

## What is the evidence for the effectiveness, appropriateness and feasibility of group clinics for patients with chronic conditions? A systematic review

*Andrew Booth, Anna Cantrell, Louise Preston,  
Duncan Chambers and Elizabeth Goyder*



***National Institute for  
Health Research***



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# Abstract

## What is the evidence for the effectiveness, appropriateness and feasibility of group clinics for patients with chronic conditions? A systematic review

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**Background:** Group clinics are a form of delivering specialist-led care in groups rather than in individual consultations.

**Objective:** To examine the evidence for the use of group clinics for patients with chronic health conditions.

**Design:** A systematic review of evidence from randomised controlled trials (RCTs) supplemented by qualitative studies, cost studies and UK initiatives.

**Data sources:** We searched MEDLINE, EMBASE, The Cochrane Library, Web of Science and Cumulative Index to Nursing and Allied Health Literature from 1999 to 2014. Systematic reviews and RCTs were eligible for inclusion. Additional searches were performed to identify qualitative studies, studies reporting costs and evidence specific to UK settings.

**Review methods:** Data were extracted for all included systematic reviews, RCTs and qualitative studies using a standardised form. Quality assessment was performed for systematic reviews, RCTs and qualitative studies. UK studies were included regardless of the quality or level of reporting. Tabulation of the extracted data informed a narrative synthesis. We did not attempt to synthesise quantitative data through formal meta-analysis. However, given the predominance of studies of group clinics for diabetes, using common biomedical outcomes, this subset was subject to quantitative analysis.

**Results:** Thirteen systematic reviews and 22 RCT studies met the inclusion criteria. These were supplemented by 12 qualitative papers (10 studies), four surveys and eight papers examining costs. Thirteen papers reported on 12 UK initiatives. With 82 papers covering 69 different studies, this constituted the most comprehensive coverage of the evidence base to date. Disease-specific outcomes – the large majority of RCTs examined group clinic approaches to diabetes. Other conditions included hypertension/heart failure and neuromuscular conditions. The most commonly measured outcomes for diabetes were glycated haemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>), blood pressure and cholesterol. Group clinic approaches improved HbA<sub>1c</sub> and improved systolic blood pressure but did not improve low-density lipoprotein cholesterol. A significant effect was found for disease-specific quality of life in a few studies. No other outcome measure showed a consistent effect in favour of group clinics. Recent RCTs largely confirm previous findings. Health services outcomes – the evidence on costs and feasibility was equivocal. No rigorous evaluation of group clinics has been conducted in a UK setting. A good-quality qualitative study from the UK highlighted factors such as the physical space and a flexible appointment system as being important to patients. The views and attitudes of those who dislike group clinic provision are poorly represented. Little attention has been directed at the needs of people from ethnic minorities. The review team identified significant weaknesses in the included research. Potential selection bias limits the generalisability of the results. Many patients who could potentially be included do not consent to the group approach. Attendance is often interpreted liberally.

**Limitations:** This telescoped review, conducted within half the time period of a conventional systematic review, sought breadth in covering feasibility, appropriateness and meaningfulness in addition to effectiveness and cost-effectiveness and utilised several rapid-review methods. It focused on the contribution of recently published evidence from RCTs to the existing evidence base. It did not reanalyse trials covered in previous reviews. Following rapid review methods, we did not perform independent double data extraction and quality assessment.

**Conclusions:** Although there is consistent and promising evidence for an effect of group clinics for some biomedical measures, this effect does not extend across all outcomes. Much of the evidence was derived from the USA. It is important to engage with UK stakeholders to identify NHS considerations relating to the implementation of group clinic approaches.

**Future work:** The review team identified three research priorities: (1) more UK-centred evaluations using rigorous research designs and economic models with robust components; (2) clearer delineation of individual components within different models of group clinic delivery; and (3) clarification of the circumstances under which group clinics present an appropriate alternative to an individual consultation.

**Funding:** The National Institute for Health Research Health Services and Delivery Research programme.



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## List of abbreviations

ADL	activity of daily living	GMA	group medical appointment
AIDS	acquired immunodeficiency syndrome	GMV	group medical visit
BMI	body mass index	HbA <sub>1c</sub>	glycated haemoglobin A <sub>1c</sub>
CADTH	Canadian Agency for Drugs and Technologies in Health	HDL	high-density lipoprotein
CASP	Critical Appraisal Skills Programme	HIV	human immunodeficiency virus
CHCC	co-operative health-care clinic	HSDR	Health Services and Delivery Research
CI	confidence interval	INR	international normalised ratio
CINAHL	Cumulative Index to Nursing and Allied Health Literature	LDL	low-density lipoprotein
COPD	chronic obstructive pulmonary disease	MeSH	medical subject heading
CRD	Centre for Reviews and Dissemination	PICO	population–intervention–comparison–outcome
DARE	Database of Abstracts of Reviews of Effects	PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
DIGMA	drop-in group medical appointment	RCT	randomised controlled trial
DMARD	disease-modifying antirheumatic drug	SCHARR	School for Health and Related Research
FAME	feasibility, appropriateness, meaningfulness, effectiveness	SMA	shared medical appointment



## Plain English summary

**G**roup clinics deliver care to small groups of patients with the same condition at the same time rather than each patient meeting a doctor on a one-to-one basis. We wanted to find out whether or not group clinics worked better and were a better use of resources than one-to-one appointments. We also wanted to find out what patients and health professionals thought about group clinics.

We have assembled the largest number of relevant studies to date (82 papers reporting 69 research projects). We looked at research about people with long-term conditions only (e.g. diabetes or heart disease). We focused on how people manage their condition and not on using a group setting for teaching.

Most research focused on people with diabetes. We found that group clinics were better than individual appointments for improving some measures of how well diabetes is controlled. Group clinics also improved the quality of life of patients. However, we did not find any other improvements for patients. Patients and health professionals tend to view group clinics positively. However, the research did not tell us much about the views of people who disliked group clinics. Several studies looked at whether or not group clinics save money but the results were unclear. Although we were interested in group clinics as an alternative to one-to-one appointments, most studies combined group approaches with an individual consultation. Most studies took place in the USA. More research is needed to see whether or not group clinics are acceptable and good value for money in the NHS.





# Scientific summary

## Background

Group clinics are a form of delivering specialist-led care in groups rather than in individual consultations. They may include aspects of clinical management as well as patient education and support. Group clinics have been suggested as a way to replace individual patient consultations with a group session focused on the management of an ongoing condition and advice. Synonyms for group clinics include group medical appointments, drop-in group medical appointments, shared medical appointments, group visits and cluster visits. In the UK, interest in group clinics is linked to a wider concern about modernising outpatient services, which account for over 90 million episodes every year and increase year on year.

## Theoretical considerations

We found supporting evidence for many candidate programme theories to explain how and why patients might benefit by attending group clinics. Particularly influential high-level theories reflected in the published accounts included social cognitive theory, social comparison theory and social learning theory. Of particular value to understanding group clinic dynamics were theories relating to the core components of chronic disease self-management developed by Corbin and Strauss and the five core self-management skills identified by Lorig and Holman: problem-solving, decision-making, appropriate resource utilisation, forming a partnership with a health-care provider and taking necessary actions. Opportunities for a partnership of clinician and patient to use all of these skills are evidenced in the standard group clinic format.

In the UK, there is little published evidence on the impact and a lack of good-quality information on the range and scale of group clinic activity in different specialties. A systematic review is needed to combine published evidence of different types, including descriptive or qualitative studies, with grey literature.

## Objective

To examine the evidence for the use of group clinics in patients who have chronic health conditions.

The review question is:

- What is the current evidence for the feasibility, appropriateness, meaningfulness, clinical effectiveness and cost-effectiveness of group clinics/group medical visits (GMVs) for patients with chronic conditions?

Specifically:

- What different models of group clinic exist (in the UK and internationally)?
- What evidence exists about the outcomes and cost-effectiveness of these clinics?
- What evidence exists about patient experience of these clinics?
- What are the possible explanatory mechanisms for any reported improvements in outcomes?

## Methods

### *Data sources*

We searched MEDLINE, EMBASE, The Cochrane Library, Web of Science and Cumulative Index to Nursing and Allied Health Literature from 1999 to 2014. Systematic reviews and randomised controlled trials (RCTs) were eligible for inclusion. Additional searches were performed to identify qualitative studies, studies reporting on costs and evidence specific to UK settings. UK studies were included regardless of the quality or level of reporting.

### *Study selection*

We sought to differentiate a group clinic from group educational interventions that are common in chronic disease management. To define inclusion in our review we required that a participating clinician do more than simply fill an educational or a facilitative role. Our focus on chronic disease meant that we excluded numerous studies of group clinics for pregnant women and for smoking cessation. We included group clinics for inherited metabolic disease because of their long-term disease management implications. Detailed inclusion and exclusion criteria for the review were as follows.

### **Population**

Adults and/or children receiving health-care services for one or more chronic health condition. We excluded visits for healthy patient groups (i.e. those without an indication related to a chronic health condition). This exclusion covers pregnant women and women planning a pregnancy (unless they also had a chronic health condition such as diabetes), as well as smoking cessation and other health promotion clinics.

### **Intervention**

Delivery of one or more services to a small group of patients (typically 8–10 patients) simultaneously. Only studies including the delivery of the intervention by one or more specialist health-care professionals met the inclusion criteria of the review. We excluded delivery of intervention by peers or non-specialist health-care professionals. We also excluded peer-facilitated support groups, as the intervention in these cases is not principally delivered by health-care professionals (although they may contribute).

### **Comparison**

Other methods of organisation of treatment (with the exception of qualitative research and surveys, only studies with a comparator group are included).

### **Outcomes**

Patient outcomes, health services outcomes, patient and carer satisfaction, and resource use.

Search results were sifted and studies were selected for inclusion by one reviewer. Where there was doubt about inclusion, a second reviewer independently examined the full text.

### *Data extraction*

Formal data extraction was employed for all included systematic reviews, RCTs and qualitative studies. Data extraction was undertaken by three reviewers using a standardised form. Quality assessment was performed for RCTs and qualitative studies. For the RCTs we used the Critical Appraisal Skills Programme (CASP) checklist for RCTs and the Cochrane risk of bias tables, and for the qualitative research we used the CASP checklist for qualitative studies. Assessment of the limitations of included studies was also undertaken using the limitations reported by study authors in the included studies.

## Data synthesis

Data were extracted and tabulated. This tabulation was used to inform a narrative synthesis. There was no attempt to synthesise quantitative data through formal meta-analysis given the heterogeneity of disease conditions and models of service delivery for group clinics. However, given the predominance of studies of group clinics in the context of diabetes and the use of common biomedical outcomes, this large group of studies was subject to quantitative analysis. For literature that made a conceptual contribution, a method known as best-fit framework synthesis was used, which involved the extraction of data against a pre-existing framework. The review provides an analysis of the quality of evidence and the strength of conclusions that can be drawn from existing studies.

## Results

### Effectiveness

A total of 13 systematic reviews and 22 RCTs (32 papers) met the inclusion criteria. This evidence base was supplemented by 12 qualitative studies, four surveys and eight papers examining costs and other economic issues. Thirteen papers reported on 12 UK initiatives.

Thirteen systematic reviews reported on multiple variations of GMVs. Twelve reviews were analysed in detail and one was available only in summary form. One further review is only at the protocol stage. The majority of reviews were disease specific, primarily with a focus on diabetes. Most included studies were performed in the USA. Reviews of diabetes reported a consistent effect of group clinics in improving glycated haemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) and systolic blood pressure. A significant effect was also found for disease-specific quality of life in a few studies. No other outcome measure showed a significant and consistent effect in favour of group clinics. Many reviews commented that the heterogeneity of group clinic interventions made it problematic to classify such initiatives, to isolate the effects of specific intervention components and, consequently, to evaluate the intervention's effects.

Recent RCTs supplementing published systematic reviews largely confirm previous findings. Eight reports of seven RCTs have been published between 2012 and 2014 to add to 15 RCTs (24 reports) previously available in existing reviews, making this the largest review to date focused on group clinics. Three of these reports supplement existing meta-analyses. Two of these reports confirm previous findings of a significant effect for improved HbA<sub>1c</sub> and systolic blood pressure associated with the use of group clinics in diabetes. One new trial found a significant effect for total cholesterol and low-density lipoprotein cholesterol but this was not consistent with previous meta-analyses and unlikely to overturn the finding of no overall significant effect.

### Qualitative studies

Qualitative research found that patients appreciate many of the features of group clinics, including socialisation, normalisation and information sharing. Clinicians appreciated the opportunity to informally monitor patients and to gain a better understanding of practical threats to treatment adherence. Again, studies from the USA were dominant, with other studies being conducted in Canada, the Netherlands and the UK (one study, two papers). Generally, the qualitative studies were of low quality, with only 5 of the 12 studies using recognised methods of both qualitative data collection and analysis.

### Costs and cost-effectiveness

Of the eight papers that provided evidence on costs, seven reported studies performed in the USA and one reported on a study in Italy. The conditions covered were diabetes, comorbid diabetes with hypertension and complex behavioural health and medical needs. This heterogeneous set of studies showed mixed effects of group clinic interventions on costs. Furthermore, certain costs were not explicitly identified in the included studies. For example, it is likely that a group clinic intervention may require specialist training of health-care staff, particularly in relation to facilitation skills.

### **Evidence from the UK**

Of the 13 papers describing group clinic initiatives in the UK, none represented evidence from rigorously conducted experimental studies. Descriptions of several initiatives were available only as abstracts. One study found that acceptability of group clinics was high among patients undergoing acupuncture for knee osteoarthritis. However, the sensitivity of health and lifestyle topics is not a key issue for this particular population. Even in this context there was an expressed demand for single-sex sessions, including in a Muslim population.

A good-quality qualitative study from the UK highlighted the importance of factors such as physical space and a flexible appointment system. The views and attitudes of those who feel that group clinic provision is unacceptable, inappropriate or not feasible were relatively poorly represented and little attention has been directed at the specific needs of those patients from ethnic minorities. Patients for whom group clinic sessions may not be appropriate include those with complex conditions and those with severe pain.

### **Conclusions**

Although there is consistent and promising evidence for an effect of group clinics for some biomedical measures, this evidence does not extend to other measures such as control of cholesterol. Disease-specific quality of life improved significantly in a small number of studies but the effects were less marked for generic health-related quality of life. Much of the evidence was derived from the USA and it will be important to engage with UK stakeholders and identify specific NHS considerations when considering issues relating to the implementation of the group clinic model.

### **Recommendations for research**

A full economic evaluation of group clinics is recommended. This should accommodate data such as the type of clinician delivering the intervention and how long each clinic lasts to derive a richer picture of the costs of group clinics. Primary research that gathers information on the running of group clinics and potential cost savings in the UK NHS context would be particularly valuable.

### **Funding**

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# Chapter 1 Background

## Chronic disease in the UK

Chronic conditions and diseases are the leading causes of mortality and morbidity in Europe. Complex conditions such as diabetes and depression continue to impose an ever-increasing health burden on societies across Europe. The World Health Organization's 'Global Burden of Disease' study estimated that, as of 2002, chronic or non-communicable conditions accounted for 87% of deaths in high-income countries.<sup>1</sup>

More than 15.4 million people in England are living with one or more long-term conditions.<sup>2</sup> Research by The King's Fund estimates that the average cost per year of treatment for a person with a single long-term condition in the health and social care system is £1000, and this rises to £3000 and £8000 for those with two or three conditions respectively.<sup>3</sup> By 2018 the number of people with three or more long-term conditions is predicted to rise from 1.9 million (2008) to 2.9 million (2018).<sup>3</sup> People with long-term conditions account for 50% of all general practitioner appointments, 64% of outpatient appointments and 70% of all inpatient bed-days.<sup>3</sup> In total, around 70% of the total health and care spend in England (£7 out of every £10) is attributed to caring for people with long-term conditions. The prevalence, morbidity and mortality from chronic diseases are expected to rise, especially in countries with rapidly ageing populations.<sup>4</sup>

Patients with chronic diseases require intense patient education, counselling, lifestyle modification and complicated pharmacological management, all of which consume a significant amount of service delivery time. These interventions are difficult to achieve in the current health-care system, where less time per patient visit is a result of increasing numbers of patients seen per day. Historically, the medical model is focused on the treatment of acute episodic health problems, and hospital facilities are correspondingly poorer equipped to handle chronically ill patients who require complex services.<sup>5</sup>

Chronic care was explicitly recognised as a priority in 2004 in the NHS Improvement Plan.<sup>6</sup> The plan set out the government's priority to improve care for people with long-term conditions by moving from reactive care towards a systematic, patient-centred approach.

*Supporting People with Long-Term Conditions* in 2005 outlined a new NHS and social care model for the care of people with long-term conditions.<sup>7</sup> It aimed to match support with need, providing personalised yet systematic health and social care to people with chronic conditions. The model categorised patients according to their level of need:

- **supported self-care** for the 80% of patients with a long-term condition who, given sufficient support, can care for themselves and their condition effectively
- **disease-specific care management** for patients with a complex single need or multiple conditions which require responsive, specialist services using multidisciplinary teams and disease-specific protocols and pathways
- **case management** for the most vulnerable people, who have highly complex, multiple long-term conditions and who require co-ordinated health and social care provision.

## What are group clinic approaches?

Group clinics are a form of delivering specialist-led care in groups rather than in individual consultations. They may include aspects of clinical management (e.g. adjusting medication in the light of health status information) as well as patient education and support. The innovative nature of group clinics, particularly as a potential vehicle for improving the maintenance and care of patients with chronic conditions (e.g. diabetes,

asthma, urological conditions and coronary disease), coupled with a need to use available resources more efficiently and the perception that the organisation of group clinics requires only modest scale redesign,<sup>8</sup> has stimulated much evaluation activity. Over the past decade, several models for group medical visits (GMVs) have emerged, mainly in managed care environments. Some of these models originated in the care of the frail elderly, a population that suffers from many chronic illnesses and comorbidities. These models have been widely used in the USA, largely for people with long-term conditions. Early findings suggested potential for considerable cost savings, equivalent or improved outcomes and higher levels of patient/staff satisfaction. Later studies have not always replicated these effects. The terminology of group clinic approaches includes 'group visits', 'shared medical appointments' (SMAs), 'cluster visits' and 'problem-solving DIGMA' (drop-in group medical appointments).<sup>9,10</sup> The four principal conceptual models of group clinic approaches are reviewed later in this chapter, alongside a variety of terms and variants.

Although the literature reflects considerable variation, both in what is understood by a 'group clinic' and in the terminology associated with such initiatives, the following vignette (*Box 1*) seeks to broadly characterise how group clinics are depicted in the professional literature.

#### BOX 1 Vignette characterising group clinic approaches

For a group clinic approach, between 3 and 20 patients with a chronic medical condition get together with one or more clinicians to share information about how to manage their disease. Typically led by a physician and/or a specialist nurse, group clinics are often supported by the involvement of a medical assistant or nurse. Other participating professionals may include a social worker, a pharmacist or a mental health professional. Patients typically learn together, so, for example, diabetics could learn together how to conduct a foot check correctly and heart patients might take their own blood pressure readings. Educational sessions may follow a set session schedule or may be offered in response to previously identified needs as expressed by the group. Typically there is an opportunity to review current medication. Patients often have the additional opportunity to meet individually with a consultant for a one-to-one consultation. Patients thus feel that they are receiving appropriate care and attention within the group appointment setting. In turn, nurses value the chance to spend more time with their patients and the apparent efficiency of being able to reach several patients at once. A typical group clinic session lasts somewhere between 60 and 150 minutes.

Most group clinic approaches include an element of between-visit care co-ordination and case management, typically provided by a nurse or nurse practitioner. Setting up a limited element of care co-ordination for attendees of group visits may trigger distal benefits in relation to improved record-keeping and co-ordination of care.

Group clinic approaches may either replace or supplement usual one-on-one care. Group clinic approaches should be distinguished from more narrowly defined group education classes, which address self-management skills, exercise and nutrition but do not provide medical evaluation, medication adjustment or the co-ordination and delivery of preventative services. Group clinic approaches typically include group education, shared problem-solving, focused private or semiprivate medical evaluations that allow individualised medication adjustment, and ordering of preventative services and referrals. One attraction for patients lies in the potential for group visits to improve access, interaction with clinicians, between-patient learning and self-efficacy.

A group clinic appointment, therefore, differs from an individual consultation in that some information giving, which would typically take place within the consultation, is activated within a group setting. In addition, the group context may facilitate collective problem-solving, peer support and the identification of positive, or at the very least realistic, role models. Peer support may be instrumental (in providing practical tips and resources), cognitive (in addressing individual uncertainties) and/or affective (in providing reassurance and a sense of solidarity and mutual support).

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Based on Davis *et al.*<sup>8</sup>

The vignette in *Box 2* embodies several assumptions, articulated in the literature, that are to be tested within this review, most notably in relation to patient and staff satisfaction and efficiency. The attractiveness of group clinics as a viable service delivery option is also founded on implicit assumptions of acceptability and feasibility.

## Potential drivers for group clinics

We have identified four principal drivers for the introduction of group clinic-type interventions:

- A **substitution** argument maintains that group clinics may be used to mitigate the supply of and demand for individual consultations without compromising continuity of care.
- A **quality of care** argument claims that group clinics result in better self-management behaviours, particularly with regard to the management of chronic symptoms.
- An **acceptability** argument affirms that patients are at least as likely to be satisfied with care provided via group clinic arrangements as they would be with individualised consultations.
- An **enhancement** model rehearses the benefits of integrating group clinic-type approaches into existing group educational provision for chronic disease where this is currently taking place.

Group clinics are used to replace either an individual patient consultation or, more commonly, pre-identified components of the consultation such as education and information giving, with a group session, focused on the management of an ongoing condition and advice. Much outpatient activity centres on the monitoring and management of people with long-term conditions such as arthritis or diabetes. Questions have been raised concerning the appropriateness of outpatient appointments. Two-thirds of missed appointments are for follow-up appointments, suggesting that there is scope for improved efficiency. The group clinic represents one suggested initiative to improve efficiency and enhance patient satisfaction.

In the UK, there is little published evidence on impact and a lack of good-quality information on the range and scale of group clinic activity in different specialties. A systematic review is needed to combine the published evidence of different types, including descriptive or qualitative studies, with grey literature.

For the potential of group clinic-type interventions to be explored fully, with a view to their possible increased utilisation within a UK NHS context, requires a systematic investigation of research evaluating their usefulness and costs, not only financially but in terms of professional training, patient satisfaction and clinical and health service outcomes.

## Hypotheses tested in the review (review questions)

### *Purpose of review*

The purpose of this systematic review is to examine the available evidence for use of group clinics with patients who have chronic health conditions.

### *Review question*

The review question is as follows:

- What is the current evidence for the feasibility, appropriateness, meaningfulness, effectiveness (FAME) and cost-effectiveness of group clinics/GMVs for patients with chronic conditions?

Specifically:

- What different models of group clinic exist (in the UK and internationally)?
- What evidence exists about the outcomes and cost-effectiveness of these clinics?
- What evidence exists about patient experience of these clinics?
- What are the possible explanatory mechanisms for any reported improvements in outcomes?



## Objectives

The primary objective of this review is:

- To identify evidence of effectiveness, or likely effectiveness, of group clinics and, where this is identified, to review evidence of impact, in particular cost-effectiveness of group clinics. This might include measures of efficiencies and clinic/staff time, use of services (hospitalisation rates), patient outcome (and surrogate clinical measures), behaviour, self-efficacy, quality of life and other patient and staff satisfaction indices.

Additional objectives were:

- to understand how group clinics have been conceptualised and to identify different models of use from a review of academic and grey literature
- to relate emerging findings on what works to current practice
- to identify research gaps for funding bodies and researchers.

## Scope

This review covers all group clinics which include a component of clinical advice and management, as well as peer learning and support, for chronic health conditions. Terms (largely US) include 'group medical visits', 'cluster visits', 'shared medical appointments' and 'co-operative health-care clinics'. The focus is on specialist-led services (i.e. replacing hospital outpatient appointments). Patient education and support groups (including expert patient groups) focused on self-management with no clinical advice or input are not the main focus of this review, although there may be some overlap in activity (see *Chapter 2* for inclusion and exclusion criteria).

In seeking to inform the review from as holistic a perspective as possible, the team decided to examine the available evidence against the FAME framework. FAME is a mnemonic for the aspects of feasibility, appropriateness, meaningfulness and effectiveness and was devised at the Joanna Briggs Institute.<sup>11</sup> *Appendix 1* sets out the FAME framework as used to guide the review process. This framework allows us to:

1. define the scope of the search strategy
2. define inclusion and exclusion criteria to specify types of studies to be included in the final report
3. construct summary tables of all included studies to present key information and findings
4. synthesise the evidence from the included studies.

It should be noted, however, that the FAME framework was selected principally to facilitate the synthesis process. In the interests of brevity we have subsumed considerations of feasibility, appropriateness and meaningfulness elsewhere under 'appropriateness' as an umbrella term, as in the report title.

## What are the existing models of group clinics?

This section starts with a brief consideration of the main models of group clinic and attempts to outline a workable typology with which to inform the subsequent analysis. Essentially, there are four principal models of group clinic approaches:

1. the co-operative health-care clinic (CHCC) model
2. the specialty CHCC model
3. the DIGMA model
4. the SMA model.



### *The co-operative health-care clinic model*

#### **Overview**

The CHCC model, developed by Kaiser Permanente in 1990, is designed to provide physicians with adequate time to deliver quality care.

#### **Designed for**

Generally used to provide care to patients over the age of 65 years with chronic conditions or who frequently utilise medical resources. The main objective of the CHCC model is to facilitate the self-management of patients' chronic condition(s) through enhanced education, encouragement of self-care, peer and professional support, and attention to the psychosocial aspects of living with chronic disease.<sup>12</sup> Specific to the CHCC model are regular scheduled visits with the same group cohort over extended periods of time.

#### **Duration**

Co-operative health-care clinics generally last from 2 to 2.5 hours and comprise no more than 20 patients at a time.

#### **Content**

Individualised medical care usually takes place in a private room near the meeting site. A physician encounters patients individually, allowing up to 5 minutes per patient, while a nurse takes vital signs and other measurements for the rest of the participants. Approximately 30 minutes is allocated for collecting patient data and conducting individual sessions; the rest of the time is spent addressing group concerns, providing educational material and answering participants' questions.<sup>13</sup> Groups may meet monthly or quarterly, according to need. Group time is structured and includes set intervals of socialising, education and medical interaction. Medical interaction may include an overview of the patient's medications, laboratory results, immunisation or any other primary care need identified at the time of meeting.<sup>14</sup>

### *The specialty co-operative health-care clinic model*

#### **Overview**

The specialty CHCC model is similar to the regular CHCC model from which it later evolved, but it focuses on a specific disease. A later variation of this model, the high-risk cohort model, targets patients of all ages with similar chronic problems, such as diabetes or coronary artery disease.<sup>13</sup>

#### **Designed for**

Offering a foundation on which to base high-risk patient population management programmes (e.g. diabetes, hypertension, hyperlipidaemia, depression, etc.), thereby assisting patients and care providers to follow clinical-based practice guidelines.

### *The drop-in-group medical appointment model*

#### **Overview**

The DIGMA model was created in 1996 to improve access to care and enable physicians to better manage their large patient panels.

#### **Designed for**

Drop-in group medical appointments are composed of different patients from meeting to meeting, who 'drop in' when they have a specific medical need. These groups may focus on a specific diagnosis or they may target all chronically ill patients within a given practice. DIGMAs are customised to the needs, goals, practice style and patient panel constituency of the individual physician.<sup>14</sup> DIGMAs have been utilised in a variety of specialties, including oncology, rheumatology and neurology.<sup>15</sup> DIGMAs can be designed as heterogeneous, mixed or homogeneous; typically, they are heterogeneous in terms of age, sex, diagnosis, marital status, race and utilisation behaviour.

In a heterogeneous DIGMA, patients with any diagnosis can attend the group session, and patients may vary by age and sex. In the mixed DIGMA model, the physician will choose a different health concern or disease each week. Those attending will vary according to the topic. For example, the physician may hold a DIGMA on chronic pain one week and then focus on hypertension and diet at the next weekly session. Different patients may attend their physician's DIGMA depending on their questions, needs or diagnosis.<sup>15</sup>

### Duration

Drop-in group medical appointments typically last for 90 minutes and involve 10 to 15 patients.

### Content

Drop-in group medical appointments often include a behaviourist who facilitates group processes and addresses each patient's psychosocial concerns. The physician conducts individual medical sessions within the group setting instead of in a separate space and often engages the group in providing solutions to patient problems; by doing so, the physician provides education throughout the visit rather than a formal lecture. After the educational session, patients who need to see their doctor privately can do so.

## *The shared medical appointment model*

### Overview

The SMA was conceived by Noffsinger in 2002<sup>16</sup> as an effective and efficient method for physicians and specialists to increase their efficiency at providing physical examinations. Noffsinger identified that the majority of time spent performing a physical examination was devoted to answering questions and exchanging information.<sup>16</sup> Noffsinger coined the term 'shared medical appointment' to describe models where several patients meet with the same physician at the same time.<sup>16</sup> SMAs have been described 'as a form of medical appointment with varying medical staff and patient populations and have been utilised for patients with chronic illnesses for whom education, self-management, and problem-solving skills are essential'.<sup>17</sup> SMAs, a subgroup of GMVs, may also be called group visits, cluster visits or chronic health-care clinics. However, unlike group visits, SMAs are not intended to substitute for an individual consultation.

### Designed for

'Groups of patients meeting over time for comprehensive care, usually involving a practitioner with prescribing privileges, for a defining chronic condition or health care state'.<sup>18</sup> Most SMAs are homogeneous in terms of age and sex.

### Duration

Shared medical appointments are regularly scheduled and typically last 90 minutes.

### Content

In the SMA, physical examinations are provided privately, but have a group component whereby an interactive group discussion answers patient questions and provides patients with information. Two weeks prior to the session, patients receive an information package that includes history forms, laboratory requisitions, screening tests and handouts. Patients complete the required procedures before the SMA. Individual examinations occur during the first 30–45 minutes of the session, with the remaining time reserved for group discussion. Questions that do not lend themselves to group discussion are addressed during a private examination. Components of SMAs include educational and/or self-management enhancement strategies, paired with medication management, in an effort to achieve improved disease outcomes. The prescriber usually performs the medication changes, often in one-on-one 'breakouts'.

## Additional terminology and definitions

Additional terms are encountered throughout the relevant literature, adding to the terminological confusion and further dissipating the distinctiveness of individual models of group clinic. Existing definitions are reproduced below for the sake of completeness.

**Chronic care clinics** are based on a chronic disease approach to illness that recognises the need for active patient participation and supports patients' confidence and skills in managing their illness.<sup>19</sup> Chronic care clinic visits involve approximately eight patients at a time. They consist of a standardised assessment and individual (not group) appointments with the primary care physician, nurse and clinical pharmacist, followed by group education and support. Typically, the chronic care clinic replaces a formal educational component with interactive discussions related to patient self-management.<sup>12</sup>

**Cluster visits** are monthly 2-hour group visits with a multidisciplinary team led by a nurse educator and including a dietitian, a pharmacist and a behavioural therapist.<sup>20</sup> Cluster visits typically involve 10–18 patients.

**Group clinics** are a potential method of integrating self-management support with routine clinical care. The term is sometimes used synonymously with 'shared medical appointment'. Group clinics are an alternative model of care to one-to-one clinic appointments, having a higher ratio of patients to health professionals and a longer duration than one-to-one appointments.

**Group medical appointments** (GMAs) are a series of one-to-one patient–clinician contacts in the presence of a group of at least two voluntary attending patients. Usually the clinician is supported by a group facilitator. A GMA generally takes 1–2 hours and is a substitute for a clinician's individual appointments with the attending patients at a primary care clinic, specialty clinic or hospital outpatient setting. The same items the clinician attends to in a one-to-one appointment are attended to during the GMA. Patients can ask questions of their fellow patients, and patients and clinicians can learn from the other attending patients and their carers.<sup>21</sup>

**Group medical visits** are defined as multiple patients seen together while in the same clinical setting. Group visits include not only group education and interaction but also most elements of an individual patient visit, such as the collection of vital signs, history taking and physical examination. As Weinger acknowledges, 'Some confusion exists regarding the term "group medical visit." Currently, no single definition of a group medical appointment is universally accepted'.<sup>22</sup> This confusion exists among the other related terminologies. She highlights how most group medical visit models include a group education component taught by a nurse, psychologist or other health professional. In her view the main difference among models is that 'some include only individual visits with the physician, whereas others include group visits through which several patients meet with the same physician at the same time. The latter typically allowed for individual appointments if necessary or if requested by a patient'.<sup>22</sup>

Jaber *et al.* define **group visits** as a cohort visit of 20 patients who meet monthly or quarterly during a 2-hour multidisciplinary session that includes individual provider time, data collection similar to an individual visit, and group discussion or education to foster self-management.<sup>23</sup> Clinicians are able to answer questions and meet the medical needs of patients who need the same education and assistance with lifestyle issues. Patients have improved access to their clinician and are able to share experiences with other patients through peer support. Two models of group visit are a scheduled high-needs group (see *The specialty co-operative health-care clinic model*) and a drop-in arrangement (see *The drop-in-group medical appointment model*).<sup>23</sup> Scheduled high-needs groups comprise patients with similar medical conditions who commit to meet regularly over time. Drop-in models allow patients to schedule in advance for a group appointment. They typically include fewer patients and are shorter in duration. These models were developed to improve patient access by offering education and support.

The above descriptions reveal considerable overlap between the purpose and content of the different models. Indeed, several models share common origins in the writings of Noffsinger.<sup>9,14,15</sup> Typical duration across the models is somewhere in the region of 90–120 minutes (*Table 1*). Several models have social, medical and behavioural components. At the same time there is considerable variation in terms of group size, composition and target group. The driver for several models is improved efficiency, and claims for improved patient and provider satisfaction are common. These claims are examined through the remainder of this report.

**TABLE 1** Typical configurations of different group clinic approaches

Model	Duration	Number of patients	Consultation type	Other components
CHCC model	120–150 minutes	15–20	Individual	Socialisation Group discussion Education Question answering
Specialty CHCC model	120–150 minutes	15–20	Individual	Socialisation Group discussion Education Question answering
DIGMA	90 minutes	10–15	Individual (but conducted in group setting)	Problem-solving Education Private follow-up if required
SMA	90 minutes	4–8	Individual	Education Self-management Medication management
Chronic care clinic	60 minutes	Approximately 8	Individual	Peer support Interactive group education
Cluster visit	120 minutes	10–18	Group with individual on request	Behavioural sessions Medication review Group education
Group clinic	60 minutes (plus 10-minute individual sessions)	5–7	Group followed by individual session	Goal setting Self-management Support
GMA	60–120 minutes	At least 2	Group	Peer support Group discussion Question answering
GMV	90 minutes	12–15	Group/individual by appointment	Group education
Group visit	120 minutes	20	Individual	Group discussion Group education

## Towards a theoretical understanding of how group clinics work

The team began by examining explicit pre-existing theory relating to the group clinic/SMA/GMV approach. This not only provides a backdrop against which the systematic reviews, randomised controlled trials (RCTs) and qualitative research studies may be considered but also acts as preparation for the subsequent realist synthesis phase (see *Chapter 3, Realist synthesis*).

The review team's initial conceptual framework centred on four principal drivers for the group clinic model:

1. perceived and actual benefits and disadvantages of a group consultation when compared with an individual consultation
2. the value of group education
3. the value of synchronicity of clinical and group activities
4. the value of multiprofessional approaches resulting from simultaneous clinical involvement.

### A conceptual model of group medical appointments

In order to initiate thinking around the elements of group clinics the team accessed a conceptual framework from the Cochrane GMA protocol<sup>21</sup> (*Table 2*). This identified key structural elements for consideration within any group clinic-based intervention. This conceptual framework helped to identify key differences with regard to the intensity of the intervention (number of GMAs × frequency interval × duration) plus the qualitative consideration of the number of patients per GMA (and by implication the staff-to-patient ratio). The issue of continuity helped to distinguish between drop-in type appointments, those with a cohort of members progressing together and those with more fluid membership. Linked to this is the issue of heterogeneity as explored in issues relating to age, gender, ethnicity and experience of the condition. As our review addresses only chronic conditions, the chronic versus non-chronic was not pertinent except in considering why chronic diseases might be more amenable to a group clinic approach. The children/adults/elderly distinction served as a reminder that, typically for children and adolescents and occasionally for adults and older people, the perspective of family members (e.g. parents or carers) may be an additional factor in assessing the acceptability of group clinics. Finally, the team considerations from the Cochrane GMA conceptual framework highlight the requirement for group facilitation and team training as a resource issue.

### High-level theory relating to social support

In order to bridge the often-reported dislocation of empirical intervention studies from their underlying or implicit theory, we conducted a brief literature survey to identify the prevalence of high-level theory in relation to group clinics. Particularly influential high-level theories reflected in the published accounts included social cognitive theory, social comparison theory, social learning theory<sup>24</sup> and social support theory (*Table 3*). In addition, from the perspective of staff delivering the intervention, SMAs may access theories in relation to shared learning and interprofessional working.<sup>27</sup> When introducing group clinics, therefore, attention should be directed to the impact of the programme on staff interaction and interprofessional learning.

**TABLE 2** Conceptual framework for GMAs (from the Cochrane GMA protocol)<sup>21</sup>

Design	Patient group	Team
Number of GMA offered	Continuity vs. non-continuity	Type of clinician
Time between successive GMA	Heterogeneous vs. homogeneous	Presence of group facilitator
Duration of GMA	Chronic vs. non-chronic	Training of team
Number of patients per GMA	Children, adults, elderly	

**TABLE 3** Theories relevant to group clinic interventions

Theory	Brief explanation
Patient	
Social cognitive theory	Highlights importance of self efficacy – the belief of an individual that they are able to achieve something such as a change in health behaviour, including self management <sup>25</sup>
Social comparison theory	Proposes that ‘conformity within a group is dependent on three main motivations: (1) dependence on others for information to self-evaluate; (2) achieving group goals and the need for approval; and (3) a desire not to seem different’ <sup>26</sup>
Social learning theory	Emphasises ‘learning through observation and modelling behaviour’ and is particularly relevant to ‘behaviours involving action or performing’ <sup>26</sup>
Social support theory	Proposes that ‘information is disseminated more effectively between networks of people with strong social ties and this confers health benefits’ <sup>26</sup>
Staff	
Social identity theory	Argues that the social group to which someone belongs at times determines both relationships and interactions between individuals. May result in changed perceptions and challenge of stereotypes <sup>27</sup>
Social practice theory	Highlights the importance of situated learning and practice on identity and includes an enhanced appreciation for the perspective of others <sup>27</sup>

### Theory relating to group interventions

Hoddinott *et al.* offer a useful generic framework against which to examine group interventions.<sup>26</sup> Interventions delivered to patient groups are addressed by their framework, which includes:

- the place, setting and context of the intervention
- the design of the intervention, the theory underlying the choice of intervention, the target population and choosing the relevant behavioural outcome to measure
- membership of the group
- how the group will influence people
- intended health outcomes and target populations
- what happens within the group.

### Theory relating to chronic disease self-management

Theories relating to the core components of chronic disease self-management, namely the tasks of medical, role and emotional management,<sup>28</sup> are particularly pertinent to the operation of group clinic approaches. These are highlighted in the rapid review, *A rapid synthesis of the evidence on interventions supporting self management for people with long-term conditions*, commissioned by the Health Services and Delivery Research (HSDR) programme.<sup>29</sup> In their review the authors<sup>29</sup> highlight the key role of self-efficacy in relation to self-management behaviours.<sup>30</sup> This resonates with Knowles’ theory of andragogy, cited in the trial by Yehle *et al.*,<sup>31</sup> which proposes that adults are self-directed and that they expect to take responsibility for decisions.

Lorig and Holman<sup>32</sup> identify five core self-management skills which can be seen to be accessed within a group clinic approach: (1) problem-solving; (2) decision-making; (3) appropriate resource utilisation; (4) forming a partnership with a healthcare provider; and (5) taking necessary actions. The standard group clinic format may be seen as an opportunity for the clinician and patient to harness all of these skills as targeted by individual components of the intervention.

### **Theory relating to monitoring**

Finally, as highlighted by Taylor *et al.*,<sup>29</sup> we can better understand the role of regular group clinic meetings by examining the complementary and evolving roles of periodic professional reviews and ongoing patient self-monitoring.<sup>33</sup> Group clinics could be conceived as a forum for juxtaposing, bringing these two roles in a potentially helpful synergy.

### **A symbolic role for group clinics?**

Group clinic approaches may also fulfil a symbolic or emblematic role by instilling in the patients a hope and belief in the treatments being offered.<sup>34</sup> Social interchange in a group setting may emphasise the universality of the condition along with recognition that one is not alone in suffering or healing. Instrumentally, the group clinic setting offers an opportunity both to impart information through instruction or dialogue and to clarify any distorted or misleading information.<sup>34</sup> A sense of community may develop over time, with individuals beginning to display altruism and to derive a sense of usefulness from contributing to the group.

The group may provide patients with potential role models in the form of other group members who are better able to manage their condition and, thus, to function more effectively.<sup>34</sup> This may in turn stimulate imitative behaviour. Socialisation may offer potential catharsis through sharing and the destigmatising of chronic medical conditions as well as fulfilling a more pragmatic role as a source of direct advice and the sharing of coping strategies.<sup>34</sup> As a forum for interpersonal learning the group may encourage the sharing of experiences with others and problem-solving as a group. These resources may be more plentiful and more creative than may be offered by an individual clinician with no direct experience of living with a chronic condition. Peer pressure, in its positive sense and as an antidote to the unequal clinician–patient relationship, may encourage patients to become more empowered and, thus, more involved in their care.<sup>34</sup>





## Chapter 2 Review methods

This systematic review was conducted within an abbreviated (7-month) time scale and, therefore, did not attempt to identify **all** relevant evidence or to search **exhaustively** for all evidence that met the inclusion criteria; instead, the search approach sought to identify the key evidence of most relevance to the review question by focusing on RCT designs. Relevance may be interpreted in multiple ways; in this particular context we sought to address a narrow and tightly defined question, as captured by an appropriate population–intervention–comparison–outcome (PICO) formulation. The PICO formulation is an accepted mechanism used in systematic reviews to frame a review question about an intervention programme, in this case group clinic approaches.<sup>35</sup> Outlining inclusion and exclusion criteria in terms of the PICO format helps to operationalise systematic and consistent approaches to selection of items for inclusion independent of either the direction or nature of results or factors empirically known to influence the direction or interpretation of results (e.g. sample size, funding source, etc.).

For logistic reasons this review examined the evidence through the ‘lens’ of evidence from existing systematic reviews and RCTs. Data extraction and quality assessment was performed on the RCTs and interventions demonstrated as actually, or potentially, effective were then investigated in further detail with regard to feasibility, acceptability, meaningfulness and cost-effectiveness. In addition, where gaps in the RCT evidence were specifically identified, we examined indicative evidence from qualitative research and cost studies to indicate the extent to which candidate interventions were likely to be feasible, appropriate and meaningful if subsequently demonstrated to be effective by future trial evidence.

### Protocol development

The protocol for the review was developed iteratively between the School for Health and Related Research (ScHARR) and the National Institute for Health Research HSDR programme. A copy of the study protocol is available on the project website (see [www.nets.nihr.ac.uk/projects/hsdr/130512](http://www.nets.nihr.ac.uk/projects/hsdr/130512)).

### Literature searching

The review incorporated a range of search methods, as outlined below, to identify evidence to address the review research questions:

- stage 1 – search for reviews on group clinics
- stage 2 – search of health and medical databases
- stage 3 – search for qualitative studies
- stage 4 – search for cost studies
- stage 5 – search for UK studies.

The search process was undertaken with reference to the protocol.

#### **Stage 1: search for reviews on group clinics**

Our initial approach was to scope the literature around group clinics by searching for recent relevant reviews. All studies included in reviews were then scrutinised for inclusion in the review. Relevant terms for the search were found during the scoping exercise. Systematic reviews were identified from the following sources: PubMed Clinical Queries, Epistemonikos (Santiago, Chile; [www.epistemonikos.org/](http://www.epistemonikos.org/)), The Cochrane Library, Database of Abstracts of Reviews of Effects (DARE) and Google Scholar (Google™, Mountain View, CA, USA; <https://scholar.google.co.uk>), combining ‘systematic review’ with terms relating to group clinics, SMAs, etc. (see *Appendix 2*).

### Stage 2: search of health and medical databases

The search strategy used a combination of free text and medical subject headings (MeSHs) and can be found in *Appendix 2*.

We searched MEDLINE and EMBASE via OVID SP, Cochrane Library via Wiley Interscience, Web of Science via Web of Knowledge and Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCOhost. MEDLINE, EMBASE, CINAHL and The Cochrane Library are commonly considered the core databases for identifying evidence relating to clinical topics.

The search strategy was limited to 1999–2014. Bibliometric analysis identified the sudden appearance of group visit studies at around 2000. Evidence was included if it was published between 1999 and 2014 and written in English.

The search results were downloaded into Reference Manager version 12 (Thomson ResearchSoft, San Francisco, CA, USA) where duplicates were removed before sifting for inclusion in the review was undertaken.

### Stage 3: search for qualitative studies

A three-part search strategy was used to identify papers reporting qualitative research, as follows:

- Stage 1 – during screening and data extraction, any papers that were relevant and included qualitative data were tagged accordingly in Reference Manager.
- Stage 2 – a search of our Reference Manager database for relevant studies was undertaken using the keywords 'qualitative', 'interview\*' or 'findings' in the title and abstract of the records. These terms have been found to have acceptable sensitivity for retrieval of qualitative research.<sup>36,37</sup>
- Stage 3 – cited records for all included trials were searched on Google Scholar using the keywords 'qualitative', 'interview\*' or 'findings' using the 'search within citing articles' check-box function. This would enable the retrieval of 'sibling' studies associated with the trials as well as more distant 'kinship' studies citing those trials for reasons of topical relevance.<sup>38</sup>

### Stage 4: search for costs studies

Three separate methods were used to identify studies for the assessment of costs and feasibility, as follows:

- Stage 1 – during screening and data extraction, any papers that were relevant and included costs data were tagged accordingly in Reference Manager.
- Stage 2 – a search of our Reference Manager database for the study was undertaken using the keywords cost\*, economic\*, charg\*, expens\*, reimburse\* in the title and abstract of the records.
- Stage 3 – a targeted search of MEDLINE and EMBASE was undertaken, with no date or language restrictions, using the following search strategy: (((shared or group) adj medical adj (visit or appointment or clinic or care)) OR (group adj (visit or appointment or clinic or care))) AND (economic\* or cost\* or charg\* or expens\* or reimburs\*).ti,ab.

### Stage 5: search for UK studies

Studies conducted in the UK were identified in two ways:

1. Geographical terms for 'united kingdom', 'uk', 'britain', 'England', 'Scotland', Wales, Ireland were used to retrieve records from the Reference Manager database.
2. Similarly, geographical terms for 'united kingdom', 'uk', 'britain', 'England', 'Scotland', Wales, Ireland were used to retrieve items from Google Scholar in conjunction with the most common terms used for the intervention, that is, 'shared medical appointments', 'group medical clinic', 'group medical visit' and 'group visit'. This search approach harnessed full-text retrieval and so added value over the title-and-abstract-based approach listed above.

## Sifting

References identified from stages 1 and 2 were downloaded into Reference Manager to be sifted for inclusion in the review. A total of 4176 of the potential titles were examined for inclusion by one reviewer. Any titles that did not meet the inclusion criteria were excluded. Following the title sift, any remaining references were scrutinised at abstract level. For any references where possible inclusion was unclear, a second reviewer independently examined the corresponding full text.

### *Progressive fractions method*

Following the sifting of 4176 titles and abstracts a further 1212 search results were scrutinised using a method of 'progressive fractions'. Progressive fractions is a method developed in-house by the ScHARR team for undertaking systematic reviews within a time-constrained period. Essentially, it involves conducting a sensitive search strategy in order to populate a project reference management database. This database then becomes the data set that is progressively 'mined' for articles for potential inclusion. Essentially, titles and abstracts are reviewed in decreasing relevance order until no further unique relevant references are retrieved. This method also minimises the likelihood of relevant references being missed through being submerged by excessive quantities of irrelevant noise (*Table 4*).

Instead of the 'big bang' approach that typifies systematic review methods and which conflates terms of low specificity alongside terms of high specificity, the progressive fractions method involves using single string strategies (e.g. 'group medical visit\*') in decreasing likelihood of unique retrieval, with the team evaluating retrieval results at each point. As each progressive fraction is executed attention is focused on the identification of unique results. When an additional relevant reference is retrieved this yields additional search terms. Quantitative results for the new search terms are used to evaluate whether or not it will be time effective to sift new results, taking into account the number of relevant studies already identified by the combined search strategy and the number of additional records to be sifted. Progressive fractions allows a review team to make iterative and informed judgements about the optimal sensitivity for a systematic review search. After precise search terms were used we had scanned 11% of our sensitive database and retrieved 89.7% of our randomised trials. The remaining four trial citations were identified by citation searching and checking existing systematic reviews. The same precise search sets were also scanned for qualitative studies.

**TABLE 4** Progressive fractions for group clinic review

Retrieval term	Number of records	Number of unique records (i.e. not already retrieved)	Cumulative number of references screened	Cumulative percentage of records screened (from 10,880)	Number of gold-standard trials in this set	Percentage of gold-standard trials in this set	Cumulative number of gold-standard trials	Cumulative percentage of gold-standard trials
'group clinic' in All NonIndexed Fields OR 'group clinic' in All Indexed Fields	696	696	696	6.4	1	2.6	1	2.6
'group medical clinic' in All NonIndexed Fields OR 'group clinic' in All Indexed Fields	7	6	702	6.5	3	7.8	4	10.4
'group medical visit'	60	59	761	7.0	5	12.8	9	23.4
Group visit	315	299	1060	9.7	13	33.4	22	56.8
Group appointment	32	32	1092	10	0	0	22	56.8
Group medical appointment	32	26	1118	10.3	2	5.2	23	62
SMA	102	84	1202	11.0	7	17.9	31	79.4
Group office visit	3	1	1203	11.0	0	0	31	79.4
Shared consultation	0	0	1203	11.0	0	0	31	79.4
Group consultation	5	0	1203	11.0	0	0	31	79.4
Group outpatient visit	2	0	1203	11.0	1	2.6	32	82
Shared medical visit	12	5	1208	11.1	1	2.6	33	84.6
Cluster visit	4	4	1212	11.1	1	2.6	34	87.1
Group patient visit	1	1	1213	11.1	1	2.6	35	89.7
Supplementary search methods					4	10.3	39 of which 32 were included	100

## Inclusion/exclusion criteria

The inclusion of studies in the review was as according to *Table 5*.

### Setting of intervention

Interventions are not initially excluded on the basis of the setting for the group intervention, given the potential for very similar interventions to be delivered in the community or primary care setting as well as in hospital/outpatient settings. Although the review team has justifiable concerns about the additional literature likely to be identified if group approaches in primary care are included within the review scope we cannot identify a sound justification for excluding such studies on conceptual grounds particularly given that the setting for interventions and definitions of 'specialist' care may cover a wide range of different settings.

**TABLE 5** Inclusion and exclusion criteria

Criteria	Inclusion	Exclusion
Population	Adults and/or children receiving health-care services for one or more chronic health condition	Group visits for healthy patient groups (i.e. those without an indication related to a chronic health condition) This exclusion covers: <ol style="list-style-type: none"> <li>1. pregnant women or those planning a pregnancy (unless they also have a chronic health condition such as diabetes)</li> <li>2. smoking cessation and other health promotion clinics</li> </ol>
Intervention	Delivery of one or more services to a small group of patients (typically 8–10 patients) simultaneously. Only studies including the delivery of the intervention by one or more specialist health-care professionals met the inclusion criteria of the review	Delivery of intervention by peers or non-specialist health-care professionals: we also exclude peer-facilitated support groups as the intervention is not principally delivered by health-care professionals (although they may contribute)
Outcome	Patient outcomes; health services outcomes; patient and carer satisfaction; resource use	
Comparison	Other methods of organisation of treatment (with the exception of qualitative research and surveys, only studies with a comparator group are included)	
Date	Cut-off date limit of 1999–2014 was applied in recognition of the distribution of the literature as identified from the scoping searches (see above)	
Language	Only studies written in English were included	

## Data extraction including development of the data extraction tool

Formal data extraction was employed for all included systematic reviews, RCTs and qualitative studies. Data extraction was undertaken by one of three reviewers (AB, AC and LP). Owing to the time constraints of the review a model of single data extraction with verification by a second reviewer was used for all included studies (see *Chapter 6, Strengths and limitations of this review*). Empirical evidence demonstrates that single data extraction results in an acceptably low rate of additional errors, when compared with optimal double data extraction. In particular, the likelihood of error relating to primary outcomes, as opposed to minor data inconsistencies, has been found to be low.<sup>39</sup>

A standardised data extraction form was designed using Google Forms to capture relevant information from the studies on a broad range of factors related to group clinics and their outcomes. The form was piloted by all three reviewers and then minor changes were made before full data extraction was undertaken. The output from Google Forms (Google Inc., Mountain View, CA, USA) was imported into Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA) to facilitate manipulation and production of tables.

For literature that made a conceptual contribution a method known as best-fit framework synthesis<sup>40,41</sup> was used, which involved extraction of data against a pre-existing framework. Any data not explained by the initial framework were then coded inductively. We identified a framework from a review entitled *Group Visits Focusing on Education for the Management of Chronic Conditions in Adults: A Systematic Review*.<sup>42</sup> This review was intended as a 'companion piece' to a SMA review conducted by the Durham Evidence-based Synthesis Program led by Edelman.<sup>18</sup> The SMA review focuses on visits led by a physician or other prescribing provider during which individual-level changes in management plan can be made and, thus, fully corresponds to the scope of our own review. In contrast the review from which we derived the best-fit framework 'focuses exclusively on literature that tests the effectiveness of group visits that have an emphasis on health education and are led by facilitators, including but not limited to non-prescribing health professionals such as nurses, dietitians, and physical therapists'.<sup>42</sup> Nevertheless, it fulfils the forgiving selection criterion for identifying a conceptual framework as specified by the 'best fit' method. A sample data extraction form is available in *Appendix 3*. Cost data were extracted into a separate purpose-created Microsoft Word® (Microsoft Corporation, Redmond, WA, USA) document.

## Quality assessment

### Systematic reviews

Systematic reviews were appraised using the guidelines employed by the Centre for Reviews and Dissemination (CRD) when populating their DARE.<sup>43</sup> This method was employed to ensure consistency of approach between our assessments and existing assessments of published reviews.

### Randomised controlled trials

Randomised controlled trials were formally assessed for quality using questions from the Critical Appraisal Skills Programme (CASP) checklist *11 questions to help you make sense of a trial*<sup>44</sup> in order to explore study limitations qualitatively and the Cochrane risk of bias tables in order to identify likely sources of bias.<sup>45</sup> Assessment of the limitations of included studies was also undertaken using the limitations reported by study authors in the included studies.

### Qualitative research

Qualitative studies were formally assessed for quality using questions from the CASP *10 questions to help you make sense of qualitative research checklist*.<sup>46</sup> Surveys were not formally appraised and, therefore, were used only to validate findings from qualitative research.

### Costs

We undertook an assessment of relevance of evidence to the study objectives by answering three questions about each paper: the currency of the data, the quality of the data sources and the relevance to a UK setting.

### UK initiatives

Research studies reporting UK initiatives were not formally assessed given the heterogeneity of study types, making comparability problematic. Nevertheless, all reports of initiatives were reviewed for any identifiable or acknowledged limitations.

### Synthesis

Data were extracted and tabulated. This tabulation was used to inform the narrative synthesis in *Chapter 3*. There was no attempt to synthesise quantitative data through formal meta-analysis, given the heterogeneity of disease conditions and models of service delivery for group clinics. However, where previous review teams had attempted to undertake meta-analysis these analyses were used as a frame of reference when assessing the likely contribution of newly appeared evidence. The review provides an analysis of the quality of evidence and the strength of conclusions that can be drawn from existing studies.

### Involvement of clinical advisers

As it emerged that there were no trials from a UK context, and the UK studies correspondingly lacked rigour, the review team identified a need to access contextual data to aid translation to a NHS context. The review was not resourced to conduct a rigorous consensus process, nor were there sufficient numbers and diversity of informants. The clinical advisers were selected on the basis of their knowledge of group approaches within a diabetes context (the most frequently researched condition) or because of their experience of running group clinic approaches.

It was recognised that this was neither a representative nor a valid sample. The review team, therefore, put in place various protections to ensure that the review findings were not overly influenced by these otherwise valuable clinical opinions. Clinical advisers were presented with a summary of the review findings and so had no influence on the selection of studies or outcomes. Their comments were elicited around a series of prespecified questions independently identified by the review team. In this way their contribution was 'ring-fenced' from overly influencing the review but was considered invaluable, particularly given the absence of 'hard' data relevant to the UK.

Five potential informants were initially identified: three from a group clinic setting and two from diabetes. Owing to resource and timing constraints only four informants were interviewed (via telephone and/or e-mail). These constituted two representing diabetes and two from group clinic approaches.





## Chapter 3 Results

### Overview of studies included in the review

This review comprises six principal components informed by five different types of data (*Table 6*). The realist synthesis was populated by data from the systematic reviews, RCTs, qualitative studies and UK initiatives. *Figure 1* shows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart for all included studies.

#### Systematic reviews

Literature searches retrieved 13 systematic reviews and one review protocol. This evidence was reviewed in *Results of the review of reviews*.

#### Randomised controlled trials

We retrieved 32 papers representing 22 different RCTs. These trials are reviewed in *Results of the review of effectiveness*.

#### Qualitative studies and surveys

We identified 12 qualitative papers reporting 10 different qualitative studies. In addition, we identified four surveys that were used to triangulate qualitative research findings. These qualitative studies and surveys are explored in *Results of the qualitative synthesis*.

**TABLE 6** Summary of included studies

Study type	Number of papers	Number of studies	Other items
Systematic reviews	13	13	One review protocol
RCTs	32	22	
Qualitative studies	12	10	
Surveys	4	4	
UK initiatives	15	12	Conference abstracts
Cost studies	8	8	
Total	82	69	
Realist synthesis includes four study types (excluding surveys and cost studies) above	84	57	

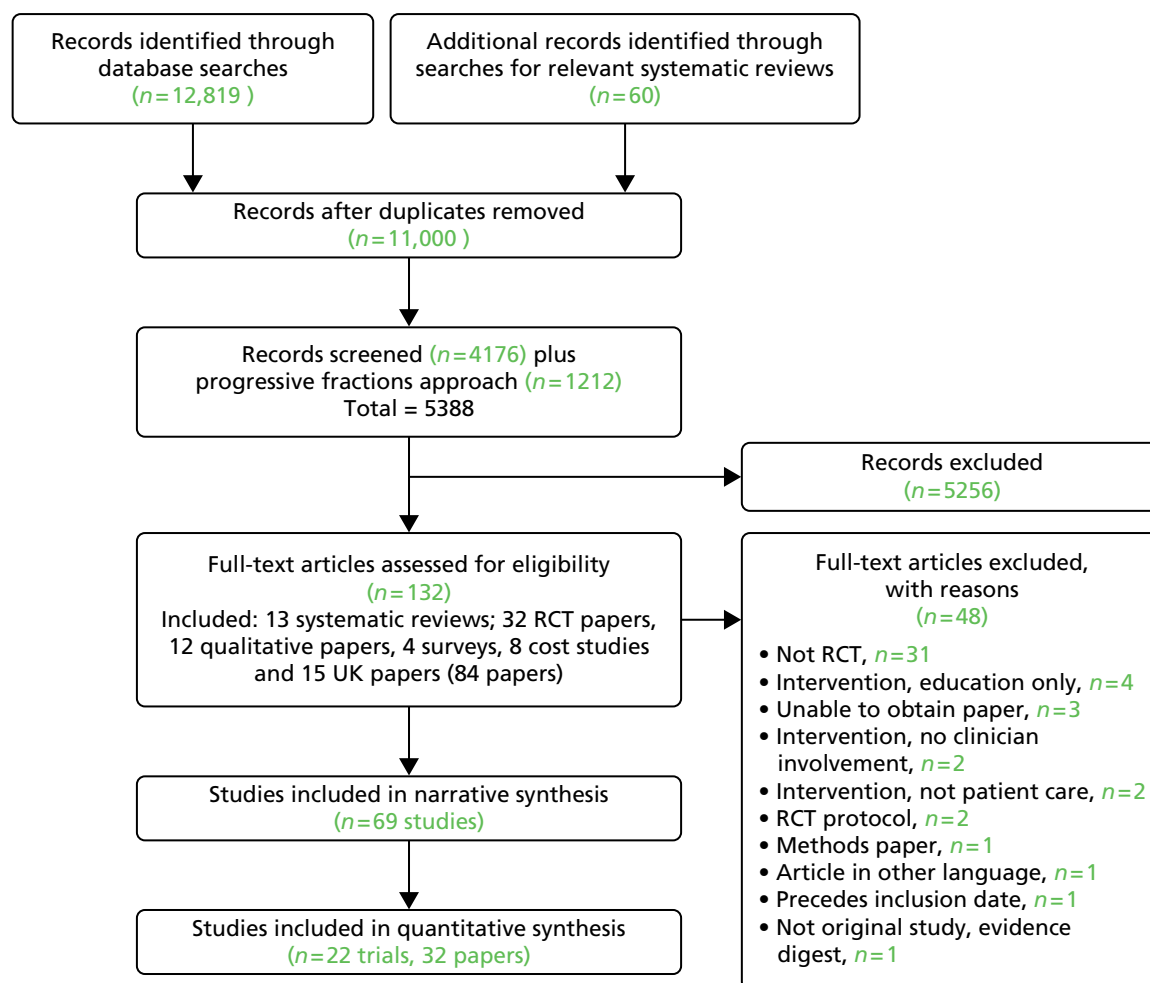


FIGURE 1 The PRISMA flow chart for all included studies.

### UK initiatives

We identified 15 papers reporting 12 UK group clinic initiatives. This review of current practice is examined in *Results of the review of UK evidence*.

### Realist synthesis

Data from the 13 systematic reviews, 22 different RCTs, 10 qualitative studies and 12 UK initiatives (a total of 75 papers) were used to inform *Chapter 4*.

### Cost studies

We identified eight cost studies either nested within RCTs or reported as separate cost-effectiveness or cost-utilisation analyses. These cost studies are analysed in *Chapter 5*.

From *Table 7* it can be seen that group clinics is the most frequently mentioned model, in 19 of the 84 papers. Other frequently used labels are SMAs (n=12) and CHCCs (n=10). A further nine labels are used in the 84 papers included in this review, with even greater variation in the non-empirical literature.

**TABLE 7** Models of group clinics as represented by the retrieved literature

Model	Effectiveness review		Qualitative review	Economic studies	UK studies		Total papers
	Number of studies	Number of papers	Number of papers	Number of papers	Number of studies	Number of papers	
Group clinic	3	5	2	1	9	11	19
SMA	5	6	5	0	1	1	12
CHCC model	6	10	0	0	0	0	10
GMV	3	4	4	1	0	0	9
Group visit	3	5	0	4	0	0	9
DIGMA	0	0	2	1	0	0	3
Chronic care clinic	1	1	0	1	0	0	2
Group medical appointment	0	0	2	0	0	0	2
Cluster visit	1	1	0	0	0	0	1
Shared medical visit	1	1	0	0	0	0	1
Specialty CHCC model	0	0	0	0	0	0	0
Other models	1	1	0	0	1	1	2

## Results of the review of reviews

The team started by identifying existing reviews that had examined aspects of the review question. No single existing review offered a complete match to the scope covered by this systematic review. Reasons for this were that the review focused on a single condition, the review included only RCT evidence, the review included general group care, the review included group education, etc. A summary of the congruity of this review with other published reviews is given below.

A total of 13 reviews involving a total of 92 trials (including duplicates) were identified for inclusion in the review (*Table 8*). No unpublished relevant reviews were obtained. However, we identified one review protocol for a Cochrane review in progress.<sup>21</sup>

*Table 8* shows coverage of studies by the existing reviews. The main contribution of our review would be to provide unique coverage of trials published over the period 2012–14. Ultimately we would be including 32 papers, whereas the previous most comprehensive review covered either 18 papers through secondary analysis or 16 studies in primary analysis (see *Table 8*).

### Review characteristics and review strategy

As a precursor to our own review of group clinics the review team identified 13 reviews that either matched or overlapped the scope of the planned review. Another review, *The effectiveness of group visits for patients with heart failure on knowledge, quality of life, self-care, and readmissions: a systematic review*,<sup>54</sup> is available only on private subscription from the Joanna Briggs Institute Library and so a summary, commissioned on request from the CRD, was used in assessing the evidence. One Cochrane review entitled *Group medical appointments for people with physical illness* is currently in progress.<sup>21</sup>

TABLE 8 Coverage of studies in existing reviews

Study (date)	Existing review										
	Deakin et al. (2005) <sup>47</sup>	Jaber et al. (2006) <sup>48</sup>	Riley and Marshall (2010) <sup>49</sup>	Brennan et al. (2010) <sup>50</sup>	Steinsbekk et al. (2012) <sup>51</sup>	Edelman et al. (2012) <sup>18</sup>	CADTH (2013) <sup>52</sup>	Housden et al. (2013) <sup>53</sup>	Slyer and Ferrara (2013) <sup>54</sup>	Edelman et al. (2014) <sup>55</sup>	Rolfe et al. (2014) <sup>56</sup>
1. Clancy et al. (2003) <sup>57</sup>	✓	✓		✓			✓ <sup>a</sup>	✓		✓	
2. Clancy et al. (2003) <sup>58</sup>	✓	✓		✓			✓ <sup>a</sup>	✓			✓
3. Clancy et al. (2003) <sup>59</sup>	✓	✓		✓		✓	✓ <sup>a</sup>	✓			
4. Clancy et al. (2007) <sup>60</sup>				✓			✓ <sup>a</sup>	✓		✓	✓
5. Clancy et al. (2007) <sup>61</sup>				✓	✓		✓ <sup>a</sup>	✓			
6. Clancy et al. (2008) <sup>62</sup>			✓				✓ <sup>a</sup>	✓			
7. Cohen et al. (2011) <sup>63</sup>						✓	✓ <sup>a</sup>	✓			✓
8. Cole et al. (2013) <sup>64</sup>											
9. Coleman et al. (2001) <sup>65</sup>	✓			✓							
10. Crowley et al. (2014) <sup>66</sup>											
11. Crowley et al. (2013) <sup>67</sup>											
12. Dorsey et al. (2011) <sup>68</sup>											
13. Edelman et al. (2010) <sup>69</sup>						✓	✓ <sup>a</sup>	✓		✓	
14. Graue et al. (2005) <sup>70</sup>			✓								
15. Griffin et al. (2009) <sup>71</sup>											
16. Gutierrez et al. (2011) <sup>72</sup>											✓
17. Junling et al. (2015) <sup>73</sup>											
18. Liu et al. (2012) <sup>74</sup>											

Study (date)	Existing review											Total
	Deakin et al. (2005) <sup>47</sup>	Jaber et al. (2006) <sup>48</sup>	Riley and Marshall (2010) <sup>49</sup>	Brennan et al. (2010) <sup>50</sup>	Steinsbekk et al. (2012) <sup>51</sup>	Edelman et al. (2012) <sup>18</sup>	CADTH (2013) <sup>52</sup>	Housden et al. (2013) <sup>53</sup>	Slyer and Ferrara (2013) <sup>54</sup>	Edelman et al. (2014) <sup>55</sup>	Rolfe et al. (2014) <sup>56</sup>	
19. Naik et al. (2011) <sup>75</sup>						✓	✓ <sup>a</sup>	✓			✓	
20. Ratanawongsa et al. (2012) <sup>76</sup>												
21. Sadur et al. (1999) <sup>20</sup>	✓			✓			✓ <sup>a</sup>	✓			✓	
22. Schillinger et al. (2008) <sup>77</sup>												
23. Schillinger et al. (2009) <sup>78</sup>												
24. Scott et al. (2004) <sup>79</sup>		✓		✓			✓ <sup>a</sup>					
25. Taveira et al. (2010) <sup>80</sup>							✓ <sup>a</sup>	✓			✓	
26. Taveira et al. (2011) <sup>81</sup>							✓ <sup>a</sup>	✓			✓	
27. Trento et al. (2001) <sup>82</sup>	✓			✓			✓ <sup>a</sup>	✓			✓	
28. Trento et al. (2002) <sup>83</sup>	✓	✓		✓			✓ <sup>a</sup>	✓			✓	
29. Trento et al. (2004) <sup>84</sup>		✓		✓			✓ <sup>a</sup>	✓			✓	
30. Trento et al. (2005) <sup>85</sup>				✓			✓ <sup>a</sup>	✓			✓	
31. Wagner et al. (2001) <sup>86</sup>		✓		✓			✓ <sup>a</sup>				✓	
32. Yehle et al. (2009) <sup>31</sup>									✓			
Total	2	9	2	13	4	12	18	16	1	12	2	

CADTH, Canadian Agency for Drugs and Technologies in Health.  
a. Only reviewed studies as contained in three previous reviews.  
The review by Burke et al.<sup>87</sup> is excluded from the table because it is not in the public domain.

### Characteristics of previous reviews

An initial task was to seek to characterise existing reviews in terms of their congruity, or otherwise, with regard to the population-intervention-study type elements. In *Table 9* total congruity with a particular element is indicated by a +++ notation. Close congruity is correspondingly indicated by ++, while a narrow specific focus is assigned a + notation. In this way, the key reviews with the greatest potential to inform our review question are clearly identified.

Only one<sup>18</sup> of the 13 reviews was congruous with our review when matched against both population and intervention (see *Table 9*). We therefore decided to undertake our review as a more comprehensive update of this systematic review by Edelman *et al.*<sup>18</sup> Three further reviews<sup>55,57,83</sup> articulated the intervention of interest to our review (although they did not employ the precise terminology of 'group clinics') but in only one specific disease/condition. We therefore decided to prioritise these three reviews as sources of potential studies for inclusion. The remaining reviews would be checked for their coverage of included studies and for suggestions of further studies for inclusion.

**TABLE 9** Relationship between existing reviews and this review

Review (date)	Population	Intervention	Included study types
Deakin <i>et al.</i> (2005) <sup>47</sup>	Type 2 DM (narrow) +	Group-based self-management education +	RCTs
Jaber <i>et al.</i> (2006) <sup>48</sup>	All populations (broad) ++	Group visits (broad) ++	Research studies
Brennan <i>et al.</i> (2010) <sup>50</sup>	Chronic-disease management in adults (narrow) ++	Group visits (broad) ++	RCTs and other experimental designs
Riley and Marshall (2010) <sup>49</sup>	Diabetes care (narrow) +	Group visits (broad) ++	Review articles and original research articles
Burke <i>et al.</i> (2011) <sup>87,88</sup>	Diabetes care (narrow) +	GMV +++	RCTs and quasi-experimental studies
Edelman <i>et al.</i> (2012) <sup>18</sup>	Chronic medical conditions +++	SMAs +++	RCTs and observational studies
Quiñones <i>et al.</i> (2012) <sup>42</sup>	Chronic disease management in adults (narrow) ++	Group visits focusing on education (narrow) +	RCTs
Steinsbekk <i>et al.</i> (2012) <sup>51</sup>	Type 2 DM (narrow) +	Group-based self-management education +	RCTs
CADTH (2013) <sup>52</sup>	Chronic disease management +++	Group care (broad) +	Health technology assessments, systematic reviews, meta-analyses, RCTs, non-randomised studies, economic studies and guidelines
Housden <i>et al.</i> (2013) <sup>53</sup>	DM +	GMV +++	RCTs and observational studies
Slyer and Ferrara (2013) <sup>54</sup>	Heart failure +	Group visits ++	RCTs, non-RCTs, and quasi-experimental trials. Qualitative study designs also considered
Edelman <i>et al.</i> (2014) <sup>55</sup>	DM +	SMAs +++	RCTs and observational studies
Rolfe <i>et al.</i> (2014) <sup>56</sup>	All populations +++	Interventions for improving patients' trust in doctors and groups of doctors +	RCTs

CADTH, Canadian Agency for Drugs and Technologies in Health; DM, diabetes mellitus. +++ represents congruity of a review with this review, ++ represents a partial match and + indicates a significant departure from our scope. An exact match of scope would, therefore, be represented by +++/+++, representing congruity of both population and intervention.

## Populations

Two of the included reviews<sup>48,56</sup> examined all populations, resulting in a focus wider than that determined for this review. A further seven reviews<sup>47,49,51,53–55,87</sup> focused on one specific condition [in all but one instance this condition was diabetes, with the exception being the review by Slyer and Ferrara<sup>54</sup> (heart failure)]. Two of the remaining reviews<sup>42,50</sup> were broadly coterminous with our own review, focusing on chronic disease in adults (however, we also included children and adolescents). Only two reviews<sup>18,52</sup> covered the exact same population as our review, namely patients of any age group with chronic disease/chronic medical conditions.

## Interventions

Three reviews demonstrated a specific group education focus.<sup>42,47,51</sup> A further five reviews had a scope for the intervention that was broader than group clinics: for four of these reviews<sup>48–50,54</sup> this focus was labelled 'group visits' and for the remaining review<sup>52</sup> this was 'group care'. Two reviews<sup>18,55</sup> focused on SMAs and two reviews targeted GMVs,<sup>53,57</sup> both of these labels were considered coterminous with our own. The Cochrane review by Rolfe *et al.* covered a heterogeneous mix of interventions for improving patient trust, one intervention of which was a group clinic approach.<sup>56</sup>

This important review-mapping phase has established the potential of our review to provide the most comprehensive and most up-to-date coverage of the topic of group clinics for chronic medical conditions to be found in the published literature.

## Review quality

In addition to mapping all 13 of the existing reviews against the population, intervention and study type characteristics (see *Table 9*), we explored reasons for a mismatch between our review question and that in other reviews (*Table 10*). We then decided to produce a brief summary of the quality of the four key reviews<sup>18,83,85,87</sup> in order to assess any uncertainties underpinning their results (*Table 11*).

## Findings from four key reviews

### Edelman *et al.*<sup>18</sup> (+++/+++)

In a review of 19 papers (including 15 RCTs), Edelman *et al.* investigated the effects of SMAs on a variety of clinical and health service outcomes.<sup>18</sup> Thirteen trials investigated diabetes mellitus and two trials evaluated group clinic interventions for older adults with high utilisation of health services.

### Diabetes

Of the 13 RCTs evaluating clinical outcomes for patients with diabetes, 10 examined type 2 diabetes only, one examined type 1 diabetes only and two examined a mixed-patient population. The authors detected statistically significant changes for glycosylated haemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) and systolic blood pressure (five studies). However, effects varied significantly across studies and this was not explained by study quality. Effects on hospital admissions and emergency department visits were explored in five studies. These showed substantial variation; in three of these, admission rates were lower with SMAs, but the result was statistically significant in only one study. Two studies found emergency department visits decreased significantly with SMAs. Four studies reported effects on total costs, but results were mixed. In one, total costs were significantly higher; in another, total costs were significantly lower; in a third, results did not differ significantly; and the fourth was conducted in Europe.

### Older adults

Edelman *et al.* retrieved three studies (two trials and one observational study) that evaluated the effects of group clinic approaches on older adults with high health-care service utilisation rates.<sup>18</sup> All studies reported positive effects on patient experience with SMAs, compared with usual care. Both trials reported effects on overall health status and functional status, but there was no difference compared with usual care for either of these measures. Biophysical outcomes were not reported. All three studies showed fewer hospital admissions in the SMA groups, and both trials reported a statistically significant decrease in emergency department visits

TABLE 10 Characteristics of key reviews

Review	Type of review	Group intervention	Condition	Type of included studies	Number of included studies	Number of overlapping studies	Reasons for mismatch
Housden <i>et al.</i> (2013) <sup>53</sup>	Systematic review and meta-analysis	GMV	Diabetes	RCTs and OS	26 studies (13 RCTs)	17	Disease specific
Jaber <i>et al.</i> (2006) <sup>48</sup>	Qualitative review	Group visit	Any	RCTs and OS	16 studies with 18 publications	9	Includes non-RCTs
Riley and Marshall (2010) <sup>49</sup> (includes three general reviews <sup>8,22,89</sup> and one specific review <sup>48</sup> )	Systematic review	Group visit	Diabetes	Review articles and original studies	12 publications (4 review articles which contained 75 publications and 8 additional articles)	2	Disease specific. Broad scope including group education
Rolfe <i>et al.</i> (2014) <sup>56</sup>	Systematic review and meta-analysis	Any (interventions to improve trust)	Any	RCTs, quasi-RCTs, controlled before-and-after studies and interrupted time series of interventions	10 studies with 10 publications	2	Not intervention specific
Slyer and Ferrara (2013) <sup>54</sup>	Systematic review	Group visit	Heart failure	RCTs, non-RCTs and quasi-experimental trials	2 studies with 3 publications	1	Disease specific
Steinsbekk <i>et al.</i> (2012) <sup>51</sup>	Systematic review and meta-analysis	Group education (self-management)	Diabetes	RCTs	21 studies with 26 publications	4	Disease specific

OS, observational study.



TABLE 11 Review quality of the four key reviews

Criteria	Burke et al. (2011) <sup>87,88</sup> +/++++	Edelman et al. (2012) <sup>18</sup> ++++/++++	Housden et al. (2013) <sup>83</sup> +/++++	Edelman et al. (2014) <sup>85</sup> +/++++
Was review question clearly defined in terms of PICO?	Review question clear. Inclusion criteria reported	Review question clear. Inclusion criteria reported	Review question clear. Inclusion criteria reported	Review question clear. Inclusion criteria reported
Was search strategy adequate and appropriate?	Three-step literature search for English language studies (1990–2010) using (a) primary search of MEDLINE, CINAHL, PsycINFO and Cochrane Central Register of Controlled Trials; (b) secondary search of non-indexed databases; and (c) search of grey literature.	Searched multiple databases (MEDLINE via PubMed), EMBASE, CINAHL, PsycINFO and Web of Science (January 1996–September 2011). Limited to English language. Full search strategy provided. Updated search in PubMed conducted in April 2012. Developed search strategy with experienced librarian. Supplemented electronic searches with citation searches for key primary articles	Relevant sources searched, but only for published studies. Authors excluded two studies not in English. Language and publication bias may be present	Used multiple databases (data sources: MEDLINE, EMBASE, CINAHL, PsycINFO and Web of Science (January 1996–April 2012). Search updated June 2013. Selected: English-language peer-reviewed publications of RCTs, non-randomised cluster controlled trials, controlled before-and-after studies or interrupted time-series designs conducted among adult patients with diabetes
Were there any restrictions on language, publication status or publication date?	Manual review of reference lists			
Were preventative steps taken to minimise bias and errors in study selection process?	Eligible articles reviewed by two independent reviewers. Disagreements between reviewers resolved by discussion or by a third reviewer	Two reviewers assessed titles and abstracts for relevance against pre-specified inclusion and exclusion criteria. Full-text articles identified by either reviewer as potentially relevant retrieved for further review. Each article examined by two reviewers against eligibility criteria. Disagreements resolved by discussion or by a third reviewer	Attempts to minimise reviewer error and bias, for much of review	Two independent reviewers used pre-specified criteria to screen titles and abstracts for full-text review. Disagreements reconciled through discussion or by a third reviewer
Were appropriate criteria used to assess quality of primary studies, and were preventative steps taken to minimise bias and errors in the quality assessment process?	Studies meeting inclusion criteria assessed for methodological quality using JBI standardised critical appraisal tools	Assessed quality and applicability using AHRQ's methods guide. Quality criteria: (1) adequacy of randomisation and allocation concealment, (2) comparability of groups at baseline, (3) blinding, (4) completeness and differential loss to follow-up, (5) whether incomplete data addressed appropriately, (6) validity of outcome measures, and (7) conflicts of interest. Assigned summary quality score (good, fair or poor) to individual RCTs	Appropriate quality assessment tool used. Assessment informed synthesis	Assessed quality using AHRQ's methods guide. Specifically addressed methodological quality; assessed specific categories of bias; included validity and reliability of outcome measurement [detection bias]; and allowed for different bias ratings for different outcomes within same study. Assessments of bias performed by two reviewers. Disagreements reconciled through discussion or by a third reviewer

continued

TABLE 11 Review quality of the four key reviews (continued)

Criteria	Burke et al. (2011) <sup>87,88</sup> +/++++	Edelman et al. (2012) <sup>18</sup> ++++/++++	Housden et al. (2013) <sup>53</sup> +/++++	Edelman et al. (2014) <sup>55</sup> +/++++
	Overall review quality: high	Overall review quality: high	Overall review quality: high	Overall review quality: high
Were preventative steps taken to minimise bias and errors in the data extraction process?	Data extraction undertaken using standardised data extraction tool (JBI-MAStARI)	One investigator abstracted data. Second reviewed completed extraction form alongside original article to check for accuracy and completeness. Disagreements resolved by consensus or by third investigator. Contacted authors for missing information	Attempts to minimise reviewer error and bias, for much of review	Two different reviewers abstracted data and rated study quality and strength of evidence
Were adequate details presented for each of the primary studies?	Adequate details of all studies presented	Adequate details of all studies presented	Adequate details of all studies presented	Adequate details of all studies presented
Were appropriate methods used for data synthesis?	Studies pooled quantitatively. Limited details on synthesis.	Used random-effects models to synthesise available evidence quantitatively. Other outcomes analysed qualitatively	Appropriate methods used for pooling data, performing sensitivity analyses and meta-regression. Authors included observational studies, but did not use these studies in synthesis	Used random-effects models to synthesise effects quantitatively, reporting by a weighted difference of means or standardised mean difference. Measured heterogeneity in study effects using forest plots, Cochran's Q, and I <sup>2</sup> . Explored heterogeneity using subgroup analyses and meta-regression analyses. Outcomes not suitable to meta-analysis summarised qualitatively
Were differences between studies assessed? Were the studies pooled, and, if so, was it appropriate and meaningful to do so?	No sensitivity analysis			
Do the authors' conclusions accurately reflect the evidence that was reviewed?	Conclusions reflect evidence but do not convey associated uncertainties around results. Limited discussion of heterogeneity	Conclusions reflect evidence. Significant heterogeneity between trials. Long-term outcome data lacking. Reliability of conclusions uncertain	Conclusions reflect evidence, from reasonable number of small to medium-sized trials, many with unclear risks of bias. Significant clinical/statistical variation between trials. Long-term outcome data lacking. Reliability of conclusions uncertain	Conclusions reflect evidence, significant heterogeneity between trials. Long-term outcome data lacking. Reliability of conclusions uncertain

AHRQ, Agency for Healthcare Research and Quality; JBI-MAStARI, Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument. ++++ represents congruity of a review with this review, ++ represents a partial match and + indicates a significant departure from our scope. An exact match of scope would, therefore, be represented by ++++/++++, representing congruity of both population and intervention.

with SMAs, compared with usual care. Total costs also were lower for the SMA group in each study but varied substantially across studies. In no study did the difference in total costs reach statistical significance.

Owing to limitations in reporting, Edelman *et al.*<sup>18</sup> were unable to establish whether or not any specific patient characteristics might lead to a better response to SMAs. Furthermore, the review team evaluated whether or not baseline HbA<sub>1c</sub> was associated with response to SMAs: it was not. None of the studies permitted the team to identify specific intervention components, or intensity, associated with the effects of SMAs. Exploration of whether or not robustness was associated with effect size demonstrated that it was not. Edelman *et al.* concluded that the evidence synthesis had found no data to assess cost-effectiveness, and there was no definitive evidence of non-patient benefits, such as improved access or staff satisfaction.<sup>18</sup> The review team were unable to isolate key elements to successful implementation. They observed that the studies were unrepresentative of a 'real world setting', in that the research was conducted either within academic health systems or in independent clinical units that lacked dependencies on other clinical units (i.e. these were 'vertically integrated systems'), as would be more typically be the case in a non-experimental environment.

### **Burke *et al.*<sup>87,88</sup> (+/+++)**

Burke *et al.*'s review of 11 RCTs and four quasi-experimental trials (2240 patients), performed for the Joanna Briggs Institute, found clear benefits of GMV for patients' HbA<sub>1c</sub> levels, which are consistent in the effect sizes for post intervention and for change from baseline.<sup>87</sup> The most significant effect observed is with the change from baseline results. Some evidence suggests post-intervention and change from baseline systolic blood pressure improvement at the 9- to 12-month interval and change from baseline improvement at the 4-year time point. The review found no evidence that group visits improve low-density lipoprotein (LDL) cholesterol values of GMV participants. The review concluded that 'GMVs should be considered by clinicians as an effective non-pharmacologic intervention that can have a positive impact on biologic markers such as glycated haemoglobin A1c (HbA1c) and systolic blood pressure'.<sup>87</sup>

### **Housden *et al.*<sup>53</sup> (+/+++)**

In a review of 26 studies including 13 RCTs, Housden *et al.*<sup>53</sup> reported a positive effect for GMAs on clinical and patient-reported outcomes, with significant reductions in HbA<sub>1c</sub>. However, the team were unable to assess the effect of GMVs on processes of care because of an insufficient number of RCTs reporting this outcome.

### **Edelman *et al.*<sup>55</sup> (+/+++)**

In the most recent review identified for this project, Edelman *et al.*<sup>55</sup> identified 25 articles representing 17 unique studies that compared SMA interventions for diabetes with usual care. They reported that SMAs improved HbA<sub>1c</sub>, improved systolic blood pressure and did not improve LDL cholesterol. Non-biophysical outcomes, including economic outcomes, were reported too infrequently to meta-analyse. This meant that it was not possible to draw conclusions for non-biophysical outcomes. The HbA<sub>1c</sub> result revealed significant heterogeneity among studies, likely to be secondary to the heterogeneity among included SMA interventions.

### **Summary of findings from other reviews**

The Canadian Agency for Drugs and Technologies in Health (CADTH) health technology assessment group<sup>52</sup> conducted a review of the clinical effectiveness, cost-effectiveness and guidelines of group care across all aspects of chronic-disease management. They identified eight studies meeting the criteria for inclusion in their review: three systematic reviews, two RCTs, two non-randomised studies and one evidence-based guideline. They concluded that there was evidence for improved glycaemic control for diabetes group care (vs. usual care) and an isolated study in favour of better blood pressure control for group care of hypertension. However, they had been unable to find any information on effectiveness of group care for either chronic obstructive pulmonary disease (COPD) or human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS). A significant observation related to the fact that variations in the structure of group care, together with inadequate detail of reporting for the usual care, meant that the group felt unable to draw meaningful conclusions.

Steinsbekk *et al.*<sup>51</sup> reviewed 21 studies, reported in 26 publications, involving a total of 2833 participants. For the main clinical outcomes, HbA<sub>1c</sub> was significantly reduced at 6 months, 12 months and 2 years, and fasting blood glucose levels were also significantly reduced at 12 months but not at 6 months. For the main lifestyle outcomes, diabetes knowledge was improved significantly at 6 months, 12 months and 2 years and self-management skills also improved significantly at 6 months. For the main psychosocial outcomes there were significant improvements for empowerment/self-efficacy after 6 months. For quality of life the authors were unable to draw any conclusion owing to high heterogeneity. For the secondary outcomes there were significant improvements in patient satisfaction and body weight at 12 months for the intervention group. The review team found no differences between the groups in mortality rate, body mass index (BMI) blood pressure and lipid profile.

In a Cochrane review of group based education for diabetes, Deakin *et al.*<sup>47</sup> identified eight RCTs ( $n = 1260$ ) and three observational studies ( $n = 272$ ). Random-effects meta-analyses showed that HbA<sub>1c</sub> and fasting glucose concentrations were lower in the intervention group than in the control group {at 4–6 months [1.4%, 95% confidence interval (CI) 0.8% to 1.9%;  $p < 0.00001$ ], at 12–14 months (0.8%, 95% CI 0.7% to 1.0%;  $p < 0.00001$ ) and at 2 years (1.0%, 95% CI 0.5% to 1.4%;  $p < 0.00001$ )}. Diabetes knowledge scores were greater in the intervention group than in the control group (standardised mean difference 0.95, 95% CI 0.72 to 1.18) (three trials,  $n = 432$ ), yet not statistically significantly so. More patients in the intervention group than in the control group reduced their use of diabetes medication over 12–14 months (relative benefit increase 825%, 95% CI 202% to 2738%) (five trials,  $n = 654$ ). One RCT ( $n = 314$ ) assessing empowerment and psychosocial self-efficacy reported greater total empowerment scores in the intervention group than in the control group throughout follow-up ( $p < 0.05$ ). This indicates that the group education element of the group clinic intervention may, in itself, be efficacious. A key issue is the added benefit, if any, that is accrued from employing other supplemental non-group education-based features of the intervention within a group clinic framework.

Two reviews fall short of current practice for systematic reviews. In a narrative review without meta-analysis, Jaber *et al.*<sup>48</sup> concluded that there are sufficient data to support the effectiveness of group visits in improving patient and physician satisfaction, quality of care and quality of life, and in decreasing emergency department and specialist visits. Significantly, Jaber *et al.* highlighted a need to abandon old nomenclatures and to clearly define the structure, processes of care, content of visits and appropriate outcome measures.<sup>48</sup>

Riley and Marshall<sup>49</sup> produced a review of existing reviews including three general reviews<sup>8,22,89</sup> as well as the previously mentioned specific review by Jaber *et al.*<sup>48</sup> They observed that, although 'a variety of successes are evident from the entire group visit approach, results are inconclusive regarding any specific model for group visits and inconsistent regarding improvement of important patient outcomes'.<sup>49</sup> Nevertheless, Riley and Marshall concluded that there was evidence that 'group visits may reduce costs, physiological outcomes may be improved, and patient and clinician satisfaction may be enhanced'.<sup>49</sup> They cautioned, however, that 'The group visit model needs further testing to determine the most effective approach, and the most effective health care provider team to facilitate the group visit, along with standardization and application across a variety of situations'.<sup>49</sup>

In a review tangentially related to the topic, looking at interventions for building up trust between patients and clinicians, Rolfe *et al.*<sup>56</sup> identified three studies that had a group visit component. However, one of these studies was excluded from our review because it involved an induction visit as part of joining a health maintenance organisation. The remaining two interventions were included. The focus on trust is, however, important, as this represents one mechanism by which the group clinic interaction is hypothesised to work.

### Overall summary of findings from reviews

All of the reviews of group clinic-type approaches exhibit methodological challenges with regard to the inconsistent use of labels and definitions for the intervention and a lack of detail relating to the intervention components. Mechanisms for action are poorly theorised, and variability in outcomes and in subsequent effect sizes makes attribution of effect problematic. With the review team sensitised to the topic via existing reviews, we attempted to examine the evidence base for effectiveness by bringing together previously identified trials with new studies identified via sensitive search strategies.

## Results of the review of effectiveness

### Study characteristics

A total of 32 papers involving 22 trials were identified for inclusion in the review. The search of MEDLINE, EMBASE, The Cochrane Library, Web of Science and CINAHL databases yielded a total of 12,819 citations. After adjusting for duplicates, 11,000 remained. Of these, 5255 studies were discarded because after reviewing the abstracts it appeared that these papers clearly did not meet the inclusion criteria. The full text of the remaining 133 citations was examined in more detail, from which the 32 papers were selected and included in the systematic review (*Tables 12 and 13*). No unpublished relevant studies were obtained. No conference abstracts were identified that met our inclusion criteria and contained sufficient information to address the review question.

### Setting characteristics

Of the 22 trials, 17 were conducted in the USA.<sup>20,31,58,60,63–66,68,71,72,75–77,79,80,86</sup> Of the remaining RCTs, two<sup>73,74</sup> were conducted in the People's Republic of China, two<sup>82,85</sup> were conducted in Italy and one was conducted in Norway.<sup>70</sup> Not a single RCT was conducted in a UK setting.

### Intervention characteristics

Included studies comprised a total of nine different interventions. Of these, the CHCC (six studies) and SMA (five studies) models featured most frequently. SMAs were represented by trials that have occurred during the comparatively recent period of 2010–14, while the CHCC studies occurred during the period 2001–4, with the exception of two recent non-US studies reflecting a resurgence of interest. There were no RCTs for two of the models, the specialty CHCC model and DIGMAs (*Table 14*).

### Intervention components

Edelman *et al.*<sup>18</sup> has characterised the main features of SMA interventions. Almost 90% of such interventions had an educational component and nearly 65% are delivered by multidisciplinary teams. A behavioural intervention is a feature of exactly half of the SMA interventions. A focus on medicine management is evidenced in the fact that 55% of interventions include medication adjustment. Almost 90% of interventions include peer-to-peer support and just over 40% include clinician training. We did not find it possible to distinguish intervention content for studies not included by Edelman *et al.* from those studies included in their review, implying that findings from their review are generalisable to a wider population of group clinic approaches.<sup>18</sup> As seen in *Appendix 4*, our review has completed a very detailed data extraction of intervention components from RCTs. However, the facility to synthesise and analyse these data is constrained by the fact that (1) these data capture the completeness of reporting of each report, not the intervention content for that report, and (2) there is considerable variability in these descriptions, implying that similar components may be described differently or, conversely, that similar-looking descriptions may mask important substantive differences in content, delivery or both. Indeed, even different reports of the same study portrayed different depictions of the same intervention. Notwithstanding these reporting limitations, we found that some element of socialisation was included in 15 of the studies<sup>57,60–62,65,66,68–70,73,74,76,77,79,81</sup> and group discussion (i.e. many-to-many interaction) was reported in 14 studies.<sup>63,64,66,68,70,71,73–77,82,85,86</sup> Eleven studies explicitly reported health education/information presentation(s) by individual clinicians,<sup>57,60,65,66–68,70,71,73–75,79</sup> with one for health education/information presentation(s) by multiple clinicians<sup>63</sup> and two for health education/information via booklet, leaflet or video.<sup>70,80</sup> Seven studies

TABLE 12 Study characteristics: RCTs

Study identifier	Included papers	Country	Study design	Sample size	Number in IG	Number in CG
CLANCY 2003	Clancy <i>et al.</i> (2003) <sup>58</sup> Clancy <i>et al.</i> (2003) <sup>57</sup> Clancy <i>et al.</i> (2003) <sup>59</sup>	USA	RCT	120	59	61
CLANCY 2006	Clancy <i>et al.</i> (2007) <sup>60</sup> Clancy <i>et al.</i> (2007) <sup>61</sup> <sup>a</sup> Clancy <i>et al.</i> (2008) <sup>62</sup>	USA	RCT	186	96	90
COHEN 2011	Cohen <i>et al.</i> (2011) <sup>63</sup>	USA	RCT	99	50	49
COLE 2013	Cole <i>et al.</i> (2013) <sup>64</sup>	USA	RCT	65	34	31
COLEMAN 2001	Coleman <i>et al.</i> (2001) <sup>65</sup>	USA	RCT	295	146	149
DORSEY 2011	<sup>b</sup> Dorsey <i>et al.</i> (2011) <sup>68</sup>	USA	RCT	58	15 patients and 14 caregivers	15 and 13
EDELMAN 2010	Crowley <i>et al.</i> (2014) <sup>66</sup> Crowley <i>et al.</i> (2013) <sup>67</sup> Edelman <i>et al.</i> (2010) <sup>69</sup>	USA	RCT	239	133	106
GRAUE 2005	Graue <i>et al.</i> (2005) <sup>70</sup>	Norway	RCT	116	62	54
GRIFFIN 2009	Griffin <i>et al.</i> (2009) <sup>71</sup>	USA	RCT	153	45	108
GUTIERREZ 2011	Gutierrez <i>et al.</i> (2011) <sup>72</sup>	USA	RCT	103	50	53
JUNLING 2015	Junling <i>et al.</i> (2015) <sup>73</sup>	The People's Republic of China	RCT	1346	692	654
LIU 2012	Liu <i>et al.</i> (2012) <sup>74</sup>	The People's Republic of China	RCT	208	119	89
NAIK 2011	Naik <i>et al.</i> (2011) <sup>75</sup>	USA	RCT	87	45	42
RATANAWONGSA 2012	<sup>c</sup> Ratanawongsa <i>et al.</i> (2012) <sup>76</sup>	USA	RCT	245	0.32	0.34
SADUR 1999	Sadur <i>et al.</i> (1999) <sup>20</sup>	USA	RCT	185	97	88
SCHILLINGER 2008	<sup>d</sup> Schillinger <i>et al.</i> (2008) <sup>77</sup> <sup>d</sup> Schillinger <i>et al.</i> (2009) <sup>78</sup>	USA	RCT	339	112	115
SCOTT 2004	Scott <i>et al.</i> (2004) <sup>79</sup>	USA	RCT	294	145	149
TAVIERA 2010 (same intervention, different population)	Taveira <i>et al.</i> (2010) <sup>80</sup> Taveira <i>et al.</i> (2011) <sup>81</sup>	USA USA	RCT RCT	118 88	58 44	60 44
TRENTO 2002	Trento <i>et al.</i> (2001) <sup>82</sup> Trento <i>et al.</i> (2002) <sup>83</sup> Trento <i>et al.</i> (2004) <sup>84</sup>	Italy	RCT	112	56	56
TRENTO 2005	Trento <i>et al.</i> (2005) <sup>85</sup>	Italy	RCT	62	31	31
WAGNER 2001	Wagner <i>et al.</i> (2001) <sup>86</sup>	USA	RCT	708	278	429
YEHLE 2009	Yehle <i>et al.</i> (2009) <sup>31</sup>	USA	RCT	52	26	26

CG, control group; IG, intervention group.

a Economic evaluation alongside RCT.

b Subgroups by insulin regimen: no insulin (oral diabetes medications only)  $n=98$ , basal insulin and oral medications  $n=62$  and complex medications  $n=79$ .

c Three-arm RCT; 34% in weekly automated telephone self-management.

d One hundred and twelve in three-arm weekly automated telephone disease management.



TABLE 13 Population characteristics: RCTs

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Differences between intervention and control group (confounding variables)
CLANCY (2003) <sup>57-59</sup>	Type 2 diabetes	HbA <sub>1c</sub> > 8.5%	18 years or older. Average age was 54.0 years (range 22–83 years); 77.5% were African American	Primary diagnosis of substance abuse or dependence, current pregnancy, dementia or inability to speak English Mean age (years): 56.1	Adjusted for age, gender, race, education level, reading level, baseline clinical outcome measures and insurance type
CLANCY (2006) <sup>60-62</sup>	Type 2 diabetes	Poorly controlled diabetes (HbA <sub>1c</sub> > 8.0%)	18 years or older		Intervention group had lower baseline levels of LDL cholesterol and total cholesterol than control group
Cohen <i>et al.</i> (2011) <sup>63</sup>	Type 2 diabetes	HbA <sub>1c</sub> 7.0%, LDL > 100 mg/dl (2.5 mmol/l) or LDL > 70 mg/dl (1.81 mmol/l) for those with coronary artery disease, and BP > 130/80 mmHg, each documented at least once in medical records 6 months before enrolment	Veterans Age (years): IG 69.8 ± 10.7; CG 67.2 ± 9.4		
Cole <i>et al.</i> (2013) <sup>64</sup>	Diabetes	Pre-diabetes as defined by American Diabetes Association diagnostic criteria for IFG (fasting blood glucose of 100–125 mg/dl)	Minimum age of 18 years, fluent in English	Diagnosis of diabetes and those not attending initial pre-diabetes education class	Significant difference in age at baseline
Coleman <i>et al.</i> (2001) <sup>65</sup>	Chronic conditions	One or more self-reported chronic conditions (e.g. asthma, COPD, congestive heart failure, diabetes and heart disease)	60 years or older 11 or more outpatient clinic visits in past 18 months Nearly all patients selected using these criteria had at least one hospitalisation in the past 18 months	Ineligible patients had lower self-reported health status ( $p = 0.01$ ) and took fewer medications per day ( $p < 0.01$ ) than eligible patients Physician-determined significant functional impairment or dementia precluding participation in group visit format	Intervention and control groups similar with respect to age, gender, marital status, self-rated health status and functional disability as measured by ADLs and instrumental ADLs. Prevalence of COPD may have differed
Dorsey <i>et al.</i> (2011) <sup>68</sup>	Parkinson's disease	Clinical diagnosis of idiopathic Parkinson's disease	Patients over 30 years	Patients not willing and able to provide informed consent and participate fully in group patient visits	

continued

TABLE 13 Population characteristics: RCTs (continued)

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Differences between intervention and control group (confounding variables)
EDELMAN (2010) <sup>66,67,69</sup>	Type 2 diabetes and hypertension	Poorly controlled diabetes (HbA <sub>1c</sub> ≥ 7.5%) and hypertension (systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg) and on medication for diabetes and hypertension	Aged population Ethnic minority population 96.9% male, mean age 62.0 years, 57.1% African American, 56.1% married, 38.8% high school or less/37.8% some college, financial burden (can pay bills without cutting spending) 69.9%	Veterans from two VAMCs, North Carolina and Virginia. Suboptimal lipid control not a criterion for study entry	Patients similar at baseline. Patients at Durham VAMC were slightly younger and heavier and had higher HbA <sub>1c</sub> levels and systolic BP. Randomisation stratified by site, baseline HbA <sub>1c</sub> (≥ vs. < 9.0%) and systolic BP (≥ vs. < 150 mmHg)
Graue <i>et al.</i> (2005) <sup>70</sup>	Type 1 diabetes	Mean HbA <sub>1c</sub> 9.3%. Mean diabetes duration 6.5 years	Adolescents. Mean age 14.2 years. Age of adolescents group split into younger (11–13 years) and older (14–17 years)		
Griffin <i>et al.</i> (2009) <sup>71</sup>	Heart disease/hypertension	On warfarin therapy for at least 30 days, with goal INR range supported by current guidelines		Excluded if warfarin therapy anticipated to be discontinued < 2 months from start of study	
Gutierrez <i>et al.</i> (2011) <sup>72</sup>	Diabetes	HbA <sub>1c</sub> 7% or higher	Hispanic patients aged 18 years or older		
Junling <i>et al.</i> (2015) <sup>73</sup>	Hypertension		Older adults Patients from four community health care centres of two districts in Shanghai, the People's Republic of China		
Liu <i>et al.</i> (2015) <sup>74</sup>	Type 2 diabetes		Aged 35–80 years living in rural communities in Shanghai, the People's Republic of China		



Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Differences between intervention and control group (confounding variables)
Naik <i>et al.</i> (2011) <sup>75</sup>	Type 2 diabetes	Mean HbA <sub>1c</sub> level of at least 7.5% on all measurements in 6 months prior to study entry	50–90 years old Have a PCP Consistent with older US veteran population, sample overwhelmingly male, multiple morbidities and of heterogeneous race	Patients excluded if they had a diagnosis of dementia or a serum creatinine level of at least 2.5 mg/dl	Participants similar at baseline across sociodemographic and clinical variables, including HbA <sub>1c</sub> level, systolic BP, BMI and duration of DM. No differences noted
Ratanawongsa <i>et al.</i> (2012) <sup>76</sup>	Type 2 diabetes	Adults with type 2 diabetes. Most recent HbA <sub>1c</sub> ≥ 8.0%	English, Spanish (44%) or Cantonese speaking		
Sadur <i>et al.</i> (1999) <sup>20</sup>	Type 1 and type 2 diabetes	Had ≥ 1 primary care visit at one of four participating clinics Recent HbA <sub>1c</sub> concentration > 8.5% or not had HbA <sub>1c</sub> concentration measured during previous year	Patients between 16 and 75 years of age	Current pregnancy, dementia, inability to speak English or inability to attend monthly meetings	
Schillinger (2008) <sup>77,78</sup>	Type 2 diabetes	Type 2 diabetes that is poorly controlled – suboptimal glycaemic control, having recent HbA <sub>1c</sub> ≥ 8.0%	Older than 17 years English, Spanish or Cantonese speaking Patients had more than one primary care visit in last year	Ethnic minority population	
Scott <i>et al.</i> (2004) <sup>79</sup>	Chronic conditions	Patients with arthritis, hypertension, difficulty hearing, heart disease, liver disease and bladder/kidney disease	Adult patients aged over 60 years with ≥ 11 outpatient visits in 18 months Health Maintenance Organisation Patients		

continued

TABLE 13 Population characteristics: RCTs (continued)

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Differences between intervention and control group (confounding variables)
Seeing <i>et al.</i> (2014) <sup>90</sup>	Chronic neuromuscular disorders	Patients identified through CRAMP, Dutch neuromuscular database, recruited from March 2009 to March 2011. Eligible if diagnosis of one of selected chronic neuromuscular disorders	Older than 18 years, currently in care of department and had not seen their neurologist 6 months before study commencement	Severe hearing problems or insufficient command of the Dutch language	In SMA group, slightly more patients diagnosed with myotonic dystrophy type 1 and fewer patients seen by their own neurologist
TAVEIRA (2010) <sup>80</sup>	Type 2 diabetes	HbA <sub>1c</sub> between 7% and 9% within the previous 6 months	18 years or older	Unable to attend group sessions	Intervention group younger and had greater tobacco use at baseline than usual care but similar in other cardiovascular risk factors
Taveira <i>et al.</i> (2011) <sup>81</sup>	Type 2 diabetes	Diagnosis and HbA <sub>1c</sub> > 6.5% within previous 6 months AND diagnosis of depression (ICD 9 311, 296.2, 296.3)	Intervention: gender (100% male), age (60.2 years mean, 9.3 years SD), white (97.7%)	Psychiatric instability (acutely suicidal, psychotic) or organic brain injury	
TRENTO (2002) <sup>82-84</sup>	Type 2 diabetes	Treated either with diet alone or with diet and oral administration of hypoglycemic agents	Aged < 80 years and had attended diabetes clinic for at least 1 year	Sex (men/women) 27/29; 34/22	
Trento <i>et al.</i> (2005) <sup>85</sup>	Type 1 diabetes	Onset before age of 30 years and insulin treatment started within 1 year of diagnosis; four daily insulin injections and self-monitoring of blood glucose	Aged < 70 years and at least 1 year's previous attendance at clinic		Control patients had different schooling levels ( $p < 0.05$ ) and higher HbA <sub>1c</sub> levels at baseline ( $p = 0.015$ )

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Differences between intervention and control group (confounding variables)
Wagner <i>et al.</i> (2001) <sup>36</sup>	Type 1 and type 2 diabetes	Receiving insulin or oral hypoglycaemic therapy	Aged > 30 years	Terminally ill, demented or psychotic, ineligible owing to communication problems and HMO disenrollment	
Yehle <i>et al.</i> (2009) <sup>31</sup>	HF	Community-living adults with established diagnosis of HF		Cognitive impairment or inability to read or speak English, or if participant resided in nursing home. Patients with cognitive impairment identified by physician/nurse practitioner. Patients residing in nursing home unable to participate in clinic visit	No difference in attrition between intervention and control groups when compared according to age, gender, insurance, hospitalisation during study, HFKT, or SCHFI

ADL, activity of daily living; BP, blood pressure; CG, control group; CRAMP, Computer Registry of All Myopathies and Polyneuropathies; DM, diabetes mellitus; HF, heart failure; HFKT, Heart Failure Knowledge Test; HMO, health maintenance organisation; IFG, impaired fasting glucose; IG, intervention group; INR, international normalised ratio; PCP, primary care physician; SCHFI, Self Care of Heart Failure Index; VAMC, Veterans Affairs Medical Center.

**TABLE 14** Prevalence of group clinic approaches by number of studies and number of papers

Model (studies)	Number of studies	Number of papers
CHCC model <sup>57–62,65,73,74,79</sup>	6	10
SMA <sup>63,64,72,80,81,90</sup>	5	6
Group clinic <sup>66,67,69,71,75</sup>	3	5
GMV <sup>68,76–78</sup>	3	4
Group visit <sup>70,82–85</sup>	3	5
Chronic care clinic <sup>86</sup>	1	1
Cluster visit <sup>20</sup>	1	1
Shared medical visit <sup>31</sup>	1	1

Specialty CHCC model, DIGMAs and GMAs received no mentions.

reported medication review and four describe completion of prescriptions.<sup>60,63,66,71,75,80,81</sup> Six studies reported individual consultation within the group session<sup>60,65,76,77,84,86</sup>, with five describing individual consultation immediately following the group session for all patients<sup>58,59,68,69,82</sup> and three for individual consultation immediately following the group session for selected patients.<sup>73,74,83</sup> Six studies reported routine medical checks being performed by multiple clinicians<sup>57,65,66,74,79,86</sup> and six reported these checks being made by individual clinicians,<sup>60,63,67,73,77,82</sup> while only two studies reported routine medical checks being conducted by the patient.<sup>69,70</sup> Only one study reported telephone follow-up.<sup>69</sup>

### Group size

The smallest group sizes started at around three or four patients and these smaller groups typically did not extend beyond seven or eight participants (*Table 15*). Typical group sizes involved between 6 and 10 patients. Three studies had around 20 participants, with the largest of these ranging between 20 and 25 patients. One group involved up to seven patients but also made provision for patients' families. It was not clear from most reports whether these numbers were aspirational, reflecting full capacity, or whether they represented typical attendance. Two studies reported means of 7.7 and 9 patients, indicating that these were actual attendance figures. It was not possible to make any observations about optimal group size. Clearly, there is a potential tension between efficiency, as reflected in higher numbers, and optimal group interaction, which may be represented in smaller numbers while nevertheless needing to realise a critical mass for viability and interaction.

### Visit frequency

Visit intervals ranged from weekly (e.g. Taveira *et al.*<sup>80</sup>) through to quarterly (e.g. Dorsey *et al.*<sup>68</sup> and Trento *et al.*<sup>82</sup>) or semiannually (e.g. Wagner *et al.*<sup>86</sup>) (see *Table 15*). Typical visit frequencies were monthly but even in those instances they varied in duration (e.g. monthly for 3 months, 6 months or 1 year). It was not clear in most instances whether these reflected a therapeutic interval (as determined by clinical need) or an evaluation interval (as determined by the needs of a particular study). Most of the studies reported these intervals only over the period covered by the study and studies made little reference to continuation beyond the study period or to issues relating to sustainability. It is not clear, therefore, what the optimal visit interval and frequency is from a therapeutic viewpoint. Some studies employed different visit frequencies for initiation and maintenance (e.g. fortnightly for first 3 months and then monthly for next 3 months<sup>73</sup> or weekly for 4 weeks and then monthly for 5 months<sup>63</sup>), suggesting a potential line for further investigation. However, the underlying assumptions for such a pattern were typically not surfaced. It was not clear whether these periods were determined by clinical considerations, by assumptions of patient burden or by the available clinical resources in the health service. One study alternated group visits and individual consultations every 3 months.<sup>70</sup> However, it was again not clear what the drivers were for this particular decision. The study with the longest follow-up required patients to visit four times a year for 2 years then a further seven times over years 3–4.<sup>83</sup>

TABLE 15 Group characteristics: quantitative

Study	Group size	Visit frequency	Individual session duration	Total duration	Number of follow-up appointments	Total time spent in group per session	Total time spent in individual consultation
CLANCY (2003)	19–20	Monthly for 6 months	2 hours	12 hours	Six (1 + 5)	75 minutes	30 minutes
Clancy <i>et al.</i> (2003) <sup>58</sup>							
Clancy <i>et al.</i> (2003) <sup>57</sup>							
Clancy <i>et al.</i> (2003) <sup>59</sup>							
CLANCY (2006)	14–17	Monthly for 1 year	2 hours	24 hours	Two at 6 and 12 months	60 minutes	60 minutes
Clancy <i>et al.</i> (2007) <sup>60</sup>							
Clancy <i>et al.</i> (2007) <sup>61</sup>							
Clancy <i>et al.</i> (2007) <sup>62</sup>							
Cohen <i>et al.</i> (2011) <sup>63</sup>	4–6	Weekly for 4 weeks then monthly for 5 months	Weekly sessions of 2 hours and monthly sessions of 90 minutes	15.5 hours	One at 6 months	Weekly sessions 2 hours and monthly sessions 90 minutes	
Cole <i>et al.</i> (2013) <sup>64</sup>	6–8	Monthly over 3 months	90 minutes	4.5 hours	Not specified	80 minutes	10 minutes
Coleman <i>et al.</i> (2001) <sup>65</sup>	8–12	Monthly	120 minutes	Indefinite	Indefinite	80 minutes	40 minutes (3.5–5 minutes each)
Dorsey <i>et al.</i> (2011) <sup>68</sup>	3–7	Once every 3 months for 12 months	90 minutes	6 hours	One at 12 months	90 minutes	10 minutes per patient

continued

TABLE 15 Group characteristics: quantitative (continued)

Study	Group size	Visit frequency	Individual session duration	Total duration	Number of follow-up appointments	Total time spent in group per session	Total time spent in individual consultation
EDELMAN (2010)	7–9	Every 2 months for seven visits over 12 months	Scheduled for 2 hours but after first session often 90 minutes	14 hours	Two (6 months and 1 year)	60–75 minutes	1 hour allocated to individual consultations (estimated 6.5–8.5 minutes per participant)
Edelman <i>et al.</i> (2010) <sup>69</sup>							
Crowley <i>et al.</i> (2014) <sup>66</sup>							
Crowley <i>et al.</i> (2013) <sup>67</sup>							
Graue <i>et al.</i> (2005) <sup>70</sup>	4–9	Every 3 months for 15 months (alternate group visits/individual consultations)	3 hours	11 hours and 15 minutes	Two at 15 months and 24 months	3 hours	45 minutes
Griffin <i>et al.</i> (2009) <sup>71</sup>	6	Not stated	60 minutes	Indefinite	Indefinite	60 minutes	Not stated
Gutierrez <i>et al.</i> (2011) <sup>72</sup>	9 (mean)	Every 2 weeks. 36 SMAs in total	Not given	Not given	Maximum 17 months, mean follow-up at 9.5 months	Not given	Not given
Junling <i>et al.</i> (2015) <sup>73</sup>	18–20	Fortnightly for first 3 months then monthly for next 3 months	120 minutes	18 hours	One at 6 months	60 minutes	60 minutes
Liu <i>et al.</i> (2012) <sup>74</sup>	20–25	Monthly for 12 months	150 minutes	30 hours	One at 12 months	90 minutes	60 minutes
Naik <i>et al.</i> (2011) <sup>75</sup>	5–7	Four visits, every 3 weeks	1 hour 10 minutes	4 hours 40 minutes	1 + 3	60 minutes	10 minutes
Ratanawongsa <i>et al.</i> (2012) <sup>76</sup>	6–10	Monthly for 9 months	90 minutes	13 hours and 30 minutes	One at 1 year	Unclear	Unclear
Sadur <i>et al.</i> (1999) <sup>20</sup>	10–18	Monthly	2 hours	Not specified	Over 6 months	Not specified	Not specified

Study	Group size	Visit frequency	Individual session duration	Total duration	Number of follow-up appointments	Total time spent in group per session	Total time spent in individual consultation
SCHILLINGER (2008)	6–10	Monthly for 9 months	90 minutes	13 hours 30 minutes	One at 1 year	90 minutes	Unclear
Schillinger <i>et al.</i> (2008) <sup>77</sup>							
Schillinger <i>et al.</i> (2009) <sup>78</sup>							
Scott <i>et al.</i> (2004) <sup>79</sup>	7.7 patients (mean)	Monthly for 24 months	2 hours 30 minutes	60 hours	One at 24 months	90 minutes	60 minutes
Taveira <i>et al.</i> (2010) <sup>80</sup>	4–8	Four once weekly	2 hours	8 hours		2 hours	0
Taveira <i>et al.</i> (2011) <sup>81</sup>	4–8	Four once weekly then five monthly	100–140 minutes	?	N/A		
Trento <i>et al.</i> (2001) <sup>82</sup>	9–10	Four times per year	120 minutes	3 hours 20 minutes		50 minutes	Not specified
Trento <i>et al.</i> (2002) <sup>83</sup>	9–10	Four times per year for 2 years then seven over years 3–4	No details	No details	No details	No details	No details
Trento <i>et al.</i> (2004) <sup>84</sup>	9–10	Four sessions per year	No details	No details	No details	No details	No details
Trento <i>et al.</i> (2005) <sup>85</sup>	No details	Every 2–3 months	40–50 minutes plus individual consultations	15 hours	15	40–50 minutes	Described as 'brief'
Wagner <i>et al.</i> (2001) <sup>86</sup>	6–10	Every 3–6 months	Half-day	Indefinite	Indefinite	60 minutes	
Yehle <i>et al.</i> (2009) <sup>81</sup>	Up to 7 patients (plus family/friends)	Every 8 weeks	No details	No details	No details	60 minutes	10 minutes
N/A, not applicable.							

### Session duration

A typical length of session was between 1.5<sup>64,68,76,77</sup> and 2 hours<sup>20,58,60,65,73,80</sup> (90–120 minutes) (see *Table 15*). Shortest sessions were 60–70 minutes in duration,<sup>71,75</sup> although sessions of 40–50 minutes might require additional time for individual consultations.<sup>85</sup> The longest sessions were 2.5 to 3 hours, although one session was described as ‘half a day’,<sup>86</sup> albeit at less frequent intervals. Two interventions reflected variable time periods either when switching to less frequent intervals (weekly sessions 2 hours and monthly sessions 90 minutes<sup>63</sup>) again with implicit assumptions about differential requirements for initiation and maintenance or reflecting differences between a scheduled period and an actual duration (e.g. scheduled for 2 hours but after first session often 90 minutes<sup>69</sup>). Methodologically it is very difficult to summarise the information about the session durations, mainly because some studies record the complete duration from arrival to departure and others include only the time spent in a group setting. Studies also handle any individual consultations differently, with some recording these as supplementary (i.e. additional time) and others including these in the group session times.

### Total duration

The value of information on the total duration of all documented sessions is questionable, partly for the reasons mentioned in *Session duration* and partly because the denominator is typically determined by the study period and not by therapeutic considerations. A further limitation is that comparability between individual and group sessions is not possible; in most cases studies follow an enhancement model, not a substitution model, and therefore individual consultation sessions take place in both arms. Equally importantly, we typically do not have details on whether or not the individual consultations in a group context are typically shorter than those in an individual treatment context. It should be borne in mind that the total time required by clinical staff is considerable, requiring preparation for the group sessions in terms of educational content, review of medical notes and results prior to the visit, etc. In addition, provision for follow-up is often not formally documented in the studies.

Notwithstanding these limitations, we can see from *Table 15* that, over the study period, total durations of 12–14 hours are common, with other studies reaching 24 or 30 hours of clinical group input. The longest duration was a total of 60 hours spread over 4 years, although some studies recorded the total duration as ‘indefinite’, implying ongoing service provision beyond the study period.

In summary, it can be seen that data on such important evaluative group features as size, frequency and session and total duration, where available, are extremely difficult to synthesise and interpret. In particular, justification for these features is rarely provided, although we can make some assumptions about their underpinning rationale (e.g. different assumptions about initiation vs. maintenance). More worryingly, such considerations seem to be determined primarily by either pragmatic or study considerations rather than by enhanced effectiveness, optimal curriculum content or empirical evidence on group processes and interactions.

### Narrative summary of study quality

The review of RCTs included 32 papers reporting 22 trials (*Table 16*). The quality of included RCTs was assessed using questions relevant for RCTs and from these responses a Cochrane risk of bias was determined for each study (*Table 17*). Of the 22 trials, nine studies (11 papers)<sup>60–63,65–70,73</sup> were categorised as having a low risk of bias, 10 studies (11 papers) were categorised as having a high risk of bias<sup>20,57–59,64,71,74,75,79–87</sup> and three studies (four papers) were categorised as unclear.<sup>72,76–78</sup> The large number of studies with a high risk of bias means that any conclusions based on these trials should be treated with caution. The discussion on the quality of the RCTs will begin by discussing general problems with the studies then consider the groups of studies with low, high and unclear risk of bias.

A key problem for all of these studies is the possibility of selection bias having impacted on the results. All studies included patients who chose to participate in group clinics. Patients who wish to participate in group clinics are likely to give more positive results on self-reported outcomes. Additionally, a patient’s choice to be involved may indicate greater concern about improving their condition and, as such, they may be more motivated to implement suggested changes to their lifestyle, thereby improving their clinical outcomes.



TABLE 16 Included RCTs with outcomes included and results

Study	Outcome measures	Results
Clancy <i>et al.</i> (2003) <sup>58</sup>	Hospital admissions ED visits Costs Concordance with 10 process-of-care indicators recommended by the ADA standards of care. (HbA <sub>1c</sub> levels and lipid profiles, urine for microalbumin, appropriate use of ACE inhibitor or angiotensin receptor blockers, use of lipid-lowering agents, daily aspirin use, annual foot examinations, annual referrals for retinal examinations and immunizations against streptococcal pneumonia and influenza)	Group visit patients showed statistically significant improvement in concordance with 10 process-of-care indicators ( $p < 0.001$ ). 76% of group visit patients had at least 9 out of 10 items up to date, compared with 23% of control patients; 86% of group visit patients had at least 8 out of 10 indicators, compared with 47% of control patients
Clancy <i>et al.</i> (2003) <sup>57</sup>	PCAT TPS. Attendance records	Patients who received care in group visits showed an improved sense of trust in their physician, compared with patients who continued to receive usual care. There was a tendency for patients in groups to report better co-ordination of their care, better community orientation and more culturally competent care. Patient attendance at groups also indicated good acceptance
Clancy <i>et al.</i> (2003) <sup>59</sup>	Feasibility Acceptability Concordance ADA standards of care	Group visit patients exhibited improvement in ADA standards of care ( $p < 0.001$ ) and improved sense of trust in physician ( $p = 0.02$ ) and tended to report better co-ordination of care ( $p = 0.07$ ), better community orientation ( $p = 0.09$ ) and more culturally competent care ( $p = 0.09$ )
Clancy <i>et al.</i> (2007) <sup>60</sup>	HbA <sub>1c</sub> BP Lipid profiles Quality of care measures (adherence to 10 ADA guidelines and three USPSTF cancer screens) at 12 months	At both measurement points, HbA <sub>1c</sub> , BP and lipid levels did not differ significantly for group visit patients vs. those in usual care. At 12 months, however, group visit patients exhibited greater concordance with ADA process-of-care indicators ( $p < 0.0001$ ) and higher screening rates for cancers of the breast (80% vs. 68%; $p = 0.006$ ) and cervix (80% vs. 68%; $p = 0.019$ )
Clancy <i>et al.</i> (2007) <sup>61</sup>	PCAT DLC survey TPS	Compared with patients in usual care, group visit patients' PCAT scores were higher for ongoing care ( $p = 0.001$ ), community orientation ( $p < 0.0001$ ), and cultural competence ( $p = 0.022$ ). Group visit patients had higher scores for the Powerful-Other Health Professional subscale of the DLC survey ( $p = 0.010$ )
Clancy <i>et al.</i> (2008) <sup>62</sup>	ED charges Outpatient visit charges	Group visit patients had reduced ED and total charges but more outpatient charges than usual care patients. Group visits increased outpatient visit charges; however, controlling for endogeneity showed that group visits statistically significantly reduced outpatient charges ( $p < 0.001$ ). Separate treatment effect model of specialty care visits confirmed that group visit effects on outpatient visit charges occurred via reduction in specialty care visits

continued

TABLE 16 Included RCTs with outcomes included and results (*continued*)

Study	Outcome measures	Results
Cohen <i>et al.</i> (2011) <sup>63</sup>	HbA <sub>1c</sub> Systolic BP LDL cholesterol Diabetes self-care behaviour questionnaires at 6 months	Randomisation groups similar at baseline in all cardiovascular risk factors except LDL; significantly lower in IG. At 6 months, significant improvements from baseline found in IG for exercise, foot care and goal attainment of HbA <sub>1c</sub> , LDL cholesterol and BP but not for control group
Cole <i>et al.</i> (2013) <sup>64</sup>	Fasting blood glucose (mg/dl) Weight (kg) BMI Systolic BP Diastolic BP HbA <sub>1c</sub> (%) Total cholesterol LDL cholesterol (mg/dl) HDL cholesterol (mg/dl) Triglycerides (mg/dl)	A total of 94 participants in two study groups with 69% completion rate at 1 year ( $n = 34$ SMA, $n = 31$ control). Average participant was Caucasian (64%), male (54%), $58.3 \pm 9.6$ years, had BMI of $30.8 \pm 4.9$ kg/m <sup>2</sup> (obese) and fasting blood glucose of $109 \pm 9.5$ mg/dl. SMA and control participants lost mean of 6.6 lb and 3.6 lb, respectively; neither group met 5% modest weight loss expected. SMA and control group experienced a mean drop in fasting blood glucose of 6 mg/dl
Coleman <i>et al.</i> (2001) <sup>65</sup>	ED visits Hospitalisations Primary care visits	On average, patients in IG attended 10.6 group visits during 2-year study period. IG patients averaged fewer ED visits (0.65 vs. 1.08 visits; $p = 0.005$ ) and were less likely to have any ED visits (34.9% vs. 52.4%; $p = 0.003$ ) than controls. These differences remained statistically significant after controlling for demographic factors, comorbid conditions, functional status and prior utilisation. Adjusted mean difference in visits was $-0.42$ visits (95% CI $-0.13$ to $-0.72$ ), and adjusted RR for any ED visit was 0.64 (95% CI 0.44 to 0.86)
Crowley <i>et al.</i> (2014) <sup>66</sup>	Total cholesterol LDL cholesterol HDL cholesterol Triglycerides	At baseline, mean total cholesterol was 169.7 mg/dl (SD 47.8 mg/dl), LDL cholesterol 98.2 mg/dl (SD 41.7 mg/dl) and HDL cholesterol 39.3 mg/dl (SD 13.0 mg/dl). Median baseline triglycerides were 131 mg/dl (interquartile range 122 mg/dl). By study end, mean total cholesterol and LDL cholesterol in GMCs were 14.2 mg/dl ( $p = 0.01$ ) and 9.2 mg/dl ( $p = 0.02$ ) lower than usual care, respectively; 76% of GMC patients met goals for LDL cholesterol vs. 61% of usual care patients ( $p = 0.02$ ). Triglycerides and HDL cholesterol remained similar between study arms. Treatment intensification occurred in 52% of group medical clinic patients vs. 37% of usual care patients between study baseline and end ( $p = 0.04$ ). Mean statin dose higher in GMC patients at study mid-point and end
Crowley <i>et al.</i> (2013) <sup>67</sup>	HbA <sub>1c</sub> Self-efficacy	Effect of GMC on HbA <sub>1c</sub> differed by baseline insulin regimen vs. usual care ( $p = 0.05$ ); no differential effect on self-efficacy ( $p = 0.29$ ). Among those using complex insulin regimens at baseline, GMC reduced HbA <sub>1c</sub> by study end compared with usual care ( $-1.0\%$ , 95% CI $-1.8\%$ to $-0.2\%$ ; $p = 0.01$ ). No HbA <sub>1c</sub> difference between GMC and UC patients using no insulin ( $p = 0.65$ ) or basal insulin only ( $p = 0.71$ ). No clinically significant differences in hypoglycaemia by baseline insulin regimen and IG

TABLE 16 Included RCTs with outcomes included and results (*continued*)

Study	Outcome measures	Results
Dorsey <i>et al.</i> (2011) <sup>68</sup>	Feasibility (ability to recruit participants and proportion of participants who completed study) Quality of life measured by Parkinson's Disease Questionnaire 39 items	30 patients and 27 caregivers enrolled. 13 out of 15 patients randomised to GPVs and 14 out of 15 randomised to usual care completed study. Quality of life measured 12 months after baseline between two groups was not different (25.9 points for GPVs vs. 26.0 points for usual care; $p = 0.99$ )
Edelman <i>et al.</i> (2010) <sup>69</sup>	HbA <sub>1c</sub> Diastolic BP Systolic BP Hospital admissions ED visits	Mean baseline systolic BP and HbA <sub>1c</sub> level were 152.9 mmHg (SD 14.2 mmHg) and 9.2% (SD 1.4%), respectively. At end of study, mean systolic BP improved by 13.7 mmHg in GMC group and 6.4 mmHg in usual care group ( $p = 0.011$ by linear mixed model), whereas mean HbA <sub>1c</sub> level improved by 0.8% in GMC group and 0.5% in usual care group ( $p = 0.159$ )
Graue <i>et al.</i> (2005) <sup>70</sup>	HbA <sub>1c</sub> Child Health Questionnaire (CHQ-CF87) DQoL	101 adolescents (55 intervention/46 control) agreed to participate, mean age 14.2 years (SD 1.5 years), mean diabetes duration 6.5 years (SD 3.6 years, range 1–16 years), mean HbA <sub>1c</sub> 9.3% (SD 1.4%, range 6.1–12.8%). 83 (72%) completed questionnaires at follow-up (intervention/control 45/38). Significant age by randomisation group interactions for diabetes-related impact ( $p = 0.018$ ), diabetes-related worries ( $p = 0.004$ ), mental health ( $p = 0.046$ ) and general behaviour ( $p = 0.029$ ), implying group visit were effective in older adolescents (above 13–14 years). No significant effects on mean HbA <sub>1c</sub> identified
Griffin <i>et al.</i> (2009) <sup>71</sup>	Number of visits INR	28/45 patients participated for the 16-week study period. Control group included 108 patients seen by pharmacist for individual anticoagulation appointments. No significant difference in percentage of INR values within therapeutic range detected between patients in group visit model vs. patients receiving individual visits (59% vs. 56.6%; $p = 0.536$ ). 73% of INR values for Group visit patients within $\pm 0.2$ of desired INR range, compared with 71.9% of control group ( $p = 0.994$ ). 79% of group visit patients within the therapeutic range at their last clinic visit, compared with 67% of patients who attended individual appointments ( $p = 0.225$ ). Group visits preferred by 51% ( $n = 38$ ) of patients who completed satisfaction survey. Of 92 patients who declined group visit participation, 36% indicated that time of day that group visits were offered was inconvenient. No thromboembolic or haemorrhagic events documented in either group
Gutierrez <i>et al.</i> (2011) <sup>72</sup>	HbA <sub>1c</sub> Quality of life Diabetes knowledge	Mean decreases in HbA <sub>1c</sub> level of 1.19% for SMA group ( $p < 0.01$ ) and 0.67% for control group ( $p = 0.02$ ). In SMA group, quality-of-life and diabetes knowledge scores increased by 5 points and 1.5 points, respectively ( $p < 0.01$ )
Junling <i>et al.</i> (2015) <sup>73</sup>	Diastolic BP Treatment compliance Self-efficacy	The average diastolic BP decrease in the group visit groups (1.5 mmHg) was significantly more than in the control groups (0.4 mmHg). In group visit groups, compliance with medicine, physical activities and diet increased to 14.7%, 9.7% and 10.1%, respectively, which is more significant than that in control groups (2.0%, 1.6% and 8.0%); self-reported health and self-efficacy also improved significantly

continued

TABLE 16 Included RCTs with outcomes included and results (continued)

Study	Outcome measures	Results
Liu <i>et al.</i> (2012) <sup>74</sup>	Systolic BP  Changes in 17 self-management behaviour, self-efficacy and health status-related variables	Group visit patients, on average, increased their duration of aerobic exercise by > 40 minutes per week ( $p = 0.001$ ); had significant increase of 0.71 in mean score on self-efficacy to manage diabetes ( $p = 0.02$ ); and had significant improvements in measures of illness intrusiveness and systolic BP. Group visit patients attended an average of 10.1 out of 12 programme sessions. 75.6% of them attended $\geq 10$ sessions
Naik <i>et al.</i> (2011) <sup>75</sup>	HbA <sub>1c</sub>	Group visit participants had significantly greater improvements in HbA <sub>1c</sub> levels immediately following active intervention [8.86–8.04% vs. 8.74–8.70% of total haemoglobin; mean (SD) between-group difference 0.67% (1.3%); $p = 0.03$ ] and differences persisted at 1-year follow-up [0.59% (SD 1.4%); $p = 0.05$ ]. Repeated-measures analysis found significant time-by-treatment interaction effect on HbA <sub>1c</sub> levels favouring intervention [ $F(2,85) = 3.55$ ; $p = 0.03$ ]. Effect of time-by-treatment interaction seems to be partially mediated by DM self-efficacy [ $F(1,85) = 10.39$ ; $p = 0.002$ ]
Ratanawongsa <i>et al.</i> (2012) <sup>76</sup>	Patient activation to create and achieve goals  Quality of care  Barriers to care	Of 113 eligible PCPs caring for 330 enrolled patients, 87 PCPs (77%) responded to surveys about 245 (74%) enrolled patients. Intervention patients more likely to be perceived by PCPs as activated to create and achieve goals for chronic care when compared with UC patients (standardised effect size for ATSM vs. UC, +0.41; $p = 0.01$ ; standardised effect size for GMV vs. UC, +0.31; $p = 0.05$ ). Primary care providers rated quality of care higher for patients exposed to ATSM than for those receiving usual care (odds ratio 3.6; $p < 0.01$ ). Compared with GMV patients, ATSM patients were more likely to be perceived by PCPs as overcoming barriers related to limited English proficiency (82% ATSM vs. 44% GMV; $p = 0.01$ ) and managing medications (80% ATSM vs. 53% GMV; $p = 0.01$ )
Sadur <i>et al.</i> (1999) <sup>20</sup>	HbA <sub>1c</sub>  Hospital admissions  ED visits  Self-reported changes in self-care practices, self-efficacy, and satisfaction	HbA <sub>1c</sub> levels declined by 1.3% in CV group vs. 0.2% in the control subjects ( $p < 0.0001$ ). Several self-care practices and several measures of self-efficacy improved significantly in CV group. Satisfaction with programme was high. Both hospital ( $p = 0.04$ ) and outpatient ( $p < 0.01$ ) utilisation were significantly lower for CV subjects after the programme
Schillinger <i>et al.</i> (2008) <sup>77</sup>	Participation among clinics, clinicians and patients  Patient representativeness; patient engagement with SMS	Participation rates high across all levels and preferentially attracted Spanish-language speakers, uninsured, and Medicaid recipients. Although both programmes engaged a significant proportion in action planning, automated telephone disease management yielded higher engagement than GMVs, especially among those with limited English proficiency and limited literacy

TABLE 16 Included RCTs with outcomes included and results (*continued*)

Study	Outcome measures	Results
Schillinger <i>et al.</i> (2009) <sup>78</sup>	Systolic BP Diastolic BP 1-year changes in structure (PACIC), communication processes (IPC), and outcomes (behavioural, functional and metabolic)	Compared with usual care group, ATSM and GMV groups showed improvements in PACIC, with effect sizes of 0.48 and 0.50 respectively ( $p < 0.01$ ). Only ATSM group showed improvements in IPC (effect sizes 0.40 vs. usual care and 0.25 vs. GMV; $p < 0.05$ ). Both SMS arms showed improvements in self-management behaviour vs. usual care arm ( $p < 0.05$ ), with gains being greater for the ATSM group than for the GMV group (effect size 0.27; $p = 0.02$ ). ATSM group had fewer bed-days per month than the usual care group (-1.7 days; $p = 0.05$ ) and GMV group (-2.3 days; $p < 0.01$ ) and less interference with daily activities than the usual care group (odds ratio 0.37; $p = 0.02$ ). No differences in HbA <sub>1c</sub> change
Scott <i>et al.</i> (2004) <sup>79</sup>	Clinic visits, inpatient admissions, emergency room visits, hospital outpatient services, professional services, home health and skilled nursing facility admissions; measures of patient satisfaction, quality of life, self-efficacy and ADLs	Outpatient, pharmacy services, home health and skilled nursing facility use did not differ between groups. CHCC patients had fewer hospital admissions ( $p = 0.012$ ), emergency visits ( $p = 0.008$ ) and professional services ( $p = 0.005$ ). CHCC patients' costs were US\$41.80 per member per month lower than those of control patients. CHCC patients reported higher satisfaction with their primary care physician ( $p = 0.022$ ), better quality of life ( $p = 0.002$ ) and greater self-efficacy ( $p = 0.03$ ). Health status and ADLs did not differ between groups
Taveira <i>et al.</i> (2010) <sup>80</sup>	HbA <sub>1c</sub> LDL cholesterol BP Fasting lipids Target goals in tobacco use recommended by the ADA	109 out of 118 participants completed study. VA-MEDIC ( $n = 58$ ) participants were younger and had greater tobacco use at baseline than usual care but were similar in other cardiovascular risk factors. After 4 months, a greater proportion of VA-MEDIC participants vs. controls achieved a HbA <sub>1c</sub> of $< 7\%$ and a systolic BP $< 130$ mmHg. No significant change found in lipid control or tobacco use between study arms
Taveira <i>et al.</i> (2011) <sup>81</sup>	HbA <sub>1c</sub> (change in the proportion of participants who achieved a HbA <sub>1c</sub> $< 7\%$ at 6 months) LDL cholesterol Hospital admissions ED visits	Compared with standard care ( $n = 44$ ), a lower proportion of patients in VA-MEDIC-D ( $n = 44$ ) had systolic BP $< 130$ mmHg at baseline, but similar in other cardiovascular risk factors and psychiatric comorbidity. Change in proportion of participants achieving an A <sub>1c</sub> $< 7\%$ was greater in the VA-MEDIC-D arm than in the standard care arm (29.6% vs. 11.9%), with odds ratio 3.6 (95% CI 1.1 to 12.3). VA-MEDIC-D participants also achieved significant reductions in systolic blood pressure, LDL cholesterol and non-HDL cholesterol from baseline, whereas significant reductions were attained only in non-HDL cholesterol with standard care. No significant change in depressive symptoms for either arm
Trento <i>et al.</i> (2001) <sup>82</sup>	HbA <sub>1c</sub> Total cholesterol Systolic BP Diastolic BP Costs Knowledge of diabetes Quality of life	After 2 years, HbA <sub>1c</sub> levels lower in group visit patients than in control subjects ( $p < 0.002$ ). Levels of HDL cholesterol had increased in patients seen in groups but had not increased in control subjects ( $p = 0.045$ ). BMI ( $p = 0.06$ ) and fasting triglyceride level ( $p = 0.053$ ) were lower. Group visit patients had improved knowledge of diabetes ( $p < 0.001$ ) and quality of life ( $p < 0.001$ ) and experienced more appropriate health behaviours ( $p < 0.001$ ). Physicians spent less time seeing 9–10 patients as a group rather than individually, but patients had longer interaction with health-care providers

continued

TABLE 16 Included RCTs with outcomes included and results (continued)

Study	Outcome measures	Results
Trento <i>et al.</i> (2002) <sup>83</sup>	HbA <sub>1c</sub> Total cholesterol Systolic BP Diastolic BP Costs Knowledge of diabetes Quality of life	Observation times were 51.2 ± 2.1 months for group visit and 51.2 ± 1.8 for control groups. HbA <sub>1c</sub> increased in control group but not in group visit patients ( $p < 0.001$ ), in whom BMI decreased ( $p < 0.001$ ) and HDL cholesterol increased ( $p < 0.001$ ). Quality of life, knowledge of diabetes and health behaviours improved with group visit ( $p < 0.001$ , all) and worsened among control group ( $p = 0.004$ to $p < 0.001$ ). Dosage of hypoglycaemic agents decreased ( $p < 0.001$ ) and retinopathy progressed less ( $p < 0.009$ ) among the group care patients than the control subjects. Diastolic BP ( $p < 0.001$ ) and relative cardiovascular risk ( $p < 0.05$ ) decreased from baseline in group patients and control patients alike. Over study period, group visit required 196 minutes and US\$756.54 per patient, compared with 150 minutes and US\$665.77 for control group patients, resulting in an additional US\$2.12 spent per point gained in the quality-of-life score
Trento <i>et al.</i> (2004) <sup>84</sup>	Knowledge of diabetes Problem-solving ability Quality of life HbA <sub>1c</sub> BMI HDL cholesterol	Knowledge of diabetes and problem-solving ability improved from year 1 with group care and worsened among control subjects ( $p < 0.001$ for both). Quality of life improved from year 2 with group care but worsened with individual care ( $p < 0.001$ ). HbA <sub>1c</sub> level progressively increased over 5 years among control subjects (+1.7%, 95% CI 1.1% to 2.2%) but not group care patients (+0.1%, 95% CI -0.5% to 0.4%), in whom BMI decreased (-1.4 kg/m <sup>2</sup> , 95% CI -2.0 to -0.7 kg/m <sup>2</sup> ) and HDL cholesterol increased (+0.14 mmol/l, 95% CI 0.07 to 0.22 mmol/l)
Trento <i>et al.</i> (2005) <sup>85</sup>	HbA <sub>1c</sub> Total cholesterol Quality of life Knowledge of diabetes, health behaviours Circulating lipids Differential costs to the Italian NHS and to patients	After 3 years, quality of life improved among patients on group care, along with knowledge and health behaviours ( $p < 0.001$ , all). Knowledge added its effects to those of group care by independently influencing behaviours ( $p = 0.004$ ), while quality of life changed independently of either ( $p < 0.001$ ). Among controls, quality of life worsened ( $p < 0.001$ ), while knowledge and behaviours remained unchanged. HDL cholesterol increased among patients on group care ( $p = 0.027$ ) and total cholesterol decreased in the controls ( $p < 0.05$ ). HbA <sub>1c</sub> decreased, though not significantly, in both. Direct costs for group and one-to-one care were €933.19 and €697.10 per patient, respectively, giving cost-effectiveness ratio of €19.42 spent per point gained in the quality of life scale
Wagner <i>et al.</i> (2001) <sup>86</sup>	HbA <sub>1c</sub> Total cholesterol Hospital admissions ED visits Costs Process of care received Satisfaction with care, and the health status of each patient	In intention-to-treat analysis at 24 months, IG received significantly more recommended preventative procedures and helpful patient education. Of five primary health status indicators, two (SF-36 general health and bed disability days) significantly better in IG. IG patients had slightly more primary care visits, but significantly fewer specialty and ER visits. There were consistently positive associations between number of chronic care clinics attended and patient satisfaction and HbA <sub>1c</sub> levels

TABLE 16 Included RCTs with outcomes included and results (continued)

Study	Outcome measures	Results
Yehle <i>et al.</i> (2009) <sup>31</sup>	Heart Failure Knowledge Test Self-Care Heart Failure Index	From baseline to 8 weeks, Heart Failure Knowledge Test scores improved more for IG than CG ( $p=0.038$ ). No difference in groups' rates of change on the total Self-Care Heart Failure Index

ADA, American Diabetes Association; ADL, activity of daily living; ATSM, automated telephone self-management support with nurse follow-up; BP, blood pressure; CV, cluster visit; DLC, Diabetes-Specific Locus of Control; DM, diabetes mellitus; DQOL, Diabetes Quality of Life questionnaire; ED, emergency department; ER, emergency room; GMC, group medical clinic; HDL, high-density lipoprotein; IG, intervention group; INR, international normalised ratio; IPC, interpersonal processes of care; PACIC, Patient Assessment of Chronic Illness Care; PCAT, Primary Care Assessment Tool; PCP, primary care physician; RR, risk ratio; SD, standard deviation; SF-36, Short Form questionnaire-36 items; TPS, Trust in Physician Scale; UC, usual care; USPSTF, US Preventive Services Task Force; VA-MEDIC, Veterans Affairs Multidisciplinary Education in Diabetes and Intervention for Cardiac risk reduction; VA-MEDIC-D, Veterans Affairs Multidisciplinary Education in Diabetes and Intervention for Cardiac risk reduction in Depression.

TABLE 17 Quality assessment of RCTs

Study identifier	Cochrane risk of bias (low, high or unclear)	Did study address clearly focused issue?	Trials: was assignment of patients to treatments randomised?	Trials: all patients entering trial properly accounted for at conclusion?	Trials: patients, health workers and study personnel 'blind' to treatment?	Trials: groups similar at start of trial?	Trials: aside from experimental intervention, groups treated equally?
CLANCY	High	Yes	Yes	Yes	No	Yes	Yes
Clancy <i>et al.</i> (2003) <sup>57</sup>							
Clancy <i>et al.</i> (2003) <sup>58</sup>							
Clancy <i>et al.</i> (2003) <sup>59</sup>							
CLANCY	Low	Yes	Yes	Yes	No	Cannot tell	Yes
Clancy <i>et al.</i> (2007) <sup>60</sup>							
Clancy <i>et al.</i> (2007) <sup>61</sup>							
Clancy <i>et al.</i> (2008) <sup>62</sup>							
Cohen <i>et al.</i> (2011) <sup>63</sup>	Low	Yes	Yes	Yes	No	No	Yes
Cole <i>et al.</i> (2013) <sup>64</sup>	High	Yes	Yes	No	No	No	Yes
Coleman <i>et al.</i> (2001) <sup>65</sup>	Low	Yes	Yes	Yes	No	Yes	Yes
Dorsey <i>et al.</i> (2011) <sup>68</sup>	Low	Yes	Yes	Yes	No	Yes	Yes
EDELMAN	Low	Yes	Yes	Yes	Yes <sup>1</sup>	No	Yes
Crowley <i>et al.</i> (2013) <sup>67</sup>							
Crowley <i>et al.</i> (2014) <sup>66</sup>							
<sup>1</sup> Edelman <i>et al.</i> (2010) <sup>69</sup>							

continued



TABLE 17 Quality assessment of RCTs (continued)

Study identifier	Cochrane risk of bias (low, high or unclear)	Did study address clearly focused issue?	Trials: was assignment of patients to treatments randomised?	Trials: all patients entering trial properly accounted for at conclusion?	Trials: patients, health workers and study personnel 'blind' to treatment?	Trials: groups similar at start of trial?	Trials: aside from experimental intervention, groups treated equally?
Graue <i>et al.</i> (2005) <sup>70</sup>	Low	Yes	Yes	Yes	No	Yes	Yes
Griffin <i>et al.</i> (2009) <sup>71</sup>	High	Yes	Yes	No	No	No	Yes
Gutierrez <i>et al.</i> (2011) <sup>72</sup>	Unclear	Yes	Yes	Cannot tell	No	Cannot tell	Cannot tell
Junling <i>et al.</i> (2015) <sup>73</sup>	Low	Yes	Yes	Yes	No	Yes	Yes
Liu <i>et al.</i> (2012) <sup>74</sup>	High	Yes	Yes	Yes	No	No	Yes
Naik <i>et al.</i> (2011) <sup>75</sup>	High	Yes	Yes	No	No	Yes	Yes
Ratanawongsa <i>et al.</i> (2012) <sup>76</sup>	Unclear	Yes	Cannot tell	Cannot tell	No	Cannot tell	Yes
Sadur <i>et al.</i> (1999) <sup>20</sup>	High	Yes	Yes	No	No	Yes	Yes
SCHILLINGER Schillinger <i>et al.</i> (2008) <sup>77</sup> Schillinger <i>et al.</i> (2009) <sup>78</sup>	Unclear	Yes	Yes	Cannot tell	No	Cannot tell	Yes
Scott (2004) <sup>79</sup>	High	Yes	Yes	Cannot tell	No	Yes	Yes
TAVEIRA Taveira <i>et al.</i> (2010) <sup>80</sup> Taveira <i>et al.</i> (2011) <sup>81</sup>	High	Yes	Yes	No	No	No	Yes
TRENTO Trento <i>et al.</i> (2001) <sup>82</sup> Trento <i>et al.</i> (2002) <sup>83</sup> Trento <i>et al.</i> (2004) <sup>84</sup>	High	Yes	Yes	No	No	No	Yes
TRENTO Trento <i>et al.</i> (2005) <sup>85</sup>	High	Yes	Yes	No	No	No	Yes
Wagner <i>et al.</i> (2001) <sup>86</sup>	High	Yes	Yes	No	No	Yes	Yes
Yehle <i>et al.</i> (2009) <sup>31</sup>	High	Yes	Yes	No	No	Yes	Yes

a Research assistant completing outcome measures blinded to group assignment. Patients and care teams running group medical clinics not blinded to treatment group assignment.



Another significant problem with these studies was that it was not possible to blind patients or health-care personnel to treatment intervention group, which could lead to bias. Two studies<sup>69,83</sup> did state that they have researchers blinded to patient's treatment groups to measures outcomes. This bias could potentially be more significant with certain outcome measures. Clinical outcomes measures, for example, blood pressure and blood glucose, would be less likely to be affected by this bias. However, outcome measures around patient satisfaction, self-efficacy, self-reported outcomes or outcomes reported by the team delivering the group clinics could be open to bias. Some studies had doctors treating patients in both the intervention and the control group, giving the possibility of a 'halo effect'.<sup>72</sup>

The majority of the studies had only a short follow-up, generally 6 months to 1 year, making it impossible to assess the longer-term impact of the interventions. Two of the studies<sup>70,79</sup> did have a 24-month follow-up. The 11 studies assigned a low risk of bias<sup>60,61,63,65-70,73,78</sup> were generally large, well-conducted trials.

A total of 13 studies were assigned a high risk of bias.<sup>20,31,57,59,64,71,74,75,79,80,82,85,86</sup> One of the studies with a high risk of bias was a pilot study<sup>57,58</sup> with small sample sizes, no blinding, patient selection bias and short-term follow-up. Five of the studies with a high risk of bias<sup>48,71,80,81,83</sup> had patients with different baseline characteristics.

Three studies were given an unclear risk of bias,<sup>72,76,77</sup> owing to insufficient details of the trials methodology being provided. One of these was a pilot study.<sup>72</sup>

### Study analyses: condition-specific clinical outcomes

Fifteen of the 22 trials included a population with diabetes. By far the majority of the trials (11 out of 22 trials) studied a population with type 2 diabetes.<sup>57,60,63,64,72,74-77,80,83</sup> A further four trials studied a mixed type 1 and type 2 diabetes population,<sup>20</sup> a type 1 diabetes-only population<sup>70,85</sup> and a population with type 2 diabetes and hypertension.<sup>66,67,69</sup>

A further group of studies examined the effects of group clinics in populations with a variety of cardiac problems (heart disease/hypertension<sup>71,73</sup> and hypertension/heart failure<sup>31</sup>). Coleman *et al.*<sup>65</sup> studied a population with one or more self-reported chronic conditions (e.g. asthma, COPD, congestive heart failure, diabetes and heart disease). Scott *et al.*<sup>79</sup> also studied a population with a range of chronic conditions (arthritis, hypertension, difficulty hearing, heart disease, liver disease and bladder/kidney disease).

Recent years have seen group clinics extended to a wider variety of conditions. Dorsey *et al.*<sup>68</sup> studied a population with Parkinson's disease and Seising *et al.*<sup>90</sup> have completed a 6-month follow-up of a population with chronic neuromuscular disorders.

### Diabetes

Eleven of the diabetes trials studied a population with type 2 diabetes only.<sup>57,60,63,64,72,74-77,80,83</sup> Sadur *et al.*<sup>20</sup> studied a population with either type 1 or type 2 diabetes. Graue *et al.*<sup>70</sup> worked with adolescents with type 1 diabetes and Trento *et al.*<sup>82</sup> intervened with a wider type 1 diabetes population. In the most recent trial, Crowley *et al.*<sup>66,67</sup> and Edelman *et al.*<sup>69</sup> intervened with a population with type 2 diabetes and hypertension. Most commonly measured outcomes are HbA<sub>1c</sub>, blood pressure, cholesterol and health-related quality of life.

### Glycated haemoglobin

We identified 13 eligible trials of group clinic approaches for diabetes<sup>20,59,61,63,67,69,72,75,80-82,85,86</sup> that measured HbA<sub>1c</sub>. Several meta-analyses exist for this outcome. In the review for the Department of Veterans Affairs, Edelman *et al.*<sup>18</sup> performed a sensitivity analysis and identified six good-quality studies<sup>20,59,69,75,81,91</sup> that demonstrated a significant effect on HbA<sub>1c</sub> in favour of group clinics. We excluded one of these studies<sup>91</sup> from our review because of a lack of evidence for clinical input, other than education. The significant effect was not maintained when Edelman *et al.*<sup>18</sup> included the results from seven poor-/fair-quality trials.<sup>61,63,72,80,82,85,86</sup> We identified one additional study with a low risk of bias that

examined this outcome measure that had not been included in the two previous meta-analyses.<sup>67</sup> The results of this additional study are difficult to integrate with previous studies because the trialists examined the effect of the complexity of insulin regimens as a possible explanatory factor. Among those using complex insulin regimens at baseline, the group medical clinic intervention reduced HbA<sub>1c</sub> by the study's end, compared with usual care (21.0%, 95% CI 21.8% to 20.2%;  $p = 0.01$ ). The trialists found no such HbA<sub>1c</sub> difference between group medical clinic and usual care patients using no insulin ( $p = 0.65$ ) or basal insulin only ( $p = 0.71$ ).<sup>57</sup>

The same outcome measure was examined by Housden *et al.*,<sup>53</sup> who included 10 studies in a meta-analysis,<sup>20,59,69,75,77,81,84–86,92</sup> seven of which are included in our review. They reported a significant effect of group clinics on HbA<sub>1c</sub>. They included a study by Rygg *et al.*,<sup>92</sup> excluded from our review owing to lack of evidence that the intervention involved more than an educational component. Despite the considerable variation in trial quality and in the trials included by each meta-analysis team, it appears that we can be fairly confident that an effect does indeed persist for HbA<sub>1c</sub>. As mentioned in the context of the Edelman *et al.* meta-analysis,<sup>18</sup> integration of the additional study we identified<sup>67</sup> is problematic given that it examined the effects of using complex insulin regimes. However, this report<sup>67</sup> originated from the Edelman trial<sup>69</sup> and would not be eligible for inclusion alongside the original report because of the risk of double counting. So, neither the meta-analysis by Edelman *et al.*<sup>18</sup> nor that by Housden *et al.*<sup>53</sup> is sensitive to the inclusion of the newly retrieved study.

### Systolic blood pressure

Five studies had previously been identified examining systolic blood pressure.<sup>63,69,80,81,91</sup> When these five studies were pooled together in a meta-analysis, the studies demonstrated a statistically significant effect favouring group clinics.<sup>20</sup> Our review found one additional study<sup>74</sup> published in 2012. Liu *et al.*<sup>74</sup> found that patients in the intervention group had significant improvements in systolic blood pressure with, on average, 3.72 mmHg lower increase in systolic blood pressure ( $p = 0.04$ ).<sup>74</sup> This additional trial, therefore, appears to strengthen the pre-existing evidence finding in favour of a positive effect of group clinics on systolic blood pressure.<sup>74</sup> However, one of these trials<sup>91</sup> was excluded from our review because we were unable to ascertain clinician involvement in anything other than an educational role.

Housden *et al.*<sup>53</sup> also included five studies (only two<sup>58,69</sup> overlapping with the Edelman review<sup>18</sup>) examining the effect of SMAs on systolic blood pressure in diabetes. Across these five trials the overall pooled effect on systolic blood pressure was  $-2.81$  (95% CI  $-6.84$  to  $1.21$ ). Four included studies<sup>78,81,82,92</sup> failed to find a significant effect. The pooled effect in both reviews is heavily dependent on the results from a single study.<sup>34</sup> Furthermore, Housden *et al.*<sup>53</sup> included a trial by Rygg *et al.*,<sup>92</sup> which we excluded owing to lack of evidence that the intervention involved more than an educational component.

### Diastolic blood pressure

Based on four trials,<sup>69,78,82,92</sup> Housden *et al.*<sup>53</sup> concluded that the effect of SMAs on diastolic blood pressure was non-significant ( $-1.02$ , 95% CI  $-2.71$  to  $0.67$ ). These trials included the trial by Rygg *et al.*,<sup>92</sup> which we excluded owing to lack of evidence that the intervention involved more than a simple educational component. We found no additional trials examining diastolic blood pressure as an outcome. The review by Edelman *et al.*<sup>18</sup> did not examine diastolic blood pressure. We have, therefore, concluded that, in contrast with systolic blood pressure, SMAs do not demonstrate an effect for diastolic blood pressure.

### Low-density lipoprotein cholesterol

Based on four previous studies,<sup>57,80,81,91</sup> Edelman *et al.*<sup>18</sup> concluded that SMAs did not have an overall effect on LDL cholesterol. We identified one additional recent study to supplement the pre-existing evidence base.<sup>66</sup> This additional trial reported that by study end, LDL cholesterol in group medical clinics was 9.2 mg/dl ( $p = 0.02$ ) lower than usual care.<sup>66</sup> Housden *et al.*<sup>53</sup> did not pool results for LDL, choosing to examine only high-density lipoprotein (HDL) cholesterol and total cholesterol. We conclude that the additional trial is probably insufficient to overturn the previously non-significant result for changes in LDL cholesterol, but this has not been demonstrated quantitatively.

### High-density lipoprotein cholesterol

Based on three studies previously meta-analysed by Edelman *et al.* looking at HDL cholesterol,<sup>18</sup> we concluded that effects of group clinics can be considered non-significant. We did not identify any additional trials to be included in the meta-analysis.

### Total cholesterol

Five studies measuring changes to total cholesterol<sup>159,82,85,86,91</sup> had previously been examined by Edelman *et al.*<sup>18</sup> They had found no statistical significance for the effect of group clinics. We had excluded one of these studies because we found no explicit mention of other than educational input from the clinicians.<sup>91</sup> We identified one further study<sup>66</sup> to augment the pre-existing data. By the end of the study, mean total cholesterol in group medical clinics was significantly lower than in usual care. However, this study was not sufficient to overturn the pooled result of the five previous studies. Housden *et al.* also examined effect on total cholesterol, identifying three studies and finding a non-significant effect for the pooled studies.<sup>53</sup> Housden *et al.*<sup>53</sup> also excluded the study by Trento *et al.*<sup>91</sup>

### Health-related quality of life

Three studies of diabetes patients had been previously identified examining disease specific quality of life;<sup>82,85,91</sup> two of these were included in our review.<sup>82,85</sup> When pooled together in a meta-analysis these studies demonstrated a statistically significant effect favouring group clinics.<sup>6</sup> Our review found no additional studies examining disease-specific quality of life as an outcome measure. We therefore uphold the previous finding of significance for disease-specific quality of life. However, it should be noted that (1) the studies all relate to the work of a particular team and therefore may not be generalisable, and (2) one of these trials was excluded from our review<sup>91</sup> because we were unable to ascertain clinician involvement in anything other than an educational role – one criterion for our definition of group clinics. The study by Gutierrez *et al.* reported measuring health-related quality of life but did not report the outcomes in the study report.<sup>72</sup>

Two studies of diabetes had been previously identified examining generic measures of quality of life.<sup>28,86</sup> When these studies were pooled together in a meta-analysis the two studies demonstrated a marginally significant effect favouring group clinics. Our review found no additional studies examining generic measures of quality of life. We therefore upheld the previous finding of marginal significance for generic quality of life.

### Other outcomes

A previous review<sup>53</sup> has examined the effect of group clinic-type interventions on BMI (four included studies),<sup>78,84,85,92</sup> weight (three included studies)<sup>84,85,92</sup> and triglycerides (three included studies).<sup>84,85,92</sup> We identified no additional studies for these outcomes. None of these outcomes was found to be statistically significant.

### Outcome intervals

Examination of the results, even for the largely significant HbA<sub>1c</sub> outcome measure, appeared to reveal that the effect of the group clinic intervention was not sustained over a longer period of time. This subanalysis requires further investigation. However, as illustrated in *Table 18*, results that are significant up to 12 months are less likely to have a continued effect after this time period. It should, however, be noted that the included studies make no allowance for trial quality and the table is based only on the availability of the data. Nevertheless, more research is required on the longer-term outcomes of group clinic interventions. It would be unwise to assume that the initial impetus of a group clinic intervention is sustained over longer periods of time as, based on the experience with group education diabetes sessions, commitment, enthusiasm and engagement with the programme are likely to decay.

### Cardiac problems

A further group of studies examined the effects of group clinics in populations with a variety of cardiac problems. Griffin *et al.*<sup>71</sup> conducted a prospective, randomised, repeated-measures, two-group, intention-to-treat comparison and survey at a pharmacist-managed anticoagulation clinic in a managed-care ambulatory care setting.<sup>71</sup> Eligible patients were randomly invited to participate in group visits.

**TABLE 18** Outcome intervals analysed by time (illustrative analysis)

Outcome	0–3 months	4–6 months	6 months to 1 year	13–24 months	> 24 months
HbA <sub>1c</sub>		<p>≥ 5 months after randomisation: 8.18% in IG and 9.33% in CG (<math>p &lt; 0.0001</math>)<sup>20</sup></p> <p>At 6 months: 9.513% in IG and 9.714% in CG; difference not significant<sup>57,59</sup></p>	<p>At 12 months: no significant difference (<math>p = 0.432</math>), <b>except in</b> patients with highest HbA<sub>1c</sub> (&gt; 7.7%) at baseline (8.2% ± 1.4% in IG vs. 8.8% ± 1.4% in CG; <math>p = 0.012</math>)<sup>92</sup></p> <p>At 1 year: 8.05% ± 1.40% in IG vs. 8.64% ± 1.39% in CG (<math>p = 0.05</math>)<sup>75</sup></p>	<p>At 24 months: no difference between groups (7.9% in both groups; <math>p = 0.9</math>)<sup>86</sup></p>	<p>At 3 years: 7.88% ± 0.20% in IG and 8.79% ± 1.38% in CG (<math>p = NS</math>)<sup>85</sup></p> <p>At 5 years: 7.3% ± 1.0% in IG and 9.0% ± 1.6% in CG (<math>p &lt; 0.001</math>)<sup>83,84</sup></p>

CG, control group; IG, intervention group; NS, non-significant.

Of 45 patients who consented to group visits, 28 participated for the 16-week study period. No significant difference was detected between patients in the percentage of international normalised ratio (INR) values within the therapeutic range in the group-visit model versus patients receiving individual visits ( $p = 0.536$ ). Seventy-three per cent of INR values for patients who attended group visits were within  $\pm 0.2$  of the desired INR range, compared with 71.9% of those in the control group ( $p = 0.994$ ). Of group-visit patients, 79% were within the therapeutic range at their last clinic visit, compared with 67% of patients attending individual appointments ( $p = 0.225$ ). Group visits were preferred by 51% ( $n = 38$ ) of patients who completed the satisfaction survey. Of 92 patients who declined group-visit participation, 36% indicated that the time of day that group visits were offered was inconvenient. No thromboembolic or haemorrhagic events were documented in either group during the study period.

In a RCT of group visits studying 1024 Chinese patients with hypertension, Junling *et al.*<sup>73</sup> reported an average diastolic blood pressure decrease in the group visit groups (1.5 mmHg), significantly more than in the control groups (0.4 mmHg). The study also reported significant differences in favour of the group visit group for compliance with medicine, physical activities and diet, as well as for self-reported health, and self-efficacy also improved significantly.<sup>73</sup>

An additional RCT comparing group care with usual care in adults with hypertension was identified.<sup>93</sup> However, this study was excluded from our review because group care involved small group educational meetings with physicians and dietitians but no apparent clinical input. According to the CADTH rapid review, which had a broader inclusion of 'group care',<sup>52</sup> this RCT<sup>93</sup> reported on fasting blood glucose, blood pressure, lipids, weight and BMI. The study did demonstrate that, compared with control, group care resulted in statistically significant improvement in blood pressure, weight and BMI, but more details of the intervention are required to establish its eligibility.

### Heart failure

We identified one RCT that examined heart failure.<sup>31</sup> The status of this study has been questioned in some reviews because the fullest account has not been published in the peer-reviewed literature. However, the study has been included in a systematic review of group visits for heart failure.<sup>54</sup> The study is small with a short period of follow-up and many patients dropped out. It is not possible to draw any conclusions on the basis of such limited evidence.

### Parkinson's disease

In a small feasibility study for a RCT Dorsey *et al.*<sup>68</sup> studied a population with randomly divided patients in two groups (12 months of group visits vs. regular 'one-on-one' style care). Four group visits were administered over 1 year, each lasting 90 minutes. A total of 30 patients and 27 caregivers participated, with quality of life not being demonstrably different between the two groups. Although group care was

feasible, it did not offer any enhancement to quality of life. A key issue for this study, as with many others, is the number of patients who had to be approached in order for this small sample of 30 patients to be achieved.<sup>68</sup> Information on reasons why patients decline participation would be helpful in targeting potential beneficiaries.

### Chronic neuromuscular disorders

Seising *et al.*<sup>90</sup> completed a RCT of SMAs in patients with chronic neuromuscular disorders.<sup>90</sup> Two hundred and seventy-two patients and 149 partners were included. Health-related quality of life showed greater improvement in patients who had attended a SMA (mean difference 2.8 points, 95% CI 0.0 to 5.7 points;  $p = 0.05$ ). Secondary outcomes showed small improvements favouring the control group for satisfaction with the appointment ( $p = 0.01$ ). Neurologists spent less time per patient during the group clinic intervention: mean 16 minutes (range 11–30 minutes) versus 25 minutes (range 20–30 minutes) for individual appointments.

### Older adults

Only two randomised trials have evaluated SMA interventions in older adults with a recent hospitalisation or other criteria for increased utilisation. Coleman *et al.*<sup>65</sup> studied a population with one or more self-reported chronic conditions (e.g. asthma, COPD, congestive heart failure, diabetes and heart disease) and measured the effect of the intervention with respect to a range of health-care utilisation measures such as emergency department visits, hospitalisations and primary care visits. Similarly, Scott *et al.*<sup>79</sup> studied a population with a range of chronic conditions using utilisation measures (e.g. clinic visits, inpatient admissions, emergency room visits, hospital outpatient services, professional services, home health and skilled nursing facility admissions); measures of patient satisfaction, quality of life, self-efficacy, activities of daily living (ADLs) and patient costs. A further trial, deemed by Edelman *et al.*<sup>18</sup> as being poor quality, predates our date-cut off, having been published in 1997.<sup>94</sup> The study by Coleman did not include any clinical outcomes and so is discussed under *Study analyses: health service utilisation measures*.<sup>65</sup> We did not find any recent trials studying an older adult population.

In the trial by Scott *et al.*<sup>79</sup> only participants expressing a strong interest in group care (37% of those eligible) were randomised occasioning significant concerns relating to external validity. Other methodological problems included failure to describe allocation concealment, outcomes assessed without blinding to intervention and poor specification of outcome measures.<sup>18</sup> SMA visits for older adults were designed in a similar way to the diabetes studies, except that fewer disciplines participated in the clinical teams.

Scott *et al.* conducted their trial in primary care in a group-model health maintenance organisation setting in the USA.<sup>79</sup> The comparison was between SMAs and usual care. The mean age of participants ranged from 73.5 to 78.2 years of age. The most common chronic conditions were arthritis, hypertension, difficulty hearing, heart disease, liver disease and bladder/kidney disease. The trial by Scott has been rated by our team as being at moderate risk of bias.<sup>79</sup>

Scott *et al.*<sup>79</sup> found that patients assigned to SMAs rated the quality of care 0.3 points higher on a 1–4 scale than usual care patients did ( $p = 0.048$ ). Scott *et al.* did not evaluate staff satisfaction using a validated measure, nor did they report comparative data on medication adherence.<sup>79</sup> Among strongly motivated participants with a high interest in group visits, Scott *et al.*<sup>79</sup> reported two or fewer visits over 24 months by approximately 25% of patients.

Biophysical outcomes were not reported, probably because of patient selection being on the basis of age and health-care utilisation rather than a particular illness.<sup>6</sup> Scott *et al.*<sup>79</sup> reported effects on overall health status (via the Likert scale) and functional status using ADLs or instrumental ADLs; there were no differences in outcomes for any of these measures. They also reported effects on health-related quality of life using a 10-point scale.<sup>79</sup> Participants randomised to SMAs rated health-related quality of life higher at 24-month follow-up versus usual care ( $p = 0.002$ ).

### Study analyses: health service utilisation measures

In addition to the biomedical outcomes, several health service utilisation measures have been measured in isolated studies. These are not suitable for meta-analysis but these are reviewed together with an assessment of the consistency around results.

#### Diabetes

Group approaches to diabetes have primarily been evaluated with regard to emergency department utilisation (see below).

#### Other conditions

We identified two randomised trials<sup>65,79</sup> that evaluated the effects of group clinic approaches on older adults with high health-care service utilisation rates. Both studies reported positive effects on patient experience from the group clinic approach (specifically SMAs) compared with usual care. There was no difference compared with usual care for overall health status or functional status. Neither study reported biophysical outcomes. Both trials showed fewer hospital admissions in the SMA groups.

### Emergency department utilisation

#### Diabetes

Edelman *et al.*<sup>18</sup> report that effects on emergency department visits were reported in five studies.<sup>20,57,69,81,86</sup> Two studies reported significantly lower visit rates<sup>69</sup> or the proportion with an emergency department visit.<sup>86</sup> Rates were not significantly different in the other three studies.<sup>20,57,81</sup>

#### Other conditions

One study of older adults found that participants in a CHCC group were significantly less likely to make any emergency visit than those in the control group (35% vs. 52%;  $p = 0.003$ ).<sup>65</sup> After controlling for age, gender, asthma, COPD, congestive heart failure, diabetes, heart disease, functional status and previous emergency utilisation, the adjusted risk ratio for a group patient making any emergency department visit compared with a control patient was statistically significant at 0.64 (95% CI 0.44 to 0.86). Similarly, CHCC participants averaged fewer emergency visits during the 2-year follow-up period than control participants (0.65 vs. 1.08;  $p = 0.005$ ). With regard to the frequency of emergency department use, Coleman *et al.*<sup>65</sup> reported that over a 24-month study period CHCC participants were less likely to have made an emergency visit and also less likely to have made multiple emergency visits ( $p < 0.001$ ).

In another population of older adults, Scott *et al.*<sup>79</sup> showed a statistically significant difference, with fewer admissions in the SMA group. SMA visits were also associated with a statistically significant decrease in emergency department visits.<sup>79</sup>

### Hospital and outpatient services utilisation

#### Diabetes

Edelman *et al.*<sup>18</sup> identified five studies of diabetes group clinics reporting the effect on hospital admissions.<sup>52,58,69,81,86</sup> Four studies reported admission rates involving 603 patients followed from 6 to 18 months. In three of these, admission rates were lower with SMAs, but the result was statistically significant in only one study.<sup>52</sup> The fifth study<sup>86</sup> followed 707 patients for 2 years and reported a statistically non-significant lower proportion of patients with a hospital admission who were randomised to SMAs (16.9% vs. 21.0%;  $p = 0.10$ ).

#### Other conditions

Coleman also examined the effect of group visits on overall utilisation in an older adult population.<sup>65</sup> On average, CHCC participants had fewer hospitalisations (0.44 vs. 0.81;  $p = 0.04$ ) than did controls.<sup>30</sup> Primary care visits did not differ between the two groups. However, once the group visits themselves were added to the primary care visits, intervention patients had significantly higher overall outpatient utilisation (23.5 vs. 13 visits over 2 years;  $p < 0.01$ ).<sup>30</sup>



### *Acceptability and sustainability*

A further important consideration with regard to the effect of group clinic type interventions is the progressive attrition of a group clinic cohort over time as one progresses along the pathway of care. We undertook a preliminary analysis using available data to explore indicative types of attrition along this pathway.

Starting with the important area of recruitment to the programme, even if levels of recruitment are impressively high (e.g. 80% of eligible patients) this still means that alternative provision, by which we would typically mean an individual consultation plus some type of information provision, is still being required by one in every five patients. A recent trial found an enrolment percentage of only 31%<sup>64</sup> – and this was with the prospect of 50% of the patients receiving usual care. Alternatively, if group clinics are mandatory as the only type of provision, this would yield a significantly large proportion of patients who would be being treated either inappropriately (e.g. those with more complex or more advanced conditions) or with a high possibility of dissatisfaction. Some commentators hypothesise that those patients most likely to opt for group care would include patients with shorter disease durations and those with less severe disease, but this cannot be established from available data.

At the next stage acceptability can be examined through attendance at the clinics. This issue is confounded because the evidence base is unable to determine optimal frequencies, intervals and intensities for the intervention. For example, a patient may attend only half of the scheduled sessions but still receive an 'effective dose' of the group clinic intervention. Even taking this factor in account we have encountered figures of 14% of patients attending no visits at all.<sup>30</sup> Again, the issue is whether these patients would be picked up by usual care or whether group clinic type provision would result in a significant proportion missing out on care altogether. Even assuming that a patient attends some of the scheduled sessions, and that this actual number of sessions still constitutes an active dose, there are still issues of inefficiency if large numbers of available slots are unoccupied. An alternative is to overbook, as with appointment systems, but this in turn may cause problems (e.g. accommodation, scheduling of individual meetings, suboptimal staff-to-patient ratios, etc.) if all eligible patients turn up for a particular session. Indicative figures suggest that between 12%<sup>73</sup> and 22%<sup>69</sup> of patients miss one session, with many more missing more than this. Of course, this must be compared with figures for attendance at individual consultations. Furthermore, Junling *et al.* separately analysed attendance for the first 3 months and then the next 6 months, and found that the percentage of those missing one session increased from 12% to 16%.<sup>73</sup> Barriers to attendance include transportation difficulty, hospitalisations, transferring clinics and scheduling conflicts.<sup>75</sup>

Next there is the issue of how many patients will continue with the intervention. Unfortunately, for this issue only limited data are available, relating to short-term attendance. Cole *et al.* found that 80% remained at 3 months, and only 69% completed the 1-year assessment.<sup>64</sup> Of course, much more critical would be the corresponding figures for continuation over 3–5 years. Housden *et al.* signal the absence of long-term evaluations of group clinic-type interventions:

*Fifteen of the 26 studies were 12 months or less in duration, and 6 studies were up to 2 years in duration. The study with the longest duration followed patients for 5 years after the intervention. Therefore, the long-term or sustainable outcomes of group medical visits are unclear.*<sup>53</sup>

Evidence from group education sessions suggests that patients 'satisfice'<sup>95</sup> with the information they have already received and once they have attained perceived benefits of the group intervention they are correspondingly less motivated to continue to attend. Certainly the evidence examined for this review indicated that less experienced patients were more likely to want to continue with the intervention than those with greater knowledge and personal resources relating to their condition.<sup>96</sup>

Finally, even where patients have adhered to treatment during a carefully prescribed trial period this does not mean that they would continue outside the limited time period of the experiment. Significantly, in a group clinic for parents and adolescents, when asked about their views of the group clinic approach, having experienced the intervention, 66% of parents returning the questionnaire would join a GMA in

future and 87% would recommend a GMA to other patients. For the adolescents, 46% would join a future GMA.<sup>96</sup> With either one-third or over half of participants preferring not to join a group medical intervention outside an experimental period, this approach does not appear well suited for the mainstream provision of chronic disease management.

These limited insights from available data suggested to the review team that circumstances under which a group clinic intervention might be more successful are:

1. during an initiation period for a particular condition over a time period as determined by both patient and clinician
2. for a potentially time-limited circumstance (e.g. during preparation for bariatric surgery for obesity).

Outside these circumstances a model that involves periodic booster sessions may prove more effective and acceptable than the implied lifelong monitoring of the condition within a group dynamic. This also raises the issue of alternative formats for such refresher sessions, for example using internet virtual technologies for the socialisation and facilitated interactions. We return to these issues in the *Chapter 6*.

### Summary of main findings from randomised controlled trials

In summary, findings from a total of 33 RCTs, of which almost half are considered to possess a low to moderate risk of bias, indicate that biomedical outcomes (e.g. blood pressure and HbA<sub>1c</sub>, specifically within the disease context of hypertension and diabetes) are most likely to be significantly affected by group clinic-type interventions. However, this is by no means the case for all such outcomes. One of our clinical advisers suggests that factors affecting modification of blood pressure and HbA<sub>1c</sub> are multifactorial and are, therefore, correspondingly more likely to respond to a complex, multifactorial intervention such as a group clinic. In contrast, measurements such as cholesterol are affected by less complex health choices for which a group intervention may be less appropriate. The reasons for this difference in results across biomedical outcomes require further investigation.

Where such effects to be demonstrated conclusively, these would be of important clinical significance. As Housden *et al.* state:

*Small decreases have . . . substantial clinical impacts: a 1.0% reduction in HbA<sub>1c</sub> may be associated with a 37% decrease in microvascular complications, up to a 14% reduction in the incidence of myocardial infarction and a 21% decrease in the risk of death from diabetes.*<sup>53</sup>

In moving away from easily monitorable and measurable outcome measures it becomes increasingly more challenging to demonstrate a causal effect. For example, disease-specific health-related quality of life demonstrates a significant effect (albeit from only three RCTs), whereas generic health-related quality of life (measured in two RCTs) at a further level of abstraction is only marginally significant. The most recent systematic review and meta-analysis, including only SMAs in a diabetes context,<sup>55</sup> concludes that published examples were so heterogeneous as to yield genuine uncertainty about which elements of the intervention make a SMA intervention successful. Furthermore, issues concerning acceptability and sustainability have been raised from the trial evidence and require further exploration. These issues are explored in the following sections examining qualitative, UK-centric and theoretical aspects of the group clinic type of intervention respectively.

## Results of the qualitative synthesis

### Characteristics of qualitative studies

The review identified 12 qualitative papers<sup>27,97-107</sup> reporting 10 studies (*Table 19*). Seven of the 10 studies were conducted in the USA,<sup>27,98-100,102,104,105</sup> with one each from the UK,<sup>97</sup> the Netherlands<sup>103</sup> and Canada<sup>101,106,107</sup> (three papers). Four studies explored SMAs<sup>27,99,102,103</sup> and one examined DIGMAs.<sup>98</sup> The remainder comprised GMVs (two studies, four papers)<sup>101,104,106,107</sup> and group clinics (three papers).<sup>97,100,105</sup>



**TABLE 19** Intervention label and country for included qualitative studies

Author (year)	Model	Country	Size and nature of sample	Disease/condition
Asprey <i>et al.</i> (2012) <sup>97</sup>	Group clinic	UK	16 patients and four nurses	Osteoarthritis
Capello (2008) <sup>98</sup>	DIGMA	USA	Random sample of 30 completers and seven non-attenders	Hypertension
Cohen <i>et al.</i> (2012) <sup>99</sup>	SMA	USA	17 veterans	Overweight/obesity, metabolic assistance and smoking cessation
Hroschikoski <i>et al.</i> (2006) <sup>100</sup>	Group clinic	USA	45 organisational leaders, external and internal change leaders, mid-level clinic managers, medical and administrative clinic leaders, front-line physicians and nurses (53 persons)	Diabetes
Kirsh <i>et al.</i> (2009) <sup>27</sup>	SMA	USA	23 medical students: 12 in SMA group; 11 in control	Non-specific chronic disease
Lavoie <i>et al.</i> (2013) <sup>101</sup>	GMV	Canada	34 providers and 29 patients	Most common conditions: diabetes (59%), high BP (52%) and arthritis (48%)
McCouston <i>et al.</i> (2014) <sup>102</sup>	SMA	USA	12 medical and administrative staff	Non-specific
Mejino <i>et al.</i> (2012) <sup>103</sup>	SMA	Netherlands	46 patients	Type 1 diabetes
Miller <i>et al.</i> (2004) <sup>104</sup>	GMV	USA	28 women with at least one chronic disease	Non-specific
Ovbiagele (2010) <sup>105</sup>	Group clinic	USA	13 Spanish-only-speaking participants; six caregivers; 11 care providers and nine administrators	Stroke
Piper (2011) <sup>106</sup>	GMV	Canada	9 patients	Chronic disease
Wong <i>et al.</i> (2013) <sup>107</sup>	GMV	Canada	63 participants: 10 family physicians; 7 nurses; 2 nurse practitioners; 4 primary health-care co-ordinators; 11 other allied health workers (e.g. nutritionists, social workers, medical office assistants and community health representatives) and 29 patients	Diabetes, depression, smoking cessation

BP, blood pressure.

### Characteristics of surveys

In addition, the review identified four surveys<sup>96,108–110</sup> to be used to corroborate findings from qualitative evidence. Three of the surveys were conducted in the USA,<sup>108–110</sup> with the remaining survey from the Netherlands<sup>96</sup> (Table 20). Two surveys explored GMAs<sup>96,110</sup> and one survey examined DIGMAs.<sup>108</sup> Jhagroo *et al.*<sup>109</sup> reported an adaptation of three models: the DIGMA, the CHCC and the physical SMA. As quality assessment of surveys is problematic, these papers were not critically appraised, and data were used only to triangulate findings and not to generate themes.

Comparison of the distribution of clinic models from the effectiveness literature with that from the qualitative literature reveals that the principal models of group clinic-type approaches are all well represented.

Eight qualitative studies<sup>111–118</sup> were excluded from the qualitative synthesis, as they were available only as conference abstracts. However, three abstracts<sup>111,117,119</sup> related to UK initiatives and so are examined further in the *Results of the review of the UK evidence*.

**TABLE 20** Intervention label and country for included surveys

Author (year)	Model	Country	Size and nature of sample	Disease/condition
Hirsh <i>et al.</i> (2001) <sup>108</sup>	DIGMA	USA	32 patients	Endometriosis
Jhagroo <i>et al.</i> (2013) <sup>109</sup>	Adapted three models: DIGMA, CHCC and physical SMA	USA	112 patients (51 ± 14 years, range 19–87 years) seen in 27 SMAs over 14 months	Kidney stones
Lock <i>et al.</i> (2012) <sup>96</sup>	GMA	Netherlands	38 parents (72%) and 14 adolescents	Haemophilia
Trotter and Schneider (2012) <sup>110</sup>	GMA	USA	122 patients	Breast cancer

### Study populations and settings

We identified a total of 12 qualitative studies of group clinic type interventions. One-third of these (four studies) examined the attitudes of patients only. One study<sup>96</sup> explored the views of patients and carers, and four studies investigated both patients and health-care providers.<sup>97,100,101,107</sup> One study investigated the views of providers in isolation<sup>102</sup> and one study included views of providers, patients and caregivers.<sup>105</sup> A final study examined the views of students regarding SMAs as an educational experience.<sup>27</sup> The quantitative review had revealed a complete absence of measurement of provider experience in the included studies. The qualitative evidence base clearly has an important part to play in addressing the wider acceptability of the group clinic intervention within a health-care delivery system.<sup>86</sup>

### Quality of included qualitative studies

The overall quality of the studies included in the review is shown in *Table 21*, and an assessment of the quality of each included study is given in *Table 22*.

**TABLE 21** Study design and overall study quality of included qualitative studies

Author (year)	Country	Study design
Asprey <i>et al.</i> (2012) <sup>97</sup>	UK	Semistructured interviews
Capello (2008) <sup>98</sup>	USA	Semistructured interviews
Cohen <i>et al.</i> (2012) <sup>99</sup>	USA	Focus groups
Hroszkoski <i>et al.</i> (2006) <sup>100</sup>	USA	Semistructured interviews
Kirsh <i>et al.</i> (2009) <sup>27</sup>	USA	Interviews
Lavoie <i>et al.</i> (2013) <sup>101</sup>	Canada	In-depth Interviews
McCuiston <i>et al.</i> (2014) <sup>102</sup>	USA	Audio-recorded key informant interviews
Mejino <i>et al.</i> (2012) <sup>103</sup>	The Netherlands	Questionnaires and online focus group
Miller <i>et al.</i> (2004) <sup>104</sup>	USA	Open-ended interviews
Ovbiagele (2010) <sup>105</sup>	USA	Focus groups and interviews
Piper (2011) <sup>106</sup>	Canada	In-depth interviews
Wong <i>et al.</i> (2013) <sup>107</sup>	Canada	Interviews and direct observation

One study<sup>102</sup> was not available by completion of report. For full version of quality assessment criteria please see *Appendix 5*.

TABLE 22 Quality assessment of included qualitative studies

Author (year)	Overall risk of bias assessment	Statement of aims	Methodology appropriate	Design appropriate	Recruitment	Data collection	Relationship	Ethical issues	Data analysis	Findings
Asprey <i>et al.</i> (2012) <sup>97</sup>	Low risk of bias	✓	✓	✓	✓	✓	✗	✓	✓	✓
Capello (2008) <sup>98</sup>	Moderate risk of bias	✓	✓	✓	✓	?	✗	✓	?	?
Cohen <i>et al.</i> (2012) <sup>99</sup>	Low risk of bias	✓	✓	✓	✓	✓	✗	✓	✓	✓
Hroszkowski <i>et al.</i> (2006) <sup>100</sup>	Low risk of bias	✓	✓	✓	✓	✓	✓	?	✓	✓
Kirsh <i>et al.</i> (2009) <sup>27</sup>	Low risk of bias	✗	✗	✗	✓	✓	✗	✓	✓	✓
Lavoie <i>et al.</i> (2013) <sup>101</sup>	Low risk of bias	✓	✓	✓	?	✓	✗	✓	✓	✓
Mejino <i>et al.</i> (2012) <sup>103</sup>	Moderate risk of bias	✓	✓	?	?	✓	?	✓	?	✓
Miller <i>et al.</i> (2004) <sup>104</sup>	Low risk of bias	✓	✓	✓	✓	✓	✓	?	✓	✓
Ovbiagele (2010) <sup>105</sup>	Low risk of bias	✓	✓	✓	✓	✓	?	?	✓	✓
Piper (2011) <sup>106</sup>	Moderate risk of bias	✓	✓	?	?	✓	?	✓	?	✓
Wong <i>et al.</i> (2013) <sup>107</sup>	Low risk of bias	✓	✓	✓	✓	✓	✓	?	✓	✓

✗, criterion not fulfilled; ✓, criterion fulfilled; ?, uncertain.  
 One study<sup>102</sup> was not available by completion of report.

### Population of the conceptual framework

We extracted qualitative data against the elements of the analytical conceptual framework<sup>13</sup> (Table 23), deconstituted into fields on a data extraction form (see Appendix 3). The best-fit framework approach provides for inclusion of additional inductive elements once the deductive stage of the synthesis is completed. The qualitative data yielded six principal themes as presented below. However, many of the data have been extracted from one particularly rich qualitative study<sup>101</sup> and, therefore, may represent views that are not necessarily typical of the study populations across all of the included qualitative studies. Eight richer studies were particularly influential in populating the conceptual framework and subsequent synthesis.<sup>96–99,101–103,111</sup>

### Findings 1: feeling supported

A common finding was that the group environment offered individuals an opportunity to derive support from others in a similar or comparable position to them. Such support could be accessed during the initial socialisation sessions or, subsequently, when engaging in group education or interaction with clinicians.

There was some evidence to suggest that this feeling of being supported subsequently led to a sense of security.

*You gain; I think you gain a feeling of security, of understanding, of sharing with other people, of compassion, of support . . . so many things that you wouldn't gain if you were one on one because of the humanity of us as people. You know we try to support one another.*

*Reproduced with permission from Piper<sup>106</sup>*

In such a climate of trust patients were more likely to share information within the group. This in turn affected the cohesion and a feeling of community within the group, described by one author as an 'esprit de corps'.<sup>99</sup>

**TABLE 23** Analytic framework to evaluate group visits<sup>13</sup>

PURPOSE or MISSION of group clinics/GMVs			
INPUTS or RESOURCES:	ACTIVITIES:	OUTPUTS:	EFFECTS (outcomes, impacts)
Clinicians	Individual consultations	Patient participation	Short term:
Support staff	Group facilitation		<ul style="list-style-type: none"> <li>● adherence</li> <li>● biophysical markers</li> <li>● patient satisfaction</li> </ul>
Premises	Peer support		
Training	Information provision		Mid-term:
Equipment	Education		<ul style="list-style-type: none"> <li>● self-efficacy</li> </ul>
CONSTRAINTS or BARRIERS to group clinic objectives:	Socialisation		Longer term:
Accessibility	Self-monitoring		<ul style="list-style-type: none"> <li>● self-management</li> <li>● better disease control</li> <li>● reduced utilisation</li> </ul>
Confidentiality			
Privacy			
CONTEXT or CONDITIONS of group clinic initiatives			
Patient characteristics			
Health-care system			

The need for feeling supported is illustrated by one extract, which attests to the feeling of isolation a patient may feel if they are not receiving necessary support from either partner (husband) or doctor:

*You've got a group that can back you up . . . understanding what you're going through . . . if I tell my husband oh my blood sugar is 2.4 today, he says . . . well you better take some insulin,' . . . he hasn't really bothered to even read about it . . . he'll get irritated with me. Well that's the last thing you need.*

*Reproduced with permission from Piper<sup>106</sup>*

### **Findings 2: learning from each other (reciprocal learning)**

A notable finding from the qualitative research studies was that the group setting offered a context in which individual group members could learn from the clinicians, where they could learn from other group members and, significantly, where the clinician could learn from the group members. This last finding was one of a number that signalled a shift in the power differential from the clinician dominance of the one-to-one consultation. This important consequence of group clinic approaches was explicitly highlighted by several commentators:

*Overall, the power dynamic between patient and physician was lessened as the patient now viewed themselves as being able to impart information to the physician.<sup>102</sup>*

### **Learning from clinicians**

Improved learning from clinicians was frequently identified as a benefit from group approaches: 'enhanced learning by being able to cover more information than what would be provided in a traditional visit'.<sup>102</sup>

Such enhanced learning was expressed in both qualitative and quantitative terms. Piper charted a move from an information flow that aligns with the power dynamic towards something more dynamic and, ultimately, more creative:

*The learning in the GMVs occurs from the shared experiences of participants and the medical expertise of the physician and the other health care providers. The loose boundaries created changed the typical linear exchange of information from authority to client to a circular flow of questions and answers . . .*

*Reproduced with permission from Piper<sup>106</sup>*

### **Learning from other group members**

The sharing of information with other members was viewed as a form of social bartering by which they could affirm their membership of, and value to, the group; many participants spoke about the satisfaction of sharing their knowledge of living with a chronic illness.

*Sharing . . . acknowledged their personal experience and it was hoped that they would be able to help others in managing their chronic condition: –You learn from other people and hopefully they learn something from me.*

*Reproduced with permission from Piper<sup>106</sup>*

The emphasis is on what is described as 'reciprocal learning':

*You feel you'd like to share with a group because you think that they can learn from this problem as well as you can learn from their problems.*

*Reproduced with permission from Piper<sup>106</sup>*

In addition to problem-solving, sharing includes the experience of the disease as well as practical tips for self-management; learning what other veterans had experienced and 'tips' on chronic disease self-management provided a much needed perspective for many. A powerful vignette of the practical value of group-based interactions is evoked in the context of a UK-based acupuncture clinic:

*Somebody perhaps will go swimming, so they'll say, 'This was a nice swimming pool and it was easy to get to' so it sort of spreads into all sorts of things . . . which you would not actually have if you were sat on your own in a cubicle.*

*Woman in her 50s<sup>97</sup>*

### Clinician learning from group members

The group situation may encourage clinicians to acquire a greater understanding of what life with a chronic condition is like for their patients.

*Yeah, they learn things they wouldn't have learned in one on one, and I could see that . . . Dr. [name] admitted it even in front, to everybody the other day. He said that more than once that he's had revelations that he would not get from one-on-one visits.*

*Reproduced with permission from Piper<sup>106</sup>*

In addition to learning that may equip a provider to demonstrate more empathy and understanding, there was some evidence of more instrumental learning:

*It [the GMV] has helped me to be more creative in looking at ways to meet people's needs. Some of that just comes from the patients themselves because they often have some really neat ideas about how to overcome challenges or difficulties in dealing with the diabetes.*

*Provider<sup>101</sup>*

Such suggestions simultaneously become a resource to the group at that time but also a future resource for use by the provider:

*. . . they've given me some really good tips and ideas . . . stuff I learned that I wouldn't have learned if I had done it on an individual basis. There's a lot of value that comes out of . . . impromptu patient teaching of each other.*

*Provider<sup>101</sup>*

Indeed, a clinician's willingness to learn did itself acquire a symbolic function as a contributing factor to improved trust in the clinician–patient relationship:

*Being emotionally present allowed the physician to listen and to be genuine in trying to understand life with a chronic condition: – I trust him [doctor] more when I see that he's open to learning and figuring out new things that are only happening in group dynamics.*

*Reproduced with permission from Piper<sup>106</sup>*

### Findings 3: legitimising question answering

A group clinic environment may represent a less intimidating clinical context for patients who are more reticent. Safety, and indeed strength, in numbers may be perceived as an antidote to the power imbalance experienced when a patient encounters a clinician on a one-to-one basis.

## A safe environment

The idea of a safe haven, both as a protection and as a source of encouragement, is expressed by several participants.

*I let the physician dominate me a little more in a one-on-one situation than . . . in a group situation. I'm more likely to open up in a group . . . because there are witnesses . . . a doctor is less likely to be verbally abusive or mistreat me when there are other people watching and listening. . .<sup>101</sup>*

## Surrogate question answering

Wider evidence suggests that patients will often be reluctant to ask questions in a one-to-one consultation. In a group context they may find that a more active participant is more able to vocalise their own concerns. Patients therefore become vicariously exposed to information that would not otherwise be forthcoming.

*And sometimes if you're a little too timid to ask the questions maybe someone else will ask them for you. So that's one of the benefits of the group, of course, is the fact that there are a number of people there up to twelve or thereabouts.<sup>101</sup>*

## Encouragement from others

Provided the group is sufficiently informal, cohesive and relaxed and, importantly, does not add to the stress already encountered from experiencing the condition, it can offer a setting that is conducive to relationships and positive interaction:

*The more relaxed, less-structured environment inherent in GMVs lends itself to meaningful relationship building for participants who might be shy in a one-on-one visit or who might need more time to build a trusting patient-provider relationship.<sup>101</sup>*

## Benefits for 'lurkers'

Even if a patient has not formulated a question that they wish to have answered that might correspond to a question asked by another group member, there is some evidence that they can still derive benefit from information being shared within the group:

*Patients reported learning from others' experiences, gaining additional information from their provider based on his/her responses to other attendees' questions . . . Both patients and providers also reported that patients felt less intimidated and more secure interacting with PHC [primary health care] providers in a group, thus sharing more health information.<sup>101</sup>*

Here the analogy is to a virtual discussion list, where some feel more comfortable as active participants while others feel equally comfortable at being 'lurkers'. Indeed, these respective roles may be transitory as lurkers ease themselves gently into the group before feeling empowered to pursue their own information agendas.

## Findings 4: structure and content

We were able to map the qualitative findings on the individual components of group clinics to those aspects of self-management (Table 24) identified in the report by Taylor *et al.*<sup>29</sup>

TABLE 24 Components of self-management as identified from Taylor et al.<sup>29</sup>

Example from group clinics	Component <sup>29</sup>
<i>There's a sort of certain socio-educational aspect to it as well, which is supportive . . . and they'll discuss other therapies such as chondroitin or that sort of thing . . . there's quite an exchange of information going on</i> <sup>97</sup>	1. Education about condition and management
<i>The nurses confirmed that this kind of information exchange took place among the patients, including discussions about the advice and treatment they had been given by different healthcare professionals</i> <sup>97</sup>	2. Information about available resources
<i>Empowering Patients in Care (EPIC) – clinician-led, patient-centred group clinic consisting of 4 sessions on setting self-management action plans (diet, exercise, home monitoring, medications, etc) and communicating about progress with action plans</i> <sup>65</sup>	3. Provision of/agreement on specific action plans and/or rescue medication
<i>And, of course, then having their conditions checked. I think there's this level of comfort too for them, they come in, they know they're being seen, they're feeling that they're being really well looked after . . . [the GMV] gives them a bit of peace of mind</i> <sup>101</sup>	4. Regular clinical review
<i>It isn't just me sitting telling you what to do. They hear from their peers which its, people will change doing something, I could tell them ten times and as soon as somebody beside them with the same condition tells them to do it they listen, they do</i> <sup>101</sup>	5. Monitoring of condition with feedback to the patient
<i>People were still struggling with integrating it into their life, right? I think just understanding those things a little bit better and just to be able to express those things seemed to be helpful . . .</i> <sup>101</sup>	6. Practical support with adherence (medication or behavioural)
No illustrative quotations	7. Provision of equipment
<i>A little bit more than just one-on-one, if it's going to be in a group medical visit you might be safer, you might not be probed, poked quite so much</i> <sup>101</sup>	8. Safety netting
<i>If you have a group medical visit on a particular subject there's a certain protection there in numbers too, I mean there's probably not going to be a whole lot of 'in your face' and things done to you or maybe even more probing questions</i> <sup>101</sup>	9. Training/rehearsal to communicate with health-care professionals
<i>. . . there was evidence that participants shared useful information with each other, particularly about managing . . . on a daily basis:</i>	10. Training/rehearsal for ADLs
<i>Or someone says 'Oh well I find if I lay this way or do that it eases it' and, of course, it all helps everybody . . . so you're picking up the information</i> <sup>97</sup>	
<i>Patients reported that peer teaching and peer pressure to adopt better self-care strategies were welcomed, and understood as supportive. When such pressures came from providers in a one-on-one CE [clinical encounter], the same behaviour was portrayed as abusive or threatening</i> <sup>101</sup>	11. Training/rehearsal for practical self-management
<i>I don't think it's all medical: a lot of it is mindset . . . it's like football players, they like to hang out with other football players . . . you hang out with other people who know what you're dealing with and you can talk to and they know what you're talking about</i>	12. Training/rehearsal for psychological strategies

Reproduced with permission from Piper<sup>106</sup>



**TABLE 24** Components of self-management as identified from Taylor *et al.*<sup>29</sup> (continued)

Example from group clinics	Component <sup>29</sup>
<i>the social aspect of it is important for people, it's like meeting old friends . . . they love coming in, having a cup of coffee with their friends and just talking about things</i> <sup>101</sup>	13. Social support
<i>Forty-two per cent of the patients and 76% of the health care providers had the opinion that more information about lifestyle is discussed during an SMA. However, 46.7% of the patients thought that the amount of information provided about lifestyle was similar to that in an individual visit</i> <sup>103</sup>	14. Lifestyle advice and support

Noticeable from the above mapping process (see *Table 24*) is that group clinics are able to fulfil many of the extended self-management roles that may be required from any clinician–patient interaction. In particular, the group context is strong in meeting a need for training/rehearsal of communication with health professionals, for ADLs, for practical self-management and for psychological strategies, providing a safe environment in which these activities can be modelled. The group setting is able to fulfil some requirements for social support, especially when these needs are not being met by a patient's significant others or by their health professional. However, what is missing from the Taylor framework<sup>29</sup> (see *Table 24*) are the functions of 'groupness' seen in socialisation, a sense of shared experience, modelling of realistic or ideal behaviours and identity through group cohesiveness. Clearly the group clinic approach cannot be conceived simply in terms of its self-management function, even though this was a major driver in the origins of group clinics.

### Findings 5: confidentiality and privacy

One qualitative study in particular<sup>107</sup> focused on issues relating to confidentiality and privacy, a frequently expressed concern in the context of group approaches. Certain protections can be easily instituted such as:

1. initiating each session with a discussion of confidentiality
2. setting ground rules with examples
3. gaining permission for disclosure of particular types of information (e.g. laboratory values)
4. emphasising that participation in the group is not dependent on sharing of personal information
5. asking specific consent to share information of a particular patient at times during a session when it is considered potentially valuable as a resource to a group.

This latter approach is described very positively by one participant as a way of allaying initial concerns about attendance:

*But he's [doctor] he's been very good because he, he makes sure each person gives permission for him to relate any information about them. You have to agree. So do you mind if I talk about your disease or whatever' and you can say yes or no.*

*Reproduced with permission from Piper*<sup>106</sup>

Reciprocal learning and circular questioning require similar protections and filters in order to protect the confidentiality of those sharing the learning. An elegant example of how the distinction between the contexts of information sharing and confidentiality is presented in a small-town context:

*[O]ne provider explained to the group that if he/she learned something about thyroid disease, then this information could be shared with others. The provider went on to tell the group that what was to remain confidential was who 'Mrs. Jones, our neighbor' was the person who has a thyroid condition.*<sup>107</sup>

### Findings 6: the life cycle of the group

It is interesting to observe different views of the group process depending on the stage a person was at in the life cycle of the group. These views can be clustered around the three phases of contemplation, initiation and maintenance of group attendance.

#### Contemplation

Initially, when the prospect of a group clinic is raised, patients may view this with apprehension. It was not uncommon for participants to express discomfort on contemplating a first visit to a group clinic: feelings of apprehension of the unknown, wondering what it would be like to speak about their health status in front of strangers and what it would be like to listen to others' stories, fearing judgement by others and feeling pressured to share their experiences of living with a chronic condition.<sup>106</sup>

This initial hesitance is described by one participant:

*I was a bit skeptical at first. I wasn't sure I wanted to sit ensconced in a clinic and learn all about everybody's problems. And then I wondered what it would be like to talk about, it's like showing off your, you know.*

*Reproduced with permission from Piper<sup>106</sup>*

Participants often need to overcome this barrier by attending at least one session:

*At first I was wary about this program, but only one visit converted me. It felt warm and friendly vs. clinical, which is exactly what I needed.*

*Breast cancer survivor<sup>120</sup>*

#### Initiation

In some cases observing other patients can serve as an antidote to the initial apprehension, as with group visits to an acupuncture clinic:

*I was just a little apprehensive at first, but I saw all the other brave ladies there not flinching or anything, so I thought, 'Oh well, it can't be too bad.'<sup>97</sup>*

In other cases it is the facilitation skills of the provider that can allay such concerns:

*But he's [doctor] he's been very good . . . it worked out very well but like I say we were a bit skeptical at first, just kind of reticent about it a bit. But after we got going it's, it's really, it's educational actually.*

*Reproduced with permission from Piper<sup>106</sup>*

The duration of this initiation period is highly variable and personalised; many of the interviewees stated that it only took attending one GMV before they became comfortable with the concept.<sup>106</sup> The initiation phase was, therefore, seen as the time when participants were at their most vulnerable, presented almost as a make-or-break time:

*Participants who have attended two or more GMVs could identify the vulnerability in first timers . . . The first one they come to they're quite quiet . . . don't ask very many questions, they just listen . . . as they come to other DIGMAS . . . they are more relaxed all the time and it works, it's working for them.*

*Reproduced with permission from Piper<sup>106</sup>*

## Maintenance

While the initial visit serves an initial function in allowing participants to understand what to expect, more observable benefits accrue with repeated attendance. Participation, and in particular sharing openly, leads to increased self-confidence in understanding their chronic condition, which leads to improved self-management.

One man spoke of how he was able to see personal growth in individual participants that led to improved self-management.

*[Y]ou can see their growth because you see them willing to take more risk . . . and be more open within the group. And if that isn't growth, you know, of the individual then growing towards self-management. That's why the group is so great, I mean . . . it gives you a great feeling.*

*Reproduced with permission from Piper<sup>106</sup>*

This level of engagement is described by one participant as really getting 'into a group':

*And these people are really taking this in and they're helping themselves and they're sharing with you . . . you don't feel comfortable until you really get into a group and become part of it and then you can.*

*Reproduced with permission from Piper<sup>106</sup>*

There is some evidence to suggest that the perceived benefits of learning in a group context may diminish over the life of the group as individual patients become more experienced. For example:

*None of the experienced patients reported an increase in acquired knowledge ( $P < 0.001$ ). In children  $\geq 12$  years, all less experienced adolescents reported learning of new aspects of their disease, unlike the 75% of experienced adolescents who reported no learning effect ( $P = 0.011$ ).<sup>96</sup>*

In contrast, other patients observed the importance of being reminded of information that they had previously learned but subsequently forgotten. Some patients reflected that they had thought they knew about high blood pressure, but learned more.<sup>98</sup>

Interestingly, none of the qualitative studies makes a distinction between an inception cohort-type group (where all members of the group grow together) and a self-replenishing group (where new members are continually added). One might anticipate that a self-replenishing group might become frustrating for those who have been with the same group for some time. However, this could be mitigated, at least partially, as group members migrate roles from being primarily beneficiaries to becoming primarily donors of information and experience.

### Summary of main findings from qualitative studies

Clearly, socialisation played a large part in the group clinic intervention, with this factor being mentioned consistently across the qualitative studies. Several respondents mentioned the relaxed atmosphere where they were not afraid to share health issues with others. Linked to this is the role of the clinician as facilitator with the group being cast in the expert role – unless misinformation needs correction.<sup>101</sup> Providers benefit from adopting this communicative role<sup>101</sup> and also learn more about their patients' experience of their condition and their medication than they typically might in a one-to-one setting.

There is some evidence of patients benefiting from role models, not necessarily in the sense of modelling ideal behaviours but often in the sense of conveying a realistic expectation for what the patients are going through.<sup>97</sup> Such modelling extended to normalisation of group behaviours, especially with regard to management of their condition.

Information exchange is a key component of the group interaction, with patients sharing technical knowledge of their condition, practical suggestions, detail on available resources and their own personal experience. However, it is interesting to observe that patients do not adopt a particular role within a group setting. To use the analogy of online forums, there are those who are active participants and those who are quite comfortable being 'lurkers'. Lurkers benefit from information shared within the group. They may also benefit from 'information surrogacy', that is someone asking a question of concern to them (either serendipitously or because this question has surfaced during socialisation and is then articulated by a more vocal member of the group). This explains why group interventions can be fulfilling for these quite different personality types:

*the interview data did not support this hypothesis [that a more gregarious personality would find the groups situation more acceptable] . . . more private people appeared to be content to read a book or a newspaper or to listen to others rather than to join in . . .<sup>97</sup>*

### Adverse events/negative opinions

Shared medical appointments were not experienced positively by all.<sup>103</sup> One parent indicated that he or she was not informed properly about the purpose of SMAs, which resulted in he or she having incorrect expectations. SMAs were also viewed negatively by some parents (25%) when patients were present who did not want to participate or when patients did not interact with each other.

### Confidentiality

Wong *et al.*<sup>107</sup> conducted in-depth interviews with 34 primary health-care providers and 29 patients living in nine rural communities in British Columbia, Canada, and the team identified three themes specifically related to confidentiality: (1) choosing to disclose – balancing benefits and drawbacks of GMVs, (2) maintaining confidentiality in GMVs and (3) gaining strength from interdependent relationships – patients learning from each other. The study concluded that confidentiality can be addressed and was not a major concern for either patients or providers.

## Results of the review of the UK evidence

### Characteristics of UK studies/initiatives

A total of 12 reports<sup>97,111,116–118,121–128</sup> reflecting nine initiatives within current UK practice were identified from the literature (*Table 25*). One further UK initiative, a phenylketonuria group clinic at Great Ormond Street Hospital,<sup>119</sup> was identified from web searching. Owing to the limited volume of UK evidence, information from conference abstracts was included, where the initiative met the inclusion criteria.

### Quality of included UK studies

Although the remit of this report was to identify all published examples of UK group clinic practice, this approach can be seen to have had a deleterious effect on quality. Of the 13 identified studies, only five<sup>97,118,125,127,128</sup> could be considered either research or evaluation and so could be formally assessed for quality (*Table 26*). Four of these were audits, service evaluations or patient questionnaires, leaving just one observational study<sup>125</sup> (moderate risk of bias) and one good-quality qualitative study.<sup>97</sup>

**TABLE 25** Summary of UK studies/initiatives

Author (date)	Type of clinic	Condition	Study type
ASPREY (2011)	Group clinics	Multiple rheumatological conditions	Abstract only
Asprey <i>et al.</i> (2011) <sup>111</sup>			Abstract only
Asprey <i>et al.</i> (2012) <sup>97</sup>			Qualitative
Berkovitz <i>et al.</i> (2008) <sup>118</sup>	Group clinics	Chronic knee pain	Audit
Birrell (2009) <sup>121</sup>	Group clinics	Rheumatoid arthritis	Abstract only
Birrell <i>et al.</i> (2010) <sup>122</sup>	Group clinics	Osteoporosis	Abstract only
Cummings (2012) <sup>123</sup>	Group clinics	Chronic knee pain	Letter
Da Costa (2003) <sup>124</sup>	Group clinics	Diabetes	Book chapter – case study
de Valois <i>et al.</i> (2012) <sup>125</sup>	Group clinics	Breast cancer	Observational study
Kay <i>et al.</i> (2012) <sup>126</sup>	Group clinics	Diabetes	Abstract only
Raymond <i>et al.</i> (2010) <sup>119</sup>	Group clinics	Phenylketonuria	Abstract only
Seager <i>et al.</i> (2012) <sup>127</sup>	SMA	Obesity	Satisfaction study
White <i>et al.</i> (2012) <sup>128</sup>	Group clinics	Knee osteoarthritis	Evaluation
Winfield <i>et al.</i> (2013) <sup>117</sup>	Group DMARD counselling clinics	Rheumatoid arthritis	Abstract only

DMARD, disease-modifying antirheumatic drug.

**TABLE 26** Quality of UK group clinic studies

Author (date)	Study type	Study quality
Asprey <i>et al.</i> (2012) <sup>97</sup>	Qualitative	Low risk of bias
Berkovitz <i>et al.</i> (2008) <sup>118</sup>	Audit	High risk of bias
de Valois <i>et al.</i> (2012) <sup>125</sup>	Observational study	Moderate risk of bias
Seager <i>et al.</i> (2012) <sup>127</sup>	Questionnaire study	High risk of bias
White <i>et al.</i> (2012) <sup>128</sup>	Service evaluation with cost savings	High risk of bias

### Contact with UK advisers

Given the absence of rigorous UK evaluations the review team decided to approach (1) clinicians involved in delivering group clinic interventions and (2) clinicians delivering care to patients with diabetes, as this was the group most represented by international evidence (15 of 22 RCTs). The team contacted three clinicians (two replies) delivering diabetes care and two academics (two replies) involved in evaluation of a group acupuncture initiative (see *Acknowledgements*). Clinicians were sent a four-page summary of review findings to date as of mid-September 2014. Questions explored with clinicians are reproduced in *Box 2*.

For ease of interpretation observations from these clinical specialists have been integrated as far as possible with relevant findings from the literature (see *Study analyses*).

**BOX 2** Questions for consultation with UK stakeholders

For this consultation we would like you to address the following questions:

1. For clinical experts (e.g. diabetes) – how might you explain the fact that group clinics appear to have a significant effect for haemoglobin and systolic blood pressure (and indeed for disease specific quality of life) but not for other biomedical or wider outcomes?
2. To what extent is it feasible to join together clinical consultation and group education activities within a National Health Service context? What are current typical levels of group education provision (i.e. is group education a common part of current service provision?)
3. Could you foresee any potential cost savings from introducing a group clinic approach?
4. Which activities do you see as most appropriate within a group clinic approach? Are there any specific populations for whom a group clinic approach would seem particularly inappropriate?
5. Which type of conditions might be most suited to a group clinic approach?
6. Have you any other observations, relating to the above information or to the topic of group clinics in general, that you would like to share with our review team?

**Patient and public involvement**

The short time frame for the review and the heterogeneity of group care models, coupled with an overall review strategy that already accommodated patient perspectives from the qualitative and UK research literature, meant that it was not considered feasible to elicit unique perspectives from current or past NHS patients. We accept that had there been more examples of current UK initiatives this could have proved a useful source of additional data. We therefore recommend that any future UK-based evaluations seek to engage patients and the public through robust involvement mechanisms.

**Study analyses****What UK models of group clinics currently exist?**

Table 27 reports the frequency of the terminology relating to group clinics in the UK ordered according to mentions in the UK literature. It is noticeable with regard to terminology that UK initiatives favour the terminology of 'group clinic' (Table 27). This tendency may mask the theoretical and philosophical origins of UK initiatives and make any attribution of potential effectiveness from US-based trial evidence potentially more problematic.

**TABLE 27** Most frequently described group clinic approaches in the UK

Model	Number of studies
Group clinic <sup>97,111,118,119,121–128</sup>	9
SMA <sup>127</sup>	1
Other: group DMARD counselling clinic <sup>117</sup>	1

DMARD, disease-modifying antirheumatic drug.

No mentions of CHCC model; specialty CHCC model; DIGMAs; chronic care clinics; cluster visits; GMAs; GMVs; group visits.

### How do UK patients feel about group clinics?

Three studies from a related programme of research by Asprey *et al.* on attitudes to group acupuncture provide some useful insights as to UK considerations for group clinic provision.<sup>97,111,128</sup> In a published abstract Asprey *et al.* reports that most patients were very positive about the clinics, reporting several benefits, both physiological (reduction of pain) and social (useful support and information sharing with fellow sufferers).<sup>111</sup> In a more extensive qualitative study by the same author there was a 'generally positive and often very enthusiastic attitude towards the group sessions'.<sup>97</sup> Significantly, patients took great pains to emphasise the differentness of their own personal experience while drawing strength from being in the same situation. This illustrates that group homogeneity may be considered an artificial construct. Group interaction can be perceived by some as 'idle chitchat' yet by others as a valuable exchange of advice, support and information. Even though people saw themselves as different from each other they were still interested in other's experience of treatment especially if it was seen to make a difference. They were also interested in learning how someone who was essentially different and yet who faced the same situation (e.g. difficulties in getting out of bed) coped with their own challenges. However, for others the need to be with like-minded people was an important factor in a satisfactory group experience.

One added benefit from the group experience relates to the perception that it will be a forum for sharing experience; this contrasts with the individual consultation where interaction between individuals is limited as they serially follow each other through the consultant's door. This suggests that certain desired features of the group clinic such as socialisation and information sharing might be harnessed without necessarily utilising the formalised group clinic structure.

An interesting observation from the group acupuncture programme of research is that patient preferences could extend in either direction between what patients received and what they would have liked to receive. Additionally, patients were not always able to anticipate accurately what their actual experience of a particular modality might be. There was thus a sense that patients would truly know how they respond to the situation only once they were receiving the modality. For example, they may feel that they have very little to contribute within a group situation only to discover that they can provide reassurance to another patient and thus feel good about their role within the group. The group dynamic also tended to deflect attention away from the therapist as a single key part of the treatment programme to focus on what the group might collectively contribute through their conversations and interactions.

Finally, the reality in a knee osteoarthritis context was that group clinic approaches might be perceived as a delaying tactic as patients were willing to try anything to put off the uncertain prospects of knee surgery for as long as possible. In such a context the altruism that one might contribute to the group could conceivably be viewed as a post hoc response to make the best of a situation where one is running out of viable alternatives.

### Are there any negative reactions to group clinics from UK patients?

One patient from 16 interviewed by Asprey *et al.* had a negative reaction to the group experience and ceased to attend.<sup>111</sup> No specific details were provided regarding the nature of this reaction. Privacy was not considered to be a problem even in mixed-sex clinics, but single-sex clinics were preferred. However, as the authors comment, the condition under study, knee osteoarthritis, does not carry any specific sensitivities. The concerns expressed related to the intimacy of conversations among women and potential embarrassment relating to physical appearance, as expressed by women or perceived by the men.<sup>97</sup> It was suggested by patient representatives that it would be helpful to forewarn patients about what the procedure will involve before their arrival at the clinic and suggest that they dress accordingly. Although this issue arises in a specific treatment context, it links with other qualitative comments about the importance of communicating realistic expectations of what will happen within the group process.



### How do UK health providers feel about group clinics?

Asprey *et al.* reported that four nurses interviewed perceived benefits of group clinics in terms of cost-efficiency, the efficacy of the acupuncture treatments and the positive effect of group interaction on their patients.<sup>111</sup> The same author further reported the specific needs, as mentioned by one nurse, to make provision for 'Asian ladies', by which the nurse specifically meant Muslim women.<sup>97</sup> Generally, single-sex clinics were preferred to mixed-sex clinics even though the level of physical privacy required for osteoarthritis clinics was not significant. Another population group for whom group approaches may not be an attractive option is those with hearing difficulties, who may find it difficult to interact and participate and may not benefit fully from information exchange.

### What evidence is there about feasibility or costs?

In an abstract presentation Winfield *et al.* described the use of group clinics for disease-modifying antirheumatic drug (DMARD) treatment in South Devon.<sup>117</sup> Over a period of 3 months 90 patients were seen in clinic, representing an average of 2 hours and 40 minutes per week saved by counselling patients in groups. The average time of wait from referral to appointment was 10 days. However, the authors report that some patients took longer than this because of abnormal tests or personal issues such as holidays. Levels of patient satisfaction were very high, with average scores ranging from 4.6 to 5 out of 5 across the seven questions in the group clinic and from 4.8 to 5 in the individual clinic. There was minimal variation between the scores given by the two groups, with the largest variation in whether or not patients felt confident in starting the medication. Here, the individual clinic gave an average score of 4.8, with the group clinic giving an average score of 4.6. Winfield *et al.* conclude that group DMARD clinics allowed the clinics to keep up with demand for slots while freeing up nurses to undertake other duties.<sup>117</sup> Patient satisfaction was generally maintained across group clinic and individual settings. However, the authors alert readers to an ongoing need to address all patient ideas, concerns and expectations.

The group acupuncture setting described by Asprey *et al.*<sup>97,111</sup> and White *et al.*<sup>128</sup> involves the use of a dual-purpose room and a carefully crafted logistic timetable. A single room is used with a single practitioner who is present for, say, 2 hours. Treatment in the group is given to patients while they are seated, with about 12 chairs situated around the room. The very first appointment is different: the patient is seen alone (to establish therapeutic relationship, and in case confidential issues arise) and treated on a couch (in case of fainting, which may occur on the first treatment with acupuncture). For convenience, the couch may be in the same room as that in which the group is held, in which case the initial, individual appointment would take place during specially identified time slots at the beginning or end of the group clinic. All subsequent attendances are in the group: patients arrive at different times and join the other patients already there, and are treated by the practitioner in the presence of the other patients.

Two clinical advisers reported unpublished experience from trying to join up the clinical consultation and group education aspects of diabetes care. This attempt had not worked very well as large numbers of patients did not attend and among those who did attend there was a fall-off in attendance as the appointments went on. These issues regarding acceptability and long-term sustainability have been previously flagged in the literature and are returned to later in this report. Interestingly, an explanation advanced from both clinical advisers from their team was that group education is currently presented as an optional extra and is not an essential part of the treatment. This observation highlights the important mechanisms that engage with the symbolic function of the group clinic.

Another concern from the group acupuncture programme of research related to the spatial implications of delivering services within a group. One participant felt that the presence of equipment for multiple patients within a confined space might impair others' experiences of group treatment. Similar considerations may well pertain where equipment and activities relate to monitoring instead of treatment. Again, we can conceive that inadequate space may serve as a symbolic as well as a practical barrier, in that inadequate resourcing of the group clinic premises may be taken as signalling a lack of importance attached to this specific activity.



### Summary of main findings from UK evidence

Thirteen papers were identified that described initiatives from the UK.<sup>97,111,117–119,121–128</sup> None of these represented experience from rigorously conducted experiments. Descriptions of several initiatives were available only as abstracts. Acceptability of group clinics is high among a population requiring group acupuncture for knee osteoarthritis. However, the sensitivity of health and lifestyle topics is not a key issue for this particular population. Even within this context there was an expressed demand for single-sex sessions, including in a Muslim population.<sup>97</sup> Patients considered that single-sex sessions represented good practice, regardless of specific religious and cultural considerations. A good-quality qualitative study from the UK highlighted the importance of situational factors such as a physical space and a flexible appointment system.<sup>97</sup> Patients for whom group clinic sessions may not be as appropriate include those with complex conditions, those with extreme pain<sup>97</sup> and those with hearing difficulties.

It should be noted that the absence of empirical studies from a UK context has led to a disproportionate reliance on the reported experience from UK group acupuncture clinics. Two particular considerations are:

1. Group acupuncture clinics differ from other group clinics because patients arrive with the expectation that they will receive treatment. For group clinics in general, treatment and follow-up is more typically contingent on the findings from the monitoring and consultation processes. Potentially, patients attending group acupuncture clinics may have stronger motivations for attendance than those attending for routine monitoring.
2. Acupuncture treatment involves patient downtime (typically at least 20 minutes) as the patient receives treatment. Although the efficiency argument (in terms of number of patients who can be seen by a consultant) is frequently rehearsed in opinion papers the driver for acupuncture clinics may be seen as an example of where a clinical team may be able to 'work smarter'. Although this driver may be seen to make group acupuncture clinics demonstrably different from other monitoring contexts this could have the potential benefit of showcasing another type of situation that might potentially benefit from group approaches in other disease areas.

Contact with the clinical experts revealed other potentially important issues, in that the acupuncturist was not formally trained in or charged with the task of facilitating the group. As a consequence, group interaction was expected to be more organic and less manufactured. Furthermore, socialisation, as we have termed it elsewhere in the report, could not really be considered a formal part of the 'programme'. However, potential benefits have been identified where group communication occurs opportunistically, such as (a) the normalisation of symptoms, (b) the sharing of information on resources available and (c) encouragement to adhere (or, more accurately, to continue to attend even though improvement may take a few weeks to become noticeable).

### Other contextual UK evidence

The review team also accessed a UK-based discussion on group clinics hosted by the GP-UK (an e-mail discussion list for the UK Education and Research communities focusing on UK general practice topics) discussion list.<sup>129</sup> Several observations from list members are worthy of note. First, one correspondent observed that use of the word 'clinic' in 'group clinics' might be considered problematic as it might create the impression of an individual session. This might remain the case even though there is provision of explanatory information to the contrary. Two studies,<sup>97,103</sup> including one from the UK,<sup>97</sup> observed that patients or their carers had different expectations of the group clinic arrangement and this resulted in negative perceptions of the clinic when these expectations were not actually met.

Some patients felt that the explanations supplied by nurses were occasionally incomplete and could be inconsistent, which would result in problems.<sup>98</sup>

*It (mixed sex clinic) wasn't something I was expecting, wasn't something I was told about before I went in . . . you know we're not all beautiful shapes or whatever, and it's sort of a bit embarrassing.*  
Woman in her 50s<sup>97</sup>

And:

*One parent indicated that he/she was not informed properly about the purpose of SMAs, which resulted in incorrect expectations.*<sup>103</sup>

The GP-UK discussion list also raised concerns about confidentiality as, for example, erectile dysfunction might be discussed during a diabetic clinic and this may be difficult if couples are present. Sudell discusses that women may feel able to discuss such matters with their female friends, but this may result in the partner feeling embarrassed.<sup>130</sup>

This observation highlights that assumptions must not be made about the content of a group discussion simply on the basis of the condition itself – a sensitive condition might engender sympathetic discussion and yet a general condition may equally yield embarrassment. The critical aspect is the dignity of those who are participating and not the condition per se.

## Chapter 4 Realist review of quantitative and qualitative evidence

### Towards programme theory

From a reading of qualitative studies and review and trial evidence, the review team developed a large number of candidate programme theories as to how the group clinics might work. In particular, we looked for mechanisms by which patients or providers might be motivated to sustain their involvement in a group clinic-type approach.

Our initial overarching programme theories are given in *Table 28*.

**TABLE 28** Overarching programme theories for group clinics

'Label'	Programme theory		
	Patients with chronic disease benefit from attending group clinics if . . .	Relevant theory	Clinic components
<b>By activity</b>			
PT1: 'feeling supported'	<b>Individuals</b> gain support from others in the same position as they are, or worse <sup>101</sup>	Social support	Group sessions; socialisation Social support
PT2: 'building trust'	<b>Individuals</b> build up relationships with care providers resulting in increased trust, sharing of concerns and responding to advice <sup>101</sup>		Individual and group components Training to communicate with health-care professionals
	<b>Individuals</b> build up relationships with peers resulting in increased trust, the sharing of concerns and responding to advice		Socialisation Social support
PT3: 'learning by doing'	<b>Individuals</b> model activities in a safe environment that they can subsequently repeat at home	Self-efficacy: social cognitive theory	Group sessions Training for practical self-management activities; training for ADLs
PT4: 'monitoring as ownership'	By participating in self-monitoring <b>individuals</b> experience greater engagement with their self-care		Self-monitoring activities
PT5: 'acquiring problem-solving strategies'	<b>Individuals</b> are exposed to a variety of problem-solving strategies from both clinicians and fellow patients <sup>101</sup>		Group sessions Training in psychological strategies
PT6: 'gaining information'	<b>Individuals</b> gain both general and personalised information for self-care <sup>97,103</sup>		Didactic group and individual components
			Information about resources

continued

TABLE 28 Overarching programme theories for group clinics (continued)

Programme theory			
'Label'	Patients with chronic disease benefit from attending group clinics if ...	Relevant theory	Clinic components
PT7: 'legitimising question asking'	<b>Individuals</b> observe and imitate other group members seeking to meet their own information needs <sup>103</sup>	Empowerment social learning theory	Didactic group and individual components  Training to communicate with health-care professionals
PT8: 'information seeking surrogacy'	<b>Individuals</b> benefit from questions asked by others on 'the group's behalf' <sup>101</sup>		Group sessions  Information about resources training to communicate with health-care professionals
PT9: 'looking for warning signs'	<b>Clinicians</b> can identify individuals who require personalised follow-up <sup>101</sup>		Review of clinical data; self-monitoring; group sessions  Monitoring with feedback to the patient
PT10: 'gaining understanding'	<b>Clinicians</b> achieve greater insight into disease experience of their patients		
<i>Symbolic/emblematic</i>			
PT11: 'observing a difference'	<b>Individuals</b> are able to observe the impact of self-care on their own health and that of group members		Self-monitoring  Monitoring with feedback to the patient
PT12: 'modelling positive behaviours'	<b>Individuals</b> observe strategies of fellow patients as role models for their own self-care		Group sessions; socialisation; specific action plans
PT13: 'normalising on group behaviour'	<b>Individuals</b> identify helpful self-care behaviours triumphing over realistic patterns of relapse	Social norms	Group sessions; socialisation  Specific action plans; lifestyle advice and support
PT14: 'signalling importance'	<b>Individuals</b> perceive that self-care for their chronic disease is important enough to justify a dedicated initiative		Regular group clinic slots
PT15: 'making a difference'	<b>Clinicians</b> gain satisfaction from a more impactful intervention as a change from routine clinics		Group clinics
PT16: 'joining-up care'	<b>Clinicians and patients</b> perceive a more joined up team-based approach with potentially greater continuity of care <sup>103</sup>		Multiprofessional team working
PT, programme theory.			

### Programme theory 1: 'feeling supported'

The group clinic model allows for support from two main sources – from clinicians and from other patients – to contribute to what has been described as a supportive environment.<sup>120</sup> In theory this dual support should result in an additive effect over that offered either by a one-to-one consultation – 'I trust him more when I see that he's open to learning and figuring out new things that are only happening in group dynamics'<sup>101</sup> or from attendance at a peer support group:

*You know we try to support one another, it's kind of human to do that. It's human to have compassion for other people who have problems and you can show that and you can feel that from other people when you're in a group, you don't in isolation.<sup>101</sup>*

Support may be verbal or may be the effect of perceived solidarity:

*I was just a little apprehensive at first, but I saw all the other brave ladies there not flinching or anything, so I thought, 'Oh well, it can't be too bad'.<sup>97</sup>*

However, other implications for this dual source of support are that patients may access support judiciously and appropriately by deciding between the two sources or that they may use the availability of an alternative source of support to compensate, for example, for the perceived inadequacies of support from clinical staff.

*The same behaviors are not portrayed as a problem by patients when coming from peers . . . When such pressures came from providers in a one-on-one CE [clinical encounter], the same behavior was portrayed as abusive or threatening.<sup>101</sup>*

Of course, the availability of both kinds of support requires careful management when misinformation is being given.

### Programme theory 2: 'building trust'

Following an effectiveness review for the Department of Veterans Affairs in the USA, two experienced researchers, Kirsh and Aron, have undertaken *Theory Driven, Context Dependent Studies of Shared Medical Appointments: A Realist Work in Progress*.<sup>131</sup> They propose that a key mechanism to the success of SMAs is the build-up of trust in the peer group. We also found evidence of trust being built up in the relationship of the patient with the care provider:

*I've learned to trust him. I trust him more than I used to and that's important, that bond of trust has to be there.<sup>101</sup>*

This establishment of trust with the care provider explains inclusion of group visit interventions in a Cochrane review of interventions to build up trust.<sup>56</sup>

### Programme theory 3: 'learning by doing'

Kirsh and Aron also identify the importance of 'learning in context'.<sup>131</sup> Although this is not a complete match with our concept of 'learning by doing', it does share mechanisms by which what is being learnt becomes familiar and therefore no longer carries a connotation of anxiety. We consider that 'learning in context' would more appropriately characterise a home-based intervention. In contrast the type of activities that we characterise as 'learning by doing' (e.g. taking blood glucose or blood pressure measurements) within a group clinic setting become familiar from experience and support. Although not by any means a home environment per se, the group clinic becomes a 'safe environment' where an individual can trial an activity and seek recourse to help before incorporating the activity into his or her independent self-management routine. Trialability is considered an important characteristic that impacts on people's likelihood to contemplate change.

**Programme theory 4: 'monitoring as ownership'**

Fundamental to a group clinic approach, as exemplified by SMAs, is the 'combination of witnessed and private individualised interactions between patients and their physicians, as well as an educational component'.<sup>132</sup> In the RCT by Edelman *et al.*,<sup>69</sup> pharmacists and physicians developed individualised plans for alterations in medication and lifestyle management, apparently before meeting with the patients themselves. However, there is sufficient evidence relating to the principles of co-creation to suggest that more effective behaviour modification will result from patients generating their own plans, with a provider simply helping to facilitate. In this context, the involvement of patients in their own monitoring, particularly where this requires hands-on engagement with monitoring equipment, may be both a practical and a symbolic way of getting them to start to engage with their own management.

**Programme theory 5: 'acquiring problem-solving strategies'**

The qualitative studies demonstrated a clear role of the group clinics in the context of problem-solving. First, patients were reassured by being placed in a group of people who shared the same problems:

*Well it was quite nice being in the group, because you kind of think, well other people have got the same sort of problems, you're not completely weird!*<sup>97</sup>

Ostensibly, problems do not seem to be conceived as problems if they are issues that other participants also have to face on a day-to-day basis. However, aside from such reassurance, there is a strong line of argument regarding the problem-solving function of the group clinic meetings:

*Yeah it's beneficial in a group from the point of view you've got someone to talk to, you've got an exchange of ideas or problems or whatever. Whereas if you sit there on your own you're basically waiting for the clock to tick round to say, 'Well I'm finished now'.*<sup>97</sup>

Furthermore, patients gain reassurance from other patients having their own problems resolved:

*[Y]ou can follow the other people and you can see what the doctor is doing for their problems . . . we can see where we're heading and try to stop it before we get there. We know we're going to get there eventually but we want to slow down getting there.*<sup>101</sup>

**Programme theory 6: 'gaining information'**

The gaining of information is seen by many patients as one of the primary purposes for participating in a group situation. This information may relate to the technical aspects of the condition or how a treatment works, or it may relate to how people cope practically or emotionally with their condition:

*There was evidence that participants shared useful information with each other, particularly about managing the arthritis on a daily basis:*

*Someone says 'Oh well I find if I lay this way or do that it eases it' and, of course, it all helps everybody . . .*<sup>97</sup>

It may relate to facilities or aids that can help to manage the implications of their condition or how to navigate health services or other facilities:

*They would exchange ideas, their own experiences, how long that they'd had the condition, how, you know, how much support locally they had, or not (laughs) . . . often they would say 'Which doctor do you see here? My doctor says this,' because they might see different consultants in this hospital.*<sup>97</sup>

*They'll say, 'This was a nice swimming pool and it was easy to get to' so it sort of spreads . . . And how the shop-mobility works . . . all sorts of things, really, which you wouldn't actually have if you were sat on your own in a cubicle.*<sup>97</sup>

### **Programme theory 7: 'legitimising question asking'**

In the context of the group clinic patients may feel more empowered to ask questions than they might otherwise be during an individual consultation. The fact that others ask questions during a group session, together with the potential modelling of how questions should (or even should not) be asked, can encourage individuals to feel that asking questions is legitimate. However, there is a corollary because people may be discouraged from asking questions either because the topic is not one they feel comfortable sharing with a group or because they are generally reticent in a group situation. Good facilitation skills are required for the group process so that no question is considered 'too stupid' and that individual contributions are valued by the group. The comparative comfort with which patients may ask questions within the group will also depend on the comparator, namely how comfortable they have felt in corresponding one-to-one situations with a health-care provider.

### **Programme theory 8: 'information seeking surrogacy'**

There is significant evidence to suggest that, in the time-pressured environment of the individual consultation, patients often forget to ask questions that concern them.<sup>133</sup> Furthermore, even if they do remember to ask pertinent questions they often forget the answers that they have been given.<sup>134</sup> Being present when others are asking questions may have several effects:

1. Someone may ask a question that addresses an issue that concerns another patient.
2. A question asked by someone else may prompt a patient to remember a related question that concerns him or her.
3. The asking of any question by someone else legitimises the question-asking process.
4. Observing the question-asking-and-response process may provide a less pressurised environment for the taking-in of information relating to the condition.

The corollary to this is that a patient may be deterred from asking a question in a group setting because of the number or characteristics of the other group members, they may consider their question less important or more trivial than other questions asked by members of the group and they may become more passive in the role that they choose to assume in the question-answering process.

Good facilitation skills are required by the provider in order to elicit questions from patients who may be reticent, to manage the influence of more vocal patients and to correct any misinformation that may arise during the group interaction.

### **Programme theory 9: 'looking for warning signs'**

One of the functions of the group clinic from a clinician's viewpoint is that it offers the possibility of unobtrusively observing and monitoring a group of patients and thus of 'triaging' those who require specific follow-up. This feature would be particularly important in a model in which individual consultation is not universal but, rather, is reserved for those for whom it is indicated and/or for a selected population with particularly complex or heavy requirements. Although in practice this type of group observation differs little from the observation that might take place during an individual consultation, it is interesting to find that the participating clinician may frame it differently:

*It [the GMV] creates an environment that is the trickery in medicine – to think people are having a social gathering and you're working the crowd and doing the medical work while they are having a good time, I mean that's optimal.<sup>101</sup>*

Although the overall impression from this data extract is that the 'trickery' is in the patients' best interests and that it is justified by the fact that the patients are enjoying themselves, this type of comment further illustrates the importance of setting initial expectations about how information gathered through the group component of the process will be used.



The same clinician then seeks to explain how such trickery might work:

*... people are enjoying themselves ... and yet there's a team going around getting all the information that needs to be gleaned ... that's the secret, so you turn it into a really positive experience for the patients so that's why they want to keep coming back ...*<sup>101</sup>

### **Programme theory 10: 'gaining understanding'**

Although much of the rhetoric of the group clinic literature relates to efficiency for the provider and improved information and social support for the patient, we were able to identify qualitative benefits to the health-care professional in terms of their improved understanding of the patient's situation, the constraints of his or her condition and, specifically, issues relating to his or her medication or wider treatment.

*I think that it [the GMV] has helped me to be more creative in looking at ways to meet people's needs. Some of that just comes from the patients themselves because they often have some really neat ideas about how to overcome challenges or difficulties in dealing with the diabetes.*<sup>101</sup>

Furthermore, the group clinic interaction also served to enhance providers' skills and awareness:

*Through interaction with patients, providers reported having gained a more advanced communication repertoire, and developed greater self- and situational awareness.*<sup>101</sup>

### **Programme theory 11: 'observing a difference'**

One of the motivations for attending a group clinic is observing a difference that is perceived to have the potential to make a difference to a participant's own life. Such a difference may be seen in a reduction in unhelpful behaviours:

*A number of the patients mentioned that they had reduced their use of pain killing drugs as a result of participating in the acupuncture clinics:*

*I took it upon myself to reduce the medication ... I have reduced it by 50% so, you know, that is a big difference, but ultimately I want to not be taking diclofenac at all.*<sup>97</sup>

In other cases patients may observe a change in their underlying health condition and be encouraged to persist. Observability is considered another characteristic that impacts on people's likelihood to contemplate change.

### **Programme theory 12: 'modelling positive behaviours'**

One of the putative mechanisms for effect in a group context is that other group members may model the desired behaviours required from the patient group and, therefore, participants will adopt the desired behaviour. This is supported at a theoretical level by the various social theories itemised in *Chapter 1*. We found some empirical data to support this effect. For example:

*... participants specifically mentioned the usefulness of meeting role models—women who were successful in coping with their disease.*<sup>127</sup>

*We always know we're not the only one in that boat, when you're in a lot of pain you think, 'Oh I don't know, is it just me, am I exaggerating? Is it mental?' like this. And you see how everyone else suffers and how they cope with it.*<sup>97</sup>

### **Programme theory 13: 'normalising on group behaviour'**

Kirsh and Aron identify an important mechanism as 'motivation to comply with others'.<sup>131</sup> This corresponds quite closely with our conception of 'normalising on group behaviour'. A group member can establish a



benchmark against which they can critically appraise their own behaviour. Although this mechanism is linked with the idea of other group members 'modelling positive behaviours', which may then encourage an individual group member to comply with others, there is some evidence that models may exhibit realistic, and hence reassuring, behaviours that might allow a person to aspire to slight but feasible behaviour modification rather than to a more dramatic and thus less attainable change. A potential adverse effect of the concept of the 'opinion leader' as such is that the very characteristics that make them stand out as an opinion leader may be the same characteristics that make their example seem unattainable to an 'average' person targeted by a group intervention.

A further issue relates to the implied need for homogeneity within the group in order to harness shared norms and values. This issue, which is apparent in web-based articles, has not been explored in depth in the research literature. It is conceivable that minority interests in the group may be overlooked or neglected and that the minority individual may feel marginalised. Interestingly, in the study by Raballo *et al.*,<sup>135</sup> the concepts most used by patients with type 1 diabetes to define group visits were as follows: 'comparing,' 'knowledge,' 'educational' and 'friendship.' In patients with type 2 diabetes, the group visit resonated with 'friendship,' 'I feel good,' 'I like this,' 'I learn' and 'interesting.'

#### **Programme theory 14: 'signalling importance'**

As illustrated in the UK evidence (see *Chapter 3, Results of the review of the UK evidence*) there are data to suggest that one mechanism for engagement relates to signalling to patients, and indeed to clinicians, that the group clinic, and by implication the activities that take place there, are considered important. These 'signals' may be literal (i.e. in the communications sent to the patients) or tacit (e.g. in the premises and activities assigned to the group clinic activity). There is reason to believe that there may be an asymmetrical effect in operation, in that negative perceptions of the premises may have a more powerful effect in deterring attendance than positive perceptions of the premises might do in encouraging attendance. However, this needs further investigation.

#### **Programme theory 15: 'making a difference'**

For clinicians, persuasion that group clinics can make a difference is important if they are to contemplate the not inconsiderable organisational and professional adjustments that may be required for such clinics' successful implementation. The qualitative studies appeared to indicate that clinicians were monitoring whether or not the group clinic interventions were making a difference and this had a positive effect on their own belief in the intervention. When clinicians witness the achievement of the group clinic approach against an implied inability to engineer change, they are moved to contemplate the advantages of the intervention:

*They will self-manage with the group. It isn't just me sitting telling you what to do. They hear from their peers . . . people will change . . . I could tell them ten times and as soon as somebody beside them with the same condition tells them to do it they listen . . .<sup>101</sup>*

This statement indicates the influence of observability and relative advantage, both of which are important characteristics when someone is contemplating behaviour change.

#### **Programme theory 16: 'joining up care'**

Group clinics are perceived by some staff as an opportunity to develop shared team approaches to patient care.<sup>100</sup> In a UK context a further mechanism relating to joining up care relates to bringing together the clinical consultation activity and the group education activity that have previously existed separately. Such co-ordination may result in potential efficiencies but may also be seen symbolically in signalling the importance of a co-ordinated approach to chronic disease management. Joining up care is therefore not simply about bringing the two activities together but about emphasising their genuine partnership as activities of complementary importance.

## Summary of consideration of theory

### Programme theory

Group clinics can improve outcomes through socialisation, improved information flows and patient self-monitoring when health professionals:

- create an atmosphere of trust in which information is freely shared
- encourage patients to take responsibility for the management of their own condition
- supply information that is genuinely attuned to the needs of the patients

and when patients:

- present to the group clinics frequently enough to allow effective monitoring
- do not perceive that group clinics are an inferior option to one-to-one consultations
- do not have reservations in respect of the issues discussed and questions to be answered
- perceive that the needs of partners, carers and significant others are being met appropriately within the group clinic arrangement.

It is helpful to consider the process of engaging with group clinics as being composed of three key stages:

1. **Contemplation** – patients must feel that group clinics are a viable and meaningful alternative to the engrained model of the one-to-one consultation. In an experimental context those refusing to contemplate a group clinic approach will refuse to enter into randomisation. In a service setting patients holding similar views will not participate in such a service.
2. **Initiation** – patients must have the desire and circumstances to start attending the group clinic sessions. In an experimental context those agreeing to participate will submit themselves to randomisation but may not subsequently attend any group clinic sessions. In a service setting an agreement to attend may be overtaken by other circumstances or events.
3. **Maintenance** – patients must experience continuing ongoing benefits from attendance at the group clinics. In essence they construct a temporal balance sheet of 'costs' versus 'benefits', and as soon as the balance sheet is perceived to be irredeemably located in the 'red' they will no longer attend. Such circumstances may relate to the perceived quality and relevance of the curriculum, the desirability of the group interaction or the effort taken to attend. It is important that such non-attendance is not solely attributed to 'problem patients'; it may equally indicate a lack of flexibility or other suitability of clinic provision. In either a research or a service context such circumstances may be reflected in infrequent attendance, a tapering-off pattern of attendance or discontinuation after a certain period of time.

A further consideration, operating at a population rather than an individual level, relates to:

4. **Sustainability** – should a clinical team continue to work with an inception cohort of patients for as long as the group remains viable, should they transfer their efforts to a more recent group, assuming that a residual effect will persist in the original group without further intervention, or is the optimal model one of periodic group replenishment with members joining or leaving as their desire and as circumstances allow? In the final case, there are challenges associated with group coherence and shared learning, although more experienced group members may increasingly become a resource to other members of the group and find this altruistic role an alternative source of fulfilment, thereby prolonging their engagement with the group.

This brief consideration of theory reveals that the question 'under what circumstances are group clinics effective for patients with chronic disease conditions' may be constructed around three key issues:

1. Under what circumstances do patients with chronic conditions agree to participate in group clinic approaches?
2. Having agreed to attend group clinics, why do some patients with chronic conditions decide not to attend any group clinic sessions?
3. Having started to attend group clinics, why do some patients with chronic conditions discontinue a group clinic programme?

Finally, given key issues 1–3 in the above list, what is the most sustainable model of group clinic delivery from (a) the ongoing cohort; (b) 'out with the old, in with the new'; and (c) periodic group replenishment.

We will return to these issues in *Chapter 6*.



## Chapter 5 Brief overview of cost issues and feasibility

### Overview

This chapter first addresses the costs of group clinic interventions before moving on to more general issues of implementation and feasibility. Using information from studies assessing the costs of group clinics and economic evaluations of interventions, this chapter aims to:

1. identify key cost elements of group clinic interventions (i.e. where costs might be incurred or saved as part of a group clinic intervention)
2. identify information relating to the actual costs of these interventions (i.e. the costs of establishing and running a group clinic intervention and the savings attributed to a group clinic intervention).

### Costs

#### Methods

The methods for this section are found in *Chapter 2*.

#### Results of the literature search

The results of the three-stage literature search are presented in *Table 29*. The analysis of costs used eight studies.

#### Included and excluded articles

The included articles consisted of one cost-effectiveness analysis,<sup>134</sup> four RCTs with costs included<sup>58,69,79,86</sup> and three cost-utilisation analyses.<sup>62,136,137</sup>

The included studies are summarised in *Table 30*. Full details of the data extraction can be found in *Appendix 3*.

#### Overview of studies

Of the eight papers included, seven reported studies undertaken in the USA<sup>58,62,69,79,86,136,137</sup> and one reported a study undertaken in Italy.<sup>134</sup> The medical conditions for which the group clinics were run were diabetes (five articles), comorbid diabetes with hypertension (one article) and complex behavioural health and medical needs (two articles). The patients in this last group were frequent users of the emergency department. For all of the papers, the perspective was of the health system. The health settings were a diabetes clinic,<sup>134</sup> Kaiser Permanente health maintenance organisation,<sup>79,137</sup> Puget Sound health maintenance organisation,<sup>86</sup> Veterans Affairs Medical Centres,<sup>69</sup> university affiliated medical centre<sup>58,62</sup> and a hospital.<sup>137</sup>

**TABLE 29** Results of the literature search: costs

Search	Retrieved and screened at abstract	Screened at full text	Included
Stage 1: identification of papers during screening for study inclusion	6	6	2
Stage 2: search of Reference Manager database	1030	17	6
Stage 3: search of MEDLINE and EMBASE	100	15 (7 duplicates)	0

**TABLE 30** Summary table of cost studies

Author (date), country	Type of study	Condition
Bondonio <i>et al.</i> (2005), <sup>134</sup> Italy	Cost-effectiveness analysis	Diabetes
Clancy <i>et al.</i> (2003), <sup>58</sup> USA	RCT	Diabetes
Clancy <i>et al.</i> (2008), <sup>62</sup> USA	Cost-utilisation analysis	Diabetes
Crane <i>et al.</i> (2012), <sup>136</sup> USA	Cost-utilisation analysis	Low-income, uninsured patients
Edelman <i>et al.</i> (2010), <sup>69</sup> USA	RCT	Diabetes
Levine <i>et al.</i> (2010), <sup>137</sup> USA	Cost-utilisation analysis	Older people
Scott <i>et al.</i> (2004), <sup>79</sup> USA	RCT	Older people
Wagner <i>et al.</i> (2001), <sup>86</sup> USA	RCT	Diabetes

### What are the key elements in examining the costs of group clinics?

#### Costs incurred in setting up/running a group clinic

Edelman *et al.*<sup>69</sup> calculated the costs of a group visit using data on staff time to run the GMV and staff time to make follow-up telephone calls. Scott *et al.*<sup>79</sup> estimated costs for CHCC meetings according to the amount of time that providers spent at the meeting and their mean hourly salaries.

#### Costs saved as a result of the group clinic

Evidence on costs saved as a result of group clinics tended to be related to health service utilisation, for example hospital admissions, urgent care visits, primary care visits, specialty visits and group visits. Clancy *et al.*<sup>62</sup> portioned charges into outpatient visits, emergency department visits and inpatient stays.

### What evidence exists for the costs of group clinics?

#### Costs incurred in setting up/running a group clinic

Edelman *et al.*<sup>69</sup> estimated a cost of US\$504 (range US\$445–578) to conduct a group visit, with an annual per-patient cost of US\$460 (range US\$393–554). Crane *et al.*<sup>136</sup> estimated the total annualised direct costs of the programme as US\$66,000. Scott *et al.*<sup>79</sup> estimated an average per-patient group cost over 24 months of US\$484. Staff salaries constituted 77.4% of the total average cost (US\$375).

Bondonio *et al.*<sup>134</sup> undertook a cost-effectiveness analysis of RCTs in type 1 and type 2 diabetes. For type 2 diabetes, they calculated that over the study period (4 years), €119.25 was spent by the Italian health service on each intervention patient, compared with €90.44 for the control group over the same period. For type 1 diabetes, over the study period (3 years), €271.24 per patient was spent on the intervention group and €120.15 per patient was spent on the control group.

#### Costs saved as a result of the group clinic

One study showed no significant difference in costs between group clinics and usual care.<sup>86</sup> There were differences in utilisation, with intervention patients visiting primary care almost one time more than usual care patients, although there were significant reductions in specialty and emergency room visits among intervention patients.

Clancy *et al.*<sup>58</sup> established that total costs were higher for intervention patients than for control patients in terms of outpatient costs (US\$1444 vs. US\$1099;  $p = 0.008$ ) and inpatient costs (US\$1410 vs. US\$365). However, emergency department costs did not differ.

There was no difference in health service utilisation in the study by Levine *et al.*<sup>137</sup> and they found that the difference in total costs between intervention and control patients was not statistically significant (US\$8845 vs. US\$10,228;  $p = 0.11$ ).

Edelman *et al.*<sup>69</sup> found a pattern of reduced health service utilisation in the group medical care group compared with the usual care group as follows: emergency care visits (0.9 vs. 1.3 visits per patient-year;  $p < 0.001$ ), primary care visits (5.3 vs. 6.2 visits per patient-year;  $p = 0.01$ ).

Crane *et al.*<sup>136</sup> compared patients before and after a DIGMA intervention in terms of emergency department and inpatient charges and also compared DIGMA patients with a control group. The median total costs (emergency department and inpatient charges) prior to the intervention starting was US\$1167 and 12 months after the intervention these had fallen to US\$230 ( $p < 0.001$ ). This was as a result of reduced utilisation: per person per month emergency department visits dropped from 0.58 in the 12 months prior to involvement to 0.23 ( $p < 0.001$ ).

Scott *et al.*<sup>79</sup> found that the intervention (CHCC) group had lower health service utilisation [admissions  $\chi^2 = 5.8$  ( $p = 0.012$ ); emergency department visits  $\chi^2 = 9.8$  ( $p = 0.008$ ); and professional services  $\chi^2 = 7.5$  ( $p = 0.005$ )]. However, in other aspects of utilisation there was no significant difference between the groups. Intervention group costs associated with emergency department visits were significantly lower for intervention than control patients; although there were no other significant differences, costs were lower for health service utilisation in the intervention group. The overall cost saving was US\$41.80 per member per month.

Group clinic patients in the study by Clancy *et al.*<sup>62</sup> found reduced emergency department (49.1% lower) and total (30.2% lower) charges but higher outpatient charges (34.7% higher) when comparing patients in the intervention group with those in the usual care group. However, controlling for endogeneity (the potential for unobserved patient characteristics to influence adherence), group clinics significantly reduced outpatient visit charges through a reduction in specialty visits (for which group clinics were found to substitute).

### Cost-effectiveness analysis

Bondonio *et al.*<sup>134</sup> undertook a cost-effectiveness analysis. For type 2 diabetes group care patients, using Diabetes Quality of Life questionnaire (modified) score as a proxy outcome, the cost-effectiveness ratio was €2.28 and for type 1 diabetes group care, it was €19.46. The authors stated that they were not able to calculate a quality-adjusted life-year outcome.

### Discussion

Group care is more expensive to set up and run, and although not many studies have actually calculated these increased costs, they have reported increased use of physician time, increased educational resources, increased frequency of appointments per patient and the existence of one-to-one appointments for patients on group care, all of which will increase costs when compared with usual care. The lack of information relating to the costs of the intervention in the studies we examined means that it is challenging to draw conclusions about the cost of group clinics. From the data from the RCTs, we can understand more about the key cost elements of group clinics. However, this information would need to be considered in a full economic analysis in order to be meaningful.

From the studies we examined, we can make better judgements on the cost savings as a result of patient participation in group clinic interventions. The majority of studies examined addressed the changes in utilisation and the subsequent changes in costs. There was a mixed pattern of changes in utilisation, with some studies reporting that intervention patients used fewer health services overall while others reported an increase in some areas (primary care, inpatient and outpatient). This mixed pattern was repeated in the assessment of changes in costs; understandably, in studies where utilisation decreased, there was a decrease in costs. With this mixed set of results, it would not be meaningful to cluster studies together in terms of utilisation and cost changes.

It would have been informative to identify whether or not the savings identified are realised over a longer period of time. We found evidence to suggest that the US health-care system reimbursement process means that these interventions will always be delivered in a standard way to ensure that insurance claims are reimbursed, thereby making costs across interventions (although not cost savings) more uniform. It may be possible to hypothesise that as group clinics become more widespread, staff costs will decrease as more staff become trained (training being a major part of establishing a group clinic, as identified in the main review).

Clancy *et al.*<sup>58</sup> aimed to determine why costs were higher for intervention patients than for control patients. In addition to small sample sizes, they note that participating in an intervention such as a group clinic might 'activate' patients who had previously missed care to catch up with the care that they had missed, thereby increasing health service utilisation. In addition, the length of study is important: improved self-care (which is often an outcome of group clinic interventions) may have a time lag, and so for a shorter study 6 months is not sufficient time to demonstrate a decrease in utilisation and, therefore, to observe a decrease in costs.

### Summary of included studies

Our assessment of costs and feasibility across a heterogeneous set of studies has showed mixed effects of group clinic interventions on costs and savings. A full economic analysis of group clinics, along with the robust collection of costs data alongside group clinic interventions, is recommended. A full economic analysis could allow for data included in RCTs, such as the type of clinician delivering the intervention and how long each group clinic lasts, to be costed in order to get a more complete picture of the costs of group clinic. Primary research assembling information on the running of group clinics and the costs that are saved specifically within a NHS setting would be essential to inform decisions about group clinic provision in a UK context.

## Feasibility

### Overview

Feasibility conflates many issues, such as acceptability to patients and providers, practicality in terms of required procedures (whether alongside or as a substitute for existing practice) and affordability, in terms of financial considerations and available equipment and premises. The evidence to be mapped against this domain is drawn from qualitative studies of provider and patient attitudes, implementation studies not otherwise included in this review and an overall picture of likely cost-effectiveness, as has emerged from *Chapter 4*. Feasibility includes general issues to be considered within any context for implementation of group clinics and specific issues relating to implementation within a NHS context.

### What are the key considerations regarding feasibility?

Key to a consideration of feasibility in this context is affordability. Although claims are made of cost savings these are based on either (1) US studies of limited geographical or temporal relevance or (2) a simplistic argument of more patients seen by a clinician per hour. In particular, there is limited evidence of cost implications in a UK study. Indeed, although the insights from group acupuncture clinics are informative in terms of the group interactions and dynamics within a UK context, the actual assessment of costs would be potentially misleading. As will be explained later in this report the achievements of the group acupuncture clinics are located within a 'work smarter' treatment delivery model. These otherwise promising achievements have, therefore, limited relevance to the monitoring model that is fundamental to group clinic provision.

A further concern relates to acceptability. Our clinical advisers point out that there is a strong expectation in the NHS of being seen by a specialist clinician within an individual consultation. Even if group clinic provision were to become the default position, a sizeable proportion of the population would still require access to the more traditional model, perhaps because of the complexity or severity of their condition or



because they would demand it through exercising patient choice. Such preference may be affirmed on commencement of treatment or, as illustrated by UK group acupuncture clinic qualitative data, may emerge following patients' experience of the group clinic provision. In particular, the willingness of patients to try a new modality of service provision should not be interpreted as those patients' commitment to that service modality on a long-term basis.

Practical issues relate to the requirement to be able to access all patient records and results in advance of a single SMA. This may place a burden on diagnostic services but may also prove problematic for the individual specialist, who would have to make time for review of the notes. The latter factor is examined in a US context of uncompensated clinician time.<sup>132</sup>

Other feasibility concerns relate to the need for clinician training, particularly in group facilitation, and the need for suitable premises. Within the wider picture of feasibility it would be worth exploring whether or not the individual components considered essential to the group clinic approach could be delivered in an alternative format. For example, in some circumstances the socialisation or the interaction with a group facilitator could be offered virtually, offering the opportunity for the clinical team to identify those needing particular help.

### **What evidence exists on the feasibility of group clinics?**

Little evidence exists on the feasibility of group clinics, even though much of the literature suggests how they might be introduced. Particularly noticeable is a shortage of data from the UK. The wider non-NHS-specific literature informs such aspects as implementation and confidentiality. A feasibility study<sup>104</sup> revealed such positive aspects of GMVs as personalised attention (77%), self-care education (69%), access to medication refills and examinations (69%) and advice from peers (62%). Negative aspects included insufficient personal attention (23%), logistical barriers (8%) and loss of confidentiality.<sup>104</sup>

Kirsh *et al.*<sup>27</sup> have explored implementation issues relating to SMAs. They identified such important promoting factors as the formation of a core team committed to quality and improvement with strong support for the clinic leadership from other team members. Notably, tailoring had to take into account such 'key innovation-hindering factors' as limited resources (such as space), potential to alter longstanding patient-provider relationships, and organisational silos (disconnected groups) with core team members reporting to different supervisors. The last point emphasises that group clinics should be seen not in isolation but as a potential vehicle towards interprofessional team working, with all of the associated culture changes that this might necessitate.

Concerns relating to confidentiality were raised consistently in the reviewed literature. This issue was examined specifically in a study by Wong *et al.*<sup>107</sup> This study aptly highlights that GMVs can impact on the clinician-patient relationship as patients are 'able to draw upon more informational resources and social support from attendees and often feel more empowered to pose questions to their providers than they might otherwise in individual encounters'.<sup>107</sup> However, providers reported that 'the most common reason for not attending a GMV was patients' concerns about confidentiality and hence a preference for individual visits'.<sup>107</sup> Nevertheless, one overall finding from the study was that patients who did attend a GMV consciously selected which information they were comfortable sharing in a group situation.<sup>107</sup> Although it could be perceived as a drawback that patients filtered the information they felt able to share, some interventions included a discussion of confidentiality with practical examples as a component of the initial group clinic sessions.

### **Discussion**

The review team has identified specific concerns relating to the interpretation of predominantly US data within a specific UK context. In particular, many of the interventions have been delivered within the context of health-care financing that determines the exact configuration of approved packages of group clinic provision and, for example, requires guaranteed access to an individual consultation if requested. Advice from our clinical advisers suggests that a model in which an increasing amount of the content of

the previous individual consultation is assumed in a group context, facilitated perhaps by a member of staff who is not the specialist clinician, may be an alternative form of substitution. This might facilitate shorter individual consultations, although this issue remains to be investigated. Importantly, however, such provision would need to be in a context where group education is seen as more central to the chronic disease management process and not as an optional extra.

### *Summary of included studies*

Although the evidence from the USA and that from a UK group acupuncture clinic context does inform a discussion of feasibility, a specific need remains for further investigation of the monitoring model of group clinics within a UK context. This research requirement sits naturally alongside the suggestion made in the previous chapter for a full UK-centric economic evaluation and the need for qualitative exploration of the attitudes of NHS patients, providers and caregivers towards group clinic provision. In addition, there is a requirement to explore the feasibility of 'substitution' of specific functions from the individual consultation with a corresponding group-based provision, along with any training and role development issues this might occasion.

## Chapter 6 Discussion

### Summary of evidence on the effectiveness of group clinics

#### Health outcomes

By far the majority of studies examining clinical outcomes relate to diabetes and focus on basic biomedical outcomes that are relatively easy to monitor routinely. It is, therefore, difficult to extrapolate these effects to other chronic conditions.

#### Diabetes

Although there is consistent and promising evidence in favour of an effect of group clinics for basic biomedical measures, particularly haemoglobin and systolic blood pressure, this evidence does not extend to other important biomedical considerations such as control of cholesterol. Group-based training for self-management strategies in people with type 2 diabetes is effective by improving fasting blood glucose levels, HbA<sub>1c</sub> and diabetes knowledge and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication.

Disease-specific quality of life improved significantly in a small number of studies and yet this effect was not found to be as significant for generic health-related quality of life.

#### Other conditions

For other conditions in older adults benefits have been observed with regard to positive effects on patient experience with group clinic approaches, compared with usual care. However, no difference from usual care was reported for overall health status, functional status and biophysical outcomes.

#### Health service outcomes

#### Diabetes

Effects of group clinic approaches on hospital admissions and emergency department visits were explored in five studies on patients with diabetes.<sup>20,58,69,81,86</sup> In three of these,<sup>58,69,82</sup> admission rates were lower with group clinic approaches, but the result was statistically significant in only one study.<sup>20</sup> Two studies found that emergency department visits decreased significantly with group clinic approaches.<sup>69,86</sup>

#### Other conditions

Two trials in older adults showed fewer hospital admissions for group clinic approaches and a statistically significant decrease in emergency department visits for group clinic approaches, compared with usual care.<sup>65,79</sup>

### Summary of evidence on the feasibility, acceptability and meaningfulness of group clinics

Practical concerns remain. A practical impact of seeing patients individually over separate consultations is a spreading of workload demand on laboratory and other diagnostic services. In contrast, a group clinic relies on all patients having their results available for the same clinic. To what extent is this feasible given the heavy time and workload pressures on diagnostic services? In mitigation it should be said that we found little reason to believe that the actual burden of workload would be any greater as a result of seeing patients as a group rather than individually; batches of diagnostic test results could still be processed within the intervals between clinics. However, there would be a need for improved record keeping. Perhaps more significantly, the expectations of patients that their test results will be available will

be shaped by 'normalisation' alongside others in attendance at the group clinic. Nevertheless, for conditions such as diabetes, a significant part of the interaction is derived from self-monitoring and not from external test results.

Confidentiality is another important consideration, and its full impact has been masked by methodological issues: those with significant concerns may well refuse to enrol in trials or qualitative studies in the first place. Furthermore, their concerns may be neglected in studies if they withdraw and are consequently lost to follow-up. On a positive note, Wong *et al.*<sup>107</sup> concluded that confidentiality can be addressed and was not a major concern for either patients or providers. In fact, they observed that patients adopted strategies to address their own and others' concerns regarding confidential health information. In turn, health-care providers used multiple strategies to maintain confidentiality within the group, including renegotiating what information is shared and providing examples of what information ought to be kept confidential. These practical considerations should be contemplated by anyone planning group clinic-type approaches.

### Summary of evidence on the cost-effectiveness of group clinics

The eight relevant studies examining the cost-effectiveness of group clinics were all associated with settings that are not directly comparable with a UK setting (i.e. seven were from the USA<sup>58,62,79,86,117,135</sup> and one was from Italy<sup>133</sup>). In addition, some studies relate to time periods that do not reflect current clinical practice. Medical conditions at which group clinics were targeted were diabetes (five articles)<sup>58,62,79,86,133</sup> comorbid diabetes with hypertension (one article)<sup>133</sup> and complex behavioural health and medical needs (two articles),<sup>79,136</sup> resulting in very narrow coverage of clinical areas that potentially could be explored in a group clinic context.

The heterogeneity of the included studies and their different time and geographical settings explain, at least in part, the uncertain effects of group clinic interventions on costs saved. A full economic analysis of group clinics, along with the robust collection of costs data alongside group clinic interventions, is recommended. A full economic analysis would accommodate data included in RCTs, such as the type of clinician delivering the intervention and how long each group clinic lasts, to derive a richer picture of the costs of group clinics. Research bringing together information on the running of group clinics and potential cost savings in a UK NHS context would be particularly valuable.

Certain costs were not explicitly identified within the included studies. For example, it is likely that a group clinic intervention may require the specialist training of health-care staff, particularly in relation to facilitation skills.

#### *Perceived and actual benefits and disadvantages of a group consultation when compared with an individual consultation*

Although crude analyses compare the number of patients seen within a group session with the number of those seen individually in the same time period, such an approach is inadequate for the purposes of a rigorous evaluation. There is substantial evidence that provision must be made for individual consultations and also that costs may be displaced to other parts of the health-care system. The cost of individual consultations must factor in the provision for such consultations within the group session, for those who are displaced to sessions outside the group clinic and for those for whom group provision is either inappropriate or unacceptable. Although one assumption encountered in the literature is that the reduction of health costs will take place over an extended time period, studies that have been conducted to date have not covered a long enough evaluation period to demonstrate this realisation of cost benefits.

#### *The value of group education*

The cost benefit of group clinic approaches depends on whether or not current provision (usual care) includes existing group education provision and, specifically, whether this is delivered by health professionals or by lay peer supporters. Group education has been found to have an effect on some of those biomedical measures addressed by group clinics but not typically to the degree realised by most

group clinic studies. The cost issue, therefore, becomes 'what is the demonstrable cost-benefit to be realised by delivering the specific group clinic intervention compared with the individual consultation plus group education sessions?'. As indicated by some of the foregoing, this question is complicated by the issue of what can be quantified as benefits. In particular, is the evaluation framework to be exclusively that of cost savings – in which case group clinics are unlikely to deliver against this agenda – or is the evaluation to be situated in the context of joined-up improved-quality interprofessional care?

### **The value of multiprofessional approaches resulting from simultaneous clinical involvement**

We found some evidence that involvement in group clinics may have accrued particular advantages in relation to interprofessional team working and mutuality:

*[T]he flexibility of the individual team members is manifest during the SMA sessions. A weekly meeting . . . continues to occur to discuss patients and processes to assure that all team members have an open forum to voice concerns and make group changes.<sup>7</sup>*

*The literature around uni-professional, multi-professional and inter-professional working emphasises flexibility of roles and a degree of interchangeability as the means by which interprofessional working might be achieved.<sup>138</sup>*

### **Issues emerging from the evidence?**

The large majority of studies have been conducted within the disease area of diabetes. Diabetes appears particularly suited to the group clinic approach; it is a chronic condition that requires regular monitoring, and a high number of potential complications are common to the experience or concerns of a large number of patients. For the clinician, the attractions of a group clinic approach for diabetes are quite compelling. As one of our clinical advisors noted, successful management of the condition requires patient co-operation in the provision of their clinical data and their participation in self-management. The consequences of non-participation may be serious in terms of both effects on health and utilisation of emergency departments or other specialist services.

The majority of studies of group clinic type approaches have been conducted in the USA. Although this is typically an underlying concern for all health service and delivery topics we found evidence that it may be particularly significant for this topic area. The US health-care funding system is very prescriptive in terms of acceptable models of GMV for the purposes of reimbursement. Extensive research and evaluation has been conducted but in only a very limited range of possible models. Such prescription is likely to result in a stifling effect with regard to experimentation and innovation, potentially denying a range of possible models from which the NHS might conceivably benefit. Our clinical advisors have highlighted that, in NHS patient culture, there is significant expectation of receiving an individual consultation, as well as a reluctance to participate in group care activities and an appetite for only minimal requisite levels of patient information and education.

A major limitation of this review is that it has not been able to examine the evidence base for the individual components of the group clinic intervention, such as the individual consultation, group education, self-monitoring, peer support, etc. We concur with Edelman *et al.* that:

*Without further, more mechanistic studies that attempt to elucidate the key components of an SMA intervention, implementation of a diabetes SMA or design of an SMA for another condition will be at least partially based on reasoned judgment rather than strict evidence-based decision making.<sup>18</sup>*

Our review was unable to find data to address some very critical key questions in relation to group clinic provision. The evidence base is insufficient to address the issue of what constitutes either a minimally effective or an optimal dose with regard to the duration, intensity and content of the GMV. Furthermore, we detected a tension between what care providers consider to be an optimal curriculum to be covered in the educational component of the GMV and the expressed requirement for a programme to be coproduced in order to meet participant needs. It would be particularly helpful to be able to answer questions regarding the time period over which clinically significant outcomes are achieved, the time period for which any positive outcomes are sustained while the participant is receiving the intervention and the 'washout period' following cessation of the intervention, after which effects are no longer achieved. Related to this final point is the effectiveness of top-up or refresher sessions, together with questions about the duration, intensity and content of any refresher provision. The discussion with our clinical advisers suggested that answers to some of these questions may be linked to research findings for group education provision more generally, although (1) data of the particularity specified above are not typically contained in published reports and (2) group clinics engage, at least in theory, with additional mechanisms when compared with group education, and so their effect might be underestimated if this source of data is used.

Discussion with our clinical advisers also revealed an evidence gap with regard to longer-term attendance. Published research studies tend to interpret attendance in a forgiving manner; some even considered that attendance at a single clinic constituted a patient being an 'attender'. More typically, an aggregate of attendances per person is given, which does not allow us to detect a decay in attendance and commitment over time. Furthermore, attendance patterns may be confounded by the flexibility or otherwise of the clinic, the number of alternatives on offer and other issues relating to access and alternative health-care provision.

### ***Under what circumstances do patients with chronic conditions agree to participate in group clinic approaches?***

From the theoretical literature, we have identified four principal components of a group clinic approach, as follows:

1. Monitoring: this is a traditional activity in the individual consultation but there is some evidence that group clinic approaches may turn this into more of a shared activity between the patient and clinician, with the patient becoming involved in some of the monitoring activities.
2. Self-management: the group clinic approach encourages patients to become more active in managing their condition. In contrast to an individual consultation, the group-based approach may offer both role models in those who manage their own condition and tips on techniques and resources acquired from fellow patients.
3. Peer support: this is a completely discrete activity from the individual consultation and one which offers additional sources of support beyond the clinician and the significant others of the patient. Commonly in the UK there is a separation between clinical activities and group education approaches.
4. Education and information: quantitatively, there is the opportunity for the clinician to share information with several patients at the same time, reducing duplication and repetition, and resulting in greater consistency in information provision. Qualitatively, patients may respond better to information shared in a less didactic manner or to information originating from fellow patients. More reticent patients may benefit vicariously from questions asked by more proactive members of the group, in effect becoming 'lurkers' within the group.

Typically, patients with chronic conditions appear to make an overall assessment of the benefits of participation before agreeing to participate. There is some evidence that the disadvantages of participation are not adequately explained to participants by clinical staff. A significant proportion of those invited to participate decline, largely because they do not recognise the benefits of group clinic approaches against the perceived advantages of an individual consultation. Expectations of being seen in an individual consultation, whether specified by a health plan as in the USA or through cultural conditioning in the UK, appear to militate against the use of a group clinic approach. Alternative provision will probably be required for this sizeable group of patients and the very availability of such an alternative may have a negative effect on uptake.



### ***Having agreed to attend group clinics, why do some patients with chronic conditions decide not to attend any group clinic sessions?***

Constraints related to the logistics of attending the group clinic appointment (e.g. timing, other commitments, etc.) play a major role in determining whether or not patients with chronic conditions will attend. However, these same constraints are also present for those seeking individual appointments. The primary consideration, therefore, appears to be the flexibility of attendance patterns. In particular, attendance may depend on whether group clinics employ a closed cohort-based approach or more of a drop-in model.

### ***Having started to attend group clinics, why do some patients with chronic conditions discontinue a group clinic programme?***

There is some evidence to suggest that some patients will attend with a specific goal of receiving sufficient information for self-management of their condition. Once they feel that they have obtained this information, their motivation for attendance wanes. For others, the social aspect of a group is particularly important and this may contribute to their motivation for ongoing attendance, even if the other benefits of attendance degrade over time. Finally, there are others for whom the sense of shared community persists, which is recognised from their transition from being beneficiaries to becoming donors to the overall group process.

### ***Which is the most sustainable model of group clinic delivery?***

The identified research literature does not support a detailed analysis of sustainability. Most initiatives were evaluated over only a relatively short time period. For example, Cohen *et al.* claimed to have demonstrated 'that the pharmacist-led group intervention program was an efficacious and sustainable collaborative care approach' and yet only evaluated the initiative over a period of 2 years.<sup>63</sup> In fact, within the context of group clinics such an evaluation period is comparatively long. Housden *et al.*<sup>53</sup> reported that 15 out of 26 studies were 12 months or shorter in duration, and six studies were up to 2 years in duration. The study with the longest duration followed patients for only a period of 5 years after the intervention. We conclude with Housden *et al.* that:

*... the long-term or sustainable outcomes of group medical visits are unclear, and it is difficult to know if the outcomes were maintained for a substantial length of time after the intervention.*<sup>53</sup>

Qualitatively, there is very little discussion in the published literature about the practicalities of managing different models of group membership. Such contrasting models have considerable implications for facilitation, educational content and the group dynamic. These are now briefly discussed, together with their possible implications.

#### **The ongoing cohort**

Explicit to the chronic care clinic and group visit models is the idea of the group representing an ongoing cohort of patients who have the opportunity to 'grow' together. However, there is no discussion in the included research studies about the implications of withdrawals and dropouts for the group viability and for its dynamics. Clearly, in an older population, or equally for those with a chronic condition, the likelihood that the numbers in attendance will diminish, either through natural wastage or through the utilisation of alternative inpatient or long-term care health services, poses a significant challenge for the ongoing sustainability of a particular group. Increasing numbers of patients with the chronic condition means that there is further need for extra facilitators, additional training and greater utilisation of premises.

#### **'Out with the old, in with the new'**

Another potential model of group membership, given that resources for facilitation and group processes are likely to be finite, would be to work with a particular group to a pre-defined temporal or developmental point and then to disband the whole group and return to individual consultations. This model was not identified in the literature, although it is unclear if this is because it is not prevalent or if the relatively short research and evaluation time frame precludes the study of its longer-term sustainability.

This model assumes that the initial life of the group is a key point in the disease trajectory, that the curriculum is relatively finite and stable and, importantly, that there is a carry-over of the group effect beyond the lifespan of the group. Such a group model makes unchallenged assumptions about shared information needs and a common pace of learning for all group members. Maintaining a group for a finite period, identified a priori, may help to sustain the impetus of the group but, paradoxically, may reduce people's commitment to the group. One challenge for the facilitator is in identifying an optimal lifespan for the group, an issue not addressed by the literature.

### Periodic group replenishment

A final model would be to treat the group as a more fluid vehicle, with patients being able to leave or join at any point, subject to the accommodation of numbers within the group membership. From an efficiency point of view such a model is attractive, as it ensures that provision is sustainable and safeguards against the attrition of members. However, this 'mixed' model may present challenges to facilitation, both in terms of building up relationships from new with facilitators and with existing group members and, educationally, in terms of planning of content for a group with heterogeneous learning needs and varying experiences. One study of this kind of fluid group, for people with haemophilia, measured discernible differences in the perceptions of the value of group attendance between parents of less experienced and parents of more experienced members of the group:

*The majority of parents (62%) did not regard the additional time investment for GMA as inconvenient (74% less experienced, 30% experienced; P-value 0.023).<sup>96</sup>*

This was further reflected in differences between the patients themselves in terms of learning:

*In children < 12 years, all less experienced adolescents reported learning of new aspects of their disease, unlike the 75% of experienced adolescents who reported no learning effect (P-value 0.011).<sup>96</sup>*

It is true that more experienced group members could be harnessed as a resource to be utilised by the facilitator to benefit newer members:

*Several veterans enthusiastically volunteered to attend future group clinics to share their chronic disease self-management experience.<sup>99</sup>*

However, the fluidity of group membership may have adverse effects in terms of commitment to the group 'community'.

### Strengths and limitations of this review

This was a protocol-driven review conducted by multiple investigators. The information specialist conducted a very comprehensive subject search of bibliographic databases and this was supplemented by the extensive pursuit of references and use of citation search techniques. In particular, this allowed us to identify clusters of associate studies reporting more complete data where available.<sup>38</sup> We believe that we have identified more published trials than any previous review; this has meant we have included more studies and have been able to review reports included in previous reviews but excluded from our own inclusion criteria, together with reasons. We performed a rigorous process of checking for inclusion and subsequent quality assessment. In implementing an innovative methodology of 'progressive fractions' we extended the review resources beyond a narrow focused question defined by the term 'group clinics' to engage with a wider body of the most relevant literature with a range of synonyms. We also employed exhaustive supplementary search techniques such as follow-up of references, citation searching and searching for study clusters. We are, therefore, confident not only that we have identified the most significant literature related to the review question but also that we have minimised the risk of missing relevant qualitative, cost and UK studies.



The time scale of this review, telescoped within half the time period of a conventional systematic review, and its ambition in covering feasibility, appropriateness and meaningfulness in addition to the effectiveness and cost-effectiveness most typically covered by comparator reviews have prompted the use of several rapid-review methods. For example, our approach was to examine the extent to which recently published evidence from RCTs has made a supplementary contribution to the existing evidence base. In actuality, because of the relatively small number of recent trial reports and the extensive quantity and coverage of previous reviews, this additive contribution has not been as significant as was initially anticipated. As this was a rapid review we were unable to perform independent double data extraction and quality assessment. However, frequent iteration between extracted data and the full text of articles minimises the likelihood of important errors.

## Methodological limitations of the included studies

In conducting the review we identified a systematic bias in the reporting of group clinic interventions. Selection bias was very likely to occur; even though some studies made strenuous efforts to locate and collect data from patients who had dropped out, success was limited,<sup>97</sup> making it 'not possible to investigate the possible disadvantages that some patients might experience'.<sup>97</sup> In addition, the positive group effect, particularly from qualitative studies, may well have been 'influenced by the fact that those who do not gain benefit drop out, leaving only patients with a positive experience'.<sup>97</sup> Furthermore, there is considerable under-representation of patients from UK relevant ethnic minority backgrounds (US studies include Latino/a and African American participants), making it 'not possible to identify any potential differences that might be experienced by these groups'.<sup>97</sup>

Included studies and their corresponding inclusion in systematic reviews typically confused different models of group clinic provision. One economic attraction of a group clinic approach relates to a 'substitution' model, that is where patients attend a group clinic *instead of* attending individual consultations. It appears that the rationale underpinning a substitution model is flawed as (1) most US provision of GMVs/SMA requires the provision of individual consultations *in addition to* group clinic provision, and (2) studies may report individual consultations at the time of the group clinic but are less likely to report these outside the group clinic session, resulting in an incomplete picture of resource use. One of our clinical advisers suggested that in a UK setting a different form of substitution might take place, in that the group clinic facilitator, typically a nurse or dietitian for primarily economic reasons, may fulfil several roles otherwise assumed by a clinician in an individual consultation (e.g. review of patient results). The challenge in such a UK substitution model lies in how to decide the extent to which the duration of the individual consultation might be reduced, the impact this might have on the topic content of the individual consultation and the logistics of co-ordinating the individual and group sessions. Unless a study demonstrates an explicit reduction within the experimental group in the corresponding time for the individual consultation input, compared with the control group, the model being described is essentially an enhanced care model (i.e. previous individual consultation enhanced by GMV).

Our typology of group clinics models characterised two further variations:

1. the group clinic plus model, where every patient is offered an individual consultation (i.e. *universal* same-session individual appointments) and savings are achieved for each patient who deems an individual consultation unnecessary
2. the group clinic triage model (i.e. an *indicated* simultaneous individual appointment), where a clinician offers a consultation only where the group session reveals a cause of particular concern and savings are achieved by not consulting with patients who do not merit special attention.

A disappointing feature of the evidence base relating to group clinics is the predominance of diabetes as a studied disease area. As Edelman *et al.*<sup>18</sup> observed, little evidence is available for other chronic conditions of interest such as coronary artery disease, chronic heart failure, asthma, COPD, hyperlipidaemia or hypertension. In addition, the included studies focus on achievement of biomedical outcomes, with comparatively little information on organisational or system-wide factors.<sup>18</sup>

We approached this review with the perhaps simplistic expectation that group clinics would represent a genuine alternative to the individual consultation. In actuality, individual consultations continued to be delivered, mainly as a result of patient expectations and the stringencies of the US health-care system. The revised research questions, for which we have remarkably little evidence, relate to the extent to which the duration of an individual consultation can be reduced and the extent to which information from this consultation can be delivered by other, less specialist staff in a group context. A further disappointment relates to the lack of clarity with regard to intervention components and their corresponding mechanisms of action. It thus becomes problematic when seeking to identify which are the active ingredients, which components might be considered essential and to map which components address each requisite from the group clinic intervention. In addition, we have identified a research paradox, in that the effectiveness of the group clinic intervention is believed to be related to the degree of coproduction achieved by patients and clinicians in the group but such coproduction makes it correspondingly more difficult to ensure the fidelity of the intervention. In addition, to this evaluation challenge there are attendant consequences in terms of subsequent implementation.

Another methodological limitation relates to the outcomes being studied. Substantial variability in outcomes, together with the previously mentioned heterogeneity of interventions, makes it problematic when seeking to explain the observed variability in intervention effects. Generally, for this reason, we have resisted the use of meta-analyses using summary measures of treatment effect, as these may not adequately describe the expected effects of the intervention (cf. Edelman *et al.*<sup>18</sup>). Indeed, the main function of the availability of analyses for such outcome measures appears to be in developing a hierarchy of outcome measures according to how easy it might be to demonstrate an effect and, indeed the converse likelihood of a systematic measurement error. We also note the comparative absence of repeated measurements for outcomes making it difficult to isolate the point at which improvements take place and, indeed, the trajectory of the management of the disease. As mentioned above, this absence of outcome data makes clinical decisions, specifically about optimal dosage, intensity and duration, problematic. Furthermore, the limited time window covered by the included studies does not address the very important issue of the long-term sustainability of such an intervention.

## Research implications

Although the review team identified a sizeable body of evidence around group clinic type approaches, the practical value of this research for the specific review question is limited. Much of the research has been conducted in the USA, within a different health system, often with a requirement to make provision for an individual consultation. The dominant model, therefore, is one of enhancement of interaction and not of substitution. There is therefore a need for research that specifically focuses on the role of group clinic approaches in substituting for identifiable components of, or the whole content of, individual consultation episodes. In addition, RCTs have been conducted predominantly in the context of diabetes and rigorous evaluations are required across a wider range of chronic conditions. Finally, the indistinct nature of the different service models, and a lack of clarity regarding their individual constituents, requires research that elicits more detail of individual service components, their putative mechanisms and their associated costs.

The team identified five ongoing trials in group clinic type interventions (see *Appendix 6*). However, none of these ongoing trials is taking place in the UK. Three of these trials relate to diabetes care, one relates to heart failure and one relates to the new disease area (with respect to group clinics) of atopic dermatitis. This research is unlikely to overturn any of the research implications or implications for practice, although the studies in the less investigated contexts of heart failure and dermatitis are to be particularly welcomed.

Numerous commentators have observed on the heterogeneous nature of group clinic type interventions<sup>6,135</sup> and this has several implications for this review. First, although we may identify some overall biomedical effects from group clinic approaches across a wide range of settings, strengthening the likelihood of generalisability, it is correspondingly more difficult to isolate the 'active ingredients' of what are essentially complex multifaceted interventions.<sup>132</sup>

In an implementation context, given the typically poor standard of description of each intervention in included studies, ensuring the fidelity of a particular type of group clinic intervention is problematic:

*Implementation fidelity is often presented as critical to achieving the levels of efficacy demonstrated in clinical trials. However, it became apparent that descriptions of SMA interventions provided insufficient detail to guide implementation into differing clinical settings.<sup>27</sup>*

This heterogeneity provides operational challenges to the definition of interventions for inclusion in this review and also explains the apparent inconsistency of inclusions across previous reviews, which in turn may partially explain some of the reported differences in effect.

From a cost viewpoint we know little about the added benefit of incremental additions to a particular group clinic model. In fact, given that there is some evidence for the effectiveness of group-based education interventions accompanied by individual clinician visits, it is unclear what the superiority or added benefit of the more complex group clinic model might be over this comparatively simpler version.

At the same time, heterogeneity, although complicating the evaluation of group clinic-type interventions, may offer attractions in the context of innovation. One potential criticism for the preponderance of US-based models is that there is little evidence of genuine innovation around a familiar-looking menu of group clinic models, perhaps due to the characteristics of the US funding system. The UK offers considerable scope for innovation, provided that the components of each model are clearly identifiable, isolatable and costable.

With regard to future comparators of the group clinic-based intervention two technological developments require further investigation. With improved availability of internet technologies virtual clinics may offer a technology-supported alternative to members of a group being present in person.<sup>139</sup> In addition, the relatively good performance of automated telephone disease management systems as a comparator for group clinics suggests that, for some patients at least, support might be offered via such technologies.<sup>77,78</sup> These weekly, rotating automated (prerecorded) telephone calls take between 6 and 12 minutes to complete with any 'out of range' responses triggering a personal call back by a nurse manager.<sup>77,78</sup> One attraction of these contrasting technological approaches is that they may cater for the needs of two quite different population demographics. Schillinger's use of telephone support was particularly welcomed by those with language difficulties.<sup>77,78</sup> These approaches need rigorous evaluation in the context of the UK NHS.

Further studies of different patient populations in various practice settings are needed to identify the best protocols and to assess the true benefits of group clinic approaches. It is hoped that these would reveal that complementary, innovative and evolving care approaches involving multidisciplinary teams are useful tools for meeting the significant challenges to access, cost and quality that now face the health-care delivery system.<sup>137</sup> Our findings confirm that there are limited data on satisfaction, patient access and other key patient-centred outcomes.<sup>18</sup>

As with the most recent review identified by this project, our review 'uncovered far more gaps in the literature than it found definitive results'.<sup>55</sup> Gaps include the heterogeneity of the group clinic approaches intervention, characterised as a 'black box', with 'many components that are hard to capture and tease out, even in a well-conducted analysis'.<sup>55</sup> In seeking to add value by examining putative context-mechanism-outcome (CMO) configurations we attempted to advance an explanation for what makes particular group clinic type interventions successful.

In summary we have identified a requirement for future research to extend the breadth of chronic conditions within a wider evaluation framework in rigorously conducted trials in a UK context, to focus on benefits of substitution not enhancement, to characterise interventions by their components rather than their labels and to target these individual components for specific evaluation of both costs and benefits.

## Chapter 7 Conclusions

### **What, if anything, does the evidence reveal about the different models of group clinics?**

The evidence reveals significant variation in the use of labels for interventions and, more significantly, in the components included in each type of group clinic approach. Indeed, many approaches share common theoretical or philosophical origins. Particularly problematic with regard to isolating the specific contribution of each of the different models are variations in the key characteristics required for evaluation. These include the frequency and duration of sessions, the numbers present, the clinician input, the role (if any) of an individual consultation and the content and duration of individual intervention components.

### **What, if anything, does the evidence reveal about the uptake and rate of the spread of group clinic approaches across different chronic conditions?**

Group clinic approaches originated in the clinical area of diabetes and were popularised in the context of older patients with multiple health conditions. Discussion with our clinical advisers confirms that diabetes is a strong candidate for such approaches because of the need for ongoing monitoring, the frequency, complexity and severity of complications and, more generally, the high prevalence of group education interventions. More recently there has been increased interest, as reflected in the published research, in the use of group clinic approaches in other common chronic conditions, such as heart disease and hypertension. In the UK there have been limited, but not rigorously evaluated, attempts at using the group clinic approach for rheumatological conditions. Limited published experience with conditions typically first encountered earlier in life, such as inherited metabolic conditions, reveals enthusiasm for group approaches early in the learning curve for an individual condition, but also possible practical difficulties in terms of access, availability and attendance, as well as diminution in support and perceived usefulness as participants become more acquainted with their condition and its management. A significant UK movement to use group clinic approaches for acupuncture seeks to capture aspects of socialisation and peer support promulgated by the models. However, as highlighted by one of our clinical advisers, acupuncture clinics have the specific requirement for a patient to be immobile while they receive treatment, and we therefore consider a regular treatment-oriented group clinic to be conceptually different from approaches that harness such mechanisms as monitoring and self-management.

### **What, if anything, does the evidence reveal about where group clinic approaches might be most promising in a UK setting?**

As mentioned when considering UK-based initiatives, it is difficult to map such experiments against the underpinning theoretical and philosophical foundations invoked by the trial evidence. In many cases the literature is mobilised generically, with little attempt made to ensure the fidelity of a particular model. Indeed, the heterogeneity and lack of distinctness of the models and terminology make it questionable as to whether or not such fidelity is actually achievable. A more promising line of inquiry may require future researchers to identify and isolate specific intervention components and their specific effects in the context of rigorous evaluation. Such an approach should specifically seek to surface the added value of a co-ordinated group clinic intervention over and above an 'individual consultation plus group education' provision, particularly given that the systematic review provides some evidence for comparable effects from group education.

Discussion with our clinical advisors suggested several models of group care that might prove more appropriate than others:

1. **Group clinics in the context of initial diagnosis, education and self-monitoring of a new condition close to onset.** Group attendance when patients have high initial anxiety, intense information needs and a requirement to learn self-management behaviours may harness patient commitment at a critical early phase in their chronic disease. This might be supported at a later time by ongoing periodic refreshment at longer intervals. A clinical advisor suggested that, in addition to being suitable for diabetes, this model might be appropriate for asthma care including instruction on inhaler use. We also located a protocol for a RCT of women carrying the breast cancer gene *BRCA1* and *BRCA2* suggesting a potential role for group clinics in supporting women with the breast cancer gene. This model requires research and evaluation.
2. **Group clinics for a time-limited circumstance.** Although the CenteringPregnancy initiative is the most common example of this approach from outside the scope of this review, in the sphere of chronic disease there is the potential for chronic conditions that lead to an acute intervention to be managed through a group clinic approach. Bariatric surgery for obesity features in the literature and was mentioned by a clinical adviser; however, in this instance attendance at group sessions is a mandatory condition of eligibility for surgery and so does not strictly conform to the voluntary philosophy of group clinics perpetuated in the US studies.
3. **Group clinics as a venue for treatment.** The best documented approach of group clinic use in a UK context involved acupuncture for knee osteoarthritis. In contrast to the model of self-monitoring and intervention where required, which characterises most of the other group clinic models, this clinic carries an expectation that patients will receive treatment. This limits the generalisability of some of the acceptance data, although evidence on the group processes does remain valid. As acupuncture treatment has a duration of about 20 minutes we have characterised this as a 'working smarter' model for group clinic intervention, confirmed by the team. Within an NHS context there may be additional opportunities to offer group clinic provision where a patient might otherwise be waiting for or undergoing treatment or other non-monitoring procedures.

### **In particular, what does the evidence from diverse sources reveal about the feasibility, appropriateness, meaningfulness, effectiveness and efficiency of group clinic approaches for chronic medical conditions?**

#### ***Feasibility (evidence from qualitative research, cost studies and UK studies and informants)***

UK informants highlighted a current separation between the clinical consultation and the provision of group education, as evidenced in diabetes care. Even within existing UK provision the coverage and quality of group education is believed to be extremely variable. Wider issues relating to feasibility concern appropriate premises for delivery<sup>97</sup> and training in facilitation skills for participating clinical staff.<sup>101</sup>

#### ***Appropriateness (evidence from qualitative research, UK studies and UK informants)***

The evidence for the appropriateness of a group clinic approach, as perceived by patients, is largely equivocal. Patients report substantively comparable perceptions of improvement across both group and individual interventions, with the groups sharing concerns about appointment availability. There was little evidence of dissatisfaction with care from those actually receiving group clinic approaches. However, other considerations may result in patients' poor adherence to the group clinic regime. More typically, those who had vocalised reservations regarding group clinic approaches expressed this concern by withholding consent to entry into a group intervention arm. We have made some initial observations based on data available on recruitment and maintenance from included studies. This suggests that any assessment of effectiveness should pay close attention to those who, although eligible, exit the intervention prior to its

commencement. In practical terms this population will require alternative health-care provision, which may make a dual model of service delivery particularly problematic.

The perceived advantages of group-based approaches include greater flexibility in duration of appointments and more time with the clinician.<sup>97,128</sup> Improved flexibility is expressed in the fact that a group clinic 'can be altered to fit various patient populations, specific physician practices/organisations, and a number of health care delivery systems'.<sup>48</sup> Recent qualitative evidence suggests that the group clinic approach may have a beneficial effect in terms of challenging the previous clinician–patient dynamic, thereby producing a 'levelled playing field'.<sup>101</sup>

Corresponding disadvantages include a perceived lack of privacy, although this was not found to be a significant problem in existing UK studies (albeit in the context of group acupuncture clinics). Of significant concern, however, is the fact that participants attending individual sessions perceive little apparent advantage in switching to a group-based approach and report difficulty in imagining how such group-based approaches might be feasible.

Given the outstanding questions about the sustainability of group clinic approaches, the severity of attrition and the lack of long-term outcome measurement (with the longest follow-up being 5 years),<sup>84</sup> it is problematic to consider the use of group clinics in the context of lifelong chronic disease management provision.

Group clinics may not be appropriate for certain patients or under certain circumstances. In addition to religious and cultural considerations, as exemplified by the specific reference to Muslim women made by a nurse in one study (see *Chapter 3, Results of the review of UK evidence, Study analyses, How do UK health providers feel about group clinics?*), group clinic approaches may be less acceptable to patients of an older generation or in instances where there is a perceived threat to patients' dignity or an increased likelihood of embarrassment (e.g. the revealing of unsightly varicose veins, etc.). Although concerns regarding privacy are underplayed in the included studies, this may reflect the types of conditions being reported and a focus on those who have consented either to randomisation (for RCTs) or to a group intervention (for other research designs). Some concerns may be alleviated by such factors as the design of single-sex group sessions or groups offered to particular ethnic populations, although providers should be sensitive to the fact that such measures may not necessarily result in the addressing of all of the target population's concerns.

Other considerations regarding appropriateness were implied by the exclusion criteria employed in the included trials. Many trials have purposely excluded patients with dementia or cognitive impairment. Others excluded those with hearing difficulties or other communication-related constraints. The exclusion of patients who do not speak the predominant language was also evident. For qualitative studies it was less obvious whether such exclusions relate to the specific group nature of the intervention or were a function of the methods of investigation. In either case, it is clear that the group clinic approaches are not suited to particular segments of the population. For other patients, concerns about access and attendance, for example in the case of those who do not have their own transport or those who work during clinic hours, are also evident.

### **Meaningfulness (evidence from UK studies and UK informants)**

Individuals using the NHS have, as a marker of good-quality individualised care, a general expectation that they will receive an individual consultation with a clinician. This impression may be strengthened by use of the word 'clinics' and by the fact that several patients will have specific expectations of the group clinic, notwithstanding any information provided. Furthermore, group education in the NHS is seen by some as an alternative to the individual consultation but typically presented as a 'bolt-on extra' and, as a result, could be regarded as optional or less important by patients and/or health providers.



### **Effectiveness (evidence from systematic reviews and randomised controlled trials)**

We identified 13 systematic reviews, including multiple variations of the GMV. Ten of these studies were analysed in detail, while one was at the protocol stage and another was unavailable and used only in summary form. The majority of these reviews are disease specific, with the primary focus being on diabetes. One Cochrane review included two studies of group visits as interventions designed to increase patient trust in their clinician, one of the putative mechanisms of the group clinic effect.

Taken as a body of evidence, the reviews shared common conclusions:

- evidence of a significant positive effect in terms of HbA<sub>1c</sub> and systolic blood pressure
- non-significant effects in relation to LDL, HDL and total cholesterol
- a significant effect in relation to disease-specific quality of life
- a moderately significant effect on generic quality of life.
- equivocal evidence in relation to potential cost savings.

Many of the reviews concluded that the heterogeneity of group clinic-type interventions made it problematic to classify such initiatives, to isolate the effect of specific intervention components and, subsequently, to evaluate their effects.

We identified 22 RCTs (32 papers) published between 1999 and 2014. A total of 17 of the 22 studies were conducted in the USA,<sup>20,31,58,60,63–66,68,71,72,75–77,79,80,86</sup> with two conducted in Italy,<sup>82,85</sup> two in the People's Republic of China<sup>73,74</sup> and one in Norway.<sup>70</sup> Included studies recruited a total of 5572 patients. Diabetes was the most represented condition, being present in 23 of the 31 papers and representing, in turn, 15 of the 23 RCTs.<sup>20,58,60,63,66,67,69,70,72,74,79,80,82,85,86</sup> One further study was conducted in a pre-diabetes population.<sup>64</sup> Other conditions included asthma,<sup>65</sup> cardiovascular disease, heart disease/hypertension (three RCTs),<sup>31,71,73</sup> stroke/transient ischaemic attack, and Parkinson's disease.<sup>68</sup>

We found six trial reports<sup>64,66,67,73,74,76</sup> (five trials) published over the period 2012–14. Only one previous review<sup>55</sup> had included any of these reports ( $n = 1$ ).

### **Biomedical outcomes**

Three reports<sup>66,67,74</sup> contributed information to existing meta-analyses. Liu *et al.*<sup>74</sup> confirmed a significant improvement effect on systolic blood pressure finding. Crowley *et al.*<sup>67</sup> confirmed previous findings of a significant effect on HbA<sub>1c</sub> in good-quality trials. However, this effect was observed only among those using complex insulin regimens at baseline, with no observed difference between group medical clinic and usual care patients using no insulin ( $p = 0.65$ ) or basal insulin only ( $p = 0.71$ ). Crowley *et al.*<sup>66</sup> found significant effects for total cholesterol and LDL cholesterol. This finding contributes to an overall pattern from a meta-analysis of previous studies that found non-significant effects for LDL cholesterol (four previous studies) and for total cholesterol (five previous studies).

In addition to the biomedical outcomes, several health service utilisation measures have been measured in isolated studies. These are not suitable for meta-analysis but they are reviewed in chronological order with an assessment of the consistency around results.

### **Health service utilisation**

Edelman *et al.*<sup>18</sup> reported that effects on emergency department visits were reported in five studies.<sup>20,58,69,81,86</sup> Two studies reported significantly lower visit rates<sup>69</sup> or the proportion with an emergency department visit.<sup>86</sup> Rates were not significantly different in the other three studies.<sup>58,81,86</sup> Group clinic participants were significantly less likely to make any emergency visit than those in the control group and averaged fewer emergency visits during the 2-year follow-up period than control participants. Coleman *et al.*<sup>65</sup> reported that, over a 24-month study period, CHCC participants were less likely to make an emergency visit and also less likely to have made multiple emergency visits.



Edelman *et al.*<sup>18</sup> identified five studies reporting the effect of SMAs on hospital admissions.<sup>20,58,69,81,86</sup> Admission rates were lower for SMAs in three studies, but the result was statistically significant in only one study.<sup>20</sup> The fifth study reported a statistically non-significant lower proportion of patients with a hospital admission in the SMA group.<sup>86</sup> In a further study, group clinic participants had, on average, fewer hospitalisations than controls.<sup>65</sup> Primary care visits did not differ between the two groups. Studies in older adults show a pattern of lower health-care utilisation, but the number of studies and participants are relatively few and these results cannot be considered conclusive. In patients with diabetes, lower hospitalisation was the most consistent effect, but effects on other utilisation outcomes are inconclusive. It is important to note that once the group visits themselves are added to primary care visits, group clinic patients have significantly higher overall outpatient utilisation.<sup>65</sup>

### **Efficiency (cost-effectiveness) (evidence from cost studies)**

The evidence for the cost-effectiveness of group clinic approaches is equivocal. The efficiency of group clinics is determined by the perspective from which the group intervention is being examined, the level of current (comparator) provision and whether or not there is recognition of a need for the provision of such enhancements as training for clinicians (e.g. to act as facilitators) and accommodation for group activities. A full economic evaluation is required in a UK setting with recognition of the factors described above regarding feasibility and the other realities of implementation.

## **Rehearsing the main arguments**

In summarising the evidence base we return to a consideration of the four principal drivers for the introduction of group clinic type interventions as identified in *Chapter 1*.

### **The substitution argument**

An initial attraction of group clinic approaches, as encapsulated in our review protocol, was the assumption that such approaches might offer a viable alternative to and substitute for individual consultations. In reality, many models make routine provision for individual consultations, offer follow-up consultation on demand or use the group setting as a mechanism for singling out those requiring specific support. The implications of these three different approaches are similarly varied. In the first instance efficiencies are gained only to the extent that the information giving that would have taken place in an individual setting is provided in a group setting and the corollary that the duplication of genuinely shared concerns may be commensurately reduced. In the second instance, the numbers of on-demand consultations may be difficult both to predict and to provide for, with the consequent dangers of under- or overutilisation of clinical staff and, in the latter case, decreased patient satisfaction. The third variant, whereby those requiring an individual consultation are 'triaged' through the group processes, is heavily dependent on the clinician's capacity to identify genuine need amid a preoccupation with group processes and facilitation. Perversely, those least likely to communicate or engage in a group setting may be the very patients who are most need of supplemental individualised care.

We found no compelling evidence that, **within the context of the entire health system**, the group clinic approach offers efficiencies over the usual care system. Considerations here are that a large proportion of patients will not take up group clinic provision – either because of initial preferences or following personal experience of the approach – and will require individual consultations. Furthermore, the large majority of group clinic approaches make provision for individual consultations within the model, with additional cost consequences. Investigation of this phenomenon, which ran counter to the original perceived rationale for conducting this review, revealed that this may be primarily an artefact of funding arrangements in the USA, where most evaluations have taken place. For example, Blue Cross/Blue Shield Corporate Reimbursements will not cover group visit (SMAs) if the patient is not able to access an individual consultation with the physician and both individual and group interaction must be documented in the patient's medical record to receive reimbursement.<sup>140</sup> Detailed evaluation in a UK setting is required

in order to assess the proportion of patients who would avail themselves of an individual consultation in addition to the group interaction or who would find a group clinic unacceptable.

### *The quality of care argument*

The achievement of positive biomedical or associated outcomes is variable. Although it is conceivable that ongoing self-monitoring, allied to hands-on experience of aspects of self-care and the positive support of realistic models and peers, may achieve a beneficial effect, it is unclear if group clinics are the optimal method for harnessing such mechanisms.

### *The acceptability argument*

Although concerns over confidentiality and privacy are not as plentiful as might be expected, it must be recognised that the views of those who are not willing to enter into a group clinic trial at all are imperfectly captured by either quantitative or qualitative studies. In addition, individuals may be able to enter a group clinic arrangement on an experimental basis but may subsequently decide that the experience was not positive enough for them to continue such an approach beyond the lifespan of the trial. Indeed, there is little evidence on the sustainability of group clinic approaches.

### *The enhancement model*

Typically, group clinic approaches have been investigated as an alternative to individual consultations. Comparisons between different types of group intervention of differing intensities and with/without clinical input are required to examine the differential benefit of the added group clinic-specific input. Considerations for the feasibility of group clinics may centre on whether or not group clinics are seen as an entirely new intervention or whether or not they represent a means of systematising and joining up existing group education and individual clinician input and, therefore, placing group education provision in a more central role than currently appears to be the case.

## Translating the evidence to a UK context: a 'translational appendix'

When translating the evidence from the (primarily) US trials to a UK context, health service managers should recognise that:

- **The research, evaluation and service delivery agenda has been heavily influenced by US health-provider funding patterns.** Although current UK initiatives favour the phrase 'group clinics', this term is not commonly used by the predominantly US-based evaluated models. This difference in terminology may mask common theoretical foundations and intervention components, making the comparability of real practice with available research particularly challenging. In addition, the solutions developed by the USA do not by any means reflect the wide range of formats, content and intensities that might be of value in a NHS setting.
- **There is little empirical evidence examining the most attractive model for the UK, namely group clinics as a substitute for the individual consultation.** In the UK patients have a strong expectation that they will be seen by a clinical specialist. For these reasons the potential to alter the content of the individual consultation by transferring some of this content to a group context, or indeed other formats, may well be more attractive than complete substitution of a new model. However, the joining up of individual consultation and group education approaches may be problematic, given that the latter are often seen as an optional extra by patients, primary care physicians and other health-care providers.

- **In particular, it must be recognised that provision must still be made for those whose complex needs or other circumstances may militate against a group clinic approach.** A particular concern is the possible effect on those who may otherwise seem disadvantaged in terms of access to health or health care. Specific populations mentioned were those with hearing impairment, for whom the group environment may be unaccommodating, and those from specific ethnic minorities, where cultural considerations may impact on dignity, respect and privacy.
- **With regard to facilities, the availability of suitable venues and of suitably trained staff is a key consideration.** If group approaches are delivered badly then this may be taken as a sign of a lack of commitment on the part of the health-care providers.



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### Contributions of authors

**Andrew Booth** (Reader in Evidence Based Information Practice): contributed to the systematic review methodology – conception of the review, review methodology, study selection, data extraction, quality assessment, report writing and consultation with clinical specialists.

**Anna Cantrell** (Information Specialist): contributed to information retrieval, project management, study selection, data extraction, quality assessment and report writing.

**Louise Preston** (Information Specialist): contributed to study selection, data extraction, quality assessment and report writing.

**Duncan Chambers** (Research Fellow): contributed to systematic reviewing, summarising and interpretation.

**Elizabeth Goyder** (Professor in Public Health, Public Health Medicine): contributed to liaison with clinical specialists and critical reading.

### Data sharing statement

All available data can be obtained from the corresponding author.



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# Appendix 1 Feasibility, appropriateness, meaningfulness, effectiveness framework

TABLE 31 Components of FAME framework<sup>11</sup>

Feasibility (F) <sup>a</sup>	Appropriateness (A) <sup>b</sup>	Meaningfulness (M) to specific populations, cultures and settings <sup>c</sup>	Effectiveness (E) <sup>d</sup>	Economic evidence (EE)
Excluding developing countries	Staff attitudes	Cultural values	Clinical outcomes Health services outcomes (including utilisation)	Costs Cost-benefit

a 'The extent to which an activity is practical and practicable. Clinical feasibility is about whether or not an activity or intervention is physically, culturally or financially practical or possible within a given context'.

b 'The extent to which an intervention or activity fits with or is apt in a situation. Clinical appropriateness is about how an activity or intervention relates to the context in which care is given.'

c Evidence of meaningfulness: 'the extent to which an intervention or activity is positively experienced by the patient. Meaningfulness relates to the personal experience, opinions, values, thoughts, beliefs and interpretations of patients or clients'.

d 'The extent to which an intervention, when used appropriately, achieves the intended effect. Clinical effectiveness is about the relationship between an intervention and clinical or health outcomes.'



## Appendix 2 Search strategies

The following electronic databases were searched for published and unpublished research evidence from 1999 to present and were searched on 1 April 2014 to 11 April 2014:

- The Cochrane Library, including the Cochrane Systematic Reviews Database, Cochrane Controlled Trials Register, DARE, HTA and NHS Economic Evaluation (NHS EED) databases
- MEDLINE (Ovid)
- EMBASE (Ovid)
- CINAHL (EBSCOhost)
- Science Citation Index (via ISI Web of Science)
- Social Science Citation Index (via ISI Web of Science)
- Conference Proceedings Citation Index – Science (CPCI-S) (via ISI Web of Science).

Search strategies for each database are provided below.

### MEDLINE

#### Search strategy

1. group visit\$.tw.
2. group clinic\$.tw.
3. \*Group Processes/
4. group appointment\$.tw.
5. group care.tw.
6. group meeting\$.tw.
7. group medical visit\$.tw.
8. group medical clinic\$.tw.
9. group medical appointment\$.tw.
10. group medical care.tw.
11. group medical meeting\$.tw.
12. gmv.tw.
13. gma.tw.
14. shared medical appointment\$.tw.
15. shared medical visit\$.tw.
16. cluster visit\$.tw.
17. (group outpatient\$ adj1 (visit\$ or clinic\$ or appointment\$ or meeting\$ or care)).tw.
18. or/1-17
19. limit 18 to (english language and yr="1999 –Current")

### EMBASE

#### Search strategy

1. group visit\$.tw.
2. group clinic\$.tw.
3. \*group process/
4. group appointment\$.tw.
5. group care.tw.
6. group meeting\$.tw.

7. group medical visit\$.tw.
8. group medical clinic\$.tw.
9. group medical appointment\$.tw.
10. group medical care.tw.
11. group medical meeting\$.tw.
12. gmv.tw.
13. gma.tw.
14. shared medical appointment\$.tw.
15. shared medical visit\$.tw.
16. cluster visit\$.tw.
17. (group outpatient\$ adj1 (visit\$ or clinic\$ or appointment\$ or meeting\$ or care)).tw.
18. or/1-17
19. limit 18 to (embase and english and yr="1999 –Current")

## The Cochrane Library

### Search strategy

ID Search

- #1 "group visit\*":ti,ab,kw (Word variations have been searched)
- #2 "group clinic\*":ti,ab,k this term only
- #4 "group appointment\*":ti,ab,kw (Word variations have been searched)
- #5 "group care":ti,ab,kw (Word variations have been searched)
- #6 "group meeting\*":ti,ab,kw (Word variations have been searched)
- #7 "group medical visit\*":ti,ab,kw (Word variations have been searched)
- #8 "group medical clinic\*":ti,ab,kw (Word variations have been searched)
- #9 "group medical appointment\*":ti,ab,kw (Word variations have been searched)
- #10 "group medical care":ti,ab,kw (Word variations have been searched)
- #11 group medical meeting\*:ti,ab,kw (Word variations have been searched)
- #12 gmv:ti,ab,kw (Word variations have been searched)
- #13 gma:ti,ab,kw (Word variations have been searched)
- #14 shared medical appointment\*:ti,ab,kw (Word variations have been searched)
- #15 shared medical visit\*:ti,ab,kw (Word variations have been searched)
- #16 "cluster visit\*":ti,ab,kw (Word variations have been searched)
- #17 "group outpatient visit\*":ti,ab,kw (Word variations have been searched)
- #18 "group outpatient clinic\*":ti,ab,kw (Word variations have been searched)

- #19 "group outpatient appointment\*":ti,ab,kw (Word variations have been searched)
- #20 "group outpatient meeting\*":ti,ab,kw (Word variations have been searched)
- #21 "group outpatient care":ti,ab,kw (Word variations have been searched)
- #22 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21  
w (Word variations have been searched)
- #3 MeSH descriptor: [Group Processes]

## Cumulative Index to Nursing and Allied Health Literature

### Search strategy

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#	Query
S22	(S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21)
S21	Ti group outpatient care OR AB group outpatient care
S20	Ti group outpatient meeting* OR AB group outpatient meeting*
S19	Ti group outpatient appointment* OR AB group outpatient appointment*
S18	Ti group outpatient clinic* OR AB group outpatient clinic*
S17	Ti group outpatient visit* OR AB group outpatient visit*
S16	Ti cluster visit* OR AB cluster visit*
S15	Ti shared medical visit* OR AB shared medical visit*
S14	Ti shared medical appointment* OR AB shared medical appointment*
S13	Ti gma OR AB gma
S12	Ti gmv OR AB gmv
S11	Ti group medical meeting* OR AB group medical meeting*
S10	Ti group medical care OR AB group medical care
S9	Ti group medical appointment OR AB group medical appointment
S8	Ti group medical clinic* OR AB group medical clinic*
S7	Ti group medical visit* OR AB group medical visit*
S6	Ti group meeting* OR AB group meeting*
S5	Ti "group care" OR AB "group care"
S4	Ti group appointment* OR AB group appointment*
S3	(MM "Group Processes")
S2	Ti "group clinic*" OR AB "group clinic*"
S1	Ti group visit* OR AB group visit*

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## Web of Science

### Search strategy

#24 #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1

Refined by: **LANGUAGES:** (ENGLISH)

*DocType=All document types; Language=All languages;*

#23 #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1

*DocType=All document types; Language=All languages;*

#22 TI=(gma)

*DocType=All document types; Language=All languages;*

#21 **TOPIC:** (gmv)

*DocType=All document types; Language=All languages;*

#20 **TOPIC:** ("group outpatient care\*")

*DocType=All document types; Language=All languages;*

#19 **TOPIC:** ("group outpatient meeting\*")

*DocType=All document types; Language=All languages;*

#18 **TOPIC:** ("group outpatient appointment\*")

*DocType=All document types; Language=All languages;*

#17 **TOPIC:** ("group outpatient clinic\*")

*DocType=All document types; Language=All languages;*

#16 **TOPIC:** ("group outpatient clinic\*")

*DocType=All document types; Language=All languages;*

#15 **TOPIC:** ("group outpatient visit\*")

*DocType=All document types; Language=All languages;*

#14 **TOPIC:** ("cluster visit\*")

*DocType=All document types; Language=All languages;*

#13 **TOPIC:** ("shared medical visit\*")

*DocType=All document types; Language=All languages;*

#12 **TOPIC:** ("group medical clinic\*")

*DocType=All document types; Language=All languages;*

#11 **TOPIC:** ("group medical meeting\*")

*DocType=All document types; Language=All languages;*

#10 **TOPIC:** ("group meeting\*")

*DocType=All document types; Language=All languages;*

#9 **TOPIC:** ("group care")

*DocType=All document types; Language=All languages;*

- 
- #8 **TOPIC:** ("group appointment\*")  
*DocType=All document types; Language=All languages;*
- #7 **TOPIC:** ("shared medical appointment\*")  
*DocType=All document types; Language=All languages;*
- #6 **TOPIC:** ("group medical appointment\*")  
*DocType=All document types; Language=All languages;*
- #5 **TOPIC:** ("group medical care")  
*DocType=All document types; Language=All languages;*
- #4 **TOPIC:** ("group medical visit\*")  
*DocType=All document types; Language=All languages;*
- #3 **TS:** ("group processes")  
*DocType=All document types; Language=All languages;*
- #2 **TOPIC:** ("group visit\*")  
*DocType=All document types; Language=All languages;*
- #1 **TOPIC:** ("group clinic\*")  
*DocType=All document types; Language=All languages;*
- 

## Search strategies for finding details of UK initiatives/experts (Google)

- S1. "united kingdom" AND "group clinics"
- S2. "united kingdom" AND "shared medical appointments"
- S3. "united kingdom" AND "group medical appointments"
- S4. "united kingdom" AND "group medical visits"
- S5. "shared medical appointments" AND host:ac.uk
- S6. "group medical appointments" AND host:ac.uk
- S7. "group clinics" AND host:ac.uk
- S8. "group medical visits" AND host:ac.uk
- S9. "shared medical appointments" AND host:nhs.uk
- S10. "group medical appointments" AND host:nhs.uk
- S11. "group clinics" AND host:nhs.uk
- S12. "group medical visits" AND host:nhs.uk





## Appendix 3 Details of studies on costs of group clinics

TABLE 32 Details of included cost studies

Study (author, date, country)	Study type	What has been measured in terms of costs?	Method for capturing cost information	Costs of staffing the group clinic (per clinic)	Costs of staffing group clinic (per patient)	Total costs of the group clinic	Costs to patients or charges incurred	Headline messages
Edelman <i>et al.</i> (2010) <sup>69</sup> USA	RCT	Cost of group clinics in terms of staff time	Staff time for clinic and for follow-up telephone calls	In 2009 USD, estimated cost of US\$504 (range US\$445–578) to conduct each group visit	Each group visit accommodates eight patients: per-patient cost is US\$63 (range US\$56–72). If patients attended all seven GMC sessions, annual per-patient cost would be US\$441 (range US\$389–506). Follow-up calls cost an additional US\$19 (range US\$4–48), which brings annual per-patient cost to US\$460 (range US\$393–554)			

Study (author, date, country)	Study type	What has been measured in terms of costs?	Method for capturing cost information	Costs of staffing the group clinic (per clinic)	Costs of staffing group clinic (per patient)	Total costs of the group clinic	Costs to patients or charges incurred	Headline messages
Clancy <i>et al.</i> (2008) <sup>62</sup> USA	RCT	Impact of group clinics on patient costs to access other parts of the health system					<p>Mann-Whitney test results show that group visit patients had 34.7% higher outpatient expenditures, 49.1% lower ED expenditures and 30.2% lower total expenditures than the control group (<math>p &lt; 0.05</math> for all). Based on these initial estimates, it seemed that group visit treatment increased outpatient costs by US\$699.52 per patient per year. Although we found a statistically significant and marginally positive effect on group visits in the outpatient cost model that did not correct for endogeneity, the treatment effect model showed a statistically significant marginally negative effect of group visit treatment on outpatient charges of US\$3065.47</p>	<p>This cost study of group visits among inadequately insured patients with type 2 DM showed statistically significant reductions in outpatient charges after controlling for endogeneity of the group visit variable in the charge model via a treatment effect model. Because the group visit model of care is an intervention that depends on patient adherence, we hypothesised and found evidence of endogeneity of the group visit variable. Therefore, we believe that future studies on group visits should consider the potential for endogeneity in estimating the effect of group visit treatment on health-care utilisation and charges</p>

continued

TABLE 32 Details of included cost studies (continued)

Study (author, date, country)	Study type	What has been measured in terms of costs?	Method for capturing cost information	Costs of staffing the group clinic (per clinic)	Costs of staffing group clinic (per patient)	Total costs of the group clinic	Costs to patients or charges incurred	Headline messages
Clancy <i>et al.</i> (2003) <sup>58</sup> USA	RCT	Outpatient, inpatient and emergency room costs and use (visits to outpatients and emergency room and admissions to inpatients) for patients who had participated in a group clinic intervention	Wilcoxon's rank test			In the 6-month study period, overall costs were significantly higher ( $p = 0.0003$ ) for group visit patients (US\$2886 per patient) than control patients (US\$1490 per patient)		Higher costs for patients in group visits differs from previous studies. Findings should be interpreted with caution given small samples group visits may have served to 'activate' participants and possible time lag for decreased costs
Wagner <i>et al.</i> (2001) <sup>86</sup> USA	RCT	Primary care visits (mean/year). ER visits (mean/year). Specialty visits (mean/year) Hospital admissions (% admitted). Totals costs (median USD) Examined intervention vs. control	Health-care uses and costs were also obtained from group health co-operative administrative data systems. The time required of the clinical study personnel is not included in the total health-care costs			Outpatient (US\$1444 intervention and US\$1099 control) and inpatient (US\$1410 intervention and US\$365 control) costs were statistically significant ( $p = 0.008$ and $p = 0.049$ ) respectively but ED costs were not		Although chronic care clinics relied on existing clinic personnel to deliver services, study nurses played an important role that must be considered when estimating the full cost of the intervention

Study (author, date, country)	Study type	What has been measured in terms of costs?	Method for capturing cost information	Costs of staffing the group clinic (per clinic)	Costs of staffing group clinic (per patient)	Total costs of the group clinic	Costs to patients or charges incurred	Headline messages
Crane <i>et al.</i> (2012) <sup>136</sup> USA	Intervention, including a DIGMA. Group size was 36 patients			Total annualised direct costs of programme, including value of donated physician time, was US\$66,000	Total annualised cost of programme was US\$66,000 ED use dropped from a rate of 0.58 per patient per month to 0.23 ( $p < 0.001$ ), and hospital charges dropped from US\$1167 per patient per month to US\$230 ( $p < 0.001$ )	Total ED and inpatient mean charges per person per month fell from US\$1167 for the 12 months before enrolment to US\$230 since enrolment ( $p < 0.001$ )	Low-income or uninsured may be more likely to use ED for non-emergent care because of reduced access to primary care or complex social, behavioural health, or physical health needs that are difficult to address in traditional primary care settings	
Levine <i>et al.</i> (2010) <sup>137</sup> USA	Retrospective case-control design	Total direct health-care costs (all costs directly related to delivering health-care services) for individual in year after first group visit was primary outcome	Evaluate differences in direct costs and utilisation during the first year of the intervention  Because a few patients incurred higher total costs than others, the distribution of total cost was heavily skewed. Natural logarithm transformation of total costs was used in a linear regression model. Multivariate negative binomial regression was used for primary care and specialty care utilisation. Multivariate logistic regression was performed for urgent care and hospital utilisation	Total annualised direct costs of programme, including value of donated physician time, was US\$66,000	Intervention patients had lower total costs in 12 months preceding intervention (mean total costs US\$7968 vs. US\$10,215; $p = 0.007$ )	Intervention patients had lower total costs in 12 months preceding intervention (mean total costs US\$7968 vs. US\$10,215; $p = 0.007$ )	After adjustment for case mix, comorbidity, baseline costs and baseline utilisation, group visit intervention was not associated with an effect on total costs  Total costs remained lower for group that participated in group visits than for controls but not statistically significant (US\$8845 vs. US\$10,288; $p = 0.11$ )  No significant differences between intervention and controls on any form of utilisation: hospital admission, urgent care visits, primary care visits and visits to specialists. Group visits were not counted in the primary care visit counts	

continued

TABLE 32 Details of included cost studies (continued)

Study (author, date, country)	Study type	What has been measured in terms of costs?	Method for capturing cost information	Costs of staffing the group clinic (per clinic)	Costs of staffing group clinic (per patient)	Total costs of the group clinic	Costs to patients or charges incurred	Headline messages
Scott <i>et al.</i> (2004) <sup>79</sup> USA	RCT	Service utilisation and resulting costs were measured for 12 months before patient's study enrolment and for 24 months after enrolment. Outpatient utilisation costs were measured for visits to each type of clinic department and provider		Average physician cost was US\$375 (77.4% of total average cost)			CHCC members had significantly lower costs associated with ED visits than controls. No other significant differences in utilisation costs. Hospital, professional services and health-plan termination costs approached significance ( $p < 0.01$ ), with lower costs in the CHCC group	Service utilisation savings came from prevention of more costly ED visits, hospital admissions and professional services
		Pharmacy charges					Average per patient group cost over 24 months was US\$484, which included salary and overheads for physician, nurse and any other provider attending the group	
		A claims and referral database that tracks services and costs not directly provided by health plan provided hospital, ED, professional services, home health and skilled nursing facility charges					The average monthly cost advantage per CHCC member over the 24 months of the study was US\$133 (US\$463 for control patients US\$330 for CHCC). The cost advantage for CHCC patients before the start of the study was US\$92 per patient per month. CHCC group members' monthly costs were	
		The total cost for all CHCC group meetings was estimated as the sum of the costs for each meeting based on the amount of time providers spent at the meeting and their mean hourly salaries. There were no adjustments for						

Study (author, date, country)	Study type	What has been measured in terms of costs?	Method for capturing cost information	Costs of staffing the group clinic (per clinic)	Costs of staffing group clinic (per patient)	Total costs of the group clinic	Costs to patients or charges incurred	Headline messages
Bondonio <i>et al.</i> (2005) <sup>134</sup> Italy	Cost-effectiveness analysis of two interventional quasi-societal point of view	Differential direct costs to health service (staff and educational material costs) or to patients (transportation and opportunity costs)	Cost-effectiveness ratios for group care are calculated with sole reference to differential outcomes and costs (i.e. so where there is an overlap between costs of usual care and costs of group clinics, these are not accounted for)	T2DM: Average estimated value of staff time led to a total cost of €126.43 per patient on group care and €66.37 per control patient	Costs to see one patient over study period: €11.50 for group care and €90.44 for individual consultations	In total, each patient on group care cost €831.57 and each control cost €731.82 with a difference of €99.75 per patient treated over the observation period  T1DM: Direct costs for Indian NHS over 3 years totalled €271.24 for group care patients and €120.15 for control patients  The total cost differential between the group care and the control procedure was, therefore, €236.60 over 3 years	US\$42 per member less than those of control members when adjusted for costs 12 months before the start of the study (US\$133 cost advantage during the study – US\$92 cost advantage before the study), but this difference was not statistically significant  Transportation costs for patients were €48.45 for group care and €38.34 for controls	Each incremental improvement in quality of life for patients on group care was obtained with an expenditure (i.e. cost-effectiveness ratio) of €2.28  T1DM: '... a cost-effectiveness ratio of €19.46 per each of 12.16 differential DQoL scores'. Not possible to calculate quality-adjusted life-years

DQoL, Diabetes Quality of Life questionnaire; DM, diabetes mellitus; ED, emergency department; ER, emergency room; GMC, group medical clinic; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; USD, US dollars.





## Appendix 4 Intervention characteristics from randomised controlled trials

TABLE 33 Intervention characteristics from RCTs

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Clancy <i>et al.</i> (2003) <sup>58</sup>	CHCC	Socialisation, health education/information presentation(s) by individual clinician, routine medical checks by multiple clinicians, immunisation, individual consultation immediately following group session – all patients	CHCC approach based on Beck model. <sup>94</sup> Those randomised to CHCCs scheduled into three groups, 19–20 patients, monthly meetings for 6 months. Main source of medical care. Each group visit session was scheduled for 2 hours (15 minutes of warm-up; 30 minutes of presentation of a health-related topic; 15-minute break, during which time the nurse and physician circulated, attending to individual needs, immunisations, appointment scheduling and other issues; 15 minutes of questions and answers; 15 minutes of planning the next session; and 30 minutes of one-on-one consultations with physician). Content of group visits guided by group members themselves, although educational topics covered included core curriculum topics (e.g. nutrition, exercise, foot care, medications, complications and the emotional aspects of diabetes <sup>20</sup> ). On conclusion of the group portion of the visit, patients had the opportunity to see the physician individually if desired	Group visits co-led by primary care internal medicine physician and diabetes nurse educator	If patients needed care between scheduled group visits, or if specific medical needs could not be accommodated in the group visit, they could schedule a one-on-one visit with an APCC provider
Clancy <i>et al.</i> (2003) <sup>57</sup>	CHCC	Socialisation, health education/information presentation(s) by individual clinician, routine medical checks by multiple clinicians, immunisation	Warm-up and socialisation (15 minutes), presentation of health topic (30 minutes), break (while physician and nurse circulated, attending to individual needs, immunisation, appointment scheduling, etc.) (15 minutes), questions and answers (15 minutes), planning the next session (15 minutes), one-on-one consultations with the physician (30 minutes)	Hospital physician and specialist nurse	Care between scheduled visits or specific needs to see individual clinician between visits scheduled as one-on-one sessions

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Clancy <i>et al.</i> (2003) <sup>59</sup>	CHCC	Socialisation, health education/information presentation(s) by individual clinician, routine medical checks by multiple clinicians, immunisation, individual consultation immediately following group session – all patients	Warm-up and socialisation (15 minutes), presentation of health topic (30 minutes), break (while physician and nurse circulated, attending to individual needs, immunisation, appointment scheduling, etc.) (15 minutes), questions and answers (15 minutes), planning the next session (15 minutes), one-on-one consultations with physician (30 minutes)	Hospital physician and specialist nurse	Care between scheduled visits or specific needs to see individual clinician between visits scheduled as one-on-one sessions
Clancy <i>et al.</i> (2007) <sup>60</sup>	CHCC	Socialisation, health education/information presentation(s) by individual clinician, routine medical checks by individual clinician, medication review, individual consultation within the group session – all patients	Patients randomised to group visits divided into six cohorts (14–17 patients). Met monthly for 1 year on different floor in same building as clinic. One-on-one visits available for care needed between scheduled group visits or for specific medical needs not amenable to group visits. Group visits scheduled for 2 hours (10–15 minutes for 'warm-up', 30–45 minutes for an interactive discussion of a health-related topic such as foot care or healthy eating strategies, and 60 minutes for one-on-one consultations with the physician). Vaccinations, foot exams, medication adjustments, laboratory orders and referrals for retinal examinations could be done in group visits. Group visit content, though patient guided, was physician directed to cover educational topics included in a core curriculum (e.g. nutrition, exercise, foot care, medications, complications of diabetes and emotional aspects of diabetes <sup>20</sup> )	Primary care internal medicine physicians. Registered nurses	Mammograms, pap smears and retinal examinations were scheduled separately

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Clancy <i>et al.</i> (2007) <sup>61</sup>	CHCC	Socialisation, health education/information presentation(s) by individual clinician, routine medical checks by individual clinician, individual consultation within the group session – all patients	CHCC approach based on Beck model. <sup>75</sup> Patients randomised to group visits divided into six groups that met monthly for 12 months, each consisting of 14–17 patients. Main source of medical care. Visit lasts 2 hours: 10–15 minutes for warm-up, 30–45 minutes for interactive discussion of health-related topic and 60 minutes for one-on-one consultations with the physician. Medical appointments requiring privacy were undertaken outside the group clinic setting. Group visit content, guided by patients, was directed by physicians to cover educational topics included in a core curriculum <sup>20</sup>	Primary care internal medicine physicians. Registered nurses	At group visits patients could schedule appointments for mammograms and pap smears and for other specific medical needs not suited to group visit (e.g. abdominal examination, electrocardiograms)
Clancy <i>et al.</i> (2008) <sup>62</sup>	CHCC	Socialisation, health education/information presentation(s) by individual clinician, routine medical checks by individual clinician, individual consultation within the group session – all patients	As above	Primary care internal medicine physicians. Registered nurses	At group visits patients could schedule appointments for mammograms and pap smears and for other specific medical needs not suited to group visit

Study	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Cohen <i>et al.</i> (2011) <sup>63</sup>	<p>Group discussion (i.e. many to many), health education/information presentation(s) by multiple clinicians, routine medical checks by individual clinician, medication review, completion of prescriptions, referral from within group to (different day) follow-up visit</p>	<p>Phase 1: VA-MEDIC-E intervention. Regular visits with a primary care provider PLUS four once-weekly 2-hour sessions, followed by five monthly booster sessions. Four to six participants in each session. Family members, friends and other sources of social support were encouraged to participate in the sessions with the participants. Two parts: education in the first half and behavioural and pharmacologic interventions for hypertension, hyperlipidaemia, and hyperglycaemia and tobacco use in the second. This part allowed for open discussions about each risk factor control, obstacles and solutions. Participants were given a cardiovascular report card (medication list, vitals and laboratory data). Participants set dietary goals, kept a food log and set goals to increase daily exercise. Medication regimens were discussed and evaluated, and dose up-titrations were made as per pre-established protocols. Participants who wanted individual assistance with exercise or dietary guidance were given referrals to the health-care provider after the four weekly sessions. Phase 2: monthly booster. Intervention booster SMA sessions occurred monthly for 5 months and lasted 90 minutes. Structure of monthly booster was similar to weekly group SMA session except that educational component was less structured and focused on group needs. Treatment plans for diet, exercise, monitoring or other self-care behaviours were followed and adjusted</p>	<p>Educational component from pharmacist, dietitian, nurse and physical therapist. Intervention component provided by clinical pharmacist who was either a nationally certified diabetes educator or a Rhode Island-certified diabetes outpatient educator</p>	<p>Visits with primary care provider as required</p>

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Cole <i>et al.</i> (2013) <sup>64</sup>	SMA	Group discussion (i.e. many to many)	A screener received patients, ensured that patients understood and signed consent form; documented height, weight and BP measurements; asked each patient to complete an individual questionnaire; and escorted patients to SMA room. SMA sessions were set up for 6–8 patients. A facilitator greeted each patient, familiarised new patients to SMA process, covered ground rules, built group cohesion and facilitated discussion on topics of interest, while a provider reviewed notes and consulted with a recorder between individual sessions. Each patient received 10 minutes' individual focused time with the provider to review their clinical and biochemical measures and challenges, successes, and questions regarding their progress in making lifestyle changes using SMART (specific, measurable, achievable, realistic and time-based) goals. All pertinent information discussed during visit was recorded in each patient's medical record by the recorder, who also scheduled a follow-up SMA appointment	Supported by a nutrition technician as a screener; a dietitian or nutrition technician as a session recorder; a certified diabetes educator registered dietitian as a provider; and a behavioural specialist, registered nurse or registered dietitian trained in group dynamics as a facilitator of sessions	No details

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Coleman <i>et al.</i> (2001) <sup>65</sup>	CHCC	Socialisation, routine medical checks by multiple clinicians, immunisation, completion of prescriptions, individual consultation within the group session – all patients	<p>Group visits were held monthly with an average attendance of 8–12 participants per group. Caregivers and spouses were invited to attend. Standard format: Visit began with a brief warm-up and socialisation period followed by a presentation on a specific health topic. Initially, topics were the same for all groups. Subsequent topics were chosen based on group consensus. Next 25 minutes were devoted to health-promotion activities and included blood-pressure assessment, administration of such immunisations as influenza and pneumococcal vaccines, and medication refills. The group then reconvened for a brief question-and-answer period on the topic that was presented. During this time, the next session and its health topic presentation were planned. The remaining time was reserved for individual sessions between patients and the physician, which served as interim assessments of ongoing chronic disease management, although acute problems were evaluated as well. The remaining patients used the time to fill prescriptions or to socialise</p>	<p>Core delivery – primary care physician, nurse and clinical pharmacist. Ancillary providers, including a dietitian, a social worker and a physical therapist, attended periodically</p>	No details

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Crowley <i>et al.</i> (2014) <sup>66</sup>	Group clinic	Socialisation, group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, routine medical checks by multiple clinicians, medication review, individual consultation within the group session – all patients	Initial study visit: collection of baseline information (demographic and medical) then randomisation then intervention (three phases). Phase 1: brief medical questionnaire, BP check, collection of patient delivered blood glucose data from patients, informal conversation between patients. Phase 2: interactive group educational session on topics selected by patients. During session, clinicians reviewed data collected in phase 1 and developed medication and lifestyle management plan with the aim of improving BP and HbA <sub>1c</sub> . Phase 3: individual meeting between pharmacist/internist/both and patient to gather patient-specific information to inform the medication and lifestyle management plan. Then patient and clinician negotiated final plan for improved disease control which was entered into patient medical record. Patient received updated medication list with instructions for any medication or lifestyle changes	Care team comprising a general internist, a pharmacist, and a nurse or certified diabetes educator	Telephone contact between GMC only when lab tests undertaken in GMC and changes to symptom management made. GMC patients continued to receive usual primary care in addition to GMC. Changes in medication noted in electronic medical record



Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Crowley <i>et al.</i> (2013) <sup>67</sup>	Group clinic	Group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, routine medical checks by individual clinician, individual consultation within the group session – all patients	Each group comprised 7–9 patients. Groups met every 2 months for 12 months (seven 120-minute sessions over 12 months). Within the groups, patients and care teams remained consistent across sessions. Each 120-minute GMC session comprised three phases. Phase 1 (30 minutes) focused on patient intake and data collection. On presentation, each patient completed a brief triage form, had a BP check and turned in recent self-monitored blood glucose or BP data. Intake also allowed time for informal conversation among group members. Phase 2 (30–45 minutes) consisted of an interactive group education class led by an assigned educator. Concurrent with the education class, the internist or clinical pharmacist reviewed patients' self-monitored data, medical records and laboratory values, and developed a plan to improve cardiovascular disease risk-factor control (including lipids). In phase 3 (30–45 minutes), the clinical pharmacist or internist met individually with patients for 5–10 minutes each to gather additional information about issues that could affect treatment decisions (e.g. medication adherence, adverse drug events). The final treatment plan was determined. Patients received an updated medication list with instructions regarding any changes. GMC patients continued to receive usual primary care alongside intervention. Lipid goals were discussed with GMC patients during phase-3 individual sessions, and lipid medications were adjusted as clinically indicated. Lifestyle modification measures explicitly targeting lipids were not addressed during GMCs but patients received extensive education in related areas, including medication adherence, diet and exercise	Care team comprising a general internist, a pharmacist and a nurse or certified diabetes educator	

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Dorsey <i>et al.</i> (2011) <sup>68</sup>	GMV	Socialisation, group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, individual consultation immediately following group session – all patients	Patients and their caregivers. Visits lasted approximately 90 minutes (5 minutes of introductions, 10 minutes of patient updates, 40-minute educational session chosen by participants, 15-minute break, 20 minutes for completing the educational session, addressing patient/caregiver questions, discussing current research opportunities and selecting educational session topics). Brief 10 minute one-on-one visits prior to or after the group session with physician. 12-month study; group visits once every 3 months. Patients could attend an unscheduled one-on-one visit with the study physician between sessions. Individuals in the usual-care group saw the physician whom they had previously seen for their care. Generally patients in the usual-care group saw their physician every 3–6 months for approximately 30-minute visits	Physician	Group patients could attend unscheduled one-on-one visit with study physician between sessions. Participants were encouraged to contact the physicians' office via telephone at any time for issues happening between visits (medicine refills, acute change in disease status)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Edelman <i>et al.</i> (2010) <sup>69</sup>	Group clinic	Socialisation, group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, health education/information presentation(s) by multiple clinicians, routine medical checks by multiple clinicians, routine medical checks by patient, medication review, individual consultation immediately following group session – all patients, telephone follow-up	Randomised patients selected a suitable GMC date. Each group comprised 7–9 patients. Groups met every 2 months for seven visits, and the same patients met with the same care team each visit. GMC sessions were scheduled for 2 hours; however, visits after the first session typically lasted approximately 90 minutes. Each session was divided into three phases. Phase 1: intake and data collection phase (brief questionnaire, BP check, assessment of self-monitored blood glucose, informal conversation). Phase 2: 30 minutes into the session – patient-chosen interactive educational session provided by the assigned educator. While patients were attending the interactive education session, the internist and the clinical pharmacist reviewed clinical information and developed a plan for medication and lifestyle management. Phase 3: a one-on-one breakout session (pharmacist/internist) for a final plan for improved disease control. At the conclusion of the meeting, patients received an updated list of their medications, with instructions for any medication or lifestyle changes and a reminder for the next visit	Care team for each group composed of a primary care general internist, a clinical pharmacist and a nurse or other certified diabetes educator	All patients received usual primary care from Veterans Affairs Medical Centre

continued

TABLE 33 Intervention characteristics from RCTs (*continued*)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Graue <i>et al.</i> (2005) <sup>70</sup>	Group visit	Socialisation, group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, health education/information via booklet, leaflet, video, routine medical checks performed by patient, computer-assisted individual consultation	Intervention group (structured educational and counselling programme) or a control group (traditional care). Intervention group: 15-month structured educational and counselling programme. At intervals of 3 months, separate group visits for the adolescents and their parents and also individual computer-assisted consultations for the adolescents. Each of the three 3-hour group visits (four to nine participants per group) followed a structured programme. Younger (11–13 years) and older (14–17 years) adolescent groups. An older, experienced adolescent with diabetes (about 3–4 years older than participants) participated as a co-leader of each group. Three 45-minute individual consultations scheduled during intervention period for the nurse to review patients' participation and understanding. Combining group visits with individual computer-assisted consultations was used to take advantage of group dynamics on the learning process. Group visits gave the opportunity to build up a social network. The patient-provider relationship was strengthened by the three individual consultations	Physician, diabetes nurse specialist, clinical psychologist, dietician and social worker	In month 4 of the programme parents attended a meeting with other parents

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Griffin <i>et al.</i> (2009) <sup>71</sup>	Group clinic	Health education/information presentation(s) by individual clinician, medication review	60-minute anticoagulation group session two mornings per week. 15-minute administrative preparation time for pharmacist. One pharmacist/student presented a health education topic and facilitated a group discussion while the other called patients one by one into a private room. During the one-to-one session the pharmacist interviewed the patient and inquired about missed doses, change in medication, changes in diet, alcohol use and bleeding or bruising experiences and measured patients' INR value. No patient-specific information was discussed with the group. If the patient required further time, he or she was asked to stay after the group discussion to complete the visit. Warfarin dosing instructions and the scheduling of follow-up appointments were discussed with each patient at the end of each visit	Pharmacist/pharmacy student	
Gutierrez <i>et al.</i> (2011) <sup>72</sup>	SMA	No details	No details	General practitioner/family physician, general nurse, pharmacist, social worker, medical assistant and registration clerk	No details

continued

TABLE 33 Intervention characteristics from RCTs (*continued*)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Junling <i>et al.</i> (2015) <sup>73</sup>	CHCC	Socialisation, group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, routine medical checks by individual clinician, individual consultation immediately following group session – selected patients	The intervention was based on CHCC model, taking into consideration Chinese culture and the Chinese guideline for hypertension management, called the Chinese hypertension group visits model. The model comprised intensive sessions and continuous usual sessions. The intensive session involved six sessions, held once per half-month. Continuous usual sessions were held once per month and followed the intensive session. Sessions were interactive, and the nurse or the community health worker facilitated conversation among the patients. A typical group visit consisted of warm-up period (15 minutes), an educational component (30 minutes on specific key hypertension topics) and a question-and-answer period, followed by an individual consultation (60 minutes) for patients who needed it, involving BP, test results, immediate health-care needs and scheduling future tests. Plus patient concerns, prescriptions and adjusted therapeutic scheme as required	General practitioner/family physician, general nurse and community health worker	No details

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Liu <i>et al.</i> (2012) <sup>74</sup>	CHCC	Socialisation, group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, routine medical checks by individual clinician, routine medical checks by multiple clinicians, completion of prescriptions, individual consultation immediately following group session – selected patients	Twelve sessions of the programme. Each session had six phases: (1) introduction/feedback; (2) group self-management education; (3) refreshments and group interaction; (4) questions and answers; (5) planning and closing; and (6) one-on-one visit with health-care providers. The length of each session was 1.5 hours plus 1 hour for selected individual visits. Group self-management education sessions focused on helping participants to build confidence in their ability to deal with diabetes by incorporating self-efficacy enhancing strategies. Each participant was to make a weekly action plan for the coming month (4 weeks) at each group session in this study. In total, each participant made 12 weekly action plans over the whole 12-month intervention period. Participants could seek further self-management support during 60-minute one-on-one visits with health-care providers at the end of each group visit session (25% uptake)	General practitioner/family physician, general nurse and preventative doctor	No details

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Naik <i>et al.</i> (2011) <sup>5</sup>	Group clinic	Group discussion (i.e. many to many), health education/information presentation(s) by individual clinician, medication review, individual consultation within the group session – all patients, communication with primary care provider	EPIC intervention. Four group sessions every 3 weeks over a 3-month period. Each session consisted of 1 hour of group interaction and then each participant had 10 minutes of individual interaction with the study clinician. For each EPIC session, the group interaction was divided into three 20-minute blocks, each conveying the session theme using different modalities – clinician led, group led and peer led. During the one-on-one consultation with the study clinician, participants discussed their DM status, received feedback on their specific DM goal and action plan, and addressed medication-related issues. Study clinicians sent a research note to PCPs after each session about HbA <sub>1c</sub> goals and actions and medication changes	Three study clinicians (primary care physicians)	No details
Ratanawongsa <i>et al.</i> (2012) <sup>6</sup>	GMV	Socialisation, group discussion (i.e. many to many), individual consultation within the group session – selected patients	GMV involved language-specific monthly GMVs visits for 9 months. GMVs involved 6–10 patients, were facilitated by a language concordant primary care physician and health educator, lasted 90 minutes and shared the same basic structure: (1) group check-in, in which participants reported any problems or progress with action plans and the group facilitates problem-solving, adjustment and/or commitment to action plans; (2) discussion of common concerns or modelling of self-management practices; (3) social break with healthy snacks; (4) short planning session to select subsequent topics; and (5) brief, individualised care to patients with unmet medical needs. All patient interactions with GMV facilitators, including action plans created and achieved, were communicated with PCPs	Hospital physician and health educator	Standard diabetes care provided by their PCPs and any diabetes education, nutritional counselling or subspecialty endocrinology care that was recommended by their PCPs



Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Sadur <i>et al.</i> (1999) <sup>20</sup>	CV	Health education/information presentation(s) by individual clinician, referral from within group to (different day) follow-up visit	Diabetes Co-operative Care Clinic, a CV model of care management. 6-month intervention. A team behaviourist conducted 1–4 individual sessions with a total of 13 patients after either patient self-referral or referral initiated by nurse or dietitian. A pharmacist reviewed medication. A medical assistant measured BP and provided clerical support. The information provided in education sessions was suggested by patients, e.g. every group opted to schedule a cluster session with the podiatrist, who lectured and screened all patients with a foot examination. Patients requiring individual therapy were scheduled for visits in the podiatry clinic. Patients requiring ophthalmology screening had examinations scheduled by the team. Doctors and nurses met to discuss patient progress. The clinic provided all patients' PCPs with copies of progress notes that went into the medical record. Near the end of the 6-month intervention, the diabetes nurse educator and the behaviourist discussed transitioning diabetes care back to PCP	Multidisciplinary diabetes care team includes dietitian, behaviourist and pharmacist. Led by a diabetes nurse educator who is supported by two diabetologists	Referrals to the behaviourist, smoking cessation or drug and alcohol rehabilitation programmes or patient's primary care physician made as appropriate. Between meetings, diabetes nurse educator reviewed diabetes management by telephone from twice monthly to every 3 days

continued

TABLE 33 Intervention characteristics from RCTs (*continued*)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Schillinger <i>et al.</i> (2008) <sup>77</sup>	GMV	Socialisation, group discussion (i.e. many to many), routine medical checks by individual clinician, individual consultation within the group session – selected patients, short planning session to decide future topics	GMV model involved language-specific monthly GMVs for 9 months. GMVs involved 6–10 patients, were cofacilitated by a language-concordant PCP and a health educator, last 90 minutes and share the same basic structure: (a) group check-in, in which participants report any problems or progress with action plans and the group facilitates problem-solving, adjustment and/or recommitment to action plans; (b) discussion of common concerns or modelling of self-management practices; (c) social break with healthy snacks; (d) short planning sessions to select subsequent topics; and (e) brief, individualised care to patients with unmet medical needs by the physician, health educator or pharmacist (to review medication regimens)	No details	No details
Schillinger <i>et al.</i> (2009) <sup>78</sup>	GMV	Socialisation, group discussion (i.e. many to many), routine medical checks by individual clinician, individual consultation within the group session – selected patients, short planning session to decide future topics	GMV arm involved 90-minute monthly sessions over 9 months, with 6–10 participants, cofacilitated by a PCP and a health educator. GMV participants received bus tokens and healthy snacks	No details	No details

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Scott <i>et al.</i> (2004) <sup>29</sup>	CHCC	Socialisation, health education/information presentation(s) by individual clinician, health education/information presentation(s) by multiple clinicians, routine medical checks by multiple clinicians, immunisation, completion of prescriptions, individual consultation immediately following group session – selected patients; referral from within group to (different day) follow-up visit	Research staff contacted intervention members by telephone to schedule an initial group meeting. Groups met with their PCP and a nurse every month for 90 minutes. Other providers (e.g. physical therapists, pharmacists, occupational therapists and individuals representing community resources) attended as needed, depending on the topics scheduled for discussion during group visit. A typical group meeting consisted of a 15-minute spontaneous or an organised warm-up period, an education component, a caregiving period and a question-and-answer period, followed by planning the next meeting. After each meeting, the physician would meet briefly one-on-one with individual patients as needed. For first few meetings, reminiscence therapy techniques were used to identify common experiences among group members to build a sense of group cohesiveness. In later groups process became more informal (e.g. jokes, stories about vacations and grandchildren). A 30-minute presentation on specific health-related topics followed warm-up period. Six core topics presented during meetings after introduction to programme: patient care notebooks, routine health maintenance, pharmacy brown bags, advanced directives, emergency care and continuing care. Other topics included chronic pain, nutrition, exercise, home safety and disease processes (e.g. stroke, hypertension, arthritis, osteoporosis and Alzheimer's disease). Participants requested some topics. The physician and other members of CHCC interdisciplinary health-care team presented	General practitioner/family physician, general nurse, pharmacist, occupational therapist, physiotherapist and dietitian	Individual consultations were available

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Seesing <i>et al.</i> (2014) <sup>30</sup>	SMA	Health education/information presentation(s) by single clinician	<p>Patients and partners were invited to attend a SMA of 1.5–2 hours in lieu of their annual appointment. During the SMA, one of two neurologists saw 5–8 patients with the same diagnosis and their partners simultaneously, addressing the same topics that are frequently covered during an individual appointment. The neurologist was supported by a group mentor who facilitated the group process by fostering interaction between patients and partners and by managing time. Both neurologists and the group mentor had received training in conducting SMAs before the study. More detailed description of content on <i>Neurology</i><sup>®</sup> website at <a href="http://Neurology.org">Neurology.org</a></p>	<p>the topics. A 20-minute caregiving period followed, during which nurse took BPs; reviewed patient charts for immunisations, laboratory tests and immediate health-care needs; and scheduled future individual physician visits, if needed. At the same time, the physician responded to minor patient concerns, refilled prescriptions and responded to individual needs. Patients not being evaluated by the nurse or physician were given the opportunity to socialise and have refreshments. 15 minutes were dedicated to questions and answers about material covered in the educational period or any other patient's inquiry. An additional 10 minutes were used to elicit ideas for the following month's education topic and to schedule next month's meeting. A 60-minute period for patients needing private office visits to meet individually with their physician for 5–10 minutes followed each group meeting</p>	<p>In both groups, patients not necessarily seen by their regular consulting physician. For both groups, care was tailored to needs of patients and their partners. Prescriptions, referrals, and medical record-keeping were as usual</p>

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Taveira <i>et al.</i> (2010) <sup>80</sup>	SMA	Health education/information presentation(s) by multiple clinicians, health education/information via booklet, leaflet, video, medication review	Patients in VA-MEDIC arm attended four weekly, 2-hour sessions in a classroom setting, with approximately 4–8 participants in each session. Family members, friends or other sources of social support were encouraged to participate in sessions with participants. Each session had two parts: education in the first half and behavioural and pharmacological interventions in the second half. The education part (40 to 60 minutes) consisted of interactive lectures covering learning objectives from curriculum of American Association of Diabetes Educators. Each session focused on one or two diabetes self-care behaviours. The pharmacological and behavioural intervention (60–80 minutes) was conducted by a clinical pharmacist who treated diabetes, hypertension, dyslipidaemia and tobacco. The clinical pharmacist began by reflecting on the content of the educational half and performed group assessment of confidence and conviction in achieving target behaviours. Medication regimens were discussed and titrated based on previously formulated medication titration algorithms for BP, cholesterol, glycaemic control and tobacco cessation. Exercise prescriptions were given following the recommendations of the American Heart Association. Participants were taught to carry a cardiovascular risk report card containing medical history, medications, vitals and laboratory values, which was obtained prior to the sessions. For tobacco cessation, VA-MEDIC interventions were based on transtheoretical model	Nurse, nutritionist, physical therapist and clinical pharmacist	Patients attended their regular visits with their PCPs

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Taveira <i>et al.</i> (2011) <sup>31</sup>	SMA	Socialisation, health education/information, routine medical checks, medication review	VA-MEDIC-D intervention: 'In addition to attending regular visits with a primary care provider' plus '4 once-weekly sessions of 2 hours followed by 5 monthly booster sessions held in a classroom with approximately 4–6 participants in each session'. 'Each session comprised of 2 parts: education in the first half, and behavioural and pharmacologic interventions . . . in the second half'. Education session lasted 40–60 minutes and included interactive lectures and focused on one or two self-care behaviours. The pharmacologic and behavioural intervention portion lasted 60–80 minutes. Led by pharmacist. Group counselling and reinforcement. Each group member was provided with individualised homework for medication changes and a behaviour-change goal	Specialist nurse, pharmacist and dietitian	Regular visits with a primary care provider

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Trento <i>et al.</i> (2001) <sup>82</sup>	Group visit	Group discussion (i.e. many to many), routine medical checks by individual clinician, individual consultation immediately following group session – all patients, hands-on activities, problem-solving exercises, real-life simulations, and role-playing	Four sessions focused on the undesirability of being overweight, meal planning, improving and checking metabolic control and preventing chronic complications. Blood samples were collected in advance of group consultation. Patients needing individual clinical attention were seen on a one-to-one basis by the same physician at the end of the group session. Each group session was structured into four phases: (1) welcome and introduction to the subject to be discussed; (2) interactive learning, (3) discussion of some of the patients' experiences; and (4) conclusions, with directions for follow-up 'homework', information about the next appointment, and where necessary, individual visits with the physician. During phase 1, the 'homework' was collected and checked. Patients were given sealed envelopes containing the results of their blood tests; these results were discussed collectively only if the patients so desired. During phases 2 and 3, which were not strictly separated, various hands-on activities, group work, problem-solving exercises, real-life simulations and role-playing were proposed. To reinforce cohesion and interpersonal relationships, the same patients and facilitators took part in same groups over time. Relatives wishing to participate were welcomed. During phase 4, a diary for the weekly monitoring of body weight and food intake was distributed as homework to be collected during phase 1 of the following session. Relatives were instructed in the procedure to help patients with literacy problems. The four-session cycle was repeated for a second year	Hospital physician, educationalist	Physicians spent 30 minutes before each session examining the case notes and the results of the patients' blood tests and another 30 minutes meeting individually with all patients who had specific clinical problems and/or had completed their yearly screenings for complications. Each individual control visit required 15–20 minutes. In total, 150–200 minutes were needed to see 10 patients with the traditional approach, whereas group consultations did not take longer than 120 minutes

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Trento <i>et al.</i> (2002) <sup>33</sup>	Group visit	Group discussion (i.e. many to many), health education/information presentation(s) by multiple clinicians, individual consultation immediately following group session – selected patients	Educational sessions were held every 3 months (1–2 physicians and educationist as facilitators). The programme included the burden of overweight, choosing food, meal planning, physical exercise, checking and improving metabolic control, smoke cessation, assuming medication and preventing complications. This curriculum, divided into four sessions, was repeated in years 1–2 and then spread over seven sessions in years 3–4 to avoid excessive repetition and to allow more in-depth discussion and learning. Patients requiring individual attention (i.e. those undergoing annual screening for complications and/or presenting clinical or biochemical abnormalities) and any who requested it were offered individual care soon after the group session. Control patients were scheduled for 3-monthly visits, or as frequently as necessary, in the general diabetes clinic by the same physicians in charge of group sessions, blinded to avoid performance bias. Knowledge on diabetes self-care was checked annually. One-to-one educational reinforcement offered accordingly by the same educationist involved in group activities, with special reference to eating habits, home monitoring of blood glucose, if practised, and preventing complications	One to two physicians and an educationist	



Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Trento <i>et al.</i> (2004) <sup>84</sup>	Group visit	Group discussion (i.e. many to many), routine medical checks by individual clinician, individual consultation within the group session – selected patients	Group sessions were held every 3 months, with one or two physicians and an educator acting as facilitators. None of the patients moved from one treatment to the other during the study period. Group care was based on a systemic education approach. The curriculum was intentionally kept to a minimum of essential concepts to be transmitted by hands-on activities, group work, problem-solving exercises, real-life simulations and role-playing. The programme included the burden of being overweight, choosing food and planning meals, physical exercise, checking and improving metabolic control, smoking cessation, correct assumption of medication and preventing complications. This curriculum, initially divided into four sessions, was repeated in years 1–2, then spread over seven sessions in years 3–4 and started again in year 5 to allow more in-depth discussion and learning. Formal teaching and medical or scientific jargon were avoided as much as possible	One or two physicians and an educator	

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Trento <i>et al.</i> (2005) <sup>35</sup>	Group clinic	Group discussion (i.e. many to many), individual consultation immediately following group session – all patients, hands-on activities, group work, problem-solving exercises, real-life simulations and role-playing	Focus groups ran in advance of the study to determine relevant topics. A nine-session programme was developed according to a systemic education approach to address these topics. After these nine sessions, the programme was reassessed in a second round of focus groups, this time involving all of the patients who had received group care. A new curriculum designed with the patients included the differences between type 1 and type 2 diabetes; principles of nutrition; classification of nutrients, composition of food and food exchanges; personal habits and day-to-day management; how to embed eating patterns into daily life as tastes and habits evolve over time; physical exercise; adaptation of insulin dosage and daily activity; hypoglycaemia and hyperglycaemia: why do they occur and how to recognise and manage them; how to inform relatives and friends; areas of insulin injection and their rotation; retinopathy, neuropathy, microalbuminuria and nephropathy; self-care; when and how to screen; and hypertension and cardiovascular aspects. The patients also requested that insulin, HbA <sub>1c</sub> and day-to-day problems be discussed whenever felt necessary. Redesign of a new nine-visit programme. Six more visits were delivered over the remainder of the 36 months, a total of 15 group care sessions. Samples were taken in advance of clinic and reviewed. Group visits were held every 2 or 3 months by a doctor and a psychoepaedeutagist, who acted as facilitators. Sessions were centred on	Doctor and psychoepaedeutagist	

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Wagner <i>et al.</i> (2001) <sup>86</sup>	Chronic care clinic	Group discussion (i.e. many to many), routine medical checks by multiple clinicians, individual consultation within the group session – all patients	hands-on activities, group work, problem-solving exercises, real-life simulations and role-playing, as well as group discussions concerned with motivational aspects, acceptance of diabetes, psychosocial problems and coping strategies. Sessions were planned to last 40–50 minutes, followed by brief individual consultations with the same doctor, to comment on laboratory results, previous group session, and yearly check-up or emerging problems, if any	PCP, nurse and clinical pharmacist	

continued

TABLE 33 Intervention characteristics from RCTs (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement	Other care received by the IG
Yehle <i>et al.</i> (2009) <sup>31</sup>	Shared medical visit		Participants privately saw the clinic's one nurse practitioner for a 10-minute physical examination and met in a group of up to six other patients with HF, plus a friend or family member, for a 1-hour semistructured education and support group. Half of the IG had physical examination before group time and half received it after group time. Education was provided by a nurse practitioner and the primary investigator. Medications and recent laboratory results were also discussed	Nurse practitioner	No details
			Participants in the control group saw the nurse practitioner for one-on-one 30-minute visit. Participant received physical examination and time to ask questions related to living with HF in addition to discussing medications and recent laboratory results. Family member may or may not have been present for the follow-up appointment		

APCC, adult primary care centre; BP, blood pressure; CV, cluster visit; DM, diabetes mellitus; EPIC, Empowering Patients in Care; GMC, group medical clinic; HF, heart failure; IG, intervention group; PCP, primary care physician; VA-MEDIC, Veterans Affairs Multidisciplinary Education in Diabetes and Intervention for Cardiac risk reduction; VA-MEDIC-D, Veterans Affairs Multidisciplinary Education in Diabetes; VA-MEDIC-E, Veterans Affairs Multidisciplinary Education in Diabetes and Intervention for Cardiac risk reduction – Extended.

## Appendix 5 Ongoing clinical trials

TABLE 34 Details of ongoing clinical trials

Official study title	Organisation	Intervention	Comparator	Sponsor and ClinicalTrials.gov ID	Funding start/stop	Status
A randomised controlled study: effects of shared medical appointments (SMAs) on parental quality of life and disease severity of children with atopic dermatitis	University-affiliated clinic	Three SMAs in outpatient clinic of Pediatric Dermatology UMC Utrecht	Three face-to-face consults in outpatient clinic of Pediatric Dermatology UMC Utrecht	The Foundation for Children's Welfare Stamps (Netherlands)	November 2009–May 2013	Study has been completed
Interprofessional Training for Improving Diabetes Care	Government	SMAs to promote establishing collaborative teams (the ReSPECT trial)	Traditional diabetes education and teleconsultation	Department of Veterans Affairs NCT00854594	September 2010–September 2012	Study has been completed
Initiating Diabetic Group Visits in Newly Diagnosed Diabetics in an Urban Academic Medical Practice	University-affiliated clinic	Group visit	Standard individual medical appointment	Oregon Health and Science University NCT01497301	February 2012–February 2013	Recruitment status of study unknown because information has not been verified recently
Heart Failure Group Clinic Appointments: Rehospitalization	University-affiliated clinic	Heart failure group clinic appointments	Standard heart failure education	Carol Smith NCT00439842	March 2007–September 2012	Study ongoing, but not recruiting participants
Group Intervention for DM Guideline Implementation	Government	Pharmacist-led GMVs for patients with type 2 DM	Usual care	Department of Veterans Affairs NCT00554671	May 2008–June 2012	Study has been completed

DM, diabetes mellitus; ID, identification; UMC, University Medical Centre.

## Appendix 6 Other UK group clinic initiatives identified

The following UK group clinic initiatives were identified during the course of the project. Contact was made with any projects identified early in the course of the review. Other projects are listed for the sake of completeness.

**TABLE 35** Ongoing UK group clinic initiatives

Title of initiative	Disease condition	Details	Contact details
Northumbria Osteoporosis Project: Group Clinics	Osteoporosis	National Osteoporosis Society Northumbria Healthcare NHS Trust	Mrs Norma Cardill, North Tyneside General Hospital, Rake Lane, North Shields, Tyne and Wear, NE29 8NH. Telephone: XXXX
Pilot study of acupuncture in a group setting for chronic knee pain: ScrutiKnee	Chronic knee pain	National Institute for Health Research Research for Patient Benefit Plymouth Hospitals NHS Trust	Dr Liz Tough, Plymouth Hospitals NHS Trust, ITTC Building, 1 Tamar Science Park, Davy Road, Plymouth, Devon, PL6 8BX XXXX
Transforming our insulin pump service	Diabetes	Nottingham University Hospitals NHS Trust, Nottingham, UK	Kay S, Soar C, Page RCL. Transforming our insulin pump service. Diabetic Medicine Conference: Diabetes UK Professional Conference, 7–9 March 2012, Glasgow, UK. <i>Diabetes Med</i> 2012; <b>29</b> :99–100





## Appendix 7 Existing systematic reviews related to group clinics

TABLE 36 Systematic reviews with outcome measures and results

Reference	Total number of patients	Biologic markers	Other outcomes/measurements
Edelman <i>et al.</i> (2014) <sup>55</sup>	(2921 in RCTs; 326 in OS)	<p>Haemoglobin: SMAs improved HbA<sub>1c</sub> (<math>\Delta = -0.55</math> percentage points, 95% CI <math>-0.11</math> to <math>-0.99</math> percentage points); HbA<sub>1c</sub> result had significant heterogeneity among studies, likely to be secondary to heterogeneity among included SMA interventions</p> <p>BP: SMAs improved systolic BP (<math>\Delta = -5.2</math> mmHg, 95% CI <math>-3.0</math> to <math>-7.4</math> mmHg)</p> <p>Cholesterol: SMAs did not improve LDL cholesterol (<math>\Delta = -6.6</math> mg/dl, 95% CI <math>2.8</math> to <math>-16.1</math> mg/dl)</p>	Non-biophysical outcomes, including economic outcomes, were reported too infrequently to meta-analyse or to draw conclusions from
Rolfe <i>et al.</i> (2014) <sup>56</sup>	11,063 patients	None	Trials showing small but statistically significant increase in trust included a trial of group visits for new inductees into a health maintenance organisation and a trial of group visits for diabetic patients. However, trust was not affected in subsequent larger trial of group visits for uninsured people with diabetes. There was no evidence of harm from any of the studies
CADTH (2013) <sup>52</sup>	Not stated	<p>Glycaemic control: better glycaemic control achieved for group care vs. usual care</p> <p>BP: one included study found that for adults with hypertension better control of BP is achieved with group care vs. usual care</p> <p>There was no information on the effectiveness of group care for COPD or HIV/AIDS</p>	No cost-effectiveness evaluations of group care models were identified. No evidence-based guideline specifically on group care for chronic disease management was identified. One guideline on diabetes management recommended that diabetes education should be delivered in groups or individually, but did not recommend a preferred model
Housden <i>et al.</i> (2013) <sup>53</sup>	2240 patients	<p>HbA<sub>1c</sub>: there were clear benefits of GMVs for HbA<sub>1c</sub> levels, which are consistent post-intervention and change from baseline effect sizes. The most significant effect is change from baseline results</p> <p>BP: there was some evidence for post-intervention, and change from baseline, systolic BP improvement at 9–12 months' interval and change from baseline improvement at 4 years</p> <p>Cholesterol: there was no evidence that GMVs improve LDL cholesterol values</p>	None reported

continued

TABLE 36 Systematic reviews with outcome measures and results (continued)

Reference	Total number of patients	Biologic markers	Other outcomes/measurements
Slyer and Ferrara (2013) <sup>54</sup>	108 participants (52 in RCT)	Two studies: one RCT (52 participants) and one cohort study (56 participants)	<p>The review examined knowledge, quality of life, self-care and readmissions</p> <p>Knowledge: the RCT reported statistically significant improvement in heart failure knowledge at 8 weeks, compared with control, which was not maintained at 16 weeks</p> <p>Quality of life and self-care: there were no statistically significant differences in self-care and health-related quality of life between groups at 8 and 16 weeks</p> <p>Readmissions: no trial data</p>
Edelman <i>et al.</i> (2012) <sup>18</sup>	4157 patients	<p>10 out of 13 RCTs evaluating outcomes for patients with diabetes examined type 2 diabetes only and one examined type 1 only. Two examined a mixed patient population</p> <p>HbA<sub>1c</sub>: studies enrolled patients with poor glucose control (thresholds varied from HbA<sub>1c</sub> 6.5% to &gt; 9%); a minority required elevated BP or lipids. All studies reported effects on average HbA<sub>1c</sub> at the end of intervention. SMAs associated with lower HbA<sub>1c</sub> vs. usual care at 4 to 48 months' follow-up (mean difference = -0.55, 95% CI -0.99 to -0.11). Effects varied significantly across studies; this was not explained by study quality</p> <p>Cholesterol: eight studies reported effects on either total or LDL cholesterol, showing small but statistically non-significant treatment effects that varied across studies</p> <p>BP: five studies reported effects on systolic BP, showing consistent and statistically significant effect (mean difference = -5.2, 95% CI -7.40 to -3.05)</p>	<p>Two trials described effects on patient experience. Neither showed greater satisfaction for SMAs vs. usual care</p> <p>Quality of life: five studies reported large improvements in health-related quality of life (SMD = -0.84; 95% CI -1.64 to -0.03). Effects were greater for disease-specific measures. Findings from OS were generally consistent with RCTs</p> <p>Admissions/ED visits: effects of SMAs on hospital admissions and ED visits were explored in five studies on patients with diabetes. In three out of the five studies admission rates were lower with SMAs. The result was statistically significant in only one study. Two studies found that ED visits decreased significantly with SMAs</p> <p>Costs: four studies reported effects on total costs. Results were mixed. In one, total costs significantly higher; in another, total costs were significantly lower; in the third, results did not differ significantly; and the fourth was conducted in Europe</p> <p>Health-care utilisation: two RCTs and one OS evaluated effects of SMAs on older adults with high health-care service utilisation rates. All studies reported positive effects on patient experience for SMAs vs. usual care. Both trials reported no difference vs. usual care for overall health status and functional status. Biophysical outcomes were not reported</p> <p>Hospital admissions/ED visits: three studies (two RCTs and one OS) showed fewer hospital admissions in SMA groups. Both trials reported statistically significant decrease in ED visits for SMAs vs. usual care. Total costs were lower for SMA group in each study but varied substantially across studies. They did not reach statistical significance for any study</p>

TABLE 36 Systematic reviews with outcome measures and results (continued)

Reference	Total number of patients	Biologic markers	Other outcomes/measurements
Steinsbekk <i>et al.</i> (2012) <sup>51</sup>	2833 participants	<p>4 out of 10 participants were male, baseline age = 60 years, BMI 31.6 kg/m<sup>2</sup>, HbA<sub>1c</sub> 8.23%, diabetes duration 8 years. 82% used medication</p> <p>HbA<sub>1c</sub> reduced at 6 months (0.44 % points; <math>p = 0.0006</math>, 13 studies, 1883 participants), 12 months (0.46 % points; <math>p = 0.001</math>, 11 studies, 1503 participants) and 2 years (0.87 % points; <math>p &lt; 0.00001</math>, three studies, 397 participants)</p> <p>Blood glucose: fasting blood glucose levels reduced at 12 months (1.26 mmol/l; <math>p &lt; 0.00001</math>, five studies, 690 participants) but not at 6 months</p>	<p>Knowledge: diabetes knowledge improved at 6 months (SMD 0.83; <math>p = 0.00001</math>, six studies, 768 participants), 12 months (SMD 0.85; <math>p &lt; 0.00001</math>, five studies, 955 participants) and 2 years (SMD 1.59; <math>p = 0.03</math>, two studies, 355 participants)</p> <p>Self-management: self-management skills improved at 6 months (SMD 0.55; <math>p = 0.01</math>, four studies, 534 participants). Improvement for empowerment/self-efficacy (SMD 0.28; <math>p = 0.01</math>, two studies, 326 participants) after 6 months</p> <p>Quality of life: no conclusion could be drawn due to high heterogeneity</p> <p>Other outcomes: significant improvements in patient satisfaction and body weight at 12 months for IG. No differences between groups in mortality rate, BMI, BP and lipid profile</p>
Burke <i>et al.</i> (2011) <sup>87,88</sup>	2240 patients	<p>HbA<sub>1c</sub>: clear benefits of GMVs for patients' HbA<sub>1c</sub> levels which are consistent in the post-intervention and change from baseline effect sizes. Most significant effect is with change from baseline results</p> <p>BP: evidence suggests post-intervention and change from baseline systolic BP improvement at 9- to 12-month interval and change from baseline improvement at the 4-year time frame</p> <p>Cholesterol: no evidence that group visits improve LDL cholesterol values of GMV participants</p>	No details
Riley and Marshall (2010) <sup>49</sup>	Not stated	HbA <sub>1c</sub> , BP, lipids: diabetes-focused group visits that incorporate group education and a health provider office visit vs. traditional brief office visit failed to demonstrate consistent statistical improvement in HbA <sub>1c</sub> , BP or lipids	Other outcomes: group visits may reduce costs, some physiological outcomes may be improved, and patient and clinician satisfaction may be enhanced
Jaber <i>et al.</i> (2006) <sup>48</sup>	Not stated	None	<p>Although heterogeneity renders assessment of group visit model problematic, there are sufficient data to support the effectiveness of group visits in improving patient and physician satisfaction, quality of care and quality of life, and in decreasing ED and specialist visits</p> <p>Future research may benefit, however, from abandoning old nomenclatures and clearly defining structure, processes of care, content of visits and appropriate outcome measures</p>

continued

TABLE 36 Systematic reviews with outcome measures and results (*continued*)

Reference	Total number of patients	Biologic markers	Other outcomes/measurements
Deakin <i>et al.</i> (2005) <sup>47</sup>	1532 participants	<p>Haemoglobin: results favour group-based diabetes education programmes for reduced HbA<sub>1c</sub> at 4–6 months (1.4%, 95% CI 0.8% to 1.9%; <math>p &lt; 0.00001</math>), at 12–14 months (0.8%, 95% CI 0.7% to 1.0%; <math>p &lt; 0.00001</math>) and 2 years (1.0%, 95% CI 0.5% to 1.4%; <math>p &lt; 0.00001</math>)</p> <p>Blood glucose levels: reduced fasting blood glucose levels at 12 months (1.2 mmol/l, 95% CI 0.7 to 1.6 mmol/l; <math>p &lt; 0.00001</math>)</p> <p>BP: reduced systolic BP at 4–6 months (5 mmHg, 95% CI 1 to 10 mmHg; <math>p = 0.01</math>)</p>	<p>Reduced body weight at 12–14 months (1.6 kg, 95% CI 0.3 to 3.0 kg; <math>p = 0.02</math>); improved diabetes knowledge at 12–14 months (SMD 1.0, 95% CI 0.7 to 1.2; <math>p &lt; 0.00001</math>)</p> <p>Reduced need for diabetes medication (odds ratio 11.8, 95% CI 5.2 to 26.9; <math>p &lt; 0.00001</math>; RD = 0.2; NNT = 5). For every five patients attending a group-based education programme, one patient would reduce diabetes medication</p>

BP, blood pressure; ED, emergency department; IG, intervention group; NNT, number needed to treat; OS, observational study; RD, risk difference; SMD, standardised mean difference.

## Appendix 8 Characteristics of qualitative studies and surveys

TABLE 37 Population characteristics: qualitative studies

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Recruitment to qualitative research	Participants
Asprey <i>et al.</i> (2012) <sup>97</sup>	Knee osteoarthritis	Participation in one of three clinics for acupuncture for knee osteoarthritis	10 women and six men aged 49–89 years	None given	Patients from clinics in two general practices in St Albans and the Royal London Hospital	Nurses asked to give information packs to approximately the same numbers of men and women and to approach as wide an age range of patients as possible. Four out of six nurses agreed to participate
Capello (2008) <sup>98</sup>	Hypertension	Participants from CTVHCS. No exclusion of any racial/ethnic group in recruitment. Participants were military veterans with hypertension as diagnosed by CTVHCS medical personnel: elevated systolic BP readings $\geq 140$ mmHg and diastolic BP readings $\geq 63$ –90 mmHg	Because of the high percentage of men receiving care from the CTVHCS, the entire sample of study participants were men	Medical or psychological conditions that may inhibit optimal functioning of group intervention (e.g. physiological diagnoses of hearing loss and psychological diagnoses as defined by DSM-IV TR [e.g. dementia, schizophrenia and schizophrenia-related disorders and other psychotic disorders (e.g. dissociative disorders and mental disorders due to a general medical condition)]). Other psychological exclusionary criteria included diagnosis of any Axis Two disorders (DSM-IV TR). Review of patient medical files assessed exclusion criteria	After pre-screening, prospective participants were contacted by telephone and invited to take part in a programme geared towards helping individuals who suffer from hypertension learn ways in which to better manage their own health. Individuals who agreed to programme enrolment were asked to attend four meetings in total in addition to one brief telephone contact after the intervention	A random sample of 30 participants who completed the programme were contacted. In addition, a random sample of seven individuals who failed to attend all DIGMA meetings were contacted

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Recruitment to qualitative research	Participants
Cohen <i>et al.</i> (2012) <sup>99</sup>	Obesity, metabolic disorders and smoking cessation (excluded)	Participation in three existing SMAs	Mean age ( $n = 17$ ) was 62 years (range 39–85 years). 94% of sample ( $n = 16$ ) was male. Ethnicity was closely divided between Caucasians ( $n = 9$ ; 53%) and African Americans ( $n = 8$ ; 47%). Majority of purposive sample was unemployed or retired ( $n = 12$ ; 70.6%). Inclusion criteria included current enrolment, English-speaking, adequate ability to hear, and under the age of 89 years with documentation of participation in SMAs	No details	17 people participated in focus groups (September 2011–January 2012) out of 145 veterans contacted	Sampling continued until all researchers agreed that saturation had been met and no new insights would be identified
Hroszkowski <i>et al.</i> (2006) <sup>100</sup>	Diabetes and depression	None given	None given	None given	No details	45 semistructured interviews with organisational leaders, external and internal change leaders, mid-level clinic managers, medical and administrative clinic leaders, front-line physicians and nurses (53 persons)

continued

TABLE 37 Population characteristics: qualitative studies (continued)

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Recruitment to qualitative research	Participants
Kirsh <i>et al.</i> (2009) <sup>27</sup>	Diabetes	Not relevant	Students on interprofessional course	No details	Students enrolled in Veteran Affairs rotation participating in four SMAs	12 medical students observing SMAs plus 11 undergoing control
Lavoie <i>et al.</i> (2013) <sup>101</sup>	Diabetes, heart disease/ hypertension, providers; arthritis  Just over half (n = 16) reported 3+ chronic conditions (%): <ul style="list-style-type: none"> <li>● Diabetes 58.6</li> <li>● Arthritis 48.3</li> <li>● High BP 51.7</li> <li>● Depression 34.5</li> <li>● Heart disease 20.7</li> <li>● Other: kidney disease 10.3</li> <li>● Other: cholesterol 6.9</li> <li>● Other++ 27.6</li> </ul> ++ patients were asked to report all chronic diseases where they were given a diagnosis	Self-reported health (1–5) + Mean (SD) (1.1)  Notes: +higher score = better health	Mean age (SD) 62.0 years (16.0 years)  Gender (% female) 65.5  Ethnicity (%): <ul style="list-style-type: none"> <li>● Caucasian 55.2</li> <li>● Aboriginal (%)</li> <li>● First Nation 41.4</li> <li>● Métis 3.5</li> </ul> Marital status (%): <ul style="list-style-type: none"> <li>● Married 79.3</li> </ul> Income (%): <ul style="list-style-type: none"> <li>● &lt; \$20,000 37.9</li> <li>● \$20,000–29,999 20.7</li> <li>● \$30,000–39,999 20.7</li> <li>● &gt; \$40,000 13.9</li> <li>● Missing 6.9</li> </ul>	Had attended a GMV (average of four GMVs in the previous year). 24 patients attended homogenous GMV where all in attendance shared similar diagnosis (e.g. pain or diabetes) and five attended heterogeneous GMV where diagnoses were mixed  Type of GMV attended (%): <ul style="list-style-type: none"> <li>● CHCC model/ homogenous 82.8</li> <li>● DIGMAs/mixed 17.2</li> </ul>	Number of chronic conditions (%):  Range 0–7 <ul style="list-style-type: none"> <li>● 0 10.3</li> <li>● 1 6.9</li> <li>● 2 27.6</li> <li>● 3 or more 55.2</li> </ul> GMVs attended in past year: <ul style="list-style-type: none"> <li>● Range 1–15</li> <li>● Mean (SD) 4 (3.0)</li> </ul>	



Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Recruitment to qualitative research	Participants
McCuijston <i>et al.</i> (2014) <sup>102</sup>	General chronic disease	N/A	Medical and administrative staff ( <i>n</i> = 12) involved with implementation of SMAs at three geographically distinct, semiautonomous divisions of medical group	No details	No details	Data collected by conducting key informant interviews focusing on SMA implementation process, including motivations, history, barriers and facilitators
Mejino <i>et al.</i> (2012) <sup>103</sup>	Type 1 diabetes	Children, adolescents, parents and health-care providers	Understand and speak Dutch Aged between 6 and 18 years Scheduled to have a SMA	No details	Parents who had previously attended SMA were asked to participate in an online focus group to exchange their experiences of SMAs with other parents	Online focus group of eight parents
Miller <i>et al.</i> (2004) <sup>104</sup>	At least one chronic disease diagnosis	No details	Low-income women with chronic disease	71% Latina	No details	No details
Oybiagele (2010) <sup>105</sup>	Stroke	No details	Elderly Spanish-only-speaking stroke patients	No details	13 Spanish-only-speaking participants aged ≥ 60 years discharged from a local government hospital in Los Angeles within 18 months of an index ischaemic stroke	13 Spanish-only-speaking participants aged ≥ 60 years, 6 caregivers, 11 care providers and 9 administrators at hospital

continued

TABLE 37 Population characteristics: qualitative studies (continued)

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Recruitment to qualitative research	Participants
Piper (2011) <sup>106</sup>	Diabetes	No details	Adults over the age of 19 who resided in Northern Health Authority and who had participated in at least one medical group visit in primary health-care delivery within the past year. Participants had to be able to understand and speak English	Excluded GMV participants who were First Nations	Communities and primary care practices in Northern Health Authority that offer GMVs were asked to identify possible participants. The research team contacted participants by telephone, answered questions and set up telephone or face-to-face interviews	Five women and four men
Wong <i>et al.</i> (2013) <sup>107</sup>	Diabetes	Not relevant	For patient participants: (1) adults aged 19 years or older; (2) living in rural community in Northern Health, and (3) no significant cognitive impairment. Providers recruited if they had either provided or taken part in GMVs in past year	No details	Rural practices delivering PHC and First Nations communities identified by Northern Health Authority partner as potential participants  Rural practices and First Nations communities were recruited if they had offered GMVs for more than 2 years. Nine communities (five family physician-led primary care practices and four First Nations communities) agreed to participate	34 PHC providers and 29 patients living in nine rural communities in British Columbia, Canada

CTVHCS, Central Texas Veterans Healthcare System; DSM-IV, *Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition*; DSM-IV TR, *Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition Text Revision*; N/A, not applicable; PHC, primary health care; SD, standard deviation.

TABLE 38 Characteristics of included surveys

Study	Health condition	Details about health condition and inclusion criteria	Other non-health characteristics	Exclusion criteria (health or non-health)	Recruitment to qualitative research	Participants
Hirsh <i>et al.</i> (2001) <sup>108</sup>	Endometriosis	History of pelvic pain of at least 3 months' duration and laparoscopic confirmation of pelvic endometriosis. Either consecutive visitors to outpatient gynaecology clinic or consecutive surgical admissions over 3 months	Average age = 62 years, mostly female, and married. Patients reported either Caucasian (55%) or Aboriginal descent – most were First Nations (41%). Almost half of patient participants reported household income of less than CA\$30,000	No details	No details	Nine parents wanted to participate, of whom eight (seven mothers, one father) actually did
Jhagroo <i>et al.</i> (2013) <sup>109</sup>	Kidney stones	Patients largely calcium or mixed-calcium stone formers (95%), recurrent (90%) and Caucasian (94%)	Patients (mean age 51 ± 14 years, range 19–87 years) seen in 27 SMAs during 14 months. Of these, 55% were women and significantly younger than males (48 ± 14 vs. 55 ± 12 years, respectively; <i>P</i> = 0.007)	Not specified	All attenders at clinics over 14 months	No further details
Lock <i>et al.</i> (2012) <sup>96</sup>	Haemophilia and von Willebrand's disease	Less experienced group (28 families with 30 children; 17 with haemophilia A, 2 with haemophilia B and 11 with von Willebrand's disease)  Experienced group (10 families with 11 children: 10 with haemophilia A and 1 with haemophilia B)	No details	3 out of 103 families (total of six children) excluded from participation in GMA owing to language problems	No details	A total of 69 parents returned questionnaire on expectations of a GMA; results of patients > 12 years ( <i>n</i> = 14) and parents ( <i>n</i> = 38) undergoing both IMA and GMA are presented
Trotter and Schneider (2012) <sup>110</sup>	Breast cancer	No details	Breast cancer survivors	No details	No details	A 22-item Likert-type questionnaire sought opinions regarding logistics and the class and function of care delivered. 122 surveys were collected

TABLE 39 Intervention details: qualitative studies

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement
Asprey <i>et al.</i> (2012) <sup>97</sup>	Group clinics	Socialisation, group information sharing	Not given	Nurses
Capello (2008) <sup>98</sup>	DIGMA	Pre meetings: chart review and telephone recruitment Orientation session: informed consent and baseline measures Session 2: initial BP reading; stress component Session 3: nutrition and exercise Session 4: medication compliance Post-BP reading and post-test measures Telephone session: contact to assess qualitative component	Before participation, all participants completed a set of self-report psychological inventories during the initial orientation meeting. One week afterwards, participants attended the first of three components of the intervention. Each meeting occurred weekly for an hour and a half on Wednesday mornings. During each meeting, primary care practitioners were on hand to monitor subjects' physiological well-being and make any necessary changes to treatment. This study took place over the course of four separate face-to-face appointments and one telephone meeting. The structure of these meetings included one orientation meeting and three group appointments as well as one individual telephone interview appointment	PCPs and other primary care staff
Cohen <i>et al.</i> (2012) <sup>99</sup>	SMA	No details	MOVE, MAGIC and smoking cessation SMAs were offered to veterans at VAMC in Salem, Virginia. The main focus of the MOVE programme was nutrition, weight loss and increasing physical activity. The MAGIC programme focused on diabetes, hypertension, weight control and hyperlipidemia management. The programmes incorporated motivational interviewing techniques and addressed depression, anxiety, stress management and coping strategies. The contents of programmes overlapped and complemented each other	Collaborative programmes included experts in primary care, health behaviour change and mental health, nutrition, exercise and smoking cessation

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement
Hirsh <i>et al.</i> (2001) <sup>108</sup>	DIGMIAS	Health education/information presentation(s) by multiple clinicians	A total of 32 women with confirmed endometriosis were asked to discuss the potential benefits of the establishment of a specialist endometriosis clinic	No details given
Hroszkowski <i>et al.</i> (2006) <sup>100</sup>	Chronic care model	No details	No details	Prepared practice teams made up of a clinician and a rooming nurse and supplemented by a registered nurse and a receptionist shared among three contiguous teams. Core prepared practice team was understood to have an expanded version that included other clinicians
Jhagroo <i>et al.</i> (2013) <sup>109</sup>	Adapted aspects of three models: DIGMA, CHCC and physical SMA	Health education/information presentation(s) by multiple clinicians	After collecting consent forms each visit began with a presentation introducing patients to SMA and providing general background information. This included epidemiology, renal physiology, pathophysiology and risk factors followed by focused diet assessment of each patient, conducted by the Registered Dietitian. Then the Registered Dietitian gathered individual medical histories and reviewed each patient's 24-hour urine study, which was projected at the front of the room. Next, clinical decisions regarding medical and nutritional management were discussed with patients in a group setting. Each patient was provided with a checklist identifying his or her specific risk factors. Finally, nutrition education was provided, including practical strategies to address common risk factors. Patients were reminded to focus particularly on therapies for individual risk factors as identified during the individual rounds. At the end of the visit the Registered Dietitian left and the medical assistant returned to administer a patient satisfaction survey and two brief tests to determine patient understanding of the core nutrition concepts. At check-out, patients received follow-up information and scheduled their next appointment	No details

continued

TABLE 39 Intervention details: qualitative studies (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement
Kirsh <i>et al.</i> (2009) <sup>27</sup>	SMA	Not relevant	SMA structured in four phases: (1) welcome and introduction to the group format with patient and staff introductions (5–15 minutes); (2) group discussion of diabetes-related topics, e.g. patient goals and 'ABCs' of diabetes (20–30 minutes); (3) patients and families/caregivers sharing experiences (44–55 minutes); and (4) individual visits in examination rooms for medication titration, note writing and development of an individualised treatment plan (10–15 minutes)	Diabetes SMA staffed by a physician (non-endocrinologist), a nurse practitioner, a health psychologist, a clinical pharmacist and a nutritionist
Lavoie <i>et al.</i> (2013) <sup>101</sup>	GMV	Social event: patients and providers emphasised the importance of the social component of GMV  Affiliation: both providers and patients highlighted that social element results in a shift in power, in part because of the presence of peers with shared experiences, but also because providers share the role of adjudicator with the patients attending the GMV  Coproduction of GMV: providers highlighted key differences between one-on-one and GMV formats, namely that GMV is coproduced by provider(s) and group	Opportunistic sample of any patients/providers with recent experience of GMVs. A total of 63 participants completed in-depth interview to provide their experiences with GMVs	Providers interviewed included family physicians (n = 10), nurses (n = 7), nurse practitioners (n = 2), PHC co-ordinators (n = 4), other Allied Health Professionals (n = 1) such as nutritionists and social workers, and supportive personnel, such as medical office assistants and community health representatives, involved in delivering a variety of GMVs

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement
Lock <i>et al.</i> (2012) <sup>96</sup>	GMA	Group information sharing with multiple professionals	All haemophilia professionals trained in different aspects of GMA management, including GMA setting and practical aspects. During the GMA, the physician proceeds as in an individual appointment under the supervision of a chairperson, in presence of other patients, parents and other haemophilia caretakers. Chairperson hosts session and facilitates group process, while monitoring the allotted time. At the beginning of each GMA, the chairperson emphasises the confidentiality of the shared experiences and the explicit oral informed consent of participants is obtained. General disease topics are discussed collectively under the supervision of the chairperson	Treating physician, haemophilia nurse, physiotherapist, social worker, clinical geneticist, guests depending on availability and topics. One medical caretaker functions as chairperson
McCouston <i>et al.</i> (2014) <sup>102</sup>	SMA	No details	No details	No details
Mejino <i>et al.</i> (2012) <sup>103</sup>	SMA		Hospitals in west, east and south parts of the Netherlands. SMAs conducted by 36 health-care providers. Each health-care team consisted of 3–6 health-care providers, such as paediatricians, diabetes nurses and psychologists. One of these providers was also moderator during a SMA	Hospital physician, general nurse, dietitian
Miller <i>et al.</i> (2004) <sup>104</sup>	GMV	Personalised attention, self-care education, access to medication refills and examinations, and advice from peers	On average, patients required 20 minutes of physician time plus 21 minutes of nurse practitioner time per session	Physician, nurse practitioner
Ovbiagele (2010) <sup>105</sup>	Group clinic	No details	No details	No details
Piper (2011) <sup>106</sup>	GMV	No details	All GMVs that participants attended were centred on chronic conditions, including diabetes, chronic pain, fibromyalgia, and heart disease and were heterogeneous according to sex	No details

continued

TABLE 39 Intervention details: qualitative studies (continued)

Study	Intervention model	Intervention components	Description of intervention	Clinical involvement
Trotter and Schneider (2012) <sup>10</sup>	GMA	Socialisation, monitoring, group information sharing with multiple professionals; individual examinations	<p>There was a 15-minute check-in period during which patients took their own vital signs and updated their treatment summary and care plan on an institution-specific document hand-generated by the NP prior to the visit. This was followed by a 45-minute facilitated group discussion with six survivors. Structured with the initial completion of a self-assessment sheet, the discussion often revolved around chronic issues (e.g. menopausal symptoms, bone health, libido issues, insomnia and latest media information about cancer). Then participants moved to individual exams with NP, but some first went (often in tandem, as extension of group camaraderie) for their mammogram and returned later for exam. Between the examination and the mammogram, participants spent time discussing nutritional issues with the dietitian or stress management/relationship issues with the social worker. Before exiting, the NP reviewed the individual treatment summary care plan with each patient. The NP completed a specific health-care plan, including recommendations for various cancer screenings, while the patient wrote both her short-term and her long-term personal goals. Patients took approximately 2.5 hours to completely work through all services. If abnormal findings were noted NP further evaluated them, referring the patient to a primary oncologist when indicated</p>	NP, registered dietitian, physical therapist, and social worker were present for sessions



Study	Intervention model	Intervention components	Description of intervention	Clinical involvement
Wong <i>et al.</i> (2013) <sup>107</sup>	GMV	Socialisation, monitoring, group information sharing with multiple professionals; individual examinations	GMVs were typically facilitated by a family physician or a nurse practitioner. GMVs offered all components of an individual clinical encounter but were delivered to groups of patients ranging in size from 12 to 20 individuals. GMVs were unique in delivering medical care, health promotion, chronic disease management, health education and group support simultaneously. There were two broad types of GMVs: (1) 'homogeneous' – (a) CHCCs and (b) physicals and SMAs; and (2) 'heterogeneous' or DIGMAs	Providers included family physicians, nurses, nurse practitioners, PHC co-ordinators, other allied health workers, e.g. nutritionists, social workers, medical office assistants and community health representatives

BP, blood pressure; IMA, individual medical appointment; MAGIC, Metabolic Assistance Group Intervention Clinic; MOVE, Managing Overweight/Obesity For Veterans Everywhere; NP, nurse practitioner; PCP, primary care physician; PHC, primary health care; VAMC, Veteran Affairs Medical Centre.



## Appendix 9 Data extraction elements

**TABLE 40** Elements of data extraction form

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Concept
Population
Facilitation
Group size
Components
Frequency
ACCESS AND CONVENIENCE
Duration
Follow-up
PEER SUPPORT
Appraisal support
Informational support
Emotional support
Instrumental support
Team composition
Other contacts
Patient characteristics
Built environment
Social support
PARTNER SUPPORT
SUPPORT FROM HEALTH PROFESSIONAL
Appraisal support
Informational support
Emotional support
Instrumental support
Adherence
Physical signs and symptoms (was biophysical markers)
Self-efficacy
Patient participation
Long-term symptom management)
Psychological status (was functional status)
Quality of life
ED visits
Rehospitalisations
Unplanned primary care office visits
Mortality
Costs
Patient confidentiality
Patient (non) participation
Missed appointments

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ED, emergency department.



## Appendix 10 Criteria used in quality assessment

For quality assessment of RCTs we used the CASP checklist for RCTs<sup>44</sup> and the Cochrane risk of bias tables.<sup>45</sup>

For quality assessment of qualitative studies we used the CASP checklist for qualitative studies.<sup>46</sup> There is no qualitative equivalent of the Cochrane risk of bias tables. Indeed, the effect of bias on quantitative research is currently unknown and requires further exploration.

- Was there a clear statement of the aims of the research?
- Is a qualitative methodology appropriate?
- Was the research design appropriate to address the aims of the research?
- Was the recruitment strategy appropriate to the aims of the research?
- Were the data collected in a way that addressed the research issue?
- Has the relationship between researcher and participants been adequately considered?
- Have ethical issues been taken into consideration?
- Was the data analysis sufficiently rigorous?
- Is there a clear statement of findings?





A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

**EME**  
**HS&DR**  
**HTA**  
**PGfAR**  
**PHR**

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