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Behavioral Management of Obesity: Enduring Models, Applications to Diabetes Prevention and Management, and Global Dissemination

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Despite countless promises from the popular media of "miracle cures" for obesity, the prevalence of obesity continues its relentless increase in both developed and developing nations (Ng, Fleming, et al., 2014). In the USA, the rapid increase in the prevalence and incidence of obesity was initially noted in the 1980s (Flegal, Carroll, et al., 1998). The prevalence of obesity had increased from 14.5% to 22.5% over the course of about 15 years (Flegal, Carroll, et al., 1998). As early as 1992, attention was being given to the number of children who were overweight or obese. An article in *Science* included obesity with issues such as teenage suicide, pregnancy of unwed mothers, and declines in college aptitude test scores as one of the pressing conditions facing children in the USA (Fuchs & Reklis, 1992). By the early turn of this century, considerable attention was being given to the obesity epidemic not only in adults but also in children (Robinson, 2000). To demonstrate the early consequences of excess fat mass, studies demonstrated that obese children were suffering from hyperlipidemia and hypertension (Freedman, Dietz, et al., 1999), at increased risk for type 2 diabetes (Pinhas-Hamiel, Dolan, et al., 1996), and developing atherosclerotic lesions (Berenson, Srinivasan, et al., 1998). Currently, 69% of adults and 31.8% of children in the USA are classified as overweight or obese (Ogden, Carroll, et al., 2014). Globally, it is estimated that 671 million individuals are obese (Ng, Fleming, et al., 2014). Not only is this a substantial increase compared to 30 years ago, the increase has accelerated in the last decade (Stevens, Singh, et al., 2012).

The obesity epidemic has occurred relatively recently, but the issue of weight loss has been

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discussed for a much longer period. Cases of individuals engaged in weight loss have been dated back to at least the fourth century A.D. (Lacey, 1982). For example, in the Middle Ages, several cases of religious women were reported to have existed on very little food over extended time periods only by virtue of spiritual power (Bell, 1985; Halmi, 1982; Hammond, 1879; Lacey, 1982). However, many of these early instances may more closely resemble eating disorders. In terms of the behavioral management of weight, William Banting developed a diet to promote weight loss in 1863 (Banting, 1863). Diets had been developed before this to address health concerns including diabetes, but Banting was among the first to develop a diet strategy that resembles the dieting of today. In the 1800s, obesity was neither a focus of medicine nor an area of scientific inquiry. It was almost 100 years later when the first behavioral studies were conducted to address obesity (Ferster, Nurnberger, & Levitt, 1962; Stuart, 1967). Studies on the "self-control of overeating" described behavioral principles (e.g., stimulus control, shaping) that are still used in obesity management today (e.g., to promote changes in diet and physical activity). In 1973, a conference on obesity was held at the National Institutes of Health in order for obesity experts to discuss "the need for heightened research on psychological, physiological, and biochemical determinants of this important health derangement" (Leavitt, 1973).

Though behavioral strategies showed promise in reducing weight, their use has not led to long-term weight maintenance (Laddu, Dow, et al., 2011). In fact, the promise of behavior modification has always been that inappropriate lifestyle behaviors could be self-controlled after patients receive training in the use of these techniques. If behavioral techniques are successful, they should be self-reinforcing because they would lead to weight loss and a sense of self-control (Foreyt, Goodrick, & Gotto, 1981). Patients who undergo behavioral training do lose weight, typically around 8% after 6 months of intervention but do not ordinarily continue weight loss following treatment. Despite the theoretical underpinnings of behavioral theory, the state of behavioral obesity treatment in the 1970s was summarized as follows:

> *Although behavior therapy has advanced the treatment of obesity, its results are still of limited clinical significance. Weight losses have been modest and the variability in results large and unexplained. Even long-term maintenance of weight loss which, it was originally hoped, would be of particular benefit of the behavioral approach, has not yet been established.* (Stunkard, 1978)

Sadly, this statement still reflects the state of behavioral weight management in most cases. However, several behavioral treatments recently have been and are being studied that suggest the long-term maintenance of clinically significant weight loss is possible (Diabetes Prevention Program Research Group, Wadden, et al., 2009; Look AHEAD Research Group, 2014a). The Diabetes Prevention Program (DPP) and Look AHEAD are models of behavioral programs that focus on lifestyle change and provide important answers on how best to treat this intractable and punishing condition.

Behavioral Treatments for Obesity

Although many necessary components (e.g., diet and physical activity-related behaviors) to treat obesity have been identified, behavior modification remains the bedrock of weight control programs (Foreyt & Pendleton, 2000). In its guide to selecting treatments for obesity, the National Institutes of Health recommends behavior modification for all individuals receiving treatment for overweight and obesity (National Institutes of Health, 2000). Changes in diet and physical activity remain the ultimate goals, but it is the behavioral strategies used that can help patients to overcome barriers that are associated with making these changes. Even in the case of bariatric surgery, behavioral management is needed to promote the lifestyle changes that are necessary for short- and long-term weight control. Behavior modification strategies with the most success take a lifestyle change approach aimed at helping patients adhere to healthy diets and sensible physical activity regimens.

The DPP and Look AHEAD studies had similar lifestyle interventions for overweight and obese adults that incorporated a tailored problem-solving approach that includes self-monitoring, goal setting, contracting, problem solving, stimulus control, cognitive restructuring, stress management, and social support (Poston & Foreyt, 2000). The goal of DPP was to determine the role of lifestyle intervention and medication in the prevention of type 2 diabetes (Diabetes Prevention Program Research Group, 2002). Along with the complementary objective of 150 min per week of moderate physical activity, the principal objective of the DPP lifestyle intervention was to assist participants at risk for diabetes in achieving and maintaining a weight loss of at least 7% (Diabetes Prevention Program Research Group, 2002). In order to achieve this objective, the lifestyle intervention of the DPP program included a comprehensive array of behavioral techniques, individual case management by "lifestyle coaches" who also delivered the intervention, frequent contact with participants throughout the duration of the study, and ongoing intervention which started with a 16-session initial core curriculum and continued with personalized maintenance sessions (Diabetes Prevention Program Research Group, 2002). Moreover, this array was flexibly tailored within sites to individual needs and across sites to site-specific cultural or regional factors.

The Look AHEAD study adapted the DPP lifestyle protocol to participants who have already been diagnosed with type 2 diabetes. It differed, however, in several ways. During the first year, the Look AHEAD treatment was provided primarily in a group rather than in an individual setting, and the use of liquid meal replacements was encouraged (Look AHEAD Research Group, Wadden, et al., 2006). The Look AHEAD study examined the impact of intentional weight loss as it relates to reduced cardiovascular morbidity and mortality (Look AHEAD Research Group, Wadden, et al., 2006). Specifically, the principal goal of the Look AHEAD study was to determine the combined effects of deaths from cardiovascular diseases, nonfatal heart attacks, nonfatal strokes, or hospitalization for chest pains during the study period of 13.5 years (Look AHEAD Research Group, Wadden, et al., 2006). Participants were randomized to either a diabetes support and education (DSE) or an intensive lifestyle intervention (ILI) condition. The DSE condition received three 1-h group meetings per year focusing on diet, physical activity, and social support (Wesche-Thobaben, 2011). Information was provided, but behavioral strategies to promote adherence were not taught. Participants in the ILI condition were encouraged to achieve a sustained weight loss of 10% of initial weight and to increase moderately intense physical activity to at least 175 min per week (Look AHEAD Research Group, Wadden, et al., 2006).

The ILI, however, utilized meal replacements as a form of portion control (Look AHEAD Research Group, Wadden, et al., 2006). Participants were given a daily calorie goal which varied (1200–1800 calories a day) depending on the individual's calorie needs (Look AHEAD Research Group, Wadden, et al., 2006). During the initial phase of treatment, participants were encouraged to replace two meals a day with a liquid shake (meal replacement) and one snack with a bar, as well as increase intake of fruits and vegetables. After month 7, calorie goals were adjusted based on weight loss during the first 6 months and individuals' future weight loss goal. A gradual shift of replacing one meal and one snack a day with a shake or bar and increasing consumption of low-energy-dense foods was encouraged.

The intervention included gradually increasing physical activity to a specific number of minutes per week, engaging in at least 10,000 steps daily, and incorporating exercise into daily lifestyle (Look AHEAD Research Group et al., 2006). Specifically, during the first 6 months of the intervention, participants were encouraged to increase activity to 125 min per week by week 16 and to 175 min per week by week 26. For the remainder of the study, participants were encouraged to engage in at least 175 min of exercise per week.

Behavioral Strategies

The following sections detail the behavioral strategies common to DPP, Look AHEAD, and most other state-of-the-art weight loss programs, including commercial applications such as Weight Watchers.

Self-Monitoring Self-monitoring is an essential component of behavioral weight loss treatments (Berkel, Poston, et al., 2005) and involves raising self-awareness through observing and recording behaviors (Kanfer, 1970). Participants in the Look AHEAD study used various self-monitoring techniques. Specifically, participants recorded their daily food intake and monitored their physical activity by totaling calories consumed and recording minutes of activity and step count, respectively. Additionally, at each weekly meeting, participants' weights were recorded in order to provide feedback about their progress and increase motivation. All of the self-monitoring methods used in Look AHEAD were strongly correlated with one another, with self-reported physical activity being the strongest correlate of weight loss at the end of the first year (Wadden, West, et al., 2009). Additionally, increased self-monitoring was related to greater treatment attendance. These findings provide clear support for the importance of self-monitoring. Even though reporting of behavioral changes may not have been accurate, self-monitoring, especially of physical activity, was still associated with weight loss. A clear example of the importance of the act of self-monitoring and not necessarily the correctness of the information recorded was demonstrated with food records. Specifically, participants who engaged in self-monitoring to a greater degree by keeping more detail on their food record at screening lost more weight at year 1 than individuals who were less detailed (Tsai, Fabricatore, et al., 2014).

In general, at the outset of treatment, self-monitoring involves observing and recording behaviors without requiring individuals to change diet or physical activity habits. Other variables that may be recorded include the time of day a food is eaten, the type of exercise completed, and the emotional state of the patient before, during, and/or after those activities. This feedback process is a significant aspect of intervention. Several studies have demonstrated a correlation between self-monitoring of food intake and one's weight with long-term weight loss and maintenance (Epstein, Valoski, et al., 1995; Williamson, Anton, et al., 2010; Israel, Guile, et al., 1994; Wing, Tate, et al., 2006).

Self-monitoring involves three processes that influence behavior change. First, self-monitoring records serve as a guide as they provide important information to individualize treatment. For example, records provide insight to patterns of behavior which can then be targeted as part of the intervention. The second process is one of increasing awareness. Even if individuals overestimate or underestimate their behaviors, the act is still effective because it is a persistent reminder of weight-related goals (Lichtman, Pisarska, et al., 1992; Trabulsi & Schoeller, 2001). A third process is that self-monitoring, especially if carried out before food is eaten, can help to break up chains of almost automatic eating that may have developed such as in eating snacks.

Goal Setting A goal-based approach for weight loss was used in both the Look AHEAD and DPP programs (Diabetes Prevention Program Research Group, Knowler, et al., 2009; Look AHEAD Research Group, Wadden, et al., 2007). Specifically, both programs used a tailored approach by identifying strategies that would be most appropriate for the specific situations of their participants.

All aspects of the Look AHEAD study included goal setting (i.e., individualized action plans); participants set goals for overall weight loss, caloric intake, and physical activity. In order to achieve the larger goals of the program, participants established small, measurable, and achievable goals at the beginning of treatment. For example, the physical activity goal during the first month was to walk for 50 min a week with the amount of minutes gradually increasing over time. Additionally, in the Look AHEAD study, it was important to establish differing goals toward a similar outcome in order to lessen the monotony of constantly working toward the same goal. This also allowed participants to choose goals that were most meaningful to them.

Goal setting is necessary as a base for effectively promoting weight loss by reinforcing small changes. Setting small, measurable, and attainable goals also is intended to increase motivation

and foster a sense of accomplishment through creating a positive momentum for future change when such goals are achieved. This momentum is important especially as many individuals try multiple times to lose weight and may feel that future attempts are unlikely to be successful. Setting realistic and effective goals is also intended to aid in treatment adherence. Additionally, encouraging changes that can easily be incorporated throughout a "regular" day is of great importance for adherence and promoting sustainability. For example, in the Look AHEAD study, participants were provided with exercises that could be incorporated into their daily routine, such as taking the stairs instead of the elevator, walking to a colleague's office instead of sending an email, and parking at the back of the parking lot instead of in the spot closest to their destination.

Focusing on lifestyle changes incorporated into a daily or weekly ritual may increase awareness of improvements in health and thus lessen the focus on unrealistic goals and increase motivation and treatment adherence. Regarding weight loss efforts, it may be helpful to focus on improvements in health, energy, and fitness that are frequently observed with an initial modest weight loss of 5–10%, which also is a realistic goal to achieve. For example, a weight loss of 5% or 10% is associated with reductions in triglycerides, blood glucose, and hemoglobin A1c (HbA1c, a measure of average blood glucose over the previous 2–3 months) and improvements in one's sense of well-being and self-esteem (Jensen, Ryan, et al., 2014). This may also lead to increasing functional and recreational activities, such as being better able to play with one's children, walking up a flight of stairs without being out of breath, or being able to tie one's shoes with less difficulty.

Contracting Contracting defines expectations and responsibilities as they relate to treatment (Foreyt, 2005). In Look AHEAD, contracts were used in combination with goal setting to enhance motivation to achieve short-term behavioral changes and ultimately successfully adhere to treatment. Contracting involves selecting and writing down realistic behavioral goals to perform between sessions and signing a document to finalize the agreement. In other cultures, this may be viewed differently, but in the USA, contracts emphasize explicit, tangible features that support change. Such goals may include limiting eating out to one less meal a week or walking for 10 extra minutes a day. In order for this strategy to be successful, it is important to understand the responsibilities and explicitly discuss what is required.

Problem Solving As with contracting, problem solving also is important for effective achievement of goals. Once realistic goals have been set, problem solving introduces methods of identifying potential barriers that may hinder achievement of these goals and brainstorming possible solutions to overcome these obstacles. In turn, this may also increase confidence in achieving goals and self-efficacy to effectively face potential problems. Problem solving is a continuous process that involves monitoring toward goals, determining the effectiveness of implemented solutions, and identifying new solutions when appropriate.

Problem solving has been shown to be an integral aspect of weight loss and maintenance efforts (Perri et al., 2001). For example, attrition is a common problem in obesity treatment. Individuals do not return for their next appointment for many different reasons, such as weight gain or not meeting a goal. Thus, it is important to acknowledge early in the intervention that setbacks are a normal part of the treatment process and to develop a plan which can be implemented when setbacks arise.

Stimulus Control Stimulus control, another important component of weight management used to facilitate behavior change, includes techniques of manipulating cues in the environment. Specifically, stimulus control is intended to alter and manage environmental cues that may trigger adaptive or maladaptive patterns of exercise and eating. For example, making unhealthy snacks unavailable may assist in decreasing caloric intake, and making a gym bag readily available may increase the likelihood of engaging in physical activity. Another technique of stimulus control

involves controlling the setting in which eating occurs. Eating at the kitchen table only and preparing one's plate before sitting down, as opposed to serving foods placed at the center of the table, are examples of methods used to create a setting that promotes healthier behaviors. Anecdotally, people report fewer thoughts and urges for food as they narrow the cues associated with them. Overall, making healthy lifestyle changes to the immediate environment is a significant aspect of successful weight management.

Complete or partial meal replacements serve as another method of stimulus control by providing exact portions and decreasing exposure to certain foods that may trigger overeating. Meal replacements also have been shown to be a safe and effective strategy for weight loss and long-term weight maintenance (Flechtner-Mors, Boehm, et al., 2010; Flechtner-Mors, Ditschuneit, et al., 2000; Heymsfield, van Mierlo, et al., 2003). The ILI group of the Look AHEAD trial successfully incorporated meal replacements by initially replacing one to two meals per day with portion-controlled, vitamin- and mineral-fortified low-energy meals (Look AHEAD Research Group, Wadden, et al., 2006).

Cognitive Restructuring Another barrier to weight loss is dysfunctional thinking patterns, such as beliefs that losing weight will resolve problems in various aspects of one's life. Cognitive restructuring identifies these patterns and manages thoughts through restructuring them to a more beneficial nature (Fabricatore, 2007; Wadden & Foster, 2000). Cognitive restructuring strategies, such as personal affirmations, are commonly used to deal with setbacks regarding weight loss. Setbacks are common triggers for dysfunctional thinking patterns (Fabricatore, 2007). Dysfunctional thinking patterns may cause one either to view a setback as a reason to abandon efforts or deny the significance of the setback. In either case, these types of thoughts may impede long-term weight loss. To overcome this barrier, cognitive restructuring assists in recognizing thoughts that are rather extreme and helps manage unrealistic expectations about weight loss.

Stress Management For some individuals, successfully engaging in behavior change may be hindered due to stress (Foreyt, 2005). This may be due to negative lifestyle changes adding to their level of stress. Individuals with high levels of stress may need support and psychological resources in order to make meaningful changes in their lives. Since physical activity reduces stress reactivity and aids in weight loss and management, it can be used as a strategy for managing stressful life situations. Additional stress management methods include progressive muscle relaxation and meditation. Progressive relaxation assists in maintaining lower levels of stress during weight loss and maintenance and meditation increases feelings of self-control. Also, meditation may act as an effective goal since it is a relatively easy strategy for patients to incorporate in their daily lives, and like aerobic exercise, meditation appears to be habit-forming for some individuals. Overall, managing stress aids in the transition toward a healthier lifestyle and also increases the likelihood of maintaining these changes.

Social Support Weight loss and long-term weight maintenance efforts can greatly benefit from social support (Foreyt & Pendleton, 2000). Social support provides many benefits including role modeling, assisting with problem solving, and serving as an emotional outlet for issues that may be experienced during weight loss treatments. Individuals can often feel that weight loss changes are daunting; however, the support of other important individuals can make these changes less difficult and demanding. Lack of social support may lead individuals to fall back into old unhealthy habits in the long-term.

In the Look AHEAD study, during the initial phase of the intervention, participants attended weekly sessions, either as a group or individually. The group sessions were designed to increase social support by encouraging participants to create a close bond with other program participants. This also promoted a sense of accountability for reaching weight loss goals. Additionally, techniques such as motivational interviewing were utilized in order to support the relationship between

participants and research staff. Participants were also encouraged to seek social support from family members, friends, and any other individuals with similar goals. For example, in order to stay on track with physical activity goals, participants were encouraged to recruit walking partners from their family and social environment.

Maintenance of Weight Loss Despite successful initial weight loss, most individuals receiving behavioral treatment remain overweight, and many regain some or all of their lost weight. This progression of weight regain was shown in Look AHEAD participants (Look AHEAD Research Group, Wing, et al., 2013); however, it was much slower than what is found in other studies. Additionally, participants in the ILI condition demonstrated significant weight loss compared to the DSE condition at every annual assessment including at 9.6 years (6% mean weight loss compared to 3.5%) (Look AHEAD Research Group, Wing, et al., 2013). Overall, Look AHEAD demonstrated that long-term weight loss is achievable with a treatment that has a high enough intensity and appropriate behavioral supports.

Incorporating Behavioral Strategies into Intervention Behavioral change strategies play a prominent role in the treatment of obesity as they are essential in assisting with making lifestyle changes. When written in a way that each behavioral strategy is discussed independently (as done in this chapter), it may seem that they are also used independently; however, behavioral strategies are meant to be used in combination with each other. For example, raising self-awareness regarding caloric intake and physical activity behaviors is essential to weight loss and maintenance efforts, and it should be followed by setting goals for gradual change in order to promote behavior change. Specifically, making gradual changes, such as steadily reducing calories and increasing physical activity, may result in losing weight at a safe rate and relatively easily. Furthermore, social support and scrutiny may support these gradual changes and ultimately long-term weight maintenance as long as individuals believe that they are under scrutiny (Berkel, Poston, et al., 2005; Jeffery, Drewnowski, et al., 2000). Finally, problem solving may be important as individuals regain weight or slowly begin to return to pretreatment behaviors (Foreyt, 2005). Individuals will almost certainly struggle to maintain the behavioral changes they have made. Problem-solving strategies to prevent relapse can include engaging in different ways of dealing with certain situations such as holidays, social interactions, the influence of friends and family members, and one's thoughts.

Key Issues for Success and Dissemination

Individual Differences Several factors can impact treatment outcomes and should be taken into account. For example, individuals with reduced income may be more averse to changing their eating habits if this results in an increased monthly food bill. They also may have less access to safe locations to engage in physical activity. Low-income individuals may be limited in their access to health care and preventative care. The impact and association of the socioeconomic environment of the individual with diabetes and its effects on health and depression have only briefly been addressed (Gary-Webb, Baptiste-Roberts, et al., 2011). Considering the ill health effects and stress that comes with living in lower socioeconomic environments, it is important to determine what these effects have on preexisting conditions such as obesity and diabetes. Look AHEAD participants living in areas of higher poverty, as compared to those living in areas of lower poverty, had significantly lower scores for overall physical and mental health as well as more limitations physically, emotionally, and socially. These findings help further illustrate the negative effects and overall poorer health status that can result from living under lower socioeconomic status (SES) conditions and demonstrate the importance of SES being taken into consideration when designing and evaluating weight management programs. The effect that SES conditions may have on weight management still requires further investigation, but evidence sug-

gest that lower SES may be related to increases in weight (Gary-Webb, Baptiste-Roberts, et al., 2011). Although research is lacking in ways to better reach low-income individuals (Harvey & Ogden, 2014), strategies to address this issue have been developed. For example, telecommunication technology may assist with these individuals by increasing the possibility of dissemination and allowing for significant tailoring to take place (Costa, Fitzgerald, et al., 2009; Griffiths, Blignault, & Yellowlees, 2006; Noh, Cho, et al., 2010). As more and more people have cell phones (Duggan & Smith, 2013), delivering interventions through this method is promising. However, the overall effectiveness of these programs to date is limited (Harvey & Ogden, 2014).

Cultural differences are also important factors that can impact weight loss attempts, and evidence suggests that ethnic minorities are underrepresented in many trials which can affect the interpretability of findings to these groups (Mount, Davis, et al., 2012). For example, in Look AHEAD, African-Americans were found to have higher adverse levels of blood pressure, heart rate, serum creatinine, and other blood markers which excluded them from being enrolled in the study (Mount, Davis, et al., 2012). Based on these findings, it may be important to modify trial eligibility in future studies to ensure greater proportions of often excluded and underrepresented populations (Mount, Davis, et al., 2012).

Genetics The roles of genetic factors in obesity have often been noted (Frayling, Timpson, et al., 2007; Herbert, Gerry, et al., 2006; Loos, Lindgren, et al., 2008; Sabatti, Service, et al., 2009; Scuteri, Sanna, et al., 2007; Speliotes, Willer, et al., 2010; Thorleifsson, Walters, et al., 2009; Willer, Speliotes, et al., 2009), but the mechanisms and processes linking genes and obesity remain unclear. Gene regions associated with higher risks for obesity, as determined from previous gene-wide association studies (GWAS), were compared to dietary intake, as measured through food-frequency questionnaires, from subjects in Look AHEAD. The study found that certain obesity risk genes were associated with various dietary patterns and habits including more eating episodes per day; eating more servings from dairy groups and products; more servings from the meat, eggs, nuts, and beans group; and lower energy use from consumed proteins. These findings suggest a genetic component may affect eating patterns as well as the type of food consumption among overweight patients with type 2 diabetes. These findings provide important information on how genes interact with health behaviors and have implications for providing a more individualized approach to weight loss (McCaffery, Papandonatos, et al., 2012).

Adherence In Look AHEAD, adherence to treatment recommendations predicted weight loss outcomes at 1 year (Wadden, West, et al., 2009). Although adherence to meal replacement recommendations and attendance at treatment sessions were significant predictors of weight loss, adherence to the recommendations for physical activity was the strongest predictor of weight loss at year 1 (Wadden, West, et al., 2009). Participants with the highest levels of self-reported physical activity lost 11.9% of their initial weight compared with 4.4% for those with the lowest physical activity. Although the study design did not allow for conclusions to be made regarding the reasons for weight loss, physical activity appears to play a critical role (Johnston, 2012).

The strongest determinant of achieving significant weight loss at 4 years in Look AHEAD was initial weight loss in year 1 (Wadden, Neiberg, et al., 2011). The oldest participants lost significantly more weight at year 4 than the youngest participants. Likewise, those who were older attended more treatment sessions, had more contacts with treatment staff, and self-reported greater behavioral adherence to the intervention. It was suggested that the older participants (age 65–74 years) may simply have more time to devote to the lifestyle intervention or that motivation to improve health may be higher in this age group. Overall, these findings are encouraging given that older adults are at increased risk in terms of both morbidity and mortality (Johnston, 2012).

Intensity and Duration of Treatment Treatment intensity may provide an effective strategy for weight management through continued contact with the intervention (Foreyt, Goodrick, et al., 1981). In the Look AHEAD trial, the intervention was intensive with participants attending weekly meetings, three group meetings and one individual meeting monthly, for the first 6 months of the intervention (Look AHEAD Research Group, Wadden, et al., 2006). Even though contact was reduced over time, long-term contact with participants also likely played an important role. In many cases, strong relationships were built between participants and study staff creating a supportive environment for long-term behavioral change. Based on these observations, it appears important to find ways to have high levels of intensity at the beginning of treatment and also to include a plan for contact over an extended period of time as this was done in both Look AHEAD and DPP. Engaging social supports may be one way to promote this in a "real-world" setting. For example, peer support has been shown to improve self-management of diabetes in multiple international settings (Fisher, Boothroyd, et al., 2012).

Primary Outcomes

The Look AHEAD intervention ended after 9.6 years due to a lack of significant results and supporting data for the study's primary outcome which was a significant decrease in cardiovascular morbidity and mortality between the ILI and DSE (Look AHEAD Research Group, Wing, et al., 2013). Even though weight loss was significantly greater in the ILI than the DSE group at every annual assessment, the primary outcome of lower rates of cardiovascular morbidity and mortality in the ILI group was unsupported. Specifically, the ILI focusing on weight loss did not significantly reduce the rate of CVD and death in overweight or obese adults with type 2 diabetes. However, many other benefits were experienced in the ILI compared to the DSE group. Most importantly, Look AHEAD demonstrated that long-term weight loss and maintenance is achievable through a lifestyle change intervention. Indeed, Look AHEAD is the largest, most comprehensive, and most successful randomized study of weight loss and maintenance to date (Perri, 2014).

In addition to its impacts on weight loss itself, the ILI intervention led to initial improvements in symptoms of sleep apnea (Foster, Borradaile, et al., 2009), cardiorespiratory fitness (Jakicic, Jaramillo, et al., 2009), physical functioning (Foy, Lewis, et al., 2011), body image (Stewart, Bachand, et al., 2011), and health-related quality of life (HRQOL) (Williamson, Rejeski, et al., 2009). The following is a brief description of some of the additional outcomes associated with the Look AHEAD intervention.

Additional Outcomes

Maintenance of Weight Loss Without follow-up care, obese individuals usually regain much of their initial weight loss within a year following treatment, and a return to baseline weight is often observed within 3–5 years (Perri, 2014). At year 1, participants in the Look AHEAD study who received the ILI achieved greater weight loss, losing 8.6% of their initial body weight compared to 0.7% for participants in the DSE (Wadden, West, et al., 2009).

Over time, participants regained some of their initial weight loss; however, on average, participants who received the behavioral lifestyle intervention maintained 4.7% weight loss at both 4 and 8 years compared to 1.1% and 2.1% for participants in the DSE, respectively (Look AHEAD Research Group, 2014a; Wadden, Neiberg, et al., 2011). Participants in the ILI had a 6.0% weight loss compared to a 3.5% weight loss in the DSE at 9.6 years (Look AHEAD Research Group, Wing, et al., 2013).

Reductions in Cardiovascular Risk Factors Improvements in weight loss were accompanied by reductions in measures of cardiovascular risk factors including fasting glucose and blood pressure as well as a decrease in the number of medicines used to treat their diabetes, blood pressure, and cholesterol compared to participants in the DSE at 1 year

(Look AHEAD Research Group, Pi-Sunyer, et al., 2007). Indicators of cardiovascular health such as cardiovascular fitness (Jakicic, Jaramillo, et al., 2009), resting heart rate (HR), an HR range, HR at 2 min following exercise, and heart rate recovery during exercise were also found to be improved in the ILI group versus the DSE group (Ribisl, Gaussoin, et al., 2012).

Severe Obesity Rates of severe obesity continue to increase, while the prevalence of overweight and mild obesity may have stabilized in recent years (Flegal, Carroll, et al., 2012). This subgroup has primarily been excluded from clinical weight loss trials due to comorbid conditions. Severe obesity is associated with higher mortality rates compared with overweight and moderately obese populations. Severe obesity not only puts individuals at risk for developing diabetes and other cardiovascular diseases, but once an individual develops type 2 diabetes, life expectancy may be significantly shortened. Since extreme categories of obesity comprise the most rapidly growing and high-risk segment of the overweight population (Flegal, Carroll, et al., 2012), effective methods for treatment are needed. Participants in the ILI condition who were severely obese (class III obesity, BMI $\geq$ 40) were compared to participants in overweight (BMI, 25 to <30), class I obese (BMI, 30 to <35), or class II (BMI, 35 to <40) obese categories. At year 1, severely obese ILI participants showed comparable weight losses in terms of percent weight loss to class I and class II obese participants. All obese participants showed significantly greater weight loss compared to the overweight participants. All BMI groups (i.e., overweight, classes I, II, III obesity) showed improvements in fitness, physical activity, cholesterol, risk factors for cardiovascular disease, and diabetes indicators. Treatment session attendance did not differ among weight categories. That is, far from being "too severe to treat with mere behavioral approaches," the severely obese benefitted in a manner parallel to those with less pronounced overweight. Although bariatric surgery is often recommended for the very severely obese, this treatment option is limited in scope. Although effective, this procedure is performed on less than 1% of the severely obese population each year. The Look AHEAD findings suggest that the behavioral treatment of obesity may be an effective treatment option for some of the severely obese population, a population that is typically presented with limited options for weight loss (Unick, Beavers, et al., 2011).

Nephropathy Overweight and obese individuals with type 2 diabetes are at increased risk for renal dysfunction which also puts these individuals at risk for cardiovascular mortality (Afkarian, Sachs, et al., 2013; Fox, Matsushita, et al., 2012). Renal dysfunction is an example of a microvascular complication resulting from poor control of blood glucose levels (Fowler, 2008). Improvement in glucose control is associated with improvement in microvascular complications resulting from type 2 diabetes. Individuals who participated in the ILI had a 31% lower risk of occurrence of very-high-risk chronic kidney disease (Look AHEAD Research Group, 2014b). Improvements in weight, HbA1c, and blood pressure were found to be associated with the decreased risk of kidney disease in these individuals. Because chronic kidney disease is a risk factor for cardiovascular-related death, reduction in one's risk of chronic kidney disease may ultimately lead to reduced mortality (Afkarian, Sachs, et al., 2013; Fox, Matsushita, et al., 2012). While the ILI was not found to reduce the rate of CVD and death after 10 years, it is possible that the beneficial effects of the ILI will take longer to appear (Look AHEAD Research Group, 2014b).

Markers of CVD Risk Cardiovascular disease is the largest single cause of death in the world (World Health Organization, 2012). Adipose tissue dysfunctions have been found to play a large role in the development of many of the metabolic abnormalities (Xu, Barnes, et al., 2003). Adiponectin is a marker of adipose health and often found in large quantities in circulation; however, adiponectin is often found in decreased amounts in obese individuals. Participants in the ILI condition demonstrated improvements in adiponectin levels by

11.9% and HDL cholesterol levels of 9.7% compared with changes in DSE which were 0.2% and 1.3%, respectively (Belalcazar, Lang, et al., 2012). When adjusting for demographic information and medical history, adiponectin changes were found to remain significantly associated with HDL-C change. Overall, these increased levels of adiponectin suggest that lower instances of cardiovascular events may be expected for individuals in the ILI condition (Belalcazar, Lang, et al., 2012).

Mobility and Bone Health As people age, they begin to experience issues such as joint pain and stiffness and decreased mobility. Obesity in older adults exacerbates these problems (Magliano, 2008). Participation in the Look AHEAD ILI that encouraged physical activity and weight loss resulted in a 48% reduction in mobility-related disability when compared with the DSE group. Improvements in weight and fitness mediated the effect of lifestyle intervention on slowing the loss of mobility (Villareal, Chode, et al., 2011). Improvements in the mobility and physical functioning of individuals with knee pain in the ILI group have also been reported (Foy, Lewis, et al., 2011).

Because decreased bone mineral density is associated with increased risk of fracture which is a common risk for older adults, the impact of weight loss on bone mineral density also was examined (Schwartz, Johnson, et al., 2012). Despite improvements in fitness, the weight loss achieved at year 1 by participants in the ILI condition was associated with greater bone loss at the hip and femoral neck than those in the DSE group. However, changes in bone mineral density at the lumbar spine and the whole body did not differ between the two groups. While there was a modest decrease in bone mineral density in the hipbone of subjects, further research will need to determine if this decrease was associated with increased risk for hip fractures (Schwartz, Johnson, et al., 2012).

Diabetes Remission Diabetes is often considered an irreversible condition; however, results from the Look AHEAD trial suggest that a lifestyle intervention can be effective to help overweight and obese participants achieve partial or complete remission of their type 2 diabetes, defined as meeting criteria of prediabetes or nondiabetic level of glycemia (i.e., fasting plasma glucose <126 mg/dl and HbA1c < 6.5% with no antihyperglycemic medication) and sustain these improvements long-term (Gregg, Chen, et al., 2012). Remission rates were higher among participants who had diabetes for a shorter amount of time, did not require insulin therapy, and had lower levels of blood sugar when they entered the study. In addition, greater weight loss and improvements in physical activity were associated with likelihood of achieving partial or complete remission (Gregg, Chen, et al., 2012).

Quality of Life Health-related quality of life (HRQOL) is a self-reported measure of a person's perceived mental and physical health (Gandek, Sinclair, et al., 2004; McHorney, 1999; Centers for Disease Control and Prevention, 2000; Selim, Rogers, et al., 2009). Participants in the ILI condition demonstrated significant improvements in HRQOL compared to those in the DSE (Williamson, Rejeski, et al., 2009). Additionally, within the ILI group, individuals with the lowest scores for HRQOL at the beginning of the study demonstrated the greatest improvements. Improved physical fitness, weight loss, and reduced physical symptoms partially contributed to the improvements in HRQOL. Much of the research on changes in HRQOL and lifestyle changes related to weight loss has yielded conflicting findings. Look AHEAD addressed some of the shortcomings of previous studies and, therefore, adds clarity to the subject (Williamson, Rejeski, et al., 2009).

Depression Depression and weight management have often been an issue when treating overweight and obese patients. In past studies, some participants suffering from depression have demonstrated further or intensified mood disorders following weight loss (Campos, 2005; Keys, Brozek, & Henschel, 1950; Rubin, Knowler, et al., 2005). The Look AHEAD study sought to further examine these factors and

determine if moderate weight loss in depressed subjects led to higher symptoms of depression and thoughts of suicide and whether initial symptoms of depression would limit weight loss after 1 year (Faulconbridge, Wadden, et al., 2012). ILI participants were found to have lost more weight and have lower depression scores compared to DSE participants. Additionally, within the ILI group, there were no significant differences in total weight loss for participants who did and did not demonstrate depressive symptomatology. These findings suggested that intentional weight loss did not worsen mild or moderate symptoms of depression but, in fact, lowered levels of depression in overweight/obese subjects with type 2 diabetes (Faulconbridge, Wadden, et al., 2012).

Extending Related Behavioral Interventions to Global Settings

The Look AHEAD intervention was conducted in the USA. The earlier pioneering work of DPP has been extended globally. DPP has gained significant support from studies focusing on diabetes prevention in Finland, China, Japan, and India with all of these showing a reduction in type 2 diabetes incidence ranging between 42% and 58% (Knowler, Barrett-Connor, et al., 2002; Tuomilehto, Lindstrom, et al., 2001; Kosaka, Noda, & Kuzuya, 2005; Pan, Yang, et al., 1997; Ramachandran, Snehalatha, et al., 2006), with generally good maintenance for up to 20 years (Li, Zhang, et al., 2008). Moreover, in preventing or postponing type 2 diabetes, the behavioral interventions have been shown to be more cost-effective than treatment with drugs such as metformin (Herman, Hoerger, et al., 2005; Ramachandran, Snehalatha, et al., 2007).

After the efficacy studies had demonstrated that lifestyle change was effective in diabetes prevention, the next step was to test whether the findings could be replicated in more "real-world" community settings and in different countries. This has taken place in two phases, starting first with implementation and dissemination studies in high-income countries (HIC) and then, followed more recently by implementation trials in low- and middle-income countries (LMIC).

DPP Translation in High-Income Countries

Both the DPP (Knowler, Barrett-Connor, et al., 2002) and the Finnish Diabetes Prevention Study (Tuomilehto, Lindstrom, et al., 2001) achieved risk reduction of 58% through a program that was intensive and conducted in research settings with special resources. For example, the Finnish study included a median number of 20 individual counseling sessions with a clinical dietitian who had high expertise on type 2 diabetes, offered a free access to gym, had a substantial number of the participants on a very-low-caloric diet, and extended over 6 years, with a median length of 4 years (Lindstrom, Ilanne-Parikka, et al., 2006). Furthermore, all participants in both studies already had impaired glucose tolerance and so were at a high risk for type 2 diabetes. Such interventions are not replicable in real-world community settings, clarifying a need for testing a less intensive and more feasible intervention.

Remarkably, the first wave of implementation studies showed similar outcomes as those of the DPP with more feasible, acceptable, and cost-effective delivery systems (Absetz, Oldenburg, et al., 2009; Ali, Echouffo-Tcheugui, & Williamson, 2012). Here we detail two of these, the GOAL program in Finland (Absetz, Valve, et al., 2007), which tested the real-world implementation of the Finnish Diabetes Prevention Study (Tuomilehto, Lindstrom, et al., 2001), and the Greater Green Triangle Diabetes Prevention Program (GGT DPP) (Laatikainen, Dunbar, et al., 2007), a study that replicated the findings of the GOAL program in Australia. Both programs were successfully scaled up after initial evaluations and are continuing to be refined in their respective countries (Oldenburg, Absetz, et al., 2011).

In contrast to the research settings of the Finnish DPS and DPP, the GOAL and the GGT DPP were designed for the primary health-care setting, where participants could be routinely

identified with the FINDRISC screening tool (Lindstrom & Tuomilehto, 2003). Health-care professionals such as dietitians and primary care nurses were identified to deliver the intervention in small groups, with a short, 3-day training for group facilitation. In Finland, the project had formed partnerships with municipal health-care centers, which implemented the program as one of their preventive care practices, while in Australia the GGT DPP project hired allied health professionals to deliver the intervention in GP practices partnering with the project.

Both the GOAL and GGT DPP included five sessions held fortnightly and one booster session at 8 months (Absetz, Valve, et al., 2007; Laatikainen, Dunbar, et al., 2007). The underlying behavior change model adopted was the health action process approach (the HAPA-model, Schwarzer & Fuchs, 1996), and the main behavior change techniques included risk appraisal, self-monitoring, goal setting, action planning and planning of coping with barriers, regular monitoring and evaluation of progress, and feedback directed toward revising individual objectives and plans for action and coping. Each GOAL session was planned to last for 2 h, while in the GGT DPP, session length was reduced to 90 min. Sessions were scheduled for weekdays (Mon–Thu) either late in the afternoon or early in the evening to fit into work schedules of both participants and health-care personnel.

Effectiveness of the GOAL program in Finland and the GGT DPP in Australia was documented in implementation studies involving over 350 participants in Finland and almost 300 in Australia (Absetz, Valve, et al., 2007; Laatikainen, Dunbar, et al., 2007). Both programs were implemented largely as planned with majority of participants and group facilitators satisfied with the programs (Oldenburg, Absetz, et al., 2011). High participant satisfaction was also reflected in the rather high retention rates throughout both programs (Oldenburg, Absetz, et al., 2011). The main source of dissatisfaction by participants as well as facilitators was the relatively short duration of the program and difficulty in handling separate worksheets instead of workbooks, both factors that were raised in the facilitator training and could be effectively dealt with later in the long-term implementation and up-scaling of the program.

The primary objective of both programs was to achieve a reduction in type 2 diabetes risk via attainment of five secondary objectives defined by the Finnish DPS (Tuomilehto, Lindstrom, et al., 2001) and entailing nutrition (total fat ≤30E%, saturated fat ≤10E%, fiber ≥15 g/1000 kcal), physical activity (≥30 min/day moderate), and weight loss (≥5%). By 12 months, 20% of the GOAL participants achieved at least four of these five key outcomes, results that were comparable to the original trial. Physical activity and weight loss goals were achieved significantly less frequently than in the original trial, 65% vs. 86% and 12% vs. 43%, respectively (Absetz, Valve, et al., 2007). Three-year follow-up of the GOAL indicated continued statistically significant risk reduction in weight (−1.0 +/−5.6 kg), BMI (−0.5 +/−2.1 kg/m^2), and serum total cholesterol (−0.4 +/−1.1 mmol/l) (Absetz, Oldenburg, et al., 2009). Twelve-month results of the GGT DPP included reductions in weight of 2.52 kg, waist circumference by 4.17 cm, fasting glucose of 0.14 mmol/l, plasma glucose 2 h after oral glucose challenge by 0.58 mmol/l (0.36–0.79), total cholesterol by 0.29 mmol/l, low-density lipoprotein cholesterol by 0.25 mmol/l, triglycerides by 0.15 mmol/l, and diastolic blood pressure by 2.14 mmHg (Laatikainen, Dunbar, et al., 2007).

For both the GOAL and GGT DPP, analyses on the psychosocial processes of lifestyle change confirmed the general applicability of the behavior change model used in the interventions (Laatikainen, Philpot, et al., 2012; Renner, Hankonen, et al., 2012), as well as its applicability across socioeconomic strata (Hankonen, Absetz, et al., 2009).

Long-Term Implementation and Up-Scaling

For scale-up and maintenance, the GOAL program has undergone some key refinements following the initial real-world implementation trial. Specific modifications have included an inaugural session to give an overview of the pro-

gram and timetable; one follow-up session to extend support up to 18 months; increased participatory and activating exercises; strengthening facilitators' training program with components on group facilitation; increased user-friendliness of the participant workbook; community-based activities in collaboration with local NGOs, e.g., healthy cooking and physical activity; and a peer support group program that has evolved as a spin-off for participants who have graduated from the GOAL program. Additionally, the training of group leaders has increased: initially, it consisted of 2 days prior to first group session plus 1 day during the program. Currently, 3 days prior to program plus 1 day annually provide adequate opportunity to build skills and self-efficacy in the program delivery and group facilitation and to share experiences with other facilitators.

The GGT DPP was translated and scaled up in the State of Victoria in Australia as the Life! Program (Dunbar, Hernan, et al., 2012; Janus, Best, et al., 2012). Multiple strategies were introduced for reaching the target population such as social marketing and incentives for GP practices and Life! Facilitators. The intervention is now offered either as a face-to-face program with one individual and five group sessions or as a telehealth coaching program with six one-on-one calls. The group sessions are also open to a partner or a friend. Facilitators' training program includes one orientation day, a self-learning period, and a 2-day workshop on session contents and facilitation skills (Reddy, Vaughan, & Dunbar, 2010). Facilitator training program is complemented with online training modules and there is a quality control system in place. Participants also have access to online supports.

DPP Translation in Low- and Middle-Income Countries

Only two of the first-wave efficacy trials were conducted in LMICs, i.e., the Da-Qing study in China (Pan, Yang, et al., 1997) and the Indian Diabetes Prevention Program (IDPP) (Ramachandran, Snehalatha, et al., 2007). The Da-Qing study included a 6-year active intervention with three lifestyle counseling arms targeting either diet or exercise only or both diet and exercise. It was delivered at community facilities in small groups of high-risk individuals identified with IGT. The study is exceptional in showing long-term effects for up to two decades: a 43% lower diabetes incidence 14 years after the 6-year active intervention had ceased. Remarkably, there was little difference in weight change between the intervention and control conditions during the active intervention. Furthermore, the three intervention arms were equally effective in risk reduction both in short- and long-term (Li, Zhang, et al., 2008). As with the other efficacy trials (Knowler, Barrett-Connor, et al., 2002; Tuomilehto, Lindstrom, et al., 2001), the IDPP tested a relatively intensive intervention comprised of individualized advice by a health provider on healthy diet and regular physical activity with monthly telephone calls to maintain motivation. The study was conducted in an urban, mainly middle-class population with persistent IGT. It achieved a 30% reduction in type 2 diabetes incidence. However, the IDPP would be difficult to "scale up" to community or national level as such, it being not feasible to provide one-on-one advice to the >20 million people with IGT in India (International Diabetes Federation, 2013). As over two-thirds of India's population lives in rural areas, strategies that are less dependent on health-care providers and health-care services are needed for broad diabetes prevention.

The limited scalability of the findings from the efficacy trials has been carefully identified in a systematic review of 30 published implementation trials of diabetes prevention programs that have utilized lifestyle interventions derived from either US DPP or Finnish DPS (Aziz, Absetz, et al., 2015). However, none of these were conducted in LMICs. The HICs represented – mainly the USA but also many Western European countries, as well as Australia and Canada – differ from LMICs in terms of their health systems, culture, traditions, and lifestyle behaviors. Further, HICs share many enabling features for disease prevention that developing countries still lack. Thus, extension of the DPP to LMICs requires

considerations of the circumstances, health systems, and cultures of those settings.

The Kerala Diabetes Prevention Program (KDPP) (Sathish, Williams, et al., 2013) in India is one of the first studies to test the feasibility and effectiveness of a culturally adapted model for diabetes prevention in a LMIC. We will describe the translation of the KDPP from the GOAL and the GGT DPP as a case example to illustrate key factors in adaptation across cultures and extension into LMICs. Before describing the program in Kerala, the following sections review considerations that guided translation from the HICs to the LMIC setting.

Health on the Public Agenda Although people in the HICs are often said to live in a so-called obesogenic environment, there are also many contextual factors that actually support healthy lifestyle and lifestyle interventions. From the 1980s onwards, health has become an important consideration in many policies, with countries such as Australia, Canada and Finland in the lead (WHO, 1986; 2012). Public and private healthcare organizations and non-governmental organizations support prevention and control of noncommunicable diseases (NCDs). Employers and their organizations increasingly recognize the need for worksite programs and policies to promote occupational health (Sparling, 2010). Furthermore, although people in HICs live in a highly motorized environment, they also often have efficient public transportation, good access to roads that are safe for walking and bicycling, as well as recreational sports facilities.

On the other hand, however, LMICs are increasingly adopting the obesogenic features of modernization, but without the counterbalancing health promoting elements. The main public health emphasis is still largely on communicable diseases, maternal and child health services, and malnutrition, as is reflected, e.g., in the United Nations' Eight Millennium Development Goals for 2015, none of which are directly related to noncommunicable diseases. In LMICs, the informal employment sector is large. Bitran (2014) estimated that in Southern and Southeast Asia, only one-third of the workforce is employed in the formal sector. Hence, with an abundance of cheap, uninsured workforce whose illness costs do not fall on the employers, there are often no incentives for NCD prevention in occupational settings. Furthermore, population awareness of prevention of noncommunicable diseases also tends to be low (Daivadanam, Absetz, et al., 2013).

Research Tradition and Infrastructures for Prevention HICs enjoy a number of resources for prevention not present in LMICs. These include:

- Financial support
- Infrastructure for program implementation and delivery, such as health-care personnel with adequate education
- Research base concerning the factors that influence the development of type 2 diabetes and its prevention

Individualistic Models of Behavior Change Many of the major diabetes prevention programs are based on behavior change models and techniques and a long tradition of behavioral scientific research that has evolved almost exclusively in the Western World. This research tradition has emphasized the individuals' role as an active decision-maker, with psychosocial constructs such as outcome expectations, self-efficacy (Bandura, 2004), and individual goals and self-regulation (Carver, 2004) for lifestyle change identified as primary determinants of behavior change. Strategies for behavior change draw largely from cognitive-behavioral therapeutic tradition such as self-monitoring, goal setting, and creation of specific action plans as some of the most effective behavior change techniques (Lara, Evans, et al., 2014; Michie, Abraham, et al., 2009). As noted earlier in the chapter, for example, the GOAL program and the GGT DPP were each based on the health action process approach (Schwarzer & Fuchs, 1996) with its emphases on risk perception, outcome expectations, self-efficacy, intention to change, and individual actions and coping. However, the relevance of these theories and the applicability and effectiveness of the techniques

in more collectivist cultures have not been well tested. Moreover, key contextual factors of a more collective nature such as household decision-making, household efficacy, and perceived household cooperation and response in relation to a change in behavior are not often factored into the intervention process or the program (Daivadanam, Wahlstrom, et al., 2014).

Strategies for Extending Diabetes Prevention to the LMICs Translation and planning of the KDPP intervention were done following the phased approach for designing complex interventions (Campbell, Fitzpatrick, et al., 2000) starting from (1) a comprehensive needs assessment including policy and research reviews and a qualitative interview study, and proceeding through (2) program translation and modeling to (3) exploratory pilot and (4) a definitive RCT, with (5) long-term implementation as the final goal and hence reflected in the entire process. The next sections describe progress to date, through the pilot study and revisions of the program for the RCT that is currently underway.

Needs Assessment: Relevance of the Problem In contrast to the long history of policies, research, and programs in NCD prevention that led to GOAL and GGT DPP, the needs assessment for the KDPP (Daivadanam, Absetz, et al., 2013) showed that, although India currently has the second largest number of people with type 2 diabetes, over 60 million, prevention of the disease still does not emerge high on the national agenda. The history of NCD prevention policy is relatively recent, and the impact still largely unevaluated. It was not until 2010 that recommendations for diet and physical activity were published as part of the National Program for Prevention and Control of Diabetes, Cardiovascular Diseases and Stroke (NPDCS). Epidemiological research revealed a very high prevalence of clinical and anthropometric risk factors for metabolic syndrome and type 2 diabetes. While modernization is increasing these risk factors in the whole of India, Kerala is by far the most advanced in this transition. The changes are largely attributable to diet and sedentary lifestyle. This is most common among women, who also have a higher prevalence of type 2 diabetes. Furthermore, sedentariness related to all aspects of life (work, leisure, and commuting) is not only an urban phenomenon but applies to rural India, too (Daivadanam, Absetz, et al., 2013).

Needs Assessment: Target Behaviors The GOAL and the GGT DPP as well as earlier diabetes prevention studies focused on moderate weight loss, increased intake of fiber, reduced total and saturated fat, and increased in physical activity (Absetz, Valve, et al., 2007; Laatikainen, Dunbar, et al., 2007). In addition to these, reduction in carbohydrates with high glycemic index such as refined rice and sugar containing foods and beverages, as well as improved sleep and reduction of smoking (among males), emerged as important targets.

Research on psychosocial determinants has been very limited in India. Still, the needs assessment review and qualitative research (Daivadanam, Absetz, et al., 2013) pointed at low awareness of personal risk and risk factors as well as low self-efficacy for and outcome expectations of prevention in general and behavior change in particular and hence supported the applicability of the health action process approach, the theoretical model behind the GOAL and the GGT DPP. However, the needs assessment also revealed a high dependence on family and cultural norms in decision-making related to lifestyle in India. Findings from the qualitative research especially suggested that application of the behavior change model would need further adjustment from a purely individualistic into a more collectivist and family-oriented focus. These observations were mirrored in other NCD interventions in India which suggested that risk reduction requires multilevel strategies including awareness raising, community empowerment, and individual and family empowerment (Balagopal, Kamalamma, et al., 2008; Daivadanam, Wahlstrom, et al., 2013, 2014; Krishnan, Ekowati, et al., 2011; Kumar, Sarma, & Thankappan, 2012; Mohan, Shanthirani, et al., 2006; Murukutla, Turk, et al., 2012; Ramachandran, Arun, et al., 2010).

Intervention Aims The KDPP adopted the same risk reduction objectives as earlier studies but

without evidence-based benchmark for similarly precise nutritional, physical activity, and weight loss objectives. Additionally, broader secondary objectives for the KDPP included:

1. To increase motivation in type 2 diabetes prevention among participants and their families and communities by
   (a) Raising awareness of type 2 diabetes risk and potential for lifestyle in preventing the disease
   (b) Increasing outcome expectations for and self-efficacy in prevention with lifestyle change
2. To strengthen individual and community skills and capability to healthy lifestyle changes with the support and help of KDPP peer group, families, and community at large
3. To increase opportunities for healthy lifestyle changes with the support and help of KDPP peer group, families, and community at large

Program Translation and Modeling Participants for the KDPP were identified from electoral wards and their diabetes risk tested with home screening using an Indian Diabetes Risk Score. The main mode of program delivery was small group meetings held in a community locality such as reading room, a local school, or participant's home that was accessible to all participants. Although participation was based on risk status, the participants were encouraged to bring family members along to the group meetings. Based on a tradition of peer-led community groups in India and findings from peer-led interventions including the US National Diabetes Prevention Program (Albright & Gregg, 2013), plans included recruiting and training peer leaders specifically for the KDPP.

The KDPP program was designed as a 12-month program to commence with an inaugural small group meeting to introduce the program and nominate peer leaders from within the group, followed by four fortnightly and subsequent monthly small group sessions of 60–90 min each until the end of the program. To meet the participants' needs for information, the program was designed to contain a half-day diabetes education session delivered in larger groups by a specially nominated KDPP expert panel and a possibility for the groups to use the expert panel also later during the program. The decision to extend the program to 1 year was due to several reasons. First, finding a suitable time for sessions was not easy and Sunday appeared to be the only free day of the week. However, there are many festivities, family gatherings, and other events to compete over participants' time so sessions could not be too frequent. Due to time constraints, 90 min was the maximum participants could be expected to spend at the sessions. The program contained a broader range of behaviors than in the GOAL and the GGT DPP. Although the official literacy rate in Kerala is very high, almost 90%, many people have had only a few years of formal education and may not have used their skills for many decades. Hence, many of the exercises in the program were expected to take longer time to complete. Finally, a common point of criticism from participants in the GOAL and GGT DPP had been that those programs should have lasted longer than they did.

Behavior Change Techniques The behavior change techniques of self-monitoring, goal setting, action and coping planning, etc. described earlier in this chapter that were common to Look AHEAD and DPP translations in developed countries also formed the basis of the KDPP behavior change model. Instead of focusing on individual control, the issues related to unhealthy lifestyles and the identification of healthier options were to be addressed collectively. For example, assessing risks and reappraising outcomes were to include consideration of the implications for families. Setting lifestyle goals took place with participants' family members and others living in the same household. By emphasizing collective problem solving and collective ways to pursue healthier lifestyles and to support one another, it was expected that not only individuals' but also families' self-efficacy would be enhanced.

In addition to its emphasis on the family, the KDPP explicitly included community empowerment as a key program objective. Strategies for community empowerment included identification of key community leaders and other influential citizens who act as local resource persons for the KDPP groups and the peer leaders, identification and partnering with key stakeholder organi-

zations in the local communities, and supporting their roles in creating social norms and planning and developing local environments, events, or programs together with the KDPP groups to enable more healthy lifestyles to all the community members.

Flexible Program Content In the GOAL and the GGT DPP, all groups followed the same structured program with predefined exercises. In the KDPP, by contrast, all the groups tackled diet and physical activity, but the specific contents of the group sessions were flexible and depended on the specific needs of each group. Suggested contents for diet covered, e.g., portion size, identifying cooking substitutions to reduce fat, increasing fruit and vegetable consumption, and decreasing sugar intake, while contents for physical activity included, e.g., finding enjoyable activities for individuals and groups, incorporating those activities into daily routines, and avoiding injuries and accidents. Tobacco control and cessation, reducing alcohol consumption, and sleep were to be dealt with based on the participants' needs and interest. The KDPP also included handbook and workbooks for the participants and a manual for the facilitators and peer leaders.

Exploratory Study An exploratory study of the KDPP was conducted with two groups to test (1) participant identification with home screening and mobile clinic testing, (2) delivery of small group sessions from inaugural meeting through session four, (3) delivery and contents of diabetes education session, and (4) peer leader selection process. This pilot highlighted some important challenges. While overall participation was moderate, male participation was a problem not only due to work constraints but also due to the belief that disease prevention activities were more appropriate for women. Although our expectations for illiteracy had been higher than the official 10%, in practice participants frequently were unable to read and write the local language (Malayalam). Many participants were familiar with type 2 diabetes through family members or relatives who already had the disease. However, this led to two things that compromised their motivation in self-care: first, many were fatalistic about getting the disease themselves, and second, they expressed that management of their significant other's disease was their first priority, not prevention of their own disease. Finally, although peer leader identification proved to be unproblematic, a major area of improvement was to find strategies to build the peer leaders' and the group members' confidence in their ability to manage sessions and benefit from them in the absence of the professional KDPP intervention team.

Modification of the KDPP from Exploratory Study Challenges identified in the exploratory pilot study led to development of a staged approach to program rollout and implementation. In the resulting plan, the first 2 months of the intervention focused on recruitment and retention with strategies highlighting the relevance and benefits of the program to participants and their families, as well as to the peer leaders. This initial phase also sought to raise awareness and support for the KDPP objectives from the communities. The community leaders of each electoral ward identified the local resource persons (LRP) to support the peer leaders and the groups. Also, an additional diabetes education session was introduced to address management of type 2 diabetes, as this had been the major concern for the pilot participants, and to link it to prevention of the disease.

The next 3 months focused on building peer leader skills and self-efficacy. The skills were targeted to enable and strengthen peer support among participants, to raise awareness of existing healthy habits and ways to improve them, as well as to build self-efficacy among participants and their families. Peer leader training in phase two included 2 days focusing on further skill building and sharing perceived benefits, positive experiences, and solutions to problems. The KDPP intervention team kept in frequent contact with the peer leaders, providing them with ongoing support both directly and via the LRPs.

The final 6 months of the 12-month program emphasized ways to maintain and expand the changes toward healthier habits with the peer support and help of extracurricular activities such

as kitchen gardening, yoga training, walking groups, etc. At this point, the groups sought to disseminate messages into their communities and develop further plans to activate their communities in diabetes prevention and a healthier lifestyle. In a workshop organized by the KDPP, peer leaders and LRPs shared ideas to develop their plans and identify community organizations with which they could partner in putting the ideas into practice.

A randomized controlled evaluation of KDPP with a 2-year follow-up is currently underway (Sathish, Williams, et al., 2013). The findings, so far, indicate that the program has been very successful in engaging those for whom it is intended. This includes recruitment rates of 75% among eligible individuals and a retention rate at the 1-year assessment of over 90%. Additional indicators of successful implementation and engagement include high participation rates – almost half of the participants attended 75% or more of the intervention sessions over 1 year – and very positive feedback from participants as well as local community and health leaders. There are also early indications that many of the activities undertaken by the peer support groups have been further implemented and have "spread" to the broader communities in which the program participants live. These early findings strongly suggest that the Kerala Diabetes Program and delivery model that have been developed for India are well accepted, adopted, and more widely implemented by people with high risk of diabetes and their communities.

Conclusions

A solid foundation for the management of obesity has been laid with behavioral change strategies playing a prominent role. Knowledge about *nutritional* approaches to weight management will continue to evolve, but these *behavioral* strategies will remain the foundation for assisting patients to make lifestyle changes to adopt healthy eating. This has been exemplified through the DPP and Look AHEAD studies. For example, not only is Look AHEAD the largest and longest randomized controlled trial for weight loss (Perri, 2014), it has demonstrated that through intensive intervention, the elusive goal of long-term weight loss is possible. Although the differences in weight loss between the ILI and DSE conditions declined over time and the trial found no significant differences in cardiovascular endpoints (Look AHEAD Research Group, Wing, et al., 2013), significant improvements were initially demonstrated across multiple areas of health including quality of life (Williamson, Rejeski, et al., 2009), mobility (Foy, Lewis, et al., 2011; Schwartz, Johnson, et al., 2012), and sleep apnea (Foster, Borradaile, et al., 2009). Notably a significant proportion of individuals experienced partial remission of their diabetes (Gregg, Chen, et al., 2012).

In the USA, dissemination of these approaches of the DPP – centered on behavior change strategies for lifestyle change – has been vigorous with appreciable successes (Albright & Gregg, 2013). The efforts to extend them globally have shown success in developed countries, through the GOAL program in Finland (Absetz, Valve, et al., 2007) and the Greater Green Triangle Diabetes Prevention Program in Australia (Laatikainen, Dunbar, et al., 2007). The Kerala Diabetes Prevention Program (Sathish, Williams, et al., 2013) has moved the dissemination efforts to low- and middle-income settings. It shows still the general applicability of the basic model and of behavior change but, stimulated by the cultural setting of India, also expands emphases on family and community.

The broad sweep of this work reveals an impressive progression of understanding and application in behavioral medicine. Without requiring change in some highly inferential personality characteristics as had long been assumed, the initial work of Stuart showed that focusing on specific eating behaviors could alter body weight (Stuart, 1967). Throughout the last third of the twentieth century, behavioral medicine researchers refined the set of behavioral change strategies useful in initiating and maintaining weight loss (Foreyt & Pendleton, 2000; Jeffery, Drewnowski, et al.,

2000; Stunkard, 1978; Wadden & Foster, 2000; Wing, Tate, et al., 2006). The twenty-first century has brought reports of the remarkable application of these approaches to major public health problems – diabetes prevention and management (Diabetes Prevention Program Research Group, 2002; Look AHEAD Research Group, Wadden, et al., 2006; Look AHEAD Research Group, Pi-Sunyer, et al., 2007; Look AHEAD Research Group, Wing, et al., 2013; Look AHEAD Research Group, 2014a; Tuomilehto, Lindstrom, et al., 2001). Dissemination is in progress in the USA and other upper-income countries (Albright & Gregg, 2013; Absetz, Valve, et al., 2007; Laatikainen, Dunbar, et al., 2007) and, now, with promising results in low- and middle-income settings (Sathish, Williams, et al., 2013).

Among the many lessons from this field, three stand out. First is a model of cultural adaptation. Consider for a moment the extent to which diet and obesity are culturally influenced and, then, how much one might expect key approaches to weight loss to vary tremendously across different groups, cultures, and countries. From that perspective, the general applicability of the basic behavior change strategies for weight management across very different settings – Australia, Finland, the USA, China, and India – is remarkable. To be sure, those principles needed to be tailored to the specific conditions in each of those settings, such as with the increased emphasis on family and community in the Kerala DPP, but still the fabric seems fairly generalizable. This reflects a model of standardization by function rather than by specific protocol or details of interventions (Aro, Smith & Dekker, 2008; Hawe, Shiell & Riley, 2004). In the present case, goal setting is an important feature of weight management programs. How those goals are set, for example, with individuals or, as in India, with families, may vary from setting to setting, but key functions, like goal setting, seem to have quite robust generality.

A second key lesson is the importance of ongoing contact or support. The Da-Qing program continued contact every 3 months throughout its course (Pan, Li, et al., 1997). Look AHEAD provided monthly contact and varied programs throughout the years it was implemented (Look AHEAD Research Group, 2014a). The idea that we can teach individuals skills with which they can autonomously manage their weight for the rest of their lives is not supported by data. Rather, sustained weight loss – like all behaviors – appears to require sustained reinforcement through ongoing contact and support. This appears also to be true of diabetes self-management. In a meta-analysis, duration of intervention was the best predictor of success of self-management programs in improving metabolic control (Norris, Lau, et al., 2002).

The third lesson emerging is the importance of context. Reflecting the importance of ongoing contact to support sustained weight loss, research also points to the importance of families and community contexts for sustained health behaviors. In this regard, the emphasis on these contexts for individuals' diabetes prevention in the Kerala DPP is noteworthy and may provide useful models for other countries in the coming years.

The needs of the 2.1 billion individuals worldwide who are overweight or obese (Ng, Fleming, et al., 2014) remain a daunting challenge. The research reviewed here shows, however, that real benefits are attainable through well-established behavioral change strategies. What is critical appears to be continued innovation in ways to adapt and disseminate those behavior change strategies with different groups, countries, and cultures, along with supportive policies to create food and community environments conducive to long-term healthy diet, physical activity, and body weight (Brownell, Kersh, et al., 2010; Gearhardt, Bragg, et al., 2012).

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