Original Research Communications

A Mediterranean diet supplemented with dairy foods improves markers of cardiovascular risk: results from the MedDairy randomized controlled trial

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ABSTRACT

Background: The Mediterranean diet (MedDiet) offers benefits to cardiovascular health but may not meet Western recommendations for calcium and dairy intake, which could impede long-term adoption.

Objective: The current study aimed to determine the effect of a MedDiet supplemented with dairy foods on cardiovascular risk factors.

Design: A randomized, controlled, crossover design compared a MedDiet with 3–4 daily servings of dairy (MedDairy) and a low-fat (LF) control diet. Forty-one participants aged ≥45 y and at risk of cardiovascular disease (CVD) were randomly allocated to their first intervention, either the MedDairy or LF diet. Participants followed each intervention for 8 wk, and an 8-wk washout period separated interventions. The primary outcome was home-measured systolic blood pressure (SBP) assessed in the morning, afternoon, and evening. Secondary outcomes included clinic-measured blood pressure (morning), body composition, blood lipids, C-reactive protein (CRP), plasma glucose, serum insulin, and the Framingham Risk Score.

Results: Compared with the LF intervention, the MedDairy intervention resulted in a significantly lower morning SBP (mean difference: −1.6 mm Hg; 95% CI: −2.8, −0.4 mm Hg; $P = 0.01$), lower morning diastolic blood pressure (mean difference: −1.0; 95% CI: −1.7, −0.2 mm Hg; $P = 0.01$) and clinic SBP (mean difference: −3.5 mm Hg; 95% CI: −6.4, −0.7 mm Hg; $P = 0.02$), significantly higher HDL cholesterol (mean difference: 0.04 mmol/L; 95% CI: 0.01, 0.06 mmol/L; $P < 0.01$), lower triglycerides (mean difference: = −0.05 mmol/L; 95% CI: −0.08, −0.01 mmol/L; $P < 0.01$), and lower ratio of total to HDL cholesterol (mean difference: −0.4; 95% CI: −0.6, −0.2; $P < 0.001$). No effects were observed for other outcome measures.

Conclusions: Following a MedDiet with additional dairy foods led to significant changes in markers of cardiovascular risk over 8 wk. The MedDiet supplemented with dairy may be appropriate for an improvement in cardiovascular risk factors in a population at risk of CVD. This trial was registered at anzctr.org.au as ACTRN12616000309482. *Am J Clin Nutr* 2018;108:1–17.

Keywords: MedDiet, blood pressure, lipids, cholesterol, CVD, calcium, Australia

INTRODUCTION

The Mediterranean diet (MedDiet) is characterized by the high consumption of extra-virgin olive oil (EVOO), vegetables, fruits, nuts, legumes, and cereals; moderate consumption of fish, eggs, poultry, dairy foods, and red wine; and low consumption of red

Supported by a Dairy Australia Research Grant (C100001408) (secured by KJM, JMH, ATW, and CRD); an Australian Government Research Training Program (RTP) Scholarship (to ATW); a National Health and Medical Research Council Senior Research Fellowship (to JMH); and a Royal Perth Hospital Medical Research Foundation Fellowship (to JMH). Dairy Australia had no role in the study design, implementation, analysis, or interpretation of data. The Almond Board of Australia donated almonds; Cobram Estate donated Australian extra-virgin olive oil; Fonterra Australia Pty. Ltd. donated cheese; and Simplot Australia Pty. Ltd. donated legumes, tuna, and salmon.

Supplemental Tables 1–3 are available from the "Supplementary data" link in the online posting of the article and from the same link in the online table of contents at https://academic.oup.com/ajcn/.

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Abbreviations used: BP, blood pressure; CRP, C-reactive protein; CVD, cardiovascular disease; DBP, diastolic blood pressure; EVOO, extra-virgin olive oil; FRS, Framingham Risk Score; HR, heart rate; LF, low-fat; MDS, MedDiet Score; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods; MedDiet, Mediterranean diet; MedLey, Mediterranean diet for cognitive and cardiovascular health in the elderly; PREDIMED, Prevención con Dieta Mediterránea; RDI, Recommended Dietary Intake; SBP, systolic blood pressure; S-MDS, Sofi MedDiet Score.

Received February 23, 2018. Accepted for publication August 2, 2018.

First published online 0, 2018; doi: https://doi.org/10.1093/ajcn/nqy207.

meat and commercial sweets (1). Through these foods, the MedDiet delivers a range of bioactive nutrients including antioxidants, fiber, vitamins and minerals, polyphenols, monounsaturated fats, and omega-3 polyunsaturated fats (2).

Previous research indicates that the MedDiet is capable of reducing cardiovascular disease (CVD) risk, reducing CVD mortality, and promoting longevity (3–7). Proposed mechanisms suggest that the MedDiet reduces inflammation (8–10), which leads to significant improvements in blood pressure (BP), lipid profiles, insulin sensitivity, oxidative stress, and atherosclerosis (3–6, 11–14).

The Prevención con Dieta Mediterránea (PREDIMED) study, a large-scale randomized controlled trial in >7000 individuals, examined the efficacy of a MedDiet against a low-fat (LF) control diet in a Spanish population at risk of CVD (15). After a median follow-up of 4.8 y, improvements were reported for ambulatory BP, lipid profiles, insulin sensitivity, and indicators of oxidation and inflammatory stress (5). Further, incidence of major cardiovascular events and CVD mortality were significantly reduced.

Western countries, including the United States, are beginning to recommend the MedDiet as a healthful dietary pattern (16). However, discrepancies between the nutrients provided by the MedDiet and those required by Western populations warrant attention. Notably, a traditional MedDiet does not satisfy the Australian Dietary Guidelines for dairy foods and calcium intake. The Australian National Health and Medical Research Council currently recommends 2.5–4 servings of dairy foods/d for adults. In contrast, a typical MedDiet only provides 1–2 servings of dairy foods/d (1). The amount of calcium provided by a MedDiet is estimated at between 700 and 820 mg/d (17, 18). During the Mediterranean Diet for Cardiovascular and Cognitive Health in the Elderly (MedLey) trial, Australian participants consumed an average of 930 mg Ca/d while achieving high adherence to the MedDiet (3). This meets the Recommended Dietary Intake (RDI) of 750 mg for European countries (19). However, Australian women up to the age of 50 y and men up to the age of 70 y are advised to consume 1000 mg/d and 1300 mg thereafter (20). If the amount of calcium provided by a traditional MedDiet does not meet Australian Dietary Guidelines it may be inadequate for the long-term health of Australians, potentially reducing the sustainability of long-term consumption.

It is unknown whether supplementing the MedDiet with dairy foods, to meet Australian guidelines and Nutrient Reference Values, will compromise the known cardiovascular benefits of the diet. Findings from individual studies indicate that dairy food consumption may improve markers of CVD (21–23), whereas meta-analyses have found either neutral or favorable associations between dairy food intake and cardiovascular-related outcomes, including hypertension, stroke, type 2 diabetes, CVD risk, and cardiovascular and all-cause mortality (23–25). The current study therefore aimed to examine the effects of a MedDiet modified to meet Australian dairy and calcium recommendations. Specifically, cardiovascular-related outcomes were evaluated in a sample of Australians at risk of CVD.

METHODS

The study protocol for a MedDiet with adequate dairy foods has been described in detail elsewhere (26).

Ethics

The trial was registered with the Australia and New Zealand Clinical Trials Registry (ACTRN12616000309482) on 9 March 2016 and was conducted according to the Declaration of Helsinki guidelines. All procedures involving human participants were approved by the University of South Australia Ethics Committee (no. 34,954).

Design

A randomized controlled trial used a 2 × 2 crossover design to compare a MedDiet with adequate dairy (MedDairy) against an LF control diet. Participants followed each dietary intervention for 8 wk, and the 2 intervention periods were separated by an 8-wk washout during which participants returned to their habitual diet (**Figure 1**). Using block randomization and a block size of 4, an independent staff member randomly assigned participants to their first dietary intervention (MedDairy or LF), stratified by gender and age. Allocation concealment ensured study personnel and participants were not aware of the allocated intervention group before enrollment.

Participants

Australian volunteers aged between 45 and 75 y and at risk of CVD were recruited from metropolitan Adelaide. Cardiovascular risk was determined by systolic BP (SBP) ≥120 mm Hg and the presence of ≥2 of the following risk factors: BMI (in kg/m^2) ≥25; abdominal adiposity (waist circumference >94 cm for men and >80 cm for women); elevated total cholesterol (≥5.5 mmol/L), triglycerides (≥2.0 mmol/L), or LDL cholesterol (≥3.5 mmol/L) or low concentrations of HDL cholesterol (≤0.9 mmol/L for men and ≤1.0 mmol/L for women); impaired glucose tolerance (between 6.1 and 7.8 mmol/L); or a family history of CVD or type 2 diabetes. Aside from cardiovascular risk, participants were free of any cardiovascular, liver, kidney, respiratory, or gastrointestinal disease; cognitive impairment; type 1 or type 2 diabetes; malignancy in the past 6 mo; and significant head trauma or psychiatric condition. Participants also completed a MedDiet screening questionnaire based on that used in the PREDIMED study to ensure that they were not already following a MedDiet.

A total of 41 community-dwelling Australian men (n = 13) and women (n = 28) commenced the study between April and June 2016. Participants were randomly allocated into 2 groups to determine their starting diet and order of interventions. Group 1 (n = 20) completed the MedDairy intervention first, followed by the LF intervention; group 2 (n = 21) completed the LF intervention first, followed by the MedDairy intervention.

Procedure

Participants attended the Sansom Institute for Health Research Clinical Trial Facility 1 wk before baseline to be enrolled by study personnel and to receive study information and equipment. Clinic assessments were conducted at weeks 0, 8, 16, and 24 while participants were fasted and included the measurement of BP, anthropometry, dual-energy X-ray absorptiometry, and the collection of fasting blood. At the beginning of each

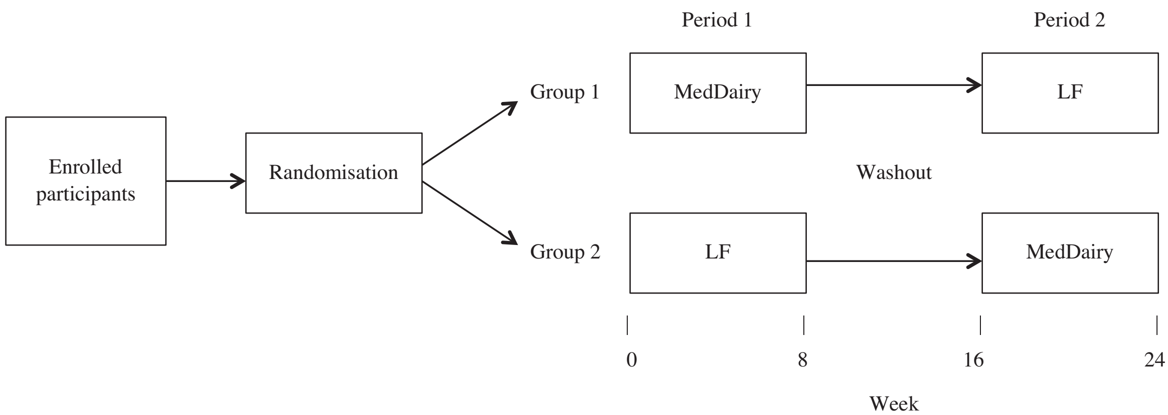

FIGURE 1 Illustration of the parallel crossover design from enrollment to 24 wk. Participants were randomly assigned into 2 groups to determine starting diet. All participants completed each dietary intervention for 8 wk, with interventions separated by an 8-wk washout period. LF, low-fat; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods.

dietary phase participants met with a dietitian to discuss dietary guidelines. At week 0, the dietitian also informed participants of their group allocation. Throughout each intervention phase participants also attended biweekly dietetic visits to discuss progress, difficulties, and possible adverse events. During the washout period, participants were instructed to return to their habitual diet. Change in medications, dietary supplements, and exercise was noted throughout the course of the study.

Dietary interventions

Guidelines for the MedDairy and LF interventions were adapted from the PREDIMED study and tailored for an Australian population (15).

The MedDairy diet

During the MedDairy intervention, participants were instructed to adhere to the following:

- 3–4 daily servings of dairy foods (1 serving = 250 mL LF milk, 40–120 g hard or semisoft to soft cheese, 200 g LF Greek yogurt, or 200 g tzatziki dip);
- ≤1 serving of cheese (any type)/d (1 serving = 40 g hard, 50 g semi-soft, or 120 g soft cheese such as ricotta and cottage cheese);
- abundant use of EVOO [minimum of 1 tablespoon (20 mL)/d];
- ≥2–3 daily servings of fresh fruit (1 serving = 150 g fresh, 40 g dried, or 1 cup canned in juice);
- ≥3 weekly servings of legumes (1 serving = 75 g);
- ≥3 weekly servings of fish and seafood (≥1 serving of oily fish; 1 serving = 100 g cooked);
- ≥5 weekly servings of nuts or seeds (1 serving = 30 g; 7.5 g hazelnuts, 15 g walnuts, 7.5 g almonds supplied for each serving);
- ad libitum consumption of whole-grain cereal products (bread, pasta, rice, cereal), nuts, eggs, and raw and cooked vegetables;
- select white meats (poultry without skin) instead of red meats or processed meats;
- limit consumption of red meat (remove all visible fat), cured ham, and chocolate to ≤1 serving/wk (1 serving of red meat/cured ham = 100 g; 1 serving of chocolate = 50 g);
- use EVOO as the main culinary fat in cooking and for dressing vegetables and salad;
- cook regularly (at least twice a week) with a tomato-based sauce (EVOO, tomato, garlic, and onion);
- dress vegetables, pasta, rice, and other dishes with EVOO, tomato, garlic, and onion sauce;
- eliminate or limit the consumption of cream, butter, margarine, cold meat, pate, duck, carbonated or sugared beverages, pastries, commercial bakery products (cakes, donuts, cookies), desserts (puddings), French fries, potato crisps, and sweets; and
- for usual drinkers, red wine was recommended as the preferred source of alcohol with a maximum of 2 standard drinks/d (200 mL = 2 standard drinks) (27).

Notably, EVOO recommendations of ≥1 tablespoon/d differ from the PREDIMED trial, in which participants were advised to consume ≥4 tablespoons olive oil/d. In contrast to the PREDIMED trial, the current study was conducted in Australia, where EVOO is not part of the habitual diet nor consumed in abundance (28). Minimum EVOO recommendations were therefore reduced in order to increase the palatability and sustainability of the MedDairy intervention. Furthermore, the MedLey trial, with the same recommendations for EVOO as were used here, reported improvements in markers of cardiovascular health after adherence to a MedDiet (3).

Consistent with Australian Dietary Guidelines (29), serving sizes of dairy foods delivered 300 mg Ca. Three to 4 servings of dairy each day provided 900–1200 mg Ca, whereas vegetables and nuts provided ˜100 mg. Based on this modeling, the MedDairy intervention provided 1000–1300 mg Ca/d, thus meeting the Australian RDI for calcium. The combination of almonds, walnuts, and hazelnuts was recommended to reflect the dietary guidelines from the PREDIMED trial and to provide a combination of MUFAs and PUFAs.

To assist with introducing the MedDairy diet to the intervention group and to assist with dietary adherence, the following foods were provided: Chobani Greek yogurt (Chobani Australia Pty. Ltd.); almonds (Almond Board of Australia); walnuts and hazelnuts; EVOO (Cobram Estate); Mainland Tasty regular-fat and reduced-fat cheese slices (Fonterra Co-Operative Group); Edgell chickpeas, cannellini beans, red kidney beans, 4-bean mix, and lentils (Simplot Australia Pty Ltd.); and canned John West tuna "tempters" and salmon "tempters" (Simplot Australia Pty. Ltd.).

The LF diet

The LF control was implemented to replicate the design of the PREDIMED trial (15). Furthermore, an LF control enables examination of the feasibility of the MedDairy intervention in Australia, where LF diets have been considered best practice and are frequently consumed and recommended for heart health.

During the LF intervention participants were instructed to follow their habitual diet while reducing their total fat intake by choosing LF foods and using LF cooking methods. Restricted foods included oil, butter, margarine, full-fat dairy products, processed and high-fat meats, nuts, chocolate, cakes, biscuits, pastry, and ice cream. Participants were instructed to replace restricted foods with LF alternatives such as breads, cereals, legumes, rice, vegetables, fruits, lean meats, and LF dairy food choices. Participants were specifically instructed to consume $\leq$20 mL oil/d and $\leq$2 teaspoons butter or margarine/d and to remove visible fat and skin from meat and fish before cooking.

Measures

BP

SBP is one of the leading modifiable risk factors for CVD and mortality (30) and was chosen as the primary outcome. Because home BP assessments have stronger predictive power than clinic BP assessments (31), participants were provided with an A&D Company Ltd. digital BP monitor to measure their SBP, diastolic blood pressure (DBP), and heart rate (HR) 3 times every morning, afternoon, and evening for 6 d in the week preceding each clinic assessment visit. This allowed the collection of 54 measurements of BP readings for analysis at 4 time points over the course of the trial (at prebaseline, week 7, week 15, and week 23). BP and HR were also measured at each of the clinic assessment visits with the use of an Omron Healthcare Co. digital BP monitor (model 1A1B Hem-7000-CIL).

Secondary outcomes

Secondary outcomes included BMI, waist-to-hip ratio, body composition (percentage body fat, lean mass, and abdominal adiposity) assessed via dual-energy X-ray absorptiometry, fasting blood lipids, C-reactive protein (CRP), fasting plasma glucose, fasting serum insulin, and the Framingham Risk Score (FRS) (32).

Lipids, CRP, glucose, and insulin were measured at an external National Association of Testing Authorities–accredited laboratory via standard procedures. Insulin resistance was calculated with the use of the HOMA2 Calculator version 2.2.3 (33). A higher HOMA2-IR score indicates greater insulin resistance.

Erythrocyte cell fatty acids were collected to determine change in the ratio of monounsaturated fat to saturated fat (MUFAs:SFAs). Samples were frozen at $-20°$C and will be stored at $-80°$C until funding can be secured for analyses.

Dietary adherence

During the MedDairy intervention a weekly semiquantitative checklist was provided to assess adherence and assist participants in becoming familiar with foods and serving sizes associated with the MedDairy diet. The semiquantitative checklist was based on that used in the MedLey study, a previous study conducted in our research center (34). Participants were instructed to complete the checklist daily with the use of a simple tick system (1 tick = 1 serving).

Participants were also provided with a 14-item MedDiet adherence tool for each fortnight during the MedDairy intervention and a 9-item LF diet adherence tool for each fortnight during the LF intervention. These tools were adapted from the PREDIMED study to align with Australian food supply and alcohol recommendations and were designed to capture a generalized pattern of consumption relevant to each dietary phase. The semiquantitative checklist and diet-specific adherence tools were completed throughout each dietary phase and returned at biweekly dietetic visits.

A 3-d weighed food record was completed 1 wk before and in the final week of each dietary intervention to calculate energy, macronutrient, and micronutrient intakes. The weighed food record was also used to calculate dietary adherence according to a 10-point MedDiet Score (MDS), adapted from Trichopoulou et al. (7). Food intake as grams per day was divided into 10 food groups, and a gender-specific median was calculated for each food group at week 0. For vegetables, fruit, legumes, cereals, nuts, fish, dairy, and MUFA:SFA, participants scored 1 point for consumption above the median and 0 for consumption under the median. For meat and meat products, participants scored 1 point for intake below the median and 0 for intake above the median. For alcohol, women consuming 5–25 g/d and men consuming 10–50 g/d were awarded 1 point. To calculate adherence to the a priori MedDiet we also applied a literature-based MedDiet score developed by Sofi et al. (35) (S-MDS). Similar to the MDS, the S-MDS includes 9 food groups relevant to the MedDiet. For food groups typically consumed within a MedDiet (vegetables, fruit, legumes, cereals, fish, and olive oil), 2 points were awarded for the highest level of consumption, 1 point for the middle level of consumption, and 0 points for the lowest level of consumption. For foods not typical of a MedDiet (meat and meat products), 2 points were awarded for the lowest level of consumption, 1 point for the middle level of consumption, and 0 points for the highest level of consumption. For alcohol, 1 point was awarded for $<$12 g/d, 2 points for 12–24 g/d, and 0 points for $>$24 g/d. In the original S-MDS, dairy intake is scored similarly to meat and meat products. However, the current study sought to increase dairy consumption and therefore awarded 2 points for the highest intake, 1 point for medium intake, and 0 points for the lowest intake (**Supplemental Table 1**).

Statistical analysis

Data were analyzed with the use of STATA (version 13; StataCorp) and IBM SPSS Statistics (version 21). To detect a clinically relevant difference of 2.5 mm Hg in the primary outcome of home SBP with ≥90% power, a sample size of 31 volunteers was required. This calculation assumes a within-group SD of 14 mm Hg, a within-subject correlation between the 4 BP measures at each visit of $r = 0.6$, and a between-phase within-subject correlation of $\rho = 0.5$. This correlation (ρ) and the crossover design reduce the number of required participants by a factor of $1 / [(1 - \rho)/2]$ (46), that is, from $n = \sim 124$ for a parallel-group design with the use of ANCOVA ($n = 62$/group) to $n = 31$ subjects in total. To account for a withdrawal rate of 30%, an additional 9 volunteers were recruited. Residuals were screened for normality, and non-normal variables were transformed through the use of log10 and square root transformations.

Linear mixed-effects models included terms for Diet (MedDairy compared with LF), Visit (1 or 2), Order (1 or 2), and Period (1 or 2). Preliminary analyses were conducted to detect significant period and carryover effects. Where significant period effects were observed, a Diet × Visit × Period term was included in the model to allow the Diet × Visit effect, the primary effect of interest, to vary by period. Where carryover effects were observed, a Visit × Period interaction was included to obtain separate estimates for the 2 intervention periods. The inclusion of the Visit term in the model provided adjustment for any group differences at baseline and allowed interpretation of any between-group differences at each visit (with the Group × Visit term) as differences in baseline-adjusted changes. The Diet × Visit effect then allowed us to estimate the differences in baseline-adjusted Visit 2 values between the 2 interventions. Participant IDs were included in the model as a random intercept. Weight at each time point was included as a covariate for all cardiometabolic outcomes, excluding measures of body composition and adiposity, because any change in weight might influence the results (36). Any missing data were accounted for in the mixed-effects models by the use of best linear unbiased predictions.

A significant Diet × Visit interaction term indicates an overall significant effect between the 2 interventions and is presented as "estimated mean difference between interventions (MedDairy compared with LF)" with 95% CIs. Positive values indicate MedDairy outcomes were greater than LF outcomes. Negative values indicate MedDairy outcomes were less than LF outcomes. Continuous variables are presented as means ± SEMs.

Results were considered significant where $P < 0.05$, unless α was adjusted for multiple comparisons. For SBP, DBP, and HR, an adjusted α of 0.02 (0.05/3) was applied to control for multiple comparisons across morning, afternoon, and evening readings. For measures of blood lipids, an adjusted α of 0.01 (0.05/5) was applied to control for multiple comparisons across total triglycerides, total cholesterol, HD cholesterol, LDL cholesterol, and cholesterol:HDL. For measures of body composition, an adjusted α of 0.006 (0.05/9) was applied to control for multiple related comparisons across weight, BMI, waist circumference, hip circumference, fat mass (%), lean mass (%), fat mass (kilograms), lean mass (kilograms), and abdominal fat. For percentage energy from macronutrients, an adjusted α of 0.01 (0.05/4) was applied to control for multiple comparisons across percentage energy from protein, percentage energy from total fat, percentage energy from carbohydrates, and percentage energy from alcohol. For fatty acids, an adjusted α of 0.02 (0.05/3) was applied to control for multiple comparisons across percentage energy from saturated fat, percentage energy from MUFAs, and percentage energy from PUFAs. An adjusted α of 0.005 (0.05/10) was applied to control for multiple comparisons across whole grains, refined grains, fruits, vegetables, legumes, meat/meat alternatives, red meat, nuts and seeds, total dairy, and EVOO. For dairy foods, an adjusted α of 0.02 (0.05/3) was applied for comparisons across milk, cheese, and yogurt.

For the primary outcome, home SBP, previous studies have indicated that readings taken on the first day might be higher than those taken on subsequent days. Daily averages were computed for home SBP at week 0, and paired-samples t tests were conducted to compare day 1 with all other days. No significant differences were detected at $P < 0.05$, and therefore day 1 SBP readings were retained in the analysis. Averages were also computed for the first, second, and third readings taken at week 0. Paired-samples t tests showed significant differences of first readings as compared with second and third readings. First readings were therefore excluded from the final analysis.

Nutrient intake was calculated with the use of Foodworks 9, databases AusFoods17 and AusBrands17 [Xyris Software (Australia) Pty. Ltd.]. The grouping of individual foods into MedDiet components is presented in **Supplemental Table 2**. Baseline medians of MedDiet food groups for the calculation of the MDS are presented in **Supplemental Table 3**. Calcium RDIs were calculated based on individual participant age and gender according to the Australian National Health and Medical Research Council guidelines (37).

RESULTS

Thirty-eight participants completed the first dietary phase and washout (MedDairy: $n = 19$; LF: $n = 19$), and 37 participants completed the second dietary phase of the study by January 2017 (MedDairy: $n = 19$; LF: $n = 18$). **Figure 2** shows the flow of participants through the study. Four participants withdrew during the study. Reasons for withdrawal included family commitments (MedDairy: $n = 1$), illness preventing adherence to the dietary intervention (MedDairy: $n = 1$; LF: $n = 1$), and difficulties in blood collection (LF: $n = 1$). All participants with baseline data ($n = 41$) were included in the following intention-to-treat analyses.

Baseline characteristics for group 1 (MedDairy intervention first) and group 2 (LF intervention first) are shown in **Table 1**. At baseline, characteristics of the 2 groups were similar, with the exception of home SBP (millimeters of mercury), which was 4.1 mm Hg higher in group 1.

Home BP and HR

Results for home BP are presented in **Table 2**. For participants who completed BP measurements at all 4 time points ($n = 37$), a mean of 49 measurements were taken, indicating 90% compliance with instruction.

Compared with LF, the MedDairy intervention resulted in significantly lower morning home SBP and DBP and significantly

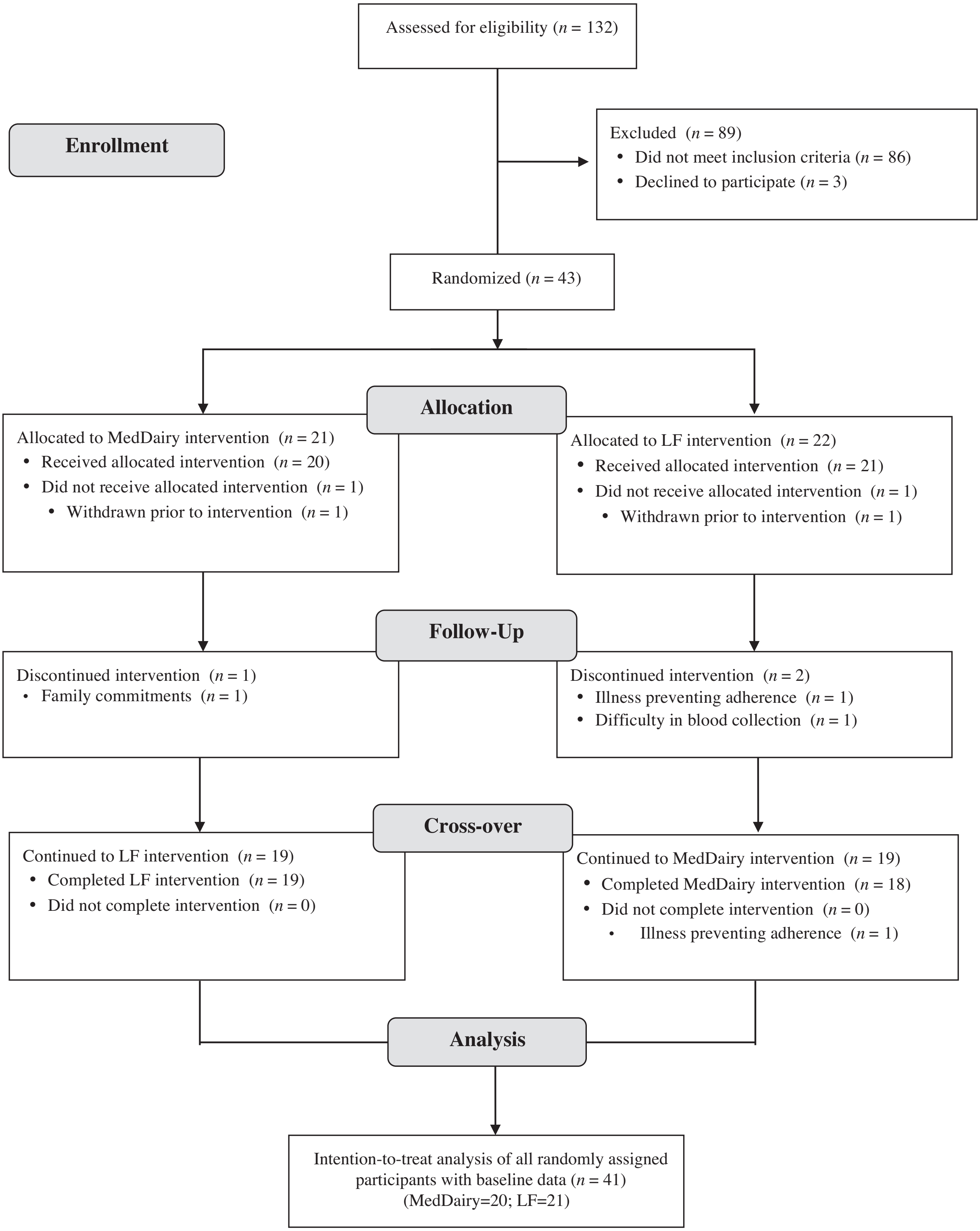

FIGURE 2 CONSORT flow diagram, which shows participation movement from enrollment through MedDairy and LF interventions and analysis. CONSORT, Consolidated Standards of Reporting Trials; LF, low-fat; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods.

TABLE 1
Demographic and clinical characteristics of the study sample at baseline, according to first dietary intervention[1]

	Group 1 ($n = 20$)	Group 2 ($n = 21$)	Total ($n = 41$)
Age, y	60.8 ± 6.3	59.6 ± 7.6	60.2 ± 6.9
Gender, *n*			
Men	6	7	13
Women	14	14	28
Education, y	15.6 ± 2.9	16.9 ± 4.3	16.2 ± 3.7
Home SBP average, mm Hg	130.2 ± 17.3	126.1 ± 15.5*	128.1 ± 16.5
Home DBP average, mm Hg	78.1 ± 11.4	78.2 ± 12.0	78.1 ± 11.7
Home HR average, mm Hg	71.7 ± 13.3	70.8 ± 25.0	71.2 ± 20.1
Clinic SBP, mm Hg	133.9 ± 16.0	131.6 ± 12.9	132.7 ± 14.3
Clinic DBP, mm Hg	86.6 ± 12.0	88.9 ± 10.0	87.8 ± 11.0
Clinic HR, bpm	68.2 ± 10.6	68.0 ± 9.1	68.1 ± 9.7
Insulin, mU/L	14.5 ± 7.5	11.6 ± 6.4	13.1 ± 7.0
Glucose, mmol/L	5.9 ± 0.6	5.4 ± 0.5*	5.7 ± 0.6
Total triglycerides, mmol/L	1.7 ± 1.2	1.4 ± 0.5	1.5 ± 0.9
Total cholesterol, mmol/L	5.9 ± 1.1	5.6 ± 1.1	5.7 ± 1.1
HDL cholesterol, mmol/L	1.5 ± 0.4	1.5 ± 0.4	1.5 ± 0.4
LDL cholesterol, mmol/L	3.7 ± 1.0	3.5 ± 0.9	3.6 ± 0.9
Cholesterol:HDL cholesterol	4.4 ± 1.6	4.0 ± 1.0	4.1 ± 1.3
Weight, kg	87.7 ± 16.8	86.2 ± 12.1	86.9 ± 14.4
Height, m	1.7 ± 0.1	1.7 ± 0.1	1.7 ± 0.1
BMI, kg/m^2	30.7 ± 4.0	30.9 ± 3.7	30.8 ± 3.8

[1]Values are means ± SDs. Group 1 received the MedDairy intervention first; group 2 received the LF intervention first. *Different between groups, $P < 0.05$. bpm, beats per minute; CRP, C-reactive protein; DBP, diastolic blood pressure; HR, heart rate; LF, low-fat; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods; SBP, systolic blood pressure.

lower afternoon home HR. No significant differences were observed for afternoon or evening home SBP or DBP.

Clinic measures

Results for clinic measures are presented in **Table 3**. Compared with the LF intervention, the MedDairy intervention resulted in significantly lower clinic SBP, significantly higher HDL cholesterol, and significantly lower total triglycerides and ratio of total cholesterol to HDL cholesterol. No significant differences were observed for clinic DBP or HR, total cholesterol, LDL cholesterol, insulin, glucose, HOMA scores, CRP, or FRS.

Compared with the MedDairy intervention, the LF intervention resulted in significantly lower fat mass (kilograms) and significantly higher lean mass (%). No significant differences were observed for BMI, waist and hip circumferences, abdominal fat, or bone mineral density.

Dietary adherence

According to the modified PREDIMED diet adherence tools, the MDS and S-MDS participants were generally adherent to both dietary interventions. The mean PREDIMED MedDiet score at screening was 5.4 out of 14 and increased to a mean ± SD of 12.9 ± 0.4 during the MedDairy intervention, indicating 92% adherence and an increase of 7.5 points, from moderate to high MedDiet adherence. The mean ± SD PREDIMED LF score across the LF intervention was 7.8 ± 0.2, out of a maximum of 9 points, indicating 87% adherence.

The mean ± SD MDS increased from 4.3 ± 1.9 at week 0 to 6.9 ± 1.4 at week 8 of the MedDairy intervention. In comparison, the MDS did not increase from week 0 to week 8 of the LF intervention (**Figure 3**). Similarly, the mean ± SD S-MDS increased from 6.7 ± 3.1 to 10.5 ± 3.2 by the end of the MedDairy intervention. During the LF intervention, the mean ± SD S-MDS increased from 6.9 ± 2.7 to 7.0 ± 2.4 (**Figure 4**).

Dairy consumption

Frequency values of dairy servings per day are presented in **Table 4**. During the MedDairy intervention, the minimum recommendation for dairy foods was 3 servings/d, equating to 42 servings/fortnight. The maximum based on 4 servings/d was 56 servings/fortnight.

Values for nutrient consumption across intervention periods are shown in **Table 5**. At baseline, mean ± SEM dairy food consumption was 2.2 ± 0.2 servings/d. At the end of the MedDairy intervention, mean ± SEM dairy consumption was 3.0 ± 0.2 servings/d. A significant effect of the MedDairy intervention led to a mean ± SEM increase of 1.0 ± 0.2 dairy servings/d. There was no change in milk intake during either intervention phase. However, there was a significant effect of the MedDairy intervention on both yogurt and cheese intake.

The Australian calcium RDI for men aged >70 y and women aged >50 y is 1300 mg/d. Mean ± SEM calcium intake at baseline was 1011.7 ± 54.3 mg/d before the MedDairy intervention and 1040.4 ± 50.8 mg/d before the LF intervention. A significant effect of diet was observed for calcium intake (milligrams per day), where intake increased significantly after the MedDairy intervention. Before the MedDairy intervention, 85% of men and 19% of women met their calcium RDI (40% of the total cohort). Before the LF intervention, 85% of men and 15% of women met their calcium RDI (40% of the total cohort). At week 8 of the MedDairy intervention, 82% of men and 58%

TABLE 2
Home blood pressure at weeks 0, 8, 16, and 24, including differences between interventions[1]

Variable	Week 0	Week 8	Week 16	Week 24	Diet × Visit interaction	Estimated mean difference between interventions (MedDairy compared with LF)[2] (95% CI)
n						
MedDairy	20	19	19	18	—	—
LF	21	19	19	19	—	—
SBP morning, mm Hg						
MedDairy	128.97 ± 1.08	127.51 ± 1.11	122.88 ± 1.00	122.00 ± 0.92	0.01*	− 1.59 (−2.81, −0.37)
LF	124.25 ± 0.95	125.04 ± 1.07	129.99 ± 1.23	127.12 ± 1.18		
SBP afternoon, mm Hg						
MedDairy	132.83 ± 1.19	128.75 ± 1.11	124.70 ± 1.08	126.01 ± 1.03	0.21	0.82 (−0.46, 2.11)
LF	128.06 ± 1.07	125.04 ± 1.16	130.31 ± 1.23	126.08 ± 1.22		
SBP evening, mm Hg						
MedDairy	128.67 ± 1.15	128.62 ± 1.18	126.05 ± 1.03	124.77 ± 0.99	0.92	0.07 (−1.19, 1.33)
LF	125.89 ± 0.97	125.63 ± 1.12	130.08 ± 1.22	127.26 ± 1.07		
SBP average, mm Hg						
MedDairy	130.15 ± 0.66	128.28 ± 0.65	124.51 ± 0.60	124.26 ± 0.57	0.64	− 0.20 (−1.01, 0.62)
LF	126.05 ± 0.58	125.24 ± 0.64	130.12 ± 0.71	126.85 ± 0.67		
DBP morning, mm Hg						
MedDairy	78.79 ± 0.76	78.42 ± 0.78	77.95 ± 0.66	77.73 ± 0.66	0.01*	− 0.95 (−1.70, −0.21)
LF	78.25 ± 0.73	79.58 ± 0.76	78.52 ± 0.77	78.74 ± 0.77		
DBP afternoon, mm Hg						
MedDairy	78.68 ± 0.73	78.18 ± 0.80	76.97 ± 0.74	77.88 ± 0.79	0.38	− 0.40 (−1.29, 0.49)
LF	79.20 ± 0.78	78.59 ± 0.80	77.43 ± 0.81	76.67 ± 0.80		
DBP evening, mm Hg						
MedDairy	76.66 ± 0.76	76.88 ± 0.82	76.14 ± 0.71	76.43 ± 0.74	0.92	0.05 (−0.98, 0.88)
LF	76.75 ± 0.77	77.58 ± 0.85	77.26 ± 0.81	75.76 ± 0.67		
DBP average, mm Hg						
MedDairy	78.05 ± 0.42	77.83 ± 0.45	77.04 ± 0.41	77.36 ± 0.42	0.10	− 0.44 (−0.96, 0.09)
LF	78.07 ± 0.44	78.60 ± 0.46	76.85 ± 0.46	77.09 ± 0.43		
HR morning, bpm						
MedDairy	68.36 ± 0.75	69.12 ± 0.86	67.60 ± 0.69	66.83 ± 0.74	0.02	0.87 (0.12, 1.62)
LF	67.05 ± 0.65	66.16 ± 0.62	69.79 ± 0.75	68.00 ± 0.77		
HR afternoon, bpm						
MedDairy	74.48 ± 0.92	71.48 ± 0.80	72.24 ± 0.78	71.20 ± 0.74	<0.01*	− 1.29 (−2.27, −0.32)
LF	73.10 ± 0.74	71.53 ± 0.66	71.50 ± 0.78	73.00 ± 0.97		
HR evening, bpm						
MedDairy	72.27 ± 0.92	69.22 ± 0.88	70.28 ± 0.75	69.43 ± 0.70	0.52	− 0.30 (−1.19, 0.60)
LF	69.54 ± 0.66	69.11 ± 0.69	73.50 ± 0.82	70.38 ± 0.93		
HR average, bpm						
MedDairy	71.66 ± 0.51	69.92 ± 0.49	70.03 ± 0.44	69.15 ± 0.43	0.58	− 0.16 (−0.71, 0.40)
LF	69.87 ± 0.41	68.88 ± 0.39	71.58 ± 0.46	70.35 ± 0.52		

[1]Values are observed means ± SEMs. Differences between interventions were analyzed by linear mixed-effects models, including fixed-effect terms for Group, Visit, Group × Visit, Period, and Order. *Different between interventions, $P < 0.02$ (adjusted α). bpm, beats per minute; DBP, diastolic blood pressure; HR, heart rate; LF, low-fat; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods; SBP, systolic blood pressure.

[2]Estimated marginal mean difference in change between interventions.

of women met their calcium RDI (66% of the total cohort). At week 8 of the LF intervention, 46% of men and 15% of women met their calcium RDI (24% of the total cohort) (**Figure 5**).

Other nutrients

The remaining nutrients are presented in Table 5. The LF diet led to significantly lower energy intake. Compared with the LF intervention, energy from fat, saturated fat, monounsaturated fat, and polyunsaturated fat was significantly higher during the MedDairy diet, whereas energy from carbohydrate was significantly lower. There was no difference between diets for percentage energy from protein or alcohol.

Compared with the LF diet, the MedDairy intervention led to significantly higher intakes of vitamin E, linoleic acid, and α-linolenic acid and a significantly lower intake of folate. No significant differences were observed for cholesterol, dietary fiber, vitamin C, vitamin A, β-carotene, sodium, potassium, iron, or zinc.

The MedDairy intervention led to a significantly higher consumption of nuts and seeds, EVOO, and legumes and a lower consumption of red meat and refined grains. No interactions were observed for fruit, vegetables, or whole grains.

TABLE 3
Clinic measures at weeks 0, 8, 16, and 24, including differences between interventions[1]

Variable	Week 0	Week 8	Week 16	Week 24	Diet × Visit interaction	Estimated mean difference between interventions (MedDairy compared with LF)[2] (95% CI)
n						
MedDairy	20	19	19	18	—	—
LF	21	19	19	19		
SBP clinic, mm Hg						
MedDairy	133.88 ± 3.57	126.70 ± 2.69	131.96 ± 2.45	124.64 ± 3.33	0.02*	− 3.51 (−6.35, −0.68)
LF	131.56 ± 2.80	127.47 ± 3.32	130.87 ± 3.21	130.28 ± 3.35		
DBP clinic, mm Hg						
MedDairy	86.57 ± 2.69	83.21 ± 2.31	86.85 ± 1.95	84.03 ± 1.98	0.25	− 1.30 (−3.54, 0.94)
LF	88.91 ± 2.18	84.77 ± 2.29	84.79 ± 2.61	84.47 ± 2.51		
HR clinic, bpm						
MedDairy	68.20 ± 2.36	66.58 ± 2.12	64.56 ± 1.75	63.32 ± 1.86	0.86	− 0.17 (−2.16, 1.83)
LF	68.01 ± 1.98	63.62 ± 1.42	67.40 ± 2.52	66.42 ± 2.89		
Insulin (log),2 mU/L						
MedDairy	1.11 ± 0.05	1.02 ± 0.05	1.02 ± 0.05	1.01 ± 0.05	0.66	0.01 (−0.04, 0.06)
LF	1.01 ± 0.05	0.98 ± 0.05	1.09 ± 0.05	1.03 ± 0.05		
Glucose, mmol/L						
MedDairy	5.90 ± 0.13	5.83 ± 0.12	5.40 ± 0.12	5.43 ± 0.15	0.38	0.06 (−0.07, 0.18)
LF	5.45 ± 0.10	5.35 ± 0.11	5.64 ± 0.14	5.76 ± 0.11		
HOMA-S, %						
MedDairy	103.71 ± 7.82	91.48 ± 5.78	106.34 ± 7.71	102.52 ± 5.15	0.92	− 0.40 (−7.80, 7.00)
LF	102.42 ± 7.33	99.41 ± 5.51	108.82 ± 7.18	95.07 ± 6.44		
HOMA-B (log),2 %						
MedDairy	1.77 ± 0.05	1.85 ± 0.05	1.86 ± 0.05	1.87 ± 0.05	0.63	− 0.01 (−0.06, 0.04)
LF	1.87 ± 0.05	1.90 ± 0.05	1.79 ± 0.05	1.85 ± 0.06		
HOMA-IR (log)[2]						
MedDairy	0.23 ± 0.05	0.15 ± 0.05	0.14 ± 0.05	0.13 ± 0.05	0.73	0.01 (−0.04, 0.06)
LF	0.13 ± 0.05	0.10 ± 0.05	0.21 ± 0.05	0.15 ± 0.06		
CRP (log),2 mg/L						
MedDairy	0.17 ± 0.09	0.14 ± 0.10	0.30 ± 0.08	0.25 ± 0.10	0.98	− 0.001 (−0.07, 0.07)
LF	0.31 ± 0.06	0.26 ± 0.08	0.23 ± 0.09	0.13 ± 0.09		
Total TGs (log),2 mmol/L						
MedDairy	0.13 ± 0.04	0.07 ± 0.04	0.12 ± 0.04	0.08 ± 0.04	<0.01**	− 0.05 (−0.08, −0.01)
LF	0.12 ± 0.03	0.11 ± 0.03	0.13 ± 0.05	0.13 ± 0.04		
Total cholesterol, mmol/L						
MedDairy	5.86 ± 0.26	5.31 ± 0.21	5.60 ± 0.26	5.46 ± 0.25	0.35	− 0.09 (−0.27, 0.10)
LF	5.55 ± 0.23	5.38 ± 0.26	5.95 ± 0.23	5.56 ± 0.20		
HDL cholesterol (log),2 mmol/L						
MedDairy	0.14 ± 0.03	0.14 ± 0.02	0.15 ± 0.03	0.16 ± 0.03	<0.01**	0.04 (0.01, 0.06)
LF	0.15 ± 0.03	0.12 ± 0.03	0.13 ± 0.03	0.11 ± 0.02		
LDL cholesterol, mmol/L						
MedDairy	3.66 ± 0.19	3.32 ± 0.19	3.46 ± 0.24	3.38 ± 0.20	0.12	− 0.13 (−0.30, 0.03)
LF	3.45 ± 0.19	3.37 ± 0.21	3.86 ± 0.22	3.57 ± 0.18		
Cholesterol:HDL cholesterol						
MedDairy	4.06 ± 0.21	3.86 ± 0.20	4.04 ± 0.30	3.87 ± 0.25	<0.001**	− 0.38 (−0.58, −0.18)
LF	3.95 ± 0.22	4.06 ± 0.22	4.51 ± 0.31	4.38 ± 0.27		
Weight (log),2 kg						
MedDairy	1.94 ± 0.02	1.93 ± 0.02	1.92 ± 0.01	1.92 ± 0.02	0.04	0.004 (0.001, 0.008)
LF	1.93 ± 0.01	1.91 ± 0.01	1.93 ± 0.02	1.93 ± 0.02		
BMI (sqrt),2 kg/m^2						
MedDairy	5.53 ± 0.08	5.48 ± 0.08	5.48 ± 0.07	5.45 ± 0.06	0.14	0.03 (−0.01, 0.06)
LF	5.55 ± 0.07	5.42 ± 0.06	5.51 ± 0.08	5.46 ± 0.08		
Waist circumference (sqrt),2 cm						
MedDairy	10.00 ± 0.14	9.91 ± 0.15	9.74 ± 0.12	9.72 ± 0.13	0.70	0.01 (−0.03, 0.05)
LF	9.90 ± 0.11	9.72 ± 0.12	9.95 ± 0.16	9.88 ± 0.15		

(*Continued*)

TABLE 3
(*Continued*)

Variable	Week 0	Week 8	Week 16	Week 24	Diet × Visit interaction	Estimated mean difference between interventions (MedDairy compared with LF)[2] (95% CI)
Hip circumference (sqrt),2 cm						
MedDairy	10.52 ± 0.11	10.49 ± 0.10	10.31 ± 0.08	10.33 ± 0.09	0.21	0.02 (−0.01, 0.05)
LF	10.48 ± 0.08	10.33 ± 0.07	10.48 ± 0.10	10.46 ± 0.10		
Fat mass, %						
MedDairy	39.87 ± 1.69	40.18 ± 1.66	38.96 ± 1.78	39.38 ± 1.92	0.01	0.51 (0.12, 0.91)
LF	41.57 ± 1.67	39.57 ± 1.79	39.95 ± 1.65	39.12 ± 1.63		
Lean mass, %						
MedDairy	60.12 ± 1.69	59.82 ± 1.66	61.03 ± 1.78	60.40 ± 1.91	<0.01***	− 0.62 (−1.03, −0.21)
LF	58.43 ± 1.67	60.43 ± 1.79	60.05 ± 1.65	60.88 ± 1.63		
Fat mass, kg						
MedDairy	34.64 ± 2.22	34.36 ± 2.26	32.59 ± 1.83	32.83 ± 1.97	<0.01***	0.69 (0.20, 1.17)
LF	35.82 ± 1.83	32.70 ± 1.78	34.44 ± 2.24	33.27 ± 2.23		
Lean mass (log),2 kg						
MedDairy	1.71 ± 0.02	1.70 ± 0.02	1.70 ± 0.02	1.70 ± 0.02	0.77	− 0.001 (−0.004, 0.003)
LF	1.70 ± 0.02	1.69 ± 0.02	1.70 ± 0.02	1.70 ± 0.02		
Abdominal fat (log),2 kg						
MedDairy	3.52 ± 0.03	3.50 ± 0.03	3.48 ± 0.03	3.48 ± 0.02	0.01	0.02 (0.004, 0.03)
LF	3.54 ± 0.02	3.48 ± 0.02	3.52 ± 0.04	3.48 ± 0.04		
BMD, g/cm^3						
MedDairy	1.22 ± 0.03	1.22 ± 0.03	1.23 ± 0.02	1.22 ± 0.02	0.12	− 0.009 (−0.019, 0.002)
LF	1.23 ± 0.02	1.22 ± 0.02	1.22 ± 0.03	1.23 ± 0.03		
BMD, *z* score						
MedDairy	1.03 ± 0.24	1.09 ± 0.22	0.87 ± 0.32	0.83 ± 0.32	0.89	0.001 (−0.13, 0.13)
LF	0.69 ± 0.31	0.82 ± 0.32	0.99 ± 0.29	1.10 ± 0.23		
FRS						
MedDairy	11.30 ± 0.55	11.11 ± 0.60	10.63 ± 0.54	10.44 ± 0.58	0.73	0.07 (−0.33, 0.47)
LF	10.44 ± 0.49	10.47 ± 0.54	11.32 ± 0.58	10.84 ± 0.50		
FRS risk, %						
MedDairy	0.94 ± 0.05	0.92 ± 0.05	0.91 ± 0.05	0.90 ± 0.06	0.72	0.01 (−0.02, 0.03)
LF	0.88 ± 0.05	0.89 ± 0.05	0.93 ± 0.05	0.90 ± 0.05		

[1]Values are observed means ± SEMs. Differences between interventions were analyzed by linear mixed-effects models, including fixed-effect terms for Group, Visit, Group × Visit, Period, and Order. *,**,***Different between interventions: $^{*}P < 0.05$, $^{**}P < 0.01$ (adjusted α), $^{***}P < 0.006$ (adjusted α). BMD, bone mineral density; CRP, C-reactive protein; DBP, diastolic blood pressure; FRS, Framingham Risk Score; HOMA-B, homeostasis model assessment—β cell function; HOMA-S, homeostasis model assessment–insulin sensitivity; HR, heart rate; LF, low-fat; log, log10-transformed values presented; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods; SBP, systolic blood pressure; sqrt, square root–transformed values presented; TG, triglyceride.

[2]Estimated marginal mean difference in change between interventions.

DISCUSSION

Before the MedDiet can be recommended at a population level, it is necessary to ensure that it meets Western dietary guidelines for essential nutrients. Current Australian Nutrient Reference Values for calcium suggest an RDI of 1300 mg/d for women aged ≥50 y and men aged ≥70 y (37). However, previous studies indicate that a traditional MedDiet may not meet these recommendations (1, 3).We have therefore conducted a randomized controlled trial to examine the effects of modifying a traditional MedDiet to meet the calcium needs of an Australian population. Our findings suggest that the MedDairy intervention is capable of improving cardiovascular health in a population at risk of CVD.

During the MedDairy intervention, participants consumed a mean of 1284 mg Ca/d, with two-thirds of participants meeting their RDI specific to age and gender. In comparison, dairy food and calcium intake decreased during the LF control intervention, and only 24% of participants met their calcium RDI. This was likely the result of efforts to reduce total fat intake. The Australian Guide to Healthy Eating informed recommendations for daily dairy servings during the MedDairy intervention. The guide suggests that men consume 2.5 servings of dairy foods/d until the age of 70 y and 3.5 servings/d thereafter. Women are recommended to consume 2.5 servings/d until the age of 50 y and 4 servings/d thereafter. While adhering to the MedDairy diet, participants consumed a mean of 3 servings of dairy products/d. Approximately 1 serving of dairy provides 300 mg Ca. Therefore ∼900 mg Ca was provided by dairy foods and the remaining 384 mg was provided by other sources (such as nuts, leafy green vegetables, and fish). These data suggest that 3 servings of dairy

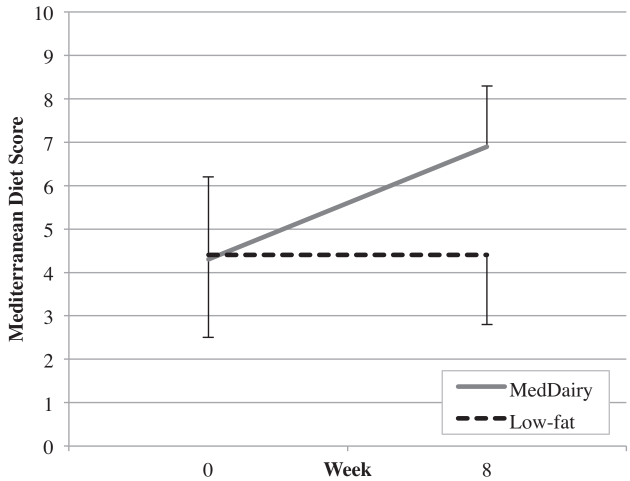

FIGURE 3 Adherence to Mediterranean diet before and during the MedDairy and LF interventions according to the MDS of Trichopoulou et al. (7). Values are means ± SDs out of a possible total of 9. LF, low-fat; MDS, Mediterranean Diet Score; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods.

consumed within a MedDiet bring calcium intake closer to the RDI for older Australians.

According to the 14-item questionnaire, adherence to the MedDiet increased during the MedDairy phase, from 5.4 points to 12.9 points. To account for cultural differences in dietary habits, the scoring scheme of the current study was adjusted for an Australian population. For example, consumption of 3–4 tablespoons of EVOO/d was necessary to score 1 point on the original questionnaire but was deemed unrealistic for an Australian sample (34). This criterion was therefore reduced to 1 tablespoon/d. It is possible that such modifications influenced the results of the current study. For example, EVOO is considered to be a beneficial bioactive ingredient of the MedDiet. By reducing

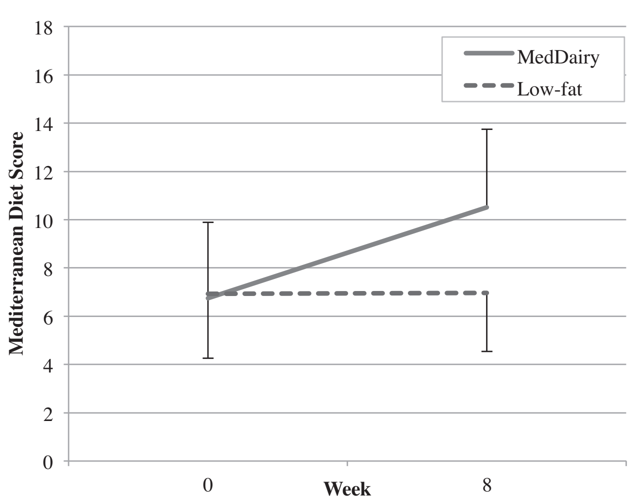

FIGURE 4 Adherence to Mediterranean diet before and during MedDairy and LF interventions, according to the S-MDS of Sofi et al. (35). Values are means ± SDs out of a possible total of 18. LF, low-fat; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods; S-MDS, Sofi MedDiet Score.

TABLE 4
Frequency of dairy servings per day at week 8 of the MedDairy ($n = 35$) and LF ($n = 37$) interventions, according to weighed food records[1]

Servings of dairy per day	MedDairy week 8, n (%)	LF week 8, n (%)
<1	1 (2.9)	6 (16.2)
≥1 to <2	3 (8.6)	14 (37.8)
≥2 to <3	13 (37.1)	10 (27.0)
≥3 to <4	13 (37.1)	6 (16.2)
≥4	5 (14.3)	1 (2.7)

[1]LF, low-fat; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods.

the required daily intake, potential benefits of EVOO may have been mitigated.

A significant effect was observed for morning readings of our primary outcome, home SBP. This finding is consistent with recent MedDiet and dairy literature (3, 5, 6, 38, 39). The effect of diet did not reach statistical significance for afternoon and evening readings. In comparison to the current study, the MedLey study found a significant effect of the MedDiet on total BP (3), driven by an effect on morning and afternoon home BP. Although the addition of dairy may have reduced effects on BP, it is possible that our failure to capture a significant change in afternoon and evening SBP was due to our comparatively short intervention duration and limited sample size.

Our analyses also indicate a significant effect of the MedDairy intervention on clinic SBP. Clinic SBP was taken between 0800 and 0930, supporting the effect of the diet on morning home SBP. Due to the characteristics of a clinical environment, clinic BP measurement can induce a reactionary stress response. As a result, clinic BP is often overestimated and may be less reliable than home BP (40, 41). In the current study, clinic SBP readings were markedly higher than home SBP readings at the baseline of each dietary intervention and at week 8 of the LF intervention (mean difference: 5 mm Hg). However, at week 8 of the MedDairy intervention, clinic and home SBP were within 1.3 mm Hg. This may indicate a true reduction in BP or BP reactivity.

A significant effect of diet was observed for afternoon HR, which decreased by 1.9 beats/min after the MedDairy intervention and increased by 1.4 beats/min after the LF intervention. The decrease in afternoon readings after the MedDairy intervention is consistent with previous cross-sectional and longitudinal studies associating the MedDiet with lower HR (42). Because elevated HR is an established predictor of cardiovascular mortality (43), the effect of the MedDairy intervention on afternoon HR is clinically relevant.

Significant effects of the MedDairy intervention were also observed for variables of blood lipids, including total triglycerides, HDL cholesterol, and the ratio of total cholesterol to HDL cholesterol. Previous investigations of the MedDiet have reported similar improvements in lipid profiles (4, 5). Furthermore, a recent review of the effects of dairy foods on LDL-cholesterol concentrations indicates a positive benefit of milk and cheese. Our results support these findings and indicate that dairy consumed within a MedDiet pattern can lead to positive effects on lipid profiles, even over a short intervention period.

The current study did not observe significant effects of diet for glucose, insulin, or indicators of insulin resistance (HOMA-IR),

TABLE 5
Nutrient intakes at weeks 0, 8, 16, and 24, including differences between interventions[1]

Variable	Week 0	Week 8	Week 16	Week 24	Diet × Visit Interaction	Estimated mean difference between interventions (MedDairy compared with LF)[2] (95% CI)
n						
MedDairy	20	19	19	18	—	—
LF	21	19	19	19	—	—
Intake per day						
Energy, MJ						
MedDairy	10.16 ± 0.51	8.95 ± 0.35	8.98 ± 0.41	8.90 ± 0.57	0.01*	0.77 (0.16, 1.38)
LF	9.03 ± 0.26	8.03 ± 0.47	9.63 ± 0.57	8.26 ± 0.46		
% en from protein						
MedDairy	17.87 ± 0.69	19.26 ± 0.71	18.20 ± 0.92	20.43 ± 1.29	0.30	− 0.81 (−2.35, 0.73)
LF	18.61 ± 0.87	20.32 ± 1.11	18.36 ± 0.96	21.02 ± 0.92		
% en from total fat						
MedDairy	37.49 ± 1.79	39.55 ± 1.37	32.47 ± 1.58	34.05 ± 1.86	<0.001***	9.60 (6.58, 12.62)
LF	34.49 ± 1.05	27.06 ± 1.75	35.27 ± 1.82	27.43 ± 1.85		
% en from SFAs						
MedDairy	12.86 ± 0.70	11.06 ± 0.48	11.18 ± 0.90	11.15 ± 0.37	0.01	1.62 (0.35, 2.88)
LF	12.03 ± 0.59	9.50 ± 0.84	13.20 ± 0.96	9.49 ± 0.77		
% en from MUFAs						
MedDairy	15.01 ± 1.04	18.71 ± 1.07	13.29 ± 0.93	15.00 ± 1.38	<0.001**	6.66 (4.91, 8.41)
LF	13.82 ± 0.54	10.38 ± 0.82	13.81 ± 0.81	10.04 ± 0.67		
% en from PUFAs						
MedDairy	5.86 ± 0.47	6.66 ± 0.52	5.22 ± 0.37	5.20 ± 0.36	<0.001**	1.45 (0.72, 2.18)
LF	5.61 ± 0.30	4.50 ± 0.32	5.19 ± 0.39	4.46 ± 0.29		
MUFAs:SFAs (log)						
MedDairy	0.06 ± 0.04	0.22 ± 0.03	0.06 ± 0.04	0.14 ± 0.03	<0.001**	0.14 (0.09, 0.20)
LF	0.06 ± 0.02	0.04 ± 0.03	0.03 ± 0.03	0.03 ± 0.03		
% en from CHO						
MedDairy	36.45 ± 2.33	32.48 ± 1.17	39.17 ± 2.12	35.35 ± 2.13	<0.001***	− 8.46 (−11.60, −5.32)
LF	37.57 ± 1.63	42.44 ± 1.65	38.91 ± 2.34	41.94 ± 1.89		
% en from alcohol (sqrt)						
MedDairy	4.58 ± 1.14	4.28 ± 0.89	5.31 ± 1.40	5.25 ± 1.33	0.66	− 0.60 (−2.16, 0.96)
LF	5.65 ± 1.45	6.16 ± 1.43	3.64 ± 1.06	4.81 ± 1.35		
Cholesterol, mg/MJ						
MedDairy	39.41 ± 3.00	30.87 ± 3.80	32.97 ± 3.26	33.90 ± 3.28	0.20	− 3.98 (−10.12, 2.15)
LF	38.45 ± 3.63	35.12 ± 3.14	37.29 ± 3.94	37.51 ± 4.69		
Fiber, g/MJ						
MedDairy	2.76 ± 0.16	3.45 ± 0.19	2.86 ± 0.24	3.21 ± 0.19	0.33	− 0.15 (−0.45, 0.15)
LF	2.95 ± 0.23	3.22 ± 0.18	2.80 ± 0.20	3.72 ± 0.30		
Vitamin C (log), mg/MJ						
MedDairy	1.01 ± 0.06	1.19 ± 0.05	1.02 ± 0.07	1.14 ± 0.06	0.88	0.01 (-0.02, 0.11)
LF	1.02 ± 0.06	1.15 ± 0.06	0.99 ± 0.08	1.17 ± 0.06		
Vitamin E (log), mg/MJ						
MedDairy	0.19 ± 0.04	0.30 ± 0.04	0.17 ± 0.04	0.23 ± 0.03	<0.001****	0.15 (0.09, 0.22)
LF	0.17 ± 0.03	0.11 ± 0.04	0.13 ± 0.04	0.11 ± 0.03		
Total vitamin A equiv. (log), µg/MJ						
MedDairy	1.91 ± 0.05	2.01 ± 0.07	1.92 ± 0.06	2.06 ± 0.04	0.77	− 0.02 (−0.11, 0.07)
LF	2.02 ± 0.05	2.06 ± 0.05	1.97 ± 0.04	2.05 ± 0.06		
Total folate (log), µg/MJ						
MedDairy	1.74 ± 0.04	1.75 ± 0.03	1.77 ± 0.03	1.78 ± 0.03	<0.01***	− 0.07 (−0.11, −0.02)
LF	1.74 ± 0.02	1.85 ± 0.03	1.73 ± 0.03	1.81 ± 0.02		
β-Carotene equiv. (log), µg/MJ						
MedDairy	2.47 ± 0.07	2.64 ± 0.09	2.44 ± 0.10	2.68 ± 0.05	0.60	− 0.04 (−0.16, 0.09)
LF	2.64 ± 0.06	2.71 ± 0.06	2.53 ± 0.06	2.69 ± 0.07		
Sodium, mg/MJ						
MedDairy	280.85 ± 17.52	228.53 ± 16.61	286.58 ± 11.77	285.49 ± 15.27	0.09	− 25.00 (−54.09, 4.11)
LF	305.37 ± 21.10	310.96 ± 16.72	265.90 ± 16.22	252.63 ± 14.44		

(*Continued*)

TABLE 5
(*Continued*)

Variable	Week 0	Week 8	Week 16	Week 24	Diet × Visit Interaction	Estimated mean difference between interventions (MedDairy compared with LF)[2] (95% CI)
Potassium, mg/MJ						
MedDairy	373.22 ± 16.48	442.31 ± 11.71	384.66 ± 19.42	444.28 ± 26.18	0.32	11.90 (−13.72, 37.52)
LF	393.45 ± 16.12	426.93 ± 20.54	375.20 ± 19.36	434.63 ± 15.43		
Calcium, mg/MJ						
MedDairy	111.99 ± 7.96	142.97 ± 7.21	101.09 ± 7.19	150.09 ± 11.07	<0.001****	25.85 (12.52, 39.18)
LF	108.51 ± 6.71	111.11 ± 7.04	116.59 ± 7.53	130.55 ± 6.73		
Iron (log), mg/MJ						
MedDairy	0.07 ± 0.02	0.12 ± 0.02	0.10 ± 0.03	0.12 ± 0.03	0.51	− 0.01 (−0.05, 0.03)
LF	0.12 ± 0.02	0.11 ± 0.02	0.07 ± 0.02	0.15 ± 0.03		
Zinc, mg/MJ						
MedDairy	1.22 ± 0.08	1.25 ± 0.04	1.18 ± 0.08	1.34 ± 0.06	0.36	− 0.07 (−0.23, 0.08)
LF	1.30 ± 0.09	1.31 ± 0.09	1.26 ± 0.08	1.41 ± 0.10		
Linoleic acid (log), g/MJ						
MedDairy	0.09 ± 0.04	0.15 ± 0.03	0.04 ± 0.03	0.08 ± 0.03	<0.001****	0.14 (0.08, 0.20)
LF	0.08 ± 0.03	− 0.03 ± 0.03	0.04 ± 0.04	− 0.03 ± 0.03		
α-Linolenic acid (log), g/MJ						
MedDairy	− 0.77 ± 0.04	− 0.81 ± 0.04	− 0.83 ± 0.04	− 0.83 ± 0.04	0.02*	0.09 (0.02, 0.16)
LF	− 0.80 ± 0.04	− 0.92 ± 0.03	− 0.83 ± 0.04	− 0.90 ± 0.04		
Servings per day						
Whole grains (log + 1)						
MedDairy	0.43 ± 0.05	0.55 ± 0.04	0.45 ± 0.06	0.48 ± 0.04	0.87	0.01 (−0.07, 0.08)
LF	0.41 ± 0.05	0.45 ± 0.03	0.45 ± 0.04	0.57 ± 0.04		
Refined grains (log + 1)						
MedDairy	0.61 ± 0.06	0.36 ± 0.04	0.63 ± 0.04	0.44 ± 0.06	<0.001****	− 0.20 (−0.28, −0.13)
LF	0.65 ± 0.03	0.66 ± 0.03	0.63 ± 0.05	0.54 ± 0.05		
Fruits (log + 1)						
MedDairy	0.43 ± 0.03	0.44 ± 0.03	0.31 ± 0.05	0.42 ± 0.06	0.94	0.003 (−0.06, 0.07)
LF	0.38 ± 0.05	0.38 ± 0.05	0.40 ± 0.05	0.46 ± 0.04		
Vegetables (log)						
MedDairy	0.51 ± 0.04	0.66 ± 0.03	0.51 ± 0.06	0.59 ± 0.06	0.01	0.11 (0.02, 0.20)
LF	0.60 ± 0.05	0.51 ± 0.06	0.53 ± 0.05	0.52 ± 0.04		
Legumes (sqrt)						
MedDairy	0.09 ± 0.04	0.64 ± 0.10	0.12 ± 0.06	0.65 ± 0.10	<0.001****	0.40 (0.29, 0.56)
LF	0.09 ± 0.04	0.21 ± 0.08	0.20 ± 0.08	0.24 ± 0.09		
Meat/meat alternatives (log + 1)						
MedDairy	0.59 ± 0.05	0.62 ± 0.03	0.52 ± 0.03	0.60 ± 0.03	<0.01	0.09 (0.03, 0.15)
LF	0.54 ± 0.03	0.50 ± 0.03	0.56 ± 0.05	0.54 ± 0.03		
Red meat (sqrt)						
MedDairy	0.55 ± 0.11	0.23 ± 0.10	0.54 ± 0.11	0.39 ± 0.11	<0.01	− 0.32 (−0.52, −0.13)
LF	0.59 ± 0.12	0.69 ± 0.11	0.70 ± 0.12	0.59 ± 0.12		
Nuts and seeds (sqrt)						
MedDairy	0.62 ± 0.09	1.05 ± 0.07	0.55 ± 0.10	0.77 ± 0.10	<0.001****	0.53 (0.38, 0.69)
LF	0.54 ± 0.07	0.30 ± 0.08	0.61 ± 0.11	0.46 ± 0.11		
Total dairy						
MedDairy	2.39 ± 0.23	3.03 ± 0.21	1.95 ± 0.25	3.05 ± 0.24	<0.001****	0.97 (0.58, 1.37)
LF	2.02 ± 0.23	1.77 ± 0.24	2.42 ± 0.24	2.38 ± 0.23		
Milk (log + 1)						
MedDairy	0.34 ± 0.03	0.31 ± 0.03	0.33 ± 0.03	0.34 ± 0.04	0.76	0.01 (−0.04, 0.05)
LF	0.35 ± 0.3	0.31 ± 0.04	0.32 ± 0.03	0.33 ± 0.03		
Cheese (sqrt)						
MedDairy	0.76 ± 0.09	0.85 ± 0.08	0.51 ± 0.08	0.82 ± 0.10	<0.01**	0.27 (0.11, 0.44)
LF	0.53 ± 0.08	0.44 ± 0.08	0.72 ± 0.10	0.69 ± 0.09		
Yogurt (sqrt)						
MedDairy	0.42 ± 0.08	1.00 ± 0.07	0.37 ± 0.10	0.85 ± 0.09	<0.001**	0.45 (0.32, 0.58)
LF	0.36 ± 0.09	0.33 ± 0.09	0.58 ± 0.09	0.60 ± 0.07		

(*Continued*)

TABLE 5
(*Continued*)

Variable	Week 0	Week 8	Week 16	Week 24	Diet × Visit Interaction	Estimated mean difference between interventions (MedDairy compared with LF)[2] (95% CI)
EVOO (sqrt), tsp/d						
MedDairy	0.34 ± 0.13	1.52 ± 0.21	0.42 ± 0.13	1.27 ± 0.19	<0.001****	1.27 (1.01, 1.54)
LF	0.25 ± 0.09	0.14 ± 0.07	1.56 ± 0.20	0.10 ± 0.06		
Servings per day per megaJoule						
Whole grains (sqrt)						
MedDairy	0.43 ± 0.04	0.54 ± 0.04	0.47 ± 0.05	0.52 ± 0.04	0.41	– 0.02 (–0.08, 0.04)
LF	0.42 ± 0.04	0.48 ± 0.03	0.45 ± 0.04	0.63 ± 0.05		
Refined grains (sqrt)						
MedDairy	0.60 ± 0.06	0.38 ± 0.03	0.62 ± 0.04	0.46 ± 0.06	<0.001****	– 0.20 (–0.27, –0.13)
LF	0.63 ± 0.03	0.68 ± 0.03	0.60 ± 0.04	0.56 ± 0.05		
Fruits (sqrt)						
MedDairy	0.42 ± 0.03	0.45 ± 0.02	0.34 ± 0.04	0.43 ± 0.05	0.72	– 0.01 (–0.07, 0.05)
LF	0.39 ± 0.04	0.40 ± 0.04	0.40 ± 0.04	0.49 ± 0.04		
Vegetables (log)						
MedDairy	– 0.49 ± 0.04	– 0.29 ± 0.04	– 0.43 ± 0.06	– 0.35 ± 0.05	0.11	0.07 (–0.02, 0.15)
LF	– 0.35 ± 0.05	– 0.39 ± 0.05	– 0.43 ± 0.04	– 0.39 ± 0.04		
Legumes (sqrt)						
MedDairy	0.03 ± 0.01	0.21 ± 0.03	0.04 ± 0.02	0.22 ± 0.03	<0.001****	0.14 (0.09, 0.18)
LF	0.03 ± 0.02	0.07 ± 0.03	0.09 ± 0.03	0.09 ± 0.03		
Meat/meat alternatives						
MedDairy	0.32 ± 0.04	0.37 ± 0.03	0.29 ± 0.04	0.36 ± 0.03	0.07	– 0.05 (–0.003, 0.10)
LF	0.29 ± 0.02	0.31 ± 0.04	0.30 ± 0.04	0.31 ± 0.02		
Red meat (sqrt)						
MedDairy	0.17 ± 0.04	0.08 ± 0.04	0.18 ± 0.04	0.14 ± 0.04	<0.001****	– 0.12 (–0.19, –0.05)
LF	0.20 ± 0.04	0.25 ± 0.04	0.22 ± 0.04	0.21 ± 0.04		
Nuts and seeds (sqrt)						
MedDairy	0.22 ± 0.04	0.35 ± 0.02	0.16 ± 0.03	0.26 ± 0.04	<0.001****	0.18 (0.13, 0.23)
LF	0.18 ± 0.02	0.10 ± 0.03	0.19 ± 0.03	0.15 ± 0.04		
Total dairy						
MedDairy	0.24 ± 0.03	0.34 ± 0.02	0.21 ± 0.02	0.36 ± 0.04	<0.001****	0.10 (0.06, 0.14)
LF	0.22 ± 0.02	0.21 ± 0.02	0.26 ± 0.03	0.29 ± 0.03		
Milk (sqrt)						
MedDairy	0.35 ± 0.03	0.34 ± 0.02	0.36 ± 0.03	0.38 ± 0.04	0.74	– 0.01 (–0.04, 0.03)
LF	0.37 ± 0.03	0.36 ± 0.03	0.34 ± 0.03	0.37 ± 0.03		
Cheese (sqrt)						
MedDairy	0.24 ± 0.03	0.28 ± 0.03	0.17 ± 0.03	0.28 ± 0.04	<0.01**	0.09 (0.03, 0.14)
LF	0.17 ± 0.03	0.15 ± 0.03	0.23 ± 0.03	0.24 ± 0.03		
Yogurt (sqrt)						
MedDairy	0.14 ± 0.03	0.33 ± 0.02	0.12 ± 0.03	0.28 ± 0.03	<0.001**	0.14 (0.10, 0.19)
LF	0.12 ± 0.03	0.012 ± 0.03	0.20 ± 0.03	0.21 ± 0.02		
EVOO (sqrt), tsp · d^{-1} · MJ^{-1}						
MedDairy	0.11 ± 0.04	0.51 ± 0.07	0.14 ± 0.04	0.42 ± 0.06	<0.001****	0.42 (0.34, 0.51)
LF	0.09 ± 0.03	0.04 ± 0.02	0.18 ± 0.07	0.04 ± 0.02		

[1]Values are observed means ± SEMs. Differences between interventions were analyzed by linear mixed-effects models, including fixed-effect terms for Group, Visit, Group × Visit, Period, and Order. *,**,***,****Different between interventions: *$P < 0.05$, **$P < 0.02$ (adjusted α), ***$P < 0.01$ (adjusted α), ****$P < 0.005$ (adjusted α). CHO, carbohydrate; en, energy; equiv., equivalent; EVOO, extra-virgin olive oil; LF, low-fat; log, log10-transformed values presented; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods; sqrt, square root–transformed values presented; tsp, teaspoons.

[2]Estimated marginal mean difference in change between interventions.

insulin sensitivity (HOMA-S), β-cell function (HOMA-B), or inflammation (CRP). It is notable that baseline values of HOMA-S, HOMA-B, HOMA-IR, and CRP were within recommended ranges (44). It is therefore not surprising that neither diet led to a significant effect on these markers. Furthermore, despite improvements in BP and lipid profiles after the MedDairy intervention, the current study did not observe significant change in 10-y absolute CVD risk, as measured by the FRS.

Significant effects were observed for measures of body composition and adiposity. Greater decreases in fat mass were observed for the LF diet. Furthermore, lean mass increased after the LF diet but decreased after the MedDairy diet. It is likely that

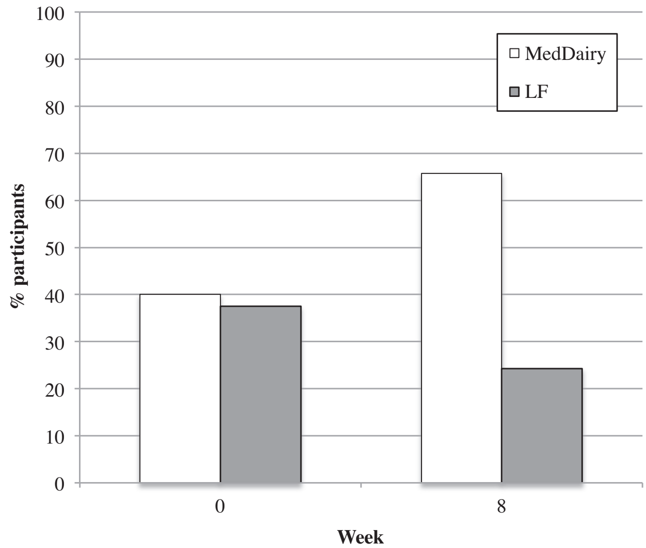

FIGURE 5 Visual representation of the percentage of participants meeting their calcium recommended dietary intake based on gender and age at visit 1 (baseline) and visit 2 (week 8) of each intervention. LF, low-fat; MedDairy, Mediterranean diet with 3–4 daily servings of dairy foods.

these differences were driven by the reduction in energy intake during the LF diet.

The current study was subject to a number of limitations. First, the current study aimed to evaluate the benefits of the MedDairy intervention compared with current best practice in dietetics in Australia. At the time of study conception, this was considered to be the LF diet. However, the use of an LF control diet may limit the generalizability of our results, as well as our capacity to evaluate the benefits of adding dairy to a traditional MedDiet. Regarding the MedDairy intervention, it is possible that recommendations for EVOO consumption during the MedDairy intervention were not reflective of a traditional MedDiet and therefore mitigated potential cardiovascular effects. However, the MedLey trial used the same dietary recommendation for EVOO and found significant improvements in BP and endothelial function (3). Furthermore, our data indicate that participants consumed a mean of 2.6 tablepoons of EVOO each day, increasing their baseline consumption by 400%.

It is possible that the addition of dairy diluted potential health benefits of the MedDiet. Indeed, dairy is not a traditional component of the MedDiet, and dairy intake receives a negative score in the 9-point MedDiet score developed by Trichopoulou et al. (7). Notably, Trichopoulou et al. reported that dairy intake was associated with a 4% increase in hazard of death for every 20-g increase in daily consumption. However, recent studies report positive relations between dairy intake and markers of cardiovascular health (22, 45), whereas a meta-analysis of prospective studies reported no associations of total dairy consumption with mortality, CVD, or coronary artery disease (24).

The calculation of sample size was based on previous research and attempted to find a clinically meaningful change in BP of 2.5 mm Hg. However, given the short time frame, the expectation of such an effect size may have been unrealistic. Therefore, the current study may have been underpowered to detect smaller, non–clinically significant effects in BP. Although previous research indicates that 8 wk is adequate to observe changes in cardiovascular outcomes, a longer intervention may have produced larger effects. Moreover, our ability to detect significant changes in home SBP may have been limited by our eligibility criterion of SBP $\geq$120 mm Hg. Although SBP $>$120 mm Hg is considered elevated and responsive to intervention, many participants reported a home SBP lower than their screening SBP, which may have been unlikely to change significantly in response to a dietary intervention.

Despite randomization, mean home SBP was 4.1 mm Hg higher for the MedDairy diet than for the LF diet at baseline. Randomization may have ensured overall balance between the 2 groups in terms of observed and unobserved confounders. However, the disparity in mean home SBP between the 2 groups was reversed at the beginning of the second intervention period, indicating the possibility of a significant carryover effect if the observed effects for SBP were real. To help address this, we allowed the estimated intervention effect for MedDairy to vary for the 2 intervention periods by including a Visit × Period interaction term in the analysis of home SBP. Despite this adjustment in our analysis, there remains the possibility of underlying differences between the 2 groups, which could potentially bias our estimates.

Finally, due to the nature of the current study, blinding of both participants and researchers was neither practical nor possible. As such, the potential for bias related to expectations must be considered when interpreting results.

The current study has achieved a number of significant and clinically relevant findings regarding the benefits of a MedDiet with adequate servings of dairy to meet the calcium needs of Australians. Namely, we have shown that following a MedDiet with 3–4 daily servings of dairy for 8 wk is feasible and achievable for an Australian population. Furthermore, a MedDiet with 3 daily servings of dairy is capable of meeting the Australian RDI for calcium while improving risk factors for CVD, including BP, lipid profiles, and HR. These findings are of particular interest to health care professionals who may wish to recommend the MedDiet to older Australians for improvement in cardiovascular health while ensuring adequate calcium intake for the prevention of osteoporosis.

We thank the following individuals: Louise Massie, for clinical trials support; Anita Lawrence, for assistance in sourcing yogurt; and research assistants Joe Mandrell and Campbell Davis, for their contributions to data entry and analysis.

The authors' contributions were as follows—KJM, JMH, ATW, and CRD: designed the project; KJM and CRD: developed the diet; KJM, ATW, JMH, and CRD: developed the cardiovascular measures; RJW: contributed to the study design and developed the statistical approach; KAD: contributed to the study design; KJM, ATW, KAD, and CRD: conducted the trial and collected study data; ATW: prepared the manuscript; and all authors: reviewed manuscript drafts and read and approved the final version. None of the authors reported a conflict of interest related to the study.

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