Translating Lifestyle Intervention to Practice in Obese Patients With Type 2 Diabetes

Improving Control with Activity and Nutrition (ICAN) study

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OBJECTIVE — To assess the efficacy of a lifestyle intervention program that can be readily translated into clinical practice for obese patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — The study consisted of a 12-month randomized controlled trial of 147 health plan members with type 2 diabetes and obesity (BMI ≥27 kg/m^2). Participants were randomized to lifestyle case management or usual care. Case management entailed individual and group education, support, and referral by registered dietitians; intervention cost was $350 per person. Individuals treated with usual care received educational material. Both groups received ongoing primary care. Outcomes were difference between groups for change in weight (kilograms), waist circumference (centimeters), HbA_{1c}, fasting lipid levels, use of prescription medications, and health-related quality of life.

RESULTS — Case management resulted in greater weight loss ($P < 0.001$), reduced waist circumference ($P < 0.001$), reduced HbA_{1c} level ($P = 0.02$), less use of prescription medications ($P = 0.03$), and improved health-related quality of life ($P < 0.001$) compared with usual care. The 12-month group difference in weight loss and waist circumference was 3.0 kg (95% CI −5.4 to −0.6) and −4.2 cm (−6.8 to −1.6). HbA_{1c} differences were greatest at 4 months (−0.59%, $P = 0.006$) but not significant by 12 months (−0.19%, $P = 0.45$). Participants in the case management group lowered their use of medications, primarily diabetes medications, by 0.8 medications per day more than participants treated with usual care ($P = 0.03$). In seven of nine quality-of-life domains, the case management group improved compared with usual care ($P < 0.05$).

CONCLUSIONS — Moderate-cost dietitian-led lifestyle case management may improve diverse health indicators among obese patients with type 2 diabetes.

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The prevalence of obesity has reached epidemic proportions in the U.S. (1) and is a major risk factor for type 2 diabetes (2,3). Modest weight loss (5–10% of body weight) results in improved insulin sensitivity (4) and decreased cardiovascular risk factors in individuals with type 2 diabetes (5,6). Independent of weight loss, diet and physical activity are effective means of improving glycemic control (7), blood pressure (8), and lipid levels (9–11). Moreover, lifestyle treatment with modest weight loss has been shown to prevent type 2 diabetes (12–14). Therefore, lifestyle treatment is vital to diabetes control in obese individuals (15).

The translation of demonstrated diabetes and obesity treatments into practice has been slow, however. The resource burden of lifestyle treatments demonstrated in efficacy trials may be too great for patients, clinicians, and health care systems to sustain long-term (16). Translation of lifestyle efficacy trials into lower-intensity, cost-effective interventions is crucial to allow management of obese individuals with type 2 diabetes in practice and to maximize the applicability and long-term maintenance of interventions (17,18).

We hypothesized that a modestly priced, registered dietitian (RD)-led case management approach to lifestyle change would be more effective than usual medical care for patients with obesity and type 2 diabetes. The objective was to compare the efficacy of lifestyle case management to usual care given in the primary care setting, as measured by clinical, health-related quality of life (HRQOL), and economic outcomes.

RESEARCH DESIGN AND METHODS

— Improving Control with Activity and Nutrition (ICAN) was a randomized controlled trial. The University of Virginia Institutional Review Board approved the study. All participants gave written informed consent.

Eligibility criteria were type 2 diabetes (International Classification of Diseases, 9th Revision [ICD-9] codes 250.XX, 357.2, 362.0, 362.02, or 366.41 and confirmed by physician), use of diabetes medications, BMI ≥27 kg/m^2, age ≥20 years, ability to comprehend English, and membership in the Southern

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Abbreviations: HRQOL, health-related quality of life; ICAN, Improving Control with Activity and Nutrition; RD, registered dietitian; SF-36, Medical Outcomes Study Short Form-36; SHS, Southern Health Services.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Health Services (SHS) health plan. In 2001, SHS served 156,000 people (2,950 with diabetes) across Virginia with commercial programs. Of those members with diabetes, 9% contacted the study, 7% were interested and eligible, and 5% entered the study. The greatest reason for nonparticipation was distance from the single study site. Of those members with diabetes within a 30-mile radius of the site, 21% contacted the study, 16% were interested/eligible, and 11% entered the study. Exclusion criteria were pregnancy, cognitive limitations, or medical reasons precluding dietary and physical activity modifications. The screening and recruitment process included identification of eligible participants from SHS data, participant-initiated contact with study personnel after mailed invitations, and finally phone and in-person screening by study personnel. Participants were evaluated at the University of Virginia Health System and General Clinical Research Center.

Eligible participants were randomly assigned to case management or usual care by the principal investigator and study coordinator using random permuted blocks with randomly chosen block sizes of two or four provided by the biostatistician. Study personnel were blinded to the allocation schedule until assignment. The sample size yields 80% power for comparing the groups on each outcome with a two-sided significance level of 5%, for an effect size of 0.4 (19).

Intervention

One RD case manager met with participants individually, in groups, and by phone for assessment, goal setting, education, and support. Goals were tailored but based on national dietary recommendations for people with type 2 diabetes and obesity (20,21). The RD measured weight and waist circumference, followed laboratory results, and discussed patient-care issues with physicians when appropriate. Individual sessions occurred six times throughout the year, totaling 4 h. Participants attended six 1-h small-group sessions. Brief monthly phone contacts provided support. The direct cost of the intervention, including written information, was $350.00 per person. Unit time was based on patient care time as designated in the protocol and estimated by the RD. Unit costs were actual cost of educational material. Salary and overhead were based on published costs from the Diabetes Prevention Program (16). Goals of the intervention were modest weight loss (5% of initial weight) and dietary intake as well as physical activity reflecting national recommendations (20–22). Usual care participants received educational material (23) and were free to join other weight management or diabetes care programs.

Outcome measures

The primary outcome measures were weight and waist circumference. Secondary measures included glycemic control (HbA_{1c}), lipid levels, use of prescription medications, and HRQOL (Medical Outcomes Study Short Form-36 [SF-36]) (24). Trained personnel recorded all measures. Body weight, height, and waist circumference were measured at baseline and at 4, 6, 8, and 12 months. HbA_{1c} was measured at baseline and at 4, 8, and 12 months and fasting lipid levels at baseline and at 12 months by the University of Virginia laboratory using standardized protocols. At baseline and at 6 and 12 months, study personnel transcribed medication name, dose prescribed, and quantity taken daily from participant prescription containers. Medications were characterized by indication/disease: diabetes, cardiovascular, antihypertensives, and other. "Other" medications included pain, asthma, and psychiatric medications. Use was defined as either total or unique number of medications. "Total" included various doses of the same medication and assessed changes in dose. "Unique" counted individual medications once and evaluated changes in type.

Statistical analysis

Group differences were analyzed using intention-to-treat methods. Repeated-measures models compared groups regarding changes in weight, waist circumference, HbA_{1c}, and use of medications. *F* tests were used to make overall comparisons. Contrasts were used to make comparisons between groups at specific follow-up times. Repeated-measures models used REML estimation, an unstructured covariance matrix, and the Kenward-Roger approximation to the degrees of freedom. The repeated-measures models used all the available data on subjects, including those who dropped out of the study or had intermittently missing data. Regression models were used to compare 12-month HRQOL between groups.

In repeated-measures models, baseline values of outcomes were used as covariates. Subsequent analyses were adjusted for additional baseline characteristics. For HbA_{1c}, models were adjusted for age, sex, duration of diabetes, and change in diabetes medications. For weight and waist circumference, models were adjusted for age, sex, and smoking. Adjusting for these covariates did not affect the results for comparing treatment groups. Secondary analyses were adjusted for use of outside behavioral resources, but this did not alter results. Statistical analyses were performed using SAS statistical software (version 8.2; SAS Institute, Cary, NC).

RESULTS — A total of 147 participants were randomized into usual care ($n = 73$) or case management ($n = 74$). After three patients withdrew before baseline assessment, the intention-to-treat analysis population comprised 71 usual care participants and 73 case management participants. A total of 29 participants (20%) withdrew from the study (usual care = 10, case management = 19; 22 by 4 months, 24 by 6 months, 27 by 8 months, and 29 by 12 months). Reasons given for dropping out were time ($n = 13$), assignment group ($n = 6$), illness ($n = 1$), or no reason ($n = 9$). A total of 118 individuals (80%) completed the 12-month intervention. Of case management participants remaining in the study, 100% attended all individual sessions and 78% attended four or more group classes. Number of classes attended was not associated with outcomes.

Baseline characteristics

Groups were similar in all demographic and clinical measures at baseline (Table 1). A total of 6% of participants reported seeing a health professional for weight control, and 0.7% were taking antiobesity medications. Less than 13% used outside behavioral resources for diabetes or weight management during the intervention. On average, participants reported 2.6 (SD 1.6) "health problems" (e.g., hypertension) besides diabetes. Mean HbA_{1c} suggested moderately good control (7.7% [SD 1.6]). Participants were taking a mean of 1.79 unique and 1.98

Table 1—*Baseline characteristics of participants by randomization group*

Variables	Usual care group	Case management group
n	71	73
Categorical variables		
Women	42 (58)	45 (62)
Caucasians	53 (74)	61 (85)
Smoking status		
Never	40 (56)	41 (57)
Former	30 (42)	27 (38)
Current	2 (3)	4 (6)
Marital status		
Never	9 (13)	4 (6)
Married	50 (69)	55 (76)
Divorced	11 (15)	9 (13)
Widowed	1 (1)	3 (4)
Other	1 (1)	1 (1)
Continuous variables		
Age (years)	53.4 ± 8.0	53.3 ± 8.6
Weight (kg)	106.7 ± 24.3	107.1 ± 25.5
BMI (kg/m^2)	37.5 ± 6.4	37.6 ± 7.7
Waist circumference (cm)	118.1 ± 16.5	116.8 ± 15.5
HbA_{1c} (%)	7.5 ± 1.5	7.9 ± 1.6
Cholesterol (mg/dl)		
Total	181 ± 37.2	183 ± 43.4
LDL	105 ± 33.3	105 ± 33.7
HDL	44.6 ± 12.3	45.4 ± 12.8
Triglycerides (mg/dl)	167 ± 77.2	193 ± 76.7
Number of prescription medications/day	5.8 ± 2.6	6.3 ± 2.9
Number of diabetes medications/day	1.8 ± 0.85	1.8 ± 0.92
Insulin (%)	22	26
Biguanides (%)	69	60
Sulfonylurea (%)	51	49
Thiazolidinediones (%)	24	25
Other diabetes medications (%)	3	7
SF-36		
Bodily pain	63.0 ± 22.8	62.6 ± 21.9
General health	53.2 ± 22.1	53.4 ± 20.4
Health transition	47.2 ± 25.4	52.8 ± 21.2
Mental health	73.7 ± 19.4	75.4 ± 16.2
Physical function	72.7 ± 25.1	71.6 ± 21.5
Role—emotional	79.6 ± 33.8	86.1 ± 28.4
Role—physical	67.6 ± 39.9	69.4 ± 38.3
Social functioning	78.8 ± 23.5	83.2 ± 23.3
Vitality	50.7 ± 21.8	44.9 ± 22.6
Average of SF-36 Scores	65.8 ± 18.4	66.0 ± 17.4

Data are *n* (%) or means ± SD unless otherwise indicated. No statistically significant differences between groups were noted.

total diabetes medications daily at baseline. Lipid levels indicated that many participants did not meet the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III targets (25) for HDL cholesterol, LDL cholesterol, and triglyceride levels; 92 (64%) participants were taking cardiovascular medications. Based on health plan data for glycemic control and LDL cholesterol levels, our population seemed to be at lower risk of diabetes and cardiovascular complications than the general health plan membership with diabetes.

Body weight and waist circumference

Mean weight changes differed significantly between the case management and usual care groups ($P < 0.001$) (Fig. 1*A*). The greatest weight loss in the intervention group (–4.0 kg, 95% CI −5.6 to −2.5) and net weight loss between groups (−5.0 kg, −7.2 to −2.9) occurred at 8 months. By 12 months, participants in the case management group lost an average of −2.4 kg (−4.1 to −0.6), whereas participants in the usual care group gained 0.6 kg (−1.0 to 2.2), a net difference of −3.0 kg (−5.4 to −0.6). More participants in the case management group than the usual care group lost up to 5% (53 vs. 32%) and ≥5% (20 vs. 14%) of initial weight ($\chi^2 = 8.7$, $P = 0.03$).

Waist circumference decreased more in the case management group than in the usual care group by 12 months ($P < 0.001$) (Fig. 1*B*). By 12 months, participants in the case management group lost −5.5 cm (−7.4 to −3.6), whereas the usual care group lost −1.4 cm (−3.1 to 0.4).

Glycemic and lipid control

HbA_{1c} differed between groups over the intervention period ($P = 0.02$). This difference was greatest at 4 months (−0.57%, −1.0 to −0.2; $P = 0.008$) but drifted closer by 8 months (−0.35%, −0.8 to 0.1; $P = 0.10$) and 12 months (−0.20%, −0.7 to 0.3; $P = 0.45$). Change in weight did not predict change in HbA_{1c} level.

Post hoc subanalyses indicated differential effects of treatment by initial glycemic control. Participants with better control (baseline HbA_{1c} ≤7.45%, mean HbA_{1c} = 6.54%) experienced significant HbA_{1c} reduction at 4 and 8 months ($P < 0.05$); 12-month reductions approached significance ($P = 0.07$) (Fig. 2*A*, left panel). Among participants with poorer glucose control (baseline HbA_{1c} >7.45%, mean HbA_{1c} = 8.89%), case management resulted in an acute (–0.91%, −1.7 to −0.08; $P = 0.032$) but transient response (12-month change −0.07, −1.1 to 0.97; $P = 0.9$) (Fig. 2*A*, *right panel*).

The 12-month between-group (case management versus usual care) differences in lipid levels were not statistically significant: −8.6 mg/dl (−22.6 to 5.5; $P = 0.23$) for total cholesterol, –0.07 mg/dl (−9.4 to 9.3; $P = 0.99$) for LDL cholesterol, −0.40 mg/dl (−1.9 to 2.7;

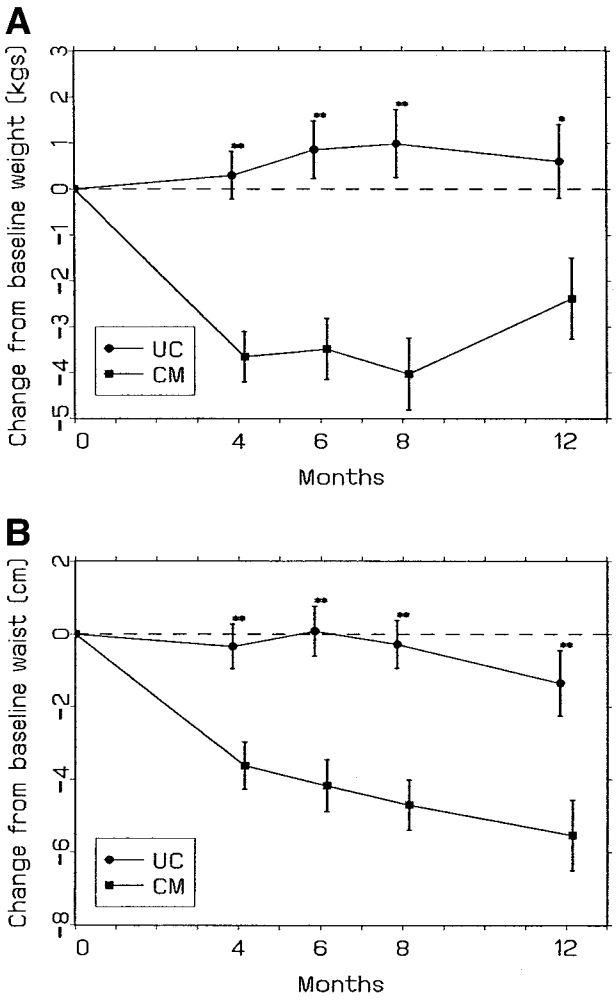

Figure 1—*Mean changes in body weight* (A) *and waist circumference* (B) *by groups. Data shown are estimated changes ±1 SE. Results are based on* n = *71, 67, 64, 63, and 63 subjects in the usual care group and* n = *72, 58, 58, 56, and 54 subjects in the case management group at baseline and at 4, 6, 8, and 12 months postbaseline, respectively.* A: *Mean ± SE body weight (kg) over time of intervention in the case management (CM) and usual care (UC) groups.* B: *Mean ± SE waist circumference (cm) over time of intervention in the CM and UC groups.* *P ≤ *0.05;* **P ≤ *0.001.*

$P = 0.73$) for HDL cholesterol, and −36.0 mg/dl (–106 to 34; $P = 0.31$) for triglycerides.

Prescription medication

By 12 months, participants in the case management group were taking 0.8 (0.05–1.1) fewer total medications per day than those in the usual care group ($P = 0.03$) (Fig. 2*B*). More individuals in the case management group decreased total medications compared with those in the usual care group (45 vs. 28%, respectively), and fewer individuals in the case management group increased medications compared with those in the usual care group (19 vs. 35%) ($\chi^2 = 6.6$, 2 df; $P = 0.03$) at 6 months. Although the magnitude of the differences remained similar (decrease: 57 vs. 39%; increase: 17 vs. 32%), these differences were no longer significant by 12 months ($P = 0.13$).

There was a decrease in unique medications primarily due to a decrease in diabetes medications ($P = 0.003$). By 12 months, the case management group reduced diabetes medications 0.46 medications per day more than those in the usual care group ($P = 0.001$). Insulin and sulfonylurea decreased most among participants in the case management group, whereas thiazolidinedione increased slightly among usual care.

Quality of life

Baseline SF-36 scores were lower than national norms but consistent with scores reported among obese individuals (26). Change in SF-36 scores in the case management group was significantly different from usual care in seven of nine domains (Fig. 3). The domains with greatest improvement in the case management group were emotional role (15.1, 3.4–26.8) and physical role (10, 1.2–24.7).

CONCLUSIONS— ICAN results suggest that a modest cost, easily translated RD case management approach to lifestyle care can improve diverse indicators of health, including weight, waist circumference, HRQOL, and use of prescription medications, among obese persons with type 2 diabetes. This study also points out that those who did not receive lifestyle care but remained medically managed gained weight, had reduced quality of life, and sustained their need for medication.

The magnitude of the 12-month weight loss observed in ICAN was modest yet similar to other 1-year interventions among obese individuals both with and without type 2 diabetes (5,6,22,27,28). The U.S. Preventive Medicine Task Force's evidence-based review of obesity interventions reported that intensive behavioral interventions produce weight loss between 3 and 5 kg by 1 year and made grade B recommendations to support intensive interventions (28). According to their definitions, the ICAN intervention was "moderate," but the net weight loss observed was within the range of intensive treatment. Additionally, obese patients with diabetes lose approximately half the weight that obese patients without diabetes lose with the same intervention (29). Furthermore, many diabetes medications can lead to weight gain (30,31), so the magnitude of weight loss in this intervention was expected to be lower than other interventions that do not address this population. The weight loss observed within ICAN was more than half that observed in another low-cost, Internet-based intervention for people without diabetes (32).

During ICAN, maximal weight loss (4.7%) occurred in the period of more frequent contact with RD case managers. From 8 to 12 months, the period of modest weight regain in the intervention group, participants received only 30 min

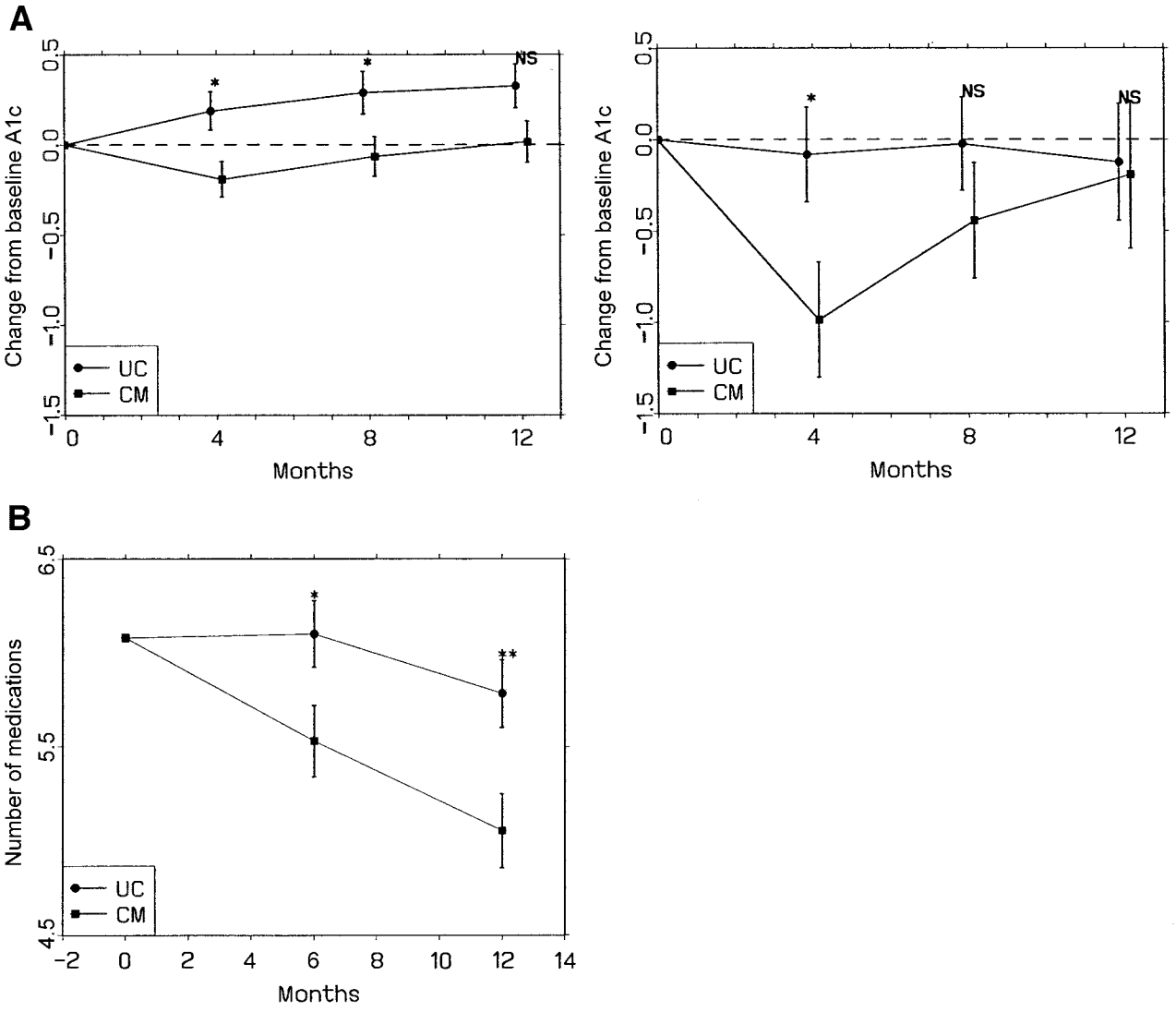

Figure 2—*Estimated changes in HbA_{1c} by baseline HbA_{1c}* (A) *and total medication changes by group* (B)*. Points displayed are estimates of changes from baseline ±1 SE.* A*: Mean ± SE in HbA_{1c} by group among participants with baseline HbA_{1c} ≤7.45%* (left panel) *and participants with baseline HbA_{1c} >7.45%* (right panel)*. The left panel is based on* n *= 36, 28, 27, and 29 subjects in the usual care (UC) group and* n *= 36, 35, 33, and 34 subjects in the case management (CM) group at baseline and at 4, 8, and 12 months postbaseline, respectively. The right panel is based on* n *= 36, 34, 34, 34 subjects in the UC group and* n *= 33, 24, 22, and 19 subjects in the CM group at baseline and at 4, 8, and 12 months postbaseline, respectively.* Left panel*: Baseline HbA_{1c} ≤7.45%.* Right panel*: Baseline HbA_{1c} >7.45%.* B*: Mean ± SE change in total number of prescription medications taken daily in the case management and usual care groups. Estimates are based on* n *= 65 and 64 subjects in the UC group and* n *= 58 and 54 subjects in the CM group at 6 and 2 months postbaseline.* *P ≤ *0.05;* **P ≤ *0.001.*

of individual time with case managers (12.5% of total individual therapeutic time) and 2 h of group classes. Although this decrease in intensity and support was intentional as a way to transition participants from intervention to maintenance, increased intensity has been positively related to amount of weight lost (33,34). Weight regain within the last 4 months of the intervention suggests the need for greater intensity during this time period and the need for ongoing lifestyle coaching to support maintenance. The weight regain may have been physiologically based. Maximal weight loss is typically observed at 6 months in obesity trials, regardless of intervention mode (behavioral, very-low-calorie diet, pharmacology) (5,6,27,35). After weight has been reduced, it takes a greater caloric deficit to maintain the lower weight. In addition, physical activity has been shown to improve weight maintenance (22). Although RD case managers supported increases in physical activity, other support for physical activity (e.g., fitness trainers) was not provided. Despite the weight regain from 8 to 12 months, almost twice as many participants in the case management group lost >5% of initial weight compared with participants in the usual care group. The National Heart, Lung, and Blood Institute guideline on obesity treatment stresses the importance of a 5–10% weight loss (22).

Within this study population, the impact on laboratory parameters was modest and not significant by 1 year. The small changes may reflect already good

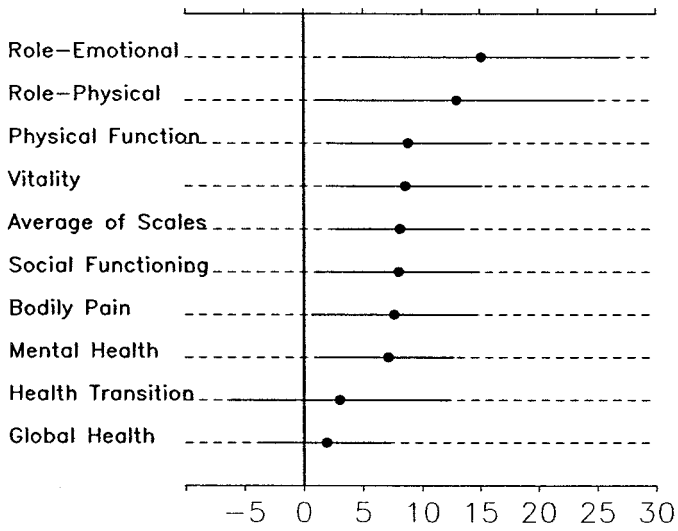

Figure 3—*Difference (case management minus usual care) (95% CI) in the 12-month HRQOL scores. Estimates from regression model using baseline scale value as a covariate. Estimates are based on* n = *64 and 53 in the usual care (UC) and case management (CM) groups, respectively. The CIs are not adjusted for multiple comparison.*

medical management. By design, ICAN participants had health insurance. All were taking diabetes medications, and most were on antihypertensive (76%) and cardiovascular medications (64%). Average baseline values of HbA_{1c} and lipid levels suggested generally good control. Despite such control, a modest-cost lifestyle intervention helped maintain lower HbA_{1c} levels. Future interventions should consider baseline values in determining the intensity of the intervention. Additionally, as we begin to translate efficacy to practice, different criteria will be needed to define "success." Instead of the magnitude of effect solely defining success, the reach, effectiveness, adoption, implementation, and maintenance of the program (RE-AIM) must be addressed (17,18).

The main limitations of ICAN include generalizability, lack of a strong physical activity component, and no long-term maintenance. Most participants were Caucasian and employed. Therefore, study results may not be generalizable to multiethnic or uninsured populations. As with all clinical trials, volunteer participants may be healthier and more motivated to change behavior than eligible nonvolunteers. On the other hand, lifestyle interventions are always voluntary in practice and are likely to be attractive to more motivated patients. Finally, the RD collected the outcomes from the case management group, creating the potential for systematic bias, however not considerably different from that of clinical practice.

Both public health and clinical interventions are needed to stem the tide of obesity and diabetes. Although there is an important emphasis at a public health level on prevention, a sizable and growing portion of the population, currently 18.2 million adults, will seek clinical treatment for diabetes (36). Most of these individuals are overweight or obese. If this population is treated without a sustainable lifestyle component, their experience will be that of the ICAN usual care group: weight gain, increased waist circumference, and lower quality of life despite greater levels of medication. Although the magnitude of weight loss may not meet patients' and physicians' expectations, the benefits from the patient, clinical, and payer perspective outweigh the relatively low cost of such a program. If sustained, improvements of the magnitude achieved in ICAN could lead to reduced cardiovascular disease. Translation of lifestyle interventions into clinical care for obese patients with type 2 diabetes remains a challenge. An RD-led case management approach is one promising path toward achieving that goal.

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