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A systematic review of the translational research on the Diabetes Prevention Program

Robin Whittemore, PhD, APRN, FAAN

Yale School of Nursing, 100 Church Street South, New Haven, CT 06536, USA

Correspondence to: R Whittemore
robin.whittemore@yale.edu

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ABSTRACT

International clinical trials have demonstrated compelling evidence on the prevention or delay of type 2 diabetes (T2D) by lifestyle change programs. Numerous studies have translated the Diabetes Prevention Program (DPP) protocol to "real-world" settings. The purpose of this paper is to review the translational research of the DPP protocol in adults at-risk for T2D. This study is a systematic review based on the guidelines from the Cochrane Handbook for Systematic Reviews. There were 16 studies that translated the DPP protocol in four distinct settings: (a) hospital outpatient, (b) primary care, (c) community, and (d) work and church. Settings varied considerably in terms of reach, efficacy, adoption, implementation, and maintenance. There were strengths and limitations to each setting. Better understanding of program adaptation and mediators and moderators to program efficacy are indicated. Future research also needs to continue to explore mechanisms to improve access and long-term outcomes.

KEYWORDS

Diabetes prevention program, Translation research

Implications

Practice: To obtain optimal reach, efficacy, adoption, implementation, and maintenance of diabetes prevention translational programs, a variety of programs, settings, and providers are necessary.

Policy: Resources for diabetes prevention programs are needed to enhance the ability to reach diverse adults at-risk for type 2 diabetes and to implement diabetes prevention programs in clinical and community settings.

Research: Future research needs to examine mechanisms for dissemination and implementation of diabetes prevention programs in clinical and community settings as well as examine mechanisms for efficient coordination of programs with follow-up.

Type 2 diabetes (T2D) is one of the most rapidly increasing chronic illnesses worldwide and is associated with significant morbidity, mortality, and societal costs. Nearly 26 million adults in the USA have diabetes and 79 million have prediabetes. Ethnic minorities have a disproportionate risk and are twice as likely as non-Hispanic whites of similar age to develop T2D. The increasing prevalence of T2D is concerning due to the numerous complications associated with the disease. T2D is the 7th leading cause of death in the USA and contributes to increased risk for cardiovascular disease, renal failure, blindness, and nontraumatic amputation. In the USA, the costs of diabetes in 2007 were estimated to be 174 billion dollars [1]. Therefore, the greatest opportunity for addressing the personal and societal burden of T2D is to prevent the development of the disease.

Recent evidence clearly demonstrates that individuals at high risk for T2D can be identified and T2D delayed, if not prevented, through lifestyle change programs. International clinical trials, including the Diabetes Prevention Program (DPP), have demonstrated compelling evidence on the reduction of T2D for at-risk adults who participated in lifestyle change programs of weight reduction and physical activity compared to a control group [2–4]. In the DPP, lifestyle change resulted in a 58% reduction in T2D compared to a 31% reduction with metformin at 2.8 years of follow-up [3]. Recent evidence indicates that the prevention or delay of T2D can continue for at least 10 years [5]. Modest weight loss of 5–7% dramatically improves insulin resistance, a precursor to T2D [6, 7].

The benefit of lifestyle change has resulted in recommendations by the American Diabetes Association advocating for lifestyle change as the first line of treatment to prevent or delay T2D [8]. Results of a cost analysis of the DPP indicate a favorable cost-effective profile of the lifestyle program at any adult age [9].

The DPP was based on behavioral science evidence and included: a collaborative approach, education, behavioral support (i.e., goal setting, problem solving), and motivational interviewing. The primary goals of the DPP were for participants

to lose 7% of initial body weight within 6 months and to participate in moderate physical activity for at least 150 min per week. The DPP consisted of a 16-week core curriculum provided individually to participants by trained health coaches followed by monthly group and/or individual meetings and a long-term maintenance program. In addition, motivational campaigns, a toolbox of additional strategies, and incentives were provided [10].

Having established efficacy in a large clinical trial, subsequent research on the DPP has been conducted on the translation of the DPP to typical or "real-world" settings. Since the completion of the DPP in 2002, numerous studies have been conducted translating the DPP to different settings with efforts to reach participants with low socioeconomic status and diverse race and ethnicity. Adaptation of programs to a new context has resulted in programs with different components, modes of delivery, length, providers, targeted population, and outcomes. Some studies have demonstrated outcomes similar to the DPP; others have reached highly diverse adults at risk for T2D with less weight loss demonstrated. Attrition in these studies has also varied considerably.

Several reviews have been conducted on diabetes prevention research, focusing on the international research [11, 12] or the comparative benefit of dietary change, physical activity, and/or weight loss [13, 14]. One review focused on community-based programs conducted in the USA prior to the DPP, with few manuscripts reporting on outcomes; rather, the process of intervention adaptation or lessons learned was reported [15]. Another review highlighted culturally relevant programs, targeting the Native American population, and proposed best practices for diabetes prevention in this population, one of which is based on the DPP [16]. One review focused on research specifically translating the DPP; however, the review was not exhaustive, and several of the programs targeted adults with type 2 diabetes [17]. Since this review, eight additional papers translating the DPP have been published. Therefore, the purpose of this paper is to systematically review the translational research on diabetes prevention programs for adults at-risk for T2D based on the DPP protocol.

Designing studies to test the translation of a research-based program (with established efficacy in clinical trials) into the healthcare or community setting requires consideration of broad processes and outcomes of care to improve dissemination. The Reach, Efficacy, Adoption, Implementation, Maintenance (RE-AIM) model is the organizing framework of this review as it was developed for use in evaluating the effectiveness of health behavior programs in terms of public health significance [18]. The major premise of the model is that public health impact of programs require more than efficacy (efficacy). Programs must also reach a diverse sample, representative of the population at-risk for T2D (reach). They must be appealing to health care providers and realistic to implement in specific practice settings (adoption). Programs must also be able to be delivered as intended (implementation). Lastly, programs must past the test of time and be sustained by both the individual and the clinical setting (maintenance). Cost will be evaluated as a proxy for maintenance in this review.

An important assumption of this model is that the characteristics that contribute to a program's efficacy in a controlled clinical trial (i.e., intensive, complex, highly standardized) may be fundamentally different to the characteristics necessary for implementation in clinical practice (i.e., broad appeal, flexible, cost-effective). Thus, it is likely that programs with demonstrated efficacy in clinical trials will need to be modified when translating into a complex healthcare environment.

METHOD

A systematic review was undertaken using the guidelines from Cochrane's Handbook for Systematic Reviews of Interventions for locating and analyzing studies [19]. A computer-assisted search was undertaken using the keywords of diabetes prevention and Diabetes Prevention Program in Medline and CINAHL from January 2002 to February 2011. Initial search results yielded 40 manuscripts. To be included, a study had to be a published report on the outcomes of a translation study evaluating a diabetes prevention program based on the DPP curriculum for adults at-risk for T2D. Manuscripts were excluded if programs were provided in schools or with cognitively impaired adults. Manuscripts reporting findings from subsamples of a larger study were excluded unless a unique intervention approach was used (i.e., telehealth). Published abstracts were excluded due to limited available data. Reference lists of all included papers were reviewed with no new manuscripts identified.

A total of 16 studies were identified that met the sampling inclusion criteria. Data were extracted from studies on study design, setting, sample, the program, how the DPP was modified, personnel who provided the program, attendance, attrition, outcomes, and data analysis procedures. Data display matrices were developed to display all of the coded information for each study by category. Graphs and charts were created to view data visually. Matrices and graphs were compared to narratively analyze and synthesize results. A meta-analysis was unable to be conducted due to variability in reporting the primary outcome of weight loss (kilograms, % body weight, and % of participants who met weight loss goals). Very few studies reported standard deviations for the outcome of kilogram weight loss.

RESULTS

Of the 16 studies, the majority were one-group designs (n=13 studies; 81%) with varied length of

follow-up ranging from 3 months to 2 years. Two studies were pilot clinical trials [20, 21] and one was a controlled cohort design [22]. Sample sizes in the studies ranged from 8 to 1,003 participants. Samples were predominately female (55–90%) and of varied race and ethnicity (0–100% non-white). Outcomes also varied considerably with weight loss at the longest point of follow-up varying between −1.0 and −8.6 kg. The percent of participants who met the 5% weight loss goal ranged from 11% to 64% across studies that reported this outcome. In studies that measured depressive symptoms, 33–35% of participants reported elevated depressive symptoms above a criterion score. Table 1 compares the DPP benchmarks and the translational research of this review. As can be seen, there is considerable variability in the diabetes prevention programs adapted for different settings with difficulty achieving the DPP benchmarks.

In order to compare the reach, efficacy, adoption, implementation, and maintenance across studies, the studies were categorized by setting. There were four distinct settings of diabetes prevention translational research: (a) hospital outpatient or diabetes education model of care [23–25] with one study a comparative effectiveness study comparing an on-site program to a telehealth program [26], (b) primary care [21, 22, 27] with one study combining primary care with an online program [28], (c) community settings (i.e., Young Men's Christian Association (YMCA)) [20, 29–31], and (d) church or workplace settings [32–35] (Tables 2, 3, 4, and 5).

Reach–All of the DPP translational studies had minimal exclusion criteria, reflecting a more heterogeneous population at-risk for T2D. Inclusion criteria were also expanded in many studies to include adults at-risk for T2D with and without prediabetes. Several studies did include some participants with T2D; however, this group represented a small proportion of the total sample (<50%) [24, 25, 28, 29]. Sample sizes varied considerably across studies from eight participants in a church-based program [33] to 1,003 in a diabetes education model of care provided in a community setting [23]. Overall, the work/church setting had the smallest sample sizes. The mean age across all studies in which age was reported (n=13) was 51.7 years, slightly older in comparison to the DPP study of 50.6 years. Mean body mass index (BMI) across studies in which BMI was reported (n=14) was 36.5 kg/m^2, considerably higher than the mean BMI of the DPP study of 30.5 kg/m^2. The majority of participants in diabetes translation programs were female (74%; n=15 studies reported gender), which is higher than in the DPP study (68% female). In studies that evaluated depressive symptoms, psychosocial comorbidity was much higher than in the DPP [21, 25].

Diversity in this review was determined by calculating the % of non-White participants. Diversity varied by setting from 0% to 100%, with greater diversity in programs provided at work or church, followed by community settings, primary care, and lastly hospital outpatient or diabetes education models of care (n=14 studies reported on diversity; Fig. 1). Two of the hospital outpatient studies did not have access to data on race or ethnicity [23, 26].

Efficacy–Weight loss was the primary outcome evaluated across all studies. Some studies reported weight loss in kilograms, others in percent body weight change, and/or the percent of participants who met a 5% or 7% weight loss goal (Tables 2, 3, 4, and 5). Evaluating weight loss was also complicated by follow-up time, which ranged from 3 to 12 months. With respect to weight loss in kilograms and at the longest point of follow-up, hospital outpatient settings achieved the most weight loss, followed by primary care, community settings, and work or church settings (Fig. 2). As can be seen, weight loss in some studies was comparable to the DPP benchmark.

When comparing reach (in terms of diversity) and efficacy (in terms of weight loss) across settings, an opposite trend is apparent. In hospital outpatient settings that demonstrate greater weight loss, there is less diversity. In settings with more diversity, there is less weight loss; although the majority of studies with diverse samples demonstrated statistically significant weight loss. As mentioned, two studies conducted in the hospital outpatient setting may have had increased diversity; however, this data was

Table 1 | DPP benchmarks and translational research

	DPP	Translation research
Sample size	N=3,234	N=8–1,003
Weight loss	−6.5 kg	−1.0 to −8.6 kg
Weight change	−6.9%	−2.7% to −6%
Percent who met 7% weight loss goal	50% at 3 months	18–49% at F/U (6–12 months)
	38% at F/U (2–4 years)	
Percent who met 5% weight loss goal		11–64% at F/U (3–12 months)
Attendance	95%	57–96%
Attrition	7%	0–43%
Diversity	46% non-White	0–100% non-White
Depressive symptoms	10%	33–35%

Table 2 | DPP translation research—hospital outpatient

	McBride et al. [24]	Pagoto et al. [25]	Vadheim et al. [26]	Vanderwood et al. [23]
Reach				
Sample size	*N*=37	*N*=118	*N*=29	*N*=1003
Mean age	52 years	48.8 years	50 years in Telehealth group 53 years in onsite group	52.3 years
Mean BMI at baseline	37.4	43.3	38.7	36.3
Gender (% female)	60%	72%	93% in Telehealth group 69% in onsite group	80%
Diversity (% non-White)	0%	9%		
Adoption and implementation				
Intervention—core	12 group sessions (1×/week) Signed contracts Charged fee (refunded) Exercise classes	16 group sessions (1×/week) Charged fee Exercise classes	16 group sessions (1×/week)	16 group sessions (1×/week) Signed contract Charged fee Exercise classes
Intervention—maintenance	F/U-1×/month	F/U-1×/month	F/U-1×/month	F/U-1×/month
Personnel	Dietician, exercise physiologist (cardiac rehab)	Dietician, exercise physiologist, clinical psychologist (weight center)	Dietician (CDE) and exercise specialist	Dietician and exercise specialist
Attendance	Stated as "good"	83%	91%	93% for core 62% for after core
Attrition	11% at 12 months	17% at 4 months	12% at 6 months	19% at 4 months 42% at 12 months
Efficacy				
Management of missing data	Analyzed completers	Last observation carried forward	Analyzed completers	Analyzed completers
Short-term weight loss (kg) (length of F/U)	5.0 kg at 3 months*	5.57 kg (SD 4.55) at 4 months[a]		6.8 kg at 4 months***
Long term weight loss (kg) (length of F/U)	4.5 kg at 12 months*		6.7 kg (SD 3.7) in Telehealth group 6.5 kg (SD 3.1) in onsite group at 6 months[b]	7.7 kg. at 12 months***
% Weight loss	4.1%	4.6%		
% Subjects who met 5% weight loss				64% at12 months
% Subjects who met 7% weight loss		30%	50% in Telehealth group 46% in onsite group	49% at 12 months
Other outcomes	Decrease in waist circumference*,% body fat*, BP*, fat intake*. Increase in METS*, fruit and vegetable intake*. Glucose and lipids not reported	Less weight loss compared to DPP*. Weight loss not significantly different from DPP when exclusion for comorbidity (type 2 diabetes, binge eating, depression)	No significant difference between telehelath and onsite group in weight loss, physical activity, or fat intake goal	Decrease in BP***, LDL cholesterol***, glucose***. Decrease in HDL*** after core, increased at 12 months***
Maintenance				
Cost of program	$250 (charged)	$800 (charged)		

Blank cell data not reported

*$p<.05$, **$p<.01$, ***$p<.001$

[a] Compared outcomes to DPP benchmarks

[b] Compared Telehealth group to onsite group

Table 3 | DPP translation research—primary care

	Kramer et al. [23]	McTigue et al. [22]	McTigue et al. [28]	Whittemore et al. [21]
REACH				
Sample size	*N*=93 (two studies)	*N*=72	*N*=50	*N*=58
Mean age		53.1 years	51.94 years	47 years
Mean BMI at baseline	35.6	38.9	36.43	38.8
Gender (% female)	80%	84%	76%	92%
Diversity (% non-White)	22%	30%	14%	55%
Adoption and implementation				
Intervention—core	12 group sessions (1×/week)	12 group sessions (1×/week) Charged fee	16 sessions online E-coaching Quarterly progress reports to provider	7 individual sessions, 5 phone sessions, 1 session with dietician (over 6 months)
Intervention—maintenance	F/U—1×/month	F/U—1×/month	F/U—1×/month	
personnel	Nurse, health educator, exercise specialist	Nurse educator	Nurse educator	Nurse practitioner, dietician
Attendance	83%		80%	96% (in person) 37% (phone)
Attrition	22% at 3 months (2 studies) 28% at 12 months (1 study)	7% at 9–12 months	10% at 12 months	12% at 6–9 months
Efficacy				
Management of missing data	Last observation carried forward (3 months) Analyzed completers (12 months)	Analyzed completers	Last observation carried forward	Last observation carried forward
Short term weight loss (kg) (length of F/U)	3.4 kg at 3 months***			
Long term weight loss (kg) (length of F/U)	4.99 at 12 months*** (one study)	5.2 kg (SD 2.51) at 9–12 months***[a]	4.79 kg (SD 2.56) at 12 months*	8.7 kg at 6–9 months[b]
% Weight loss	3.5%			
% Subjects who met 5% weight loss	52%		30%	25%
% Subjects who met 7% weight loss	23%	27%	18%	
Other outcomes	Decrease in waist circumference**, fasting glucose* (one study). Decrease in waist circumference***, cholesterol**, LDL**, and BP*** maintained at 12 months (except cholesterol) Increase HDL** at 12 months (one study)	Enrollees had 4.38 times the odds of clinically significant weight loss	Decrease in systolic BP*	Improvement in both groups for nutrition and exercise***. Trend for increase in exercise and HDL in DPP group. No significant difference in HOMA, glucose, LDL, cholesterol, or waist circumference
Maintenance				
Cost of program	$300 (estimated)	$150 (charged)		

Blank cell data not reported

*$p<.05$, **$p<.01$, ***$p<.001$

[a] Compared enrollees to non-enrollees

[b] Compared treatment and control group

Table 4 | DPP translation research—community

	Ackerman et al. [20]	Matvienko and Hoehns [29]	Mau et al. [30]	Seidel et al. [31]
Reach				
Sample size	*N*=92	*N*=31	*N*=239	*N*=88
Mean age	58 years	55.8 years	49 years	54 years
Mean BMI at baseline	31.5	36.1	39.1	
Gender (% female)	55%	61%	83%	84%
Diversity (% non-White)	18%	6%	98%	27%
Adoption				
Intervention—core	16 group sessions (1×/week)	16 individual sessions (over 6 months)	8 group sessions (over 12 weeks)	12 group sessions (1×/week)
		Exercise classes		Free YMCA membership
Intervention—maintenance	F/U-1×/month	F/U-1×/month (individual)		
		Monthly phone calls		
Personnel	YMCA staff (with health degree or equivalent experience)	Exercise science graduate students	Community peer educators	Dietician and exercise specialist, plus 2 lay health coaches
Attendance	57%			70% attended≥75% of classes
Attrition	16% at 4 months	6% at 6 months	29% at 3 months	22% at 3 months
	33% at 12 months	16% at 12 months		43% at 6 months
Efficacy				
Management of missing data	Analyzed completers	Analyzed completers	Analyzed completers	Last observation carried forward
Short term weight loss (kg) (length of F/U)	5.7 kg at 4 months***[a]	6.1 kg at 6 month***	1.5 kg (SD 0.5) at 3 month*	
Long term weight loss (kg) (length of F/U)	5.7 kg at 12 months**[a]	6.1 kg at 12 months**		
% Weight loss	6%			
% Subjects who met 5% weight loss		39% at 6 months	11%	46% at 3 months (88% sustained at 6 months)
		56% at 12 months		
% Subjects who met 7% weight loss		25% at 6 months		26% at 3 months
		32% at 12 months		(67% sustained at 6 months)
Other outcomes	Decrease in cholesterol at 4 months*** and 12 months** compared to control group. No difference in HbA1c, BP, or HDL	Decrease in waist circumference***, DBP*, cholesterol*, LDL*, HDL* at 6 months. No significant change in SBP. Decrease in waist circumference** and DBP* at 12 months	Decrease in BP*, dietary fat intake*. Increase in physical functioning*, physical activity*	44% of participants improved in one metabolic parameter (i.e., BP) at 3 months
Maintenance				
Cost of program	$275–325 (estimated)			

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*p<.05, **p<.01, ***p<.001

[a] Compared treatment and control group

Table 5 | DPP translation research—work/church

	Aldana et al. [32]	Boltri et al. [33]	Davis-Smith et al. [34]	Dodani and Fields [35]
Reach				
Sample size	*N*=37	*N*=8	*N*=10	*N*=40
Mean age		52 years		46 years
Mean BMI at baseline	30.95	31.6	35.7	(49% obese, 32% morbidly obese)
Gender (% female)	64%		70%	85%
Diversity (% non-White)	50%	100%	100%	100%
Adoption and implementation				
Intervention—core	24 group sessions (1×/week)+4 individual sessions and when requested Free gym membership	16 group sessions (1×/week)	6 group sessions (1×/week)	12 group sessions
Intervention—maintenance	F/U-1×/month			
Personnel	Nurse, certified health educator	Volunteer health professional with diabetes prevention experience	Volunteer health professional	Volunteer health professionals
Attendance		65%	78%	
Attrition	6% at 12 months	0% at 12 months	10% at 12 months	12% at 3 months
Efficacy				
Management of missing data		Last observation carried forward	Last observation carried forward	Analyzed completers
Short term weight loss (kg) (length of F/U)	2.94 kg at 6 months*	2.6 kg at 6 months*	4 kg at 3 months*	
Long term weight loss (kg) (length of F/U)	3.3 kg at 12 months*	0.5 kg at 12 months	4.8 kg at 12 months*	
% Weight loss		3.6%		
% Subjects who met 5% weight loss	46%			48% at 3 months
% Subjects who met 7% weight loss				26% at 3 months
Other outcomes	Decrease in waist circumference*, glucose,* insulin*, cholesterol*, triglyceride*, at 6 months. Decrease in glucose* and triglyceride* at 12 months. Increase in aerobic fitness* at 6 and 12 months	Decrease in glucose*, BP* at 6 and 12 months	Decrease in glucose*, BP* at 4 and 12 months	
Maintenance				
Cost of program			$108 (estimated)	

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*$p<.05$, **$p<.01$, ***$p<.001$

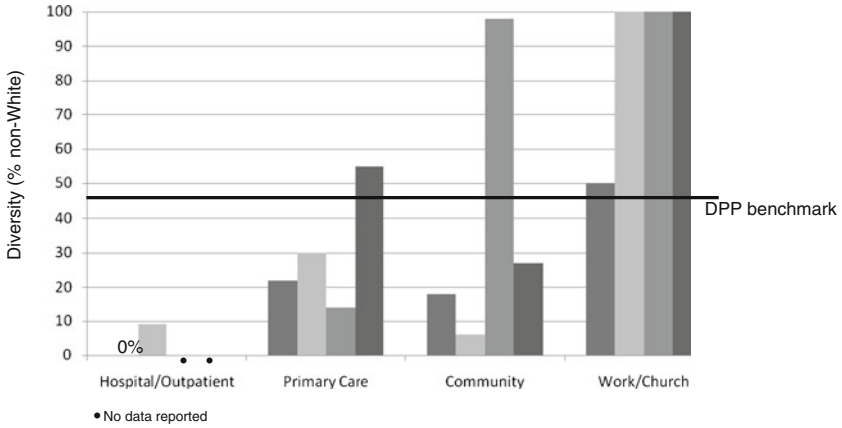

Fig 1 | Diversity of the sample across settings

not available. In addition, studies with diverse samples may have had other implementation factors that affected efficacy (i.e., type and skill of interventionist, protocol fidelity, and sample size).

Some studies also demonstrated significant improvements in other clinical indicators (i.e., fasting glucose, waist circumference, blood pressure, cholesterol) and behavioral indicators (i.e., dietary intake, and physical activity; Tables 2, 3, 4, and 5).

Adoption–As previously mentioned, diabetes prevention translation programs have been conducted in different settings. Despite this variability, the majority of programs have utilized health care providers (health coaches, dieticians, exercise physiologists, certified diabetes educators, nurses, and nurse practitioners) as the interventionist (n=12). Three programs provided in the church setting trained volunteer health professionals to provide the program. Only one program was provided by trained community peer educators [30] which reached a highly diverse and large sample (n=293), provided the fewest sessions (n=6), yet demonstrated little weight loss (1.5 kg at 3 months). One program employed a community health worker to assist health professionals [31].

Implementation–Translational research typically involves some modification to adapt the program for the targeted population and setting. The majority of DPP translational studies modified the program to be provided in a group setting (81%). Programs not provided as a group included individual sessions [21, 29], a combination of group sessions and individual sessions [32], and a combination of group online sessions and individual sessions [28]. All programs eliminated the intensive toolbox strategies of the DPP (i.e., free sneakers), substituting less expensive or no strategies.

All programs utilized the DPP curriculum. Some programs provided all 16 sessions of the original DPP core curriculum; however, the majority modified the curriculum to decrease the number of classes and some of the content. Most studies used a collaborative approach with providers to adapt the program to the local context; only two studies used a community-based participatory research process involving health professionals and members of the community [30, 35]. When programs were adapted to decrease the number of sessions, most reports did not identify which sessions were eliminated and/or combined. With the exception of hospital outpatient

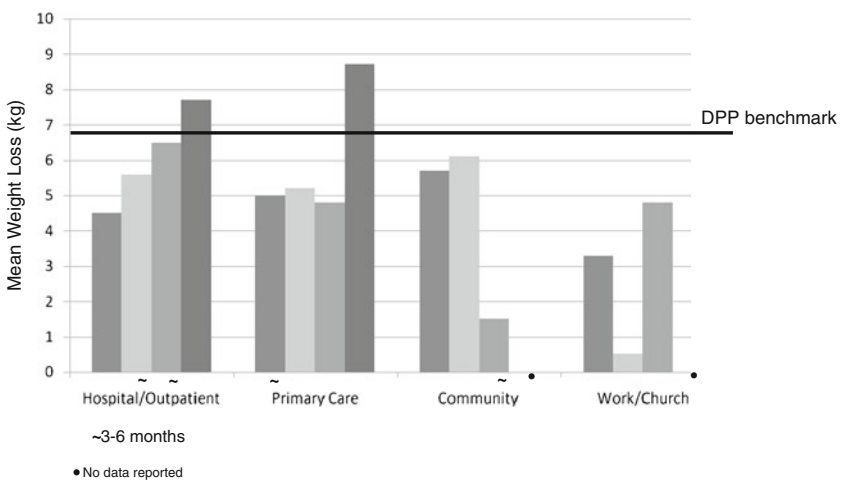

Fig 2 | Weight loss across settings at longest point of follow-up

programs that provided a 16-session curriculum, there was not any consistent pattern with respect to the number of sessions and outcomes across settings.

All programs provided education on healthy eating and physical activity. In addition, all programs provided behavioral support in terms of goal setting, problem solving, and relapse prevention. There was little evidence that motivational interviewing was a major component of any of the programs with the exception of one study provided as individual sessions in the primary care setting [21]. Only two studies provided evidence of intervention fidelity, both of which were randomized pilot trials [20, 21].

Three of the four hospital outpatient programs required participants to sign a contract indicating readiness or motivation to engage in the program and make lifestyle changes [23–25]. One of these programs conducted a thorough assessment of all eligible participants to determine and enhance motivation; only those motivated were enrolled in this study. In addition, this program charged a fee ($800.00) for the program [25]. The two other hospital outpatient programs that required contracts charged a fee for the program ($250.00 in one, not reported in the other) that were reimbursed for "good attendance" or upon completion of the program [23, 24]. There was one primary care program that also charged a fee ($150.00) [22].

Other indicators of implementation include attendance and attrition. Hospital outpatient programs and primary care had the highest attendance (80–96%), followed by the work/church setting (65–78%), and community settings (57%). With respect to attrition, the work/church setting had the lowest attrition (0–12%), followed by primary care settings (7–28%), hospital outpatient (11–42%), and community settings (16–43%). The comparison of attrition by setting is provided in Fig. 3.

Maintenance–The majority of studies were pilot or feasibility studies, evaluating the core curriculum of the DPP. Ten studies followed participants for 1 year, with eight of these studies providing a maintenance program. Programs with a maintenance component demonstrated weight loss at 1 year ranging from 3.3 to 7.7 kg [20, 22–24, 27–29, 32]. The other two studies with 12 month follow-up were in a church setting and did not provide a maintenance component; one demonstrated weight loss maintenance at 1 year [34], the other program did not [33].

The ability to maintain programs in "real-world" settings, particularly low-resource settings can also be evaluated by examining the cost of the program. Few studies evaluated cost. One program provided in primary care estimated the cost of the program at $300.00 per participant [27]. Another program, provided in the YMCA, cost approximately $275.00–325.00 per participant [20]. A program provided in a church with donated space and volunteer personnel estimated a cost of $108.00 for supplies for 10 participants [34]. These estimates are considerably lower than the cost of the DPP at approximately $1400.00 [36].

DISCUSSION

Limitations in this review include studies with primarily one-group designs, small sample sizes, variable outcomes reported, variable follow-up timing, low to moderate methodological quality, and the potential for publication bias. Despite these limitations, there are important clinical and research implications of this translational research. Diabetes prevention programs that have translated the DPP protocol to a "real-world" setting do have the potential to achieve positive outcomes in terms of the reach, efficacy, adoption, implementation, and maintenance of programs. However, there were strengths and limitations of each type of setting in which these programs were translated.

Hospital outpatient or diabetes education models of care are excellent settings to provide a modified DPP protocol with weight loss demonstrated in all four studies. Adoption and implementation were also high in these settings as health care professionals who provide diabetes self-management programs are highly qualified to provide a DPP. In addition, facilities where the program can be

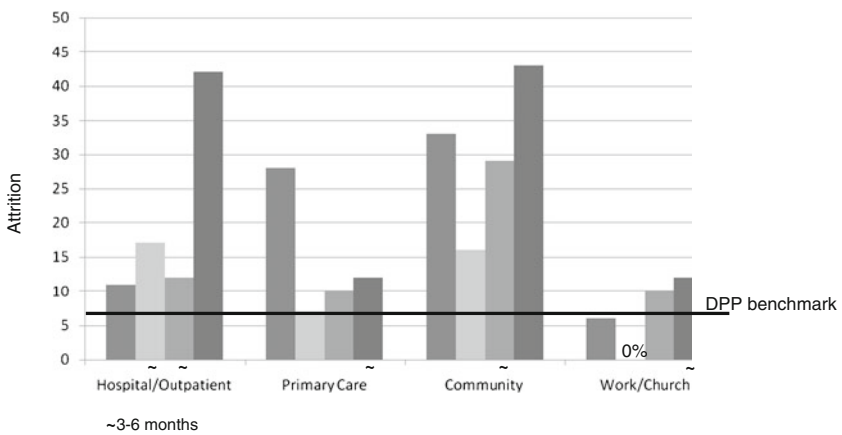

Fig 3 | Attrition across settings at longest point of follow-up

delivered and access to electronic systems to facilitate scheduling and maintenance of records are readily available. Billing for select services can also be accomplished (i.e., dietary counseling for adults with metabolic syndrome); however, hospital outpatient settings may not reach adults of diverse race or ethnicity who are at-risk for T2D due to cost or transportation challenges. Of the two studies in this setting that reported on diversity, diversity of samples was 0% and 9% [24, 25]. In addition, diabetes prevention programs in these settings reached a highly motivated sample, committed to making lifestyle change.

The primary care setting does have the potential to reach adults of diverse race and ethnicity, be efficacious (less than the DPP), adopted, implemented, and maintained. A potential benefit of the primary care setting is that participants of the program have established relationships with providers, which may enhance intervention efficacy and implementation as well as decrease attrition. In addition, primary care settings can also manage comorbidities that frequently occur in adults at-risk for T2D (i.e., hypertension). The major challenge of implementing a DPP in primary care is the need to provide adequate components of the protocol while simultaneously addressing efficiency in terms of who provides the intervention and how the program is implemented. Not all primary care practices have access to health educators, nurses, or dieticians, and implementing group-based interventions in primary care is challenging due to scheduling and space. One program in this review provided individual sessions supplemented with phone sessions and home reading, although phone sessions were challenging to complete [21]. Another program provided the DPP curriculum via the internet and supplemented this with monthly group sessions and e-counseling [28].

Community and work/church settings have the greatest potential to reach adults of diverse race and ethnicity at-risk for T2D; however, these programs had the greatest variability with respect to other RE-AIM indicators. Some programs were efficacious; other programs were not. Some programs had considerable implementation challenges. While further research is indicated, it appears that programs linked to existing structures of care (i.e., YMCA) or social structures (i.e., work/church) may enhance adoption, implementation, and maintenance of programs. It also appears that community health workers may not be optimal providers for a DPP. Additional research is indicated as a preliminary report of a DPP provided by health professionals and community health workers with T2D has demonstrated promising results [37, 38]. The effectiveness of community health workers in other behavioral interventions has been variable, depending on their role and the population served. Community health workers can aid in increasing access to care in underserved populations and can improve the reach and relevance of health promotion programs as part of professional teams [39].

All of the programs translating the DPP protocol to a different setting included a core curriculum with sessions provided frequently over 3–6 months. Several programs included a maintenance program of monthly sessions up to 1 year. The hospital outpatient setting or diabetes education model of care was able to translate the DPP with little adaptation from the original protocol. Other programs demonstrated varying degrees of adaptation. In adapted programs, optimal components of core and maintenance programs, as well as dose, have yet to be determined. One challenge of translational research is to retain essential elements of the original protocol while adapting to a local context. Highly structured protocols may be impossible to implement [40], and highly adapted protocols may not include key components of the protocol [41]; both of which may impact outcomes. Therefore, protocol adaptation needs to be systematic, carefully considered, and adequately described [42]. In addition, program fidelity needs to be systematically evaluated in translational research, particularly with complex behavioral interventions [43]. Program adaptation and fidelity were not adequately described in most studies of this review. For example, motivational interviewing was a major component of the DPP; however, it is not clear if and how this behavioral counseling was applied in the majority of programs included in this review, particularly those provided with a group or media-based approach. The primary purpose of motivational interviewing is to assist adults to enhance motivation to change health behaviors and to resolve ambivalence to change [44]. Therefore, motivational interviewing may be indicated when an individual demonstrates low readiness or motivation to change and/or inability to meet incremental behavioral goals. Hospital outpatient programs required participants to demonstrate motivation to change health behaviors, which may have limited the need for motivational interviewing.

Future translational research also needs to include an adequate description of sample characteristics, including characteristics or conditions that may interfere with the ability to make lifestyle change, such as race and ethnicity, income, and depressive symptoms. For example, attitudes and beliefs about physical activity vary by race and ethnicity, which may influence physical activity [45]. Low socioeconomic neighborhoods have been shown to have less access to healthy food [46]. Increased depressive symptoms in adults at risk of T2D have been reported, ranging from 33% to 48% [21, 25, 47]. Depression has been shown to negatively impact self-management in T2D [48], which may be similar in adults at-risk for T2D. Pagoto et al. [25] demonstrated that participants with depression, binge eating disorder, or T2D were less likely to improve weight outcomes and suggested that participants with these conditions

may require a more intensive or different approach to lifestyle change. Other potential moderators to program outcomes include age, baseline BMI, and physical functioning [21, 25, 31]. Expanding the reach of diabetes translational research to more heterogenous samples enhances generalizability but has the potential to confound the interpretation of results. Statistical control or examination of moderators is indicated.

Mediators to program efficacy also need to be examined. Previous research has supported that participants of weight loss or diabetes prevention programs who consistently self-monitor diet and physical activity behavior, and who are able to meet behavioral goals, demonstrate greater weight loss [49, 50]. Health literacy, self-efficacy, adherence to protocol, and stress may be other mediators to consider, particularly with adults at risk for T2D with low education and/or socioeconomic status.

Greater consistency in how weight loss outcomes are reported and analyzed is also indicated in future diabetes prevention translational research. In order to compare studies, data on mean weight loss in kilograms, mean percent of body weight loss, and the percent of participants meeting a 5% and 7% weight loss goal all need to be reported. Mean values can be biased by outliers who have extreme weight loss or gain. Participants meeting weight loss goals can be biased by attrition, with weight loss over-estimated when there is systematic attrition. To address these issues, assumptions of statistical analyses, treatment of outliers, and data management for program attendance and study completion should be specified. Analyses comparing completers to noncompleters on baseline weight, weight loss, and demographic characteristics will allow for determination of systematic attrition. Power analysis recalculations can determine if the final sample has adequate power to test the primary hypothesis. Careful consideration of missing data also needs to be undertaken as per protocol analyses or data imputations with the last observation carried forward may overestimate treatment effects. Statistical models accounting for incomplete data (i.e., mixed linear model, GEE model) are recommended [51]. To further improve methodological quality, more randomized trials and pilot studies need to be conducted.

Future research also needs to continue to explore mechanisms to improve access and outcomes. Financial incentive-based approaches for weight-loss, based on behavioral economics, are beginning to be explored [52] and may be particularly successful in persons with limited resources. Technology-based programs (i.e., telehealth, internet, smart phones), while potentially expensive to develop, may be a cost-effective intervention extender. Multilevel, multifaceted approaches involving individuals, families, communities, and policy have also been advocated for curtailing the rising prevalence of T2D. Lastly, research with larger sample sizes and more males as well as research examining cost-effectiveness, are also indicated.

CONCLUSION

Considerable research has translated the DPP protocol to different settings for adults at risk with T2D, with promising results. Ongoing development of innovative programs for diverse adults with low health literacy and low socioeconomic status are indicated. More rigorous evaluation of program reach, adoption, implementation, and maintenance is needed.

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