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Review article

# Whole-diet interventions and cardiovascular risk factors in postmenopausal women: A systematic review of controlled clinical trials

Mojgan Amiri<sup>a</sup>, Irma Karabegović<sup>a,a</sup>, Anniek C. van Westing<sup>a,b,#</sup>, Auke J.C.F. Verkaar<sup>b</sup>, Sara Beigrezaei<sup>c,d</sup>, Macarena Lara<sup>a</sup>, Wichor M. Bramer<sup>e</sup>, Trudy Voortman<sup>a,b,\*</sup>

<sup>a</sup> Department of Epidemiology, Erasmus MC University Medical Center, Rotterdam, The Netherlands

<sup>b</sup> Division of Human Nutrition and Health, Wageningen University and Research, Wageningen, The Netherlands

<sup>c</sup> Department of Nutrition, School of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

<sup>d</sup> Nutrition and Food Security Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

<sup>e</sup> Medical Library, Erasmus MC University Medical Center, Rotterdam, The Netherlands

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#### ABSTRACT

*Objectives:* Menopause is accompanied by many metabolic changes, increasing the risk of cardiometabolic diseases. The impact of diet, as a modifiable lifestyle factor, on cardiovascular health in general populations has been well established. The purpose of this systematic review is to summarize the evidence on the effects of whole diet on lipid profile, glycemic indices, and blood pressure in postmenopausal women.

*Methods*: Embase, Medline, Cochrane Central Register of Controlled Trials, and Google Scholar were searched from inception to February 2021. We included controlled clinical trials in postmenopausal women that assessed the effect of a whole-diet intervention on lipid profile, glycemic indices, and/or blood pressure. The risk of bias in individual studies was assessed using RoB 2 and ROBINS-I tools.

*Summary of evidence*: Among 2,134 references, 21 trials met all eligibility criteria. Overall, results were heterogenuous and inconsistent. Compared to control diets, some studies showed that participants experienced improvements in total cholesterol (TC), low-density lipoprotein cholesterol (LDL), systolic blood pressure (SBP), fasting blood sugar (FBS), and apolipoprotein A (Apo-A) after following fat-modified diets, but some adverse effects on triglycerides (TG), very low-density lipoprotein cholesterol (VLDL), lipoprotein(a) (Lp(a)), and highdensity lipoprotein cholesterol (HDL) concentrations were also observed. A limited number of trials found some effects of the Paleolithic, weight-loss, plant-based, or energy-restricted diets, or of following American Heart Association recommendations on TG, TC, HDL, insulin, FBS, or insulin resistance.

*Conclusion:* Current evidence suggests that diet may affect levels of some lipid profile markers, glycemic indices, and blood pressure among postmenopausal women. However, due to the large heterogeneity in intervention diets, comparison groups, intervention durations, and population characteristics, findings are inconclusive. Further well-designed clinical trials are needed on dietary interventions to reduce cardiovascular risk in postmenopausal women.

#### 1. Introduction

Menopause is reflected by reduced secretion of progesterone and estrogen hormones [1]. Reduced estrogen may result in unfavorable weight gain, changes in body fat distribution, reduced glucose tolerance, and adverse changes in lipoprotein pattern [2–4]. The cumulative effect of these changes might explain the consistently observed adverse associations between menopause and metabolic syndrome, independent of age [5], resulting in increased risk of cardiovascular, osteoarthritis, diabetes, cancers, and chronic kidney diseases [6–11]. Although menopause is a part of women life and its subsequent symptoms could affect their quality of life, this topic has only recently gained momentum in the scientific literature.

Dietary intervention is widely considered to be one of the most important modifiable lifestyle factors as primary prevention for cardiovascular events in the general population [12]. In women, it has been

\* Corresponding author.

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E-mail address: trudy.voortman@erasmusmc.nl (T. Voortman).

<sup>&</sup>lt;sup>#</sup> These authors contributed equally in this systematic review.

suggested that the dietary intakes are also associated with menopausal symptoms severity, although the findings are inconsistent and inconclusive [13].

So far, the majority of studies have investigated the effects of supplements, nutrients, or isolated single foods on menopausal health issues in postmenopausal women [14-18] and fewer studies have paid attention to the impact of a whole diet on cardiovascular risk factors in this population. In this regard, several controlled clinical trials with various intervention diets and different findings on cardiovascular risk factors were published. For example, findings of Women's Health Initiative Dietary Modification Trial (WHI-DM), designed to assess the effects of a low-fat dietary pattern during 6 years in comparison with dietary guidelines for Americans, showed no considerable differences between intervention and control groups on cardiovascular risk factors [19, 20]. A parallel comparison between a healthy diet and habitual dietary intakes showed decreases in fasting blood sugar (FBS), total cholesterol (TC), and triglyceride (TG) levels in intervention group without any considerable differences compared to the control group [21]. On the other hand, a diet providing less than 30 % of energy from fats could considerably improve FBS, insulin, and insulin sensitivity in comparison with habitual dietary intakes [22]. Also, a meta-analysis of clinical trials, published in 2014, observed no considerable effects following a low-fat diet intake on lipid markers in postmenopausal women [23].

There is a lack of consensus regarding an optimal diet for improving cardiometabolic health in postmenopausal women. Although previous reviews focused on of the role of supplements or single food components, the impacts of a whole diet on cardiovascular risk factors in this population have been scarcely investigated. Thus, the purpose of this systematic review is to summarize current evidence from controlled clinical trials on the effects of dietary interventions on lipid profile, glycemic indices, and blood pressure in postmenopausal women. This knowledge could assist further research in dietary intervention studies and inform the development of dietary guidelines specifically for postmenopausal women.

#### 2. Methods

#### 2.1. Review Design

The current systematic review was conducted and reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [24, 25]. The protocol of this review was registered in PROSPERO (CRD42021242980).

#### 2.2. Data Sources and Search Strategy

A systematic search in Embase, Medline, Cochrane Central Register of Controlled Trials, and Google Scholar was performed to identify controlled clinical trials examining the effects of the whole diet compared to other diets, habitual diets, or general recommendations on lipid profile, glycemic indices, and blood pressure in postmenopausal women irrespective of health status, from inception to February 2021. Related key terms to post-menopause, diet, lipid profile, glycemic indices, blood pressure, and clinical trials were used to build the search strategy. More information on PICO details and search strategy is provided in the Supplementary Tables 1 and 2. A librarian expert (WMB) was involved in developing the search strategy. Additionally, the reference lists of the eligible studies were screened to identify relevant articles.

#### 2.3. Inclusion and Exclusion Criteria

Studies were included if they met the following criteria: 1) were randomized or non-randomized controlled clinical trials; 2) designed to assess the effects of a whole diet (e.g. low-fat, plant-based, low/highcarbohydrates diets); 3) conducted only in post-menopausal women irrespective of health or disease status (in both intervention and control groups); 4) reported at least one of the following outcomes: total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL), non-HDL, low-density lipoprotein cholesterol (LDL), very low-density lipoprotein cholesterol (VLDL), lipoprotein (a) (Lp(a)), apolipoprotein A and B (Apo A and Apo B), FBS, Insulin, Hemoglobin A1C (HbA1C), insulin sensitivity and resistance indices (Homeostatic Model Assessment for Insulin Resistance (HOMA), quantitative insulin sensitivity check index (QUICKI), systolic blood pressure (SBP), or diastolic blood pressure (DBP); 5) published in English.

We excluded all studies that 1) were uncontrolled clinical trials, observational, editorials, reviews, or conference abstracts; 2) were designed to assess the impacts of only specific food components, nutrients, supplements, or combined interventions (e.g. combination of diet and physical activity/exercise, stress management, smoking cessation); 3) were conducted in men or women other than post-menopausal women.

#### 2.4. Study Selection and Data Extraction

Studies were selected in duplicate by independent researchers (MA, IK, AVW, AV, ML) in two steps. In the first step, the titles/abstracts of the identified articles were screened according to the eligibility criteria. Afterward, the full-texts of the included articles from the previous step were screened to identify the final number of eligible studies. Five researchers (MA, IK, AVW, AV, SB) extracted the following data from each study: 1) general information (first author, publication year, country); 2) trial characteristics (design, sample size, intervention duration, intervention/control details, feeding/nonfeeding, isocaloric or not); 3) participants' characteristics (health status and age); 4) summary of results regarding the mentioned lipid profile markers, glycemic indices, and blood pressure, and any adjustments. On condition that multiple articles reporting on the same outcomes from the same study, the information of the article reporting the most complete groups of outcomes was extracted. In the case of several intervention durations, findings of the longest period were extracted. Any lack of consensus about study selection or data extraction was adjudicated by a discussion with the principal investigator (TV).

#### 2.5. Quality Assessment

The quality of the included trials was assessed using Cochrane tool for assessing risk of bias in randomized trials (RoB 2 tool) [26] and Risk Of Bias In Non-randomized Studies of Intervention (ROBINS-I) [27]. RoB 2 tool estimates the risk of bias based on five domains, including 1) randomization process; 2) deviations from intended interventions; 3) missing outcome data; 4) measurement of the outcome; 5) selection of the reported result. ROBINS-I assesses the quality of the studies in specific domains in three levels, pre-intervention (bias due to confounding and selection of participants), at intervention (bias in classification of interventions), and post-intervention (bias due to deviations from intended interventions, missing data, measurement of outcomes, selection of the reported result). Two investigators (SB and MA) performed the quality assessments and disagreements were resolved by discussion.

#### 3. Results

#### 3.1. Search Outcome

Our search strategy yielded 2,134 references. Ninety-one articles were included after titles/abstracts screening. Full-texts screening resulted in exclusion of 63 articles, of which ten studies were conference abstracts [28–37], eight were conducted in populations other than post-menopausal women [38–45], twenty-three did not meet our intervention criteria [46–68], and twenty-two were excluded since they were derived from the same projects and/or did not report relevant

outcomes [69–90]. Also, one full-text, published in 1987, could not be retrieved [91]. Eventually, 27 articles, reporting on 21 unique trials, were included in the current systematic review [19–22, 92–114]. Figure 1 represents the study selection procedure.

#### 3.2. Study Characteristics

The included studies were published between 1990 and 2018. Studies were conducted in Poland [92], Mexico [99], Sweden [109], the United States [19, 22, 93–95, 97, 98, 101, 102, 108, 112], Iran [21], Canada [113], Australia [100], Ireland [96], Italy [103], Denmark [114], and one study was conducted in several centers (Miami, Atlanta, Birmingham, and Seattle) [107]. Nine trials included an apparently healthy or general population of postmenopausal women [19, 21, 96-98, 103, 107, 108, 112]. Twelve studies included women with a specific risk factor or history or disease only: six studies included obese or overweight participants only [22, 93, 101, 109, 113, 114], one included only postmenopausal women with metabolic syndrome [92], one with hypertension [100], one only moderate hypercholesterolemia [95], and three studies were conducted on women with a history of breast cancer [94, 99, 102]. Regarding dietary interventions, most of the trials intervened low/modified fat/fatty acids diets [19, 93–95, 97–99, 102, 107, 108, 112] and other interventions included Mediterranean diet [92], Paleolithic diet [109], healthy diet [21], diet based on American Heart Association recommendations [113], low-sodium DASH-type diet [100], very low-carbohydrates diet [101]. high-sodium, high- protein diet [96], plant-based diet [103], weight-loss

diet [22], and energy-restricted diet [114]. Four trials provided isocaloric diets [97, 101, 108, 112], and the diets of five trials were ad libitum or self-selected, or were not isocaloric [93, 94, 103, 107, 109]. The rest of included studies did not provide information on whether diets were isocaloric. In six trials, prepared meals or raw food ingredients were provided to the participants [92, 99–101, 108, 112] and in one study only the pre-prepared meals were obtained for the control group [98]. The remaining trials included nutrition counseling, individual goals, and meals/cooking classes as the intervention methods. The intervention duration ranged between 3 weeks to 12 months for most studies, one study lasted for 2 years and one for 6 years [19, 109]. Fourteen trials were designed as parallel [19, 21, 22, 92–94, 99, 100, 102, 103, 107, 109, 113, 114] and seven were designed as cross-over [95–98, 101, 108, 112]. Characteristics of the included studies are presented in Table 1.

#### 3.3. Quality and Risk of Bias

The details of risk of bias of 19 trials based on RoB 2 domains are summarized in Table 2. Among the included studies, 2 trials did not provide any information on randomization, thus we assumed them as non-randomized trials. The quality of these studies are presented in Table 3 using ROBINS-I tool. For randomized controlled trials, overall risk identified "High risk" for two studies [21, 114] and the rest of studies were identified as "Some concerns". Concerning the non-randomized trials, one scored as "Critical" [95] and the other one as "Serious" [98].

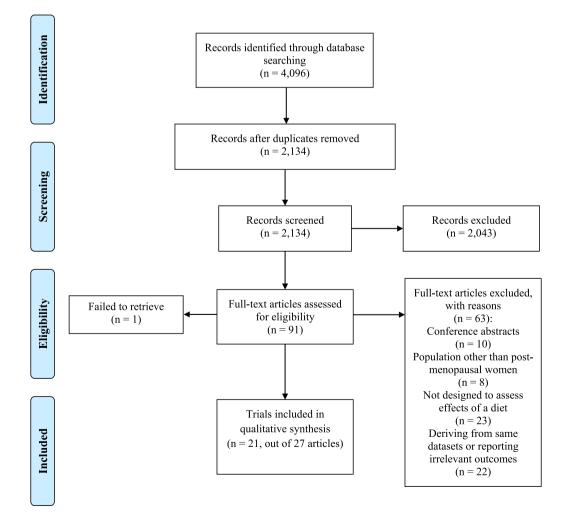


Fig. 1. Study selection process.

## Table 1Characteristics of the included studies.

Source	Country/ Study name <sup>1</sup>	Design/ Randomization	No. of Participants/ Intervention	Age <sup>2</sup> (years)	Health status	Intervention	Control	Duration	Dietary intake assessment	Results
General/healthy population of postmenopausal women										
Young <sup>3</sup> , 2013 [1]	United states	C/ R	17/ 17	57±6	Healthy	1- Low-fat diet: 20 E% fats, 65 E% CHO, 15 E% Pr 2- Low-fat, high n-3 diet:23 E fats, 62 E% CHO, 15 E% Pr	High-fat diet: 40 E% fat, 45 E% CHO, 15 E% Pr	8 w	Daily compliance records	Insulin, FBS, HOMA
McColley <sup>3</sup> , 2011 [2]	United states	C/ R	16/16	56.3±1.5	Healthy	1- Low-fat diet: 20 E% fats, 65 E% CHO, 15 E% Pr. 2- Low- fat, high n-3 diet: 23 E fats, 62 E% CHO, 15 E% Pr	High-fat diet: 40 E% fat, 45 E% CHO, 15 E% Pr	8 w	Daily compliance records	TG↓ <sup>C</sup>
Jeppesen, 1997 [3]	United states	C/ R	10/5	66±5	Healthy, non-diabetic	Low-fat, high- CHO diet: 25 E % fats, 60 E% CHO, 5 E% Pr	High-fat, low-CHO diet: 45 E % fats, 40 E% CHO, 15 E% Pr	3 w	NM	TG↑*, TC, VLDL↑*, LDL, HDL↓*,TC:HDL↑ *
Kasim-Karakas <sup>£</sup> , 2000 [4]	United states	C/ NR	54/ 54	61±11	Healthy	Low-fat diet: 15E% fats	1- 35%-fat diet 2- 25%-fat diet	8 m	7-day food records	Insulin, FBS↓*, HbA1C
Shikany <sup>4</sup> , 2011 [5]	United states/ WHI DM	P/ R	2,263/ 892	I:61.5±6.9 C:61.6±6.8	General population, without T1DM and cancer	Low-fat diet: reducing total fat intake to 20% of energy, increasing vegetable and fruit intakes to $\geq$ 5 servings and grain	Dietary Guidelines for Americans and other health- related materials	6 y	FFQ	Insulin, FBS, HOMA, QUICKI
Howard <sup>4</sup> , 2010 [6]	United states/ WHI DM	P/ R	2,730/ 1,068	I:61.6±6.9 C:61.8±6.9	General population, without T1DM and cancer	Low-fat diet: reducing total fat intake to 20% of energy, increasing vegetable and fruit intakes to $\geq$ 5 servings and	Dietary Guidelines for Americans and other Health- related materials	6 y	FFQ	TC, LDL, HDL, TG, non-HDL, TC:HDL, Lp[a]
Tinker <sup>4</sup> , 2008 [7]	United states/ WHI DM	P/ R	45,887/18,376	I:62.2±6.9 C:62.2±6.9	General population, without T1DM and cancer	grain Low-fat diet: reducing total fat intake to 20% of energy, increasing vegetable and fruit intakes to $\geq$ 5 servings and	Dietary Guidelines for Americans and other Health- related materials	6 у	FFQ	SBP, DBP
Bhargava <sup>5</sup> , 2006 [8]	Multicenter <sup>#</sup> / WHTFSMP	P/ R	994/ 615	50-79	General population	grain low-fat diet: Reducing energy intakes from fat to 20% and increasing the consumption of fruits, vegetables, and grain products	General dietary guideline recommendations	12 m	FFQ	$LDL\downarrow^{IC_{*}},$ $HDL\downarrow^{IC_{*}}$
Dallas Hall <sup>5</sup> , 2003 [9]	Multicenter <sup>#</sup> / WHTFSMP	P/ R	Glycemic: 1,067/660 BP: 1,749/ 1,101	50-79	General population	low-fat diet: Reducing energy intakes from fat to 20% and increasing the consumption of fruits, vegetables, and grain products	General dietary guideline recommendations	6 m	FFQ	Insulin, FBS, SBP↓*, DBP

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Table 1 (continued)

Source	Country/ Study name <sup>1</sup>	Design/ Randomization	No. of Participants/ Intervention	Age <sup>2</sup> (years)	Health status	Intervention	Control	Duration	Dietary intake assessment	Results
Ginsberg, 1998 [10]	Multicenter <sup>##</sup> / DELTA	C/ R	18/ 18	57.5	Healthy	1- NCEP: 30 E% fats (9 E% SFA, 14 E% MUFA, and 7 E% PUFA), 55 E% CHO, 15 E% Pr. 2- Low-Sat diet: 26 E% fats (5 E% SFA, 14 E% MUFA, and 7 E% PUFA), 59 E% CHO, 15 E % Pr	Average American diet: 37 E % fats (16 E% SFA, 14 E% MUFA, and 7 E% PUFA), 48 E% CHO, 15 E% Pr	8 w	NM	TC↓*, LDL↓*, HDL↓*, TG, Apo A-1↓*, Apo B, Lp (a) ↑*, TC:HDL
Harrington, 2004 [11]	Ireland	C/ R	26/26	57.1±5.1	Healthy	High-sodium, high- protein diet: 180 mmol/d day of Na and 90 g/day of Pr	Low- sodium, usual-protein intake	4 w	4-day food records	SBP, DBP
Abedi, 2012 [12]	Iran	P/ R	64/35	I:51.4 ±4.9 C:51.6±5.7	Healthy	Healthy diet: fruits and vegetables ≥5 servings, whole grain foods, high fiber foods, fish (two times per week), <10 E% SFA, cholesterol <300 mg/day, salt <5 g/day	Habitual intakes	6 m	24-hour recall	TC↓ <sup>IC</sup> , TG↓ <sup>I</sup> , LDL, HDL, FBS↓ <sup>I</sup> , SBP, DBP
Muti <sup>6</sup> , 2003 [13]	Italy/ DIANA	P/ R	99/ 50	50-65	Healthy	Plant based diet: Mediterranean vegetarian and macrobiotic recipes	A leaflet based on Europe against Cancer program: were advised to increase the fruit and vegetables consumption.	18 w	24-h diaries	TC↓*
Berrino <sup>6</sup> , 2001 [14]	Italy/ DIANA	P/ R	99/ 50	50-65	Healthy	Plant based diet: Mediterranean vegetarian and macrobiotic recipes.	A leaflet based on Europe against Cancer program: were advised to increase the fruit and vegetables consumption.	18 w	24-h diaries	Insulin, FBS
Postmenopausal women with cardiovascular risk factors										
Barnard, 2005 [15]	United states	P/ R	59/29	I:57.4 C:55.6	Overweight	Low-fat, plant-based diet: 10 E% fats, 75 E% CHO, 15 E% Pr	NCEP: 30 E% fat (7 E% SFA), 55 E% CHO, 15 E% Pr, Cholesterol <200 mg/day	14 w	3-day food record	Insulin↓ <sup>I</sup> , FBS↓ <sup>I</sup> , Insulin sensitivity↑ <sup>I</sup>
Denke, 1994 [16]	United states	C/ NR	39/39	61±6	Moderate hypercholesterolemia	Fat-modified step 1 diet: Based on NCEP and AHA recommendations (30 E% fats, 10 E% saturated fats, <300 mg/d dietary cholesterol )	High-Sat diet: 40 E% fats, 16 E% SFA, 450 mg/d dietary cholesterol	3 m	7-day food records	$TC\downarrow^{I_*}$ , $LDL\downarrow^{I_*}$ , VLDL, HDL, TG
C J Segal-Isaacson 2004 [17]	United states	C/ R	4/2	52.3±3.8	Overweight/obese	Very low-CHO diet: 5 E% to 10 E% CHO	Low-fat diet: Same energy and protein content	6 w	FFQ	TC $\downarrow^{IC}$ , TG $\downarrow^{I}$ , LDL $\downarrow^{IC}$ , HDL $\downarrow^{IC}$ , Insulin, FBS $\downarrow^{IC}$
Svendsen, 1993 [18]	Denmark	P/ R	72/51	53.8±2.5	Overweight	Energy-restricted Diet: Up to 4.2 MJ/day.	Habitual intakes	12 w	7-day food diary	TG $\downarrow$ *, TC $\downarrow$ *, HDL, VLDL $\downarrow$ *, LDL $\downarrow$ *, HDL: LDL $\uparrow$ *, SBP $\downarrow$ *, DBP

(continued on next page)

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Source	Country/ Study name <sup>1</sup>	Design/ Randomization	No. of Participants/ Intervention	Age <sup>2</sup> (years)	Health status	Intervention	Control	Duration	Dietary intake assessment	Results
Mason, 2011 [19]	United states/ NEW	P/ R	185/ 105	I:58.1±5.9 C:57.4±4.4	Overweight/obese	1200–2000 kcal/day, <30 E% fats, and 10% weight loss	Habitual intakes	12 m	FFQ	Insulin↓*, FBS↓*, HOMA↓*
Sénéchal, 2012 [20]	Canada	P/ R	19/9	62.6±4.1	Obese	AHA recommendations: 30 E % fats, 55 E% CHO, 15 E% Pr	Habitual intakes	12 w	Food diary	$TC\downarrow^{I}, TG\downarrow^{I}, \\HDL\downarrow^{I_{*}}, LDL\downarrow^{I}, \\TC:HDL, Insulin, \\FBS, HOMA, \\QUICKI, SBP\downarrow^{I}, \\DBP\downarrow^{I}$
Bajerska, 2018 [21]	Poland	P/ R	144/72	60.5	Metabolic Syndrome	Mediterranean diet: 37 E% fats (20 E% MUFA, 9 E% PUFA, 8 E% SFA), 45 E% CHO, 18 E% Pr	Central European diet: Based on NCEP and AHA recommendations (27 E% fats [10 E% MUFA, 9 E% PUFA, 8 E% SFA], 55 E% CHO, 18 E% Pr. Emphasis on dietary fiber)	16 w	3-day food diary	$TC\downarrow^{IC}, LDL\downarrow^{I}, \\HDL\downarrow^{C}, TG\downarrow^{IC}, \\Insulin\downarrow^{IC}, \\FBS\downarrow^{IC}, \\HOMA\downarrow^{IC}, \\SBP\downarrow^{IC}, DBP\downarrow^{IC}$
Otten <sup>7</sup> , 2016 [22]	Sweden	P/ R	41/ 25	I:61±6 C:62±6	Obese	Paleolithic diet: 40 E% fats, 30 E% CHO, 30 E% Pr. Recommended to intake higher MUFA and PUFA	Nordic Nutrition Recommendations (4 <sup>th</sup> edition): 25–30 E% fats, 55–60 E% CHO, 15 E% Pr. Emphasis on low-fat dairy products and high-fiber products	24 m	4-day food records	HOMA
Mellberg <sup>7</sup> , 2014 [23]	Sweden	P/ R	49/ 27	I:59.5±5.5 C:60.3±5.9	Obese	Paleolithic diet: 40 E% fats, 30 E% CHO, 30 E% Pr. Recommended to intake higher MUFA and PUFA	Nordic Nutrition Recommendations (4 <sup>th</sup> edition): 25–30 E% fats, 55–60 E% CHO, 15 E% Pr. Emphasis on low-fat dairy products and high-fiber products	24 m	4-day food records	TC, HDL, LDL, TG↓ <sup>I</sup> *, Insulin, FBS, SBP, DBP,
Nowson, 2009 [24] Postmenopausal	Australia	P/ R	95/46	1:60±0.7 C:58.4±0.7	Hypertensive	Low-sodium DASH-type diet: with a low dietary acid load containing 6 servings of 100g lean red meat/week. Rich in fruit and vegetables and had a higher potassium and magnesium content.	Higher acid load healthy diet: based on general dietary guidelines to reduce fat intake and increase intake of breads and cereals	14 w	3-day food record	SBP↓ <sup>IC</sup> , DBP↓ <sup>IC</sup> ,
women with										
breast cancer Buzzard, 1990 [25]	United states	P/ R	28/17	I:60±2 C:61±3	Breast cancer	Low-fat diet: Reducing total fat intake, using combination of education, goal setting, evaluation, feedback, and participant self-monitoring.	No counseling regarding fat intake	3 m	4-day food records	TC↓I
Thomson 2010 [26]	United states	P/ R	38/20	57.8±9.3	Breast cancer survivors	Low-fat diet: 25 E% fats, 55–60 E% CHO, 15–20 E% Pr	Low-CHO diet: Modified Atkins diet (35–40 E% fats with greater MUFA, 35 E% CHO, 25–30 E% Pr)	24 w	FFQ	TC $\downarrow^{I}$ , LDL $\downarrow^{I}$ , HDL $\uparrow^{I}$ , TC:HDL, TG $\downarrow^{C}$ , FBS, HbA1c $\downarrow^{C}$ , utinued on next page)

Source     Country/Study     Design/ Participants/ Intervention     No. of Participants/ Intervention     Age <sup>2</sup> (years)     Health status     Intervention     Duration     Duration     Duration       name <sup>1</sup> Randomization     Participants/ Intervention     Age <sup>2</sup> (years)     Health status     Intervention     Duration     Duration     Duration       name <sup>1</sup> Randomization     Participants/ Intervention     Participants/ Intervention     Age <sup>2</sup> (years)     Health status     Intervention     Duration       Murllo-Ortiz,     Mexico     P/R     100/ 50     I:50.5±7.9     Breast cancer     Low-fat diet: 12 E% fats, 68 E     American Dictetic     6 m     NM       2017     2017     2017     020 E% Pr     % CHO, 20 E% Pr     Association: 30 E% fats, 50 E     6 m     NM											
Mexico P/R 100/50 1:50.5±7.9 Breast cancer Low-fat diet: 12 E% fats, 68 E American Dietetic 6 m C:52.3±6.1 % CHO, 20 E% Pr Association: 30 E% fats, 50 E	Source	Country/ Study name <sup>1</sup>	Design/ Randomization	No. of Participants/ Intervention	Age <sup>2</sup> (years)	Health status	Intervention	Control	Duration	Dietary intake assessment	Results
% CHO, 20 E% Pr	Murillo-Ortiz, 2017 [27]	Mexico	P/R	100/ 50	l:50.5±7.9 C:52.3±6.1	Breast cancer	Low-fat diet: 12 E% fats, 68 E % CHO, 20 E% Pr	American Dietetic Association: 30 E% fats, 50 E % CHO, 20 E% Pr	6 ш	WN	Insulint <sup>C</sup> HOMA1 <sup>C</sup> QUICKI, <sup>I</sup> , SBP1 <sup>I</sup> , DBP, FBS↓ <sup>I</sup>

15 Years; 5%: Percent of energy intake; CHO: Carbohydrates; Pr: Proteins; PUFA: Polyunsaturated fatty acids; MUFA: Monounsaturated fatty acids; BP: Blood pressure; FFQ: Food frequency questionnaire; AHA: American Heart Association; NCEP: National Cholesterol Education Program; DASH: dietary approaches to stop hypertension; TG: Triglyceride; TC: Total cholesterol; LDL: Low-density lipoprotein cholesterol; VLDL: Very low-FBS: Fasting blood sugar; HOMA: Homeostatic Model Assessment for <sup>C</sup> Significant changes within control group. \*Significant changes in the intervention group compared to the control group. Insulin Resistance; QUICKI: Quantitative insulin sensitivity check index; HDA1c: Hemoglobin A1c; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; density lipoprotein cholesterol; HDL: High-density lipoprotein cholesterol; Apo: Apo lipoprotein; TC:HDL: TC to HDL ratio; Lp(a): Lipoprotein(a); Significant changes within intervention group.

Only one of the interventions (low-Sat diet) compared to the control.

<sup>3</sup> Both articles were conducted on a same project. <sup>4</sup> These papers were published from findings of the Women's Health Initiative Randomized Controlled Dietary Modification Trial (WHI DM). <sup>5</sup> These papers were derived Although this study reported some other outcomes of interest, we decided to only use glycemic indices results. In this study, dietary intervention accrued in two phases: 15% fat diet (as the intervention) and low-fat diets These papers are derived from the same project. from Women's Health Trial: Feasibility Study in Minority Populations (WHT:FSMP). <sup>6</sup> These papers were derived from Diet and Androgens Study (DIANA). <sup>7</sup>

in which fat intake was reduced in a stepwise manner from 35% to 15% (as the control). The last diet in the control duration (15%) was similar to the intervention diet, so we decided to extract only findings that compare the effects of intervention diet to 35% and 25% fat diets as the control periods

# Three clinical centers (Miami, Atlanta, Birmingham) and the Fred Hutchinson Cancer Research Center in Seattle. ## Columbia University, Pennington Biomedical Research Center, Pennsylvania State University, and University of Minnesota.

#### 3.4. Summary of Evidence

Due to the nature of the data, limited number of studies, and large heterogeneity among studies, including various designs, population characteristics, and comparisons, we decided to systematically summarize current evidence and to not perform a quantitative metaanalysis. In the following paragraphs, the findings of the included studies are explicated. If available, within and/or between mean changes are reported.

#### 3.4.1. General/healthy population of postmenopausal women

Out of 21 trials, 9 reported the effects of diet on lipid profile, glycemic indices, and blood pressure in general/healthy population of postmenopausal women. Among these trials, low-fat diets were the most diet as the intervention and dietary recommendations were used as the most comparisons.

A cross-over trial assessed the effects of two low-fat diets (low-fat diet and low-fat, high n-3 diet) compared to a high-fat diet in 17 healthy postmenopausal women for 8 weeks. The authors reported no significant differences following the treatment periods compared to the control period for serum insulin levels, FBS, and HOMA (p > 0.05) [112]. Additionally, finding of this study on 16 participants demonstrated that the high-fat diet reduced TG level considerably (-35.5 mg/dl, p < 0.05) without any significant between-group differences [111].

Another cross-over trial observed significant increases for TG (p <0.001), VLDL (p < 0.05) levels, and TC:HDL (p < 0.002) and a significant decrease in HDL (p < 0.05) concentration following a low-fat, highcarbohydrate diet compared to a high-fat, low-carbohydrates diet after 3 weeks of intervention. No considerable effects were observed on TC and LDL levels in this small sample (n = 10) [97].

A cross-over study on 54 healthy postmenopausal women investigate the effects of a 15 % fat diet compared to 25 and 35% fat diets. This study showed no significant changes in insulin and HbA1c levels while the intervention diet considerably reduced FBS in comparison with the control diets [98].

Findings of three sub-studies of 6-year WHI-DM trial are presented in the following paragraphs. This clinical trial aimed at investigating the effects of a reduced-fat diet in comparison to a control group (Dietary Guidelines for Americans) on glycemic indices, lipid profile, and blood pressure. Statistical analysis on 2,263 postmenopausal women without diabetes and cancer showed no significant differences for FBS, insulin sensitivity, and insulin resistance between the intervention and control groups (p > 0.05) [105]. Also, a sub-study by Howard et al. among 2,730 participants, did not find any significant within or between-arms changes in the levels of either TC, LDL, HDL, TG, non-HDL, TC:HDL, and Lp(a) (p > 0.05), when comparing the intervention and control groups [19]. And Tinker et al. showed the insignificant effect of the intervention on SBP and DBP in (p > 0.05) 45,887 participants as well [20]

Another intervention with a low-fat diet compared to general dietary guideline recommendations on 994 participants of Women's Health Trial: Feasibility Study in Minority Populations (WHTFSMP) reported significant reductions in LDL and HDL levels in both intervention and control groups as well as between groups after 12 months (p < 0.05) [106]. In addition, according to the findings of this trial reported by Dallas Hall et al. on 1,067 participants no considerable changes in FBS (-0.2 vs -0.1 mmol/L, p > 0.05) and insulin (-0.5 vs 0.3  $\mu lU/mL,\,p >$ 0.05) levels after 6 months of intervention compared to the control diet were observed. However, adhering to the low-fat diet showed a significant reduction in SBP compared to the general dietary recommendation, while no significant effect on DBP was reported [107]. And neither a high-sodium, high- protein diet nor a low-sodium, usual-protein diet significantly affected DBP or SBP levels in 26 postmenopausal women in a 4-week cross-over trial [96].

The delta Study, a multicenter 8-week cross-over study, on 18 healthy postmenopausal women compared the effects of two diets (one

#### Table 2

Risk of bias in randomized trials (RoB 2 tool).

First author, year	Randomization process	deviations from intended interventions	missing outcome data	measurement of the outcome	selection of the reported result	Overall assessment
McColley et al., 2011 [1]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns
Jeppesen et al., 1997 [2]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns
Howard et al., 2006 [3]	Some concerns	Some concerns	Low risk of bias	Low risk of bias	Low risk of bias	Some concerns
Dallas Hall et al., 2003 [4]	Some concerns	Some concerns	Some concerns	Low risk of bias	Low risk of bias	Some concerns
Ginsberg et al., 1998 [5]	Some concerns	Low risk of bias	Some concerns	Some concerns	Low risk of bias	Some concerns
Harrington et al., 2004 [6]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns
Abedi et al., 2010 [7]	Some concerns	Some concerns	High risk of bias	Some concerns	Low risk of bias	High risk of bias
Berrino et al., 2001 [8]	Some concerns	Some concerns	Low risk of bias	Low risk of bias	Low risk of bias	Some concerns
Barnard et al., 2005 [9]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns
C J Segal-Isaacson 2004 [10]	Some concerns	Some concerns	Some concerns	Some concerns	Low risk of bias	Some concerns
Svendsen et al., 1993 [11]	High risk of bias	Some concerns	Low risk of bias	Low risk of bias	Low risk of bias	High risk of bias
Mason et al, 2011 [12]	Some concerns	Some concerns	Low risk of bias	Low risk of bias	Low risk of bias	Some concerns
Seíneichal et al. 2011 [13]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns
Bajerska et al., 2018 [14]	Low risk of bias	Some concerns	Low risk of bias	Low risk of bias	Low risk of bias	Some concerns
Mellberg et al., 2014 [15]	Low risk of bias	Some concerns	Low risk of bias	Low risk of bias	Low risk of bias	Some concerns
Nowson et al., 2009 [16]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns
Buzzard et al., 1990 [17]	Some concerns	Some concerns	Some concerns	Some concerns	Low risk of bias	Some concerns
Thomson et al., 2010 [18]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns
Murillo-Ortiz et al., 2017 [19]	Some concerns	Some concerns	Low risk of bias	Some concerns	Low risk of bias	Some concerns

#### Table 3

Risk of bias in non-randomized trials (ROBINS-I).

First author, year	Risk of confounding	Risk of selection bias	Risk of Misclassification of interventions	Risk of deviation from intended interventions	Risk of missing data	Risk of misclassification of outcomes	Risk of reporting bias	Overall risk of bias
Denke, 1994 [20]	Critical	Low	Low	Low	Low	Low	Low	Critical
Kasim- Karakas, 2000 [21]	Serious	Low	Low	Low	Moderate	Low	Low	Serious

based on national Cholesterol Education Program (NCEP) and the other one, a low-saturated-fat diet) with the average American dietary intakes. TC, LDL, and HDL concentrations were significantly decreased in both intervention groups in comparison with the control group (p < 0.05) while no considerable differences were observed in TG, Apo B, and TC: HDL levels (p > 0.05). This study also indicated that the low-saturatedfat diet significantly reduced Apo A-1 and increased Lp(a) levels compared to the control group (p < 0.05) [108].

A 6-month intervention on 64 healthy postmenopausal women compared the effects of a healthy diet with habitual dietary intakes. After comparing pre and post-intervention values of this parallel study, significant decreases in serum levels of TC were found in both intervention (-12 mg/dl) and control (-12 mg/dl) groups (p < 0.05) and significant decrease in TG levels was only found in the healthy diet arm (-18.9 mg/dl, p < 0.05). No considerable effect was shown on HDL and LDL concentration (0.40 vs -0.1 mg/dl, -6 vs -7 mg/dl, respectively, p > 0.05) as well as FBS level. However, FBS was significantly decreased within the healthy diet group (-4.5 mg/dl, p < 0.05) [21].

Findings of the Diet and Androgens Randomized Trial (DIANA), an 18-week intervention on 99 healthy postmenopausal women done by Muti et al., showed a considerable reduction of TC level in participants who followed a plant-based diet compared to the control group (-14% vs -4%, p = 0.005). In this study, the control women were not given any specific dietary instruction, they were advised to increase the consumption of fruit and vegetables [104]. Also, another report from DIANA study performed by Berrino et al. revealed insignificant effects of this plant-based diet compared to the control group on insulin (-10,6% vs 5.2%, p = 0.72) and FBS (-5.7% vs -1.2%, p = 0.05) levels [103].

#### 3.4.2. Postmenopausal women with cardiovascular risk factors

Among included studies, 9 trails investigated the effects of diet on the outcomes of interest in postmenopausal women with CVD risk factors, including obesity/overweight, metabolic syndrome, hypertension, and hypercholesterolemia. A variety of diets were intervened in this population, such as fat-modified, energy-restricted, Mediterranean, DASH, and Paleolithic diets.

A parallel trial assessed the effects of a low-fat, plant-based diet compared to the NCEP recommendation in 59 overweight postmenopausal women. After 14 weeks of intervention, FBS and insulin levels were significantly decreased and insulin sensitivity was increased in the low-fat, plant-based group without any considerable differences with the control group [93]. Results of a 3-month cross-over trial on 39 postmenopausal women with moderate hypercholesterolemia showed significant decreases in TC (-5%) and LDL (-6%) levels (p < 0.005) within the fat-modified step 1 diet and in comparison with the high-fat, high-saturated diet. Between and within-group changes for VLDL, HDL and TG were not statically considerable (p > 0.05) [95].

Segal-Isaacson et al. showed that both a very low-carbohydrate diet and a low-fat diet resulted in significant decreases of TC, LDL, HDL, and FBS levels ( $p \le 0.05$ ) during 6 weeks follow up in 4 overweight or obese postmenopausal women. The concentration of TG was significantly reduced only in the very low-carbohydrate diet group. Neither of the diets affected the insulin level significantly. No statistically considerable differences between intervention and control groups were observed for any of the outcomes (p > 0.05) [101].

Svendsen et al. noted that an energy-restriction diet in postmenopausal women with overweight improved TG, TC, LDL, HDL:LDL, VLDL, and SBP levels in comparison with a usual diet (p < 0.001). No differences were observed for HDL and DBP in 72 women during the 12 weeks follow up period [114].

Findings from Mason et al. in 185 overweight or obese postmenopausal women which investigated the effect of a weight loss diet (providing 1200–2000 kcal/day, and less than 30% of energy intake from fats) compared to the habitual intakes for 12 months indicated the reducing effects of the intervention group compared to the control group for FBS, insulin and HOMA levels [22].

Senechal et al. compared the effects of AHA recommendations to habitual dietary intakes on 19 obese postmenopausal women. Twelve weeks of intervention caused significant improvements in TC, TG, LDL, SBP, and DBP levels in the intervention group, while no differences were observed between groups (p > 0.05). Additionally, AHA recommendations led to a significant reduction of HDL levels in comparison with the control group ( $p \le 0.05$ ) and no significant changes were observed with respect to TC:HDL. Also, intervention diet resulted in no significant within or between differences in the levels of insulin, FBS, HOMA, and QUICKI (p > 0.05) [113].

Findings of a study done by Bajerska et al. in 144 women with metabolic syndrome showed decreases in TG (-33.9 vs -38.8 mg/dl), TC (-15.5 vs -11.2 mg/dl), FBS (-6.4 and -5.4 mg/dl), insulin (-3.5 and -3.1  $\mu$ U/ml), HOMA (-0.46 and -0.42), DBP (-6.7 and -8.1 mmHg), and SBP (-10.02 and -10.04 mmHg) for either of the Mediterranean diet and Central European diet without any considerable differences between them. Within groups decrease in LDL concentration was noted for women consuming Mediterranean diet (-9.4 mg/dl, p < 0.05) while the women consuming Central European diet showed a decrease in HDL level (-2 mg/dl, p < 0.05) after 16 weeks intervention [92].

A 24-month parallel comparison between the Paleolithic diet and 4<sup>th</sup> edition Nordic nutrition recommendations done by Mellberg et al. illustrated the insignificant effects of the Paleolithic diet on TC, LDL, HDL, insulin, FBS, HOMA, and blood pressure levels in 49 obese postmenopausal women in comparison with the control. A significant reduction of TG levels was observed in the intervention group (-0.23 vs -0.01 mmol/L, p = 0.004) compared to the control group [109, 110].

Nowson and colleagues compared a vitality diet and a higher acid load healthy diet in 95 women with hypertension followed for 14 weeks. Decreases in SBP (-5.6 mmHg, p < 0.001 and -2.7 mmHg, p < 0.01) and DBP (-4.1 mmHg, p < 0.001, and -2.9 mmHg, p < 0.001) were observed in both groups without any significant differences between groups [100].

#### 3.4.3. Breast cancer survivors

The findings of 3 trials in post-menopausal women with breast cancer are presented below. In all 3 trials the effects of a low-fat diet were investigated. Habitual intake, low-carbohydrate diet and American Dietetic Association (ADA) were recommended as the comparisons.

Findings of a parallel comparison between a low-fat diet and a lowcarbohydrate diet in 38 breast cancer survivors demonstrated improvements of TC (-5.2 mg/dl, p = 0.02), LDL (-7.8 mg/dl, p = 0.007), HDL (0.4 mg/dl, p = 0.002) and SBP (-8.6 mmHg, p = 0.03) levels in the low-fat diet group. A considerable within-group decreases in TG (-31.1 mg/dl, p = 0.01), insulin (-2.6  $\mu$ U/ml, p = 0.002), and HbA1c (-0.1, p = 0.006) was noted in low-carbohydrate arm. The reductions of HOMA in both diets (-1.2, -0.7, p = 0.03) and QUICKI in low-fat diet (p = 0.005) were observed. TC:HDL, FBS, and DBP were not affected considerably by intervention or control arms. No changes were observed between the two groups during a follow up of 24 weeks [102].

Also, another parallel clinical trial in which 28 postmenopausal women with breast cancer received either counseling to lower their fat intake or not. After 3 months, TC concentration significantly decreased with 0.48 mmol/L (p < 0.01) in intervention arm and no considerable between groups changes were reported [94].

Murillo-Ortiz et al. performed a clinical trial investigating the effects of a reduced-fat diet compared to a ADA recommendation on 100 postmenopausal women with breast cancer. After 6 months, a significant decrease in FBS was observed in the intervention group compared to its baseline level (-7.5 mg/dl, p < 0.0001) [99].

#### 4. Discussion

This systematic review summarizes the available evidence on the effect of whole diets on cardiovascular risk factors in postmenopausal women. We observed that various types of diet have been used in intervention studies in this population, which the majority focused on modified-fat diets. To summarize, some studies showed that fatmodified diets led to improvements of some risk factors such as LDL, TC, SBP, FBS, or Apo A; however, harmful effects on TG, VLDL, Lp(a) and HDL were also observed. Furthermore, some interventions other than fat-modified diets, including the Paleolithic diet, AHA recommendations, a plant-based diet, and energy-restricted or weight-loss diets, found benificial effects on some cardiovascular risk factors such as TG, TC, HDL, insulin, FBS, HOMA compared to the control diets. However, these findings should be interpreted with caution due to the large heterogeneity between intervention diets, comparison groups, intervention durations, and population characteristics. Additionally, some of these findings are based on single studies only.

Chronic diseases are the leading causes of morbidity and mortality worldwide and aging is one of its greatest risk factors. Additionally, in women, physiological manifestations resulting from menopause could lead to long-term chronic diseases such as CVD [115]. Diet has been studied as an modifiable lifestyle factor for cardiometabolic health. Findings of the Brisighella Heart Study, a prospective population-based cohort, are suggestive of protective effects of nutritional education against SBP elevation, hypercholesterolemia, and prevalence of metabolic syndrome related to menopause [116]. However, healthy dietary patterns assessed with various diet quality scores (such as DASH, MED, aMED, HEI-2010, MDS, MexD), were not associated with risk of metabolic syndrome in the recent Women's Health Initiative observational prospective cohort study [117]. Nonetheless, a higher healthy eating index (HEI-2010) score was significantly associated with lower levels of TG and FBS and higher level of HDL. Moreover, better adherence to the DASH diet was associated with lower glucose levels and higher HDL levels [117]. The association of HEI with metabolic risk factors in postmenopausal women were studied by two cross-sectional studies, concluding that inappropriate dietary habits may negatively affect cardiometabolic indicators/ risk factors [118, 119]. The impacts of diets on cardiovascular health could be defined by different mechanisms. For instance, increasing the consumption of some food groups like whole grains and legumes might improve TC, blood glucose, and insulin due to the high content of soluble fiber [120, 121]. Several nutrients such as vitamin C, folic acid, potassium, magnesium, flavonoids, and carotenoids have been suggested to improve endothelial function or to cause vasodilation, which may play a role in the blood pressure lowering effects of fruits and vegetables [122, 123]. Higher intake of n-3 fatty acids may result in a reduction of cardiovascular risk factors [124, 125] and a lower intake of saturated fats may cause a reduction in cardiovascular events [126]. In this regard, according to a presidential advisory from the American Heart Association, randomized controlled trials that replaced dietary saturated fats intake with polyunsaturated vegetable oils reduced the risk of CVD by about 30%; however, no association was observed when these fats were replaced by refined carbohydrates and sugar. Additionally, in both population-based studies and trials, replacement of saturated fats with unsaturated fats lowered the concentration of LDL, as a cause of atherosclerosis [127].

On a higher level, dietary interventions may be part of larger overall lifestyle interventions. Some studies suggested that lifestyle modification may reduce the risk of diseases such as diabetes and coronary heart diseases and improve cardiovascular risk factors in different populations [128–132]. A 6-month clinical trial on postmenopausal women concluded that lifestyle intervention may be also an effective tool for improving cardiovascular risk factors in this population. In this study, exercise, nutrition education, eating behavior self-monitoring, attitudes, and relationships were modified as lifestyle factors [133]. Also, a combination of a Mediterranean low-saturated fat diet, stress management, exercise, group support, and smoking cessation improved HbA1c and body composition in postmenopausal women with type 2 diabetes [134].

Although the beneficial effects of different diets on cardiometabolic health have been established [135-137], this study shows inconsistent findings and lack of high-quality information on the effects of whole diets on cardiovascular risk factors specifically in postmenopausal women. Some of the included trials have shown benefits of diet on some lipid profile makers, glycemic indices, and blood pressure in postmenopausal women [21, 22, 92, 93, 99, 101, 102, 104, 106, 108, 109, 113]; however, others have not [19, 20, 96, 103, 105, 107, 109, 110, 112] and the majority of them did not find any considerable differences between the intervention diets and the controls. Underrepresentation of the elderly population and women in cardiovascular clinical trials has been discussed for several years [138-140] while due to the hormonal changes and lipid abnormalities, like increased concentrations of LDL and TC [141], the development of CVD is higher after menopause [142-144] and CVD is a major health issue at older ages in women [145]. Also, despite sharing lipid abnormalities, for example in individuals with diabetes, women suffer from a more aggressive form of coronary artery disease and are more susceptible to death from CVD in comparison to men [146, 147]. These consequences and complications associated with menopause show the importance of exclusive attention to women and optimized treatment of comorbidities not only to alleviate risk factors but also to decrease the cardiovascular mortality in this population [145], which diet is a promising way to reduce risks of various of these risk factors and consequences.

In order to achieve more conclusive results regarding the impact of diet on cardiovascular risk factors and consequently to find the most relevant diet for postmenopausal women, the limitations of the current evidence should be noted to improve future research. The assessments of risks of bias demonstrated the low quality of the included studies in design or conducting. The majority of the studies did not report information on the randomization and concealment methods, increasing the risk of selection bias. For those studies that were not randomized, potential confounding could be present. Additionally, participants were not blinded to the diets in most studies; however, for whole diet interventions that is hardly possible. We also observed that most of the studies were conducted in the United States. Concerning the lifestyle and genetic background differences and their effects on the findings of the research, more studies in other societies are granted. Finally, most interventions are on low/modified fats while studies on other promising dietary interventions such as Paleolithic, plant-based, DASH, Mediterranean, low/high carbohydrates, and etc. are more lacking. Considering that menopause worsens the CVD risk factors and diet, as an inseparable part of lifestyle, is a way to control them, we recommended more

interventions specifically with the mentioned diets using well-designed controlled clinical trials in different regions exclusively in this population.

#### Conclusion

To the best of our knowledge, this is the first review that systematically summarizes the effects of whole diet interventions on lipid profile, glycemic indices, and blood pressure exclusively in postmenopausal women. This study confirmed that this area has a limited level of evidence. Even though some diets showed considerable effects on various cardiometabolic risk factors, the number of trials for each diet are too limited to draw firm conclusions.

This systematic review highlights the need to conduct well-designed controlled clinical trials with a larger population and stronger statistical approaches in this underrepresented population, helping to develop better targeted dietary recommendations for postmenopausal women.

#### Contributors

Mojgan Amiri contributed to the conception and design of the study, screened titles/abstracts and full texts, determined the eligibility of the articles, extracted the data, assessed the quality of the included studies, participated in drafting the manuscript, and revised and finalized the manuscript.

Irma Karabegović screened titles/abstracts and full texts, extracted the data, and participated in drafting the manuscript.

Anniek C. van Westing screened titles/abstracts and full texts, determined the eligibility of the articles, extracted the data, and participated in drafting the manuscript.

Auke J.C.F Verkaar screened titles/abstracts and full texts, and extracted the data.

Sara Beigrezaei extracted the data and assessed the quality of the included studies.

Macarena Lara screened titles/abstracts and full texts.

Wichor M. Bramer developed and applied the search strategy.

Trudy Voortman contributed to the conception and design of the study, and revised and finalized the manuscript.

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The authors declare that they have no competing interests.

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