Preventive Medicine Research Institute

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

Dean Ornish, M.D.
Founder and President, Preventive Medicine Research Institute
Clinical Professor of Medicine, University of California, San Francisco
900 Bridgeway, Suite 1, Sausalito, California 94965
phone: 415/332-2525 x222; FAX: 415/332-2588
e-mail: Dean.Ornish@PMRI.org

September 13, 2021

Chiquita Brooks-LaSure, MPP
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P, Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Re: **CMS-1751-P—**Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure,

My colleagues and I appreciate the opportunity to comment on the CMS proposed 2022 physician fee schedule (PFS) payment rule (Proposed Rule).[1]

On August 12, 2010, after many years of review, CMS created a new benefit category, "intensive cardiac rehabilitation," (ICR), which provided Medicare coverage for the lifestyle medicine program my colleagues and I developed and scientifically studied for over four decades (CPT/HCPCS codes G0422 and G0423).[2]

This lifestyle program is the only one scientifically proven in randomized controlled trials to often reverse the progression of even severe coronary heart disease by lifestyle changes alone, without drugs or surgery. The results of these clinical trials and demonstration projects were published in leading peer-reviewed journals, including *The Lancet*,[3] *Journal of the American Medical Association*,[4] [5] [6] *American Journal of Cardiology*,[7] [8] [9] [10] [11] and others.[12] [13] [14] [15] [16] [17] [18]

Also, a panel of nutrition and health experts from *U.S. News & World Report* has rated what they called "The Ornish diet" as "#1 for Heart Health" for ten years from 2011-2021, which is the diet used in this intensive cardiac rehabilitation program.

Patients in this intensive cardiac rehabilitation program meet twice/week for nine weeks, for four hours per session:

- one hour of supervised aerobic exercise (the same as in traditional cardiac rehabilitation programs)
- one hour of stress management techniques such as meditation
- one hour of a support group
- one hour lecture plus a group meal

CMS has been providing reimbursement for this lifestyle program when offered virtually since October 2020. Aetna, which has been covering this program when offered in the bricks & mortar world for many years, has also been reimbursing this program since May of this year when offered virtually.[19]

I am currently directing the first randomized controlled trial to determine if intensive lifestyle changes may reverse the progression of early-stage Alzheimer's disease in collaboration with senior neurologists at Harvard Medical School, UCSD, and The Cleveland Clinic. This is the same lifestyle intervention as in our intensive cardiac rehabilitation (ICR) program.

In March 2020, with the advent of Covid-19, it was no longer safe to meet in person with such a vulnerable population. Because of this, we virtualized this lifestyle intervention—patients continued to meet for four hours/session but all done via two-way Zoom in real-time.

Each of these Zoom sessions is led by a modality specialist (e.g., exercise physiologist, certified stress management teacher, clinical psychologist, and registered dietitian) as well as a registered nurse at each session to monitor patient safety. Physician supervision is always available virtually if needed.

My colleagues and I have found that this lifestyle program is comparably effective when offered virtually in real-time via Zoom as it is in the bricks and mortar world. Also, physician supervision is safe and effective when offered virtually in this way. It enables us to reach patients wherever they live.

We appreciate and strongly support that CMS has agreed to extend coverage of many telehealth programs when offered virtually through the end of CY 2023 in Category 3.

However, we are very concerned that CMS is proposing to exclude virtual outpatient intensive cardiac rehabilitation from the Category 3 list of payable telehealth services and end virtual "direct supervision" at the end of this calendar year or at the end of the PHE. Traditional cardiac rehabilitation was also excluded. This would substantially compromise equitable access to evidence-based cardiac care for Medicare beneficiaries.

Unless something is done, according to Table 11 of the Federal Register, Medicare coverage for this scientifically proven intensive cardiac rehabilitation program when offered virtually will end at the end of this calendar year or at the end of the PHE.[20] No rationale was given. The section of the Federal Register that describes this decision begins here (please see reference) and continues for several paragraphs until Table 11, which lists this virtual ICR program as not being covered beyond the end of this calendar year or the end of the PHE.[21]

Perhaps this was an oversight. We would be grateful if this intensive cardiac rehabilitation program could be moved to Category 3, which would continue to provide coverage when offered virtually until the end of CY 2023, as CMS has agreed to do with many other programs. We also support the inclusion of traditional cardiac rehabilitation programs in Category 3 as well.

This would enable us to gather more data on utilization, adherence, clinical outcomes, and costs during the next two years when our ICR program is offered virtually. There are clearly enough data already to justify the usefulness of gathering this information until CY 2023.

We agree with CMS that this extension would "allow [CMS] time to collect more information regarding utilization of these services during the pandemic, and provide stakeholders the opportunity to continue to develop support for the permanent addition of appropriate services to the telehealth list through our regular consideration process."[22] A Category 3 designation for intensive cardiac rehabilitation would allow for additional data collection and subsequent consideration of permanent placement. Also, this also enables us to reach many more patients who do not live within driving distance of one of the hospitals or clinics we've trained, especially those living in rural areas.

We already have demonstrated that we can achieve bigger changes in lifestyle and patient engagement, better clinical outcomes, and larger cost savings in the first year than any other lifestyle program we are aware of. For example, 94% of people who enrolled in our intensive cardiac rehabilitation program complete all 72 hours of the intervention after 9 weeks of this program, and 85-90% are still adhering after one year.

Attached is an article from the peer-reviewed *American Journal of Health Promotion* (AJHP) describing improved outcomes in all measures in 2,974 men and women from 24 socioeconomically diverse sites in West Virginia, Nebraska, and Pennsylvania who participated in our ICR program offered and reimbursed by Highmark Blue Cross Blue Shield.[23]

Below is a chart summarizing similar clinical outcomes in all measures in 10,180 additional serial patients who went through our intensive cardiac rehabilitation program after nine weeks who were on maximal medical therapy at baseline (e.g., LDL-cholesterol was 90.1 mg/dl at baseline but still showed additional 20% reductions despite reducing medications):

74% reduction in reported angina after 9 weeks.

In addition to these results, many participants reduced or discontinued medications to lower BP, lipids, and blood sugar with approval of their physicians.

These improvements would have been even greater if medications were unchanged.

	BASELINE	9 WEEKS	CHANGE
Weight Loss	199.6	189.6	-5.0%
Total Cholesterol	165.5	140.1	-15.4%
LDL Cholesterol	90.1	71.2	-20.0%
Triglycerides	146.7	129.4	-11.8%
Systolic Blood Pressure	128.1	121.7	-5.9%
Diastolic Blood Pressure	74.6	70.4	-5.7%
HbA1c	6.6	6.2	-6.2%
Depression Score (CESD)	11.1	5.7	-48.6%
Exercise Capacity (Mets)	3.7	5.5	45.9%

This intensive cardiac rehabilitation program is cost effective as well as medically effective. Highmark Blue Cross Blue Shield found that overall health care costs were decreased by 50% in the first year when compared to a control group matched for age, gender, and disease severity. Costs were reduced *four-fold* in the first year in patients who had made more than $25,000 in health claims in the prior year.

Mutual of Omaha found that they saved almost $30,000/patient in the first year in patients who went through this program compared to the control group. Almost 80% of patients who otherwise would have undergone revascularization were able to safely avoid it by choosing this lifestyle program as a direct alternative.[24]

President Clinton has talked publicly about how this intensive cardiac rehabilitation program has helped him reverse the progression of his coronary heart disease.[25]

My colleagues and I achieved similar adherence, engagement, and outcomes when this lifestyle program is offered virtually. Given these high levels of adherence, it is justifiable to determine if this level of adherence in cardiac patients can be maintained from data we can collect if this ICR program can be listed on Category 3 so it can be offered virtually until the end of CY 2023.

The exercise component of intensive cardiac rehabilitation is the same as in traditional cardiac rehabilitation. As described below, the risk of traditional cardiac rehabilitation when offered virtually is no higher than when offered in hospitals or clinics. The other aspects of ICR (meditation, support groups, and a whole foods plant-based diet) are beneficial and very low risk.

In many studies that directly compare virtual to center-based cardiac rehabilitation, there is no difference across the following key outcomes measures: (a) exercise capacity, (b) mortality and morbidity, (c) modifiable risk factors, (d) health-related quality of life, and (e) adherence. Some studies show that outcome measures are actually *better* in virtual cardiac rehabilitation.

For example, a randomized controlled trial, which included a six-year follow-up examining hospital versus home-based exercise training after coronary artery bypass graft surgery found that there were significant between-group differences in peak VO2 max in favor of the virtual cardiac rehabilitation group. Also, the total number of hospitalizations (cardiac and non-cardiac) was greater in center-based patients than in the home-based group participating in virtual cardiac rehabilitation (79 versus 42, p<0.0001). The authors reported there were no significant between-group differences in clinical events.[26]

A January 2021 publication from the American College of Cardiology concludes that "available data suggest that HBCR [home-based (or virtual) cardiac rehabilitation] is equivalent to CBCR [center-based cardiac rehabilitation]."[27]

During the COVID-19 pandemic in Canada and Japan virtual cardiac rehabilitation programs were "found to be as effective as on-site programs offered in hospitals."[28]

Several studies have shown that virtual cardiac rehabilitation achieves equivalent improvements in exercise capacity, measured by peak oxygen uptake as compared with center-based programs.

For example, the REMOTE-CR randomized controlled trial showed no significant differences between virtual cardiac rehabilitation with synchronous oversight compared with center-based rehabilitation, measured by change in VO2 max (adjusted mean difference = 0.51 (95% CI −0.97 to 1.98) mL/kg/min, p=0.48).[29]

The FIT@Home randomized controlled trial showed patients in both groups (virtual and center-based) improved their peak VO2 from baseline to discharge (center-based +11% $p < 0.01$, virtual + 15% $p < 0.01$) without significant between-group differences ($p = 0.25$).[30]

Another study concluded that the mean change in 6-minute walk test distance (to assess exercise capacity) was significantly greater for patients enrolled in virtual cardiac rehabilitation than in center-based rehabilitation (+101 versus +40 m; P<0.001).[31]

A randomized controlled trial investigating long-term exercise adherence after high-intensity interval training showed no significant difference between virtual and center-based groups in change in VO2 max. Additionally, the virtual group showed a strong trend towards increased physical activity compared with hospital-based groups.[32]

Studies comparing virtual with center-based rehabilitation have reported that all-cause mortality data for up to 12 months after the intervention revealed no statistically significant difference in mortality between the groups. Two studies reported no difference in revascularization or recurrent myocardial infarction events between virtual and center-based programs.[33] [34] [35] [36] [37] [38]

A Cochrane Review of 23 trials that randomized a total of 2,890 participants found no evidence of differences between virtual and cardiac rehabilitation in clinical primary outcomes, including exercise capacity, for up to 12 months of follow up.[39]

Cardiac rehabilitation services using real-time audio/video technology have a strong safety profile, with an extremely low incidence of adverse events. Research since the 1980s has demonstrated the low rates of serious cardiovascular events in cardiac rehabilitation. Only 1 cardiac arrest per 111,996 patient-hours, 3.4 myocardial infarctions per 293,990 patient-hours, and 1 death per 783,972 patient-hours.[40]

Several studies have shown that with appropriate screening and monitoring procedures, virtual cardiac rehabilitation is feasible and safe even in higher risk patients. For example, Dalal et al[41] and Jolly et al[42] found no significant difference in coronary revascularization or recurrent myocardial infarction events between home-based and center-based groups.

Oerkild et al stated that there were no between-group differences (home-based versus center-based) in the number and length of admissions and adverse events including myocardial infarction, progressive angina, decompensated congestive heart failure, severe bleeding, new malignant disease and performance of percutaneous coronary intervention.[43]

The HF-ACTION study assessed the safety of exercise training provided initially in a center but later at home. With 2,331 enrolled patients (higher risk per American Association of Cardiovascular and Pulmonary Rehabilitation guidelines[44]), no significant difference was reported between the exercise and usual care groups for the overall rate of hospitalization (1.9% versus 3.2%, respectively) or death (0.4% versus 0.4%, respectively) during or within 3 hours after exercise. The investigators also identified 1,053 patients from the HF-ACTION trial who had an implantable cardioverter-defibrillator at baseline and were randomized to the above exercise intervention versus control. Exercise training was not associated with the occurrence of implantable cardioverter-defibrillator shock (hazard ratio, 0.9 [95% CI, 0.7–1.2]). Other adverse events were similar between groups.[45]

Even the minimal risk of a cardiac event while exercising (which is no higher when cardiac rehabilitation is offered virtually) is more than offset by avoiding the risk of being exposed to Covid-19 by other cardiac patients, who are an especially vulnerable population to Covid-19, when intensive cardiac rehabilitation is offered only in the bricks and mortar world.

Since it is unlikely that the U.S. will achieve herd immunity any time soon given the Delta variant and ongoing resistance to getting vaccinated, it is much safer for cardiac patients to receive this intensive cardiac rehabilitation program when offered virtually in the safety of their home than being exposed to other patients in many hospitals or clinics, especially since exercise (heavy breathing and perspiring) increases the risk of transmission.[46]

Also, many patients who do not live within driving distance of one of the hospitals or clinics we have trained could benefit from having our ICR program available virtually, especially those living in rural areas. The Government Accountability Office confirmed that telehealth during the PHE has improved access to care.[47]

A study from the Veterans Health Administration found that patients offered a referral to virtual or center-based cardiac rehabilitation were four times more likely to participate than those offered referral to center-based programs alone.[48] The "Home-based versus center-based cardiac rehabilitation Cochrane Review" found virtual cardiac rehabilitation to be associated with higher adherence (RR 1.04, 95% CI 1.01 to 1.07).[49] The FIT@Home (n=90) randomized controlled trial showed that patient satisfaction was higher in the virtual cardiac rehabilitation group (p=0.02).[50]

We found that these same lifestyle changes also may reverse the progression of early-stage prostate cancer;[51] beneficially change gene expression;[52] reverse the progression of type 2 diabetesADD REF AJHP; and lengthen telomeres.[53] [54] The reason that these same lifestyle changes beneficially affect so many chronic diseases is that they share common biological mechanisms, including chronic inflammation, overstimulation of the sympathetic nervous system, changes in oxidative stress, angiogenesis, telomeres, the microbiome, and others.[55]

An additional benefit to offering this intensive cardiac rehabilitation program virtually is that it may also reduce deaths from Covid-19 by increasing resilience to infection rather than only avoiding it.

For example, a recent study of almost 600,000 people by researchers at Harvard Medical School and King's College, London, found that a dietary pattern characterized by healthy plant-based foods (part of this intensive cardiac rehabilitation intervention) was associated with a 41% lower risk of severe COVID-19. These association may be particularly evident among individuals living in areas with higher socioeconomic deprivation.[56]

A study of 2,884 frontline doctors and nurses with extensive exposure to Covid-19 who were following plant-based diets were 73% less likely to develop moderate to severe illness.[57]

Per CMS guidelines for cardiac rehabilitation programs, services must be performed under the direct supervision of a physician. Direct supervision by a physician is performed equally effectively in a virtual setting as in a center-based setting. In a virtual program the physician is immediately available to join a two-way audio/video conference with both the patient and the other overseeing clinician (usually a nurse or a clinical exercise physiologist) monitoring the exercise session. The physician can communicate simultaneously with the patient and the clinician, or privately with the clinician. The supervising physician has immediate access to live patient vitals data, can communicate via live audio/video with the patient, and can intervene fully and effectively as they would in a center-based session.

Data previously cited indicate adverse events are exceptionally rare, particularly given that supervising physicians ensure that only clinically appropriate patients enter virtual cardiac rehabilitation. Examples of when a supervising physician would be called include automatic vital sign derangement detection outside of expected limits and concerning symptoms (i.e., chest pain, light-headedness, etc.) reported by the clinical exercise physiologist or patient suggestive of a rare complication such as myocardial infarction.

In summary, there is clearly enough information already to justify including intensive cardiac rehabilitation (as well as traditional cardiac rehabilitation) in Category 3 and to continue to allow direct supervision by a physician to be performed in a virtual setting. This will allow CMS to gather additional information for two more years until the end of CY 2023 on patient engagement, safety, outcomes, and cost savings when intensive cardiac rehabilitation is offered virtually, which will be to everyone's advantage.

Thank you so much for your consideration, which my colleagues and I sincerely appreciate. Please let me know if you have any questions or would like any additional information.

Dean Ornish, M.D.
Founder & President, Preventive Medicine Research Institute
Clinical Professor of Medicine, University of California, San Francisco
dean.ornish@pmri.org
telephone: 415-332-2525 x222

References:

[1] 86 Fed. Reg. 39104 (July 23, 2021).

[2] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=240&NcaName=Intensive+Cardiac+Rehabilitation+(ICR)+Program+-+Dr.+Ornish%2527s+Program+for+Reversing+Heart+Disease&NCDId=341&ncdver=1&IsPopup=y&bc=AAAAAAAAEAAA&

[3] Ornish DM, Brown SE, Scherwitz LW, et al. Can lifestyle changes reverse coronary atherosclerosis? The Lifestyle Heart Trial. *The Lancet.* 1990; 336:129-133. (Reprinted in *Yearbook of Medicine* and *Yearbook of Cardiology* (New York: C.V. Mosby, 1991).

[4] Ornish DM, Scherwitz LW, Doody RS, Kesten D, McLanahan SM, Brown SE, DePuey G, Sonnemaker R, Haynes C, Lester J, McAllister GK, Hall RJ, Burdine JA, Gotto AM. Effects of stress management training and dietary changes in treating ischemic heart disease. *JAMA.* 1983;249:54-59.

[5] Gould KL, Ornish D, Scherwitz L, Stuart Y, Buchi M, Billings J, Armstrong W, Ports T, Scherwitz L. Changes in myocardial perfusion abnormalities by positron emission tomography after long-term, intense risk factor modification. *JAMA.* 1995;274:894-901.

[6] Ornish D, Scherwitz L, Billings J, Brown SE, Gould KL, Merritt TA, Sparler S, Armstrong WT, Ports TA, Kirkeeide RL, Hogeboom C, Brand RJ. Intensive lifestyle changes for reversal of coronary heart disease Five-year follow-up of the Lifestyle Heart Trial. *JAMA*. 1998;280:2001-2007.

[7] Gould KL, Ornish D, Kirkeeide R, Brown S, et al. Improved stenosis geometry by quantitative coronary arteriography after vigorous risk factor modification. *American Journal of Cardiology.* 1992; 69:845-853.

[8] Koertge J, Weidner G, Elliott-Eller M, Scherwitz L, Merritt-Worden TA, Marlin R, Lipsenthal L, Guarneri M, Finkel R, Saunders DE, McCormac P, Scheer JM, Collins RE, Ornish D. Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the Multicenter Lifestyle Demonstration Project. *Am J Cardiol.* 2003;91:1316-1322.

[9] Chainani-Wu N, Weidner G, Purnell DM, Frenda S, Merritt-Worden T, Kemp C, Kersh E, Ornish D. Relation of B-type natriuretic peptide levels to body mass index after comprehensive lifestyle changes. *Am J Cardiol*. 2010 Jun 1;105(11):1570-6. Epub 2010 Apr 10.

[10] Dod HS, Bhardwaj R, Sajja V, Weidner G, Hobbs GR, Konat GW, Manivannan S, Gharib W, Warden BE, Nanda NC, Beto RJ, Ornish D, Jain AC. Effect of intensive lifestyle changes on endothelial function and on inflammatory markers of atherosclerosis. *Am J Cardiol*. 2010 Feb 1;105(3):362-7.

[11] Chainani-Wu N, Weidner G, Purnell DM, Frenda S, Merritt-Worden T, Pischke C, Campo R, Kemp C, Kersh ES, Ornish D. Changes in emerging biomarkers after an intensive lifestyle intervention. *Am J Cardiol*. 2011 Aug 15;108(4):498-507. doi: 10.1016/j.amjcard.2011.03.077. Epub 2011 May 31.

[12] Dunn-Emke SR, Weidner G, Pettengill EB, Marlin RO, Chi C, Ornish DM. Nutrient adequacy of a very low-fat vegan diet. *J Am Diet Assoc.* 2005 Sep;105(9):1442-6.

[13] Pischke CR, Weidner G, Elliott-Eller M, Ornish D. Lifestyle changes and clinical profile in coronary heart disease patients with an ejection fraction of </=40% or >40% in the Multicenter Lifestyle Demonstration Project. Eur J Heart Fail. 2007 Sep;9(9):928-34.

[14] Dewell A, Weidner G, Sumner MD, Chi CS, Ornish D. A very-low-fat vegan diet increases intake of protective dietary factors and decreases intake of pathogenic dietary factors. *J Am Diet Assoc.* 2008 Feb;108(2):347-56.

[15] Govil S, Weidner G, Merritt-Worden T, Ornish D. Socioeconomic Status and Improvements in Lifestyle, Coronary Risk Factors, and Quality of Life: The Multisite Cardiac Lifestyle Intervention Program. *Am J Public Health*. 2009; 99: 1263-1270.

[16] Schulz U, Pischke CR, Weidner G, Daubenmier J, Elliot-Eller M, Scherwitz L, Bullinger M, Ornish D. Social support group attendance is related to blood pressure, health behaviours, and quality of life in the Multicenter Lifestyle Demonstration Project. *Psychol Health Med*. 2008 Aug;13(4):423-37.

[17] Pischke CR, Scherwitz L, Weidner G, Ornish D. Long-term effects of lifestyle changes on well-being and cardiac variables among coronary heart disease patients. *Health Psychol*. 2008 Sep;27(5):584-92.

[18] Pischke CR, Frenda S, Ornish D, Weidner G. Lifestyle changes are related to reductions in depression in persons with elevated coronary risk factors. *Psychol Health*. 2010 Nov;25(9):1077-100.

[19] http://www.aetna.com/cpb/medical/data/200_299/0267.html

[20] https://www.federalregister.gov/d/2021-14973/p-325

[21] https://www.federalregister.gov/d/2021-14973/p-325

[22] 86 Fed. Reg. 39137 (July 23, 2021).

[23] Silberman A, Banthia R, Estay IS, Kemp C, Studley J, Hareras D, Ornish D. The effectiveness and efficacy of an intensive cardiac rehabilitation program in 24 sites. *Am J Health Promot.* 2010;24[4]:260–266.

[24] Ornish D. Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project. *Am J Cardiol.* 1998;82:72T-76T.

[25] https://www.aarp.org/health/healthy-living/info-08-2013/bill-clinton-vegan.html

[26] Smith KM, McKelvie RS, Thorpe KE, Arthur HM. Six-year follow-up of a randomised controlled trial examining hospital versus home-based exercise training after coronary artery bypass graft surgery. Heart. 2011.

[27] "Cardiac Rehabilitation and Implications During the COVID-19 Era," acc.org, American College of Cardiology, 4 January 2021, https://www.acc.org/Latest-in-Cardiology/Articles/2021/01/04/14/03/Cardiac-Rehabilitation-and-Implications-During-the-COVID-19-Era.

[28] "Remote cardiac rehabilitation programs are effective alternatives to on-site services," heart.org, American Heart Association, 9 November 2020, https://newsroom.heart.org/news/remote-cardiac-rehabilitation-programs-are-effective-alternatives-to-on-site-services.

[29] Maddison R et al. Effects and costs of real-time cardiac telerehabilitation: randomised controlled non-inferiority trial. BMJ. 2019.

[30] Kraal et al. Clinical and cost-effectiveness of home-based cardiac rehabilitation compared to conventional, center-based cardiac rehabilitation: Results of the FIT@Home study. Eur J Prev Cardiol. 2017.

[31] "Effects of Home-Based Cardiac Rehabilitation on Time to Enrollment and Functional Status in Patients With Ischemic Heart Disease," ahajournals.org, American Heart Association, https://www.ahajournals.org/doi/10.1161/JAHA.120.016456.

[32] Aamot IL, Karlsen T, Dalen H, Støylen A. Long-term exercise adherence after high-intensity interval training in cardiac rehabilitation: a randomized study. Physiother Res Int. 2016.

[33] Moholdt T, Bekken Vold M, Grimsmo J, Slørdahl SA, Wisløff U. Home-based aerobic interval training improves peak oxygen uptake equal to residential cardiac rehabilitation: a randomized, controlled trial. PLoS One. 2012.

[34] Oerkild B, Frederiksen M, Hansen JF, Simonsen L, Skovgaard LT, Prescott E. Home-based cardiac rehabilitation is as effective as center-based cardiac rehabilitation among elderly with coronary heart disease: results from a randomised clinical trial.Age Ageing. 2011.

[35] Piotrowicz E, Baranowski R, Bilinska M, Stepnowska M, Piotrowska M, Wójcik A, Korewicki J, Chojnowska L, Malek LA, Klopotowski M, Piotrowski W, Piotrowicz R. A new model of home-based telemonitored cardiac rehabilitation in patients with heart failure: effectiveness, quality of life, and adherence. Eur J Heart Fail. 2010.

[36] Dalal HM, Evans PH, Campbell JL, Taylor RS, Watt A, Read KL, Mourant AJ, Wingham J, Thompson DR, Pereira Gray DJ. Home-based versus hospital-based rehabilitation after myocardial infarction: a randomized trial with preference arms–

Cornwall Heart Attack Rehabilitation Management Study (CHARMS). Int J Cardiol. 2007.

[37] Jolly K, Lip GY, Taylor RS, Raftery J, Mant J, Lane D, Greenfield S, Stevens A. The Birmingham Rehabilitation Uptake Maximisation study (BRUM): a randomised controlled trial comparing home-based with center-based cardiac rehabilitation.Heart. 2009.

[38] Oerkild B, Frederiksen M, Hansen JF, Simonsen L, Skovgaard LT, Prescott E. Home-based cardiac rehabilitation is as effective as center-based cardiac rehabilitation among elderly with coronary heart disease: results from a randomised clinical trial. Age Ageing. 2011.

[39] Lindsey Anderson, Georgina A Sharp, Rebecca J Norton, Hasnain Dalal, Sarah G Dean, Kate Jolly, Aynsley Cowie, Anna Zawada, Rod S Taylor. Home-based versus center-based cardiac rehabilitation. 2017.

[40] Van Camp SP, Peterson RA. Cardiovascular complications of outpatient cardiac rehabilitation programs. JAMA. 1986.

[41] Dalal HM, Evans PH, Campbell JL, Taylor RS, Watt A, Read KL, Mourant AJ, Wingham J, Thompson DR, Pereira Gray DJ. Home-based versus hospital-based rehabilitation after myocardial infarction: a randomized trial with preference arms–Cornwall Heart Attack Rehabilitation Management Study (CHARMS). Int J Cardiol. 2007.

[42] Jolly K, Taylor R, Lip GY, Greenfield S, Raftery J, Mant J, Lane D, Jones M, Lee KW, Stevens A. The Birmingham Rehabilitation Uptake Maximisation Study (BRUM): home-based compared with hospital-based cardiac rehabilitation in a multi-ethnic population: cost-effectiveness and patient adherence. Health Technol Assess. 2007

[43] Oerkild B, Frederiksen M, Hansen JF, Simonsen L, Skovgaard LT, Prescott E. Home-based cardiac rehabilitation is as effective as center-based cardiac rehabilitation among elderly with coronary heart disease: results from a randomised clinical trial. Age Ageing. 2011.

[44] "AACVPR Stratification Algorithm for Risk of Event," aacvpr.org, American Association of Cardiovascular and Pulmonary Rehabilitation, 2012. https://registry.dev.aacvpr.org/Documents/AACVPR%20Risk%20Stratification%20Algorithm_June2012.pdf.

[45] O'Connor CM, Whellan DJ, Lee KL, Keteyian SJ, Cooper LS, Ellis SJ, Leifer ES, Kraus WE, Kitzman DW, Blumenthal JA, Rendall DS, Miller NH, Fleg JL, Schulman KA, McKelvie RS, Zannad F, Piña IL; HF-ACTION Investigators. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. JAMA. 2009.

[46] Brilliant L et al. The Forever Virus. *Foreign Affairs*, July/August 2021. https://www.foreignaffairs.com/articles/united-states/2021-06-08/coronavirus-strategy-forever-virus]

[47] "COVID-19 Program Flexibilities and Considerations for Their Continuation," gao.gov, United States Government Accountability Office, 19 May 2021, https://www.gao.gov/assets/gao-21-575t.pdf.

[48] Schopfer DW, Krishnamurthi N, Shen H, Duvernoy CS, Forman DE, Whooley MA. Association of Veterans Health Administration home-based programs with access to and participation in cardiac rehabilitation. JAMA Intern Med. 2018.

[49] Ashworth NL et al. Home versus center based physical activity programs in older adults. A Cochrane Review. Cochrane Database Syst Rev. 2005 Jan 25;2005(1):CD004017.

[50] Kraal et al Clinical and cost-effectiveness of home-based cardiac rehabilitation compared to conventional, center-based cardiac rehabilitation: Results of the FIT@Home study. Eur J Prev Cardiol. 2017.

[51] Ornish DM, Weidner G, Fair WR, Marlin R, Pettengill EB, Raisin CJ, Dunn-Emke S, Crutchfield L, Jacobs NF, Barnard RJ, Aronson WJ, McCormac P, McKnight DJ, Fein JD, Dnistrian AM, Weinstein J, Ngo TH, Mendell NR, Carroll PR. Intensive lifestyle changes may affect the progression of prostate cancer. *Journal of Urology*. 2005;174:1065-1070.

[52] Ornish D, Magbanua MJM, Weidner G, Weinberg V, Kemp C, Green C, et al. Changes in prostate gene expression in men undergoing an intensive nutrition and lifestyle intervention. *Proc Nat Acad Sci USA* 2008; 105: 8369-8374.

[53] Ornish D, Lin J, Daubenmier J, Weidner G, Epel E, Kemp C, Magbanua MJM, Marlin R, Yglecias L, Carroll P, Blackburn E. Increased telomerase activity and comprehensive lifestyle changes: a pilot study. *The Lancet Oncology*. 2008; 9: 1048–57.

[54] Ornish D, Lin J, Chan JM, Epel E, Kemp C, Weidner G, Marlin R, Frenda SJ, Magbanua MJM, Daubenmier J, Estay I, Hills NK, Chainani-Wu N, Caroll PR, Blackburn EH. Effect of comprehensive lifestyle changes on telomerase activity and telomere length in men with biopsy-proven low-risk prostate cancer: 5-year follow-up of a descriptive pilot

study. Lancet Oncol. 2013 Oct;14(11):1112-20. doi: 10.1016/S1470-2045(13)70366-8. Epub 2013 Sep17. PMID: 24051140.

[55] Ornish D. UnDo It. New York: Random House/Ballantine Books, 2019.

[56] Merino J et al. Diet quality and risk and severity of COVID-19. MedRxiv. doi: https://doi.org/10.1101/2021.06.24.21259283;

[57] Kim H et al. BMJ Nutrition, Prevention & Health. http://dx.doi.org/10.1136/bmjnph-2021-000272; https://nutrition.bmj.com/content/4/1/257