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Rapid review of literature for health literacy in people with diabetes

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International Centre for Allied Health Evidence

Rapid review of literature for health literacy in people with diabetes

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EXECUTIVE SUMMARY

Background

Diabetes mellitus has become one of the most challenging public health problems in Australia. People with diabetes are expected to take an active role in the management of their condition and this can be particularly challenging when limited health literacy is an issue. Adequate health literacy is therefore a critical aspect to a person's ability to engage with health services, and their self-management of, and knowledge about their condition.

The purpose of this rapid review was to provide a synthesis of the best available research evidence on the impact of health literacy strategies in adults with diabetes. The findings of this review will inform the Position Statement of the Australian Diabetes Educators Association on Health Literacy.

Methodology

A rapid review of the published literature was undertaken to provide a brief synthesis and judgment of the available research evidence related to the effectiveness of health literacy programs among adults with diabetes. The evidence base for this review was limited to the "best available evidence" (as is the nature of any rapid review) such as systematic reviews and meta-analyses.

Review answers

A total of 47 systematic reviews/meta-analyses were included in the rapid review.

What is the link between individual health literacy and outcomes in people with diabetes?

There is a positive association between health literacy and knowledge outcomes in people with diabetes. There is inconsistent evidence concerning the relationship between individual health literacy and other outcomes such as clinical measures, self-management behaviours, self-efficacy, and the nature of patient-provider interactions.

What approaches and/or strategies have been used to develop or improve individual health literacy in people with diabetes? Have these approaches and/or strategies employed the use of credentialed diabetes educators?

The approaches or strategies used to develop or improve individual health literacy in people with diabetes varied considerably in their content, format and scope, the ways in which they are delivered, length of exposure, duration of the intervention, and the personnel involved in promoting health literacy. Education seemed to be an integral component of any health literacy strategy, either alone or in combination with other strategies such as behavioural interventions and/or psychological approaches. The most commonly reported formats or modes of delivery were face-to-face, phone calls or web-based, delivered by a health practitioner or a multi-professional team of medical practitioners, dieticians/nutritionists, diabetes nurse, community health workers and educators. Some reviews reported strategies which utilised passive means of delivering the intervention such as didactic lecture or dissemination of printed information, whereas others used a more interactive approach or both. The duration of the intervention and length of exposure varied from as little as two hours of contact time to as long as 12 months of continuous contact or four years of contact with break periods.

What are the outcomes of approaches and/or

Interventions aimed at increasing health literacy showed benefits in improving metabolic/glycaemic control outcomes particularly in the short-term; however,

strategies used to develop or improve individual health literacy in people with diabetes?	trends in other clinical outcomes such as blood pressure, cholesterol, triglycerides/lipids, BMI/weight/waist circumference were less consistent. Improvements in diabetes knowledge were observed in the short and longer term. Positive effects were also reported for quality of life outcomes, patient satisfaction, the use of information technology for health-care purposes, and providing links between community and healthcare providers by way of culturally appropriate interventions. A positive trend towards reduced health care costs and health service utilisation was described in the literature. Findings were promising for depression, empowerment / self-efficacy, health care attitudes, and the provision of support. In terms of self-management behaviour, however, the evidence was inconsistent and varied for most outcomes, particularly for physical activity and medication adherence. Whether an association exists between health literacy and diabetes complications was also unclear. Limited low level evidence of a relationship between health literacy and patient-provider communication, and the use of information technology for health-related learning preclude any definitive conclusions.
What are the characteristics of effective approaches and/or strategies (e.g. health literacy environment) aimed at developing or improving individual health literacy in people with diabetes?	Education combined with behavioural or psychological interventions was most effective for increasing knowledge and achieving physiologic control of diabetes. Successful interventions for health literacy generally consisted of patient education, problem solving training sessions, engaging patients in skills building. A structured program utilising both didactic and interactive approaches and delivered by a multidisciplinary team of educators (e.g. nurse educators, pharmacists, community health workers, dieticians, diabetes educators) was linked to positive health outcomes. Culturally appropriate interventions were fundamental to an effective intervention for promoting health literacy. Use of principles of empowerment, participation and adult learning were effective for delivering education and teaching self-management skills. Use of health technologies including cellular phones and internet or web-based interventions has a role in improving health literacy. Multiple or high intensity interventions delivered over a long period of time enhanced the effectiveness of interventions and helped sustain the beneficial effects of educational programmes.
Gaps in the literature	Within the body of literature, a number of research gaps were identified, including the lack of consistency in the health literacy and diabetes management nomenclature, large range of variability in the nature of interventions and outcome measures used, and the lack of studies aimed at investigating the success rate of different and specific individual components of interventions/approaches/strategies.

Health literacy in people with diabetes

Background

Health literacy is a set of skills that people require to function effectively in the healthcare environment (Berkman et al 2010). Individual health literacy is described as *'the knowledge, motivation and competencies of a consumer to access, understand, appraise and apply health information to make effective decisions about health and health care and take appropriate action'* (Sorensen et al 2012). It is considered fundamental to a person's ability to manage their health and make appropriate health decisions. Adequate levels of health literacy are reported to assist in reducing health care cost, preventing illness and chronic diseases, and reducing mortality rates (Canadian Council on Learning 2008). Low health literacy, on the other hand, is a strong determinant of poor health outcomes. There is a growing body of evidence which demonstrates that limited health literacy is associated with higher utilisation of health services and poorer health status (Keleher & Hagger 2007). According to the Australian Bureau of Statistics, 60% of adult Australians have low health literacy (ABS 2008).

Diabetes mellitus has become one of the most challenging public health problems in the world. In Australia, there are over 1.5 million cases of diabetes including those who are undiagnosed (Baker IDI Heart and Diabetes Institute 2012). By 2031, it is estimated that 3.3 million Australians will have type 2 diabetes (Vos et al. 2004). Despite scientific discoveries and advances in health technology, the burden of diabetes continues to escalate. Optimal management of diabetes requires patients to take an active role in the management of their condition. The literature suggests that people with diabetes provide about 95% of their own care (Krichbaum et al 2003). There are many activities that people with diabetes are responsible for, including manipulation of complex medication schedules, executing detailed dietary recommendations, glucose monitoring, promoting physical activity and participation in preventative care strategies (Boren 2009; Cavanaugh 2011). These activities can be particularly challenging when limited health literacy is an issue. In an era of patient-centred care, possessing adequate health literacy is critical to a person's ability to engage with health services, and their self-management of, and knowledge about their condition. Addressing or improving health literacy can therefore empower consumers by providing them the knowledge and skills to make effective decisions about their health and take appropriate actions.

The Australian Diabetes Educators Association (ADEA) is committed to the highest standards of practice and professional and believes in the provision of patient-centred care in diabetes management. The most important attribute of patient-centred care is the active engagement of patients when health care decisions must be made, and this is enhanced when people are health literate and the health service environment facilitates health literacy.

The focus of this rapid review was to examine the impact of different strategies or approaches to improving health literacy in people with diabetes.

Methodology

Objective of this review

The purpose of this rapid review was to provide a synthesis of the best available research evidence on the impact of health literacy strategies in adults with diabetes. The findings of this review will inform the Position Statement of the Australian Diabetes Educators Association on Health Literacy.

Review questions

This rapid review addressed the following questions:

1. What is the link between individual health literacy and outcomes in people with diabetes?
2. What approaches and/or strategies (e.g. health literacy environment) have been used to develop or improve individual health literacy in people with diabetes? Have these approaches and/or strategies employed the use of credentialed diabetes educators?
3. What are the outcomes of approaches and/or strategies used to develop or improve individual health literacy in people with diabetes?
4. What are the characteristics of effective approaches and/or strategies (e.g. health literacy environment) aimed at developing or improving individual health literacy in people with diabetes?

Methods

A rapid review of the published literature was undertaken to provide a brief synthesis and judgment of the available research evidence related to the effectiveness of health literacy programs among adults with diabetes aged over 18 years. The evidence base for this review was limited to “best available evidence” (as is the nature of any rapid review) and hence the research evidence was drawn primarily from existing systematic reviews, meta-analyses, and economic evaluations. A staged approach to interrogating the literature was undertaken, whereby reviewers examined the best available research evidence (i.e. systematic reviews / meta-analyses) as they are the most comprehensive source of evidence. In the absence of the best available research evidence, primary research evidence (such as randomized controlled trials) was considered to fulfill such evidence gaps.

Search strategy

In agreement with the project officer from the Australian Diabetes Educators Association and liaison Deb Kay, specific criteria for inclusion in this review were considered using the PECOT framework (as shown in Table 1). Only English articles published in the past ten years were included in order to capture the most recent scientific evidence on health literacy programs. For the purposes of this review, the following key operational definitions were used:

Individual health literacy is the knowledge, motivation and competencies of a consumer to access, understand, appraise and apply health information to make effective decisions and take appropriate action for their health and health care (Sorensen et al 2012).

The *health literacy environment* is the infrastructure, policies, processes, materials and relationships that exist within the health system that make it easier or more difficult for consumers to navigate, understand and use health information and services to make effective decisions and take appropriate action about health and health care (Brach et al 2012, Groene and Rudd 2011, Rudd 2013).

Table 1 Criteria for considering studies in the review

Population	*Adults with diabetes aged over 18 years (to control for developmental change in general literacy levels through childhood), non-pregnant(to exclude gestational diabetes)*
Exposure	*Health literacy programs conducted in any healthcare or community setting, and where applicable, a subset of these delivered by or involving credentialed diabetes educators*
Comparator	*Health literacy programs delivered by professional staff other than credentialed diabetes educators ,other diabetes self-management programs (without a health literacy component/focus), no intervention or usual practice/care*
Outcomes	*A range of outcomes will be considered including, but not limited to:* • *Haemoglobin* A_{1c} • *Systolic blood pressure* • *Quality of life measures* • *Diabetes knowledge, self-efficacy and health literacy tests (e.g. Diabetes Knowledge Test, Diabetes Health Belief Model Scale, Test of Functional Health Literacy in Adults)* • *Self-report of diabetes complications(e.g. retinopathy, nephropathy, lower extremity amputation, cerebrovascular disease, ischaemic heart disease, hypertension)* • *Number of hospital admissions and/or GP visits related to diabetes* • *Cost-effectiveness*
Time	*Short and long term*

A combination of search terms (as shown in Table 2) was used to identify and retrieve articles in the following databases.

○ Biomed Central Gateway
○ CINAHL database
○ Cochrane Library
○ EMBASE
○ ERIC
○ MEDLINE
○ PsychInfo
○ PubMed
○ Scopus
○ Web of Knowledge
○ Web of Science

Table 2 Search terms for the review

Search terms 1	***Search terms 2***	***Search terms 3***
Health literacy Health education Information needs/seek/use/utilisation/literacy Communication Access to information Information dissemination Information storage and retrieval Information services Education/skill/teaching/training/coaching/instruct Early intervention/education Teaching materials Teaching Computer/internet/online/e-health/website/informatics	Adult*	Diabetes

The titles and abstracts identified from the above search strategy were assessed for eligibility by the *i*CAHE researchers and stakeholders from the Australian Diabetes Educators Association. In order to avoid duplication and "double counting" data, umbrella reviews (review of reviews) were excluded. These umbrella reviews were utilised to identify other relevant articles by pearling their reference lists. Full text copy of eligible articles was retrieved for full examination.

Critical appraisal

Two reviewers independently appraised the methodological quality of all included articles using the Assessment of Multiple Systematic Reviews (AMSTAR) tool. Differences in opinion were resolved by discussion.

The AMSTAR is an 11-item instrument which was developed by exploratory factor analysis and a nominal group technique involving methodological experts to develop its face and content validity (Shea et al 2007). A copy of the AMSTAR instrument is provided in Appendix 1. Further psychometric testing of AMSTAR has demonstrated substantial inter-rater agreement for individual items (mean Kappa 0.70, 95% CI 0.57, 0.83) and acceptable construct validity for total sum scores (ICC 0.84, 95% CI 0.65, 0.92) when compared with the Overview of Quality Assessment Questionnaire (ICC 0.91, 95% CI 0.82, 0.96) and Sacks' instrument (ICC 0.86, 95% CI 0.71, 0.94) (Shea et al 2007).

Data extraction

Data were extracted from the identified publications using a data extraction tool which was specifically developed for this review. The following information were extracted from individual studies:

- Evidence source (Author, date)
- Characteristics of participants
- Health literacy strategies or approaches: nature, setting, delivery, format,

intensity/dose/duration

- Personnel involved in the intervention
- Outcome measures
- Results of the review (e.g. evidence of effectiveness, cost-effectiveness)
- Characteristics of effective approaches

Data synthesis

Findings from the included publications and their methodological quality (based on critical appraisal scores) were synthesised in a narrative summary. The strength of the body of evidence was determined based on the Australian National Health and Medical Research Council (NHMRC) Evidence Grading Matrix (Table 3). Recommendations or plain language summaries for each of the review questions are also provided.

Table 3 NHMRC evidence grading table

	A	**B**	**C**	**D**
Component	**Excellent**	**Good**	**Satisfactory**	**Poor**
Volume of evidence	several level I or II studies with low risk of bias	one or two level II studies with low risk of bias or a SR/multiple level III studies with low risk of bias	level III studies with low risk of bias, or level I or II studies with moderate risk of bias	level IV studies, or level I to III studies with high risk of bias
Consistency	all studies consistent	most studies consistent and inconsistency may be explained	some inconsistency reflecting genuine uncertainty around clinical question	evidence is inconsistent
Clinical impact	very large	substantial	moderate	slight or restricted
Generalisability	population/s studied in body of evidence are the same as the target population for the guideline	population/s studied in the body of evidence are similar to the target population for the guideline	population/s studied in body of evidence different to target population for guideline but it is clinically sensible to apply this evidence to target population*	population/s studied in body of evidence different to target population and hard to judge whether it is sensible to generalise to target population

Applicability	directly applicable to Australian healthcare context	applicable to Australian healthcare context with few caveats	probably applicable to Australian healthcare context with some caveats	not applicable to Australian healthcare context

Results

Evidence Sources

The search yielded 319 articles, which were reviewed by the authors for duplicates. A total of 128 systematic reviews were screened for possible inclusion in the rapid review and only 59 were considered potentially relevant and were retrieved for further examination. After scrutiny, 12 articles were excluded for a number of reasons, leaving 47 systematic reviews for inclusion in the rapid review. Figure 1 illustrates the process involved in study selection.

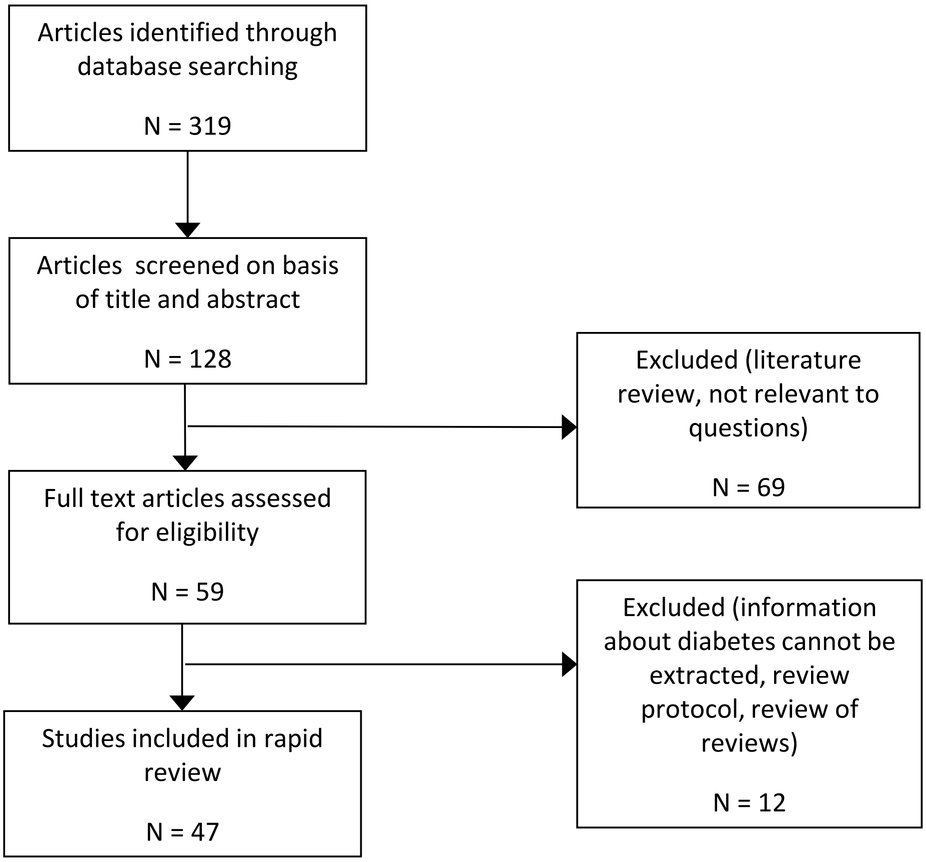

Figure 1 Flow chart of search results

Characteristics of included studies

Type of participants

All reviews included adults with diabetes, with most reviews (n=27, 57.4%) including only adults with type 2 diabetes. However, specific subgroups of participants with diabetes were the focus of several reviews, and these comprised:

- adults with type 1 or 2 diabetes (Albano et al 2008, Al Sayah et al 2012, Boren et al 2009, El-Gayar et al 2013, Krishna et al 2009, Jayasekara et al 2011, Wubban and Vivian 2008), adults with only type 1 diabetes (Srinivasan et al 2008b),
- adults with type 1 or 2 diabetes, and diabetic kidney disease (Dorresteijn 2012, Li et al 2011)
- adults with type 1 or 2 diabetes, from low socioeconomic and specific ethno-racial

groups including African Americans, Mexican Americans & Native Americans (Glazier et al 2006),

- adults with type 2 diabetes from minority ethnic groups (and/or vulnerable populations) residing in middle or high-income countries (Hawthorne et al 2010) including those from African American (Sarkisian et al 2003, Walker et al 2013), Chinese (Qingping et al 2011), Hispanic (Hunt et al 2011), and Latino (Perez-Escamilla et al 2008, Sarkisian et al 2003) backgrounds
- adults and children with type 1 or 2 diabetes (Loveman 2009)
- adults with type 2 diabetes and other chronic conditions (Viswanathan et al 2012), including congestive cardiac failure, coronary artery disease, chronic obstructive pulmonary disease, or hypertension (and/or their carers) (Dennis et al 2013)

Type of interventions

The type of interventions reported by the included studies is described under ‘Question 1’, page 14.

Type of outcomes

There were only twelve systematic reviews (25.5%) that stipulated *a priori* the evaluation of outcomes using validated and/or standardised measures (Boren 2009, Deakin et al 2009, Hawthorne et al 2010, Jayasekara et al 2011, Li et al 2011, Loke et al 2012, Loveman et al 2008, Loveman et al 2009, Minet et al 2010, Perez-Escamilla et al 2008, Vermeire et al 2011, Zhang et al 2007). In addition, few included systematic reviews (n=8, 17%) specified *a priori* the timing of, and duration of follow-up for, outcome measures, and these ranged from at least twelve weeks following interventions (Ellis et al 2004) across the short (Deakin et al 2009, Duke et al 2009, Steinsbekk et al 2012, Vermeire et al 2011), medium (Dorresteijn et al 2012, Loveman et al 2009), and long term (Loveman et al 2008, Loveman et al 2009). Included systematic reviews varied considerably in the number, type and timing of (primary and secondary) outcomes of interest, and there was a lack of consistency in the terms used to report and describe these. Therefore, in this review, outcomes (recorded verbatim from included articles) were categorised as follows: clinical outcomes (physiological and functional measures), knowledge, self-management behaviours, health care use/cost analyses, psychosocial, diabetic complications, and additional outcomes (Appendix 2). Clinical outcomes were most commonly evaluated (n=43 systematic reviews, 91.5%), and these were predominantly physiological measures of glycated haemoglobin (HbA1c) (n=35, 74.5%), lipid profiles (e.g. [total] cholesterol, HDL, LDL, triglycerides) (n=20, 42.6%), blood pressure (n=18, 38.3%), and anthropometry (e.g. body weight, BMI, waist circumference) (n=16, 34%). Of the knowledge outcomes, measures relating specifically to diabetes knowledge were most prevalent (n=9, 19.1%). The greatest range of measures were for self-management behaviour outcomes, and these included: medication adherence (n=14, 29.8%); self-monitoring of blood glucose (n=11, 23.4%); problem solving, self-management or coping skills (n=6, 12.8%); and behaviours or behavioural changes relating to diet/nutrition (n=14, 29.8%), exercise/physical activity (n=14, 29.8%), foot care practices (n=7, 14.9%), smoking cessation (n=4, 8.5%), self-care activities (n=4, 8.5%), eye checks, immunisations, compliance and communicating with doctors/clinic visits (n=1, 2.1%).

Health literacy outcomes

There were four systematic reviews that assessed health literacy in people with diabetes, all of which were published within the last five years (Al Sayah et al 2012, Boren 2009, Fransen et al 2011, Loke et al 2012).

A range of general health literacy measures were included in the reviews, of which the most common was the Test of Functional Health Literacy in Adults–short form (s-TOFHLA) (Al Sayah et al 2012, Boren 2009, Fransen et al 2011, Loke et al 2012), followed by the Rapid Estimate of Adult Literacy in Medicine (REALM) (Al Sayah et al 2012, Boren 2009, Loke et al 2012)and the revised REALM-R (Al Sayah et al 2012, Fransen et al 2011, Loke et al 2012). Two studies (Al Sayah et al 2012, Loke et al 2012) used the original long form of the TOFHLA to evaluate health literacy. Diabetes-specific measures of literacy and/or numeracy were used less commonly, and included the Diabetes Numeracy Test (Al Sayah et al 2012, Boren 2009), Nutritional Literacy Scale, Single Item Literacy Screener, Literacy Assessment for Diabetes, and Spoken Knowledge in Low literacy Patients with Diabetes (Boren 2009)

Quality of the evidence

For this review, inter-rater reliability of the critical appraisal process (for AMSTAR individual items) was established by each of the two reviewers individually critically appraising a random sample of ten included systematic reviews (98.2% consistency). The list of remaining systematic reviews (n=37) were divided between the two reviewers and appraised, with queries relating to individual items resolved by discussion and consensus. Included studies varied in the number and type of AMSTAR items met (Table 4), with Cochrane reviews satisfying most (n=10) of the eleven AMSTAR criteria (Deakin et al 2009, Dorrestejn et al 2011, Dorrestejn et al 2012, Duke et al 2009, Li et a 2011, Loveman et al 2009, Vermeire et al 2009 – highlighted in grey).

Table 4 Critical appraisal of included reviews

Study	**AMSTAR tool items**										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Sarkisian et al 2003	Y	CA	Y	N	N	Y	Y	Y	Y	N	Y
Ellis et al 2004	Y	Y	Y	Y	N	Y	N	N	Y	N	N
Yamaoka & Tango 2005	Y	CA	N	N	N	Y	N	N	Y	Y	Y
Glazier et al 2006	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Jackson et al 2006	Y	Y	Y	Y	N	Y	N	N	Y	N	Y
Sigurdardottir et al 2007	Y	CA	Y	N	N	Y	Y	Y	Y	N	Y
Zhang et al 2007	Y	Y	Y	Y	N	Y	N	N	Y	Y	N
Adaji et al 2008	CA	Y	Y	Y	N	N	N	N	N	N	N
Albano et al 2008	CA	Y	Y	N	N	N	N	N	CA	N	N
Loveman et al 2008	Y	N	Y	N	Y	Y	Y	Y	Y	N	Y
Perez-Escamilla et al 2008	CA	CA	N	N	N	Y	N	N	Y	N	Y
Srinivasan 2008	Y	N	Y	N	N	N	Y	Y	Y	N	Y
Srinivasan 2008b	Y	N	Y	N	N	N	Y	Y	Y	N	Y
Wubben et al 2008	Y	N	Y	Y	N	Y	CA	CA	Y	N	Y
Boren 2009	CA	N	Y	N	N	Y	N	N	Y	N	N
Boren et al 2009	CA	Y	Y	Y	N	Y	N	N	Y	N	N
Deakin et al 2009	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y

Duke et al 2009	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Fan & Sidani 2009	Y	N	N	N	N	Y	N	N	Y	N	Y
Krishna et al 2009	Y	CA	N	N	N	Y	N	N	Y	N	Y
Loveman et al 2009	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Medical Advisory Secretariat 2009	Y	Y	Y	N	N	Y	Y	Y	Y	N	N
Vermeire et al 2009	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Hawthorne et al 2010	CA	Y	Y	N	N	Y	Y	Y	Y	CA	Y
Minet et al 2010	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y
Misono et al 2010	CA	Y	Y	N	N	Y	N	N	Y	N	Y
Dorrestejn et al 2011	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Hunt et al 2011	CA	Y	N	Y	N	Y	N	N	Y	N	N
Jayasekara et al 2011	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Leelarathna et al 2011	Y	N	Y	N	N	N	Y	Y	Y	N	Y
Li et al 2011	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Qingqing et al 2011	CA	CA	N	N	N	Y	N	N	N	N	Y
Ramadas et al 2011	Y	CA	Y	Y	N	Y	Y	N	Y	N	Y
Al Sayah et al 2012	CA	Y	Y	N	N	Y	Y	Y	Y	N	Y
Dale et al 2012	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y
Dorrestejn et al 2012	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Fransen et al 2012	Y	CA	N	N	N	Y	Y	Y	Y	N	N
Loke et al 2012	CA	Y	Y	CA	N	Y	Y	Y	Y	N	Y
Omran et al 2012	Y	N	Y	N	N	Y	Y	Y	Y	N	Y
Steinsbekk et al 2012	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y
Viswanathan et al 2012	Y	N	Y	N	N	Y	Y	Y	Y	N	Y
Dennis et al 2013	Y	N	N	N	N	N	N	N	Y	N	N
El-Gayar et al 2013	Y	Y	Y	N	N	N	N	N	Y	N	Y
Fitzpatrick et al 2013	Y	Y	Y	N	N	Y	N	N	Y	N	Y
Pennington et al 2013	Y	N	Y	N	N	N	Y	Y	Y	Y	Y
Walker et al 2013	Y	N	N	N	N	Y	CA	CA	Y	N	N
Williams et al 2014	Y	CA	N	N	N	Y	N	N	Y	N	Y

Question 1

What approaches and/or strategies (e.g. health literacy environment) have been used to develop or improve individual health literacy in people with diabetes? Have these approaches and/or strategies employed the use of credentialed diabetes educators?

The approaches or strategies used to develop or improve individual health literacy in people with diabetes varied considerably in their content, format and scope, the ways in which they are delivered, length of exposure, duration of the intervention, and the personnel involved in promoting health literacy. Education seemed to be an integral component of any health literacy strategy, either alone or in combination with other strategies such as behavioural interventions and/or psychological approaches. The most commonly reported formats or modes of delivery were face-to-face, phone calls or web-based, delivered by a health practitioner or a multi-professional team of medical practitioners, dieticians/nutritionists, diabetes nurse, community health workers and educators. There were almost an equal number of reviews which reported one-on-one approach, group approach or a combination of both. Some reviews reported strategies which utilised passive means of delivering the intervention such as didactic lecture or dissemination of printed information, whereas others used a more interactive approach or both. The duration of the intervention and length of exposure varied from as little as two hours of contact time to as long as 12 months of continuous contact or four years of contact with break periods. As there was significant heterogeneity in the health literacy strategies, the different interventions were categorised based on their outcome focus and core elements: *interventions focused on self-management, interventions targeted to vulnerable groups (e.g. low socio-economic status, minority groups), healthcare provider role interventions/use of peers or lay advisors, educational interventions for specific outcomes, multi-component or complex interventions, and e-learning.* Table 5 shows the evidence sources for each of these categories. Of the 47 systematic reviews that were included in this rapid review, only 39 described strategies for improving or developing health literacy in people with diabetes.

For this report, the evidence base for every category is presented, and where reported, the nature, setting, format or mode of delivery, intensity, frequency and duration of the specific strategies are also described.

Interventions focused on self-management

The reviews grouped under this category reported interventions which focused on providing education, alone or in combination with other interventions, to improve self-management of diabetes. Nine systematic reviews examined the impact of a range of interventions on self-management behaviour (Sarkisian et al 2003; Loveman et al 2008; Fan & Sidani 2009; Minet et al 2010; Vermeire et al 2009; Steinsbekk et al 2012; Viswanathan et al 2012; Ftizpatrick et al 2013; Williams et al 2014).

Sarkisian et al (2003) reviewed the literature on self-care interventions that sought to improve glycemic control or health-related quality of life among older, African American, or Latino adults with diabetes. The interventions had two or more of the following characteristics: behaviour oriented, culturally tailored, age tailored, nurse educators, nutritionist educator, one-to-one counselling, group counselling, physician involvement, supervised exercise, and family involvement. All interventions were aimed at changing behaviour rather than simply educating patients.

Loveman et al (2008) determined the effectiveness of patient education on multiple aspects of diabetes self-management. The majority of included studies reported using a group education format. The hours of contact ranged from 2.5 hours (in a 6-month intervention) to 52 hours [in a 1-year intervention]. Some interventions began with two to four intensive sessions of 90–120 minutes followed up with additional sessions. The shortest intervention was two hours and the longest consisted of approximately 30 hours of contact. The interventions also varied considerably in whether sessions were provided over a short interval or were spaced out over time. In one of the longest studies, the interventions were spread throughout a 4-year period but the timing varied among patients. The briefest interventions lasted for one month.

Fan & Sidani (2009) categorised diabetes self-management education into educational (focused on providing information to improve patients' knowledge of diabetes self-management), behavioural (focused on active skills training and emphasised change in skills and/or lifestyle), psychological (focused on addressing negative mood states and improving coping skills) or mixed interventions (combination of the first three types).

The interventions were delivered in different settings such as hospital settings, outpatient clinics, community clinics, and in the participants' home. Some interventions were didactic, others were interactive, and the majority used a mixed approach. The interventions were delivered using a range of approaches such as face-to-face, online/web-based, video, phone contact, or a combination of these approaches. Some interventions were conducted in a group; some were one-on-one whereas others were undertaken using both formats.

Minet et al (2010) examined two categories of self-care management interventions, including educational interventions (techniques based on didactic-oriented intervention focusing on the knowledge acquisition, skills and information in order to improve diabetes self-management were categorised as education) and behavioural psychosocial interventions (interventions were categorised as behavioural psychosocial if the intervention was based on cognitive, behavioural or motivational approaches, or if the study specified that the patients were receiving psychologically centred counselling involving relaxation, problem-solving, or motivational interviewing).

Vermeire et al 2011 determined the effects of interventions for improving adherence to treatment recommendations in primary care, outpatient settings, community, and hospital settings. These interventions consisted of nurse-led interventions, home aids, diabetes education, pharmacy-led interventions, and adaptation of dosing and frequency of medication taking.

Steinsbekk et al (2012) assessed the effects of group-based diabetes self-management education compared to routine treatment on clinical, lifestyle and psychosocial outcomes. The duration of interventions varied, with the least intensive being three hours per year for two years. The majority ranged from 6-20 hours of group-based education over a period of between four weeks and 10 months; the most intensive varied from 52 hours over one year, 36 hours over six months, 30 hours over 2.5 months and 96 hours over six months.

Viswanathan et al (2012) examined the comparative effectiveness of patient, provider, systems, and policy interventions that aimed to improve medication adherence for a range of chronic conditions including diabetes. Information relevant to diabetes has shown that case management, care coordination and collaborative care were effective for medication adherence. Collaborative care with in-person patient visits for education and counselling seemed to be effective for patients with depression and diabetes.

Fitzpatrick et al (2013) reviewed the effect of problem solving interventions on diabetes self-management and disease control. The interventions reported in the individual studies varied: one was solely problem-solving based; in some studies, problem solving was one component of a larger intervention that utilised other treatment approaches; a few other studies utilised a problem solving-based support group. The interventions utilised a range of strategies including a face-to-face (individual or group) approach, phone-based, DVD-based, internet-based, and videoconferencing.

Williams et al (2014) examined all interventions targeted at improving medication adherence. The interventions involved the use of one or a combination of the following: education, skills training, mobile phone use, one-on-one interaction, telephone use, assistance in problem-solving, use of nurse educators/case managers, diabetic educator, community health worker, pharmacist, and physicians.

Interventions targeted to vulnerable groups

The reviews classified under this category synthesised evidence that described interventions for vulnerable groups such as those who belong to the low socio-economic population and socially disadvantaged group (Glazier et al 2006; Perez-Escamilla et al 2008; Hawthorne et al 2010; Hunt et al 2011; Walker et al 2013).

Glazier et al (2006) examined patient, provider and health system interventions to improve diabetes care in adults with diabetes who belong to low socio-economic status and specific ethno-racial groups including African Americans, Mexican Americans, and Native Americans. Diabetes education was the main focus in many of the included studies; others focused on innovative health care provide roles, whereas others focused on specific aspects of diabetes-related care such as physical activity sessions, a focused education and support intervention to improve ophthalmic examinations, implementation of a visual communication tool, reminder cards for diabetes care indicators and rapid A1C testing. The educational interventions used a variety of methods including didactic lectures, skill building, problem solving, behavioural strategies, feedback, family member participation, and/or individualised assessment.

Hawthorne et al (2010) reviewed the literature on culturally appropriate health education for diabetes in ethnic majority groups. Some educational programs recognised theoretical models of behavioural change and innovative approaches such as soap dramas, storytelling, and lay workers to deliver health messages were used. A group approach was used in some studies, whereas other studies used one-to-one interviews or a mixed approach. Duration of the intervention lasted from one session to 12 months. Many studies used a repeated intervention between six and 12 weeks.

Two systematic reviews examined interventions delivered by community health workers. Hunt et al (2011) reviewed the evidence on the effect of community-health advisors interventions targeted at vulnerable and underserved populations including African Americans, Hispanics, Latinos, and Pacific Islanders. Major roles of community health advisors included: supporter, educator, case manager, advocate, and program facilitator. Activities of community health advisors involved coordinating educational programs, conducting educational courses for patients, serving as a link between patients and healthcare professionals, providing counselling, and leading peer support meetings. On the other hand, Perez-Escamilla et al (2008) assessed the impact of peer education/counselling on nutrition and health outcomes among Latinos, the largest minority ethnic group in the United States. Included studies reported a wide variety of designs and methods of nutrition education delivered by community health workers. Several programs employed women with diabetes or with a relative with diabetes.

Walker et al (2013) determined whether behavioural interventions targeted at African Americans (one of the ethnic minority groups in the United States) are effective at improving glycemic control. The behavioural interventions varied in terms of their theoretical backgrounds and techniques used. Some interventions were underpinned by an empowerment theoretical concept whereas others used the health beliefs model. Motivational interviewing, health promotion strategies, nursing case management and a coordinated service delivery were reported in many studies.

Healthcare provider role interventions/peer support/use of lay advisor

The reviews grouped under this category summarised studies which described interventions delivered or led by a specific health provider or other personnel such as peers or lay advisor. Omran et al (2012) and Wubben & Vivian (2008) examined the impact of pharmacist-led interventions; Pennington et al (2013) determined the cost-effectiveness of providing lay-led lifestyle advice to patients, while Dale et al (2012) synthesised the evidence on the effectiveness of peer support for adults with diabetes.

In the Omron et al (2012) review, a range of interventions to improve adherence to oral anti-diabetic medications were considered, including an educational-based strategy, behavioural interventions, affective interventions and provider-targeted interventions. The educational-based strategy was designed to improve patient knowledge of drug therapy, explain drug side effects and methods to help minimise them, describe the risk of diabetes complications or discuss the advantages and disadvantages of adapting healthy lifestyle choices. This strategy comprised of in-person meetings between pharmacist and patient, and some printed information. Wubben & Vivian (2008), on the other hand, reviewed the effectiveness of diabetes quality improvement strategies delivered by pharmacists in outpatient settings. Interventions involved patient visits with outpatient pharmacists, whose roles were expanded from drug dispensing to care for adults with diabetes; the new roles ranges from evaluation of drug therapy only to patient education on lifestyle and/or diabetes self-care to case management. One-on-one visits were the usual mode of delivery, with a few studies reporting the use of telephone contacts or a group visit.

Pennigton et al (2013) synthesised the evidence on the cost-effectiveness of health-related lifestyle advice delivered by peer or lay advisors. The studies reported different methods of delivering lay-led lifestyle and disease management advice to poor, urban patients with diabetes.

Dale et al (2012) summarised the evidence on the impact and effectiveness of peer support for adults with diabetes. There was considerable heterogeneity in the format and scope of the interventions, and in the ways in which peers were recruited and trained for their role. The most commonly reported formats were group face-to-face format, telephone calls in addition to a group support, phone calls alone, peer interaction over the internet and use of information kiosk.

Educational interventions for specific outcomes

The reviews that fit within this category examined studies which investigated a range of educational strategies aimed at improving one or more diabetes-related outcomes.

Ellis et al (2004) examined the effects of patient education on glycated haemoglobin. The interventions varied in the techniques used for education, including a didactic teaching method, dictated goal setting, a goal setting negotiated teaching method, situational problem solving, cognitive reframing interventions, and a combination of teaching methods. The contents are also diverse, with many studies reporting education about diet, exercise, self-monitoring of blood glucose, basic diabetes knowledge, medication adherence, and psychosocial topics. The duration and number of interventions ranged from one month to one year and from one to 36 episodes, respectively.

Deakin et al (2009) assessed the effectiveness of group-based education programs on a range of diabetes outcomes. Some interventions had adapted the Diabetes Treatment and Teaching Programme (DTTP) originally developed in Germany for adults with type 1 diabetes and is based on therapeutic patient education. Different models of educational programmes were reported including an empowerment model, an adult learning model, a public health model, a health belief model and a transtheoretical model. The number of patients for group educational programs varied, with the smallest group comprising of four to six and the largest groups comprising of 16 to 18 patients. Programs varied in duration with the least intensive being three hours per year for two years and three or four hours per year for four years. The educators were mostly health professionals including physicians, dietician, nurse, community workers, and paramedical staff. In some programs, a family member or friend was also invited to attend.

Yamaoka & Tango (2005) evaluated the efficacy of lifestyle education for preventing type 2 diabetes in high risk individuals. Lifestyle education interventions reported in the included studies varied widely. Lifestyle education (combined diet and exercise) was conducted in majority of the trials and a solely lifestyle education intervention was carried out in a few studies.

Sigurdardottir et al (2007) examined the outcomes of educational interventions for improving glycemic control in diabetes. Some of these interventions were theory-guided and content was often reported as teaching about basic diabetes knowledge and self-care skills such as diet and exercising, medication, adherence, self-monitoring of blood glucose and psychosocial aspects. Group education with individual education was common and method of delivery was face-to-face; telecommunication and written instructions were less common; some used a combination of face-to-face, telecommunication, and written instructions. Collaborative teaching methods such as goal setting, problem solving and cognitive reframing were common. Duration of education ranged from eight weeks to 12 months and the majority used more than 11 hours of intervention.

Zhang et al (2007) reported the effectiveness of educational and behavioural interventions in improving the health-related quality of life of patients with diabetes. However, this review did not describe in detail the components of the intervention.

Albano et al 2008 described the characteristics and developments of therapeutic education in diabetes. Group education represented the most widespread educational strategy. Education at patient's home was the second used educational strategy which was commonly undertaken through the use of printed materials, web, and other means such as learning and decision aids programs, video cassettes or telephone coaching. Most studies indicated that education was usually undertaken by a multi-professional team. Nurses were often cited, followed by medical doctors, then dieticians and pharmacists. Community health workers and congregation leaders were reported in a few studies.

Duke et al (2009) evaluated the effectiveness of individual patient education on metabolic control, diabetes knowledge and psychosocial outcomes. The majority of interventions involved face-to-face education and covered a wide range of diabetes topics. The content of the education typically covered pathophysiology of diabetes, diabetes control through diet, diabetes control through exercise, compliance with medication, exercise and exercise regimes, glucose self-monitoring, diabetic complications, foot care, services available, motivation and behavioural strategies. The total face-to-face time varied significantly across studies, as did the frequency of the sessions and the number of months it was carried over. Most studies involved two to four hours of face-to-face time, some contained less than 2 hours, with a few involving greater than five hours of contact time. The majority of the interventions were carried out by diabetes educators and dieticians.

Jayasekara et al (2011) established the effectiveness of approaches to providing education to adults with diabetes using or initiating insulin pump therapy. The educational methods were diverse; major components of education and training programs were blood glucose monitoring, carbohydrate counting, adjustment of insulin dose (initial basal rates and pre-meal boluses), practical aspect of insulin pump including identification of malfunctions, prevention and management of acute complications, and lifestyle changes. Multidisciplinary teams comprising of doctors, nurses and dieticians and diabetes educators were involved in the programs. The duration and frequency of the educational intervention were adapted to suit individual needs.

Li et al (2011) examined the benefits and harms of education programmes for people with diabetic kidney disease. There was significant heterogeneity in the content and scope of the interventions. These include self-management education, motivational coaching, diabetes care self-monitoring and management, and general discussion about the difficulties of living with diabetes, including both practical and psychosocial difficulties. Intervention duration also varied, and ranged from five weeks to 12 months.

Qingqing et al 2011 assessed and summarised the evidence on diabetes education in China. Most of the educational content was relatively comprehensive, including diabetes process and treatment options, nutrition, physical activity, monitoring of blood glucose, and complications. Some studies specialised in nutrition, others provided patients with blood glucose monitors and a low glycemic diabetes-specific nutritional meal replacement in addition to monthly group lectures.

Dorresteijn et al (2012) synthesised the evidence on educational programmes (or programmes that include education) aimed at reducing the incidence of foot ulceration in people with diabetes. The programs varied in content and format, with the majority reporting on foot care and skin hygiene. Some programs were tailored to patients' individual needs, whereas others were generic. The number of sessions provided to patients differed across studies, and the format of delivery ranged from a lecture style, through to the use of instructional videos, handouts and telephone calls.

Multi-component or complex interventions

One review examined the literature on health literacy and diabetes, and has included studies which reported on interventions for improving health literacy (Boren 2009). These interventions were diverse and included patient education, a low-literacy reminder card, computer multimedia that included audio/video sequences to communicate information, provide psychological support, and promote diabetes self-management skills without extensive text or complex navigation, individually tailored disease management communication, and notifying physicians of patients with limited health literacy with a reminder notice affixed to the patient's chart.

One systematic review assessed the effectiveness of complex interventions to reduce the incidence of foot ulceration in people with diabetes (Dorresteijn et al 2011). A complex intervention was defined as an integrated approach, combining two or more prevention strategies on at least two different levels of care: the patient, the healthcare provider and/or the structure of health care. The majority of studies reported educationally-orientated interventions where both patients and healthcare providers received educational sessions in addition to other interventions (e.g. for patient, therapeutic interventions, behavioural contracts, reminders; for healthcare provider, guides for clinical assessments and treatment, revision of professional role). Other studies investigated more intensive and comprehensive complex interventions; for example, patients received thorough assessment and weekly visits, self-care advice, podiatry, provision of support; at the structural level, arrangements for follow up were organised, provision of care for high risk patients was intensified, 'formal integration services.'

E-learning

Seven reviews which summarised evidence on the use of electronic media and information, and communication technologies for learning or teaching of patients with diabetes were grouped under this category (Jackson et al 2006; Adaji et al 2008; Medical Advisory Secretariat 2009; Krishna et al 2009; Ramadas et al 2011; Dennis et al 2013; El-Gayar 2013).

Jackson et al (2006) synthesised the literature to determine how interactive IT has been used to enhance care for adults with type 2 diabetes. Generally, the included studies sought to evaluate the effectiveness of technology-enabled programs to improve diabetes education, clinical outcomes, patients' perceived quality of life and support, as well as patient and provider processes of care (visits, testing, and documentation of adherence). The studies focused on three different categories of IT interventions, namely, internet, telephone and computer-assisted integration of clinical information. The studies in the internet category used interactive web technology to enhance patient self-management and clinical management by providing diabetes education and feedback of resulting data. Articles in the telephone category used interactive, automated telephone calls and telemedicine to enhance patient self-management through self-care education calls and feedback of self-monitored information to the provider. Articles in the computer-assisted integration of clinical information category consisted of computerized patient education and interventions that integrated electronic practice guidelines, reminder systems, and feedback of clinical data to enhance both self and clinical management. All 3 categories included technology focusing on self and/or clinical management and differed mainly by their mode of delivery.

Adaji et al (2008) evaluated the use of IT interventions (i.e. web-based programs, electronic medical records, messaging systems) for diabetes management in medical practice. The complexity of the IT systems used in the studies varied considerably, ranging from the use of web based interventions to the use of an electronic medical record (EMR) without being connected to the internet. Some of the interventions used clinical guidelines, patient registries (a register of patients with diabetes including key demographic and clinical data) and email systems.

Krishna et al (2009) examined the evidence on the use of cellular phone with voice or text messaging for delivery of health information or educational intervention. The average duration of intervention was six months, and ranged from three weeks to 12 months. Dennis et al (2013), on the other hand evaluated the effectiveness of telephone-based coaching services for the management of patients with chronic diseases. Telephone coaching involved a two-way conversation by telephone/video (e.g. Skype) between a patient & provider (including trained lay people).

The Medical Advisory Secretariat of the Ministry of Health and Long-term Care in Ontario, Canada (2009) determined whether home telemonitoring of blood glucose is effective for improving glycaemic control in adults with type 2 diabetes. This intervention refers specifically to the use of medical devices to remotely collect a patient's vital signs and/or other biologic health data and the transmission of such data to a monitoring station for interpretation by a physician or third-party assistant. The review included wireless and modem-compatible blood glucose monitors that can automatically upload blood glucose readings at the request of the user via Internet or telephone/cellular lines, and “web entry” technologies consisting of websites to which patients enter self-measured biological health data. The duration of intervention equated to the length of follow-up as the intervention was continuous, and ranged from six to 30 months.

Ramadas et al (2011) reviewed the evidence on web-based, self-management or self-monitoring interventions. The studies had almost similar self-monitoring method in the intervention, where the participants were required to log in to enter their blood glucose readings daily or weekly. Patients then receive their recommendations provided by medical professionals after the uploaded information was assessed. The duration of the intervention ranged between 12 and 52 weeks, with an average of 27.2±18.3weeks.

El-Gayar et al (2013) determined how IT has been used to improve self-management for adults with Type 1 and Type 2 diabetes. Internet was used commonly as a primary technology for diabetes self-management. The other studies have employed telemedicine, cellular phone, decision support, or a combination of multiple technologies. With respect to the communication patterns, the majority of included studies showed a pattern of a two-way communication. A two-way communication refers to the active involvement of both patients and clinicians in diabetes management. A feedback system based on an algorithm or a decision support component was reported in some studies.

Table 5 Different approaches to health literacy mapped against evidence sources

Evidence source	Approaches or strategies for developing or improving health literacy					
	Interventions focused on self-management	Interventions targeted to vulnerable groups	Healthcare provider role interventions, peers, lay advisors	Educational interventions for specific outcomes	Multi-component or complex interventions	E-learning
Sarkisian et al 2003	√					
Ellis et al 2004				√		
Deakin et al 2009				√		
Yamaoka & Tango 2005				√		
Glazier et al 2006		√				
Jackson et al 2006						√
Sigurdardottir et al 2007				√		
Zhang et al 2007				√		
Adaji et al 2008						√
Albano 2008				√		
Loveman et al 2008	√					
Perez-Escamilla et al 2008		√				
Wubben & Vivian 2008			√			
Boren 2009					√	
Duke et al 2009				√		
Fan & Sidani 2009	√					
Krishna et al 2009						√
Loveman et al 2008	√					
Medical Advisory Secretariat 2009						√
Dorresteijn et al 2011					√	
Hawthorne et al 2010		√				
Minet et al 2010	√					
Hunt et al 2011		√				
Jayasekara et al 2011				√		
Li et al 2011				√		
Qingping et al 2011				√		
Ramadas et al 2011						√
Vermeire et al 2009	√					

Evidence source	Approaches or strategies for developing or improving health literacy					
	Interventions focused on self-management	Interventions targeted to vulnerable groups	Healthcare provider role interventions, peers, lay advisors	Educational interventions for specific outcomes	Multi-component or complex interventions	E-learning
Dale 2012			√			
Dorresteijn 2012				√		
Omran et al 2012			√			
Steinsbekk et al 2012	√					
Viswanathan et al 2012	√					
Dennis et al 2013						√
El-Gayar 2013						√
Fitzpatrick et al 2013	√					
Pennington et al 2013			√			
Walker et al 2013		√				
Williams et al 2014	√					

Question 2 **What is the link between individual health literacy and outcomes in people with diabetes?**

The findings of four systematic reviews that assessed health literacy in people with diabetes were all characterised by a positive association between health literacy and knowledge (Al Sayah et al 2012, Boren 2009, Loke et al 2012, Fransen et al 2011). However, within this body of literature, there is inconsistent and insufficient low-level evidence concerning the relationship between health literacy and other outcomes such as clinical measures (e.g. HbA1c, blood pressure, diabetes complications) (Al Sayah et al 2012, Boren 2009), self-management behaviours (e.g. medication adherence) (Al Sayah et al 2012, Loke et al 2012), self-efficacy (Al Sayah et al 2012, Boren 2009, Fransen et al 2011) the nature of patient-provider interactions (Al Sayah et al 2012, Boren 2009), and social support (Al Sayah et al 2012, Fransen et al 2011) in this population.

Question 3 **What are the outcomes of approaches and/or strategies used to develop or improve individual health literacy in people with diabetes?**

The outcomes of approaches and/or strategies (i.e. interventions) used to develop or improve individual health literacy in people with diabetes varied among the included reviews ranging from those that favoured the intervention to others where the effects were inconclusive. There were no studies where outcomes favoured the control or comparator condition. Due to the heterogeneity of included reviews, summaries of the main findings and authors’ conclusions are presented for each main outcome category according to whether results favoured the intervention or were inconclusive.

Clinical outcomes

There were 26 reviews that evaluated the effect of approaches and strategies on clinical outcomes, and these were predominantly measures of metabolic control (Appendix 3). Of these, 16 reviews (61.5%) reported that metabolic/glycaemic control outcomes (e.g. HbA1c, blood glucose levels) favoured the intervention groups, particularly in the short-term (e.g. at 3 month follow-up). The magnitude of improvement ranged from small to large (Fan and Sidani 2009, Fitzpatrick et al 2013, Minet et al 2010). Trends in outcomes for blood pressure, cholesterol, triglycerides/lipids, BMI/weight/waist circumference were less consistent among the included reviews (Appendix 3).

Knowledge

Knowledge was evaluated in 12 reviews (Appendix 4). Relatively consistent (n=10 reviews) and substantial (effect sizes 0.46 to 1.84) improvements in diabetes knowledge was reported for people with diabetes in the short (e.g. 3-6 months) and longer-term (e.g. 12-14 months). A positive relationship and significant association between knowledge and health literacy was specifically evaluated and reported in two reviews (Al Sayah et al 2012, Fransen et al 2011).

Self-management behaviours

Nineteen reviews evaluated the effect of approaches and strategies on a range of self-management behaviours (Appendix 5). The results were inconsistent and varied for most outcomes, but particularly for physical activity (Dale 2012, Fitzpatrick et al 2013, Hunt et al 2011) and medication adherence (Omran et al 2012, Viswanathan et al 2012, Williams et al 2014). However, it is important to note that only five of these reviews reported on interventions with a specific self-management focus (Fan & Sidani 2009; Steinsbekk et al 2012; Viswanathan et al 2012; Fitzpatrick et al 2013; Williams et al 2014). The summary of reviews that were specific to the diabetes population included positive effects for diet and global diabetes adherence (Fitzpatrick et al 2013) and general self-management behaviours (Fan & Sidani 2009, Steinsbekk et al 2012); while one review was unable to draw firm conclusions due to study heterogeneity (Williams et al 2014). In addition, three reviews evaluated the association between health literacy and self-care or self-management behaviours; findings were inconclusive (Al Sayah et al 2012, Loke et al 2012, Fransen et al 2011).

Quality of life

Quality of life was evaluated in seven reviews (Appendix 6). Three reviews reported improvements in a range of quality of life outcomes for people with diabetes following interventions (Leelarathna et al 2010, Srinivasan et al 2008b, Zhang et al 2007), two of which focused on middle to longer term quality of life outcomes (e.g. six to 12 months) for interventions when compared with usual care and waiting list control conditions (Leelarathna et al 2010, Srinivasan et al 2008b), and one which calculated pooled effects from randomised controlled trials for outcomes such as physical function, mental health and bodily pain (Zhang et al 2007). The conclusions from the remaining four reviews were limited by the heterogeneity of included studies (Loveman et al 2009, Omran et al 2012, Srinivasan et al 2008a, Steinsbekk et al 2012).

Health care costs and health service usage

There were thirteen reviews that evaluated health care costs or health service usage for people with diabetes (Appendix 7). Summaries of findings among the majority of reviews indicated a positive trend towards reduced health care costs (Deakin et al 2009, Pennington et al 2013, Viswanathan et al 2012, Wubben & Vivian 2008) and improved health service utilisation (Adaji et al 2008, Boren et al 2009, Jackson et al 2006). The findings of the remaining reviews were predominantly limited by a lack of data and methodological issues in small numbers of included studies.

Psychosocial outcomes

Nine reviews evaluated psychosocial outcomes for people with diabetes following intervention (Appendix 8). Overall, findings were promising for depression (Dale et al 2012, Fitzpatrick et al 2013), empowerment / self efficacy (Dale et al 2012, Steinsbekk et al 2012), health care attitudes (Jackson et al 2006), and the provision of support (Adaji et al 2008, Dale et al 2012). However, the specific effects of different models of peer support were unable to be determined by Dale et al (2012), and limited numbers of eligible studies precluded meta-analysis in the review by Duke et al (2009). The evidence was inconsistent and insufficient for the relationship between health literacy and psychosocial outcomes (Al Sayah et al 2012, Fransen et al 2011).

Diabetes complications

Inconclusive findings were reported among the six reviews that evaluated the effects of interventions on the prevalence or risk of diabetes complications (Appendix 9). While the included studies in three reviews were characterised by high risk of bias (Al Sayah et al 2012, Dorresteijn et al 2011, Dorresteijn et al 2012), the main limitations were inconsistencies in the evidence (Al Sayah et al 2012, Dorresteijn et al 2012), the existence of few relevant studies (Dorresteijn et al 2011), and a lack of data (Duke et al 2009, Loveman et al 2009, Omran et al 2012). Given the current research literature in this area, it is not possible to comment on whether an association exists between health literacy and diabetes complications (Al Sayah et al 2012).

Other outcomes

Seven reviews evaluated the efficacy of interventions across a range of other outcomes (Appendix 10), with positive effects reported for patient satisfaction (Dennis et al 2013, Steinsbekk et al 2012), the use of information technology for health-care purposes (Al Sayah et al 2012, El-Gayar et al 2013), bioclinical, educational, psychosocial, and economical criteria (Albano et al 2008), and providing links between community and healthcare providers by way of culturally appropriate interventions (Hunt et al 2011). One review was concerned with identifying barriers to information technology use in diabetes care (Adaji et al 2008). There was limited low level evidence of a relationship between health literacy and patient-provider communication, and the use of information technology for health-related learning (Al Sayah et al 2012).

Question 4

What are the characteristics of effective approaches and/or strategies (e.g. health literacy environment) aimed at developing or improving individual health literacy in people with diabetes?

Figure 2 summarises the characteristics of effective approaches to improving or developing health literacy in people with diabetes

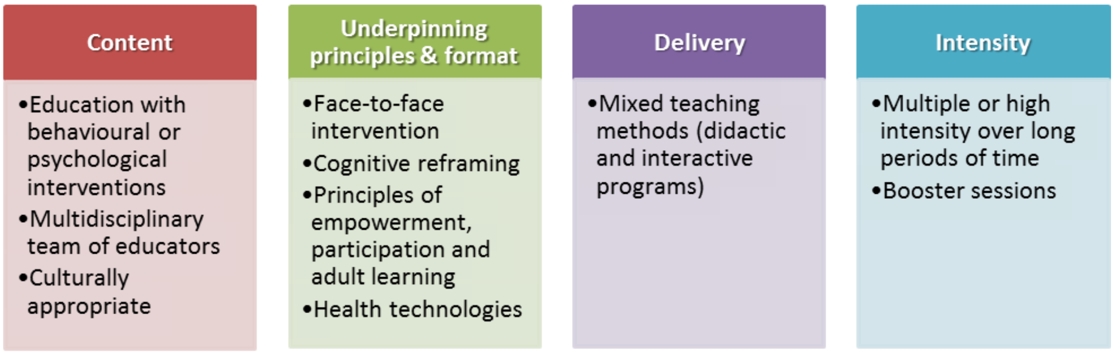

Figure 2 Effective approaches to health literacy

Content

Education combined with behavioural or psychological interventions was most effective for increasing knowledge and achieving physiologic control of diabetes (Fan and Sidani 2009). Successful interventions for health literacy generally consisted of patient education, problem solving training sessions, engaging patients in skills building (e.g. self-management skills), and counselling (Sarkisian 2003; Loveman et al 2008; Fan and Sidani 2009; Fitzpatrick 2013).

Educational interventions linked to positive health outcomes consist of multiple components (Loveman et al 2008), were structured (Leelarathna 2010) and delivered by a multidisciplinary team of educators (e.g. nurse educators, pharmacists, community health workers, dieticians, diabetes educators) trained to facilitate a diabetes education program (Deakin et al 2005; Albano 2008; Loveman et al 2008; Walker et al 2013; Williams et al 2014). Education delivered with some degree of reinforcement of that education made at additional points of contact provided the best opportunity for improvements in patient outcomes (Loveman et al 2008). A standardised diabetes education that is accessible to all diabetes patients was also proposed (Qingping 2011).

Culturally appropriate interventions that are tailored to the needs of the patients was highlighted in the literature as fundamental to an effective intervention for promoting health literacy (Glazier et al 2006; Hunt et al 2011; Walker et al 2013).

Underpinning principles and format

Diabetes education that relies on face-to-face interaction enhanced communication and was more likely to be successful (Ellis et al 204; Fan and Sidani 2009). Educational models that utilised cognitive reframing as a method for teaching tend to promote psychosocial interaction and require patients to be more engaged in the process, potentially leading to better outcomes (Ellis et al 204). Use of principles of empowerment, participation and adult learning proved effective for delivering education and teaching self-management skills (Deakin et al 2005).

Use of health technologies including cellular phones and internet or web-based interventions played a role in improving health literacy (Boren 2009; Ramadas et al 2011; El-Gayar et al 2013; Williams et al 2014. However, not all patients were motivated to incorporate technology in their daily routine (El-Gayar et al 2013). Providing appropriate incentives (El-

Gayar et al 2013), fitting the technology to the needs, viewpoints, experiences and requirements of the patient (Boren 2009; El-Gayar et al 2013), and increasing user-friendliness can increase its use (El-Gayar et al 2013). Constant tracking of patients' progress, setting personalised goals, strong theoretical background, self-monitoring, providing social and peer support were important determinants of the success of a web-based intervention (Ramadas et al 2011). In addition to health technology already outlined, Boren (2009) suggested that when designing intervention for people with limited literacy, the following information and communication technologies might be appropriate:

- Computer-based algorithms that take a patient's characteristics into account such as language, age, gender, ethnicity, reading ability, health literacy level, and specific goals or needs
- Electronic medical record to prompt the use of plain language, limit the number of concepts covered, and assess patient understanding by using tell back or teach back
- Interactive multimedia programs for education and counselling
- Health information prescriptions that include a link or recommendation to an appropriate website and/or referral to a health librarian;

Telephone coaching seemed to work for vulnerable populations who have difficulty accessing health services (Dennis et al 2013). Where the aim is primarily to provide information and increase knowledge and education, a scripted model of telephone coaching appeared effective in providing health education. However, if the focus is on active management of diabetes, a reactive telephone coaching seemed to be more effective.

Delivery

Mixed teaching methods (i.e. didactic and interactive programs) were more effective than either didactic or interactive method alone in improving knowledge, physiologic control or self-management behaviour (Fan and Sidani 2009). Glazier (2006) argued that those interventions that used mainly didactic teaching that focused only on diabetes knowledge are associated with negative outcomes.

Intensity

Multiple or high intensity interventions delivered over a long period of time enhanced the effectiveness of interventions and helped sustain the beneficial effects of educational programmes (Glazier 2006; Fan and Sidani 2009; Qingping 2011; Fitzpatrick 2013). Fitzpatrick (2013) proposed approximately four or more sessions, while Glazier (2006) suggested more than 10 contact times for a period of at least six months to achieve positive effects. Providing additional sessions (i.e. booster sessions) on an annual basis has long lasting benefits and helps maintain the desired changes (Deakin et al 2005; Fan and Sidani 2009).

Identified gaps in the literature

Within this body of literature, several research gaps were identified, including:

- Lack of consistency in the health literacy and diabetes management nomenclature

- Large range of variability in the nature of interventions and outcome measures used
- No studies aimed at investigating the success rate of different and specific individual components of interventions/approaches/strategies (e.g. randomised controlled trials with a number of treatment arms/control)

Conclusion

The evidence from a range of literature sources has been summarised using the NHMRC Body of Evidence Matrix (NHMRC 2009). This framework considers different dimensions of research evidence and ranks them accordingly.

After considering various dimensions of evidence underpinning the rapid review questions, the overall body of evidence using this matrix was **B**.

Component	Evidence Grading
Evidence base *The evidence base is assessed in terms of the quantity, level and quality (risk of bias) of the included studies.*	A
Consistency *The consistency component of the 'body of evidence' assesses whether the findings are consistent across the included studies.*	C
Clinical impact *Clinical impact is a measure of the potential benefit from application of the findings to a population.*	B
Generalisability *This component covers how well the subjects and settings of the included studies match those of the recommendations.*	B
Applicability *This component addresses whether the evidence base is relevant to the Australian healthcare setting generally.*	A

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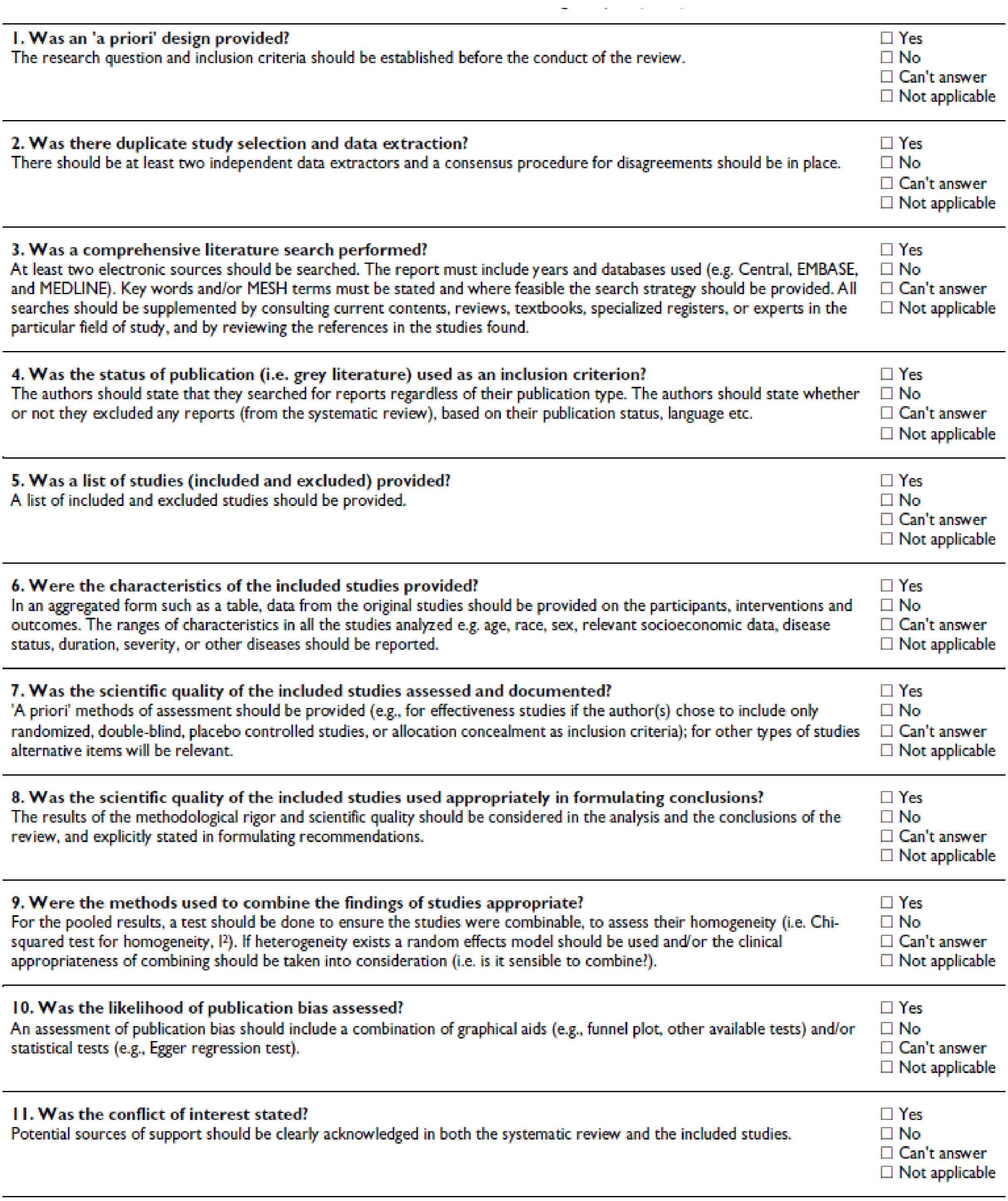
APPENDIX 1

AMSTAR Critical Appraisal Tool



1. Was an 'a priori' design provided? The research question and inclusion criteria should be established before the conduct of the review.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
3. Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
7. Was the scientific quality of the included studies assessed and documented? 'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
11. Was the conflict of interest stated? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable

APPENDIX 2

Summary of outcomes assessed in included reviews

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
1	Fan & Sidani 2009	gamma hydroxybutyrate (GMA), fasting blood glucose, systolic blood pressure, diastolic blood pressure, cholesterol, triglycerides, body weight/body mass index (BMI)		knowledge	diet, exercise, self-monitoring blood glucose, medication, recognition of complications, foot care					
2	Fitzpatrick et al 2013	HbA1c, total cholesterol, low density lipoprotein (LDL), high density lipoprotein (HDL), systolic blood pressure, diastolic blood pressure, weight, BMI, waist circumference, and symptoms of hypo/hyperglycaemia			diet, exercise, self-monitoring of blood glucose, medication adherence, problem solving skill or process			self-efficacy, patient activation, depression, patient-provider communication		
3	Glazier et al 2006	A1C (glycosylated haemoglobin), weight/BMI, lipids, blood pressure, eye examination, diabetes care indicators	physical activity	Diabetes knowledge				Physician trust		
4	Medical Advisory Secretariat 2009	HbA1C								
5	Krishna et al 2009	blood sugar level, HbA1c								
6	Leelarathna et al	HbA1c				Quality of life				

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
	2010									
7	Williams et al 2014	HbA1c			Medication adherence (measured through pharmacy claims, electronic monitoring, pill count, self-report or serum/blood levels)					
8	Loveman et al 2008	glycated haemoglobin, blood pressure, BMI/weight, cholesterol and triglycerides								
9	Minet et al 2010	HbA1c								
10	Omran et al 2012	fasting blood glucose, blood pressure, cholesterol, BMI			Medication adherence (as measured by patient self-report, pharmacy refill records or pill counts or more than one method)	Quality of life	Health expenditure		10-year risk of cardiovascular event	
11	Pennington et al 2013	HbA1c					Cost-effectiveness			
12	Sarkisian et al 2003	A1c				Quality of life				
13	Sigurdardottir et al 2007	HbA1c		Basic diabetes knowledge	diet or nutrition, physical activity, medication adherence, and self-monitoring of blood glucose					
14	Srinivasan et al 2008a	glycohaemoglobin, HbA1, HbA1c				Quality of life				
15	Srinivasan et al 2008b	HbA1c				Quality of life				
16	Steinsbekk et al 2012	HbA1c, mortality rate, body mass index, blood			self-care activities, health behaviour conduct, problem	Quality of life, and	cost-effectiveness, cost of delivering	self-efficacy/empowerment		patient satisfaction

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	**Function**							
		pressure and lipid profile			solving, self-monitoring of blood glucose		the program			
17	Viswanathan et al 2012				Medication adherence					
18	Walker et al 2013	HbA1c								
19	Wubben & Vivian 208	A1c, blood pressure, lipid profile					Cost of intervention			
20	Yamaoka & Tango 2005	2-h plasma glucose, risk of developing diabetes (incidence)								
21	Zhang et al 2007					Quality of life using SF-36				
40	Deakin et al 2009	PRIMARY Glycated haemoglobin (%) and fasting blood glucose (mmol/L) Body weight (Kg)/body mass index (BMI)(Kg/m2); SECONDARY • Blood pressure (systolic/diastolic) (mmHg); • Lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides) (mmol/L);		Diabetes knowledge		Quality of life		Empowerment/self-efficacy	Diabetes complications (myocardial infarction, angina, heart failure, stroke, renal failure, neuropathy, retinopathy, peripheral vascular disease); Diabetes-related mortality (death from myocardial infarction, stroke, peripheral vascular disease, renal disease, hyper- or hypoglycaemia or sudden death; • Adverse effects e.g. increased hypoglycaemia.	Patient treatment satisfaction
41	Li et al 2011	Change in kidney functional measures during follow-up		Knowledge of DKD.	Patients' behavioural changes (e.g.	QOL by any scale		Attitude scales. Measures of patient	• Incidence of kidney death during	Adverse effects of educational

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
		(e.g. creatinine clearance (CrCl), glomerular filtration rate (GFR), serum creatinine (SCr), proteinuria) for patients with DKD. Changes in blood pressure, blood glucose (HbA1c) and lipids.			smoking cessation, increased exercise, modifying diet, adherence to medications)			empowerment and self-efficacy	follow-up: need to start RRT, either haemodialysis (HD) or peritoneal dialysis (PD) in patients with DKD. • Total and specific mortality rates from causes attributable to DKD • Incidence of cardiovascular disease (CVD).	programmes (e.g. deteriorating QoL or biomedical parameters).
42	Vermeire et al 2011	blood glucose level, urinary glucose level, glycated haemoglobin concentration, levels of a prescribed drug in the blood, weight, blood lipids (cholesterol, triglycerides), serum creatinine, blood pressure	self-reported or self-monitored functional status measured using validated instruments (functional status defined as the ability to perform daily life activities (for example, walking, preparing meals, communicating with others,...) (ideally, measured using validated instruments);)		smoking habits (if the intervention was also aimed at smoking cessation); pill counts, refill records. self-reported or self-monitored adherence, using validated instruments;	quality of life, well being, perceived health quality (ideally, measured using validated instruments);	hospitalisation rate or readmission rates to hospital, and referral to specialised diabetes care providers (for example physicians, podologists, dieticians); appointment making and keeping, use of preventive services costs;	self-reported or self-monitored well-being or perceived health quality using validated instruments;	diabetes related morbidity (hypoglycaemia and cardiovascular, neurologic, ophthalmologic and nephrologic complications), total and diabetes related mortality (death from myocardial infarction, stroke, peripheral vascular disease, renal disease, hyper- or hypoglycaemia or sudden death),	self-reported or self-monitored patient satisfaction using validated instruments; obstacles to adherence (for example, dosing, packaging, the treatment's complexity, the understanding of given instructions, issues related

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
							.			to the health care system) adverse effects of the intervention
43	Dorresteijn et al 2012			foot care knowledge scores,	patients' behaviour assessment scores.		number and duration of hospital admissions for diabetic foot problems.		Foot ulceration or ulcer recurrence. Amputation callus development, resolution of callus, fungal infection,	
44	Loveman et al 2009	glycosylated haemoglobin (HbA1c); BMI				QOL (ideally using a validated instrument)	Emergency admissions costs		sort term diabetic complications (hypoglycaemic episodes, ketoacidotic incidents); long term diabetic complications (e.g. diabetic retinopathy, neuropathy, nephropathy) mortality.	Adverse effects
45	Dorresteijn et al 2011			foot care knowledge scores;	patients' behaviour assessment scores (e.g. washing, creaming, foot inspection, cutting		• number and duration of hospital admissions for diabetesrelated foot problems		incidence of foot ulceration; rates of amputation (partial or total)	• adverse events.

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
					toe nails, use of pumice stones, foot gymnastics);		costs;		callus development (e.g. presence of lesions, or a detailed description of the number, location or diameter of lesions); resolution of callus;	
47	Dennis et al 2013	Physiological measures of disease, e.g. improvement in HbA1c			Health behaviour, e.g. improvement in diet/exercise Adherence (e.g. Medication use increase. More uploads resulted in greater reduction in HbA1c)	QOL	Health service use, e.g. higher Medicare claims	Self-effiacy Health status		Satisfaction (found it convenient & improved problem solving skills) Acceptability
48	Al Sayah et al 2012	Glycemic control (HBA1c) Hypoglycaemia BP LDL		Diabetes knowledge	Self monitoring of blood glucose & other self-management			Self-efficacy	Diabetes complications	Health literacy Patient-provider communication Patient trust Use of computers internet Other outcomes
50	Hawthorn et al 2010	biomedical measures of		validated questionnaire		a patient-oriented	acute hospital admissions,	Patient attitude	recorded long-term diabetic	Patient satisfaction

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	**Function**							
		glycated haemoglobin (HbA1c) and blood pressure (BP). body mass index (BMI), lipid levels,		s of knowledge of diabetes and its management .		measure of quality of life as measured using validated tools	health economic assessments	empowerment and self efficacy	complications mortality rates, episodes of hypoglycaemia.	
54	Jayasekara et al 2011	Glycaemic control measured by glycated haemoglobin concentration (HbA1c-level) and/or fasting plasma glucose level • Continuous blood glucose monitoring • Body mass index and weight		Insulin pump knowledge					Episode of diabetic ketoacidosis (DKA) • Frequency and severity of hypoglycaemia • Frequency of admission/presentation/contact with healthcare professionals for blood glucose level problems • Frequency of site complications (including infection)	
55	Perez-Escamilla et al 2008	Type 2 diabetes metabolic outcomes,		nutrition knowledge	Type 2 diabetes behavioral outcomes nutrition behaviors.			attitudes		
57	Fransen et al 2011	HBA1c		DK knowledge (DKQ) Knowledge complications Knowledge food values	Medication adherence Self-management (SDSCA, SBMG, subjective scale for diabetes self-Mx activities)			Self-efficacy (self-report)		Health literacy (REALM-R, subjective literacy, s-TOFHLA) Patient trust (HCR trust

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
				Knowledge self-management	Glucose self-monitoring Diabetes Health Beliefs (DMBM)					scale) Social support (MOS social support survey)
59	Qingping et al 2011	Non-invasive / physical: BMI, SBP, DBP, WHR, Waist circumference Internal / biochemical: FBS, PBS, HbA1c, TC, TG, HDL/LDL, creatinine, UA, TP		Diabetes knowledge Knowledge of nutrition Knowledge of exercise Knowledge of medication Knowledge of management & monitoring Knowledge of diagnostic criteria	Diet control Calorie intake Oil intake Meat & egg intake Choosing low GI foods Exercise SMBG Medication on time Foot care Clinic visits Stop smoking Controlling emotion Communicating with doctors	Health status: Somatisation symptoms, obsessions, interpersonal sensitivity, depression, anxiety, hostile, horror, paranoid, psychotic symptoms, SAS, SDS, HAMD, QOL, self-effiacy				
61	Adaji et al 2008				Foot check Eye check					Uses of IT to support diabetes care

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
					Immunisations Nutrition advice & changes Smoking cesstion & advice Physical activity & advice Medications					Impact of IT in diabetes care Barriers & facilitators to using IT in diabetes care
62	Ramadas et al 2011	HbA1c, FBC, Weight, cholesterol			Physical activity behaviour	QOL		Self-effiacy		Social support Diabetes risk factors (clinical composite score)
63	Hunt et al 2011	HBA1c BP Cholesterol, HDL, LDL, triglycerides	"Health status"	Diabetes knowledge	Physical activity Dietary changes / adherence to nutrition practices Self-monitoring blood glucose Foot care Adherence to medication Self-reported learning of self-management skills Self-reported learning of problem-solving skills		ED visits Annual foot exams (by a physician)	Diabetes related mental well-being Increased perceived social support Self-reported receipt of support, assistance, encouragement, and motivation Realization of the importance of diabetes knowledge, challenges for self-management, and selfcare practices in diabetes management and		

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
					Self-reported learning of coping skills Adoption of self-care practices			improved self-efficacy		
64	Jackson et al 2006	HBA1c body weight, blood pressure, microalbumin, creatinine, lipids, hematocrit values		patients' understanding of their medical condition (knowledge)	Self-report & documentation of diabetic crises Personal health care patient skills (interventions easy to use & understand)	QOL	Hospitalisations Primary care visits Foot exams Eye exams HBA1c tests Costs (associated with interventions)	depression, perceived support		Rate of completion of intervention Patient satisfaction (with intervention)
66	Boren et al 2009	BMI Waist & hip circumference/waist :hip ratio HBA1c Lipid levels LDL BP		Food portion knowledge		QOL	Medical claims cost total health care costs, total diabetes related costs outpatient costs, inpatient costs, medication costs, cost per quality-adjusted life year,	Diabetes-related distress		

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
							cost of primary prevention of diabetes, number needed to treat to reduce 1 case of diabetes, cost per depression-free day cost of restricted activity			
67	Ellis et al 2004	Glycemic control – HbA1c								
76	Loke et al 2012	INR variability & time in therapeutic range % of INRs within therapeutic age; maximum INR, number of dose within therapeutic range ; dose change and number of dose alterations;		Health literacy – REALM-R; TOFHLA; REALM; S-TOFHLA	Adherence measures – Morisky adherence scale (self reported); phone interview postdiascharge (based on Medication Knowledge and Compliance Scale); questions re: drugs in previous week compared to weekly doses; (missed) clinic visits DRUGS CMG					

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
77	Boren 2009	HbA1c SBP DBP		Measures of Literacy/Numeracy specific to diabetes: Nutritional Literacy Scales Diabetes Numeracy Test Single Item Literacy screener Literacy Assessment for Diabetes Spoken knowledge in low literacy patients with diabetes Health literacy assessments: REALM WRAT3 DNT S-TOFHLA NART RSPM, and Self-reported health literacy. (Interviewers asked participants how often they have	Self-reported: Optimal diet Exercise Self-monitoring blood glucose Foot care Medication adherence		Healthcare access	Self-efficacy Depressive symptoms Self-rated health	Self-reported diabetes complications	Trust Interest in telephone support

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
				problems learning about their medical condition because of difficulty understanding written information.) Knowledge of symptoms of hypoglycemia						
5	El-Gayar 2013	HbA1c BMI BP Glucose values Fasting plasma glucose Weight Insulin (dose) LDL			Behaviour – intake of healthy food Healthy behaviour Physical activity	QOL		Depression, anxiety & mental disorder		Usability Composite rating
12	Dale 2012	HbA1c BP Cholesterol Symptoms of hypo- & hyperglycemia BMI/weight/body fat/waist	Fatigue	Knowledge outcomes	Physical activity/fitness Glucose monitoring Diet Insulin therapy		Clinic & communication visits	Self-efficacy Depression/health distress Perceived social support		Perceived barriers acceptability

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
		measurement								
17	Duke 2009	HbA1c physical measures (body mass index (BMI, kg/m2), weight (kg), blood pressure (systolic and diastolic (mmHg)); metabolic (lipids - total cholesterol (mmol/L), HDL cholesterol (mmol/L), LDL cholesterol (mmol/L), triglycerides (mmol/L)).		Diabetes knowledge	patient self-care behaviours (dietary habits, physical activity levels) self management skills (medication administration, use of equipment);	QOL	health service utilisation and health care costs (admission and readmission rates, average length of stay, visits to the general practitioner and the emergency department).	psychosocial outcomes (quality of life, psychological problems such as depression);	diabetes complications (eg retinopathy, nephropathy, neuropathy, lower limb amputation, cardiovascular disease	
22	Albano 2008	<u>Bioclinical criteria:</u> HbA1c Blood glucose Cholesterol BP BMI Cardiovascular risk factors		Diabetes knowledge	Development of self-management skills: Foot care Physical activity Diet Control of blood glucose Prevention of hypo & hyperglycemia crises Compliance Self-care competencies	QOL	Days of hospitalisation Admission rate to ED	<u>Self-assertion:</u> Self-consciousness Self-expression Self-efficacy Decision-making ability Degree (reduction in) external dependence Depression Tobacco assumption Wellbeing <u>(Improved: patient's relation towards the disease</u>: (higher) motivation and compliance to	Long-term diabetes ocmplications "better" use of health care system Cost-efficiency ratio (positive)	level of satisfaction towards TPE Barriers to therapeutic patient education (TPE)

No.	Author, date	Clinical outcomes		Knowledge	Self-management behaviour	Quality of life	Healthcare cost/health service use	Psychosocial outcomes	Diabetes complications	Others
		Physiological	Function							
								treatment, (more) active participation to education, positivisation of health beliefs, feeling of wellbeing, improved quality of life, (Improvement in) the relationship with the Others: (better) social functioning and communication with health care providers, increased confidence in the doctors Social functioning		

APPENDIX 3

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on clinical outcomes, mapped according to whether results favoured the intervention or were inconclusive

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
Fan & Sidani 2009	The weighted mean effect size of the diabetes self-management education interventions was 0.51 for metabolic control (e.g. HbA1c, fasting blood glucose, blood pressure, cholesterol, triglycerides and weight/BMI).	
Fitzpatrick et al 2013	Fifty per cent of studies reported significant improvements in HbA1c following intervention, ranging from -0.09 to -0.93. These improvements in HbA1c were seen over 3–12 months of follow-up. In three studies, however, the improvement in HbA1c was not maintained at 6-month follow-up, 12-month follow-up , or 18-month follow-up.	Mixed and/or inconclusive results for the outcomes of total cholesterol, LDL, HDL, systolic/diastolic blood pressure, waist circumference, weight/BMI, and symptoms of hyper/hypoglycaemia.
Glazier et al 2006		Interventions (patient, provider, and health system interventions to improve diabetes care) for socially disadvantaged populations can be effective and have the potential to reduce health disparities in diabetes care and outcomes; key intervention features may predict success.
Medical Advisory Secretariat 2009	Based on low quality evidence, blood glucose home telemonitoring and management technologies confer a statistically significant reduction in HbA1c of approximately 0.50% when used adjunctively to a broader telemedicine initiative in comparison to usual care in adults with type 2 diabetes.	
Krishna et al 2009	Information and education interventions delivered through wireless mobile technology resulted in clinical improvements in HbA1c and blood sugar levels.	
Leelarathna et al 2010		Immediate insulin dose adjustment training to enable dietary freedom (Dose Adjustment for Normal Eating [DAFNE] training) may be more effective than waiting list control at improving HbA1c levels at six and 12 months in adults with type 1 diabetes.
Loveman et al 2008		Studies of multi-component educational interventions yielded mixed results: • Some trials reported significant improvements on measures of diabetic control but others did not.

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
		• Positive effects may be attributable to longer-term interventions with a shorter duration between the end of the intervention and the follow-up evaluation point. • There may also be an effect of having a multi-professional team delivering the educational programme. • Studies of focused educational interventions did not yield consistent results. Some effects were shown on measures of diabetic control in studies that focused on diet or exercise alone.
Minet et al 2010	The analysis showed a 0.36% (95% CI 0.21–0.51) improvement in glycaemic control in people who received self-care management treatment. In type 2 diabetes, there are improvements in glycaemic control in people who receive self-care management treatment with a small advantage to interventions with an educational approach.	
Omran et al 2012		Effect of pharmacist interventions on this outcome cannot be established
Pennington et al 2013	Significant decrease in HbA1c levels (no pooled results were reported) was reported for health-related lifestyle advice delivered by peer or lay advisors (using low intensity telephone, group or individual counselling)	
Sarkisian et al 2003		Many of the studies included in the review had several methodological weaknesses that limit conclusions about the impact of the interventions (Self-care interventions). The findings are meant to guide future research than to serve as final answers to how care should be designed for older adults with diabetes.
Sigurdardottir et al 2007	For initial levels of HbA1c ≤7.9% the diabetes education intervention achieved a small change in HbA1c level, or from 0.1 to 0.7%. For initial levels of HbA1c ≥8.0%, a significant drop in HbA1c level of 0.8-2.5% was found.	Duration, educational content, teaching methods and intensity of education did not predict changes in HbA1c level.
Srinivasan et al 2008a		For intensive education compared with control: Educational interventions may be more effective at reducing glycated haemoglobin levels (very low-quality evidence). For intensive education compared with usual care: A six-month education programme may be more effective at reducing HbA1c levels at six weeks (very low-quality evidence). For group education compared with usual care: Group education may be

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
		more effective at reducing HbA1c levels at two years (very low-quality evidence). For group education compared with individual education: unclear (very low-quality evidence).
Srinivasan et al 2008b		Compared with usual care/waiting list control in adults: Immediate insulin dose adjustment training to enable dietary freedom (Dose Adjustment for Normal Eating [DAFNE] training) may be more effective at improving HbA1c levels at six months, and may maintain the improvement at one year (low-quality evidence).
Steinsbekk et al 2012	Group-based diabetes self-management education: HbA1c was significantly reduced at six months (0.44% points; P = 0.0006, 13 studies, 1883 participants), 12 months (0.46% points; P = 0.001, 11 studies, 1503 participants) and two years (0.87% points; P<0.00001, 3 studies, 397 participants) and fasting blood glucose levels were also significantly reduced at 12 months (1.26 mmol/l; p<0.00001, 5 studies, 690 participants) but not at six months. There were significant improvements in patient satisfaction and body weight at 12 months for the intervention group. There were no differences between the groups in mortality rate, body mass index, blood pressure and lipid profile.	
Walker et al 2013		All studies with statistically significant results used problem solving with the patient, were culturally tailored and used a nurse educator.
Wubben & Vivian 208	Overall improvement in HbA1c was reported for patients receiving pharmacist outpatient intervention	
Yamaoka & Tango 2005	Lifestyle education intervention reduced 2-h plasma glucose by 0.84 mmol/l (95% CI 0.39 –1.29) compared with the control group. The 1-year incidence of diabetes was reduced by ~50% (RR 0.55, 95% CI 0.44–0.69) compared with the control group.	
Deakin et al 2009	Fourteen publications describing 11 studies were included involving 1532 participants. The results of the meta-analyses in favour of group-based diabetes education programmes were: reduced glycated haemoglobin at four to six months (1.4%; 95%CI 0.8 to 1.9; P < 0.00001),	

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
	at 12-14 months (0.8%; 95% CI 0.7 to 1.0; $p < 0.00001$) and two years (1.0%; 95% CI 0.5 to 1.4; $P < 0.00001$); reduced fasting blood glucose levels at 12 months (1.2 mmol/L; 95% CI 0.7 to 1.6; $P < 0.00001$); reduced body weight at 12-14 months (1.6 Kg; 95% CI 0.3 to 3.0; $P = 0.02$); and reduced systolic blood pressure at four to six months (5 mmHg: 95% CI 1 to 10; $P = 0.01$).	
Vermeire et al 2011	Twenty-one studies assessing interventions aimed at improving adherence to treatment recommendations, (not to diet or exercise Recommendations) in people living with type 2 diabetes in primary care, outpatient settings, community and hospital settings, were included. Outcomes evaluated in these studies were heterogeneous, there was a variety of adherence measurement instruments. Nurse led interventions, home aids, diabetes education, pharmacy led interventions, adaptation of dosing and frequency of medication taking showed a small effect on a variety of outcomes including HbA1c.	
Loveman et al 2009		Six trials including 1382 participants followed for six to 12 months were included. Two trials were in adolescents. Due to substantial heterogeneity between trials a meta-analysis was not performed. Glycated haemoglobin (HbA1c) in the intervention groups was not found to be significantly different from the control groups over a 12 month follow up period. One study demonstrated a significant reduction in HbA1c in the presence of the diabetes specialist nurse/nurse case manager at 6 months. Significant differences in episodes of hypoglycaemia and hyperglycaemia between intervention and control groups were found in one trial. No information was found regarding BMI.
Al Sayah et al 2012	<u>Diabetes knowledge</u>: Consistent and sufficient evidence showed a positive association between health literacy and diabetes knowledge (eight studies). <u>Blood Pressure</u>. Two studies explored the relationship between health literacy and blood pressure in people with diabetes, although only one adjusted for potential confounders.20 Both studies reported that lower health literacy was associated with better control of blood pressure. This evidence was rated low.	There was a lack of consistent evidence on the relationship between health literacy or numeracy and clinical outcomes, e.g.HbA1c (13 studies), self-reported complications (two studies), and achievement of clinical goals (one study); behavioural outcomes, e.g. self-monitoring of blood glucose (one study), self-efficacy (five studies); or patient-provider interactions (i.e. patient-physician communication, information exchange, decision-making, and trust), and other outcomes. The majority of the studies were from US primary care setting (87.5 %), and there were no randomised or other trials to improve health literacy.

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
		Glycemic Control: The relationship between health literacy and HbA1c was explored in 13 studies; 12 of which were cross-sectional and one longitudinal. Some of the identified studies showed that higher levels of health literacy were associated with better glycemic control and this relationship was mostly observed in studies that adjusted for age, sex, race, education, and treatment regimen. Moreover, few studies reported that health literacy has indirect effect on glycemic control, but did not show any direct associations. Overall, evidence on the relationship between health literacy and glycemic control was inconsistent across studies, and the heterogeneity did not permit the estimation of an overall effect. Therefore, this evidence was rated insufficient. We were able to observe a trend between confounders controlled for and reported estimates in studies that explored the relationship between health literacy and HbA1c. The association between health literacy and HbA1c was significant in studies that did not adjust for diabetes knowledge; however, that association was not observed in studies that controlled for diabetes knowledge. Similar trends were not observed for other outcomes because of the small number of available studies. Hypoglycemia. Two studies explored the relationships between low health literacy and self-reported hypoglycemia, and one of these studies reported that lower health literacy was associated with higher frequency of self-reported hypoglycemia. The quality of evidence from these two studies was rated low. Low-Density Lipoprotein (LDL). One study that adjusted for potential confounders explored the relationship between health literacy and low-density lipoprotein (LDL), and showed that health literacy was not associated with LDL levels.
Hawthorn et al 2010	Few studies fitted the selection criteria, and were heterogeneous in methodologies and outcome measures, making meta-analysis difficult. HbA1c showed an improvement at 3 months [weighted mean difference (WMD) 0.32%;95%confidence interval (CI)) 0.63, 0.01]	

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
	and 6 months post intervention (WMD) 0.60%, 95% CI)0.85,)0.35). Culturally appropriate health education was more effective than 'usual' health education in improving HbA1c and knowledge in the short to medium term. Due to poor standardization between studies, the data did not allow determination of the key elements of interventions across countries, ethnic groups and health systems, or a broad view of their cost-effectiveness.	
Jayasekara et al 2011		A total of five descriptive studies were included in the review. The included papers reported a variety of educational methods and different outcome measures.
Qingping et al 2011	Based on the 34 articles, studies often took place in inpatient and outpatient department. Popular methods used were class teaching, or one-on-one teaching, and knowledge and glycemic control were mostly selected as the outcome measurements. Beneficial effects of diabetes education on glycemic control were demonstrated in studies during a relatively short follow up (3–6 months).	Limitations to the studies selected were that the effects of interventions on behaviour change, BMI, blood pressure, lipids, and medical costs were not clearly addressed, and long term outcomes and adherence to diabetes education was unknown.
Adaji et al 2008	IT use has been associated with a corresponding improvement in measures of diabetes care including HbA1c, blood pressure and lipids, and in the frequency of eye and foot exams.	
Ramadas et al 2011	Twenty articles representing 13 different studies were reviewed. None of the studies were ranked as low in the methodological quality. Goal-setting, personalised coaching, interactive feedback and online peer support groups were some of the successful approaches which were applied in e-interventions to manage type 2 diabetes mellitus. Strong theoretical background, use of other technologies and longer duration of intervention were proven to be successful strategies as well.	
Hunt et al 2011	Community health advisors' theoretical interventions were based on providing culturally appropriate care and resolution of health disparities within minority populations. Typically community health advisors were patients themselves living with type 2 diabetes mellitus. Major roles of community health advisors included: supporter, educator, case manager, advocate, and program facilitator. Activities of community health advisors were: coordinating educational programs, conducting educational courses for patients, serving as a link between patients and healthcare	

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
	professionals, providing counselling, and leading peer support meetings. The effectiveness of interventions by community health advisors was mixed. Examples of outcome criteria were improvements in: knowledge, Hb A1C, low density lipoprotein levels, blood pressure, and physical activity. Community health advisors provide culturally appropriate interventions to promote and restore health and prevent diseases while serving as links between community and healthcare providers.	
Jackson et al 2006		There were 26 studies (27 reports): internet (n=6; 3 RCTs), telephone (n=7; 4 RCTs), and computer-assisted integration of clinical information (n=13, 7 RCTs). The median (range) sample size was 165 (28 to 6,469 participants) for patients and 37 (15 to 67) for providers; the median duration was 6 (1 to 29) months. Ethnic minorities or underserved populations were described in only 8 studies. Six of 14 interventions demonstrated moderate to large significant declines in haemoglobin A1c levels compared with controls.
Ellis et al 2004	Twenty-eight educational interventions (n ¼ 2439) were included in the analysis. The net glycemic change was 0.320% lower in the intervention group than in the control group. Meta-regression revealed that interventions which included a face-to-face delivery, cognitive reframing teaching method, and exercise content were more likely to improve glycemic control. Those three areas collectively explained 44% of the variance in glycemic control. Current patient education interventions modestly improve glycemic control in adults with diabetes. These three components of educational interventions may predict an increased likelihood of success in ameliorating glycemic control.	
Boren 2009	Twenty-four articles were included in this review. Five articles reported on measures of literacy or numeracy specific to diabetes. Thirteen of the fifteen cross-sectional studies (87%) associated limited health literacy with poorer diabetes outcomes. Two of the four (50%) health literacy intervention studies lead to improved health outcomes.	
Dale 2012		Twenty-five studies, including fourteen randomized, controlled or comparative trials, met the inclusion criteria. There was considerable heterogeneity in the design, setting, outcomes and measurement tools. Peer support was associated with statistically significant improvements in

Study	Clinical outcomes	
	Favoured intervention	**Inconclusive effect**
		glycaemic control (three out of 14 trials), blood pressure (one out of four trials), cholesterol (one out of six trials), BMI⁄ weight (two out of seven trials), physical activity (two out of five trials), self-efficacy (two out of three trials), depression (four out of six trials) and perceived social support (two out of two trials). No consistent pattern of effect related to any model of peer support emerged.
Duke 2009	Nine studies involving 1359 participants met the inclusion criteria. Six studies compared individual education to usual care and three compared individual education to group education (361 participants). There were no long-term studies and overall the quality of the studies was not high. However, there did appear to be a significant benefit of individual education on glycaemic control in a subgroup analysis of three studies involving participants with a higher mean baseline HbA1c greater than 8% (WMD -0.3% (95% CI -0.5 to -0.1, P = 0.007).	In the six studies comparing individual face-to-face education to usual care, individual education did not significantly improve glycaemic control (weighted mean difference (WMD) in HbA1c -0.1% (95% confidence interval (CI) -0.3 to 0.1, P = 0.33) over a 12 to 18 month period. In the two studies comparing individual to group education, there was no significant difference in glycaemic control between individual or group education at 12 to 18 months with a WMD in HbA1c of 0.03% (95% CI -0.02 to 0.1, P = 0.22). There was no significant difference in the impact of individual versus usual care or group education on body mass index, systolic or diastolic blood pressure.

APPENDIX 4

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on diabetes knowledge, mapped according to whether results favoured the intervention or were inconclusive

Study	**Knowledge**	
	Favoured intervention	**Inconclusive effect**
Fan & Sidani 2009	The weighted mean effect size of the diabetes self-management education interventions was 1.29 for knowledge.	
Steinsbekk et al 2012	Diabetes knowledge was improved significantly at 6 months (SMD 0.83; P = 0.00001, 6 studies, 768 participants), 12 months (SMD 0.85; P<0.00001, 5 studies, 955 participants) and 2 years (SMD 1.59; P = 0.03, 2 studies, 355 participants) and self-management skills also improved significantly at 6 months (SMD 0.55; P = 0.01, 4 studies, 534 participants).	
Deakin et al 2009	Fourteen publications describing 11 studies were included involving 1532 participants. The results of the meta-analyses in favour of group-based diabetes education programmes were: improved diabetes knowledge at 12-14 months (SMD 1.0; 95% CI 0.7 to 1.2; P < 0.00001)	
Li et al 2011	Two studies (207 patients) were eligible. The methodological quality was not high. Compared with no educational programmes, educational programmes for patients with diabetes on dialysis improved patients' knowledge for the following outcomes: diagnosis (SMD 1.14, 95% CI 0.93 to 1.90); monitoring (SMD 1.51, 95% CI 1.0 to 2.01); hypoglycaemia (SMD 1.67, 95% CI 1.16 to 2.17), hyperglycaemia (SMD 0.80, 95% CI 0.35 to 1.25); medication with insulin (SMD 1.21, 95% CI 0.74 to 1.68); oral medication (SMD 0.98, 95% CI 0.52 to1.43); personal health habits (SMD 1.84, 95% CI 1.33 to 2.36); diet (SMD 0.53, 95% CI 0.09 to 0.97).	
Al Sayah et al 2012	Diabetes Knowledge. Nine studies, six of which adjusted for potential confounders and three of which did not, provided high evidence that higher health literacy levels were associated with better diabetes knowledge.	
Hawthorn et al 2010	Knowledge scores improved in the intervention groups at 6 months (standardized mean difference 0.46, 95% CI 0.27, 0.65).	
Fransen et al 2011	Ten studies investigated the association between health literacy and knowledge (n = 8), beliefs (n = 2), self-efficacy (n = 3) and/or social support (n = 1). Significant associations were found between health literacy and knowledge (n = 6).	
Qingping et al 2011	Beneficial effects of diabetes education on knowledge were demonstrated in studies during a relatively short follow up (3–6 months).	
Hunt et al 2011	Community health advisors' theoretical interventions were based on providing culturally appropriate care and resolution of health disparities within minority populations. Typically community health advisors were patients themselves living with type 2 diabetes mellitus. Major roles of community health advisors included: supporter, educator, case manager, advocate, and program facilitator. Activities of community health advisors were:	The effectiveness of interventions by community health advisors was mixed.

Study	Knowledge	
	coordinating educational programs, conducting educational courses for patients, serving as a link between patients and healthcare professionals, providing counselling, and leading peer support meetings. An example of outcome criteria was improvements in knowledge. Community health advisors provide culturally appropriate interventions to promote and restore health and prevent diseases while serving as links between community and healthcare providers.	
Jackson et al 2006	Most studies reported overall positive results and found that IT-based interventions improved health care attitudes and knowledge.	
Duke 2009		There were too few studies to perform a meta-analysis on the effect of individual education on diabetes knowledge.

APPENDIX 5

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on self-management behaviours, mapped according to whether results favoured the intervention or were inconclusive

Study	Self-management behaviour	
	Favoured intervention	**Inconclusive effect**
Fan & Sidani 2009	The weighted mean effect size of the diabetes self-management education interventions was 0.36 for self-management behaviour.	
Fitzpatrick et al 2013	Fifteen (88%) studies with adults reported self-management behaviours as intervention outcomes. Most frequently reported were diet (n = 10), exercise (n = 11), self-monitoring of blood glucose (n = 8), and medication adherence (n = 5). Of the 10 studies reporting dietary outcomes, six (60%) reported a significant effect of the intervention on one or more aspects of following a healthy diet, while 4 studies reported no effect of the intervention on any aspect of following a healthy diet. While none of the 5 studies assessing medication adherence reported a significant effect of the intervention, both studies reporting global diabetes adherence (Summary of Diabetes Self-Care Activities scale) found significant improvement in self-management behaviours overall following intervention.	Of the 11 studies reporting physical activity outcomes, three (27%) reported a significant effect of the intervention on one or more aspects of physical activity, while 8 studies reported no effect of the intervention on physical activity. All 8 studies assessing self-monitoring of blood glucose reported no effect of the intervention. Similarly, none of the 5 studies assessing medication adherence reported a significant effect of the intervention.
Williams et al 2014		Heterogeneity of the study designs and measures of adherence made it difficult to identify effective interventions that improved medication adherence. However, interventions should be simple and tailored to patients' individual needs to increase the likelihood of effectiveness and improved outcomes.
Omran et al 2012	Interventions to help improve medication adherence generally included an educational strategy combined with one or more other strategies to address behavioural, affective and provider-related issues of adherence.	
Viswanathan et al 2012		Case management, care coordination and collaborative care appeared to be effective for diabetes (medication adherence), however this evidence was based on the findings of one study (RCT) in an African-American population. All other intervention types studied for diabetes (n=2 RCTs) had insufficient evidence of benefit, generally due to results that were inconsistent or not statistically significant. Collaborative care with in-person patient visits for education and counselling seemed to be effective

Study	Self-management behaviour	
		primarily for patients with depression or with depression and diabetes.
Dorresteijn et al 2012	Patients' foot care knowledge was improved in the short term in five of eight RCTs in which this outcome was assessed, as was patients' self-reported self-care behaviour in the short term in seven of nine RCTs.	
Dorresteijn et al 2011		Only five RCTs met the criteria for inclusion. The study characteristics differed substantially in terms of healthcare settings, the nature of the interventions studied and outcome measures reported. In three studies that compared the effect of an education-centred complex intervention with usual care or written instructions only, little evidence of benefit was found. Two studies compared the effect of more intensive and comprehensive complex interventions with usual care. One of these reported improvement of patients' self care behaviour. In the other study a significant and cost-effective reduction of lower extremity amputations (RR 0.30, 95% CI 0.13 to 0.71) was achieved. All five included RCTs were at high risk of bias, with hardly any of the predefined quality assessment criteria met.
Dennis et al 2013	The review found 1756 papers, which was reduced to 30 after screening and relevance checks. Most coaching services were planned (as opposed to reactive) and targeted patients with complex needs who had one or more chronic disease. Several studies reported improvements in health behaviour, self-efficacy, health status and satisfaction with the service. More than one-third of the papers targeted vulnerable people and telephone coaching was found to be effective for these people.	
Al Sayah et al 2012		Self-Care. Four studies that reported adjusted results showed no association between health literacy and self-care behaviours, namely diet, exercise, blood sugar testing, foot care, smoking cessation, and medication adherence. Since the evidence on this relationship was consistent, it was rated moderate. Self-Management. Three studies explored the relationship between health literacy and self-monitoring of blood glucose (SMBG) and self-management support, and all adjusted for potential confounders. One study did not show an association between health literacy and the frequency of SMBG, and another study did not show an association with medication adherence. The third study showed that higher health literacy levels were associated

Study	Self-management behaviour	
		with higher self-management support ratings. The evidence from each of these studies was rated low.
Perez-Escamilla et al 2008	Peer nutrition education has a positive influence on diabetes self-management and breastfeeding outcomes, as well as on general nutrition knowledge and dietary intake behaviours among Latinos.	
Fransen et al 2011	Ten studies investigated the association between health literacy and knowledge (n = 8), beliefs (n = 2), self-efficacy (n = 3) and/or social support (n = 1). Significant associations were found between health literacy and self-efficacy (n = 1) and social support (n = 1).	Of the three studies evaluating the effect of these socio-cognitive variables on diabetes self-management, only one found proof for a mediating variable (social support) in the pathway between health literacy and self-management. Of the 11 relevant studies, three reported a significant positive association between health literacy and specific diabetes self-management domains.
Qingping et al 2011		Limitations to the studies selected were that the effects of interventions on behaviour change were not clearly addressed, and long term outcomes and adherence to diabetes education was unknown.
Adaji et al 2008	IT use has been associated with a corresponding improvement in measures of diabetes care including the frequency of eye and foot exams.	
Hunt et al 2011	Community health advisors' theoretical interventions were based on providing culturally appropriate care and resolution of health disparities within minority populations. Typically community health advisors were patients themselves living with type 2 diabetes mellitus. Major roles of community health advisors included: supporter, educator, case manager, advocate, and program facilitator. Activities of community health advisors were: coordinating educational programs, conducting educational courses for patients, serving as a link between patients and healthcare professionals, providing counselling, and leading peer support meetings. An example of the outcome criteria was improvement in physical activity. Community health advisors provide culturally appropriate interventions to promote and restore health and prevent diseases while serving as links between community and healthcare providers.	The effectiveness of interventions by community health advisors was mixed.
Jackson et al 2006	Most studies reported overall positive results and found that IT-based interventions improved health care utilization, behaviours and skills.	
Loke et al 2012		A total of 1310 citations were reviewed, including 9 articles that reported on 7 research studies. Most studies were retrospective, and all were based

Study	**Self-management behaviour**	
		in the US. Of the 7 included studies, only 1 found a demonstrable association between health literacy and refill adherence. One clinical trial failed to show significant improvements in medication adherence after an intervention to improve health literacy.
Dale 2012		Twenty-five studies, including fourteen randomized, controlled or comparative trials, met the inclusion criteria. There was considerable heterogeneity in the design, setting, outcomes and measurement tools. Peer support was associated with statistically significant improvements in physical activity (two out of five trials). No consistent pattern of effect related to any model of peer support emerged.
Duke 2009		There were too few studies to perform a meta-analysis on the effect of individual education on dietary self-management, and smoking habits. No data were available on the other main outcome measures of diabetes complications or health service utilization and cost analysis in these studies.
Steinsbekk et al 2012	Self-management skills improved significantly at 6 months (SMD 0.55; P = 0.01, 4 studies, 534 participants).	

APPENDIX 6

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on clinical outcomes, mapped according to whether results favoured the intervention or were inconclusive

Study	**Quality of life**	
	Favoured intervention	**Inconclusive effect**
Leelarathna et al 2010	Immediate insulin dose adjustment training to enable dietary freedom (DAFNE training) may be more effective than waiting list control at improving quality of life (measured by Diabetes Quality Of Life [DQOL]) at 6 months in adults with type 1 diabetes.	
Omran et al 2012		Effect of pharmacist interventions on this outcome cannot be established
Srinivasan et al 2008a		For group education compared with individual education: unclear in terms of its impact on improving quality of life (very low-quality evidence).
Srinivasan et al 2008b	Compared with usual care/waiting list control in adults: Immediate insulin dose adjustment training to enable dietary freedom (DAFNE training) may be more effective at improving diabetes-dependent quality of life at 6 months which is maintained at 1 year (low-quality evidence).	
Steinsbekk et al 2012		For quality of life no conclusion could be drawn due to high heterogeneity
Zhang et al 2007	Pooled effects from randomised controlled trials of educational interventions demonstrated significantly improved physical function [3.4 (95% CI, 0.1-6.6)] and mental health [4.2 (95% CI, 1.8-6.6)] and a decrease in bodily pain [3.6 (95% CI, 0.6-6.7)].	
Loveman et al 2009		Where reported, quality of life was not found to be significantly different between groups.

APPENDIX 7

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on health care costs or health service usage, mapped according to whether results favoured the intervention or were inconclusive

Study	Healthcare cost/health service use	
	Favoured intervention	**Inconclusive effects**
Omran et al 2012		Effect of pharmacist interventions on this outcome cannot be established
Pennington et al 2013	Cost-effectiveness is influenced by the size of the health gain from the lifestyle changes targeted, and the benefits from improved management of diabetes are potentially large. Hence, programmes directed towards improved diabetes management have the potential to be cost-effective.	
Viswanathan et al 2012	Moderate-strength evidence for policy interventions that reduced patient out-of-pocket expenses to improve adherence to medications used to treat diabetes.	
Wubben & Vivian 2008	The interventions can reduce long term costs by improving glycaemic control and thus diminishing future diabetes complications.	
Deakin et al 2009	Fourteen publications describing 11 studies were included involving 1532 participants. The results of the meta-analyses in favour of group-based diabetes education programmes were: reduced need for diabetes medication (odds ratio 11.8, 95% CI 5.2 to 26.9; P < 0.00001; RD = 0.2; NNT = 5). Therefore, for every five patients attending a group-based education programme we could expect one patient to reduce diabetes medication.	
Loveman et al 2009		Where reported, emergency admissions were not found to be significantly different between groups. No information was found regarding costs.
Dorresteijn et al 2011		In one study, significant and cost-effective reduction of lower extremity amputations (RR 0.30, 95% CI 0.13 to 0.71) was achieved. However, all included RCTs were at high risk of bias, with hardly any of the predefined quality assessment criteria met.
Hawthorn et al 2010		There was only one longer-term follow-up study, and one formal cost-effectiveness analysis.
Qingping et al 2011		Limitations to the studies selected were that the effects of interventions on medical costs were not clearly addressed, and long term outcomes and

Study	Healthcare cost/health service use	
		adherence to diabetes education was unknown.
Adaji et al 2008	IT has been used to enhance changes in healthcare delivery and provide clinicians with access to expertise and timely, useful data about individual patients and populations. IT use has been associated with a corresponding improvement in the frequency of eye and foot exams.	
Jackson et al 2006	Most studies reported overall positive results and found that IT-based interventions improved health care utilization.	
Boren et al 2009	Twenty-six papers were identified that addressed diabetes self-management training and education. Study designs included meta-analysis (1); randomized controlled trials (8); prospective, quasi-experimental, and pre-post studies (8); and retrospective database analyses (9). The studies conducted cost analyses (6), cost-effectiveness analyses (13), cost-utilization analyses (7), and number needed to treat analyses (2). More than half (18) of the 26 papers identified by the literature review reported findings that associated diabetes education (and disease management) with decreased cost, cost saving, cost-effectiveness, or positive return on investment. The findings indicate that the benefits associated with education on self-management and lifestyle modification for people with diabetes are positive and outweigh the costs associated with the intervention. More research is needed to validate that diabetes education provided by diabetes educators is cost-effective.	Twenty-six papers were identified that addressed diabetes self-management training and education. Study designs included meta-analysis (1); randomized controlled trials (8); prospective, quasi-experimental, and pre-post studies (8); and retrospective database analyses (9). The studies conducted cost analyses (6), cost-effectiveness analyses (13), cost-utilization analyses (7), and number needed to treat analyses (2). More than half (18) of the 26 papers identified by the literature review reported findings that associated diabetes education (and disease management) with decreased cost, cost saving, cost-effectiveness, or positive return on investment. Four studies reported neutral results, 1 study found that costs increased, and 3 studies did not fit into these categories.
Duke 2009		There were too few studies to perform a meta-analysis on the effect of individual education on dietary self-management, diabetes knowledge, psychosocial outcomes and smoking habits. No data were available on the other main outcome measures of diabetes complications or health service utilization and cost analysis in these studies.

APPENDIX 8

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on psychosocial outcomes, mapped according to whether results favoured the intervention or were inconclusive

Study	Psychosocial outcomes	
	Favoured intervention	**Inconclusive effects**
Fitzpatrick et al 2013	Problem solving interventions consistently have a positive effect on several psychosocial outcomes; evidence appeared strongest for effectiveness of intervention on depression in adults with diabetes.	
Steinsbekk et al 2012	There were significant improvement for empowerment/self-efficacy (SMD 0.28, P = 0.01, 2 studies, 326 participants) after 6 months.	
Dennis et al 2013	The review found 1756 papers, which was reduced to 30 after screening and relevance checks. Most coaching services were planned (as opposed to reactive) and targeted patients with complex needs who had one or more chronic disease. Several studies reported improvements in health behaviour, self-efficacy, health status and satisfaction with the service. More than one-third of the papers targeted vulnerable people and telephone coaching was found to be effective for these people.	
Al Sayah et al 2012		Self-Efficacy. Five studies provided evidence on the relationship between health literacy and self-efficacy. Three studies reported adjusted results and showed no association between health literacy levels and self-efficacy. One study that adjusted for confounders27 showed no association between health literacy and self-efficacy, and the unadjusted study showed that higher health literacy levels were associated with higher self-efficacy scores. The evidence was inconsistent and rated insufficient.
Fransen et al 2011		Of the 11 relevant studies, three reported a significant positive association between health literacy and specific diabetes self-management domains. Ten studies investigated the association between health literacy and knowledge (n = 8), beliefs (n = 2), self-efficacy (n = 3) and/or social support (n = 1). Significant associations were found between health literacy and self-efficacy (n = 1) and social support (n = 1). Of the three studies evaluating the effect of these sociocognitive variables on diabetes self-

Study	Psychosocial outcomes	
		management, only one found proof for a mediating variable (social support) in the pathway between health literacy and self-management.
Jackson et al 2006	Most studies reported overall positive results and found that IT-based interventions improved health care attitudes.	
Dale 2012	Twenty-five studies, including fourteen randomized, controlled or comparative trials, met the inclusion criteria. There was considerable heterogeneity in the design, setting, outcomes and measurement tools. Peer support was associated with statistically significant improvements in self-efficacy (two out of three trials), depression (four out of six trials) and perceived social support (two out of two trials).	No consistent pattern of effect related to any model of peer support emerged.
Duke 2009		There were too few studies to perform a meta-analysis on the effect of individual education on psychosocial outcomes.
Adaji et al 2008	IT has been used to provide support to patients.	

APPENDIX 9

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on outcomes relating to diabetes complications

Study	Diabetes complications
	Inconclusive effects
Omran et al 2012	Effect of pharmacist interventions on this outcome cannot be established
Dorresteijn et al 2012	Of the 12 RCTs included, the effect of patient education on primary end points was reported in only five. Pooling of outcome data was precluded by marked, mainly clinical, heterogeneity. One of the RCTs showed reduced incidence of foot ulceration (risk ratio (RR) 0.31, 95% confidence interval (CI) 0.14 to 0.66) and amputation (RR 0.33, 95% CI 0.15 to 0.76) during one-year follow-up of diabetes patients at high risk of foot ulceration after a one-hour group education session. However, one similar study, with lower risk of bias, did not confirm this finding (RR amputation 0.98, 95% CI 0.41 to 2.34; RR ulceration 1.00, 95% CI 0.70 to 1.44). Three other studies, also did not demonstrate any effect of education on the primary end points, but were most likely underpowered. Callus, nail problems and fungal infections improved in only one of five RCTs. Only one of the included RCTs was at low risk of bias.
Loveman et al 2009	No information was found regarding mortality, long term diabetic complications, or adverse effects.
Dorresteijn et al 2011	In one study a significant and cost-effective reduction of lower extremity amputations (RR 0.30, 95% CI 0.13 to 0.71) was achieved. However all included RCTs were at high risk of bias, with hardly any of the predefined quality assessment criteria met.
Al Sayah et al 2012	Diabetes Complications. The relationship between health literacy and self-reported complications was explored in two studies, both adjusted for potential confounders. One study reported that lower health literacy was associated with retinopathy and stroke, but not with nephropathy, lower extremity amputation or ischemic heart disease. The other study showed no association between health literacy and self-reported complications. The evidence from these studies was inconsistent and rated insufficient.
Duke 2009	No data were available on the other main outcome measures of diabetes complications in these studies.

APPENDIX 10

Summary of the main findings of and authors' conclusions in included reviews regarding the effectiveness of interventions on other outcomes, mapped according to whether results favoured the intervention or were inconclusive

Study	Other outcomes	
	Favoured intervention	**Inconclusive effects**
Dennis et al 2013	The review found 1756 papers, which was reduced to 30 after screening and relevance checks. Most coaching services were planned (as opposed to reactive) and targeted patients with complex needs who had one or more chronic disease. Several studies reported improvements in satisfaction with the service. More than one-third of the papers targeted vulnerable people and telephone coaching was found to be effective for these people.	
Al Sayah et al 2012	Patient–Provider Communication. Two studies, where only one reported adjusted results, showed that higher health literacy levels were associated with better patient– physician communication. The evidence from these studies was rated low. Use of Computers and Internet. Two studies, where only one reported adjusted results, explored the relationship between health literacy and patient's use of computers and Internet for health-related learning. These studies provided low evidence that higher health literacy was associated with more frequent use of computers and Internet.	Trust. Two studies explored the relationship between health literacy and patient trust, where only one reported adjusted results and showed that higher health literacy levels were associated with higher scores on patient trust scores. The other study did not show an association between health literacy and patient trust. The evidence from the two studies was rated insufficient. Patient Information Exchange and Involvement in Decision- Making. One study reported adjusted results and showed that higher health literacy was associated with better information exchange between patients and their physicians. The evidence from this study was rated low. Another study that did not adjust for confounders showed no association between health literacy and patient's involvement in decision making with their physicians. The evidence from this study was rated insufficient. Other Outcomes. Six studies explored the relationship between health literacy and prevalence of heart failure, prevalence of depressive symptoms, health-related quality of life (HRQL), diabetes health-related beliefs, medication beliefs, and healthcare discrimination respectively, where all but one reported adjusted findings. In these studies, there was no association between health literacy and prevalence of heart failure, prevalence of depressive symptoms, HRQL, or diabetes health-related

Study	Other outcomes	
		beliefs. One study showed that lower health literacy was associated with medication beliefs, particularly with more concern about the harmfulness of medications, and another showed that lower health literacy was associated with higher reporting of healthcare discrimination. The evidence on these relationships was rated low, except for HRQL, which was rated insufficient.
Adaji et al 2008		Important barriers to using IT in diabetes care include confidentiality concerns, inadequate funding, workforce shortages, lack of time and anxiety about change. Adequate training and integration into the usual process of care are essential facilitators to implementing IT.
Hunt et al 2011	Community health advisors provide culturally appropriate interventions to promote and restore health and prevent diseases while serving as links between community and healthcare providers.	
El-Gayar 2013	Overall, 74% of studies showed some form of added benefit, 13% articles showed no-significant value provided by IT, and 13% of articles did not clearly define the added benefit due to IT. Information technologies used included the Internet (47%), cellular phones (32%), telemedicine (12%), and decision support techniques (9%). Limitations and research gaps identified include usability, real-time feedback, integration with provider electronic medical record (EMR), as well as analytics and decision support capabilities.	
Albano 2008	Articles consistently related to patient education in diabetes (80 among 118) were included. The selected articles were published in 43 scientific journals. The majority of them concern TPE for adult patients with type 2 diabetes. TPE is delivered in several structures and education to groups of patients represents the most widespread educational strategy mostly provided by a multiprofessional team. A total of 70% of the studies show the effectiveness of TPE based on bioclinical, educational, psychosocial, economical criteria. The problem of barriers to TPE concerns 21% of the studies we have analysed and most of the authors propose the implementation of specifically-designed TPE programs as strategy to overcome them. A large number of studies still assess the positive effects of TPE. Nowadays the problems of accessibility to TPE and the barriers to this practice have become a major issue for research.	
Steinsbekk et al 2012	<u>Group-based diabetes self-management education</u>: There were significant improvements in patient satisfaction at 12 months for the intervention group.	