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*** TX REPORT ***
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TRANSMISSION OK

TX/RX NO	1626
CONNECTION TEL	97205437
CONNECTION ID	USDA SECRETARY
ST. TIME	12/30 18:50
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RESULT	OK

THE WHITE HOUSE
Washington, DC

OFFICE OF THE STAFF SECRETARY

Fax Transmittal Sheet

To: SECRETARY GLICKMAN

Fax Number: 202-720-5437 **Telephone Number:**

From: Office of the Staff Secretary

Subject: see note from the President

Date: December 30, 1998

Number of Pages (including cover sheet): 3

Message:

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Washington, DC

OFFICE OF THE STAFF SECRETARY

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(If all pages are not received, please call (202) 456-2702.)

THE WHITE HOUSE

WASHINGTON

DATE: December 30, 1998

NOTE FOR: Honorable Dan Glickman
Secretary of Agriculture

The President has reviewed the attached, and it is forwarded to you for your:

Information ☐

Action xx

Thank you.

Staff Secretary
(x6-2702)

cc:

JIMMY CARTER

12 30 98

December 21, 1998

To President Bill Clinton

I realize that you have other things on your mind, but I'd like to bring to your personal attention the most serious crisis among farmers that I have witnessed since the Great Depression. I have discussed this issue with Secretary Glickman last week, and am convinced that only direct action by you can resolve the problem.

Hog farmers are faced with almost immediate disaster, with prices having fallen from a high of 43 cents/pound down to the most recent public sale in South Georgia of 8-1/2 cents. As you well know from your years as governor of Arkansas, there is an inexorability of production and then sale of mature hogs that forces farmers to accept whatever the market offers. At the same time, they have to continue buying feed for their remaining brood stock.

Very few hog farmers use government loans to finance their operation, so the extension of loan repayments will not be of much help. More pork for school lunch programs and increased exports are too long range in their effect. What they need immediately is the availability of low interest emergency loans, which will tide them over until the market rallies back to the break-even point.

I hope you will address this crisis directly.

Best wishes,

Jimmy

G. Sperling,
cc Bill Glickman
What about this
can we do anything

BJ

The Honorable Bill Clinton
The President of the United States
The White House
Washington, D.C. 20500-2000

Cc: Secretary Dan Glickman
Vice-President Al Gore

Copied
Sperling
Glickman
Podesta

12-30-98

[illegible]

jgill @ penfield-gill.com
12/19/98 07:47:00 PM

Record Type: Record

To: Nancy V. Hernreich

cc:

Subject: Funding & Edge Democracy - increase diversity, resilience

December 19, 1998

VIA EMAIL

Dear Mr. President,

Today was most unpleasant. Monologues by sanctimonious hypocrites of the Sunbelt GOP drowned out, prevented, a true dialog with the people at the edges. A travesty.

In any case, you may find David Reed's ideas of interest. I believe they are worth exploring as a means to avoid these sorts of problems in the future.

What ever you do, we are counting on you to stand and fight, not resign. As you know, you have our support in this struggle.

Best regards and Season's Greetings,

Jock

copied
VP
Smith
Grossman
Podesta

I've been turning some of my interests very heavily toward the campaign finance issue, ever since folks have made it clear that Hammer DeLay wields power via that route (and his anti-Shays-Meehan role seems to confirm his awareness of his power source).

It seems to me that the issue is not to create a bottleneck via limits on contributions and legal hurdles that make it hard for individuals to contribute without inviting FBI scrutiny of their connections (the real message behind the Chung prosecution). These are partisan approaches, and are targeted at boosting party power while appearing to limit abuses.

Could it be that there are approaches that increase diversity, resilience, "edge democracy" [a la Gill's point], etc. rather than boosting party power?

If you read Downes and Mui's "Killer App" book, you are probably aware of Coase, the Nobel economist who noted that organizations' size is in proportion to transaction costs. Their point is that

digital technologies have driven down transaction costs, so organization size should be much smaller in the digital world. The trouble is that the current philosophies of campaign and campaign finance reform are based on non-digital approaches. What will drive out the parties' control of power is the use of digital technologies to eliminate transaction costs at all points in the political process.

The answer would have to be a network where control is _decentralized_. As in the Internet, such a structure could never _guarantee_ lack of abuse, but it might compensate by creating opportunities for dynamics that could _circumvent_ abuse when it happens. For example, how would one break DeLay's monopoly on funds flow?

The real barriers to fighting DeLay used to be the difficulty of assembling coalitions that can assist in delivering campaign messages, via money, etc.

Now the 'net reduces delay in forming affiliations, and should thus limit DeLay's power and that of those like him.

I'd like to see groups like "moveon.org" be able to fund candidates directly, whatever party they belong to, in a transparent way. That is, to fund candidates that are dedicated to the goals of the affiliation. If moveon can't do so, perhaps it can provide a place where candidates who support its short-term agenda can ask voters directly for funds through links, etc.

It is not necessary for moveon to actually receive the funds itself, but instead to act as a link to sites of candidates who would like the funds. Those links could even be bi-directional, allowing the candidates to request additional support from interested supporters.

And here's the neat thing: the sites like moveon may not have to disclose their membership lists of potential contributors - those contributors could remain anonymous until they actually contribute. Think about what this means in terms of transferring power to individual funders.

This is not a PAC, because it holds no actual campaign funds, but instead maintains a real-time linkage between interested funders and candidates that the site (call it a PAN for "Political Action Nexus") has links with.

Why does this improve control? Because funds contributed to a party are intermingled as the party wishes. I may not like large tax bills, so I may contribute to the republicans. But I hate the Christian right, and the funds are redirected to abortion haters even against my will.

In the digital world, things like "the cost of mailings" and need for a budget reserve are much less than in traditional politics.

What we still need is a way to limit abuse, though. The likely solution is "transparency", following on another recent book, The Transparent Society by David Brin. If all transactions to fund campaigns are published, with no anonymity allowed, I believe that all the other mechanisms of the information society will work to reduce abuse to a tolerable level.

Can we achieve such a structure? I'd like to think that pragmatic Americans can do so, because it fits with our basic ethics and philosophy of government.

But there will be resistance, mostly from those who gain power from the current structure, on all sides.

- David

WWW Page: http://www.reed.com/dpr.html

--

Jock Gill
www.penfield-gill.com
Infrared Internet Vision

12-30-98

copied Podesta opening

"Financial Solutions For The 21st Century"

Wall Street Project

Small Business Investment Company (SBIC)

- **Program established in 1958 to address the gap in capital for long term financing of smaller growth oriented businesses in the $500K to $5 million range.**

- **Under SBIC program, SBA licenses, fund venture capital investment firms. Funds n through SBA guarantees are referred to a equal 2 to 3 times the invested private cap decisions are made by the SBIC. The priv is always at risk ahead of the funds guara**

- **Minimum equity capital requirements are**

  - **Participating Securities:**
  - **Debenture Program:**

- **Currently: 320 SBICs $7.5 Billion Capital Resources**
  39 Years Provided $17 Billion 113,000 Financings
  80,000 Small Business Concerns

- **SBICs Minority & Women Ownership**

Women:	**2**	**African American:**	**0**
Hispanic:	**1**	**Asian American:**	**0**
		Native American:	**0**

12-30-98

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- **Minimum equity capital requirements are:**

  - **Participating Securities: $10 million**
  - **Debenture Program: $ 5 million**

- **Currently: 320 SBICs $7.5 Billion Capital Resources**
  39 Years Provided $17 Billion 113,000 Financings
  80,000 Small Business Concerns

- **SBICs Minority & Women Ownership**

Women:	**2**	**African American:**	**0**
Hispanic:	**1**	**Asian American:**	**0**
		Native American:	**0**

O. Turner & Associates

"Financial Solutions For The 21st Century"

Wall Street Project

12-30 98

Small Business Lending Company (SBLC)

- **Established in 1975 to promote small business access to capital**
- **SBLCs are non-depository lenders who enter into participation agreements with the U.S. Small Business Administration (SBA) to provide business loans to qualified small businesses.**
- **Currently, there are fourteen (14) SBLCs in existence which account for as much as 10 percent of SBA's FY 1997 loan volume and 20 percent of its dollar volume.**
- **A moratorium was placed on licensing new SBLCs in 1982 due to concerns over SBA's capacity to adequately monitor.**
- **SBA had planned to expand this program as a result of focusing on the New Markets (Minorities, women & veterans) small businesses located in rural, distressed or inner cities and exporting.**
- **SBLCs Minority & Women Ownership**

Women:	**0**	**African American:**	**0**
Hispanic:	**0**	**Asian American:**	**0**
		Native American:	**0**

PRELIMINARY AND CONFIDENTIAL -- NOT FOR DISTRIBUTION

AMERICA'S UNTAPPED MARKETS AGENDA
DRAFT -- As of December 29, 1998

Background:

Following a series of meetings between White House, Cabinet Officials, and the Reverend Jesse Jackson, President Clinton directed his National Economic Council (NEC) to convene a high-level working group, including the Small Business Administration (SBA), Treasury Department (TR), Department of Housing and Urban Development (HUD), Department of Commerce (CM), and the Office of the Vice President (OVP), and the Office of Management and Budget (OMB), to consider whether there was more that the government could do:

- to act as a catalyst for greater private sector economic activity in America's untapped markets; and

- to build the capacity of community-based institutions that provide credit, equity, and technical assistance for economic development in underserved areas.

In addition, the Vice President specifically challenged the SBA to find ways to better serve the needs of minority and underserved communities.

The NEC-led working group consulted widely -- within the government and with investment professionals trying to work in underserved markets, Reverend Jackson himself, and other urban advocay groups -- about the strengths and weaknesses of existing programs, including the SBA's Small Business Investment Company (SBIC) program. They found that, while the SBIC program has been successful in stimulating venture capital investments that have allowed small businesses to grow, it has not been used to a significant degree in underserved markets. Improvements were needed to encourage investors to use SBICs to make investments in underserved areas, to allow for larger investments in the kind of larger firms that can serve as the anchor for a neighborhood revitalization, and to deal with the needs of smaller firms that needed not only equity investment, but also management capacity and support, in order to take advantage of business opportunities.

Description of Initiative

In response to these findings, the NEC Working Group on Untapped Markets developed the eight-part agenda described below. The plan calls for new or expanded programs that, in total, will leverage billions in new investment for inner cities and rural areas like Appalachia.

PRELIMINARY AND CONFIDENTIAL -- NOT FOR DISTRIBUTION

Elements of the agenda are undergoing final Administration review in preparation for a January announcement. Exact numbers are still being worked out, subject to overall budget constraints. Program names, elements, and details are subject to change.

1. ***A New "Untapped Market Investment Tax Credit"*** – Tax credits would be available for qualified equity investments made in selected targeted investment vehicles. An investor could receive total tax credits up to a fixed percentage of her investment. The program will be designed so that investors will have as much certainty as possible about the investment's eligibility for the credit prior to making their investment decisions. Investment vehicles created under most programs in the Untapped Market Agenda, as well as other community development investments, will be eligible to apply for the credit.

2. ***A New SBIC-Like Program for Larger Firms*** – In response to concerns that the SBICs were too limited in size to meet the need for larger-scale investment in underserved areas, the President will propose a new program to stimulate equity investments in larger-scale businesses in, or relocating to, central cities or rural areas. This new program will provide government guarantees on debt up to two times the amount of equity investment allowing several investment firms each with up to $300 million to invest. The program will be jointly administered by HUD and SBA, bringing SBA's business investment expertise together with HUD's expertise on large scale urban revitalization. (Program name could be something like "America's Private Investment Companies (APICs).)

3. ***New Markets Venture Capital Firms ("NMVC")*** – A new program at SBA designed to help small-sized firms in underserved areas that have market opportunities to grow, but need not only investment but also technical assistance to take advantage of their market opportunity. Investors will get government guarantees on debt matching the level of equity investment, provided they also match technical assistance and administer it to the business to support the investment. The program should provide long-term, patient growth capital and facilitate critically needed technology and management skills development for these firms.

4. ***SBIC Targeting for Underserved Areas*** -- In a video hookup to a Trillion Dollar Roundtable event in New York City last summer, the Vice President specifically challenged the SBA to find ways to meet better the needs of minority firms and underserved markets. In response, SBA developed:

    a. ***An Outreach Plan to Meet the Capital Needs of Inner City and Rural Businesses:*** SBA will hold a series of workshops throughout the country to educate the business and investment community about the SBIC program and to promote the formation of SBICs focused on equity capital for underserved areas.

b. ***New SBICs Targeted to Underserved Areas:*** Under program changes to the existing SBIC program, investors will get a new form of patient government-guaranteed debt leverage equal to their equity investment and get more favorable regulatory treatment if they invest in businesses in underserved areas (or which draw a significant proportion of its employees from those areas).

5. ***New Markets Lending Companies ("NMLC")*** -- For the first time in many years, SBA will approve new 7(a) non-bank lenders (firms authorized to originate SBA-guaranteed loans) but the firms selected must have a plan to target their lending to underserved areas.

6. ***A Microenterprise Investment Strategy:*** In many underserved areas, fostering opportunities for the smallest of entrepreneurs can help to build the job base and provide economic stability to a community. The President's budget calls for a two and a half increase in funding for technical assistance and lending to very small businesses.

7. ***Continued Growth for CDFIs:*** The President's initiative to develop community development financial institutions, locally-based institutions with expertise in lending and investment in underserved areas, will continue to grow with a $15 million increase.

8. ***BusinessLink:*** The President's budget will include seed money for an innovative public-private partnership spearheaded by the Vice President and CEOs to demonstrate the business benefits to large firms if they to help develop the capacity of small and minority business partners. Funding would support demonstrations throughout the country.

Possible Private Sector Response:

In response, private investment managers may create vehicles that would target underserved markets. Large, national investment funds could invest in various investment vehicles set up to participate in the NMVC program and the new SBIC-like programs targeted to underserved areas, CDFIs, direct investments in underserved markets, and other non-targeted investments.

Tentative Announcement Plans:

Assuming final budget approval, the untapped market agenda may be announced by the President with Reverend Jackson at the Wall Street Project event on January 15th (Martin Luther King's Birthday). Other senior Administration officials, including possibly Secretaries Rubin and Cuomo, Administrator Alverez, and NEC Director Gene Sperling, also will be there either to speak or to provide more detail and promote the initiative.

JIMMY CARTER

12.30.98

December 21, 1998

To President Bill Clinton

I realize that you have other things on your mind, but I'd like to bring to your personal attention the most serious crisis among farmers that I have witnessed since the Great Depression. I have discussed this issue with Secretary Glickman last week, and am convinced that only direct action by you can resolve the problem.

Hog farmers are faced with almost immediate disaster, with prices having fallen from a high of 43 cents/pound down to the most recent public sale in South Georgia of 8-1/2 cents. As you well know from your years as governor of Arkansas, there is an inexorability of production and then sale of mature hogs that forces farmers to accept whatever the market offers. At the same time, they have to continue buying feed for their remaining brood stock.

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What about this
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BR

The Honorable Bill Clinton
The President of the United States
The White House
Washington, D.C. 20500-2000

Cc: Secretary Dan Glickman
Vice-President Al Gore

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Sperling
Glickman
Podesta

12-30 98

Jennings
Podesta
Burkhardt - for reply

Preventive Medicine Research Institute

A non-profit public institute dedicated to research, education, and service

Dean Ornish, M.D.
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Preventive Medicine Research Institute
Clinical Professor of Medicine
School of Medicine, University of California, San Francisco
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Sausalito, California 94965
phone: 415/332-2525 x222; FAX: 415/332-5730
e-mail: DeanOrnish@aol.com

December 18, 1998

TO: Friends of PMRI (The Preventive Medicine Research Institute)

FROM: Dean Ornish, M.D. Dean Ornish

My colleagues and I at PMRI have made considerable progress during the past several months. We are excited by what we are accomplishing and want to share it with you.

REVERSING HEART DISEASE

Lifestyle Heart Trial

The Lifestyle Heart Trial was the first study to demonstrate that heart disease is often reversible by making comprehensive changes in diet and lifestyle. The original study was one year in duration.

In our research, we found that within a few weeks after making comprehensive lifestyle changes, the patients in our research reported a 91 percent average reduction in the frequency of angina. Most of the patients became essentially pain-free, including those who had been unable to work or engage in daily activities due to severe chest pain. Within a month, we measured increased blood flow to the heart and improvements in the heart's ability to pump. And within a year, even severely blocked coronary arteries began to improve in 82% of the patients. These research findings were published in the most well-respected peer-reviewed medical journals, including *The Lancet, Circulation, The Journal of the American Medical Association The American Journal of Cardiology,* and others.

One of the most meaningful findings in our research has been that the major determinant of improvement was neither age nor disease severity but rather how much people changed their lifestyles. When I began the Lifestyle Heart Trial, I believed that the younger patients with milder disease would be more likely to show regression, but I was wrong. Instead, the primary determinant of change in their coronary artery disease was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. No matter how old they were, on average, the more people changed, the better they became. Indeed, the oldest patient in our study showed more reversal than anyone. This is a very hopeful message, since the risks of bypass surgery and angioplasty increase with age, but the benefits of comprehensive lifestyle changes may occur at any age.

With support from the National Heart, Lung, and Blood Institute of the National Institutes of Health, my colleagues and I extended our study from one year to five years. Earlier this week, *The Journal of the American Medical Association* published our five-year research findings. These findings were widely reported in the media, including the Associated Press, Today Show, *Boston Globe, Wall Street Journal, Los Angeles Times, Washington Post*, CNN, and so on.

We found that most of the study participants were able to maintain comprehensive lifestyle changes for five years. On average, they demonstrated even more reversal of heart disease after five years than after one year. In contrast, the patients in the comparison group who made only the moderate lifestyle changes recommended by most physicians (i.e., a 30% fat diet) worsened after one year and their coronary arteries became even more clogged after five years. These findings add important scientific evidence and credibility to our program. Also, we found that the incidence of cardiac events (e.g., heart attacks, strokes, bypass surgery, and angioplasty) was 2.5 times lower in the group that made comprehensive lifestyle changes after five years.

Multicenter Lifestyle Demonstration Project

The idea that the progression of heart disease is often reversible—a radical idea when I conducted my first study 21 years ago—has become mainstream and generally accepted by most cardiologists. The next question was: how practical is this lifestyle program?

Beginning five years ago, my colleagues and I established the Multicenter Lifestyle Demonstration Project. It was designed to determine (a) if we could train other teams of health professionals in diverse regions of the country to motivate their patients to follow our program of comprehensive lifestyle changes; (b) if this lifestyle program may be an equivalently safe and medically effective but more cost-effective alternative to bypass surgery and angioplasty in selected patients with severe but stable coronary artery disease; and (c) the resulting cost savings. In other words, can patients avoid bypass surgery and angioplasty by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

Data from 15 different sites indicate that the program is working. Our program is both medically effective and cost-effective in significantly reducing health care expenditures.

In the past, lifestyle interventions have been viewed as prevention, increasing costs in the short run for a possible savings years later. In the new model we are studying, our program is offered as an alternative treatment to many patients (with their doctor's permission and oversight) who otherwise were eligible for coronary artery bypass surgery or angioplasty, thereby resulting in an *immediate* and *substantial* cost savings.

We found that almost 80% of patients who were eligible for bypass surgery or angioplasty were able to avoid it by changing diet and lifestyle. Mutual of Omaha calculated an average savings of $29,529 per patient. These patients reported reductions in angina comparable to what can be achieved with bypass surgery or angioplasty.

These findings were published last week in the *American Journal of Cardiology*. Now that we are demonstrating the cost-effectiveness of our approach, over forty other insurance companies are now reimbursing the cost of our program at the hospitals we have trained.

MEDICARE

Because of the success of our demonstration project, the Health Care Financing Administration (HCFA) conducted their own internal peer review of our lifestyle program. HCFA is now planning to move forward with a demonstration project to determine the medical effectiveness of our program in the Medicare population. I have been in dialogue with HCFA for over four years, so this represents a major step forward. If they validate the cost savings that we have already shown in the Multicenter Lifestyle Demonstration Project, then they may decide to cover this program as a defined benefit for all Medicare beneficiaries. If this happens, then most other insurance companies may do the same, thereby making the program available to the people who most need it. Medicare coverage also affects medical training and education. If we demonstrate the cost-effectiveness of our program in the Medicare population, we will provide a new model for lowering Medicare costs without compromising the quality of care or access to care.

CAN PROSTATE CANCER BE SLOWED, STOPPED, OR REVERSED BY CHANGING LIFESTYLE?

We are conducting the first randomized controlled trial to determine if prostate cancer may be affected by making comprehensive changes in diet and lifestyle, without surgery, radiation, or drug (hormonal) treatments.

The scientific evidence from animal studies, epidemiological studies, and anecdotal case reports in humans is very similar to the way it was with respect to coronary heart disease when I began conducting research in this area over twenty years ago. For example, the incidence of clinically significant prostate cancer (as well as heart disease, breast cancer, and colon cancer) is much lower in parts of the world that eat a predominantly low-fat plant-based diet. Subgroups of people in the U.S. who eat a low-fat plant-based diet also have much lower rates of prostate cancer and breast cancer than those eating a typical American diet.

This study is being conducted in collaboration with William Fair, M.D. (Professor and recent Chairman of Urology at Memorial Sloan-Kettering Cancer Center in New York) and with Peter Carroll, M.D. (Chairman, Department of Urology, UCSF School of Medicine). We received approval from the Protocol Review Committee of the Cancer Research Center at UCSF and approval from the Committee on Human Research at UCSF. We have recruited 55 of the 130 patients for this study.

Because of these epidemiological, animal, and anecdotal human data, I am encouraged by the possibility of being able to determine if the progression of prostate cancer may be modified in humans. If we are successful in demonstrating the reversibility of prostate cancer, the implications for helping to prevent prostate cancer may be of equal importance. Also, these findings may extend to some other forms of cancer, including breast cancer and colon cancer, both of which have been linked to high-fat diets. We have the opportunity to determine the effects of diet and comprehensive lifestyle changes on prostate cancer without confounding variables, a study that would not be ethically possible in breast cancer, colon cancer, or related illnesses. Whatever we show, the data will be of wide interest.

In our study, patients are tested with PSA levels and free PSA levels twice at baseline and again every three months thereafter for one year. Additional tests include MRI and MR spectroscopy

scans of the prostate to determine tumor size and activity. These are performed at baseline and after one year.

The intervention began in April 1997. While it is too soon to draw any definitive conclusions, our preliminary data are encouraging. I presented our preliminary findings at the annual national scientific meeting of the American Urological Association on June 2nd in San Diego. We are extending the study for one more year (for a total of two years) to determine if these trends continue over time.

CAN LIFESTYLE CHANGES PREVENT HEART TRANSPLANTS?

In the Multicenter Lifestyle Demonstration Project, four patients with such severe heart disease that they were on the heart transplant list (ischemic cardiomyopathies) improved sufficiently that they were able to get off the heart transplant list. This improvement was not only clinically but also objectively verified by cardiac PET scans and/or echocardiograms.

Based on the encouraging data from this small number of patients, we propose to conduct a randomized controlled trial to determine more conclusively if comprehensive lifestyle changes may prevent the need for heart transplants in selected patients. Many of these patients are highly motivated, since they are just waiting for a donor to become available.

Eligible patients will be randomly assigned to an experimental group who receives the comprehensive lifestyle change intervention or a control group who does not. Both groups would be tested with echocardiograms and PET scans at baseline and after one year. A heart transplant costs several hundred thousand dollars, so the cost savings would be dramatic if patients can avoid it. Also, a heart transplant often lasts only a few years before the patient needs another one.

In some respects, this study represents the ultimate high tech/low tech juxtaposition: to determine if comprehensive lifestyle changes can be a scientifically valid alternative to a heart transplant.

RETREATS

To make our program more widely available, we at PMRI will offer week-long residential retreats in 1999. The goal of these retreats is to provide both the information and the experience of how powerful comprehensive lifestyle changes can be. These retreats are for anyone who wishes to learn more about our program. For more information, please call 1-800-775-7674 x 221.

THANKS FOR YOUR SUPPORT

My colleagues and I love doing this work and feel very thankful to those who make it possible. It provides us with a strong sense of meaning and gratitude to know that this work is making a difference in the lives of so many people who may be helped by it, and we hope you share these good feelings. All contributions are tax deductible under section 501(c)(3) of the IRS code. Please accept our sincere and heartfelt appreciation for your interest and support.
We wish you a holiday season and a new year filled with health, joy, and love.

Intensive Lifestyle Changes for Reversal of Coronary Heart Disease

Dean Ornish, MD; Larry W. Scherwitz, PhD; James H. Billings, PhD, MPH; K. Lance Gould, MD; Terri A. Merritt, MS; Stephen Sparler, MA; William T. Armstrong, MD; Thomas A. Ports, MD; Richard L. Kirkeeide, PhD; Charissa Hogeboom, PhD; Richard J. Brand, PhD

Context.—The Lifestyle Heart Trial demonstrated that intensive lifestyle changes may lead to regression of coronary atherosclerosis after 1 year.

Objectives.—To determine the feasibility of patients to sustain intensive lifestyle changes for a total of 5 years and the effects of these lifestyle changes (without lipid-lowering drugs) on coronary heart disease.

Design.—Randomized controlled trial conducted from 1986 to 1992 using a randomized invitational design.

Patients.—Forty-eight patients with moderate to severe coronary heart disease were randomized to an intensive lifestyle change group or to a usual-care control group, and 35 completed the 5-year follow-up quantitative coronary arteriography.

Setting.—Two tertiary care university medical centers.

Intervention.—Intensive lifestyle changes (10% fat whole foods vegetarian diet, aerobic exercise, stress management training, smoking cessation, group psychosocial support) for 5 years.

Main Outcome Measures.—Adherence to intensive lifestyle changes, changes in coronary artery percent diameter stenosis, and cardiac events.

Results.—Experimental group patients (20 [71%] of 28 patients completed 5-year follow-up) made and maintained comprehensive lifestyle changes for 5 years, whereas control group patients (15 [75%] of 20 patients completed 5-year follow-up) made more moderate changes. In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year (a 4.5% relative improvement) and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement). In contrast, the average percent diameter stenosis in the control group increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening) ($P = .001$ between groups. Twenty-five cardiac events occurred in 28 experimental group patients vs 45 events in 20 control group patients during the 5-year follow-up (risk ratio for any event for the control group, 2.47 [95% confidence interval, 1.48-4.20]).

Conclusions.—More regression of coronary atherosclerosis occurred after 5 years than after 1 year in the experimental group. In contrast, in the control group, coronary atherosclerosis continued to progress and more than twice as many cardiac events occurred.

JAMA. 1998;280:2001-2007

From the Department of Medicine (Dr Ornish), and the Division of Cardiology (Dr Armstrong), California Pacific Medical Center, San Francisco; the Department of Medicine (Dr Ornish), the Division of Cardiology, Cardiac Catheterization Laboratory, Cardiovascular Research Institute (Dr Ports), and the Division of Biostatistics (Drs Brand and Hogeboom), School of Medicine, University of California, San Francisco; the Division of Cardiology, University of Texas Medical School, Houston (Drs Gould and Kirkeeide); and the Preventive Medicine Research Institue, Sausalito, Calif (Drs Ornish Scherwitz, and Billings, Mr Sparler, and Ms Merritt).

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THE LIFESTYLE Heart Trial was the first randomized clinical trial to investigate whether ambulatory patients could be motivated to make and sustain comprehensive lifestyle changes and, if so, whether the progression of coronary atherosclerosis could be stopped or reversed without using lipid-lowering drugs as measured by computer-assisted quantitative coronary arteriography. This study derived from earlier studies that used noninvasive measures.[1,2]

After 1 year, we found that experimental group participants were able to make and maintain intensive lifestyle changes and had a 37.2% reduction in low-density lipoprotein (LDL) cholesterol levels and a 91% reduction in the frequency of anginal episodes.[3] Average percent diameter stenosis regressed from 40.0% at baseline to 37.8% 1 year later, a change that was correlated with the degree of lifestyle change. In contrast, patients in the usual-care control group made more moderate changes in lifestyle, reduced LDL cholesterol levels by 6%, and had a 165% increase in the frequency of reported anginal episodes. Average percent diameter stenosis progressed from 42.7% to 46.1%.

Given these encouraging findings, we extended the study for an additional 4 years to determine (1) the feasibility of patients sustaining intensive changes in diet and lifestyle for a much longer time, and (2) the effects of these changes on risk factors, coronary atherosclerosis, myocardial perfusion, and cardiac events after 4 additional years.

METHODS

The design, recruitment, and study population were previously described.[3-5] In brief, we recruited men and women

Table 1.—Baseline Characteristics of Experimental and Control Groups*

Characteristic	Experimental (n = 20)	Control (n = 15)	P Value
Men, No.	20	12	.07
Women, No.	0	3	
Age, mean (SD), y	57.4 (6.4)	61.8 (7.5)	.08
Education, mean (SD), y	15.5 (2.7)	14.5 (3.4)	.29
Employed, No.	14	6	.10
Body mass index, mean (SD), kg/m²	28.4 (4.1)	25.4 (3.5)	.03
No. with history of myocardial infarction	12	5	.17
Average No. of lesions studied, mean (SD)	5.3 (2.7)	5.3 (3.2)	.93
No. with history of percutaneous transluminal coronary angioplasty	5	4	>.99
No. with history of coronary artery bypass graft	1	0	>.99
Reported angina, No. (%)	11 (55)	6 (40)	.49

*Values are statistics unless otherwise indicated. P values are 2-tailed.

with coronary atherosclerosis documented by quantitative coronary arteriography.

We identified 193 patients as potentially eligible for our study who agreed to undergo quantitative coronary angiography. Following angiography, 93 patients remained eligible and were randomly assigned to experimental or control groups using a randomized invitational design to minimize crossover, ethical concerns, nocebo effects, and dropout. Of these 93 patients who were eligible, 53 were randomly assigned to the experimental group and 40 to the usual-care control group. Patients were then contacted and invited to participate in the study; 28 (53%) and 20 (50%) agreed to participate in the experimental and control groups, respectively. The primary reason for refusal in the experimental group was not wanting to undergo intensive lifestyle changes and/or not wanting a second coronary angiogram; control patients refused primarily because they did not want to undergo a second angiogram. To detect possible selection biases, we collected data on age, marital status, reported angina, history of myocardial infarction, height, weight, number of diseased lesions, and stenosis severity for all patients who were randomized into the study but refused to participate. We did not exclude any experimental group patients who volunteered even if we doubted their ability to adhere to the lifestyle program. All patients who volunteered were followed up using the intention-to-treat principle.

After 1 year, 7 patients did not provide angiographic data, and the reasons for loss to follow-up have been reported.[3] Of the remaining 41 patients at baseline most had severe coronary atherosclerosis: 28 had 3-vessel disease, 12 had 2-vessel disease, and 1 had 1-vessel disease. Two of these patients whose angiographic data were not usable after 1 year agreed to undergo quantitative coronary arteriography after 5 years; these results are included in the baseline to 5-year comparisons.

Four experimental and 4 control patients who had an angiogram at 1 year did not have a third angiogram after 5 years. Three of these 4 patients in the experimental group refused a third angiogram (patients only volunteered for a 1-year study that was subsequently extended), and 1 died between years 1 and 4; of the 4 control group patients who did not undergo a third angiogram, 1 died, 2 underwent revascularization of the arterial lesions under study, and 1 developed Parkinson disease and became too ill to be safely tested. Cine arteriograms made in San Francisco, Calif, were sent to the University of Texas Medical School, Houston, for blinded quantitative analyses as previously described in detail.[4]

All results, except lesion changes at 1 year (18 experimental and 15 control subjects) and cardiac events after 5 years (all 28 experimental and 20 control subjects), are based on the total of 35 patients (20 experimental and 15 control subjects) who had both baseline and 5-year angiograms. From these 35 patients, there were 224 lesions studied at baseline, of which 24 were 100% occluded and were excluded a priori from the lesion-change analyses per the study protocol. Of the remaining 200 lesions, 14 were lost to the 4-year follow-up, as follows: in the experimental group, 2 lesions were excluded due to technical failure during the angiogram and 2 had views that did not match; in the control group, views did not match for 3 lesions, 3 lesions were excluded due to technical failure, 1 was excluded due to angioplasty, and 3 were excluded due to coronary artery bypass surgery. Of the 186 lesions available for analysis at 4 years, 109 were from the experimental group and 77 were from the control group.

The 1-year original study and the 4-year extension were approved by the committees on human research at California Pacific Medical Center and University of California, San Francisco, and each patient signed a written consent form after being fully informed of the study requirements.

Patients completed a 3-day diet diary at baseline and after 1 and 5 years to assess nutrient intake and dietary adherence.[6] Methods of lipid assays were the same as previously reported.[3] These 3-day diet diaries were analyzed with a software package (CBORD Diet Analyzer; CBORD Group Inc; Ithaca, NY) using the US Department of Agriculture database. Also, patients were asked to complete a questionnaire reporting the frequency and duration of exercise and of each stress management technique. Information from these sources was quantified into continuous scores using an a priori determined formula. The adherence measure was a continuous score reflecting daily intake of cholesterol (in milligrams), fat (in grams), frequency and duration of exercise, frequency and duration of stress management techniques, and smoking. A score of 1.0 equalled 100% adherence but scores could be greater than 1.0 if participants exceeded the recommended intensive lifestyle changes.

The technicians responsible for performing all medical tests were blinded to patient group assignment. Also, different personnel implemented the lifestyle intervention, conducted the tests, and computed statistical analyses, although the dietitian was made aware of the nutrient analysis to monitor patients' safety and adherence. Quantitative coronary arteriograms were blindly analyzed without knowledge of group assignment.

Program Intervention

Experimental group patients were prescribed an intensive lifestyle program that included a 10%-fat vegetarian diet, moderate aerobic exercise, stress management training, smoking cessation, and group psychosocial support previously described in detail.[3,7-10] Patients were encouraged to avoid simple sugars and to emphasize the intake of complex carbohydrates and other whole foods. Only 1 patient in the experimental group was actively smoking at baseline, and she quit at entry. Control group patients were asked to follow the advice of their personal physicians regarding lifestyle changes.

Statistical Methods

We decided a priori to use percent diameter stenosis as the primary dependent variable. Statistical methods to compare the 2 groups were previously described.[3] Analysis of adherence variables and risk factor levels used time-structured repeated measures in which levels from all 3 measurement times (baseline, 1 year, and 5 years) were in-

Table 2.—Adherence to Exercise, Stress Management, and Dietary Guidelines

	Mean (SEM) at Baseline		Mean (SEM) at 1 Year			Mean (SEM) at 5 Years		
	Experimental (n = 20)	Control (n = 15)	Experimental (n = 20)	Control (n = 15)	P Value* Baseline-1 Year	Experimental (n = 20)	Control (n = 15)	P Value* Baseline-5 Years
Exercise								
Times per week	2.66 (0.84)	2.38 (0.77)	4.97 (0.35)	2.87 (0.70)	.06	4.34 (0.49)	3.57 (0.56)	.64
Hours per week	2.26 (0.85)	2.42 (0.99)	5.02 (0.61)	2.52 (0.70)	.12	3.56 (0.56)	2.90 (0.65)	.50
Stress management								
Times per week	0.70 (0.41)	0.15 (0.10)	8.22 (0.73)	0.49 (0.25)	<.001	4.93 (1.02)	0.74 (0.39)	<.001
Minutes per day	6.01 (3.56)	1.71 (1.19)	87.25 (7.85)	4.47 (2.79)	<.001	48.53 (10.36)	8.44 (6.11)	.001
Fat intake								
Grams per day	63.67 (4.35)	57.42 (5.94)	12.71 (1.06)	52.38 (5.31)	<.001	17.34 (2.30)	44.09 (6.66)	<.001
% of Energy intake	29.71 (1.8)	30.52 (2.9)	6.22 (0.3)	28.76 (2.3)	<.001	8.51 (1.0)	25.03 (2.7)	<.001
Dietary cholesterol, mmol/L [mg/dL]	5.47 (0.672) [211.4 (26.0)]	5.49 (0.908) [212.5 (35.1)]	0.08 (0.002) [3.3 (0.8)]	4.69 (0.636) [181.3 (24.6)]	<.001	0.48 (0.140) [18.6 (5.4)]	3.59 (0.641) [138.7 (24.8)]	.002
Energy intake, J/d	8159 (473)	7159 (489)	7623 (473)	7004 (489)	.64	7724 (485)	6581 (489)	.86
Total adherence score†	0.62 (0.08)	0.60 (0.07)	1.29 (0.08)	0.64 (0.07)	<.001	1.06 (0.08)	0.72 (0.07)	<.001

*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.
†Percentage of minimum recommended level of combined lifestyle change; includes all the above plus smoking cessation.

Table 3.—Baseline Levels, 1-Year, and 5-Year Change Scores in Coronary Artery Lesions*

	Mean at Baseline (95% CI)		Change Scores at 1 Year (95% CI)			Change Scores at 5 Years (95% CI)		
	Experimental (n = 20)	Control (n = 15)	Experimental (n = 18)	Control (n = 15)	P Value† Baseline-1 Year	Experimental (n = 20)	Control (n = 15)	P Value† Baseline-5 Years
Diameter stenosis, %	38.92 (35.29 to 42.54)	42.50 (38.18 to 46.81)	−1.75 (−4.08 to 0.58)	2.28 (−3.0 to 4.86)	.02	−3.07 (−5.91 to −0.24)	11.77 (3.40 to 20.14)	.001
Minimum diameter, mm	1.64 (1.44 to 1.84)	1.74 (1.50 to 1.97)	0.01 (−0.10 to 0.12)	−0.12 (−0.25 to −0.001)	.11	0.001 (−0.11 to 0.11)	−0.34 (−0.66 to −0.02)	.05
Normal diameter, mm	2.65 (2.39 to 2.92)	2.96 (2.64 to 3.27)	−0.06 (−0.16 to 0.03)	−0.10 (−0.27 to 0.06)	.68	−0.13 (−0.26 to 0.01)	0.045 (0.017 to 0.072)	.01

*CI indicates confidence interval.
†All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

cluded in a single regression model. Statistical significances of group differences were obtained for baseline levels, 1-year changes, and 5-year changes using F tests. All repeated measures analyses were implemented using PROC MIXED under SAS version 6.08.[11] Analysis of lesion data used a repeated measures model in which the repeated measures were baseline or change values for multiple lesions within each subject. Change scores were used for the baseline to 1-year and baseline to 5-year follow-up periods, and analysis of baseline levels, 1-year changes, and 5-year changes were done separately. Again, F tests provided by SAS PROC MIXED were used to test significance of differences between groups with respect to baseline levels, 1-year changes, and 5-year changes. The SAS PROC MIXED linear regression, which allowed for dependence in data, was used to determine the relationship between adherence and percent diameter stenosis changes. Relative rates for cardiac events were analyzed and tested by Poisson regression using exact tests (Stata 5.0, College Station, Tex).

RESULTS

Baseline Comparisons of Volunteers With Refusals

Those who declined the invitation to be in the study were similar to those who volunteered in all available data except those who volunteered were more likely to have a history of angina (87% vs 65%; $P = .02$), a greater number of lesions (4.5 vs 3.5; $P = .04$), and slightly more severely stenosed lesions (2.3 vs 2.0 on a 3-point scale; $P = .05$).

Baseline Comparisons of Experimental Group With Control Group

Analyses across the 35 volunteers at baseline for whom 4-year lesion data were available showed no significant differences between the experimental group and the control group in demographic characteristics, history of myocardial infarction, angioplasty, bypass surgery, lesion number, lesion stenosis, dietary fat or cholesterol intake, exercise and stress management practice, blood pressure, exercise capacity, and psychosocial measures (Tables 1-3).

Among the many comparisons, only a few differed significantly ($P<.05$). More women were randomly assigned to the control group (4) than to the experimental group (1); this fact accounted for half the weight difference (10 kg) between the 2 groups and most of the height difference (6 cm).

Experimental group patients had a slightly larger body mass index (measured as the weight in kilograms divided by the square of the height in meters) (28.4 vs 25.4 kg/m^2; $P = .03$) and had lower high-density lipoprotein (HDL) cholesterol levels (1.04 mmol/L [40.1 mg/dL] vs 1.36 mmol/L [52.4 mg/dL]; $P = .04$), which was also reflected in lower apolipoprotein A-I levels (3.45 mmol/L [133.1 mg/dL] vs 4.08 mmol/L [157.5 mg/dL]; $P = .03$). The lower body mass index in the control group may be due to the larger number of women in the control group. Other lipid values, including ratios of total cholesterol to HDL and LDL to HDL, did not differ significantly at baseline (Table 4).

Program Adherence

In the experimental group, adherence to all aspects of the program was excellent during the first year and good after 5 years, whereas control group patients maintained more moderate changes during the 5 years consistent with conventional guidelines (Table 2). The percentage of daily energy (calories) provided by fruits, vegetables, whole grains, soy, other legumes, nonfat dairy, and alcohol was comparable at 1 year and at 5 years. In the experimental group, fat intake decreased from approximately 30% to 8.5%, cholesterol from 211 to 18.6 mg/d, energy from 8159 to 7724 J (1950-1846 cal), protein from 17% to 15%, and carbohydrates increased from 53% to 76.5%. In

Table 4.—Changes in Risk Factors

Risk Factor	Mean (SEM) at Baseline		Mean (SEM) at 1 Year	
	Experimental (n = 20)	Control (n = 15)	Experimental (n = 20)	Control (n = 15)
Serum lipids, mmol/L [mg/dL]				
Total cholesterol	5.83 (0.31) [225.1 (11.9)]	6.42 (0.24) [247.9 (9.4)]	4.22 (0.22) [162.9 (8.4)]	6.33 (0.38) [244.3 (14.7)]
Low-density lipoprotein	3.72 (0.29) [143.80 (11.21)]	4.30 (0.19) [166.40 (7.46)]	2.24 (0.24) [86.56 (9.41)]	4.25 (0.38) [164.13 (14.85)]
High-density lipoprotein	1.04 (0.07) [40.05 (2.78)]	1.36 (0.14) [52.36 (5.54)]	0.94 (0.10) [36.28 (3.81)]	1.34 (0.10) [51.87 (3.81)]
Triglyceride	5.90 (0.69) [227.8 (26.5)]	5.78 (1.63) [223.3 (63.0)]	6.69 (0.75) [258.2 (29.1)]	4.30 (0.40) [166.1 (15.5)]
Apolipoproteins, g/L				
A-I	1.331 (0.046)	1.575 (0.092)	1.308 (0.057)	1.761 (0.121)
B	1.000 (0.054)	1.024 (0.062)	0.7685 (0.046)	1.085 (0.053)
Blood pressure, mm Hg				
Systolic	135.3 (4.0)	137.2 (4.5)	126.4 (3.9)	128.8 (4.5)
Diastolic	81.70 (2.05)	80.27 (3.15)	77.03 (2.01)	75.07 (8.15)
Weight, kg	91.40 (3.42)	75.74 (4.37)	80.64 (2.48)	77.18 (4.73)

*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

Table 5.—Reported Angina Symptoms

	Mean (SD) at Baseline		Mean (SD) at 1 Year			Mean (SD) at 5 Years		
	Experimental (n = 18)	Control (n = 14)	Experimental (n = 18)	Control (n = 14)	*P* Value* Baseline-1 Year	Experimental (n = 18)	Control (n = 14)	*P* Value* Baseline-5 Years
Chest pain frequency, times per week	5.8 (14.7)	1.4 (1.8)	0.5 (0.8)	4.0 (9.3)	.08	1.6 (2.7)	0.9 (1.9)	.32
Chest pain duration, min	3.1 (4.8)	3.2 (8.4)	1.8 (4.7)	7.6 (15.9)	.11	0.9 (1.3)	1.0 (2.7)	.93
Chest pain severity (1-7 scale)	1.5 (1.5)	0.6 (0.8)	0.7 (1.2)	1.4 (1.2)	<.001	0.9 (1.4)	0.6 (1.1)	.29

*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

the control group, fat intake decreased from 30% to 25%, cholesterol from 212.5 to 138.7 mg/d, energy from 5.49 to 3.59 J (1711-1573 cal), protein from 19% to 18%, and carbohydrates increased from 51% to 52%. Since patients volunteered originally only for a 1-year study, there was a significant decrease in meeting attendance after 1 year for 4 of the patients. Walking was the recommended form of exercise, but some patients jogged or did more strenuous exercise.

Risk Factor Changes

Patients in the experimental group lost 10.9 kg (23.9 lbs) at 1 year and sustained a weight loss of 5.8 kg (12.8 lbs) at 5 years, whereas weight in the control group changed little from baseline. In the experimental group, LDL cholesterol levels decreased by 40% at 1 year and remained 20% below baseline at 5 years. In the control group, LDL cholesterol levels decreased by 1.2% at 1 year and by 19.3% at 5 years. There were no statistically significant differences in LDL levels between the 2 groups at 5 years, primarily because 9 (60%) of 15 control patients took lipid-lowering drugs between year 1 and year 5 of the study. None of the experimental group patients took lipid-lowering drugs during the 5 years of the study. Fourteen patients in the experimental group and 11 patients in the control group took aspirin during the study.

Triglycerides did not change significantly in either group. Apolipoprotein A-I did not change in the experimental group, but it increased in the control group ($P = .04$). High-density lipoprotein levels and blood pressure did not differ between the 2 groups.

Angina Pectoris

Experimental group patients had a 91% reduction in reported frequency of angina after 1 year and a 72% reduction after 5 years (Table 5). In contrast, control group patients had a 186% increase in reported frequency of angina after 1 year and a 36% decrease in frequency after 5 years. The decrease in angina in the control group after 5 years was in large part because 3 of the 5 patients who reported an increase in anginal episodes from baseline to 1 year underwent coronary angioplasty between years 1 and 5. Because of this reduction in angina in control group patients who underwent revascularization, the between-group differences were no longer significant after 5 years (Table 5).

Angiographic Changes

All detectable lesions that matched at baseline and 5-year follow-up and were not 100% occluded at baseline were included in the analyses (n = 186). At baseline, there were no significant differences between the experimental and control groups in any measure of lesion severity (Table 3). In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year (a 4.5% relative improvement) and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement). In contrast, the average percent diameter stenosis in the control group increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening). These between-group differences were statistically significant after both 1 year and 5 years ($P = .02$ and $P = .001$, respectively, Figure 1).

Figure 2 shows the experimental group changes in percent diameter stenosis from baseline to 5 years according to tertiles of adherence to the lifestyle intervention. As seen at 1 year,[3] there was also a strong correlation between adherence and percent diameter stenosis after 5 years in a dose-response relationship; the tertile of patients that was most adherent to the program had the most regression, the tertile with intermediate adherence had less regression, and the tertile with the least adherence halted the progression of disease without regression ($P = .04$). Of interest is that this relationship was not related to age or disease severity. There was no significant relationship between adherence and lesion changes in the control group, perhaps because many of these patients began taking lipid-lowering drugs, which may have confounded the ability to detect a possible relationship. Indeed, we found significant correlations between changes in lipid levels (LDL and total cholesterol) and changes

P Value* Baseline-1 Year	Mean (SEM) at 5 Years: Experimental (n = 20)	Control (n = 15)	P Value* Baseline-5 Years
.004	4.87 (0.20) [188.0 (7.8)]	5.62 (0.20) [217.0 (7.9)]	.60
.003	2.99 (0.20) [115.35 (7.59)]	3.47 (0.21) [133.80 (8.25)]	.76
.35	0.90 (0.05) [34.75 (2.03)]	1.28 (0.12) [49.27 (4.47)]	.54
.17	6.11 (0.59) [236.1 (22.9)]	5.48 (0.78) [211.5 (30.2)]	.78
.11	1.302 (0.092)	1.839 (0.139)	.04
.004	1.014 (0.072)	0.991 (0.083)	.63
.96	130.0 (3.9)	123.3 (4.7)	.19
.91	76.63 (2.01)	73.61 (3.25)	.74
.001	85.64 (2.88)	77.09 (4.5)	.001

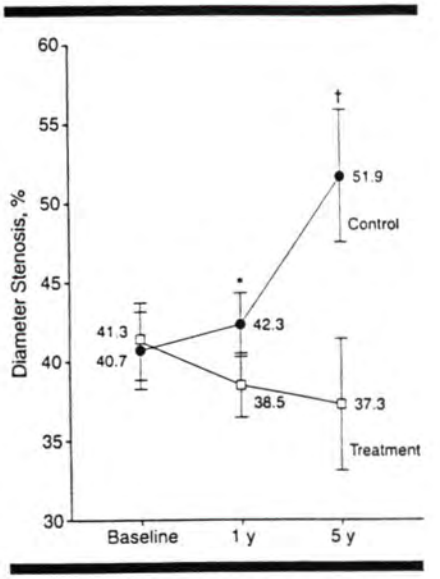

Figure 1.—Mean percentage diameter stenosis in treatment and control groups at baseline, 1 year, and 5 years. Error bars represent SEM; asterisk, $P = .02$ by between-group 2-tailed test; dagger, $P = .001$ by between-group 2-tailed test.

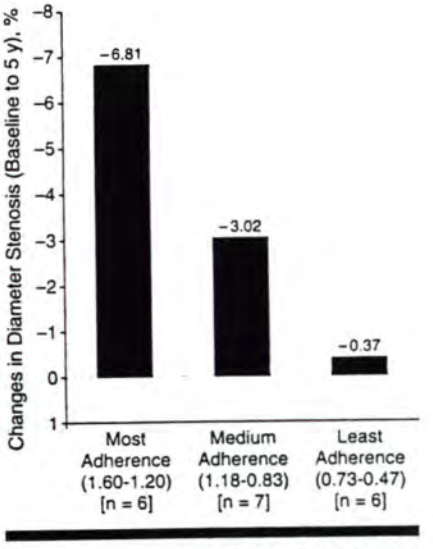

Figure 2.—Changes in percentage diameter stenosis by 5-year adherence tertiles for the experimental group.

in lesions in both groups. These correlations remained significant when examining either the lipid values at 5 years or the change in lipid values from baseline to 5 years.

As a secondary analysis, we examined the results in control group patients who began taking lipid-lowering drugs during the study. Percent diameter stenosis progressed from 45.7% to 51.7%, a change of 6.0 absolute percentage points. In the control patients who did not take lipid-lowering drugs the disease progressed from 40.7% to 59.7%, a much greater change of 19.0 absolute percentage points. (No experimental group patients took lipid-lowering drugs during the study.)

The change in body mass index from baseline to 1 year ($r = -0.85$; $P < .001$) and from baseline to 5 years ($r = -0.72$; $P = .001$) was significantly correlated with the change in percent diameter stenosis in the control group only. In other words, those who gained weight were more likely to show progression of atherosclerosis.

Cardiac Events

Data on cardiac events were obtained from all 48 patients. Cardiac events included myocardial infarction, coronary angioplasty, coronary artery bypass surgery, cardiac-related hospitalizations, and cardiac-related deaths. At 5 years, there were more cardiac events in the control group (45 events for 20 patients, or 2.25 events per patient) than the experimental group (25 events for 28 patients, or 0.89 events per patient) (Table 6). Control group patients were more likely to have undergone coronary angioplasty and bypass surgery and/or to have been hospitalized for cardiac-related problems than were experimental group patients.

COMMENT

The primary end point of this study, chosen a priori, was percent diameter stenosis. On average, there was more reduction (continued improvement) after 5 years than after 1 year in experimental group patients who were asked to make intensive lifestyle changes. In contrast, control group patients showed much more progression (continued worsening) in average percent diameter stenosis after 5 years than after 1 year, even though more than half of the control group patients were prescribed lipid-lowering medications during the course of the study. Although the sample size was relative small,[12] these differences were statistically significant at both 1 year and 5 years. These findings support the feasibility of intensive lifestyle changes in delaying, stopping, or reversing the progression of coronary artery disease in ambulatory patients over prolonged periods.

We found more than twice as many cardiac events per patient in the control group than in the experimental group. These findings are consistent with other clinical trials showing that even small changes in percent diameter stenosis are often accompanied by marked reductions in cardiac events.[13-16] Other studies have demonstrated how quickly the coronary artery endothelium stabilizes in response to lipid-lowering drugs.[17,18]

Although there was some reduction in adherence to the intensive lifestyle intervention between years 1 and 5 in the experimental group, long-term adherence remained remarkably high in this sample of self-selected patients. The level of lifestyle change, even at 5 years, is greater than in any other published study of ambulatory populations. These results are especially encouraging because these patients initially volunteered to participate for only 1 year when they entered the study.

The experimental group reduced LDL cholesterol levels by 40% at 1 year and by 20% after 5 years; these reductions are comparable with those achieved with lipid-lowering drugs in an ambulatory population.[19] In contrast, the Step II diet reduces LDL cholesterol by only 5% or less.[20,21]

High-density lipoprotein levels decreased and triglycerides increased in experimental group patients overall, although the ratio of LDL to HDL was improved. Recent reports assert that this phenomenon, which is often seen in very low-fat diets, may be harmful.[22,23] However, patients in the Lifestyle Heart Trial showed even more regression of coronary atherosclerosis after 5 years than after 1 year as well as significantly decreased cardiac events. Low

Table 6.—Cardiac Events During 5-Year Follow-up

	No. of Events				
	Experimental* (n = 28)	Control† (n = 20)	Risk Ratio	95% Confidence Interval	P Value
Myocardial infarction	2	4	2.74	0.393-30.3	.26
Percutaneous transluminal coronary angioplasty	8	14	2.40	0.939-6.60	<.05
Coronary artery bypass graft	2	5	3.43	0.561-36.0	.14
Cardiac hospitalizations‡	23	44	2.62	1.55-4.55	<.001
Deaths	2	1	0.685	0.012-13.2	.81
Any event	25	45	2.47	1.48-4.20	<.001

*Person-years of observation was 108.04.
†Person-years of observation was 78.81.
‡Includes myocardial infarction, percutaneous transluminal coronary angioplasty, and coronary artery bypass graft.

HDL cholesterol levels due to reduced fat intake are the result of a decreased transport rate rather than the increased catabolism that is responsible for most cases of low HDL cholesterol levels in persons consuming a typical Western diet.[24] Populations consuming low-fat, plant-based diets have low HDL cholesterol levels and low rates of coronary heart disease. Our data provide evidence using quantitative coronary arteriography in this population that diet-induced lowering of HDL cholesterol does not confer the same risk of atherosclerosis as do low HDL cholesterol levels in Americans consuming a high-fat diet.[25] Experimental group patients whose triglycerides increased during the first year were asked to minimize their intake of simple carbohydrates, and triglyceride levels decreased between year 1 and year 5.

The experimental group's marked reduction in frequency, severity, and duration of angina after 1 year was sustained at similar levels after 5 years. This long-term reduction in angina is comparable with that achieved following coronary artery bypass surgery or angioplasty and helps to maintain long-term adherence.[26] Between-group differences in most measures of chest pain were not statistically significant after 5 years because there was a large variability in angina and control group patients who were the most symptomatic underwent revascularization.

When we began this study, we believed that the younger patients with milder disease would be more likely to show regression, but we did not find this to be true. Instead, we found that the primary determinant of change in percent diameter stenosis in the experimental group was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. This relationship of adherence to percent diameter stenosis in the experimental group was found after 1 year[3] and also after 5 years in a dose-response relationship. Coronary artery minimum diameter remained stable in the experimental group but markedly narrowed in the control group during the 5 years of the study. At 5 years, the differences between the experimental and control groups were statistically significant for both percent diameter stenosis and minimum diameter, even though control group patients reported risk reduction behavior consistent with a Step II diet of the National Cholesterol Education Program and the American Heart Association: they consumed an average of 25% of energy (calories) from fat and exercised an average of 3.5 times per week. These data are consistent with other studies indicating that moderate changes in diet and lifestyle may not be sufficient to stop the progression of coronary atherosclerosis unless combined with lipid-lowering drugs.[27]

After 5 years, the normal diameter (the segment of least narrowing proximal to the minimum diameter) decreased slightly in the experimental group but widened slightly in the control group. A slight decrease in normal diameter, at least up to a point, may improve myocardial perfusion by streamlining flow—decreasing the forward flow losses that occur when going from a larger to a sharply reduced lumen diameter.[4] Conversely, the slight increase in the normal diameter and reduction in the minimum diameter seen in control group patients increased the entry angle, further reducing blood flow. These theoretical considerations are consistent with the substantially increased myocardial perfusion in the experimental group and decreased myocardial perfusion in the control group that we measured using cardiac positron emission tomography scans.[5]

A much earlier study by Morrison[28] found that moderate reductions in fat and cholesterol intake improved cardiac survival: after 12 years, all of the control group patients had died compared with only 62% of experimental group patients in a nonrandomized trial. More recently, an important study by Esselstyn et al[29] reported that a similar diet plus lipid-lowering drugs in 11 patients caused regression of 11 lesions and stabilization in the remaining 14 lesions after 5.5 years. Although there was no control group, those who were adherent to the diet reported substantially fewer cardiac events than those who were not adherent.[29]

Like all clinical trials, our study has limitations. Although the study participants were a diverse group, they may not be representative of the general population of patients with coronary heart disease. Half of the patients who underwent quantitative coronary arteriography in the participatory hospitals did not meet all of the inclusion and exclusion criteria and were not invited to participate in the study. Also, half of the patients who were invited declined to enroll in the study. Nevertheless, it is encouraging that 50% of the patients who were contacted agreed to volunteer despite the requirement for repeated arteriography and that experimental group patients were able to make and maintain comprehensive lifestyle changes. The angiographic measures lost to follow-up may have affected the treatment and control groups differently, although there are no data to suggest that this occurred. In addition, there is a possibility of differential loss of lesions in patients, although no evidence indicates that this occurred; in both groups, there were 14 lesions that were lost to follow-up. Also, 4 lesions were lost in the control group to bypass surgery or angioplasty; since these lesions were worsening sufficiently to require revascularization, the exclusion of these lesions from analysis would make between-group differences more difficult to detect. We recently completed a multicenter demonstration project to assess the practicality and cost-effectiveness of this intervention in a larger sample of economically and geographically diverse patients with coronary heart disease.[30]

Although we did not use lipid-lowering drugs in the experimental group, their value has been demonstrated in studies that have been published since the Lifestyle Heart Trial began. We do not know if experimental group patients may have demonstrated even more improvement by including lipid-lowering drugs.[14-16] Patients in the control group who were not prescribed lipid-lowering drugs during the study showed more than 3 times as much progression in percent diameter stenosis as those who were. No experimental group patients took lipid-lowering drugs during the study, yet they showed better results than control group patients who were taking these drugs. Lipid-lowering drugs are expensive, compli-

ance is difficult to achieve,[31] and long-term safety is unknown.[32] In practice, patients may be offered a range of therapeutic options, including comprehensive lifestyle changes, lipid-lowering drug therapy, and revascularization, either separately or in combination.

In summary, these ambulatory patients were able to make and maintain comprehensive changes in diet and lifestyle for 5 years and showed even more regression of coronary atherosclerosis after 5 years than after 1 year as measured by percent diameter stenosis. In contrast, patients following more conventional lifestyle recommendations showed even more progression of coronary atherosclerosis after 5 years than after 1 year, and had more than twice as many cardiac events as patients making comprehensive lifestyle changes.

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A Symposium: Summit on Cholesterol and Coronary Disease

2ND NATIONAL CONFERENCE ON LIPIDS IN THE ELIMINATION AND PREVENTION OF CORONARY DISEASE

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EXCERPTA MEDICA

Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project

Dean Ornish, MD, for the Multicenter Lifestyle Demonstration Project Research Group

The Multicenter Lifestyle Demonstration Project was designed to determine if comprehensive lifestyle changes can be a direct alternative to revascularization for selected patients without increasing cardiac events. A total of 333 patients completed this demonstration project (194 in the experimental group and 139 in the control group). We found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality. These patients reported reductions in angina comparable with what can be achieved with revascularization.
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The idea that the progression of coronary artery disease is often reversible was once a radical concept but now has become mainstream, as these proceedings clearly demonstrate. A number of interventions have been shown to arrest or reverse the progression of coronary atherosclerosis, many of which have been detailed in this symposium. These include comprehensive changes in diet and lifestyle,[1–3] lipid-lowering drug therapy,[4–6] partial ileal bypass surgery,[7] and parenteral nutrition.[8]

Approximately 500,000 coronary artery bypass graft (CABG) operations and approximately 600,000 percutaneous transluminal coronary angioplasties (PTCAs) were performed in the United States in 1994 at a combined cost of approximately $15.6 billion, more than for any other surgical procedure. The cost of treatment of coronary artery disease (CAD) in the United States was estimated to be $56.3 billion in 1994.[9] Thus, there is a potential for significant cost savings if safe and comparably effective, but less expensive, alternative interventions can be implemented.

The Multicenter Lifestyle Demonstration Project was designed to determine (1) if we could train other teams of health professionals in diverse regions of the country to motivate their patients to follow a program of comprehensive lifestyle changes; (2) if this lifestyle program may be an equivalently safe and medically effective but more cost-effective alternative to revascularization in selected patients with severe but stable coronary artery disease; and (3) what the resulting cost savings might be. In other words, can patients avoid revascularization by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

Earlier studies demonstrated that the progression of even severe coronary artery disease often can begin to reverse in many patients by an intensive, multifactorial program of comprehensive lifestyle changes. These lifestyle changes include a very low-fat, low-cholesterol diet (approximately 10% fat, <10 mg/day dietary cholesterol, a whole-foods vegetarian diet high in complex carbohydrates and low in simple sugars), stress management techniques, moderate exercise, and psychosocial support. Endpoint measures included quantitative coronary arteriography to assess coronary artery stenosis and cardiac positron emission tomography to assess myocardial perfusion.[2,10]

In the past, insurance companies, managed care organizations, and Medicare have been reluctant to pay for lifestyle interventions, in part because these have been viewed as prevention—increasing costs in the short run for a possible savings years later. Also, since approximately 20–30% of patients change their insurance plans each year, even if cost savings result from lifestyle interventions, they may accrue to another insurance company.

However, a program of comprehensive lifestyle changes may be offered as a much less costly alternative treatment to revascularization for selected patients who are eligible for CABG or PTCA (under the supervision of the referring physician), thereby resulting in immediate and substantial cost savings.

Also, providing lifestyle changes as a direct alternative for patients who otherwise would receive CABG or PTCA may result in significant long-term cost savings. Despite the expense of bypass surgery and angioplasty, 30–50% of bypass grafts reocclude after only 5–7 years, and 30–50% of angioplastied arteries restenose after only 4–6 months.[11,12] When this occurs, then bypass surgery or angioplasty is often repeated, thereby incurring additional costs.

CABG is effective in decreasing angina and improving cardiac function. However, when compared with medical therapy and 16 years of follow-up, CABG improved survival only in a very small subgroup of patients: those with decreased left ventricular function and stenotic lesions of the left main coronary artery of >59%. Median survival was not prolonged in patients with left main coronary artery stenosis <60% and normal left ventricular function, even if a significant right coronary artery stenosis >70% was also present.[13–16]

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PTCA was developed with the hope of providing a less invasive, lower-risk approach to the management of coronary artery disease and its symptoms. Although widely utilized, PTCA has never been compared with medical therapy in a randomized trial in stable patients with coronary artery disease; therefore, the mortality and morbidity benefits of PTCA are unknown.

The use of various types of stents (the insertion of a mesh brace into the lumen of the coronary artery during angioplasty) may slow the rate of restenosis, but there are no randomized controlled trial data supporting the efficacy of these approaches. The use of the left internal mammary artery in bypass surgery may reduce reocclusion, but vein grafts also must be used when patients have multivessel disease. Thus, in addition to the costs of the original bypass or angioplasty, there are costs of further procedures when restenosis and reocclusion occur.

The majority of adverse events related to coronary artery disease, myocardial infarction, sudden death, and unstable angina are due to the rupture of an atherosclerotic plaque of <40–50% stenosis. This often occurs in the setting of vessel spasm and results in thrombosis and occlusion of the vessel.[17] CABG and PTCA usually are not performed on lesions <50% stenosed and do not affect nonbypassed or nondilated lesions, whereas comprehensive lifestyle changes (or lipid-lowering drugs) may help stabilize all lesions, including mild lesions (<50% stenosis). Also, mild lesions that undergo catastrophic progression usually have a less well-developed network of collateral circulation to protect the myocardium than do more severe stenoses.

Bypass surgery and angioplasty have risks of morbidity and mortality associated with them, whereas there are no significant risks from eating a well-balanced low-fat, low-cholesterol diet, stopping smoking, or engaging in moderate walking, stress management techniques, and psychosocial support.

ASSESSING COSTS OF LIFESTYLE CHANGE

Thousands of dollars are saved immediately for every CABG candidate who can avoid the procedure by making intensive changes in diet and lifestyle. However, cost savings in avoided revascularization will occur only if patients who are trained in this lifestyle program adhere to it over time. If patients do not adhere, costs would increase rather than decrease because insurers would end up paying for both lifestyle training and subsequent revascularization. The missing link, therefore, are the data to demonstrate whether patients will adhere to this intensive lifestyle program. We wanted to determine whether patients who are motivated to make comprehensive lifestyle changes can maintain these changes in an ambulatory setting if given the proper support.

To address this question, we began the Multicenter Lifestyle Demonstration Project in 1993 at 8 sites. Also, we have trained practitioners at.0001 additional sites whose data are not included here. These sites are geographically, socioeconomically, racially, and culturally diverse. Approximately 40 insurance companies are now reimbursing at least part of the cost of this program at these sites for selected patients.

We trained teams of health professionals at each of these clinical sites, including cardiologists, registered dietitians, exercise physiologists, psychologists, chefs, stress management specialists, registered nurses, and administrative support personnel. These teams, in turn, worked with their patients to motivate them to make and maintain comprehensive lifestyle changes.

Patients were selected who had angiographically documented coronary artery disease severe enough to warrant revascularization and who were approved for insurance indemnity to undergo a procedural intervention.

In addition, patients were excluded for any of the following: (1) >50% stenosis in the left main coronary artery; (2) CABG within 6 weeks or angioplasty within 6 months; (3) chronic unresponsive congestive heart failure; (4) malignant uncontrolled arrhythmias; (5) myocardial infarction within 1 month; (6) homozygous hypercholesterolemia; (7) psychosis; (8) hypotensive response to exercise; (9) alcohol or drug abuse; and (10) life-threatening comorbidity.

Patients and staff met 3 times per week for 12 weeks plus once per week for the remaining 9 months. Most sessions were 4 hours long: 1 hour of exercise, 1 hour of stress management techniques, 1 hour of group support, and a 1-hour meal. The cost of the 1-year program averaged $7,000 per person. (Shorter and less-expensive versions of the program are now available for people with less severe coronary artery disease.)

All hospitals sent data directly to the independently funded data coordinating center at the Massachusetts General Hospital. Matched control-group patients were provided by Mutual of Omaha. Patients were matched for age, gender, left ventricular ejection fraction (<25%, 25–40%, or >40%), and cardiac score defined as the sum of the severity score for each of the 3 main coronary arteries rated as 0 (<50% stenosis), 0.5 (50–75% stenosis), or 1.0 (>75% stenosis). All control group patients were within 1 month of having undergone revascularization.

Although a randomized controlled trial intervention comparing comprehensive lifestyle changes with revascularization may seem ideal, it is not feasible in practice. The attitude of someone willing to make comprehensive lifestyle changes is often quite different from that of someone who wants to undergo revascularization. The decision to make comprehensive lifestyle changes requires commitment, discipline, and a willingness to assume personal responsibility for one's health. The decision to undergo revascularization is often made by patients who want the doctor to "fix" them—the other end of the personal responsibility spectrum. This is not a value judgment, only a reflection of different approaches, both of which may be valid. To be randomized, a patient has to be willing to undergo either treatment (revascularization or comprehensive lifestyle changes). Since the mindset is so different, it would be very difficult to find patients

who were willing to accept either choice determined by someone else; most patients want to choose one or the other for themselves.

Baseline demographics: A total of 333 patients completed this demonstration project. Of these, 194 were in the experimental group and 139 were in the control group.

At baseline, there were no significant differences between the experimental group and control group in age, gender, marital status, employment status, or history of hypertension, hypercholesterolemia, diabetes, smoking, or family history of heart disease. In the experimental group, the average age was 58 years, 79% were male, and 77% were married. Of particular note is that 63.5% of these patients were currently working yet were able to find time to adhere to the intervention of comprehensive lifestyle changes. Furthermore, 50% were hypertensive, 62% had hyperlipidemia, 19.6% had diabetes, 66% had smoked cigarettes, and 58% had a family history of heart disease. Finally, 54% of the experimental group patients and 32% of control group patients were taking lipid-lowering drugs.

Angiographic severity of coronary artery disease was comparable in both groups. However, 55% of experimental group patients had a prior myocardial infarction compared with only 28% in the control group; also, experimental group patients had a longer history of coronary artery disease than those in the experimental group. Taken together, these factors may bias toward higher morbidity for the experimental group than the control group during the demonstration project.

Adherence and changes in risk factors: These adherence data, changes in risk factors, and a more detailed description of the demonstration project will be described in greater detail in a forthcoming article. Not all patients completed adherence questionnaires; the validity of our adherence data depends on the assumption that the patients who did not provide follow-up data had the same adherence as those who did. If patients who had low adherence were more likely to avoid follow-up, then the adherence rates that we estimated would be overly optimistic.

RESULTS

In brief, patients exercised an average of 1.6 hours/week at baseline, increasing to 3.9, 3.5, 2.9, and 2.7 hours/week at 3 months, 1 year, 2 years, and 3 years, respectively. Patients practiced stress management techniques an average of 0.19 hours/week at baseline and 4.5, 2.6, and 2.0 hours/week at 1 year, 2 years, and 3 years, respectively.

Based on the results of 3-day diet diaries, the percentage of total calories as dietary fat was 6.5%, 6.8%, 7.4%, and 8.3% after 3 months, 1 year, 2 years, and 3 years. The cholesterol intakes for these 4 time periods were 14.1, 19.0, 22.7, and 25.7 mg/day.

Low-density lipoprotein (LDL) cholesterol levels decreased from a mean of 122.9 mg/dL at baseline to 106.1 mg/dL after 3 months ($p < 0.0001$), 104.2 mg/dL after 1 year ($p < 0.0001$), 107.5 mg/dL after 2 years ($p < 0.0001$), and 101.7 mg/dL after 3 years ($p < 0.0001$). Total cholesterol decreased from a mean of 202.0 mg/dL at baseline to 183.7 mg/dL after 3 months ($p < 0.0001$), 182.6 mg/dL after 1 year ($p < 0.0001$), 187.3 mg/dL after 2 years ($p < 0.0001$), and 183.4 mg/dL after 3 years ($p < 0.0001$). Thus, reductions in LDL and total cholesterol levels were maintained throughout the 3-year interval, although the lifestyle intervention was only 1 year long.

High-density lipoprotein (HDL) cholesterol levels initially decreased from 36.7 mg/dL to 32.8 mg/dL after 3 months ($p < 0.0001$) and to 36.1 mg/dL after 1 year ($p = 0.120$) but increased to 40.1 mg/dL after 2 years ($p < 0.005$) and increased to 42.2 mg/dL after 3 years ($p = 0.001$). Triglycerides initially increased nonsignificantly from 229.8 mg/dL to 235.7 after 3 months ($p = 0.494$), but stabilized after 1 year to 228.8 ($p = 0.946$) to 213.0 ($p = 0.607$) to 200.8 after 3 years ($p = 0.339$). These changes in HDL-cholesterol and triglyceride levels are particularly relevant in light of recent controversies in this area.[18]

Mean weight decreased from 187.3 lb at baseline to 178.0 lb after 3 months ($p < 0.0001$), to 177.0 lb after 1 year ($p < 0.0001$), to 176.6 after 2 years ($p < 0.0001$), to 179.9 lb after 3 years ($p = 0.007$). Long-term reductions in weight are unusual.[19] Percent body fat decreased from 25.7% at baseline to 22.9% after 3 months ($p < 0.0001$), to 21.3% after 1 year ($p < 0.0001$), to 22.4% after 2 years ($p < 0.0001$), to 23.4% after 3 years ($p = 0.134$).

Exercise capacity increased from 9.59 METS at baseline to 11.15 after 3 months ($p < 0.0001$), to 11.66 after 1 year ($p < 0.0001$), to 10.88 after 2 years ($p < 0.0001$), to 11.03 after 3 years ($p < 0.0001$).

CAN PATIENTS SAFELY AVOID REVASCULARIZATION?

We found that 150/194 of experimental-group patients were able to avoid revascularization and the frequency of adverse cardiac events was not increased. The number of cardiac events per patient-year of follow-up when comparing the experimental group with the control group was as follows: 0.012 versus 0.012 for myocardial infarction (p = not significant), 0.014 versus 0.006 for stroke (p = not significant), 0.006 versus 0.012 for noncardiac deaths (p = not significant), and 0.014 versus 0.012 for cardiac deaths (p = not significant).

As described above, a primary benefit of revascularization is reduction of angina. In the Multicenter Lifestyle Demonstration Project, we used a very conservative measure of angina: no angina at all in during the prior 30 days. For example, if a patient who had frequent angina at baseline—as many as 10 episodes per day—had even 1 episode in the prior 30 days, then the patient was still considered to have angina.

Of the experimental group patients who reported angina at baseline, 49% had no chest pain during the prior 30 days after 3 months, 65% had no chest pain during the prior 30 days after 1 year, 61% had no chest pain during the prior 30 days after 2 years, and 61% had no chest pain during the prior 30 days after 3

years. These reductions in angina are comparable with what can be achieved with revascularization but without the morbidity and costs.

As noted above, the average cost of the 1-year intensive lifestyle intervention was $7,000. The average cost for PTCA (with cardiac catheterization) was $31,000 and for CABG was $46,000. All of the experimental group patients were eligible for revascularization both by medical criteria and by reimbursement criteria from Mutual of Omaha. However, only 31 PTCAs were performed on the 194 experimental group patients (0.064 events per patient-year of follow-up) and 26 CABGs were performed on the 194 experimental group patients (0.053 events per patient-year of follow-up) after entry. Thus, the costs in the experimental group were: $(31 \times \$31,000) + (26 \times \$46,000) + (194 \times \$7,000) = \$3,515,000$, or an average cost of $18,119/patient.

All of the 139 control group patients were selected for having had a recent PTCA or CABG before entry: 66 underwent PTCA, and 73 underwent CABG. In addition, there were 23 PTCAs and 11 additional CABGs in the control group after entry. Thus, the costs in the control group were: $(66 \times \$31,000) + (23 \times \$31,000) + (73 \times \$46,000) + (11 \times \$46,000) = \$6,623,000$, or an average cost of $47,647/patient.

The average savings per patient, therefore, were: $\$47,647 - \$18,119 = \$29,529$. This number is a conservative estimate, since 8 experimental group patients who had a PTCA after enrolling had ≥1 additional PTCAs or CABGs during the study. Restenosis within 6 months following PTCA is a failure of the angioplasty rather than intensive lifestyle changes, yet we counted all procedures in this cost analysis, even PTCAs occurring within 6 months after a prior PTCA.

There is no way to know with certainty how many of the patients who were eligible for revascularization actually would have undergone revascularization in the absence of the lifestyle program. Whether or not a patient undergoes revascularization is a function of many factors, including disease severity, patterns of practice in the local community, individual preferences among cardiologists and cardiac surgeons, and method of reimbursement. Revascularization rates tend to be much higher when reimbursed on a fee-for-service basis than on a capitated basis. One of the sites in our demonstration project, for example, performed more angioplasties (17) than the other 7 hospital sites combined (14).

Given the large cost differential between the cost of revascularization and the cost of the year-long lifestyle intervention program, it would have been cost-effective to offer comprehensive lifestyle changes even if only 18% of patients who were eligible for revascularization actually would have had it in the absence of this program.

In practice, we believe that patients with coronary artery disease should be offered a range of therapeutic options, including comprehensive lifestyle changes, medications (including lipid-lowering drugs), angioplasty, and bypass surgery. The physician should explain the relative risks, benefits, costs, and side effects of each approach and then support whatever the patient decides.[20] At this time, however, most third-party payers will cover most of the costs of drug therapy and revascularization but not the costs of training patients in a program of comprehensive lifestyle changes. Approximately 40 insurance companies are covering this lifestyle program in the sites we have trained, but this is still a relatively small number.

Comprehensive lifestyle changes are not for everyone. We do not know how many patients with coronary artery disease in the United States would be interested in choosing to make comprehensive lifestyle changes rather than undergo revascularization. In practice, however, the primary limiting factor has been the lack of widespread insurance coverage rather than a shortage of motivated patients.

This is a particularly rewarding and emotionally fulfilling way to practice medicine, both for patients and the physicians and other healthcare professionals who work with them. Much more time is available to spend with patients addressing the underlying lifestyle factors that influence the progression of coronary artery disease, yet costs are substantially lower. Patients usually show rapid decreases in angina and often report other improvements within weeks; these rapid improvements in well-being sustain motivation and help to explain the high levels of adherence in these patients. The major reason that most stable patients undergo CABG or PTCA is to decrease the frequency of angina, and comparable results may be obtained by making comprehensive lifestyle changes alone. Instead of pressuring physicians to see more patients in less time, this is a different approach that is caring and compassionate as well as cost-effective and competent.

CONCLUSION

In summary, in the Multicenter Lifestyle Demonstration Project, we found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality.

Acknowledgment. Special appreciation to Marjorie McClain, Sam Lind, Zanse Smith and Bob Finkel for their invaluable assistance.

APPENDIX

Multicenter Lifestyle Demonstration Project Research Group: *Preventive Medicine Research Institute, Sausalito, CA*: Dean Ornish, MD, President and Director; James H. Billings, PhD, MPH, Director, Clinical Services; Lee Lipsenthal, MD, Medical Director; Melanie Elliot-Eller, MSN, RN, Director of Nursing Services; Terri Merritt-Worden, MS, Director of Exercise Science Services; Nischala Devi, Director of Stress Management Services; Sarah Ellis, RD, Director of Nutrition Services; Helen Roe, RD, Former Director of Nutrition Services; Larry Scherwitz, PhD, Director of Research; Jean-Marc Fullsack, Director, Food Services; Glenn Perelson, Director, Network Development; Patty McCormac, RN, Hospital Liaison; Ruth Marlin, MD, Hospital Liaison, Ana Regalia, CPA, Director, Grants & Contracts; Bryce Williams, MS, Controller; *Massachusetts General Hospital Data Coordinating Center, Charlestown, MA*: Alexander Leaf, MD, Director; Judy Scheer, MPH, RN, Center Coordinator; David Schoenfeld, PhD, Consulting Statistician.

Program Sites: *Alegent Immanuel Medical Center/Alegent Heart Institute, Omaha, NE*: Richard Collins, MD, Medical Director; Sheila McGuire, Program Director; *Alegent Bergen Mercy Medical Center, Omaha, NE*: Dennis Tierney,

MD, Medical Director; Steve Luppes, Program Director; *Beth Israel Medical Center, New York, NY*: Steven Horowitz, MD, Medical Director; Roberto Roberti, MD, Co-Medical Director; Laurie Jones, Program Director; *Mercy Hospital Medical Center/Iowa Heart Center, Des Moines, IA*: William Wickemeyer, MD, Medical Director; Philip Bear, MD, Co-Medical Director; Shakun Advani, MD, Co-Medical Director; Diane McIlhon, RD, Program Director; *Broward General Medical Center, Fort Lauderdale, FL*: Brenda Sanzobrino, MD, Medical Director; Caroll Moody, MD, Co-Medical Director; Michael Chizner, MD, Co-Medical Director; Terry Ray, RN, Program Director; *Palmetto Richland Memorial Hospital, Columbia, SC*: Donald Saunders, MD, Medical Director; Joseph Hollins, MD, Co-Medical Director; Donna Greenwold, RN, Program Director; *Mt. Diablo Medical Center/Heart Health Center*: Peter Kunkel, MD, Medical Director; Lynn Olison, PhD, Program Director; *Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, MA:* Jackie Hart, MD, Medical Director; Caitlin Hosmer, RD, Program Director; *ScrippsHealth, Shiley Sports & Health Center, La Jolla, CA*: Erminia Guarneri MD, Medical Director; Betty Christensen, Program Director.

Additional Program Sites: *University of California San Francisco/California Pacific Medical Center, San Francisco, CA*: Anne Thorson, MD, Medical Director; Kevin Worth, RN, Program Director; *Highmark Blue Cross/Blue Shield of Western Pennsylvania, Pittsburgh, PA*: Howard Grill, MD, Medical Director; Anna Silberman, MPH, Vice President; Tina Palaggo-Toy, MS, Director, Health Place; Amy Wilhelm, MEd, Program Administrator; *Franciscan Health System of the Ohio Valley, Cincinnati OH*: Freidoon Ghazi, MD, Medical Director; Roy Jacobsen, MD, Co-Medical Director; Judy Steele, RN, Program Director; Michael Wizer, PhD, Co-Program Director; *SwedishAmerican Health System, Rockford, IL*: Dean Thomas, MD, Medical Director; Roger Greenlaw, MD, Co-Medical Director; Carol Klint, RN, Program Director; Nancy Halberstadt-Dagerfoerde, RN, Co-Program Director; *Swedish Medical Center/First Hill, Seattle, WA*: Anne Kinnaman, Program Director; Suzanne Westcott, Program Coordinator.

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THE WHITE HOUSE

WASHINGTON

December 28, 1998

12-30-98

Copied
Streett
Steinberg
Echaveste
Solis-Doyle
Podesta

MEMORANDUM TO THE PRESIDENT

FROM: **STEPHANIE STREETT** SS
AVIVA STEINBERG AS

SUBJECT: **HILTON HEAD**

COPY: **MARIA ECHAVESTE**
PATRICIA SOLIS-DOYLE

Currently you depart for Hilton Head, SC sometime on Wednesday, December 30th. There is an inquiry by Linda Lader wanting to know if you and the First Lady would be interested in a low-key buffet dinner hosted by Dennis and Eileen Bakke at the home of Governor John and Lois West (their home is in Palmetto Dunes) on the evening of Wednesday, December 30. Listed below is a potential guest list if you and the First Lady would like to have this dinner put together -- Linda thought you might want to relax with old friends.

Do you want to have a buffet dinner on December, 30th at the home of Governor West?

YES _____ **NO** _____

If yes, please choose from the following list or add names of your own.

Ken Bartels and Jane Condon
Larry Baskir and Marna Tucker
Veronica and Franklin Biggins
Joel Fleishman
Charles and Mary Fraser
Jim and Kristina Hamilton
Paul London and Paula Stern
Ira and Suzanne Magaziner
Jim and Stelle Ramey
Tom and Cynthia Schneider
Larry Schneider and Susan Ness
Andy Tobias
Joan Zofnass
Paul Zofnass and Rene Ring
Bud and Mouza Zumwalt

Others? _____

While you do not need to commit to a time to depart on Wednesday, the Air Force One crew, the Secret Service and the press office, among others, would like a ballpark time to properly plan for.

Do you plan to leave around:

11:00 am? _____

12:00 pm? _____

1:00 pm? _____

Other? _____

Attached is a list of Renaissance Weekend participants as of December 24 as well as a copy of the current Renaissance Weekend schedule of events.

THE WHITE HOUSE

WASHINGTON

22Dec98

MEMORANDUM

TO: The President

FROM: Guy L. Smith

SUBJ: Renaissance Weekend

CC: The First Lady, Maria Echaveste, Ann Lewis

Mr. President:

Attached is the list of those attending this year's Renaissance Weekend at Hilton Head, S.C. (29Dec98--2Jan99, 18th year/now five weekends each year/450 families/1350 participants).

Linda asked me to tell you that Gov. and Mrs. (Lois) John West have offered to host a small buffet dinner party at their home the evening you arrive Rev. Tony Campola and Peggy in adjacent Palmetto Dunes and Dennis Bakke has agreed to pay for it. Linda recommends you do it and that you all ask about 20 or so old friends. If this is something you and the First Lady want, just let either Linda or me know.

Also attached are two fact sheets on this year's weekend.

A number of Renaissance participants have been very helpful on the impeachment issue over the last several months. Undoubtedly there will be a number of participants who have helped us and we are not aware of what they have done. Those we know about are listed below:

Don Baer, Sr VP, Discovery Communications: participates in daily surrogate conference call; makes some appearances.
Susan Low Bloch, Georgetown Law: organized constitutional scholars; TV and radio appearances.
Steve Brick, former Pres., San Francisco Bar: letters-to-editor/op-eds.
Rev. Tony Campola and Peggy
Prof. Sheryll Cashin, Georgetown Law: signed constitutional scholar letter.

Delaware Gov. Tom Carper: worked with Rep. Castle/talked with GOP governors/issued statement: "It is regrettable that the House GOP leadership denied Congressman Mike Castle and others the opportunity to offer a bipartisan motion of censure to heavily fine the President and to condemn his behavior. It is my hope that the Senate now will move quickly to adopt a censure and then move on."
DeeDee Corradini, Salt Lake City Mayor: statement: "What the President did was wrong, deplorable. What the Congress has done amounts to a highly partisan national tragedy. It may permanently damage the Office of the Presidency, and, in the process, bring great harm to the nation. I hope the Senate will vote quickly to censure the President, bring this sorry moment in our nation's history to a close, and free the President to devote his full attention to the truly serious concerns that face our country."
Betty Friedan: press appearances/statements
Jim Hamilton: legal counsel/participates in daily conference call/op-ed pieces, including a on-going debate via Slate Magazine on the Internet with Bill Krystol.
Prof. Emma Coleman Jordan, Georgetown Law: signed constitutional scholar letter.
Sandra Mackey, author on Middle East: backgrounders with media.
Dean Ornish, MD: is preparing an op-ed bringing together his theory of good health, love, and the current politics of hate; has not yet appeared.
Andy Tobias, columnist: radio appearances; columns on the Internet (very forceful columns!)
Dru Ramey, Executive Director, San Francisco Bar Assn: letters/calls/discussions with Rep. Tom Campbell's associates.
Allen Weinstein, Pres., Center for Democracy: background discussions on the Hill.

Some other categories of attendees:

ATTENDING FROM THE SENATE

Senator Kent Conrad, ND: no recent statements

FROM THE HOUSE

Rep. Carolyn McCarthy, D-NY: voted against all articles
Rep. Mark Sanford, R-SC: voted for articles 1, 3 and 4

FROM THE MEDIA

Jonathan Alter, Newsweek
Eleanor Clift, Newsweek
Howard Fineman, Newsweek
Peter Arnett, CNN

Regarding you and/or the First Lady speaking, Linda indicated that you can speak or not as you please, whenever you want, either seperately or together as the past two years.

I recommend that you and the First Lady use the traditonal New Year's Eve time slot to speak, the First Lady speaking first, with her introducing you. I think you should address the politics of personal destruction issue, followed by some benign comments about where things are with the Senate, and a look ahead at your agenda for 1999.

This is an opportunity to try out some themes from the upcoming State of the Union.

Ann Lewis will be attending.

Tom Schneider will play his usual role, with help from me.

Linda reports that they are printing the lists of panels and as soon as I get it I'll get it to you.

If you need anything, just let me know.

Cheers!

Guy

THE WHITE HOUSE

WASHINGTON

22Dec98(Revised 23Dec)

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If you need anything, just let me know.

Cheers!

Guy

Jeremy D. Orchin, D.D.S., P.C.
5301 Wisconsin Ave., N.W., Suite 200
Washington, D.C. 20015

THE PRESIDENT HAS SEEN
12-30-98

Dr. Miss Monica

PRESIDENT CLINTON

FOUR STREAMS
GOLF CLUB

JEREMY D. ORCHIN, D.D.S., P.C.
5301 WISCONSIN AVE., N.W.
WASHINGTON, D.C. 20015

12-30-98

Four Streams Golf Club is dedicated to the advancement of golf as it was meant to be played ... on an exhilarating, challenging course, in a serene setting totally devoted to the enjoyment of the game of golf .

12-30-98
To Burkhardt for Reply
OK

FOUR STREAMS GOLF CLUB FREQUENTLY ASKED QUESTIONS

Q. **Why Four Streams Golf Club?**

A. Four Streams Golf Club is planned to offer an experience uniquely different from other area clubs. It is intended to be a true "golfers club". There will be no tennis courts, swimming pools or residential development associated with the club. The atmosphere will be relaxed and informal, but the service and amenities will be of the finest caliber in keeping with the ideals and goals that have created this club. A limitation on the number of members will assure that your golfing experience will be unhurried, uncrowded and relaxed. An extensive caddie program is an example of the high level of service and respect for the traditions of golf that you will encounter at Four Streams. Four Streams will be a club for men and women who want a real golf experience.

Q. **What is Four Streams Golf Club?**

A. Four Streams Golf Club will be a private membership Golf Club. It will provide golfers with an extremely challenging 7,100 yard tournament caliber golf course and an excellent practice complex. The intimate clubhouse will contain a grille room, pro shop, small banquet facility and locker room facilities. An outdoor patio area overlooking the ninth and eighteenth holes will provide a dramatic view to unwind after you have finished your round.

Q. **What facilities will be available at the Club?**

A. The 18-hole championship golf course is a signature design from world renowned golfer Nick Price. Nick Price has won more than 30 tournaments worldwide, and was the winner of the 1992 and 1994 PGA Championship, and the 1994 British Open. Steve Smyers, architect who collaborated with Nick Price on the design of the course, recently completed Chart Hills Country Club in London, England. It was recently named the "Number One Inland Course in the British Isles." Steve Smyers has several other notable courses to his credit in

the United States including Wolf Run in Indiana and Southern Dunes in Florida.

The Club facilities include an 18-hole championship golf course with putting green and an excellent golf practice complex. The practice area includes an expansive all bent grass tee area, a short game area with bunker and regulation green and a myriad of target greens. There is a second practice tee at the far end of the three hundred yard practice range which also includes a green for putting and chipping which will be used exclusively as part of the state of the art individual private lesson program. The clubhouse will include a grille, pro shop, small banquet facility and locker room facilities for both men and women. The clubhouse will be elegant but the atmosphere relaxed. Construction of the clubhouse is expected to begin after the Club has its first 100 memberships.

Q. **What types of memberships will the Club offer?**

A. The Club is initially offering three categories of memberships: Charter, Corporate and Non-Resident Memberships.

Q. **Who will be eligible to acquire a membership in the club?**

A. Memberships are available by invitation only. The club will make memberships available to men and women who apply for and are approved for membership in the Club and pay the required fees, dues and other charges.

Q. **How many Members will there be?**

A. There will be a maximum of 425 total members which will include Charter or Designated Users of Corporate memberships. The 425 member limit will not be exceeded without a majority vote of the members of the club.

Q. **What are the expenses that I will pay ?**

A. All members will pay golf cart fees, caddie fees and locker rental fees. Each member will be assigned a number and will have full charge privileges. Members are discouraged from paying for any goods or services with cash, and tipping is not permitted.

Q. **What are the privileges of a Charter Membership?**

A. A Charter Membership entitles the member to unlimited use of the golf course, clubhouse and dining facilities and complimentary use of the practice complex. Charter Members are not required to pay greens fees. Spouses are entitled to play at a discount of 25% of the regular guest fee rates. Accompanied guests are permitted at the full guest rate. Currently, Charter

Members have a thirty day sign-up privilege for tee times.

Q. **What are the privileges of a Corporate Membership?**

A. Corporate Memberships may be issued to bona fide business organizations. Each Corporate Membership permits the owner to designate individual officers or employees as the "Designated Users" of the membership, upon approval by the Club. Corporate Memberships must have a minimum of two Designated Users and a maximum of four Designated Users. The Designated User of the Corporate Membership is entitled to unlimited use of the golf course, clubhouse and dining facilities and complimentary use of the practice complex golf. Designated Users are not required to pay greens fees. Designated Users currently have a thirty day sign-up privilege for tee times. Each Designated User is allowed two foursomes per day, and have the right to sponsor limited numbers of unaccompanied guests to play golf.

In order to insure the exclusivity of the Club, limitations will be placed on the frequency of changes of the Designated User and a Transfer Fee of $2,500 will be charged for each transfer within a twelve month period. All Designated Users must apply for and be approved for membership in the Club.

Q. **What are the privileges of a Non-Resident Membership?**

A. Non-Resident Memberships entitles the member to the use of all of the golf, clubhouse and dining facilities. Non-Resident memberships are available only to persons who do not have a residence or place of business within a geographical area that would require a full Membership. Qualification for Non-Resident status is always in the discretion of the Club. Non-Resident Members are not required to pay greens fees, but do pay golf cart fees and caddie fees. Non-Resident Members have the right to play the course a maximum number of fifteen times per year and unlimited use of the clubhouse and dining facilities and complimentary use of the practice complex golf when playing a round of golf. Accompanied guests are permitted at the full guest rate. Non-Resident Memberships are convertible to Charter or Corporate Memberships if memberships are available. Non-Resident Members have a fourteen day sign-up privilege for tee times. Residents of the District of Columbia, and the counties of: Montgomery (MD), Carroll (MD), Prince Georges (MD), Frederick (MD), Howard (MD), Fairfax (VA), Loudon (VA), and Frederick (VA) are not eligible for Non–Resident memberships.

Q. **When will I have to pay the Initiation Deposit?**

A. The Initiation Deposit is payable in four installments. The first installment of $2,500 is payable when the reservation form is submitted. The first installment is fully refundable at any time until the membership documents have been provided and a Membership Subscription Agreement has been signed. The second installment of $7,500 will be due at that time. The third installment of $5,000 will be due on or before March 15, 1998, and the balance will be due upon opening of the golf course.

Q. **Is any part of the Initiation Deposit refundable?**

A. Yes. Currently, the amount of the deposit paid by a Charter, Corporate, or Non-Resident Membership is 100% refundable if a member resigns from the Club. After the Member resigns and is replaced by a new member, the greater of the amount of the deposit originally paid by the resigning member or 80% of the deposit being charged by the Club for a similar membership will be paid at the time of refund. Each member will receive a certificate showing the amount of the deposit paid and the amount that is refundable. Memberships are not transferable. The terms and conditions of the refundability of memberships is more fully defined in the Club By - Laws.

Q. **Can I sell my Membership?**

A. Your membership is non-transferable. However, in the event of your death, your membership may be assigned to an immediate member of your family.

Q. **Will my spouse and family be able to use the Club?**

A. Memberships in the Club are available to men and women and are individual not family memberships. Spouses and immediate family members may play at a 25% discount of the regular guest fee rate. The immediate family includes the member, spouse and children between the ages of 13 and 25.

Q. **Will non-members be permitted to use the facilities of the Club?**

A. Members will be able to sponsor guests. However, limitations upon guest use will be implemented in order to ensure reasonable access to all Club Facilities by members, particularly on weekends. Corporate and special event play sponsored by members will be permitted. However, the Club will limit this play and give priority to members.

Q. **How will annual dues be established?**

A. Each year, the Club will determine the amount of dues to be payable by all members for the next membership year. Dues will be payable monthly. Included in your dues is complimentary use of the practice complex and complimentary bag storage. No minimum food and beverage requirements are planned at this time.

Q. **Will there be any assessments?**

A. It is not anticipated that there will be any need for assessments. Three percent of each initiation fee and all other revenues that the club generates will go into an operating and capital reserve fund that should be ample to meet any unanticipated needs that might arise.

Q. **Will the members of the Club have any influence on the Club's management?**

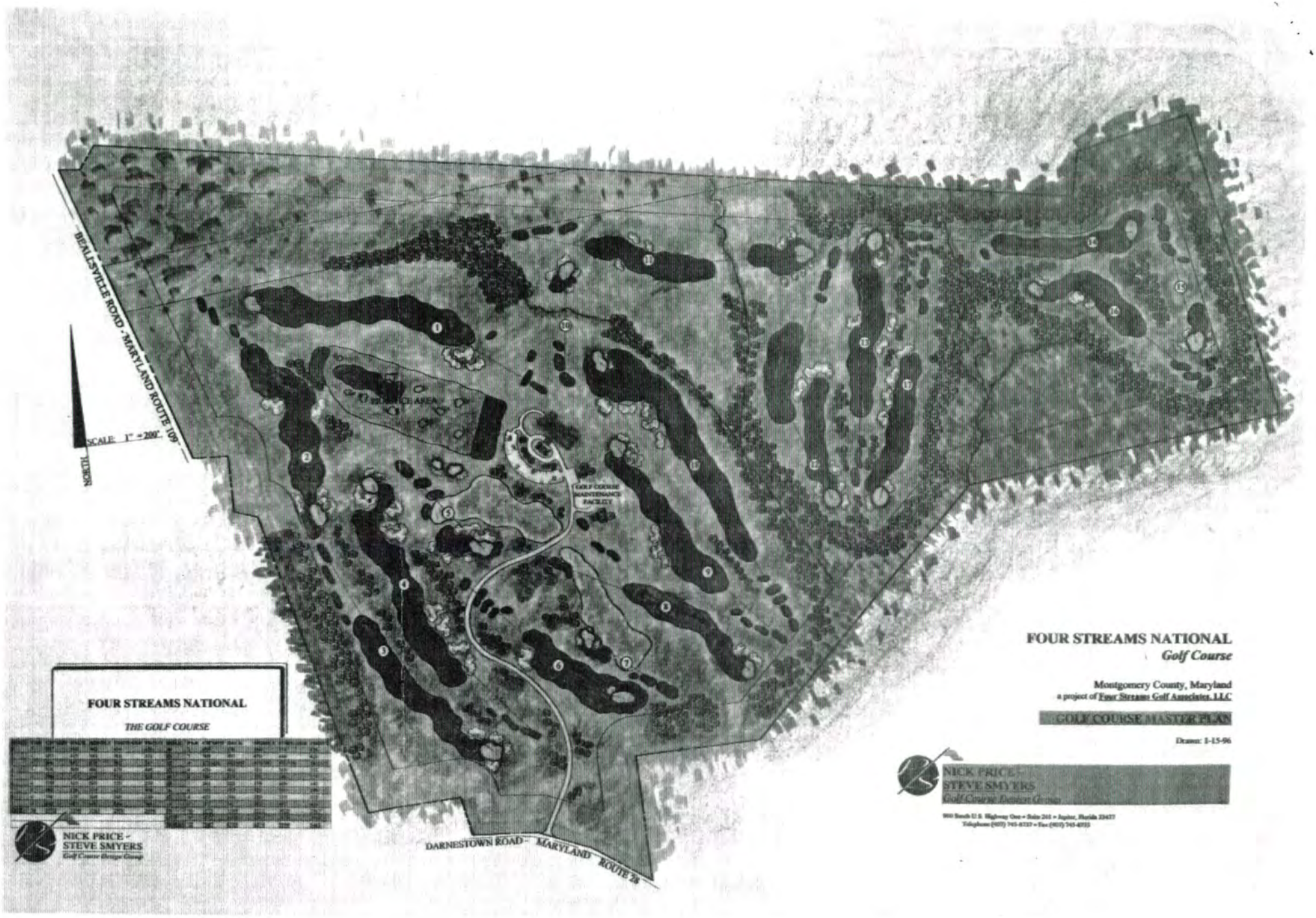
A. An Advisory Board selected from the Club's membership will serve as a liaison between the members and the Club. The Advisory Board serves only in an advisory capacity and has no duty or power to act on behalf of the members of the Club.

Q. **How do I apply for membership in the Club?**

A. Prospective members desiring to apply for a membership in the Club must fully complete, execute and submit an Application for Membership and a Reservation of Membership or Membership Subscription Agreement, along with a check for the amount of the Reservation Deposit due to the Club. A sponsor is required and a personal interview will also be required.

If you have questions or would like further information concerning the membership program at Four Streams Golf Club, please contact Rachel Bush at (410) 727-3200 ext.221.

This is a general description of Four Streams Golf Club, its membership program and facilities. This document is for informational purposes only and may not be relied upon as a basis for a decision to acquire a membership in the Four Streams Golf Club. The actual terms and conditions of the offering of memberships will be set forth in the Club Rules and Regulations and other documents. Membership in the Club may only be acquired thereunder. In the event of any inconsistency between these questions and answers and the Club Rules and Regulations and other documents, the Club Rules and Regulations and other documents shall control.


BEALLSVILLE ROAD - MARYLAND ROUTE 109
TILDEN
SCALE 1" = 200'
GOLF COURSE MAINTENANCE FACILITY
DARNESTOWN ROAD - MARYLAND ROUTE 28
FOUR STREAMS NATIONAL
THE GOLF COURSE
NICK PRICE - STEVE SMYERS
Golf Course Design Group
FOUR STREAMS NATIONAL
Golf Course
Montgomery County, Maryland
a project of Four Streams Golf Associates, LLC
GOLF COURSE MASTER PLAN
Drawn: 1-15-96
NICK PRICE - STEVE SMYERS
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