LSAW Nutrition and Dietary Intake

Description	Variable	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2010	2013
		Baseline	12 mo	24 mo	36 mo	48 mo	60 mo	72 mo	84 mo	96 mo	114 mo	120 mo	144 mo	180 mo
	Beverages	343					1232		1023			842	657	495
Diet	**Victorian Cancer Council FFQ (Food frequency, Food intake, Energy and nutrients)**	1485			106		1221		1006			795	383	209
	Flavonoids	1429					1232							
	Tea and coffee questionnaire	343												
	Urinary 4-O-methylgallic acid (tea) and urinary isoferulic acid (coffee)	275												
	Vitamin B12 intake	1429					1225							
Serum	**Red cell folate**		1214											
	Homocysteine		1214											
Urine	**Heavy metals/creatinine or specific gravity adjusted**	1333												

Overview

Participants

The participants involved in this study were recruited in 1998 to a 5-year, randomized, controlled trial of oral calcium supplements to prevent osteoporotic fractures as described previously [1]. Briefly, women were recruited from the Western Australian general population of women aged over 70 years by mail using the electoral roll a requirement of citizenship. Over 99% of Australians of this age are registered on the roll. Of the 5,586 women who responded to a letter inviting participation 1,510 women were willing and eligible and of these 1,460 women were recruited for the study. Participants were ambulant and did not have any medical conditions likely to influence 5-year survival. They were excluded if they were receiving bone-active agent, including hormone replacement therapy. Participants were similar in terms of disease burden and pharmaceutical consumption to whole populations of this age but they were more likely to be from higher socio-economic groups [2]. In the 5 years of the trial, participants received 1.2 g of elemental calcium as calcium carbonate daily or a matched placebo.

Overview of CAIFOS randomized controlled trial

Patients received calcium carbonate tablets, 0.6g twice per day (with morning and evening meals), or identical placebo tablets (Wyeth Consumer Healthcare, Baulkham Hills, Australia). The randomization list was produced by generating 146 blocks of 10 numbers. In each block, 5 positions representing placebo and 5 positions representing calcium treatment were ordered using a letter code according to a random number generator. The numbered blocks were ordered according to randomly generated numbers, and an identification number was assigned in order to each letter code in the randomized list. The Pharmacy Department of the Sir Charles Gairdner Hospital, Nedlands, Australia, assigned a treatment to the letter code and assigned the appropriate medications to the patient according to this list. The randomization was stratified by allocating patients to blocks according to whether a prevalent non-traumatic fracture had occurred after age 50 years, ensuring that an equal number of patients with and without a prevalent fracture received placebo or calcium. Medication compliance was checked at the completion of the study by counting returned tablets at each 12-month review and was calculated as a percentage of the optimum. Average yearly compliance of less than 80% was classified as non-compliant.

Ethics statement

The Human Ethics Committee of the University of Western Australia approved the study and written informed consents were obtained from all participants.

Beverages

An interviewer-administered 24 h dietary recall was used to collect food and beverage intake data during a clinic visit. Tea and coffee intake was assessed in cups. Tea intake included black tea and green tea, but not "herbal teas". Almost all tea consumed within this population was black tea with added milk. Almost all coffee consumed was instant (soluble) coffee. The food intake data were analysed to obtain nutrient intakes using Foodworks Professional (Xyris, Brisbane Australia) based on the Australian Food Composition Database (NUTTAB 95, Australian Government Nutrient Database, Canberra, Australia).

Victorian Cancer Council FFQ

A validated semi-quantitative food frequency questionnaire (FFQ) from the Cancer Council Victoria was used to assess dietary intake including dairy products (milk, yoghurt and cheese) consumption[3] in the previous 12 months. Food models, cups, spoons and charts were provided to help participants identifying serving sizes. Energy and nutrient intakes were estimated based on frequency of consumption and an overall estimate of usual portion size[4]. Participants whose questionnaires yielded extremely low or high energy intake [(below 800 kcal/d (3,347 kJ/d) or above 4,200 kcal/d (17,573 kJ/d)] were excluded, similar to previous studies[5,6].

Urinary 4-O-methylgallic acid (4OMGA) - biomarker of tea consumption

A 24 h urine sample was collected for the period corresponding to the dietary recall information. Urinary 4OMGA concentrations were used as a marker of tea-derived polyphenol intake [7] and metabolism[8]. 4-O-methylgallic acid was measured in urine samples using gas chromatography-mass spectrometry according to a previously described method[2,8]. The intra-assay variability was 5%.

Vitamin B12

Dietary vitamin B12 intake was assessed using a validated semi-quantitative food frequency questionnaire (FFQ) developed by the Anti-Cancer Council of Victoria was used to assess baseline (2003) dietary intake [3,4]. Estimates of the vitamin B12 content of foods in the FFQ was derived from the NUTTAB 2010: Australian Food Composition Tables [9] developed by Food Standards Australia and New Zealand. Intakes of Vitamin B12 in μg/d were calculated by multiplying the estimated intake (g edible portion/d) from FFQ, with the vitamin B12 content (μg/g edible portion) of each food item on the questionnaires. Serum vitamin B12 was assessed from venous blood samples were collected in the morning after an overnight fast from 10 pm. The serum was rapidly separated from the blood after collection. Total serum vitamin B12 levels were measured on Architect ci16200 analyser (Abbott). The Architect B12 assay is a two-step assay with an automated sample pre-treatment, for determining the presence of vitamin B12 in human serum and plasma using Chemiluminescent Microparticle Immunoassay (CMIA) technology with a limit of detection of 92 pmol/L and a CV of 7.6%. Low vitamin B12 was defined as serum levels < 350 pg/mL (258.23 pmol/L) [10].

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