



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Health technology assessment of chronic disease self- management support interventions

Stroke (*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 – Stroke

The key findings of this HTA in relation to self-management support interventions in post-stroke patients, which precede and inform HIQA's advice, are as follows:

- Based on 27 systematic reviews (228 randomised controlled trials), four broad types of self-management support intervention were identified. These focused on rehabilitation therapy (including general rehabilitation, virtual reality-based rehabilitation and telerehabilitation), self-management programmes, information provision and 'other' self-management support interventions.
- Good evidence was found that general rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living and extended activities of daily living. Virtual reality-based rehabilitation was found to improve upper limb function and activities of daily living when used as an add-on to usual care.
- Some evidence was found that:
 - information provision improves patient and carer knowledge of stroke, aspects of patient satisfaction, with small reductions (which may not be clinically significant) in patient depression scores.
 - stroke liaison emphasising education and information can have a positive impact on quality of life.
- Based on the available evidence, it is not possible to draw conclusions in relation to the effectiveness of:
 - self-management programmes delivered to post-stroke patients.
 - psychosocial interventions, motivational interviewing, lifestyle interventions, multidisciplinary care or family-orientated models of care.
- The identified economic literature was limited to four costing and cost-effectiveness studies relating to exercise-based programmes and computer-based rehabilitation therapy. The four included studies provided very limited evidence regarding the costs or cost-effectiveness of self-management programmes for post-stroke patients.

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

The best evidence was found for general rehabilitation therapy which if delivered in early stroke recovery has a positive impact on activities of daily living and extended activities of daily living. Virtual reality-based rehabilitation improves upper limb function and activities of daily living when used as an add-on to usual care.

Some evidence was found that information provision can improve patient and carer knowledge of stroke and some aspects of patient satisfaction with some evidence that stroke liaison emphasising education and information can have a positive impact on quality of life.

Evidence regarding the clinical and cost-effectiveness of other self-management support interventions for post-stroke patients is more limited, or conflicting.

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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

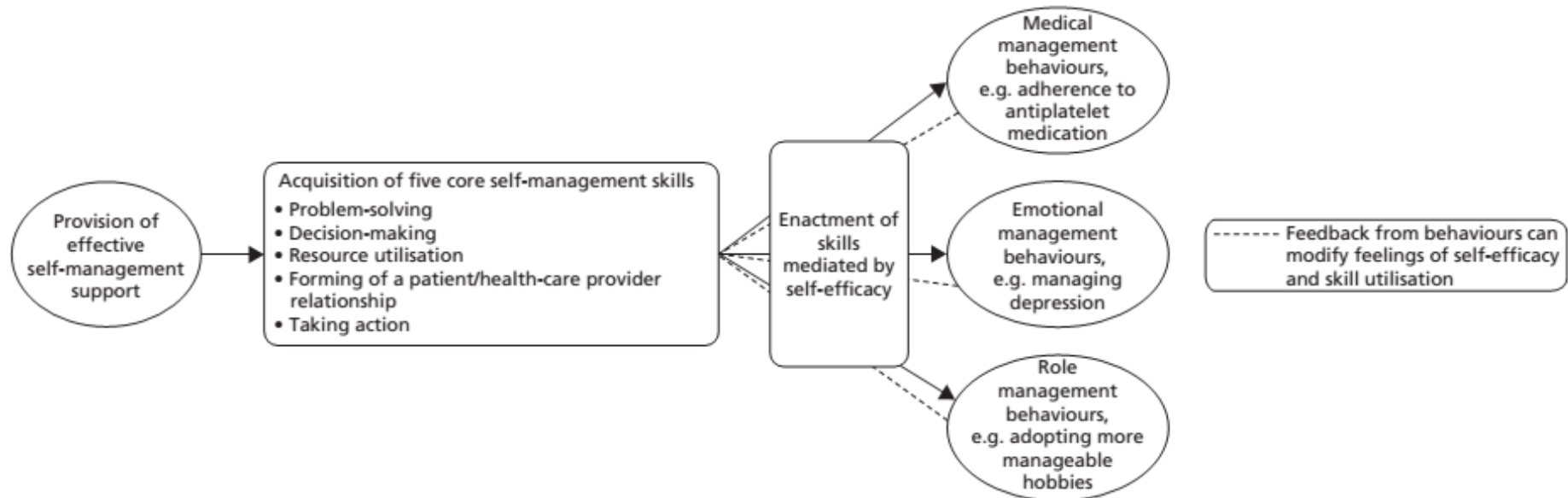
A broad range of self-management and self-management support definitions exist. For this review, the 2003 definitions agreed by the US Institute of Medicine are used:

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 modelTM (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, cardiovascular 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	<p>Phase I: Adults \geq 18 years old with at least one chronic disease. This includes common physical conditions such as asthma, COPD, arthritis, diabetes and cardiovascular diseases.</p> <p>Phase II: Adults \geq 18 years old with the specified disease (Type I or Type II diabetes mellitus, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).</p>
Intervention	<p>Phase I: Any generic self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support.</p> <p>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.</p> <p>Phase II: Any disease-specific self-management support intervention which helps patients manage aspects of their chronic disease through education, training and support.</p>

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	<ul style="list-style-type: none"> ▪ 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 indicated 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.
+/-	$0.05 \geq p > 0.01$	Some evidence of effect in favour of intervention/control.
++/- --	$0.01 \geq p > 0.001$	Strong evidence of effect in favour of intervention/control.
+++/- --	$p \leq 0.001$	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	<p>Phase I: Adults \geq 18 years old with at least one chronic condition.</p> <p>Phase II: Adults \geq 18 years old with the specified disease (Diabetes Type I or Type II, asthma, COPD, ischaemic heart disease, heart failure, hypertension or stroke).</p>
Intervention	<p>Phase I: Any generic self-management support intervention that helps patients to manage aspects of their chronic disease care through education, training or support.</p> <p>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.</p>
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⁾

8 Stroke

This health technology assessment (HTA) of stroke self-management support (SMS) is one of a series of rapid HTAs assessing SMS interventions for chronic diseases. Section 8.1 provides a brief description of stroke followed by separate reviews of the clinical (Section 8.2) and cost-effectiveness (Section 8.3) literature for SMS interventions in stroke survivors.

Brief descriptions of the background and methods used are included with full details provided in a separate document (Chapter 3). Section 8.4 includes a discussion of both the clinical and cost-effectiveness findings. This section of the report concludes with a list of key points in relation to interventions for stroke survivors (Section 8.5).

8.1 Description of the disease

Stroke is the neurological condition that results from brain damage caused by either blockage or rupture of a blood vessel in the brain. About 80% of strokes occur following a blockage of a vessel (ischaemic stroke) and 20% from vessel rupture (haemorrhagic stroke).^(244;245) A small number of strokes result from other causes. Transient ischaemic attack (TIA) is a related and often indistinguishable condition producing similar symptoms where the supply of blood to the brain is temporarily interrupted, but without causing permanent damage. TIAs are often a warning sign of an impending stroke. Consistent with stroke survivors, patients who experience a TIA require active risk management to reduce the risk of further TIA episodes or stroke. This may include management of other co-morbid chronic conditions (including, for example, hypertension, diabetes, coronary artery disease and obesity). However, as noted, unlike stroke survivors who require rehabilitation and physical and emotional support to deal with long-term neurological conditions, TIAs do not result in permanent neurological damage.⁽²⁴⁵⁾

Each year in Ireland, approximately 7,000 people are hospitalised following stroke.⁽²⁴⁶⁾ Total annual stroke costs in Ireland were estimated to be between €489 million and €805 million in 2007, with nursing home care needs and indirect costs accounting for the largest proportion of costs.^(246;247) Due to an aging population, the burden of stroke-related disease is expected to increase, with predicted increases of 11% to 15% in the proportion of the population aged 65 or older by 2021.⁽²⁴⁸⁾ Stroke can cause a range of permanent impairments associated with movement and coordination, memory and attention, and can cause depressive symptoms, all affecting an individual's rehabilitation. It is estimated that between 30% and 40% of stroke survivors develop some degree of functional dependence requiring assistance in performing basic activities of daily living (ADLs).

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

8.2.1 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 HTA is to review the clinical effectiveness of self-management support (SMS) interventions for a number of chronic conditions including stroke. 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 itself 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 (Population, Intervention, Comparator, Outcomes, Study design) agreed with the key stakeholder, this assessment is limited to SMS interventions for adults aged 18 years and over. Results of the updated search are reported in addition to a summary of the findings of the PRISMS report.

Data extraction and quality assurance of the systematic reviews, meta-analyses and the risk of bias associated with the primary literature were 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 SMS interventions, quality assurance of both the systematic review methodology (R-AMSTAR) and the meta-analyses (Higgins et al.'s quality assessment tool)⁽²³⁾ was undertaken. 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 it was reported, information on the risk of bias of the primary studies was extracted from the systematic reviews.

8.2.2 Description of the interventions

A general description of self-management and typical SMS interventions is included in Chapter 2 of this HTA. Stroke-specific interventions introduced in this Phase IIb report include stroke-specific self-management programmes and various methods of stroke rehabilitation such as telerehabilitation and virtual reality-based rehabilitation for stroke survivors. As noted in Chapter 2, generic chronic disease self-management programmes (CDSMP), for example the Stanford Programme, are behaviour-change programmes that mainly focus on improving self-efficacy and are designed to enable people to take an active part in managing their own condition. This includes necessary lifestyle adjustments to enhance quality of life, and also mechanisms to deal with the psychosocial consequences of their condition. SMS programmes specific to stroke survivors encompass a number of common SMS interventions, typically information provision, goal setting, problem solving and the promotion of self-efficacy.⁽²⁴⁹⁾ Telerehabilitation, which stems from the broader approach of telehealth, is an alternative method of delivering conventional rehabilitation services using information and communication technologies. It typically includes some form of therapist communication at a distance. It can also encompass virtual reality interventions. Stand-alone virtual reality-based rehabilitation is a recent treatment approach in stroke rehabilitation that uses commercial gaming consoles or specifically developed consoles adopted in clinical settings.

Outcomes specific to this review include, primary activities of daily living (ADL) and extended ADL. Being able to complete fewer ADLs indicates an increased disability or dependence on the help of carers. 'Primary ADL' is typically limited to functional ability and personal care (for example, feeding, bathing and dressing measures) whereas 'extended ADL' includes more complex tasks necessary for community and domestic participation (for example, shopping, cooking and transportation use).⁽²⁾

8.2.3 Results — clinical-effectiveness

The PRISMS review retrieved a total of 11 quantitative systematic reviews of stroke-specific SMS interventions for stroke survivors.⁽²⁾ Summary details of the reviews are included in Table 8.1. The publication dates of the systematic reviews ranged from 2003 to 2012 while that of the included RCTs ranged from 1981 to 2009. The reviews included 101 individual RCTs and were conducted in the UK, USA, China, Australia, the Netherlands, Sweden and Denmark. Not all of the systematic reviews recorded where the individual RCTs were conducted.

The PRISMS review was updated to April 2015 using the search string in Appendix 1. A further 16 applicable systematic reviews were retrieved (see Figure 8.1) that assessed a diverse range of SMS interventions for stroke survivors, including general stroke rehabilitation,⁽²⁵⁰⁾ telerehabilitation⁽²⁵¹⁾ and virtual reality-based

rehabilitation,⁽²⁵²⁻²⁵⁵⁾ self-management programmes,^(249;256;257) information provision,⁽²⁵⁸⁾ psychosocial,⁽²⁵⁹⁾ lifestyle⁽²⁶⁰⁾ or family-orientated interventions,⁽²⁶¹⁾ motivational interviewing,⁽²⁶²⁾ leisure therapy⁽²⁶³⁾ and multidisciplinary care⁽²⁶⁴⁾ (see Table 8.1). Study overlap was assessed to identify studies that added little or no additional evidence. When substantial overlap was observed between two or more systematic reviews, we based our analyses on the higher quality or more comprehensive review. Based on this, the reviews by Lohse et al.,⁽²⁵⁴⁾ Rodrigues-Baroni et al.⁽²⁵⁵⁾ and Imam et al.⁽²⁵²⁾ on virtual reality-based rehabilitation, while listed for completeness, are not discussed. Instead, the more recent comprehensive Cochrane review by Laver et al. (2015)⁽²⁵³⁾ is discussed. The review by Lo et al.⁽²⁵⁶⁾ on self-management programmes is not discussed further as the three component RCTs are included within the review by Lennon et al. (2013) on the same topic.⁽²⁴⁹⁾ Similarly, only the results from three of the six RCTs in the narrative review by Warner et al.⁽²⁵⁷⁾ on self-management programmes are discussed as the remaining RCTs are included in the review by Lennon et al..

For the additional systematic reviews identified in the updated search, the number of included RCTs per review ranged from 1⁽²⁶²⁾ to 37^(250;253) with the number of participants per systematic review ranging from 411⁽²⁶²⁾ to 7,742⁽²⁶⁰⁾. Study overlap is reported in Table 8.2. The publication dates of the systematic reviews ranged from 2012 to 2015 while that of the included RCTs ranged from 1989 to 2014. Study locations of RCTs were typically in Asia, Europe (mainly the UK) or North America. Study location was not reported in two reviews. The R-AMSTAR scores for the additional systematic reviews identified in the updated search ranged from 24 to 38, 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), nine of the systematic reviews were categorised as providing the highest quality evidence (three star *** review) while four reviews each were rated as two-star**. Two were rated as one-star* reviews in terms of their quality and size. Of the 23 systematic reviews discussed, 13 included a meta-analysis of which 10 were assessed as high quality, and three as moderate quality. The conclusions in the latter are at risk of bias, but are likely to be broadly accurate, while studies graded as high quality are very likely to have conclusions that accurately reflect the available evidence (see also Chapter 3, Table 3.1) In total, 228 unique RCTs are included in the retrieved systematic reviews.

Figure 8.1 Flowchart of included studies from updated search

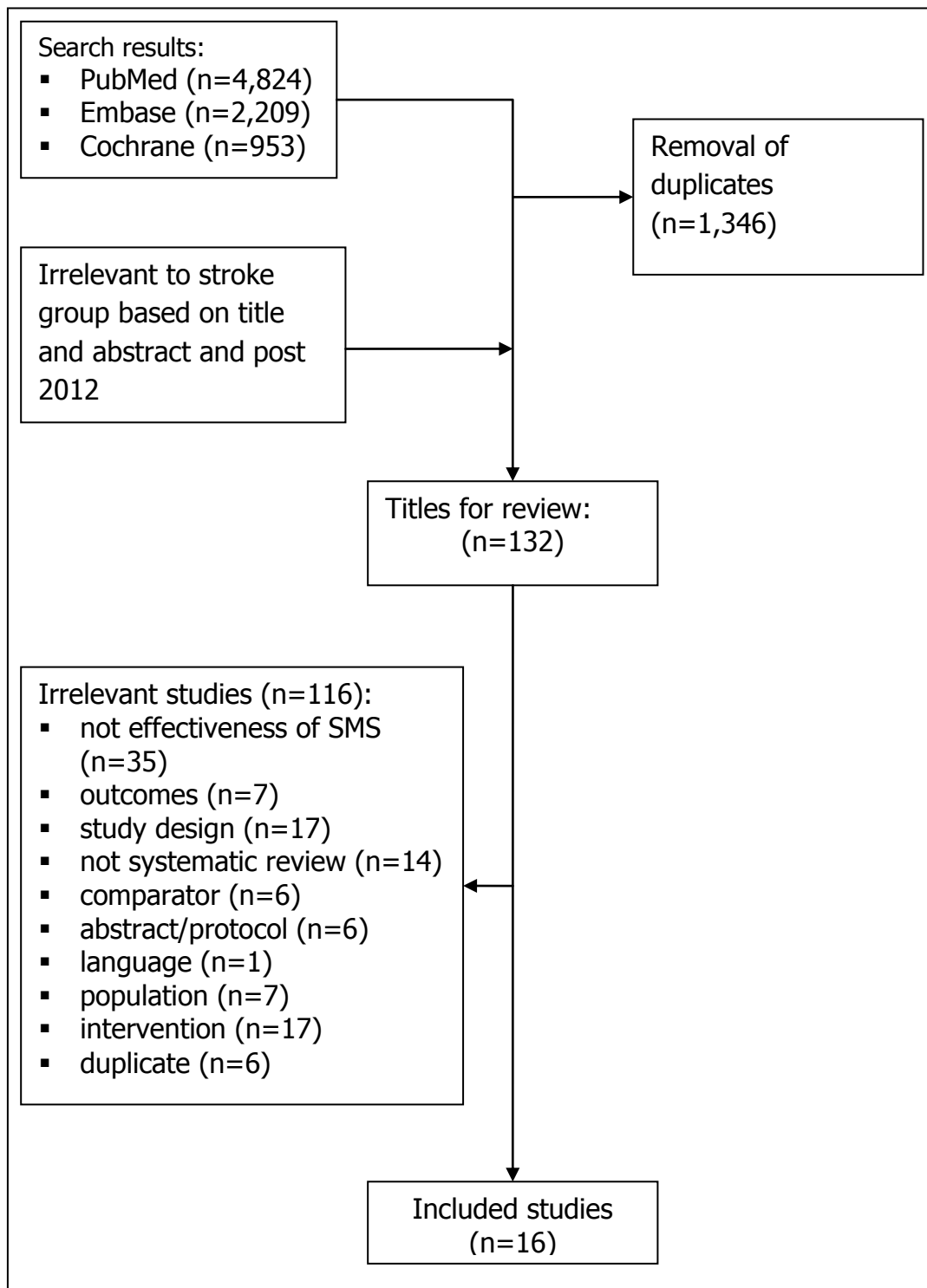


Table 8.1 Stroke — summary of systematic reviews retrieved in the PRISMS review and the updated search, classified by intervention type

Author (year)	Intervention
PRISMS studies retrieved	
Rehabilitation therapy	
<i>General Rehabilitation</i>	
Aziz (2008) CR ⁽²⁶⁵⁾	Rehabilitation therapy — one-year post stroke
Hoffman (2010) CR ⁽²⁶⁶⁾	Occupational therapy (OT) rehabilitation for cognitive impairment
Legg (2006) CR ⁽²⁶⁷⁾	OT rehabilitation
OST (2003) CR ⁽²⁶⁸⁾	Rehabilitation therapy
Poulin (2012) ⁽²⁶⁹⁾	Rehabilitation therapy for cognitive impairment
Steultjens (2003) ⁽²⁷⁰⁾	OT rehabilitation
Walker (2004) ⁽²⁷¹⁾	OT rehabilitation
Stroke self-management programmes	
Korpershoek (2011) ⁽²⁷²⁾	Self-efficacy enhancing
Information provision	
Smith (2008) CR ⁽²⁷³⁾	Information provision (patients and caregivers)
Other SMS	
Ellis (2010) CR ⁽²⁷⁴⁾	Stroke liaison
Lui (2005) ⁽²⁷⁵⁾	Caregiver problem solving
Reviews retrieved in updated search	
Rehabilitation therapy	
<i>General Rehabilitation</i>	
Dorstyn (2014) ⁽²⁶³⁾	Leisure therapy in stroke rehabilitation
Zhang (2013) ⁽²⁵⁰⁾	Stroke rehabilitation in China
<i>Virtual Reality-Based Rehabilitation</i>	
Imam (2014) ⁽²⁵²⁾	Virtual reality rehabilitation
Laver (2015) CR ⁽²⁵³⁾	Virtual reality rehabilitation
Lohse (2014) ⁽²⁵⁴⁾	Virtual reality therapy
Rodrigues-Baroni (2014) ⁽²⁵⁵⁾	Virtual reality-based walking training
<i>Telerehabilitation</i>	
Laver (2013) CR ⁽²⁵¹⁾	Telerehabilitation services (range including computer-based training programmes)
Stroke self-management programmes	
Lennon (2013) ⁽²⁴⁹⁾	Stroke self-management programmes
Lo (2013) ⁽²⁵⁶⁾	Stroke theory-based self-management programmes

Author (year)	Intervention
Warner (2015) ⁽²⁵⁷⁾	Stroke self-management programmes
Information provision	
Forster (2012) CR ^{(258)*}	Information provision (patients and caregivers)
Other self-management support	
Cheng (2014) ⁽²⁵⁹⁾	Psychosocial interventions (such as counselling, psychoeducation, behavioural or cognitive interventions, social support group)
Cheng (2015) CR ⁽²⁶²⁾	Motivational interviewing
Fens (2013) ⁽²⁶⁴⁾	Range of multidisciplinary care (≥ 2 different care professionals working together as, or supported by, a team)
Lennon (2013) ⁽²⁶⁰⁾	Lifestyle interventions (including education) for secondary disease prevention
Vallury (2015) ⁽²⁶¹⁾	Family-oriented interventions to reduce post-stroke depression

Key: CR = Cochrane review; OT = occupational therapy; QA = quality assurance.

* The CR by Forster et al. CR (2012) is an update of the 2008 CR by Smith et al..

Table 8.2 Stroke — study overlap between the included systematic reviews (PRISMS report plus the systematic reviews from the updated search).⁶ Adapted from PRISMS review⁽²⁾

Review (year)	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	
1 Aziz (2008)	5																											
2 Hoffman (2010)	0	1																										
3 Legg (2006)	0	0	9																									
4 OST (2003)	0	0	7	14																								
5 Poulin (2012)	0	0	0	0	3																							
6 Steultjens (2003)	0	0	6	6	0	18																						
7 Walker (2004)	0	0	7	8	0	6	8																					
8 Ellis (2010)	0	0	0	1	0	0	0	16																				
9 Korpersoek (2011)	0	0	0	0	0	0	0	0	4																			
10 Lui (2005)	0	0	0	0	0	0	0	0	1	6																		
11 Smith (2008)	0	0	0	0	0	0	0	0	1	1	17																	
Reviews retrieved in updated search																												
12 Cheng (2014)	0	0	0	0	0	0	0	2	0	3	2	13																
13 Cheng (2015)	0	0	0	0	0	0	0	0	0	0	0	0	1															
14 Dorstyn (2014)	0	0	1	3	0	3	2	0	0	0	0	0	0	8														
15 Fens (2013)	0	0	0	0	0	0	0	1	0	0	0	0	0	1	14													
16 Forster (2012)	0	0	0	0	0	0	0	1	1	1	17	3	0	0	0	21												
17 Imam (2014)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11											
18 Laver (2013)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	10										
19 Laver (2015)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	1	37									
20 Lennon (2013) SMP	0	0	0	0	0	0	0	0	1	0	0	2	0	0	1	1	0	0	0	9								
21 Lennon (2013)	0	0	0	0	0	0	0	1	0	0	2	0	0	0	2	2	0	0	0	2	17							
22 Lo (2013)	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	3	0	3						
23 Lohse (2014)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6	1	15	0	0	0	0	25					
24 Rodrigues-Baroni (2014)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0	3	0	0	0	0	3	7				
25 Vallury (2015)	0	0	0	1	0	0	0	8	1	1	3	1	0	0	1	3	0	1	0	0	0	0	1	0	22			
26 Warner (2015)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	2	0	0	0	0	6		
27 Zhang (2013)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	37

Notes. 1 The Cochrane review (CR) by Forster et al. (2012) is an update of the 2008 CR by Smith et al.. 2 PRISMS included studies by Ko (2010) and Rae-Grant (2011) were excluded as there were no applicable RCTs. 3 Reviews by Lohse, Imam and Rodrigues-Baroni are not discussed further due to study overlap; the more recent, comprehensive Cochrane review by Laver (2015). The review by Lo et al. on self-management programmes is not discussed further as the RCTs overlap with the review by Lennon et al. (2013).

⁶ PRISMS review is based on a search from 1993 to June 2012. This search was updated to April 2015.

8.2.3.1 Summary of findings

Detailed summaries 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 are included in Appendix A8.1. The following are reported based on the findings from PRISMS and the additional systematic reviews retrieved in the updated search. 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: rehabilitation therapy (largest body of evidence retrieved), stroke self-management programmes, information provision and other SMS interventions. 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 8.3 below 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 stroke.

Table 8.3 Summary characteristics and findings for selected outcomes for included studies

Study	Quality of Systematic Review			Primary Studies		Quality of Meta-analysis	ADL (SMD)	Extended ADL (SMD)	Poor outcomes or death (OR)
	R-AMSTAR score	Participants	Quality	n	low-risk ^a				
Rehabilitation therapy									
General rehabilitation									
Aziz 2008 ⁽²⁶⁵⁾	40	487	**	5	2	High	NS	NS	0.32 (0.14 to 0.71)
Dorstyn 2014 ⁽²⁶³⁾	24	610	*	8		N/A			
Hoffmann 2010 ⁽²⁶⁶⁾	35	33	**	1		N/A			
Legg 2006 ⁽²⁶⁷⁾	42	1258	***	9	8	High	0.18 (0.04 to 0.32)	0.21 (0.03 to 0.39)	0.67 (0.51 to 0.87)
OST 2003 ⁽²⁶⁸⁾	41	1617	***	14	9	High	0.14 (0.02 to 0.25)	0.17 (0.04 to 0.30)	0.72 (0.57 to 0.92)
Poulin 2012 ⁽²⁶⁹⁾	32	109	**	3		N/A			
Stultjens 2003 ⁽²⁷⁰⁾	32	1825	***	18	4	Moderate	0.31 (0.03 to 0.60) ²	NS	
Walker 2004 ⁽²⁷¹⁾	35	1143	***	8	6	High	OR 0.71 (0.52 to 0.98)	WMD 1.30 (0.24 to 2.79) 1.61 (0.72 to 2.49) ³	NS
Zhang 2013 ⁽²⁵⁰⁾	33	5,916	***	37	1	Moderate	1.04 (0.88 to 1.21)		
Virtual reality-based rehabilitation									
Laver 2015 ⁽²⁵³⁾	39	1,019	***	37	17	High	0.43 (0.18 to 0.69)		
Telerehabilitation									
Laver 2013 ⁽²⁵¹⁾	38	933	**	10	1	High	0.0 (-0.15 to 0.15) ⁴		

Abbreviations: ADL = activities of daily living; N/A = not applicable; NS = non-significant; OR = odds ratio; SMD = standard mean difference; WMD = weighted mean difference.

Note: ^a Number of the total primary studies identified as being at low risk of bias.

Table 8.3 (continued) Summary characteristics and findings for selected outcomes for included studies

Study	Quality of Systematic Review			Primary studies		Quality of meta-analysis	ADL (SMD)	Extended ADL (SMD)	Poor outcomes or death (OR)
	R-AMSTAR score	Participants	Quality	n	low-risk ^a				
Stroke self-management programmes									
Korpershoek 2011 ⁽²⁷²⁾	24	630	*	4		N/A			
Lennon 2013 ⁽²⁴⁹⁾	29	1,191	**	9		N/A			
Warner 2015 ⁽²⁵⁷⁾	28	<1,000	*	6		N/A			
Information provision									
Smith 2008 ⁽²⁷³⁾	40	2831	***	17	9	High			NS
Forster 2012 ⁽²⁵⁸⁾	39	3579	***	21	2	High			0.86 (0.59 to 1.25)
Other interventions									
Cheng 2014 ⁽²⁵⁹⁾	34	3,559	***	18	2	High			
Cheng 2015 ⁽²⁶²⁾	39	411	**	1		N/A			
Ellis 2010 ⁽²⁷⁴⁾	35	4,759	***	16	13	High	NS	NS	0.55 (0.38 to 0.81)
Fens 2013 ⁽²⁶⁴⁾	29	2,389	**	14		N/A			
Lennon 2013 ⁽²⁶⁰⁾	29	7,742	**	17	6	Moderate	NS		1.13 (0.85–1.52)
Lui 2005 ⁽²⁷⁵⁾	24	1,676	**	6		N/A			
Vallury 2015 ⁽²⁶¹⁾	26	3,739	**	22		N/A			

Abbreviations: ADL = activities of daily living; N/A = not applicable; NS = non-significant; SMD = standard mean difference; WMD = weighted mean difference.

Note: ^a Number of the total primary studies identified as being at low risk of bias.

8.2.3.2 Rehabilitation therapy

Three star (***) reviews

Based mainly on four three-star reviews, PRISMS reported that there is strong evidence that general rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living (ADL) and extended ADL, but has no impact on mood.^(267;268;270;271) When delivered later in stroke recovery, there is some evidence of a beneficial effect on extended ADL, but there is some evidence to suggest no impact on ADL or quality of life (QoL). Regardless of whether rehabilitation therapy is delivered in early or late stroke recovery, there is no evidence of effect on mood. The majority of rehabilitation therapy interventions reported in the PRISMS identified systematic reviews were delivered by occupational therapists (OTs). While OTs can play an important role in delivering SMS, PRISMS noted that a more integrated whole-systems approach is needed for optimal SMS. They highlighted that a focus on longer-term support is also required.

There is good evidence that virtual reality-based rehabilitation using interactive video games is beneficial in improving upper limb function and ADL when used as an add-on to usual care. This finding is based on a Cochrane review and meta-analysis of 37 RCTs by Laver et al. published in 2015, with the author proposing that these improvements are due to an increase in overall therapy time.⁽²⁵³⁾ However, they highlight that it is unclear at present which characteristics of virtual reality are most important and if the effects are sustained in the longer term.

While a high-quality systematic review and meta-analysis of a diverse range of stroke rehabilitation interventions in China was identified in the search, its results are not applicable to the Irish setting as the comparator used was no rehabilitation.

Two star (**) reviews

A Cochrane review and meta-analysis of telerehabilitation by Laver et al. (2013) found no significant improvements in ADL or upper limb function for post-stroke patients compared with usual care.⁽²⁵¹⁾

One star (*) reviews

We identified a single narrative review of 32 RCTs evaluating the effect of leisure therapy on short-term psychological and leisure outcomes in adults who have sustained a stroke.⁽²⁶³⁾ The review was of poor quality and found limited evidence of effect.

Summary statement for rehabilitation therapy

Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials, there is good evidence that rehabilitation therapy provided mainly by occupational therapists and delivered in early stroke recovery has a positive impact on ADL and extended ADL. There is good quality evidence that virtual reality-based rehabilitation improves ADL and upper limb function. Based on limited evidence, telerehabilitation does not improve ADL or upper limb function for post-stroke patients compared with usual care.

8.2.3.3 Stroke-specific self-management programmes**Two star (**) reviews**

There is limited evidence of effectiveness of stroke-specific self-management programmes delivered to stroke survivors based on one narrative review by Lennon et al.⁽²⁴⁹⁾ They reported that six out of nine RCTs showed a significant treatment effect. However, three of these RCTs are potentially not applicable due to the nature of the intervention (n=1) or the comparator used (n=2).

One star (*) reviews

PRISMS identified a single lower-quality narrative review of interventions to enhance self-efficacy which suggested that a chronic disease self-management course had a significant positive effect on quality of life.⁽²⁷²⁾ However, this finding was based on two RCTs with the review author stating that these results should be interpreted with caution.

A single narrative review of pre-post, quasi-experimental and RCT study designs evaluating the impact of self-management programmes for stroke patients was identified.⁽²⁵⁷⁾ The review was of poor quality and identified limited evidence of effect for a single unique RCT evaluating a programme based on a tailored nursing intervention.

Summary statement for stroke-specific self-management programmes

Based on the available evidence, it is not possible to draw conclusions in relation to the effectiveness of self-management programmes delivered to post-stroke patients.

8.2.3.4 Information provision

Three star (***) reviews

The effectiveness of information provision (education) in a timely and effective format to allow for active decision-making was assessed in a Cochrane review and meta-analysis by Forster et al. (2012).⁽²⁵⁸⁾ This review was an update to the 2008 review by Smith et al. included in the PRISMS report. Forster et al. reported that information provision improves patient and carer knowledge of stroke, and aspects of patient satisfaction. While they reported a small reduction in patient depression scores, they highlighted that this may not be clinically significant. They noted that the best way to provide information is still unclear, but that interventions using active information provision may be more effective than passive information, such as giving a patient a leaflet, for the clinically important outcomes of patient depression and anxiety symptoms. The latter included information provided on a single occasion with no subsequent systematic follow up or reinforcement, while active information interventions included a purposeful attempt to allow the participant to assimilate the information and included a subsequent agreed plan for clarification and consolidation or reinforcement. They found no evidence that information interventions are associated with improvements in activity limitation, participation or changes in service use.

Summary statement for information provision

There is some evidence that information provision improves patient and carer knowledge of stroke, aspects of patient satisfaction, with small reductions (which may not be clinically significant) in patient depression scores. Interventions using active information provision may be more effective than passive information, such as giving patients a leaflet, for patient depression and anxiety symptoms.

8.2.3.5 Other SMS interventions

Three star (***) reviews

PRISMS reported some evidence that stroke liaison emphasising education and information can have a positive impact on quality of life, but that general stroke liaison has no measurable benefits for stroke survivors. This is based on one systematic review by Ellis et al. (2010) who defined a stroke liaison worker as:

"someone whose aim is to increase participation and improve wellbeing for patients and carers. Typically they provide emotional and social support and information to stroke patients and their families and liaise with services with the aim of improving aspects of participation and quality of life for patients with stroke, their carers, or both."⁽²⁷⁴⁾

Stroke liaison workers are not limited to a specific professional group; the term spans both individuals from the voluntary sector and those from a range of health or social care professionals.⁽²⁷⁴⁾

A systematic review and meta-analysis by Cheng et al. in 2014 reported limited evidence of effectiveness of psychosocial interventions, with this term being applied to cognitive, behavioural and, or social mechanisms of action (such as counselling, psychoeducation, behavioural or cognitive interventions, social support group) that aim to improve the psychosocial and physical wellbeing of caregivers and the outcomes of stroke survivors.⁽²⁵⁹⁾ They placed no restriction on the format (individual, group, telephone or web-based), setting (hospital, home or community), duration or frequency of intervention. A pooled analysis of two RCTs on individual psychoeducational programmes showed a small effect on improving family functioning.

Two star () reviews**

A 2015 Cochrane review by Cheng et al. comprising one RCT which reported insufficient evidence to support the use of motivational interviewing to improve ADL after stroke.⁽²⁶²⁾

A review and meta-analysis by Lennon et al. in 2013 concluded that there was insufficient high-quality research to support efficacy of lifestyle interventions post-stroke or transient ischaemic attack (TIA) on mortality, cardiovascular-disease event rates or cardio-metabolic risk-factor profiles.⁽²⁶⁰⁾

Based on one narrative review by Fens et al. in 2013, there is limited evidence of effectiveness for multidisciplinary care delivered to stroke patients living in the community.⁽²⁶⁴⁾ Four main types of interventions were assessed: structured assessment (n=2 RCTs); assessment combined with follow-up care (n=8); rehabilitation (n=3); education (n=1).

A low-quality narrative review by Vallury et al. reported limited evidence that family-orientated models of care can be effective in reducing depression in patients and their caregivers.⁽²⁶¹⁾ This was based on a statistically significant reduction in post-stroke depression in five out of 22 included RCTs.

Summary statement for other SMS interventions

There is some evidence that stroke liaison emphasising education and information can have a significant positive impact on quality of life.

However, based on available evidence, it is not possible to draw conclusions in relation to the effectiveness of psychosocial interventions, motivational interviewing,

lifestyle interventions, multidisciplinary care or family-orientated models of care in the management of post-stroke patients.

8.3 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 survivors of stroke. Studies were included if they compared the costs and consequences of a SMS intervention with routine care.

8.3.1 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, 14 systematic reviews of SMS interventions were identified through the results of the clinical effectiveness search, which included cost or economic outcomes, and 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 8.4 below.

Table 8.4 PICOS analysis for identification of relevant studies

Population	Adults \geq [greater than or equal to] 18 years old that had experienced a stroke.
Intervention	Any self-management support intervention that helps patients with post-stroke rehabilitation 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.

The following study types were excluded if:

- a nursing home or non-community dwelling population was included,

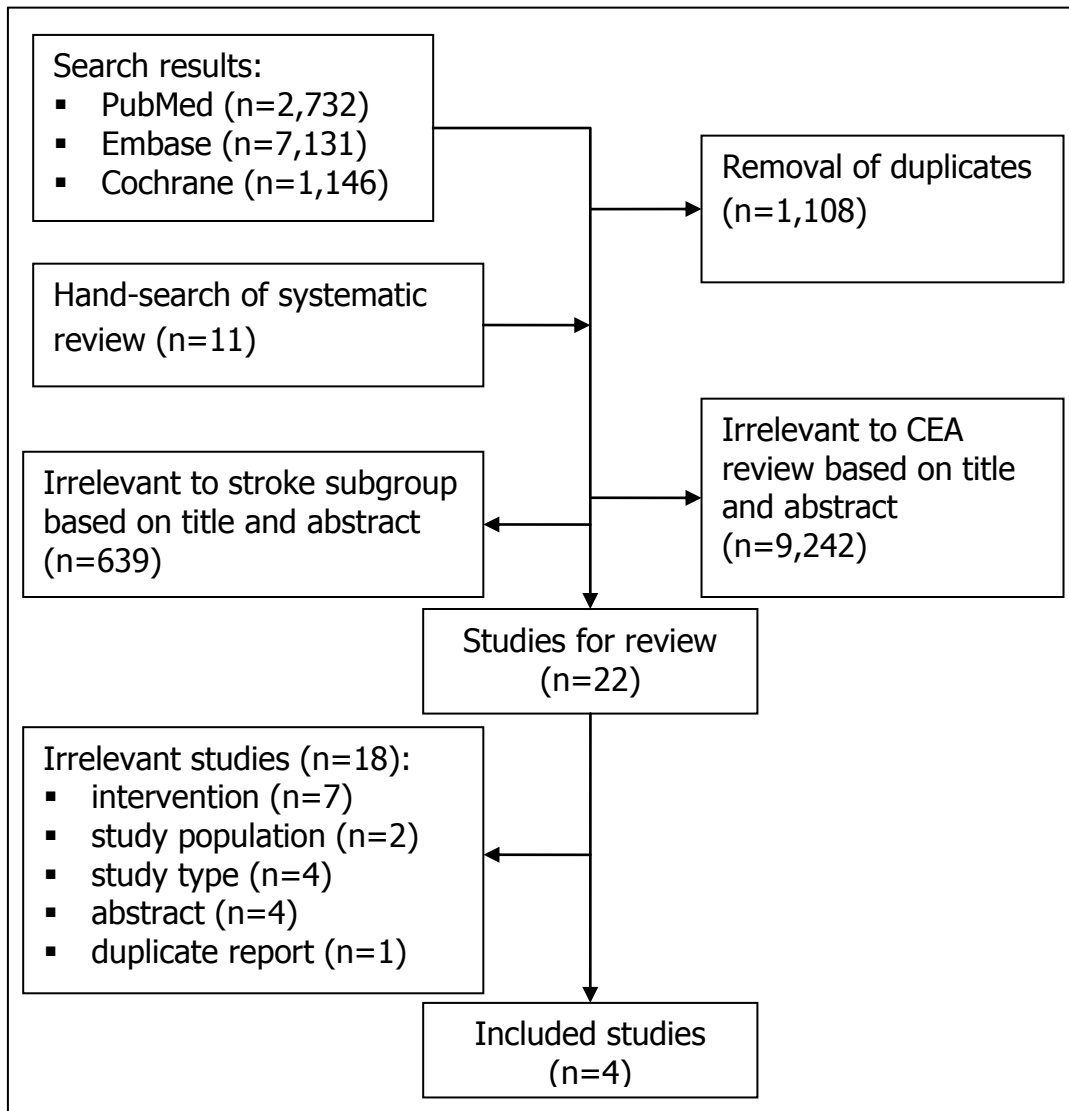
- it included a paediatric population,
- cost data were not clearly reported,
- published prior to the year 2000 (limited relevance).

As outlined in Chapter 3.2.2 and in accordance with national HTA guidelines, assessment of the quality of the studies using the Consensus on Health Economic Criteria (CHEC)-list was performed independently by two people. 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).

8.3.2 Results – cost-effectiveness

The bibliographic search returned 11,009 studies from across the three databases, which equated to 9,901 unique studies after removal of duplicates (see Figure 8.2). After removing studies not relevant to the review of cost-effectiveness based on the titles and abstracts, 661 studies were identified that may be costing or cost-effectiveness studies. A further 639 studies were identified as not relevant to a review of stroke interventions based on title and abstract. Finally, a further 18 were excluded based on the various exclusion criteria, leaving four included studies. Assessment of eligibility of studies and data extraction was carried out independently by two people with any disagreements resolved by discussion. Costs reported in each of the studies were inflated to 2014 prices using the local consumer price index and expressed in euro using the purchasing power parity index.

Figure 8.2 Flowchart of included studies



Key. CEA = Cost-effective analysis.

Two of the studies were based in the UK, and one in each of Canada and Spain. The included studies were published between 2008 and 2015. The characteristics of the included studies are given in Table 8.5.

Table 8.5 Included studies

Study	Country	Intervention
Huijbregts (2008) ⁽²⁷⁶⁾	Canada	Self-management programme with land and water-based exercise
Harrington (2010) ⁽²⁷⁷⁾	UK	Exercise and education programme
Latimer (2013) ⁽²⁷⁸⁾	UK	Self-managed computer therapy
Llorens (2015) ⁽²⁷⁹⁾	Spain	Virtual reality-based telerehabilitation

The studies were classified into two intervention types: exercise-based programmes and computer-based rehabilitation therapy.

8.3.2.1 Exercise-based programmes

Two trial-based costing studies were identified that evaluated exercise programmes. See Table A8.3 in the appendices for a summary of the study details and results.

A 2008 Canadian study evaluated a self-management programme with land and water-based exercise, compared with a standard six-week educational programme that is considered part of routine care in Canada.⁽²⁷⁶⁾ The intervention consisted of 17 two-hour, group-based sessions, twice per week for eight weeks, with a booster session six weeks later. The first hour of each session involved the discussion of weekly topics, short-term goal setting, and problem solving. The second hour was devoted to exercise. Assessments at baseline, programme completion, and three-month follow-up included the Reintegration to Normal Living (RNL) Index, Activity-specific Balance Confidence (ABC) scale, exercise participation, and goal attainment (for the MOST group). Significant improvements in balance confidence at follow-up were observed in the intervention group and there was some evidence of between-group differences.

The cost of the programme per person was €313 for the intervention and €86 for routine care. Due to the marginal nature of the benefits, the cost per unit increase in balance was more expensive in the intervention group than in the control group. The study used a small sample of 30 self-selected participants, was non-randomised, and there is no indication that assessors were blinded to treatment allocation. The study is therefore at high risk of bias.

A community-based exercise and education scheme was evaluated in the UK using a randomised controlled trial (RCT).⁽²⁷⁷⁾ The scheme comprised twice-weekly sessions for eight weeks that combined one hour of exercise with one hour of interactive education. The study included 243 stroke survivors that had returned to living in the community

for at least three months prior to the start of the study. Standard care involved a follow-up contact from a stroke coordinator at six weeks and a six-month review. Clinical improvement was measured using a variety of physical, social, activity and mobility indices. Participants in the intervention group showed greater improvements than the control group in the Subjective Index of Physical and Social Outcome (SIPSO) score and in the psychological domain of the quality of life measure. The delivery of the intervention programme cost €371 per participant, compared with €147 per participant for routine care. When all costs were taken into account, the average cost in the intervention group was €1,108 more than that for the control group.

8.3.2.2 Computer-based rehabilitation therapy

There were two studies assessing computer-based rehabilitation interventions. See Table A8.4 in the appendices of this report for a summary of the study details and results.

A UK study estimated the cost-utility of self-managed computer therapy for stroke survivors with long-standing aphasia.⁽²⁷⁸⁾ The intervention was compared with usual care which comprised general language stimulation. The evaluation used a decision-analytic model that was populated with data on 28 patients collected as part of a previous RCT. The model had three health states (initial level of aphasia, response state, and death) and followed participants to end of life. The gain in quality-adjusted life years (QALYs) were 3.07 for controls and 3.22 for the intervention. The total cost was €25,036 for controls and €25,621 for intervention participants. The incremental cost-effectiveness ratio (ICER) was therefore €4,097 per QALY. The authors concluded that there was a high likelihood of the intervention being cost-effective at a willingness-to-pay threshold of £20,000 per QALY. The utility data used in the model were not well-described in either the article or the cited trial, therefore making it impossible to determine if some of the assumptions in the model were appropriate. The underlying trial was a pilot study and used a very small sample size.⁽²⁸⁰⁾ Hence, it is not possible to state whether the findings of the study are applicable to the Irish setting.

Additionally, a virtual reality-based telerehabilitation programme in Spain, comparing home-based and clinic-based delivery of the programme, was assessed.⁽²⁷⁹⁾ The intervention used a computer system linked to a motion-sensing device to provide interactive exercise routines for stroke patients with residual hemiparesis (weakness of one side of the body, in its severest form, a complete paralysis of the side of the body). The data were derived from an RCT with 30 participants followed up over three months. Both intervention and control groups showed significant improvements in balance, although no significant differences were found between the groups. The mean cost per participant was €820 for the intervention, and €1,461 for controls. The clinic-based treatment required more physical therapist time and

greater patient travel costs. The home-based treatment generated greater equipment costs (US \$800 [€784] per participant). The relevance of the study is questionable as the intervention is not compared with routine care.

8.4 Discussion

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

8.4.1 Clinical effectiveness

As a chronic disease, stroke is very different to other long-term illnesses in that it is a sudden onset disease with varying levels of sudden, potentially permanent impairments. Stroke patients typically require greater professional care initially, and where possible followed by a transition to greater responsibility by the individual for their own care. This is reflected in the stroke self-management support (SMS) clinical-effectiveness literature retrieved, which is largely focused on rehabilitation therapy. Self-management for stroke is not as clearly defined as in other chronic diseases. However, rehabilitation therapy, although not specifically termed self-management, involves varying components of self-management support such as problem solving, goal setting and improving self-efficacy and decision-making.

It was difficult to categorise the remaining reviews retrieved by intervention type as there was large heterogeneity across the interventions. However, to aid interpretation of the results the reviews were broadly categorised as 'stroke self-management programmes', 'information provision' and other 'SMS interventions'. The 'other SMS interventions' included one review per intervention and included motivational interviewing, psychosocial interventions, interventions to improve self-efficacy, caregiver problem solving, multidisciplinary care at home, lifestyle interventions (including education) and family-orientated interventions.

The duration of follow-up for all stroke-component randomised controlled trials (RCTs) was inconsistently reported by the included systematic reviews, with a maximum duration of follow-up of 12 months reported. This makes it difficult to draw conclusions in relation to the sustainability of any effect observed.

The largest evidence base retrieved by PRISMS — and in the updated search — was for rehabilitation therapy. There is strong evidence that general rehabilitation therapy delivered in early stroke recovery has a positive impact on activities of daily living (ADL) and extended ADL. The majority of general rehabilitation therapy interventions reported in the identified systematic reviews were delivered by occupational therapists (OTs). The updated search added little to the existing knowledge on general rehabilitation. However, it identified new evidence for the use of virtual reality-based and telerehabilitation interventions in post-stroke care.

PRISMS did not include telemedicine interventions in stroke based on limited evidence retrieved.

The findings for virtual reality-based interventions are based on the most comprehensive of the four systematic reviews retrieved (n=37 RCTs). It reported that the use of virtual reality and interactive video games may be beneficial in improving upper limb function and activities of daily living when used in addition to usual care as it increases overall therapy time. However, it was highlighted that it was unclear if effects are sustained in the longer term. Based on limited evidence, however, telerehabilitation does not improve activities of daily living or upper limb function for post-stroke patients compared with usual care.

Although not meeting our inclusion criteria, evidence from a Cochrane review of early supported discharge supports these findings for early delivery of rehabilitation therapy. This Cochrane review assessed any intervention that aimed to accelerate discharge from hospital for a selected group of post-stroke patients (moderate disability) via providing support (with or without a therapeutic rehabilitation intervention) in a community setting (early supported discharge). Compared with conventional care, patients who received early supported discharge returned home earlier and were more likely to be independent and living at home six months post-stroke. They were also more likely to express satisfaction with the care received, with no apparent adverse effects on mood or subjective health status of the patients or their carers.⁽²⁸¹⁾

Based on one Cochrane review, the PRISMS report concluded that there is some evidence that 'information provision', particularly when provided in a way that more actively involves patients and carers, has beneficial effects on mood. Our update is broadly consistent with this finding in that the update to this Cochrane review reported a smaller, but still significant effect in terms of depression, which, however, may not be clinically significant. It is reported that there is a high incidence of mood disorders in stroke patients (31%)⁽²⁸²⁾ and PRISMS qualitative analysis suggests that stroke survivors continue to struggle once their physical recovery has plateaued and their rehabilitation therapy is withdrawn. PRISMS also noted that 'information provision' using education via lectures, for example, was associated with improvements in patient and carer knowledge of stroke. The best way to provide information is reported as unclear, but that active information provision (that is, included a purposeful attempt to allow the participant to assimilate the information and included a subsequent agreed plan for clarification and consolidation or reinforcement) may be more effective than passively providing information. Findings in the updated search were consistent with this. Of note, in defining the evidence-based criteria for official certification as a European Stroke Organisation (ESO) stroke unit or ESO stroke centre, the ESO has included the provision of information

to patients and their carers as one of the stated criteria — this should include information about diagnostics, therapies, rehabilitation and prognosis.⁽²⁸³⁾

A range of other SMS interventions were identified between the PRISMS review and the updated search, each comprising one systematic review per intervention. PRISMS found some evidence that stroke liaison, emphasising education and information, can have a positive impact on quality of life. However, based on the available evidence, it is not possible to draw conclusions in relation to the efficacy of other SMS interventions including stroke self-management programmes, psychosocial intervention, motivational interviewing, multidisciplinary care or family-orientated models of care in the management of post-stroke patients.

It would appear that the evidence should be somewhat applicable to the Irish healthcare setting given the description of the stroke patient populations and the healthcare systems in which the interventions were provided. A potential caveat to this assumption is the extent to which the intervention or comparator (usual care) in these RCTs is representative of usual care in Ireland. With 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, this assumption is not unreasonable in relation to acute post-stroke care. However, post-stroke rehabilitation services have historically been chronically under resourced in Ireland and lacked a coherent national strategy to guide their development.

The 2010 *Cost of Stroke in Ireland* report estimated that total direct and indirect stroke costs were between €489 million and €805 million in Ireland in 2007. Nursing home costs accounted for the largest proportion of total direct costs (greater than 60%), followed by hospital costs (greater than 15%, including inpatient rehabilitation) and drug costs (approximately 3%). The report highlighted the limited availability of national data on the proportion of patients receiving inpatient and community rehabilitation, thereby making it difficult to determine gaps in service provision.⁽²⁴⁷⁾ The HSE's National Clinical Programme for Rehabilitation Medicine was established in 2010 with an objective of extending access to specialist rehabilitation services for people with acquired disability (including stroke survivors) to enable them to maximise their ability, reduce their dependency, and increase societal participation. A model of care has been developed by the HSE that advocates a framework where patients are managed by specialist rehabilitation clinicians working as part of a managed clinical rehabilitation network (MCRN).⁽²⁸⁴⁾ Similar to the National Policy and Strategy for the Provision of Neuro-Rehabilitation services in Ireland published by the Department of Health in 2011,⁽²⁸⁵⁾ the draft model of care document identified key gaps in relation to the provision of supports in Ireland, specifically: an extensive shortage of key specialists involved in the provision of neurological rehabilitation services; a lack of: inpatient rehabilitation beds,

appropriate post-acute rehabilitation facilities, services in residential facilities and nursing homes and appropriate community rehabilitation; an absence of pathways to signpost appropriate services, and referral and transition processes; patchy access for patients to certain services determined by historical availability rather than clinical need; lengthy delays in effecting house adaptations; inadequate provision of essential aids, appliances and assistive technology. The proposed model of care outlines a blueprint for future provision of services that addresses these deficits.

Due to the volume of evidence available, and in the interest of efficiency, this assessment of SMS interventions in stroke survivors 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 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 this overview of reviews would be sufficient to substantially alter recommendations informing major policy decisions.

8.4.2 Cost-effectiveness

The four included studies provided very limited evidence regarding the costs or cost-effectiveness of self-management programmes for survivors of stroke. Only one of the studies could be considered to be high quality, although that study did not include any sensitivity analysis.

The studies gathered cost data as part of an RCT or non-randomised trial with relatively small sample sizes. A number of the studies were framed as exploratory or pilot studies, with three of the studies having samples sizes of between 28 and 30 patients. Where reported, the cost of the intervention was typically low, particularly relative to the overall cost of care. Whether costs would be similar in a programme rolled out to a larger population, or if economies of scale might apply, is unclear.

The periods of follow-up were typically short with the longest duration being 12 months. The length of follow up may have implications for estimates of both costs and clinical effectiveness. Longer-term evidence would be required to determine if benefits in intervention groups are sustained, and whether costs change over time.

Only one study was structured as a conventional economic evaluation.⁽²⁷⁸⁾ That study was based on a small RCT with eight months of follow-up and made a number of assumptions about clinical effectiveness that may not have been supported by the evidence. That study was also specific to stroke survivors with long-standing aphasia, which is estimated to affect approximately one in three people who survive stroke.

The best evidence was generated by the UK RCT of an exercise and education programme.⁽²⁷⁷⁾ That study used a relatively large sample size of 243 patients and collected follow-up data at 12 months. The study showed a statistically significant benefit of an individual's ability to reintegrate to a 'normal' lifestyle in terms of the Subjective Index of Physical and Social Outcome scale at 12 months and some evidence of benefit in terms of quality of life. It also showed that the cost of care was higher for the intervention group, which was only partly accounted for by the greater cost of the intervention itself.

In summary, there is very limited evidence on the cost-effectiveness of chronic disease SMS interventions for stroke survivors, which comprised results from a number of RCTs with typically small sample sizes and short follow-up periods. This is in contrast to the review of the clinical-effectiveness literature, which included 27 systematic reviews of 228 unique RCTs. The UK study of an exercise and education intervention may be applicable in an Irish setting.⁽²⁷⁷⁾ That study found the intervention resulted in improvements in the Subjective Index of Physical and Social Outcome scale. Costs associated with those in the intervention group were, on average, €1,108 higher over 12 months than for those in the control group. It is unlikely that the remaining three identified studies would be applicable to introducing a SMS programme for stroke survivors in Ireland.

8.5 Key points

- Twenty seven systematic reviews of self-management support interventions in adults with stroke were retrieved in this overview of reviews.
- A diverse range of heterogeneous interventions were identified, thereby making it difficult to categorise the results by intervention type. The largest volume of evidence (n=14) retrieved was for rehabilitation therapy (general rehabilitation therapy (n=9); virtual reality rehabilitation (n=4); and telerehabilitation (n=1). Three reviews assessed stroke self-management programmes and two assessed information provision. The remaining reviews assessed a range of interventions with one review per intervention type.
- The quality of the systematic reviews varied, with 10 rated as being higher quality reviews.
- The primary evidence underpinning the systematic reviews was found to be generally at moderate to high risk of bias, meaning that studies may have over- or under-estimated effect sizes. It comprised 228 unique randomised controlled trials published between 1981 and 2014.
- Based on the quantity and quality of the systematic reviews and the underpinning primary randomised controlled trials, there is good evidence that general rehabilitation therapy delivered in early stroke recovery has a positive

impact on activities of daily living and extended activities of daily living. Virtual reality-based rehabilitation improves upper limb function and activities of daily living when used as an add-on to usual care.

- Based on the available evidence, it is not possible to draw conclusions in relation to the effectiveness of self-management programmes delivered to post-stroke patients.
- There is some evidence that 'information provision' improves patient and carer knowledge of stroke, aspects of patient satisfaction, with small reductions (which may not be clinically significant) in patient depression scores.
- There is some evidence that stroke liaison emphasising education and information can have a positive impact on quality of life.
- Based on the available evidence, it is not possible to draw conclusions in relation to the effectiveness of psychosocial interventions, motivational interviewing, lifestyle interventions, multidisciplinary care or family-orientated models of care.
- There is very limited evidence on the cost-effectiveness of chronic disease self-management support interventions for stroke survivors with only four relevant studies retrieved. These were based on cost data collected alongside randomised controlled trials that used small sample sizes and short follow-up periods.
- Where reported, the cost of the self-management support interventions was typically low, particularly relative to the overall cost of care. However, it is unclear if costs would be similar when programmes are rolled out to a larger population or if economies of scale might apply. Longer-term evidence would be required to determine if benefits in intervention groups are sustained, and whether costs change over time.
- Based on the description of the healthcare systems, the epidemiology, and the stroke patient populations in the included studies, and assuming that what constitutes 'usual care' is similar in Western countries, the majority of findings of this overview of clinical effectiveness are expected to be applicable to the Irish healthcare setting, while results of only one cost-effectiveness study on exercise-based interventions was likely to be relevant.

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 to 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])
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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)
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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)
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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 A8 - Stroke

Table A8.1 Stroke — results of meta-analyses from PRISMS review and the systematic reviews from the updated search. Table adapted from the PRISMS review

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance ⁹	ES (95% CI)
Aziz (2008) ^{(265)**}	Rehabilitation therapy 1 year post stroke	1o ADL	3-12 months	5 RCTs; 487 participants	0	-
		Extended ADL			0	-
		QoL			0	-
		2o Mood			0	-
		Poor outcome(s) or death			+	0.32 95% CI (0.14 to 0.71) p= 0.03
Legg (2006) ^{(267)***}	OT rehabilitation	1o ADL	3-12 months	9 RCTs (8 relevant); 1,258 participants	++	Increased ADL scores (SMD 0.18, 95% CI 0.04 to 0.32; p= 0.01).
		Extended ADL			+	Increased extended ADL scores (SMD 0.21, 95% CI 0.03 to 0.39; p= 0.02).
		QoL			0	-
		2o Mood			0	-
		Poor outcome(s) or death			+	Reduction in odds of poor outcome or death (OR 0.67, 95% CI 0.51 to 0.87; p = 0.003). Reduction in odds of deterioration or death (OR 0.60, 95% CI 0.39 to 0.91; p = 0.02).
OST (2003) ^{(268)***}	Rehabilitation therapy for cognitive impairment	1o ADL	3-12 months	14 RCTs (11 relevant); 1,617 participants	+	Increased ADL scores (SMD 0.14, 95% CI 0.02 to 0.25; p= 0.02).
		Extended ADL			++	Increased extended ADL scores (SMD 0.17, 95% CI 0.04 to 0.30; p= 0.01).
		QoL			0	-
		2o Mood			0	-
		Service use			0	-
		Poor outcome(s) or death			++	Reduction in odds of a poor outcome or death (OR 0.72, 95% CI 0.57 to 0.92; p = 0.009)
Steultjens	OT rehabilitation	Comprehensive OT:	NR	18 RCTs (6	+	Small but significant ES on ADL (SMD 0.31, 95% CI

⁹ Significance 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.

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance ⁹	ES (95% CI)
(2003)***		1o ADL		relevant); 1,825 participants		0.03 to 0.60).
		Extended ADL			0	-
		Community reintegration			0	-
		Cognitive function: 1o ADL				-
		Training of skills:			0	-
		1o ADL			+	Significant effect on ADL in one study (SMD 0.46, 95% CI 0.05 to 0.87)
Walker (2004) ^{(271)***}	OT rehabilitation	1o ADL	End of intervention 1.25–6months. End of trial 4.5–12 months	8 RCTs; 1,143 participants	+	Positive effect on ADL (OR 0.71, 95% CI 0.52 to 0.98) at intervention end
		Extended ADL			+	Positive effect on extended ADL (WMD 1.30 points, 95% CI 0.47 to 2.13 points)
		Community reintegration			+	(WMD 1.51 points, 95% CI 0.24 to 2.79 points) at trial end
		2o Mood			0	
		Poor outcome(s) or death			0	
		OT emphasising ADL: 1o Extended ADL			+	Improved extended ADL (WMD 1.61 points, 95% CI 0.72 to 2.49 points).
		Community reintegration			0	
		OT emphasising leisure: 1o Extended ADL				
		Community reintegration			0	
					+	Improved community reintegration (WMD 1.96 points, 95% CI 0.27 to 3.66 points)
Ellis (2010) ^{(274)***}	Stroke liaison	1o ADL	NR	16 RCTs; 4,759 participants	0	
		Extended ADL			0	
		Community reintegration			0	
		QoL			0	
		2o Mood			0	
		Poor outcome(s) or death			0	
		Education and			+	Positive subgroup result for QoL (SMD -0.24, 95% CI -

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance ⁹	ES (95% CI)
		information emphasis: 1o QoL				0.44 to -0.04; p = 0.02)
		Barthel Index 15–19: 2o Poor outcome(s) or death			++	(mild to moderate disability): significant reduction in dependence (OR 0.62, 95% CI 0.44 to 0.87; p= 0.006), death or dependence (OR 0.55, 95% CI 0.38 to 0.81; p= 0.002). Significant subgroup heterogeneity found for Barthel Index 15–19 group (χ^2 p < 0.05)
Smith (2008) ^{(273)***}	Information provision	1o ADL	1 week–1 year	17 RCTs (9 relevant); 2,831 participants	0	
		Community reintegration			0	
		QoL			0	
		2o Mood			++	Clinically small evidence of benefit of information provision on depression scores (WMD -0.52, 95% CI - 0.10 to 0.93; p= 0.01, for continuous data outcomes). Active information vs. passive information: active information significantly more effective than passive for patient depression (p < 0.02 for trials reporting dichotomous or continuous data), and anxiety (p < 0.05 dichotomous data, p < 0.01 continuous data)
		Service use			0	
		Compliance			0	
		Poor outcome(s) or death			0	
HIQA studies						
Cheng (2014) ^{(259)**}	Psychosocial interventions for stroke family caregivers and stroke survivors	Psychosocial wellbeing: effects on caregivers burden	Immediately post-intervention – 4 months	2 RCTs, 1 quasi-RCT; 167 participants	0	SMD: 0.18, 95% CI: -0.13 to 0.48, p = 0.25
		Psychosocial wellbeing: caregiving competency			0	SMD: -0.09, 95% CI: -0.49 to 0.31, p = 0.66
		Psychosocial wellbeing: depression			0	SMD: 0.19, 95% CI: -0.11 to 0.48, p = 0.22
		Family functioning			+	SMD: -0.12, 95% CI: -0.23 to -0.01, p = 0.03

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance ⁹	ES (95% CI)
Forster (2012) ^{(258)***}	Information provision (update to Smith's CR above)	Patient knowledge	1 week to 1 year (NR in 4 RCTs)	participants		
		Patient knowledge		6 RCTs, 536 participants	++	SMD 0.29, 95% CI 0.12 to 0.46, P < 0.001
		Patient knowledge: Passive v active		4 RCTs (passive), 2 RCTs (active)	0	SMD 0.26, 95% CI 0.04 to 0.48, active: SMD 0.34, 95% CI 0.07 to 0.61, test for subgroup differences P = 0.65)
		Anxiety (dichotomised data)		6 RCTs, 681 participants	0	OR 0.89, 95% CI 0.57 to 1.38, P = 0.60
		Anxiety (continuous data)		7 RCTs, 720 participants	0	MD -0.34, 95% CI -1.17 to 0.50, P = 0.43
		Depression (dichotomised data)		8 RCTs, 956 participants	0	OR 0.90, 95% CI 0.61 to 1.32, P = 0.59
		Depression (continuous data)		7 RCTs, 720 participants	+	MD -0.52, 95% CI -0.93 to -0.10, P = 0.015
		Patient satisfaction with information about causes and nature of the stroke		5 RCTs, 541 participants	++	OR 2.07, 95% CI 1.33 to 3.23, P = 0.001
		Patient satisfaction with information about allowances and services		4 RCTs, 452 participants	0	OR 1.18, 95%CI 0.76 to 1.83, P = 0.46
		Patient satisfaction with information (causes and nature of stroke): Passive v active		5 RCTs, 541 participants	0	passive: OR 1.86, 95% CI 0.81 to 4.27; active: OR 2.16, 95% CI 1.28 to 3.67, test for subgroup differences P > 0.2
		Death		9 RCTs, 1553 participants	0	OR 0.86 95% CI 0.59 to 1.25, P = 0.43
		Carer knowledge		4 RCTs, 336 participants	+	SMD 0.74, 95% CI 0.06 to 1.43, P = 0.03
		Carer emotional outcome: Psychological distress (dichotomised data)		4 RCTs, 498 participants	0	OR 1.13, 95% CI 0.65 to 1.97, P = 0.65
		Carer satisfaction with information about recovery and rehabilitation		2 RCTs, 165 participants	0	OR 1.78, 95% CI 0.88 to 3.60, P = 0.11
Carer satisfaction with	3 RCTs, 214	0	OR 1.30, 95% CI 0.71 to 2.37, P = 0.39			

Reference and weighting outcome	Intervention and comparator	Outcome	Time (from initiation of intervention)	Sample size	Significance ⁹	ES (95% CI)
		information about allowances and services		participants		
Laver (2013) ^{(251)**}	Telerehabilitation (comparator: inperson rehabilitation (usual care) or no rehabilitation)	Independence in ADL	1-6 months	2 RCTs, 661 participants	0	Case management after discharge -telephone calls and home visits: SMD 0.00, 95% CI -0.15 to 0.15, p=0.99
		Upper limb function		2 RCTs, 46 participants	0	Computer software programme to retrain upper limb function: MD 3.65, 95% CI -0.26 to 7.57, p=0.067
Laver (2015) ^{(253)***}	Virtual reality rehabilitation (comparator: conventional therapy)	ADL outcome		8 RCTs; 253 participants	+++	SMD: 0.43, 95% CI: 0.18 to 0.69, p=0.00086. (Grade: very low)
		Upper limb function		12 RCTs; 397 participants	+	SMD: 0.29, 95% CI: 0.09 to 0.49, p=0.0048 (Grade: low)
		Grip strength		2 RCTs; 44 participants	0	MD: 3.55, 95% CI -0.20 to 7.30, p=0.063
		Gait speed		3 RCTs; 58 participants	0	MD: 0.07, 95% CI: -0.09 to 0.23, p=0.38 (Grade: very low)
		Global motor function		2 RCTs; 27 participants	0	SMD: 0.14 95% CI: -0.63 to 0.9, p= 0.73. (Grade: very low)
Lennon (2013) ^{(260)**}	Lifestyle interventions for secondary disease prevention	Mortality		8 RCTs; 2,478 participants	0	RR: 1.13 95% CI: 0.85–1.52, p=0.40
		CVD events		4 RCTs; 1,013 participants	0	RR:1.16 95% CI: 0.80–1.71, p=0.43
		Physical activity participation		5 RCTs; 657 participants	++	SMD: 0.24 95% CI: 0.08– 0.41, p=0.004
Zhang (2013) ^{(250)***}	Stroke rehabilitation in China	Functional outcome (changes in ADL: functional recovery expressed as a change in BI, Barthel Index)		31 RCTs; 5,220 participants	+++	SMD BI: 1.04 (95% CI: 0.88–1.21, P ≤0.001; (I ² = 85.9%; P < 0.001). WMD: 20.6 points (95% CI: 18.7–23.0, P < 0.001). It is noted that a 20-point improvement constitutes an improvement of 1/5th of the potential BI scale.
		Change in impairment (Fugl-Meyer Score, FMS)		27 RCTs; 4,501 participants.	+++	SMD: 1.10 (95% CI, 0.82–1.38, P < 0.001. (I ² = 94.3%; P < 0.001). WMD: 17.2 points (95%CI: 13.5–20.9, P <0.001), with high heterogeneity (I ² = 95.1%; P <0.001).

Key: 1o: Primary; 2o: Secondary; **ADL:** Activities of Daily Living; **BI:** Barthel Index; **CI:** Confidence Interval; **MD:** Mean Difference; **NR:** Not reported; **OR:** Odds Ratio; **RCT:** Randomised Controlled Trial; **SMD:** Standard Mean Difference; **WMD:** Weighted Mean Difference.

Table A8.2 Stroke — summary of results from systematic reviews, Table extracted from PRISMS review and systematic reviews from updated search

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author)
Aziz (2008) ^{(265)**}	Rehabilitation therapy one year post stroke	Meta-analysis	5 RCTs; 487 participants	Poor outcome(s) or death: The only positive finding is based on a single study: 0.32 95% CI (0.14 to 0.71) p= 0.03.	Inconclusive evidence whether or not therapy-based rehabilitation intervention one year post-stroke was able to influence any relevant patient outcome
Hoffman (2010) ^{(266)**}	OT rehabilitation for cognitive impairment	Narrative review	1 RCT (0 relevant); 33 participants	ADL: No significant findings to report.	There is a paucity of RCTs evaluating cognitive rehabilitation in stroke survivors as only one RCT was identified
Legg (2006) ^{(267)***}	OT rehabilitation	Meta-analysis	9 RCTs (8 relevant); 1,258 participants	ADL: Increased scores (SMD 0.18, 95% CI 0.04 to 0.32; p= 0.01). Extended ADL: Increased scores (SMD 0.21, 95% CI 0.03 to 0.39; p= 0.02). Poor outcome or death: Reduction in odds (OR 0.67, 95% CI 0.51 to 0.87; p = 0.003). Deterioration or death: Reduction in odds (OR 0.60, 95% CI 0.39 to 0.91; p = 0.02)	OT rehabilitation has positive outcomes on Extended ADL + personal ADL.
OST (2003) ^{(268)***}	Rehabilitation therapy for cognitive impairment	Meta-analysis	14 RCTs (11 relevant); 1,617 participants	ADL: Increased scores (SMD 0.14, 95% CI 0.02 to 0.25; p= 0.02). Extended ADL: Increased scores (SMD 0.17, 95% CI 0.04 to 0.30; p= 0.01). Poor outcome or death: Reduction in odds (OR 0.72, 95% CI 0.57 to 0.92; p = 0.009)	Both positive outcomes indicate therapy-based rehabilitation to have a positive effect on personal ADL.
Poulin (2012) ^{(269)**}	Rehabilitation therapy for cognitive impairment	Narrative review	3 RCTs (1 relevant); 109 participants	ADL: Positive effect on cognitive failures in daily living (ES=0.80; p=0.005). Extended ADL: Positive effect (p<0.01). More improvement in problem-solving self-efficacy for face-to-face training vs. intervention delivered via computer assisted training, or online through video conferencing (F=6.45; p=0.003). Positive effect on compliance in activities achieved (z=2.953, p=0.003)	All findings are based on a single study so are taken with caution. Strategy training is the only intervention which meets our definition of self-management support. The review offers some support for the effectiveness of strategy training on improving extended ADL. All RCTs involved individuals in the chronic phase of recovery, highlighting need for research into cognitive rehabilitation at early stages
Steultjens (2003) ^{(270)***}	OT rehabilitation	Meta-analysis	18 RCTs (6 relevant); 1,825	ADL: Comprehensive OT subgroup: small but significant ESs on ADL (SMD 0.31, 95% CI 0.03 to	Comprehensive OT (only subgroup we define as self-management support) positively affected more

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author)
		Narrative review	participants	0.60). ADL: Training of skills subgroup: significant effect on ADL in one study (SMD 0.46, 95% CI 0.05 to 0.87) Extended ADL: Significant effect on extended ADL in another study (SMD 2.29, 95% CI 1.26 to 3.32).	outcomes than any other subgroup. Outcomes reported for comprehensive OT are composite of six RCTs. Isolated OT elements were less effective than comprehensive OT; only training of skills found any beneficial effects based on single study so must be taken with caution. No RCTs explored education of family/caregivers by OT. Education provision is an important role of OT, but is unlikely to be done in isolation. This may explain the paucity of RCTs in this area.
Walker (2004) ^{(271)***}	OT rehabilitation	Meta-analysis	8 RCTs; 1,143 participants	ADL: Positive effect on ADL (OR 0.71, 95% CI 0.52 to 0.98) at intervention end. Extended ADL: Positive effect on extended ADL (WMD 1.30 points, 95% CI 0.47 to 2.13 points) Community reintegration: (WMD 1.51 points, 95% CI 0.24 to 2.79 points) at trial end. Extended ADL: OT emphasising ADL subgroup: improved extended ADL (WMD 1.61 points, 95% CI 0.72 to 2.49 points). Community reintegration: OT emphasising leisure subgroup: improved reintegration (WMD 1.96 points, 95% CI 0.27 to 3.66 points)	Effect of ADL-based intervention on extended ADL varied by patient age; older patients appeared to benefit more than younger ones (interaction term between age and intervention; $p = 0.01$). Patients with lower levels of dependency appeared to benefit more in leisure scores (WMD 2.86 points, 95% CI 0.70 to 5.02 points). Duration and intensity of intervention did not appear to mediate effect on primary outcome (data not shown). Review provides support for OT rehab, showing positive effects on extended ADL and leisure scores. Subgroup analysis highlights lack of applicability between OT interventions targeting ADL or leisure
Ellis (2010) ^{(274)***}	Stroke liaison	Meta-analysis	16 RCTs; 4759 participants		No positive overall effects were demonstrated for stroke liaison. Post-hoc analysis found positive effects for those individuals with mild to moderate disability.
Ko (2010)**	Patient-held medical records	N/A	0 RCTs; 0 participants	No RCTs were identified which studied the use of patient-held medical records in stroke survivors. This highlights an area of potential stroke self-management where more primary research is required.	
Korpershoek (2011) ^{(272)*}	Self-efficacy enhancing	Narrative review	4 RCTs (2 relevant); 630 participants	HRQoL: Significant positive effect on HRQoL outcomes, including mobility ($p < 0.01$), self-care ($p < 0.001$), thinking ($p < 0.01$) and social roles ($p < 0.001$). Computer generated tailored information: Anxiety scores changed significantly in favour of control (95% CI 0.2 to 2.8; $p = 0.03$)	Results must be taken with caution: each subgroup represents a single study. From descriptions provided by the review authors we can only be confident of chronic disease self-management course meeting our definition of self-management support. We reject information provision intervention as self-management support because it

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author)
					was a relatively passive intervention. The chronic disease self-management course shows positive results on a range of HRQoL outcomes, but results from one RCT must be interpreted with caution
Lui (2005) ^{(275)**}	Caregiver problem-solving	Narrative review	6 RCTs; 1679 participants	Community reintegration: Better patient adjustment at 12 months after stroke ($p < 0.01$). Improvement of social outcome in patients with mild disability at 6 months ($p = 0.03$)	Inconclusive evidence. The reported positive results represent only one study each. There is a paucity of evidence exploring caregiver problem-solving that report outcomes on stroke survivors (only three of six RCTs reported outcomes for stroke survivors)
Rae-Grant (2011)*	Self-management programmes	N/A	0 RCTs; 0 participants	No RCTs were identified. There is an absence of RCTs explicitly.	
Smith (2008) ^{(273)***}	Information provision	Meta-analysis	17 RCTs (9 relevant); 2831 participants	Depression: Clinically small evidence of benefit of information provision on depression scores (WMD – 0.52, 95% CI –0.10 to 0.93; $p = 0.01$, for continuous data outcomes) Active information significantly more effective than passive for patient depression ($p < 0.02$ for trials reporting dichotomous or continuous data), and anxiety ($p < 0.05$ dichotomous data, $p < 0.01$ continuous data)	We take active, but not passive, information provision to be self-management support. This review provides evidence that active information has a positive impact on anxiety and depression in stroke survivors
Cheng (2014) ^{(259)**}	Psychosocial interventions for stroke family caregivers and stroke survivors	Meta-analysis	18 RCTs; 3,559 participants	Family functioning: Pooled analysis of 2 individual psychoeducation programs showed a small effect on improving family functioning.	Evidence on effects of psychosocial interventions limited. More RCTs of multifaceted psychoeducation programs needed to further examine the optimal dose and format. Caregivers receiving psychoeducation that aimed at equipping caregivers with the skills of problem-solving, caregiving, and stress-coping appeared to have a more positive influence on the caregivers' psychosocial wellbeing and a reduced use of healthcare resources by stroke survivors.
		Narrative review		Hospital readmissions: Stroke survivors in social support group had significantly fewer hospital readmissions (66%) than control group ($p < 0.01$).	
		ED visits: Fewer stroke survivors in social support group visited ED within 12-months of intervention ($p < 0.01$).			
		Physician visits: Significantly fewer stroke survivors in psychoeducation group visited physicians at 3-months post-intervention ($p < 0.01$)			
				Placements in residential / nursing home:	

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author)
				Stroke survivors in individual psychoeducation group had significantly fewer placements in a residential or nursing care home ($p = 0.03$) at 11- months post-intervention. Remaining at home: More stroke survivors in psychoeducation group remained at home compared with control group ($p = 0.04$) at 2-years post-intervention.	
Cheng (2015) ^{(262)**}	Motivational interviewing (MI)	Narrative review	1 RCT, 411 participants	ADL, death rate, mood: No significant differences between groups receiving MI or usual stroke care for participants who were not dependent on others for ADL, nor on the death rate after 3- and 12-month follow-up, but participants receiving MI more likely to have normal mood than those who received usual care at 3- and 12-months follow-up.	There is insufficient evidence to support the use of MI for improving ADL after stroke. Further well designed RCTs are needed.
Dorstyn (2014) ^{(263)**}	Leisure therapy in community based stroke rehab	Narrative review	8 RCTs; 610 participants	QoL (SA-SIP): Treatment gains noted for psychological measures relating to QoL (difference = 2.10, 95% CI 0.84 - 3.37)) immediately post intervention. Medium effect. Mood – depression: Depression (Centre for Epidemiological Studies Depression Scale) produced a medium effect (difference = 0.54) in 1 RCT (95% CI 0.05 - 1.03). Medium effect. Leisure activity: difference range, 0.81 to 1.23) following 2 individually delivered leisure programmes Mobility & independence: difference = -0.51, 95% CI -0.95 -0.07. Negative effect. Longer-term effects of leisure therapy: non-significant treatment effects (difference range, -0.07 to 0.13) across individual measures of mood and physical functioning at 6 months following an active leisure rehabilitation program. Large effect.	The findings of this systematic review are promising and show that leisure therapy helps to optimise the short-term psychological and leisure outcomes of adults who have sustained a stroke. Only 1 RCT assessed effect in longer term (6 months) with no effect.
Fens (2013) ^{(264)**}	Multidisciplinary care delivered to stroke patients	Narrative review	14 RCTs; 2,389 participants	ADL: None of the studies found an effect of the intervention on daily activities. QoL: 2 RCTs reported favourable effects of the	The definition of usual care differed considerably between studies, such as outpatient rehabilitation at a day clinic, inpatient case management, care

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author)
	living in the community			intervention on QoL. SA-SIP30: Experimental group: 0.8 (SD –), Control:0.71 (SD –) (Significant difference) EQ-5D: Experimental group: 0.71 (IQR 0.59–0.81, Control: 0.54 (IQR 0.26–0.73) (Significant difference).	from a GP, home care services with non-professional support or a service information pack. Little evidence for effectiveness of multidisciplinary care for stroke patients being discharged home. Additional research should provide more insight into potentially effective multidisciplinary care for community living stroke patients.
Forster (2012) ⁽²⁵⁸⁾ ***	Information provision	Meta-analysis	21 RCTs; 3,579 participants (2,289 patient; 1,290 carers)	Patient knowledge, carer knowledge, patient satisfaction, patient depression: Meta-analyses showed a significant effect in favour of intervention on patient knowledge, carer knowledge, one aspect of patient satisfaction, and patient depression scores. There was no significant effect (P > 0.05) on number of cases of anxiety or depression in patients, carer mood or satisfaction, or death.	There is evidence that information improves patient and carer knowledge of stroke, aspects of patient satisfaction, and reduces patient depression scores. However, the reduction in depression scores was small and may not be clinically significant. Although the best way to provide information is still unclear there is some evidence that strategies that actively involve patients and carers and include planned follow-up for clarification and reinforcement have a greater effect on patient mood.
		Narrative review		Qualitative analyses found no strong evidence of an effect on other outcomes.	
Laver (2013) ⁽²⁵¹⁾ **	Telerehabilitation (comparator: in-person rehabilitation (usual care) or no rehabilitation)	Meta-analysis	10 RCTs; 933 participants	ADL: no statistically significant results for independence in ADL (2 studies, 661 participants) were noted when a case management intervention was evaluated. Upper limb function: No statistically significant results (2 studies, 46 participants) were observed when a computer programme was used to remotely retrain upper limb function. HRQoL / patient satisfaction: Evidence was insufficient to draw conclusions on effects of intervention on mobility, HRQoL or participant satisfaction with the intervention.	We found insufficient evidence to reach conclusions about the effectiveness of telerehabilitation after stroke. Which intervention approaches are most appropriately adapted to a telerehabilitation approach remain unclear, as does the best way to utilise this approach.
		Narrative		Participant satisfaction: No significant differences between intervention and control groups. Self-reported HRQoL: 1 study reported that people in the intervention group were more likely to respond to one or more of the outcomes within the SF-36 subscales (OR: 1.41, 95% CI 1.11 to 1.79).	

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author)
Laver (2015) ⁽²⁵³⁾ ***	Virtual reality rehabilitation (comparator: conventional therapy)	Meta-analysis	37 RCT; 1,019 participants	Upper limb function: Results were statistically significant for upper limb function. Grip strength, gait speed, global motor function: There were no statistically significant effects for grip strength, gait speed or global motor function. ADL: Results were statistically significant for ADL.	We found evidence that the use of virtual reality and interactive video gaming may be beneficial in improving upper limb function and ADL function when used as an adjunct to usual care (to increase overall therapy time) or when compared with the same dose of conventional therapy. There was insufficient evidence to reach conclusions about the effect of virtual reality and interactive video gaming on grip strength, gait speed or global motor function. It is unclear at present which characteristics of virtual reality are most important and it is unknown whether effects are sustained in the longer term. There were few adverse events reported across studies and those reported were relatively mild.
Lennon (2013) ⁽²⁴⁹⁾ **	Self-management programmes	Narrative review	9 RCTs; 1,191 participants	Statistically significant improvement over the control group in measures of: disability and confidence in recovery (n=1 RCT); the stroke-specific QoL sub-scales of family roles (p < 0.010) and fine motor tasks (p < 0.05) (n=1); stroke knowledge (n=1); the physical component summary of the HRQoL and the Modified Rankin (n=1).	Significant treatment effects in favour of the self-management intervention were found in 6/9 RCTs in this review. However, 2 of these were based on the CCM with no reference to SMS and 2 were not compared to 'usual care'. Randomised controlled studies in this review rated from poor to moderate quality.
Lennon (2013) ⁽²⁶⁰⁾ **	Lifestyle interventions for secondary disease prevention	Meta-analysis	17 RCTs; 7,742 participants	Physical activity participation: SMD: 0.24 95% CI: 0.08– 0.41, p=0.004. Mortality, CVD events, physical activity participation: No significant difference	There is currently insufficient high quality research to support lifestyle interventions post-stroke or TIA on mortality, CVD event rates and cardio-metabolic risk factor profiles. Promising blood pressure reductions were noted in multimodal interventions which addressed lifestyle.
Vallury (2015) ⁽²⁶¹⁾ ***	Family-oriented interventions reduce post-stroke depression	Narrative review	22 RCTs; >3,739 participants	Depression: Only five of 22 RCTs reported statistically significant reductions in post-stroke depression among stroke survivors.	Family-oriented models of care can be effective in reducing depression in patients and their caregivers post-stroke. Four reported improved PSD outcomes in stroke survivors only and one had positive impacts on depression for both stroke survivors and their family caregivers.
Warner (2015) ⁽²⁵⁷⁾ **	SM Programmes	Narrative review	6 RCTs; only results included	No significant differences in 2 RCTs. Statistically significant difference between intervention (based on	Conclusions are based on a range of study types so are not included here.

Reference and weighting outcome	Focus	Synthesis	RCTs, n; Participants, n; date range	Main results	Main conclusions (review author)
			for 3 RCTs in addition to Lennon (2013) above.	Orem) and control in function (FIM) from baseline to 6-month assessment. Also significant differences in global assessment of health, adherence, and psychosocial symptoms.	
Zhang (2013) ^{(250)***}	Stroke rehabilitation in China	Meta-analysis	37 RCTs; 5,916 participants	<p>Functional outcome: SMD BI: 1.04 (95% CI: 0.88–1.21, $P \leq 0.001$; $I^2 = 85.9\%$; $P < 0.001$). WMD: 20.6 points (95% CI: 18.7–23.0, $P < 0.001$). It is noted that a 20-point improvement constitutes an improvement of 1/5th of the potential BI scale.</p> <p>Change in impairment: SMD: 1.10 (95% CI, 0.82–1.38, $P < 0.001$. ($I^2 = 94.3\%$; $P < 0.001$). WMD: 17.2 points (95%CI: 13.5–20.9, $P < 0.001$), with high heterogeneity ($I^2 = 95.1\%$; $P < 0.001$).</p>	<p>Data provide some evidence that rehabilitation post-stroke is more effective than no rehabilitation, improving ADL and reducing disability. Although results are limited by low reporting quality and study heterogeneity, conducting research in countries in which rehabilitation is not standard care provides an opportunity to advance our understanding and should be encouraged.</p> <p>There were insufficient data reported on adverse events, deaths, or institutionalisation to allow separate analyses of these variables.</p> <p>The rehabilitation interventions in the Chinese RCTs were often not well described. Many of the trials included also incorporated traditional Chinese therapies such as acupuncture as part of the rehabilitation package.</p>

Key_1o: Primary; **2o:** Secondary; **ADL:** Activities of Daily Living; **BI:** Barthel Index; **CI:** Confidence Interval; **MD:** Mean Difference; **NR:** Not reported; **OR:** Odds Ratio; **RCT:** Randomised Controlled Trial; **SMD:** Standard Mean Difference; **WMD:** Weighted Mean Difference;

Table A8.3. CEA Studies investigating exercise-based programmes

Study	Study design	Intervention	Comparators	Population	Findings
Huijbregts (2008)⁽²⁷⁶⁾	Non-randomised trial-based costing study with 6 months follow-up (n=30).	Self-management programme with land and water exercise.	Standard education programme.	Stroke survivors at least 3 months post stroke, had completed all active stroke rehabilitation. Mean age 68 years.	<p>The intervention group showed significant improvements in balance. Differences between intervention and control were not significant.</p> <p>The intervention cost \$384 (€313) per person while routine care cost \$105 (€86) per person.</p>
Harrington (2010)⁽²⁷⁷⁾	RCT-based costing study with 12 months follow-up (n=243).	Exercise and education programme.	Routine care.	Stroke survivors at least 50 years old at time of stroke and had returned to living in the community for at least 3 months. Mean age 70 years.	<p>Significant differences between groups on SIPSO scale.</p> <p>The intervention cost £250 (€371) per person while routine care cost £99 (€174) per person.</p> <p>Participants in the intervention group cost on average £746 (€1,108) (95% CI – £432 to £924) more to care for than those in the control group.</p>

Abbreviations: RCT, randomised controlled trial; SIPSO, Subjective Index of Physical and Social Outcome.

Table A8.4 CEA Studies investigating computer-based rehabilitation therapy

Study	Study design	Intervention	Comparators	Population	Findings
Latimer (2013) ⁽²⁷⁸⁾	Decision analytic model based on RCT data with 8 months follow-up (n=28).	Self-managed computer therapy.	Routine care (general language stimulation).	Stroke survivors with long-standing aphasia experiencing word-finding difficulties. Mean age 68 years.	<p>The QALYS were 3.07 for controls and 3.22 for intervention, which resulted in an incremental QALY increase of 0.14.</p> <p>The total cost was £18,687 (€25,036) for controls and £19,124 (€25,621) for intervention participants.</p> <p>The intervention had an ICER of £3,058 (€4,097) compared with usual care. The likelihood of the intervention being cost-effective was 75.8 percent at a cost-effectiveness threshold of £20,000 per QALY gained.</p>
Llorens (2015) ⁽²⁷⁹⁾	RCT-based costing study with 3 months follow-up (n=30).	Home-based virtual reality telerehabilitation.	Clinic-based virtual reality telerehabilitation.	Stroke survivors with residual hemiparesis aged 40 to 75 years and at least 6 months post-stroke. Mean age 56 years.	<p>Both intervention and control groups showed significant improvements in balance. No significant differences were found between the groups.</p> <p>The mean cost per participant was \$836 (€820) for the intervention, and \$1,490 (€1,461) for controls.</p> <p>Home-based virtual reality telerehabilitation may be less costly and as effective as a clinic-based programme.</p>

Abbreviations: RCT, randomised controlled trial; QALY, quality-adjusted life year.

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