Living Well With Diabetes: 24-Month Outcomes From a Randomized Trial of Telephone-Delivered Weight Loss and Physical Activity Intervention to Improve Glycemic Control

Elizabeth G. Eakin,[1,2] Elisabeth A. Winkler,[1] David W. Dunstan,[2,3,4,5] Genevieve N. Healy,[1,2,6] Neville Owen,[1,2,7,8] Alison M. Marshall,[9] Nicholas Graves,[9] and Marina M. Reeves[1]

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OBJECTIVE

To evaluate the effectiveness of a telephone-delivered behavioral weight loss and physical activity intervention targeting Australian primary care patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS

Pragmatic randomized controlled trial of telephone counseling (*n* = 151) versus usual care (*n* = 151). Reported here are 18-month (end-of-intervention) and 24-month (maintenance) primary outcomes of weight, moderate-to-vigorous-intensity physical activity (MVPA; via accelerometer), and HbA_{1c} level. Secondary outcomes include dietary energy intake and diet quality, waist circumference, lipid levels, and blood pressure. Data were analyzed via adjusted linear mixed models with multiple imputation of missing data.

RESULTS

Relative to usual-care participants, telephone counseling participants achieved modest, but significant, improvements in weight loss (relative rate [RR] −1.42% of baseline body weight [95% CI −2.54 to −0.30% of baseline body weight]), MVPA (RR 1.42 [95% CI 1.06–1.90]), diet quality (2.72 [95% CI 0.55–4.89]), and waist circumference (−1.84 cm [95% CI −3.16 to −0.51 cm]), but not in HbA_{1c} level (RR 0.99 [95% CI 0.96–1.02]), or other cardio-metabolic markers. None of the outcomes showed a significant change/deterioration over the maintenance period. However, only the intervention effect for MVPA remained statistically significant at 24 months.

CONCLUSIONS

The modest improvements in weight loss and behavior change, but the lack of changes in cardio-metabolic markers, may limit the utility, scalability, and sustainability of such an approach.

[1]*School of Population Health, Cancer Prevention Research Centre, University of Queensland, Brisbane, Queensland, Australia*
[2]*Baker IDI Heart and Diabetes Institute, Melbourne, Victoria, Australia*
[3]*School of Sport Science, Exercise and Health, University of Western Australia, Perth, Western Australia, Australia*
[4]*School of Exercise and Nutrition Sciences, Deakin University, Melbourne, Victoria, Australia*
[5]*School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia*
[6]*School of Physiotherapy, Faculty of Health Sciences, Curtin University, Perth, Western Australia, Australia*
[7]*Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Victoria, Australia*
[8]*Central Clinical School, Monash University, Melbourne, Victoria, Australia*
[9]*School of Public Health and Social Work, Faculty of Health, Queensland University of Technology, Brisbane, Queensland, Australia*

Corresponding author: Elizabeth G. Eakin, e.eakin@sph.uq.edu.au.

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The high prevalence of overweight and obesity is driving a worldwide type 2 diabetes epidemic (1). Diabetes prevalence in adults has increased over the last decade from 8.2 to 11.3% in the U.S. (2) and from 8.5 to 12% in Australia (3), with type 2 diabetes accounting for >90% of cases (2). Lifestyle interventions—both intensive programs (4,5) as well as scalable community-based versions (6,7)—have had considerable success in reducing diabetes incidence and risk factors in populations at high risk.

For those individuals in whom diabetes has already been diagnosed, the challenges of applying lifestyle intervention programs have received considerable recent attention. The Look AHEAD study (8), a seminal trial that evaluated a multiyear, highly resourced, intensive lifestyle intervention compared with standard diabetes education, demonstrated significant improvements in weight loss, related behavioral changes, HbA_{1c} level, and other cardio-metabolic markers. Despite this, the Look AHEAD intervention was not successful at inducing changes in the primary end point of cardiovascular events (9). Nevertheless, from a clinical perspective, the improvements achieved for diabetes management should not be underrated, as they are associated with reduced risk of diabetes-related vascular complications, associated organ damage, loss of function, and reduced quality of life (10). As such, the promotion of lifestyle changes, particularly regular participation in physical activity (11) and moderate weight loss, remain crucial aspects of diabetes management (10).

The issue of how to translate intensive lifestyle interventions into protocols more feasible for widespread delivery via primary health care and community settings, with long-term sustainable impacts, requires attention. Telephone-delivered interventions are increasingly being investigated as they have the potential for broad population reach, and for delivering the repeated contacts necessary to promote maintenance of behavior change and related clinical improvements (12–15).

Living Well With Diabetes (LWWD) was a pragmatic trial of a telephone-delivered behavioral weight loss intervention targeting Australian primary care patients with type 2 diabetes. It was designed to test a more scalable and sustainable version of an intensive intervention protocol. The initial (6-month) outcomes of the LWWD trial showed small intervention effects for weight loss and physical activity, but not for HbA_{1c} level (16). The purpose of this article is to report on the outcomes achieved at the end of the extended 18-month intervention, as well as at the final 24-month maintenance follow-up. Primary outcomes were weight loss, moderate-to-vigorous-intensity physical activity (MVPA), and HbA_{1c} level. Secondary outcomes were dietary energy intake and diet quality, waist circumference, fasting blood lipid levels, and blood pressure.

RESEARCH DESIGN AND METHODS

The LWWD trial was a two-arm randomized controlled trial, the protocol for which has been published (17). Participants were recruited from nine general (primary care) practices in the city of Logan (population 270,000), a large ethnically and socioeconomically diverse community in the state of Queensland, Australia, 35 km from Brisbane (the state capital). Ethical approval was granted from The University of Queensland Behavioral and Social Sciences Ethical Review Committee.

Patient Recruitment and Randomization

Within practices, 1,407 eligible patients (i.e., those with a diagnosis of type 2 diabetes; age range 20–75 years; with a listed telephone number) were identified using electronic medical records (Fig. 1). Patients not initially excluded by general practitioner (GP) screening for contraindications to unsupervised physical activity (n = 908) were sent study materials by the GP and, if not declining further contact (n = 206), were followed up by study staff for eligibility and consent. Eligible patients were inactive (self-reported <5 days/week of ≥30 min planned exercise) and/or overweight or obese (BMI ≥ 25.0 kg/m^2), not using weight loss medications, and without previous or planned bariatric surgery. Of those patients who were reached via telephone and were eligible (n = 420), 302 (71.9%) agreed to participate, completed the baseline assessment, and were randomized to either the telephone counseling or usual-care groups.

Randomization was by the minimization method (18) using the MINIM program (www.sghms.ac.uk/depts/phs/guide/randser.htm). The minimization method balanced treatment groups across the following prognostic factors (without weighting for importance): sex; age (≥55 years); BMI (≥40 kg/m^2); HbA_{1c} level (≥8%); self-reported physical activity level (meeting Australian guidelines of ≥150 min and ≥5 days/week) (19); and self-reported diabetes management (i.e., insulin or combination therapy, traditional oral hypoglycemic medications, glucagon-like peptide 1 [GLP-1] agents, or lifestyle alone). GLP-1 agents (e.g., GLP-1 mimetics, such as exenatide, and GLP-1 enhancers, such as sitagliptin) were considered separately as these medications may cause less weight gain than traditional diabetes medications (20).

Usual Care

Usual-care participants were mailed a brief summary of their results following each assessment, as well as standard, diabetes self-management education brochures. GPs in trial practices were not asked to change their management practices in any way and were involved only in participant recruitment.

Telephone-Delivered Weight Loss Intervention

The intervention, delivered entirely over the telephone, used a combined approach of increasing physical activity, reducing energy intake, and behavioral therapy. Participants received a detailed workbook and up to 27 telephone calls over the 18 months (4 initial weekly calls; fortnightly calls for 5 months; monthly calls for 12 months) to support the initiation and maintenance of weight loss. The intervention followed a motivational interviewing approach (21) grounded in social cognitive theory constructs of self-efficacy, social support, and outcome expectancies (22), and emphasized behavior change strategies. These included the following: identifying the benefits of weight loss; setting goals for gradual changes to physical activity and dietary intake; self-monitoring progress; problem solving; using available supports; and focusing on achievements with appropriate rewards (23). Intervention targets for weight loss, physical activity, and dietary intake were consistent with management

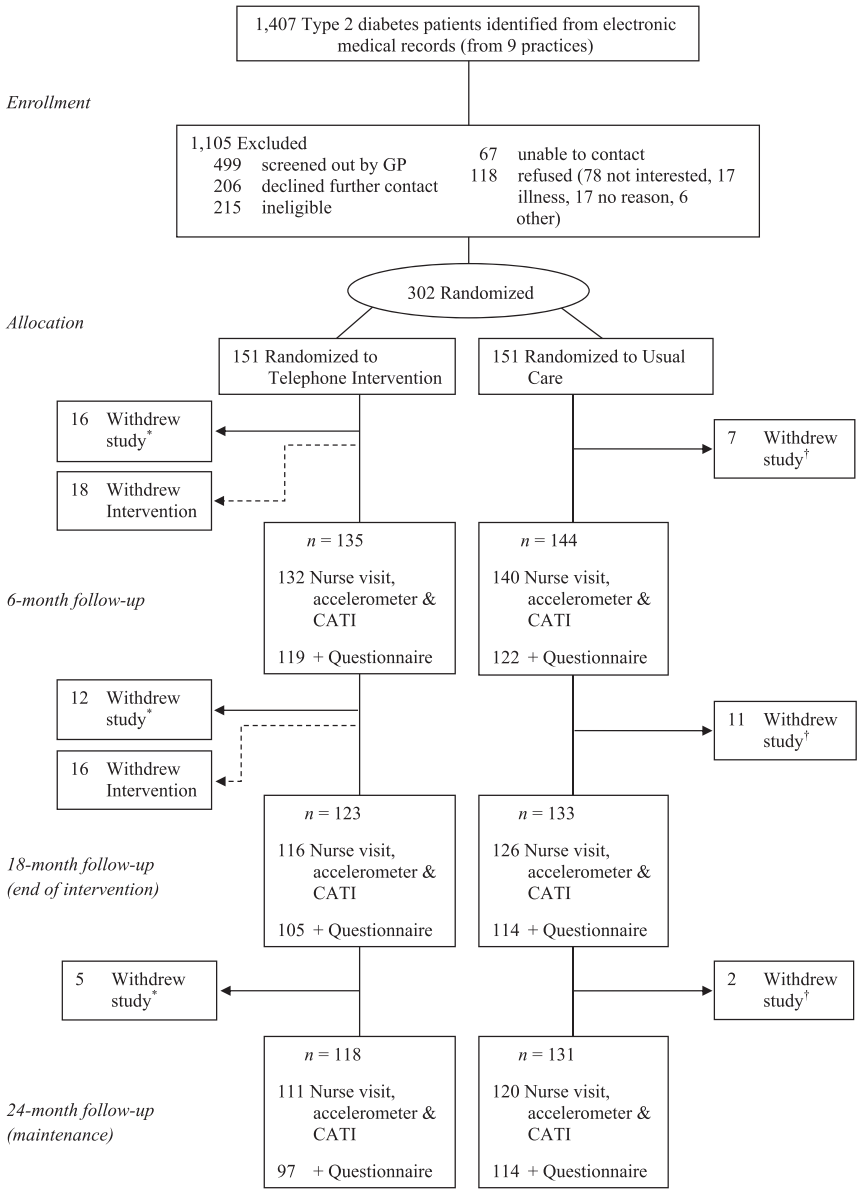

Figure 1—LWWD trial flowchart. *Reasons for study withdrawal in telephone counseling intervention group: too busy/life stresses (n = 11), personal/family illness (n = 7), not interested/benefiting (n = 5), happy with health (n = 3), moved residence (n = 3), study assessments too difficult/inconvenient (n = 2), and uncontactable (n = 2). †Reasons for study withdrawal in usual-care group: too busy/life stress (n = 6), not interested/benefiting (n = 6), moved residence (n = 4), personal illness (n = 2), deceased (n = 1), and uncontactable (n = 1). CATI, computer-assisted telephone interviewing.

goals for type 2 diabetes (10), with the aim to reduce HbA_{1c} level to <7%. Participants were encouraged to achieve moderate weight loss of 5–10% of initial body weight, an amount consistent with clinically meaningful disease prevention and management, with a loss of 1–2 kg/month (10). A target of at least 210 min/week (30 min every day) of moderate-intensity planned aerobic activity was recommended, consistent with the level of physical activity necessary to promote and maintain weight loss (24), along with resistance exercise (two to three sessions per week) (25). Individualized advice (26) was used to encourage participants to reduce daily energy intake by 2,000 kJ (~500 kcal) by following healthy eating principles, including following a low-fat diet (i.e., total fat <30% of energy; saturated fat <7% of energy) with sufficient dietary fiber (25 g/day for women; 30 g/day for men). Participants were provided with a pedometer and a set of digital scales. Fidelity of intervention delivery was monitored via feedback to counselors following randomly recorded telephone calls and fortnightly clinical supervision meetings. Call attempts, completions, and duration were tracked in the trial database.

Primary and Secondary Outcomes, Data Collection, and Measures

Primary outcomes were weight, accelerometer-derived MVPA, and HbA_{1c} level. Secondary outcomes were dietary energy intake and diet quality, waist circumference, fasting blood lipid levels, and blood pressure. Data were collected at baseline, 6 months, 18 months (end

of intervention), and 24 months (maintenance) via home visits by a nurse and telephone interviews by research staff who were blind to participants' group allocation. Weight was measured in duplicate, without shoes or heavy clothing, using standard calibrated scales (model TI TBF-350; Tanita Inc., Tokyo, Japan) to the nearest 0.1 kg. Height was measured in duplicate at baseline only using a portable stadiometer (Seca 214 height rod; Seca, Hamburg, Germany) to the nearest 0.1 cm. Waist circumference was measured to the nearest 0.5 cm at the superior border of the iliac crest. Blood pressure was measured in duplicate with the patient in the seated position by a portable sphygmomanometer (Gamma G5; Heine, Herrsching, Germany). Blood samples were obtained by registered nurses early in the morning after an overnight fast (at least 10 h), with participants instructed not to take any glucose-lowering medication prior to the assessment. Current diabetes medications were recorded. HbA_{1c} level was measured from whole-blood samples by the high-performance liquid chromatography method (Variant II; Bio-Rad, Sydney, New South Wales, Australia). Total cholesterol, HDL cholesterol, and triglycerides were measured by an enzymatic colorimetric assay with a Modular Chemistry Analyzer (Roche, Tokyo, Japan). LDL cholesterol was determined using the Friedewald equation (27).

Nurses provided participants with a GT1M accelerometer (ActiGraph, Fort Walton Beach, FL) to collect physical activity data. The monitor, worn on the hip, was set to record in 60-s epochs. Participants were asked to wear the monitor for 7 days during waking hours (except during water-based activities) and to record wear/removal times. Wear time was ascertained by the research staff, who estimated wearing periods from times that movement stopped or began coinciding with participant self-reported wear/removal periods. Using SAS 9.2 (SAS Institute, Cary, NC), MVPA was identified as time spent at ≥1,952 counts per minute (cpm) during the time the device was worn on valid days (i.e., ≥10 h of wear, no excessive counts ≥20,000 cpm). Weekly MVPA was estimated as seven times the mean MVPA on valid days, with a requirement of at least 1 valid day. At baseline, 6, 18, and 24 months, at least 4 valid days were provided by 98% of participants (297 of 302), 97% of participants (265 of 273), 95% of participants (234 of 246), and 96% of participants (229 of 239), and the mean (±SD) daily wear times for those participants with ≥1 valid wear day were 13.5 ± 1.6, 13.7 ± 1.7, 13.6 ± 1.8, and 13.7 ± 1.8 h.

Telephone interviews included a previously validated food frequency questionnaire assessing intake over the previous month (28). Coupled with the NUTTAB95 nutrient composition database (29), the questionnaire was used to derive the average daily energy and nutrient intake. Overall dietary quality was summarized in terms of the Diet Quality Index Revised score (30), which ranges from 0 (worst) to 100 (best) in terms of the following 10 dietary characteristics, relative to current Australian dietary recommendations (31): total fat, saturated fat, dietary cholesterol, fruit, vegetables, grains, calcium, iron, dietary diversity, and dietary moderation. Demographic data and adverse events were also collected during the telephone interview.

Statistical Analysis

Analyses were performed in SPSS version 21 (IBM, New York, NY) and STATA version 12 (StataCorp, College Station, TX). Statistical significance was set at $P < 0.05$ (two-tailed). The sample size was chosen a priori to provide at least 90% power (with two-tailed significance of 5%) to detect minimum differences of interest (MDI) in primary outcomes of 5% weight loss (4.7 kg), 0.6% HbA_{1c} (absolute), and 60 min/week MVPA (17). It was expected to provide adequate (≥80%) power to detect MDIs for diet (2 MJ energy intake and 0.5 SD diet quality [5.5]), waist circumference (5 cm), HDL cholesterol level, total/HDL cholesterol ratio (5%), and triglyceride level (10%), but low power to detect MDIs for blood pressure (70% for 5 mmHg systolic and 56% for 3 mmHg diastolic), total cholesterol (57% for a 5% difference), and LDL cholesterol (12.1% for a 5% difference).

Intervention effects were examined via linear mixed models, which corrected for baseline values and potential confounders, identified as those variables with a significant association with the outcome $P < 0.2$ (Supplementary Table 1). Changes within groups were also examined using mixed models. For outcomes that were log-transformed to improve normality (HbA_{1c} level, MVPA, cholesterol level, and triglyceride levels), model results were exponentiated and expressed as relative rates. Models did not display problems with heteroscedasticity, nonlinearity, or non-normality.

To evaluate the sensitivity of the conclusions to missing data, both multiple imputation and completers analyses were performed. Multiple imputation was evaluated by chained equations in STATA 12, using all analytic variables, variables associated with dropout, and, when required, auxiliary variables to aid in the prediction of missing covariates. The results presented are based on multiple imputation, unless indicated otherwise. The analyses were repeated with a lower (≥574 cpm) and higher (≥2743 cpm) cut point for MVPA (32) to evaluate the sensitivity of conclusions to the choice of cut point.

RESULTS

The sample characteristics (Table 1) largely resembled the Australian diabetes population with very little evidence of participation bias (16). The sample (56% men) had a mean (±SD) age of 58 ± 8.6 years, a BMI of 33.1 ± 6.1 kg/m^2, and a median diabetes duration of 5 years (25th, 75th percentile: 2, 10 years). Most participants were Caucasian (87.4%) and obese (68.2%) or overweight (26.2%), and did not meet the physical activity guidelines (69.5%). Diabetes treatment over the course of the intervention (in completers), including medication use, is shown in Supplementary Table 2. In the telephone counseling (n = 151) and usual-care groups (n = 151), respectively, insulin use was low at baseline (15.2% and 13.2%); based on imputation, this increased by 24 months (23.5% and 23.9%), and the percentages of participants not receiving diabetes medications dropped between baseline (19.9% and 17.2%) and 24 months (18.2% and 12.8%).

Study withdrawal rates were low and diminished over the duration of the study (Fig. 1). Loss to follow-up was not significantly different (P = 0.278) between the telephone counseling (26.5%) and usual-care (20.5%) groups. Dropouts had significantly higher HDL cholesterol levels and greater use of insulin at

Table 1—Baseline characteristics of study participants randomized to telephone counseling (*n* = 151) and usual care (*n* = 151)

Characteristics	Telephone counseling (*n* = 151)	Usual care (*n* = 151)	All (*n* = 302)
Age, mean (SD), years	57.7 (8.1)	58.3 (9.0)	58.0 (8.6)
Male sex, *n* (%)	84 (55.6)	86 (57.0)	170 (56.3)
Weight, mean (SD), kg	94.5 (18.7)	95.3 (20.1)	94.9 (19.4)
BMI, mean (SD), kg/m^2	33.1 (6.3)	33.2 (6.0)	33.1 (6.1)
Overweight/obese (≥25 kg/m^2), *n* (%)	141 (93.4)	144 (95.4)	285 (94.4)
Duration diabetes, median (25th, 75th percentile), years	4.0 (2.0, 7.0)	5.0 (2.0, 10.0)	5.0 (2.0, 10.0)
Diabetes medication, *n* (%)			
Traditional OHAs	114 (75.5)	119 (78.8)	233 (77.2)
Insulin	23 (15.2)	20 (13.2)	43 (14.2)
GLP-1 agents	7 (4.6)	5 (3.3)	12 (4.0)
Other chronic conditions, *n* (%)			
CVD-related condition	127 (84.1)	113 (74.8)	240 (79.5)
Musculoskeletal condition	51 (33.8)	50 (33.1)	101 (33.4)
Lung condition	14 (9.3)	18 (11.9)	32 (10.6)
Smoking status, *n* (%)			
Never smoker	77 (51.0)	67 (44.4)	144 (47.7)
Ex-smoker	60 (39.7)	67 (44.4)	127 (42.1)
Current smoker	14 (9.3)	17 (11.3)	31 (10.3)
Born in Australia, *n* (%)	99 (65.6)	108 (71.5)	207 (68.5)
Caucasian, *n* (%)	131 (86.8)	133 (88.1)	264 (87.4)
Employment, *n* (%)			
Full-/part-time or casual	97 (64.3)	93 (61.6)	190 (62.9)
Retired	40 (26.5)	42 (27.8)	82 (27.2)
Other	14 (9.3)	16 (10.6)	30 (9.9)
Income (<$1,000/week), *n* (%)	49 (32.5)	61 (40.4)	110 (36.4)
Education (<high school), *n* (%)	9 (6.0)	26 (17.2)	35 (11.6)
Physical activity, median (25th, 75th percentile), min/week*	93.5 (28.8, 151.9)	92.2 (39.2, 185.1)	92.7 (38.4, 180.5)
HbA_{1c}, median (25th, 75th percentile)			
%	7.6 (6.3, 8.5)	7.0 (6.4, 7.9)	7.1 (6.4, 8.0)
mmol/mol	60 (45, 69)	53 (46, 63)	54 (46, 64)
Energy intake, mean (SD), MJ	7.1 (2.3)	6.9 (2.2)	7.0 (2.2)
Diet quality, mean (SD) , 0–100	65.6 (13.6)	65.5 (10.7)	65.6 (11.0)

CVD, cardiovascular disease; OHA, oral hypoglycemic medication. *Accelerometer MVPA time spent at ≥1,952 cpm.

baseline than completers (Supplementary Table 3). There was a nonsignificant tendency for dropouts to be male, use oral hypoglycemic medication, and have longer diabetes duration. Of the 27 possible intervention calls, median (25th, 75th percentile) number of call receipts was 16 (9, 22) among telephone counseling group participants (*n* = 151), and 17 (21, 23) in the 60.9% of telephone counseling participants who had not withdrawn from intervention or the study before the end of the intervention (*n* = 92). Respectively, the completion of ≥75% of scheduled calls was achieved by 36.4% (55 of 151) of telephone counseling group participants or 57.6% (53 of 92) of telephone counseling participants who had not withdrawn from the intervention or the study. The mean (±SD) duration of intervention calls was 24.6 ± 10.6 min.

Intervention Effects at End of Intervention

Intervention effects on primary and secondary outcomes are shown in Table 2. Interim (6-month) outcomes (16) were not substantially different from end-of-intervention (18-month) outcomes and so are not discussed separately. At the end of intervention (18 months), the telephone counseling group had modest, but significantly favorable, outcomes relative to the usual-care group, respectively, for the primary outcomes of weight loss (−1.42% of baseline body weight [95% CI −2.54 to −0.30% of baseline body weight] or −1.52 kg [−2.64 to 0.39 kg]) and MVPA, which was 42% higher in telephone counseling than usual-care participants (relative rate [RR] 1.42 [95% CI 1.06−1.90] or 43.06 min/week [95% CI 15.04−71.09] min/week), but not for HbA_{1c} % (mmol/mol) level (RR 0.99 [95% CI 0.96−1.02] (0.99 [95% CI 0.95−1.03]) or −0.06% [95% CI −0.16 to 0.20]% (−0.7 mmol/mol [95% CI −1.7 to 2.2] mmol/mol)). In terms of secondary outcomes, modest but significant intervention effects were observed for diet quality (RR 2.72 [95% CI 0.55–4.89]) and waist circumference (−1.84 cm [95% CI −3.16 to −0.51 cm]), but not for energy intake, cholesterol, triglyceride levels, or blood pressure. Consideration of the 95% CIs ruled out as unlikely any meaningful intervention effects for HbA_{1c} level, energy intake, and diastolic blood pressure. When changes within groups were examined, the telephone counseling group exhibited modest improvements in all outcomes except MVPA, HbA_{1c} level, and diet quality (Supplementary Table 4). Additionally, significant,

Table 2—Primary and secondary outcomes adjusted for baseline values and confounders (completers) and multiple imputation

	Multiple imputation*,†			Completers†	
Outcomes	Tel-UC	*P*	*n* Tel/UC	Tel-UC	*P*
Weight loss (%)					
6 months	−1.31 (−2.40 to −0.22)	0.019	136/141	−1.29 (−2.13 to −0.46)	0.002
18 months	−1.42 (−2.54 to −0.30)	0.013	121/131	−1.37 (−2.56 to −0.18)	0.024
24 months	−0.72 (−1.85 to 0.41)	0.212	115/127	−0.61 (−1.95 to 0.73)	0.371
Weight loss (kg)‡					
6 months	−1.31 (−2.40 to −0.22)	0.019	136/141	−1.30 (−2.14 to −0.46)	0.003
18 months	−1.52 (−2.64 to −0.39)	0.008	121/131	−1.45 (−2.63 to −0.26)	0.017
24 months	−0.80 (−1.95 to 0.36)	0.177	115/127	−0.67 (−2.00 to 0.67)	0.327
MVPA (min/week)§					
6 months	1.34 (1.05–1.70)	0.019	132/140	1.35 (1.09–1.66)	0.005
18 months	1.42 (1.06–1.90)	0.018	117/126	1.41 (1.03–1.94)	0.031
24 months	1.44 (1.12–1.85)	0.004	112/121	1.44 (1.16–1.79)	0.001
HbA_{1c} (%)§					
6 months	0.99 (0.96–1.02)	0.442	136/141	0.99 (0.96–1.02)	0.421
18 months	0.99 (0.96–1.02)	0.541	121/131	0.99 (0.97–1.02)	0.502
24 months	0.98 (0.95–1.01)	0.195	115/127	0.98 (0.96–1.01)	0.262
HbA_{1c} (mmol/mol)§					
6 months	0.98 (0.94–1.02)	0.354	136/141	0.98 (0.94–1.02)	0.312
18 months	0.99 (0.95–1.03)	0.493	121/131	0.99 (0.95–1.03)	0.511
24 months	0.97 (0.94–1.01)	0.183	115/127	0.98 (0.94–1.02)	0.261
Energy intake (MJ)‡					
6 months	−0.69 (−1.08 to −0.30)	0.001	135/141	−0.69 (−1.1 to −0.30)	0.001
18 months	−0.31 (−0.71 to 0.11)	0.151	119/129	−0.29 (−0.7 to 0.12)	0.163
24 months	−0.28 (−0.70 to 0.14)	0.189	114/123	−0.27 (−0.70 to 0.16)	0.215
Diet quality (0–100)‡					
6 months	4.09 (2.01–6.17)	<0.001	135/141	4.06 (2.01–6.11)	<0.001
18 months	2.72 (0.55–4.89)	0.014	118/129	2.74 (0.48–4.99)	0.018
24 months	1.79 (−0.42 to 3.99)	0.112	113/122	1.85 (−0.36 to 4.05)	0.100
Waist circumference (cm)‡					
6 months	−1.66 (−2.95 to −0.38)	0.011	132/140	−1.62 (−2.70 to −0.55)	0.003
18 months	−1.84 (−3.16 to −0.51)	0.007	117/126	−1.78 (−3.22 to −0.34)	0.016
24 months	−0.95 (−2.29 to 0.40)	0.167	112/121	−0.86 (−2.32 to 0.60)	0.248
Total cholesterol (mmol/L)§					
6 months	1.00 (0.95–1.04)	0.822	134/140	1.00 (0.97–1.04)	0.936
18 months	1.03 (0.98–1.07)	0.232	119/129	1.02 (0.98–1.06)	0.407
24 months	1.02 (0.97–1.06)	0.432	114/125	1.01 (0.97–1.06)	0.602
HDL cholesterol (mmol/L)§					
6 months	1.01 (0.97–1.05)	0.513	135/141	1.01 (0.97–1.05)	0.609
18 months	1.01 (0.97–1.05)	0.778	121/131	1.00 (0.97–1.04)	0.870
24 months	1.00 (0.96–1.05)	0.878	115/127	1.00 (0.96–1.05)	0.833
LDL cholesterol (mmol/L)§					
6 months	1.01 (0.95–1.08)	0.663	133/140	1.01 (0.95–1.07)	0.707
18 months	1.02 (0.95–1.10)	0.551	119/130	1.02 (0.96–1.09)	0.531
24 months	1.03 (0.96–1.10)	0.392	114/125	1.03 (0.97–1.11)	0.334
Total/HDL cholesterol§					
6 months	0.98 (0.93–1.03)	0.406	134/140	0.98 (0.93–1.03)	0.340
18 months	0.99 (0.94–1.05)	0.814	119/130	1.00 (0.95–1.05)	0.878
24 months	0.99 (0.94–1.05)	0.850	114/126	0.99 (0.94–1.04)	0.750
Triglycerides (mmol/L)§					
6 months	0.96 (0.89–1.05)	0.373	135/140	0.96 (0.89–1.04)	0.327
18 months	0.97 (0.89–1.06)	0.474	119/130	0.97 (0.89–1.06)	0.536
24 months	0.93 (0.85–1.02)	0.122	114/126	0.94 (0.85–1.03)	0.181
Systolic BP (mmHg)‡					
6 months	−2.43 (−5.52 to 0.65)	0.122	135/141	−1.76 (−4.7 to 1.17)	0.238
18 months	−2.36 (−5.57 to 0.86)	0.150	120/131	−1.69 (−4.78 to 1.41)	0.284
24 months	−0.28 (−3.55 to 2.99)	0.868	114/127	0.51 (−2.81 to 3.83)	0.763

Continued on p. 2183

Table 2—Continued

	Multiple imputation*,†			Completers†	
Outcomes	Tel-UC	*P*	*n* Tel/UC	Tel-UC	*P*
Diastolic BP (mmHg)					
6 months	−0.66 (−2.52 to 1.21)	0.491	113/140	−0.11 (−1.74 to 1.51)	0.890
18 months	−0.56 (−2.52 to 1.39)	0.572	118/129	0.01 (−1.89 to 1.92)	0.989
24 months	−0.60 (−2.61 to 1.40)	0.553	113/125	−0.27 (−2.29 to 1.75)	0.792

Data are reported as the difference between groups (95% CI), unless otherwise stated. BP, blood pressure; UC, usual care; Tel, telephone counseling. *n* = 151 Tel and 151 UC. *Imputation by chained equations in STATA version 12 with 20 imputations and a burn-in of 100 imputations. †All models adjust for baseline values, and confounders listed in Supplementary Table 3. ‡Modeled as changes from baseline. §Back-transformed from natural log, results expressed as relative rates.

meaningful within-group change was observed in usual-care participants for some of the cholesterol outcomes (HDL cholesterol, LDL cholesterol, total cholesterol/HDL cholesterol ratio). Notably, the intervention effects for MVPA related to a significant 25% decline in the usual-care group (RR 0.80 [95% CI 0.66–0.98]) rather than improvement in the telephone counseling group. Adverse events requiring hospitalization were reported by 4 of the telephone counseling participants (3.4%) and 4 of the usual-care participants (3.1%), with events plausibly related to study participation (i.e., musculoskeletal problems and digestive disturbance) reported by 17 (14.4%) and 28 (21.9%) of the participants, respectively. No hypoglycemic events were reported.

Maintenance

MVPA was the only outcome in which there was a significant intervention effect after the 6-month noncontact period (i.e., at 24 months), with mean MVPA being 44% higher in the telephone counseling group than in the usual-care group, respectively (RR 1.44 [95% CI 1.12–1.85] or 38.95 min/week [95% CI 12.55–65.35] min/week). Although not statistically significant, there was some attenuation in the intervention effect sizes, respectively, for weight loss (−0.72% vs. −1.42%), diet quality (1.79 vs. 2.72 units), and waist circumference (−0.95 vs. −1.84 cm) (Table 3).

Target/Recommendation Adherence

At the end of intervention, only a small percentage of the telephone counseling and usual-care groups, respectively, achieved program targets of ≥5% weight loss (21.0% vs. 13.2%), ≥210 min/week MVPA (34.8% vs. 27.8%), and ≥2 MJ energy reduction (22.8% vs. 18.8%) (Supplementary Fig. 1). However, both the telephone counseling and usual-care groups, respectively, quite commonly met the recommendations for HbA_{1c} level ≤7% (10) both at baseline (45.7% vs. 53.0%) and at end of intervention (43.9% vs. 42.4%) (Supplementary Fig. 1). Weight gain (≥1%) was common at 6, 18, and 24 months, more so within the usual-care group (38.6%, 43.1%, and 36.6%, respectively) than in the telephone counseling group (29.5%, 31.5%, and 18.7%, respectively) (Supplementary Fig. 1).

Sensitivity Analyses

Completers analysis and the multiple imputation yielded almost identical results (Table 2). Conclusions were robust to the choice of MVPA cut point; significant intervention effects favoring the telephone counseling group were still observed even with a very low (≥574) and a very high (≥2,743) cut point for MVPA (32) (data not shown). Given

Table 3—Difference between end of maintenance (24 months) and end of intervention (18 months)

	Tel (*n* = 151)		UC (*n* = 151)		Tel-UC (*n* = 151)	
Variables	Mean (95% CI)	*P*	Mean (95% CI)	*P*	Mean (95% CI)	*P*
Weight loss, % of initial weight	0.12 (−0.56 to 0.80)	0.733	−0.58 (−1.23 to 0.07)	0.082	0.70 (−0.25 to 1.64)	0.147
Weight loss, kg	0.11 (−0.56 to 0.78)	0.752	−0.61 (−1.24 to 0.01)	0.055	0.72 (−0.18 to 1.62)	0.117
MVPA, min/week*,†	0.92 (0.73–1.16)	0.489	0.91 (0.74–1.11)	0.352	1.02 (0.74–1.39)	0.924
HbA_{1c}*						
%	0.99 (0.97–1.01)	0.399	1.00 (0.98–1.02)	0.987	0.99 (0.96–1.02)	0.548
mmol/mol	0.99 (0.95–1.02)	0.392	1.00 (0.97–1.03)	0.931	0.99 (0.94–1.03)	0.575
Energy, MJ	0.20 (−0.11 to 0.51)	0.209	0.18 (−0.12 to 0.48)	0.240	0.02 (−0.41 to 0.45)	0.929
Diet quality, 0–100	−0.30 (−1.99 to 1.39)	0.727	0.63 (−1.00 to 2.26)	0.446	−0.94 (−3.28 to 1.41)	0.435
Waist circumference, cm	0.32 (−0.61 to 1.26)	0.498	−0.57 (−1.46 to 0.33)	0.216	0.89 (−0.41 to 2.19)	0.179
Total cholesterol, mmol/L*	1.00 (0.96–1.03)	0.807	1.00 (0.97–1.04)	0.769	0.99 (0.95–1.04)	0.707
HDL cholesterol, mmol/L*	0.99 (0.96–1.02)	0.585	0.99 (0.96–1.03)	0.676	1.00 (0.95–1.05)	0.920
LDL cholesterol, mmol/L*	0.99 (0.94–1.04)	0.629	0.98 (0.93–1.03)	0.406	1.01 (0.94–1.08)	0.816
Total/HDL cholesterol ratio*	1.01 (0.96–1.05)	0.811	1.00 (0.96–1.05)	0.863	1.00 (0.95–1.06)	0.960
Triglycerides, mmol/L*	1.00 (0.94–1.08)	0.895	1.04 (0.98–1.11)	0.177	0.96 (0.87–1.06)	0.422
Systolic BP, mmHg	0.73 (−1.93 to 3.39)	0.590	−1.35 (−3.89 to 1.18)	0.296	2.08 (−1.59 to 5.75)	0.266
Diastolic BP, mmHg	−0.09 (−1.63 to 1.44)	0.906	−0.05 (−1.63 to 1.52)	0.948	−0.04 (−2.13 to 2.04)	0.969

Table presents mean changes at 24 months minus 18 months (95% CI) from linear mixed models, adjusted for baseline values and confounders. BP, blood pressure; UC, usual care; Tel, telephone counseling. *Back-transformed from natural log (i.e., relative rate). †Measured by ActiGraph GT1M accelerometer, as time ≥1,952 cpm.

relatively good levels of baseline glycemic control, models were also run including an interaction term for baseline HbA_{1c} level, which suggested that intervention effects varied minimally by baseline HbA_{1c} level (data not shown).

CONCLUSIONS

The LWWD trial evaluated a broad-reach, telephone-delivered intervention targeting sustained improvements in weight loss and physical activity in adults with type 2 diabetes recruited from primary care settings. At the end of the 18-month intervention, statistically significant, but clinically modest, benefits were observed for weight loss, MVPA, and diet quality. Changes were maintained at the 24-month follow-up, though they were only statistically significant for MVPA. There were no statistically significant improvements in any of the cardio-metabolic biomarkers, including HbA_{1c} level.

The LWWD trial sought to recruit a representative sample of Australian primary care patients with type 2 diabetes and deliver an intervention that made participation as easy as possible (i.e., without the need for clinic visits). While the sample was largely representative, engaging telephone counseling participants in the intervention proved challenging. Attrition at 24 months was nondifferential and modest in both groups, yet ~40% of telephone counseling participants chose to discontinue receiving the intervention by withdrawal from either the intervention or study participation altogether. Further, even among telephone counseling group participants who did not withdraw, intervention delivery was difficult, with just over half of participants completing at least 75% of scheduled intervention calls. This was despite documentation of multiple call attempts and mostly participant-related reasons for missed intervention calls. While the optimal dose of intervention cannot be examined given the study design, planned analysis of the associations between call completion and study outcomes will further inform the issue of participant engagement.

Despite challenges in intervention delivery, findings for weight loss are not substantially different from those seen in previous trials of lifestyle and behavioral weight loss interventions involving people with type 2 diabetes. In a meta-analysis of 22 such studies, Norris et al. (33) reported pooled weight loss of 1.7 kg (95% CI 0.3–3.2 kg) or 3.1% of baseline body weight, compared with the LWWD intervention effect for weight loss of 1.52 kg (95% CI −2.64 to −0.39 kg) or −1.42% of baseline body weight (95% CI −2.54 to −0.30% of baseline body weight). As anticipated, the magnitude of the weight loss observed in the LWWD trial was less than that seen in the intensive Look AHEAD trial (8). It was also considerably lower than the intervention target of 5–10% weight loss. Weight changes in the LWWD trial were related both to weight loss in the telephone counseling group and to prevention of weight gain, with 36.6% of usual-care participants and only 18.7% of telephone counseling participants experiencing weight gains of ≥1% of body weight over 2 years.

Our intervention effect for MVPA is similar to what has been previously reported in patients with type 2 diabetes (34). The modest but significant improvement of ~40 min/week is consistent with the modest standardized weighted mean difference in objectively measured physical activity of 0.45 (95% CI 0.21–0.68) reported in a recent meta-analysis (34). Further, as with weight loss, there was some suggestion of a prevention effect, with a considerable decline in MVPA observed in the usual-care group at 24 months.

Since the onset of this 5-year LWWD trial, a number of studies of telephone-delivered interventions to improve glycemic control in patients with type 2 diabetes have been published and are summarized in a meta-analysis (15). Our findings for HbA_{1c} level were at the lower end of what might be expected based on the review by Wu et al. (15), which reported a standardized weighted mean difference of −0.44 (95% CI −0.93 to 0.06) (i.e., an effect that is estimated as moderate but could plausibly be anywhere between no effect and a large beneficial effect). The review also showed that the interventions were not consistent in their impact on HbA_{1c} level (i.e., significant heterogeneity). Even the results in three randomized controlled trials that were similar in recruitment and intervention protocols to the LWWD trial were still mixed: no effect on glycemic control (also no meaningful weight loss) (35); significant improvement in glycemic control (despite no meaningful weight loss) (36); and, significant improvement in glycemic control (weight loss not reported) (37).

The strengths of the LWWD trial include recruitment of a largely representative sample of Australian primary care patients with type 2 diabetes; objective assessment of primary clinical, anthropometric and behavioral outcomes (i.e., MVPA via accelerometer); inclusion of a maintenance assessment; and systematic tracking of implementation. Limitations of the study include the collection of fairly crude data on diabetes medication usage and thus the inability to comprehensively control for the effects of medication usage and medication changes on primary outcomes, particularly HbA_{1c} level.

In summary, like most similar interventions, the effectiveness of the LWWD trial was limited in terms of weight loss and behavior change; accordingly, there was no evidence that the LWWD trial benefited glycemic control. This may limit the utility and scalability of the approach, making it important that future studies of telephone-delivered interventions in individuals with type 2 diabetes evaluate strategies to increase participation and adherence. These could include mobile phone text messaging and smart phone applications that may be able to address some of the challenges of participant engagement experienced in the LWWD trial.

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