

University of Groningen



Group medical appointments for people with physical illness

Seesing, Femke M.; Zijlstra, Wieneke; Pasmans, Suzanne G.M.A.; L'Hoir, Monique P.; Drost, Gea; van Engelen, Baziel G.M.; van der Wilt, Gert Jan

Published in: Cochrane Database of Systematic Reviews

DOI: 10.1002/14651858.CD010721

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version Publisher's PDF, also known as Version of record

Publication date: 2013

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA): Seesing, F. M., Zijlstra, W., Pasmans, S. G. M. A., L'Hoir, M. P., Drost, G., van Engelen, B. G. M., & van der Wilt, G. J. (2013). Group medical appointments for people with physical illness. *Cochrane Database of Systematic Reviews*, *2013*(10), [CD010721]. https://doi.org/10.1002/14651858.CD010721

Copyright Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: https://www.rug.nl/library/open-access/self-archiving-pure/taverneamendment.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): http://www.rug.nl/research/portal. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.



Cochrane Database of Systematic Reviews

Group medical appointments for people with physical illness (Protocol)

Seesing FM, Zijlstra W, Pasmans SGMA, L'Hoir MP, Drost G, van Engelen BGM, van der Wilt GJ

Seesing FM, Zijlstra W, Pasmans SGMA, L'Hoir MP, Drost G, van Engelen BGM, van der Wilt GJ. Group medical appointments for people with physical illness. *Cochrane Database of Systematic Reviews* 2013, Issue 10. Art. No.: CD010721. DOI: 10.1002/14651858.CD010721.

www.cochranelibrary.com



TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
BACKGROUND	2
OBJECTIVES	5
METHODS	5
ACKNOWLEDGEMENTS	8
REFERENCES	9
APPENDICES	10
CONTRIBUTIONS OF AUTHORS	11
DECLARATIONS OF INTEREST	11
SOURCES OF SUPPORT	12



[Intervention Protocol]

Group medical appointments for people with physical illness

Femke M Seesing¹, Wieneke Zijlstra², Suzanne GMA Pasmans^{2,3}, Monique P L'Hoir⁴, Gea Drost⁵, Baziel GM van Engelen¹, Gert Jan van der Wilt⁶

¹Department of Neurology, Radboud University Medical Centre, Nijmegen, Netherlands. ²Department of Pediatric Dermatology and Allergology, UMC Utrecht, Wilhelmina's Children's Hospital, Utrecht, Netherlands. ³Department of Pediatric Dermatology, Children's Hospital, Erasmus University Medical Center, Rotterdam, Netherlands. ⁴Department of Child Health, TNO, Leiden, Netherlands. ⁵Department of Neurology, University Medical Centre Groningen, Groningen, Netherlands. ⁶Department for Health Evidence, Radboud University Nijmegen Medical Center, Nijmegen, Netherlands

Contact address: Gert Jan van der Wilt, Department for Health Evidence, Radboud University Nijmegen Medical Center, PO Box 9101, Nijmegen, 6500 HB, Netherlands. g.vanderwilt@ebh.umcn.nl.

Editorial group: Cochrane Consumers and Communication Group. **Publication status and date:** New, published in Issue 10, 2013.

Citation: Seesing FM, Zijlstra W, Pasmans SGMA, L'Hoir MP, Drost G, van Engelen BGM, van der Wilt GJ. Group medical appointments for people with physical illness. *Cochrane Database of Systematic Reviews* 2013, Issue 10. Art. No.: CD010721. DOI: 10.1002/14651858.CD010721.

Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of group medical appointments (GMAs) on the health status and well-being of patients with a primary physical illness as compared to one-to-one patient-clinician appointments.



BACKGROUND

Since Hippocrates' times, patients and clinicians have been meeting on a one-to-one basis. It is unclear, however, whether oneto-one appointments are the most effective and efficient way of informing patients about their health status and improving their ability to manage their own health and illness. Group medical appointments (GMAs) could be a valid alternative in outpatient care, leading to improved health status and well-being for patients with a primary physical illness (chronic or non-chronic). At the same time GMAs could help to make better use of one of the most precious resources in health care: time. In recent decades, GMAs have been offered to patients in various healthcare organisations in the US and other western countries. This protocol describes our methods for systematically analysing the effects of GMAs in outpatient care settings. For the purpose of this review, the term 'outpatient care' is used to cover a range of ambulatory care modes and includes care delivered in primary care, specialty clinics and hospital outpatient settings.

Description of the condition

GMAs are currently being offered to several patient groups with a primary physical illness, in outpatient care. Patient groups range from children and adults with diabetes, to patients recovering after bone marrow transplantation (Sadur 1999; Meehan 2006; Edelman 2010; Rijswijk 2010). Most of the patients who attend GMAs have a chronic condition needing continuous management, although GMAs are also delivered to patients with a non-chronic physical illness, for example a total hip or knee replacement. The focus of this review will be on patients with a primary physical illness, both chronic and non-chronic. Patients with a physical illness can have mental health issues as well. Most of the time mental health issues will be on the agenda during the GMA, particularly when they influence the course or management of the physical disease. However studies focusing solely on mental illness will not be included in this review.

Description of the intervention

A GMA is 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 to 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. In this review, carers can be spouses, partners, parents, children or other family members or friends who are closely involved with the patient's life. In a GMA the clinician may have more time to give information compared to a one-to-one clinician contact by not having to repeat information which is similar for all patients. This time can be redirected to more time for the patient's medical needs, psychosocial needs, patient education, and patient empowerment.

Distinction between GMAs and other group meetings

GMAs are not to be confused with meetings for a group of patients, such as group therapy, group education or peer support groups. As opposed to a GMA, the focus of these group meetings is not primarily medical issues, although the working mechanisms can be similar. The goal of a GMA is to substitute for a whole consultation with the clinician, whereas the other types of group meetings are often intended to substitute for one part of the consultation such as education, support or therapy (Noffsinger 2009; Zantinge 2009; Edelman 2010). The difference between GMAs and group therapy or a peer support group is that the GMA focuses primarily on management of the physical illness and secondarily on the additional psychosocial aspects, while group therapy or peer support groups primary focus on emotional, psychological or social matters. The difference between a GMA and group education relates to the agenda setting which is led by patients' individual questions during a GMA, compared with being pre-specified and clinician-led during group education.

Conceptual framework

There is large diversity in the design of GMAs, as well as the types of patients and clinicians involved in them. These issues pose key challenges for this review. We have devised a conceptual framework in order to provide a consistent approach to describe and assess the different types of GMAs. Our conceptual framework describes three key domains as shown below:

Conceptual framework for GMAs

Design	Patient Group	Team
Number of GMAs offered	Continuity versus non-continuity	Type of clinician
Time between successive GMAs	Heterogenous versus homogenous	Presence of group facilita- tor
Duration of GMA	Chronic versus non-chronic	Training of team
Number of patients per GMA	Children, adults, elderly	

Design

The design of the GMA has four components: number of GMAs offered (typically around 8 with a broad range from 1 to 36), time

between successive GMAs (from every month to every 3 months), number of patients per GMA (6 to 10 patients in most cases) and duration of the GMA (typically 2 hours with a range of 1 to 3.5 hours).

Differences in these components of the GMA could hypothetically be supposed to account for differences in effects on outcomes.

The effects on patients attending GMAs with a longer duration, or attending multiple GMAs, may be reinforced due to receiving repeated information. Participants attending multiple GMAs could feel more comfortable by becoming accustomed to the GMA care model and to other patients, which could improve satisfaction. Second, the number of patients who attend the GMA could influence outcome measures. Edelman 2010 suggested an ideal group size of 5 to 10 patients. Fewer patients endanger the interaction and information exchange, while more patients could make attention to individual needs more challenging . Time between successive GMAs might also influence outcomes. It is conceivable, for instance, that a long period between the GMAs (for example six months or longer) may reduce their effectiveness, compared with two GMAs in a short interval (for example one to three months). After a year patients have to make a new start in the group, and may forgotten information provided earlier.

Types of patient groups

Types of patient groups can be divided into continuity GMAs and non-continuity GMAs, heterogeneous or homogeneous patient groups, patients with chronic or acute illness and patients of different ages.

Non-continuity GMAs are free-standing and so different groups of patients may attend the appointments, although they usually comprise a homogenous group of patients with the same diagnosis. Non-continuity groups can be divided into drop-in groups where no scheduling is necessary in advance (the so-called Drop In Group Medical Appointments (DIGMAs)), and GMAs for which scheduling is necessary. GMAs, with the exception of DIGMAs, are usually diagnosis- or population-specific.

Depending on the design DIGMAs can consist of homogeneous or heterogenous patient groups with a different group of patients from appointment to appointment who 'drop in' to the appointment in the same day or week as their specific medical need arises (Pennachio 2003; Noffsinger 2003).

During continuity GMAs, patients are offered multiple appointments with the same cohort of patients during a given period of time (Pennachio 2003; Trilling 1999). The same group of patients attending every appointment may create a safe atmosphere in which patients feel free to ask their questions. In heterogenous groups with different diagnoses, patients might learn less from each other than patients in homogeneous groups with the same diagnoses. It is conceivable that GMAs in groups of patients with chronic illnesses show different effects compared to groups of patients with non-chronic illnesses. On the one hand, characteristics of a chronic disease (unexpected relapses and recoveries) may imply a higher need for peer support, and therefore reinforce the effect of peer support through a GMA. On the other hand peer support in non-chronic diseases may be less organised through patient advocacy groups. Consequently the effect of peer support through GMAs may have a bigger effect in people with nonchronic than in chronic diseases.

Patients of different ages may be offered GMAs; we consider the following different age groups: children (< 18 years), adults (18 to 65 years) and elderly people (over 65 years). Depending on

the preferences of the organisation, carers of the patients may be invited to attend the GMA. The attendance of carers may reinforce the positive effects of GMAs, for example by remembering more new information.

Team

The third key domain features the team of care providers conducting the GMA. We identify the profession of clinician, the presence of a group facilitator and the training of the GMA team as key features. The team usually consists of a clinician, a group facilitator and sometimes an administrator (Noffsinger 2009). The clinician is defined as a health professional whose consultations with the patient are substituted by the GMA. This can be a physician, physician assistant, specialised nurse, nurse practitioner or paramedical professional. Usually one clinician is present, but more than one may attend. The group mentor is a facilitator of the group process, who fosters interaction between fellow patients, and between patients and health professionals, and is responsible for time management. Consequently the attendance of a group facilitator may reinforce the effects of a GMA. This role can be occupied by different professionals, for example a psychologist, a behaviourist or a specialised nurse who is acquainted with group processes. Some GMAs are designed without an attending group mentor. The education or training of the GMA team can differ, from targeted training to 'learning by doing' and also depends on the background of the team members. A team trained in conducting GMAs, for example by learning extra interview techniques or managing group processes, may enhance the effects of GMAs.

Description of control intervention

The effects of GMAs will be compared to usual care defined as one-to-one patient-clinician appointments. Studies that include additional care such as telephone follow up or home visits alongside GMAs will not be included in this review.

How the intervention might work

Interest in GMAs derives from motivation on the part of consumers and healthcare providers to continuously search for the most effective and efficient way for care to be delivered. The effects of GMAs might be found on three different levels: patients and carers, clinicians and costs.

Patients and carers

In the literature, GMAs have been reported to result in fewer hospitalisations and emergency visits, increased patient satisfaction and increased self-efficacy as compared to usual one-to-one outpatient appointments in chronically-ill older patients (> 60 years) and improved self-efficacy and general health status in patients with diabetes (Sadur 1999; Wagner 2001; Scott 2004). In the latter group, a randomised controlled trial demonstrated more frequent preventive procedures among patients attending GMAs, resulting in better general health status (Scott 2004). Sadur 1999 found greater satisfaction with diabetes care, greater self-efficacy, better glycaemic control, and lower service utilisation among diabetic patients who were randomly allocated to GMAs as compared to their counterparts receiving usual care.

Evidence demonstrates that GMAs can have substantial added value, deriving not only from sharing a healthcare professional's time, but also from sharing mutual experiences, particularly for

Group medical appointments for people with physical illness (Protocol) Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.



patients with a chronic disease (Sadur 1999; Wagner 2001; Scott 2004; Edelman 2010). GMAs could contribute to improving selfmanagement and quality of life by influencing patients' selfefficacy. The quality of life of chronically-ill patients is influenced strongly by self-management. Optimal self-management involves people taking responsibility for their own health and well-being, as well as learning to manage any long-term illnesses (Lorig 2003). One way to measure the self-management abilities of patients is to measure self-efficacy, defined as whether a patient feels confident to successfully perform a specific health-related task or behaviour (Bandura 1997). Self-efficacy can be facilitated by increased knowledge, social support and successful earlier experiences, either by oneself or by others to whom one can relate (Bandura 1997; Bodenheimer 2002; Bandura 2004; Sol 2005). These attributes are more readily available during a GMA than during oneto-one appointments. Therefore the positive effects of GMAs may be mediated by improved self-efficacy through increasing social support and learning about successful earlier experiences from others.

Information from fellow patients can be just as, or even more, important as information provided by clinicians (Tattersall 2002). During a GMA, peers who have real life experience can be strong advocates and a living example of the impact and pros and cons of a treatment or lifestyle change. Patients and carers acting as experts on their own disease can be a valuable support for peers during GMAs. Finally, patients may have more time with their clinician and may receive more and different information about their disease and symptoms in a GMA setting (Zantinge 2009).

GMAs might also have adverse effects. The foremost challenge is in securing patients' privacy when medical care is offered in a group; a second is ensuring that patients are able to talk freely about their problems. To guarantee privacy and safety is very important. This can be done in several different ways, depending on the legislation of the specific country and the policy of the healthcare organisation. First, patients need to be informed correctly and in advance about what to expect; they will need to give permission for discussion of their medical information in the group; patients and their carers need to declare they will not share information about other patients with third parties; and participation in GMAs has to be voluntary, with attendance at a one-to one appointment with the clinician an option at all times. Patients may not feel free to raise all issues relevant to the management of their condition during a GMA, for example, those concerning requests for certain medication or related to sensitive information such as fertility. Patients might perceive less attention to individual needs. On the other hand, patients with the same complaints or disease often have the same questions and get their questions answered more in depth. The time investment of 1 to 2 hours could place a larger burden on patients' schedules than the 10 to 30 minutes a one-toone appointment usually takes. One could imagine people having a full-time job being more reluctant to attend a GMA.

Clinicians

Several advantages for clinicians have been described. Clinicians state that GMAs allow them more time to provide information to patients and more time to address psychosocial aspects of the disease (Zantinge 2009; Rijswijk 2010). The time gained from not having to repeat the same information to all patients might be used instead to stimulate exchange of experiences between fellow patients and to elaborate on specific aspects of a disease.

Clinicians report learning from their patients during a GMA; paying more attention to psychological and social aspects of the disease; having the opportunity to see a group of patients with the same disease at a time; and see their patients interact with other patients which can stimulate them to ask critical questions (Zantinge 2009). Clinicians who participated in GMAs have reported a high level of job satisfaction (Zantinge 2009; Blumenfeld 2003).

Offering GMAs is not suitable for all clinicians. The health professional has to have a basic interest in offering health care to a group of patients and will have to have or develop specific skills in order to be able to conduct a GMA. Usually, training to gain skills in group facilitation is necessary (Beck 1997; Blumenfeld 2003; Zantinge 2009).

Costs

Improving efficiency by implementing GMAs can be seen from two different perspectives:

- 1. patients might use fewer care resources after GMA participation; and
- 2. the cost price per outpatient visit could be reduced through GMAs.

Studies show that the effects of GMAs on costs vary considerably (Jaber 2006). Although there is some evidence of reduced resource use by patients after having attended a GMA, such as lower emergency department use, hospital admissions and visits to medical specialists (Sadur 1999; Coleman 2001; Clancy 2008), there is no consistent evidence of cost savings, and this can vary for the different reimbursement systems in use (Scott 2004; Trento 2008). The cost price of a GMA depends on the number of patients attending, the time scheduled for one-to-one appointments with the same patient group, the number of health professionals who are on the team, and the reimbursement system. If clinicians are able to see more patients in the same timeframe than they would with one-to-one appointments and the reimbursement system accounts for the participating patients, this can be a more efficient way of using valuable clinician time. However to train clinicians and group mentors to implement GMAs is a cost investment in time and training. Offering a series of GMAs to patients who would otherwise attend fewer one-to-one appointments could increase costs as well. Costs from a societal point of view can be higher when patients attend a GMA of 1 to 2 hours instead of a one-to-one appointment of 10 to 30 minutes' for example, patients might have less time to participate in other activities like employment.

Why it is important to do this review

GMAs may be an effective and efficient way of delivering health care to patients with a chronic or non-chronic physical illness. This review aims to assess the effects of group medical appointments systematically, and understand the overall effectiveness of group medical appointments as a tool for providing ongoing care for patients with a physical illness.

A number of Cochrane reviews contain management options for specific problems - for example interventions for improving medication adherence (Haynes 2008), or patients' trust in doctors (McKinstry 2008) - that include GMAs as one of the studied interventions. Other reviews focus on the effects of GMAs for a specific condition (Gagnon 2007; Homer 2012). Two other reviews summarise the effects of GMAs for various patient groups (Jaber



2006; Edelman 2012). Our review differs from the latter two reviews in the following ways: Jaber's review is a qualitative review with a search strategy limited to PubMed and MEDLINE; it included both observational and randomised studies and was executed seven years ago. Although Edelman et al recently conducted an extensive systematic review on GMAs, they limited their review to studies in the English language, patients aged over 18 years with chronic conditions, and evaluations of a series of at least two GMAs.

Our review aims to give information on effectiveness of the GMA model, irrespective of condition, age and number of appointments evaluated, which differentiates it from existing Cochrane and non-Cochrane reviews.

OBJECTIVES

To assess the effects of group medical appointments (GMAs) on the health status and well-being of patients with a primary physical illness as compared to one-to-one patient-clinician appointments.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) including cluster RCTs.

Types of participants

All patients with a primary physical illness, including newlydiagnosed patients.

A physical illness can be a chronic physical illness as well as a non-chronic health problem such as infertility, with the exception of medical emergencies which need acute medical attention. We will include children and adults who attend a primary care clinic, specialty clinic or hospital outpatient clinic (defined in this review as 'outpatient care'). Patients may attend group medical appointments (GMAs) alone or together with a carer. Carers are defined as people who are closely involved with the patient's life and can be spouses, partners, parents, children or other family members or friends. Studies that solely target carers of patients will be excluded. Studies that include only patients will not be analysed separately from those that include patients plus carers. Carers can be present at the GMA, but the GMA is primarily offered as patient care.

Newly-diagnosed patients and patients who are familiar with the condition for a longer time can be seen in separate GMAs or can attend the same appointment. People with a primary physical illness may also have mental health issues, but we will exclude from the review studies focusing on mental illnesses only.

Types of interventions

A group medical appointment (GMA) is defined as a series of one-toone patient-clinician contacts, in the presence of a group of at least two voluntary attending patients with a physical illness - and when appropriate, their carers - aimed at making better use of patients' knowledge and experience, the clinicians' time and expertise and the interaction between all present, and intended as a substitute for the one-to-one appointment with a particular clinician (Jaber 2006; Noffsinger 2009). A group consists of at least 2 patients, but typically of 5 to 15 patients. We will exclude studies that solely provide group therapy, (parent) support groups, group self-management programs or group educational programs. A GMA differs from these groups, since a GMA is intended as a complete substitute for one-to-one appointments with a clinician and focuses primarily on the current health status of the patient.

The control intervention will be one-to-one patient-clinician appointments. Studies that include additional care such as telephone follow up or home visits alongside GMAs will not be included in this review.

Types of outcome measures

Outcomes will relate to patients and carers, health professionals and health organisations including government and insurance companies. Types of outcomes will not be used as an inclusion criteria during the selection of the studies. We have prioritised the outcomes as follows:

Primary outcomes

Primary patient-related outcomes reflect changes to patient and/ or carer health and well-being overall, captured by measures in the following two outcome categories:

Health-related quality of life

Health-related quality of life of patients/carers (generic as well as specific), measured through Patient Related Outcome Measures (PROMS).

Physical health

Physical health of patient, as evaluated by a health professional, laboratory or physiological markers, eg blood pressure, glycated haemoglobin.

Secondary outcomes

Patient and/or carer

- Psychological health, assessed by measures such as depression or anxiety scores.
- Self-efficacy: confidence one has in his or her ability to reach a specified goal.
- Skills acquisition: Self-care skills, symptom control skills.
- Health behaviour: Treatment adherence, adherence to a recommended lifestyle change.
- Knowledge: Knowledge of condition, knowledge of treatment and/or management options.
- Support: Practical or social support.
- Evaluation of care: Patient-clinician interaction, perception of and satisfaction with quality of care.
- Adverse effects: Did patients give permission for discussion of their medical or private information in the group? Did patients feel free to raise all issues relevant to their physical and psychological condition? Was the time investment on group visits a burden to patients' schedules?

Health professionals

- Job satisfaction.
- Knowledge and understanding of patient problems.



Health economic outcomes

 Costs of care, cost price of intervention, time spent per patient and costs from a societal perspective, for example employment rates, absenteeism through sickness and medical expenses.

Service use

• Number and length of hospital admissions, emergency department visits, primary care visits.

To select outcomes within each outcome category, where more than one is reported, we will adopt the following process: the outcomes reported in each trial will be listed, without considering either the effect size or its statistical significance. These outcomes will be considered independently by two review authors, using discussion to reach consensus, and a decision made about which outcome measure is most clinically important, for inclusion in analyses.

Search methods for identification of studies

Electronic searches

We will search the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*)
- MEDLINE (OvidSP)
- PsycINFO (OvidSP)
- EMBASE (OvidSP)

The MEDLINE search strategy is presented at Appendix 1. This search strategy will be tailored to the other databases. We will search all databases from their start date to the present.

Searching other resources

We will search the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and the NHS HTA database on *The Cochrane Library*.

We will also search conference proceedings, dissertation abstracts, and ProQuest Theses & Dissertations to identify grey literature. We will examine the reference lists of included trials for additional studies. We will search Science Citation Index for publications that cite the studies that we include and we will search the following clinical trials registries: clinical trials.gov and the ISRCTN. Finally, we will contact authors of included studies to locate any unpublished data. There will be no language restriction.

Data collection and analysis

Selection of studies

Two authors (FS and WZ) will screen all titles and abstracts identified from the search. All citations that are thought to meet the inclusion criteria by one of the screeners will be retrieved in full text. Full texts of selected studies will be reviewed independently to decide which articles fulfil the inclusion criteria. If the same study is described in multiple reports, the data will be linked together to determine whether the study is eligible for inclusion. Any disagreement will be resolved by discussion and consensus between the two authors. Potentially-relevant studies excluded after the full-text version has been examined will be listed in the

table 'Characteristics of Excluded Studies', with the reason for exclusion given.

Data extraction and management

Two review authors (FS and WZ) will independently extract the data using a data extraction form based on the template developed by the Cochrane Consumers and Communication Review Group. It will include the following components:

Methods

We will extract data about the study design, the methods of recruitment of participants, the inclusion and exclusion criteria for participants, whether informed consent is obtained, whether ethical approval has been described, information on funding of the study, statistical methods used and consumer involvement. We will assess the risk of bias of included studies as described below (see Assessment of risk of bias in included studies).

Participant characteristics

From each study we will record the following information on participants: description (patients and or carers, clinicians), number of participants, age, gender, ethnicity, geographic location, primary health problem or diagnosis and the treatment received. We will record the following information on the study: healthcare setting (hospital outpatient clinic, primary care clinic, speciality care clinic, community health), type of healthcare system, type of reimbursement system.

Intervention

We will use the conceptual framework (see Description of the intervention) as the basis for data extraction, which includes the following domains:

- 1. Design of GMA: We will record means, medians and ranges of the duration and number of GMAs offered to the patient, time between the GMAs, and number of patients, as well as the possibility of attending a one-to-one appointment directly after the GMA, and physical examinations conducted during the GMA.
- 2. Patient groups in the GMA: We will describe continuity versus non-continuity groups including drop-in groups or scheduled appointments; heterogeneous or homogeneous patient groups; chronic versus non-chronic diseases including the diagnoses of the patients; and the mean, medians and range of the age of patients; attendance of carers (number and specification of the relationship between patient and carers).
- Team: number of clinicians attending GMAs and their professional characteristics, which clinician's appointment is substituted; presence of a group mentor; other attending clinicians or assistants and their role/s; GMA competence/ experience; kind of training the team received on GMAs.

Outcomes

We will list all primary and secondary outcomes reported in each included study and describe how they were assessed. We will report on the timing and length of follow up. Our analyses will be confined to those outcomes selected a priori as described at Types of outcome measures.



Results

Results per selected outcome measure will be reported for intervention and control groups. Both dichotomous and continuous outcomes will be reported separately.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included individual RCTs in accordance with the Cochrane Handbook (Higgins 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2011), which recommend the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data; selective outcome reporting.

For cluster RCTs we will additionally assess recruitment bias and loss of clusters.

Other sources of bias include baseline imbalances for both individual and cluster RCTs and comparability with individually randomised trials for cluster RCTs.

In all cases, two authors (FS and WZ) will independently assess the risk of bias of included studies, with any disagreements resolved by discussion and consensus, resulting in a rating of high, unclear or low risk of bias for each domain.

Studies will be deemed to be at the highest risk of bias if they are scored as at high or unclear risk of bias on the sequence generation, allocation concealment and completeness of outcome data domains. Completeness of outcome data will be rated as at low risk of bias if there are complete data for 75% or more of participants; unclear if completeness of data cannot be determined; and at high risk of bias if completeness of data is less than 75%.

We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the 'Risk of bias' assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment of the risk of bias of included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect

We will use relative risks (RR) and 95% confidence intervals (CI) to compare dichotomous outcomes between groups. Continuous data from the same scale will be compared by mean differences (MD) and 95% CI, and continuous data from different scales by standardised mean differences (SMD).

Unit of analysis issues

In case of individual randomised controlled trials the unit of analysis will be individual patients with physical illness. The analysis must take into account the level at which randomisation occurred. If we identify included studies using a cluster-randomised design, but where inference is intended at the level of the individual, they need to be analysed with intra-cluster correlations (ICCs) taken into account. Estimates of the ICCs will be obtained from contacting authors or imputed using external estimates. If this is not possible we will report effect estimates and annotate 'unit of analysis error' (Horvat 2011).

If the cluster randomised trials are analysed correctly, we will use the adjusted Mantel-Haenszel test as described by Donner and Klar (Donner 2002) to combine the results of the individually randomised controlled trials with the results of the cluster randomised trials.

If case studies compare more than two intervention groups, all relevant experimental intervention groups of the study will be combined into a single group, and all relevant control intervention groups will be combined into a single control group (Higgins 2011).

Dealing with missing data

When possible, we will use the results from intention-to-treat analyses. We will contact the trial authors in case of missing summary data. For the remaining missing outcome or summary data we will impute missing data where possible and report any assumptions in the review. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates. In case of missing summary data of a study, we will report on the levels of loss to follow-up and assess this as a source of potential bias, and discuss the potential implications of its absence from the meta-analysis.

Assessment of heterogeneity

In order to decide whether a meta-analysis of the data is justifiable, we will assess both clinical and statistical heterogeneity.

We will assess clinical heterogeneity by examining the similarity and differences of the interventions based on our framework and its major domains. We anticipate effects to vary according to exposure, i.e. single sessions versus multiple sessions. If there is sufficient similarity amongst the interventions in the trials to allow meaningful conclusions from a pooled result, we will go on to assess statistical heterogeneity.

Based on the Description of the intervention section, we will use the following four components of the GMA design as guide for examining the clinical heterogeneity:

- Number of GMAs offered: single sessions; multiple sessions,
- Time between successive GMAs: <= 1 month, 1 to 6 months, > 6 months,
- Number of patients per GMA: small groups (<= 8 people), large groups (> 8 people)
- Duration of the GMA: ≤ 2 hours, > 2 hours

In addition, we will examine the following components from the 'patient group' domain and describe notable differences:

- Continuity versus non-continuity GMAs: non-continuity GMAs include drop-in GMAs (DIGMAs),
- Heterogenous versus homogeneous patient groups,
- People with chronic versus non-chronic illness.

If studies are sufficiently similar, then we will assess the degree of statistical heterogeneity of these studies by visual inspection of the forest plot and by examining the Chi² test for heterogeneity. Statistical heterogeneity will be quantified using the I²statistic. An



I² value of 50% or more will be considered to represent substantial levels of heterogeneity, but this value will be interpreted in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi² test (Higgins 2011). If significant statistical heterogeneity is apparent, we will explore the reasons behind the heterogeneity

by conducting subgroup analyses.

If there is considerable clinical and/or statistical heterogeneity in the included studies, it may be misleading to conduct a metaanalysis to cite a pooled value for the intervention effect. In this case the effect of the intervention will be systematically described in tables and text.

Assessment of reporting biases

If 10 or more studies are included in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and using formal tests. For continuous outcomes we would use the test proposed by Egger 1997, and for dichotomous outcomes we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or suggested by the visual assessment, we will contact study authors asking them to provide missing outcome data. If this is not possible, and the missing data is likely to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by conducting a sensitivity analysis.

Data synthesis

We will combine data across studies quantitatively in a metaanalysis only if it is appropriate to do so. Due to the anticipated variability in the included studies' populations and interventions, we will use a random-effects model for meta-analysis. If metaanalysis is possible (i.e. there are at least two studies which are sufficiently similar), we will pool effect measures (relative risks, mean differences or standardised mean differences) and calculate 95% confidence intervals to assess the effects of GMA visits compared with usual care. We will describe the findings in the review text, considering the potential impact of bias and the degree of heterogeneity and its possible sources. The results will be presented for subgroups (see Subgroup analysis and investigation of heterogeneity), as appropriate.

If we are unable to conduct meta-analysis we will conduct a narrative synthesis of results. In a narrative synthesis, for the comparison 'GMA versus care as usual', we will report: the number of comparisons showing a positive direction of effect; the median effect size across all comparisons; the median effect size across comparisons without unit of analysis errors; and the number of comparisons showing statistically significant effects. In the narrative synthesis and in any statistical synthesis we will synthesise first according to the different types of interventions (grouping similar interventions together), second according to the types of outcomes, and third according to the strength of evidence by using the GRADE guidelines.

Subgroup analysis and investigation of heterogeneity

Subgroup analyses will be conducted to explore possible explanations for observed heterogeneity. The following subgroup

analyses (by narrative methods and also by meta-analysis if appropriate) will be conducted if sufficient data are available:

Domain: Design of GMA:

• Number of GMAs offered (1, 2 to 8, > 8).

Sensitivity analysis

We plan to undertake sensitivity analyses based on the 'Risk of bias' assessment. Studies at the highest risk of bias will be removed from the analysis for a sensitivity analysis, which can only be done when the number of included studies is large enough. Studies at the highest risk of bias will be defined as a trial scoring high or unclear risk on the sequence generation, allocation concealment and completeness of outcome data domains of the 'Risk of bias' tool. We will also investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.

'Summary of findings' table

We will prepare a 'Summary of findings' table to present the results of meta-analysis, based on the methods described in chapter 11 of the Cochrane Handbook for Systematic Reviews of Interventions (Schünemann 2011). We will present the results of meta-analysis for the major comparison of the review, for each of the major primary outcomes, including potential harms, as outlined in the Types of outcome measures section. We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE system to rank the quality of the evidence using the GRADEprofiler (GRADEpro) software (Schünemann 2011). If meta-analysis is not possible, we will present results in a narrative 'Summary of findings' table format.

Ensuring consumer relevance

For this review, we will ensure consumer relevance by drawing on the list of consumer-focused outcomes from the Cochrane Consumers and Communication Review Group (see http:// cccrg.cochrane.org/author-resources).

Representatives of two relevant patient advocacy groups in the Netherlands agreed to participate in a consultation group. These are the Dutch Association of People with Atopic Dermatitis (www.vmce.nl) and the Dutch Society of Muscle Disorders (www.spierziekten.nl). The consultation group will provide feedback on the draft protocol and the draft review, from a consumer's point of view. Four of the authors are clinicians with experience with GMAs and will comment from their point of view. The protocol and review also receive consumer feedback through the Cochrane Consumers and Communication Review Group's editorial processes.

ACKNOWLEDGEMENTS

We thank Bernd Arents, president of the board, Dutch Association of People with Atopic Dermatitis and Anja Horemans, head of Quality of Care, Dutch Society of Muscle Disorders, for their comments from the consumer's point of view. We thank the staff and editors of the Cochrane Consumers and Communication Review Group, particularly Megan Prictor and Rebecca Ryan for their guidance and assistance, John Kis-Rigo for his help with the search strategy and Sophie Hill, sign-off editor for this protocol. We also thank the external peer reviewers for their comments.

Group medical appointments for people with physical illness (Protocol) Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.



REFERENCES

Additional references

Bandura 1997

Bandura A. The anatomy of stages of change. *American Journal of Health Promotion* 1997;**12**(1):8-10.

Bandura 2004

Bandura A. Swimming against the mainstream: the early years from chilly tributary to transformative mainstream. *Behaviour Research and Therapy* 2004;**42**(6):613-30.

Beck 1997

Beck A, Scott J, Williams P, Robertson B, Jackson D, Gade G, et al. A randomized trial of group outpatient visits for chronically ill older HMO members: the cooperative health care clinic. *Journal of the American Geriatrics Society* 1997;**45**:543-59.

Blumenfeld 2003

Blumenfeld A, Tischio M. Center of excellence for headache care: group model at Kaiser Permanente. *Headache* 2003;**43**:431-40.

Bodenheimer 2002

Bodenheimer T, Lorig TK, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA* 2002;**288**(19):2469-75.

Clancy 2008

Clancy DE, Dismuke CE, Magruder KM, Simpson KN, Bradford D. Do diabetes group visits lead to lower medical care charges?. *American Journal of Managed Care* 2008;**14**(1):39-44.

Coleman 2001

Coleman EA, Eilertsen TB, Kramer AM, Magid DJ, Beck A, Conner D. Reducing emergency visits in older adults with chronic illness. A randomized, controlled trial of group visits. *Effective Clinical Practice* 2001;**4**(2):49-57.

Donner 2002

Donner A, Klar N. Issues in the meta-analysis of cluster randomized trials. *Statistics in Medicine* 2002;**21**:2971-80.

Edelman 2010

Edelman D, Frederickson SK, Melnyk SD, Coffman CJ, Jeffreys AS, Datta S, et al. Medical clinics versus usual care for patients with both diabetes and hypertension, a randomized trial. *Annals of Internal Medicine* 2010;**152**(11):689-96.

Edelman 2012

Edelman D, McDuffie JR, Oddone E, Gierisch JM, Nagi A, Williams JW Jr. Shared Medical Appointments for Chronic Medical Conditions: A Systematic Review. Washington Department of Veterans Affairs, Veterans Health Administration, Quality Enhancement Research Initiative, Health Services Research & Development Service, Washington 2012.

Egger 1997

Egger M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**315**:629-34.

Gagnon 2007

Gagnon AJ, Sandall J. Individual or group antenatal education for childbirth or parenthood, or both. *Cochrane Database of Systematic Reviews* 2007, Issue 3. [DOI: 10.1002/14651858.CD002869]

Harbord 2006

Harbord RM, Egger M, Sterne JA. A modified test for smallstudy effects in meta-analyses of controlled trials with binary endpoints. *Statistics in Medicine* 2006;**25**:3443-57.

Haynes 2008

Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence. *Cochrane Database of Systematic Reviews* 2008, Issue 2. [DOI: 10.1002/14651858.CD000011.pub3]

Higgins 2011

Higgins JPT, Altman DG, Sterne JAC. Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011], Available from www.cochrane-handbook.org. The Cochrane Collaboration, 2011.

Homer 2012

Homer CSE, Ryan C, Leap N, Foureur M, Teate A, Catling-Paull CJ. Group versus conventional antenatal care for women. *Cochrane Database of Systematic Reviews* 2012, Issue 11. [DOI: 10.1002/14651858.CD007622]

Horvat 2011

Horvat L, Horey D, Romios P, Kis-Rigo J. Cultural competence education for health professionals. *Cochrane Database of Systematic Reviews* 2011, Issue 10. [DOI: 10.1002/14651858.CD009405]

Jaber 2006

Jaber R, Braksmajer A, Trilling JS. Group visits: a qualitative review of current research. *Journal of the American Board on Family Medicine* 2006;**19**:276-90.

Lorig 2003

Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. *Annals of Behavioral Medicine* 2003;**26**(3):1-7.

McKinstry 2008

McKinstry B, Ashcroft R, Car J, Freeman GK, Sheikh A. Interventions for improving patients' trust in doctors and groups of doctors. *Cochrane Database of Systematic Reviews* 2008, Issue 3. [DOI: 10.1002/14651858.CD004134.pub2]

Meehan 2006

Meehan KR, Hill JM, Root L, Kimtis E, Patchett L, Noffsinger EB. Group medical appointments: organization and implementation in the bone marrow transplantation clinic. *Supportive Cancer Therapy* 2006;**3**(2):84-90.



Noffsinger 2003

Noffsinger E, Sawyer DR, Scott JC. Group medical visits: a glimpse into the future? (enhancing your practice). *Patient Care* 2003;**37**:18-27.

Noffsinger 2009

Noffsinger EB. Running Group Visits in Your Practice. New York: Springer, 2009.

Pennachio 2003

Pennachio DL. Should you offer group visits?. *Medical Economics* 2003;**80**(2):82-5.

Rijswijk 2010

Rijswijk C, Zantinge E, Seesing F, Raats I, van Dulmen S. Shared and individual medical appointments for children and adolescents with type 1 diabetes; differences in topics discussed?. *Patient Education and Counseling* 2010;**79**(3):351-5.

Ryan 2011

Ryan R, Hill S, Prictor M, McKenzie J. Cochrane Consumers and Communication Review Group. Study Quality Guide May 2011; Vol. http://www.latrobe.edu.au/chcp/cochrane/resources.html.

Sadur 1999

Sadur CN, Moline N, Costa M, Michalik D, Mendlowitz D, Roller S, et al. Diabetes management in a health maintenance organization. Efficacy of care management using cluster visits. *Diabetes Care* 1999;**22**(12):2011-7.

Schünemann 2011

Schünemann HJ, Oxman AD, Higgins JPT, Vist GE, Glasziou P, Guyatt GH, on behalf of the Cochrane Applicability and Recommendations Methods Group and the Cochrane Statistical Methods Group. Chapter 11: Presenting results and 'Summary of findings' tables. Cochrane Handbook for Systematic Reviews of Interventions 2011; Vol. Version 5.1.0:Available from www.cochrane-handbook.org.

APPENDICES

Appendix 1. MEDLINE search strategy

1. "appointments and schedules"/

- 2. office visits/
- 3. "referral and consultation"/
- 4. (visit? or consult* or appointment* or clinic?).tw.
- 5. disease management/
- 6. exp practice management/
- 7. physicians practice patterns/
- 8. or/1-7
- 9. group processes/

Scott 2004

Scott JC, Conner DA, Venohr I, Gade G, McKenzie M, Kramer AM, et al. Effectiveness of a group outpatient visit model for chronically ill older health maintenance organization members: a 2-year randomized trial of the cooperative health care clinic. *Journal of the American Geriatrics Society* 2004;**52**(9):1463-70.

Sol 2005

Sol BG, van der Bijl JJ, Banga JD, Visseren FL. Vascular risk management through nurse-led self-management programs. *Journal of Vascular Nursing* 2005;**23**(1):20-4.

Tattersall 2002

Tattersall RL. The expert patient: a new approach to chronic disease management for the twenty-first century. *Clinical Medicine* 2002;**2**(3):227-9.

Trento 2008

Trento M, Basile M, Borgo E, Grassi G, Scuntero P, Trinetta A, et al. A randomised controlled clinical trial of nurse-, dietitianand pedagogist-led Group Care for the management of Type 2 diabetes. *Journal of Endocrinological Investigation* 2008;**31**(11):1038-42.

Trilling 1999

Trilling J. Selections from current literature: focus group technique in chronic illness. *Family Practice* 1999;**16**:539-41.

Wagner 2001

Wagner EH, Grothaus LC, Sandhu N, Galvin MS, McGregor M, Artz K, et al. Chronic care clinics for diabetes in primary care: a system-wide randomized trial. *Diabetes Care* 2001;**24**(4):695-700.

Zantinge 2009

Zantinge EM, Seesing FM, Tol FE, Raats CJ, Spreeuwenberg PM, van Dulmen AM. Shared Medical Appointments: experiences of patients and care givers [Gezamenlijk Medisch Consult: samen naar de dokter. Ervaringen van patienten en zorgverleners]. *Nederlands Tijdschrift Voor Geneeskunde* 2009;**153**:A828.



10. (group adj (based or basis or approach or education*)).tw.

11. or/9-10

12.8 and 11

13. (shared adj (visit? or consult* or session* or appointment* or setting* or care)).tw.

14. ((group or cluster) adj (visit? or consult* or appointment* or setting* or care or clinic?)).tw.

15. ((shared or group or cluster) adj (medical or patient or outpatient or office or education*) adj (visit? or consult* or session? or appointment* or setting* or discussion* or clinic? or approach* or care or basis or model*)).tw.

16. ((shared or group or cluster) adj2 (visit? or consult* or appointment*)).tw.

17. (cooperative health* adj2 clinic?).tw.

18. (cooperative adj3 care clinic?).tw.

19. (chronic adj3 care clinic?).tw.

20. or/12-19

- 21. randomized controlled trial.pt.
- 22. controlled clinical trial.pt.
- 23. randomized.ab.
- 24. placebo.ab.
- 25. drug therapy.fs.
- 26. randomly.ab.
- 27. trial.ab.
- 28. groups.ab.

29. or/21-28

- 30. exp animals/ not humans.sh.
- 31. 29 not 30
- 32. 20 and 31

CONTRIBUTIONS OF AUTHORS

Prof. dr. Gert Jan van der Wilt is the contact review author and guarantor of the review. Drs. Femke Seesing and drs. Wieneke Zijlstra contributed equally to the protocol and are responsible for the protocol, the searches, study selection and appraisal, and writing the review. Dr. Monique L'Hoir and prof. dr. Gert Jan van der Wilt are supervising the study selection and the realization of this protocol and review. Dr. Baziel van Engelen, dr. Suzanne Pasmans and dr. Gea Drost are supervising and writing the protocol and the review. This protocol has been read and approved by all authors.

DECLARATIONS OF INTEREST

All authors are authors of (future) potentially eligible studies. In order to minimise possible bias resulting from this, the trial author will not be involved in selection, data extraction or analysis of his or her own trial.

Dr. van Engelen is research director of the European Neuromuscular Centre (ENMC) and receives institutional support from the Radboud University Nijmegen Medical Centre and the ENMC, grant support from the Global FSH, Netherlands Organization for Scientific Research, Prinses Beatrix Fonds, and the Dutch FSHD Foundation.



SOURCES OF SUPPORT

Internal sources

• No sources of support supplied

External sources

• The Netherlands Organization for Health Research and Development ZONMW (ID ZonMW 170882703), Netherlands.

Financial support for author salary of FSStichting Kinderpostzegels, Netherlands.

Financial support for salary of WZ