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## A Lifestyle Program of Exercise and Weight Loss is Effective in Preventing and Treating Type 2 Diabetes Mellitus: Why Are Programs Not More Available?

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### Abstract

There is substantial evidence that type 2 diabetes mellitus (T2DM) can be prevented in high-risk individuals by a lifestyle program of regular exercise and weight reduction. Additionally, there is emerging evidence that new onset T2DM (< 1 year) can go into remission after weight loss and exercise in a majority of motivated individuals, obviating a need for glucose lowering medications. Yet, lifestyle programs to support such behavior change are not widely available. Moreover, health care insurance companies generally do not provide coverage for behavioral weight loss programs to prevent or treat T2DM. Consequently, physicians caring for individuals with T2DM may find it much easier to start a chronic glucose lowering medication rather than attempting to motivate and support patients through long-term behavior change. The cardiac rehabilitation model of disease management, with a network of over 2,000 programs in the US, is well suited to deliver medically-supervised lifestyle programs. National organizations such as the American Diabetes Association and the American Association of Cardiovascular and Pulmonary Rehabilitation should support greater availability and use of lifestyle programs for T2DM treatment and prevention.

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In 2012 the prevalence of diabetes in the U.S. approached 26 million individuals with an annual incidence of over 2 million new cases (1). Diabetes was the 7th leading cause of death in the U.S. in 2010 and its diagnosis approximately doubles individual medical costs (2, 3). Its increasing incidence has paralleled the obesity epidemic (1) thus its origin has a strong behavioral component.

There is substantial evidence that type 2 diabetes mellitus (T2DM) can be prevented in high-risk individuals with a program of exercise and behavioral weight loss (“lifestyle program”) (4,5). In the Diabetes Prevention Program a lifestyle program of at least 150 minutes per week of physical activity and a behavioral weight loss program aiming to reduce body weight by 7% was applied to overweight, glucose intolerant individuals at high risk for the

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development of T2DM (4). Compared with placebo, over a follow up period of 2.8 years, the lifestyle intervention reduced the incidence of T2DM by 58%. To prevent one case of T2DM over a period of 3 years, just 6.9 persons would have to participate in the lifestyle-intervention program.

A study from Finland found similar results (5). Subjects in the lifestyle intervention received dietary counseling to change the quality and quantity of their diet along with counseling to increase physical activity. After 4 years, the risk of developing T2DM was again reduced by 58%, leaving little doubt that this costly and disabling disease can be prevented or postponed by a formal lifestyle program of exercise and weight loss.

One would assume that pursuant to these well publicized findings, medical care systems in the U.S. and elsewhere would have put programs into place to obtain these same benefits in the clinical setting, as has been the case with cardiac rehabilitation programs for coronary artery disease. However, such as not been the case. Cost effectiveness analysis suggests that the lifestyle intervention to prevent T2DM is cost effective compared either with no intervention or with metformin medical therapy (6,7). Yet, particularly in the U.S., physicians rarely have the option of referring appropriate patients to a formal diabetes prevention program and third party insurance coverage is rarely provided, effectively putting comprehensive clinical implementation on the back shelf. While there has been some success establishing low cost “out of pocket” programs through community centers and YMCA's, this approach is unlikely to provide widely available comprehensive coverage (8,9).

If pre-diabetes or insulin resistance syndrome is left untreated, T2DM will develop in 11-23% of high risk individuals over a period of 2.8–4 years (4,5). At the time when T2DM is initially diagnosed, selected individuals may be highly motivated to undertake a “last chance” lifestyle program given that the competing option is the cost and daily discomfort of medical therapy and frequent glucose monitoring. Is it then too late for lifestyle therapy to be effective?

The evidence that *recently diagnosed* T2DM can be put into remission (partial or complete) is less strong than the evidence for its prevention. Partial remission of T2DM is defined as HbA1c of 5.7% - 6.5% whereas a complete remission was defined as an HbA1c of < 5.7% (10 Buse). In the Look AHEAD study of combined weight loss and exercise in over 5,000 individuals with T2DM, which achieved a mean weight loss of 8.6% and a fitness improvement of 21% , the partial remission rate at 1-year was only 11.5% (11). However, the mean duration of T2DM from the time of diagnosis in this study was 5 years. In a subset of individuals with T2DM of less than 2 years duration, the combined remission rate increased to 22%. Factors associated with remission (mostly partial) included a shorter duration of T2DM, lower baseline HbA1c, no insulin therapy and greater weight loss. Unfortunately, there are remarkably little data describing the benefits of weight loss and exercise for individuals with *recently diagnosed* (< 1 year) T2DM. Thus, the effectiveness of a comprehensive behavioral weight loss program at the time of initial diagnosis of T2DM is not well known.

In a small, recent, non-randomized study of weight loss and exercise in individuals with recently diagnosed (<1 year, mean  $3.1 \pm 3.8$  mo) T2DM, naive to metformin therapy, subjects lost a mean of  $9.7 \pm 5.2$  kg and improved aerobic fitness by 18% (12). Although 2 subjects withdrew for unrelated medical reasons, 8 of 10 completers (80%) went into partial T2DM remission with the mean HbA1c decreasing from  $6.8 \pm 0.2$  to  $6.2 \pm 0.3\%$ . This study implies that the one-year remission rate for *recent onset* T2DM may be higher than that found in the Look AHEAD study if the intervention is undertaken at the time of diagnosis of T2DM rather than years later. This, however, has not been established in a randomized controlled trial setting .

The American Diabetes Association / European Association SD treatment algorithm for new T2DM states that “at diagnosis, highly motivated patients with a HbA1c level of < 7.5% should be given the opportunity to engage in lifestyle changes for 3-6 months before embarking on pharmacotherapy (usually metformin)” (13). In the clinical setting, however, less than 40% of patients with T2DM even see a Certified Diabetes Educator for 1-3 sessions prior to the institution of glucose lowering medications much less embark upon a serious and intense long-term program of exercise and weight loss (14). This contrasts with the situation for patients with new onset coronary artery disease where insurance coverage for cardiac rehabilitation programs in the U.S. is almost universal, programs are widely available (> 2000 certified programs throughout U.S.) and hundreds of thousands of patients participate annually (15).

For lifestyle treatment programs to be more widely available for individuals at risk of or recently diagnosed with T2DM, consideration should be given for such programs to be delivered at certified cardiac rehabilitation programs (16). These programs are staffed by physicians, nurses, exercise physiologists, dieticians and other health care professionals and highly capable at delivering safe and effective exercise and weight loss programs (15,17,18). Over a period of 36 sessions of exercise training and counseling delivered over a 3-4 month period, mean fitness increases by 17% (19Ades Circ 2006). Furthermore, when behavioral weight loss counseling is provided to overweight patients in cardiac rehabilitation, a mean weight loss of 3.7 – 8.2 kg is attained along with a significant increase in insulin sensitivity (18). Cardiac rehabilitation programs have been shown to be cost-effective when compared to other treatments for coronary heart disease second only to smoking cessation counseling (20Ades Cost Effectiveness). Referral and medical communication processes have already been established between primary care providers and cardiac rehabilitation programs and in the hypothetical situation where new-onset T2DM becomes a qualifying diagnosis, referral of well-motivated patients would be straightforward.

In the absence of cardiac rehabilitation type coverage for new onset T2DM, an alternative approach is suggested by the 2011 Center for Medicare Services favorable coverage determination for intensive behavioral therapy for obesity treatment in the primary care setting for individuals with a BMI > 30kg/m<sup>2</sup> (21). For diabetes prevention, or treatment of new T2DM in the Medicare age group, intensive behavioral therapy supplemented by a home walking program should be considered although the absence of a supervised exercise program may be a limitation.

Physicians caring for individuals with new onset T2DM should consider changing their approach to treatment of new T2DM, as motivating the initiation of significant behavior change can be more complex and time consuming than simply prescribing a pill. Working collaboratively, however, primary care physicians and cardiac rehabilitation professionals have the influence, expertise and experience to provide lifestyle programs to optimally treat individuals with, or at high risk for developing T2DM. Organizations such as the American Diabetes Association and the American Association of Cardiovascular and Pulmonary Rehabilitation should individually and collaboratively support efforts to make lifestyle treatment programs T2DM more widely available.

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- Exercise and weight loss are effective in preventing type 2 diabetes mellitus (T2DM)
- Exercise and weight loss may put T2DM into remission if applied early after diagnosis
- Diabetes prevention programs are not readily available in the clinical setting