Type 2 diabetes prevention in the community

12-Month outcomes from the Sydney Diabetes Prevention Program

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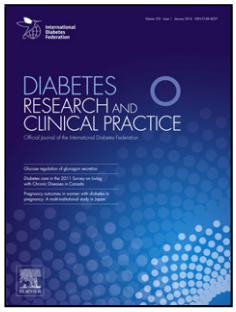

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Type 2 diabetes prevention in the community: 12-month outcomes from the Sydney Diabetes Prevention Program.

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Abstract

Aims h pothesis The Sydney Diabetes Prevention Program (SDPP) was a community-based type 2 diabetes prevention translational research study with screening and recruitment in the primary health care setting. We aimed to investigate the program's effectiveness in reducing risk factors for diabetes as well as the program's reach, adoption and implementation.

Methods 1238 participants aged 50-65 years at high-risk of developing type 2 diabetes were recruited by primary care physicians in the greater Sydney region. The intervention, delivered by trained allied health professionals, included an initial consultation, three group sessions/individual sessions, three follow-up phone calls, and a final review at 12 months. Biomarkers and behavioural goals were compared between baseline and 12 months.

esults At baseline, the mean age of those who entered the program was 58.8 $\pm$ 4.4 years, 63% female, and the mean body mass index was 31.6 $\pm$ 5.2 kg/m^2. There was a significant weight reduction of 2 $\pm$ 4.3 kg ($p<0.02$) in the 850 participants who completed the 12-month follow-up accompanied by improvements in diet (total fat, saturated fat, and fibre intake) and physical activity. There were also significant reductions in waist circumference 2.6 $\pm$ 4.7 cm ($p<0.001$) and total cholesterol -0.2 $\pm$ 0.8 mmol/L ($p<0.001$) but not blood glucose. The diabetes risk reduction was estimated to be 30%, consistent with similar trials.

Conclusions interpretation This study demonstrates that a community-based lifestyle modification program is effective in reducing important risk factors for diabetes in individuals at high-risk of developing type 2 diabetes.

e ords

Diabetes prevention, primary health care setting, lifestyle modification, research translation

ntroduction

The prevalence of type 2 diabetes continues to increase and prevention of type 2 diabetes is a worldwide public health priority [1] There is strong and consistent evidence from randomised controlled trials that type 2 diabetes can be prevented or delayed through lifestyle modification interventions which improve diet, increase physical activity and achieve weight loss in high-risk people [2, 3, 4]. The Finnish [3] and United States (US) [4] studies achieved a 58% reduction in type 2 diabetes incidence with lifestyle modification, and Chinese [5], Finnish [6], and US [7] studies all demonstrated long-term diabetes risk reduction in those who were exposed to the interventions compared with control groups.

The challenge is to translate this evidence into effective community-based programs that can be scaled up and rolled out. An emerging body of translational studies in a range of settings suggests that such community based programs can be effective, but the risk reduction may be less than is achieved in randomised controlled efficacy trials [8, 9, 10]. This paper reports on a type 2 diabetes prevention program in which screening and recruitment were conducted exclusively in the primary care setting, with the lifestyle intervention delivered by trained allied health professionals in community-based settings.

Methods

The Sydney Diabetes Prevention Program (SDPP) was a 12 month lifestyle modification program targeting people aged 50-65 years at high-risk of developing type 2 diabetes conducted in the greater Sydney area [11]. This study was developed and evaluated as a real world

implementation study to inform policy and practice. Effectiveness was measured by comparing nutrition and physical activity behavioural outcomes, weight changes and other modifiable risk factors at 12 months in a cohort screened and recruited in the primary health care setting.

The content and design of the lifestyle intervention was adapted from other successful programs [4, 8]. The intervention, delivered by Lifestyle Officers (LO), who where trained allied health professionals from a range of backgrounds (nurses, dietitian, exercise physiologist, psychologists) included one individual and three two-hour face-to-face group sessions of behavioural intervention using a health coaching approach [12] which aimed to increase physical activity, reduce total and saturated fat, increase fibre, and reduce weight. At the initial consultation participants unable to attend groups were offered an individual session module consisting of three telephone health coaching sessions covering the same content as the group sessions [11]. The program was free and was delivered in English.

All participants were then offered 3 monthly follow-up telephone health coaching calls from their LO (at three, six and nine months). A final 12 month review was conducted with a face-to-face visit to both the LO and primary care physician (PCP). The specific goals of the intervention were to increase moderate to vigorous physical activity (MVPA; including both strengthening and aerobic activities) to at least 30 minutes per day (210 minutes per week); reduce total daily fat intake (≤30% total energy (E)); reduce daily saturated fat intake (≤10% of E); increase daily fibre intake (≥15g/1000 kcal per day); and reduce body weight by 5%.

In total, 222 PCPs in 83 primary care centres (PCC) agreed to participate in the study and they screened and recruited participants from September 2008 until June 2010. Risk status was assessed using a validated Australian risk questionnaire (The Australian Diabetes Risk

Assessment Tool (AUSDRISK)) that included waist circumference (WC) [13]. The risk test took approximately 5 minutes to complete and high-risk was defined as a risk score of ≥15 [14]. Exclusion criteria included previously undiagnosed diabetes, use of blood glucose lowering or weight loss medications, recent cancer, severe cognitive impairment or behavioural disturbance, inability to undertake moderate physical activity, not being able to speak English, or, unstable cardiovascular disease. Prevalent diabetes was excluded by measurement of either a fasting plasma glucose (FPG), an oral glucose tolerance test (OGTT) if required, or glycated haemoglobin (HbA_{1c}) [15]. PCCs employed several screening procedures including opportunistic approaches or direct mail to patients [16].

Height, weight and WC were measured at the initial consultation and 12 month review by the LOs who undertook standardised training. Level of education, employment status, income, and having private health insurance were assessed at baseline by Computer Assisted Telephone Interview (CATI). General health (using the item from the SF12 [17]) and physical activity (Physical Activity Scale for the Elderly (PASE [18]) were assessed at baseline and again at 12 months by CATI. Total PASE score, minutes per week of moderate to vigorous physical activity including progressive resistance training (PRT), and walking minutes, were calculated. Body mass index (BMI) was calculated by dividing weight (kg) over height squared (m^2). Non-weighed three-day food diaries were completed by participants at baseline and the 12-month review. Nutrient intake was analysed by Xyris software [19] by trained dietitians. The key measures assessed were total fat intake (%E), saturated fat (%E), fibre intake (g/1000 kcal), MVPA (mins/week) and weight change from baseline (kg). Fasting lipids (total cholesterol, triglycerides, HDL, and calculated LDL) and FPG were measured in commercial pathology laboratories. Other outcomes included changes in WC from baseline to 12 months.

rogram evaluation and statistical anal ses

The RE-AIM (Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance) evaluation framework for complex implementation trials was utilized to analyse the reach, effectiveness, adoption and implementation of the intervention. Continuous data were assessed for normality and non-normally distributed data are presented as median (range) and were log-transformed prior to use with parametric statistics. Repeated measures ANOVAs were used for continuous variables and chi-square tests for categorical data to assess within subject changes of the outcomes between baseline and 12 month follow-up. Computations were performed using the Statistical Package for Social Sciences (SPSS) version 21 (SPSS Inc. 2012, Armonk, NY) and the Statistical Analysis Software version 9.3 (SAS Institute, 2011, Cary, NC).

thics

Ethics approval to conduct this study was granted by the Research Ethics Review Committee of the Sydney South West Area Health Service - Eastern Zone (ID Number X08-0053). Written informed consent was obtained from all participants prior to enrolment.

esults

Screening and recruitment

In total, 4,055 English-speaking people were screened of whom 49% (n=1983) were at high-risk (Figure 1). Fifty cases of previously undiagnosed diabetes were detected and a further 260 (116 males; 144 females) did not fulfil the entry criteria. Of those at high-risk, eligible and without undiagnosed diabetes (n=1,821), just over a quarter (26%) declined to participate resulting in 1,238 people (464 males; 774 females) who began the study.

[Insert Figure 1 about here]

each and representativeness

The baseline response rates for the CATI and three-day food diary were 92% and 91%, respectively. The mean age of the participants who began the program was 58.8 $\pm$ 4.4 years, 63% were female and the mean BMI was 31.6 $\pm$ 5.2 kg/m^2. One-third had not completed high school and almost two-thirds were in paid employment. To assess representativeness the SDPP cohort was compared with an age-matched randomly selected population sample from the same region [20] (Table 1). Due to the SDPP not being randomly selected significance testing was not appropriate. SDPP participants were as likely to be employed, more likely to have a university education (35.7% versus 27.8%) and private health insurance (66% versus 58%), less likely to be smokers (8.8% versus 17.4%), or speak a language other than English at home (7.3% v versus 21.1%). At baseline, 51.3% of the participants were not meeting any of the nutrition goals or the physical activity goal. Fewer females than males met the physical activity goal (6.6% versus 15.4%; $p<0.001$) and total fat goal (27.4% versus 37.2%; $p<0.001$). However, more females than males (20.2% versus 15.3%; $p<0.05$) were achieving the fibre goal.

[Insert Table 1 about here]

Adoption and implementation

At the initial consultation participants were encouraged to attend groups. However, if they were unwilling to attend groups they were offered an alternative individual phone-only module. One hundred and twenty two (10% of the total) participants chose the individual phone counselling option and 1,116 (90%) chose the group sessions. Overall 84% of participants attended either a group session or had an individual health coaching phone call with 62% of participants completing all three sessions of the group-based or individual-phone modules. The completion rate for the three, six and nine month follow-up phone calls was 77%, 75% and 76% respectively. During the 12-month period 8 people developed diabetes, 234 participants withdrew and 116 were unable to be contacted or were lost to follow-up. A total of 880 participants (71% of those who began the intervention) attended a 12-month review. A further 9 had developed diabetes and 11 were excluded from the final analyses as they reported taking weight loss or blood glucose lowering medications leaving a total of 850 who had data collected at the 12 month review (316 males; 534 females). The 12-month response rates for the CATI and three-day food diary were 93% and 84%, respectively. Males were as likely as females to be lost to follow-up. The two most common reasons given for withdrawing were ‘

(21%) or ‘ (18%). Those who chose the individual sessions were more likely to have dropped out compared with those who chose the group sessions (44% versus 35%; $p<0.01$). The 350 participants who dropped out (who were not excluded and did not develop diabetes) had a higher BMI ($p<0.05$); lower income ($p<0.0001$), did not have private insurance ($p<0.001$) and were younger ($p<0.05$) compared with those who completed the program.

ffectiveness

At 12 months the overall mean weight loss was 2 ± 4.3 kg ($p<0.02$) and the mean reduction in WC was 2.6 ± 4.7 cm ($p<0.001$) (Table 2). There were significant reductions in energy intake (1,127 ± 1988 kJ), total fat intake (2.9% ± 7.3%), saturated fat intake (1.7% ± 3.6%) and an increase in fibre intake (1.9 ± 4.0/1000 kcal), all $p<0.001$. Females were more likely to reduce their total fat intake than males ($p<0.05$). A small change in total weekly minutes of MVPA of 17 ± 160.8 minutes ($p<0.05$) was found as PRT increased 17.6 ± 66 minutes ($p<0.05$). There was a significant increase in the PASE score of 15.7 ± 78.7 ($p<0.001$). Females were more likely than males to increase their weekly MVPA ($p<0.05$). There were significant reductions in total cholesterol (-0.2 ± 0.8 mmol/L), triglycerides (-0.1 ± 0.9 mmol/L) and LDL cholesterol (-0.1 ± 0.8 mmol/L), all $p<0.001$, with no gender differences. FPG did not change. Self-reported general health improved with a higher proportion reporting very good or excellent health at 12 months compared with baseline (42.4% versus 34.2%; $p<0.01$) and on stratification by gender, it was only significant in females (45.2% versus 35.1%; $p <0.001$).

Multivariate analysis of baseline factors (age, gender, BMI, family history of diabetes and AUSDRISK score) which may have influenced weight loss showed that baseline BMI was the only significant factor.

[Inset Table 2 about here]

There were significant improvements over the 12 months in the proportion of subjects achieving the three nutrition goals, but not the physical activity goal (Table 3). More than one-fifth

achieved 5% weight loss. For the participants with complete data at 12 months to assess all five goals (n=634), the proportion achieving no goals was 24.3%; 1 goal, 23%; 2 goals, 23.3%; 3 goals, 18.9%; 4 goals, 9.6%; and 5 goals, 0.8%; respectively. There were no gender differences.

[Insert Table 3 about here]

iscussion

The aim of this translational study was firstly, to examine the feasibility of screening and recruiting participants at high-risk of developing diabetes in the primary care setting and secondly, to assess the acceptability and effectiveness of a moderate intensity lifestyle modification intervention to prevent or delay diabetes.

We found it was feasible to screen and recruit high-risk participants using the AUSDRISK tool. Engaging with the primary care setting and supporting PCPs to screen and refer participants required considerable effort, highlighting the challenges in providing prevention activities in this setting. In addition, the screening and referral process was complex requiring several steps: (1) identifying high-risk individuals: (2) formally excluding prevalent diabetes; and (3) providing medical clearance. While screening could be done by PCC staff, excluding diabetes and providing medical clearance required the involvement of the PCP. Excluding diabetes required blood testing. The Australian guidelines at the time the program began included an OGTT in some individuals with elevated FPG [14]. This proved to be a significant barrier. During the course of this study HbA_{1c} became accepted as a diagnostic criterion for diabetes [15] and was

incorporated in our screening and recruitment process. This streamlined the process and increased referral rates. It is also worth noting that the AUSDRISK tool was only released on July 1, 2008 and hence was not in routine practice in the primary care setting when this study began. Research staff spent considerable time working with the PCCs to facilitate screening and recruitment strategies. Our experiences suggest the Australian primary care system has limited capacity to identify and refer high-risk participants. Other programs in Australia [21], Finland [22] and the US [23] have demonstrated effective recruitment of participants through multiple community settings and a mix of strategies. These 'real world' studies suggest that recruitment should use multiple settings to identify high-risk individuals, in addition to the primary care setting. System changes are required to facilitate prevention activities in the Australian primary care setting.

Of the 1821 eligible people identified at high-risk, 26% chose not to enrol in the SDPP. Previous analyses comparing those who were eligible and began the program and those who were eligible and did not, found physically inactive individuals, those with a family history of diabetes, and those with a history of high blood glucose levels were significantly more likely to enrol, whereas individuals who smoked and were born in a country with high diabetes risk were significantly less likely to begin the program [16]. The specific reasons for individuals not accepting the offer to participate were not explored systematically but general feedback from LOs suggested that the reasons participants gave were more person-related than program-related. Since the SDPP was free it is unlikely that costs were a significant barrier. Further research is required to explore the reasons why some at risk people decline to participate in community-wide diabetes prevention programs.

SDPP participants were more likely to be women, highly educated and less likely to smoke which is consistent with other diabetes prevention programs [10]. The majority being females may reflect more frequent visits to their PCP and/or their general willingness to take preventive action irrespective of the health issue compared with men [24]. Diabetes prevention programs need to consider how to specifically target recruitment strategies that increase participation by males, smokers, those who are socioeconomically disadvantaged and other underrepresented high-risk groups [25].

The adherence rates for the different components of the program were very good suggesting the intervention was acceptable to this population. The completion rate of 71% is consistent with other studies of similar duration in real-life settings [26]. Adherence is critical since a clear dose response relationship exists between the number of contacts and weight loss [10]. It may be possible to improve adherence rates by delivering diabetes prevention programs in other formats such as by internet/webinar, email prompts, or in combination with smart phone applications [27,28]. Emerging evidence suggests that using telephone delivered lifestyle modification programs is effective and more cost effective than face to face interventions [29]. It may also be possible to better target interventions according to level of risk with a recent post-hoc analysis of the US DPP reporting benefits of lifestyle modification across all risk categories while the benefit of metformin was almost entirely restricted to the highest risk quartile [30]. Since all of our subjects were in the AUSDRISK high risk categories, we were unable to perform a similar sub-analysis in our study.

The primary aim of the 12-month intervention was to influence risk markers for diabetes, rather than demonstrate an actual reduction in diabetes incidence in this short time period. The SDPP achieved significant beneficial changes in weight, WC, intakes of fat, saturated fat and fibre.

Overall, participants found it easier to modify their diets compared with increasing their MVPA levels. Although MVPA increased significantly, it was not enough to increase the proportion of participants who were achieving the physical activity goal of 210 minutes of MVPA per week. It was encouraging that PRT increased by 18 minutes per week given its beneficial effects on glycaemia [31]. The limited improvements in physical activity levels may be due to the fact that the SDPP did not have supervised exercise classes as in some of the more intensive programs such as the US Diabetes Prevention Program [4] and the Finnish Diabetes Prevention Study [3].

The mean 2 kg weight loss is comparable to other community-based programs [9, 23] and is estimated to equate to a 30% diabetes risk reduction assuming that the weight loss is maintained for a further two years [32]. Interestingly, those who chose the individual sessions module delivered entirely over the phone did as well as those that attended face-to-face groups. Conversely, those who chose the face-to-face groups were less likely to drop out of the SDPP. This could have been due to those participants who chose the individual module session being less motivated to participate as they were only offered this secondary option after they indicated they were not interested in attending groups. Longer-term follow-up is underway to determine whether the physical and behavioural changes at 12 months are sustained, and to ascertain if the SDPP has delayed or prevented the onset of diabetes.

Strengths of this study are that BMI, weight, WC and metabolic profile were objectively measured at baseline and follow-up, and that once enrolled, loss to follow-up was relatively small (29%). Limitations included the self-reporting of dietary intake and physical activity. In addition, dropouts differed from participants who completed the SDPP being younger, having a higher BMI, and less income. A public health challenge remains recruiting those who could potentially benefit the most from lifestyle modification programs. Targeting those who are likely

to dropout with additional behavioural reinforcement strategies is also required. The target group of this particular study was English-speaking people at high-risk of type 2 diabetes and consequently the study cohort lacked ethnic diversity.

This translational study demonstrated the feasibility and effectiveness of developing and implementing a community-based lifestyle modification diabetes prevention program with participants screened and referred in the primary care setting. There is compelling evidence that we now know what people should do to reduce the progression to type 2 diabetes. What is lacking is how best to persuade those who could benefit the most to take action [26]. With the diabetes epidemic increasing, tackling it requires integrating primary care and public health action targeting both high-risk individuals and the general population [33].

ists of abbreviations used

AUSDRISK: The Australian Diabetes Risk Assessment Tool; BMI: body mass index; CATI: Computer Assisted Telephone Interview; FPG: fasting plasma glucose; HbA_{1c}: glycated hemoglobin A_{1c}; HDL: high density lipoprotein; LDL: low density lipoprotein; LO: Lifestyle Officer, MVPA: moderate to vigorous physical activity; PASE: Physical Activity Scale for the Elderly; PCC: Primary Care Centre; PCP; Primary Care Physician; PRT: progressive resistance training; RCT: randomised controlled trial; RE-AIM: Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance; SPSS: Statistical Package for Social Sciences; SAS: Statistical Analysis Software; SDPP: Sydney Diabetes Prevention Program; WC: waist circumference.

Ac no ledgements

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Authors' contribution

In this study all authors participated in the design and coordination of the study. SC conceived the study, and led the design, evaluation and implementation. PV contributed to the design, implementation and evaluation and was responsible for the implementation and evaluation of the study. AB contributed to the study design and implementation while conceiving and overseeing the evaluation. MCM participated in the design of the study and contributed to the evaluation. AM, LJ, MFS, MM, MW, RP, and JS contributed to the study design, its implementation and evaluation. All authors made contributions to the conception, design and writing of the

manuscript and had the opportunity to critically review the manuscript during its development and all approved the final manuscript.

Conflicting interests

The authors declare that they have no conflicting interests.

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Table . Comparison of socio demographic characteristics, smo ing status and M ith age matched regionall similar population sample

	SDPP cohort (n =1,133) % (±95%CI)[b]	[a]Regional sample (n=1,380) % (±95%CI [b]
Education level		
Primary school	2.1 (1.3-3.0)	4.2 (3-5.3)
Incomplete secondary school	30.9 (28.3-33.7)	29.2 (25.4-30.9)
Completed secondary school	13.2 (11.1-15.1)	18.8 (15.2-20.2)
Technical college	18.1 (15.8-20.3)	20.0 (17.5-22.5)
University degree or higher	35.7 (33.0-38.6)	27.8 (25-30.6)
Household income range		
Up to $20,000	14.9 (13.0-17.1)	16.7 (14.4-19)
>$20,000-60,000	24.6 (22.2-27.2)	29.1 (26.3-31.9)
>$60,000-80,000	11.5 (9.7-13.5)	10.6 (8.6-12.5)
>$80,000	28.6 (26.1-31.1)	25.5 (22.7-28.3)
Refused to answer/don't know	20.4 (18.1-22.8)	18.1 (15.6-20.5)
Employment		
In paid employment	60.3 (57.4-63.1)	58.0 (55-61.1)
Unemployed or unpaid job	39.7 (37.0-42.6)	42.0 (38.9-45)
Covered by private health insurance	65.9 (63.2-68.7)	58.0 (54.8-61.1)
Speak language other than English	7.3 (5.9-8.9)	21.1 (18.4-23.7)
Current smoker	8.8 (7.3-10.6)	17.4 (14.8)
Mean BMI (kg/m^2)	31.6 (28.3-35.7)	26.6 (23.6-30.2)

[a]Source (Sydney South West Area Health Service region only). New South Wales Population Health Survey 2007-2009 (HOIST). Centre for Epidemiology and Research, NSW Ministry of Health

[b]Significance testing between the two samples was not possible due to NSW Health data being weighted while the SDPP data was unweighted. The 95% confidence intervals are displayed to indicate whether differences are more or less likely.

Table 2. AUSDRISK, age, risk factors and behaviours at baseline and changes at 12 month follow-up in those who completed the SDPP.

	n	Baseline mean (SD)	Change from baseline to 12 month follow-up (SD)	P value
AUSDRISK score	850	18.7 (3.3)	n/a	[a]n/a
Age (years)	850	58.3 (4.4)	n/a	[a]n/a
Weight (kg)	829	88.9 (17.5)	-2.00(4.3)	<0.02
BMI (kg/m^2)	829	32.1 (5.7)	-0.7 (1.6)	<0.01
WC (cm)	824	106.2 (12.7)	-2.6 (4.7)	<0.0001
Fasting plasma glucose (mmol/L)	628	5.3 (0.6)	-0.02 (0.6)	0.50
Total cholesterol (mmol/L)	750	5.3 (1.0)	-0.2 (0.8)	<0.0001
LDL cholesterol (mmol/L)	666	3.2 (0.9)	-0.1(0.8)	<0.01
HDL cholesterol (mmol/L)	678	1.4 (0.4)	0.01(0.3)	0.54
Triglycerides (mmol/L)	744	1.6 (1.0)	-0.1 (0.9)	<0.01
PASE score	738	125.4 (70.1)	15.7 (78.7)	<0.0001
Physical activity (minutes of MVPA + PRT per week)	738	67.1 (155.5)	17.0 (160.8)	<0.05

Table 2. AUSDRISK, age, risk factors and behaviours at baseline and changes at 12 month follow-up in those who completed the SDPP.

	n	Baseline mean (SD)	Change from baseline to 12 month follow-up (SD)	P value
+ PRT per week)				
Walking only (mins per week)	738	202 (273.8)	-0.5 (338.7)	0.97
PRT only (mins per week)	738	15.4 (51.8)	17.6 (66.0)	<0.0001
kJ saturated fat/total kJ	681	12.3 (3.4)	-1.7 (3.6)	<0.0001
kJ total fat/total kJ	681	33.2 (6.1)	-2.9 (7.3)	<0.0001
Grams of fibre/1000kcal	681	12.3 (4.0)	1.9 (4.0)	<0.0001
Total energy (kJ/day)	681	8090.4 (2085.6)	-1127.4 (1998.6)	<0.0001
General health (% rating health as very good or excellent)	726	34.2	8.2	<0.01

[a]n/a = not applicable. AUSDRISK was only measured at baseline

Table . roportion of participants meeting the S goals baseline versus months

S goal	Number of participants	aseline	months
At least 210 minutes of MVPA per week	712	11.1%	10.5%
No more than 30% of total energy from fat per day	681	31.0%	51.5%
No more than 10% of total energy intake from saturated fat per day	681	24.7%	49.0%
At least 15g/1000 kcal of fibre per day	681	19.8%	40.5%
At least 5% weight loss at 12 months	829	n/a	21.7%

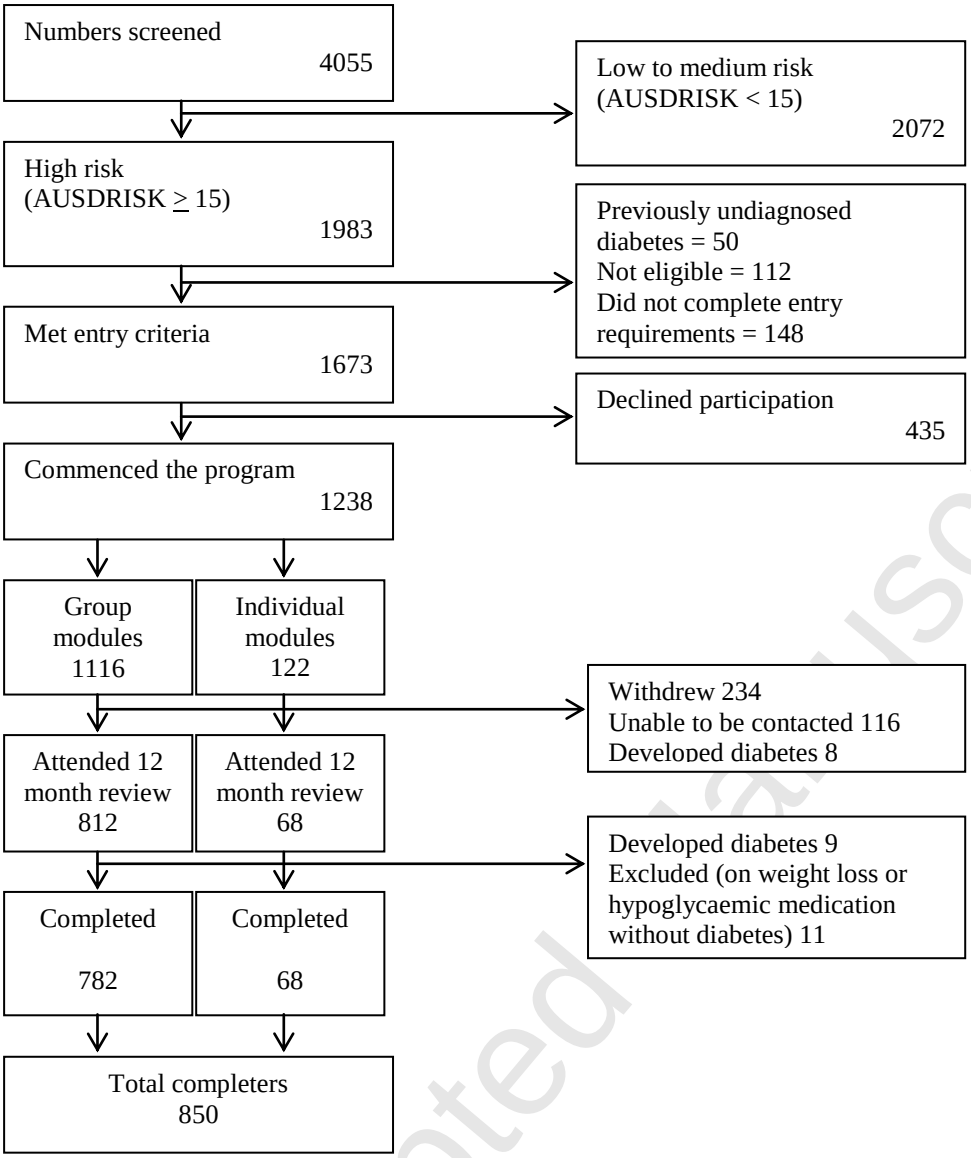

Figure 1. Flow of participants