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Long-term changes in dietary and food intake behaviour in the Diabetes Prevention Program Outcomes Study

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Abstract

Aims—To 1) compare change in dietary intake, with an emphasis on food groups and food behaviors, over time across treatment arms in a diabetes prevention trial and 2) assess differences in dietary intake across demographic groups within treatment arms.

Methods—Data are from the Diabetes Prevention Program and Diabetes Prevention Program Outcomes Study. Participants were randomized to lifestyle (n = 1079), metformin (n = 1073), or placebo (n = 1082) for an average of 3 years when the initial results regarding the benefits of the lifestyle intervention were released and all participants were offered a modified lifestyle intervention. Dietary intake was assessed using a food frequency questionnaire at baseline and at 1, 5, 6, and 9 years post-randomization.

Results—Compared to the metformin and placebo arms, lifestyle participants maintained a lower total and saturated fat, and higher fiber intake up to 9 years post-randomization; and lower intakes of red meat and sweets were maintained up to 5 years. Younger participants had higher intakes of poultry and lower intakes of fruits compared to their older counterparts, particularly in the lifestyle arm. African Americans tended to have lower dairy and higher poultry intakes compared to Caucasians and Hispanics. In the lifestyle arm, men tended to have higher grain, fruit and fish intakes compared to women.

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<u>Conflicts of interest</u>: LD has a financial interest in Omada Health, a company that develops online behavior-change programs, with a focus on diabetes. LD's interests were reviewed and are managed by Massachusetts General Hospital and Partners HealthCare in accordance with their conflict of interest policies.

Conclusions—Changes in nutrient intake among lifestyle participants were maintained for up to 9 years. Younger participants reported more unhealthy diets over time and thus may benefit from additional support to achieve and maintain dietary goals.

INTRODUCTION

In 2012, 471 billion US dollars were spent on diabetes treatment worldwide [1]. Although genetic predisposition contributes to developing type 2 diabetes (T2D) [2], the Diabetes Prevention Program (DPP) and other randomized, controlled trials of lifestyle interventions among individuals with impaired glucose tolerance have proven to be both efficacious [3-6] and cost-effective [7] to prevent or delay diabetes onset.

Prospective observational studies have suggested that certain food groups and dietary patterns are associated with incident T2D: meat and Western dietary patterns may increase risk while whole grains, low-fat dairy products, Mediterranean dietary patterns, and low-fat prudent dietary patterns may decrease risk [8-13]. Although some prevention trials have evaluated long-term adherence to specific dietary intervention goals—e.g., decreasing percent of calories from total fat and increasing fiber density [6,14,15]—to our knowledge, only one has characterized long-term changes in food group intake [16].

There is also a dearth of scientific evidence relating to demographic predictors of long-term dietary modifications. Clinical trial data have linked self-reported Hispanic and African American race/ethnicity to poorer dietary adherence [17]. Evaluating how race/ethnicity and other demographic factors are related to achieving dietary intervention goals may inform tailoring strategies, which is important for translating the DPP lifestyle intervention.

The objectives of this study were to: 1) compare change in dietary intake, with an emphasis on food groups and food behaviors, across treatment arms and 2) assess differences in dietary intake across age, race/ethnicity, and gender groups within treatment arms.

METHODS

Sample Population

The DPP was a multicenter, randomized, controlled trial that enrolled participants at highrisk of developing T2D between 1996 and 1999 [18]. Recruitment goals included: 50% women, 20% > 65 years old, and 50% African American, Hispanic, American Indian, Asian American, or Pacific Islander [18]. 3234 participants were randomized to intensive lifestyle intervention (n = 1079), 850 mg metformin twice daily (n = 1073), or placebo (n = 1082) [19]. The lifestyle intervention involved a 16-session core curriculum over the first 24 weeks followed by an individualized counseling curriculum (at least monthly contact) with primary intervention goals of achieving and maintaining a weight loss of 7% initial body weight and a moderate intensity activity level of 150 minutes per week [20]. Participants were advised to reduce dietary fat gram intake to < 25% of total calories based on a calorie estimate to achieve the weight loss goal, with the addition of a calorie goal if weight loss was not achieved after the first 7 sessions [20]. Session materials and strategies to reduce fat and calorie intake were tailored to the needs of an ethnically diverse population.

In July 2001, after the DPP results were released, participant intervention assignment was unmasked and all participants were offered a group-administered version of the 16-session lifestyle intervention curriculum [21]. Beginning in September 2002, a long-term follow-up study of DPP participants, the Diabetes Prevention Program Outcomes Study (DPPOS), began in which all participants were offered lifestyle intervention sessions every 3 months [22]. Lifestyle participants were also offered two 4-session group classes per year during this time [22]. Of the 3234 randomized participants, a total of 2766 (86%; n = 910 lifestyle; n= 924 metformin, n = 932 placebo) were enrolled in DPPOS.

Study protocols were approved by Institutional Review Boards at all sites and written informed consent was obtained for all participants.

Dietary Intake Assessment

A modified version of the validated Insulin Resistance Atherosclerosis (IRAS) study food frequency questionnaire (FFQ) was used to assess dietary intake in the DPP [23]. The 117item questionnaire was administered by trained interviewers at baseline and at 1, 5, 6, and 9 years post-randomization. Six food groups were developed based on the Food Guide Pyramid and 27 additional food groups were developed by the DPP Nutrition Coding Center [23]. A total of 8 food groups were evaluated in the present analysis (Supplemental Online Material). Nutrient content of foods was determined using the DietSys Nutrient Analysis Program and Nutrition Data System (version 2.6/8A/23, Nutrition Coordinating Center, University of Minnesota, Minneapolis, Minnesota).

Statistical Analysis

Univariate statistics including median, 25th and 75th percentiles, and percent (n) are presented for dietary variables over time. Due to space limitations and the similarity between years 5 and 6, we choose to present baseline and 1, 5, and 9 years post-randomization data. However, all statistical tests and models included year 6 data.

Repeated measures analysis of variance with generalized estimating equation (GEE) was used to assess changes in nutrients and food groups across treatment arms and demographic strata over time [24]. Proportional odds modeling with GEE was used to model food behavior variables over time [25]. Because of the treatment and time interaction, we assessed demographic differences in nutrient intake stratified by treatment group. Due to the intensive lifestyle intervention in the first year of DPP, the effect of time is not linear and therefore time is included in the models as a categorical variable. Baseline nutrient intake was adjusted in all models. As a sensitivity analysis to explore the independence of demographic effects, multivariate models including age, race/ethnicity, and gender were evaluated. Statistical significance was considered for P < 0.05. All analyses were conducted using SAS (version 9.3, Cary, North Carolina).

RESULTS

Nine years post-randomization, 74% of the original lifestyle participants and 77% of the original metformin and placebo participants had dietary data. Detailed participant

demographic information is published elsewhere [5]. There were no differences in age, gender, or race/ethnicity across treatment arms at any time point.

Because age has been reported in previous DPP/DPPOS analyses as a key predictor of achieving intervention goals [26,27], we chose to present results stratified by age (Tables 1-3). Key differences across racial/ethnic groups and gender are described in the text and presented in Figs. 1 and 2. Results were consistent in sensitivity analyses of multivariate models including all demographic variables, and therefore parsimonious models with only the demographic variable of interest are presented.

Effect of treatment arm on dietary intake and food behaviors over time

Lifestyle participants maintained a lower percent of calories from total fat and saturated fat, and higher fiber intake compared to metformin and placebo participants up to 9 years post-randomization (Table 1).

One year post-randomization, lifestyle participants had significantly higher fruit and vegetable intake, and lower red meat, dairy, and sweet intakes compared to metformin and placebo participants. By 5 years post-randomization, the observed difference in fruit intake was only marginally significant (p = 0.07), and though the lower red meat and sweet intakes remained statistically significant, the difference was small, only 0.1 servings/day. Overall p-values comparing 9-year averages were statistically significant for fruit, vegetables, poultry, red meat, and sweets (Table 2).

Lifestyle participants were more likely to report using low-fat foods "often/always" at every time point, though the proportion decreased over time (Table 3). They were also more likely to report using fat/oil in cooking less than once per week up to 5 years post-randomization.

Effect of age on dietary intake and food behaviors over time

Compared to younger participants (25 to < 45 years of age), older participants (60 years of age) had a lower percent of calories from total fat and saturated fat, and a higher fiber intake in all treatment arms (Table 1).

Older participants had higher fruit and lower poultry intakes compared to younger participants in all treatment arms (Table 2). In the lifestyle arm, older participants also had higher vegetable intakes compared to younger participants. In the metformin arm, older participants had lower red meat and dairy intakes.

Older participants were more likely to report drinking alcohol at least once per week compared to younger participants in all treatment arms (Table 3). In the placebo arm, older participants were also more likely to report using fat/oil in cooking less than once per week compared to younger participants.

Effect of race/ethnicity on dietary intake and food behaviors over time

In all treatment arms, on average across the 9 years of observation, Caucasians and African Americans had a higher percent of calories from fat compared to Hispanics (all p < 0.05) and Asian Americans (p = 0.07 for comparisons in the lifestyle arm; p < 0.05 in the

metformin and placebo arms) (Fig. 1a). American Indians had the highest percent of calories from fat of all the racial/ethnic groups; differences were significant compared to Hispanics (p < 0.001) and Asian Americans (p = 0.006) and approached significance when compared to Caucasians (p = 0.06) and African Americans (p = 0.11). Hispanics tended to have higher fiber intakes compared to Caucasians in all treatment arms (all p < 0.05), compared to African Americans (p = 0.001) and American Indians (p = 0.007) in the placebo arm, and compared to American Indians (p < 0.001) in the lifestyle arm (Fig. 1b).

No consistent differences in fruit intake across racial/ethnic groups were observed in any of the treatment arms, though Caucasians and American Indians tended to have lower fruit intakes compared to Hispanics in the lifestyle arm (p = 0.05 and p = 0.006, respectively) (Fig. 1c). Additional analysis of a food group including only fruit juice indicated that African Americans had significantly higher fruit juice intakes compared to all other racial/ ethnic groups in the lifestyle arm and compared to all other racial/ethnic groups except American Indians in the metformin and placebo arms (p = 0.05 and p = 0.50 comparing African Americans and American Indians in the metformin and placebo arms, respectively). The 9-year average intake for African Americans in the lifestyle arm was 0.67 servings/day compared to, for example, 0.51 servings/day for Caucasians (p < 0.001) and 0.53 servings/day for Hispanics (p = 0.009). In the lifestyle arm, Caucasians had higher red meat intakes compared to African Americans (p = 0.0002), Hispanics (p = 0.01), and Asian Americans (p = 0.0003), but there was no statistically significant difference compared to American Indians (p = 0.80) (Fig. 1d). American Indians had significantly higher red meat intake compared to all other racial/ethnic groups in the placebo arm and compared to African Americans (p = 0.02) and Asian Americans (p = 0.005) in the lifestyle arm. Asian Americans and American Indians had lower vegetable intakes compared to Caucasians (p =0.03 and p = 0.006, respectively) and Hispanics (p = 0.03 and p = 0.001, respectively) in the lifestyle arm. African Americans had higher fish intakes compared to Caucasians and American Indians in the metformin (p = 0.01 and p < 0.001, respectively) and placebo (p < 0.001) 0.001 and p = 0.002, respectively) arms. African Americans also had higher poultry intakes compared to all other racial/ethnic groups in the lifestyle and placebo arms (p < 0.01 for all racial/ethnic groups in both arms) and compared to all other racial/ethnic groups except Hispanics (p = 0.49) in the metformin arm. Additional analysis of a food group including only fried fish and chicken indicated that African Americans had significantly higher intakes of fried fish and chicken compared to all other race/ethnicities except American Indians in the lifestyle arm (p = 0.13) and Asian Americans in the metformin arm (p = 0.09). The 9year average intake for African Americans in the lifestyle arm was 0.12 servings/day compared to, for example, 0.07 servings/day for Caucasians (p < 0.001) and 0.06 servings/day for Hispanics (p < 0.001). Finally, African Americans had lower dairy intakes compared to Caucasians (p < 0.001 in all treatment arms) and Hispanics (p < 0.001 in lifestyle arm; p = 0.03 in metformin arm; p = 0.002 in placebo arm).

In the lifestyle arm, Caucasians were more likely to report using low-fat foods "often/ always" (p = 0.001) and to consume alcohol at least once per week (p < 0.0001) compared to other racial/ethnic groups. While nearly 20% of Caucasians and African Americans reported using fat/oil in cooking less than once per week only 3% of Asian Americans reported this low frequency in the lifestyle arm 9 years post-randomization (data not shown;

p = 0.0007). Similar differences in alcohol intake were observed in the metformin and placebo arms (p < 0.0001).

Effect of gender on dietary intake and food behaviors over time

Women had higher percent of calories from total fat (Fig. 2a) and saturated fat compared to men in all treatment arms, but no difference in fiber intake was observed (Fig. 2b).

Men had higher grain intakes in the lifestyle (p = 0.005) and metformin (p = 0.006) arms. In the lifestyle arm, men also had higher fruit (p = 0.02; Fig. 2c) and fish (p = 0.007) intakes, but no differences were observed in either the metformin or placebo arms. Additional analysis of the fruit juice food group indicated that males had significantly higher fruit juice intake compared to females in all treatment arms. The 9-year average intake for men in the lifestyle arm was 0.64 servings/day compared to 0.50 servings/day for women (p < 0.001); 0.64 and 0.55 servings/day for men and women respectively in the metformin arm (p = 0.01); and 0.61 and 0.54 servings/day for men and women respectively in the placebo arm (p = 0.002), but this relationship only reached marginal significance in the lifestyle arm (p = 0.05) and was not significant in the placebo arm (p = 0.005), but no differences were observed in either the lifestyle or metformin arms.

Men were more likely to report "seldom/never" using low-fat foods in the metformin (p = 0.02) and placebo (p < 0.0001) arms and in all treatment arms men were more likely to consume alcohol (p < 0.001).

DISCUSSION

This is the first study to describe long-term changes in nutrient and food group intake and dietary behaviors in a large, diverse sample of individuals participating in a diabetes prevention trial. The DPP lifestyle intervention outlined specific goals for lowering fat gram and calorie intake, however participants were taught they could achieve these goals in flexible ways (e.g., eat high-fat foods less often, eat smaller portions of high-fat foods, or use lower-fat food alternatives) [20]. This paper provides insight into how study participants chose to modify their food choices and behaviors.

Lifestyle participants reported statistically significantly higher fruit intake and lower red meat and sweet intakes compared to metformin and placebo participants up to 5 years post-randomization, but median intakes only differed by 0.1 servings/day. Treatment arm differences in reported use of low-fat foods were more dramatic: 12.3% of lifestyle participants reported using low-fat foods "often/always" compared to only 6.4% of metformin participants and 8.0% of placebo participants at 9 years post-randomization. Nonetheless, there was a substantial drop in the proportion of lifestyle participants reporting use of low-fat foods "often/always" from 1 to 9 years post-randomization: 40.7% to 12.3%.

The oldest participants in the lifestyle arm achieved a lower percent of calories from fat and saturated fat and higher fiber intakes compared to their younger counterparts through

healthier diets characterized by high intakes of fruits and vegetables. Participants 60 years old in the metformin and placebo arms also achieved a lower percent of calories from fat and saturated fat and higher fiber intakes compared to participants < 45 years old. Although Caucasians in the lifestyle arm had lower fruit intakes compared to Hispanics and higher red meat intakes compared to most other racial/ethnic groups, they were more likely to report using low-fat foods and had lower reported frequencies of use of fat/oil in cooking. Men tended to report higher grain, fruit, fruit juice, fish, and red meat intakes compared to women in the lifestyle arm, and were less likely to report using low-fat foods.

There were some noteworthy eating pattern differences across racial/ethnic groups. Hispanics had a lower percent of calories from fat compared to Caucasians and African Americans and a higher fiber intake compared to African Americans, which is consistent with their higher reported fruit intake. In contrast, African Americans tended to have a higher percent of calories from fat, perhaps due to their reportedly higher fried fish and chicken intakes. American Indians, including those receiving the lifestyle intervention, had lower fiber intakes and higher reported red meat intakes compared to other racial/ethnic groups. One clinical trial reported that both Hispanics and African Americans were at increased risk of not achieving goals for reducing fat intake [17]. Our study suggests that over time, African Americans and American Indians may be at even greater risk of high-fat, low-fiber diets. Finally, Asian Americans were more likely to report using fat/oil in cooking at least once per day, which may explain why this demographic group had the smallest decrease in percent of calories from fat 1 year post-intervention. Although these findings are likely to have multiple contributing factors (behavioral, cultural, economical), they present potential targets for translation into practice.

A recent clinical trial, the PREDIMED study, showed that a non-calorie-restricted Mediterranean diet supplemented with either olive oil or nuts in the absence of a significant change in body weight or physical activity could prevent diabetes [28], and this is consistent with observational studies [8-13]. It is therefore important to describe the food intakes and food behaviors of participants over time in the previously conducted T2D prevention trials. Prior to this analysis, only a single clinical trial evaluated data on participant food consumption [16]; the remaining literature related to nutrients. That previous study reported that higher levels of high-fiber foods and vegetables in the intervention group were maintained up to 5 years post-randomization [16]. In this analysis, within the lifestyle arm, the higher fiber intake observed 1-year post-randomization was relatively better-maintained 8 years later than the lower fat intake. Potential hypotheses underlying this differential retention of dietary changes include the inclusion of simplified dietary self-monitoring tools focused on the goal of achieving 5 servings of fruits and vegetables per day in the later phases of the trial and concurrent changes in external forces over time. For example, changes in the US dietary guidelines, which placed greater emphasis on fiber benefits, and voluntary increases in the fiber content of foods by industry [29]) may have made it easier for participants to maintain a higher fiber intake. Further research is needed to explore this phenomenon.

A limitation of this analysis is the measurement error associated with self-reported dietary intake. The FFQ used in the DPP/DPPOS was developed from the IRAS instrument, which

was validated against eight 24-hour recalls administered over a 1-year period in a multiethnic population [30], and included an open-ended query for foods not included within the line items. Nonetheless, it is possible that certain food items were missed. Furthermore, it is possible that the validity of the FFQ was compromised in participants with < 12 years of education [30]. Because Hispanic participants were significantly more likely to have < 12 years of education in this sample, this measurement error could have been differential, though interviewers were trained to administer the FFQ in Spanish as needed in an effort to overcome this limitation. To address the potential for social desirability bias, the DPP/ DPPOS study protocol ensured that interventionists working directly with participants did not conduct the FFQ interview, and all interviewers were trained and certified, with one primary interviewer at each site certified directly by the Nutrition Coding Center. While we acknowledge that social desirability biases may have still occurred, we would not expect them to be differential with respect to treatment arm given that all participants were aware of the benefits of weight loss in the prevention of T2D. Finally, the DPP/DPPOS did not query the frequency of cooking by participants, and therefore it is possible that participant responses imply that they use fat/oil in cooking infrequently when they may not cook at all.

A key innovation of this study is the evaluation of food groups and behaviors, in addition to traditionally evaluated nutrients. Because individuals eat foods, not nutrients, the results of this study may be more easily translated and accepted by participants and practitioners. The large, diverse sample and relatively low dropout rate improve the generalizability of this study to adults at high risk of developing diabetes in the US.

We described significant changes in dietary intake across treatment and demographic groups in the DPP/DPPOS. A lower percent of calories from total fat and saturated fat, and higher fiber intake were observed in lifestyle participants compared to metformin and placebo participants up to 9 years post-randomization; these positive changes were more likely to be observed among older participants and were observed despite overall low attendance at lifestyle sessions during the DPPOS (average attendance at any single session offered was no more than 20% for any treatment arm). Changes in nutrient intake were more likely to be sustained over time compared to the food groups and behaviors, perhaps because the intervention focused on nutrient intake targets. Age, gender, and race/ethnicity differences were expected based on the flexibility that participants were given regarding the food and behavior changes that they could integrate into their lifestyle to reach nutrient intake targets. Because the intervention was comparable in its efficacy across the various population subgroups [5], this analysis is compatible with the accommodation of different preferences, and adaptation to local community/cultural contexts, to achieve dietary goals.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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All authors were involved in the development of the research questions and analysis plan. YM performed the statistical analyses. LMJ wrote the manuscript. All authors contributed to interpreting the data and critically reviewing/editing the manuscript. All authors approved the final version submitted for publication.

Clinical trials registry: NCT00004992, NCT00038727

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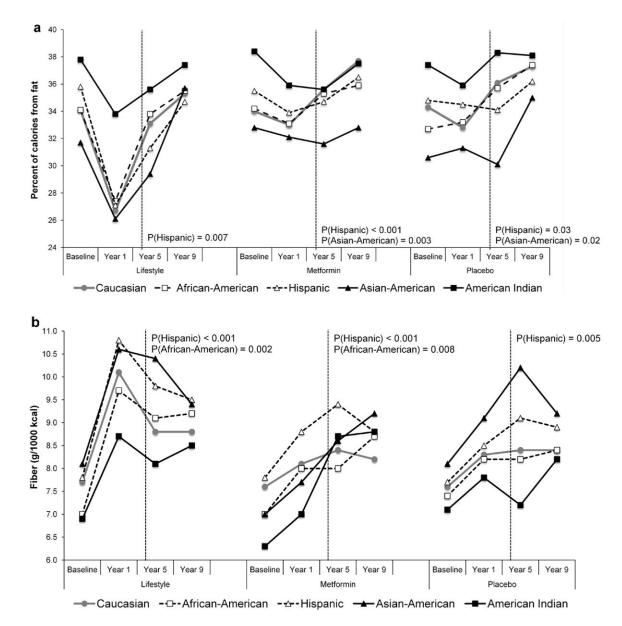
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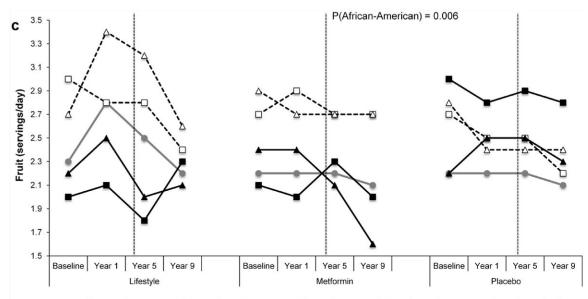
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Novelty statement

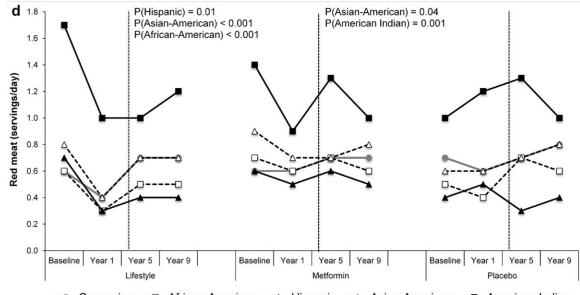
- This is the first study to evaluate long-term changes in food group intake and diet-related behaviors among a large, diverse sample of adults participating in a diabetes prevention trial in the US.
- Significant differences in foods and behaviors were observed between the lifestyle arm and the metformin and placebo arms up to 9 years post-randomization.
- Key demographic groups at high-risk of having poor dietary intake and behaviors were identified and represent an important point of intervention.

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---Caucasian -⊡-African-American -☆-Hispanic -★-Asian-American -■-American Indian

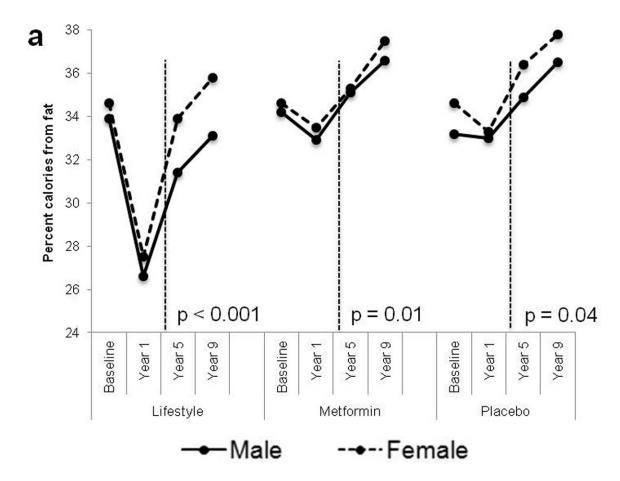


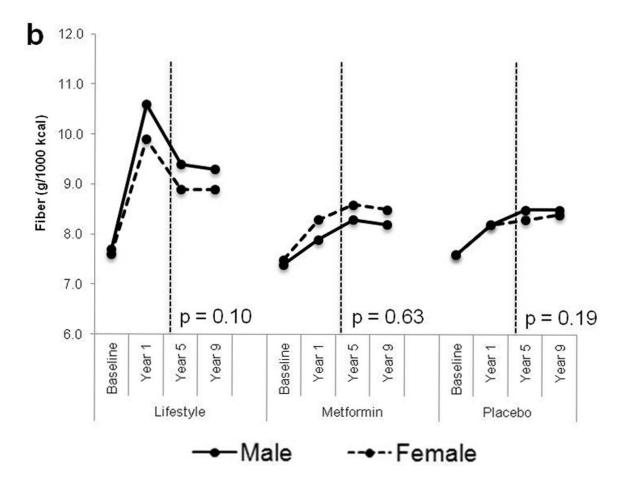
---Caucasian ---African-American ---Hispanic ---Asian-American ---American Indian

Figure 1.

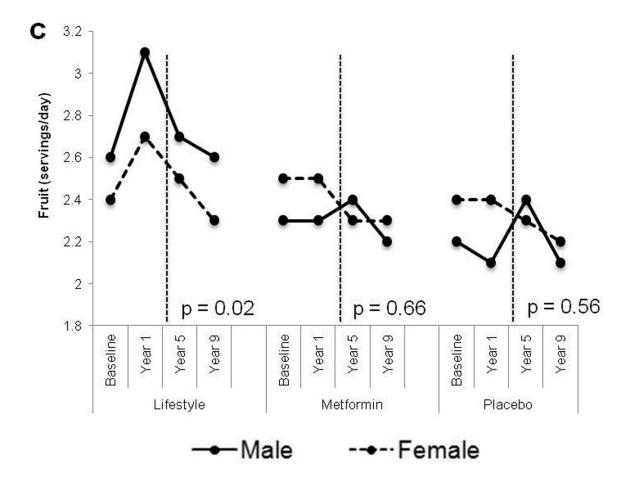
Median (a) percent calories from fat, (b) dietary fiber intake (g/1000 kcal), (c) fruit intake (servings/day), and (d) red meat intake (servings/day) over time according to treatment arm and race/ethnicity. Line indicates approximate point at which treatment arm assignment was unmasked and all participants were offered a modified lifestyle intervention. P-values are for significant pairwise comparisons between Caucasians and other racial/ethnic groups of 9-year average dietary intake from generalized estimating equations, adjusted for baseline intake.

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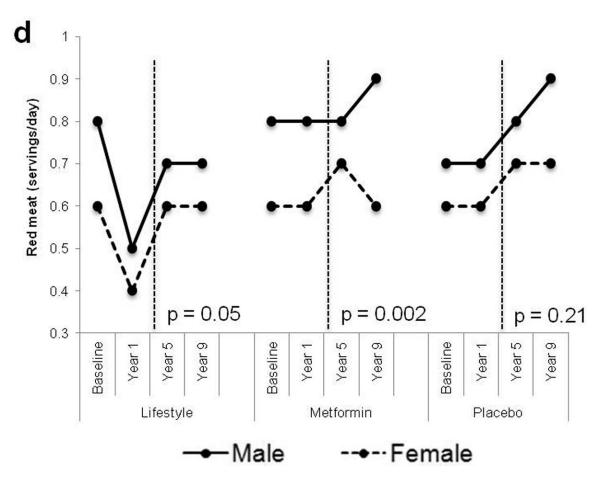


Figure 2.

Median (a) percent calories from fat, (b) dietary fiber intake (g/1000 kcal), (c) fruit intake (servings/day), and (d) red meat intake (servings/day) over time according to treatment arm and gender. Line indicates approximate point at which treatment arm assignment was unmasked and all participants were offered a modified lifestyle intervention. **P-values** are for pairwise comparison (men versus women) of 9-year average dietary intake from generalized estimating equations, adjusted for baseline intake.

		Life	Lifestyle			Metformin	vrmin			PI	Placebo	
	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9
Total calories All	1876 (1452-2550)	1521 (1192-1986)	1565 (1210-2039)	1560 (1223-2027) $^{\hat{T}}$	1915 (1475-2607)	1713 (1307-2213)	1664 (1294-2144)	1641 (1262-2115) [†]	1889 (1426-2506)	1702 (1298-2255)	1617 (1255-2171)	1613 (1227-2090)†
25-<45 years	2059 (1533-2859)	1580 (1228-2090)	1594 (1262-2187)	1640 (1271-2199)	2091 (1615-2892)		1859 (1412-2424)	1759 (1375-2242)	1977 (1469-2666)	1711 (1357-2367)	1656 (1259-2220)	1623.2 (1225-2161)
45-<60 years 60 years	1881 (1442-2511) 1758 (1340-2195)	1514 (1192-1971) 1468 (1101-1870)	1573 (1243-2011) 1450 (1140-1901)	1578 (1238-2007) 1494 (1171-1905)	1921 (1468-2582) 1692 (1380-2255)	1713 (1305-2189) 1602 (1268-2062)	1629 (1273-2091) 1547 (1258-2019)	1670 (1284-2115) 1454 (1156-1871)	1920 (1473-2526) 1666 (1328-2191)	1734 (1278-2293) 1611 (1273-2095)	1659 (1288-2249) 1496.5 (1129-1873)	1663 (1269-2173) 1501 (1128-1868)
Percent of calories from fat	ories from fat											
All	34.4 (29.6-38.5)	27.1 (23.0-31.5)	32.9 (28.3-38.6)	$35.3~(29.7-40.2)^{\ddagger}$	34.4 (29.1-39.1)	33.3 (29.1-37.7)	35.2 (30.9-40.8)	$37.2~(32.4-41.8)^{\dagger}$	34.1 (29.2-38.9)	33.3 (28.9-37.5)	36.0 (30.8-41.1)	$37.3 (32.5-42.4)^{\ddagger}$
25-<45 years	35.6 (31.3-39.8)	28.5 (24.4-33.0)	35.2 (29.5-39.8)	37.5 (32.1-41.6) [*]	35.7 (31.1-40.4)	34.5 (30.8-38.5)	36.9 (33.3-42.0)	39.1 (34.6-43.9) [*]	35.6 30.4-39.8)	34.5 (30.4-38.7)	38.4 (33.6-43.5)	38.8 (34.1-44.1) [*]
45-<60 years	34.4 (29.7-38.5)	26.8 (22.8-31.0)	32.7 (28.1-38.1)	35.1 (29.7-40.4)	34.5 (29.1-38.9)	33.2 (28.6-37.6)	35.2 (30.9-41.0)	36.9 (32.2-41.6)*	34.2 (29.3-38.7)	33.0 (29.0-37.4)	36.0 (31.0-40.9)	37.2 (32.8-42.1) [*]
60 years	32.6 (26.9-36.6)	25.7 (21.7-29.6)	31.3 (26.7-36.0)	33.0 (27.6-38.0)	31.6 (26.5-37.5)	31.9 (27.2-36.4)	33.1 (29.3-38.7)	34.7 (31.2-39.7)	31.3 (26.9-37.1)	31.2 (26.3-35.7)	32.7 (27.9-37.8)	35.0 (30.3-39.3)
Percent of cal	Percent of calories from saturated fat	l fat										
All	11.6 (9.3-13.6)	8.5 (6.9-10.5)	11.2 (9.1-13.6)	12.1 (10.4-14.9) †	11.6 (9.4-13.5)	11.2 (9.3-13.0)	12.2 (10.3-14.2)	13.1 (10.9-15.1) †	11.4 (9.2-13.7)	11.0 (8.9-13.1)	12.3 (10.1-14.6)	13.1 (10.8-15.2) ‡
25-<45 years	12.3 (10.4-14.0)	9.4 (7.5-11.4)	11.9 (9.8-14.4)	$12.8(10.4-14.9)^{*}$	12.3 (10.4-14.2)	11.9 (10.3-13.7)	12.9 (11.2-14.7)	$13.8\ (11.8-15.9)^{*}$	12.2 (9.9-14.1)	11.9 (9.9-13.7)	13.5 (11.2-15.5)	$14.0(11.7-15.9)^{*}$
45-<60 years	11.5 (9.1-13.6)	8.4 (6.9-10.1)	11.0 (8.9-13.4)	$12.1 (9.9-14.3)^{*}$	11.5 (9.3-13.4)	11.0 (9.0-13.0)	12.2 (10.1-14.2)	$13.0\ (10.7-15.0)^{*}$	11.4 (9.4-13.6)	11.0 (8.9-13.0)	12.4 (10.3-14.4)	12.8 (10.7-15.2)*
60 years	10.4 (8.4-12.7)	7.7 (6.3-9.6)	10.2 (8.3-13.0)	11.0 (8.9-13.3)	10.5 (8.1-12.6)	10.5 (8.5-12.1)	11.3 (9.7-13.1)	12.2 (10.2-14.0)	10.0 (8.2-12.3)	9.8 (7.8-12.1)	11.0 (8.8-13.4)	12.2 (9.9-14.4)
Percent of cal	Percent of calories from carbohydrates	lrates										
All	48.6 (43.6-54.1)	54.4 (49.2-60.0)	48.9 (43.2-54.6)	$46.6~(40.8-52.6)^{\dagger\prime}$	48.2 (43.1-54.0)	49.0 (44.2-54.0)	46.7 (41.4-52.1)	$45.2~(40.1\text{-}50.4)^{\dagger\prime}$	48.3 (43.4-54.2)	49.0 (43.8-54.0)	45.9 (40.5-51.6)	44.7 (39.2-49.7) [†]
25-<45 years	47.5 (42.1-51.9)	52.3 (47.7-58.1)	46.5 (41.5-52.2)	44.2 (39.2-50.0) [*]	47.1 (42.1-52.1)	47.8 (43.4-52.8)	45.5 (40.1-49.8)	42.7 (37.9-47.7) [*]	47.0 (42.4-52.3)	47.1 (42.4-52.3)	43.5 (38.5-49.2)	42.4 (37.1-47.7)*
45-<60 years	48.8 (43.4-54.2)	54.7 (49.3-60.3)	48.6 (43.3-54.7)	46.6 (41.3-52.5)	48.0 (43.0- 53.6)	49.0 (44.5-53.9)	46.5 (41.5-52.0)	45.0 (39.9-50.5)*	48.7 (43.6-54.1)	49.3 (44.4-54.1)	46.1 (40.9-51.2)	$44.9~(40.0-49.8)^{*}$
60 years	51.4 (46.3-57.2)	56.2 (51.6-61.0)	51.8 (45.9-56.2)	49.3 (44.2-55.2)	50.7 (45.6-57.5)	51.2 (45.3-56.8)	51.0 (43.8-55.5)	47.8 (43.8-53.1)	50.0 (45.2-56.5)	50.5 (46.4-55.6)	49.7 (43.7-54.7)	47.3 (42.1-52.4)

Table 1

		TR	Lifestyle			Met	Metformin				Placebo	
	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9
All	7.7 (6.0-9.8)	10.0 (8.0-12.3)	9.0 (7.3-11.7)	9.0 (7.1-11.2) [†]	7.4 (6.0-9.4)	8.1 (6.4-10.3)	8.4 (6.7-10.8)	8.4 (6.7-10.7) ‡	7.6 (6.0-9.6)	8.2 (6.5-10.3)	8.3 (6.5-10.8)	8.5 (6.7-10.5) [†]
25-<45 years	25-<45 years 6.8 (5.5-8.5)	8.9 (6.9-11.0)	8.1 (5.9-10.0)	7.3 (5.7-8.6)*	6.6 (5.4-8.2)	7.1 (6.0-9.0)	6.7 (5.6-9.4)	6.7 (5.6-9.1)*	6.8 (5.5-8.5)	7.3 (6.1-9.4)	7.1 (6.0-9.2)	6.8 (5.7-9.7)*
45-<60 years	45-<60 years 7.7 (6.2-9.9)	10.0 (8.3-12.2)	8.5 (7.1-10.8)	8.6 (6.9-10.7)*	7.6 (6.1-9.7)	8.2 (6.5-10.2)	8.0 (6.6-10.1)	8.0 (6.4-10.0)*	7.6 (6.0-9.5)	8.3 (6.6-10.2)	7.8 (6.4-10.0)	$7.9 \left(6.5 - 9.9\right)^{*}$
60 years	8.9 (7.0-11.6)	11.4 (9.4-13.5)	10.3 (8.4-12.9)	9.7 (7.8-12.1)	8.6 (6.8-10.7)	9.0 (7.2-11.4)	9.6 (7.4-12.3)	8.9 (7.4-11.2)	9.0 (7.1-11.4)	9.2 (7.5-11.5)	9.7 (7.8-12.0)	9.3 (7.3-11.5)
I Values reported	Values reported as median (25 th -75 th percentile).	h percentile).										
† Overall P < 0.0	. Overall P < 0.05 from repeated measures analysis of variance with generalized estimating equation assessing changes in nutrient intake across treatment arms over time, adjusted for baseline nutrient intake.	ures analysis of varia	ince with generalized	estimating equation as	ssessing changes in n	utrient intake <u>across 1</u>	t <i>reatment arms</i> over t	ime, adjusted for base	line nutrient intake.			

* Overall P < 0.05 from pairwise comparison (60 years old as referent) for repeated measures analysis of variance with generalized estimating equation assessing changes in nutrient intake across age strate over time, adjusted for baseline nutrient intake.

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Food group intake (servings/day) for lifestyle, metformin, and placebo participants over time according to age group.¹

		Lift	Lifestyle			Mett	Metformin			Pla	Placebo	
	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9
Grains All	3.3 (2.3-4.7)	2.9 (2.1-4.0)	2.7 (1.9-4.1)	2.6 (1.9-3.7)	3.4 (2.4-4.9)	3.1 (2.2-4.2)	2.9 (2.0-4.0)	2.7 (1.9-3.6)	3.4 (2.3-4.8)	3.0 (2.1-4.2)	2.8 (1.9-4.0)	2.7 (1.7-3.8)
25-<45 years 45-<60 years 60 years	3.4 (2.4-5.2) 3.4 (2.4-4.7) 2.8 (2.1-4.0)	3.2 (2.3-4.5) 3.1 (2.2-4.2) 2.9 (2.0-3.9)	2.9 (2.0-4.4) 2.7 (1.9-4.0) 2.7 (1.8-3.9)	2.6 (1.9-3.8) 2.7 (1.8-3.7) 2.5 (1.8-3.6)	3.8 (2.8-5.5) 3.4 (2.4-4.8) 3.2 (2.1-4.2)	3.2 (2.3-4.5) 3.1 (2.2-4.2) 2.9 (2.0-3.9)	3.2 (2.2-4.4) 2.7 (1.9-4.0) 2.8 (2.0-3.7)	2.8 (1.9-3.9) 2.7 (1.9-3.7) 2.4 (1.8-3.3)	3.6 (2.5-5.0) 3.5 (2.3-4.8) 3.1 (2.1-4.3)	3.2 (2.2-4.4) 3.0 (2.1-4.1) 3.1 (2.2-4.2)	2.9 (2.0-4.0) 2.9 (1.9-4.1) 2.6 (1.9-3.9)	2.8 (1.8-4.0) 2.7 (1.8-3.9) 2.4 (1.7-3.3)
Fruits All	2.5 (1.3-3.8)	2.8 (1.6-4.0)	2.5 (1.4-3.8)	$2.4(1.4-3.7)^{\circ}$	2.4 (1.3-3.7)	2.4 (1.4-3.8)	2.4 (1.4-3.8)	$2.2~(1.3-3.5)^{\dagger}$	2.4 (1.2-3.9)	2.3 (1.4-3.8)	2.3 (1.2-3.5)	$2.2 (1.3-3.4)^{\dagger}$
25-<45 years 45-<60 years 60 years	2.0 (1.0-3.5) 2.5 (1.3-3.9) 2.7 (2.0-4.4)	2.4 (1.3-3.5) 2.9 (1.7-3.9) 3.4 (2.2-4.7)	2.1 (1.1-3.2) 2.6 (1.5-3.9) 3.1 (2.2-4.5)	1.8 (1.0-3.2)* 2.4 (1.4-3.5)* 3.1 (1.9-4.2)	2.0 (1.0-3.5) 2.5 (1.4-3.6) 2.7 (1.5-4.4)	2.0 (1.1-3.4) 2.5 (1.5-3.8) 2.7 (1.9-3.9)	1.8 (1.2-3.3) 2.5 (1.4-3.8) 2.7 (1.8-4.1)	1.6 (1.0-2.9)* 2.4 (1.4-3.6) 2.6 (1.7-4.1)	1.9 (1.0-3.3) 2.4 (1.3-4.0) 2.8 (1.6-4.3)	2.0 (1.0-3.2) 2.4 (1.5-3.9) 2.8 (1.7-4.4)	1.7 (0.9-2.8) 2.4 (1.3-3.7) 2.6 (1.8-4.1)	1.8 (1.0-2.8)* 2.4 (1.4-3.4) 2.6 (1.6-3.6)
Vegetables All	2.5 (1.8-3.6)	2.8 (1.8-3.9)	2.6 (1.7-3.8)	$2.6(1.8-3.7)^{\ddagger}$	2.6 (1.7-3.7)	2.5 (1.8-3.6)	2.6 (1.8-3.6)	$2.6(1.7$ - $3.6)^{\ddagger}$	2.6 (1.7-3.7)	2.6 (1.8-3.8)	2.5 (1.7-3.7)	2.5 (1.7-3.5) [†]
25-<45 years 45-<60 years 60 years	2.5 (1.8-3.4) 2.6 (1.8-3.8) 2.5 (1.8-3.5)	2.6 (1.8-3.7) 2.8 (1.8-4.0) 3.0 (2.1-4.0)	2.6 (1.6-3.6) 2.6 (1.7-3.9) 2.8 (1.8-4.0)	2.5 (1.6-3.4)* 2.6 (1.9-3.8)* 2.8 (1.8-3.9)	2.4 (1.6-3.7) 2.8 (1.9-3.7) 2.5 (1.7-3.8)	2.5 (1.6-3.6) 2.6 (1.8-3.6) 2.5 (1.9-3.7)	2.5 (1.8-3.4) 2.8 (1.8-3.8) 2.5 (1.9-3.5)	2.5 (1.6-3.7) 2.6 (1.8-3.7) 2.6 (1.7-3.4)	2.5 (1.7-3.5) 2.7 (1.7-3.7) 2.6 (1.7-3.8)	2.5 (1.8-3.7) 2.6 (1.8-3.8) 2.7 (1.8-3.7)	2.4 (1.7-3.4) 2.6 (1.7-3.8) 2.6 (1.9-3.5)	2.4 (1.6-3.5) 2.6 (1.7-3.6) 2.4 (1.8-3.6)
Fish All	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)	0.2 (0.1-0.4)
25-<45 years 45-<60 years 60 years	0.2 (0.1-0.4) 0.2 (0.1-0.4) 0.2 (0.1-0.4)	0.2 (0.1-0.3) 0.2 (0.1-0.4) 0.2 (0.1-0.4)	0.2 (0.1-0.4) 0.2 (0.1-0.5) 0.2 (0.1-0.4)	0.2 (0.1-0.4) 0.3 (0.1-0.4) 0.2 (0.1-0.4)	0.2 (0.1-0.3) 0.2 (0.1-0.4) 0.2 (0.1-0.3)	0.2 (0.1-0.4) 0.2 (0.1-0.4) 0.2 (0.1-0.3)	0.2 (0.1-0.4) 0.2 (0.1-0.4) 0.2 (0.1-0.4)	0.2 (0.1-0.4) 0.3 (0.1-0.4) 0.2 (0.1-0.4)	0.2 (0.1-0.3) 0.2 (0.1-0.4) 0.2 (0.1-0.4)	0.2 (0.1-0.4) 0.2 (0.1-0.4) 0.2 (0.1-0.4)	0.2 (0.1-0.4) 0.3 (0.1-0.4) 0.2 (0.1-0.5)	0.2 (0.1-0.3) 0.2 (0.1-0.4) 0.2 (0.1-0.4)
Poultry All	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.8)	$0.5~(0.3-0.8)^{\dot{f}}$	0.5 (0.3-0.8)	0.5 (0.3-0.7)	0.5 (0.3-0.7)	$0.5 (0.2 - 0.7)^{\dagger}$	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.7) [†]

		Lif	Lifestyle			Metf	Metformin			Pla	Placebo	
	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9
25-<45 years	0.6 (0.3-0.9)	0.6 (0.3-0.9)	0.5 (0.3-0.8)	0.5 (0.3-0.9)*	0.6 (0.3-0.9)	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.6 (0.3-0.8)*	0.5 (0.3-0.9)	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.8)*
45-<60 years	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.8)*	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.7)*	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.8)	0.5 (0.3-0.7)*
60 years	0.4 (0.2-0.6)	0.4 (0.2-0.6)	0.4 (0.2-0.6)	0.4 (0.2-0.7)	0.3 (0.1-0.6)	0.4 (0.2-0.5)	0.3 (0.2-0.5)	0.3 (0.1-0.5)	0.4 (0.2-0.6)	0.4 (0.2-0.6)	0.4 (0.2-0.6)	0.3 (0.1-0.5)
Red meat												
All	0.7 (0.4-1.2)	0.4 (0.2-0.8)	0.6 (0.3-1.1)	$0.7~(0.3-1.1)^{\dagger}$	0.7 (0.4-1.2)	0.6 (0.3-1.0)	0.7 (0.4-1.2)	$0.7~(0.4-1.2)^{\dagger}$	0.6 (0.3-1.1)	0.6 (0.3-1.0)	0.7 (0.4-1.2)	$0.7~(0.4 \text{-} 1.2)^{\dagger}$
25-<45 years	0.8 (0.4-1.5)	0.5 (0.3-0.8)	0.8 (0.4-1.3)	0.8 (0.4-1.3)	0.8 (0.4-1.3)	0.7 (0.4-1.2)	1.0 (0.5-1.6)	0.9 (0.5-1.4)*	0.7 (0.3-1.2)	0.6 (0.4-1.2)	0.8 (0.4-1.4)	0.9 (0.5-1.4)
45-<60 years	0.6(0.4-1.1)	0.4 (0.2-0.7)	0.6 (0.3-1.1)	0.6 (0.3-1.1)	0.7 (0.4-1.2)	0.6 (0.3-1.0)	0.7 (0.4-1.2)	0.7 (0.4-1.2)*	0.6 (0.3-1.1)	0.6 (0.3-1.0)	0.8 (0.4-1.3)	0.7 (0.4-1.2)
60 years	0.5 (0.3-0.9)	0.3 (0.2-0.7)	0.5 (0.2-0.8)	0.5 (0.3-0.9)	0.6 (0.2-0.9)	0.6 (0.3-0.9)	0.6 (0.3-1.0)	0.6 (0.3-0.9)	0.5 (0.2-0.9)	0.5 (0.3-0.9)	0.6 (0.3-1.0)	0.6 (0.3-1.0)
Dairy												
All	1.2 (0.6-2.1)	0.9 (0.5-1.6)	1.3 (0.7-2.2)	1.4 (0.8-2.2)	1.3 (0.7-2.2)	1.2 (0.6-2.0)	1.3 (0.8-2.2)	1.4 (0.7-2.3)	1.3 (0.7-2.1)	1.1 (0.6-1.9)	1.3 (0.7-2.1)	1.4 (0.8-2.4)
25-<45 years	1.3 (0.7-2.3)	1.1 (0.6-1.6)	1.4 (0.8-2.3)	1.5 (0.9-2.5)	1.5 (0.8-2.5)	1.4 (0.7-2.1)	1.5 (0.9-2.5)	1.5 (0.8-2.4)*	1.3 (0.8-2.4)	1.2 (0.7-2.0)	1.4 (0.8-2.2)	1.4 (1.0-2.3)
45-<60 years	1.1 (0.6-2.0)	0.9 (0.5-1.6) 1.3 (0.7-2.2)	1.3 (0.7-2.2)	$1.4 (0.8-2.1)^{*}$	1.2 (0.6-2.0)	1.1 (0.6-2.0)	1.3 (0.7-2.1)	1.4 (0.8-2.4)	1.3 (0.6-2.1)	1.0 (0.6-1.9)	1.3 (0.7-2.2)	1.4 (0.8-2.5)
60 years	1.1 (0.5-1.9)	0.8 (0.5-1.5)	1.1 (0.7-2.0)	1.3 (0.8-2.1)	1.1 (0.6-2.0)	1.0 (0.5-1.8)	1.2 (0.7-2.0)	1.1 (0.7-1.9)	1.2 (0.5-1.8)	1.1 (0.6-1.8)	1.3 (0.6-1.9)	1.3 (0.9-2.2)
Sweets												
All	1.1 (0.5-2.0)	0.6 (0.3-1.1) 0.6 (0.2-1.1)	0.6 (0.2-1.1)	$0.5~(0.2 ext{-}1.0)^{\dagger}$	1.1 (0.6-1.9)	0.8 (0.4-1.4)	0.7 (0.3-1.3)	$0.6 (0.3 - 1.1)^{\dagger}$ 1.0 (0.5 - 1.8)	1.0 (0.5-1.8)	0.7 (0.4-1.4)	0.7 (0.3-1.2)	$0.6~(0.3\text{-}1.1)^{\dagger}$
25-<45 years	1.2 (0.6-2.5)	0.6 (0.3-1.3)	0.6 (0.2-1.1)	0.6 (0.3-1.1)	1.3 (0.6-2.3)	0.9 (0.5-1.6)	0.8 (0.4-1.5)	$0.6\ (0.3-1.1)^{*}$	1.2 (0.6-2.0)	0.9 (0.4-1.5)	0.7 (0.3-1.4)	$0.6\left(0.3\text{-}1.1 ight)^{*}$
45-<60 years	1.0 (0.5-2.0)	0.6 (0.2-1.0)	0.6 (0.2-1.2)	0.5 (0.2-0.9)	1.1 (0.5-1.9)	0.8 (0.4-1.4)	0.6 (0.3-1.2)	0.6 (0.3-1.1)	1.0 (0.5-2.0)	0.7 (0.4-1.3)	0.7 (0.3-1.3)	0.6 (0.3-1.1)
60 years	1.0 (0.5-1.7)	0.6 (0.3-1.0)	0.5 (0.3-1.0)	0.6 (0.3-1.2)	1.0 (0.5-1.6)	0.8 (0.4-1.2)	0.6 (0.3-1.1)	0.6 (0.3-1.0)	0.7 (0.4-1.4)	0.6 (0.3-1.0)	0.6 (0.2-1.0)	0.5 (0.2-0.9)
I Values reported	I Values reported as median (25 th -75 th percentile).	th-75th percenti	le).	-			~					
$\dot{\tau}$ Overall P < 0.0)5 from reneated	measures analy	t Aberall P < 0.05 from reneated measures analysis of variance with generalized estimating equation assessing changes in food groun intake across treatment arms over time adjusted for baseline food	vith veneralized e	stimating equat	ion assessing ch	anges in food o	ronn intake <i>acros</i>	ss treatment arm	s over time. adi	usted for baselir	e food
group intake.	""""""""""""""""""""""""""""""""""""""	ווורמסעו עס מוועון			שהלה צוווווווני	TA SurceAcen HOL	anges m roos g	oup mux arres	D PLEMINETER WITH	<u>8</u> 0'vu uuuv, uu		2010

* Overall P < 0.05 from pairwise comparison (60 years old as referent) for repeated measures analysis of variance with generalized estimating equation assessing changes in food group intake <u>across age</u> <u>strata</u> over time, adjusted for baseline food group intake.

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				Lift	Lifestyle			Metf	Metformin			Pla	Placebo	
			Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9	Baseline	Year 1	Year 5	Year 9
		IIV	33.5 (353)	9.0 (89)	24.0 (203)	$24.3(193)^{\ddagger}$	29.9 (316)	30.3 (302)	35.6 (309)	$34.5(284)^{\ddagger}$	30.7 (326)	27.4 (272)	35.5 (305)	$32.4~(268)\dot{7}$
	Seldom/never		37.4 (131)	11.2 (36)	25.8 (65)	24.7 (57)	32.9 (102)	32.9 (94)	40.1 (89)	38.0 (81)	31.0 (99)	27.4 (78)	32.2 (73)	28.8 (64)
		45-<60 years	32.2 (153)	9.3 (42)	21.9 (87)	23.3 (88)	28.6 (152)	29.1 (147)	32.2 (148)	32.6 (143)	31.7 (173)	28.0 (146)	36.8 (172)	33.3 (150)
		60 years	30.1 (69)	5.2 (11)	26.0 (51)	25.9 (48)	29.0 (62)	29.6 (61)	38.5 (72)	35.3 (60)	27.3 (54)	25.8 (48)	36.4 (60)	34.6 (54)
		All	55.5 (585)	50.3 (496)	63.2 (535)	$63.4(503)^{\ddagger}$	57.3 (605)	55.7 (556)	56.8 (493)	$59.0(485)\dot{\uparrow}$	55.8 (593)	57.9 (574)	57.1 (491)	59.7 (494) [†]
Use of low-fat foods	Sometimes	25-<45 years	53.4 (187)	49.4 (159)	63.1 (159)	64.1 (148)	58.4 (181)	55.2 (158)	51.4 (114)	55.4 (118)	58.0 (185)	60.7 (173)	59.5 (135)	62.2 (138)
		45-<60 years	57.3 (272)	50.4 (229)	64.8 (258)	63.8 (241)	57.7 (307)	56.1 (284)	59.3 (272)	60.1 (264)	55.0 (300)	55.9 (291)	55.8 (261)	58.0 (261)
		60 years	55.0 (126)	51.2 (108)	60.2 (118)	61.6 (114)	54.7 (117)	55.3 (114)	57.2 (107)	60.6 (103)	54.5 (108)	59.1 (110)	57.6 (95)	60.9 (95)
		All	11.0 (116)	40.7 (402)	12.8 (108)	$12.3(98)^{t/2}$	12.8 (135)	14.0 (140)	7.6 (66)	$6.4~(53)\dot{f}$	13.5 (143)	14.7 (146)	7.4 (64)	$8.0~(66)^{\ddagger}$
	Often/always	25-<45 years	9.1 (32)	39.4 (127)	11.1 (28)	11.3 (26)	8.7 (27)	11.9 (34)	8.6 (19)	6.6(14)	11.0 (35)	11.9 (34)	8.4 (19)	9.0 (20)
		45-<60 years	10.5 (50)	40.3 (183)	13.3 (53)	13.0 (49)	13.7 (73)	14.8 (75)	8.5 (39)	7.3 (32)	13.2 (72)	16.1 (84)	7.5 (35)	8.7 (39)
		60 years	14.8 (34)	43.6 (92)	13.8 (27)	12.4 (23)	16.4 (35)	15.0 (31)	4.3 (8)	4.1 (7)	18.2 (36)	15.1 (28)	6.1 (10)	4.5 (7)
		All	21.9 (229)	35.4 (349)	23.3 (166)	$16.9(114)^{\ddagger}$	20.7 (218)	24.4 (243)	15.3 (108)	$15.2(101)^{\ddagger}$	20.5 (217)	22.0 (219)	17.3 (122)	$14.8~(102)^{\ddagger}$
	< 1 /week	25-<45 years	16.4 (57)	32.4 (104)	18.5 (39)	15.9 (31)	16.0 (49)	22.9 (65)	8.6 (15)	12.5 (22)	17.0 (54)	19.4 (55)	17.2 (33)	11.5 (21)*
		45-<60 years	20.4 (96)	35.5 (161)	22.0 (73)	14.3 (46)	19.8 (105)	24.8 (125)	15.6 (59)	12.6 (44)	19.1 (104)	19.2 (100)	15.0 (57)	12.8 (48) [*]
		60 years	33.3 (76)	39.8 (84)	31.8 (54)	23.3 (37)	29.9 (64)	25.7 (53)	22.5 (34)	25.2 (35)	29.8 (59)	34.0 (64)	23.7 (32)	25.0 (33) [*]
Use of fat/oil in cooking		All	56.1 (587)	53.9 (531)	68.4 (488)	72.1 (487) ‡	56.8 (598)	58.4 (581)	75.3 (530)	$73.0(485)^{\ddagger}$	56.5 (599)	60.4 (600)	72.8 (515)	74.8 $(516)^{\ddagger}$
	1-6 /week	25-<45 years	59.8 (208)	58.3 (187)	72.0 (152)	70.3 (137)	60.6 (186)	59.2 (168)	77.7 (136)	73.9 (130)	56.6 (180)	64.1 (182)	72.4 (139)	77.0 (141)*
		45-<60 years	56.9 (268)	52.4 (238)	68.7 (228)	76.0 (244)	59.3 (315)	59.8 (302)	75.1 (284)	73.6 (257)	59.6 (324)	62.3 (325)	74.2 (282)	75.5 (283) [*]
		60 years	48.7 (111)	50.2 (106)	63.5 (108)	66.7 (106)	45.3 (97)	53.9 (111)	72.8 (110)	70.5 (98)	48.0 (95)	49.5 (93)	69.6 (94)	69.7 (92) [*]
	1 /day	All	22.1 (231)	10.8 (106)	8.3 (59)	$11.0(74)^{\dot{T}}$	22.4 (236)	17.2 (171)	9.4 (66)	$11.7~(78)^{\ddagger}$	23.0 (244)	17.6 (175)	9.9 (70)	$10.4~(72)\dot{f}$

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Placebo

Lifestyle

Metformin

			Bacalina	Voor 1	Voor 5	Voor 0	Bacalina	Voor 1	Voor 5	Voor 0	Receline	Voor 1	Voor 5	Voor 0
			Dascille	T LOUI T	TCAL	TCAL	Dascille	T COL T	1001	T Call	Dascille	1 1001	TCOLO	T Call 2
		25-<45 years	23.9 (83)	9.3 (30)	9.5 (20)	13.8 (27)	23.5 (72)	18.0 (51)	13.7 (24)	13.6 (24)	26.4 (84)	16.5 (47)	10.4 (20)	11.5 (21)*
		45-<60 years	22.7 (107)	12.1 (55)	9.3 (31)	9.7 (31)	20.9 (111)	15.4 (78)	9.3 (35)	13.8 (48)	21.3 (116)	18.6 (97)	10.8(41)	11.7 (44) [*]
		60 years	18.0 (41)	10.0 (21)	4.7 (8)	10.1 (16)	24.8 (53)	20.4 (42)	4.6(7)	4.3 (6)	22.2 (44)	16.5 (31)	6.7 (9)	5.3 (7)*
		ЧI	56.2 (592)	59.1 (585)	52.0 (440)	51.5 (409)	54.4 (575)	54.1 (540)	47.7 (414)	48.4 (398)	56.9 (605)	58.4 (581)	51.9 (446)	53.3 (441)
	None	25-<45 years	74.0 (259)	75.5 (243)	54.0 (136)	54.5 (126) [*]	70.0 (217)	65.7 (188)	47.3 (105)	51.6(110)*	74.7 (239)	73.7 (210)	55.1 (125)	50.9 (113) [*]
		45-<60 years 49.9 (237)	49.9 (237)	54.7 (249)	53.0 (211)	52.1 (197) [*]	49.9 (266)	50.8 (257)	48.4 (222)	46.2 (203) [*]	50.7 (277)	54.6 (285)	51.5 (241)	55.3 (249) [*]
		60 years	41.9 (96)	43.7 (93)	47.4 (93)	46.5 (86) [*]	43.0 (92)	46.1 (95)	46.5 (87)	50.0 (85) [*]	44.9 (89)	45.7 (86)	48.5 (80)	50.6 (79) [*]
		All	19.6 (207)	18.0 (178)	23.8 (201)	17.6 (140)	19.5 (206)	20.1 (201)	26.0 (226)	18.1 (149)	17.9 (190)	16.9 (168)	22.6 (194)	15.7 (130)
Alashal intelse	Joon 1	25-<45 years	12.6 (44)	11.8 (38)	27.0 (68)	19.5 (45) [*]	15.2 (47)	18.9 (54)	32.0 (71)	21.6 (46) [*]	9.7 (31)	11.6 (33)	23.8 (54)	15.3 (34) [*]
PUCOLICI IIIIANO	1 / wccv	45-<60 years	23.8 (113)	21.3 (97)	25.1 (100)	18.3 (69) [*]	20.1 (107)	20.2 (102)	24.8 (114)	$18.9(83)^{*}$	22.5 (123)	18.2 (95)	22.0 (103)	14.7 (66) [*]
		60 years	21.8 (50)	20.2 (43)	16.8 (33)	14.1 (26) [*]	24.3 (52)	21.8 (45)	21.9 (41)	$11.8(20)^{*}$	18.2 (36)	21.3 (40)	22.4 (37)	19.2 (30)*
		All	24.2 (255)	22.9 (227)	24.2 (205)	30.9 (245)	26.1 (276)	25.8 (257)	26.3 (228)	33.5 (275)	25.3 (269)	24.7 (246)	25.6 (220)	31.0 (257)
	1 /week	25-<45 years	13.4 (47)	12.7 (41)	19.0 (48)	26.0 (60) [*]	14.8 (46)	15.4 (44)	20.7 (46)	26.8 (57) [*]	15.6 (50)	14.7 (42)	21.1 (48)	33.8 (75) [*]
		45-<60 years	26.3 (125)	24.0 (109)	21.9 (87)	29.5 (112) [*]	30.0 (160)	29.1 (147)	26.8 (123)	34.9 (153) [*]	26.7 (146)	27.2 (142)	26.5 (124)	30.0 (135)*
		60 years	36.2 (83)	36.2 (77)	35.7 (70)	39.5 (73) [*]	32.7 (70)	32.0 (66)	31.6 (59)	38.2 (65)*	36.9 (73)	33.0 (62)	29.1 (48)	30.1 (47) [*]
¹ Values reported as % (n).	; % (n).													
⁷ Overall P < 0.05 proportional odds modeling with generalized estimating equation assessing changes in food behaviors across treatment arms over time, adjusted for baseline food behavior.	roportional odd	ds modeling wit	th generalized	d estimating	equation asso	essing change	s in food beh	aviors <u>across</u>	s treatment a	r <u>ms</u> over time.	, adjusted for	baseline foo	d behavior.	
* Overall P < 0.05 from proportional odds modeling with generalized estimating equation assessing changes in food behaviors across age strata over time, adjusted for baseline food behavior.	rom proportion	al odds modelii	ng with gener	ralized estim	ating equatio	n assessing ch	anges in foo	d behaviors <u></u>	tcross age sti	r <u>ata</u> over time	s, adjusted for	r baseline foo	od behavior.	