Relias Media
From Relias

Integrative Medicine

Evidence-based summaries and critical reviews on the latest developments in integrative therapies [ALERT]

Vol. 24, Issue 12, December 2021
ReliasMedia.com

DIET

ABSTRACT & COMMENTARY

Fish Consumption, Omega-3 Fatty Acids, and Cardiovascular Disease

By Rakesh Calton, MD

Dr. Calton is Associate Professor, Clinical Foundations, Ross University School of Medicine, Barbados, West Indies.

SYNOPSIS: This article argues whether there is enough scientific evidence to suggest that there are associations between fish consumption and risk of cardiovascular disease, or of mortality, among people who consume fish compared to those who do not consume fish.

SOURCE: Mohan D, Mente A, Dehghan M, et al. Associations of fish consumption with risk of cardiovascular disease and mortality among individuals with or without vascular disease from 58 countries. *JAMA Intern Med* 2021;181:631-649

High consumption of fish, a rich source of long-chain omega-3 fatty acids, has been shown to improve cardiovascular disease (CVD) risk.[1-3] Various studies have shown a beneficial role of omega-3 fatty acids in managing CVD, hyperlipidemias, and hypertension.[1-3] However, the literature does not provide conclusive evidence to these effects.[4] While some studies have shown a positive correlation in omega-3 fatty acid consumption and improvement in cardiovascular events, coronary heart diseases, and cardiovascular event-related mortality, other studies did not show similar beneficial effects. The authors hypothesized that, since increased fish intake improves blood lipid levels, there should be significant differences in the association between fish intake and cardiovascular outcomes and mortality among those with CVD vs. those without CVD.

The authors conducted a pooled analysis between January 2020 and June 2020 of participant data obtained from 191,558 individuals from four cohort studies. (*See Table 1.*) The data taken from Prospective Urban Rural Epidemiology (PURE) in 21 countries included 147,645 individuals (mean age 54.1 ± 8 years), 139,827 of whom did not have CVD while 7,818 had preexisting CVD. All outcome events known until July 31, 2019,

Financial Disclosure: Dr. Rebecca H. Allen (author) reports that she receives grant/research support from Bayer and is a consultant for Bayer, Mylan, and Merck. All of the relevant financial relationships listed have been mitigated. None of the remaining authors or planners for this educational activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Integrative Medicine [ALERT]

Integrative Medicine Alert (ISSN 2325-2820) is published monthly by Relias LLC, 1010 Sync St., Ste 100, Morisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Integrative Medicine Alert*, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.

GST Registration Number: R128870672.

SUBSCRIBER INFORMATION
(800) 688-2421
customerservice@reliasmedia.com
ReliasMedia.com

Questions & Comments:
Please contact Associate Editor
Mike Gates at mgates@relias.com

Back issues: $42. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue's date.

Canada: Add 7% GST and $30 shipping.
Elsewhere: Add $30 shipping.

ACCREDITATION

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Relias LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

The Relias LLC designates this enduring material for a maximum of 2 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The American Osteopathic Association has approved this continuing education activity for up to 2 AOA Category 2-B credits.

This CME activity is intended for physicians and researchers interested in integrative medicine. It is in effect for 36 months from the date of the publication.

Summary Points

- In this pooled analysis of four cohort studies, the authors studied mortality and major cardiovascular disease (CVD) events in 191,558 individuals to determine if there is a difference in the association of fish consumption with the risk of CVD or mortality between individuals with and individuals without CVD.
- The researchers found a lower risk of major CVD and total mortality associated with higher fish intake of at least 175 g weekly among high-risk individuals or patients with vascular disease. This association was not found in general population without CVD.
- Consumption of oily fish, rich in omega-3 fatty acid, was associated with greater benefits.

Table 1. Age and Gender Distribution of Participants

	PURE Trial	ONTARGET and TRANSCEND	ORIGIN Trial	Pooled
Total number of subjects	147,645	31,491	12,422	191,558
Number of participants	0.6 (95% CI, 0.4-0.8)	0.4 (95% CI, 0.3-0.5)	0.3 (95% CI, 0.3-0.4)	43,887
Mean age (standard deviation) in years	21.8 (95% CI, 20.6-22.9)	18.1 (95% CI, 17.7-18.5)	18.5 (95% CI, 18.3-18.6)	54.1 (8.0)
Number of males	15,020 (40%)	1,779 (63.5%)	2,136 (59.8%)	91,666 (47.9%)

PURE: Prospective Urban Rural Epidemiology; ONTARGET: Ongoing Telmisartan Alone and in Combination with Ramipril Global End Point Trial; TRANSCEND: Telmisartan Randomized Assessment Study in ACE-Intolerant Subjects with Cardiovascular Disease; ORIGIN: Outcome Reduction with Initial Glargine Intervention; CI: confidence interval.

were included in the analysis. The other set of data was obtained from 43,413 participants published in three prospective studies from 40 countries:

- The Ongoing Telmisartan Alone and in Combination with Ramipril Global End Point Trial (ONTARGET), a randomized clinical trial of antihypertensive medication for 25,620 patients aged 55 years or older;
- Data from 5,926 participants of the Telmisartan Randomized Assessment Study in ACE-Intolerant Subjects with Cardiovascular Disease (TRANSCEND), a randomized controlled trial of telmisartan vs. placebo; and
- Data from 12,422 participants from the Outcome Reduction with Initial Glargine Intervention (ORIGIN) trial.

Variables collected from all of the studies included demographic factors, lifestyle, health history, and medication. Physical assessment included data on weight, height, waist, hip circumference, and blood pressure. In the PURE study, habitual food intake was recorded using country-specific validated food frequency questionnaires (FFQ). In ONTARGET and TRANSCEND, dietary information was obtained using a 19-question FFQ. The ORIGIN study used a 25-question, qualitative FFQ on individual foods. However, for fish consumption, it used a separate 28-question FFQ.

Statistical analysis involved a calculation of adjusted hazard ratio (HR) by multilevel Cox regression analysis within each of the above-mentioned studies and then pooling using random-effects metanalysis.

Median fish intake was calculated overall, as well as for the geographical regions, with adjustments made for age and gender. For each

of these cohorts, participants were divided into groups based on their fish consumption: lower than 50 g per month, between 50 g and 175 g per month, between 175 g and 350 g per month, and more than 350 g per month.

Analysis of covariance was performed to determine mean lipid blood levels and blood pressure levels among fish intake groups, adjusted for covariates. A two-stage participant meta-analysis also was performed. In the first stage, association between fish intake and events in each cohort were determined separately. In the second stage cohort, specific HRs and 95% confidence intervals (CIs) were pooled in a random-effects meta-analysis.

Proportionality assumption was tested using a global goodness-of-fit test and Schoenfeld residuals in each cohort. A test of heterogenicity were conducted by employing the I^2 statistic. Additionally, for the PURE study, Cox frailty models with random effects were used to correlate between fish intake and the outcomes.

Results included the following:

- A total of 191,558 participants with a mean age of 54.1 ± 8.0 years were included in the present analysis. Of these, 91,666 participants (47.9%) were males.
- In the PURE study, over a follow-up period of 9.1 years, intake of 350 g/week or more was not associated with risk of major CVD (HR, 0.95; 95% CI, 0.86-1.04) or total mortality (HR, 0.96; 0.88-1.05).
- In the other three cohorts, the HR for risk of major CVD (HR, 0.84; 95% CI, 0.73-0.96) and total mortality (HR, 0.82; 95% CI, 0.74-0.91) was lowest with intakes of at least 175 g/week.
- There was no further apparent decrease in HR with consumption of 350 g/week or higher.
- Consumption of fish with higher amounts of omega-3 fatty acids were strongly associated with a lower risk of CVD (HR, 0.94; 95% CI, 0.92-0.97 per 5-g increment of intake).
- A lower risk was found among patients with vascular disease. This benefit was not seen in general populations without CVD (for major CVD, $I^2 = 82.6$ [$P = .02$]; for death, $I^2 = 90.8$ [$P = .001$]).

■ COMMENTARY

This well-designed meta-analysis of pooled data from four studies found a strong correlation between consumption of fish with a higher amount of omega 3 fatty acids and lower risk of CVD among patients with vascular disease. This observation is in accordance with other studies. The 1989 DART trial reported a 29% reduction in all-cause mortality over a two-year follow-up period in male myocardial infarction survivors when advised to increase their intake of oily fish to 200 g/week to 400 g/week.[5]

Hu et al conducted a meta-analysis of data from 13 trials and found a positive correlation between consumption of marine omega-3 fatty acid supplementation and lowered risk for myocardial infarction, coronary heart disease (CHD) death, total CHD, CVD death, and total CVD.[6] The authors in the present study recommend consumption of at least two servings of fish rich in omega-3 fatty acids per week in patients with preexisting CVD. This is consistent with the recommendations made by the American Heart Association.[7]

The study is well-designed and has appropriate statistical measures employed. The problem statement is well-articulated and is based on a sound hypothesis. The research topic is relevant to the complementary and alternate medicine approach while dealing with cardiovascular morbidity and mortality.

The conceptual framework is explicit and well-justified, and the constructs being investigated are clearly identified and presented. The authors have conducted a thorough and well-researched review of the literature. However, the gaps in the available literature could have been better highlighted.

The research is well-designed, and appropriate statistical tools are employed wherever warranted to ensure trustworthiness. The study conforms to external validity by taking in account participants, settings, and conditions. The internal validity is maintained by addressing potential confounding variables and biases. Given the information provided by the analysis, clinicians should feel confident prescribing 175 g (approximately two servings) of fish rich in omega-3 fatty acids for their patients with prior CVD. ■

REFERENCES

1. Filion KB, El Khoury F, Bielinski M, et al. Omega-3 fatty acids in high-risk cardiovascular patients: A meta-analysis of randomized controlled trials. *BMC Cardiovasc Disord* 2010;10:24.
2. Mozaffarian D, Wu JH. Omega-3 fatty acids and cardiovascular disease: Effects on risk factors, molecular pathways, and clinical events. *J Am Coll Cardiol* 2011;58:2047-2067.
3. Rizos EC, Ntzani EE, Bika E, et al. Association between omega-3 fatty acid supplementation and risk of major cardiovascular disease events: A systematic review and meta-analysis. *JAMA* 2012;308:1024-1033.
4. Fialkow J. Omega-3 fatty acid formulations in cardiovascular disease: Dietary supplements are not substitutes for prescription products. *Am J Cardiovasc Drugs* 2016;16:229-239.
5. Burr ML, Fehily AM, Gilbert JF, et al. Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: Diet and reinfarction trial (DART). *Lancet* 1989;2:757-761.
6. Hu Y, Hu FB, Manson JE. Marine omega-3 supplementation and cardiovascular disease: An updated meta-analysis of 13 randomized controlled trials Involving 127,477 participants. *J Am Heart Assoc* 2019;8:e013543.
7. Jain AP, Aggarwal KK, Zhang P-Y. Omega-3 fatty acids and cardiovascular disease. *Eur Rev Med Pharmacol Sci* 2015;19:441-445.

ABSTRACT & COMMENTARY

Children and Electronics: A Longitudinal Study

By Ellen Feldman, MD

Altru Health System, Grand Forks, ND

SYNOPSIS: This Finnish study looking at electronic media (e-media) use in young children found 95% of 5-year-olds in the study exceeded guidelines for time spent with e-media, noted an association between increased screen time and increased psychosocial symptoms at 5 years old and found these associations were less prominent when measuring use of electronic games alone.

SOURCE: Niiranen J, Kiviruusu O, Vornanen R, et al. High-dose electronic media use in five-year-olds and its association with their psychosocial symptoms: a cohort study. *BMJ Open* 2021;11:e040848.

Guidelines from the American Academy of Pediatrics (AAP) state:[1]

- For children younger than 18 months, avoid use of screen media other than video-chatting. Parents of children 18 to 24 months of age who want to introduce digital media should choose high-quality programming and watch it with their children to help them understand what they are seeing.
- For children ages 2 to 5 years, limit screen use to one hour per day of high-quality programs. Parents should co-view media with children to help them understand what they are seeing and apply it to the world around them.

These recommendations from the AAP echo guidelines from the World Health Organization (WHO) regarding young children and electronic media (e-media), which is defined as watching programs, using social media, and playing electronic games.[1,2]

Given the evolving nature and prevalence of e-media, studies pointing toward detrimental and beneficial effects of its use in young children, and the lack of longitudinal data, Niiranen et al designed a study to investigate the amount of e-media use at 18 months of age and any association with psychosocial symptoms at 5 years of age.[3,4] This investigation also looked at e-media use at age 5 years and associated psychosocial symptoms as well as evaluated such symptoms in the context of viewing programs vs. playing electronic games.

Participants for this study were drawn from a larger Finnish investigation — the CHILD-SLEEP longitudinal birth cohort study — for which parents were recruited at 32 weeks of gestation and followed periodically post-partum until the child reached 5 years of age.[5] The 699 children in the Niiranen et al study all had parents who completed one or both questionnaires regarding behavior at the five-year check-in and replied to the e-media usage questions. Out of this group, 585 of these children had parental documentation of e-media use at age 18 months; psychosocial symptoms were not assesed at this age.

Parents of 18-month- and 5-year-olds reported children's e-media use per weekday and weekend. The parents of 5-year-olds were asked to differentiate program viewing vs. electronic game playing. Notably, this was omitted for the 18-month-olds, since there were few games available for this age group at the time of the study. In a nod to the rapid growth of e-media, Niiranen et al noted that, by the conclusion of the study, electronic games for 18-month-olds were more common.

To determine median frequency of use, a weighted daily average of e-media use in minutes was calculated. For the 5-year-olds, this was divided into separate averages for program vs. electronic game playing as well as total use. A 75-percentile cut-off was determined for each category to represent the children with the highest reported use of e-media.

The questionnaires used to measure psychosocial symptoms are validated, frequently used research tools for this age group. The Five to Fifteen and Strengths and Difficulties (SDQ) questionnaires have subscales measuring emotional problems, behavioral problems and inattention and are designed to be completed by parents or guardians.[6,7] Table 1 displays some basic findings from the study.

When looking at children in the 75th percentile for e-media use, it appears that, at 18 months, the highest users of e-media had a high level of peer problems (as measured by a SDQ subscore) at 5 years of age. However, this association became nonsignificant when results were adjusted for multiple covariates, including gender, maternal education, number of siblings, and daycare participation.

Summary Points

- This study from Finland is drawn from a more comprehensive child development study with parent recruitment beginning at 32 weeks of gestation and follow-up measurements via parental questionnaires occurring periodically until age 5 years.
- At 18 months of age, children in the study spent a mean time of 31.0 min/day on a device. Higher times spent on a device at 18 months of age were associated with an unadjusted increased risk of peer problems at 5 years of age. However, this association became nonsignificant when results were adjusted for multiple covariates, including gender, maternal education, number of siblings, and daycare participation.
- At 5 years of age, children spent a mean time of 114.1 min/day on a device, with 94.6% spending > 1 hour daily. Higher times spent on a device were associated with a variety of psychosocial problems in the unadjusted model.
- When screen time was specified as either program viewing or electronic games, results showed an association of multiple psychosocial problems, with higher program viewing at age 5 years, but no significant problems with higher use of electronic games at this same age.

Table 1. Electronic Media Use of Children Aged 18 Months and 5 Years

Age	Mean Time on Device	> 60 minutes E-Media Use/Day	75th Percentile for Total Use	Program Viewing Time	Electronic Game Time
18 months (n = 585)	32.4 minutes (range 0-253 minutes)	22.7%	> 46 minutes/day	N/A (only total e-media use measured)	N/A (only total e-media use measured)
5 years (n = 699)	114.1 minutes (range 0-321.4 minutes)	94.6%	> 135 minutes/day	80.4 minutes (range 0-225 minutes)	33.4 minutes (range 0-182.1 minutes)

E-media: electronic media

At age 5 years, increased level of screen time was associated with a variety of psychosocial symptoms, but this association became nonsignificant for most symptoms when the results were adjusted for the multiple covariates. The only exception was a continued association with internalizing symptoms (such as depression and anxiety).

Finally, when analyzing time spent viewing programs vs. playing games at five years, these results show a significant association of program viewing with multiple psychosocial symptoms, even with multivariable adjustment. On the other hand, playing games has no statistically significant association with psychosocial symptoms in the fully adjusted model. Table 2 displays these results.

■ COMMENTARY

This longitudinal study adds depth to our baseline knowledge about the potential risks and use of e-media for young children and suggests that high e-media use at a young age (5 years), especially program viewing, is associated with a range of psychosocial symptoms. However, there was little indication that high e-media use at age 18 months translated to more psychosocial problems at age 5 years, and it appeared that higher use of e-games was not associated with psychosocial symptoms. That being said, the median time spent playing games at age 5 years was less than one-half the median time for program viewing, which may have skewed the results and deserves further study. It is notable that there may be a bidirectional association at play here, with parents encouraging behaviorally challenging children to settle down using e-media. This is an avenue for future investigations.

The rapidly evolving nature of technology makes the effect of e-media use in young children a difficult area to study and draw conclusions. This phenomenon is well illustrated in this investigation; Niiranen et al note that electronic games were not differentiated from screen viewing at age 18 months because, at the onset of the study, these games were not as available for this age group as they were at the conclusion. It is likely that, as games and e-media in general continue to change to keep pace with demand (or to change and encourage demand), use patterns and association with psychosocial symptoms also may evolve.

While recognizing recommendations and limits may change over time, this study lends data to an area of concern for many parents of young children. The guidelines

Table 2. 75th Percentile of E-Media Users and Association With High levels of Psychosocial Problems (Results Adjusted for Multivariables)

Symptoms (Questionnaire)	Age 18 Months	Age 5 Years, Total Viewing	Age 5 Years, Program Viewing	Age 5 Years, Electronic Game Playing
Attention and concentration (FTF)	OR 1.41 (95% CI, 0.89-2.22); *P* = 0.14	OR 1.57 (95% CI, 0.97-2.53); *P* = 0.07	OR 1.91 (95% CI, 1.19-3.08); *P* = 0.01*	OR 0.67 (95% CI, 0.38-1.17); *P* = 0.16
Hyperactive/impulsive (FTF)	OR 1.14 (95% CI, 0.72-1.80); *P* = 0.59	OR 1.14 (95% CI, 0.72-1.80); *P* = 0.59	OR 1.67 (95% CI, 1.04-2.69); *P* = 0.03*	OR 0.82 (95% CI, 0.48-1.42); *P* = 0.48
Internalizing symptoms (e.g., depression) (FTF)	OR 1.13 (95% CI, 0.69-1.72); *P* = 0.82	OR 2.01 (95% CI, 1.21-3.34); *P* = 0.01*	OR 1.71 (95% CI, 1.03-2.84); *P* = 0.04*	OR 1.36 (95% CI, 0.78-2.40); *P* = 0.28
Externalizing symptoms (e.g., conduct) (FTF)	OR 1.06 (95% CI, 0.65-1.72); *P*= 0.82	OR 1.54 (95% CI, 0.94-2.52); *P* = 0.09	OR 1.19 (95% CI, 0.72-1.96); *P* = 0.50	OR 1.42 (95% CI, 0.83-2.42); *P* = 0.20
Peer problems (SDQ)	OR 1.56 (95% CI, 0.98-2.46); *P* = 0.06	OR 0.85 (95% CI, 0.51-1.42); *P* = 0.53	OR 0.87 (95% CI, 0.52-1.44); *P* = 0.58	OR 0.83 (95% CI, 0.48-1.44); *P* = 0.51

E-media: electronic media; OR: odds ratio; CI: confidence interval; FTF: Five to Fifteen Questionnaire; SDQ: Strengths and Difficulties Questionnaire

*Statistically significant values

regarding time limits on e-media for young children provided by WHO, AAP, and other organizations are clear, but it is equally clear from this study and others that many parents do not adhere to these recommendations. For example, a 2020 U.S. survey (with the last interview concluded prepandemic) found that total e-media use among 2- to 4-year-olds averaged 2.5 hours daily — more than double the recommended amount of e-media time for young children.[8]

This U.S. survey was conducted by Common Sense Media, which may be the only organization systematically tracking use of e-media in young children in the United States. With data going back to 2011, Common Sense Media noted the total amount of screen time is slowly rising among the 0- to 8-year-old age group (median use in 2011 was two hours and 16 minutes), but the type of devices and content viewed is changing dramatically. For example, time spent on online video sites, such as YouTube, has doubled since 2011, and mobile device viewing is more prominent, with nearly one-half (46%) of 2- to 4-year-olds having a device (tablet or smartphone).[8]

While this longitudinal study can only point to associations and not determine cause and effect, it is worth considering that time spent on e-media may not in itself be detrimental to a child's emotional and social development. However, it may be replacing more optimal interactions for a child. This is another area worth exploring as research in the field continues. The results of this study suggest that high levels of e-media use may come at a developmental and behavioral cost for young children.

While this study is far from conclusive, it is clear that e-media occupies a central role in the daily life of many young children. The integrative provider is well-situated to remind parents of general guidelines for e-media use, including recommended time limits and co-viewing, and to explore with them pros and cons of adopting such limits. ■

REFERENCES

1. American Academy of Pediatrics. American Academy of Pediatrics announces new recommendations for children's media use. Published Oct. 21, 2016. https://www.aap.org/en/news-room/news-releases/aap/2016/aap-announces-new-recommendations-for-media-use/
2. American Optometric Association. New WHO guidance: Very limited daily screen time recommended for children under 5. Published May 6, 2019. https://www.aoa.org/news/clinical-eye-care/public-health/screen-time-for-children-under-5?sso=y
3. Ralph R. Media and technology in preschool classrooms: Manifesting prosocial sharing behaviours when using iPads. *Tech Know Learn* 2018;23:199-221.
4. Lawrence A, Choe DE. Mobile media and young children's cognitive skills: A review. *Acad Pediatr* 2021;21:996-1000.
5. Saarenpää-Heikkilä O, Paavonen J, Himanen S, et al. Child sleep — The Finnish birth cohort study. *Sleep Med* 2013;14(Suppl 1): e252-e253.
6. Lambek R, Trillingsgaard A. Elaboration, validation and standardization of the five to fifteen (FTF) questionnaire in a Danish population sample. *Res Dev Disabil* 2015;38:161-170.
7. [No authors listed]. What is the SDQ? Updated Jan. 1, 2012. https://www.sdqinfo.org/a0.html
8. Rideout V, Robb MB. The Common Sense census: Media use by kids age zero to eight. https://www.commonsensemedia.org/sites/default/files/uploads/research/2020_zero_to_eight_census_final_web.pdf

ABSTRACT & COMMENTARY

Plant-Based Diets and Menopausal Hot Flashes

By Rebecca H. Allen, MD, MPH

Associate Professor, Department of Obstetrics and Gynecology, Warren Alpert Medical School of Brown University, Women & Infants Hospital, Providence, RI

SYNOPSIS: In this clinical trial, women randomized to a low-fat, vegan diet including one-half cup of cooked whole soybeans daily experienced a reduction in total hot flashes of 79% compared to 49% in the control group over 12 weeks of observation.

SOURCE: Barnard ND, Kahleova H, Holtz DN, et al. The Women's Study for the Alleviation of Vasomotor Symptoms (WAVS): A randomized, controlled trial of a plant-based diet and whole soybeans for postmenopausal women. *Menopause* 2021;28:1150-1156

This study was conducted to evaluate the effectiveness of whole soybeans and a plant-based vegan diet in reducing the frequency and severity of menopausal hot flashes. Previous studies have found some indication that soy (phytoestrogen) supplements can modestly reduce hot flashes, although data are limited.[1] This was a randomized controlled trial performed over 12 weeks among women with postmenopausal hot flashes. Inclusion criteria were women 40 to 65 years of age, moderate to severe hot flashes at least twice a day, last menses within the preceding 10 years, and no menses in the preceding 12 months. Exclusion criteria were use of hormonal medications in the previous two months, smoking, substance abuse, history of an eating disorder, use of weight loss medications in the past six months, attempting to lose weight, body mass index (BMI) of < 18.5 kg/m^2, soy allergy, and current diet already matching the study diet.

The intervention group followed a low-fat vegan diet and was provided with soybeans to consume one-half cup per day. Intervention participants attended weekly one-hour group sessions and were given information on meal planning and food preparation (a pressure cooker was provided for the soybeans) and were asked weekly about adherence to the diet. Control group participants followed their usual diet, also were given a pressure cooker, and attended four one-hour group sessions. For both groups, alcohol was limited to one drink per day. Data collection was performed at baseline and at 12 weeks and included three-day dietary intake record, body weight and height, health status, medication use, physical activity, menopausal symptoms (hot flashes), and the Menopause-Specific Quality of Life (MENQOL) questionnaire.

The authors considered this a pilot study and aimed to enroll a total of 40 participants. Women were recruited through social media and screened by telephone. Ultimately, 38 women were randomized. There was no significant difference between the two groups in terms of age, race, and BMI. Mean body weight decreased by 3.5 kg in the vegan diet group compared to a 0.8-kg gain in the control group (P = 0.002). Total hot flashes decreased by 79% in the intervention group (6.2 vs. 1.3 events per seven days) compared to 49% in the control group (4.9 vs. 2.5 events per seven days) (P = 0.01). Moderate to severe hot flashes decreased 84% in the intervention group compared to 42% in the control group (P = 0.013). From 0 to 12 weeks, 59% (10/17) of intervention-group participants reported becoming free of moderate to severe hot flashes compared to no change in the control group (P = 0.0003). The MENQOL questionnaire showed significant reductions in all the vasomotor, psychosocial, physical, and sexual domains compared to the control group.

■ COMMENTARY

Vasomotor symptoms, or hot flashes, are common in the perimenopausal transition and menopause. The most effective treatment for hot flashes is systemic estrogen therapy. For women who do not want to use hormones, there are a few nonhormonal medications that have proven effective: selective serotonin reuptake inhibitors, selective serotonin-norepinephrine reuptake inhibitors, clonidine, and gabapentin.[2] However, the goal of this study was to evaluate the usefulness of whole soybeans because many women are seeking nonhormonal and nonpharmacological options to treat menopausal symptoms.

This study was sponsored by the Physicians Committee for Responsible Medicine, a nonprofit organization that promotes plant-based diets for preventive medicine and conducts clinical research in this area. Phytoestrogens are plant-derived substances with estrogenic biologic activity. Examples include the isoflavones genistein and daidzein, which are found in high amounts in soybeans, soy products, and red clover. Previous studies have shown that soy products may be modestly useful in treating menopausal

Summary Points

- The goal of this study was to evaluate the usefulness of whole soybeans in menopausal hot flash reduction. The intervention group followed a low-fat vegan diet, consumed one-half cup of soybeans per day, attended weekly one-hour group sessions, were given information on meal planning, and were asked weekly about adherence to the diet.
- Mean body weight decreased by 3.5 kg in the vegan diet group compared to a 0.8-kg gain in the control group ($P = 0.002$). Total hot flashes decreased by 79% in the intervention group (6.2 vs. 1.3 events per seven days) compared to 49% in the control group (4.9 vs. 2.5 events per seven days) ($P = 0.01$). Moderate to severe hot flashes decreased 84% in the intervention group compared to 42% in the control group ($P = 0.013$).

hot flashes.[1] However, current evidence has not been strong enough to recommend soy products on a routine basis.[2]

This study showed that a vegan diet with whole soybeans (one-half cup per day) reduced hot flashes significantly and almost eliminated moderate to severe hot flashes. The control group also experienced a decrease in hot flashes. The authors speculated this was because the control group also was aware of the vegan diet in the intervention group and possibly also followed it. However, the study was limited by the small sample size and short duration. But the findings were dramatic and deserve further study. Certainly, there may be other health benefits to a plant-based vegan diet, and eating soybeans does not have a downside. Therefore, this may be an option for patients who do not want to use medications and do not find enough benefit from regular lifestyle changes, such as layering clothing, lowering ambient temperatures, and consuming cool drinks. ■

REFERENCES

1. Franco OH, Chowdhury R, Troup J, et al. Use of plant-based therapies and menopausal symptoms: A systematic review and meta-analysis. *JAMA* 2016;315:2554-2563.
2. The American College of Obstetricians and Gynecologists. Management of menopausal symptoms. Practice Bulletin Number 141. Published January 2014. https://www.acog.org/clinical/clinical-guidance/ practice-bulletin/articles/2014/01/management-of-menopausal-symptoms

CME QUESTIONS

1. **Which of the following are shown to have the most beneficial effect on cardiovascular disease morbidity and mortality?**
   a. Omega-6 fatty acids
   b. Omega-3 fatty acids*
   c. Omega-7 palmitoleic acid
   d. A diet high in unsaturated fatty acids
2. **In the study by Barnard et al, intervention-group participants were asked to follow which of the following diets?**
   a. Pescatarian (vegetarian plus seafood) diet
   b. Paleo diet
   c. Vegan diet plus soybeans*
   d. Vegetarian diet plus black beans
3. **A Finnish study regarding electronic media (e-media) in young children:**
   a. is not applicable to the United States, where young children rarely are exposed to e-media.
   b. conclusively links higher e-media exposure in young children to hyperactivity and conduct problems in preschool.
   c. shows an association between high use of program viewing and psychosocial symptoms in 5-year-olds.*
   d. shows an association between high use of e-media and multiple psychosocial problems from ages 18 months to 5 years of age.

[IN FUTURE ISSUES]

- Yoga Breathing for COVID
- Flavinoid-Rich Foods and Lower Blood Pressure
- Structural Racism and Very Preterm Birth