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How Does Your Garden Grow? Organic vs. Conventional Food

ABSTRACT & COMMENTARY

By *Russell H. Greenfield, MD, Editor*

Synopsis: Authors of a recently published systematic review concluded that organic foods offer no significant nutritional benefit when compared with conventionally raised fare; however, the conclusions reached were based on extremely limited data, as stated by the authors, and focused solely on a small number of nutrients, with no attention paid to potential chemical / pesticide exposure to those ingesting the food, nor to environmental issues.

Source: Dangour AD, et al. Nutritional quality of organic foods: A systematic review. *Am J Clin Nutr* 2009 Jul 29; Epub ahead of print; doi:10.3945/ajcn.2009.28041.

THE RESEARCHERS BEHIND THIS SYSTEMATIC REVIEW SOUGHT TO quantify the differences in nutrient content between organic and conventionally raised foodstuffs. The research team performed a literature search for articles published in peer-reviewed journals with an English language abstract that directly compared the nutrient composition of foods raised organically vs. conventionally. Searching and data extraction were performed by two research assistants, with project leader oversight, and data from foreign language articles were extracted by native speakers. A total of 162 articles were finally assessed for study quality. Studies included in the analysis used one of three different study designs: field trials (comparing adjacent parcels of land), farm surveys (comparing products from organic and conventional farms), and basket studies (comparing foods available through retail outlets).

From the start, the authors state they did not attempt to address differences in potential contaminant exposure or associated environmental consequences of the two agricultural practices. Instead, the focus was solely on nutrient content. Data were found on more than 400 nutrients and nutritionally relevant substances, but there were not sufficient data to allow direct analysis by specific food, so the authors chose to make comparisons based on nutrient content across

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all study designs, ultimately choosing a pragmatic approach that statistically assessed only those nutrient categories reported in at least 10 studies (n = 11 nutrients) and at least four livestock trials (n = 2 nutrients).

Crop studies showed no evidence of a difference in nutrient content for eight of the 11 nutrient categories assessed (vitamin C, phenolics, magnesium, potassium, calcium, zinc, copper, and total soluble solids). Conventionally grown crops contained higher nitrogen levels, while organic produce was found to contain more phosphorous and titratable acidity. The researchers state these differences could be due to differences in ripeness at harvest, as well as differences in fertilizer use. For the two nutrient categories evaluated for livestock (ash and unspecified fats), no differences were identified.

The authors conclude that their analysis suggests no significant nutritional benefit of organic foods over conventionally raised foodstuffs with respect to nutrient composition.

■ COMMENTARY

The organic food movement has gained tremendous momentum over the past few years largely because shoppers believe they may be getting healthier fare, and also perhaps in part due to a sense of environmental and social responsibility. Recall that the very term “organic” implies the use of agricultural methods that limit or eliminate use of fertilizers, pesticides, fungicides, and genetically modified seeds, and as relates to livestock, less risk of exposure to antibiotics and growth hor-

mones. Yet there has been constant debate about whether organic foods actually provide noticeable health benefits for the usually higher store price. Such were the circumstances in which the authors of this paper began their work; however, they quickly found that even with all the research published in this arena, there were major limitations.

Some of the articles examined did not specify the organic certifying body, which is important since the associated regulations can vary, and others employed a variety of laboratory methods to gain their results. Study quality was a major issue, with the authors stating, “Our review again highlighted the heterogeneity and generally poor quality of research in this area.” The researchers forthrightly acknowledge they could not find the full text of 11 articles of potential interest to the study, and that two new studies of possible impact to their findings had recently been published but not reviewed.

The authors pragmatically focused on a total of 11 nutrients in produce and two nutrients in livestock across all study designs. Their reasoning makes sense, but they extend their reach too far when making broad conclusions based upon such limited data points. Consider all the phytonutrients already identified that offer potential health benefits that were not included in the assessment, organic or not, and the limited scope of the published conclusions comes further into view. Previous studies suggest that organic fare actually contains higher levels of select nutrients compared to matched conventional food, while others refute these findings.

Perhaps most importantly, however, is the fact that the authors did not “address differences in contaminant contents ... or the possible environmental consequences of organic and conventional agricultural practices because this was beyond the scope of our review.” Debate continues about the nutrient contents of organic vs. conventionally raised foods, but there is no debate about the increased potential for chemical exposure through the ingestion of conventional fare when compared to certified organic produce and livestock, an area of growing concern to scientists across the globe, especially as relates to the proper development of young children.

Regularly eating a wide variety of produce and moderate intake of animal protein can be the cornerstone for a healthy diet, but issues around organic and conventional farming methods have yet to be fully fleshed out. The present study does little to clarify matters, only pointing out the need for methodologically sound investigations to help answer persistent questions of nutrient content and chemical exposure. In general, it’s fair to ask our patients to lean organic for the foods we know to be

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more likely tainted with chemicals associated with conventional agriculture methods (peaches, milk, and strawberries, for example) where accessible and affordable, but not to scare them away from eating a wide variety of conventional foods. We don't have to eat everything organic to be healthy, but in certain instances organic may be the prudent choice. ❖

Extra Calcium Does Not Prevent Weight Gain Among Overweight/Obese Patients

ABSTRACT & COMMENTARY

By David Kiefer, MD

Dr. Kiefer is Clinical Instructor, Family Medicine, University of Washington, Seattle; Clinical Assistant Professor of Medicine, University of Arizona, Tucson; and Adjunct Faculty, Bastyr University, Seattle; he reports no financial relationship to this field of study.

Synopsis: *This randomized, double-blind, placebo-controlled trial measured the effect of 1,500 mg of calcium carbonate daily on total body weight and body fat mass in 340 overweight and obese individuals. After two years, both the placebo group and the calcium group showed equal gains in total body weight and body fat mass, leading the researchers to conclude that supplemental calcium is not effective in preventing weight gain in this population.*

Source: Yanovski JA, et al. Effects of calcium supplementation on body weight and adiposity in overweight and obese adults: A randomized trial. *Ann Intern Med* 2009;150:821-829.

THE SEARCH CONTINUES FOR DIETARY CHANGES OR supplements that can help spur improvements in the obesity epidemic.¹ This research trial was an attempt to extrapolate from previous research connecting calcium and weight loss, and determine whether calcium supplementation would prevent weight gain in already obese or overweight adults. Previous research had shown that in some cases people on lower-calcium diets may gain more weight than people consuming higher amounts of calcium, and that calcium may help both dieters and non-dieters to lose weight, all of which could be accounted for by calcium's ability to decrease fatty acid absorption while increasing adipocyte triglyceride deposition.²

The authors of this clinical trial recruited volunteers aged 18-80 from the Washington D.C. area who had a body mass index (BMI) of at least 25 kg/m². Potential participants were excluded from the study for any of a variety of medical conditions, if they used daily supplemental calcium or vitamin D in excess of 300 mg or 400 IU, respectively, or if they were women and had been told by their health care provider to take calcium supplementation for any reason. At the end of the screening process, a total of 340 individuals (72% women) were randomized to either calcium carbonate (1,500 mg of elemental calcium) or placebo, taken in divided doses twice daily with meals, and followed for two years. Study parameters followed included body weight, fat mass, blood pressure, food diaries, and levels of serum 25-hydroxyvitamin D and serum parathyroid hormone.

At baseline, 39% of the participants were overweight (BMI = 25-29.9 kg/m²), 61% were obese (BMI ≥ 30 kg/m²), and 75% had dietary calcium intake less than the recommended 1,200 mg daily. Seventy-five percent finished the two-year trial (equal numbers in the treatment and placebo groups), and the results were analyzed using intention-to-treat statistical analyses.

Over two years, participants gained an average of 1.31 kg total body weight (0.82 kg in body fat mass), showing no difference between the calcium group and the placebo group. There was also no difference in BMI, abdominal circumference, hip circumference, triceps skinfold thickness, dietary or supplemental calcium intake, mood, or energy level. Subgroup analyses by race and gender also found no differences. Of note, serum parathyroid concentration decreased in the calcium group compared to the placebo group ($P < 0.001$), which the researchers interpreted as further corroborating the compliance that was noted during pill counts. The authors concluded that 1,500 mg daily of elemental calcium failed to alter weight or fat gain over two years in overweight or obese individuals.

Concerns about this trial were mentioned by the authors. Past trials showing small decreases in weight gain paired supplemental vitamin D with calcium, though this trial noted similar serum 25-hydroxyvitamin D levels in each group, possibly debunking the role that vitamin D played in these results. As with many dietary recall questionnaires, small relevant changes in substances or foods ingested may have been missed; in particular, baseline dairy calcium intakes may have confounded the effects of supplementation. In addition, the researchers pointed out that because the vast majority of study participants were women, the broad applicability of these results is lessened.

■ COMMENTARY

Industrialized countries are facing an epidemic of obesity and obesity-related health problems, and the race is on to find any and all possible “cures.” The medical literature is rife with the weight-loss effects of low-carbohydrate diets or low-fat diets (and all combinations thereof), diets that emphasize low glycemic index foods, several pharmaceuticals, and a variety of dietary supplements purported to block dietary fat absorption, increase metabolism, or change fat mass to lean muscle mass. Some researchers are examining subsets of patients who are insulin-resistant, realizing that weight-loss recommendations for them may be different than for individuals who are insulin-sensitive. There are also some people, more so in the lay press than scientific community, calling into question the premise that weight and weight loss are merely an “energy in, energy out” phenomenon. (Do we merely have to tell our patients to exercise more?) This complexity and the evolving science make it easy to understand why a simple supplemental nutrient, such as calcium, would be an attractive magic bullet to put an end to, in the case of this trial, undesired weight gain.

The “negative” results of this double-blind, placebo-controlled trial are on one level no surprise; the failure to show benefits of calcium supplementation on future weight gain in an “at-risk” population (overweight and obese individuals tend to gain more weight over time than people at normal BMI) could probably have been predicted. For example, neither continued weight gain with low-calcium diets (as demonstrated in some past studies), nor augmented weight loss during calcium-supplemented dieting, are even in the same ball park as the hypothesis proposed by these researchers. It is possible that entirely different mechanisms are at work in low-calcium vs. high-calcium states, and weight loss vs. prevention of weight gain scenarios in dieting or non-dieting people.

The myriad exclusions in the recruitment of people for randomization in this trial is also a major problem. To exclude any women who received recommendations for calcium supplementation from their health care providers surely leaves an interesting subset, especially given how common knowledge is regarding the importance of calcium supplementation. There potentially is some lifestyle, dietary, or behavioral correlate not measured by these researchers that could have affected how such a non-calcium-using group responded or didn't respond to this intervention. Not to mention the lack of applicability given that most of our female patients presumably are taking calcium (hopefully on our professional recommendations).

Another issue is that dovetailing these results with prior research proves difficult. Past trials have followed either dairy calcium levels or calcium supplementation or both, and tried to correlate this with body composition changes, or changes in weight, in a variety of different populations. It is possible that calcium from dairy behaves differently physiologically from calcium supplements, or that certain demographics (as briefly discussed above) respond differently to certain interventions. In addition, there is the issue of calcium form (carbonate, citrate, gluconate, etc.) and absorption, and which one(s) may best achieve desired clinical outcomes.

Finally, it seems the authors had low expectations for already overweight and obese individuals, merely hoping to curtail their weight gain, rather than fostering weight loss. Of course, the latter is the therapeutic goal in improving risk for the many weight-related comorbidities already identified. ❖

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Does Yoga Untie the Pretzel of Anxiety and Depression?

ABSTRACT & COMMENTARY

By Judith L. Balk, MD, MPH, FACOG

Dr. Balk is Associate Professor, Magee-Womens Hospital, University of Pittsburgh; she reports no financial relationship to this field of study.

Synopsis: *Yoga may be helpful for psychological disorders. This randomized, controlled trial assessed the effects of yoga vs. wait-list control on anxiety and depression in women referred to a yoga clinic. Depression did not differ either between the two groups or before and after intervention; however, anxiety appeared to decrease significantly in the yoga group, compared to no change reported in the control group. This study is limited by small sample size, unclear description of the participants and recruitment methods, and limited description of the intervention. The analyses are not clearly spelled out, and it appears that the two groups*

(intervention and control) may not have been equivalent at baseline, although the authors state that the groups were “almost similar.” Lastly, the term “prevalence” is consistently used, although it appears that prevalence is not being described.

Source: Javnbakht M, et al. Effects of yoga on depression and anxiety of women. *Complement Ther Clin Practice* 2009; 15:102-104.

YOGA HAS OFTEN BEEN PERCEIVED AS A METHOD OF stress management that can assist in alleviating depression and anxiety disorders. This study involved a convenience sample of women who were referred to a yoga clinic from July 2006 to July 2007.

All new cases were evaluated on admission using a personal information questionnaire, as well as Beck and Spielberger tests. Participants were randomly assigned to an experimental or a control group. The experimental group (n = 34) participated in twice-weekly yoga classes of 90 minutes duration for two months. The control group (n = 31) was assigned to a waiting list and did not receive yoga. Both groups were evaluated again after the two-month study period.

The average prevalence of depression in the experimental group pre- and post-yoga intervention was 12.82 ± 7.9 and 10.79 ± 6.04 respectively, a statistically insignificant decrease ($P = 0.13$). However, when the experimental group was compared to the control group, women who participated in yoga classes showed a significant decrease in state anxiety ($P = 0.03$) and trait anxiety ($P < 0.001$).

The authors conclude that participation in a two-month yoga class can lead to significant reduction in perceived levels of anxiety in women who suffer from anxiety disorders. This study suggests that yoga can be considered as a complementary therapy or even an alternative to conventional medical therapy in the treatment of anxiety disorders.

■ COMMENTARY

The idea behind this study holds merit, and other studies have pointed to a therapeutic benefit for yoga in depression and anxiety. The overall design, a randomized controlled trial, is reasonable. The conclusions, however, must be taken with a grain of salt.

The subjects included “new female patient referrals who decided to have yoga experience without any documented psychological disorders or specialist recommendation for taking this therapy.” In addition, “cases with history of psychiatric disorders, drug abuse, and experience of yoga practices in past were excluded.” Thus, this

study of yoga for anxiety and depression effectively did not enroll anyone with a history of anxiety or depression, or anyone referred for anxiety or depression. The article describes the depression prevalence only in the yoga group: Roughly 15% (5 subjects) had either moderate or severe depression. The average baseline depression score in the yoga group was 12.82, and in the control group it was 11.2. Thus, one might expect that even fewer than 15% had moderate or severe depression in the control group. Other issues include no reporting on attrition, recruitment efforts, missing data, and other treatments for depression and anxiety used during the course of the study.

Method of randomization is not stated, and it is not clear if randomization was successful at equalizing the groups. At baseline, state anxiety was 2.29 in the yoga group, and it was 1.13 in the control group. While the authors note that the groups were “almost similar” in state anxiety, this is suspect because the pre-post change of 2.29 to 1.85 in the yoga group was statistically significant ($P = 0.03$). It is not clear which statistical tests were used for these comparisons, but a statistically significant pre-post change from 2.29 to 1.85 would point to a between-group comparison of 2.29 to 1.13 most likely being significant also.

The anxiety category distributions show that all subjects had at least mild anxiety; there is no category shown for “no anxiety.” The distribution of the State-Trait Anxiety Inventory scores is not revealed. The trait anxiety component, which typically reflects one’s consistent tendency to react with anxiety to stressful situations, also showed a significant decline after yoga, whereas the control group did not. The text in the article, however, does not match the data in Table 2; it appears to erroneously use the term “experimental group” whereas it is actually referring to the control group. Lastly, the conclusion in the abstract by the authors is that participation in a yoga class can lead to reduction of anxiety in women who suffer from anxiety disorders. However, the women in this study were not selected for having anxiety disorders; the findings might be different for those who had documented anxiety disorders.

Given the methodological issues in this study, can we make a firm conclusion about the role of yoga in anxiety and depression? No. Is it possible that yoga does help with anxiety and depression? Certainly. Recall that the overall design is reasonable, and some significant changes between pre- and post-yoga for anxiety were identified.

As the authors note, several studies demonstrate that yoga improves symptoms associated with depression

and anxiety. Yoga significantly reduced symptoms of depression compared to the control group in four of five randomized trials¹ and in six of six randomized studies of anxiety,² although all studies had some limitations. What is the mechanism by which yoga might improve anxiety and depression? One pilot study found that GABA levels increased when yoga practitioners performed yoga compared to when control subjects had a reading period.³ Which component of yoga might be responsible? Relaxation techniques including meditation,⁴ pranayama (breathing exercises),⁵ and physical exercise⁶ can help with symptoms of anxiety and depression. Perhaps social support, attention, and the Hawthorne effect also play a role in the findings. In any case, adding yoga to the armamentarium of treatment options for patients with anxiety or depression is reasonable, as long as standard of care is also met and the patient is thus kept safe from worsening anxiety or depression. ❖

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Public Perceptions of and Behavioral Changes in Response to the H1N1 Flu Outbreak

ABSTRACT & COMMENTARY

By **Dónal P. O'Mathúna, PhD**

Dr. O'Mathúna is Senior Lecturer in Ethics, Decision-Making & Evidence, School of Nursing, Dublin City

University, Ireland; he reports no financial relationship to this field of study.

Synopsis: A telephone survey revealed that the UK general public had a relatively low level of anxiety about H1N1 flu, and also made relatively few behavioral changes to reduce the risk of transmission. People's likelihood to make changes was associated with a number of perceptions regarding H1N1 flu (swine flu).

Source: Rubin GJ, et al. Public perceptions, anxiety, and behaviour change in relation to the swine flu outbreak: Cross sectional telephone survey. *BMJ* 2009;339:b2651.

THIS ARTICLE REPORTS ON THE RESULTS OF A TELEPHONE survey about “swine flu” (caused by the novel H1N1 virus) conducted in England, Scotland, and Wales in May 2009, about a month after the outbreak was first reported. Almost 1,000 adult members of the public participated in the survey. Of the participants, 37.8% reported performing any of the recommended behavioral changes over the previous four days because of H1N1 flu. These recommendations included using tissues when sneezing, washing hands regularly with soap and water, or setting up a network of “flu friends” to provide mutual assistance if anyone should become sick. Only 4.9% of participants reported carrying out any social avoidance behavior because of H1N1 flu (like avoiding public places).

Thirty-nine items were included in the survey to assess key perceptions about H1N1 flu and how they were related to behavior changes. Making the recommended changes was associated with perceptions that H1N1 flu is severe, that the risk of catching it is high, that the outbreak will continue for a long period of time, that the authorities can be trusted, that good information has been provided, that people can control their risk of catching H1N1 flu, and that specific behaviors are effective in reducing the risk. On the other hand, people were less likely to make the recommended changes if they scored high in “uncertainty” about the outbreak and if they perceived that the outbreak had been exaggerated or hyped up. The strongest predictor of behavior change was ethnicity, with participants from ethnic minorities being more likely to make recommended changes (odds ratio [OR], 3.2; 95% confidence interval [CI], 2.0-5.3) and carry out avoidance behaviors (OR, 4.1; 95% CI, 2.0-8.4).

The authors concluded that their results support efforts to inform the public about H1N1 flu and specific actions that can reduce its risks. They also noted that tackling the perception that the outbreak has been “overhyped” will be difficult, but should be undertaken. The

association between ethnicity and behavioral responses warrants further research.

■ COMMENTARY

In the United Kingdom (UK), media coverage of H1N1 flu began on April 25, 2009, and peaked on April 30 when the World Health Organization (WHO) raised its pandemic alert status to 5. This survey was conducted between May 8 and 12. At that time, 65 people in the UK had been confirmed as having H1N1 flu. The survey was conducted after the UK government carried out a large-scale public awareness campaign. This included an information leaflet sent to every home explaining H1N1 flu, the government's response, and how individuals could protect themselves and others from infection. The WHO raised its alert to level 6 on June 11, after this survey had been completed.

The survey used random digit dialing and proportional sampling to ensure respondents were representative of the general population. Participants were asked nine questions about recent behaviors, three of which had been recommended by the government to reduce risk of H1N1 flu and six which had not. Six items asked how strongly respondents believed specific behaviors reduced their risk of contracting H1N1 flu. The six-item version of the validated State Trait Anxiety Inventory was used specifically in relation to H1N1 flu. Thirty-nine items asked about perceptions related to H1N1 flu, which were grouped into six categories: trust in authorities, likelihood of infection, severity of illness, exaggeration of risk, timeline of the outbreak, and good information.

Less than two weeks after the WHO alert was raised to level 5, and several dozen cases were confirmed in the UK, public anxiety was relatively low in the UK. About 24% reported some anxiety about H1N1 flu, but only 2% reported high anxiety. Behavioral changes were also limited. Most (62%) had not changed any relevant behavior. Most people did not change the frequency of hand washing (72%), disinfecting items (83%), or developing "flu friends" (83%).

Regarding the government information leaflet, 39.3% reported receiving the leaflet and 25.6% said they had read it. No significant differences were found between those who had received the leaflet and those who had not in terms of anxiety, adopting recommended behaviors, or adopting avoidance behaviors. However, the group who had read the leaflet were significantly less anxious than those who had not read the leaflet ($P = 0.03$).

These results confirm other findings that the public's first response to a novel threat is not over-reaction or panic. The authors concluded that, "In practice, convinc-

ing the public that the threat is real is often a more pressing task for public health agencies than providing reassurance." The data on public perceptions offer some insight into how recommendations could be delivered more effectively. The higher the perception of the seriousness of the outbreak, the higher the rate of compliance with the recommendations. Information that was clear and removed uncertainty also increased compliance and reduced anxiety. Those who did not adopt recommended changes were more likely to perceive government health warnings as being exaggerated.

The survey had some limitations because it was designed and delivered very quickly in the immediate aftermath of the H1N1 flu outbreak. However, it provided helpful information on the public response immediately after the outbreak and a government education campaign. The effectiveness of this campaign appears to have been relatively limited, although those who read the leaflet did have reduced anxiety. The campaign also used other media, so the influence of any one portion would be difficult to separate from the others.

Health care professionals can play an important role in clarifying and explaining the information provided in such campaigns, and reinforcing the importance of adopting health-promoting behaviors. Asking patients about their perceptions of H1N1 flu can help elucidate whether they may be more or less likely to adopt public health recommendations. ♦

When Statins Hurt: Red Yeast Rice and LDL-cholesterol

ABSTRACT & COMMENTARY

By Russell H. Greenfield, MD, Editor

Synopsis: In a well-designed RCT, researchers showed that a combination of healthy lifestyle training and the supplement red yeast rice successfully lowers LDL-cholesterol levels in people intolerant of prescription statin drugs due to myalgias, and without significant side effects. Variability in the quality of available red yeast rice supplements remains a significant concern.

Source: Becker DJ, et al. Red yeast rice for dyslipidemia in statin-intolerant patients: A randomized trial. *Ann Intern Med* 2009;150:830-839.

IN A RANDOMIZED, CONTROLLED INTERVENTION trial, researchers investigated the effectiveness and

tolerability of red yeast rice in combination with training in therapeutic lifestyle change to treat elevated cholesterol levels in people with previous statin-associated myalgia (SAM). Subjects were recruited from a single cardiology practice in suburban Philadelphia and were 21-80 years of age with dyslipidemia and a history of discontinuation of statin therapy due to myalgias. A total of 174 subjects were screened and 112 were deemed ineligible or refused to participate, leaving 62 participants (40 women), with evaluable data available on 59 at trial's end (30 in the red yeast rice group). They were randomly assigned to receive either 1,800 mg (three 600 mg tablets) of red yeast rice twice daily or placebo twice daily for a total of 24 weeks. All subjects were also enrolled in a 12-week therapeutic lifestyle change program comprising a weekly 3.5 hour meeting where information was shared about cardiovascular disease, nutrition, exercise, and relaxation techniques. Participants were stratified into four categories: LDL-cholesterol < 3.9 mmol/L (150 mg/dL); LDL-cholesterol > 3.9 mmol/L (150 mg/dL); BMI < 27 kg/m²; and BMI > 27 kg/m². Baseline laboratory tests and measurements were taken. All patients and study team members were blind to treatment allocation.

Subjects received a 30-day supply of tablets at monthly visits, at which time exercise and dietary logs were reviewed. At the end of the initial 12-week intervention period, lab tests and measurements were again taken. At that time, subjects were instructed to continue taking their pills and to follow the lifestyle instructions they had been given. Final fasting laboratory tests and measurements were performed at trial's end (week 24). Primary outcome was LDL-cholesterol, which was measured at baseline, 12 weeks (end of therapeutic lifestyle intervention), and at 24 weeks. Secondary outcomes included total cholesterol, HDL-cholesterol, triglycerides, liver function tests, creatinine kinase (CK), body weight, and results of the Brief Pain Inventory.

In the red yeast rice group at week 12, LDL-cholesterol had decreased by 1.11 mmol/L (43 mg/dL) from baseline. At week 24 a decrease of 0.90 mmol/L (35 mg/dL) was noted; in the placebo group, LDL-cholesterol decreased by 0.28 mmol/L (11 mg/dL) at week 12 and by 0.39 mmol/L (15 mg/dL) at week 24. LDL-cholesterol levels were significantly lower in the red yeast rice group than in the placebo group at both weeks 12 and 24, and significant treatment effects were observed on total cholesterol at both measurement times. The mean percentage change in LDL-cholesterol level from baseline for the red yeast rice group was -27.3% at week

12 and -21.3% at week 24; in the placebo group, mean percentage LDL-cholesterol change from baseline was -5.7% at 12 weeks and -8.7% at week 24. At week 24, nine of 30 subjects in the red yeast rice group achieved an LDL-cholesterol level of < 2.6 mmol/L (100 mg/dL) compared with two of 29 in the placebo group. No other significant changes were identified between measurements of the two groups.

Two of 29 in the red yeast rice group developed persistent intolerable myalgias and discontinued treatment, but their CK levels were within normal limits. One red yeast rice subject discontinued the agent due to dizziness, and one because of loose stools. One of the 30 members of the placebo group developed persistent intolerable myalgias and discontinued therapy but completed the study protocol. The groups did not differ with respect to development of myalgias or CK levels at week 12 or 24. The authors concluded that red yeast rice, when combined with therapeutic lifestyle change, may be a treatment option for dyslipidemic patients who cannot tolerate statins.

■ COMMENTARY

This well-done study promotes a treatment for patients previously without a viable option, but the authors do not rest on the laurels of a positive study; instead they appropriately encourage further investigation to address lingering questions about red yeast rice, statin therapy, and dyslipidemia.

Statin therapy is generally well-tolerated, but a significant number of people (estimated by some to be up to 10% prescribed statin drugs, or up to 1.3 million people in the United States alone) develop SAM (which includes muscle weakness or fatigue), less frequently myositis (denoted by an elevation in CK), and rhabdomyolysis. Other known side effects include gastrointestinal upset and liver damage. While most people believe that side effects with statin therapy develops early on, SAM can occur up to 48 months after institution of therapy. Patients with SAM for whom treatment for elevated cholesterol levels is still indicated, and the practitioners caring for them, have previously been without good therapeutic choices.

Red yeast rice naturally contains monacolin K (or lovastatin) as well as other monacolins that inhibit HMG-CoA reductase. The incidence of recurrent SAM with a change in statin therapy is very high (estimated at 57%), yet therapy with red yeast rice appears to offer less risk for this side effect. The question is why, since both contain monacolins. While the answers currently promoted are not definitive, they make sense. First, it is known that SAM development is dose-dependent. The

dosage of red yeast rice used in this study was 1,800 mg/d, high by usual standards, yet equivalent to only about 6 mg of lovastatin, far less than the typically prescribed dose of 20–40 mg/d. The low dosage may have been too low to elicit SAM, but there is no arguing the fact that treatment with red yeast rice was effective at lowering LDL-cholesterol. The researchers point out that perhaps there are other ingredients present within red yeast rice besides monacolins that play a therapeutic role and do not contribute to the incidence of SAM. In addition, the six-month trial duration may have been too short for SAM to show up.

Many practitioners rely on the concomitant use of coenzyme Q10 for their patients on statin therapy in the hope of forestalling SAM. Though some research results question this policy, experience has been good, for the most part. Noteworthy are the findings of recent studies that have implicated low vitamin D levels as contributing to development of mild-to-moderate SAM.¹

Keep in mind that the study, while very good, had a small sample size and monitored adherence to study protocol by self-report. The trial was also of relatively short duration and was performed in a relatively affluent community, raising questions of generalizability. It is important not to lose sight of the contribution of healthy lifestyle training to the positive results (a decrease of LDL-cholesterol at trial's end of 8.7%). Interestingly, the improvement in the red yeast rice group lessened from 12 to 24 weeks (the authors believe this to be secondary to diminished protocol compliance).

Prevention through dietary and lifestyle measures remains the cornerstone of lipid-lowering therapy. Specifically with regard to red yeast rice, there is a paucity of data on long-term effects on cardiovascular disease risk reduction, if any, and incidence of SAM and other side effects. In addition, red yeast rice is a supplement available over the counter without a practitioner's involvement. Side effects such as SAM and liver dysfunction have been associated with red yeast rice use, and supplement quality can still vary between products to this day. Red yeast rice appears a reasonable choice for the treatment of hyperlipidemia in patients previously intolerant of statins due to SAM, but still should be instituted under a doctor's supervision. ❖

Reference

1. Ahmed W, et al. Low serum 25 (OH) vitamin D levels (<32 ng/mL) are associated with reversible myositis-myalgia in statin-treated patients. *Transl Res* 2009;153:11-16.

A New Movement: Feldenkrais and Falls

ABSTRACT & COMMENTARY

By *Russell H. Greenfield, Editor*

Synopsis: Results of this small pilot trial suggest that a specialized movement program based on the principles of Feldenkrais therapy, when offered to elderly community-dwelling subjects twice weekly for 10 weeks, improves objective measures of balance and movement as well as self-confidence in both areas.

Source: Connors KA, et al. Feldenkrais method balance classes improve balance in older adults: A controlled trial. *Evid Based Complement Alternat Med* 2009 June 24; Epub ahead of print; doi:10.1093/ecam/nep055.

RESEARCHERS FROM AN AUSTRALIAN REHABILITATION center sought to determine whether a series of Feldenkrais method classes could improve balance and mobility in community-dwelling older adults using a prospective, controlled, non-randomized design. A convenience sample of 26 subjects (median age, 75 years) who were already enrolled in Feldenkrais method classes (“Getting Grounded Gracefully”) were compared with 37 volunteers (median age, 76.5 years) who were recruited for participation as controls (no intervention). Subjects in the intervention group attended two 1-hour classes a week for 10 weeks, with each class emphasizing different movement tasks such as moving from sitting to standing, or shifting weight while standing. In addition, postural control exercises were a core component of each session. The instructor employed what is described as an “exploratory learning approach,” where participants were verbally guided through movement sequences and progressed at their own pace. Both groups underwent tests for balance and mobility at baseline and after three months (at the end of the series of classes for the intervention group, and after a three-month period of time for the control group).

Outcome measures of interest were all related to balance, motion, and self-confidence in walking. Tests employed included the Activities-specific Balance Confidence (ABC) questionnaire (a self-rated scale used to assess confidence in balance), the Four Square Step Test (FSST, where ambulation and ability to change direction are tested), and self-selected gait speed (the latter chosen because slower gait speed has been associated with an increased risk of falls and impaired balance). Testing

was performed by one of the investigators and a research assistant.

At trial's end, the intervention group showed significant improvement on all measures, while the control group improved on but one measure (FSST); however, even on the FSST, subjects in the Feldenkrais group had significantly greater improvements when compared with the control group. Of particular interest were the results of the ABC questionnaire, where the control group's scores declined slightly (nonsignificantly), while the intervention group's results improved significantly, implying enhanced confidence in the ability to move without falling. The authors conclude that a modified form of Feldenkrais movement therapy may help improve balance in older adults.

■ COMMENTARY

The Feldenkrais method was developed by Dr. Moshe Feldenkrais (1904-1984), a physicist, mechanical engineer, and expert in judo. The approach borrows significantly from the martial arts in that there is a focus on engaging all parts of the body in balance and movement training. Classes are often described as gentle, as well as upbeat and optimistic in character. Participants typically have movement disorders due to a variety of maladies, ranging from traumatic injury to stroke to uncomplicated back and neck pain. The authors note that some research results suggest balance training may be more effective in lowering falls risk than strength or endurance training.

Results of the current trial are intriguing but, as with many pilot trials, there are methodological concerns, not the least of which is the potential for bias. The authors chose pragmatism and so used subjects for the intervention group who had already enrolled in the series of classes, suggesting an inherent interest in and belief in potential benefit from Feldenkrais therapy. This likely created an impact on results of at least the ABC questionnaire. In addition, the lack of blinding to group allocation is a significant weakness.

Little research has been published on the Feldenkrais method, yet a growing number of people are exploring this unique approach to improving physical function. Patients can participate in one-on-one sessions or join group classes. As noted, there is an emphasis on self-rated progression and pace of learning, and an inherent optimism girding Feldenkrais method classes that typically makes them enjoyable. Experience suggests this approach can be of benefit to patients experiencing limitations in movement, and can bolster confidence, the lack of which contributes to lessened physical activity. The current study does what a good pilot trial should —

it encourages further investigation and permits consideration of the treatment, but is not a critical assessment in and of itself. ❖

CME Questions

31. The study comparing organic vs. conventionally grown food determined which of the following?

- a. Organic food has increased nutrient content.
- b. Organic food has decreased contaminant exposure.
- c. Organic produce has higher levels of phosphorous, while conventionally grown food has higher levels of nitrogen.
- d. None of the above

32. Compared to the wait-list control, the yoga group showed a significant decrease in depression.

- a. True
- b. False

33. Which of the following was part of the flu prevention strategies recommended in the United Kingdom?

- a. Setting up a network of "flu friends"
- b. Washing hands regularly with soap and water
- c. Using tissues when sneezing
- d. All of the above

Answers: 31. c, 32. b, 33. d.

CME Instructions

Physicians participate in this continuing medical education program by reading the articles, using the provided references for further research, and studying the CME questions. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity, participants must complete the evaluation form provided at the end of each semester (June and December) and return it in the reply envelope provided to receive a credit letter. When an evaluation form is received, a credit letter will be mailed to the participant.

CME Objectives

After completing the program, physicians will be able to:

- a. present evidence-based clinical analyses of commonly used alternative therapies;
- b. make informed, evidence-based recommendations to clinicians about whether to consider using such therapies in practice; and
- c. describe and critique the objectives, methods, results and conclusions of useful, current, peer-reviewed clinical studies in alternative medicine as published in the scientific literature.

Use of CAM in the United States: Cost Data

IN THE 2007 NATIONAL HEALTH INTERVIEW SURVEY (NHIS), approximately 38% of adults reported using complementary and alternative medicine (CAM) in the previous 12 months. The CAM component of the NHIS, developed by the National Center for Complementary and Alternative Medicine and the National Center for Health Statistics, also collected data about CAM costs, including cost of CAM use, frequency of visits made to CAM practitioners, and frequency of purchases of self-care CAM therapies.

According to the 2007 NHIS survey, 83 million U.S. adults spent \$33.9 billion out-of-pocket on visits to

CAM practitioners and on purchases of CAM products, classes, and materials (see Figures 1-3).

At \$33.9 billion, CAM accounts for approximately 1.5% of total health care expenditures and 11.2% of total out-of-pocket expenditures on health care in the United States. The \$14.8 billion spent on nonvitamin, nonmineral, natural products is equivalent to approximately one-third of total out-of-pocket spending on prescription drugs (\$47.6 billion), and the \$11.9 billion spent on CAM practitioner visits is equivalent to approximately one-quarter of total out-of-pocket spending on physician visits (\$49.6 billion). ❖

Source: Nahin, RL, et al. *Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007*. National Health Statistics Reports; No 18. Hyattsville, MD: National Center for Health Statistics; 2009.

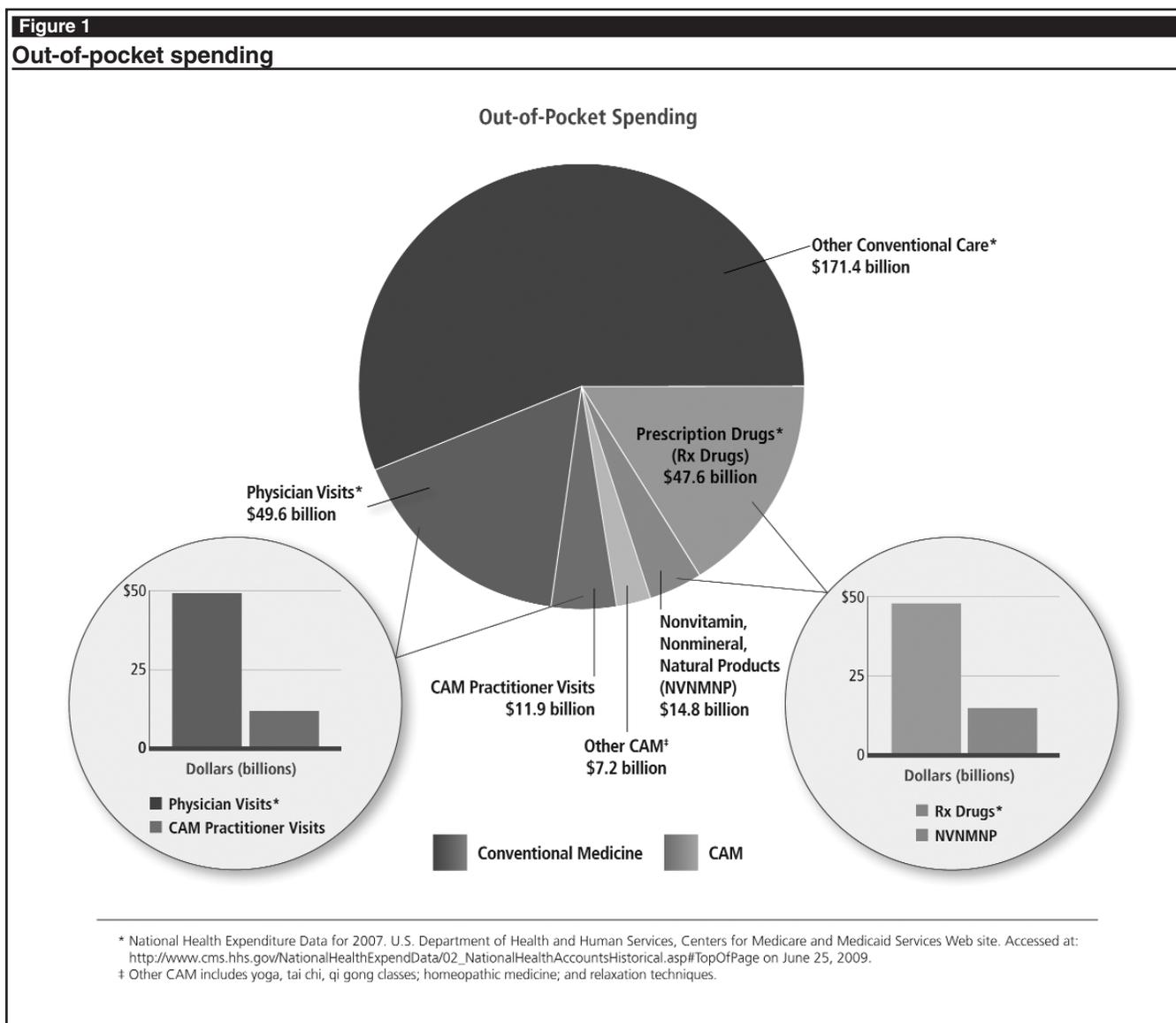
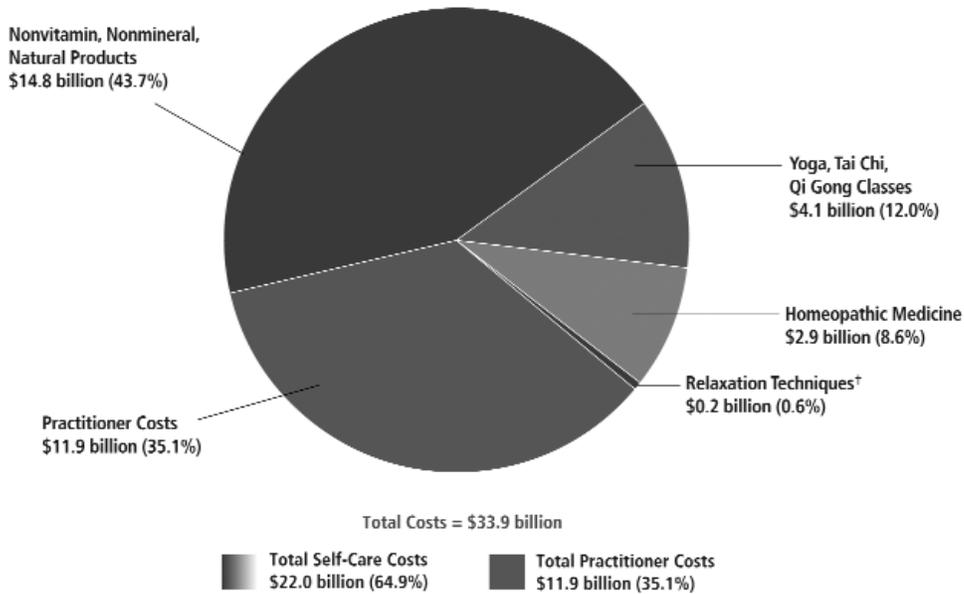


Figure 2

CAM out-of-pocket spending: Self-care* vs. practitioner costs

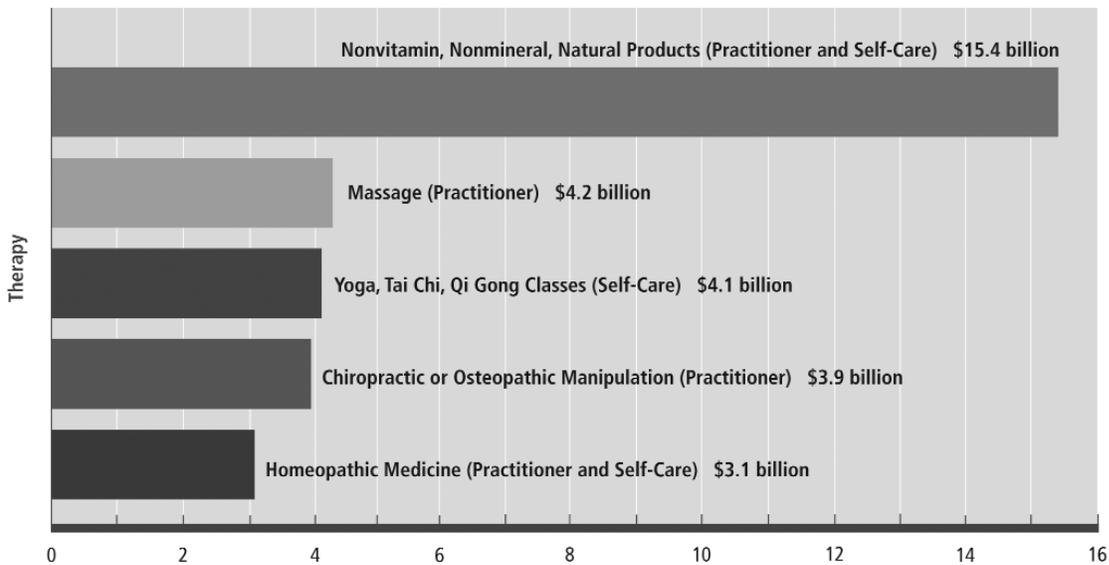


* Self-care costs include CAM products, classes, and materials.

† Relaxation techniques include meditation, guided imagery, progressive relaxation, and deep breathing exercises.

Figure 3

Out-of-pocket costs for select CAM therapies



* Totals for nonvitamin, nonmineral, natural products and homeopathy include both CAM practitioner costs and costs of purchasing CAM products. Totals for massage and chiropractic and osteopathic manipulation are only CAM practitioner costs. Totals for yoga, tai chi, and qi gong classes are only the cost of purchasing CAM products.

In Future Issues:

Can a Deep Breath Really Manage Your Pain?