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, PhD1, Elisabeth A Winkler, PhD1, David W Dunstan2,4,5,6, PhD, Genevieve N Healy1,2,7, PhD, Neville Owen2,8,9,10, PhD, Alison M Marshall3, PhD, Nicholas Graves3, PhD, Marina M Reeves4 PhD

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

Running title: Living Well with Diabetes 24-month outcomes
ABSTRACT

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 HbA1c. Secondary outcomes include dietary energy intake and diet quality, waist circumference, lipids and blood pressure. Data were analyzed via adjusted linear mixed models with multiple imputation of missing data.

RESULTS: Relative to Usual Care, Telephone Counseling participants achieved modest, but significant improvements in weight loss (-1.42, 95% CI: -2.54, -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, 95% CI: -3.16,-0.51 cm), but not in HbA1c (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 key diabetes management outcomes observed following behaviorally-based telephone counseling for adults with type 2 diabetes need to be considered in terms of their potential for broad population reach.
The high prevalence of overweight and obesity is driving a type 2 diabetes epidemic worldwide (1). Diabetes prevalence in adults has increased over the last decade from 8.2% to 11.3% in the USA (2) and from 8.5% to 12% in Australia (3), with type 2 diabetes accounting for over 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 already diagnosed with diabetes, the challenges of applying lifestyle intervention programs have received considerable recent attention. The Look AHEAD study, a seminal trial that evaluated a multi-year, highly-resourced, intensive lifestyle intervention compared to standard diabetes education, demonstrated significant improvements in weight loss, related behavioral changes, HbA1c and other cardio-metabolic markers (8). Despite this, the Look AHEAD intervention was not successful at inducing changes in the primary endpoint 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, 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 increasing 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 (six-month) outcomes of LWWD showed small intervention effects for weight loss and physical activity, but not HbA1C (16). The purpose of this paper is to report on 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 HbA1c. Secondary outcomes were dietary energy intake and diet quality, waist circumference, fasting blood lipids and blood pressure.

RESEARCH DESIGN AND METHODS
LWWD 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 kilometres 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, 1407 eligible patients (i.e., diagnosed type 2 diabetes; aged 20–75 years; with a listed telephone number) were identified using electronic medical records (Figure 1). Patients not initially excluded by General Practitioner (GP) screening for contraindications to unsupervised physical activity (n=908) were posted 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 ≥30min planned exercise) and/or overweight or obese (body mass index [BMI] ≥25.0 kg/m\(^2\)), not using weight loss medications and without previous or planned bariatric surgery. Of those reached via telephone and eligible (n=420), 302 (71.9%) agreed to participate, completed the baseline assessment and were randomized to the either 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): gender; age (≥ 55 years); BMI (≥ 40 kg/m\(^2\)); HbA1c (≥ 8%); self-reported physical activity level (meeting Australian guidelines of ≥150 minutes and ≥5 days per 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 assessment results following each assessment, as well as standard, diabetes self-management education brochures.

**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 (four initial weekly calls; fortnightly calls for five months; monthly calls for 12 months) to support
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: identifying benefits of weight loss; setting goals for gradual changes to physical activity and dietary intake; self-monitoring progress; problem-solving; utilizing available supports; and, focusing on achievements with appropriate rewards (23).

Intervention targets for weight loss, physical activity and dietary intake were consistent with management goals for type 2 diabetes (10), with the aim to reduce HbA1c to less than 7%.

Participants were encouraged to achieve moderate weight loss of 5–10% of initial body weight, with a loss of 1–2 kg per month (10). A target of at least 210 minutes per week (30 minutes 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 (2–3 sessions/week) (25). Individualised advice (26) was used to encourage participants to reduce daily energy intake by 2000 kJ (approximately 500 kcal) by following healthy eating principles, including following a low-fat diet (i.e., total fat < 30% of energy and saturated fat < 7% of energy) with sufficient dietary fiber (25 grams/day for women and 30 grams/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 moderate- to vigorous-intensity physical activity (MVPA) and HbA1C. Secondary outcomes were dietary energy intake and diet quality, waist circumference, fasting blood lipids and blood pressure. Data were collected
at baseline, six-, 18- (end of intervention), and 24-months (maintenance) via nurse home visits and telephone interviews by research staff 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, 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 in the seated position by a portable sphygmomanometer (Gamma G5, Heine, Germany). Blood samples were taken by registered nurses early in the morning after an overnight fast (at least 10 hours), with participants instructed not to take any glucose-lowering medication prior to the assessment. Current diabetes medications were recorded. HbA1c was measured from whole blood samples by the high performance liquid chromatography method (Bio-Rad Variant II, Sydney, Australia). Total cholesterol, high density lipoprotein (HDL) cholesterol and triglycerides were measured by an enzymatic colorimetric assay with Roche Modular Chemistry Analyser (Tokyo, Japan). Low density lipoprotein (LDL) cholesterol was determined using the Friedewald equation (27).

Nurses provided participants with a GT1M accelerometer (Actigraph, LLC, Fort Walton Beach, Florida) to collect physical activity data. The hip-worn monitor was set to record in 60-second epochs. Participants were asked to wear the monitor for seven days during waking hours (except during water-based activities) and to record wear/removal times. Wear time was ascertained by research staff, who estimated wearing periods from times movement stopped or began coinciding with participant self-reported wear/removal periods. Using SAS 9.2 (SAS Institute Inc., Cary, NC), MVPA was identified as time spent at ≥1952 counts per minute (cpm) during worn time on valid days (i.e., ≥10 hours of wear, no excessive counts ≥20,000 cpm). Weekly MVPA was estimated as seven times mean MVPA
on valid days, with a requirement of at least one valid day. Respectively at baseline, 6-, 18- and 24-months at least four valid days were provided by 98% (297/302), 97% (265/273), 95% (234/246) and 96% (229/239) of participants and mean (±standard deviation) daily wear time for those with ≥ 1 valid wear day was 13.5±1.6 hours, 13.7±1.7, 13.6±1.8, and 13.7±1.8 hours.

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

Demographic data and adverse events were also collected during the telephone interview.

Statistical analysis

Analyses were performed in SPSS version 21 (IBM Corporation, NY) and STATA version 12 (StataCorp, 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 HbA1c% and 60 minutes/week MVPA (17). It was expected to provide adequate (≥80%) power to detect MDIs for diet (2 MJ energy intake and √2 a standard deviation diet quality [5.5]), waist circumference (5cm), HDL cholesterol and total/HDL cholesterol ratio (5%), and triglycerides (10%), but low power to detect MDIs for blood pressure (70% for 5 mmHg systolic and 56% for 3mmHg 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 \( p<0.2 \) (listed in Supplemental Table S1). Changes within groups were also examined using mixed models. For outcomes that were log-transformed to improve normality (HbA1c, MVPA, cholesterol and triglycerides), model results were exponentiated and expressed as relative rates. Models did not display problems with heteroscedasticity, non-linearity or non-normality.

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

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 (± Standard Deviation) age of 58 (± 8.6) years and 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%), obese (68.2%) or overweight (26.2%), and not meeting physical activity guidelines (69.5%). In the Telephone Counseling (n=151) and Usual Care groups (n=151), respectively, insulin use was low at baseline (15.2%, 13.2%) but increased by 24-months (23.5%, 23.9%), and the percentages not on diabetes medications dropped between baseline (19.9%, 17.2%) and 24-months (18.2%, 12.8%).
Withdrawal rates were low and diminished over study duration (Figure 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 and greater use of insulin at baseline than completers (Supplemental Table S2). There was a non-significant tendency for dropouts to be male, use oral hypoglycemic medication and have longer diabetes duration. Out of the 27 possible intervention calls, median (25th, 75th percentile) call receipt was 16 (9, 22) among Telephone group participants (n = 151), and 17 (21, 23) in the 60.9% of Telephone participants who had not withdrawn from intervention or the study before end of intervention (n=92). Respectively, completion of ≥75% of scheduled calls was achieved by 36.4% (55/151) of Telephone group participants, or, 57.6% (53/92) of non-withdrawn Telephone participants.

**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 end-of-intervention (18-months) the Telephone Counseling group had modest, but significantly favorable outcomes relative to Usual Care for the primary outcomes of weight loss (-1.42 [95% CI: -2.54, -0.30]% of baseline body weight or -1.52 [-2.64, 0.39] kg) and MVPA, which was 42% higher in Telephone than Usual Care participants (RR = 1.42, 95% CI: 1.06, 1.90, or, 43.06 minutes/week, 95% CI:15.04, 71.09 minutes/week), but not for HbA1c (RR=0.99, 95% CI: 0.96, 1.02, i.e., -0.06%, 95% CI: -0.16, 0.20% or -0.7, 95% CI: -1.7, 2.2 mmol/mol). In terms of secondary outcomes, modest but significant intervention effects were observed for diet quality (2.72, 95% CI: 0.55, 4.89) and waist circumference (-1.84 cm, 95% CI: -3.16,-0.51 cm), but not for energy intake, cholesterol, triglycerides or blood pressure. Consideration of
the 95% confidence intervals ruled out as unlikely any meaningful intervention effects for HbA1c, energy intake and diastolic blood pressure. When changes within groups were examined, the telephone group exhibited modest improvements in most outcomes (Supplemental Table S3). Additionally, significant, meaningful within-group change was observed in both Telephone Counseling and Usual Care participants for some of the cholesterol outcomes (HDL, LDL, Total/HDL ratio). Notably, the intervention effects for MVPA related to a significant 25% decline in the usual care group (RR=0.8, 95% CI: 0.66, 0.98) rather than improvement in the telephone group. Adverse events requiring hospitalisation were reported by 4 (3.4%) of Telephone Counseling and 4 (3.1%) of Usual Care participants, with events plausibly related to study participation (ie, musculoskeletal problems and digestive disturbance) reported by 17 (14.4%) and 28 (21.9%), respectively. No hypoglycemic events were reported.

**Maintenance**

MVPA was the only outcome in which there was a significant intervention effect after the six-month non-contact period (i.e., at 24-months), with mean MVPA being 44% higher in the Telephone Counseling group than the Usual Care group (RR = 1.44, 95% CI: 1.12, 1.85, or 38.95, 95% CI: 12.55, 65.35 mins/week). Although not statistically significant, there was some attenuation in the intervention effect sizes 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 end-of-intervention, only a small percentage of Telephone Counseling and Usual Care groups respectively achieved program targets of ≥ 5% weight loss (21.0%, 13.2%), ≥210 mins/week MVPA (34.8%, 27.8%), ≥ 2MJ energy reduction (22.8%, 18.8%) (Supplemental
Figure SF1). However both Telephone and Usual Care groups, respectively, quite commonly met recommendations for HbA1c ≤ 7% (10) both at baseline (45.7%, 53.0%) and end-of-intervention (43.9%, 42.4%) (Supplemental Figure SF1). Weight gain (≥ 1%) was common at 6-, 18-, and 24-months, more so within the Usual Care group (38.6%, 43.1%, 36.6%) than the Telephone group (29.5%, 31.5%, 18.7%) (Supplemental Figure SF1).

**Sensitivity analyses**

Completers analysis and the multiple imputation yielded almost identical results (Table 2). Conclusions were robust to the choice of MVPA cutpoint; significant intervention effects favoring the Telephone Counseling group were still observed even with a very low (≥ 574) and a very high cutpoint for MVPA (≥ 2743) (32) (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 were only statistically significant for MVPA. There were no statistically significant improvements in any of the cardio-metabolic biomarkers, including HbA1c (one of the primary outcomes).

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 non-differential and modest in both groups, yet approximately 40% of
Telephone participants chose to discontinue receiving the intervention either by withdrawal from the intervention or from study participation all together. Further, even among Telephone group participants who did not withdraw, intervention delivery was difficult, with just over half 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 and the characteristics of those completing fewer and more calls will further inform the issue of participant engagement.

Despite challenges in intervention delivery, our findings for weight loss are not different to 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 and colleagues reported pooled weight loss of 1.7kg (95% CI 0.3 to 3.2kg) or 3.1% of baseline body weight, compared to the LWWD intervention effect for weight loss of 1.52kg (95% CI -2.64 to -0.39kg) or -1.42% (95% CI -2.54 to -0.30%) of baseline body weight (33). As anticipated, the magnitude of the weight loss observed in LWWD was less than that seen in the intensive Look AHEAD trial (8). Additional analyses, via categorisation of the weight changes, suggested that the changes observed in LWWD were related both to the weight loss in the Telephone group as well as prevention of weight gain, with 36.6% of Usual Care participants and only 18.7% of Telephone group participants experiencing weight gains ≥1% of body weight over two years.

Our intervention effect for MVPA is similar to what has been previously reported in type 2 diabetes (34). The modest but significant intervention effect of approximately 40 minutes per 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 reports of studies of telephone-delivered interventions to improve glycemic control in type 2 diabetes have been published, and are summarized in a meta-analysis (15). Our findings for HbA1c were at the lower end of what might be expected based on Wu and colleagues’ review (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 to a large beneficial effect. The review also showed that the interventions were not consistent in their impact on HbA1c (i.e., significant heterogeneity). Even three randomized controlled trials that were similar in recruitment and intervention protocols to LWWD, results 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).

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 include the collection of fairly crude data on diabetes medication usage and thus the inability to comprehensively control for medication usage and medication changes on primary outcomes, particularly HbA1c.

In summary, reviews and individual studies of telephone-delivered diabetes management and lifestyle interventions, including LWWD, show fairly modest and in some cases null effects for glycemic control, weight loss and physical activity. As would be expected, these outcomes are considerably more modest than those observed in the intensive,
multi-year lifestyle Look AHEAD intervention. A similar attenuation of intervention effects has been reported in the adapted versions of the landmark USA and Finnish Diabetes Prevention Programs that have been scaled for delivery in resource-limited primary health care and community health contexts (6; 7). The question then becomes whether scarce resources should be devoted to intensive programs producing substantial improvements in clinical indicators and underlying behaviors for few, or to scalable programs producing small improvements, with the potential for broad population reach and impact on many, such as LWWD (38).

In terms of lifestyle programs for adults living with type 2 diabetes, various jurisdictions in many developed countries now financially support the delivery of scaled diabetes prevention programs in community contexts. With some adaptations, such programs could also be made available to those living with type 2 diabetes. In Australia, a number of state health departments now offer a free, six-month telephone lifestyle and weight loss coaching service (the Get Healthy Information and Coaching Service or GHS) available to any adult in the state via clinician or self-referral. Moderate weight loss and behavioral improvements and maintenance following GHS completion have been reported (39; 40). While not specifically targeting diabetes prevention or management, those at risk for or living with diabetes are eligible, following clinician referral.

These longer-term intervention and maintenance outcomes from the LWWD trial suggest that telephone counseling for adults with type 2 diabetes is effective in producing significant but modest weight loss and in maintaining physical activity improvements, but not in improving glycemic control. Telephone-delivered lifestyle coaching may be a vehicle through which to achieve wide population reach for those with and those living with, and at risk for, type 2 diabetes. Future research is needed to evaluate this, along with alternative, broad-reach intervention delivery modalities, such as 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.
AUTHOR CONTRIBUTIONS

All authors contributed to study design and manuscript writing. Additionally, E.W. conducted data analyses.

ACKNOWLEDGEMENTS

We wish to thank the patients, general practitioners and practice staff of the Greater Metro South Brisbane Medicare Local (Logan, Australia) who participated in the study, and Diabetes Australia Queensland for their endorsement and provision of materials for the usual care group. We would also like to thank project staff for their integrity and commitment: Kym Spathonis, Charlotte Brakenridge, Erin Robson, Amy Chatwin, Jennifer Job, Fiona Heys, Natalie Doyle, Jodie Jetann, Ellen Baker, Lisa Ulyate, Fiona Porter and Charani Kiriwandeniya. This study was supported by a National Health and Medical Research Council (NHMRC) project grant and an Australian Diabetes Society National Diabetes Strategy Grant in Memory of Barry Young. Eakin is guarantor of the research and is supported by a NHMRC Senior Research Fellowship; Reeves is supported by a National Breast Cancer Foundation Research Fellowship; Winkler is supported by Queensland Health core infrastructure funding; Healy is supported by an NHMRC [# 569861] Training Fellowship and a Heart Foundation Postdoctoral Fellowship [PH 12B 7054]; Dunstan is supported by an Australian Research Council Future Fellowship; Owen is supported by a NHMRC Senior Principal Research Fellowship; Marshall is supported by a NHMRC Career Development Award. The trial is registered with the Australian Clinical Trials Registry #ACTRN12608000203358. The authors have no conflicts of interest to disclose.
REFERENCES


