（表 3）肥満の定義の国際比較

台湾		韓国		中国		日本	
<18.5	Underweight	<18.5	Underweight			<18.5	Underweight
18.5 – 24	Normal	18.5 – 22.9	Normal			18.5 – 24.9	Normal
24 – 27	Overweight	23 – 24.9	At-risk of obesity	24 – 27.9	Overweight	25 – 29.9	Obesity Grade1
27 – 30	Mild obesity	25 – 29.9	Obesity	28 –	Obesity	30 – 34.9	Obesity glade2
30 – 35	Moderate obesity	30 –	Severe obesity			35 – 39.9	Obesity grade3
35 –	Severe obesity					40 –	Obesity Grade4

(表 4)「特定健診・保健指導」に関する厚生労働科学研究成果

番号	研究年度	研究タイトル	研究代表者
1	2012	特定健診・保健指導開始後の実態を踏まえた新たな課題の整理と、保健指導困難事例や若年肥満者も含めた新たな保健指導プログラムの提案に関する研究	横山　徹爾
2	2012	生活習慣病予防活動・疾病管理による健康指標に及ぼす影響と医療費適正化効果に関する研究	津下　一代
3	2012	糖尿病の重症化・合併症予防に資する地域連携の多角的評価の研究	春日　雅人
4	2012	わが国の健康増進事業の現状把握とその評価および今後のあり方に関する調査研究	清原　裕
5	2012	CKD 進展予防のための特定健診と特定保健指導のあり方に関する研究	木村　健二郎
6	2012	慢性腎臓病（CKD）に関する普及啓発のあり方に関する研究	秋澤　忠男
7	2012	成人を対象とした眼検診プログラムの臨床疫学、医療経済学的評価	山田　昌和
8	2011	医療・介護・検診情報を接合した総合的パネルデータ構築と地域医療における「根拠に基づく健康政策（ＥＢＨＰ）」の立案と評価に関する研究	岩本　康志
9	2011	口腔機能に応じた保健指導と肥満抑制やメタボリックシンドローム改善との関係についての研究	安藤　雄一
10	2010	医療保険者による特定健診・特定保健指導が医療費に及ぼす影響に関する研究	岡山　明
11	2010	今後の特定健康診査・保健指導における慢性腎臓病（CKD）の位置付けに関する検討	渡辺　毅
12	2010	未受診者対策を含めた健診・保健指導を用いた循環器疾患予防のための地域保健クリティカルパスの開発と実践に関	岡村　智教

		する研究	
13	2010	特定保健指導プログラムの成果を最大化及び最適化する保健指導介入方法に関する研究	今井　博久
14	2010	各種健診データとレセプトデータ等による保健事業の評価に関する研究	水嶋　春朔
15	2009	保健指導への活用を前提としたメタボリックシンドロームの診断・管理のエビデンス創出のための横断・縦断研究	門脇　孝
16	2008	生活習慣病対策における健診・保健指導による行動変容にかかる成功事例の収集及びガイドラインの作成に関する研究	中原　俊隆
17	2007	レセプトデータでみる医療費適正化政策の有効性評価に関する研究	財団法人医療経済研究社会保険福祉協会
18	2007	生活習慣病予防のための効果的な栄養教育手法に関する研究	山本　茂
19	2007	疾病予防サービスの制度に関する研究	永井　良三
20	2007	健康診査の精度管理に関する研究	渡邊　清明
21	2007	職域における健康診査の効率的なプロトコールに関する研究	松田　晋也

（表 5）健康日本 21 に関する厚生労働科学研究成果

番号	研究年度	研究タイトル	研究代表者
1	2012	生活習慣病予防活動・疾病管理による健康指標に及ぼす影響と医療費適正化効果に関する研究	津下　一代
2	2012	肥満残存高血圧合併睡眠時無呼吸患者に対する防風通聖散及び大柴胡湯の治療効果の比較と病態生理の解明	陳　和夫
3	2012	2010 年国民健康栄養調査対象者の追跡開始（NIPPON DATA 2010)とＮＩＰＰＯＮ　ＤＡＴＡ８０/９０の追跡継続に関する研究	三浦　克之
4	2012	未成年者の喫煙・飲酒状況に関する実態調査研究	大井田　隆
5	2012	健康寿命における鍾愛予測と生活習慣病対策の費用対効果に関する研究	橋本　修二
6	2010	わが国の成人の喫煙行動及び受動喫煙曝露の実態に関する全国調査	尾崎　米厚
7	2010	健康日本 21 の中間評価・糖尿病等の「今後の生活習慣病対策の推進について（中間取りまとめ)」を踏まえた今後の生活習慣病のためのエビデンス構築に関する研究	緒方　裕光
8	2008	健康寿命の地域指標算定の標準化に関する研究	橋本　修二
9	2007	健康日本２１こころの健康づくりの目標達成のための休養・睡眠のあり方に関する根拠に基づく研究	内山　真
10	2006	ＮＩＰＰＯＮ　ＤＡＴＡ９０の１５年目の追跡調査による健康寿命およびＡＤＬ、ＱＯＬ低下に影響を与える要因の分析とＮＩＰＰＯＮ　ＤＡＴＡ８０の１９年追跡調査の分析	上島　弘嗣
11	2006	地方健康増進計画の技術的支援に関する研究	河原　和夫

12	2006	未成年者の喫煙実態状況に関する調査研究	林　謙治
13	2005	国民健康・栄養調査における各種指標の設定及び精度の向上に関する研究	吉池　信男
14	2004	健康日本２１計画の改訂と改善に資する基礎研究	長谷川　敏彦
15	2004	行動科学に基づく栄養教育と支援的環境づくりによる地域住民の望ましい食習慣形成に関する研究	武見　ゆかり

(表 6)「食事バランスガイド」に関する厚生労働科学研究成果

番号	研究年度	研究タイトル	研究代表者
1	2010	胎児期から乳幼児期を通じた発育・食生活支援プログラムの開発と応用に関する研究	瀧本　秀美
2	2009	日本人の食事摂取基準の活用方法に関する検討	由田　克士
3	2008	食事バランスガイドを活用した栄養教育・食環境づくりの手法に関する研究	武見　ゆかり
4	2008	食品の安全についての普及啓発のためのツールおよびプログラムの開発に関する研究	丸井　英二
5	2007	生活習慣病予防のための効果的な栄養教育手法に関する研究	山本　茂
6	2006	若い女性の食生活はこのままで良いのか？次世代の健康を考慮に入れた栄養学・予防医学的検討	吉池　信男

(表 7)「運動指針・エクササイズガイド」に関する厚生労働科学研究成果

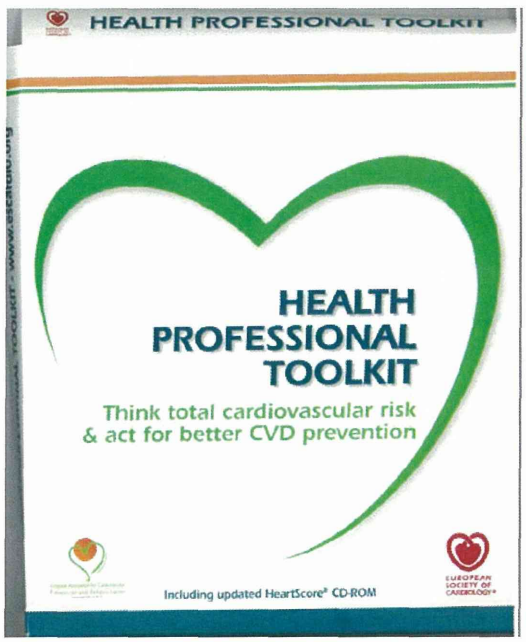
番号	研究年度	研究タイトル	研究代表者
1	2012	健康づくりのための運動基準・運動指針改定ならびに普及・啓発に関する研究	宮地　元彦
2	2009	健康づくりのための運動基準・エクササイズガイド改定に関する研究	田畑　泉
3	2008	エネルギー必要量推定法に関する基盤的研究	田中　茂穂
4	2008	生活習慣病一次予防に必要な身体活動量・体力基準値策定を目的とした大規模介入研究	高橋　佳子
5	2006	「健康づくりのための運動指針」に関する研究－身体活動量増加による生活習慣病の一次予防効果－	田畑　泉

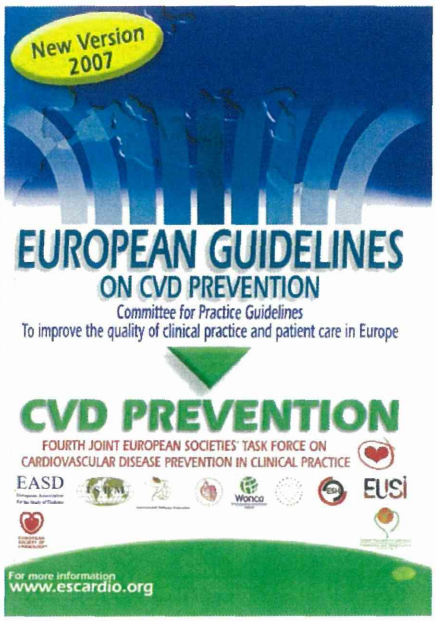
（図１）

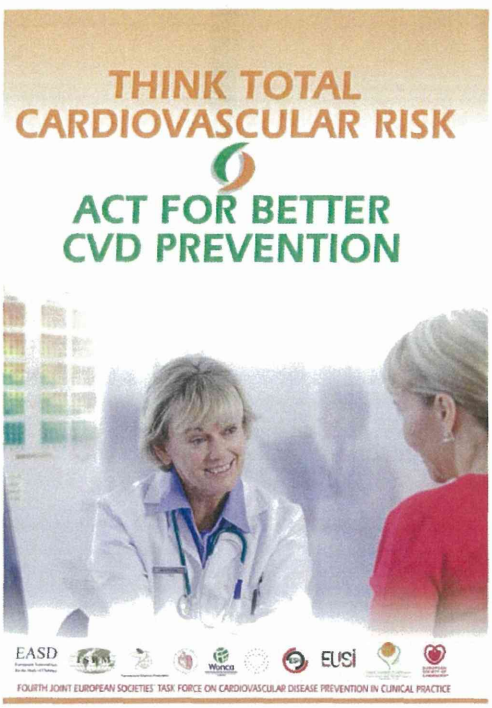
日本の政策


昭和53年
国民健康づくり対策
平成12年
健康日本21
食生活指針
平成18年
健康日本21改訂
食事バランスガイド
健康づくりのための運動指針2006
特定健診・保健指導
食生活改善普及運動
平成25年
健康づくりのための運動指針2013

（資料 1）Health Professional Toolkit, European Society of Cardiology







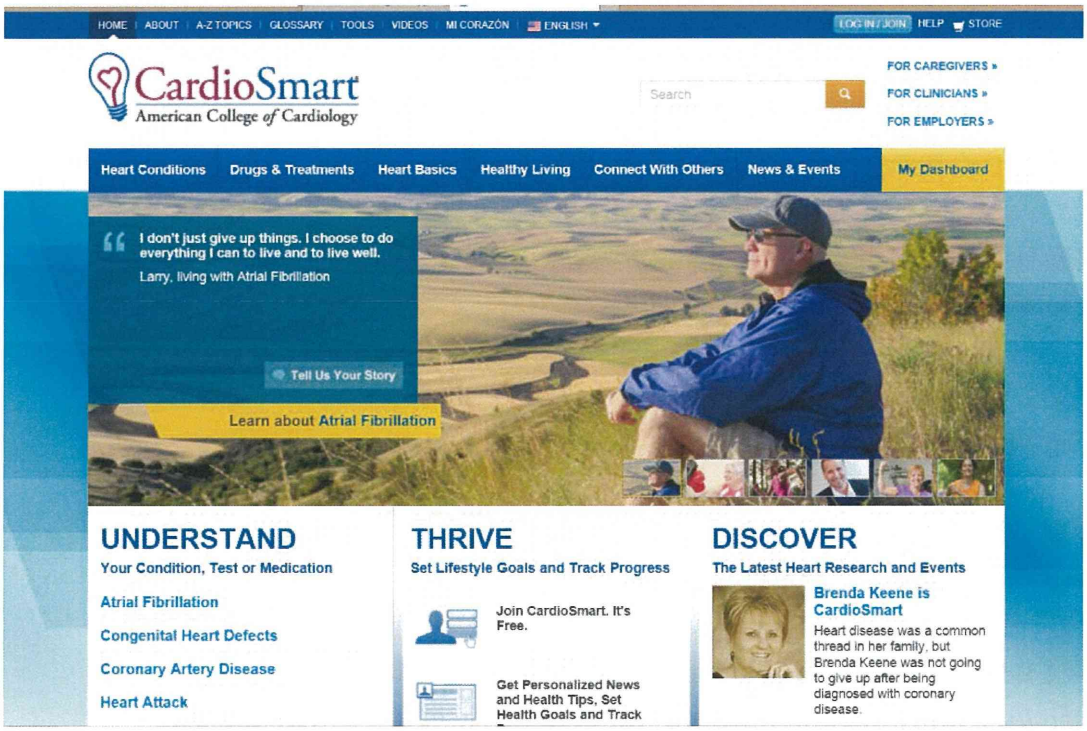
（資料 2）「Wellness LINK®」，OMRON
http://www.wellnesslink.jp/p/

（資料 3）My Life Check, American Heart Association

http://mylifecheck.heart.org/

（資料 4）CardioSmart, American College of Cardiology

https://www.cardiosmart.org/



（資料 5）参考文献

「健康づくりのための運動指針 2006～生活習慣病予防のために～＜エクササイズガイド 2006＞」、運動所要量・運動指針の策定検討会、平成 18 年

「健康づくりのための身体活動指針（アクティブガイド）」、厚生労働省

「健康づくりのための身体活動基準 2013」、厚生労働省

健康日本 21
http://www.kenkounippon21.gr.jp/

厚生労働科学研究成果データベース
http://mhlw-grants.niph.go.jp/

食事バランスガイド
http://www.maff.go.jp/j/balance_guide/

平成 23 年国民健康・栄養調査結果の概要、厚生労働省
http://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html

平成 24 年国民健康・栄養調査結果の概要、厚生労働省
http://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html

独立行政法人　農畜産業復興機構
http;//www.alic.go.jp/chosa-c/joho01_000537.html

American College of Cardiology. CardioSmart.
https://www.cardiosmart.org/

American Heart Association. My Life Check
http://mylifecheck.heart.org/

Berry JD, Dyer A, Cai X, Garside DB, Ning H, Thomas A, Greenland P, Van Horn L, Tracy RP, Lloyd-Jones DM. Lifetime risks of cardiovascular disease. N Engl J Med. 2012; 366(4): 321-9.

Bei-Fan Z; Cooperative Meta-Analysis Group of Working Group on Obesity in China (December 2002). "Predictive values of body mass index and waist circumference for risk factors of certain related diseases in Chinese adults: study on optimal cut-off points of body mass index and waist circumference in Chinese adults". Asia Pac J Clin Nutr. 11 Suppl 8: S685–93.

Bibbins-Domingo KB, Chertow GM, Coxson PG, Moran A, Lightwood JM, Pletcher MJ, Goldman L. Projected effect of dietary salt reductions of future cardiovascular disease. N Engl J Med 2010;362:650-652.

Casazza K, Fontaine KR, Astrup A, Birch LL, Brown AW, Bohan Brown MM, Durant N, Dutton G, Foster EM, Heymsfield SB, McIver K, Mehta T, Menachemi N, Newby PK, Pate R, Rolls BJ, Sen B, Smith DL Jr, Thomas DM, Allison DB. Myths, presumptions, and facts about obesity. N Engl J Med 2013; 368(5): 446-54.

Cummins S, Flint E, Matthews SA. New neighborhood grocery store increased awareness of food access but did not alter dietary habits or obesity. Health Affairs 2014 33:2283-291.

de Ruyter JC, Olthof MR, Seidell JC, Katan MB. A trial of sugar-free or sugar-sweetened beverages and body weight in children. N Engl J Med 2012; 367(15): 1397-406.

de Ruyter JC, Olthof MR, Kuijper LD, Katan MB. Effect of sugar-sweetened beverages on body weight in children: design and baseline characteristics of the Double-blind, Randomized INtervention study in Kids. Contemp Clin Trials. 2012; 33(1): 247-57.

Ebbeling CB, Feldman HA, Chomitz VR, Antonelli TA, Gortmaker SL, Osganian SK, Ludwig DS. A randomized trial of sugar-sweetened beverages and adolescent body weight. N Engl J Med. 2012; 367(15): 1407-16.

Fujioka S, et al: Contribution of intra-abdominal fat accumulation to the impairment of glucose and lipid metabolism in human obesity. Metabolism 36(1):54-9, 1987.

General Assembly of the United Nations. High-level meeting on non-communicable diseases. 2011.
http://www.un.org/en/ga/president/65/issues/ncdiseases.shtml.
(Accessed June 25, 2012.)

Huffman MD, Capewell S, Ning H, Shay CM, Ford ES, Lloyd-Jones DM. Cardiovascular health behavior and health factor changes (1988-2008) and projections to 2020: results from the National Health and Nutrition Examination Surveys. Circulation. 2012; 125(21): 2595-602.

Ikeda N, Inoue M, Iso H, Ikeda S, Satoh T, Noda M, Mizoue T, Imano H, Saito E, Katanoda K, Sobue T, Tsugane S, Naghavi M, Ezzati M, Shibuya K. Adult mortality attributable to preventable risk factors for non-communicable diseases and injuries in Japan: a comparative risk assessment. PLoS Med. 2012; 9(1): e1001160.

Kanazawa M, Yoshiike N, Osaka T, Numba Y, Zimmet P, Inoue S (December 2002). "Criteria and classification of obesity in Japan and Asia-Oceania". Asia Pac J Clin Nutr. 11 Suppl 8: S732–S737.

Marteau T, et al. Judging nudging: can nudging improve population health? BMJ, 2011; 342: 263-265.

Mozaffarian D, Afshin A, Benowitz NL, Bittner V, et al. Population approaches to improve diet, physical activity, and smoking habits: A scientific statement from the American heart association. Circulation 2012; 126: 1514-1563.

Nakao YM, Miyawaki T, Yasuno S, Nakao K, Tanaka S, Ida M, Hirata M, Kasahara M, Hosoda K, Ueshima K, Nakao K. Intra-abdominal fat area is a predictor for new onset of individual components of metabolic syndrome: MEtabolic syndRome and abdominaL ObesiTy (MERLOT study). Proc Jpn Acad Ser B Phys Biol Sci. 2012;88(8):454-61.

OMRON, Wellness LINK®
http://www.wellnesslink.jp/p/

Powell LM, Chaloupka FJ. Food prices and obesity: evidence and policy implications for taces and subsidies. Milbank Q. 2009;87:229-257.

Ramsden CE, Zamora D, Leelarthaepin B, Majchrzak-Hong SF, Faurot KR, Suchindran CM, Ringel A, Davis JM, Hibbeln JR. Use of dietary linoleic acid for secondary prevention of coronary heart disease and death: evaluation of recovered data from the Sydney Diet Heart Study and updated meta-analysis. BMJ. 2013; 346: e8707.

Rose G. Rose's strategy of preventive medicine. OXFORD 2008

Sassi F. Obesity and the Economics of Prevention, OECD publishing, 2010.

Smith-Spangler CM, Juusola JL, Enns EA, Owens DK, Garber AM. Population strategies to decrease sodium intake and the burden of cardiovascular disease: a cost-effectiveness analysis. Ann Intern Med 2010; 152(8): 481-7.

Stack F, Deutsch R. Reflective and impulsive determinants of social behavior. Pers Soc Psychol Rev 2004; 8: 220-47.

Susan K. Neely. New England Journal of Medicine opinion column suggests ineffective shortcuts to solve obesity challenge.
http://www.ameribev.org/news-media/news-releases-statements/more/158/

Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. BMJ. 2012; 346: e7492.

Watts ML, Hager MH, Toner CD, Weber JA. The art of translating nutritional science into dietary guidance: history and evolution of the Dietary Guidelines for Americans. Nutr Rev 2011: 69(7):404-12.

WHO Regional Committee for Europe. Behaviour change strategies and health: the role of health systems. WHO, 2008.

Ⅲ. 研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Tanaka S, Yoshimura Y, Kamada C, Tanaka S, Horikawa C, Okumura R, Ito H, Ohashi Y, Akanuma Y, Yamada N, Sone H; Japan Diabetes Complications Study Group.	Intakes of dietary fiber, vegetables, and fruits and incidence of cardiovascular disease in Japanese patients with type 2 diabetes.	Diabetes Care	36(12)	3916-22	2013
Kodama S, Horikawa C, Fujihara K, Yoshizawa S, Yachi Y, Tanaka S, Ohara N, Matsunaga S, Yamada T, Hanyu O, Sone H.	Quantitative relationship between body weight gain in adulthood and incident type 2 diabetes: a meta-analysis.	Obes Rev.	15(3)	202-14	2014
Ida M, Hirata M, Odori S, Mori E, Kondo E, Fujikura J, Kusakabe T, Ebihara K, Hosoda K, Nakao K.	Early changes of abdominal adiposity detected with weekly dual bioelectrical impedance analysis during calorie restriction.	Obesity	Sep;21(9)	E350-3.	2013
Ida M, Hirata M, Hosoda K, Nakao K.	Abdomen specific bioelectrical impedance analysis (BIA) methods for evaluation of abdominal fat distribution.	Nihon Rinsho	71(2)	262-5.	2013

Nakao K, Son C.	Concept and classification of obesity.	Nihon Rinsho	71(2)	201-4.	2013
Nakao YM, Miyawaki T, Yasuno S, Nakao K, Tanaka S, Ida M, Hirata M, Kasahara M, Hosoda K, Ueshima K, Nakao K.	Intra-abdominal fat area is a predictor for new onset of individual components of metabolic syndrome: MEtabolic syndrome and abdominaL ObesiTy (MERLOT study).	Proc Jpn Acad Ser B Phys Biol Sci	88(8)	454-61	2012
Nakao YM, Yasuno S, Miyawaki T, Ueshima K, Nakao K.	MONK study and MERLOT study	Nihon Rinsho	In press		2014

Intakes of Dietary Fiber, Vegetables, and Fruits and Incidence of Cardiovascular Disease in Japanese Patients With Type 2 Diabetes

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OBJECTIVE—Foods rich in fiber, such as vegetables and fruits, prevent cardiovascular disease (CVD) among healthy adults, but such data in patients with diabetes are sparse. We investigated this association in a cohort with type 2 diabetes aged 40–70 years whose HbA_{1c} values were ≥ 6.5% in Japan Diabetes Society values.

RESEARCH DESIGN AND METHODS—In this cohort study, 1,414 patients were analyzed after exclusion of patients with history of CVDs and nonresponders to a dietary survey. Primary outcomes were times to stroke and coronary heart disease (CHD). Hazard ratios (HRs) of dietary intake were estimated by Cox regression adjusted for systolic blood pressure, lipids, energy intake, and other confounders.

RESULTS—Mean daily dietary fiber in quartiles ranged from 8.7 to 21.8 g, and mean energy intake ranged from 1,442.3 to 2,058.9 kcal. Mean daily intake of vegetables and fruits in quartiles ranged from 228.7 to 721.4 g. During the follow-up of a median of 8.1 years, 68 strokes and 96 CHDs were observed. HRs for stroke in the fourth quartile vs. the first quartile were 0.39 (95% CI 0.12–1.29, $P = 0.12$) for dietary fiber and 0.35 (0.13–0.96, $P = 0.04$) for vegetables and fruits. There were no significant associations with CHD. The HR per 1-g increase was smaller for soluble dietary fiber (0.48 [95% CI 0.30–0.79], $P < 0.01$) than for total (0.82 [0.73–0.93], $P < 0.01$) and insoluble (0.79 [0.68–0.93], $P < 0.01$) dietary fiber.

CONCLUSIONS—Increased dietary fiber, particularly soluble fiber, and vegetables and fruits were associated with lower incident stroke but not CHD in patients with type 2 diabetes.

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Type 2 diabetes is a significant cause of premature mortality and morbidity related to cardiovascular disease (CVD), and medical nutritional therapy is an essential component of diabetes care aimed toward prevention of CVD. Current guidelines for diabetes care in many countries encourage consumption of dietary fiber, nondigestible carbohydrates, and lignin that are intrinsic and intact in plants, setting a variety of goals for daily intake of total dietary fiber (14 g/1,000 kcal in the U.S. [1], 40 g in Europe [2], 25–50 g in Canada [3], and 20–25 g in Japan [4]). An increase in dietary fiber can reduce CVD risk through a variety of mechanisms, such as decreasing total and LDL cholesterol (5), reducing postprandial glucose concentration and insulin secretion (6), lowering blood pressure (7), reducing clotting factors (8), and reducing inflammation (9). Lipid-lowering effects were attributable to soluble fiber (5), which reduces absorption of fat and binds bile acids (10). The effects of an unfortified high-fiber (50 g per day) diet on glycemic control and lipids were also demonstrated in a randomized trial in patients with type 2 diabetes (11).

Cohort studies of healthy adults suggest that foods rich in fiber protect against coronary heart disease (CHD) (12) and stroke (Supplementary Table 1) (13–19), but data on patients with type 2 diabetes are sparse (20–22) despite the integral role of medical nutritional therapy. All of the earlier studies in diabetes were conducted in the U.S. and Europe, and the effects of dietary fiber on CVD remain unknown for Asian patients, who account for >60% of the diabetic population worldwide (23). In comparison with type 2 diabetic patients in Western countries, those in East Asian countries, including Japan, are known to have different features regarding cardiovascular complications (24) including a much lower incidence rate of CHD than in Western countries (25) and obesity as a lesser cardiovascular risk factor (20). Therefore, it is still uncertain whether dietary recommendations established by the earlier studies are universally applicable to patients with type 2 diabetes, particularly to Japanese patients. This study therefore aimed to investigate the incidence rates of stroke and CHD in relation to intake of dietary fiber in total, soluble form, and insoluble form and vegetables and fruits in a cohort of Japanese patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS

—This study is part of the Japan Diabetes Complications Study

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(JDCS), an open-labeled randomized trial originally designed to evaluate the efficacy of a long-term therapeutic intervention mainly focused on lifestyle education. The original primary end points were CHD, stroke, diabetic retinopathy, and overt nephropathy. The primary results (26) of the JDCS have previously been described. Eligibility criteria were previously diagnosed patients with type 2 diabetes aged 40–70 years whose HbA_{1c} levels were ≥6.5% in Japan Diabetes Society values. From outpatient clinics in 59 university and general hospitals nationwide that specialize in diabetes care, 2,205 patients were initially registered from January 1995 to March 1996. Of the 2,033 patients who met the eligibility criteria and were randomized, 1,588 patients responded to the baseline dietary survey. There was no notable difference in baseline characteristics between responders and nonresponders (27). After exclusion of 174 patients with impaired glucose tolerance, a history of angina pectoris, myocardial infarction, stroke, peripheral artery disease, familial hypercholesterolemia, type III hyperlipidemia (diagnosed by broad β-band on electrophoresis), or nephrotic syndrome (urine protein >3.5 g/day and serum total protein <6.0 mg/dL) or serum creatinine levels >1.3 mg/dL (120 μmol/L) at baseline, 1,414 patients were included in the current analysis. We analyzed follow-up data collected until March 2003. The protocol was approved by the institutional review boards of all of the participating institutes. We obtained written informed consent from all patients.

Outcome measures

A fatal or first nonfatal manifestation of CHD comprised of angina pectoris or myocardial infarction was diagnosed according to criteria defined by the World Health Organization/Multinational Monitoring of Trends and Determinants in Cardiovascular Disease (WHO/MONICA) project, and angina pectoris was defined as typical effort-dependent chest pain or oppression relieved at rest or by use of nitroglycerine as validated by an exercise-positive electrocardiogram or angiography. A patient with a first percutaneous coronary intervention or coronary artery bypass graft was also counted as having a CHD event. Diagnosis of stroke was according to guidelines defined by the Ministry of Health, Labour and Welfare of Japan and WHO criteria. Stroke events were defined as a constellation of focal or global neurological deficits or disturbance of cerebral function that was sudden or rapid in onset and for which there was no apparent cause other than a vascular accident such as epilepsy or brain tumors on the basis of a detailed history, neurological examination, and ancillary diagnostic procedures such as computed tomography, magnetic resonance imaging, cerebral angiography, and lumbar puncture. Stroke events were classified as cerebral infarction (including embolus), intracranial hemorrhage (including subarachnoid hemorrhage), transient ischemic attack, or stroke of undetermined type in accordance with WHO criteria. No cases of asymptomatic lesions detected by brain imaging (i.e., silent infarction) were included. Only first-ever CHD or stroke events during the study period were counted in the analysis and in a patient having both CHD and stroke events; each event was counted separately. Information regarding primary outcome and other clinical variables for each subject was collected through an annual report that included detailed findings at the time of the event from each participating diabetologist who was providing care to those patients. Adjudication of CHD and stroke events was by central committees comprised of experts who were masked to risk factor status and was based on additional data such as a detailed history, sequential changes in ECG and serum cardiac biomarkers, and results of coronary angiography or brain imaging.

Dietary assessment

The Food Frequency Questionnaire based on food groups (FFQg) (28) was administered at baseline. In brief, the FFQg elicited information on the average intake per week of 29 food groups and 10 kinds of cookery in commonly used units or portion sizes. The FFQg was externally validated by comparison with dietary records for seven continuous days of 66 subjects aged 19–60 years (28). The ratios of the estimates obtained by the FFQg against those by the dietary records ranged from 72 to 121%, and the average was 104% (1,666 kcal/1,568 kcal for total energy, 10.0 g/9.5 g for total dietary fiber, 51.0 g/48.0 g for green-yellow vegetables, and 64.8 g/54.7 g for fruits). After patients completed the questionnaire, the dietitian reviewed the answers and in the case of questionable responses interviewed the patient. We use standardized software for population-based surveys and nutrition counseling in Japan to calculate nutrient and food intakes (Excel EIYO-KUN, version 4.5, developed by Shikoku University Nutrition Database; KENPAKUSHA, Tokyo, Japan).

Statistical analysis

Hazard ratios (HRs) and 95% CIs for the incidence of stroke or CHD in relation to dietary intakes were estimated by Cox regression with adjustment for age, sex, BMI, HbA_{1c}, diabetes duration, diabetic retinopathy, treatment by insulin, treatment by oral hypoglycemic agents, systolic blood pressure (SBP), LDL cholesterol, HDL cholesterol, triglycerides (log transformed), current smoking, physical activity, alcohol intake, proportions of total fat, saturated fatty acids, n-6 fatty acids and n-3 fatty acids, cholesterol intake, and sodium intake as confounders. In addition to the multivariate adjustment, we applied the standard multivariate method for energy adjustment. We performed both quartile and linear Cox regression analyses, and the primary analysis was conducted using linear regression. Potential nonlinear relationships between dietary fiber and stroke were explored by a spline function, a smooth curve of incidence rate of stroke depending on dietary fiber. The spline function and 95% CI were estimated by energy-adjusted generalized additive models, and the degree of freedom was determined by generalized cross-validation. Potential effect modification by age ≥60 years, sex, HbA_{1c} ≥9%, duration of diabetes ≥10 years, overweight (BMI ≥25 kg/m^2), smoking status, hypertension (SBP ≥130 mmHg, diastolic blood pressure ≥85 mmHg, or treatment by antihypertensive agents), and dyslipidemia (LDL cholesterol ≥120 mg/dL, HDL cholesterol <40 mg/dL, triglycerides ≥150 mg/dL, or treatment by lipid-lowering agents) was explored by subgroup analysis and Wald tests for interaction terms using energy-adjusted Cox regression. All *P* values are two-sided, and the significance level is 0.05. All statistical analyses and data management were conducted at a central data center using SAS, version 9.2 (SAS Institute, Cary, NC).

RESULTS—The baseline characteristics and daily dietary intake of the 1,414 patients according to quartiles of total dietary fiber are shown in Table 1. Mean total dietary fiber in quartiles ranged from 8.7 to 21.8 g. Mean energy intake in quartiles ranged from 1,442.3 to 2,058.9 kcal.