

Table D: Dietary advisory committee’s review of dietary patterns and health

Evidence Listed		Overall ranking given to the data by the DGAC Report	Trial name and reference	Type of Data	Study Description	Conclusion	Was this study appropriately included?	If not, why?	Does this data support the hypothesis?	Limitations of the data
DIETARY PATTERNS AND HEART DISEASE										
1. NEL Reviews on Patterns and CHD										
	NEL Question: “What is the relationship between adherence to dietary guidelines/recommendations or specific dietary patterns, assessed using an index or score, and risk of cardiovascular disease?”	"Strong"		Review of 8 RCTs in 14 papers. Other evidence provided is observational data (Each of the 8 RCTs are listed below)						
	NEL Review #1 in detail, by RCT	Original RCT	Reference	Type of Data	Study Description	Results/Conclusion	Appropriate?	If not, why?	Support?	Limitations of the data

		DASH (original)	<u>Appel, 1997</u>	RCT	459 adults; all received a control SAD for 3 weeks then randomized to (i) control (ii) a diet rich in fruits and veg (FV) or (iii) a "combination diet" (combo) rich in fruits, veg, and low-fat dairy with reduced total and sat. fat; 8 week intervention. Note that combo and FV have similar % energy of fat and SFA while combo is lower in both (table 1).	Systolic and diastolic BP was reduced by FV and further reduced by combo. No other relevant outcomes were measured.	<u>Yes</u>		Limited	Only outcome tested was blood pressure and on a non-normal, hypertensive population
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			<u>Conlin, 2000</u>	RCT	133 hypertensive participants; 3 wk control run-in; randomized to (i) control (ii) high fruit veg (FV) (iii) combo rich in fruits, veg, low fat dairy, w/ whole grains, fish, poultry, nuts, reduced red meat, sweet, and sugar sweetened beverages. Sodium and body weight held constant.	BP was lowest in combo diet, then FV, then control. Relative risk for hypertension was: con (1.00), FV 0.72), combo (0.39). " a diet that emphasizes fruits, vegetables, and low-fat dairy products, includes whole grains, poultry, fish, and nuts, and is reduced in fat, red meats, sweets, and sugar-containing beverages led to significant hypertension control in persons with Stage 1 hypertension"	<u>Yes, except blinding</u>		Limited	Only outcome is BP and on a non-normal, hypertensive population. Not acceptable as advice for the general population.
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			<u>Obarzanek, 2001</u>	RCT, outpatient	436 DASH trial participants; 3 wk-run in; 8 wk diet intervention: (i) control (ii) high fruit and veg (also more whole grains and less sweets, but similar macros to control) (iii) DASH (hi fruit/veg/low fat dairy, reduced fat/SFA/cholesterol)	" changes (in the DASH diet compared to controls) represented net reductions of 7.3%, 9.0%, and 7.5% in mean concentrations of total, LDL, and HDL cholesterol, respectively." No significant changes in TG (trended up), TC:HDL, LDL:HDL. No significant changes from FV diet in the whole study group (LDL, HDL, TG trended down and approached significance at p = .055), some significant lipid changes observed in some groups (i.e. men and non-African Americans saw reduced	<u>Yes, even though "method of handling withdrawals" was not described</u>		Limited	Adherence to DASH reduced risk based on Framingham equation, but the drop in HDL and upward trend in triglycerides indicate worsening CVD risk. On a non-normal, hypertensive population
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						<p>TC:HDL). "higher baseline HDL was associated with greater reductions in HDL." " The observation that reduced-fat diets lower HDL has led to controversy over the advisability of lower-fat, higher-carbohydrate diets and whether CHD risk is reduced when HDL is lowered along with LDL." "The DASH diet substantially reduced systolic and diastolic blood pressure, caused favorable changes in total and LDL cholesterol, resulted in no changes in triacylglycerol,</p>				
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						and reduced HDL cholesterol." To determine total effect of lipid changes (some good, some bad) they used the Framingham equation and estimated 10-y CHD risk decreased by 12.1% in DASH and increased 0.9% in control				
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			<u>Moore, 1999</u>	RCT	354 subjects; 3 wk SAD run in; randomize to continuation of SAD control, high fruits and veg, or combo emphasizing fruits, veg, and low fat dairy. 8 wk intervention	Combo diet reduced SBP and DBP, not much else going on in this study. "the combination diet exerted its BP-lowering effect throughout the day and night. With the combination diet, both SBP and DBP fell significantly during 24 hours, daytime, and night in all participants combined"	<u>NEL worksheet does not exist</u>		Limited	Only outcome is blood pressure and on a non-normal, hypertensive population
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		DASH (Variation)	<u>Blumenthal</u> <u>Babyak</u> <u>Sherwood, 2010</u>	RCT	144 overweight men and women with high BP assigned to (i) DASH alone (DASH-A) (ii) hypocaloric DASH + exercise (DASH-WM) (iii) usual diet control. Intervention appears to be 4 months. (The only relevant comparison here is control vs. DASH-A)	Despite clinically significant reductions in blood pressure, the DASH diet alone, without caloric restriction or exercise, resulted in minimal improvements in insulin sensitivity or lipids.	<u>Yes</u>		No	The only meaningful change was in blood pressure. The DASH diet did not otherwise result in beneficial cardiovascular effects.
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			<u>Saneei, 2013</u>	RCT, crossover	60 post-pubescent adolescent girls (11-18 yr) with MetSyn; 2 wk run in control diet; randomized to DASH or usual dietary advice (UDA); crossover after 4 wk washout	"Despite a slight decline in the prevalence of the MetS and its features, we failed to find a significant effect of recommendations to follow the DASH diet on most of its features." "No significant changes were found in glucose and lipid profiles. T	<u>Yes, except adjustments were not made for confounding factors</u>		Very limited	In short, DASH significantly reduced BMI while UDA insignificantly reduced BMI, however the between group comparison of BMI was not significant. DASH and UDA significantly reduced waist circumference. UDA significantly increased diastolic BP while DASH did not (trended
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		DASH Sodium	<u>Sacks, 2001</u>	Multi-center RCT (NEL worksheet says non-randomized)	412 subjects with BP over 120/80 including stage 1 hypertensive; 2 wk run in (high Na control); randomized to control or DASH matched at 1 of 3 Na levels - hi (150 mmol/d, reflects average consumption), intermediate (100 mmol/d, reflects guidelines upper limits), or lo (50 mmol/d, hypothesized to produce greater benefits); parallel crossover where each subject ate their assigned diet (con or	"reduction of sodium intake significantly lowered systolic and diastolic blood pressure in a stepwise fashion, with both the control diet and the DASH diet. The level of dietary sodium had approximately twice as great an effect on blood pressure with the control diet as it did with the DASH diet." " DASH diet, as compared with the control diet, resulted in a significantly lower systolic blood pressure at every sodium level and in a significantly lower diastolic blood pressure at the high and intermediate sodium levels."	<u>Listed as a "non-randomized crossover trial" under study design, but the checklist says their method of randomization is appropriate</u>		Limited	Only outcome is BP and results are limited to those with raised blood pressure. Not acceptable as advice for the general population.
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					DASH) at each Na level for 30 days, so it appears the crossover is only per Na level, not diet.	Weight was lower in DASH at each Na level, but baseline values are not given and they say weight remained stable (as per the design) so weight change is probably not relevant here.				
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			<u>Svetkey, 2004</u>	RCT	412 stage 1 hypertensive adults age 22+; this is from DASH-sodium using the control or DASH diets at hi, medium, and lo sodium levels	Both the DASH diet and a reduced sodium intake significantly improved BP control in persons with hypertension and led to optimal or normal BP in many persons with high-normal BP.	-	Same data as Sacks, 2001, but presented differently. Does not add to the robustness of the evidence.	Limited	Only outcome is blood pressure and results are limited to those with hypertension. Not acceptable as advice for the general population.
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		NORDIET	<u>Adamsso n, 2011</u>	RCT	88 mildly hypercholesterolemia Swedes randomized to a control (standard western) or Nordic diet (ND) for 6 weeks. ND profile (daily basis): 2200 kcal; 45-60:25-35:10-20 %CHO:Fat:Protein; >3g fiber/MJ; >3g β -glucans <8% SFA; 5-10 % PUFA; <2161 mg Na. Diet was given <i>ad libitum</i> in the sense that equal calories were provided but participants were free to leave food or request more. Primary outcome was 6-wk changes in LDL-C and	"The ND causes a significant lowering of plasma levels of cholesterol, LDL-C, HDL-C, apoA1 and apoB compared with the CD. ApoB1/apoA1 and LDL/HDL ratios were significantly decreased after the ND compared with the CD. Compared to the CD group, there was also a significant decrease in insulin concentrations and HOMA-IR, as well as systolic BP (SBP) in the ND group. Reduction in diastolic BP (DBP) after 6 weeks of the ND was not statistically significant.	<u>No</u>	No comparable control group. Researchers provided all meals to experimental group while control group was left to usual care.		
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					"other blood lipids," secondary outcomes were BP and insulin sensitivity.					
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		OmniHeart Trial	<u>Appel,</u> <u>2005</u>	RCT	164 people for 19 weeks 3 period crossover		<u>Yes</u>		No	The low-fat diet high in fruits and vegetables, which mostly closely resembles the DGA Dietary Patterns, had the least favorable CVD outcomes, compared to the diets higher in protein and unsaturated fats.
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		Women's Health Initiative	<u>Howard, 2006</u>	RCT		"The diet had no significant effects on incidence of CHD (hazard ratio [HR], 0.97; 95% confidence interval [CI], 0.90-1.06), stroke (HR, 1.02; 95% CI, 0.90-1.15), or CVD (HR, 0.98; 95% CI, 0.92-1.05)."	<u>They say Yes...</u>	but I'd argue this study is irrelevant based on relevance question 1 (Would implementing the studied intervention or procedure result in improved outcomes?) because no meaningful decrease in incidence was	No	Intervention diet had no effect on disease incidence
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								seen. They had some favorab le lipid		
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		PREMIER	<u>Lien, 2007</u>	RCT	796 pre-hypertensive or stage 1 hypertensive subjects, 399 who had metabolic syndrome; randomized to an advice only group, "established recommendations" (EST) of lifestyle modifications for lowering BP, or DASH+EST; 6 month intervention.	The SBP reduction from EST (1.58 mm Hg when calculated net of control) was less than the SBP reduction from EST+DASH." No difference in DBP. "EST significantly improved total triglycerides as compared with control...EST+DASH did not significantly improve triglycerides as compared with control...Changes in HDL cholesterol were unremarkable. However, the EST and EST DASH interventions were more effective than advice only in reducing total cholesterol...ch	<u>Yes</u>	Dropouts/attrition/response rate (section 4.2), inadequate statistical analyses (section 8).	Limited	The addition of the DASH diet did not significantly improve cardiovascular outcomes. The main benefits were seen in the behavioral program, compared to controls.
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						<p>anges in low-density lipoprotein cholesterol in those with MetSyn did not achieve statistical significance, both EST and EST DASH tended to improve low-density lipoprotein cholesterol...regardless of MetSyn status." "Both EST and EST DASH interventions led to greater reductions in fasting insulin levels and in the HOMA index (ie, greater improvements in insulin resistance) than the advice only group." "Our data suggest that behavioral strategies aimed at</p>				
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						lowering BP in individuals with MetSyn may be enhanced by recommendations to adopt the DASH dietary pattern. Further research should assist in confirming this assessment"				
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		Vegetarian	<u>Margetts, 1985</u>	RCT, crossover	58 mild untreated hypertensive subjects; 2 wk run-in with usual diet; randomized to maintain their standard diet for 12 weeks or follow a ovo-lacto vegetarian (OLV) for either the first or last 6 weeks of the study.	"Mean levels of systolic blood pressure fell significantly ($P < 0.05$) when subjects ate an OLV diet. There was no significant effect of diet on diastolic blood pressures. Subjects with the highest pre-experimental systolic blood pressure recorded the greatest falls in blood pressure during the trial." "consumption of a vegetarian diet by mild untreated hypertensive subjects is associated with an average reduction of systolic blood pressure of the order of 5 mmHg."	<u>Neutral (issues with statistics and drop outs)</u>		Yes, to a degree	Only outcome is BP and results are limited to those with raised blood pressure. Not acceptable as advice for the general population.
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	End of NEL Review #1 break-out section									
NEL Reviews, continued										
	2. "Are prevailing patterns of diet behavior in a population, assessed using factor or cluster analysis, related to risk of cardiovascular disease?"	"Limited"		Review					No	Data is deemed to be only "limited," which is Grade III, or the lowest rank for data when available.
	3. What is the relationship between adherence to dietary guidelines/rec ommendations or specific dietary patterns, assessed using reduced rank regression analysis, and cardiovascular disease?	"Not Assignable "		Review					No	Data is deemed to be only "Not assignable ," which is Grade IV, or the lowest overall rank for data

<p>2. Review by the American Heart Association/American College of Cardiology and the NHLBI Lifestyle Report (these are the same report, although they are referenced in the DGAC Report as if they were separate)</p>										
										<p>Tthe AHA and ACC are private organizations, with significant funding from pharmaceutical and food companies. This presents potential conflicts of interest in objectively interpreting the science</p>

				Review (RCT data below is cited with particular emphasis by the DGAC Report)			No	This is a review examining the impact of diet on obesity , not CHD.		
			DASH	RCT	459 subjects for 8 weeks	A diet low in saturated fats reduces blood pressure	No	This trial is already included in multiple papers in the NEL review, above.		

			The OmniHeart trial	RCT	<p>164 people for 19 weeks 3 period crossover on 3 diets: a carbohydrate-rich diet similar to the Dietary Approaches to Stop Hypertension diet (58% carbohydrate, 15% protein, and 27% fat), a higher protein diet that had 10% more protein and 10% less carbohydrate (48% carbohydrate, 25% protein, and 27% fat), and a higher unsaturated fat diet that had 10% more unsaturated fat and 10% less carbohydrate (48% carbohydrate,</p>	<p>High protein and high-unsaturated fat diets improved LDL-C and BP to a greater extent than a low-fat, FV-rich diet. The high protein diet was the most successful in lowering triglycerides</p>	No	<p>This trial is already included in the NEL review above.</p>		
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					15% protein, and 37% fat).					
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			PREDIME D	RCT	7,447 people for 5 years	A Mediterranean diet reduces strokes and heart attacks.	No	The diet in this study did not seek to reduce red meat and was relative ly high in fat (41% of calories). Both these feature s are unlike the Pattern s. The low-fat control group with worse outcom es in this study more closely resemb	No	Diet tested was unlike the USDA Patterns in important ways.
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								led the USDA Pattern s.		
3. DGAC ad hoc review of the scientific literature from 2008 to present										
										No systemati c methodol ogy is given for the selection of these studies. It is therefore impossibl e to know if they fairly represent the literature

										since 2008. There is also no methodology for weighing the different types of evidence or any measures taken to prevent double counting of studies included in these reviews
			Huang et al on the Mediterranean diet	Review paper of observational studies	Compiled results from 7 studies with a total of 124,706 participants	Vegetarians have a significantly lower ischemic heart disease mortality (29%)			Limited	Data is observational and can show only associations, not causation.
			Martinez - Gonzalez 2014	Review paper of observational studies and 1 RCT	Recent cohort studies on the Med diet		No	Mediterranean diet in the largest of these	No	

								studies was unlike the USDA Dietary Pattern s in fundam ental ways		
			Rees et al 2013 (Cochrane Review)	Review paper of RCTs	11 RCTs (15 papers) on 52,044 participants randomised	Med diets lower total cholesterol and LDL compared to controls. Mixed results regarding HDL and TGs (mostly no change, but some differ)			Limited	Conclusions are not strong. Limited evidence includes: no reporting of clinical events, bias in some included study (>20% dropout), not all data usable. "Overall, the studies included in this review, especially the

										smaller short-term trials, were at some risk of bias or there was insufficient information to judge the risk of bias; hence, results should be treated with some caution"
			Salehi-Abargouei et al 2013	Review paper of observational studies	6 cohort studies on DASH diet reviewed	DASH diet is cardioprotective			Limited	Data is observational and can show only associations, not causation. Review selected without any methodology.

			Sofi F et al 2014	Review paper of observational studies	Review of cohort studies on the Mediterranean diet	The Mediterranean diet was found to be a healthy dietary pattern in terms of morbidity and mortality.	No	Mediterranean diet in the largest of these studies was unlike the USDA Dietary Patterns in fundamental ways. This review includes many of the same studies that were included in the other review of the Mediterranean diet, which	
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								amounts to double-counting the same data.		
			Yokoyama et al 2014	Review paper of RCTs	Review of RCTs and cohort studies on the vegetarian diet and blood pressure	In the 7 controlled trials (a total of 311 participants; mean age, 44.5 years) and 32 observational studies (a total of 21 604 participants; mean age, 46.6 years), consumption of vegetarian diets was associated with lower mean systolic and diastolic BP compared with the consumption of omnivorous diets.	No	This review addresses the effect of the Patterns on blood pressure, not overall cardiovascular risk factors or outcomes.	Limited	Blood pressure is the only outcome

Dietary Patterns and obesity										
	1. "What is the relationship between adherence to dietary guidelines/recommendations or specific Dietary Patterns, assessed <i>using an index or score</i> , and measures of body weight or obesity?"	"Moderate," Grade II Evidence		Review paper: RCT evidence is listed directly below						
			Estruch AIM (2006):	RCT	Trial tested a Mediterranean diet on 772 men and women, ages 50 to 80 years, for 3 months	This trial failed to demonstrate that subjects on the Mediterranean diet lost more weight than those in a control group. There was "no significant changes in body weight and adiposity occurred within or between groups"	No	The diet in this study did not seek to reduce red meat and was relatively high in fat (41% of calories). Both these	No	Trial did show very small total weight loss, and the Mediterranean diet was not superior than a low-fat diet in producing weight loss.

								features are unlike the Patterns.		
			Jacobs AJCN (2009):	Post-hoc analysis of RCT	The diet score increased by approximately 2 +/- 5.5 in both diet groups, with a decrease of an equivalent amount in the exercise and control groups. "Weight change" was greater with higher adherence to the diet		No	This study was a post-hoc analysis on dietary adherence rather than a paper on the effectiveness of the diet itself.	No	This is a post-hoc analysis of a clinical trial and significance of adherence to a diet, but not a paper on a clinical trial itself. The trial itself suggests greater weight loss on USDA Dietary Pattern, but data

										is not clear.
	“Are prevailing patterns of diet behavior in a population, assessed using factor or cluster analysis, related to body weight or risk of obesity?”	"Limited," Grade III data.							No	Data is deemed to be "Limited," which is Grade III, or the lowest rank for data when available.

	“What is the relationship between adherence to dietary guidelines/recommendations or specific dietary patterns, assessed using reduced rank regression analysis, and measures of body weight or obesity?”	"Not Assignable," Grade IV data.						No	Data is deemed to be only "Not assignable," which is Grade IV, or the lowest overall rank for data
	“What is the relationship between adherence to dietary guidelines/recommendations or specific dietary patterns (assessed using methods other than index/score, cluster or factor, or reduced rank regression analyses) and	"Moderate," Grade II Evidence	Blumenthal 2010	Review paper: RCT evidence is listed directly below	4 month trial on the DASH diet		Yes	Very limited	Weight loss was mainly seen in the group that was treated with diet + exercise, but not diet alone.

	body weight status?"									
			Howard 2006:		Women's Health Initiative (WHI) study, on nearly 49,000 women for an average of 7 years			A low-fat eating pattern does not result in weight gain in postmenopausal women .	No	The low-fat diet was effective at producing greater weight loss at year 1, but this benefit was not observed by the end of the study

			Carty 2011:		Women's Health Initiative (WHI) study, on nearly 50,000 women for an average of 7 years		No	This is the same trial as the one already listed in Howard 2006, so including it again amounts to double counting.		
			Esposito 2004:		This 2-year trial on 180 subjects with metabolic syndrome		Yes	Mean (SD) body weight decreased more in patients in the intervention group (-4.0 [1.1] kg) than in those in the control group	Yes	Trial was on a non-normal population (subjects with metabolic syndrome).

									different types of evidence or any measures taken to prevent double counting of studies included in these reviews	
			Ambrosini et al	Review	Review of 7 observational studies on dietary patterns (high in fat and low in fiber) in childhood and later obesity			"dietary patterns that are high in energy-dense, high-fat and low-fibre foods predispose young people to later overweight and obesity.	No	Studies show mixed results. Quality of data is weak and definition of the diet differed significantly between studies

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			Esposito et al 2011	Review	Review of 16 RCTS of the Mediterranean diet		No	The Mediterranean diets in these studies do not, on the whole, resemble the USDA Dietary Patterns: the Mediterranean diet in Mediterranean countries is not low in fat. Also, this review paper includes the		

								Esposito 2004 trial that is already cited in the NEL review, which amounts to double counting.		
DIETARY PATTERNS AND DIABETES										
NEL Review of Dietary Patterns and Diabetes										
	What is the relationship between dietary patterns and risk of type 2 diabetes?	"Limited," Grade III data							No	"Limited" data is the lowest rank given when data is available. (The DGAC states that it upgrades

											<p>this grade to "Moderate," Grade II, but does not provide any additional data to justify this upgrade.)</p>
DIETARY PATTERNS AND CANCER											
1. World Cancer Report 2007											
	Findings relevant to the USDA Patterns:										<p>The World Cancer Report supports findings from only two aspects of the USDA Patterns: vegetables and</p>

								red meat. The other aspects of the Patterns are either not supported or contradicted.		
	Vegetables: non-starchy vegetables <i>decrease</i> the risk for stomach cancers; Allum vegetables reduce risk for colorectum cancers vegeables decrease the risk of colorectum cancer	"Probable"					Yes		Limited	Observational data can show associations but not causation. The degree of association ("relative risk ratios" are small)

	What is the relationship between dietary patterns and risk of cancer?	Part 1: "Moderate," Grade II: For colorectal cancer		Review of RCTS and cohort studies (Single RCT included is listed directly below)						
			Women's Health Initiative source	RCT: Only 1 RCT is included in this review	On some 49,000 women on the USDA diet for an average of 7 years			A low-fat dietary pattern intervention did not reduce the risk of colorectal cancer in postmenopausal women during 8.1 years of follow-up	No	No benefits for cancer prevention were seen in the experimental group, compared to controls.

		Part 2: "Moderate ," Grade II: For breast cancer, post- menopaus al		Review of RCTS and cohort studies						
			Women's Health Initiative	RCT: Only 1 RCT is included in this review	On some 49,000 women on the USDA diet for an average of 7 years			Among postme nopaus al women , a low- fat dietary pattern did not result in a statistic ally signific ant reducti on in invasiv e breast cancer risk over an 8.1- year averag e	No	No benefits for cancer preventio n were seen in the experime ntal group, compared to controls.

								follow-up period.		
		Part 3: "Limited," Grade III: For breast cancer, pre-menopausal							No	"Limited" data is the lowest rank for data when available
		Part 4: "Limited," Grade III: For lung cancer							No	"Limited" data is the lowest rank for data when available
		Part 5: "Not Assignable," Grade IV: For prostate cancer							No	"Not Assignable" is the lowest rank for data overall;

	What is the relationship between dietary patterns and risk of neurological and psychological illnesses?	Grade III-IV, "Limited" to "Not assignable"							No	"Limited" data is the lowest rank for data when available; "Not Assignabl e" is the lowest rank for data overall.
DIETARY PATTERNS AND NEUROLOGICAL OR PSYCHOLOGICAL ILLNESSES										
NEL Review of the Evidence										
	What is the relationship between dietary patterns and bone health?	Grade III-IV, "Limited" to "Not assignable"							No	"Limited" data is the lowest rank for data when available; "Not Assignabl e" is the lowest rank for

