

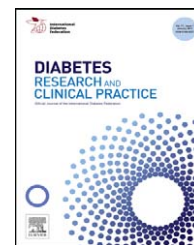


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Review article

Behavioral strategies in diabetes prevention programs: A systematic review of randomized controlled trials

Michael K. Baker^{a,*}, Kylie Simpson^b, Bradley Lloyd^b,
Adrian E. Bauman^c, Maria A. Fiatarone Singh^{a,d}

^aBoden Institute of Obesity, Nutrition and Exercise, Sydney Medical School, The University of Sydney, Sydney, NSW 2006, Australia

^bExercise Health and Performance, The University of Sydney, Lidcombe, Australia

^cSchool of Public Health, The University of Sydney, Camperdown, Australia

^dHebrew Senior Life and Jean Mayer USDA Human Nutrition Research Center on Aging, Tufts University, Boston, MA USA

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ABSTRACT

The worldwide epidemic of type 2 diabetes (T2D) emphasizes the need for guidelines regarding community implementation of lifestyle modification prevention programs. An understanding of effective behavioral strategies is needed if evidence translation is to be realized. The aim of this paper is to systematically review the behavioral change strategies for lifestyle T2D prevention programs.

Methods: Randomized controlled trials (RCTs) of lifestyle interventions for the prevention of T2D were reviewed with a systematic literature search. Data relating to the behavioral strategies and trial outcomes were extracted.

Results: Overall, lifestyle interventions were successful in reducing the incidence of T2D. The behavioral strategies utilized in these interventions were drawn from a variety of theoretical backgrounds. All RCTs utilized intensive modes of delivery and were associated with low dropout rates of 5.5–13.4%.

Conclusions: The available evidence shows that a robust behavioral change strategy is an essential part of an effective lifestyle modification program, as the absence of intensive individualized advice or “information only” more closely resembles the control group interventions used in these RCTs.

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* Corresponding author. Tel.: +61 2 9351 9858; fax: +61 2 9351 9204.

E-mail address: michael.baker@sydney.edu.au (M.K. Baker).

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The number of people developing type 2 diabetes (T2D) is rising dramatically worldwide, and is expected to more than double between 2000 and 2030 [1]. Depending on the cohort surveyed and definition of T2D employed, between 20 and 50% of T2D is undiagnosed [2]. Direct health care costs of T2D in the USA in 2007 were estimated at \$116 billion [3].

Epidemiological studies have repeatedly demonstrated that low levels of physical activity, low levels of physical fitness and obesity are prominent, independent and modifiable risk factors for the development of insulin resistance, metabolic syndrome, and T2D [4,5], adding to genetic predisposition and other environmental or acquired risk factors. This robust and consistent observational evidence has given rise to large-scale randomized controlled trials (RCTs) that have used a lifestyle intervention (including behavioral strategies for reinforcement of prescribed changes in nutritional intake, physical activity, or both) in populations at high risk of developing T2D. The aim of these trials was to reduce the rate of incident diabetes, as well as ameliorate risk factor profiles associated with both T2D and cardiovascular morbidity and mortality. The optimum strategy for the delivery of lifestyle programs in order to maintain adherence and compliance in this population remains unclear. Although excellent reviews of diabetes prevention trials have been published [6,7], none of these reviews have systematically extracted and compared the details of the behavioral components and goals of the intervention groups in these trials, which differ markedly between trials. Thus, the purpose

of this paper was to systematically review the behavioral change strategies for lifestyle modification in adults with impaired glucose tolerance (IGT) and to assess adherence and compliance to these interventions within these published RCTs. This critical appraisal of the interventions is necessary to inform the translation of this evidence base into guidelines for community-based programs and public health policy.

1. Methods

1.1. Criteria for study inclusion/exclusion

1.1.1. Design

Randomized controlled trials, published in full in English were considered.

1.1.2. Subjects

Studies that involved adults at-risk of T2D were included, defined as being dysmetabolic or having IGT according to World Health Organization (WHO) criteria, at the time of the trial. Studies with participants already diagnosed with T2D were not included.

1.1.3. Interventions

Studies were included if they incorporated exercise training/physical activity and/or nutritional intervention as a means of diabetes prevention.

1.1.4. Outcome

Incidence of diagnosis of T2D as a primary outcome. Studies including intermediate endpoints only (e.g. weight, waist circumference) were not included.

1.2. Search strategy

A comprehensive, systematic database search for manuscripts was conducted from 1966 or database inception to 2009 using computerized databases which included Medline and PreMedline, CINAHL, EMBASE, PsycINFO and Cochrane Central Register of Controlled Trials, with the final search performed in Feb 2009 (KS and MB). The search was limited to full text and English language articles in human subjects. Key search terms included 'type 2 diabetes', 'prevention', 'exercise', and 'diet' (see Fig. 1). Reference lists of the included articles were manually examined for additional articles. In addition, recent position stands, consensus statements, and other reviews were retrieved to extract relevant citations, and database searches were done using the names of the primary trials identified to find subsequent publications from the same trial. Websites developed by these RCTs were accessed where available to obtain copies of study protocols, manuals, and other educational/behavioral tools used in the implementation of programs, to provide additional details beyond those reported in the published papers. As most trials had many associated publications, data extracted from all retrieved sources were merged to summarize the trial characteristics and outcomes.

1.3. Quality assessment

Once studies were collected based on a minimum quality threshold, defined as having met all inclusion criteria, a more detailed assessment of the study quality was conducted. The quality of the studies retrieved was assessed according to a modified Delphi list [8] (KS and MB). Additional elements considered were the supervision of exercise sessions (which has been shown to result in superior adherence to prescriptions and physiological adaptations [9,10]) and appropriate between-group statistical analysis.

1.4. Data extraction and synthesis

Four assessors (MFS, KS, BL, and MB) independently extracted data from primary articles and resolved discrepancies by consensus. Outcomes for incidence of T2D, adherence and compliance were extracted (KS and MB).

1.5. Statistical analysis

Due to the heterogeneity of behavioral interventions, exercise/dietary prescriptions, cohort characteristics, outcomes assessed and measurement tools used, and our *specific intent to compare across strategies used in different trials* rather than merge into a singular result, a systematic and critical review of the behavioral strategies was conducted rather than a meta-analysis.

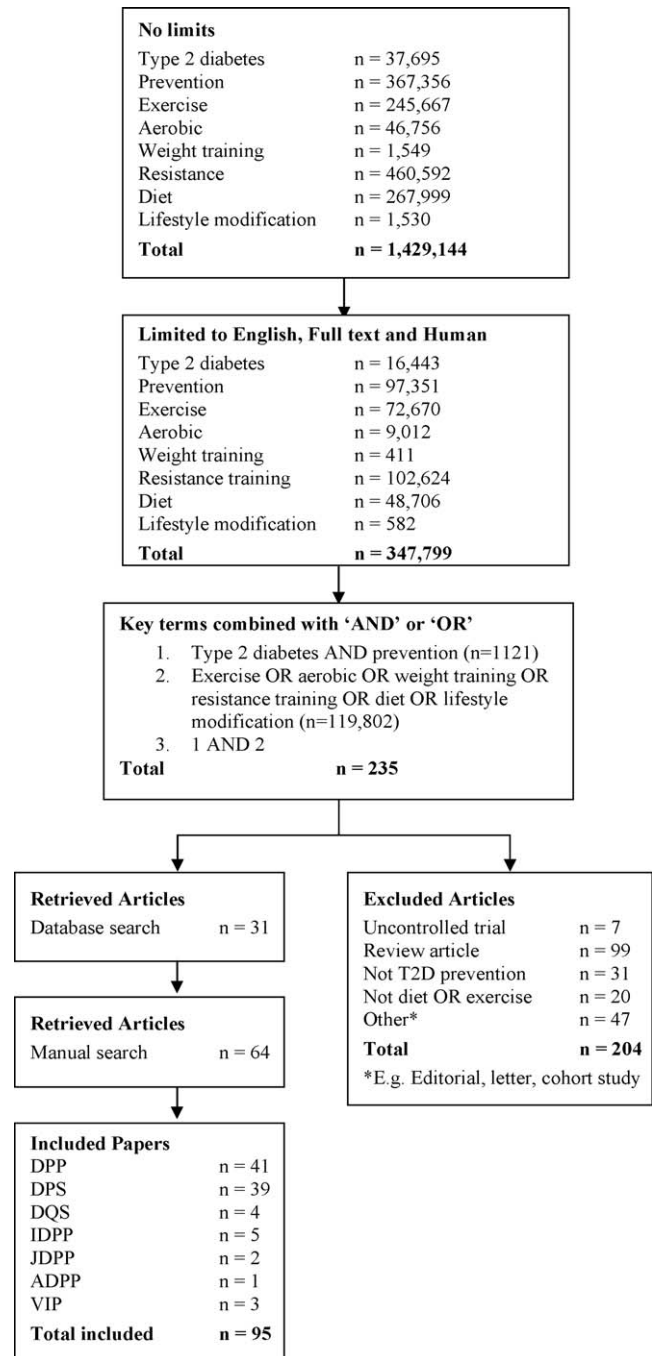


Fig. 1 – Flow of studies included/excluded for review. DPP, Diabetes Prevention Program (USA); DPS, Diabetes Prevention Study (Finland); DQS, Da Qing IGT and Diabetes Study (China); IDPP, Diabetes Prevention Program (India); JDPP, Diabetes Prevention Program (Japan); ADPP, Asti Diabetes Prevention Program (Italy); VIP, Västerbotten Intervention Program (Sweden); T2D, Type 2 Diabetes.

The size of the treatment effect for incident T2D in all trials was measured by extraction and/or calculation of the relative risk reduction (RRR), absolute annual and cumulative risk (AR), absolute risk reduction (ARR), and number needed to treat (NNT) [11].

An effect size (ES) [12,13] over the intervention time (standardized mean difference) for outcomes in each of the arms of the studies was calculated using the equation:

$$ES = \frac{\text{Mean}_{\text{POST}} - \text{Mean}_{\text{PRE}}}{SD_{\text{PRE}}}$$

The relative ES as a difference between the control and the intervention group ES is presented:

$$ES_{\text{RELATIVE}} = ES_{\text{INTERVENTION}} - ES_{\text{CONTROL}}$$

Hedge's bias corrected effect sizes are presented with 95% confidence intervals [14].

Clinical importance of the outcomes was assessed via ascertainment that the changes in disease risk were of a magnitude judged clinically important, and that the lower limit of the CIs of the effect size excluded clinically unimportant changes, as recommended by the National Health and Medical Research Council (NHMRC) [15]. For the purpose of this review, a conservative estimate of clinical importance was used, defined by the authors as a RRR $\geq 10\%$. This would represent a reduction of approximately 150,000 new cases of T2D annually in the U.S compared to usual care/no treatment.

2. Results

2.1. Study inclusion/exclusion

The process of study inclusion/exclusion at each step is presented in Fig. 1. Seven separate RCTs with prevention of type 2 diabetes as their primary outcome were identified. Trial results were generally published in multiple papers, all of which were included in the data extraction process, in contrast to previous systematic reviews which have used only one or a small number of papers as source documents for each trial.

• Diabetes Prevention Program (DPP), U.S.A.	- 41 publications
• Diabetes Prevention Study (DPS), Finland	- 39 publications
• Da Qing IGT and Diabetes Study (DQS), China	- 4 publications
• Diabetes Prevention Program (IDPP), India	- 5 publications
• Diabetes Prevention Program (JDPP), Japan	- 2 publications
• Asti Diabetes Prevention Program (ADPP), Italy	- 1 publication
• Västerbotten Intervention Program (VIP), Sweden	- 3 publications

2.2. Study quality

In general, all included studies specified their inclusion criteria, randomly assigned groups, reported standard deviations or confidence intervals, and reported baseline characteristics. However, some studies failed to report important details of baseline health status including co-morbid disease, medication use, weight and BMI. While all studies reported dropout/loss to follow-up, only two studies reported adherence with exercise or educational sessions (DPP and DPS). The occurrence of adverse events was reported in five of the seven studies (DPP, DPS, DQS, IDPP, and ADPP) and six of the seven

studies included intention-to-treat analysis (explicitly stated or presented data from all subjects randomized); the DQS did not report data from dropouts, and was therefore interpreted as a complete case analysis. Statistical treatment of missing data was only reported in one study (VIP).

2.3. Participants

In total the seven studies consisted of 5825 subjects with the mean cohort age ranging from 42 ± 9 to 56 ± 6 years of age. Studies recruited their subjects from the general community and one study recruited from patients being routinely screened at a medical facility (JDPP). The DPP, DPS and VIP had a minimum body mass index (BMI) of ≥ 24 , >25 and >27 respectively, while no BMI cut-off was specified for the other studies. Among the seven studies, six were in mixed cohorts, and one study included males only (JDPP), totaling a combined 44% of the sample being male across all studies. Exclusion criteria commonly included normal glucose tolerance or indication of diabetes; unstable, terminal or progressive disease; however, the exact burden of disease present at baseline is not clear as most (5/7) studies did not report detailed exclusion criteria or baseline health status.

2.4. Interventions

Table 1 summarizes the lifestyle interventions employed. All studies included a combined exercise/physical activity and dietary intervention with the aim of achieving and/or maintaining weight loss. The intervention duration for these programs ranged from 1 year (ADPP and VIP) to 6 years (DQS).

2.4.1. Exercise

Participants in all studies were individually advised to increase physical activity. The weekly volumes of exercise prescribed ranged from ≥ 150 min/week at moderate intensity (DPP, ADPP, and VIP), up to 30-40 min/day (i.e. 210-280 min/week) at moderate intensity (JDPP). All studies prescribed moderate intensity aerobic activity as the primary form of exercise. Both the DPP and DQS allowed for a reduction in exercise volume if activity was performed at a more vigorous intensity. The DPP included moderate intensity progressive resistance training in some clinics, and in the DPS moderate intensity progressive resistance training and power training were included as a part of the exercise prescription. The VIP counseled participants on the importance of performing muscle strengthening exercise twice a week. The DPP and DPS provided supervised exercise sessions to participants free of charge 2 days per week for the duration of the program [16,17], and the VIP included an initial 1-month residential component where 2.5 h of physical activity were provided daily [18]. The remainder of the trials did not provide supervised exercise.

2.4.2. Nutrition

Participants in all studies were individually advised to modify their dietary intake. Reviewed studies included a reduction in energy intake with all studies recommending a reduction of fat intake, commonly to <20 -30% of total energy intake (DPP, DPS, DQS, and VIP). Five of the seven studies specifically

Table 1 – Lifestyle change goals in the intervention groups.

Study (country)	Exercise/physical activity					Diet/nutrition					
	Duration (min/wk)	Intensity	Structured exercise	Supervised exercise	Aerobic activity	PRT activity	Occupational activity	Portion control	↓Fat	↓Alcohol	↑Fiber
DPP (USA)	≥150 ^a	Moderate	✓	✓	✓	✓	✓	✓	✓	✓	×
DPS (Finland)	≥210	Moderate to strenuous	✓	✓	✓	✓	✓	×	✓	×	✓
DQS (China)	≥35-420 ^b	Light to very strenuous	✓	×	✓	×	×	✓	✓	×	×
IDPP (India)	≥210	Moderate	✓	×	✓	×	×	✓	✓	×	✓
JDPP (Japan)	210-280	Moderate	✓	×	✓	×	×	✓	✓	✓	×
ADPP (Italy)	≥150	Moderate	✓	×	✓	×	×	✓	✓	✓	✓
VIP (Sweden)	≥150 ^c	Low-Moderate	✓	✓	✓	✓	×	✓	✓	✓	✓

PRT, progressive resistance training; DPP, Diabetes Prevention Program (USA); DPS, Diabetes Prevention Study (Finland); DQS, Da Qing IGT and Diabetes Study (China); IDPP, Diabetes Prevention Program (India); JDPP, Diabetes Prevention Program (Japan); ADPP, Asti Diabetes Prevention Program (Italy); VIP, Västerbotten Intervention Program (Sweden).

^a Energy expenditure ≥700 kcal/week was the primary objective, and the target volume (min/week) was allowed to be increased/decreased based on the intensity of activities performed.

^b 35-210 min/week for persons ≥50 years; 70-420 min/week for persons <50 years.

^c 2.5 h per day prescribed as supervised exercise in the first month.

included portion control as a part of the prescription. Specific increases in dietary fiber intake were recommended as part of four studies (DPS, IDPP, ADPP, and VIP), whereas an increased intake in fiber-rich foods such as fruits and vegetables was advised as a part of all studies. Overall, energy reduction and energy density shift, and changes to macronutrient composition were common elements, albeit to varying degrees, in all studies.

2.5. Behavioral strategies

Table 2 shows a summary of the behavioral strategies of all reviewed studies. While none of the studies specified a specific behavioral theory that underpinned their approach, a number of strategies were employed to bring about behavior change. The behavioral strategies utilized in these interventions are, however, consistent with a variety of theoretical approaches including Social Cognitive Theory, the Transtheoretical Model, and the Theory of Planned Behavior.

2.5.1. Contacts

The number of contacts, defined as face-to-face counseling, assessments, and telephone contact, between participants and researchers/facilitators over the first 12 months in each study ranged from 6 in the JDPP and ADPP, to ≥22 in the VIP and DPP [16]. When supervised exercise sessions are included, the number of contacts in the first 12 months ranges up to 165 in the DPS. All studies included initial face-to-face assessment and re-assessment as well as either group or individual counseling. Counseling for behavioral change and education was predominately delivered on an individual basis in all studies except for the DQS and ADPP where counseling in small groups was provided after an initial individual counseling session [19-21]. The DPP, DPS and VIP each had a comprehensive and structured educational program addressing self-management strategies such as: barriers to adherence, setting and evaluating goals, addressing triggers for behavioral relapse, and educating participants about the benefits of lifestyle modification. These sessions were delivered over 16 and 6 sessions respectively for the DPP and DPS [16,22] and over the 1-month live-in residential phase for the VIP [18]. Individualization was achieved in the DPP by providing lifestyle coaches with a ‘tool-box’ of adherence strategies [16]. The IDPP provided individual counseling at baseline and at 6-monthly intervals, as well as monthly contact via telephone. The JDPP conducted individual educational sessions every 3-4 months that coincided with scheduled re-assessment.

2.5.2. Staff

All diabetes prevention studies employed a team of highly trained staff to deliver a lifestyle intervention to participants. The JDPP, IDPP, DQS, and ADPP all utilized a clinical outpatient setting with a team that included physicians and nurses [20,21,23,24]. The DPS and the DPP primarily had registered dietitians oversee the program [25,26]. In some cases, the DPP used other allied health professionals, who held a minimum of a master’s degree in exercise physiology, psychology or health education, to deliver the lifestyle program. The VIP utilized a multi-disciplinary team comprised of physicians, nurses, dietitians, physical fitness therapists and psychologists

Table 2 – Specific behavioral interventions used in diabetes prevention programs.

Study (country)	Group	Group counseling	Individual counseling	Supervised exercise sessions	Goal setting	Record keeping	Assessment	Contacts in first 12-months ^a	Total contacts in 12-months including supervised exercise	Program delivery
DPP (U.S.A.)	Diet + exercise	Face-to-face sessions (group or individual) every 2 months after first 6 months of individual sessions	16 initial individual educational sessions in first 24 weeks. Phone contact once between face-to-face sessions	Twice weekly exercise sessions were offered (including circuit and moderate intensity resistance training, aerobic exercise and one-on-one personal training)	Individual goals for diet and exercise	Logging of diet (fat and calories) and minutes of physical activity during first 24 weeks. Self-weighing each week. Logging encouraged for 1 week/month after initial sessions	Baseline assessment Re-assessment every 6 months	22	126	Registered dietitians Masters degree in exercise physiology or psychology
DPS (Finland)	Diet + exercise	None	7 Individual initial counseling sessions in the first year (three in first 6 weeks), then once every 3 months	Supervised exercise (circuit training, and moderate-high intensity resistance training) sessions were offered free of charge	Individual goals for diet and exercise	3-Day food records and 24 h exercise logs were completed four times per year Regular self-weighing was encouraged	Baseline assessment Re-assessment every 12 months	9	165	Dietitians
DQS (China)	Diet	Group sessions weekly for 1 month, monthly for 3 months, then once every 3 months	Individual initial counseling session	None	Individual goals for diet	No logging of diet or exercise	Baseline assessment Re-assessment every 3 months	14	14	Health care clinic Physicians Nurses Technicians
	Exercise	Group sessions weekly for 1 month, monthly for 3 months, then once every 3 months	Individual initial counseling session	None	Individual goals for exercise	No logging of diet or exercise	Baseline assessment Re-assessment every 3 months	14	14	Health care clinic Physicians Nurses Technicians
	Diet + exercise	Group sessions weekly for 1 month, monthly for 3 months, then once every 3 months	Individual initial counseling session	None	Individual goals for diet and exercise	No logging of diet or exercise	Baseline assessment Re-assessment every 3 months	14	14	Health care clinic Physicians Nurses Technicians
IDPP (India)	Diet + exercise	None	Individual counseling session at baseline and every 6 months Phone contact after 2 weeks and then monthly thereafter	None	Individual goals for diet and exercise	No logging of diet or exercise	Baseline assessment Re-assessment every 6 months	16	16	Clinical team including: physician, lab technicians, dietician, and social worker
JDPP (Japan)	Diet + exercise	None	Individual educational sessions every 3-4 months	None	Individual goals for diet and exercise	No logging of diet or exercise Self-weighing each week	Baseline assessment Re-assessment every 2-3 months	≤6	≤6	Clinical outpatient setting Physicians Nurses
ADPP (Italy)	Diet + exercise	Four 60 min group sessions	Individual physician counseling session, and an individual nutritionist counseling session at baseline	None	Individual goals for diet and exercise	No logging of diet or exercise	Baseline assessment Re-assessment at 12 months	7	7	Health care clinic Physicians Nutritionists Dieticians

VIP (Sweden)	Diet + exercise	140 h of scheduled activity delivered in the first month	Individual initial counseling session Phone contact once after 6 months	Supervised exercise (walking, gymnastics, bicycling, and swimming) sessions were offered in the first month (2.5 h a day)	Individual goals for diet and exercise	Self-monitoring was encouraged	Baseline assessment at 12 months	32 (>140 h of scheduled activity and assessment contacts in the first month)	32	Residential inpatient setting (wellness center) Physician, nurse, dietician, physical fitness therapist, psychologist, and physiotherapists
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DPP, Diabetes Prevention Program (USA); DPS, Diabetes Prevention Study (Finland); DQS, Da Qing IGT and Diabetes Study (China); IDPP, Diabetes Prevention Program (India); JDPP, Diabetes Prevention Program (Japan); ADPP, Asti Diabetes Prevention Program (Italy); VIP, Västerbotten Intervention Program (Sweden).

^a Contacts include face-to-face counseling, assessments, and telephone contact and range from brief contacts to 24-h of residential contact.

[18,26,27]. All staff received training in the delivery of the specific intervention for each study.

2.5.3. Follow-up and monitoring

The DPS, DPP and VIP used logging of behaviors as a method of providing feedback and motivation. Logs were kept of physical activity, caloric intake and fat intake. In the DPS, participants completed 3-day food records and 24-h exercise logs before attending each individual counseling session. In the DPP however, logging was done much more intensively with daily logging of behaviors in the initial 24 weeks, and for 1 week out of every month thereafter. The DPS, DPP and JDPP encouraged participants to weigh themselves regularly while the IDPP, DQS and ADPP did not encourage regular self-monitoring.

The DPP and DPS also included supervised exercise sessions twice and three times a week respectively for participants for the duration of the study free of charge. These contacts, shown in Table 2, added up to 126 contacts in DPP, and 165 in DPS in the first 12 months. This was designed to lead to a greater uptake of supervised structured exercise, as the potential 'barrier' to participation of cost and access to supervised facilities would be removed. Daily supervised exercise was provided intensively to VIP participants in the first month only, totaling 32 contacts.

2.5.4. Control

All control groups received usual care, and in some cases written material relevant to healthy lifestyle. In the DQS and DPS, controls received general information about diabetes, including brochures and general instructions for diet and exercise. In the DPP, controls received written instructions on the Diet and Food Pyramid [28], exercise advice, as well as a placebo pill. In the JDPP, controls who were overweight by Asian standards (BMI > 24) were advised to lose weight via portion control and exercise, although a specific behavioral intervention or exercise program did not accompany this advice. Control subjects in the ADPP and VIP received counseling and lifestyle advice, with written information also given in the VIP. Control subjects did not receive any contact from researchers/facilitators between outcome assessment time-points.

2.6. Outcomes

Though efficacy varied widely, all studies were successful in reducing incident T2D. Results from the DPP and DPS both indicate a RRR of 58% (95% CI 48–66, $P < 0.001$ and $P < 0.001$, respectively) [29,30] in the incidence of T2D as a result of intensive lifestyle modification incorporating both diet and exercise when compared to the rate in controls. The greatest reduction in incidence was reported by the VIP and ADPP with a RRR of 74 and 75% compared to controls [18,21]. By comparison, the DQS only reported a 38% reduction in T2D incidence (calculated from reported data) in the combined diet and exercise group [19]. It cannot be determined whether this may be attributed to the primarily group-based counseling during the course of this study, the small sample size, or the less prescriptive approach to the exercise intervention. In the IDPP lifestyle intervention, only a 29% reduction in T2D risk was achieved despite individual counseling and regular telephone contact (95% CI 20.5–37.3, $P = 0.018$) [24]. As shown in Fig. 2, the

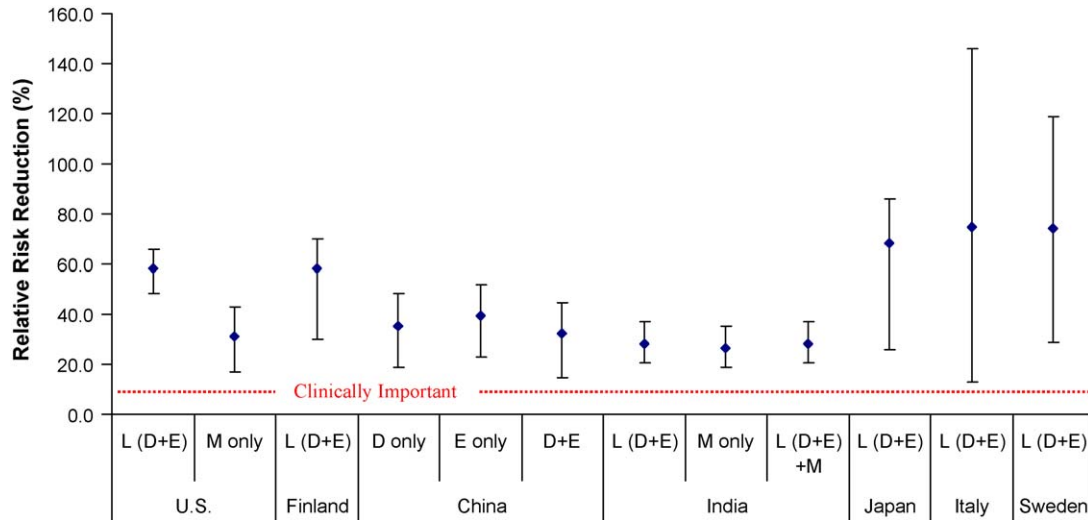


Fig. 2 – Relative risk reduction in all groups. Reported relative risk reduction (95% confidence intervals). *RRR is calculated at the 95% CI for the studies that did not report a CI. L, lifestyle; D, diet; E, exercise; M, metformin; DPP, Diabetes Prevention Program (USA); DPS, Diabetes Prevention Study (Finland); DQS, Da Qing IGT and Diabetes Study (China); IDPP, Diabetes Prevention Program (India); JDPP, Diabetes Prevention Program (Japan); ADPP, Asti Diabetes Prevention Program (Italy); VIP, Västerbotten Intervention Program (Sweden).

lower CIs of the RRR published or calculated for all trials are well above our estimate of a *clinically important* effect of 10% reduction in risk of incident diabetes (dotted line in Fig. 2).

Thus, there is strong evidence not only of the consistency of the findings, each with a high level of statistical significance, but also of the clinical meaningfulness of the results observed across these seven highly disparate behavioral strategies within diverse cultural and ethnic cohorts with IGT. In all cases, the NNT was relatively low (ranging from 4.6 in DQS to 18.5 in the 1 year ADPP), suggesting that lifestyle modification is an efficient way to prevent diabetes in such targeted, high-risk populations. The baseline risk, observed in the control groups, varied greatly between studies. Risk reductions achieved in the lifestyle groups are plotted against the incidence observed in the control groups in Fig. 3.

2.7. Fidelity to the intervention and goals

2.7.1. Loss to follow-up

Overall, loss to follow-up was very low compared to previous drug trials for IGT [31], ranging in the lifestyle intervention groups from 6.9 to 13.4%. Such dropout rates (below 15%) are considered robust by most quality criteria [32].

2.7.2. Adherence/attendance

Although log books were kept in some studies, unfortunately no data is presented on rate of attendance at supervised exercise sessions, or frequency of participation in unsupervised exercise for any of the studies reviewed. Thus behavioral strategies and cohort differences cannot be evaluated in regards to these program elements.

2.7.3. Goal achievement

Measures of physical activity levels varied greatly between studies and no physical activity data was reported for the IDPP

and JDPP. Effect sizes for changes in physical activity measures could be calculated for the DPP, DQS, and ADPP with small relative effect sizes of 0.20, 0.15, and 0.4 respectively. Effect sizes for changes in body mass could be calculated for six of the seven studies. Relative effect sizes ranged from negligible

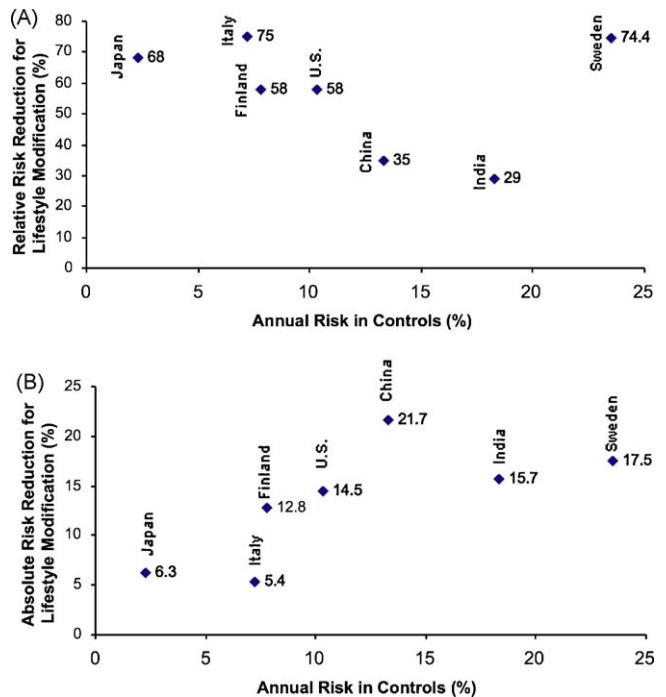


Fig. 3 – Lifestyle risk relative to controls. (A) Relative risk reduction in the lifestyle intervention groups, versus baseline risk (controls). (B) Absolute risk reduction in the lifestyle intervention groups, versus baseline risk (controls).

to small (–0.05 in the IDPP to –0.43 in the VIP) all favored the lifestyle intervention groups over the control groups.

3. Discussion

Clinical guidelines are needed for the optimal community implementation of evidence-based diabetes prevention programs. Successful translation of RCT evidence into public health practice requires an understanding of the most effective behavioral strategies. Thus, we reviewed all available evidence regarding behavioral strategies used in RCTs of lifestyle interventions for preventing T2D in at-risk individuals. Overall, lifestyle interventions targeting multiple physical activity and nutritional goals simultaneously have been highly successful in preventing the onset of T2D when compared to either usual care controls or pharmacological intervention.

3.1. Behavioral strategies

The behavioral strategies utilized in these interventions included a variety of theoretical approaches including Social Cognitive Theory, the Transtheoretical Model, and the Theory of Planned Behavior. The diabetes prevention studies implemented behavioral strategies that focused on the individual in their social context, such that a combination of intra- and inter-personal theories underpinned the interventions in these trials. Some of the elements related to behavior change utilized in the diabetes prevention RCTs included:

- Staging of information provision and individual tailoring of the program components.
- Multiple sessions, reinforcement, specified small group size; individual or group programs.
- Written materials to reinforce verbal advice; self-management and self-monitoring through keeping physical activity, weight and diet logs.
- Specifically for nutrition, shaping of behavior change (small steps), vicarious and observational learning (about food, cooking demonstrations, shopping trips), identification of barriers to change and problem solving, learning to deal with relapse, increasing confidence to change (self-efficacy).
- Specifically for physical activity, the studies utilized a prescriptive approach including progressive increases required in the volume and frequency of the outcome physical activity behaviors, self-monitoring, structured programs (observational learning and modeling the behavior), building problem solving and decisional balance into increasing motivation for activity, and in three of the studies direct supervision of exercise.

The elements outlined above are derived predominantly from Social Cognitive Theory (SCT), previously called social learning theory [33]. In addition, some elements are derived from the stages of change (SOC) model, which is a part of the Transtheoretical Model [34], and this SOC component is based on an initial assessment of an individual's motivational readiness to change, followed by tailoring and individualizing materials and advice to the identified stage of change. This SOC component of the broader Transtheoretical Model is used

to classify individuals as to their readiness to change, from those not even thinking about change (pre-contemplators), considering making change (contemplators), and starting to make initial changes (preparation phase). These are often used in resource development to support nutrition and physical activity behavior change, and are also used to tailor or individualize advice. The diabetes prevention trials contained few behavioral strategies specific to the Theory of Planned Behavior (TPB), although there is some focus on attitudes to the risk of diabetes and on behavioral intention [35]. Many strategies, such as goal-setting, which was common to all studies, are consistent with more than one theoretical model. In the TPB, goal-setting influences intention towards a behavior both directly and via the participant's perceived control. Social Cognitive Theory incorporates goal-setting where it interacts with personal factors such as self-efficacy – such that higher levels of self-efficacy allow more challenging goals to be set and attained. Where the Transtheoretical Model is used, a 'staging' approach is used to set goals at a level appropriate to the participant's stage of change.

All of the published RCTs to date have utilized a highly skilled personnel- and resource-intensive mode of delivery during the induction period, involving a moderate (6) to very large (165) number of face-to-face contacts with research and clinical staff in the first 12 months. In addition, all these trials have included maintenance/adherence contacts, in person or by phone at regular intervals for the entire duration of the program. Two of the studies with high RRR in obese cohorts (DPS and DPP) provided supervised exercise sessions free of charge to study participants for the duration of the trial. This approach was designed to maximize changes in behavior and long-term adherence, given the perceived high risk of dropout that was assumed to be present in the overweight, sedentary, and ethnically diverse individuals targeted for these trials. This mode of delivery was highly effective, as reviewed above, and also associated with very low dropout rates of 5.5–13.4%.

3.2. Control groups

Analysis of the active and control intervention details suggests that lifestyle modification for the prevention of T2D requires a substantial behavior change component in order to be effective. In five of the seven studies the control group received what might be considered an "intervention" that involved an initial contact with study staff, followed by advice to modify their lifestyle along with explicit written material on exercise and nutrition. In the case of the DPP, this included detailed dietary guideline information for example. Our review clearly shows that this information and advice approach as a secondary prevention strategy is not sufficiently effective, particularly in comparison to the detailed, theoretically based, lifestyle interventions described above. Therefore, optimal translation and dissemination of this RCT evidence into a community-based setting should include intensive behavioral change strategies.

3.3. Outcomes

The ADPP and VIP had the highest RRR despite only the VIP providing supervised sessions; however the much lower

incident diabetes risk in the ADPP cohort makes it difficult to compare RRR across these dissimilar cohorts. The results presented in Fig. 3 emphasize the differences in risk observed in the control groups, suggesting that baseline risk in the population may affect the efficacy of the treatment. However, the relationship is more varied and complex than simply those with lower baseline risk tending to achieve higher relative risk reductions. Previous studies have highlighted the role of genetic variability in the varied physiological adaptations observed as a result of lifestyle interventions, where more favorable genotypes are associated with an increased response to the treatment compared to the less favorable genotypes [36]. The broad range of racial and ethnic groups represented in these studies are likely to have quite different distributions of important allele frequencies, significantly affecting the efficacy of a lifestyle intervention [37–40].

3.4. Intervention goals

Each of the reviewed studies was effective in preventing or delaying the onset of T2D despite the small-to-moderate effect sizes seen in physical activity levels and weight loss in studies where reported. Relative effect sizes for changes in physical activity were low; however they represented significant increase in absolute physical activity levels from baseline levels in each study. For example the DPP had a mean increase of 73 min per week of moderate intensity exercise. Effect sizes for weight loss were low when compared to previously reported effect sizes for lifestyle interventions that specifically target weight loss in similarly obese populations [41], but again represented clinically important absolute weight loss in the obese DPP and DPS cohorts of 4.5 and 2.4 kg respectively at the end of the intervention [42,43]. Regardless of these somewhat modest improvements in intermediate study goals, the lifestyle interventions had a powerful effect in preventing the onset of T2D with RRR ranging from 29% (IDPP) to 75% (ADPP). Two studies reported that changes in behavior were significantly related to diabetes prevention itself. In the DPS, positive lifestyle changes such as achieving a higher number of diet and exercise goals, lower fat intake, higher fibre intake, and greater volume of physical activity were all associated with a reduction in diabetes risk suggesting a dose–response relationship [17,44]. Greater success in achieving lifestyle goals related to weight loss, fat reduction, and exercise was also independently related to risk reduction in the DPP [45]. This suggests that a behavioural change strategy that focuses on achievable, modest changes across multiple lifestyle goals may be the key to diabetes prevention.

3.5. Future research

The level of evidence is moderate with regard to the effectiveness of behavioral strategies for changing targeted exercise components, with no studies reporting frequency of physical activity or adherence to supervised activity or planned exercise. All studies report a very low rate of dropout or loss to follow-up, suggesting a high effort to retain participants or selection at baseline of motivated individuals; however this does not provide an insight into intervention compliance with the lifestyle prescription. There is a need for future studies, including

implementation studies, to document adherence to prescribed volumes, intensities and progression of exercise/physical activity and dietary goals rather than only presenting dropout rates. Further investigation is needed on the optimal number of patient contacts required during a lifestyle intervention, thus enabling a cost-effective yet successful community implementation of broad public health approach. For example, similar results were achieved with 9 versus 22 individual contacts (excluding supervised exercise sessions) in the DPS and DPP, respectively. More evidence is needed to establish whether such intensive face-to-face individual implementation strategies are feasible in the long-term, whether group-based or remote contact provides comparable efficacy in a more cost-effective manner, and whether less-skilled personnel can deliver these same interventions. The key challenge is whether such evidence-based interventions can be replicated in community settings. For these benefits to be realized on a large scale globally, the challenge now is to translate these ‘efficacious programs’ into ‘effective programs’. Already, results from a few translational studies in diabetes prevention have been published, with outcomes from much larger population studies soon to follow [46–56]. The next generation of diabetes prevention research should focus on this question of program generalizability and population-wide dissemination. Further studies are required that investigate the heterogeneity of response to lifestyle interventions within populations, including identification of genotypes and phenotypes of high and low responders, and barriers to the adoption of lifestyle interventions.

4. Conclusion

The results of this paper may be clinically relevant when considering the implementation of T2D prevention programs in a community setting. The available evidence shows that a robust behavioral change strategy is a critical part of such a prevention program. The absence of an intensive individualized delivery with the provision of advice or information only more closely resembles the control group interventions used by the RCTs, and cannot be considered optimally effective.

5. Conflicts of interest

There are no conflicts of interest.

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