



# Partial Meal Replacement Plan and Quality of the Diet at 1 Year: Action for Health in Diabetes (Look AHEAD) Trial



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## ARTICLE INFORMATION

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## ABSTRACT

**Background** Little is known about diet quality with a reduced-energy, low-fat, partial meal replacement plan, especially in individuals with type 2 diabetes. The Action for Health in Diabetes (Look AHEAD) trial implemented a partial meal replacement plan in the Intensive Lifestyle Intervention.

**Objective** To compare dietary intake and percent meeting fat-related and food group dietary recommendations in Intensive Lifestyle Intervention and Diabetes Support and Education groups at 12 months.

**Design** A randomized controlled trial comparing Intensive Lifestyle Intervention with Diabetes Support and Education at 0 and 12 months.

**Participants/setting** From 16 US sites, the first 50% of participants (aged 45 to 76 years, overweight or obese, with type 2 diabetes) were invited to complete dietary assessments. Complete 0- and 12-month dietary assessments (collected between 2001 and 2004) were available for 2,397 participants (46.6% of total participants), with 1,186 randomized to Diabetes Support and Education group and 1,211 randomized to Intensive Lifestyle Intervention group.

**Main outcome measures** A food frequency questionnaire assessed intake: energy; percent energy from protein, fat, carbohydrate, polyunsaturated fatty acids, and saturated fats; *trans*-fatty acids; cholesterol; fiber; weekly meal replacements; and daily servings from food groups from the Food Guide Pyramid.

**Statistical analyses performed** Mixed-factor analyses of covariance, using Proc MIXED with a repeated statement, with age, sex, race/ethnicity, education, and income controlled. Unadjusted  $\chi^2$  tests compared percent meeting fat-related and food group recommendations at 12 months.

**Results** At 12 months, Intensive Lifestyle Intervention participants had a significantly lower fat and cholesterol intake and greater fiber intake than Diabetes Support and Education participants. Intensive Lifestyle Intervention participants consumed more servings per day of fruits; vegetables; and milk, yogurt, and cheese; and fewer servings per day of fats, oils, and sweets than Diabetes Support and Education participants. A greater percentage of Intensive Lifestyle Intervention participants than Diabetes Support and Education participants met fat-related and most food group recommendations. Within Intensive Lifestyle Intervention, a greater percentage of participants consuming two or more meal replacements per day than participants consuming less than one meal replacement per day met most fat-related and food group recommendations.

**Conclusions** The partial meal replacement plan consumed by Intensive Lifestyle Intervention participants was related to superior diet quality.

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**A** PARTIAL MEAL REPLACEMENT PLAN CONTAINS two portioned-controlled, vitamin/mineral-fortified meal replacements, usually beverages and food bars, per day and one balanced meal consisting of lower-energy, high nutrient-dense, conventional foods.<sup>1</sup> While a partial meal replacement plan has been found to be an efficacious strategy for weight loss,<sup>1</sup> little is known about how a

reduced-energy, low-fat, partial meal replacement plan influences diet quality, particularly in regards to meeting Dietary Guidelines recommendations.<sup>2</sup> Only three investigations have examined macro- and micronutrient intake of healthy obese older adults<sup>3</sup> and healthy overweight and obese women<sup>4,5</sup> prescribed a reduced-energy, low-fat, partial meal replacement plan. One investigation found lower total and saturated fat intake with the partial meal replacement plan in comparison with an attention control group,<sup>3</sup> one investigation found lower total fat and cholesterol intake with the partial meal replacement plan in comparison with a reduced-energy, low-fat diet composed of conventional foods,<sup>5</sup> and all studies found greater key micronutrient intake (ie, calcium, vitamin D, vitamin E, and vitamin C) in the partial meal replacement plan as compared with either an attention control group<sup>3</sup> or a reduced-energy, low-fat diet composed of conventional foods.<sup>4,5</sup> None of the studies examined overall food group intake or the percentage of participants meeting recommendations for food group intake when prescribed a reduced-energy, low-fat, partial meal replacement plan. In addition, although diet quality of a partial meal replacement plan has been examined in healthy overweight and obese individuals, diet quality of a partial meal replacement plan has not been examined in individuals with type 2 diabetes.

The Action for Health in Diabetes (Look AHEAD) trial is a 16-center, randomized controlled trial, the purpose of which was to investigate the influence of weight loss achieved via an intensive lifestyle intervention on long-term cardiovascular health in overweight or obese adults with type 2 diabetes. There are two study arms in Look AHEAD: Intensive Lifestyle Intervention, which focuses on weight loss through a lifestyle intervention, and Diabetes Support and Education, which provides education on nutrition and physical activity and social support to participants.<sup>6,7</sup> The 12-month changes in weight indicated that participants in the Intensive Lifestyle Intervention group lost a significantly greater amount of their initial body weight than those in the Diabetes Support and Education group ( $-8.6\pm 6.9\%$  vs  $-0.7\pm 4.8\%$ ).<sup>8</sup> To achieve weight loss, the Intensive Lifestyle Intervention was prescribed a reduced-energy, low-fat diet, partial meal replacement plan. Look AHEAD provides an opportunity to examine diet quality in patients with type 2 diabetes consuming a partial meal replacement plan.

The aim of this investigation was to investigate diet changes in the Intensive Lifestyle Intervention and Diabetes Support and Education groups from 0 to 12 months and to examine diet quality at 12 months between the two groups. In addition, within the Intensive Lifestyle Intervention group, diet quality was examined in participants who self-reported consumption of less than one, one to less than two, or two or more meal replacements per day. Measures of diet quality included macronutrient and Food Guide Pyramid<sup>9</sup> food group intake. Percentage of participants at 12 months meeting fat, cholesterol, and minimum daily Food Guide Pyramid group serving recommendations of the 2000 Dietary Guidelines for Americans<sup>2</sup> in each group, and in Intensive Lifestyle Intervention by meal replacement consumption category, was examined. These recommended guidelines were used in this investigation, as these were the guidelines in place during the first year of the Look AHEAD trial. Because of the previous findings related to macro- and micronutrient intake when a reduced-energy, low-fat, partial meal replacement is consumed, it was hypothesized that at 12 months, the Intensive Lifestyle

Intervention group would have a greater percentage of participants meeting fat-related and food group intake recommendations than the Diabetes Support and Education group, and that in the Intensive Lifestyle Intervention group, a greater percentage of participants consuming two or more meal replacements per day as compared with the percentage of participants consuming less than one meal replacement per day would report meeting these same recommendations.

## METHODS

### Research Design and Participants

Participants were recruited for Look AHEAD during 2.5 years beginning in 2001.<sup>7</sup> Look AHEAD randomized 5,145 participants with type 2 diabetes aged 45 to 76 years (the age range was changed to 55 to 76 years in the second year of recruitment to increase the rate of anticipated cardiovascular events) with a body mass index (BMI; calculated as  $\text{kg}/\text{m}^2$ )  $\geq 25$  ( $\geq 27$  if taking insulin) and no upper limit for BMI.<sup>7</sup> The goal of recruitment was to achieve equal numbers of men and women, a minimum of 33% of participants from racial/ethnic minority groups, and to have  $\leq 30\%$  of participants taking insulin.<sup>7</sup> Exclusion criteria included inadequate control of diabetes (ie, A1C  $> 11\%$ ), factors affecting a participant's ability to adhere to interventions, and underlying diseases likely to limit lifespan and/or affect the safety of the interventions.<sup>7</sup> Eligibility for Look AHEAD was determined using a series of screening visits. In addition, potential participants completed a 2-week run-in in which food intake and physical activity was recorded for 2 weeks. Those potential participants who did not keep satisfactory records for at least 12 of 14 days were considered ineligible. All participants gave informed consent, consistent with the Helsinki Declaration and the study was approved by the Institutional Review Board of each center.

For this investigation, participants who completed the dietary assessment component of the trial at 0 and 12 months were included. At each site, the first 50% of participants assessed were asked to complete dietary assessments. At baseline, 2,973 dietary assessments were completed before randomization. Of the 2,397 with 0- and 12-month assessments, 1,186 (49.5%) were randomized to Diabetes Support and Education and 1,211 (50.5%) were randomized to Intensive Lifestyle Intervention. Participants were provided \$100 for completion of the 12-month follow-up.

### Interventions

After completion of baseline measures, participants were randomized to Intensive Lifestyle Intervention or Diabetes Support and Education. For Intensive Lifestyle Intervention, in the first 6 months of the program, participants were prescribed a low-energy (1,200 to 1,500 kcal/day for those  $< 113.6$  kg and 1,500 to 1,800 kcal/day for those  $\geq 113.6$  kg), low-fat ( $< 30\%$  kcal from fat, with  $< 10\%$  from saturated fat) diet.<sup>6</sup> The Intensive Lifestyle Intervention prescription also included a partial meal replacement plan in which for the first 4 months (weeks 3 to 19 of the trial), meal replacements (beverages and food bars) were recommended to be consumed to replace two meals per day and one or two snacks per day.<sup>10</sup> The meal replacements were provided to participants. One meal was to be consumed from conventional foods, with an emphasis on adding fruits and vegetables to the diet.<sup>6</sup> Starting week 20 until completion of the first year of the trial, participants were encouraged to replace

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