Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment of chronic disease self-management support interventions

Diabetes *(extracted from main report)*

16 December 2015

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent Authority established to drive high quality and safe care for people using our health and social care and support services in Ireland. HIQA's role is to develop standards, inspect and review health and social care and support services, and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the quality and safety of services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for health and social care and support services in Ireland.
- **Regulation** – Registering and inspecting designated centres.
- **Monitoring Children's Services** – Monitoring and inspecting children's social services.
- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care and support services.

Advice to the Health Service Executive (HSE)

This health technology assessment (HTA) examined the clinical and cost-effectiveness of non disease specific (or generic) self-management support interventions for chronic diseases and disease-specific interventions for asthma, chronic obstructive pulmonary disease (COPD), diabetes (Type 1 and Type 2) and cardiovascular disease (stroke, hypertension, coronary artery disease and heart failure).

Broadly, self-management support interventions are any interventions that help patients to manage portions of their chronic disease, or diseases, through education, training and support.

The review of clinical effectiveness was restricted to self-management support interventions evaluated through randomised controlled trials in adult populations. Given the volume of literature available, the clinical effectiveness of self-management support interventions was evaluated using an 'overview of reviews' approach where systematic reviews were reviewed rather than the primary evidence. Systematic reviews were undertaken for each disease area. In the case of asthma, COPD, Type 1 and Type 2 diabetes, stroke and hypertension, these were undertaken as updates to a recent high quality review (PRISMS report) commissioned by the UK National Institute for Health Research that was published in 2014.

The cost-effectiveness of generic and disease-specific self-management support interventions was evaluated by undertaking systematic reviews of the available literature for each area.

General findings common across all the sections of this report are presented below. Specific advice in relation to the various generic and disease-specific interventions is outlined in the dedicated advice sections.

The general findings of this HTA, which precede and inform HIQA's advice, are as follows:

- A broad range of self-management and self-management support interventions exist which impacts on the clarity of what constitutes effective self-management support. The interventions described by the included studies were heterogeneous and frequently complex, comprising numerous components.
- This HTA considered evidence from over 2,000 randomised controlled trials as presented across 160 systematic reviews of clinical effectiveness. Evidence on

the likely cost implications and cost-effectiveness of self-management support interventions was considered from 181 costing and cost-effectiveness studies.

- Evidence of the clinical-effectiveness of chronic disease self-management support interventions provides a complex picture. An overview of reviews makes use of pooled clinical effectiveness data, sometimes across a large number of primary studies, and in many cases of heterogeneous data. While the pooled estimate may show limited effect, individual studies may show more or less effect. As with any intervention, there may be subgroups of patients that experienced greater treatment effect than others.
- Randomised controlled trials typically had small sample sizes and a short duration of follow-up, limiting the applicability and validity of the findings, and potentially failing to capture long-term benefits or to demonstrate if observed benefits could be sustained.
- Most economic analyses were conducted alongside these randomised controlled trials, limiting their ability to determine if observed savings could be sustained. The costing methodology and perspective adopted differed greatly between studies making it difficult to summarise and aggregate findings. Evidence of cost-effectiveness for a wide range of self-management support interventions in patients with chronic disease was generally of limited applicability to the Irish healthcare setting.
- International evidence suggests that most self-management support interventions are relatively inexpensive to implement. Reported costs vary according to the intensity of the intervention, but are typically low relative to the overall cost of care for the chronic disease in question. In some instances, the interventions resulted in modest cost savings through reduced healthcare utilisation. However, it is unclear if costs would be similar if programmes are rolled out to a larger population or if economies of scale might apply. Longer-term evidence is required to determine if benefits are sustained and if costs change over time. Although generally inexpensive on a per patient basis, the budget impact of these interventions could be substantial due to the large number of eligible patients.
- The individuals eligible for self-management support interventions are likely to experience high levels of multimorbidity whereby they have multiple chronic conditions, a number of which may be amenable to self-management. For people with multimorbidity, a coherent evidence-based approach that acknowledges their various conditions and how they interact is essential.
- Where chronic disease self-management support interventions are provided, it is critical that the implementation and delivery of the interventions are subject to

routine and ongoing evaluation. This would help to ensure that they are delivering benefits to patients, and allow the content and format of the interventions to be refined.

Based on these findings HIQA's advice to the Health Service Executive (HSE) is as follows:

Good evidence of effectiveness was found for certain chronic disease self-management support interventions, while limited or no evidence of effectiveness was found for others. The evidence for generic and the disease-specific interventions is presented in the following advice sections.

The HSE should prioritise investment in those interventions for which there is good evidence of clinical effectiveness. Where chronic disease self-management support interventions are provided, it is critical that an agreed definition of self-management support interventions is developed and the implementation and delivery of the interventions are standardised at a national level and subject to routine and ongoing evaluation.

Most interventions are relatively inexpensive to implement relative to the costs of treating chronic disease and, in some instances, can result in modest cost savings through reductions or shifts in healthcare utilisation. However, due to the numbers of eligible patients, the budget impact of these interventions may be substantial.

Advice – Diabetes

The key findings of this HTA on self-management support interventions for adults with Type 1 and Type 2 diabetes, which precede and inform HIQA's advice, are as follows:

- For Type 1 diabetes, two systematic reviews were identified. These related to psychological self-management support interventions (11 randomised controlled trials) and structured diabetes education (15 randomised controlled trials).
- For adults with Type 1 diabetes:
    - Based on a single systematic review, there is no evidence of effectiveness of psychological treatments in improving glycaemic control and reducing psychological distress.
    - Based on a single systematic review of structured education programmes, there is very limited evidence that these interventions lead to improved outcomes of quality of life and episodes of severe hypoglycaemia.
- For Type 2 diabetes, based on 27 systematic reviews (347 randomised controlled trials), identified self-management support interventions were broadly grouped into education interventions, chronic disease self-management programmes, telemedicine and 'other' self-management support interventions.
- For adults with Type 2 diabetes, there is:
    - Very good evidence that education, including culturally-appropriate education, improves blood glucose control in the short term (less than 12 months).
    - Good evidence that behavioural interventions (specifically patient activation interventions which actively engage patients by promoting increased knowledge, confidence and, or skills for disease self-management) are associated with modest improvements in blood glucose control (HbA1C).
    - Good evidence that various forms of telemedicine are associated with improvements in blood glucose control in the short term. Some evidence that chronic disease self-management programmes are associated with small improvements in blood glucose control in the short term.
    - Evidence of improvements in blood glucose control for a diverse range of self-management support interventions and in particular educational

interventions which differ also in their frequency, intensity and mode of delivery.

- Based on the available evidence, it is not possible to provide clear recommendations on the optimal content and format of self management support for adults with Type 2 diabetes. Evidence suggests that various models of delivery may be equally effective. Impact on resource utilisation was not assessed in any of the reviews. Quality of life remained unaltered.
- Based on 38 costing and cost-effectiveness studies, the economic literature for Type 1 and Type 2 diabetes was grouped into three main intervention types: education programmes, telemedicine, and pharmacist-led programmes. The better quality studies used data from randomised controlled trials and then extrapolated lifetime benefits using one of a number of simulation models that predict outcomes based on risk-factors.
- The best economic evidence was found in support of self-management support education programmes with modelled results suggesting that the interventions are cost-effective relative to usual care.
- Based on limited evidence it is not possible to say if telemedicine interventions are cost-effective relative to usual care while there was insufficient evidence of adequate quality to consider the cost-effectiveness of pharmacist-led interventions.

Based on these findings, HIQA's advice to the Health Service Executive (HSE) is as follows:

There is very limited evidence that structured education programmes lead to improvements in quality of life and episodes of severe hypoglycaemia for adults with Type 1 diabetes.

There is very good evidence that education, including culturally-appropriate education improves blood glucose control in patients with Type 2 diabetes in the short term (less than 12 months).

There is good evidence that behavioural interventions are associated with modest improvements in blood glucose control (HbA1C).

There is good evidence that various forms of telemedicine are associated with improvements in blood glucose control in the short term.

There is some evidence of short term improvements in blood glucose control with chronic disease self-management programmes and for a diverse range of self-

management support interventions and in particular educational interventions which differ also in their frequency, intensity and mode of delivery.

Based on the available evidence, it is not possible to provide clear recommendations on the optimal content and format of self management support for adults with Type 2 diabetes. Evidence suggests that various models of delivery may be equally effective.

Economic studies suggest that education programmes may be cost-effective relative to usual care.

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List of abbreviations used in this report

BRUCIE	Better Regulation Using Carbohydrate and Insulin Education (Diabetes programme)
CBT	cognitive-behavioural therapy
CDSMP	chronic disease self-management programme – Stanford programme
CODE	Community Orientated Diabetes Education (Diabetes programme developed by Diabetes Ireland)
DAFNE	Dose Adjustment For Normal Eating
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (Diabetes Programme)
ES	effect size
EPP	Expert Patient Programme (UK programme based on Stanford model)
HC	health coaching
HTA	health technology assessment
I(C)T	information (and communication) technology
MI	motivational interviewing
NIHR	National Institute of Health Research
PICO	population - intervention - comparator – outcomes
PRISMS	Practical Systematic Review of Self-Management Support
QoL	quality of life
RCT	randomised controlled trial
R-AMSTAR	Revised Assessment of Multiple Systematic Reviews
SD	standard deviation
SMBP	self-monitoring of blood pressure
SMD	standard mean difference
SMS	self-management support

1 Introduction

1.1 Background to request

In December 2014, the Health Information and Quality Authority (HIQA) received a request from the Health Service Executive (HSE) to examine the clinical and cost-effectiveness of generic self-management support (SMS) interventions for chronic diseases and disease-specific interventions for chronic obstructive pulmonary disease (COPD), asthma, cardiovascular disease and diabetes.

1.2 Terms of Reference

Following an initial scoping of the technology, the terms of reference for this assessment were agreed between the Authority and the HSE:

- **Phase I:** To review the clinical and cost-effectiveness of generic chronic disease self-management support interventions.
- **Phase II:** To review the clinical and cost-effectiveness of disease-specific chronic disease self-management support interventions.
    - **Phase IIa:** The diseases include chronic obstructive pulmonary disease (COPD), asthma, and diabetes.
    - **Phase IIb:** The diseases include cardiovascular disease – stroke, hypertension, heart failure and ischaemic heart disease.
- Based on this assessment, to advise on the optimal chronic disease self-management support interventions to be implemented by the HSE.

1.3 Overall approach

This health technology assessment (HTA) was conducted using the general principles of HTA and employing the processes and practices used by HIQA in such projects. In summary:

- The Terms of Reference of the HTA were agreed between HIQA and the Health Service Executive.
- An Expert Advisory Group was established. The role of the Expert Advisory Group was to inform and guide the process, provide expert advice and information and to provide access to data where appropriate. The terms of reference of the Expert Advisory Group are included below. A full list of the

membership of the Expert Advisory Group is available in the acknowledgements section of this report.

- An evaluation team was appointed comprising internal HIQA staff. Additionally, Dr Fiona Cianci, a Public Health Specialist Registrar in the Health Service Executive (HSE), Shaun Walsh and Dr Mark Gouldson assisted with the systematic review and data extraction.
- Following review by the Expert Advisory Group with amendments made, as appropriate, the final draft report was submitted to the Board of the Authority for approval. The completed report was submitted to the Minister for Health and the HSE as advice and published on the Authority's website.

The Terms of Reference of the Expert Advisory Group were to:

- Contribute to the provision of high quality and considered advice by HIQA to the HSE.
- Contribute fully to the work, debate and decision-making processes of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues outside of group meetings, as requested.
- Provide advice to HIQA regarding the scope of the analysis.
- Support the Evaluation Team led by HIQA during the assessment process by providing expert opinion and access to pertinent data, as appropriate.
- Review the project plan outline and advise on priorities, as required.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to HIQA's development of its approach to HTA by participating in an evaluation of the process on the conclusion of the assessment.

2 Chronic disease self-management

This chapter describes the general purpose of self-management support (SMS) interventions. It provides a description of the different types of SMS interventions evaluated in the following chapters and the theories that underpin them.

2.1 Description of self-management

A broad range of self-management and self-management support (SMS) definitions exist which may reflect the lack of clarity on what constitutes effective SMS.

For the purpose of this review, the 2003 definitions of self-management and SMS agreed by the US Institute of Medicine are used. Self-management is defined as 'the tasks that individuals must undertake to live with one or more chronic diseases. These tasks include having the confidence to deal with the medical management, role management and emotional management of their conditions'. SMS is thus defined as 'the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support.'[1;2]

Figure 2.1 (on page 6) by Taylor et al. shows the process by which SMS enables individuals to improve their medical, emotional and risk management behaviours.[2;3] This illustrates that to effect change, individuals need to acquire or develop five core self-management skills: problem-solving; decision-making; appropriate resource utilisation; forming a partnership with a health-care provider; and taking necessary actions.[2;4;5] The final step is mediated by the patient's self-efficacy which is required to enact these skills and deliver behaviour change. Self-efficacy, one of the core concepts of social cognitive theory, focuses on increasing an individual's confidence in their ability to carry out a certain task or behaviour, thereby empowering the individual to self-manage.[2] SMS interventions to enhance these five core self-management skills and to improve self-efficacy can include different components (education, training, provision of information or equipment) delivered in a variety of formats such as, education programmes, telemedicine, health coaching and motivational interviewing. A range of delivery methods also exist such as group or individual, face-to-face or remote, professional or peer-led. These interventions can be generic, that is, they can be used across a range of chronic diseases or disease-specific, that is, designed for a specific disease type.

Generic SMS is currently provided in Ireland through programmes such as those run by Arthritis Ireland, Beaumont hospital and the HSE's ('Quality of Life') SMS programme. These programmes are all based on a model developed in Stanford University (Stanford model). Disease-specific programmes are also available. For

example, there are a range of diabetes-specific programmes for both Type 1 (DAFNE and Berger programmes) and Type 2 diabetes (DESMOND, X-PERT, and the CODE programme developed by Diabetes Ireland). A wide range of education programmes and peer-support groups are also available, including those provided by voluntary organisations, such as the Asthma Society, COPD Ireland, Croí, Diabetes Ireland, and the Irish Heart Foundation. However, the efficacy of many of these programmes has not been evaluated at a national level nor an assessment made as to the optimal programme or programmes that should be implemented and to whom they should be made available.

SMS interventions may be a worthwhile adjunct to best medical care to allow patients to take control of and manage portions of their own care. The cost of the intervention is predicted to be low relative to, for example, the potential resource savings associated with a reduction in the number of general practitioner (GP) visits, emergency department visits or hospitalisations. However, at present there is uncertainty regarding the benefits of SMS interventions in the short and long term. Also there is uncertainty about the optimal format that SMS should take. Should it be programme-based and if so, what type of programme is best? Should remote solutions be implemented? What is the evidence of cost-effectiveness? While some initiatives are already available in Ireland, their implementation is not consistent and may not be adequate to meet the growing burden of chronic diseases. With co-morbidity being common in the ageing population and the rise in the number of patients with multi-morbidity, is there a need for generic SMS interventions that can be applied across a range of chronic diseases? Are generic skills sufficient to manage chronic diseases? Evidence on the general care of patients with multiple morbidities is limited, but it has been reported that interventions that focus on particular risk factors may be more effective.[6] Alternatively, is there a need for disease-specific SMS interventions to manage certain aspects of selected chronic diseases? Or can a combination of generic tools combined with disease-specific components be used to optimise care?

The uncertainty regarding the format of optimal SMS presents an obstacle to informed decision making about the provision of this intervention in the Irish public healthcare system.

Summary statement

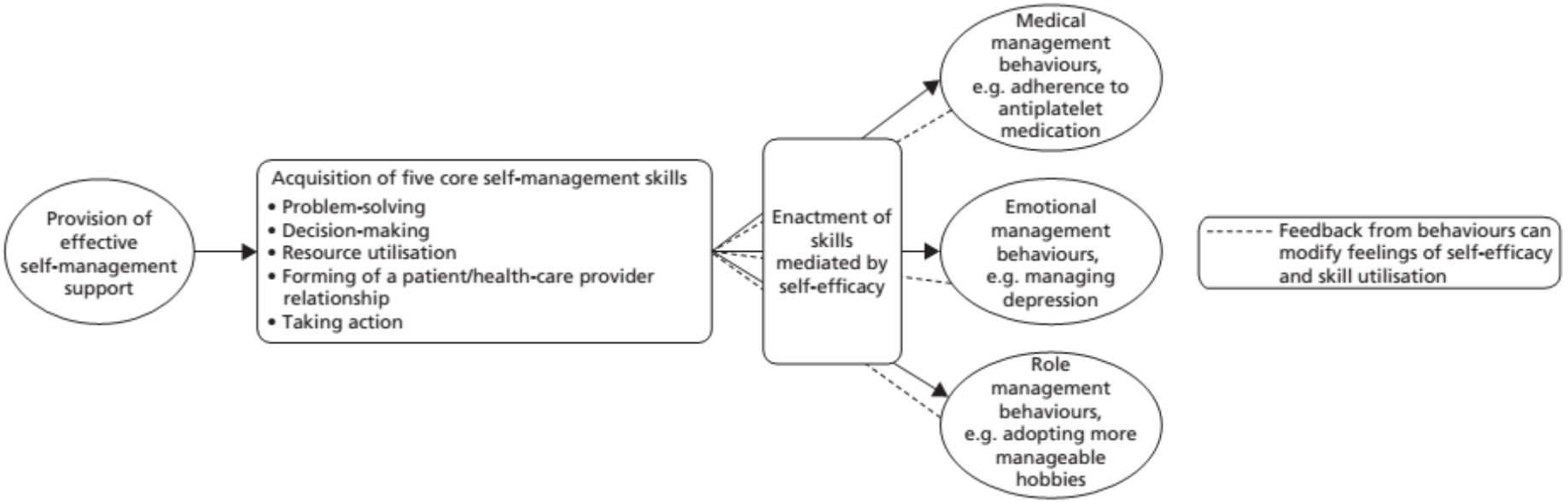
A broad range of self-management and self-management support definitions exist. For this review, the 2003 definitions agreed by the US Institute of Medicine are used:

Self-management is defined as 'the tasks that individuals must undertake to live with one or more chronic diseases. These tasks include having the confidence to deal with medical management, role management and emotional management of their conditions. '

Self-management support is defined as 'the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support.'

Self-management support interventions are any interventions that help patients to manage portions of their chronic disease or diseases through education, training and support.

Figure 2.1 The process of adoption of self-management behaviours taken from Taylor et al. (adapted from Corbin and Strauss and Lorig and Holman).[2;3;5]



2.2 Description of the interventions

Phase I and Phase II of this assessment include appraisal of generic and disease-specific SMS interventions that help patients manage portions of their chronic disease through education, training and support, respectively. Included were:

- All formats and delivery methods (group or individual, face-to-face or remote, professional or peer-led).
- All studies that include a large component of SMS.

The following sections include some descriptions of well known SMS interventions. Further disease-specific interventions are discussed in the chapters on individual diseases.

2.2.1 Chronic disease self-management models/programmes

The following section includes a brief description of the most well-known and widely-used health behaviour change theories and health behaviour change interventions and programmes. A recent review by the New Zealand Guidelines Group included a detailed description of some of these interventions, and as such portions of these descriptions are summarised and referenced below.[7] Disease-specific programmes, where relevant, are discussed in the individual disease-specific sections of this report.

Health behaviour change theories

Trans-Theoretical Theory[7]

This model is based on the theory that behaviours can be modified. It is related to a person's readiness to change, the stages that they progress through to change and doing the right thing (processes) at the right time (stages). As such, tailoring interventions to match a person's readiness or stage of change is said to be essential. The model comprises emotions, cognitions and behaviours, and includes measures of self-efficacy and temptation. It has been used to modify target behaviour such as smoking cessation and stress management.

Social Learning/Social Cognitive Theory[7]

This theory proposes that behaviour change is affected by environmental influences, personal factors, and attributes of the behaviour itself. A central component of this theory is also self-efficacy. As well as belief in the behavioural change, the individual must value the outcomes they believe will occur as a result.

Theory of Reasoned Action and Theory of Planned Behaviour[7]

This social cognitive theory of reasoned action states that individual performance of a target behaviour is determined by the person's intention to perform that behaviour based on their attitude toward the behaviour and the influence of their social environment or subjective norm. The shared components are behavioural beliefs and attitudes, normative beliefs, subjective norms and behavioural intentions. The Theory of Planned Behaviour adds to the Theory of Reasoned Action, the concept of perceived control over the opportunities, resources, and skills necessary to perform a behaviour. These are considered to be critical in behavioural change. This is congruent with the concept of self-efficacy.

Cognitive Behavioural Theory and Cognitive Behavioural Therapy (CBT)[7]

This is a highly-structured psychotherapeutic method used to alter distorted attitudes and problem behaviours by identifying and replacing negative inaccurate thoughts and changing the rewards for behaviours. CBT attempts to help an individual make sense of overwhelming problems by breaking them down into smaller parts. CBT can take place on a one-to-one basis or with a group of people. It can be conducted from a self-help book or computer programme. The duration of the intervention can range from six weeks to six months depending on the problem and the individual; sessions usually last 30 to 60 minutes with a trained therapist.

Behaviour change programmes or models based on a single health behaviour change theory (including adaptations or modifications)

The Chronic Care Model

This model was developed by Wagner in the MacColl Institute in the 1990s in response to the increasing burden of chronic disease and the varying approaches of management and care (social learning/cognitive theory).[8;9] It is focused on changing a reactive system – responding mainly when a person is sick – to a more proactive system which focuses on supporting patients to self-manage. A principle part of the model is that the patient has a central role in managing their health and in particular self-efficacy. It is a high-level organisational or system level of health service provision and identifies the essential elements of a health care system that encourage high-quality care including the community, the health system, SMS, delivery system design, decision support and clinical information systems. As such, this is a higher level model than for example, the Stanford model and UK Expert Patient Programme which are discussed below, as SMS is only one component of the chronic care model.

Personalised care planning or 'building the house of care'

The management and care of long-term conditions tends to be seen as the clinician's responsibility rather than a collaborative endeavour with active patient involvement and effective SMS. In the UK, the King's Fund describe the 'house of care' in 2013, a metaphor which was devised to help those working in primary care adapt the chronic care model to their own situation. It encompasses all people with long-term conditions; and assumes an active role for patients, with collaborative personalised care planning at its heart.[(10)] Personalised care planning is described as a collaborative process in which patients and clinicians identify and discuss problems caused by, or related to the patient's condition, and develop a plan for tackling these. It has been described as a conversation, or series of conversations, in which they agree goals and actions for managing the patient's condition.[(11)]

Stanford Programme

This is based on the concept of self-efficacy within social learning theory. It was originally developed by Stanford University in the US. It uses peer educators to build self-efficacy in a group setting. The Stanford chronic disease self-management programme (CDSMP) is a generic programme, that is, it can be used for patients with a range of chronic diseases. It is based on the fact that people with chronic disease have similar concerns and, with specific skills and training, can effectively manage aspects of their own conditions.[(12)] The programme consists of two and a half hour workshops once a week for six weeks and while generally administered in community settings, is also available online.

UK Expert Patient Programme (EPP)

This is a modification of the Stanford model above and was introduced into the UK in 2002 and branded the EPP.[(13)] Similar to Stanford's CDSMP, it uses peer educators and consists of six weekly workshops conducted in community settings; it is also available as an on-line tool. The topics discussed during the workshops are also similar to those presented in the Stanford workshops. It covers topics such as: healthy eating, exercise, pain management, relaxation, action planning and problem solving.[(13)] It promotes patient knowledge by teaching the skills necessary for people to effectively manage their own chronic conditions, with support from physician team members.

Behaviour change programmes or models based on multiple health behaviour change theories

Flinders Programme™

The Flinders programme™ is a clinician-driven, behavioural change programme (based on multiple health behaviour change theories) that emphasises the role physicians have in building patient self-efficacy and the need to actively engage patients using the principles of cognitive behavioural therapy (CBT) during patient-physician interactions (one-on-one). The programme has seven principles of self-management which allow individuals to:[14]

1. Have knowledge of their condition.
2. Follow a treatment plan (care plan) agreed with their health professionals.
3. Actively share in decision making with health professionals.
4. Monitor and manage signs and symptoms of their condition.
5. Manage the impact of the condition on their physical, emotional and social life.
6. Adopt lifestyles that promote health.
7. Have confidence, access and the ability to use support services.

Other programmes or models

Other SMS interventions are based on behavioural theories such as the health belief model, the theory of reasoned action, the trans-theoretical model, the information-motivation-behavioural skills model and the theory of planned behaviour. They all specify determinants of behaviour that could potentially be changed to improve health and quality of life. The other SMS interventions that were identified as part of the systematic review of efficacy were motivational interviewing and health coaching which are similar, but distinct approaches.[15] The differences between these interventions are described briefly below.

- Motivational interviewing – based on the trans-theoretical model of behavioural change and 'readiness to change'. It uses a brief approach such as 60 minutes of counselling and education to increase motivation and commitment to change. Once that is achieved, other approaches are pursued.
- Health coaching – based on the trans-theoretical model of behavioural change and 'readiness to change'. It is a standalone, comprehensive intervention with a minimum of six sessions.
- Information-motivation-behavioural skills model – This is a behavioural theory which identifies constructs (including information, motivation and behaviour skills) that are needed for successful self-management or adherence.

2.2.2 Chronic disease self-management – Telemedicine including internet support

Telemedicine, a term coined in the 1970s, literally means 'healing at a distance' and signifies the use of information and communication technology (ICT) to improve patient outcomes by increasing access to care and medical information.[16] However, there is no one universally accepted definition of telemedicine, so that the literature in this area describes a myriad of interventions delivered through different mechanisms for different purposes. A 2007 publication found 104 definitions of telemedicine in the peer-reviewed literature. Despite this, telemedicine was found to typically comprise four major elements: supply of medical care, use of technology, mitigation of issues of distance, and provision of benefits.[17] The World Health Organisation (WHO) has adopted the following broad description:

> 'The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.'[16;18]

Telemedicine is constantly evolving to incorporate new advancements in technology and to respond and adapt to changing health needs. Telemedicine applications typically have two formats; synchronous which involves real-time interaction (that is, via the telephone or videoconferencing) or asynchronous communication (not real-time, for example via text messages, email or devices that permit store-and-forward transmission of data [for example, a home glucose metre]). Asynchronous methods that use store-and-forward transmission typically forward the data to a health professional who reviews the data and uses their clinical judgement to make recommendations to the individual. Telemedicine also includes internet- or web-based support (sometimes referred to as e-health). This can include internet versions of, for example, the online version of the Stanford CDSMP described above. Internet-based support offers an alternative to face-to-face interventions which could be beneficial if resources are limited.

2.3 Key messages

- Self-management is defined as the tasks that individuals must undertake to live with one or more chronic diseases.
- Self-management support interventions are any interventions that help patients to manage portions of their chronic disease or diseases through education, training and support.
- Self-efficacy, one of the core concepts of social cognitive theory, focuses on increasing an individual's confidence in their ability to carry out a certain task or behaviour, thereby empowering the individual to self-manage.
- Self-management support interventions can include a variety of formats such as, education programmes, telemedicine (text messages, email, internet-based support), health coaching and motivational interviewing. A range of delivery methods also exist such as group or individual, face-to-face or remote, professional or peer-led.
- There are several behaviour change programmes which focus mainly on improving self-efficacy. These include generic programmes such as the UK Expert Patients Programme (peer-led) and the Flinders model™ (physician-led), and the generic and disease-specific Stanford programme (peer-led).

3 Methodology

3.1 Clinical-Effectiveness

This health technology assessment (HTA) of self-management support (SMS) interventions was undertaken as a series of rapid HTAs. As per the terms of reference, individual disease-specific assessments were prepared for asthma, chronic obstructive pulmonary disease, diabetes, cardiovasculuar disease (hypertension, stroke, ischaemic heart disease, and heart failure) as well as an assessment of generic SMS interventions not tailored to any one specific disease. The term 'rapid HTA' is analogous to that of a 'mini-HTA'; both terms are widely used in the international HTA setting to refer to a HTA with restricted research questions whose purpose is to inform decision making in a particular service setting or for a specific group of patients. Based on the approach used in a full HTA assessment, a rapid HTA uses a truncated research strategy with the review of published literature often restricted to a review of the secondary literature (including systematic reviews, meta-analysis, guidelines etc.) and does not include development of an independent economic model. This approach is useful when undertaking assessments that are proportionate to the needs of the decision maker.

A systematic review of chronic disease self-management support (SMS) interventions was undertaken for generic interventions and disease-specific interventions for each of the identified chronic diseases to identify, appraise and synthesise the best available evidence on their clinical effectiveness and safety.

This review included:

- development of a systematic review protocol
- appraisal and synthesis of all available evidence in line with international best practice in systematic reviews of interventions.

3.1.1 Literature review

A scoping review of the literature was carried out in preparation for this project and a large body of clinical effectiveness literature was identified. This included multiple systematic reviews of varying quality and scope that evaluated a range of SMS interventions. Based on the volume of literature available and the project timelines, an overview of reviews was considered to be the most efficient method to assess the clinical effectiveness of SMS interventions.

'Overviews of reviews' also known as, 'meta-reviews' or 'reviews of reviews' are an efficient way to gather a large body of the best available evidence in a single source to provide broad, cumulative statements that summarise the current evidence on the effectiveness of interventions. The term 'overview of reviews' is used by the

Cochrane Library and will be used in this report from this point on. An overview of reviews allows the findings of separate reviews to be compared and contrasted, thereby providing clinical decision makers with the evidence they need. The overview of reviews is limited to a summary of systematic reviews, that is reviews that are prepared using a systematic approach, and is itself done according to the principles of systematic reviewing. The disadvantage of this approach is the inability of an overview of reviews to reflect the most recent literature: following publication of a randomised controlled trial (RCT), it must first be captured in a systematic review, before subsequently being captured in an overview of reviews. This approach would therefore be less suitable for a fast-moving area where there are rapid advances in the technology. However, given their sample sizes, it is not appropriate to draw conclusions on the effect of an intervention based on a single, or a number of small RCTs. Therefore, it is unlikely that more recent RCTs not captured in an overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions. As noted the scoping review identified a large body of clinical effectiveness literature. For efficiency, it was agreed that if a recent high quality review that met our inclusion criteria was retrieved, then it would be used as a starting point for this report.

Phase I:

A de novo search for systematic reviews evaluating generic chronic disease SMS interventions was conducted in PubMed, Embase and the Cochrane Library (Database of Abstracts of Reviews of Effects [DARE], Cochrane Database of Systematic Reviews [CDSR] and Health Technology Assessment Database [HTA]). No language restrictions were applied. The search was limited to reviews of randomised controlled trials (RCTs) and systematic reviews of RCTs. Initially a start date of 1993 (the year in which the Cochrane Collaboration was established) was used as it marked the widespread initiation of high-quality systematic reviews. However, this was subsequently amended to 2009 due to the volume of systematic reviews retrieved. This was deemed appropriate given that the retrieved high quality reviews published after 2009 included the earlier RCT data. All searches were carried out up to 10 February 2015. A search of reference lists of relevant studies and previous review articles was also performed. The criteria used for including studies are shown in Table 3.1. Full details of the search strings used and the retrieved results are provided in Appendix A3.1.

Phase II:

During scoping, the following recent high quality overview of reviews was retrieved: "A rapid synthesis of the evidence on interventions supporting self-management for people with long-term conditions: PRISMS – Practical systematic Review of Self-Management Support for long-term conditions",[(2)] hereafter referred to as the PRISMS report. This review was commissioned by the UK National Institute for

Health Research (NIHR) in 2012 and published in 2014. Based on a systematic search of the literature up to 1 June 2012, it summarised the best available evidence for SMS for a range of diseases including asthma, chronic obstructive pulmonary disease (COPD), Type 1 and Type 2 diabetes, stroke and hypertension.1 For these diseases, this assessment therefore was limited to an update to the PRISMS report and was completed by running additional searches in PubMed, Embase and the Cochrane Library from 2012 to 1 April 2015, see Appendix A3.1. The results of the updated search as well as the original PRISMS findings are reported in the relevant chapters of this assessment with any changes to the PRISMS findings clearly documented. PRISMS also included a qualitative meta-review and implementation systematic review which assessed SMS at an organisational and professional level.[(2)] These sections of the PRISMS review were not updated and the results are not included here as it was beyond the immediate scope of this HTA. PRISMS did not include telehealth reviews as they deemed them to be typically about mode of delivery rather than content of what was delivered. Telehealth interventions were included in the updated review. De novo systematic reviews were undertaken for the remaining diseases included in the Terms of Reference for this project (heart failure and ischaemic heart disease) as these were not assessed in the PRISMS report. Systematic searches were run in PubMed, Embase and the Cochrane Library from 2009 to 1 April 2015, see Appendix A3.1.

Table 3.1. PICOS criteria for study eligibility

Population	**Phase I:** Adults ≥ 18 years old with at least one chronic disease. This includes common physical conditions such as asthma, COPD, arthritis, diabetes and cardiovascular diseases. **Phase II:** Adults ≥ 18 years old with the specified disease (Type I or Type II diabetes mellitus, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).
Intervention	**Phase I:** Any generic self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support. All formats and delivery methods (group or individual, face-to-face or remote, professional or peer-led). All studies that include a large component of self-management support. The intervention is assessed in more than one chronic disease. **Phase II:** Any disease-specific self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support.

[1] The dates for the searches varied for the different diseases, however, June 2012 was the earliest review.

	All formats and delivery methods (group or individual, face-to-face or remote, professional or peer-led). All studies that include a large component of self-management support. The intervention is assessed in diabetes mellitus (Type I and Type II), asthma, COPD, ischaemic heart disease, heart failure, hypertension, or stroke.
Comparator	Studies where self-management support plus best medical care is compared with best medical care.
Outcomes	▪ Health care utilisation (including unscheduled use of healthcare services – for example, GP visits, emergency department visits, hospital (re)admissions, hospital length of stay) ▪ Patient-centered outcomes relating to patient quality of life, patient satisfaction, self-efficacy ▪ Health outcomes (including biological markers of disease)
Study design	Systematic reviews of randomised controlled trials or systematic reviews (overview of reviews).

Key: **COPD** – chronic obstructive pulmonary disease; **GP** – general practitioner.

As noted in Section 2.1, there is no universally accepted definition for self-management or SMS. This creates problems when attempting to identify, analyse and assess the available literature. Interventions may target different recipients (for example, patients, carers, health care professionals), include different components (for example, education, information, practical support, provision of equipment, social support, lifestyle advice, prompts, financial incentives), be delivered in different formats (for example, face-to-face, remote, web-based), be provided or facilitated by different individuals including healthcare personnel and trained or untrained lay persons, as well as differing in their intensity and duration. However, a consistent theme is that SMS interventions are typically complex interventions that include more than one component of SMS. For this reason, and consistent with the PRISMS report, with the exception of education interventions, this review did not assess single component SMS (for example, simple text message appointment reminders and drug reminder packaging). Other disease-specific inclusion or exclusion criteria are included in the individual disease chapters.

Given the wide range of SMS interventions identified, where possible the SMS interventions were classified by intervention type. Categorising the interventions into groups facilitated reporting and allowed study cross-over (overlap) to be assessed per intervention type.

3.1.3 Data extraction and quality assurance

Preliminary screening of all returned results was carried out by a single person to eliminate studies that were clearly not relevant. Assessment of eligibility of studies and identification of multiple reports from single studies was carried out independently by two people. Any disagreements were resolved by discussion.

Data extraction was performed independently by two people, with disagreements resolved by discussion. To adequately inform decisions in relation to the quantity and quality of evidence underpinning the findings of this assessment, quality assurance of the systematic reviews and meta-analyses was undertaken. The approach adopted and the tools used are discussed below. The quality of the primary studies underpinning the systematic reviews were not directly evaluated, instead information was extracted from the systematic reviews on the quality of the primary evidence, where reported.

Phase I and Phase II

Assessment of the quality of included systematic reviews was performed by two people independently using the Revised Assessment of Multiple Systematic Reviews (R-AMSTAR) quality appraisal tool.[19;20] This is an 11-item tool with item scores ranging from 1 to 4, providing therefore a possible range of up to 44 for the R-AMSTAR total scores. The methodology used by the PRISMS group was adopted given the validity of their approach and to facilitate interpretation and reporting of systematic reviews. The evidence was weighted by the quality of the systematic reviews retrieved (as indicted by the R-AMSTAR score) and the size of the studies they included (total number of participants included within the systematic review) to give an overall value (range * to ***) for each review (Table 3.2).

Table 3.2. PRISMS quality ratings for systematic reviews[2]

Quality of studies		
Overall Value	**Quality of systematic review using R-AMSTAR**	**Systematic review sample size**
*	Lower quality (R-AMSTAR score <31)	Smaller sample size (<1,000 participants).
**	Lower quality (R-AMSTAR score <31)	Larger sample size (≥1,000 participants)
**	Higher quality (R-AMSTAR ≥31)	Smaller sample size (<1,000 participants).
***	Higher quality (R-AMSTAR ≥31)	Larger sample size (≥1,000 participants)

Note: This table is taken from the PRISMS study by Taylor et al..[2]

If an included systematic review performed a quality of evidence assessment, this information was also collected during the data extraction process. Tools used included the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system criteria[21] and the Jadad Scale.[22] GRADE identifies five key elements that can be used to rate confidence in the estimates of intervention effects. The criteria are: risk of bias; inconsistency of results; indirectness of evidence; imprecision; and publication bias. Assessing and combining these components determines the quality of evidence for each outcome of interest as 'high' (further research is very unlikely to change our confidence in this estimate of effect); 'moderate' (further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate); 'low (further research is likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate); and 'very low (any estimate of effect is very uncertain). The Jadad scale is a validated seven-item scale that assesses the quality of RCT methods relevant to random assignment, double blinding and the accountability of all patients including withdrawals; scores range from 0 (very poor) to 5 (rigorous). An 11-item scale with a range of 0 to 13 points has also been described; scores of nine or less are considered poor quality, while scores greater than nine are considered to be of good quality.

If a meta-analysis was undertaken, the quality and strength of evidence were evaluated in order to facilitate interpretation of the findings. Each meta-analysis was reviewed using a 43-item questionnaire that evaluated the data sources used, the analysis of individual studies by meta-analysts, the conduct of the meta-analysis, and its reporting and interpretation.[23] Based on this, each meta-analysis was graded as being of low, moderate or high quality. A grading of 'low quality' referred to studies where the conclusions were at high risk of bias due to poor data collection or methods of data synthesis. The conclusions in studies identified as 'moderate quality' were at risk of bias, but were likely to be broadly accurate, while studies graded as 'high quality' were very likely to have conclusions that accurately reflected the available evidence.

Where available, data on the validity of the RCTs included in each meta-analysis were extracted to determine their risk of bias, that is, the risk that they overestimated or underestimated the true intervention effect. Biases are broadly categorised as selection bias, performance bias, detection bias, attrition bias, reporting bias and other potential sources of bias. Bias is typically assessed using a specific tool, such as the Cochrane Risk of Bias Tool. For each element the risk of bias is assessed as low, high or unclear. For each meta-analysis, the number of primary studies that were rated as being at low risk of bias (or rated as high quality) was reported relative to the total number of primary studies.

Finally, as done by the PRISMS group, a value ranging from 0 (no evidence of effect) to *** / --- very strong evidence of effect in favour of the intervention/control was assigned to each finding based on the probability of the event (Table 3.3). Effect sizes reported in the individual reviews are not just based on probabilities but include ranges of effects and confidence intervals.

Table 3.3 PRISMS evidence of effect[2]

Evidence of effect		
Value	**Probability**	**Evidence of effect**
0	p>0.05	No evidence of effect.
+/–	0.05≥p>0.01	Some evidence of effect in favour of intervention/control.
++/– –	0.01≥p>0.001	Strong evidence of effect in favour of intervention/control.
+++/– – –	p≤0.001	Very strong evidence of effect in favour of intervention/control.

Note: This table is taken from the PRISMS study by Taylor et al..[2]

3.2 Costs and Cost-Effectiveness

3.2.1 Literature review

A review of cost-effectiveness studies was undertaken to assess the available evidence for self-management support (SMS) interventions. Studies were included if they compared the costs and consequences of a SMS intervention to routine care.

A search was carried out to identify economic analyses of SMS interventions. In tandem with the systematic review of clinical effectiveness, the search for economic evaluations was carried out in PubMed, EMBASE and the Cochrane Library. The same search terms were used with the exception of terms for systematic review and meta-analysis. In place of these, search terms and filters for economic evaluations were applied. In addition, systematic reviews of SMS interventions identified through the clinical effectiveness search that included cost or economic outcomes were used to identify additional studies. The search was carried out up until 4 March 2015.

The PICOS (Population, Intervention, Comparator, Outcomes, Study design) analysis used to formulate the search is presented in Table 3.4 below.

Table 3.4. PICOS analysis for identification of relevant studies

Population	**Phase I:** Adults ≥ 18 years old with at least one chronic condition. **Phase II:** Adults ≥ 18 years old with the specified disease (Diabetes Type I or Type II, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).
Intervention	**Phase I:** Any generic self-management support intervention that helps patients to manage aspects of their chronic disease care through education, training or support. **Phase II:** Any disease-specific self-management support intervention that helps patients to manage aspects of their chronic disease care through education, training or support.
Comparator	Routine care.
Outcomes	Cost or cost-effectiveness of intervention.
Study design	Randomised controlled trials, case-control studies, observational studies, economic modelling studies.

Key: **COPD** – chronic obstructive pulmonary disease.

Studies were excluded if:

- application of the SMS was limited to a population with a single specified chronic disease (Phase I only),
- a nursing home or non-community dwelling population was included,
- they included a paediatric population,
- cost data were not clearly reported,
- published prior to 2000 (limited relevance).

3.2.2 Data extraction and quality assurance

Preliminary screening of all returned results was carried out by a single person to eliminate studies that were clearly not relevant. Assessment of eligibility of studies and identification of multiple reports from single studies was carried out independently by two people. Any disagreements were resolved by discussion.

Studies were classified into intervention types, where applicable, corresponding to the categories used for the assessment of clinical effectiveness.

In accordance with national HTA guidelines, assessment of the quality of the studies identified was performed independently by two people with the studies subsequently assessed for their transferability to the Irish healthcare setting. Any disagreements were resolved by discussion. The Consensus on Health Economic Criteria (CHEC)-list was used to assess the quality of the studies.[24] This tool is useful to evaluate economic evaluations that are being considered for inclusion in a systematic review with a view to increasing the transparency and comparability of the reviews. For studies that included an assessment of cost-utility or an economic modelling approach, assessment of the relevance of the studies to the Irish healthcare setting and their credibility was considered using a questionnaire from the International Society of Pharmacoeconomic Outcomes Research (ISPOR).[25] This tool is used and tailored towards appraising conventional economic evaluations which typically assess a set number of interventions in a specific population.

Costs reported in each of the studies were inflated to 2014 using the local consumer price index and expressed in Irish Euro using the purchasing power parity exchange rate.[26]

7 Diabetes Mellitus

This health technology assessment (HTA) of diabetes self-management support (SMS) is one of a series of rapid HTAs assessing SMS interventions for chronic diseases. Given their differences and the differing requirements for SMS in Type 1 and Type 2 diabetes mellitus, the clinical effectiveness of SMS supports for these conditions were assessed separately. The HTA does not cover pre-diabetes or gestational diabetes. Section 7.1 provides a brief description of diabetes followed by separate reviews of the clinical (Section 7.2) and cost-effectiveness (Section 7.3) literature for diabetes-specific SMS interventions. Brief descriptions of the background and methods used are included with full details provided in a separate document (Chapter 3). Section 7.4 includes a discussion of both the clinical and cost-effectiveness findings. The report concludes with a list of key points in relation to diabetes SMS support (Section 7.5).

7.1 Description of the disease

Diabetes is a progressive disease with disabling long-term complications if not properly managed. Persistently high blood sugar levels and high blood pressure can result in damage to both large and small blood vessels with ensuing eye, kidney, nerve, heart and circulatory complications. Tight control of these parameters and as well as other risk factors such as cholesterol and triglyceride levels, can reduce or delay their progression. Symptoms of diabetes include excessive excretion of urine (polyuria), thirst (polydipsia), constant hunger, weight loss, vision changes and fatigue.[170]

Type 1 diabetes (previously known as insulin-dependent, juvenile or childhood-onset) is characterised by deficient insulin production and requires daily administration of insulin.[170] The cause of Type 1 diabetes is not known.[170] Type 2 diabetes (formerly called non-insulin-dependent or adult-onset diabetes) results from the body's ineffective use of insulin.[170] Type 2 diabetes comprises 90% of people with diabetes around the world, and is largely the result of excess body weight and physical inactivity.

7.2 Review of clinical-effectiveness of self-management support interventions

7.2.1 Background and Methods

Details of the background and methods for this assessment are included in Chapters 1 to 3 of this report. Briefly, an aim of this health technology assessment (HTA) is to review the clinical effectiveness of disease-specific self-management support (SMS)

interventions for a number of chronic conditions including diabetes. Given the large volume of literature available, it was noted that an update of an existing high-quality systematic review of SMS interventions could be considered sufficient to inform decision making.

In December 2014 a high-quality overview of reviews was published by the National Institute for Health Research (NIHR) in the UK. The Practical Systematic Review of Self-Management Support for long-term conditions (PRISMS) study comprised an overview of systematic reviews of randomised controlled trials (RCTs) up to 1 June 2012, and was undertaken according to the principles of systematic reviewing. An update to the PRISMS report was completed by running additional searches in Pubmed, Embase and the Cochrane library from 2012 to 1 April 2015, see Appendix A3.1. In accordance with the PICOS agreed with the key stakeholder, this assessment was limited to SMS interventions for adults aged 18 and over. This restriction had implications for the assessment of SMS interventions in Type 1 diabetes in particular. The onset of Type 1 diabetes typically occurs in childhood, with the result that interventions (such as structured education programmes for Type 1 diabetes) primarily target a mixed paediatric and adult population. Unless disaggregated results could be retrieved, the identified studies were excluded. Results of the updated search are reported in addition to a summary of the findings of the PRISMS report for adults. The PRISMS report did not include telehealth reviews as they were typically about mode of delivery rather than content of what was delivered, however relevant telehealth interventions that incorporated a significant component of self management support were included in this updated review.

Following the PRISMS approach, reviews focusing on self monitoring of blood glucose (SMBG) were excluded as it is a thoroughly researched area with up-to-date clinical recommendations already in place.[2] Results from a 2012 Cochrane review concur with published guidelines that SMBG is beneficial in individuals who are newly diagnosed with Type 2 diabetes, but is less effective in those who have been diagnosed for one or more years.[2;171;172] In addition, following the PRISMS approach reviews combining data for Type 1 and Type 2 diabetes were also excluded. An exception was made for SMS interventions specifically targeting diabetic foot ulcer or diabetic kidney disease as the two conditions require broadly similar self-management irrespective of whether the patients has Type 1 or Type 2 diabetes.

Data extraction and quality assurance of the systematic reviews, meta-analyses and the risk of bias associated with the primary literature was undertaken as described in Chapter 3.1.3. In summary, in order to determine the quantity, quality, strength and credibility of evidence underpinning the various interventions, quality assurance of both the systematic review methodology (R-AMSTAR weighting by patient or

participant trial size) and the meta-analyses (Higgins et al.'s quality assessment tool),[23] While the R-AMSTAR score was used to determine the quality of the systematic reviews, the scores were then weighted by patient or participant trial size, with the quality of evidence being downgraded if the review was based on fewer than 1,000 participants. The quality of the primary evidence was not evaluated directly; however, where reported, information on the risk of bias in the primary studies was extracted from the systematic reviews.

7.2.2 Description of the interventions

A general description of self-management and typical self-management support (SMS) interventions is included in Chapter 2. Examples of generic patient self-management programmes include the Stanford chronic disease self-management programme (CDSMP) and the Expert Patient Programme in the UK which are described in Phase I of this HTA. New disease-specific interventions which are introduced in this report include Type 1 diabetes self-management education programmes. These include the 'Dose Adjustment For Normal Eating programme' (DAFNE) and Berger programme, a comprehensive diabetes self-care skills course, both delivered by healthcare professionals.[173] Both courses are currently available in Ireland.[173] However, as noted, because this HTA was limited to adults aged 18 years and over, evidence for diabetes self-management programmes that included paediatric populations was excluded unless disaggregated data were reported.

Interventions for Type 2 diabetes which are introduced in this report include disease-specific education programmes. Several diabetes self-management education programmes have been developed, with access to some of these available in Ireland. These include the 'diabetes education and self-management for ongoing and newly diagnosed' (DESMOND) programme for people with newly diagnosed Type 2 diabetes, as well as the 'Rethink Organization to iMprove Education and Outcomes' (ROMEO) and the 'Diabetes X-PERT Programme' for people with Type 2 diabetes. The Community Orientated Diabetes Education programme has also been developed by Diabetes Ireland and is a structured education programme for people with diabetes. The DESMOND, X-PERT-Ireland and Community Orientated Diabetes Education programmes are currently available in Ireland.[173]

7.2.3 Results – Clinical-effectiveness Type 1 diabetes mellitus

The PRISMS review retrieved a total of five systematic reviews of Type 1-specific SMS interventions and generic interventions used in patients with Type 1 diabetes mellitus.[2] However, as this assessment is limited to SMS interventions for adults aged 18 and over, only one review from PRISMS met our inclusion criteria. The PRISMS report was updated to April 2015 using the search string in Appendix 1. One

additional review was retrieved for Type 1 diabetes in our updated review (Figure 7.1).

The one eligible review identified in the PRISMS report included 11 unique randomised controlled trials (RCTs) with 516 adult participants. The review was published in 2006 with the publication date of the included RCTs ranging from 1985 to 2005. RCT study locations were mainly in the US (11 studies) with the remainder from Canada and Europe. The R-AMSTAR score was 41, with scores of 31 or more indicating a high-quality systematic review. When weighted according to the number of participants in the original RCTs (less than <1,000 or greater than or equal to ≥ 1,000), the systematic review was assigned the highest quality rating (`*three-star*', ***).[174]

The additional study identified as part of the update was a clinical guideline published in August 2015 by the National Clinical Guideline Centre in the UK. The guideline included systematic reviews of a variety of interventions, one of which was structured education programmes. The review included 15 RCTs with 1,994 participants. All 15 studies were carried out in Europe. The systematic review scored 35 on the basis of R-Amstar and was rated as high-quality (`*three-star*', ***).

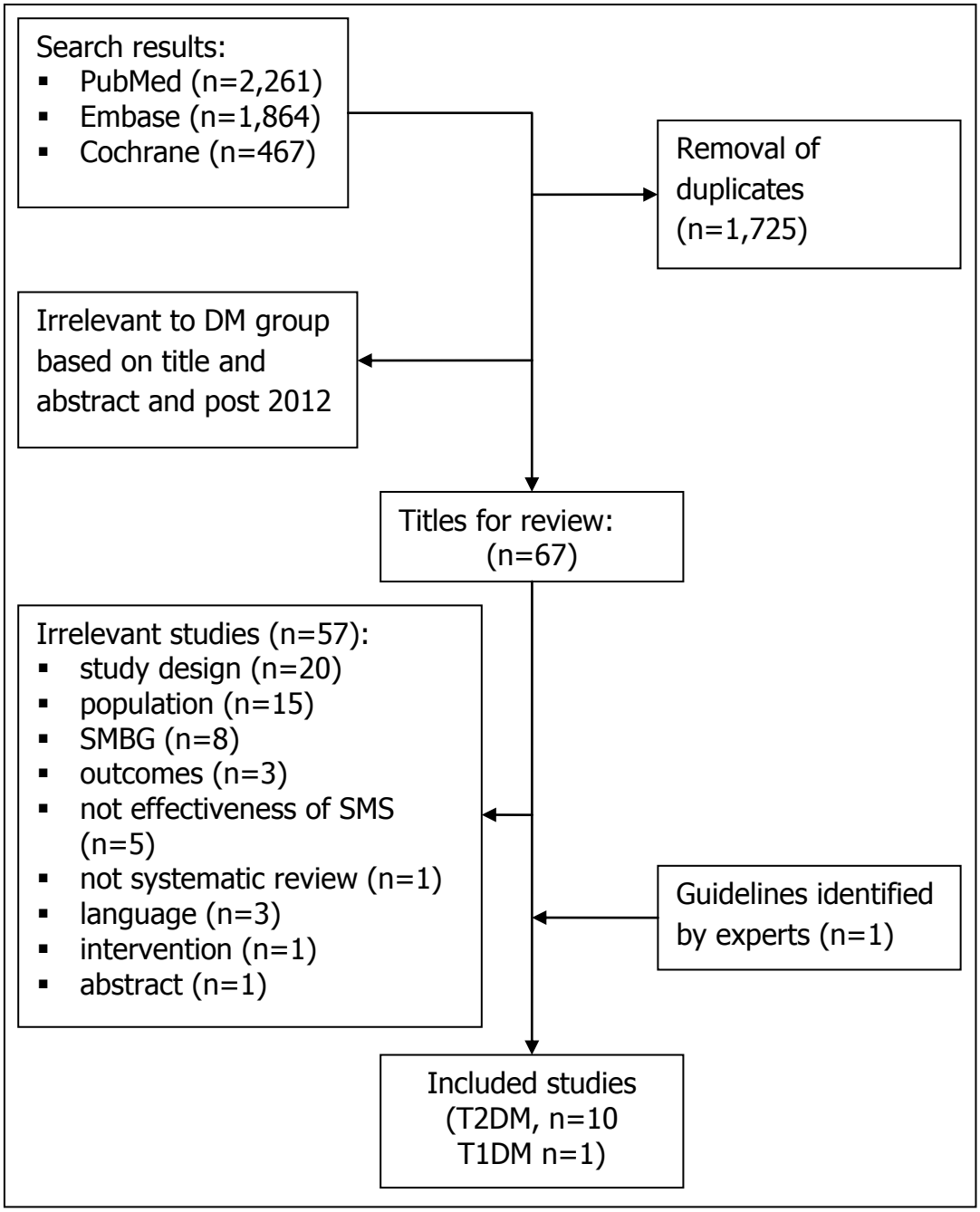
Table 7.1 Type 1 diabetes mellitus: Summary of reviews retrieved (adults ≥ 18 years)

Author (year)	Intervention
PRISMS studies retrieved	
Winkley (2006)[174]	Psychological interventions
Reviews retrieved in updated search	
NICE (2015)[175]	Structured education programmes

7.2.3.1 Summary of findings

A detailed summary of the systematic reviews including the intervention, outcomes assessed, duration of follow-up, sample size (number of RCTs and total number of participants), and the evidence of effect is included in Appendix A.7.1. As per Chapter 3, the quality of the meta-analysis was assessed and graded. Studies graded as 'high-quality' are very likely to have conclusions that accurately reflect the available evidence (see also Chapter 3, Table 3.1). Table 7.2 below details the results of the quality assurance assessment of the single identified systematic review assessing the impact of SMS interventions in Type 1 diabetes and provides a summary of findings for selected outcomes from its meta-analysis.

Figure 7.1 Flowchart of included studies from updated search



Abbreviations: T1DM = Type 1 diabetes mellitus; T2DM = Type 2 diabetes mellitus

Table 7.2 Type 1 diabetes mellitus: Summary characteristics and findings for selected outcomes for included studies

Study	Quality of systematic review			Primary studies		Meta-analysis quality	Glycated haemoglobin (SMD)
	R-AMSTAR score	Participants	Quality	n	Low risk of bias[a]		
Winkley 2006[174]	41	1,105	***	11	1	High	-0.17 (-0.45 to 0.10)
NICE 2015[175]	35	1.194	***	15	1	Low	[b]

Abbreviations: **SMD** = standardised mean difference;

[a] Number of the primary studies identified as being at low risk of bias.

[b] Due to potential issues with the reported outcome measures, the results of the meta-analyses are not included here.

7.2.3.2 Psychological interventions

Three star (***) reviews

Based on one three-star review, PRISMS reported that there is no evidence for the effectiveness of psychological treatments in improving glycaemic control and reducing psychological distress in adults with Type 1 diabetes.

Summary statement for psychological interventions

There is no evidence of effectiveness of psychological treatments in improving glycaemic control and reducing psychological distress in adults with Type 1 diabetes.

7.2.3.3 Structured education programmes

Three star (***) reviews

Based on one three-star review, the evidence regarding structured education programmes in adults with Type 1 diabetes was graded as low- or very low-quality. Although individual studies showed a beneficial effect of the intervention on glycated haemoglobin and severe hypoglycaemia, results were heterogeneous. Most outcomes were reported for single studies only. Individual studies showed benefits in terms of quality of life. Due to the different measures used, data could not be pooled.

Summary statement for structured education programmes:

There is very limited evidence of effectiveness of structured education programmes improving outcomes of severe hypoglycaemia and quality of life in adults with Type 1 diabetes.

7.2.4 Results – Clinical-effectiveness of Type 2 diabetes mellitus

The PRISMS review retrieved a total of 17 systematic reviews of Type 2 diabetes mellitus-specific self-management support interventions and generic interventions used in patients with Type 2 diabetes.[2] Summary details of the reviews are included in Table 7.3.

The PRISMS report was updated to April 2015 using the search string in Appendix A3.1. A further 10 systematic reviews were retrieved (Figure 7.1) which assessed a diverse range of SMS interventions for Type 2 diabetes including patient activation interventions,[176] telemedicine interventions,[177-181] motivational interviewing,[182] pharmacy care to improve medication adherence,[183] lifestyle interventions[184] and

culturally appropriate education.[185] Based on the range of SMS interventions retrieved, it was decided to classify and report the results by intervention type. The categories of systematic review include: education (which accounted for the largest body of evidence retrieved), telemedicine, self-management programmes, and other self-management support (SMS) interventions.

The number of included RCTs per systematic review ranged from two[184] to 138,[176] with the number of participants ranging from 207[186] to 33,124.[176] The study overlap between the 27 included systematic reviews is reported in Table 7.4. The publication dates of the systematic reviews ranged from 2001 to 2015, while that of the included RCTs ranged from 1985 to 2014. RCT study locations were typically in Europe or North America with 347 unique RCTs.

The quality of the systematic reviews (R-AMSTAR scores) ranged from 23 to 41, with scores of 31 or more indicating a high-quality systematic review. When weighted according to the number of participants in the original RCTs (less than <1,000 or greater or equal to ≥ 1,000), 14 of the systematic reviews were assigned the highest quality rating (*'three star'****)/11 reviews were rated as *'two star'*** and two as *'one star'** in terms of their quality and size. If a meta-analysis was completed, its quality was assessed as per Chapter 3 and graded as being of low, moderate or high-quality. A grading of 'low-quality' referred to studies where the conclusions were at high-risk of bias due to poor data collection or methods of data synthesis. The conclusions in studies identified as 'moderate quality' were at risk of bias, but were likely to be broadly accurate, while studies graded as 'high-quality' were very likely to have conclusions that accurately reflected the available evidence (see also Chapter 3, Table 3.1). In terms of the meta-analyses carried out in these reviews, 11 reviews were assessed as high-quality, six were assessed as moderate quality, and one as low-quality; no meta-analysis was undertaken in nine of the reviews.

Table 7.3 Type 2 diabetes mellitus: Summary of systematic reviews retrieved

Author (year)	Intervention
PRISMS reviews retrieved	
Self-management programmes	
Chodosh (2005)[187]	Self-management programmes[a]
Education	
Dorresteijn (2010/14)[b][188]	Education programmes – focus on foot care
Duke (2009)[189]	Education – individual patient education programmes
Li (2011)[186]	Education programmes –used for people with DKD
Minet (2010)[190]	Self-care SMS interventions using education or behavioural strategies
Norris (2001)[191]	Educational interventions
Norris (2002)[192]	SM Education
Sigurdardottir (2007)[193]	Education re diabetes self-care
Steinsbekk (2012)[194]	Education – group based
Education – culturally tailored	
Hawthorne (2008)[195]	Education – culturally tailored
Khunti (2008)[196]	Education – South Asian populations
Nam (2012)[197]	Education – culturally tailored
Pérez-Escamilla (2008)[198]	Education – peer nutrition and counselling for Latinos
Other SMS interventions	
Gary (2003)[199]	Behavioural or counselling component
Heinrich (2010)[200]	Multi-component aimed at SMS interventions
Newman (2004)[201]	SMS interventions – increase patient involvement
van Dam (2005)[202]	Social support interventions
Reviews retrieved in updated search	
Telemedicine	
Cotter (2014)[177]	Internet interventions to support lifestyle modification
Huang (2015)[178]	Telecare
Pal (2014)[179]	SMS interventions - Computer-based
Saffari (2014)[180]	Education via mobile phones
Zhai (2014)[181]	Telemedicine
Education – culturally tailored	
Attridge (2014)[c][185]	Education – culturally tailored
Other SMS	
Antoine (2014)[183]	Pharmacy care – adherence
Bolen (2014)[176]	Patient activation interventions
Schellenberg (2013)[184]	Lifestyle Interventions
Song (2014)[182]	Motivational interviewing

Abbreviations: **DKD** = diabetic kidney disease; **SM** = self-management; **SMS** = self-management support.
[a] Programmes assessed for a range of diseases, results included for diabetes programmes only. Generic programmes were assessed for arthritis only in this review, these results are not included.
[b]Dorresteijn's Cochrane review was updated in 2014.
[c] Attridge's Cochrane review is an update to Hawthorne's CR with an additional 33 RCTs included.

Table 7.4 T2DM: Study overlap between the included systematic reviews (PRISMS report plus the systematic reviews from the updated search).[5] Adapted from PRISMS review.[(2)]

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17		18	19	20	21	22	23	24	25	26	27
	PRISMS reviews retrieved																												
1	Chodosh (2005)	**26**																											
2	Dorrejstein (2010/ 14 update)	0	**11/ 12**																										
3	Duke (2009)	1	0	**9**																									
4	Gary (2003)	4	2	2	**18**																								
5	Hawthorne (2008)	2	0	2	1	**11**																							
6	Heinrich (2010)	1	0	2	0	2	**14**																						
7	Khunti (2008)	0	0	2	0	4	0	**5**																					
8	Li (2011)	0	0	0	0	0	1	0	**2**																				
9	Minet (2010)	2	0	8	1	5	8	0	1	**43**																			
10	Nam (2012)	1	0	2	1	9	2	3	0	4	**12**																		
11	Newman (2004)	4	0	2	2	3	0	0	0	5	1	**21**																	
12	Norris (2001)	16	10	4	9	3	0	1	0	6	3	3	**72**																
13	Norris (2002)	8	4	4	7	3	0	1	0	6	3	3	30	**31**															
14	Pérez-Escamilla (2008)	0	0	0	0	0	0	0	0	0	0	0	0	0	**2**														
15	Sigurdardottir (2007)	2	0	4	0	1	1	0	0	7	2	5	3	3	0	**18**													
16	Steinsbekk (2012)	1	0	0	0	3	4	1	0	7	2	2	3	3	1	4	**21**												
17	van Dam (2005)	1	0	0	0	1	0	0	0	2	0	2	2	1	0	1	1	**6**											
	Reviews retrieved in updated search																												
18	Pal (2014)	0	0	0	0	0	1	0	0	0	0	0	2	1	0	0	0	0		**16**									
19	Song (2014)	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0		0	**10**								
20	Antoine (2014)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	**6**							
21	Schellenberg (2013)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0	0	0	**11**						
22	Attridge (2014) (CR)	3	0	1	2	11	2	4	0	6	12	3	4	4	3	2	4	1		0	0	0	0	**33**					

[5] PRISMS review is based on a search from 1993 to June 2012. This search was updated to April 2015. Note: Dorrejstein's Cochrane review was updated in 2014 and included 1 additional RCT. The main findings of the review do not change and the updated results are included in this report.

23	Saffari (2014)	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0		1	0	0	0	0	**10**				
24	Cotter (2014)	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0		2	0	0	0	1	0	**9**			
25	Bolen (2014)	4	2/2	4	3	2	8	0	1	18	1	3	10	8	1	3	8	1		6	1	0	1	14	1	4	**138**		
26	Huang (2015)	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0		3	0	0	0	0	3	1	9	**18**	
27	Zhai (2014)	2	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0		5	0	0	0	0	5	4	12	9	**35**

*Attridge's Cochrane review is an update to Hawthorne's CR with an additional 33 RCTs included.

Table 7.5 Study details, quality assurance and summary of findings from meta-analysis of impact of self-management support interventions on blood glucose control, health-related quality of life and mortality

Study	Quality of systematic review			Primary studies		Meta-analysis quality	HbA1c (MD)[b]	Total GHb (MD)
	R-AMSTAR score	Participants	Rating	n	Low risk of bias[a]			
Self-management programmes								
Chodosh 2005[(187)]	34	2,579	***	26	NR	High	-0.36 (-0.52 to -0.21)	
Education								
Attridge 2014[(185)]	39	7,453	***	33	5	High	-0.30 (-0.60 to -0.10)	
Dorresteijn 2014[(188)]	39	2,739	***	12	2	High		
Duke 2009[(189)]	36	1,359	***	9	3	High	-0.08 (-0.25 to 0.08)	
Hawthorne 2008[(195)]	41	1,603	***	11	3	High	-0.10 (-0.40 to 0.20)	
Khunti 2008[(196)]	30	1,004	**	5	NR	NA		
Li 2011[(186)]	41	207	**	2	0	High		
Minet 2010[c(190)]	37	7,677	***	43	NR	Moderate	-0.36 (-0.51 to -0.21)	
Nam 2012[(197)]	35	1,495	***	12	6	Moderate	-0.29 (-0.46 to -0.13)	
Norris 2001[c(191)]	27	NR	*	72	NR	NA		
Norris 2002[c(192)]	31	4,263	***	31	NR	Moderate		-0.76 (-1.18 to -0.34)
Perez-Escamilla 2008[(198)]	25	214	*	2	NR	NA		
Sigurdardottir 2007[(193)]	26	4,293	**	18	7	NA		
Steinsbekk 2012[(194)]	37	2,833	***	21	2	Moderate	-0.87 (-1.25 to -0.49)	
Telemedicine								
Cotter 2014[(177)]	24	1,913	**	9	NR	NA		
Huang 2015[(178)]	35	3,798	***	18	4	High	-0.54 (-0.75 to -0.34)	
Pal 2014[(179)]	38	3,578	***	16	2	High	-0.20 (-0.40 to -0.10)	
Saffari 2014[(180)]	35	960	**	10	4	Moderate	-0.595 (-0.833 to -0.356) -0.436 -0.671 to -0.203) SMS only -0.500 (-0.716 to -0.285) SMS + internet	
Zhai 2014[(181)]	36	8,149	***	35	11	High	-0.37 (-0.49 to -0.25) -0.53 (-0.81 to -0.26) Telephone based -0.62 (-0.82 to -0.42) Internet based	

Other SMS								
Antoine 2014[183]	28	1,025	**	6	0	NA		
Bolen 2014[176]	35	33,124	***	138	43	High	-0.37 (-0.45 to -0.28)	
Gary 2003[199]	36	2,720	***	18	5	Moderate	-0.52 (-0.96 to -0.08)	-0.43 (-0.71 to -0.14)
Heinrich 2010[200]	24	1,778	**	14	NR	NA		
Newman 2004[201]	23	2,032	**	21	NR	NA		
Schellenberg 2013[184]	32	>5,145	***	11	0	High		
Song 2014[182]	29	2,957	**	10	3	Low	0.10 (-0.04 to 0.24)	
Van Dam 2005[202]	31	712	**	6	3	NA		

Key: **MD** = mean difference; **LT** = Long-term; **NR** = not reported; **NA** = not applicable; **QoI** = quality of life; **RR** = relative risk; **ST** = short-term; **T2DM** = Type 2 diabetes mellitus.

[a] Number of the total primary studies identified as being at low risk of bias
[b] Where multiple follow-up durations were analysed, data presented for longest duration analysed.
[c] Data on risk of bias of primary studies was reported, but not in a format that could be reliably extracted.

Table 7.5 (continued) Study details, quality assurance and summary of findings from meta-analysis of impact of SMS interventions on blood glucose control, health-related quality of life and mortality

Study	Quality of systematic review			Primary studies		Meta-analysis quality	QoL (MD)	Mortality (RR)
	R-AMSTAR score	Participants	Rating	n	Low risk of bias[a]			
Self-management programmes								
Chodosh 2005[187]	34	2,579	***	26	NR	High		
Education								
Attridge 2014[185]	39	7,453	***	33	5	High		
Dorresteijn 2014[188]	39	2,739	***	12	2	High		
Duke 2009[189]	36	1,359	***	9	3	High		
Hawthorne 2008[195]	41	1,603	***	11	3	High		
Khunti 2008[196]	30	1,004	**	5	NR	NA		
Li 2011[186]	41	207	**	2	0	High		
Minet 2010[c][190]	37	7,677	***	43	NR	Medium		
Nam 2012[197]	35	1,495	***	12	6	Medium		
Norris 2001[c][191]	27	NR	*	72	NR	NA		
Norris 2002[c][192]	31	4,263	***	31	NR	Medium		
Perez-Escamilla 2008[198]	25	214	*	2	NR	NA		
Sigurdardottir 2007[193]	26	4,293	**	18	7	NA		
Steinsbekk 2012[194]	37	2,833	***	21	2	Medium	0.31 (-0.15 to 0.78)	
Telemedicine								
Cotter 2014[177]	24	1,913	**	9	NR	NA		
Huang 2015[178]	35	3,798	***	18	4	High		
Pal 2014[179]	38	3,578	***	16	2	High		
Saffari 2014[180]	35	960	**	10	4	Moderate		
Zhai 2014[181]	36	8,149	***	35	11	High		
Other SMS								
Antoine 2014[183]	28	1,025	**	6	0	NA		

Bolen 2014[176]	35	33,124	***	138	43	High		OR 0.70 (0.49 to 1.01) LT OR 0.90 (0.64 to 1.28) ST
Gary 2003[199]	36	2,720	***	18	5	Medium		
Heinrich 2010[200]	24	1,778	**	14	NR	NA		
Newman 2004[201]	23	2,032	**	21	NR	NA		
Schellenberg 2013[184]	32	>5,145	***	11	0	High		0.75 (0.53 to 1.06)
Song 2014[182]	29	2,957	**	10	3	Low		
Van Dam 2005[202]	31	712	**	6	3	NA		

Key: **MD** = mean difference; **LT** = Long-term; **NR** = not reported; **NA** = not applicable; **QoL** = quality of life; **RR** = relative risk; **ST** = short-term; **T2DM** = Type 2 diabetes mellitus.

[a] Number of the total primary studies identified as being at low risk of bias

[b] Where multiple follow-up durations were analysed, data presented for longest duration analysed.

[3] Data on risk of bias of primary studies was reported, but not in a format that could be reliably extracted.

7.2.4.1 Summary of findings

Detailed summaries of the systematic reviews including the intervention and comparator, outcomes assessed, duration of follow-up, sample size (number of RCTs and total number of participants, and the evidence of effect are included in Appendix A7.1. The following are reported based on the findings from PRISMS and the additional systematic reviews retrieved in the updated search. In order to emphasise the relevance of the findings, results are grouped by the quality of the systematic review (using the R-AMSTAR score and size of the patient population). Table 7.5 above details the results of the quality assurance assessment of the systematic reviews and provides a summary of findings for selected outcomes from the various meta-analyses assessing the impact of SMS interventions in T2DM.

The types of intervention retrieved by PRISMS included self-management programmes or multi-component interventions aimed at self-management; education; behavioural or counselling strategies and social support. PRISMS reported their findings by outcomes for all interventions and reported on blood glucose control for eight meta-analyses based on eight systematic reviews[187;189;190;192;194;195;197;199] and a further five narrative reviews.[191;196;198;201;202] They reported that there is very good evidence that SMS improves blood glucose control in the short term (less than 12 months). Longer term, they found less evidence for effectiveness, and noted that this is likely to be because of a lack of studies reporting longer-term data. They also stated that overall these SMS interventions do not appear to improve individuals' quality of life or their psychological well-being. They concluded that SMS may be provided in a variety of ways by a variety of people and that it is not possible to state definitively what the optimum mode of delivery is.

7.2.4.2 Education programmes

Three star (***) reviews

PRISMS reported their results by outcome across a range of intervention types. Table 7.5 above shows that PRISMS reported results for interventions broadly classified as education for seven three star reviews.[188-190;192;194;195;197] Of these five reported results for HbA1c with four reporting statistically significant improvements.[190;194;195;197] One review did not find a statistically significant improvement in quality of life.[194]

In the updated search, one additional high-quality systematic review was identified. This 2014 Cochrane review by Attridge et al. compared culturally-appropriate health education with conventional health education.[185] It reported that culturally appropriate health education has short- to medium-term effects (less than 12

months) on glycaemic control and on knowledge of diabetes and healthy lifestyles. They also noted that none of the studies were long-term trials, and so clinically important long-term outcomes could not be studied. The heterogeneity of the studies made subgroup comparisons difficult to interpret with confidence.

Summary statement for education

Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs there is very good evidence that education including culturally appropriate education improves blood glucose control in the short term (less than 12 months) in people with Type 2 diabetes.

7.2.4.3 Self-management programmes

Three star (***) reviews

PRISMS reported their results by outcome across a range of intervention types. Table 7.5 above shows that PRISMS reported results for interventions broadly classified as self-management programmes for one three star review by Chodosh et al.. They reported that there is some evidence that a range of self-management programmes assessed in Type 2 diabetes improve blood glucose control in the short term (less than 12 months). Interventions were identified as self-management programmes if they were systematic interventions targeted at patients with chronic disease with an aim of helping them actively participate in self-monitoring (of symptoms or physiological functions) and, or decision-making (managing the disease or its impact through self-monitoring).

No additional evidence for self-management programmes assessed in Type 2 diabetes was identified in the updated search.

Summary statement for self-management programmes assessed in Type 2 diabetes

There is some evidence that self-management programmes assessed in Type 2 diabetes are associated with small improvements in blood glucose control in the short term.

7.2.4.4 Telemedicine

PRISMS did not include telemedicine applications in their review of Type 2 diabetes, however relevant telemedicine interventions that included a significant component of self-management support were included in the updated search. Three three-star and two two-star systematic reviews relating to SMS telemedicine interventions in Type diabetes were identified.

Three star (***) reviews

A Cochrane review and meta-analysis by Pal et al. of 11 RCTs 2,637 participants compared computer-based diabetes self-management interventions with usual care (in five RCTs) or a range of controls (in six RCTs) to manage Type 2 diabetes.[179] The intervention included computer-based software applications that responded to user input and aimed to generate tailored content to improve one or more of the self-management domains (cognitive, behaviour and skills, and emotion) through feedback, tailored advice, reinforcement and rewards, patient-decision support, goal setting or reminders. The interface used included clinic-based touch screens and computers providing education and customised plans; home-based online peer support, education, and tailored plans; pagers; and mobile devices (primarily mobile phones) to deliver advice and personalised feedback in response to inputted self-monitoring data. All were compared with usual care. It reported a small beneficial effect on blood glucose control; this effect was larger in the mobile phone subgroup. They noted that a small treatment effect (2.3 mmol/mo or 0.2%) on HbA1c with computer-based self-management support interventions that would be important if it could be achieved and sustained across the population via the internet at a very low cost. However, this would be of limited relevance if significant nursing support and, or additional drugs were required. The results were associated with large heterogeneity indicating possible inconsistencies between the effects of the interventions. There was no evidence to show improvement in health-related quality of life. A total of three deaths were reported in 16 studies with one study reporting one dropout due to study-related anxiety. Due to the limitation of the primary studies, the authors concluded that the effectiveness of existing information technology (IT)-based interventions was unclear and difficult to attribute solely to the interventions.

A meta-analysis by Huang et al. (18 RCTs with 3,798 participants) reported that patients monitored by telecare showed significant improvement in glycemic control in Type 2 diabetes when compared with routine follow-up.[178] The intervention arm comprised self monitored transmission of glucometer data and feedback by health professionals, or automatic medical devices and was compared with routine care. Feedback was classified as human calls (that is to say, interactive phone calls), automated calls (pre-recorded voice messages), or automated text. Based on subgroup analysis, greater reductions in HbA1c levels were observed in studies with Asian populations, small sample size, baseline HbA1c less than 8.0% and human calls-based interventions when compared with those monitored by routine follow-up. No effect was observed for automated call interventions.

A meta-analysis by Zhai et al., including 36 RCTs with 8,149 participants, reported that overall, pooled results from telemedicine studies revealed a small, but

statistically significant, decrease in HbA1c following telemedicine intervention, when compared with conventional follow-up.[181] The intervention arm included telephone support in the form of a call or text message; internet-based programmes employing video-conferencing and, or informational websites; and electronically transmitted recommendations from clinicians in response to internet-based reporting of monitoring data by patients. The authors noted that significant publication bias was detected, suggesting that the literature should be interpreted with caution.

Two star (**) reviews

A meta-analysis by Saffari et al. reported that health education via mobile text-messaging statistically significantly improved glycemic control in patients with Type 2 diabetes.[180] The effect size was greater among studies that used both text-messaging and the internet for health education. When results were stratified by patient age, it was noted that although reductions in HbA1C remained significant in both age brackets, the effect size found in younger patients indicated a larger reduction in HbA1c than in patients over 55 years of age.

A narrative review by Cotter et al. reported that when compared with routine care, two of nine studies demonstrated improvements in diet and, or physical activity while two of nine studies demonstrated improvements in glycaemic control with web-based SMS interventions. [177]

Summary statement for telemedicine

There is good evidence that various forms of telemedicine are associated with improvements in blood glucose control in the short term for people with Type 2 diabetes.

7.2.4.5 Other self-management supports

Three star (***) reviews

PRISMS reported their results by outcome across a range of intervention types. Table 7.5 above shows that PRISMS reported results for interventions broadly classified as 'other SMS' for one three star review.[199] It reported a statistically significant improvement in HbA1c.

The updated literature search identified two *'three-star'* and two *'two-star'* systematic reviews relating to a range of other SMS interventions for Type 2 diabetes.

A high-quality meta-analysis by Bolen et al. assessed activation interventions in patients with Type 2 diabetes.[176] These are a subset of behavioural interventions which actively engage patients by promoting increased knowledge, confidence and, or skills for disease self-management. They reported that patient activation

interventions modestly improve HbA1c in adults with Type 2 diabetes without impacting short-term mortality.

A meta-analysis and narrative review by Schellenberg et al. reported on lifestyle interventions for those with, and those at risk of developing Type 2 diabetes. Only the results for patients with Type 2 diabetes are presented here.[184] The control used was standard care or standard care plus a range of other SMS components. Pooled results for all-cause mortality showed no difference between the intervention and control groups at more than 10 years of follow-up. This was based on two RCTs with 'low strength of evidence'. A further narrative review of 11 RCTs reported that the evidence of benefit from comprehensive lifestyle interventions on patient-oriented outcomes is less clear.

Two star (**) reviews

A meta-analysis by Song et al. concluded that compared with usual care, short-term motivational interviewing (less than or equal to ≤ 6 months) is associated with reductions in HbA1c levels and improved self-management ability (diet control, exercise, foot care, glucose control, prevention and treatment of hypoglycaemia). However, the long-term effects (greater than > 6 months) are uncertain.[182] Usual care was defined as traditional diabetes health education.

A review by Antoine et al. reported that although pharmacist interventions might potentially improve adherence to Type 2 diabetes medication, high-quality studies are needed to assess effectiveness.[183] The review mainly compared pharmacist intervention to usual care or education. Possible limitations identified included differences in how pharmacists provide their adherence intervention and reduced applicability of the findings to an Irish context due to differences to the level in which pharmacists are established within the healthcare system in different counties.

Summary statement for other self-management support

There is good evidence that behavioural interventions are associated with modest improvements in blood glucose control (HbA1C). Based on the available evidence, it is not possible to draw conclusions in relation to the efficacy of the diverse range of other SMS interventions identified in this review.

7.3 Review of cost-effectiveness of self-management support interventions

A review of cost-effectiveness studies was carried out to assess the available evidence for self-management support (SMS) interventions for adults with Type 1 or Type 2 diabetes. Studies were included if they compared the costs and consequences of an SMS intervention to routine care.

7.3.1 Search strategy

A search was carried out to identify economic analyses of SMS interventions. In tandem with the systematic review of clinical effectiveness, the search for economic evaluations was carried out in MEDLINE, EMBASE and the Cochrane Library. The same search terms were used with the exception of terms for systematic review and meta-analysis. In place of these, search terms and filters for economic evaluations were applied. In addition, systematic reviews of SMS interventions identified through the results of the clinical effectiveness search that included cost or economic outcomes were used to identify additional studies. The search was carried out up until 4th March 2015.

The PICOS (Population, Intervention, Comparator, Outcomes, Study design) analysis used to formulate the search is presented in Table 7.6 below.

Table 7.6 PICOS analysis for identification of relevant studies

Population	Adults ≥ 18 years old that had diabetes.
Intervention	Any self-management support intervention that helps patients with diabetes through education, training or support.
Comparator	Routine care.
Outcomes	Cost or cost-effectiveness of intervention.
Study design	Randomised controlled trials, case-control studies, observational studies, economic modelling studies.

Studies were excluded if:

- a nursing home or non-community dwelling population was included,
- they included a paediatric population,
- cost data were not clearly reported,
- published prior to 2000 due to limited relevance.

As outlined in Chapter 3.2.2 and in accordance with national health technology assessment(HTA) guidelines, the quality of the studies was assessed using the Consensus on Health Economic Criteria (CHEC)-list was performed independently by two people.[24] For studies that included an assessment of cost-utility or an economic modelling approach, assessment of the relevance to the Irish healthcare setting and their credibility was considered using a questionnaire from the International Society of Pharmacoeconomics and Outcomes Research (ISPOR).[25]

7.3.2 Results – Cost-effectiveness

The initial search identified 118 potentially relevant articles. Three reviewers independently evaluated studies based on title, abstract and full text. Thirty eight studies were identified as applicable. Data extraction was carried out independently by two reviewers. The review includes studies relating to either Type 1 or Type 2 diabetes, or both. Studies that compared blood glucose self-monitoring to usual care were excluded on the grounds that self-monitoring is now considered part of usual care.

There were 20 studies from the United States (US), six from the United Kingdom (UK) three from Germany, two from Ireland, and one from each of Australia, Bulgaria, Canada, Denmark, India, Italy, and the Netherlands. The included studies were all published between 2001 and 2014. The characteristics of the included studies are given in Table 7.7.

Table 7.7 Characteristics of the studies included

Study	Country	Intervention
Albisser (2001)[203]	US	SMS education
Banister (2004)[204]	US	SMS education
Barnett (2007)[205]	US	Telemedicine
Biermann (2002)[206]	Germany	Telemedicine
Brown (2012)[207]	US	SMS education
Brownson (2009)[208]	US	SMS education
Dall (2011)[209]	US	SMS education
Farmer (2009)[210]	UK	SMS education
Fedder (2003)[211]	US	Telemedicine
Fera (2009)[212]	US	Pharmacist
Fischer (2012)[213]	US	Telemedicine
Garrett (2005)[214]	US	SMS education
Gillespie (2012)[215]	Ireland	SMS education
Gillespie (2014)[216]	Ireland	SMS education
Gillett (2010)[217]	UK	SMS education
Gilmer (2005)[218]	US	SMS education
Gilmer (2007)[219]	US	SMS education
Gordon (2014)[220]	Australia	SMS education
Handley (2008)[221]	US	Telemedicine
Ismail (2010)[222]	UK	SMS education
Jacobs-van der Bruggen (2009)[223]	The Netherlands	SMS education
Kesavadev (2012)[224]	India	Telemedicine
Kruger (2013)[225]	UK	SMS education
Kuo (2011)[226]	US	SMS education
Letassy (2003)[227]	US	Pharmacist
Mason (2006)[228]	UK	Telemedicine
Molsted (2012)[229]	Denmark	SMS education
Moreno (2009)[230]	US	Telemedicine

O'Reilly (2007)[231]	Canada	SMS education
Palmas (2010)[232]	US	Telemedicine
Petkova (2006)[233]	Bulgaria	Pharmacist
Ritzwoller (2011)[234]	US	SMS education
Salzsieder (2011)[235]	Germany	Telemedicine
Schechter (2012)[236]	US	Telemedicine
Shearer (2004)[237]	UK	SMS education
Stock (2010)[238]	Germany	SMS education
Trento (2002)[239]	Italy	SMS education
Wiegand (2008)[240]	US	SMS education

The studies were classified according to the type of intervention assessed: SMS education programmes, telemedicine, and community pharmacist-based interventions. Some interventions combined elements of different intervention types. Four studies specified a population with Type 1 diabetes, 19 specified Type 2 diabetes (all, or non-insulin dependent only), and 15 included all adult patients with diabetes.

As noted, study quality was assessed using the Consensus on Health Economic Criteria (CHEC) list,[24] while the applicability of the findings from studies that included an assessment of cost-utility or an economic modelling approach, were evaluated using the ISPOR questionnaire.[25] The quality of the included studies was predominantly poor, and the following discussion sections will focus on the studies found to be of good quality. Costs reported in each of the studies were inflated to 2014 pricing levels using the local consumer price index and expressed in Irish Euro using the purchasing power parity exchange rate.[105]

7.3.2.1 Education

There were 24 studies found that evaluated SMS education programmes. Of the identified studies, 15 included cost-utility analyses and the remaining nine were generally costing or cost-minimisation studies. Seven of the cost-utility analyses and one of the costing studies were found to be of good quality.

A 2009 UK study by Farmer et al. compared blood glucose self-monitoring with and without an educational component in patients with non-insulin-treated Type 2 diabetes.[210] Patients were recruited for a randomised controlled trial (RCT) in a primary care setting. Standard self-monitoring focused on clinician interpretation of monitoring results, while a more intensive alternative involved training in self-interpretation and application of the results to diet, physical activity and medication adherence. Patients were aged at least 25 years and had a glycosylated haemoglobin (A1c) greater than or equal to ≥ 6.2%. In the RCT, 150 patients were randomised to standard self-monitoring and 151 to more intensive self-monitoring. The trial results were then entered into the UKPDS model to infer the impact of

clinical results to life expectancy. This model uses data from a large UK trial to link risk factors (such as A1c) to longer term outcomes. Intervention costs for intensive self-monitoring were slightly less expensive, at €12 over 12 months, but less effective than standard self-monitoring. Both forms of blood glucose self-monitoring were found to be more costly and less effective than standardised usual care.

A 2009 study carried out in the Netherlands by Jacobs-van der Bruggen et al. evaluated lifestyle modification interventions involving nutrition or exercise programmes for adults with Type 2 diabetes.[223] The authors compared seven different interventions (DESMOND, BGI, Look AHEAD, MLP, X-PERT, ICAN, and CAN). Intervention durations ranged from six hours to 24 months. Clinical effectiveness data were extracted from published trial data and incorporated into a chronic disease model that simulated the long-term consequences of lifestyle changes in the population of the Netherlands with Type 2 diabetes. All seven modelled programmes were expected to lead to quality adjusted life years (QALY) gains (from 0.1 to 0.14 QALYs per patient). The seven interventions were considered cost-effective relative to routine care; incremental cost effectiveness ratios (ICERs) ranged from €11,414 per QALY to €49,460 per QALY. The interventions were not compared to each other, so it is not possible to state what the ICERs were relative to each other. It should also be noted that major uncertainty was identified in relation to how long improvements were sustained.

The diabetes education and self-management for ongoing and newly diagnosed (DESMOND) intervention was assessed in the UK in 2010.[217] DESMOND comprises a six-hour structured group education programme delivered in the community by two professional healthcare educators. A cost-utility analysis was undertaken by incorporating the outcomes from a 12-month multicentre, cluster RCT into the Sheffield Type 2 diabetes model. The intervention was estimated to lead to non-statistically significant reductions in A1c, total cholesterol and systolic blood pressure. The intervention was estimated to cost €282 per patient based on the 2004 trial. The ICER based on the DESMOND trial data was estimated to be €7,477 per QALY. The validity of the results depends partly on the sustainability of the effect of the programme.

Ritzwoller at al. undertook an economic evaluation of the Viva Bien trial in the US in 2011, assessing multiple-risk-factor lifestyle interventions targeting Latinas with Type 2 diabetes.[234] The trial randomised 138 patients to usual care and 142 to the intervention. The cost of the intervention per participant was €4,702, which included costs that accrued to the participants. The study estimated a cost of €7,866 per unit reduction in A1c.

A 2012 Irish study evaluated the cost-effectiveness of a peer support programme for adults with Type 2 diabetes.[215] A cost-utility analysis was undertaken by incorporating the outcomes from a two year RCT into the UKPDS diabetes model. The intervention involved group meetings led by trained peers from participants' general practices. The trial found a non-statistically significant reduction in A1c. Intervention set-up was €291 per patient. The intervention was more effective (0.09 additional QALYs) and less costly (reduction of €738) compared to routine care. The intervention was the most cost-effective option at a range of thresholds using both payer and societal perspectives.

Kruger et al. carried out an economic evaluation of the Dose Adjustment for Normal Easting (DAFNE) structured education programme in the UK in 2012 for a simulated cohort of adults with Type 1 diabetes.[225] The study used data from a trial comparing usual care to training in flexible intensive insulin therapy as provided in the DAFNE programme. The trial data were then entered into the Sheffield Type 1 diabetes model to simulate the long-term effects of the intervention. Training was associated with an increased life expectancy (0.08 life year gained per patient) and an average QALY gain of 0.03 QALYs per patient. The cost of the intervention was obtained from the literature (€432 per patient). The ICER for the intervention was estimated to be €17,432 per QALY.

A 2014 Irish study examined the cost-effectiveness of group follow-up compared to individual follow-up after participation in the DAFNE programme for adults with Type 1 diabetes.[216] The trial supporting the study was designed to evaluate whether group follow-up might be more effective at maintaining the benefits of participating in the programme longer-term. Group follow-up was less costly and less beneficial than individual follow-up. At thresholds of €20,000 and €45,000, individual follow-up was the most cost effective option. At thresholds of €15,000 and less, group follow-up was most cost effective. The findings of this study are only relevant to participants in the DAFNE programme.

7.3.2.2 Telemedicine

There were 11 studies found that evaluated telemedicine programmes, including four cost-utility analyses and seven costing or cost-minimisation studies (Table A7.7). One of the cost-utility analyses and one of the costing studies were found to be of good quality.

A 2008 US study by Handley et al. evaluated a telephone self-management support intervention with nurse care management for patients with Type 2 diabetes.[221] The study was based on the results of a 12 month randomised controlled trial (RCT) involving 226 patients in a primary care setting. The SF-36 questionnaire was used to assess health-related quality of life. Start up and running costs were €436 and

€429 per patient per annum, respectively. The ICER for the intervention, including start-up costs, compared with routine care was €72,097 per QALY. Uncertainty was only assessed by varying the QALY data by plus or minus 10%.

A 2010 US study evaluated the costs associated with the IDEATel intervention, which used telemedicine case management in medically underserved patients with diabetes mellitus.[232] Project intervention costs were estimated as €662 per participant per month of intervention delivered. The mean annual payments were estimated at €9,615 for the usual care group and €10,284 for the telemedicine group. Telemedicine case management did not reduce Medicare claims for clinical services. The authors concluded that to be viable and adopted in clinical settings, less costly technology will be required, most likely incorporating mobile phone technology and computers that are owned and maintained by participants. This may not be a viable option for medically underserved patients.

7.3.2.3 Pharmacist-based programmes

Three studies were identified that evaluated pharmacy-based interventions (Table A7.8). All three studies were considered poor quality and at high-risk of bias.

7.3.2.4 Other self-management support programmes

A 2010 UK study evaluated motivational enhancement therapy (MET) and cognitive behaviour therapy (CBT) delivered by general nurses with additional training in these techniques.[222] Patients were adults with a confirmed diagnosis of Type 1 diabetes for a minimum duration of two years and a current A1c value between 8.2% and 15%. The study carried out a cost-utility analysis using data generated by an RCT. The unit cost for a 50-minute MET session was estimated at €74 and €73 per session including and excluding training, respectively. The respective estimates for a 50-minute session of CBT with and without training were €123 and €111, respectively. The average total cost of each treatment approach was approximately €296 for MET and €1,003 for MET in combination with CBT. Compared to usual care, MET had an ICER of €473,919 per QALY from the NHS perspective, and €244,316 per QALY from a societal perspective. Compared to usual care, MET combined with CBT had ICERs of €474,147 per QALY from the NHS perspective, and €412,385 per QALY from the societal perspective. The programme based on MET alone dominated (that is, was less expensive and more effective than) the combination of MET and CBT. The ICERs reported in this study would not generally be considered cost effective using conventional UK willingness to pay thresholds of between £20,000 per QALY and £30,000 per QALY.

7.4 Discussion

This section discusses the main findings from the review of the clinical-effectiveness and cost-effectiveness literature.

7.4.1 Clinical-effectiveness Type 1 diabetes mellitus

In accordance with the Terms of Reference, this assessment was limited to a review of the clinical effectiveness of chronic disease self-management interventions in adults aged 18 years and older. It is noted that this restriction had particular implications for the assessment of SMS interventions in Type 1 diabetes. While clinical presentation of Type 1 diabetes can occur at any age, peak incidence occurs in childhood, with only approximately 25% of cases diagnosed in adults. One review from the PRISMS report met our inclusion criteria. It found no evidence for the effectiveness of psychological treatments in improving glycaemic control and reducing psychological distress in adults. No additional reviews were retrieved in our updated search which ran to 1 April 2015. However, subsequent to this, a high-quality systematic review of structured education programmes for adults with Type 1 diabetes was published as part of a guideline by the UK's National Institute for Health Care and Excellence (NICE) on the diagnosis and management of Type 1 diabetes in adults in August 2015. Given its relevance to this health technology assessment (HTA) and the absence of other literature, this assessment was updated to include the review. Based on evidence that was graded as low- or very low-quality, the review found limited evidence to show that structured education programmes can have a beneficial effect on severe hypoglycaemia and quality of life.

Structured education programmes are currently available in Ireland for adults with Type 1 and Type 2 diabetes. A 2009 Health Service Executive (HSE) review of diabetes structured education provided a definition for structured education, specifically that it is 'a planned and graded process that facilitates the knowledge, skills and ability for diabetes self-management and empowers individuals to live healthily, to maintain and improve their quality of life and assume an active role in their diabetes care team' and outlined key criteria for structured diabetes education in Ireland. The review outlined six of the structured programmes available in Ireland (Type 1 diabetes: Berger and DAFNE programmes; Type 2 diabetes – CODE, Desmond, and X-PERT Ireland; Paediatric – BRUCIE) and noted that these should be integrated into standard diabetes care. This finding is consistent with the 2015 UK's National Institute for Health Care and Excellence (NICE) guideline which concluded that on the basis of evidence rated as being of low- or very low-quality, adults with Type 1 diabetes should be offered a structured education programme of proven benefit (and specifically recommending the DAFNE programme as an example),

stating that it should be offered six to 12 months after diagnosis. They also note that if the structured education is not taken up by 12 months that it can be offered at anytime that is clinically appropriate. The guideline also specified required components of any structured education programme for adults with Type 1 diabetes including that it be evidence-based, delivered by trained educators, quality assured and reviewed by trained competent assessors who measure it against criteria that ensure consistency, with regular audit of outcomes.[173;175]

7.4.2 Clinical-effectiveness Type 2 diabetes

A diverse range of SMS interventions and in particular education interventions were assessed for people with Type 2 diabetes. These differed in the frequency, intensity and mode of delivery. Despite the heterogeneity within the intervention classes, there was a tendency for their findings to be combined, so the results of the meta-analyses should be interpreted with caution. The findings from the 2014 PRISMS systematic review and the additional findings from this updated review indicate that there is consistent evidence that SMS interventions, mainly education, improve blood glucose control in the short-term. Few interventions assessed long-term follow-up with little evidence that the benefit was sustained. Expert clinical feedback noted that blood pressure control contributes as much to survival as glycaemic control in patients with diabetes.[241] Impact of SMS interventions on systolic and, or diastolic blood pressure was assessed in four systematic reviews with no evidence of effect seen for individual patient education programmes, group-based diabetes education or culturally-tailored education; a small improvement weighted mean difference (WMD) of -2.2 (95%CI -3.5 to -1.0) was observed for patient activation interventions on the basis of low- and very low-quality evidence in a systematic review by Bolen et al. (in 54 RCTs with 7,630 participants).[176]

SMS may be delivered in a huge variety of ways and by a large cast of different professionals and lay people; however, the optimal model of delivery is unclear. The PRISMS report noted that given the large number of RCTs and reviews included within its meta-review, the failure to reach any conclusion on the optimal model of delivery suggests that there may not be just one way. They noted that the evidence suggests that various models of delivery may be equally effective and consideration may instead need to be given to other factors which may influence effectiveness, such as the real-world context.

Improvement was seen for some secondary outcomes, but it generally did not persist beyond the intervention phase and the clinical significance is unclear. The evidence suggests that the SMS interventions do not impact on quality of life, which remained unaltered. PRISMS reported that the fact that quality of life remains unaltered in these interventions may be considered a positive outcome considering

the often high demands on participants' time; which could potentially impact negatively on quality of life. However, equivalence studies would be needed to confirm whether the fact that they are unchanged is significant. The PRISMS report noted that the large body of RCT evidence originating in many countries suggests that findings are likely to be highly generalisable. Impact on resource utilisation (hospitalisations, emergency department visits, or use of unscheduled care) was not evaluated in any of the reviews. As noted, there was significant heterogeneity in the format and intensity of the SMS interventions, the study populations, follow-up duration and assessed outcomes. This makes it difficult to formulate clear recommendations regarding the most effective form and content of SMS in Type 2 diabetes.

Due to the volume of evidence available, and in the interest of efficiency, this assessment of SMS interventions in diabetes was undertaken in the form of an overview of reviews. As discussed in Chapter 3.4.1, a disadvantage of this approach is the inability of an overview of reviews to reflect the most recent literature. Following publication of an RCT, it must first be captured in a systematic review, before subsequently being captured in an overview of reviews. However, given their typical sample sizes, it may not be appropriate to draw conclusions on the effect of an intervention based on a single, or a number of small, RCTs. Therefore, it is unlikely that more recent RCTs not captured in this overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions.

It should also be noted that an overview of reviews makes use of pooled clinical effectiveness data, sometimes across a large number of primary studies, and that in many cases the data were very heterogeneous. Studies were often pooled despite the fact that they implemented a variety of different interventions that were only broadly similar. In many cases the pooled estimates gave an indication of the effectiveness of a broad type of intervention rather than a specific and well-defined programme. Although the pooled estimate may show limited effect, individual studies will have shown more or less effectiveness than the average effect. In the event of a policy decision to systematically provide diabetes SMS interventions, it would be advisable to consider the findings of high-quality systematic reviews and the primary evidence they included to determine which intervention might generate the greatest treatment effect.

It would appear that the evidence should be somewhat applicable to the Irish healthcare setting given the description of the diabetes patient populations and the healthcare systems in which the interventions were provided. Potential caveats to this assumption are the extent to which usual care in these RCTs is representative of usual care in Ireland, and differences in how healthcare is provided. Given the increasing tendency for usual or standard of care to be determined by evidence-

based clinical guidelines and the convergence of such guidelines in Western countries, the assumption that the stated standard of care is similar is reasonable. However, differences in healthcare systems may contribute to differences in the adherence to stated standard of care. For example, usual care for diabetes in the Irish primary care setting may differ to that in the UK's NHS system where adherence to quality standards is incentivised by the quality of outcomes framework.

As noted in Section 7.4.1, a 2009 HSE review of diabetes structured education in Ireland outlined key criteria for structured diabetes education and described five of the structured programmes available in Ireland. Of these, three were indicated for Type 2 diabetes in adults (CODE, Desmond, and X-PERT Ireland) and the review noted that these should be integrated into standard diabetes care. This recommendation is consistent with 2011 guidelines from the UK National Institute for Health and Care Excellence (NICE) which highlighted the need to use patient education programmes to improve patient outcomes by offering structured education around the time of diagnosis, with annual reinforcement and review. However, the NICE guidelines emphasise that the success of these programmes is dependent on the personal and sociological background of patients, and that such educational programmes should be tailored to patient groups or individuals.[173;242] The HSE's National Clinical Programme for Diabetes is currently developing a model of care through which it proposes all diabetes patients could have access to a structured integrated care package covering all aspects of their diabetes care.[243]

7.4.3 Cost-effectiveness

Thirty eight economic evaluation studies of chronic disease self-management interventions for patients with diabetes were identified as relevant. Twenty four of these were SMS education programmes, with 11 investigating telemedicine programmes and three pharmacist-led programmes). Four studies specified a population with Type 1 diabetes, 19 specified Type 2 diabetes (all, or non-insulin dependent only), and 15 included all adult patients with diabetes. The quality of the studies was generally poor. A number of the studies either used historical controls or compared outcomes to baseline data. The analysis here focused on the studies considered good quality.

The economic evaluations of SMS education programmes reported a range of results, but the majority estimated greater benefits and higher costs. The better quality studies identified in this review used data from RCTs and then extrapolated lifetime benefits using a number of chronic disease simulation programmes that estimate long-term outcomes based on patient risk-factors such as obesity, smoking, and HbA1c. Simulated results generally suggested ICERs of less than €45,000 per QALY relative to usual care. The applicability of these results depend on the extent to which the effect sizes estimated in trials, which typically involve no more than 18

months follow-up (typically six to 12 months), persist over patients' lifetimes. The results of these studies should therefore be interpreted with caution, although the general finding is of potential cost-effectiveness.

In addition, several of the evaluations were based on trials of interventions where they observed a benefit but it was not found to be statistically significant. Interpretation of the results of a subsequent economic evaluation can be complicated, and focus should in those instances be on the cost findings rather than the effectiveness data. The population of three of the evaluations of SMS education programmes was limited to adults with Type 1 diabetes.[216;225;237] The studies reported that structured education could be considered cost-effective relative to usual care. The study by Kruger et al. related to the DAFNE programme and was used to inform the 2015 NICE guideline alluded to in Section 7.4.1. A similar economic evaluation by Shearer et al. reported that a structured training and teaching programme (STTP) was more effective and less costly than usual care, while and Irish study by Gillespie et al. noted that group follow-up post structured education using DAFNE is less costly and more beneficial than individual follow-up.

In terms of telemedicine interventions, only one good quality study reported a cost-utility analysis. The study of a telephone self-management support intervention with nurse care management for patients with Type 2 diabetes reported an ICER of €72,097 per QALY relative to usual care, which would not generally be considered cost effective using conventional US willingness to pay thresholds of $50,000 per QALY. This study was based on 12 months' follow-up data from a trial of 226 patients.[221]

There was insufficient evidence of adequate quality to consider the cost-effectiveness of pharmacist-led interventions.

Some of the studies have been based on medically underserved populations or specific sub-populations. These sub-groups may be more likely to have poorly-controlled diabetes and may also have a greater probability of other risk-factors (such as smoking or obesity) than the general population. Therefore, the effectiveness of interventions may be overestimated in these studies and they may be less cost-effective when applied to a general population.

The cost per patient of interventions was highly variable, making it difficult to draw any conclusions about the typical implementation cost of self-management support programmes for people with diabetes. Higher costs may be anticipated for telemedicine programmes on account of the need for support technology. However, the cost of SMS education programmes ranges from less than €135 to €4,720 (over six months) per patient over the duration of the trial.

In summary, the review of cost-effectiveness found 38 studies where the effectiveness of interventions was generally derived from RCT evidence. This is in contrast to the review of the clinical effectiveness literature which included 27 systematic reviews of 347 unique RCTs for Type 2 diabetes and two systematic reviews of 26 unique RCTs for Type 1 diabetes. Given the diverse range of study populations, health systems and methodological approaches that have been used to estimate the cost-effectiveness of different self-management programmes for diabetes, the applicability of the available evidence to a prospective Irish programme is considered low. However, relatively recent studies from Ireland and the UK involving peer support and education programmes for patients with diabetes have reported results that would generally be considered cost-effective given conventional willingness-to-pay thresholds used in Ireland.

7.5 Key points

- Limited evidence was retrieved for self-management support interventions in adults with Type 1 diabetes mellitus with only two reviews being identified for inclusion in this overview of reviews. The reviews assessed psychological treatments and structured education programmes, with both rated as high-quality reviews.
- The primary evidence underpinning the systematic reviews was found to be at moderate to high-risk of bias, meaning that the studies may have over- or under-estimated the effect size. The randomised controlled trials (RCTs) were published between 1983 and 2005.
- Based on a single systematic review, there is no evidence of effectiveness of psychological treatments in improving glycaemic control and reducing psychological distress in adults with Type 1 diabetes mellitus.
- Based on a single systematic review of structured education programmes, there is very limited evidence that these interventions lead to improved outcomes in severe hypoglycaemia and quality of life in adults with Type 1 diabetes mellitus.
- Twenty-seven systematic reviews of self-management support interventions in adults with Type 2 diabetes mellitus were identified for inclusion in this overview of reviews.
- Broadly, 13 studies assessed education interventions, five assessed some form of telemedicine, one assessed self-management programmes in Type 2 diabetes and eight assessed other self-management support interventions.
- The quality of the systematic reviews was good, with 15 rated as being higher quality reviews.
- The primary evidence underpinning the systematic reviews was generally found to be at moderate- to high-risk of bias, meaning that the studies may have over-

or under-estimated the effect size. The 347 unique RCTs for Type 2 diabetes were published between 1985 and 2014.

- Based on the quantity and quality of the systematic reviews and the underpinning primary RCTs, there is very good evidence that education, including culturally-appropriate education, improves blood glucose control in the short-term (less than 12 months) in people with Type 2 diabetes.
- There is some evidence that chronic disease self-management programmes in Type 2 diabetes are associated with small improvements in blood glucose control in the short-term.
- There is good evidence that various forms of telemedicine are associated with improvements in blood glucose control in the short term for people with Type 2 diabetes.
- There is good evidence that behavioural interventions are associated with modest improvements in blood glucose control (HbA1C).
- There is evidence of improvements in blood glucose control for a diverse range of self-management support interventions; particularly educational interventions which differ in their frequency, intensity and mode of delivery.
- It is not possible to provide clear recommendations on the optimal content and format of self-management support for Type 2 diabetes. Evidence suggests that various models of delivery may be equally effective. Impact on resource utilisation was not assessed in any of the reviews. Quality of life remained unaltered.
- Thirty eight economic evaluation studies of chronic disease self-management interventions for patients with diabetes were identified as relevant. The studies evaluated self-management support education programmes, telemedicine, and pharmacist-led programmes.
- Self-management support education programmes had the greatest quantity and quality of evidence. Simulated results generally suggested ICERs of less than €45,000 per QALY relative to usual care.
- In terms of telemedicine interventions, there was only one good quality cost-utility analysis, which reported an ICER of €72,097 per QALY relative to usual care.
- There was insufficient evidence of adequate quality to consider the cost-effectiveness of pharmacist-led interventions.
- The better quality studies identified in this review used data from RCTs and then extrapolated lifetime benefits using one of a number of simulation models that predict outcomes based on risk-factors. The results of these studies should therefore be interpreted with caution.
- Based on the description of the healthcare systems and the Type 2 diabetes

mellitus patient populations in the included studies, and assuming that what constitutes 'usual care' and how it is provided is similar in Western countries, the findings of this overview of clinical effectiveness of self-management support interventions are expected to be applicable to the Irish healthcare setting. However, the applicability of some of the cost-effectiveness results to a general population is questionable due to the nature of the included trial population (for example, medically underserved populations). Therefore, the results of those studies are at risk of bias.

12 Discussion

A health technology assessment (HTA) is intended to support evidence-based decision-making in regard to the optimum use of resources in healthcare services. Measured investment and disinvestment decisions are essential to ensure that overall population health gain is maximised, particularly given finite healthcare budgets and increasing demands for services provided. The purpose of this HTA was to examine the clinical and cost-effectiveness of self-management support (SMS) interventions for chronic diseases. Self-management can be broadly defined as the tasks that individuals must undertake to live with one or more chronic diseases. These can broadly be defined as interventions that help patients to manage portions of their chronic disease or diseases through education, training and support.

12.1 Scope of the study

This HTA examined the clinical and cost-effectiveness of generic self-management support (SMS) interventions for chronic diseases and disease-specific interventions for diabetes (Type 1 and Type 2), chronic obstructive pulmonary disease (COPD), asthma, cardiovascular disease (stroke, hypertension, ischaemic heart disease [IHD] and heart failure).

For the purpose of this review, the 2003 definitions of self-management and SMS developed by the US Institute of Medicine were used. Self-management was thus defined as: 'the tasks that individuals must undertake to live with one or more chronic diseases. These tasks include having the confidence to deal with the medical management, role management and emotional management of their conditions.' SMS was defined as: 'the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support.'

SMS interventions may: target different recipients (for example, patients, carers, healthcare professionals); include different components (for example, education, information, practical support, providing equipment, social support, lifestyle advice, prompts, financial incentives); be delivered in different formats (for example, face-to-face, remote, web-based); be delivered by different individuals (including healthcare personnel and trained or untrained lay persons); differ in their intensity and duration.

A consistent theme is that SMS interventions are typically complex interventions that include more than one component of SMS. For this reason, with the exception of education interventions, this report did not assess single component SMS (for

example, simple text message appointment reminders and drug-reminder packaging).

The review of clinical effectiveness was restricted to SMS interventions evaluated through randomised controlled trials (RCTs) in adult populations. Given the volume of literature available, the clinical effectiveness of SMS interventions was evaluated using an 'overview of reviews' approach, where systematic reviews were reviewed rather than the primary evidence. Where existing high-quality overviews were identified, these were updated rather than undertaking a de novo overview of reviews. The cost-effectiveness of generic and disease-specific SMS interventions was evaluated by undertaking systematic reviews of the available literature for each of the disease categories.

12.2 Previous reviews

In December 2014, a high-quality overview of reviews was published by the National Institute for Health Research (NIHR) in the UK. The Practical Systematic Review of Self-Management Support for long-term conditions (PRISMS) study comprised an overview of systematic reviews of RCTs up to 1 June 2012, and was itself undertaken according to the principles of systematic reviewing. The PRISMS study included reviews of SMS interventions for asthma, chronic obstructive pulmonary disease, diabetes (Type 1 and Type 2), hypertension, and stroke.

In broad terms, the PRISMS study concluded that effective SMS interventions are multifaceted, disease-specific, tailored to the individual, and should be underpinned by a collaborative relationship between the patient and healthcare professional. The PRISMS study also included interventions that were applied to children, and included reviews of qualitative implementation studies. These were outside the terms of reference of this project and were not included in this report.

12.3 Additional evidence

This HTA updated the PRISMS reviews to April 2015. The inclusion of the most recent evidence is particularly relevant for telemedicine and computer-based interventions given the rapid rate of technological advance. We identified an additional 47 systematic reviews for the disease areas included in the PRISMS review. PRISMS did not include telehealth reviews as they deemed these to be typically about mode of delivery rather than content of what was delivered. Relevant telehealth interventions that incorporated a significant component of self-management support were, however, included in this updated review.

The PRISMS review did not include generic SMS interventions that were not tailored for specific diseases. Chronic disease self-management programmes such as the Stanford model are designed to be used in populations with a range of chronic

conditions. Generic interventions have the benefit of being potentially applicable to a large proportion of people with one or more chronic diseases. This study evaluated the evidence for generic interventions for which 26 systematic reviews were identified.

Ischaemic heart disease (IHD) and heart failure were also not included in the PRISMS review, but were identified by the HSE as relevant to the scope of this assessment. De novo overviews of reviews were carried out as part of this assessment, identifying 14 reviews of IHD interventions and 20 reviews of heart failure interventions.

Furthermore, corresponding to the reviews of clinical effectiveness, this assessment carried out systematic reviews of the cost-effectiveness literature. These reviews provide valuable evidence on the likely cost implications and cost-effectiveness of SMS interventions. We identified and reviewed 181 costing and cost-effectiveness studies.

In total, this study considered the evidence of over 2,000 RCTs as presented across 160 systematic reviews.

12.4 Summary of findings

The clinical effectiveness of self-management support interventions was reviewed in relation to each disease. A broad range of intervention types were assessed. Some intervention types were only applied to a single or small number of diseases.

Generic (non-disease-specific) self-management support interventions

As noted, a de novo overview of reviews was undertaken in respect of generic self-management support (SMS) interventions. The largest volume of evidence was retrieved for the chronic disease self-management programmes, mainly the Stanford programme. There is some evidence of short-term improvements in patient-reported outcomes such as self-efficacy, health behaviour (exercise) and health outcomes (pain, disability, fatigue, depression). Short-term improvements in health status were found for telephone-delivered cognitive-based therapy. There is insufficient evidence to determine if computer-based chronic disease self-management programmes are superior to usual care or standard programmes. There is some evidence that a range of SMS interventions can lead to a small, but significant reduction in healthcare utilisation; however, it is not possible to identify which types of SMS interventions or components contribute to this positive result. Based on the available evidence, the best possible format of generic self-management support, the diseases in which it is likely to be beneficial, and the duration of its effectiveness, if any, remain unclear.

Asthma

Good evidence was found that SMS interventions can improve quality of life and reduce hospital admissions and use of urgent or unscheduled healthcare in patients with asthma. While the optimal intervention format is unclear, the evidence suggests that the best asthma self-management should include education supported by a written asthma action plan, as well as improved skills training including the use of inhalers and peak flow meters. Behavioural change techniques were noted to be associated with improved medication adherence and a reduction in symptoms.

Chronic obstructive pulmonary disease (COPD)

The assessment found wide variation in the interventions and patient populations, thereby making it difficult to make recommendations on the most effective content of SMS. Very good evidence was found that education is associated with a reduction in COPD-related admissions with limited evidence found that it is associated with improvements in health-related quality of life. Very good evidence was found for pulmonary rehabilitation that included exercise therapy in improving health-related quality of life (HRQoL) and functional exercise capacity of people with COPD. However, because of the substantial variation in the design of pulmonary rehabilitation programmes, the optimal format, intensity and duration of such programmes are unclear. Good evidence was found that complex SMS interventions (that is involving multiple components including education, rehabilitation, psychological therapy, and integrated disease management and or multiple professionals delivered by a variety of means) are associated with improvements in HRQoL in patients with COPD. Some evidence was found that telehealth (as part of a complex intervention) decreases healthcare utilisation while some evidence was also found of improvements in health-related quality of life for nursing outreach programmes. Given the complexity of the interventions assessed, it is difficult to identify the optimal content of a SMS intervention for COPD. Nonetheless, the inclusion of education, exercise and relaxation therapy elements have emerged as important themes.

Diabetes

As the scope of this HTA was limited to adults aged 18 years and older, the majority of the evidence related to the management of Type 2 diabetes. Only two systematic reviews for SMS interventions in Type 1 diabetes were identified for inclusion in this overview of reviews. Very limited evidence was found that structured educational programmes lead to improved outcomes of quality of life and episodes of severe hypoglycaemia in adults with Type 1 diabetes. Very good evidence was found that education, including culturally-appropriate education, improves blood glucose control in the short term (less than 12 months) in adults with Type 2 diabetes, although

quality of life remains unaltered. Some evidence was found that self-management programmes are associated with small improvements in blood glucose control in the short term in Type 2 diabetes, while good evidence was found that behavioural interventions are associated with modest improvements in blood glucose control (HbA1c). Evidence of improvements in blood glucose control for a diverse range of SMS interventions — and in particular educational interventions which differ also in their frequency, intensity and mode of delivery — was also found. Given the complexity of SMS interventions assessed, it is not possible to provide clear recommendations on the optimal content and format of SMS for Type 2 diabetes, other than they should include an education component, with evidence suggesting that various models of delivery may be equally effective. Impact on resource utilisation was not assessed in any of the reviews.

Stroke

There is good evidence that general rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living (ADL) and extended ADL for stroke survivors. There is good evidence that virtual reality-based rehabilitation (that is, using commercial gaming consoles or specifically developed consoles adopted in clinical settings) improves upper limb function and ADL when used as an adjunct to usual care. Based on the available evidence for stroke, it is not possible to draw conclusions in relation to the effectiveness of self-management programmes or a range of interventions including motivational interviewing, psychosocial or lifestyle interventions delivered to stroke survivors. There is some evidence that provision of providing information improves patients and carers' knowledge of stroke and aspects of patients' satisfaction, with small reductions (which may not be clinically significant) in patients' depression scores. Some evidence of effect was also noted for improvements in health-related quality of life for stroke liaison emphasising education and information provision.

Ischaemic heart disease (IHD)

Good evidence was found that exercise programmes (including exercise-based cardiac rehabilitation) are associated with a significant reduction in mortality in suitable patient cohorts with follow-up periods greater than 12 months. Exercise-based interventions were also found to be associated with fewer rehospitalisations. Some evidence was found that patient-education interventions are associated with interim outcomes such as smoking cessation and blood pressure control. Limited evidence was found to demonstrate the effectiveness of behavioural modification interventions, although there were some reported positive effects on smoking cessation and symptom management. Limited evidence was found that home- and telehealth-based cardiac rehabilitation interventions achieve similar outcomes to centre-based cardiac rehabilitation. Interventions such as education, exercise and

behavioural changes are core components of cardiac rehabilitation, so the boundary between standard cardiac rehabilitation services and chronic disease self-management support is ill-defined.

Hypertension

Good evidence was found that self-monitoring of blood pressure, alone or using a range of additional support measures including telemedicine, is beneficial in lowering systolic and diastolic blood pressure. Limited evidence of effectiveness was found for patient-education interventions when used alone to improve medication adherence or blood pressure control. Some evidence was found that community pharmacist interventions, which include patient education, can lead to statistically significant reductions in systolic and diastolic blood pressure. However, for all interventions, the clinical significance of improvements in blood pressure control and medication adherence and the durability of the effect were unclear. As with the other chronic conditions, specific recommendations in relation to the optimal format of a SMS intervention for patients with hypertension is not possible, with evidence for a range of interventions, including education, delivered in a variety of formats. Given the heterogeneity of the patient population, tailoring the components to the individual patient may be beneficial.

Heart failure

Statistically significant reductions in the rate of hospital readmissions were reported for exercise interventions, telehealth interventions and home-visit programmes for patients with heart failure. Similarly, statistically significant reductions in mortality were reported for both telehealth interventions and home-visit programmes. However, despite positive results for telehealth interventions, concerns have been raised about these being the consistent standard of care for patients with heart failure due to inconsistent findings across studies and a lack of understanding about which elements of the intervention contribute to improving outcomes. Limited evidence of effect was found for patient education and behavioural modification interventions for patients with heart failure. As with ischaemic heart disease it is noted that interventions such as education, exercise and behavioural changes are core components of cardiac rehabilitation, so the boundary between standard cardiac rehabilitation services and chronic disease self-management support is ill-defined.

Evidence of cost-effectiveness

Evidence of cost-effectiveness for a wide range of SMS interventions in patients with chronic disease was generally of limited applicability to the Irish healthcare setting. To be cost-effective, an intervention must first be clinically effective; given the heterogeneity of interventions assessed in the clinical effectiveness review and the

variability in the format, intensity and mode of delivery of the interventions assessed, it is difficult to generalise the evidence. A common theme identified is that SMS interventions can typically be delivered at a relatively low cost per patient, although cost is noted to vary according to the intensity of the intervention provided. Therefore, if there is evidence of clinical benefit, typically the intervention will be cost-effective or may even be cost saving (usually driven by reductions or changes in healthcare utilisation). While international evidence suggest that self-management support interventions are potentially low cost on a per-patient level, the budget impact of these interventions could be substantial due to the large numbers of eligible patients.

12.5 Gaps in the evidence

One factor that may contribute to the inconsistent evidence on SMS is the lack of a clear definition of self-management across both primary studies and systematic reviews. Some of the telemedicine interventions, for example, enabled remote consultations between clinicians and patients, but the self-management aspect was a minor element of the overall intervention. The inclusion and exclusion criteria of identified systematic reviews were often based on very broad descriptions of interventions, adding to the heterogeneity of the data. A consensus on the definition of self-management would facilitate the identification of a more narrowly defined, but possibly less heterogeneous evidence-base.

With the exception of generic SMS interventions, the identified reviews related to disease-specific interventions. The included populations are likely to experience high levels of multimorbidity whereby patients have multiple chronic conditions, a number of which may be amenable to self-management. Providing a single disease-specific intervention may not be suitable for enabling successful self-management. Equally, exposure to numerous interventions may be counter-productive, placing an unsustainable burden on the individual. A systematic review of interventions for managing patients with multimorbidity found four studies that could be described as SMS interventions. The authors found that interventions that were linked to healthcare delivery or specific functional difficulties were more effective.[6] For people with multimorbidity, a coherent evidence-based approach that acknowledges their various conditions, and how they interact, is essential.

In many primary studies, interventions were implemented in addition to usual care. Because of this, many studies were structured in a manner that resulted in intervention group patients having more contact with clinical staff than the usual care group. The increased intensity of contact with health professionals may contribute to part of observed treatment effects. In some interventions, the benefit may be changing patterns of healthcare utilisation, such as the substitution of different health professionals (for instance, pharmacist support in place of general

practitioner consultations). Unfortunately, the available evidence does not support an analysis of which features of an intervention may contribute to observed effects on clinical outcomes.

Few of the included systematic reviews included outcomes of patient satisfaction. The lack of data regarding the patient experience means it was not possible to investigate the acceptability of SMS interventions to patients. As such interventions typically aim to improve or increase self-efficacy, it could be anticipated that these interventions may empower patients in their own care. However, some patients could perceive SMS negatively, for example, if they feel they have less clinician support. Further information on the patient experience would be beneficial and could give insights into why some types of SMS intervention are more effective than others.

The identified systematic reviews generally included a quality appraisal of the included primary studies, typically using the Cochrane Risk of Bias Tool or the Jadad score. These tools consider different aspects of study design such as randomisation and blinding. However, an important feature of studies is the quality of the implemented intervention, and this is not captured by the quality assessments. Poor implementation could occur in a variety of ways, such as poor quality educational material or malfunctioning equipment. Although some outcomes such as poor compliance or programme completion rates may be indicative of quality problems, they are not adequate for assessing treatment fidelity. A common audit or evaluation framework could support assessment of intervention quality, but could not be applied retrospectively. Consideration needs to be given to how the quality of intervention implementation and delivery can be evaluated.

12.6 Limitations

The evidence presented in this health technology assessment (HTA), and the approach used to obtain the evidence, are subject to a number of limitations that should be taken into account when considering the findings.

The review-of-reviews approach enabled an assessment of a large quantity of evidence for a range of intervention types across a number of disease areas in a relatively short period of time. Carrying out systematic reviews would not have been feasible and would have necessitated substantial resources to identify, acquire, evaluate and summarise primary evidence where others have already done this work to an acceptable standard. However, a review of reviews places one at a remove from the primary evidence and reliant on the quality of the available reviews. More recent RCTs may not be captured in this approach. However, given their typical sample sizes, it is not possible to draw strong conclusions about effectiveness based on a single RCT, or a number of small RCTs. Therefore it is unlikely that more recent

RCTs not captured in an overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions. It is clear that the quality of the identified systematic reviews was variable. Reviews are, as with the primary evidence, at risk of bias. Some reviews were optimistic in their interpretation of the available evidence and concentrated on evidence showing positive effects. By evaluating the quality of the systematic reviews using a recognised method and focusing on high-quality reviews, we have minimised the risk of bias in our review.

The majority of the trials underpinning the clinical effectiveness data had relatively short-term follow-up of participants. The majority of systematic reviews were based on RCTs with no more than 12 months of follow-up. It is unclear whether effects observed at six or 12 months might be sustained over longer time horizons. Continued beneficial effects may be contingent on ongoing exposure to the intervention, and it is unclear whether good levels of compliance are likely to be maintained over longer periods. Two reviews included trials with 10 years of follow-up data, but that does not provide enough evidence to determine the potential longer-term impact of chronic disease self-management interventions. The length of follow-up also influences the types of outcomes included in studies, with some relying on risk factors or intermediate endpoints rather than clinical endpoints. Differences in mortality, for example, may be difficult to detect over six months in trials that are powered to detect differences in relation to a more common primary outcome. Trials with longer-term follow up could provide a stronger basis to evaluate both clinical outcomes and also data on whether sustained compliance is a potential issue.

Many of the primary studies were based on small sample sizes, which were sometimes presented as pilot or feasibility studies. Small sample sizes inevitably lead to imprecise effect estimates and an inability to detect a statistically significant effect. A benefit of the systematic review approach and meta-analysis techniques is that it enables the pooling of data across studies to improve precision. While this is useful for estimates of clinical effectiveness, this is less relevant for cost-effectiveness. Due to the greater variability in cost data, studies powered to detect a clinical effect are often underpowered to generate stable cost estimates. The cost-effectiveness data was mostly generated as part of an RCT, often with a small sample population. For this reason and because of differences between RCT and real world settings, cost estimates generated by RCTs should be viewed with caution.

There was a marked lack of consistency across studies in terms of the interventions, the definition of routine care, and the outcomes reported. Within a specific disease and for a particular intervention type there could still be substantial heterogeneity. This heterogeneity poses challenges in interpreting the available evidence and forming recommendations for practice. Where possible we have evaluated the

applicability of the evidence. That is, we assessed the extent to which the available data could be used to determine what would happen if the intervention was provided to the eligible patient population in Ireland. The applicability of the evidence is contingent on it reflecting the type of intervention that would be rolled out, that it was applied to similar population, that it has been compared to an approximation of routine care in Ireland, and that the outcomes are relevant to the Irish population. Due to the inconsistency of the evidence in many instances, it is only possibly to make broad statements regarding applicability.

The studies reporting costs and cost-effectiveness were generally found to be of poor quality. In many cases the studies used data collected as part of a small RCT. There is a risk of publication bias in that studies might be more likely to publish the cost data if they either observed a clinical effect or a reduction in costs. Studies that used modelling approaches made assumptions about the sustainability of effects observed with short-term follow-up. High-quality studies tested these assumptions and used sensitivity analyses to determine the impact of effects ceasing at the end of trial follow-up. The available modelling studies often extrapolated long-term outcomes on the basis of intermediate risk factors, for example, a reduction in A1c or blood pressure, using data such as the Framingham Heart Study. The cost-effectiveness data should be viewed in conjunction with the clinical effectiveness data to reduce the risk of biased interpretation, and to ensure that cost-effectiveness is only considered where there is consistent evidence of positive clinical effect.

12.7 Applicability of the evidence

Clinical effectiveness

A very substantial body of literature was reviewed for this HTA, describing the clinical effectiveness of both generic and disease-specific self-management support (SMS) interventions. The applicability of the evidence is a function of the study populations, spectrum of disease, definition of routine care, health system infrastructure, and other features that impact on patient outcomes. In most cases, it was found (with caveats) that the evidence reviewed was broadly applicable to the Irish healthcare setting. A key issue was often the definition of routine care and the extent to which it corresponded to routine care as provided in Ireland.

The healthcare setting must also be considered when evaluating the applicability of the evidence. Many of the primary studies originated from the US, and due to differences in the financing and provision of healthcare, this may impact on the applicability. For example, many of the economic evaluations for SMS interventions in diabetes related to specific insurance plans, medically underserved (low income or uninsured) individuals or specific ethnic groups (for example Hispanics or Latinos), all with limited relevance to the Irish healthcare setting.

It should be borne in mind that an overview of reviews makes use of pooled clinical effectiveness data, sometimes across a large number of primary studies, and that in many cases the data were very heterogeneous. Studies were often pooled despite the fact that they implemented a variety of different interventions that were only broadly similar. In many cases the pooled estimates gave an indication of the effectiveness of a broad type of intervention rather than a specific and well-defined programme. Although the pooled estimate may show limited effect, individual studies will have shown more or less effectiveness than the average effect. Similarly, as with any healthcare intervention, within studies, some patients will have experienced a greater treatment effect than others. However, it was not possible to determine patient subgroups for which certain intervention types may be more effective. Equally it could not be stated which specific programme types might be more effective within broad intervention groupings. In the event of a policy decision to systematically provide SMS interventions, it would be advisable to consider the findings of high-quality systematic reviews and the primary evidence they included to determine what implementation might generate the greatest treatment effect.

A number of reviews included outcomes of healthcare utilisation. In some cases, studies reported either reduced utilisation or a shift in utilisation from secondary to primary care. The applicability of this evidence must be considered in conjunction with the potential for unmet need in the Irish healthcare setting. Some interventions require an element of clinician contact, for example, to carry out periodic office-based measurements. For any currently underserved patient groups, such an intervention could generate additional but appropriate utilisation. Hence, predicted reductions in service use based on international data may not translate into equivalent reductions when rolled out in Ireland.

Cost-effectiveness

The data on costs and cost-effectiveness came from a wide range of settings, and were often RCT-based analyses. Estimates of cost-effectiveness or cost-utility, when reported, are probably of limited applicability. However, the per-patient cost of SMS interventions tended to be low, and this finding is anticipated to be applicable to the Irish setting. While per-patient costs are typically low, the overall budget impact could be substantial particularly for high-prevalence conditions.

12.8 Conclusions

What did we look at?

This HTA examined the clinical and cost-effectiveness of generic self-management support (SMS) interventions for chronic diseases and disease-specific interventions. The review of clinical effectiveness was restricted to SMS interventions evaluated through randomised controlled trials (RCTs) in adult populations. The study

considered in excess of 2,000 RCTs included across 160 systematic reviews. The quality of the primary studies underpinning those reviews was often poor. In addition, the study reviewed 181 costing studies.

What did we find?

SMS interventions comprise a heterogeneous group with little clarity or consistency between studies. There is a clear need for an agreed definition of what constitutes self-management support. For the purpose of this review, the 2003 definitions of self-management and self-management support developed by the US Institute of Medicine were used. Self-management support interventions aim to help patients to manage portions of their chronic diseases through education, training and support. In theory, by improving self-efficacy, patients should be better able to manage their condition potentially leading to better health outcomes, fewer acute events, and reduced healthcare utilisation.

Evidence of the clinical-effectiveness of chronic disease self-management support interventions provides a complex picture. Certain forms of disease-specific interventions have been shown to improve outcomes over periods of six to 12 months. Longer-term outcome data are generally not collected. In particular, very good evidence was found that:

- Exercise programmes for patients with ischaemic heart disease are associated with a significant reduction in mortality in studies with greater than 12-months follow up. Exercise-based interventions are also associated with fewer rehospitalisations.
- Education is associated with a reduction in COPD-related hospital admissions.
- Pulmonary rehabilitation that includes exercise therapy improves quality of life and functional exercise capacity of people with COPD.
- Education, including culturally-appropriate education, improves blood glucose control in the short term (less than 12 months) in adults with Type 2 diabetes, although quality of life remains unaltered.
- Exercise interventions are associated with statistically significant reductions in the rate of hospital readmissions for patients with heart failure. Similar significant reductions in hospital readmission and mortality are noted for telehealth interventions and home-visits programmes. However, concerns have been raised in relation to telehealth interventions becoming the standard of care due to inconsistent findings across studies and lack of understanding about which elements of the intervention contribute to improving outcomes.

Good evidence was found that:

- Complex SMS interventions (that is involving multiple components including education, rehabilitation, psychological therapy, and integrated disease management and or multiple professionals delivered by a variety of means) are associated with improvements in health-related quality of life in patients with COPD.
- SMS interventions can reduce hospital admissions and use of urgent scheduled and unscheduled healthcare in patients with asthma. Optimal asthma SMS support should include education supported by a written action plan as well as improved skills training including the use of inhalers and peak flow meters
- General rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living and extended activities of daily living. Good evidence was also found that virtual reality-based rehabilitation improved upper limb function and activities of daily living when used as an add-on to usual care.
- Behavioural interventions (specifically patient activation interventions) are associated with modest improvements in blood glucose control in adults with Type 2 diabetes.
- Self-monitoring of blood pressure, alone or in conjunction with a range of additional support measures — including telemedicine — is beneficial in lowering systolic and diastolic blood pressure.

Some evidence of effect was noted that:

- Provision of information improves patients and carers' knowledge of stroke and aspects of patient satisfaction in stroke survivors
- Stroke liaison which emphasises education and information provision improves health-related quality of life in stroke survivors
- Self-management programmes are associated with small improvements in blood glucose control in the short term in Type 2 diabetes patients
- Community pharmacist interventions, which include patient education, can lead to statistically significant reductions in systolic and diastolic blood pressure in patients with hypertension.

Based on the available evidence, the optimal format of generic self-management support, the diseases in which it is likely to provide benefit, and the duration of effectiveness, if any, remain unclear.

There is limited evidence regarding the cost-effectiveness of chronic disease self-management support. With the exception of some telehealth interventions and more intensive rehabilitation programmes, most SMS interventions have a relatively low

cost per patient to implement and in some instances can result in modest cost savings through reductions or shifts in healthcare utilisation. However, budget impact is likely to be substantial if implemented for all eligible patients. Most economic analyses were conducted alongside randomised controlled trials, limiting their ability of determine if observed cost savings could be sustained. The costing methodology and perspective adopted differed greatly between studies making it difficult to summarise and aggregate findings.

Is it relevant?

The data from the primary studies was very heterogeneous, reflecting the very wide range of interventions that have been implemented. Despite the many limitations of the available evidence, the findings of the clinical effectiveness are broadly applicable to the Irish healthcare setting. The extent to which the clinical effectiveness data apply to Ireland depends on the definition of routine care, the adherence to the stated standard of care, and the similarities of the healthcare systems. Evidence of cost-effectiveness for a wide range of interventions was generally of limited applicability to the Irish healthcare setting. International data suggest a relatively low cost per patient of SMS interventions, however, consideration must be given to the size of the population, particularly for high prevalence conditions, when considering the potential budget impact of implementing SMS.

What is the bottom line?

SMS interventions have the potential to improve patient outcomes through improved self-efficacy. This HTA gives the evidence base for the SMS interventions that should be prioritised and for which diseases. Where chronic disease self-management support interventions are provided, it is critical that the implementation and delivery of the interventions are subject to routine and ongoing evaluation. This would help to ensure that they are delivering benefits to patients, and allow the content and format of the interventions to be refined. Evaluation will also provide a longer-term perspective not currently available in the literature and will support decisions about the optimal delivery of such interventions. The best evidence of benefit was found for the disease-specific interventions.

Appendix A3

Appendix A3.1 – Search details

Clinical Effectiveness Review Basic search terms:

Chronic disease terms	(Chronic disease[Mesh], chronic health/condition/ illness, long term illness/disease/ condition, diabetes[Mesh], asthma[Mesh], chronic obstructive pulmonary disease[Mesh], stroke[Mesh], hypertension[Mesh], heart failure[Mesh], coronary artery disease[Mesh], ischemic heart disease[Mesh])

AND

Self-management terms	(self care[Mesh], self management, self monitor, self help, self medication, self administration, diagnostic self evaluation[Mesh], self regulation, self treat, self test, self efficacy[Mesh]) (telemedicine[Mesh], e-Health, m-Health, telecare, e-Therapy, telenursing, telemonitor, Computer-Assisted Instruction[Mesh], telephone[Mesh], Cell Phones[Mesh]), Text Messaging[Mesh]), SMS, Self help groups[Mesh], group based, Social learning theory, Behaviour change theory, Behaviour change program, Behaviour change model, motivational interview, peer led, peer support, lay led, lay support, health coach, Action plan, Care plan, Patient education as topic[Mesh], Flinders program/model, chronic care model, expert patients programme, Stanford model/program, internet[MeSH Terms], pulmonary rehab, cardiac rehab)

AND

Systematic review terms or filter	(systematic review, review[Publication Type]), Meta-analysis[Publication Type], Meta-Analysis as Topic[Mesh], meta review, meta-synthesis, overview of reviews, review of reviews, cochrane review)

Clinical Effectiveness Review Basic search strategy:

Phase I	Search from 2009 to February 2015.
Phase IIa	Use PRISMS results prior to 2012. New search from 2012 to April 2015.
Phase IIb	Stroke and hypertension: Use PRISMS results prior to 2012. New search from 2012 to April 2015.
	Heart failure and ischaemic heart disease: Search from 2009 to April 2015.

Appendix A7 - Diabetes

Table A7.1 T1DM: Results of meta-analyses.

Reference and weighting Outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance	ES (95% CI)
Reviews retrieved by PRISMS (QA completed by PRISMS)						
Winkley (2006)[174]***	Psychological interventions	GHb (adult only)	NR	11 RCTs; 516 participants	0	SMD–0.17 (–0.45 to 0.10); p=0.22
		Psychological distress (adult)	NR	Six RCTs	0	SMD–0.25 (–0.51 to 0.01); p=0.059
Additional reviews retrieved (QA completed by HIQA)						
NICE (2015)[175]***	Structured education programmes	¥	¥	¥	¥	¥

Key: GHb: Glycohemoglobin; **NR:** Not reported; **QA:** Quality Assured; **RCT:** Randomised Controlled Trial; **SMD:** Standard Mean Difference
¥: Due to potential issues with the reported outcome measures, the results of the meta-analyses are not included here.

Table A7.2 T1DM: Summary of results from quantitative systematic reviews. Table adapted from PRISMS review.

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
Reviews retrieved by PRISMS (QA completed by PRISMS)					
Winkley (2006)[174]***	Psychological interventions	29 RCTs; 1,709 participants; 1985–2005	Meta-analysis	No significant effect found to support a real reduction in GHb and psychological distress for adult populations.	This review provides no evidence for the effectiveness of psychological treatments in improving glycaemic control and reducing psychological distress in adults.
			Narrative	Restriction to group cognitive behavioural therapy delivered to adults resulted in a pooled ES [SMD 0.02 (95% CI–0.41 to 0.44); p=0.95]	
Additional reviews retrieved (QA completed by HIQA)					
NICE (2015)[175]***	Structured education programmes	15 RCTs; 1,994 participants; 1983-2013	Narrative	Some trials showed a positive effect on outcomes including glycated haemoglobin, severe hypoglycaemia, and quality of life. In the broader educational programmes, the results of the DAFNE and PRIMAS studies were superior to others.	GRADE analysis suggested that the data on structured education programmes is generally of low or very low quality.

Key: ES: Effect size; **GHb**: Glycohemoglobin; **NR**: Not reported; **QA**: Quality Assured; **RCT**: Randomised Controlled Trial; **SMD**: Standard Mean Difference

Table A.7.3T2DM: Results of meta-analyses from PRISMS review and HIQA review Adapted from PRISMS review.[2]

Reference and weighting Outcome	Intervention and comparator	Outcome	Time	Sample size	Significance	ES (95% CI)
PRISMS reviews retrieved (QA completed by PRISMS)						
Self-management programmes						
Chodosh (2005)[187]***	Self-management programmes for older adults	HbA1c	NR	20 RCTs	+	–0.36 (–0.52 to–0.21)
		Fasting blood glucose	NR	13 RCTs	+	–0.28 (–0.47 to–0.08)
		Weight	NR	17 RCTs	0	–0.04 (–0.16 to 0.07)
Education						
Duke (2009)[189]***	Individual patient education systematic programmes v usual care	HbA1c	<12 months	3 RCTs; 295 participants	0	WMD–0.2% (–0.5% to–0.03%);p=0.08
			≥12 months	4 RCTs; 632 participants	0	WMD–0.1% (–0.3% to 0.1%);p=0.33
		SBP	≥12 months	3 RCTs; 625 participants	0	WMD–2 mmHg (–5 to 1 mmHg);p=0.19
		DBP	≥12 months	3 RCTs; 624 participants	0	WMD–2 mmHg (–3 to 0 mmHg);p=0.05
		Cholesterol	≥12 months	3 RCTs; 627 participants	0	WMD–0.03 mmol/l (–0.2 to 0.1 mmol);p=0.66
		BMI	≥12 months	2 RCTs; 312 participants	0	WMD–0.2 kg/m^2 (–1.0 to 0.62 kg/m^2); p=0.62
	individual education vs. group education	HbA1c	<12 months	2 RCTs; 148 participants	+++	WMD 0.8% (0.3% to 1.3%); p=0.0007
			≥12 months	2 RCTs; 112 participants	0	WMD 0.03% (–0.02% to 0.10%);p=0.22
		SBP	≥12 months	2 RCTs; 95 participants	0	WMD 4 mmHg (–4 to 12 mmHg
		DBP	≥12 months	2 RCTs; 95 participants	0	WMD 2 mmHg (–4 to 7 mmHg)
		BMI	<12 months	2 RCTs; 169 participants	0	WMD–0.1 kg/m^2 (–0.9 to 0.7 kg/m^2); p=0.77
			≥12 months	2 RCTs; 123 participants	0	WMD–0.01 kg/m^2 (–0.8 to 0.7 kg/m^2); p=0.98

Reference and weighting Outcome	Intervention and comparator	Outcome	Time	Sample size	Significance	ES (95% CI)
Gary (2003)[199]***	Clear behavioural or counselling component	GHb (total GHb, HbA1, HbA1c)	NR	18 RCTs	++	–0.43 (–0.71 to–0.14); p=0.003
		Fasting blood glucose	NR	12 RCTs	0	WMD–12.22 mg/dl (–25.1 to 0.67 mg/dl)
		Total GHb	NR	6 RCTs	0	WMD–0.4% (–0.73% to 0.08%)
		HbA1	NR	7 RCTs	0	WMD–0.77% (–1.88% to 0.34%
		HbA1C	NR	5 RCTs	+	WMD–0.52% (–0.96% to–0.08%); p=0.02
		Weight	NR	7 RCTs	0	WMD–4.64 lb (–9.95 to 0.66 lb)
Minet (2010)[190]***	Self-care management interventions	HbA1c	Overall	43 RCTs; 7677 participants	+	MD 0.36% (0.207% to 0.509%)
Norris (2002)[192]***	Self-management education	GHb	Immediate	20 RCTs	+	–0.76% (–0.34% to–1.18%)
			1–3 months	9 RCTs	0	–0.26% (–0.73% to 0.21%)
			≥4 months	8 RCTs	+	–0.26% (–0.48% to–0.05%)
Sigurdardottir (2007)[193]**	Education	HbA1c	NR	NR	++	p=0.008
Steinsbekk (2012)[194]***	Group-based diabetes education	HbA1c	<12 months	13 RCTs; 1827 participants	+++	MD–0.44% (–0.69% to–0.19%); p=0.0006
		HbA1c	12 month	11 RCTs; 1503 participants	+++	MD–0.46% (–0.74% to–0.18%); p=0.001
		HbA1c	2 years	3 RCTs; 397 participants	+++	MD–0.87% (–1.25% to–0.49%); p<0.00001
		Fasting blood glucose	<12 months	3 RCTs; 401 participants	0	NR
			≥12 months	5 RCTs	+++	MD–1.26 mmol/l (–1.69 to–0.83 mmol/l); p<0.00001
		QoL	<12 months	3 RCTs; 473 participants	0	SMD 0.31 (–0.15 to 0.78); p=0.19

Reference and weighting Outcome	Intervention and comparator	Outcome	Time	Sample size	Significance	ES (95% CI)
		Self-efficacy	<12 months	2 RCTs; 326 participants	++	SMD 0.28 (0.06 to 0.5); p=0.01
		Self management behaviours	<12 months	4 RCTs; 534 participants	++	SMD 0.55 (0.11 to 0.99); p=0.01
		SBP	<12 months	5 RCTs; 815 participants	0	–0.34 mmHg (–5.19 to 4.51 mmHg)
		DBP	<12 months	5 RCTs; 815 participants	0	–0.46 mmHg (–2.31 to 1.39 mmHg)
		SBP	≥12 months	2 RCTs	0	–3 mmHg (95% CI –7 to 2 mmHg)
		DBP	≥12 months	2 RCTs	0	0.17 mmHg (–4.46 to 4.80 mmHg)
		Total cholesterol	<12 months	7 RCTs; 1161 participants	0	–0.06 mmol/l (–0.23 to 0.12 mmol/l)
		Triglycerides	<12 months	7 RCTs; 1161 participants	0	–0.05 mmol/l (–0.19 to 0.08 mmol/l)
		Total cholesterol	≥12 months	4 RCTs	0	0.07 mmol/l (–0.09 to 0.20 mmol/l)
		Triglycerides	≥12 months	4 RCTs	0	0.03 mmol/l (–0.42 to 0.48 mmol/l)
		HDL	<12 months	6 RCTs; 932 participants	0	0.01 mmol/l (–0.05to 0.03 mmol/l)
		LDL	<12 months	6 RCTs; 932 participants	0	0.05 mmol/l (–0.2 to 0.1 mmol/l)
		Body weight	<12 months	3 RCTs; 433 participants	0	–2.08 kg (–5.55 to 1.39 kg); p=0.24
		BMI	<12 months p=0.51	7 RCTs; 1159 participants	0	0.21 kg/m^2 (–0.86 to 0.43 kg/m^2);
		Body weight	≥12 months	4 RCTs; 492 participants	+	MD–1.66 kg (–3.07 to– 0.25 kg);p=0.02
		BMI	≥12 months	7 RCTs; 1092 participants	0	–0.22 kg/m^2(–1.13 to 0.69 kg/m^2); p=0.63
		Mortality	NR	NR	0	OR 1.10 (0.37 to 3.29)

Reference and weighting Outcome	Intervention and comparator	Outcome	Time	Sample size	Significance	ES (95% CI)
Hawthorne (2008)[195]***	Culturally tailored education	HbA1c	3 months	Five RCTs	+	WMD–0.3% (–0.6% to–0.01%)
		HbA1c	6 months	Six RCTs	+	WMD–0.6% (–0.9% to–0.4%)
		HbA1c	≥12 months	Three RCTs	0	WMD–0.1% (–0.4% to 0.2%)
		QoL	<12 months	Three RCTs	0	NR
		Self-efficacy	NR	Three RCTs	0	NR
		BP	Overall	Four RCTs	0	NR
		Total cholesterol	<12 months	NR	0	NR
		HDL	<12 months	NR	0	NR
		LDL	<12 months	NR	0	NR
		Total cholesterol	≥12 months	Three RCTs	+	WMD–0.39 g/dl (–0.64 to–0.14 g/dl)
		Triglyceride	<12 months	Three RCTs	0	NR
		BMI	Overall	Three RCTs	0	NR
Nam (2012)[197]***	Culturally tailored education	HbA1c	Overall	12 RCTs	+	–0.29 (–0.46 to–0.13)
			3 months	Eight RCTs	0	–0.21 (–0.47 to 0.05)
			6 months	Five RCTs	+	–0.41 (–0.61 to–0.21)
			≥12 months	Two RCTs	0	–0.14 (–0.39 to 0.11)
Additional reviews retrieved (QA completed by HIQA)						
Pal (2014) (CR)[179]***	Computer-based DM self-management interventions	HbA1c	2-12 months	11 RCTs; 2637 participants	++	Small, statistically significant difference of 2.3 mmol/mol. MD -0.2% (95% CI -0.4 to -0.1); I^2 = 58%; P=0.009
		HbA1c - mobile phone subgroup	2-12 months	3 RCTs;	+++	-5.5 mmol/mol or -0.5% (95% CI -0.7 to -0.3); I^2 = 0%; P<0.001
		HbA1c – longer term (> 6 months)	> 6 months	6 RCTs;	0	-1.5 mmol/mol or -0.1% (95% CI -0.3 to 0.1); P=0.33

Song (2014)[182]**	Motivational interviewing effect on self-management	Self-management ability: Diet control	6 months (not reported in 1 RCT)	3 RCTs; 280 participants	+++	MD, 2.46 95% CI, 1.58-3.34; p<0.00001; I^2 =0%;
		Self-management ability: regular exercise			++	MD 2.41 95% CI 0.64 to 4.19; p=0.008
		Self-management ability: medication adherence			+	MD 1.53 95% CI -0.10 to 3.16; p=0.07
		Self-management ability: glucose monitoring			++	MD 2.12 95% CI 0.81 to 3.42; p=0.001
		Self-management ability: foot care			+++	MD 2.67 95% CI 1.67 to 3.68; p<0.00001
		Self-management ability: prevention and treatment of hyperglycaemia and hypoglycaemia			++	MD 3.23 95% CI 1.30 to 5.17; p=0.001
		HbA1c	3 months of MI	2 RCTs; 160 participants	+++	WMD -0.66; 95% CI -1.02 to -0.30; p=0.0003
			6 months of MI	6 RCTs; 714 participants	++	WMD -0.44; 95% CI -0.73 to -0.15; P=0.003; I^2 = 73%;
			12 months of MI	2 RCTs; 845 participants	0	WMD 0.10; 95% CI -0.04 to -0.23; p=0.16
			14 months of MI	1 RCT; 940 participants	0	WMD -0.10; 95% CI 0.50 to 0.10; p=0.19
			18 months of MI	1 RCT; 217 participants	0	WMD 0.00 95% CI -0.28 to 0.28; p=1.00
			24 months of MI	1 RCT	0	WMD -0.20; 95% CI -0.50 to 0.1; P=0.19
Schellenberg (2013)[184]***	Lifestyle Interventions for Patients With and at Risk for T2DM (results for patients with diabetes only included)	All-cause mortality: (strength of evidence rated as low for this outcome)	> 10 years follow-up	2 RCTs; 5305 participants	0	RR 0.75 [CI, 0.53 to 1.06] P=0.10
Attridge (2014) (CR)[185]***	Culturally appropriate health education for people in ethnic minority groups	HbA1c	3 months	14 trials; 1442 participants;	++	MD -0.4% (95% CI -0.6 to -0.1); P=0.003; I^2 = 45%. [high-quality evidence]
			6 months	14 trials; 1972 participants;	+++	MD -0.5% (95% CI -0.7 to -0.4); P<0.001; I^2 = 37%. [high-quality evidence]
			12 months	9 trials; 1966 participants	+	MD -0.2% (95% CI -0.3 to -0.04); P=0.015; I^2 =

						17%.
			24 months	4 trials; 2268 participants;	+	(MD -0.3% (95% CI -0.6 to -0.1); P=0.019; I^2 = 61%. [moderate-quality evidence]
		Knowledge scores	3 months	10 trials; 936 participants;	++	SMD 0.4 (95% CI 0.1 to 0.6); P=0.005; I^2=65%
			6 months	9 trials; 994 participants;	+++	SMD 0.5 (95% CI 0.3 to 0.7); P<0.001; I^2 = 43%.
			12 months	2 trial; 328 participants;	++	SMD 0.4 (95% CI 0.1 to 0.6); P=0.002; I^2 = 0%.
Saffari (2014)[180]**	Health education via mobile phones (SMS only, SMS plus internet)	HbA1c		10 trials; 960 participants	+++	SMD -0.595 (95% CI -0.833 to -0.356); p<0.001;
		HbA1c – SMS only		6 trials;	+++	SMD -0.595 (95% CI -0.671 to -0.202); p<0.001;
		HbA1c – SMS + internet		4 trials;	+++	SMD -0.500 (95% CI -0.716 to -0.285); p<0.001;
Bolen (2014)[176]***	Patient activation interventions	Long-term Mortality	> 2 years	6 RCTs; 2,733 participants	0	OR 0.70 (95% CI 0.49 to 1.01); I^2 = 60%.
		Short-term mortality	≤ 24 months	38 RCTs;	0	OR 0.90 (95% CI 0.64 to 1.28)
		A1c (%)	> 3 months	111 RCTs; 12,780 participants		WMD -0.37 (95% CI -0.45 to -0.28)
		SBP (mmHg)	> 3 months	54 RCTs; 7,630 participants		WMD -2.2 (95% CI -3.5 to -1.0)
		CVD morbidity	> 3 months	1 RCT; 141 participants		RD: 20% less CVD morbidity in intervention group
		LDL-c (mg/dL)	> 3 months	37 RCTs; 4,845 participants		WMD -4.2 (95% CI -6.9 to -1.5)
		HDL-c (mg/dL)	> 3 months	34 RCTs; 4,908 participants		WMD 0.03 (95% CI -0.8 to 0.8)
		Body weight (pounds)	> 3 months	43 RCTs;5,749 participants		WMD -2.3 (95% CI -3.2 to -1.3)

Huang (2015)[178]***	Telecare interventions	HbA1c	3 to 60 months	18 RCTs; 2,793 participants	+	WMD -0.54 95% CI -0.75 to -0.34; p<0.05
		BMI		4 RCTs; 346 participant	0	WMD -0.59kg/m^2 95% CI -1.52 to 0.34; p=0.21
		Weight change		4 RCTs; 724 participants	0	WMD 1.01 pounds 95% CI -3.31 to 5.33; p=0.65.
Zhai (2014)[181]***	Telemedicine	HbA1c	3 to 60 months	35 RCTs; 8,149 participants	+++	MD -0.37 95% CI -0.49 to -0.25; p<0.001
		HbA1c – telephone based interventions		12 RCTs	+++	MD -0.53 95% CI -0.81 to -0.26; p<0.001
		HbA1c – internet based interventions		19 RCTs	+++	MD -0.62 95% CI -0.82 to -0.42; p<0.001

Key: CVD: cardiovascular disease; **DM:** diabetes mellitus **HbA1c:** Haemoglobin A1c (specific portion of four-part haemoglobin molecule); **NR:** Not reported; **SBP:** Systolic blood pressure; **SMD:** Standard Mean Difference; **WMD:** weighted Mean Difference. **BMI**: Body Mass Index

Table A.7.4 T2DM: Summary of results from quantitative systematic reviews from PRISMS and updated reviews. Table adapted from PRISMS review.[2]

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
Chodosh (2005)[187]***	Self-management programmes, interventions that aim to improve active participation in either self-monitoring, or decision-making, or both	26 RCTs; 2579; 1983–2004	Meta-analysis	Compared with control, a statistically significant reduction in HbA1c (ES –0.36) and blood glucose (ES–0.28) were found. Interventions were not found to impact on weight when compared with control.	Chronic disease self-management programmes improved glycaemic control. Feedback associated with improvement in HbA1c Possible publication bias.
			Additional	Feedback the only factor associated with a significant improvement in HbA1c. Did not identify any other elements significantly associated with greater efficacy of self-management programmes.	
Duke (2009)[189]***	Individual patient education systematic programmes, delivered face to face which addressed a wide range of self-management issues	Nine RCTs; 1359; 1996–2007	Meta-analysis	Individual education interventions had no significant effect on HbA1c, BP, cholesterol or weight compared with usual care Compared with individual education, group education had a greater impact on HbA1c reduction in the short term (WMD 0.8%). No differences in BP or BMI outcomes were found between individual and group education.	Group education more effective than individual education in reducing HbA1c short term. However, for people with higher baseline HbA1c, individual education may be more effective. Included studies were generally poor quality with the majority having a high-risk of bias.
			Additional	For people with HbA1c>8%, individual education suggested to be most effective Impact on QoL unclear, small tentative suggestion that group education may produce greater improvements in QoL than individual education.	
Gary (2003)[199]***	Clear behavioural or counselling component aimed at improving long-term diabetes	18 RCTs; 2720; 1984–9	Meta-analysis	Strong evidence on GHb reduction compared with control (ES–0.43). Also evidence of reduction in HbA1c (WMD –0.52). No effect was found on other measures of glycaemic control or weight.	Educational or behavioural interventions improved glycaemic control. Physician-led interventions may cause greater improvements in HbA1c; however, authors suggest this may be due to manipulation of medical regimens. Possible publication bias.
			Additional	Physician led interventions may cause larger improvements in HbA1c than those led by	

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
	self-care behaviour			nurses or dieticians.	
Heinrich (2010)[200]**	Multi-component interventions aimed at self-management. Interventions had to target at least two behaviours or had to be focused on self-management or diabetes in general	14 RCTs; 1778; 2001–9	Narrative synthesis	Dietary changes appear to be the outcome most responsive to interventions, regardless of intervention form Interventions most successful in increasing PA focused on self-management behaviours and lifestyle changes SMBG frequency appears reactive to interventions regardless of intervention form.	Dietary change and SMBG appear reactive to multi-component interventions. Suggests interventions aiming to increase PA should focus on self-management behaviours and lifestyle changes.
Minet (2010)[190]***	Self-care management interventions using educational or behavioural strategies (mainly face-to-face)	43 RCTs; 7677; 1988–2007	Meta-analysis	Evidence of benefit in HbA1creduction compared with control (MD 0.36%)	Self-care management interventions improve glycaemic control. Greater improvements found in those RCTs with shorter follow-up, suggesting reduced impact long-term. More compact interventions may also be of greater benefit. Three studies had several intervention groups, with each intervention arm compared with the control group and considered as an individual study.
			Additional	Interventions with shorter follow-up found larger improvements in HbA1c. Some suggestion that educational techniques are more effective than behavioural or psychosocial techniques for improving HbA1c. In addition, suggestion that interventions of shorter duration are more effective than those lasting more than 9 months	
Newman (2004)[201]**	Interventions that aim to increase patients' involvement and control in their lives with chronic illness	21 RCTs; 2032; 1997–2002	Narrative	Majority of interventions reduce HbA1cat some point, evidence suggests that reductions can be sustained after 6 months Little effect on QoL found No difference in psychological well-being between intervention and control, evidence suggests cognitive–behavioural components to be most effective for improving psychological well-being Interventions identified positive changes in self-management behaviours compared with	Interventions improve glycaemic control and self-management behaviours. Little effect on QoL, and no difference in psychological well-being. Long-term effectiveness unclear.

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
				control. Few interventions assessed outcomes long-term, and in those that did, many found benefits not to be sustained at long-term follow-up. Of those interventions that had long-term effectiveness, design varied, suggesting there is no one correct approach.	
Norris (2001)[191]*	Educational interventions, or multi-component interventions where the effects of the educational component could be examined separately	72 RCTs; NR; 1981–99	Narrative synthesis	Evidence shows improved short-term glycaemic control compared with usual care. Less evidence to support improvements longer term. Group support meetings focusing on coping skills may be beneficial in improving glycaemic control. Beneficial effects were found for weight loss, dietary change, and frequency and accuracy of SMBG. Benefits for psychological outcomes, QoL, BP, cholesterol and PA were all mixed, as were interventions focusing on foot care. Characteristics of interventions demonstrating greater effect: shorter follow-up periods; collaborative; repetitive; ongoing; interactive; individualised. It remains unclear if the use of computers and videos for education is advantageous.	Interventions improve glycaemic control short term. Also benefits for weight loss, and self-management behaviours.
Norris (2002)[192]***	Teaching individuals to manage their diabetes through self-management education	31 RCTs; 4263; 1981–99	Meta-analysis	Evidence of benefit in GHb after 4 months or more compared with control (ES–0.26%)	Self-management education interventions improve glycaemic control short term No study fulfilled all reviewer quality criteria for bias.
			Additional	On average, 23.6 hours of contact between the educator and patient are needed to achieve a 1% reduction in GHb. Duration of contact time between educator and patient was the only significant predictor of effect.	
Sigurdardottir (2007)[193]**	Education which aims to enhance	18 RCTs; 4293; 2001–5	Meta-analysis	Strong evidence of reduction in HbA1c compared with control	Educational interventions improve glycaemic control. Greater reduction in those with high baseline HbA1c.
			Additional	There is strong evidence to suggest greater	

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
	diabetes-related self-care			reduction in HbA1c in individuals with baseline HbA1c≥8% compared with individuals with baseline HbA1c<8%	
Steinsbekk (2012)[194]***	Group-based diabetes education	21 RCTs; 2833; 1988–2007	Meta-analysis	Very strong evidence of effect on HbA1c Short term (SMD–0.44%), at 12 months (SMD –0.4%) and long-term (SMD–0.87%). Also strong evidence of reduction in fasting glucose long-term (SMD –1.26 mmol/l). Some evidence of benefit on self-efficacy (SMD 0.28) and self-management behaviours (SMD 0.55). Suggestive evidence of benefit on body weight long-term (SMD 1.66 kg). No evidence of benefit on QoL, BP, cholesterol or mortality.	Group-based education improves glycaemic control short and long-term. Some evidence of benefit on self-efficacy, self-management behaviours and body weight Two studies were classified as having a low risk of bias, 12 studies as having moderate risk of bias, and seven studies were classified as having a high-risk of bias.
			Additional	Suggests the following factors to be associated with reduced effectiveness: reporting theoretical model; combination of different educator types; baseline HbA1c≥7%; include follow-up; completed education delivery in 12 months; 9–12 hours education; family member or friend invited to participate; fewer than 6 or more than 10 sessions Suggests the following factors to be associated with increased effectiveness: diabetes specialist nurse or dietician as only educator; conducted in primary care settings; lasting 1–10 months; provide 19–52 hours education; between 14–18 participants per group; between 6 and 10 sessions	
Van Dam (2005)[202]**	Social support interventions which may be emotional support, appraisal support,	Six RCTs; 712; 1991–2002	Narrative synthesis	No beneficial effect of social support on glycaemic control. Findings suggest social support to help increase self-management behaviours, lifestyle adjustments and psychosocial functioning support from spouse may help weight loss in women, but not in men.	Social support does not improve glycaemic control, but may increase self-management behaviours, weight loss and psychosocial well-being.

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
	informational support or tangible assistance				
Dorresteijn (2010)[188]***	Educational programmes which aim to promote foot self-care and to prevent the occurrence of foot lesions	11 RCTs; 3114; 1986–2008	Narrative synthesis	Found foot education interventions not to be associated with increased self-management behaviours. However, small but inconclusive suggestion that intensive educational interventions or foot education tailored to individual needs are associated with increased self-management behaviours.	Foot education not found to be effective; interventions should be tailored or intensive to increase likelihood of changing behaviour.
Li (2011)[186]**	Educational programmes (or programmes which include education) used for people with DKD	Two RCTs; 207; 2002–5	Narrative synthesis	Suggest that interventions may improve some aspects of QoL Unclear effects on self-efficacy; some suggestion of benefits for specific forms of self-efficacy Some suggestion of improvement in self-management behaviours. No effect on mortality was found.	Educational programmes for people with DKD may improve some aspects of QoL and self-management behaviours.
Hawthorne (2008)[195]***	Education tailored to the cultural or religious beliefs and linguistic skills of the community being approached	11 RCTs; 1603; 1997–2007	Meta-analysis	Positive effect of intervention compared with control on HBA1cshort term (WMD –0.6%) and total cholesterol long-term (WMD–0.39 g/dl). No evidence of benefit on QoL, self-efficacy, BP or BMI.	Education tailored to cultural or religious beliefs improves glycaemic control short-term and cholesterol long-term. Better outcomes found when combinations of providers and approaches used. Possible publication bias.
			Additional	Health educator type appears to make no difference. Better outcomes with combinations of provider and approaches. No difference found between one to one and one to one plus group.	
Khunti (2008)[196]**	Any educational intervention for migrant South Asian populations	Five RCTs; 1004; 1997–2006	Narrative synthesis	Suggestion of benefit for improved glycaemic control in the short term, less evidence of benefit longer term Some suggestion of improved BP outcomes Mixed findings for cholesterol, suggests some benefit Mixed findings for weight/BMI, inconclusive, No	Educational interventions for migrant South Asian populations improved glycaemic control in the short term, but not long-term. Also some suggestion of improved BP.

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
				difference between group and one to one	
Nam (2012)[197]***	Culturally tailored diabetes education interventions	12 RCTs; 1495; 1997–2009	Meta-analysis	Overall reduction on HbA1ccompared with control (ES–0.29). No evidence of benefit long-term.	Culturally tailored interventions improve glycaemic control short term. Community-based interventions may have larger benefits than hospital or clinic based.
			Additional	Suggestion that community-based interventions may lead to larger benefits than hospital based interventions. Suggestion of marginally increased benefit in individual with lower baseline HbA1c.	
Pérez-Escamilla (2008)[198]*	Peer nutrition education and counselling - delivered to Latinos by community	Two RCTs; 214; 1997–2007	Narrative synthesis	Inconclusive mixed effects community health workers associated with greater completion rates.	Peer nutrition education had inconclusive mixed effects.
Additional reviews retrieved (QA completed by HIQA)					
Pal (2014) (CR)[179]***	Computer-based DM self-management interventions	11 RCTs; 2637 participants	Meta-analysis	Computer-based diabetes self-management interventions to manage T2DM appear to have a small beneficial effect on blood glucose control and the effect was larger in the mobile phone subgroup.	There is no evidence to show benefits in other biological outcomes or any cognitive, behavioural or emotional outcomes. An exploratory analysis which considered which techniques featured most in effective interventions, these included 'prompting self-monitoring of behavioural outcomes and providing feedback on performance. Due to the limitations of the studies reviewed, the authors reported that the effectiveness of existing IT based interventions was unclear and difficult to attribute solely to the interventions. The review concluded that future research efforts needed to focus on methodological issues to produce valid, reliable and generalisable findings.
		16 RCTs; 3578 participants	Narrative	HRQoL: 5 studies reported this outcome, none showed statistically significant differences.	
				Death from any cause: three died in two studies out of the 16 RCTs.	
				Cognitions: 4four studies reported positive effects of the interventions on knowledge.	
				Self-efficacy: both studies measuring self-efficacy suggested positive effects of interventions.	
				Physical activity: There seemed to be difficulty in converting the positive effects on knowledge and self-efficacy into behavioural change such as physical activity: in only two	

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
				out of five studies did there appear to an increase in physical activity. The effects of interventions on physical activity were generally mixed.	
				Diet: six studies looked at changes in diet and five reported statistically significant improvements. Clinical benefits and impact on health outcomes of these changes is unknown as the effects of interventions on weight or BMI, were not convincing with no statistically significant improvements in weight seen when the results from five studies were combined in a meta-analysis	
				Blood pressure: The evidence for computer-based self-management interventions improving blood pressure was mixed.	
				Cholesterol: Effects of interventions on cholesterol were mixed.	
				Adverse events: 1one study reported a participant withdrawing due to anxiety related to the study. One study noted non-statistically significant increase in minor hypoglycaemic episodes in the intervention group but no difference in major or nocturnal hypoglycaemic episodes. One study specifically reported no adverse events.	
Song (2014)[182]**	Effect of motivational interviewing on self-management in patients with T2DM	10 RCTs; 2957 participants	Meta-analysis		MI was associated with improved self-management abilities among patients with T2DM, and short-term MI (≤6 months) effectively decreased the HbA1c level. The effect of long-term MI (>6 months) on the HbA1c level remains uncertain. Large-scale, higher-quality randomised controlled trials are needed to confirm the present findings.
Antoine (2014)[183]**	Improving the adherence of	5 RCTs, 1 cluster RCT; 1025	Narrative	Six publications were included. Two studies mainly examining educational interventions	Although pharmacist interventions might potentially improve adherence to T2DM

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
	T2DM patients with pharmacy care	participants		showed a significant improvement in adherence. The quality of the included studies was deficient.	medication, high-quality studies are needed to assess effectiveness. A possible limitation is that pharmacists might differ in the way they provide their adherence intervention.
Schellenberg (2013)[184]***	Lifestyle Interventions for Patients With and at Risk for T2DM	2 RCTs; 5305 participants	Meta-analysis	For all-cause mortality, the pooled results showed no difference between the intervention and control groups at more than 10 years of follow-up. The strength of evidence was low for this outcome.	Limitations of this review include low- or insufficient strength evidence for most outcomes across the various interventions. These low grades were driven by high- or unclear risk of bias within individual studies (largely due to inability to blind patients in the treatment group), lack of direct evidence for patient-important outcomes, and lack of consistency and precision among studies.
		11 RCTs; Number of participants ranged from 72 to 5145	Narrative	In patients who have T2DM, the evidence for benefit of comprehensive lifestyle interventions on patient-oriented outcomes is less clear. There is no evidence of benefit in all-cause mortality and insufficient evidence to suggest benefit on cardiovascular and microvascular outcomes. Improvement was seen for some secondary outcomes, but it generally did not persist beyond the intervention phase, and the clinical significance is unclear.	
Attridge (2014) (CR)[185]***	Culturally appropriate health education for people in ethnic minority groups	33 RCTs; 7453 participants	Meta-analysis	Glycaemic control (HbA1c) showed improvement following culturally appropriate health education at 3 months (MD -0.4%) and at 6 months (MD -0.5%) post intervention compared with control groups (usual care). Sustained to a lesser extent at 12 months (MD -0.2%). Neutral effects on HRQoL measures were noted and there was a general lack of reporting of adverse events in most studies.	Culturally appropriate health education has short- to medium-term effects on glycaemic control and on knowledge of diabetes and healthy lifestyles. None of the studies were long-term trials, and so clinically important long-term outcomes could not be studied. The heterogeneity of the studies made subgroup comparisons difficult to interpret with confidence. Long-term, standardised, multi-centre RCTs are needed to compare different types and intensities of culturally appropriate health education within defined ethnic minority groups, as the medium-term effects could lead to clinically important health outcomes, if sustained.
			Narrative	HRQoL: Neutral effects on HRQoL measures were noted and there was a general lack of reporting of adverse events in most studies - the other two primary outcomes for this review.	

Reference and weighting Outcome	Focus	RCTs, n; Participants, n; Date range	Synthesis	Main results	Main conclusions (review author); *Important quality concerns (review author)*
				Neutral effects on total cholesterol, low-density lipoprotein (LDL) cholesterol or high-density lipoprotein (HDL) cholesterol were reported at any follow-up point.	
				Other outcome measures (blood pressure, body mass index, self-efficacy and empowerment) also showed neutral effects compared with control groups.	
				Data on the secondary outcomes of diabetic complications, mortality and health economics were lacking or were insufficient.	
Saffari (2014)[180] **	Health education via mobile phones	10 RCTs; 960 participants	Meta-analysis	HbA1c: Statistically significant effect in favour of health education via mobile phones. Effect greater among studies which used both SMS and internet for health education (n=4RCTs).	The findings of this systematic review and meta-analysis support the hypothesis that health education through mobile text-messaging may help to improve glycemic control in patients with Type2 diabetes. The effect size was greater among studies that used both text-messaging and internet for health education. They noted that although significant in both age brackets, the effect size found in younger patients indicates a higher reduction in HbA1c than in patients over age 55 years.
Cotter (2014)[177]**	Internet interventions to support lifestyle modification	8 RCTs (1 quasi-experimental)	Narrative review	Physical activity: 2/8 reported a statistical significant improvement.	Two studies demonstrated improvements in diet and/or physical activity and two studies demonstrated improvements in glycemic control comparing web-based intervention with control. Successful studies were theory-based, included interactive components with tracking and personalised feedback, and provided opportunities for peer support.
				Dietary changes: 1/5 reported a statistical significant improvement.	
				HbA1c: 2/7 reported a statistical significant improvement.	
				BMI: 1/4 reported a statistical significant improvement in weight.	
				Diabetes knowledge:	

Bolen (2014)[176]***	Patient activation interventions	138 RCTs; 33,124 participants	Meta-analysis	A1c: WMD 0.37 %, CI 0.28–0.45 %, I^2 83 %; SBP: WMD 2.2 mmHg, CI 1.0–3.5 mmHg, I^2 72 %; Body weight: WMD 2.3 lbs, CI 1.3–3.2 lbs, I^2 64 %; LDLc: WMD 4.2 mg/dL, CI 1.5–6.9 mg/dL, I^2 64 %].	Patient activation interventions modestly improve A1c in adults with T2DM without increasing short-term mortality. The evidence was moderate for A1c, low/very low for other intermediate outcomes. Higher baseline A1c, pharmacist-led interventions, and longer follow-up were associated with larger A1c improvements. No intervention strategy outperformed any other in adjusted meta-regression.
Huang (2015)[178]***	Telecare interventions	18 RCTs; 3,798 participants	Meta-analysis	HbA1c: -0.54 95% CI -0.75 to -0.34; p<0.05 BMI: -0.59kg/m^2 95% CI -1.52 to 0.34; p=0.21 Weight change: 1.01 pounds 95% CI -3.31 to 5.33; p=0.65.	Patients monitored by telecare showed significant improvement in glycemic control in Type 2 diabetes when compared with those monitored by routine follow-up. Subgroup analysis indicate that studies that observed greater reductions in HbA1c levels were associated with Asian populations, small sample size, baseline HbA1c greater than 8.0%, and human calls-based intervention. No effect was observed for automated calls interventions.
Zhai (2014)[181]***	Telemedicine	35 RCTs; 8,149 participants	Meta-analysis	HbA1c: MD -0.37 95% CI -0.49 to -0.25; p<0.001 HbA1c (telephone based): MD -0.53 95% CI -0.81 to -0.26; p<0.001 HbA1c (internet based): MD -0.62 95% CI -0.82 to -0.42; p<0.001	Overall, pooled results from the studies revealed a small, but statistically significant, decrease in HbA1c following intervention, compared to conventional treatment. Optimisation of telemedicine approaches could potentially allow for more effective self-management of disease in Type 2 diabetes patients, though evidence to-date is unconvincing. Furthermore, significant publication bias was detected, suggesting that the literature should be interpreted cautiously.

***Key:** **CCM:** Chronic care model; **ED:** Emergency department; **HCP:** Healthcare professionals; **NNT:** Numbers needed to treat; **OR:** Odds ration; **PEFR:** Peak expiratory flow rate; **QoL:** Quality of life; **RCT:** Randomised controlled trial; **SMD:** Standardised mean difference; **T1DM:** Type 1 diabetes mellitus; **T2DM:** Type 2 diabetes mellitus; **WAPs:** Written action plans.

Table A7.5 – Appraisal of study quality for included cost-effectiveness studies

Study	Quality	Reasons for downgrading
Albisser (2001)	Low	Longitudinal observation study reporting costs.
Banister (2004)	Low	Observational cohort study with historical comparison group that reported costs - risk of bias.
Barnett (2007)	Low	Unclear whether all relevant costs have been identified and included appropriately. Insufficient sensitivity analyses to determine effect of uncertainty.
Biermann (2002)	Low	Poorly described costing study. Insufficient information to determine perspective and if all relevant costs were included.
Brown (2012)	Low	Data derived from single trial involving 30 patients receiving the intervention. High-risk of bias.
Brownson (2009)	Low	It is unclear that discounting has been correctly applied.
Dall (2011)	Low	Poorly described costing study. Insufficient information to determine if all relevant costs were included.
Farmer (2009)	High	
Fedder (2003)	Low	Poorly described costing study. Insufficient information to determine if all relevant costs were included and appropriately interpreted.
Fera (2009)	Low	Poorly described costing study. No assessment of uncertainty.
Fischer (2012)	Low	Poorly described costing study. Unclear purpose and design. No assessment of uncertainty.
Garrett (2005)	Low	Analysis at risk of bias as it is based on pre-post analysis of medical claims data.
Gillespie (2012)	Moderate	Clinical effectiveness was not shown in the underlying trial.
Gillespie (2014)	Moderate	Unclear that sensitivity analysis was comprehensive.
Gillett (2010)	High	
Gilmer (2005)	Low	Costing study based on small sample with no sensitivity analysis.
Gilmer (2007)	Low	Figures reported by type of health insurance cover - unclear applicability to Irish setting.
Gordon (2014)	Low	The validity of the model is unclear as are the sources of the transition probabilities.
Handley (2008)	Moderate	Unclear that discounting has been appropriately applied. Lack of sensitivity analysis to determine effect of uncertainty.
Ismail (2010)	High	
Jacobs-van der Bruggen (2009)	High	
Kesavadev (2012)	Low	Costing study based retrospective cohort study.
Kruger (2013)	High	
Kuo (2011)	Low	The validity of the model is unclear. Inadequate assessment of impact of uncertainty.
Letassy (2003)	Low	Before and after comparison reporting estimated cost savings. Study design at high-risk of bias.
Mason (2006)	Low	Study poorly described with inadequate information to determine whether perspective and costs were appropriate.
Molsted (2012)	Low	Poorly described costing study. Inappropriate design. No assessment of uncertainty.

Moreno (2009)	Low	Poorly described study with no analysis of uncertainty.
O'Reilly (2007)	Low	Model data sourced from single RCT of 401 patients.
Palmas (2010)	High	
Petkova (2006)	Low	Inappropriate study design.
Ritzwoller (2011)	High	
Salzsieder (2011)	Low	Not all relevant costs identified. Insufficient analysis of uncertainty.
Schechter (2012)	Low	Not all relevant costs included in the analysis.
Shearer (2004)	Low	Effectiveness data from single RCT with 169 patients. Inadequate analysis of the impact of uncertainty.
Stock (2010)	Low	Matched pair wise comparison using registry data and national drug and hospital costs. Design at risk of bias.
Trento (2002)	Low	Discounting not applied appropriately. No analysis of uncertainty.
Wiegand (2008)	Low	Presented as preliminary investigation. Poorly described with data sources not clearly listed.

Table A7.6 Cost effectiveness studies investigating SMS education programmes in diabetes mellitus

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Albisser (2001)[203]	Comparison of education alone, education with self management training and education with computer assisted self care in patients with diabetes	A total of 978 health plan members with diabetes within a mixed model HMO were included in the initiatives for improving blood glucose control.	Country: US Study Type: Longitudinal observational study reporting costs	With the education alone initiative, A1c and body weight were unchanged. When education was supplemented with ongoing self-management training, A1c fell 1.1% ($p<0.01$) and body weight rose by 11 kg ($p<0.01$). When education was supplemented with ongoing computer-assisted self-care, A1c also dropped by 1.1% ($p<0.01$), body weight was unchanged ($p<0.4$)	With the education alone initiative, costs were unchanged. When education is supplemented with ongoing self-management training cost of care increased by $18 per member per month. When education is supplemented with ongoing computer-assisted self-care, cost of care was $1.31 per member per month. (Cost year NR)	The authors concluded that in choosing a diabetes disease management programme, it would appear that costs should be the primary consideration and methodologies that control body weight should be a priority.
Banister (2004)[204]	Diabetes self-management involving a four hour training session, dietician consultations and monthly support meetings	70 adults with Type 2 diabetes attending a diabetes self management community clinic in areas below the US federal poverty level. Mean age 49 years.	Country: US Study Type: Observational cohort study with historical comparison group that reported costs	After 2 to 12 months of programme participation, mean A1C improved from 9.7±2.4% to 8.2±2.0% ($p<.001$)	The cost of community clinic DSMT was approximately $280 (€367) per person per year, $185 (€242) for each point reduction in A1C.	The authors concluded that community clinic DSMT can improve glycaemic control at a modest cost.
Brown (2012)[207]	Lifestyle modification programme led by community health workers	Hispanic adults aged 18 or older with Type 2 diabetes	Country: US Model Type: Mathematical with continuous time Perspective: Societal Discount rate:3% on costs and benefits Time Horizon: 20 years	The analysis used a previously validated mathematical model that projected changes in A1c levels on to future health outcomes and rate of diabetes complications.	Costs of medical treatment and staff costs were taken from the area in which the intervention was carried out (Laredo, Texas).	The ICER in the primary analysis was $33,319 (€30,671)/QALY. The intervention was more cost-effective in the subgroup of people with high glycaemic index (A1c level>9%).

Brownson (2009)[208]	CDSM - self-management programmes in primary care settings (different programme in each of four sites)	Patients with Type 2 diabetes living in disadvantaged areas.	Country: US Study Type: CEA using data from four sites (with UKPDS model assumptions) Perspective: health systems perspective Discount rate: 3% costs and benefits Time horizon: diagnosis to age 95	14.36 QALYs for usual care, 14.65 QALYs for intervention	Costs: $866 (€999) per annum for intervention; $49,474 (€57,047) or usual care; $61,234 (€70,607) for intervention	The incremental cost-effectiveness ratio was $39,563 (€45,619 /QALY.
Dall (2011)[209]	Diabetes self management programme involving the posting out of educational materials and telephone counselling once a month	37,370 people in a health insurance programme for military service personnel, retirees and their dependents in the United States.	Country: US Study Type: Observational cohort study with historical comparison group that reported costs	Participants in the programme were reported to have reduced inpatient bed-days, fewer ED visits, more ambulatory care episodes and greater frequency of testing that historical controls	Total care costs for participants from 2007 and 2008 for hospital care, ED visits, ambulatory care and prescriptions were compared to predicted costs in the absence of the programme, based on historical data	Per-person total saving from participation in the programme were estimated to be $783 (€769), primarily as a result of fewer inpatient days and fewer prescriptions.
Farmer (2009)[210]	CDSM - Blood glucose self-monitoring with and without an educational component	Patients with non-insulin treated Type 2 diabetes, aged ≥ 25 years and with glycosylated haemoglobin (A1c) ≥ 6.2%. Mean age 65.7 years.	Country: UK Study Type: CEA simulation Perspective: NHS Discount rate: 3.5% costs and benefits Time horizon: lifetime horizon	Utilities at follow-up (and baseline): 0.772 (0.828) for intensive, and 0.761 (0.798) for standard self monitoring.	Intervention cost of £173 (€262) for intensive and £181 (€274) for standard self monitoring. Usual care (with no self monitoring) had an intervention cost of £89 (€135).	The mean estimates suggest that both forms of SMBG are more costly and less effective than standardised usual care, with relatively wide CIs around the point estimates.
Garrett (2005)[214]	CDSM - pharmacists supported patients through a structured series of visits that focused on knowledge, skills, and performance	Patients with diabetes covered by employers' health plans. Mean age 55 years.	Country: US Study Type: Pre-post analysis of medical claims data Perspective: payer Discount rate: not applicable	Not applicable.	Baseline data: mean total healthcare cost per patient = $8,185.(€9,851) Year one actual = $8,464. (€10,187) Year one projected = $9,382 (€11,292).	Projected costs for the study year were based on national market changes as agreed to by the pilot site implementation committee employers

			Time horizon: mean 10 months after enrolment			and health benefit consultants.
Gillespie (2012)[215]	CDSM – peer support for patients with Type 2 diabetes	Patients with Type 2 diabetes in Irish general Practice. Mean age 64.6 years.	Country: Ireland Study Type: Estimate from RCT data and UKPDS model Perspective: societal provider Discount rate: 3.5% costs and benefits Time horizon: lifetime	Lifetime QALYs: 6.76 for intervention, 6.67 for usual care.	Intervention set-up was €246 (€291) per patient.	The intervention was more effective and less costly than routine care. The intervention is the most cost-effective option at a range of thresholds using both payer and societal perspectives.
Gillespie (2014)[216]	CDSM – group follow-up post DAFNE facilitated by trained educators using a structured curriculum compared to individual follow-up	Patients with a diagnosis of Type 1 diabetes and who completed the DAFNE programme. Mean age 40.8 years.	Country: Ireland Study Type: trial based CEA Perspective: healthcare provider Discount rate: no discounting applied Time horizon: 18 months	Utilities at 18 month follow-up (and baseline): 0.88 (0.87) for group, and 0.90 (0.88) for individual follow-up.	With respect to total healthcare costs at 18 months, the mean cost per patient was €4,337 (€4,999) for individual follow-up and €3,551 (€4,019) for group follow-up.	Group follow-up is less costly and less beneficial than individual follow-up. At thresholds of €20,000 and €45,000, individual follow-up is the most cost-effective option. At thresholds of €15,000 and less, group follow-up is most cost effective.
Gillett (2010)[217]	A six hour structured group education programme delivered in the community by two professional healthcare educators	Patients with newly diagnosed Type 2 diabetes in primary care trusts in the UK. Mean age 61 years	Country: UK Model Type: Markov Perspective: NHS Discount rate:3.5% on costs and benefits Time Horizon: 80 years	Estimates of the effect of the intervention were taken from a 12 month RCT carried out in the UK in 2004 (DESMOND trial). This found no significant difference in A1c levels. Long-term outcomes were then modelled using the Sheffield Type 2 diabetes model.	Intervention cost of £203 (€282) per patient. Intervention costs were calculated using data from the 2004 trial. A secondary analysis was carried out that included economy of scale saving associated with larger patient groups.	The ICER based on the DESMOND trial data was estimated to be £5,387 (€7,477)/QALY. In the secondary analysis that included projected savings associated with large scale rollout the ICER was £2,092 (€2,904) /QALY.

Gilmer (2005)[218]	CDSM - a combined stepped-care diabetes nurse case management programme and culturally oriented peer-led self-empowerment training program	Uninsured adults with diabetes. Mean age 51.5 years.	Country: US Study Type: pre-post analysis of medical claims data compared to historical controls Perspective: payer Discount rate: not applicable Time horizon: 12 months	Project Dulce participants had reductions in A1c (0.8%), systolic and diastolic blood pressure, total cholesterol, and low-density-lipoprotein cholesterol.	Diabetes management = $507 (€635). Total costs: intervention = $5,711 (€7,150); control = $4,365 (€5,465).	Project Dulce led to improved clinical outcomes for control of diabetes and related conditions in a medically indigent, culturally diverse population.
Gilmer (2007)[219]	CDSM - a culturally specific diabetes case management and self-management training programme (Project Dulce)	Low-income adults with diabetes. Mean age 51.2 years.	Country: US Model Type: Markov Perspective: Third party payer Discount rate: 3% on costs and benefits Time Horizon: Lifetime	Clinical outcomes were obtained from an observational study involving four cohorts defined by health insurance status, all of which had lower A1c scores following the implementation of the intervention. The intervention was expected to produce QALY gains of between 0.9 to 0.2 QALYs per patient.	Total costs were $1,383(€1,664) higher among participants during the first year of case management, including increased costs of visits to clinicians, participation in group classes, and administrative overheads, pharmaceuticals and supplies; and an offset by reduced hospital and emergency room expenditures.	Costs per QALY were reported by insurance status (increasing wealth): uninsured $10,141(€12,205); CMS $24,584 (€29,588); Medi-Cal $44,941 (€54,088); Commercial $69,587 (€83,750). At a threshold of $50,000/QALY, only the commercial cohort has a probability less than 0.5 of being most cost-effective.
Gordon (2014)[220]	Telephone-linked care intervention for patients with Type 2 diabetes	Simulated cohort of patients with Type 2 diabetes.	Country: Australia Model Type: Markov Perspective: Health Service Discount rate:5% on costs and benefits Time Horizon: 5 years	QALY outcomes were obtained from an RCT that measured QoL using the SF-36. There was no statistically significant difference in SF-6D scores at the end of this study.	All costs were inflated to 2011 Australian dollars. Costs savings associated with the intervention were as a result of lower medication costs across a broad range of medication categories, some of which were unrelated to the intervention	The intervention dominated routine care in the primary analysis (cost saving and generated 0.004 QALYs per person), with a 55% chance of being cost-effective at a WTP threshold of $50,000 (€31,512)/QALY

Ismail (2010)[222]	CDSM – motivational enhancement therapy (MET) and cognitive behaviour therapy (CBT) delivered by general nurses with additional training in these techniques	The study population was adults with a confirmed diagnosis of Type 1 diabetes for a minimum duration of 2 years and a current A1c value between 8.2% and 15%. Mean age 36.4 years.	Country: UK Study Type: trial based CEA Perspective: health and social care; and societal Discount rate: not applied Time horizon: 12 months	Mean for first year: MET = 0.77; MET + CBT = 0.782; usual care = 0.789 (all based on EQ-5D)	The unit cost for a 50-minute MET session was estimated at £49 (€74) and £48 (€73) per session including and excluding training, respectively. The respective estimates for a 50-minute session of CBT were £81(€123) and £73 (€111). The average total cost of each treatment approach was approximately £195 (€296) for MET and £660 (€1,003) for MET + CBT.	Results here relate to EQ-5D. MET vs. usual care: £48,636 (€73,919)/QALY (payer), £160,750 (€244,316) /QALY (societal). MET+CBT vs. usual care: £311,970 (€474,147)/QALY (payer), £271,333 (€412,385)/QALY (societal). MET dominates MET+CBT.
Jacobs-van der Bruggen (2009)[223]	Lifestyle modification interventions involving at least nutrition or exercise programmes for Type 2 diabetes (seven different interventions were modelled)	Simulated cohort of patients with Type 2 diabetes.	Country: The Netherlands Model Type: Markov Perspective: Health Service Discount Rate: 4% on costs, 1.5% on benefits Time Horizon: Lifetime	All 7 modelled programmes were expected to lead to QALY gains (from 0.1 to 0.14 QALYs per patients). However major uncertainty exists in relation to how long improvements are maintained.		ICERs for each of the 7 interventions were considered cost-effective (ICERs ranged from €9,000 (€11,414) /QALY to €39,000 (€49,460)/QALY. The ICER for the intervention with the greatest utility gain was €10,000 (€12,682)/QALY.
Kruger (2013)[225]	Training in flexible intensive insulin therapy as provided in the DAFNE programme, compared with no training	Simulated cohort of adults with Type 1 diabetes.	Country: UK Model Type: Markov Perspective: NHS Discount Rate: 3.5% on costs and benefits Time Horizon: Lifetime	Training was associated with increased life expectancy (0.08 LYG per patient) and an average QALY gain of 0.03 QALYs per patient.	The cost of the intervention was obtained from the literature £359 (€432) per patient.	The ICER for the intervention was estimated to be £14,475 (€17,432)/QALY

Kuo (2011)[226]	Chronic care model for diabetes management delivered through a diabetes outreach clinic (DOC) in a medical centre run by the US military compared to usual care based on matched cohort with no access to the DOC.	9,405 diabetes patients aged 18 year or over. Adult patients (veterans) with a diagnosis of Type 2 diabetes. Mean age 50 years.	Country: US Model Type: Markov Perspective: Health Service and societal Discount rate: 3% on costs and benefits Time Horizon: 20 years	Outcome data was taken from a primary study carried out in the US military setting and from published literature. The base case assumed a 0.3% decrease in A1c.	Treatment costs were taken from the records of the military funded setting, and from published literature. The societal perspective included the cost of patient time and travel costs.	In the primary analysis the ICER from the perspective of the payer was $45,495 (€41,880)/QALY, and from a societal perspective it was $42,051 (€38,709).
Molsted (2012)[229]	CDSM - an empowerment-based structured diabetes self-management education programme patients with Type 2 diabetes	Patients with Type 2 diabetes, diagnosed at least 12 months before programme start. Mean age 61 years.	Country: Denmark Study Type: costing study Perspective: not reported (assume health system) Discount rate: not applicable Time horizon: 12 months before and after.	Not applicable.	Cost of programme estimated at €489 (€489) per patient.	The intervention can be implemented in a primary care setting and can improve glycaemic control and other metabolic parameters as well as change lifestyle in patients with T2DM.
O'Reilly (2007)[231]	Multidisciplinary diabetes care programme involving nurse liaison, patient education and the additional of a diabetes tracker component into the patients electronic medical record	Modelled cohort was based on 401 adults with Type 2 diabetes, with a mean age of 61 years.	Country: Canada Model Type: Mathematical model using 18 months of trial data Perspective: Health Service Discount rate:3% on costs and benefits Time Horizon: 40 years	Results of the primary study found that patients who participated in the programme had an average A1c reduction of 1.02%. The long-term implications of this were modelled, using an assumption that the treatment effect persisted for one year	Intervention and care costs were taken from the primary study and from national Canadian data sources (2001 Canadian dollars).	Cost per patient for the intervention was $664 (€525). The ICER for the intervention compared with routine care was estimated at $5,992 (€4,738)/QALY.

Ritzwoller (2011)[234]	CDSM – a culturally adapted lifestyle change programme	Latinas with Type 2 diabetes.	Country: US Model Type: trial based costing study Perspective: societal Discount rate: not applicable Time horizon: six months	Not applicable.	Per participant cost of $4,634 (€4,720) Per unit reduction in A1c = $7,723 (€7,866)	Given the benefits of Viva Bien, cost reductions are recommended to enhance its efficiency, adoption, and long-term maintenance without diluting its effectiveness.
Shearer (2004)[237]	A structured treatment and teaching programme (STTP) combining dietary freedom with insulin adjustment for Type 1 diabetes.	Simulated cohort of patients with Type 1 diabetes	Country: UK Model Type: Markov Perspective: NHS Discount rate:6% on costs and 1.5% on benefits Time Horizon: 10 years	The net survival gain accruing after 10 years is 5.31 life-years per 100 patients (5.16 discounted life-years), which is equivalent to an expected increase in longevity of 19 days per patient.	National UK costs estimates were used, but no year was reported. Discounted over 10 years, STTPs save £2,200 per patient and break even at approximately four years post intervention.	The intervention was the dominant strategy, yielding immediate effectiveness gains and saving money in the long-term.
Stock (2010)[238]	Incentivised national chronic disease self management programme for diabetes patients.	19,882 matched pairs from national insurance records	Country: Germany Study Type: Match pair wise comparison using registry data and national drug and hospital costs	The study found a mortality rate of 2.3% in the treatment group, compared to 4.7% in the control group.	Drug and hospital costs, length of hospital stay and average number of hospitalisations were lower from patients participating in the programme.	The mean difference in cost per patient before and after the introduction of the programme was $1,444, (€1,147) compared with $1,890 (€1,501) in the control group.
Trento (2002)[239]	Lifestyle intervention by group care	Patients with non-insulin-treated Type 2 diabetes (n=56)	Country: Italy Study Design: randomised controlled clinical trial Perspective: Healthcare system and patient Discount Rate: N/A Time Horizon: 4 year	The HR-QOL scores improved with group care but worsened among the control patients. An average of 8.4 patients attended the 12 sessions monitored, resulting in 12.4 min per patient-session or 196 min spent by INHS staff per patient over the study. Seeing	In total, each patient on group care cost US $756.54 (€1,120) and each control US $665.77 (€985), with a difference of US $90.77 (€134) per patient treatment over the observation period. Taking the differential DQOL/Mod score as a proxy outcome, each incremental	Group care by systemic education is feasible in an ordinary diabetes clinic and cost-effective in preventing the deterioration of metabolic control and quality of life in Type 2 diabetes without increasing pharmacological

				patients individually 12.0 minutes per patient, or 150 minutes of INHS staff per patient over the study.	improvement in QoL on group care was obtained with an expenditure of only US $ 2.12 (€3.14).	treatment.
Wiegand (2008)[240]	CDSM - a behaviour change intervention to enhance medication adherence	Patients aged over 16 years with Type 2 diabetes.	Country: US Study design: theoretical model Perspective: payer Discount rate: not reported Time horizon: 16 years	Not reported.	Annual cost per patient of $29. Assuming 100% medication adherence, potential cost savings of $22,954. (US $ cost year NR)	It appears that the cost to implement this behavioural intervention is reasonable and permits further evaluation in other chronic conditions with notoriously poor adherence levels.

***KEY: CI**: Confidence Interval; **ICER**: Incremental cost-effectiveness ratio; **NR**: Not reported **QALY**: Quality adjusted life year; **RCT**: Randomised Control trial; **SMS**: Self-management support; **T1DM**: Type I Diabetes Mellitus; **T2DM**: Type II Diabetes Mellitus, **CDSM** – Chronic Disease Self Management; **CBT** – Cognitive behavioural therapy; **WTP** – Willingness to pay; QoL – Quality of life

Table A7.7 Cost effectiveness studies investigating telemedicine programmes in diabetes mellitus

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Barnett (2007)[205]	Telemedicine (home messaging device to monitor veterans with diabetes)	Veterans with diabetes; two or more VA hospitalisations or VA ED visits in the 12 months before enrolment; multiple (>10) medication prescriptions; access to a working telephone line; and were not institutionalised. Mean age 68.2 years.	Country: US Study Type: CEA using data from retrospective cohort Perspective: direct costs to the Department of Veterans Affairs Discount rate: not specified Time horizon: 12 months	Not clearly reported	Not clearly reported	The overall mean ICER for the full sample was $60,941
Biermann (2002)[206]	Telemedicine – automated uploading of blood glucose monitor data to a diabetes centre	Patients with diabetes mellitus on intensified insulin therapy. Mean age 30.3 years.	Country: Germany Study Type: trial-based costing study Perspective: not reported Discount rate: not applicable Time horizon: maximum 8 months	Not applicable.	No costs reported.	Not applicable.
Fedder (2003)[211]	Telemedicine – Community Health Worker Outreach (CHW) programme combining in-home visits and phone calls	Medicaid enrollees with DM. Mean age 57.4 years.	Country: US Study Type: retrospective costing study Perspective: payer Discount rate: not applicable Time horizon: 12 months before and after	Not applicable.	Expenditure per enrolled patient decreased from $8,266 to $6,020. No comparator data provided. US $ Cost year NR	The CHW programme resulted in an average savings of $2,245 per patient per year, and a total savings of $262,080 for 117 patients, with improved quality of life (QOL) indicating cost effectiveness.

Fischer (2012)[213]	Nurse-Run, Telephone-Based Outreach program	Adults with diabetes at a federally funded community health centre (aged >17 years) (n=762)	Country: US Study Design: Prospective RCT. Perspective: Healthcare system Discount Rate: N/A Time Horizon: 20 months	The intervention group performed significantly better than the usual-care group on our primary outcome, the percent of patients with an LDL less than 100 mg/dL in the preceding year (increased from 52.0% to 58.5% vs. decreased from 55.6% to 46.7%. No change was report in glycaemic control.	Incorporating programme costs, the average cost per patient to the healthcare system was €$6,600 (€7,019) whereas the average cost per patient for those with diabetes not enrolled in the programme was $9,033 (€9,607). The difference in average per patient cost between these two groups was $2,433 (€2,588).	Nurses can improve lipid control in patients with diabetes in a primarily indigent population through telephone care using moderately complex algorithms, but a more targeted approach is warranted. Telephone-based outreach may decrease resource utilisation, but more study is needed.
Handley (2008)[221]	Telephone self-management support intervention with nurse care management for patients with Type 2 diabetes	226 primary care patients with Type 2 diabetes with a mean age of 56 years.	Country: US Study Design: RCT Perspective: Health Service Discount Rate: Not reported Time Horizon: 12 month study period	QoL scores for patients in the intervention and control arm were recorded using the SF-36	Per patients start up costs were $394 (€436) and annual running costs were $388 (€429). All costs were in 2005 USD.	The ICER for the intervention (including start-up costs) compared with routine care was $65,167 (€72,097)/QALY.
Kesavadev (2012)[224]	Telemedicine - blood glucose self-monitoring supported by the Diabetes Tele-Management System	T2DM patients enrolled in DTMS-based management, 30-75 years old, eligible for a glycosylated haemoglobin (A1c) target <6.5% and actively participating in various components of DTMS	Country: India Model Type: retrospective cohort study Perspective: NR Discount rate: NR Time horizon: 6 months	The mean ± SD A1c value was 8.5 ± 1.4% at the initial visit and was reduced to 6.3 ± 0.6% at 6 months	The recurring extra cost to patient for DTMS, not considering cost of oral drugs and insulin, was equivalent to 9.66 US dollars/month	The intervention appears to be safe and cost-effective in the intensive treatment of T2DM without serious co-morbidities.

Mason (2006)[228]	Telemedicine (via telephone) to support glycaemic control in patients with Type 2 diabetes	591 patients with Type 2 diabetes, with a mean age of 67 years	Country: UK Study Design: CEA alongside RCT Perspective: NHS Discount Rate: 5% on costs and benefits	Treated patients achieved an average reduction in A1c of 0.31%, giving a number needed to treat to achieve a 1% reduction in A1c of 10	Annual cost of running the call centre was £93,690 (€148,680). Cost per patient: £1,088 (€1,727) (trial caseload), £714 (€1,133) (routine caseload)	The cost for a 1% reduction in A1c was estimated to be between £1,600 (€2,539) and £3,500 (€5,554), with a corresponding cost per QALY of between £33,700 (€53,480) and £43,400 (€68,873). Based on trial and routine-use estimates, the probability of cost-effectiveness at £30,000 (€47,608)/QALY was 0.10 and 0.29, respectively.
Moreno (2009)[230]	Diabetes Education and Telemedicine (IDEATel) Home Telemedicine Demonstration	Eligible Medicare beneficiaries with Type 2 diabetes. (n=2169)	Country: US Study Design: RCT Perspective: N/A Discount Rate: N/A Time Horizon: 6 years	N/A	Total intervention costs were $8,924 and $8,437 per person per year for phases I and II, respectively. The savings in total Medicare expenditures in any site or cohort were either nonexistent or too small to offset the high costs of the intervention.	For IDEATel to be cost-effective, the intervention-related costs would have to be drastically reduced, while maintaining clinical impacts.

Palmas (2010)[232]	Telemedicine - case management with usual care	Older, ethnically diverse, medically underserved participants with diabetes mellitus in urban and rural settings. Mean age 70.8 years.	Country: US Study Type: trial-based costing study Perspective: payer Discount rate: not applicable Time horizon: 5 years	Not applicable.	Project intervention costs were estimated at $622 (€662) per participant per month of intervention delivered. Mean annual payments were estimated as $9,040(€9,615) and $9,669 (€10,284) for the usual care and telemedicine groups, respectively.	In conclusion, telemedicine case management did not reduce Medicare claims for clinical services in the medically underserved older adult population enrolled in the IDEATel project. To be viable and adopted in clinical settings, less costly technology will be required, most likely incorporating mobile phone technology and computers that are owned and maintained by participants.
Salzsieder (2011)[235]	Telemedicine-based eHealth programs using personalised decision support (PDS)	Adult diabetes patients (n=538)	Country: Germany Study Design: RCT Perspective: Insurer Discount Rate: N/A Time Horizon: 2 years	Significant reductions were found in A1c (7.1% to 6.7%). In contrast, in the group of patients whose physicians denied KADIS-based PDS, the A1c values increased significantly by 0.5% (6.8% to 7.3%).	The cost of the intervention was €2,908 (€2,908). The insurance company revealed an annual cost reduction of about €918 (€918) per participant in the programme. There was an increase in the costs of medication and of costs for financing the telemedicine supported healthcare services, including PDS, provided by the Diabetiva	KADIS-based PDS in combination with telemedicine has high potential to improve the outcome of routine outpatient diabetes care.

					programme. These enhanced costs, however, were completely compensated by the reduction in both the number of diabetes-	
Schechter (2012)[236]	A telephonic behavioural intervention to promote glycaemic control	Adults with Type 2 diabetes	Country: US Model Type: Mathematical Perspective: Health service Discount rate: 0% Time Horizon: 1 year	Results from a previous study involving this intervention showing a 0.36% decrease in A1c were applied.	Staff costs were obtained for 2009 from the US Department of Labour. Telephone charges were also included.	The total cost of the intervention for the telephone group was $180.61 (€172) per person, or $490.58 (€467) per percentage improvement in A1c.

*__KEY: ICER__: Incremental cost-effectiveness ratio; __NR__: Not reported __QALY__: Quality adjusted life year; __RCT__: Randomised Control trial; __SMS__: Self-management support, __DTMS__: Diabetes Tele Management System; __USD__- US Dollars; __VA__: Veterans Association; __ED__: Emergency Department

Table A7.8 Cost-effectiveness studies investigating pharmacist programmes in diabetes mellitus

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Fera (2009)[212]	Pharmacist - the Diabetes Ten City Challenge (DTCC), a multisite community pharmacy health management programme for patients with diabetes	Patients with diabetes who had baseline and year one medical and pharmacy claims and two or more documented visits with pharmacists. Mean age 57 years.	Country: US Study Type: Pre-post analysis of medical claims data Perspective: payer Discount rate: not applicable Time horizon: 12 months before and after	Not applicable.	Baseline data: mean total healthcare cost per patient = $13,131 (€13,966). Year one actual = $13,829 (€14,708). Year one projected = $14,909 (€15,857).	Positive clinical and economic outcomes were identified for 573 patients who participated in the programme for at least one year, compared with baseline data.
Letassy (2003)[227]	Pharmacist-led diabetes education programme	136 patients with Type 2 diabetes, with a mean age of 55 years	Country: US Study Design: Before and after comparison reporting estimated cost savings	After one year the average reduction in A1c was 3.1%	Estimates of the average saving from a sustained 1% A1c reduction were obtained from the literature ($685(€698) per patient per year, 2001 dollars)	The overall cost implications of the intervention were crudely estimated as $244,500 (€320,475) for a cohort of 600 patients
Petkova (2006)[233]	Five month diabetes educational programme delivered by pharmacists	24 patients with Type 2 diabetes, with a mean age of 64 years	Country: Bulgaria Study Design: Case series reporting cost data	After six months blood glucose levels had decreased and quality of life scores had increased, compared to the baseline results.	The total cost of the six month programme was €5.95 (€7.28) per person (costs in 2004 Euro)	Total cost of the programme for all 24 patients was €142.80 (€175). The cost per a one mmol/l decrease in blood glucose levels was €7.50 (€9.17).

Table A7.9 Cost-effectiveness studies investigating other self-management support programmes in diabetes mellitus

Study	Intervention	Population	Analysis Details	Clinical & QALY Outcomes	Costs	Results
Ismail (2010)[222]	CDSM – motivational enhancement therapy (MET) and cognitive behaviour therapy (CBT) delivered by general nurses with additional training in these techniques	The study population was adults with a confirmed diagnosis of Type 1 diabetes for a minimum duration of two years and a current A1c value between 8.2% and 15%. Mean age 36.4 years.	Country: UK Study Type: trial based CEA Perspective: health and social care; and societal Discount rate: not applied Time horizon: 12 months	Mean for first year: MET = 0.77; MET + CBT = 0.782; usual care = 0.789 (all based on EQ-5D)	The unit cost for a 50-minute MET session was estimated at £49 (€74) and £48 (€73) per session including and excluding training, respectively. The respective estimates for a 50-minute session of CBT were £81(€123) and £73 (€111). The average total cost of each treatment approach was approximately £195 (€296) for MET and £660 (€1,003) for MET + CBT.	Results here relate to EQ-5D. MET vs. usual care: £48,636 (€73,919)/QALY (payer), £160,750 (€244,316) /QALY (societal). MET+CBT vs. usual care: £311,970 (€474,147)/QALY (payer), £271,333 (€412,385)/QALY (societal). MET dominates MET+CBT.

*__KEY__: __QALY__: Quality adjusted life year;

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