk Ratio	Conclusion
Schwingshackl & Hoffman (2014). RCTs. 12 studies. 7,150 people			
All cause mortality	Modified fat intake	0.92 [0.68, 1.25]	No sig difference
CVD mortality	Modified fat intake	0.96 [0.65, 1.42]	No sig difference
CVD events	Modified fat intake	0.85 [0.63, 1.15]	No sig difference
MIIs	Modified fat intake	0.76 [0.54, 1.09]	No sig difference
All cause mortality	Reduced fat intake	0.79 [0.42, 1.48]	No sig difference
CVD mortality	Reduced fat intake	0.93 [0.66, 1.31]	No sig difference
CVD events	Reduced fat intake	0.93 [0.65, 1.34]	No sig difference
MIIs	Reduced fat intake	1.18 [0.88, 1.59]	No sig difference
Harcombe (2015). RCTs to 1977/1983. 6 studies. 2,467 people			
All cause mortality	Reduced or modified fat	0.98 [0.87, 1.10]	No sig difference
CHD mortality	Reduced or modified fat	0.95 [0.78, 1.15]	No sig difference

Other reviews of the evidence

7 Systematic Reviews & Meta-Analyses (4/4)

Measure	Fat	Risk Ratio	Conclusion
Hooper (2015). RCTs. 12 studies. 55,858 people			
Total mortality	Reduced saturated fat	0.97 [0.93, 1.05]	No sig difference
CVD mortality	Reduced saturated fat	0.95 [0.80, 1.12]	No sig difference
CVD events	Reduced saturated fat	0.83 [0.72, 0.96]	Sig difference
MIIs	Reduced saturated fat	0.90 [0.80, 1.01]	No sig difference
Non-fatal MIIs	Reduced saturated fat	0.95 [0.80, 1.13]	No sig difference
Stroke	Reduced saturated fat	1.00 [0.89, 1.12]	No sig difference
CHD mortality	Reduced saturated fat	0.98 [0.84, 1.15]	No sig difference
CHD events	Reduced saturated fat	0.87 [0.74, 1.03]	No sig difference
RESULTS 35 out of 39 No sig difference. 4 out of 39...			
Mozaffarian	Replacing SFA with PUFA	CHD events	UR/ZH (Ref 43)
Hooper (2011)	All RCTs	CVD events	Next page
Chowdhury	Trans fats	Coronary disease	Agree
Hooper (2015)	Reduced SFA	CVD events	Next page

Other reviews of the evidence

Hooper (2011 & 2015)

- Same finding, repeated: “*The findings are suggestive of a **small but potentially important** reduction in **cardiovascular risk** on **modification of dietary fat**, but not reduction of total fat, in longer trials.*” (2011)
- “*The findings of this updated review are suggestive of a **small but potentially important** reduction in **cardiovascular risk** on **reduction of saturated fat** intake. Replacing the energy from saturated fat with polyunsaturated fat appears to be a useful strategy, and replacement with carbohydrate appears less useful, but effects of replacement with monounsaturated fat were unclear due to inclusion of only one small trial.*” (2015)

Other reviews of the evidence

Hooper (2011 & 2015)

- 2011: 11/12 non significant results.
- 2015: 7/8 non significant results.
- Nothing sig. for all-cause mortality; Or CVD mortality; Or CHD mortality; Or MIs; Or non-fatal MIs; Or stroke; Or CHD events.
- 11 studies in 2015 PUFA conclusion: only 1 reported SFA reduction & PUFA replacement (Dayton).
- Why different to other reviews? Only study to include 4 studies (n=646) *not* about CVD/CHD: Diabetes/Houtsmuller; Hypercholesterolemia/Moy (*); Skin cancer/ Black (*); Glucose Intolerance/Ley(*). (*) Unpublished data used.
- Dr Trudi Deakin - Sensitivity test (with only the RCTs that had reduced SFA) failed statistical significance.
- Not one study of healthy people of both genders included in either significant result: Results not generalisable.

Conclusion

Complete review of the evidence

Paper	RCTs Then	RCTs Now	Epid. Then	Epid. Now
Type	SR & MA	SR & MA	SR	SR & MA
Focus	Dietary fat, Serum cholesterol, Mortality (CHD & all-cause)		Dietary fat (total & SFA), Serum cholesterol, Mortality (CHD)	
# of studies	6 (5S/1C)	10 (7S/1P/2C)	6 (5P/1C)	7 (1S/6P)
Tested DFGs	0	0	0	0
Participants	2,467 M	62,421 (86%W)	31,445 M	89,801 (94%M)
Key findings?	No sig diff in all-cause mortality No sig diff in CHD mortality		0/6 assoc total fat (TFA) 1/6 assoc SFA	No sig diff in CHD mortality & TFA or SFA
Results Generalisable?	No	No	No	No

<http://www.zoeharcombe.com/phd-thesis/references/> S/P/C = Secondary/Primary/Combined

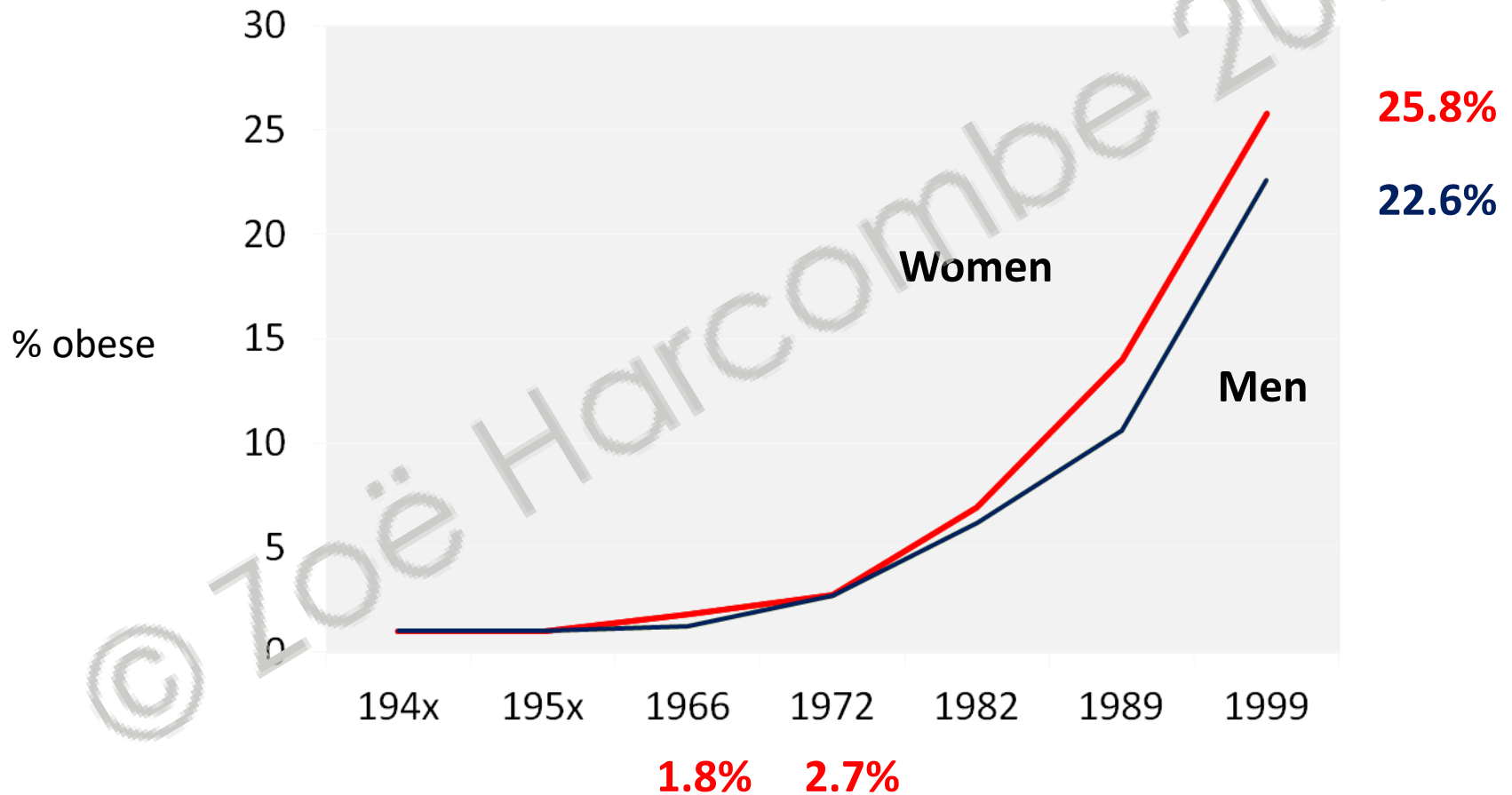
Conclusion

The consequences

- *“There will undoubtedly be many people who will say we have not proven our point.” (Hegsted)*
- *“Lack of consensus among nutritional scientists and other health professionals.” (Senators Percy, Schweiker, Zorinsky)*
- *“Some witnesses have claimed that physical harm could result from the dietary modifications recommended in this report.”*
- *“...the select committee finds that **no physical or mental harm could result from the dietary guidelines recommended for the general public...**”*

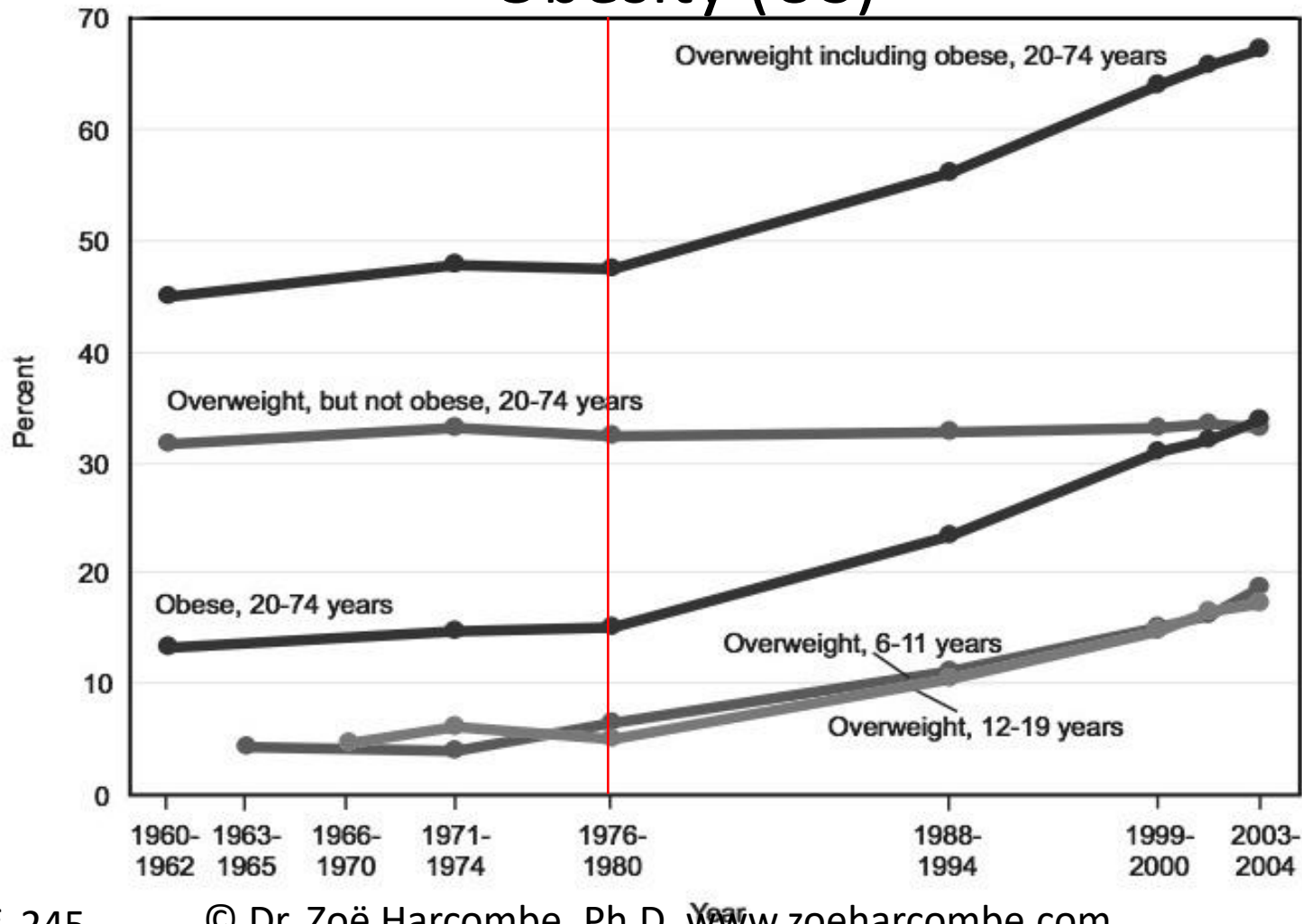
Conclusion

Obesity (UK)



Conclusion

Obesity (US)



The end!
Thank you for listening

Breckenridge
February 2017
Dr. Zoë Harcombe, Ph.D