

The clinical effectiveness of nursing models of diabetes care: A synthesis of the evidence

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ABSTRACT

Objectives: To determine the clinical effectiveness (glycemic control, other biological measures, cost-effectiveness and patient satisfaction) of primary care nurse-led interventions for diabetes.

Design: A systematic review following methods described for complex interventions and using PRISMA guidelines for reporting was undertaken. Nurse-led care for diabetes can be regarded as a complex intervention requiring the measurement of more than one outcome and for this reason we chose a range of outcomes clinical (symptoms), patient-centred (experiences) and organisational (cost-effectiveness). **Data sources:** An extensive literature search using MEDLINE (PubMed) EMBASE, and CINAHL was conducted.

Review methods: Primary studies with adults in primary care with both quantitative (comparison with physician-led care and cost-effectiveness) and qualitative (patient experiences of nurse-led care) methodologies from 2003 until June 2018. All studies were appraised using the Cochrane Collaboration's tool for assessing risk of bias. The appraisal involved evaluation of the degree of risk of bias in selection, performance, detection, attrition and reporting. Because of the complexity of multiple outcomes (quantitative and qualitative) a narrative synthesis was undertaken.

Results: The search generated 18 published studies that met our eligibility criteria. Three randomized controlled trials and one historical control trial found statistically significant differences in glycemic levels in favour of the nurse-led interventions. Two cluster randomized trials, two randomized pragmatic trials and two randomized controlled trials found no differences between groups. The three open-label studies found statistically significant improvements in HbA1c levels. The audit identified that more patients had lower HbA1c levels after the initiation of a nurse-led intervention. Three randomized controlled trials found significant improvements in biological outcomes and one did not. The four studies measuring cost-effectiveness found the nurse-led intervention was associated with less costs. Four studies examined patient satisfaction with nurse-led care and found this was very good.

Conclusion: This review which incorporated a broad range of studies to capture the complexity of nurse-led interventions has identified that there is evolving evidence that nurse-led interventions for community treatment of diabetes may be more clinically effective than usual physician-led care.

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What is already known about the topic?

- Diabetes is a worldwide problem with rapidly growing prevalence rates.
- Most people with diabetes are cared for in traditional primary care settings and many have sub-optimal glycemic control.

- A core aspect of the nursing role in diabetes care is the promotion of self-management which may differ from a physician-led model of diabetes care that has more of a disease-management focus.

What this paper adds

- There is developing evidence from well-designed trials that nurse-led models may be more clinically effective than usual care in improving HbA1c and other biological outcomes.

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- Nurse-led care has good patient satisfaction and is more cost-effective than traditional physician-led models.

1. Introduction

The global prevalence of diabetes has nearly doubled since 1980, rising from 4.7%–8.5% in the adult population (World Health Organisation, 2016, p. 8). Recommended treatment involves diabetes self-management education and support; promotion of healthy eating patterns and physical activity; smoking cessation; psychosocial evaluation; and establishing glycemic, blood pressure and lipid targets (American Diabetes Association, 2016; Ministry of Health, 2015; National Institute for Health and Care Excellence, 2015). Most people with diabetes receive physician-led care in primary care and many have poor glycemic control (American Diabetes Association, 2016). It has been identified that this poor control is related to the costly and time-intensive needs of these patients and high general practitioner patient loads, clinical inertia (i.e., the failure to initiate, change, or intensify treatment therapy), patient diversity, cultural and language differences, racial insensitivity, lack of treatment protocols, and complex and difficult-to-follow algorithms (King and Wolfe, 2009; Richardson et al., 2014). As diabetes has become increasingly prevalent, proportionally more care is being delivered and managed by nurses in primary care, although not in as large numbers as previously expected (15–50%) (Murrells et al., 2015).

A core aspect of the nursing role is the promotion of self-management which may differ from a physician-led model of diabetes care that has more of a disease-management focus. A Cochrane review of the effectiveness of specialist diabetes nurses in comparison to usual care found that glycated haemoglobin (HbA1c) was not significantly different than usual care and while there was some evidence of improvement at six months this was not sustained at 12 months (Loveman et al., 2003).

The focus in this review is on clinical effectiveness rather than clinical efficacy because nurse-led interventions are real world interventions that occur in everyday clinical settings and involve a combination of behavioural and biological approaches.

The primary clinical outcome for evaluating the effectiveness of diabetes treatment is measurement of haemoglobin A1c or the glycated haemoglobin test (HbA1c) that identify the three-month average plasma glucose concentration.

2. Background

A cross-national study (Nicolucci et al., 2013) identified that most people with diabetes experience it as a significant physical and psychological burden. They found that although they found their healthcare teams to be supportive, many indicated that key aspects of their care had not been discussed, such as anxieties and diet; insufficient attention had been paid to psychological aspects of living with diabetes and the potential for individuals to take an active role in self-management; and only half had received education about diabetes and its management.

They found the role of nurses providing specialist diabetes care involved education, counselling and disease management (including medication management). Other reviews have supported the effectiveness of nurse-led care on HbA1c (Welch et al., 2010) and cardiovascular risk factors (Clark et al., 2011; Tshiananga et al., 2012). While the evidence is mixed it has been suggested that primary care could release significant resources with no adverse effect by switching their services to nurse-led care (Murrells et al., 2015).

This review aims to examine the evidence (quantitative and qualitative) since 2003 of the clinical effectiveness of nurse-led diabetes care across a range of outcomes (glycemic control, other

biological measures, cost-effectiveness and patient satisfaction). The focus is on clinical effectiveness rather than simply clinical efficacy of the nurse-led interventions because nurse-led interventions are real-world interventions in everyday clinical settings that involve a combination of behavioural and biological approaches. It is important therefore, to evaluate the clinical effectiveness (the combination of improved biological outcomes, patient satisfaction, and cost-effectiveness) rather than just clinical efficacy (statistical significance of one component e.g., HbA1c) because nurse-led interventions are complex interventions. As described by Craig et al. (2008) complex interventions have a number of interacting components with a range of effects. Because they often take place in everyday practice the nurse-led intervention may be tailored to individual needs rather than be a standardised protocol.

The objective is to build on previous quantitative evidence from a Cochrane review (Loveman et al., 2003) by also including qualitative research, in order to establish if there is still a case for nurse-led diabetes care despite the relatively low numbers in these roles and some resistance from some primary care physicians.

3. Methods

The systematic review method used reflects the discussion of how to review studies of complex interventions provided by Petticrew et al. (2015). They suggest that it may be helpful to start by formulating the issues of complexity as specific research questions and then move on toward identifying what type of evidence of complexity will be sought to answer them. This evaluation of studies into the effectiveness of nurse-led care identified the complexities related to a range of interventions that nurses could provide: diabetes education, self-management education, lifestyle education (diet and exercise), monitoring of glucose, blood pressure and lipid levels, behavioural and psychological interventions; which were tailored to individual need. The review question needed to be broader than measurement of outcomes for one intervention and therefore it was decided to evaluate a range of outcomes: clinical (symptoms), patient-centred (experiences) and organisational (cost-effectiveness).

3.1. Review question

Is nurse-led primary care for diabetes clinically effective (improvements in glycemic and other biological measures, patient satisfaction and cost-effectiveness) for community-dwelling adults?

3.2. Eligibility criteria

See Table 1 for eligibility criteria.

3.3. Search method

Three databases (CINAHL, EMBASE and Ovid Medline) were searched using the following search terms (nursing care OR nursing role OR models OR nursing theory OR nursing models of care OR model specialties) AND (diabetes OR type 2 diabetes OR NIDDM OR non-insulin diabetes) AND (adult). Reference lists of papers identified by the on-line search were manually searched.

3.4. Assessment of relevance for inclusion

Two reviewers independently screened the abstracts of titles identified by the search strategy. The full papers of those abstracts that focused on nursing models of care for the management of patients with diabetes were then reviewed in relation to the

Table 1
Eligibility criteria.

Inclusion	Exclusion
Primary qualitative and quantitative research from peer reviewed journals	Grey literature, opinion pieces, primary research not peer reviewed
Quantitative studies that compared usual care/physician-led care with nurse-led care.	Studies that include adolescents
Focus on community /primary care settings	Languages other than English
Glycemic control, biological measures, cost-effectiveness or patient satisfaction outcomes reported in quantitative studies	Studies undertaken in secondary or tertiary care
Qualitative studies examining patient experiences of nurse-led care	Pilot/feasibility studies
From 2003 – June 2018	Studies in which the model of care is not described
Adults over 18 years	Studies in which nurses deliver care in physician-led models

inclusion and exclusion criteria. The two reviewers discussed and came to consensus on those papers that should be included.

3.5. Search outcome

The abstracts of all studies identified by the search strategies ($n = 254$) and manual searching ($n = 12$) were examined. There was a total of 262 papers following removal of duplicates. Two reviewers working independently screened the abstracts in relation to the inclusion and exclusion criteria. Seventy-one full texts were then read and assessed in relation to eligibility criteria. Fifty-three studies were excluded. Two reviewers independently conducted the quality appraisal. Eighteen papers were included in the review (see Fig. 1 for flow diagram).

3.6. Quality appraisal

All studies were appraised using the Cochrane Collaboration's tool for assessing risk of bias (Higgins et al., 2011). The appraisal involved evaluation of the degree of risk of bias in selection, performance, detection, attrition and reporting (see Table 2). Two reviewers worked independently to make decisions on the papers in relation to each criterion.

3.7. Data extraction and synthesis

Descriptive data were extracted from each study in relation to: Country, sample size, aim, method and findings, characteristics of the model and control intervention. Because of the complexity of

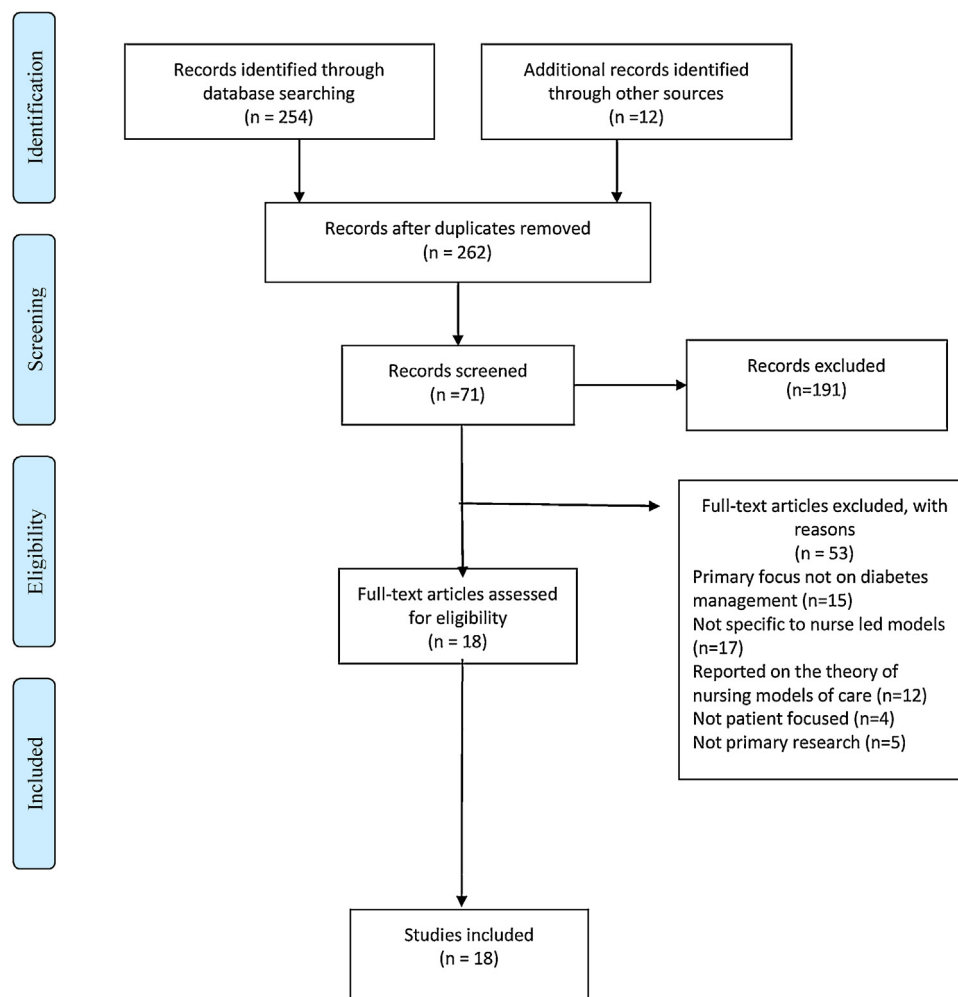


Fig. 1. PRISMA flow diagram.

Table 2
Risk of bias.

Author	Selection	Performance	Detection	Attrition	Reporting	Overall	Comments
Biernacki et al. (2015) Open label	Unclear	High	High	Low	Low	High	Open label design
Blackberry et al. (2013) Cluster randomized controlled	Low	High	Low	Low	Low	Low	Authors state: The intensity and fidelity of the intervention was compromised.
Moreno and Andrade (2005) Randomized pragmatic	Low	High	Unclear	Unclear	Unclear	High	Not controlled Some potential risks of bias not reported
Chan et al. (2006) Open label	Low	High	High	Unclear	Low	Unclear	Open label design
Denver et al. (2003) RCT	Low	High	Unclear	Low	Low	Low	Patients knew if receiving intervention. Not clear who conducted follow-up measurements
Edelman et al. (2015) RCT	Low	High	Low	Low	Low	Low	Patients knew which intervention they received.
Edwall et al. (2008) Qualitative	N/A	N/A	N/A	N/A	N/A	High	Qualitative study
Harris and Cracknell (2005) Historical control cohort study	Unclear/low	Low	Low	Low	Low	Low	Although historical control used all recruitment and measures the same.
Hiss et al. (2007) RCT	Unclear	High	Unclear	Low	Low	Unclear	Randomization and blind measurement not clear
Houweling et al. (2011) Randomized pragmatic trial	Unclear	Unclear	Unclear	Low	Low	Unclear/high	Aspects of study not reported e.g., process of randomization, blind measurement and blind to intervention.
Jansink et al. (2013) Cluster randomized trial	Low	Unclear	Low	Low	Low	Low	
Juul et al. (2012) Audit	N/A	N/A	N/A	N/A	N/A	N/A	Not a trial design. Possibility of bias across all domains.
Kuo et al. (2015) Retrospective cohort study	Unclear	Low	Low	Low	Low	Low	Matched groups based on prevalence rates
Moran et al. (2011) Open label	Unclear	High	High	Unclear	Unclear	High	Open label design
Odnoletkova et al. (2016a) RCT	Unclear	Unclear	Low	Low	Low	Low	Process of randomization unclear
Shea et al. (2006) RCT	High	Unclear	Low	Low	Low	Low	Cluster randomization according to practices
Stenner et al. (2011) Qualitative	N/A	N/A	N/A	N/A	N/A	High	Qualitative
Taylor et al. (2003) RCT	Low	Unclear	Low	Low	Low	Low	Not clear if patients were aware

multiple outcomes (quantitative and qualitative) a narrative synthesis of the findings will be undertaken as suggested by [Thomas et al. \(2004\)](#) and [Petticrew et al. \(2015\)](#). The synthesis involved narrative aggregation of outcomes from all studies.

4. Results

There were 18 published studies that met inclusion criteria for the review. The studies were conducted in USA (n = 7), UK (n = 3), Netherlands (n = 2) and one each from Australia, Belgium, Hong Kong, Brazil, Sweden and Denmark. There was a total of 33,971 participants across the studies with both Type-1 and Type-2 diabetes. The sample sizes ranged from 20 – 14,811 (median 170). There were 10 controlled clinical trials (including six randomised controlled trials, two trials with a historical control and two cluster randomized trial), two randomized pragmatic trials, three open-label designs, two qualitative studies, and one audit (See [Table 3](#)).

One study published secondary outcome data related to cost-effectiveness ([Odnoletkova et al., 2016b](#)). In the quantitative studies HbA1c levels were the primary outcome measurement in 12 studies; cardio-vascular measures in two and cost effectiveness in one, however all measured HbA1c. The follow-up points were varied (12 weeks – 120 weeks). The qualitative studies evaluated the participants' experiences of the nurse-led intervention. Although all studies examined nurse-led diabetes care, the models of care delivery differed.

The risk of bias was low in nine studies [Blackberry et al. \(2013\)](#); [Denver et al. \(2003\)](#); [Edelman et al. \(2015\)](#); [Harris and Cracknell \(2005\)](#); [Jansink et al. \(2013\)](#); [Kuo et al. \(2015\)](#); [Odnoletkova et al. \(2016a\)](#); [Shea et al. \(2006\)](#); [Taylor et al. \(2003\)](#) although none of these studies had no risk of bias. This was mainly due to performance risk in that it is difficult to blind patients to which intervention they are receiving when there is a usual care control intervention (see [Table 2](#)). All of the randomized controlled trials had usual physician-led control interventions apart from one study that provided a generic health information intervention ([Edelman et al., 2015](#)).

4.1. Models of nurse-led care delivery

All models differed in the design of the nurse-led intervention and some interventions were usual nurse practitioner care (n = 3). Apart from nurse practitioners, the training provided for nurses was not specified although one study described them as 'trained diabetes nurses' ([Chan et al., 2006](#)), another as 'RN certified diabetes educator' ([Moran et al., 2011](#)) and another as a 'diabetes nurse specialist' ([Edwall et al., 2008](#)). The other nurses were described as practice nurses (n = 4), nurse care/ case managers (n = 4) and a number of other titles (see [Table 4](#)). The specifically designed interventions which focused on self-management education were between 3 and 30 months duration. The frequency

Table 3
Data extraction.

Author	Country	N	Aim	Method	Findings
Biernacki et al. (2015)	USA	937	Implement and evaluate a care delivery model and evaluate changes in diabetes mellitus quality indicators	Open-label	Positive statistically significant differences in pre and post scores for A1c ($p = .001$). Significant change in systolic BP ($p = .08$). Patient satisfaction very good for education, responsiveness, better control
Blackberry et al. (2013)	Australia	473	To evaluate the effectiveness of goal focused telephone coaching by practice nurses (trained in a telephone coaching programme) in improving glycemic control in patients with type 2 diabetes	Cluster-randomized Control usual care	At 18 months follow up the effect on glycemic control did not differ significantly between the intervention and control groups adjusted for HbA1c (mean difference 0.02). There were no significant differences in lipids, renal function, blood pressure and body mass index.
Moreno and Andrade (2005)	Brazil	80	Effect on HbA1c levels over 12 months	Randomized pragmatic trial Control usual care	Intervention significantly reduced HbA1c levels at 6 and 12 months but while intervention showed improvement over TAU not significant
Chan et al. (2006)	Hong Kong	150	Effectiveness of clinic in controlling poor glycemia in older patients over 12 weeks	Open-label	Significant drop in HbA1c ($p < 0.001$) but no significant differences in blood pressure and body weight.
Denver et al. (2003)	UK	120	To compare effectiveness of a nurse-led hypertension clinic with usual care in management of uncontrolled hypertension in patients with T2D.	RCT Control usual care	Nurse-led hypertension clinic more effective in reaching target systolic blood pressure over 6 months. Systolic and diastolic BP fell in both groups. Fall in diastolic BP similar in both groups but fall in systolic BP significantly greater in nurse-led intervention.
Edelman et al. (2015)	USA	377	To assess the effectiveness of nurse behavioral management of Diabetes mellitus and hypertension in community practices among patients with both diseases	RCT Control generic health information	Mean A1c were similar between arms at the primary endpoint of 24 months. Similarly, no difference between arms in mean A1c at 6 or 12 months was noted. There were no significant differences in blood pressure.
Edwall et al. (2008)	Sweden	20	Patients' experiences of diabetes nurse specialist care	Qualitative	Patient-centred needs-focused. Provided guidance and education. Enabled confidence and independence.
Harris and Cracknell (2005)	UK	170	To see if re-organizing diabetes care and introducing a nurse-led clinic would improve parameters of care for patients with diabetes	Historical control Control usual care	18% improvement in patients with HbA1c $< 7.4\%$ (inclusive) $p < 0.05$. 27% improvement in blood pressure.
Hiss et al. (2007)	USA	220	To demonstrate potential value of nurse case manager	RCT Control usual care	Significant improvement in A1C and mean systolic blood pressure if received > 2 nurse visits.
Houweling et al. (2011)	Netherlands	230	To determine if transfer of management of T2D to nurses in primary care is effective	Randomized pragmatic trial Control usual care	No significant differences between groups on HbA1c, blood pressure and lipids Patients more satisfied with nurse-led care.
Jansink et al. (2013)	Netherlands	940	To determine effectiveness of nurse-led comprehensive diabetes programme in general practice	Cluster randomized controlled trial Control usual care	Active participation in intervention was no more effective than usual care in relation to HbA1c levels, diet and physical activity.
Juul et al. (2012)	Denmark	12,960	Assess whether involvement of general practice nurses in type 2 diabetes care is associated with improved adherence to national guidelines on regular type 2 diabetes monitoring and with lower HbA1c and cholesterol	Audit	In practices with well implemented nurse led type 2 diabetes consultations mean proportion of measurement of HbA1c was 74.8% versus 68.3% in practices with no nurses employed.

Table 3 (Continued)

Author	Country	N	Aim	Method	Findings
			levels in type 2 diabetes population		Proportion of patients with HbA1c >8% also differed by 3.7%.
Kuo et al. (2015)	USA	14,811	To compare cost of care for older adults cared for by Nurse Practitioners vs primary care physicians	Retrospective cohort study Control physician-led care	Both groups had a similar number of visits but the costs for primary care service and inpatient care were significantly lower in those receiving care from Nurse Practitioners
Moreira et al. (2015)	USA	34	To implement and evaluate a nurse-led care delivery model to assist in achieving positive clinical and cost outcomes in diabetes care	Open label	Significant improvements in A1c between pre and post test. Patient program satisfaction scores ranged from 4.38 to 10 with mean of 9.34 + 1.18. Study showed potential revenue-generating opportunities with efficiency revenue generated from provider time saved.
Odnoletkova et al. (2016a)	Belgium	574	a) To examine effect of intervention on HbA1c	RCT	a. Significant improvement in HbA1c levels within nurse-led intervention.
			b) To examine the life-long cost-effectiveness of a nurse-led tele-coaching programme compared to usual care in people with T2D.	Control usual care	b. Significant improvements in total cholesterol and BMI. c. The results suggest that the intervention had potential to be highly cost-effective particularly in the sub-group of participants who had poor glycemic control at baseline.
Shea et al. (2006)	USA	1,665	Hypothesis was that IDEATel intervention would improve haemoglobin A1c, blood pressure, and lipid levels compared to usual care.	RCT	There were significant improvements in HbA1c, blood pressure and lipids in favour of the nurse-led group.
				Control usual care	
Stenner et al. (2011)	UK	41	To explore the views patients with diabetes have about their consultations with nurse prescribers and any impact this may have on their medication management	Qualitative study	Key aspects of nurse consultation style = non-hurried approach, care and rapport, approachability, continuity, and providing clear information based on specialist knowledge. Benefits described: improved access to appropriate advice and medication, greater understanding and ability to self-manage, ability to address problems and improved confidence, trust and wellbeing.
Taylor et al. (2003)	USA	169	Evaluate the efficacy of a nurse-care management system designed to improve outcomes in patients with complicated diabetes.	RCT Control usual care	Significant improvement in A1c levels in intervention group ($p < 0.03$). At year 1 mean reductions in HbA1c, total cholesterol, and LDL cholesterol were significantly greater for the intervention group compared with usual care. Significantly more patients in the intervention group met the goals of HbA1c ($< 7.5\%$) than patients in usual care (42.6 vs 24.6%, $p < 0.03$.)

was highly variable. Most were delivered face-to-face ($n = 10$) some were delivered in a combination of face-to-face and phone ($n = 5$); phone only ($n = 2$) and online ($n = 1$). Most had individual components and four incorporated group components (See Table 4).

4.2. Glycemic control outcomes

Three randomized controlled trials (Odnoletkova et al., 2016a; Shea et al., 2006; Taylor et al., 2003) and one historical control trial (Harris and Cracknell, 2005) found statistically significant

Table 4
Characteristics of nurse-led interventions.

Author	Content	Nurse type	Duration	Frequency	Mode
Biernacki et al. (2015)	Patient education (the disease process, diet and weight management, medication regime, and self-management skills) and referral to community support.	RN	6 months	One individual visit at baseline, group education and email support	Face-to-face and email
Blackberry et al. (2013)	Patient Engagement and Coaching for Health (PEACH) program. Self-management education.	Practice Nurse	18 months	5 telephone coaching sessions at intervals of 6 weeks in the first 6 months, telephone coaching sessions at months 8 and 10, a face to face coaching session at 12 months, and a final telephone coaching session at 15 months.	One face-to-face and 8 phone calls
Moreira et al.(2015)	Primary care case management with home visits and one-hour appointments over 12-month period. Teach patients self-care and monitoring.	RN (nursing case manager)	12 months	Monthly home visits and phone support	Face-to-face and phone
Chan et al. (2006)	Nurse-led clinic providing monitoring of home blood sugar results and medication, diet and exercise education. 30-minute appointment per month with fortnightly phone calls.	Trained diabetes nurse	12 weeks	Monthly 30-minute appointment. Two-weekly phone calls.	Face-to-face and phone
Denver et al. (2003)	Blood pressure measurement and discussion of medication adherence. Healthy living education.	Hypertension nurse	6 months	Monthly for 3 months then every 6 weeks for 3 months	Face-to-face
Edelman et al. (2015)	Tailored telephone-delivered behavioral nurse intervention	RN	2 years	Phone call every 2 months	Phone
Edwall et al. (2008)	Nurse-led primary care clinic	Diabetes nurse specialist	1 year	1-6 check-ups	Face-to-face
Harris and Cracknell (2005)	Intensive treatment for those with poor glycemic control	Practice nurse	30 months	Dependent on HbA1c levels	Face-to-face
Hiss et al. (2007)	Individual counselling, problem identification, care planning and management recommendations	Nurse care manager	6 months	Mean 5.8 face-to-face contacts and 1 phone call	Face-to-face and phone
Houweling et al. (2011)	Nurses had prescribing rights and treated glucose levels, BP and lipids according to a protocol.	Nurse practitioner	14 months	Unclear	Face-to-face
Juul et al. (2012)	Usual nurse led consultation in primary practice (blood tests, blood pressure measurement and a conversation about living with type 2 diabetes).	Practice nurse	2 months	Unclear	Face-to-face
Jansink et al. (2013)	Lifestyle counselling based on motivational interviewing	Primary care nurse	14 months	Integrated into usual care. Frequency unclear	Face-to-face
Kuo et al. (2015)	Usual nurse practitioner care	Nurse practitioner	12 months	9 visits	Face-to-face
Moran et al. (2011)	Nurse-led self-management sessions	RN (certified diabetes educator)	4 months	4 x monthly group sessions	Face-to-face
Odnoletkova et al. (2016a)	COACH programme. Bridging the knowledge gap, assertiveness training, setting an action plan and reassessment.	RN	6 months	5 x phone calls mean duration 30 minutes delivered at a mean interval of 5 weeks.	Phone
Shea et al. (2006)	Biometric glucose monitoring, on-line consultation and access to on-line education.	Nurse case manager	12 months	Unclear	On-line
Stenner et al. (2011)	Usual nurse practitioner care	Nurse practitioner	Data collected over one year	Unclear	Face-to-face
Taylor et al. (2003)	Patients met with a nurse-care manager to establish individual outcome goals with focus on self-care	Nurse case manager	44 weeks	One initial goal-setting appointment, 4 x weekly group sessions and 8 x follow-up phone calls	Face-to-face and phone

improvements in HbA1c in favour of the nurse-led interventions. Two cluster randomized trials (Blackberry et al., 2013; Jansink et al., 2013), two randomized pragmatic trials (Houweling et al., 2011; Juul et al., 2012) and three randomized controlled trials (Denver et al., 2003; Edelman et al., 2015; Hiss et al., 2007) found no significant differences between groups.

The nurse-led telecoaching intervention (Odnoletkova et al., 2016a) recruited 287 patients with type-2 diabetes to that intervention and 287 to usual care. All patients were receiving hypoglycemic agents and at baseline the median age was 64 years, there were 62% male and the average time since diagnosis was seven years. The mean baseline HbA1c was 7.0. The intervention was the COACH programme which is a structured telephone and mail-out programme. Support is provided for nutrition, weight, physical activity, blood glucose levels, blood pressure and cholesterol once a month for six months. After six months intervention or usual care those receiving the intervention had a mean HbA1c of 6.8% and the usual care group was unchanged, and at 18 months the intervention group had a level of 6.9% and the usual care 7.0%. The statistically significant difference was $p = 0.003$ at six months and $p = 0.046$ at 18 months. A sub-group analysis of patients with elevated HbA1c levels at baseline (mean 7.9%) found that this group had a mean drop to 7.4% in the intervention group and 7.8% in the control group at six months ($p = 0.001$) and this was maintained in the intervention group at 18 months while the usual care group had a level of 7.7% ($p = 0.023$).

The telemedicine case management intervention (Shea et al., 2006) recruited 1705 patients. The intervention groups received a home telemedicine unit that provided video conferencing with nurse case managers, remote monitoring of glucose, access to clinical data and secure messaging and access to an educational website. The patients in control group received usual care. The mean age at baseline was 71 years and 69.5% were female. At one-year HbA1c decreased from 7.35% to 6.97% in the intervention group ($p = 0.006$). The cost of the unit was \$US3,535 in 2006.

The nurse-care management system (Taylor et al., 2003) recruited 341 patients. The intervention group consisted of a 90-minute individual appointment, group class (1–2 h) for four weeks and nine 15-minute follow-up phone calls. The emphasis of the intervention was a self-management plan which was developed in the individual appointment. The control group received usual care. At baseline the mean age was 54.8 years and 55.3% were male. The mean HbA1c at baseline was 9.5%. Mean changes in HbA1c at 44 weeks were -1.14% in the intervention group and -0.35% in the usual care group ($p = 0.01$).

A weekly nurse-led clinic that recruited 86 patients was compared to a historical twice-yearly physician-led clinic of 68 patients (Harris and Cracknell, 2005). In the nurse-led clinic each patient had a self-management plan. The establishment of the nurse-led clinic saw an 18% increase in patients with HbA1c levels $<7.4\%$ ($p < 0.05$).

The three open-label studies which were all nurse-led self-management interventions found statistically significant improvements in HbA1c levels (Biernacki et al., 2015; Chan et al., 2006; Moran et al., 2011; Vrijhoef et al., 2002). The audit identified that following implementation of a nurse-led model more HbA1c levels were measured according to national guidelines and more patients had lower HbA1c levels (Juul et al., 2012).

4.3. Other biological outcomes

Three randomized controlled trials found significant improvements: Hiss et al. (2007) found improvements in blood pressure for those patients who received more than two nurse visits; Odnoletkova et al. (2016a) found decreases in total cholesterol and body mass index; and Denver et al. (2003) found significant improvements in blood pressure. One randomized controlled trial

found no significant improvements in blood pressure and lipids (Houweling et al., 2011). In the open label studies Biernacki et al. (2015) found significant improvement in blood pressure and Chan et al. (2006) found no significant improvement in blood pressure or body weight. The historical control study (Harris and Cracknell, 2005) found a 27% decrease in blood pressure measurement.

4.4. Cost effectiveness

Four studies reported results on the cost effectiveness of the nurse-led model. One randomized controlled trial found that the intervention had the potential to be highly cost-effective particularly in the sub-group of participants who had poor glycemic control at baseline (Odnoletkova et al., 2016b). Chan et al. (2006) found that there were significant differences in health care service utilization at 12 weeks in favour of the nurse-led non-prescribing model. Moran et al. (2011) found a benefit based on programme costs, performance incentives, revenue, provider time saved and patient health care utilization in favour of the nurse-led non-prescribing model. Kuo et al. (2015) found that while both groups had a similar number of visits the costs were less for the nurse-led group.

4.5. Patient satisfaction with nurse-led models

Four studies investigated patient satisfaction with the nurse-led care they received. Biernacki et al. (2015) found that the majority of patients felt their diabetes was better controlled due to the education from nurses. Houweling et al. (2011) found that patients were more satisfied with the nurse-led care than their usual care. In the two qualitative studies Stenner et al. (2011) identified that patients were very satisfied with the provision of health-related knowledge that nurses provided, and it was this knowledge which helped control their health problems; and Edwall et al. (2008) found that patient satisfaction with the nurse-led model was related to a patient-centred focus, the guidance and education provided and the development of confidence and independence.

5. Discussion

At the time of Loveman et al.'s (2003) review there was no evidence from the trials available, that nurse-led models of diabetes care were significantly more effective than usual physician-led care. This review which incorporated a broader range of studies to attempt to capture the complexity of the intervention, has identified that there is evolving evidence that nurse-led interventions for community treatment of diabetes may be more clinically effective than usual physician-led care. Three of the six randomized controlled trials found statistically significant differences in HbA1c levels between the nurse-led intervention and usual care in both the short-term (six months) and longer term (18 months) and all had low risk of bias (Odnoletkova et al., 2016a; Shea et al., 2006; Taylor et al., 2003). Three randomized controlled trials found statistically significant improvements in other biological outcomes and two of these had low risk of bias (Denver et al., 2003.; Odnoletkova et al., 2016a).

The cost-effectiveness of nurse-led interventions was demonstrated in four trials but only two of these had low risk of bias (Kuo et al., 2015; Odnoletkova et al., 2016a). Only one study examining patient satisfaction had low risk of bias (Edelman et al., 2015). All the open-label trials that identified significant improvements in nurse-led care were a high risk of bias. The interventions in the studies that found a significant difference in favour of the nurse-led interventions were all more intensive than the control interventions that mostly involved usual care.

The interventions that had a low risk of bias and demonstrated statistically significant improvements were a mixture of modes of delivery and duration, but all had an emphasis on self-management: the COACH programme (Odnoletkova et al., 2016a) was delivered by phone over six months; the nurse-monitored telemedicine unit took place over 12 months (Shea et al., 2006); and the structured self-management support was delivered face-to-face, in groups and by phone over 44 weeks (Taylor et al., 2003).

While there is a developing body of evidence that nurse-led care leads to statistically significant improvements in HbA1c levels and other biological outcomes there was also some evidence that they may also be more cost effective. These findings support other studies that have found nurse-led models of care to be of equal quality to medical models of care, more satisfactory for patients and more cost effective (Arts et al., 2012; Bauer, 2010). Murrells et al. (2015) found that more consultations are being undertaken by nurses and that nurses provide longer consultations than doctors. This was confirmed by Arts et al. (2012) who found that nurses spent 93.3 min per consultation while medical staff spent 38.5 min. The short-term cost effectiveness of this model was similar to usual care (nurses were cheaper but spent nearly two and a half times longer with patients) however, it would be interesting to identify whether the longer consultations led to improved longer-term savings.

Our review also found that patients were more satisfied with nurse-led interventions. Those studies that evaluated satisfaction found that the helpful components of the nurse-led intervention were: a patient-centred approach was used 2) the education was individualized; and these factors resulted in improved confidence and independence. There is some evidence that primary care physicians do not provide the care many patients want. A study by Crowe et al. (2017) found that the most pervasive theme described by participants was that general practitioners did not provide information and education relevant to their individual needs; many were just given pamphlets. Poor communication and lack of provision of relevant information within a medical approach to treatment have been identified as a challenge for managing long-term conditions (Mirzaei et al., 2013). There is considerable evidence that poor patient-provider communication is associated with poor treatment adherence (Ciechanowski et al., 2001; Nam et al., 2011); and that improving self-management is associated with the development of a collaborative relationship with the healthcare provider (Nagelkerk et al., 2006). This is important because diabetes self-management education is associated with significant improvements in glycemic control (Chrvala et al., 2016); yet medical treatment approaches have been found to provide insufficient facilitation of self-care (Mirzaei et al., 2013). It has been suggested that nurses may be more successful in delivering patient-centred behaviour change rather than a disease-focused approach which is often the cornerstone of a standardized medical model of care (Mulder et al., 2015). Clinical guidelines recommend a patient-centred approach to diabetes management because as a long-term condition it does not fit well with a traditional medical approach that focuses on the disease and its cure (Inzucchi et al., 2012; Ministry of Health, 2015; National Institute for Health and Care Excellence, 2015).

There have been other reviews and meta-analyses of nurse-led interventions in primary care. Martinez-Gonzalez et al. (2014) reviewed studies of nurse-led care for a range of conditions including diabetes and found greater reductions in systolic blood pressure in favour of nurse-led care and similar outcomes to physician-led care on diastolic blood pressure, total cholesterol and HbA1c. A later meta-analysis conducted by Massimi et al. (2017) examining nurse-led interventions for chronic conditions found they had a positive effect on HbA1c and blood pressure.

A census of the composition of primary health care teams across a number of countries identified that the numbers of nurse practitioners was low (Freund et al., 2015). It has been suggested that one of the main obstacles relates to the structure of the local health services, particularly the interface between primary and hospital care and the integration of nurse-led services into mainstream health delivery (Riordan et al., 2017). Most health authorities have restrictions on the scope of nursing practice although this differs between countries and localities (Freund et al., 2015). There is also resistance from within the medical profession (Iglehart, 2013).

The inclusion of studies with a range of methodologies is both a strength and limitation of this review. The different methodologies provided the opportunity to consider the effectiveness of nurse-led models from a broader perspective. Because the nurse-led intervention can be considered to be a 'complex intervention' as described by Craig et al. (2008) it has been suggested that wherever possible, evidence should be combined from different sources that do not share the same weaknesses (Academy of Medical Sciences, 2007).

The qualitative studies were particularly helpful in identifying the strengths of nurse-led models. Rather than speculating on this it enabled us to incorporate patient descriptions of their experiences. The heterogeneity of methodologies is also a limitation in that not all studies could be compared and no meta-analysis could be conducted on the outcomes. Another possible limitation is that some studies may not have been identified in the search strategy.

6. Conclusion

This review found that there is evolving evidence from well-designed trials that nurse-led models are more effective than usual physician-led care in improving HbA1c, other biological outcomes, are more cost effective and demonstrate better patient satisfaction. All the clinically effective nurse-led interventions were more intensive than usual care and had an emphasis on self-management rather than a medical management only approach. The nurse-led interventions may be more cost-effective because although they were more intensive there were less costs involved in delivery. The studies included in this review that examined patient satisfaction found that this was related to: better education, being more patient-centred, more time being provided, and continuity of care which led to improved knowledge and confidence.

Nurse-led interventions are complex interventions that need to be evaluated from a broader perspective than statistical significance in methodologies designed for drug trials. Examination of clinical effectiveness provides an approach that focuses on a broader range of factors including patient factors. This review suggests that there is emerging evidence that nurse-led interventions can lead to statistically significant improvements in HbA1c but also improvements in blood pressure and lipids; while also being more cost effective and resulting in better patient satisfaction.

Conflict of interest

None

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