

Primary health care provider–focused interventions for improving outcomes for people with type 2 diabetes: a rapid review

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Key points

- This rapid review found evidence that a variety of provider-focused primary health care interventions have positive impacts on some biochemical, clinical, psychological and health-related quality-of-life outcomes for people with type 2 diabetes
- Interventions that showed a positive impact included computerised decision support, culturally tailored programs, feedback on diabetes care quality and practice nurse involvement. The only intervention studied for which there was no evidence of benefit was decision aids, and no single intervention led to improvements in all outcomes of interest
- The challenge now is to further evaluate the applicability of these interventions in the Australian context, and to make those that are suitable for our primary health care system more widely available and improve their uptake

Abstract

Objectives and importance of the study: The bulk of care for people with type 2 diabetes occurs in primary health care. This rapid review evaluated the effectiveness of primary health care provider–focused interventions in improving biochemical, clinical, psychological and health-related quality-of-life outcomes in people with type 2 diabetes.

Methods: We searched Medline, Embase, All EBM Reviews, CINAHL, PsycINFO and grey literature focusing on the Organisation for Economic Co-operation and Development (OECD) member countries. We selected studies that targeted adults with type 2 diabetes, described a provider-focused intervention conducted in primary health care, and included an evaluation component. Four researchers extracted data and each included study was assessed for quality by two researchers.

Results: Of the 15 studies identified, there was one systematic review (high quality), four randomised controlled trials (RCTs) (two strong quality, one each moderate and weak) and 10 cluster RCTs (two strong quality, five moderate, three weak). The range of follow-up periods was 3–32 months. In all but one study, the intervention was compared against usual care. The applied interventions included: computerised and noncomputerised decision support; culturally tailored interventions; feedback to the healthcare provider on quality of diabetes care; practice nurse involvement; and integrated primary and specialist care. All interventions aimed to improve the biochemical outcomes of interest; 13 studies also included clinical, psychological and/or health-related quality-of-life outcomes. Outcome results were mixed.

Conclusions: All interventions had mixed impacts on the outcomes of interest except the one study testing a decision aid, which did not show any improvement. A number of interventions are already available in

Australia but need wider adoption. Other effective interventions are yet to be broadly adopted, and need to be evaluated for their applicability, feasibility and sustainability in the Australian context.

Introduction

Type 2 diabetes (T2D) prevalence continues to grow in Australia, affecting an estimated 4.4% of people in 2014–15, up from 3.8% in 2011–12.¹ T2D greatly affects the person's health status and quality of life (QoL) in terms of physical, social and psychological wellbeing. Many people with T2D are not being effectively managed², which puts them at risk of developing complications. As diabetes management frequently occurs within primary health care³, many innovative interventions have been implemented involving primary health care providers (hereafter 'providers').

This brokered rapid review aimed to identify effective primary health care-based interventions that focused on capacity building, and use of technology and enablers to integrated care, and which were replicable in the Australian health environment. The research question was: Which provider-focused interventions are effective in improving clinical, biochemical, psychological and health-related QoL outcomes for people with T2D?

Methods

Selection criteria

Eligible studies were randomised controlled trials (RCTs), cluster RCTs or systematic reviews/meta-analyses incorporating RCT or cluster RCT designs, that evaluated effectiveness of provider-focused interventions. Studies were conducted in primary health care or in the community with primary health care providers (e.g. physicians and practice nurses), and included adult (i.e. older than 18 years) patients with T2D. We included studies that also involved patients with other diabetes types only if data on patients with T2D were reported separately. The interventions used attempted to change either individual providers' behaviour with their patients or how the providers' care was organised, to indirectly influence patient outcomes.^{4,5}

Outcomes of interest were:

- Clinical outcomes (blood pressure [BP], and body mass index [BMI] or weight)
- Biochemical outcomes (glycosylated haemoglobin [HbA1c], lipid profile and renal function)³
- Psychological outcomes (anxiety, depression, diabetes-related distress, perceived seriousness and vulnerability, self-efficacy and self-care)⁶
- Health-related QoL measures from participant self-report.

The search was limited to studies conducted in Organisation for Economic Co-operation and Development (OECD) member countries and published in English. The search for systematic reviews and meta-analyses was limited to January 2006 to June 2017, and the search for other study types to January 2012 to June 2017. Systematic reviews were excluded if more than 50% of the included studies did not evaluate one of the outcomes of interest.

Search strategy

We performed searches using five electronic databases: Medline, Embase, All EBM Reviews, CINAHL and PsycINFO. For grey literature, we searched websites in the following jurisdictions: UK/Europe (11), Australia/New Zealand (10), US (9), Canada (7), the World Health Organization (1) and the International Diabetes Federation (1). (See supplementary file for further information: figshare.com/s/8d5042a7a401ae2600d0.)

Study selection

To assess study eligibility, one researcher reviewed each systematic review (from title and abstract), and two researchers reviewed the other study types. For selected abstracts, full-text articles were retrieved and reviewed by four researchers (with each article assessed by two researchers). At any stage of review, disagreements were resolved through team discussion.

Data extraction

Four researchers completed data extraction from included studies and entered the data into Microsoft Excel. Two other researchers conducted the grey literature search and extracted and tabulated data into a summary table.

Methodological quality assessment

Six researchers assessed the included articles for methodological quality using standardised scoring tools (with each article assessed by two researchers).^{7,8}

Results

Study selection

From the database search we identified 15 studies that fulfilled our eligibility criteria: one systematic review, four RCTs and 10 cluster RCTs. The grey literature search did not identify any eligible studies. PRISMA flow diagrams are presented in Figures 1 and 2.

Figure 1. PRISMA flow diagram – database search for systematic reviews

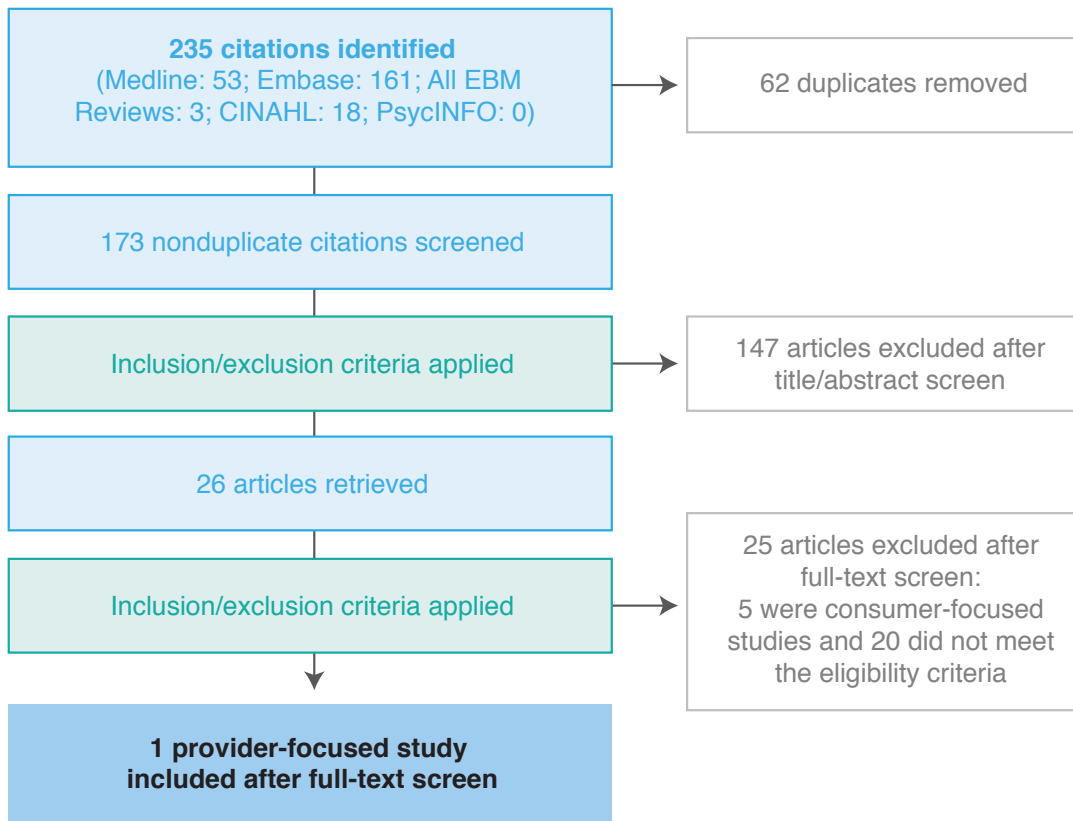
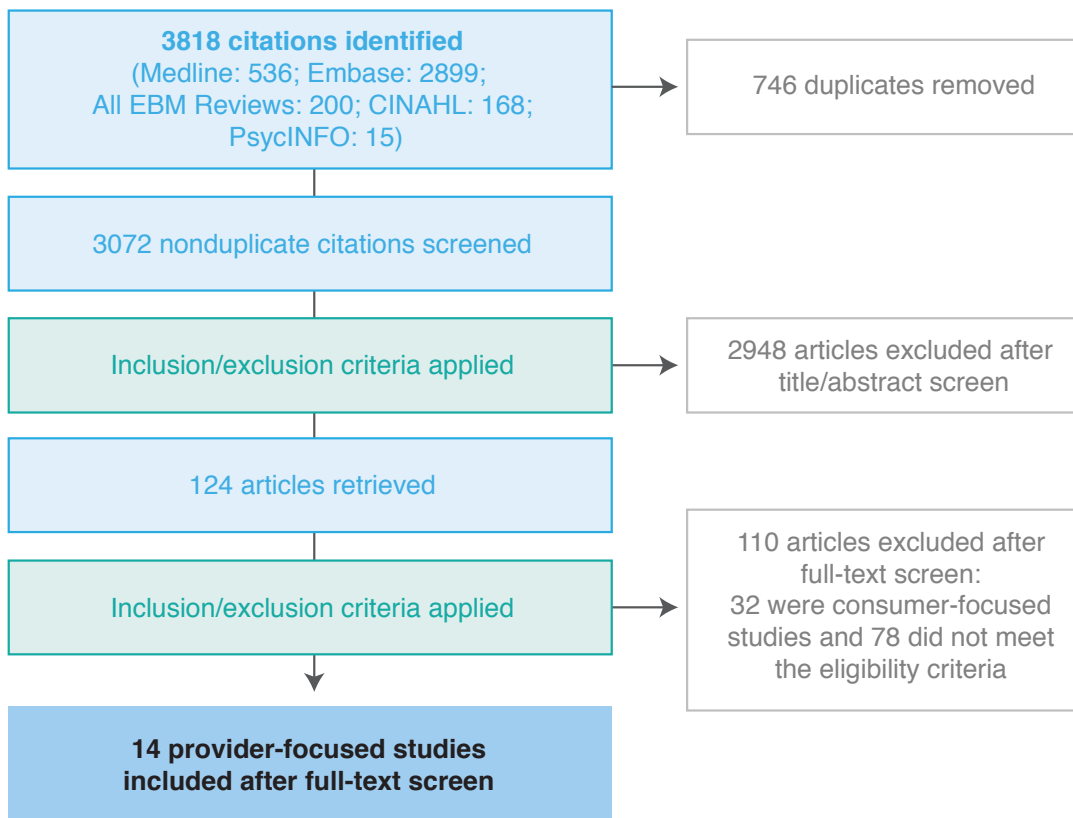


Figure 2. PRISMA flow diagram – database search for randomised controlled trials (RCTs)



Methodological quality assessment

The systematic review was scored highly at 7/11.⁹ Of the four RCTs, two were of strong quality^{10,11}, one was moderate¹² and one was weak.¹³ Of the 10 cluster RCTs, two were of strong quality^{14,15}, five were moderate¹⁶⁻²⁰ and three were weak²¹⁻²³ (Table 1).

Types of interventions identified

We classified the included studies into six categories according to the intervention applied (Table 1): i) computerised decision-support systems (CDSS)^{9,20}; ii) decision aid¹⁶; iii) feedback on quality of diabetes care^{14,17}; iv) culturally tailored programs^{11,12,19}; v) practice nurse involvement^{13,15,18,21-23}; and vi) integrated primary health care and specialist care.¹⁰ More than half the studies included in the systematic review⁹ were conducted in the US. The 14 (RCT) studies were conducted in the US^{11-13,16}, Australia^{19,21,23}, Switzerland²², Japan¹⁷, the UK¹⁰, Europe (multicentre)¹⁴, Denmark¹⁸, the Netherlands¹⁵ and Spain.²⁰ In the systematic review, the randomised patient sample sizes ranged from 62 to 7412, and in the included RCTs from 103 to 4034.

Of the outcomes of interest, all the studies evaluated biochemical outcomes. Ten studies evaluated clinical outcomes^{9-11,13,14,17,19,21-23}, six evaluated psychological outcomes^{12,13,15,18,21,23} and five evaluated health-related QoL outcomes.^{13,15,21-23}

Description of interventions

Computerised decision-support systems

The only systematic review identified, by Cleveringa et al.⁹, reviewed 20 studies that evaluated either CDSS alone or CDSS combined with a reminder system and/or performance feedback and/or case management. They found that CDSS did not lead to improved outcomes unless combined with other interventions.

Saenz et al.²⁰ designed and validated a simple and quick-to-use computer application to help providers make decisions about insulin therapy. The intervention group obtained statistically significant HbA1c reductions compared to the control patients, although a significant proportion of patients did not reach a target HbA1c level of less than 7.0%.

Decision aids

Branda et al.¹⁶ compared decision aids administered to patients for starting statins or choosing antihyperglycaemic agents against usual care, after providing minimal training to the clinicians. The study found no significant impact on patients' biochemical measures.

Feedback on quality of diabetes care

In two cluster RCTs^{14,17}, benchmarking data were collected prospectively and provided to clinicians to inform their treatment planning. In one of these, the feedback group demonstrated a significantly greater HbA1c improvement than the control group.¹⁷

Culturally tailored programs

Three studies evaluated culturally tailored programs that involved intensively trained community health workers, and which were aimed at overcoming linguistic and cultural barriers to providing appropriate/adequate care. McDermott et al.¹⁹ evaluated a case-management approach to the care of Indigenous adults in remote Australia, while studies in the US focused on the Latino population.^{11,12} The Australian study and one of the US studies^{11,19} achieved improved HbA1c levels; the other US study¹² achieved significant improvements in health status, and depression and anxiety symptoms.

Practice nurse involvement

One RCT and five cluster RCTs involved nurses. In Australia²³, a trial involved practice nurses taking on an enhanced role in managing insulin dosing in liaison with general practitioners. The practice nurses, mentored by a diabetes educator, attended a training session of 60–90 minutes. Patients showed improved HbA1c and mental health. Another Australian study²¹ evaluated structured telephone coaching by practice nurses, who received 2 days of training. At follow-up, the effect on biochemical and clinical outcomes did not differ significantly between intervention and control groups.

Frei et al.²² investigated whether a team-based approach including a trained practice nurse would improve patients' cardiovascular risk profiles. The training included a 6-day course that empowered practice nurses for their role in the team. Although no improvement was seen in HbA1c, BP and low-density lipoprotein (LDL) cholesterol did improve.

Gabbay et al.¹³ trained practice nurses in motivational interviewing and behaviour-change counselling. After the intervention, they found systolic BP and depression symptom scores were better among the intervention group compared to the control group. Juul et al.¹⁸ evaluated the effectiveness of nurses undergoing a 16-hour self-determination, theory-based course, which included communication training, delivered over 10 months. The study found no effect on patient HbA1c compared with usual practice, although patients' cholesterol levels did improve. In another study¹⁵, practice nurses attended three 8-hour training sessions, followed by booster sessions, to integrate biopsychosocial self-management support into routine consultations. No significant differences were seen between the intervention and control arms for any outcomes.

Table 1. Summary characteristics of included studies by intervention type

Intervention category	Study (year)	Study type (quality assessment)	Provider type (total providers <i>n</i>)	Total patients (<i>n</i>)	Follow-up (months)	Control	Intervention	Study outcomes ^a		
								Measures	Results (95% CI)	<i>p</i> value ^b
Computerised decision-support systems	Cleveringa et al. (2013) ⁹	Systematic review of 20 studies (7/11)	NSp	62–7412	6–32	Usual care	CDSS only (4 ^c) CDSS in combination with: (i) reminders (5 ^c) (ii) performance feedback (3 ^c) (iii) case management or case management + reminders (2 ^c) (iv) reminders + performance feedback (4 ^c) (v) reminders, performance feedback + case management (2 ^c)	CDSS only ^d : HbA1c (0/3); lipids (0/2); BP (0/2) (in 1 study SBP increased significantly in the intervention arm) CDSS in combination: (i) HbA1c (0/1); LDL-C (0/1); SBP (0/1) (ii) HbA1c (1/2); lipids (0/2); SBP (0/1) (iii) HbA1c (2/2); SBP (1/1) TC (1/1); HDL-C (1/1); percentage achieving HbA1c <7% target Weight (1/1) DBP (0/1) (iv) HbA1c (3/4) SBP (0/3); DBP (0/2); LDL-C (0/2) (v) Composite of HbA1c <7+SBP <130+LDL-C <100mg/dL (2/2) HbA1c (0/1) SBP; DBP; TC; LDL-C; composite of HbA1c <7+SBP <140+LDL-C <2.5 (1/1)		0.009 <0.01 <0.05 <0.001 0.02 0.01 0.002 <0.05
	Saenz et al. (2012) ²⁰	Cluster RCT (moderate)	Primary care physicians (66)	697	18	Usual care	CA offered automated recommendations related to insulin therapy	HbA1c ^e	–0.52	0.01

(continued)

Table 1. Summary characteristics of included studies by intervention type (continued)

Intervention category	Study (year)	Study type (quality assessment)	Provider type (total providers <i>n</i>)	Total patients (<i>n</i>)	Follow-up (months)	Control	Intervention	Study outcomes ^a		
								Measures	Results (95% CI)	<i>p</i> value ^b
Decision aids	Branda et al. (2013) ¹⁶	Cluster RCT (moderate)	Physicians, nurses, physician assistants (NSp)	103	9	Usual care	Clinicians implemented the Diabetes Medication Choice decision aid and usual care statin discussion or the Statin Choice decision aid and usual care for antihyperglycaemic medications discussion	HbA1c; LDL-C		NS
Feedback on quality of diabetes care	Hayashino et al. (2016) ¹⁷	Cluster RCT (moderate)	Primary care physicians (192)	2199	12	Usual care	Physicians received a monthly report on care quality. Patients received reminders for physician visits and lifestyle modifications	HbA1c ^e	-0.14 (-0.26, -0.02)	0.027
								BMI ^e	-0.21 (-0.33, -0.98)	0.002
								SBP; DBP		NS
	Hermans et al. (2013) ¹⁴	Cluster RCT (strong)	Primary care physicians (477)	3996	12	Usual care	Standard care with feedback benchmarked against colleagues	Percentage achieving targets for:		
							SBP	40.0 vs 30.1	<0.001	
							LDL-C	54.3 vs 49.7	0.006	
							HbA1c+SBP+LDL-C	12.5 vs 8.1	<0.001	
							HbA1c		NS	

(continued)

Table 1. Summary characteristics of included studies by intervention type (continued)

Intervention category	Study (year)	Study type (quality assessment)	Provider type (total providers <i>n</i>)	Total patients (<i>n</i>)	Follow-up (months)	Control	Intervention	Study outcomes ^a		
								Measures	Results (95% CI)	<i>p</i> value ^b
Culturally tailored programs	Wagner et al. (2016) ¹²	RCT (moderate)	CHWs (1)	107	3	DE session	In addition to DE, participants attended stress management sessions (a culturally based intervention delivered in Spanish)	PHQ-8 ^f	4.7 vs 6.2	0.002
								PROMIS ^f	1.7 vs 2.0	0.005
								Health status ^f	3.1 vs 3.4	0.023
	McDermott et al. (2015) ¹⁹	Cluster RCT (moderate)	CHWs (6)	213	18	Usual care	Indigenous CHWs recruited as part of PHC teams to help patients make and keep appointments; self-manage condition; and understand medications, nutrition and smoking effects	HbA1c; PAID; SDSCA		NS
								HbA1c ^g	-1.0 (-1.4, -0.5) vs -0.2 (-0.7, 0.2)	0.02
								BP; lipid profile; BMI; renal function		NS
Perez-Escamilla et al. (2015) ¹¹	RCT (strong)	CHWs (2)	211	18	Usual care	Bilingual/bicultural CHWs visited participants weekly at home for culturally and health literacy-tailored education and counselling	HbA1c ^e	-0.51 (-0.83, -0.19)	0.002	
							FPG ^e	-0.08 (-1.78, -0.39)	0.002	
							Lipids; weight; SBP		NS	
Practice nurse involvement	Furler et al. (2017) ²³	Cluster RCT (weak)	General practitioners (162) Practice nurses (103)	266	12	Usual care	'Stepping Up' model of care including an enhanced role for practice nurses in leading discussion with patients about intensifying treatment through insulin initiation and titration. Role of specialist registered nurse reoriented to mentoring the practice nurse rather than providing direct patient care	HbA1c ^h	-0.6 (-0.9, -0.3)	<0.001
								Percentage achieving HbA1c ≤7	OR 2.2 (1.2, 4.3)	0.02
								PHQ-9 ^h	-0.8 (-1.6, -0.01)	0.047
								AQoL-8D ^h (mental health)	0.04 (0.002, 0.08)	0.04
								AQoL-8D (physical health); PAID		NS

(continued)

Table 1. Summary characteristics of included studies by intervention type (continued)

Intervention category	Study (year)	Study type (quality assessment)	Provider type (total providers <i>n</i>)	Total patients (<i>n</i>)	Follow-up (months)	Control	Intervention	Study outcomes ^a		
								Measures	Results (95% CI)	<i>p</i> value ^b
Practice nurse involvement, continued	van Dijk-de Vries et al. (2015) ¹⁵	Cluster RCT (strong)	Practice nurses (40)	264	12	Usual care	Practice nurses trained to integrate detection and follow-up phase of self-management support into daily practice. Training followed by booster sessions	HbA1c; PAID; SF12; self-efficacy		NS
	Frei et al. (2014) ²²	Cluster RCT (weak)	Practice nurses (NSp)	326	12	Usual care	Implementation of CCM elements via a trained practice nurse: organisation of healthcare and delivery system design; clinical information systems (using a monitoring tool); decision support (with guideline-based instructions on the monitoring tool and requiring the availability of a diabetes specialist); and self-management support	SBP ^h	-3.63 (-7.26, 0.00)	0.050
								DBP ^h	-4.01 (-6.23, 11.78)	<0.001
								LDL-C ^h	-0.21 (-0.39, -0.02)	0.033
								HbA1c ^h		NS
	Juil et al. (2014) ¹⁸	Cluster RCT (moderate)	Practice nurses (1–5/each, 40 practices)	4034	18	Usual care	Over 10 months, practice nurses received a 16-hour course which met the SDT-based recommendations on provider behaviour including communication training	TC ^e	0.08 (0.01, 0.15)	0.02
								HbA1c; PAID; SF12		NS
	Gabbay et al. (2013) ¹³	RCT (weak)	Nurse case managers (3)	545	24	Usual care	Bilingual and bicultural nurse case managers received motivational interview training and provided motivational interview-guided behaviour-change counselling. Visits, conducted in language of choice, included review of test results, lifestyle behaviour, medication adherence and complications screening. Referrals made and primary care physicians prompted for medication titrations, when necessary	SBP ^f	131 vs 135	0.045
CES-D ^f								10 vs 14	0.02	
HbA1c; LDL-C; DBP									NS	

(continued)

Table 1. Summary characteristics of included studies by intervention type (continued)

Intervention category	Study (year)	Study type (quality assessment)	Provider type (total providers <i>n</i>)	Total patients (<i>n</i>)	Follow-up (months)	Control	Intervention	Study outcomes ^a		
								Measures	Results (95% CI)	<i>p</i> value ^b
Practice nurse involvement, continued	Blackberry et al. (2013) ²¹	Cluster RCT (weak)	Practice nurses (70)	473	18	Usual care	Practice nurses taught to deliver telephone coaching on self-management, and trained to engage patients through scheduled and structured telephone sessions on lifestyle issues, medication adherence and dosing, self-monitoring, and taking greater initiative in therapeutic alliance with the treating doctor, facilitating appropriate intensification of medications to achieve treatment goals	HbA1c; lipids; renal function; weight; BMI; BP; self-efficacy; AQoL; PHQ-9		NS
Integrated primary health care and specialist care	Basudev et al. (2016) ¹⁰	RCT (strong)	Specialist nurses, diabetologists, general practitioners (NSp)	208	12	Usual care	Exposure to a 'virtual clinic', which included clinical review, assessment of clinical needs and therapy review, management plan formulation, and a follow-up patient consultation to agree on a care plan	SBP ^g	-6 ± 16 vs 2 ± 18	0.008
								HbA1c; DBP; TC; weight; BMI; eGFR		NS

AQoL = Assessment of Quality of Life; BMI = body mass index; BP = blood pressure; CA = computer application; CCM = chronic care model; CDSS = computerised decision-support system; CES-D = Center for Epidemiologic Studies Depression; CHW = community health worker; CI = confidence interval; DBP = diastolic blood pressure; DE = diabetes education; eGFR = estimated glomerular filtration rate; FPG = fasting plasma glucose; HbA1c = glycosylated haemoglobin; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; NS = not significant; NSp = not specified; OR = odds ratio; PAID = Problem Areas in Diabetes; PHQ = Patient Health Questionnaire; PHC = primary health care; PROMIS = Patient-Reported Outcomes Measurement Information System; RCT = randomised controlled trial; SBP = systolic blood pressure; SDSCA = Summary of Diabetes Self-Care Activities; SDT = Self-determination theory; SF = Short Form; TC = total cholesterol

^a Of interest only

^b As reported in papers

^c Number of included studies

^d In parenthesis, numerator indicates studies with significant outcomes out of the total studies reporting that variable

^e Follow-up group difference, mean (with or without 95% CI)

^f Follow-up means (control vs intervention)

^g Baseline and follow-up difference (95% CI or ± SD)

^h Between-group baseline to follow-up difference, mean (95% CI)

Note: Unless specified otherwise, units for each measure are BMI: kg/m²; BP: mmHg; FPG: mmol/L; HbA1c: %; lipids: mmol/L; weight: kg.

Integrated primary health care and specialist care

Basudev et al.¹⁰ evaluated a model of integrated primary health care and specialist care, based on a 'virtual clinic', which was intended to enhance clinical expertise among primary health care providers. The intervention group showed better control of BP than the control group.

Discussion

The shift of T2D clinical care from specialist to primary care requires additional support for primary health care providers to deliver appropriate management. This is especially important in rural regions in which specialised services are less accessible than in urban areas.²⁴ This rapid review evaluated which (if any) interventions targeted at primary health care providers led to positive changes in outcomes in patients with T2D. We identified 15 studies (one systematic review, four RCTs and 10 cluster RCTs) of varying quality with risk of bias identified, which used six different types of interventions. All interventions had mixed impacts on the outcomes of interest, except the one study testing a decision aid, which did not result in any improvement.

Our study identified mixed evidence for improved outcomes in response to interventions provided in primary care involving CDSS, feedback on performance, enhanced roles for practice nurses, integrated care and culturally tailored programs.

Feedback on performance and CDSS could be readily applied in the Australian context, given the high level of computerisation and the existence of evidence-based guidelines for diabetes management in primary health care.^{3,25} However, this is hampered by poor connectivity with specialist services and concern about potential distortions caused by performance-based funding mechanisms.²⁶ The development of the Australian Government's My Health Record initiative and shared electronic systems for care planning provide opportunities for these types of interventions to be more widely and systematically implemented.²⁷

Greater practice nurse involvement in diabetes care is consistent with how practice nurse roles are currently construed and defined. However, involvement of practice nurses is hindered by a number of factors, including general practitioners' negative attitudes towards practice nurses having a greater role in patient management, competing demands on nurse time, lack of space and restrictive practice nurse job descriptions.^{28,29} There is also a need for continuing professional development of practice nurses, especially in dietary assessment and advice, and intensification of medication management.^{23,30} However, the six studies we identified in which practice nurses had an enhanced role in T2D management and received specific training showed mixed results, with improvements in some but not all parameters.

Australia is culturally diverse, yet many ethnic groups experience socio-economic disadvantage and higher

levels of health risk.³¹ Aboriginal and Torres Strait Islander Australians in particular experience high rates of T2D.² The culturally tailored programs that we reviewed involved community health workers, who have well-established roles in diabetes care overseas, delivering education or self-management support. In Australia, Aboriginal health workers have increasing roles in supporting chronic disease self-management³²; however, community health workers have not been systematically involved in the primary care of other culturally and linguistically diverse groups. While consistent with the objectives of the Australian National Diabetes Strategy 2016–2020, the involvement of community health workers is not specifically mentioned in the strategy.³³ The widespread adoption of a community health worker role in diabetes care in Australia requires clear policy direction to overcome professional barriers. It also requires investment and implementation by Local Health Networks, Primary Health Networks and nongovernment organisations.

Limitations

This review identified only six types of interventions. Other interventions might exist but were not included according to the selection criteria. The results on the effectiveness of interventions might also change when trialled in different settings and with different population groups for longer periods of time. Furthermore, we were interested in surrogate outcomes and hence did not identify long-term clinical outcomes such as development of cardiovascular disease.

Conclusions

We found evidence that computerised decision support, culturally tailored programs, feedback on diabetes care quality, and practice nurse involvement have the potential to exert a positive influence on some biochemical, clinical, psychological and health-related QoL outcomes in patients with T2D. One study involving an intervention that aimed to integrate primary health care and specialist care showed some evidence of improvement in patients' blood pressure, but not other outcomes.

Of the various effective provider-focused interventions we identified, some are already part of the current Australian primary health care environment – for example, the provision of feedback to general practitioners on quality of diabetes care, and the role of practice nurses in diabetes care. The challenge, however, is to make these interventions more widely available and improve their uptake. Evidence-based interventions that are yet to be broadly adopted include culturally tailored programs involving community health workers that target immigrant populations, and diabetes decision support incorporated into practice software. For these interventions, research is needed to further evaluate their applicability, feasibility and sustainability in the Australian context.

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Peer review and provenance

Externally peer reviewed, not commissioned.

Competing interests

MH is a board member of the Central and Eastern Sydney Primary Health Network.

Author contributions

NF and LT were responsible for the design of the review, analysis of data and drafting and editing of the manuscript. SP contributed to the design, study review and manuscript editing. BH-R contributed to the design, analysis of data, study review and manuscript editing. JT and CS contributed to the design and were responsible for study review and manuscript editing. VW provided clinical advice and reviewed and edited the manuscript. MH was responsible for the design of the review, interpretation of findings and drafting and editing of the manuscript.

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