



The Green Card Pilot: A Randomized Controlled Trial of an Education/Reward Intervention to Aid Diabetes Self-management

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Abstract

The Green Card Project is a small randomized controlled trial (RCT) designed to test the effectiveness of an intervention to aid diabetes self-management carried out in a general practice setting in rural New South Wales. Participants were given a card with four key predictors of long term diabetes health and offered incentives for positive changes in these indicators. Controls received standard care. Fifty four participants and 68 controls completed the project. There was an average decline of 0.20 (se 0.15) in HbA1c for males in the intervention group compared to an average increase of 0.23 (se 0.13) in the control group. For women, the opposite occurred, with the intervention women exhibiting an average increase of 0.24 (se 0.13) and the controls an average reduction of 0.12 (se 0.127). For lipids, there was a significant reduction in both intervention and control. Both males and females in the intervention group demonstrated a significant reduction in waist circumference, whereas the control group had a non-significant increase in waist circumference. Male participants saw the program in a competitive light, while women were focused on the discount voucher. Education strategies for diabetes may benefit from research into gender specific information delivery systems. The trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) as ACTRN12613000414718.

Summary statement

What is known about the topic?

Assisting patients to attain the desired goals of diabetes self-management is difficult.

What does this paper add?

Addressing gender specific attitudes to T2DM may prove crucial in contributing to lifestyle change in patients and their families.

Keywords: Diabetes; Randomized controlled trial; Self-management; Primary health care

Introduction

Type 2 Diabetes mellitus (T2DM) is one of the most serious health problems in Australia, and most people afflicted with it do not adhere to optimal management of their condition [1]. Positive incentives and patient oriented education systems have shown effectiveness in the management of T2DM [2-4]. Multi-faceted intervention strategies are needed [5,6] and several have been developed in Australia [7]. While general practice (GP) may be the optimum support setting for people attempting to lose weight and achieve a healthy lifestyle, few people use the resource of their GP when attempting to lose weight [8], and of those that do, only a minority consider it effective in their efforts to control T2DM [9].

In Australia, it has proven difficult to enrol people, especially high risk people, in behaviour/lifestyle modification programs [10]. Incentives can increase the motivation for people to act in their own

best interest [11]. While some controversy exists around the use of positive incentives programs in the health arena [12], cautious success has been demonstrated in a variety of programs [13] from smoking cessation in pregnancy [14], to managing asthma [15] and quitting IV drug use [16]. Reasonable grounds for optimism exist for designing a tool to encourage health and lifestyle gains in that complex and difficult group, people with T2DM.

We describe The Green Card Project, a small randomized controlled trial (RCT) designed to test the effectiveness of an intervention including tailored personal health information, and small retail discounts as patient rewards, that was carried out in a rural general practice setting with the involvement of community merchants.

Methods

Participant selection

Participants were drawn from a single general practice in rural New South Wales, Australia. The practice was chosen because the community in which it is located is a classic example of a traditional Australian country town characterized by an elderly, semi-retired population.

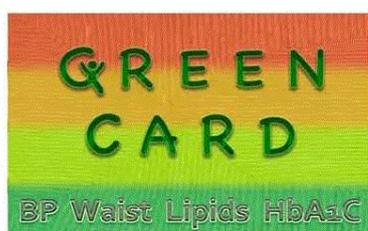
Eligibility criteria were a diagnosis of T2DM and up-to-date medical records held with the practice. Potential participants were contacted via random sampling from this group. Those who agreed to participate were given a participants information statement and signed a consent form for participation. They were then enrolled via a 15 minute

interview appointment with the study organizer or an assisting senior medical student at which baseline health data was collected.

lipoprotein/high density lipoprotein (LDL/HDL) ratio, waist measurement, and HbA1C level) ("Understanding Diabetes,") on the front, and a scale of measurement for these on the reverse (Figure 1).

Intervention

Participants were given a card (The Green Card) with the four key predictors of long terms diabetes health; blood pressure, low density



≥ 150/95	≥ 7.6	≥ 110	≥ 105	≥ 9%
141/90 - 150/95	5.6 - 7.5	101-110	96 - 104	8.1 - 9%
131/80 - 140/90	3.5 - 5.5	91-100	86 - 95	7.1 - 8%
≤ 130/80	≤ 3.5	≤ 90cm	≤ 85cm	≤ 7%
BP	LDL/HDL	(M) WAIST (F)	HbA1C	

Figure 1: The green card.

Every three months, participants in the intervention group were mailed an individual health summary that progressively tracked their personal scores in each of these predictors. Points were awarded for being in the green zone, moving towards the green zone (compared to the previous summary), and for attending a three monthly check with either their GP or the diabetic nurse. The maximum value of points attainable at each summary equated to an AU\$5.00 discount voucher, which could be redeemed at a range of participating local businesses, such as the pharmacy, newsagent, and optometrist.

Participants in the control group received standard care from their general practitioner, without the intervention of the Green card and rewards program. Health data on participants were obtained from practice records.

Quantitative

Primary methodology was a randomized controlled trial of the 'Green Card'. Design and analysis of the RCT were carried out in accordance with Boutron's modification of the CONSORT protocol for randomised trials of nonpharmacologic treatment [17,18].

The primary outcome of interest was statistically significant improvement in core health predictors of T2DM, particularly HbA1c, in the intervention group compared to controls from baseline to completion (12 months). Data from the Australian National Diabetes Information Audit & Benchmarking (ANDIAB) final report for 2009, based on a sample of 8563 people with diabetes, indicate that the mean HbA1c in people with Type I Diabetes is normally distributed with a mean of 8.4% and standard deviation 1.5. While problematic [19], HbA1c is currently the best diagnostic metric to evaluate condition

prognosis, and treatment efficacy in persons with T2DM [20]. The project goal was to achieve a 5% improvement in participants (a reduction in mean HbA1c to 8%, assuming a starting HbA1c of 8.4%). Sample size calculation indicated a minimum 65 intervention participants and 65 control subjects to be able to reject the null hypothesis of no difference in the response over time with probability (power) 0.9 at $p < 0.05$. Secondary outcomes included waist circumference measurement in cm (waist) and Low density lipoprotein/High density lipoprotein (LDL/HDL) ratio scores (lipid).

Statistical analysis

Baseline group differences were assessed for HbA1c and lipids using independent t-tests and two way analysis of variance with gender, group, and gender by group interaction for waist circumference.

In order to assess possible gender differences associated with physiological measures, three way repeated measures analysis of variance (RM ANOVA) for primary (HbA1c) and secondary (waist and Lipid) outcomes were undertaken. The three-way models included the following main effects: Time (baseline/completion) as the within-subject factor and the between-subject factors of Group (Intervention/Control) and Gender (male/female), all two way interactions (Time by Group, Time by Gender, Group by Gender) and the three way interaction of Time by Group by Gender.

Separate two way repeated measures ANOVA (Model 2: Time, Group and Time by Group) for males and females were undertaken if Gender-specific interactions or main effects were significant ($p < 0.05$) in the three-way models. Similarly if gender effects were non-significant ($p > 0.05$) the simpler two-way RM-ANOVA (Model 2) was

undertaken. A significant Time by Group interaction will determine the difference in the response over time between Groups. For significant effects, estimates of marginal means and pairwise comparisons between baseline and completion were examined to determine the nature of the interaction.

As a sensitivity analysis, all completing participants were assessed as to if they achieved a reduction equal to or better than 0.5 in HbA1c, with group differences assessed overall, and for males and females separately using Pearson's χ^2 (chi squared), or Fishers exact test if required. All analyses were performed using SPSS Version 22 (<http://www-01.ibm.com/software/analytics/spss/>) with two-tailed tests with significance of $p < 0.05$.

Qualitative

Participant's views on diabetes and motivation for participation in the study were examined through in-depth interviews with each participant at the clinical visit when they were inducted into the study. Interviews were conducted by the principal investigator or the research assistant, and only the Interviewer and participant were present during the interview. The interview script was designed to elicit the participant's basic knowledge and control of T2DM, and to identify factors that motivated the participant to volunteer to be part of the study.

Ethics

The project was approved by the University of Sydney Human Research Ethics Committee, Reference number 11-2209/12094 on 30 November 2009. Ethical issues addressed for the ethics committee included the monetary value of the incentive provided, approval of the project by Diabetes Australia (NSW) [21], and whether participating retailers received any financial incentive to participate (they did not).

The trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) as ACTRN12613000414718.

Results

A total of 138 participants were recruited and randomized between intervention and control groups. Demographic information and baseline descriptive statistics for physiological parameters for the intervention and control groups with all participants and for participants available at completion are presented in Table 1. There was no statistical difference in the gender distribution at either baseline or at completion (χ^2 (chi squared)=1.045, $p=0.307$ and $\chi^2=1.291$, $p=0.256$ respectively).

		Attribute	Intervention n (%)	Controls n (%)
All respondents N=138	Gender	Male	30 (43.5)	36 (52.2)
		Female	39 (56.5)	33 (47.8)
		All	69	69
	Age	Mean (SD)	69 (11.9)	70.8 (11.9)
		Range	50-88	41-93
Completing respondents N=122	Gender	Male	29 (43)	36 (53)
		Female	31 (57)	32 (47)

	All	54	68
Age	Mean (SD)	69 (12.0)	70.7 (12.0)
	Range	50-88	41-93

Table 1: Participant demographics.

As with any longitudinal study, discontinuation of participation was expected and encountered. Three participants from the intervention arm were excluded from analysis due to misclassified medical status and one died. Two participants from the intervention, both women, withdrew from the study. The first withdrawal was a female participant who called the principal investigator immediately on receiving her first summary. Her waist measurement had increased from baseline, and she felt strongly that this was intrusive and personally insulting information that a person should not have to view via their letterbox. The second withdrawal was from a woman, who said she had checked with her GP, and her diabetes was 'the genetic kind', so there was no point in her being in a study which encouraged lifestyle change. One person withdrew from the control arm with no reason given. Eleven participants' data (10 from intervention, 1 from control) were excluded from analysis due to missing data.

Quantitative

Fifty four participants in the intervention group and 68 in the control group completed the project. Figure 2 presents a flow chart of participants and controls through the study.

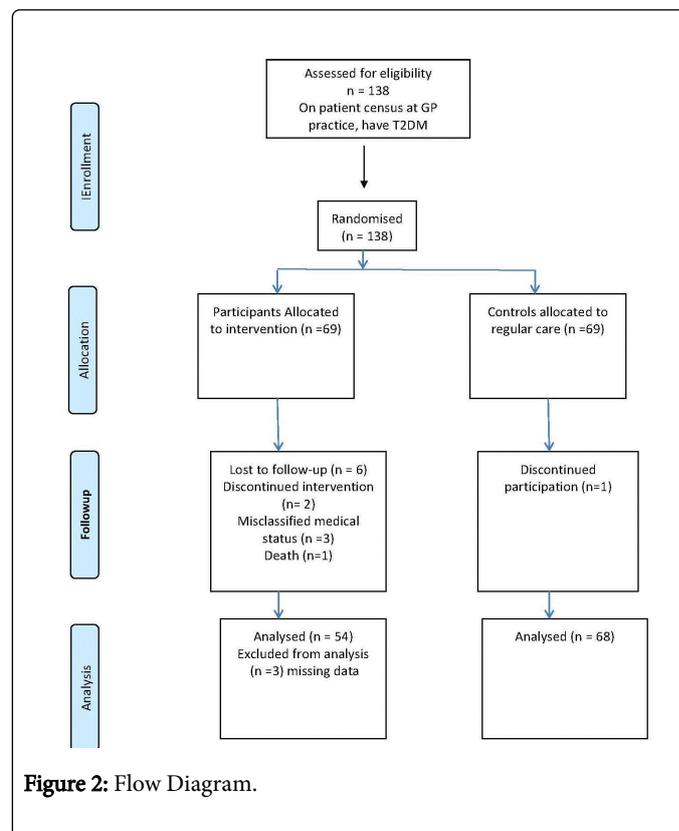


Figure 2: Flow Diagram.

At baseline there were no significant group differences for HbA1c ($t_{136}=-0.026$, $p=0.979$). However lipids were significantly higher for the control group $t_{135}=-2.14$ $p= 0.034$ whereas waist circumference

was significantly higher for intervention males ($t_{60}=2.136, p=0.037$) but did not differ significantly for females ($t=0.386, p=0.701$).

At baseline, for participants who subsequently completed the study there were no significant group differences ($t_{120}=-0.242, p=0.809$) for HbA1c or lipids ($t_{119}=-1.53, p=0.129$). However waist circumference, when analysed separately for males and females, was significantly

higher for intervention males ($t_{53}=2.119, p=0.039$), but did not differ significantly for females ($t_{59}=0.303, p=0.763$). Baseline means and standard deviations for all outcome variables are presented in Table 2. There was no significant difference in any of the outcome measures between participants completing the study and those who withdrew.

		Intervention														
		Male					Female					All				
Outcome	Time	Mean	SD	Min	Max	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	N
HbA1c	Baseline	7.2	1.40	5.8	10.6	23	7.0	0.86	5.5	8.3	31	7.1	1.11	5.5	10.6	54
	Completion	7.0	1.38	5.6	12.3	23	7.2	1.14	5.5	9.7	31	7.2	1.24	5.5	12.3	54
Lipid	Baseline	3.6	1.31	2.1	7.9	23	3.8	1.31	2.1	8.0	30	3.7	1.30	2.1	8.0	53
	Completion	3.2	0.66	2.4	5.1	22	3.5	1.11	1.9	6.7	29	3.3	0.95	1.9	6.7	51
Waist circumference	Baseline	114.5	10.99	93.0	135.0	23	103.7	16.4 ₁	68.0	148.0	31	108.3	15.2 ₂	68.0	148.0	54
	Completion	109.6	12.10	86.0	130.0	22	99.8	15.5 ₇	67.0	139.0	30	103.9	14.9 ₁	67.0	139.0	52
		Control														
		Male					Female					All				
		Mean	SD	Min	Max	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	N
HbA1c	Baseline	7.1	0.76	5.4	9.0	36	7.0	0.99	5.4	9.6	32	7.1	0.87	5.4	9.6	68
	Completion	7.3	0.85	5.6	8.8	36	6.9	0.98	5.2	10.4	32	7.1	0.93	5.2	10.4	68
Lipid	Baseline	4.1	1.38	1.8	9.6	36	4.2	1.81	1.9	9.5	32	4.1	1.59	1.8	9.6	68
	Completion	4.0	1.15	2.0	6.0	36	3.8	1.33	1.7	6.7	32	3.9	1.23	1.7	6.7	68
Waist circumference	Baseline	107.7	12.37	85.0	139.0	32	102.5	15.6 ₃	69.0	134.0	30	105.2	14.1 ₇	69.0	139.0	62
	Completion	109.9	14.20	72.5	139.0	31	105.0	16.3 ₁	75.0	135.0	27	107.6	15.2 ₈	72.5	139.0	58

Table 2: Outcomes of Hb1Ac, Lipid and waist circumference with mean, sd, minima, maxima by gender at baseline and completion for Intervention and Control groups for completers only.

Influence of gender: The results of the three way repeated measures analyses of variance, which were inclusive of gender as a main effect, are presented in Table 3. Only HbA1c indicated a significant three-way

(time by group by gender) interaction ($p=0.003$). Waist circumference indicated a significant gender main effect ($p=0.021$) and lipids indicated no significant effects with respect to gender.

Model components		Outcomes					
		Hb1Ac Error df=118		Waist Error df=113		Lipid Error df=115	
		F	P	F	P	F	P
Main effects	Time (within subject)	0.331	0.566	13.711	<0.001	16.719	<0.001
	Group (between subject)	0.057	0.812	0.012	0.9163	5.174	0.025
	Gender (between subject)	0.364	0.548	5.520	0.021	0.526	0.470
2-way interaction	Time by Group	0.085	0.771	51.021	<0.001	0.003	0.956

	Time by Gender	0.127	0.722	0.010	0.922	1.304	0.256
	Group by Gender	0.282	0.596	0.891	0.347	0.914	0.341
3-Way interaction	Time by Group Gender	9.123	0.003	0.721	0.397	0.370	0.544

Table 3: Results of full factorial three-way repeated measures ANOVA for Hb1Ac, Lipids and waist circumference (bold denotes significant components).

Outcome	Group	Time		Time by Group		p	
		F	p	F	p		
HbA1c	Male	0.039	0.845	0.018	0.893	4.136	0.047
	Female	0.329	0.568	0.064	0.440	5.180	0.026
Waist Circumference	Male	0.456	0.503	5.452	0.023	24.103	<0.001
	Female	0.467	0.497	9.014	0.004	27.476	<0.001
Lipid	All	0.135	0.713	16.830	<0.001	0.016	0.900

Primary Outcome: Due to the presence of the interaction with gender, the results of the gender specific two way repeated measures analysis with time and group are presented in Table 4. For both males and females the time by group interaction was significant, with p=0.047 and p=0.026 respectively. However the interaction responses were in opposite directions as evident in the estimated marginal means and standard errors and change means presented for Gender, group and time combinations in Table 5. Whereas for HbA1c males in the intervention group experienced an average decline of 0.20 (se 0.15) compared to an average increase of 0.23 (se 0.13) in the control group. For women the opposite occurred, with the intervention women exhibiting an average increase of 0.24 (se 0.13) and the controls an average reduction of 0.12 (se 0.127).

Table 4: Results of two-way repeated measures ANOVA for Hb1Ac and waist circumference separately for males and females and for genders combined for lipids (bold denotes significant components).

Outcome	Group	Group	Baseline (T1)		At completion (T2)		Change T2-T1		P value for
			Mean	SE	Mean	SE	Mean	SE	
HbA1c	Male	Intervention	7.24	0.22	7.04	0.23	-0.20	0.17	0.229
		Control	7.07	0.18	7.31	0.18	0.23	0.13	0.088
	Female	Intervention	7.00	0.17	7.25	0.19	0.24	0.11	0.036
		Control	7.05	0.16	6.93	0.19	-0.12	0.11	0.290
Waist	Male	Intervention	113.7	2.35	108.1	2.11	-4.86	0.99	<0.001
		Control	108.1	2.11	109.9	2.37	1.73	0.90	0.059
	Female	Intervention	104.5	2.76	100.4	2.85	-4.08	0.67	<0.001
		Control	104.7	2.99	105.8	3.09	1.11	0.73	0.133
Lipid	Male	Intervention	3.68	0.20	3.38	0.16	-0.30	0.11	0.006
	Female	Control	4.17	0.17	3.88	0.14	-0.28	0.09	0.003

Table 5: Estimated marginal means and standard errors by group and time together with the mean change for Intervention and control groups and gender for HbA1C and waist measurement and mean change over time for lipids. Negative scores in change (T2-T1) indicate a reduction in the outcome measure.

In assessing whether a reduction in HbA1c of at least 0.5 was achieved, gender specific comparisons showed significantly more men in the intervention group, 6 or 26.1%, achieved this target compared to 2 (5.6%) of the control group (Fisher Exact test p=0.047). In contrast

there was no significant difference reduction (Fisher Exact test p=0.732) between groups for women, with 4 (12.9%) and 6 (18.8%) in the intervention and control group respectively.

Secondary outcomes: Lipid and waist circumference: For waist circumference, both males and females demonstrated a significant time by group interaction (males $F_{1, 54}=24.103$, $p<0.001$; females $F_{1, 59}=27.476$, $p<0.001$). Both males and females in the intervention group demonstrated a significant reduction of 4.9 cm (se 1.0) and 4.1 cm (se 0.9) respectively ($p<0.0001$) whereas the control group had on average a non-significant increase in waist circumference of 1.7 (se 0.9) and 1.1 (0.7) for males and females respectively. Table 5 provides details of the analyses and changes. For lipids there was no significant time by group interaction ($F_{1, 117}=0.016$, $p=0.90$) although the main effect of time was significant ($F_{1, 117}=16.83$, $p<0.001$) indicating a similar reduction in both groups, of 0.302 (se 0.109, $p=0.006$) and 0.284 (se 0.093, $p=0.003$) for the intervention and control groups respectively.

Qualitative

Participant interviews during the initial enrolment process revealed a difference in response to the study along gender lines.

Male participants saw the program in a competitive light. They particularly commented on being able to compete against themselves (rather than an unattainable 'health norm'). Three also asked whether the project would be selecting an 'overall winner'-the participant with the greatest improvement in diabetes self-management score. Several men specifically commented that they were not interested in redeeming discount vouchers. A majority considered receiving their information through the mail, rather than having to discuss it in person with medical staff, to be an advantage.

By contrast, women were very focused on the discount voucher aspect, and all of their specific queries related to the when, where and how of redeeming these. Eleven queries were made by female participants (zero by males) about the maximum possible number of redeemable points, and many seemed confident that achieving these would be a straightforward process. There was also a recurrent theme from women of 'genetic inevitability'. Four of the most clinically obese women in the trial stated that the disease had nothing at all to do with their diets; it was just that 'sugar ran in their family'.

Discussion

This group of rural Australians aged between 41 and 93 showed distinct gender differences in the health benchmarks measured in the trial. HbA1c benchmarks for men in the intervention arm appeared better than controls at the end of the project, while those for women were worse than controls. For waist circumference, both males and females in the intervention group demonstrated a significant reduction, indicating potential value for this intervention strategy.

In this age group and social environment, women are overwhelmingly the dominant provider of household meals [22], so addressing gender specific attitudes to T2DM may prove crucial in contributing to lifestyle change both in this group and within their wider families. Addressing the education deficit in a way that is not perceived as personally critical could be pivotal in changing both their health outcomes, and those of their 'sugar' afflicted families.

The negative influences of social networks on efforts at dietary self-management have been documented [23]. Consistent with previous research [24,25], men across the study population showed slightly improved clinical outcomes in this small trial. This trend is echoed in the self-assessed health status of Australians aged 55 and over, by age

and sex [26], where women consistently rate their health status score more highly than men.

Older Australian women are more likely to have regular face to face social encounters with their peers than their male counterparts [27,28] they also undertake the bulk of domestic food preparation [22]. They therefore have an important social and domestic role both generally in terms of peer to peer information sharing, and domestically in providing food that will either assist or hinder their families in avoiding or minimizing diabetes. Strategies that harness the energies of this group could have a disproportionate social reach in effecting diet and lifestyle change among their peers and families. Hence, the results of this small study suggest that education strategies for T2DM may benefit from research into gender specific information delivery systems.

Assisting patients to attain the desired goals of diabetes self-management is difficult, and failures frequently occur [29]. Intensive interventions have shown greater potential for positive results [30-32] and larger scale randomized trials designed to identify intervention strategies to control T2DM are currently underway [33-37].

Conflicts of interest

The authors declare no conflict of interest

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