APPENDIX A. SEARCH STRATEGIES

Table A-1. Search strategy for RCTs and observational studies (PubMed, April 2012)

Step	Category	Terms	Result
1	Terms for "group appointment"	(visit[ti] OR visits[ti] OR appointment[ti] OR appointments[ti] OR clinic[ti] OR clinics[ti] OR "Appointments and Schedules"[Mesh]) AND (group[ti] OR shared[ti] OR cluster[ti])	**744**
2	Terms for "shared visits"	("shared medical appointment"[tiab] OR "shared medical appointments"[tiab] OR "group care"[tiab] OR "group medical appointment"[tiab] OR "group medical appointments"[tiab] OR "cluster visit"[tiab] OR "cluster visits"[tiab] OR "group visit"[tiab] OR "group visits"[tiab] OR "shared medical visit"[tiab] OR "shared medical visits"[tiab] OR "group medical clinic"[tiab] OR "group medical clinics"[tiab])	**313**
3	Combined intervention terms	**#1 OR #2**	**961**
4	Terms for RCT study design	(randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR Clinical trial[pt] OR "clinical trial"[tw] OR "clinical trials"[tw] OR "evaluation studies"[Publication Type] OR "evaluation studies as topic"[MeSH Terms] OR "evaluation study"[tw] OR evaluation studies[tw] OR "intervention studies"[MeSH Terms] OR "intervention study"[tw] OR "intervention studies"[tw] OR "cohort studies"[MeSH Terms] OR cohort[tw] OR "longitudinal studies"[MeSH Terms] OR "longitudinal"[tw] OR longitudinally[tw] OR "prospective"[tw] OR prospectively[tw] OR "follow up"[tw] OR "comparative study"[Publication Type] OR "comparative study"[tw] OR systematic[subset] OR "meta-analysis"[Publication Type] OR "meta-analysis as topic"[MeSH Terms] OR "meta-analysis"[tw] OR "meta-analyses"[tw]) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp]) NOT (animals[mh] NOT humans[mh])	**4216173**
5	Intervention AND RCT	**#3 AND #4**	**466**
6	Terms for observational studies	"pre-post"[tiab] OR "post-test"[tiab] OR "post test"[tiab] OR pretest[tiab] OR pre-test[tiab] OR "pre test"[tiab] OR quasi-experiment*[tiab] OR quasiexperiment*[tiab] OR quasirandom*[tiab] OR quasi-random*[tiab] OR quasi-control*[tiab] OR quasicontrol*[tiab] OR ("time series"[tiab] AND interrupt[tiab]) OR ("time points"[tiab] AND (multiple[tiab] OR one[tiab] OR two[tiab] OR three[tiab] OR four[tiab] OR five[tiab] OR six[tiab] OR seven[tiab] OR eight[tiab] OR nine[tiab] OR ten[tiab] OR month*[tiab] OR day*[tiab] OR week*[tiab] OR hour*[tiab]) OR (before[tiab] AND after[tiab]) OR (*before[tiab] AND during[tiab])	**44225**
7	Intervention and Observational	**#3 AND #6**	**11**
8	Applies limits to combined RCT and observational studies	**#5 OR #7 with limits:** English, Publication Date from 1996 to 2011	**323**

APPENDIX B. EXCLUDED STUDIES

All articles listed below were reviewed in their full-text version and excluded for the reason indicated. An alphabetical reference list follows the table.

Table B-1. Excluded studies with reasons

Reference	Not full publication, peer-reviewed, or primary data	Not study population of interest	Not eligible study design	Comparator not of interest	Intervention does not meet protocol definition	Not an outcome of interest reported at ≥3 months
AHRQ, 2003 (943)	X					
AHRQ, 2007 (844)	X					
Anonymous, 1996 (946)	X					
Anonymous, 2001 (913)	X					
Anonymous, 2001 (944)	X					
Anonymous, 2003 (351)	X					
Antonucci, 2008 (835)	X					
Barud, 2006 (730)			X			
Block, 2010 (747)	X					
Bray, 2005 (299)			X			
Bronson, 2004 (1331)			X			
Brooks, 2007 (265)			X			
Campbell, 2007 (518)		X				
Clancy, 2003 (347)						X
Clancy, 2007 (259)						X
Conrad, 2008 (775)		X				
Desouza, 2010 (157)			X			
Anonymous, 2001 (373)	X					
Dontje, 2011 (607)			X			
Falck-Ytter, 2009 (1286)	X					
Geller, 2011 (142)			X			
Harris, 2010 (178)		X				
Jaber, 2006 (780)	X					
Jeanfreau, 2008 (732)	X					
Anonymous, 2002 (955)	X					
Katz, 1975 (596)	X					
Kirsh, 2006 (1312)	X					
Krywkowski-Mohn, 2009 (1508)	X					
Lin, 2008 (214)			X			
Loney-Hutchinson, 2009 (703)			X			
Mackay, 2011 (649)		X				
Masley, 2001 (386)					X	
Mayo Clinic Proceedings, 2008 (507)					X	
McCulloch, 1998 (410)			X			
McHugh, 1998 (420)					X	
Miller, 329 (329)			X			
Murray, 2005 (313)	X					
Ostroff, 2010 (1278)	X					
Palaniappan, 2011 (135)		X				
Peterson, 2007 (929)	X					
Porta, 2004 (326)						X
Reiber, 2004 (328)					X	

Reference	Not full publication, peer-reviewed, or primary data	Not study population of interest	Not eligible study design	Comparator not of interest	Intervention does not meet protocol definition	Not an outcome of interest reported at ≥3 months
Rivard, 2009 (498)	X					
Rossi, 2011 (1269)	X					
Salinas, 2006 (1308)	X					
Salinas-Martinez, 2009 (1282)	X					
Sanchez, 2011 (608)			X			
Scott, 1998 (426)	X					
Shahady, 2008 (795)	X					
Shahady, 2010 (465)	X					
Stoner, 2001 (375)					X	
Taveira, 2008 (1686)			X			
Thompson, 2000 (875)	X					
Thompson, 2001 (389)		X				
Trento, 2006 (291)						X
Trento, 2008 (1291)	X					
Trento, 2008 (238)						X
Trento, 2009 (1283)	X					
Trento, 2009 (1284)	X					
Trento, 2009 (904)				X		
Vachon, 2007 (237)			X			
Vinci, 2006 (1311)	X					
Watkinson, 2004 (976)	X					
Watts, 2009 (1582)			X			
Weber, 2004 (1333)	X					
Westheimer, 2009 (666)			X			
Wheelock, 2009 (211)			X			
Worth, 1990 (557)					X	
Yehle, 2007 (689)	X					
Yehle, 2009 (213)						X
Yu, 2010 (165)					X	

LIST OF EXCLUDED STUDIES

Agency for Healthcare Research and Quality. Group visits to primary care doctors by disadvantaged diabetes patients result in better diabetes care than individual visits. *AHRQ Research Activities*. 2003(278):14-14.

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APPENDIX C. DATA ABSTRACTION ELEMENTS

Study Characteristics:

- Study Sites and Setting
- Study Design
- Comparator Type
- Enrollment Approach
- Study Enrollment/Study Completion (N's)
- Patient Eligibility Criteria for Study

Population Characteristics:

- Demographic
- Baseline Biophysical Characteristics

Intervention Components:

- Time period of intervention
- Type of model session and care team
- Number and duration of visits planned
- Number of health professionals present
- Was the prescribing clinician present?
- Size of patient group
- Were family members/friends invited to participate?
- Were medication changes made during the SMA visit?
- Did any clinician spend time with group members individually?
- Was the contact with the patients over the telephone outside of the SMA?
- Health professionals who conducted the educational session
- Theoretical orientation of the intervention
- Did group member have input on education topics?
- Topics covered during the session
- Strategy used with SMA group
- Were printed materials provided, and were they tailored?

Outcome Components:

- Target conditions
    - Biophysical markers postintervention values
        - HbA1c
        - Blood Pressures
        - Lipids
- Patient and staff experience
- Adherence (medication, visit, and self-management)
- Symptom severity
- Quality of life
- Functional status
- Resource utilization
- Direct cost and total cost
- Adverse effects

APPENDIX D. CRITERIA USED IN QUALITY ASSESSMENT

General Instructions:
For each risk of bias item, rate as "Yes," "No," or "Unclear." After considering each of the quality items, give the study an overall quality rating of good, fair, or poor.

Detailed Quality Items:
If an item is rated as "No," describe why in the comments column.

Randomization and allocation concealment:

a. **Randomization adequate?* Was the allocation sequence adequately generated?

❑ Yes ❑ No ❑ Not reported/Unclear

b. **Allocation concealment?* Was allocation adequately concealed?

❑ Yes ❑ No ❑ Not reported/Unclear

Outcomes:

a. **Outcome assessors blinded (hard outcomes)?* Were *Outcome assessors* blind to treatment assignment for "hard outcomes" such as mortality?

❑ Yes ❑ No ❑ Not reported/Unclear

b. **Outcome assessors blinded (soft outcomes)?* Were *Outcome assessors* blind to treatment assignment for "soft outcomes" such as symptoms?

❑ Yes ❑ No ❑ Not reported/Unclear

c. *Lack of measurement bias?* Were the measures used reliable and valid? If so, choose "Yes," indicating no important measurement bias.

❑ Yes ❑ No ❑ Not reported/Unclear

Data analysis:

a. **All outcomes reported?* Are reports of the study free of suggestion of selective outcome reporting (systematic differences between planned and reported findings)?

❑ Yes ❑ No ❑ Not reported/Unclear

b. **Incomplete outcome data adequately addressed?*

❑ Yes (no systematic differences between groups in withdrawals from study and no high overall loss to follow-up; all eligible, randomized patients are included in analysis (ITT)

❑ No

❑ Not reported/Unclear

c. *Adequate power for main effects?*

❑ Yes ❑ No ❑ Not reported/Unclear

Results:

a. *Other selection bias?* Were systematic differences observed in baseline characteristics and and prognostic factors across the groups compared?

❑ Yes ❑ No ❑ Not reported/Unclear

b. **Comparable groups maintained?* (Includes crossovers, adherence, and contamination). Consider issues of crossover (e.g., from one intervention to another), adherence (major differences in adherence to the interventions being compared), contamination (e.g., some members of control group get intervention), or other systematic differences in care that was provided.

❑ Yes ❑ No ❑ Not reported/Unclear

Conflict of interest:

a. *Was there the absence of potential important conflict of interest?* The focus here is financial conflict of interest. If no financial conflict of interest (e.g., if funded by government or foundation and authors do not have financial relationships with drug/device manufacturer), then answer "Yes."

❑ Yes ❑ No ❑ Not reported/Unclear

* Items contained in Cochrane Risk of Bias Tool

Overall study rating:

Choose an item.

Please assign each study an overall quality rating of "Good," "Fair," or "Poor" based on the following definitions:

A "Good" study has the least bias, and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to alternative treatments; has a low dropout rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results.

A "Fair" study is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid.

A "Poor" rating indicates significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

Comments:

Form status:

❑ Fully complete – ready for export

❑ Not ready for export – should be discussed further/changes reconciled with the abstractor

APPENDIX E. PEER REVIEW COMMENTS

Reviewer	Comment	Response
Question 1: Are the objectives, scope, and methods for this review clearly described?		
1	Yes. The authors present the objectives and scope in a very succinct fashion. The methods are described in great detail. The key questions for review are very relevant in my opinion. Key question 1(KY 1) was well defined and the authors found 18 studies to evaluate. However KY2 and 3 are quite broad and not as clearly defined as KY 1. (Page 1, line 43, Page 2, Line 2). As there were not enough studies to address these questions, I can only speculate that if the questions were more focused, that the authors would have had better luck. They are to be commended for a thorough and detailed lit review, anyway to answer the call.	Thank you. The key questions were developed in collaboration with our stakeholders.
2	Yes. The terms "objectives" and "scope" were not used exactly; however the intent of this section was clearly described. The methods were superbly articulated.	Thank you.
3	Yes. Very clear.	Acknowledged
4	Yes. No comment.	Acknowledged
5	Yes. No comment.	Acknowledged
6	Yes. But comments under question 4.	Acknowledged
7	Yes. No comment.	Acknowledged
Question 2: Is there any indication of bias in our synthesis of the evidence?		
1	No. No comment.	Acknowledged
2	No. Risk of bias was evaluated when rating the body of evidence. Threats to internal validity of the systematic review conclusions were accounted for in potential selection bias, performance bias, and attribution and detection bias. Bias was accounted for by using criteria in the quality assessment tool in Appendix D for the review of the literature.	Thank you.
3	No. No comment.	Acknowledged
4	No. No comment.	Acknowledged
5	No. No comment.	Thank you.
6	No. But comments under question 4.	Acknowledged
7	No. No comment.	Acknowledged
Question 3: Are there any published or unpublished studies that we may have overlooked?		
1	No. Not that I am aware of.	Acknowledged
2	No. Not that I am aware of.	Acknowledged
3	No. No comment.	Acknowledged
4	No. I am not a SME on this topic so I may not be aware of some overlooked studies.	Acknowledged
5	Yes. I have unpublished retrospective pre-test/post-test study data awaiting consideration for publication from Diabetes Care Journal. N=1170 with ~ 1% A1c level drop.	Thank you for informing us about your data. We were unable to obtain a copy of this manuscript prior to finalizing our report.

Reviewer	Comment	Response
6	No. I am not aware of any, but I would be surprised if I knew of them from routine practice while the authors used a rigorous process. They do not include the many group interventions directed at weight control. I am not sure why these escaped their search criteria. I think they are not viewed as medical appointments by indexers, even though most would think the programs defined by the AHEAD study or even many MOVE! programs are medical encounters	Our focus on specific chronic conditions—asthma, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, diabetes mellitus, hyperlipidemia, hypertension—was developed in collaboration with stakeholders. Obesity was considered but not included since medication management is not as prominent a component compared to the included conditions.
7	Yes. Published - Cohen, L. B., Taveira, T. H., Khatana, S. A., Dooley, A. G., Pirraglia, P. A., & Wu, W. C. (2011). Pharmacist-led shared medical appointments for multiple cardiovascular risk reduction in patients with type 2 diabetes. [Randomized Controlled Trial Research Support, Non-U.S. Gov't]. Diabetes Educ, 37(6), 801-812. doi: 10.1177/0145721711423980 Unpublished - Pharmacist-led Group Medical Visits to Help With Diabetes Management (MEDIC-1 year), NCT00554671	Thank you for making us aware of this study. It was published after our literature search but is now included in the review. Thank you for making us aware of this study. It has been added to the appendix of ongoing clinical trials.
Question 4: Please write additional suggestions or comments below. If applicable, please indicate the page and line numbers from the draft report		
1	Few suggestions include: 1. (Page 3, Line 13) of executive summary: Mentioning the duration of the studies for the reader to get a snapshot would beneficial, as meaningful change in chronic disease takes time. See below. 2. (Page3, Line 37) of the executive summary: SMAs were associated with lower A1c than usual care (mean difference=0.58; 95% CI, -1.05 to -0.11) Again mentioning the time frame would be useful, especially as this was one of the main outcomes of their work. It is described on (page 22, line 18), assessed at 6 months to 4 years. 3. Page 24: Figure 4. Forest plots for meta-analysis on cholesterol. The headings for mean and SD says (mm Hg). Should say (mg/dl). I believe this is an error. 4. Page 24: Figure 5. Headings for mean SBP, should say (mmHg)	1. We added the range of followup to this section. 2. Thank you. This addition was made. 3. Thank you. This correction was made. 4. Thank you. This correction was made.

Reviewer	Comment	Response
1 cont.	I would like to commend the authors very highly for undertaking this extensive review. There is certainly great need to recognize, investigate and assess newer models of care for chronic illness in the 21st century. They present the current state of chronic illness care clearly, (page 8, line 22-26) which forms a nice background to the topic The methodology used is described in great detail and clear. Their conclusion after an extensive rigorous analysis of the literature highlights how complicated and inter-linked management of chronic disease really is. Their conclusion is not overstated.	Thank you.
	In the past decade, several breakthrough collaboratives introducing quality improvement methodology, rather than RCT's have been implemented in the US, mainly focusing on system improvements to address some of the key questions cited by the authors and addressing the six aims outlined by the Institute of medicine. This review did not analyze them. Only 18 studies qualified for analysis by the methods for SMA's being a newer model of care.	We followed the Cochrane Effective Practice and Organization of Care guidance, and included comparative patient or cluster RCTs, nonrandomized cluster controlled trials, controlled before-and-after studies, and interrupted time series designs. Any published breakthrough collaborative studies meeting these design specifications would have been included.
	As several components are inter-linked that leads to improvement in this model, it was hard to show significance with the rigor used in RCT's, the gold standard, as seen in this review. So in terms of future research, I am not convinced that large scale RCT's to address for e.g. diabetes outcomes will be feasible and answer the question described in (Table ES-2: evidence gaps and future research). One thought is to look at different models of care scientifically, to identify best practices and health systems with improved outcomes along with the economic cost for chronic illness management.	As stated above, we included comparative nonrandomized designs. We have modified the future research table to include these study design options.
	In conclusion, this paper has many strengths. (As cited by the authors). It is well described, clear and thoughtful with an exhaustive review and analysis of the literature. Going forward, it is an important topic for discussion in primary care and I greatly appreciate the opportunity to review this work.	Thank you.
2	On page 8 of the document (numbered as page 4), I noted in this paragraph, there needs to be a change in this word (see below in red). *Put page/paragraph here*	We have made this change.
	All three studies showed fewer hospital admissions in ……	The typo "shower" was changed to "showed."
	In addition, on page 13 under the table where there are words describing what is meant by "provider", would you consider changing advance nurse practitioner to this Advanced Practice Registered Nurse (APRN) as this is the more correct term to describe the nurse provider. Thank you.	We made the suggested change.
3	No comment from reviewer 5.	Acknowledged

Reviewer	Comment	Response
4	The scope of this data synthesis severely limited by limited number of high quality studies. It would seem that sufficient studies of sufficient design were not available to address KQ2 and KQ3. KQ1 of interest but only addresses initial questions of SMA effectiveness, and then only in diabetes. Some Tables not self-explanatory, such as Table ES-1 which refers to consistency, directness and precision but the definitions and measurement not clearly described.	We reviewed all Tables and edited or footnoted so that tables will "stand on their own."
	More analysis of issues raised in page 9 paragraph 2 would be helpful. Most of the SMA intervention studies suggest deployment of significant employee resources, sometimes on a limited number of patients in the group visit. These additional resources may have been largely responsible for the small improvement in intermediate outcomes seen in diabetes SMA. Left unresolved is whether it is worthwhile for facilities to invest these resources without clear return on investment. And for which patients?	We agree that this is a critical issue and attempted to determine factors associated with effect. Given the limits on intervention reporting and relatively small number of studies, our analysis did not identify the critical factors. For resource use, we were limited to the small amount of data reported.
5	p.9 2nd paragraph additional reasons for improved outcomes of SMA to consider-interprofessional synergism and motivational interviewing that goes on in the discussion section of SMA's.	Thank you. These are good points that have been added to the introduction.
	p.33 Table 6 Implementation issues-not clear that MD was most prevalent prescribing clinician if pharmacist & nurse practitioners listed with MD or without an MD were mentioned 11 studies and MD prescribers only as 8 times -may want to say have a prescribing clinician present.	We have attempted to clarify by describing the clinical leads and team composition in more detail (see KQ 3 results) and modifying the implementation table to reflect that a prescribing clinical is needed, rather than an MD.

Reviewer	Comment	Response
6	RE: EXECUTIVE SUMMARY	
	I note that the executive summary is readable in length and well formatted. The writing is clear and crisp, which will be helpful to the eventual consumer.	Thank you.
	However, I am disappointed in several aspects of the presentation and data selected for presentations:	
	The Executive Summary emphasizes quantitative over qualitative commentary. There is very little discussion of the specific aspects of the interventions that are studied; if the reader is not familiar with what goes on in an SMA, then they won't know after reading this, either. Similarly, one has very little information about what the usual care control treatments are, or how one qualifies to get into the study. There is no exploration of the mechanism of action.	Thank you. We added a description of the common intervention components to the executive summary and the KQ 3 results. We have also added a section on the comparison condition in the initial description of the studies.
	Although I recognize that the summary must be brief, it is hard to imagine that all the tables pointing out that it is not possible to draw definitive conclusions based on a couple of studies of non-diabetic high users, or draw conclusions about economic effects when most studies did not report them.	Results are briefly summarized in text. The table also summarizes results but adds the strength of evidence (SOE). Unfortunately, the SOE was insufficient for many outcomes
	This is especially disappointing since the readers are not naïve – they are likely to be aware of the literature suggesting a benefit from SMA based on prominent studies, several in VA, that have had this finding. What the reader needs is guidance regarding what one should or should not do if one is attempting to be evidence based. I think that requires description of commonalities in the study designs, even if you can't comment on whether one aspect or another was demonstrably better.	Unfortunately, the literature does not yet establish the characteristics of SMA associated with benefit. However, in the KQ 3 results, we describe the common features and echo these findings in the discussion.
	Since the introduction suggests a couple mechanisms of action, perhaps one could say whether the results say anything about these. In the case of improved access, for example, I guess the answer is that this is NOT the mechanism, since the control people would have also benefited from the provider having more clinic slots. Similarly, if the mechanism were expertise, I would like to see commentary on the expertise of the providers who participated in the SMA – my sense from the articles I have reviewed is that they are not content area experts.	Thank you. This is a good point, but few studies reported intermediate outcomes (e.g., self-management behaviors) or provider training. We report the available results and have added to the discussion the point that few studies report on the potential mechanisms of action.

Reviewer	Comment	Response
6 cont.	RE: METHODS I think that these are well described. But I wish that there was more of a sense that clinical experts were doing the synthesis and they were thinking about how they made sense. The AHRQ methodology does not seem to exclude this. Moreover, I acknowledge it seems like it is not very rigorous and might be open to bias on the part of the reviewers. So I think that this is why you have people like me review the opinion and offer a counterpoint. And I am confident that the Durham VA and Duke has a lot of people who could offer opinions and give the consumer confidence that the recommendations are in the end based on opinion, but very well informed and vetted opinion.	The research team included physicians (one who is expert in shared medical appointments) and psychologists. Our goal was to summarize the evidence so that policy makers could incorporate the best available evidence into decision making.
	Thus, I would like to see an attempt to present the rationale for why they think they won't change their mind (i.e., strength of evidence "High") or that they are not yet convinced. I would not want this to be devoid of quantitative thinking, rather, I would like an exposition of why they think what they think – this can be that it just does not make sense or that it is very consistent with lots of less strong studies or that the quantitative analysis is particularly convincing or is subject to error due to some methodological consideration, despite a nominally significant p value or important effect size (e.g., the condemnation of IMG carotid endarterectomy complication rates based on a trivial number of cases – Ann Intern Med 1990;113:747-753).	The approach to assigning SOE is summarized in the methods section. The summary table in the discussion presents our judgments about each domain (study design, risk of bias, consistency, directness, precision) that forms the foundation for these judgments.
	RE: RESULTS: I am surprised that there is no description of the eligibility criterion. Obviously, the DM trials required the patients to have DM, but there is no information about whether this was to be poorly controlled or of a certain duration, or if the patients had to have a stable medical regimen or be taking or not taking insulin or ??	Thank you. We have added descriptions of the eligibility criteria to the results (see KQ 1).
	Outcomes are well reported in tabular form. Although there are no statistically effects by study or patient characteristics, I would have liked some exploration of individual examples with greater or smaller effect size, and some assessment of why one had more effect than another.	Effects were consistent for blood pressure outcomes but varied for glucose control and HRQOL. We explored three factors hypothesized a priori to be related to effect size: baseline severity, intervention robustness, and study quality.

Reviewer	Comment	Response
6 cont.	It is presumably because the study authors did not include the information, but one wonders if there are any process measures like medication changes or behavior changes that could explain the change in control. For example, with all the BP improvement, did this reflect a drop in weight, a change in prescribed medication, a change in medication adherence, a change in physical activity or what ? Or do we just not know? It seems most likely that this reflects a medication effect, since the effect on A1c, LDL and BP are all sensitive to this, and there is no evidence of a change in weight – I assume this was examined and will be reported in the revised version.	The authors of the individual studies did not provide this data consistently. A few studies report effects on self-management behaviors and these results are reported in KQ 1 "treatment experience and adherence outcomes." We also abstracted information on medication changes and report these results in the same section
	RE: DISCUSSION: I love that there is an explicit paragraph labeled "Should SMAs be Implemented?" But I am disappointed that it does not appear that they answer this question. Since the VA in particular paid for this synthesis, one would think there would at least be an answer for VA. It might be something along the lines of "The evidence available suggests that the VA should be implementing an SMA in all hospitals. This should be made available for all patients who have inadequate control. However, one should require referral by the primary care provider." One would obviously provide caveats and nuance the presentation, but it is unfortunate that when the explicit goal is to help policy makers change policy, the guidance is vague.	Our goal is to synthesize the evidence to inform policymaking. Although we try to describe some of the considerations (in addition to evidence of intervention effect) that might influence policy, it is not our role to prescribe policy.
	RE: APPENDIX C – DATA ELEMENTS ABSTRACTED Hard to imagine that weight was not abstracted from at least some of the studies, given that all the disease specific studies were about diabetes.	Weight was not specified as an outcome of interest by our study team or stakeholders.
	"Health professionals who conducted the educational session" is not reported with much specificity – that is, we see only MD as the descriptor. Is there evidence of specialists versus generalists? The same question applies to the pharmacists. Or are they just people who are interested in the area or researcher team members.	Specialty, training and experience of the MD professionals were almost never described.
	RE: APPENDIX G – Study characteristics of included studies The column labeled "Target condition HBA1c % (for total population)" appears to be mislabeled. The number in parentheses seems to be the standard deviation, not the value of A1c for the total population. Or the percent of the total population included – I am not sure what they mean by this.	Thank you. We relabeled the column to improve clarity.
	Usual care could have been described in more detail. Particularly in situations where the DM control was poor at baseline, one would imagine that the correct comparator would be some other, non-group approach to improved control – probably as simple as having the prescribing provider see the person for better control.	We have added a paragraph describing the Comparison Conditions in more detail in the "Study Characteristics" section of the results.
	Since the introduction suggests that access to an expert provider might be the mechanism of action, I wonder if there is information about the training of the MD or pharmacist.	Unfortunately, information about the specialty training and experience of the MD clinician or clinical pharmacist was give rarely.

Reviewer	Comment	Response
7	Other elements to assess in explaining heterogeneity of study results in diabetes is the clinician expertise in diabetes and group management, e.g. do the clinician(s) have training in diabetes or conduction of group visits prior to starting the trial – such as being a certified diabetes educator, do the clinician(s) manage diabetes in other settings – such as individual diabetes clinics, how many disciplines were in the team, etc.	Although this is a good idea, and could explain heterogeneity in intervention effects, clinician expertise and certification as a diabetes educator were not described consistently enough for analysis.
Optional Dissemination and Implementation Questions		
Question 5: Are there any VA clinical performance measures, programs, quality improvement measures, patient care services, or conferences that will be directly affected by this report? If so, please provide detail.		
1	I do not work in the VA setting, so am unable to comment on this.	Acknowledged
2	The Office of Nursing Service (ONS) conducts courses on EBP; use of this document may enhance learning for the participants who would attend this conference; given that the EBP course is for the properly targeted audience. The other group that could benefit is the Clinical Practice Portfolio of the ONS as this ES is timely to impact recommendations for intervention for both PACT and Specialty Care services. In addition, a presentation on the findings would be beneficial for the Advanced Practice Nursing Advisory Group as this group of providers would be influenced by these findings.	Acknowledged Acknowledged
3	PACT compass, Office of Patient Care Service, Office of Nursing Service, Office of Academic Affiliations: Centers of Excellence in Primary Care Education	Acknowledged
4	PACT implementation included an emphasis on SMA and group visits as a means to enhance access and implement a chronic care model. The ability to improve access is not addressed by this data synthesis. A SMA of reasonable size might improve access by reducing reliance on routine clinic visits. This hypothesis was not evaluated. A concern from the perspective of PACT is that the SMA might adversely affect patient continuity with their primary care provider. The information regarding whether the intervention preserved patient continuity with the provider or not is not provided. An evaluation of the benefits of SMA versus the trade-offs might ultimately be very helpful.	Acknowledged Most studies describe the intervention as additional care, rather than a substitute for primary care. We have added a statement to this effect in the discussion. No studies reported access outcomes directly or information on continuity with their PCP. Few reported effects on patient experience.
5	PACT initiative in Primary Care is promoting SMA's.	Acknowledged
6	The authors are clear that there is not enough evidence that we can say that use or non-use of SMA is a quality issue. I think there are a number of conferences where the results will be of interest – certainly HSR and QUERI and hopefully the leadership meetings.	The results of this review and a parallel "realist" review are being presented at the July 2012 HSR&D conference.
7	PACT compass that includes SMA as one of its components, in addition to the traditional diabetes performance measures in Primary care	Acknowledged

Reviewer	Comment	Response
Question 6: Please provide any recommendations on how this report can be revised to more directly address or assist implementation needs.		
1	No comments by reviewer 2	
2	Report is very well done. Are companion presentations done in conjunction with the report (PowerPoint, to be used for presenting to interested groups)?	Thank you. There will be a presentation at the July 2012 HSR&D/QUERI meeting.
3	Executive summary very direct and to the point. Recommendations for future research offer usable directions	Thank you.
4	More information about the intervention would have been helpful. Key elements that may result in successful implementation are hinted at in Table 6, but are not fully discussed. This table is also not self-explanatory: for example what is meant by "Team continuity"?	We revised Table 6 and footnoted other tables to more improve clarity. Detailed information on the intervention is presented in Appendix H and summarized in Table 3.
5	A table of the roles of each providers (along with quality) in the studies would help as sites try to implement SMA's	Although team composition was described, roles of individual providers were not described consistently enough to develop the requested table.
6	See response to #4	Addressed above.
7	I believe this report is an unbiased assessment and synthesis of current literature and clearly points out the strengths and weaknesses of the available data	Thank you.
Question 7: Please provide us with contact details of any additional individuals/stakeholders who should be made aware of this report.		
1	No. No comment	Acknowledged
2	Once completed: Christine Engstrom, Anna Alt-White	Acknowledged
3	PACT e-mail group, Centers of Excellence in Primary Care Education	Acknowledged
4	Richard Stark; Joanne Shear	Acknowledged
5	No comment	Acknowledged
6	None in particular	Acknowledged
7	No comment	Acknowledged

APPENDIX F. ONGOING CLINICAL TRIALS

Table F-1. Ongoing clinical trials

Official study title	Organization	Intervention	Comparator	Sponsor and ClinicalTrials.gov ID	Funding Start/Stop	Status
Interprofessional Training for Improving Diabetes Care	Government	Shared medical appointments to promote establishing collaborative teams (ReSPECT)	Traditional diabetes education and teleconsultation	Department of Veterans Affairs NCT00854594	Sep 2010–Sep 2012	Recruiting
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	Feb 2012–Feb 2013	Not yet open for participation
Heart Failure Group Clinic Appointments: Rehospitalization	University-affiliated clinic	Heart Failure Group Clinic Appointments	Standard heart failure education	Carol Smith, RN, PhD, FAAN (NHLBI) NCT00439842	Mar 2007–Sep 2012	Ongoing, but not recruiting
Group Intervention for DM Guideline Implementation	Government	Pharmacist-led group medical visits for patients with type 2 diabetes mellitus	Usual care	Department of Veterans Affairs NCT00554671	May 2008–June 2012	Ongoing, but not recruiting participants

Abbreviations: DM=diabetes mellitus; NHLBI=National Heart, Lung, and Blood Institute

APPENDIX G. SMA STUDY CHARACTERISTICS

Table G-1. SMA study characteristics

Study	Location Setting Organization Total N	Age in Years (SD) Sex (%) Race/ethnicity (%)	Target Condition Mean Baseline HBA1c % (SD) (for Diabetes Studies)	SMA Planned Visits Study Duration	Comparator	Quality
Beck, 1997	US Primary care HMO 321	73.5 (NR) Male (34%) NR	Chronically ill older adults Not applicable	12 >12 months	Usual care	Poor
Bray, 2005	US Primary care University-affiliated clinic 160	59.4 (14.3) Male (44%) NR	Diabetes; hypertension HBA1c: 8.2 (2.4)	4 12 months	Usual care	Fair
Clancy, 2003	US Primary care University-affiliated clinic 120	54.0 (NR) Male (22%) Black (77.5%)	Type 2 diabetes HBA1c: 10.4 (NR)	6 6 months	Usual care	Good
Clancy , 2007	US Primary care University-affiliated clinic 186	56.0 (NR) Male (28%) Black (83.3%)	Type 2 diabetes HBA1c: 9.1 (2.0)	12 12 months	Usual care	Fair
Cohen, 2011	US Primary care VA Health system 99	69.8 (10.7) Male (100%) NR	Type 2 diabetes HbA1c: 7.8 (1.0)	4 once weekly + 5 monthly booster session 6 months	Usual care	Fair
Culhane-Pera, 2005	US Federally qualified health center Government 61	56.8 (NR) Male (36%) NR	Type 2 diabetes HBA1c: 9.4 (NR)	7 visits 28 months	Usual care	Poor
Edelman, 2010	US Primary care VA Health system 239	62.0 (9.7) Male (96%) Black (59.0%)	Diabetes; hypertension HBA1c: 9.2 (1.4)	7 visits 12 months	Usual care	Good
Gutierrez, 2011	US Primary care University-affiliated clinic 103	NR (NR) Male (NR) Hispanic (100%)	Type 2 diabetes HBA1c: NR (NR)	36 visits offered 17 months	Usual care	Poor

Study	Location Setting Organization Total N	Age in Years (SD) Sex (%) Race/ethnicity (%)	Target Condition Mean Baseline HBA1c % (SD) (for Diabetes Studies)	SMA Planned Visits Study Duration	Comparator	Quality
Kirsh, 2007	US Primary care VA Health system 79	61.0 (9.9) Male (NR) NR	Type 2 diabetes HBA1c: 10.1 (NR)	NA (drop-in) 4 months)	Usual care	Fair
Levine, 2010	US Primary care HMO 1236	78.2 (7.2) Male (35%) NR	High usage of clinic services Not applicable	12 visits 12 months	Usual care	Fair
Naik, 2011	US Primary care VA Health system 87	63.6 (7.9) Male (NR) Black (31.0%)	Type 2 diabetes HBA1c: 8.8 (1.3)	4 visits 3 months intervention; 12 months followup	Enhanced usual care (2 required diabetes group education sessions)	Good
Sadur, 1999	US Primary care HMO 185	56.0 (9.1) Male (57%) White (74.6%)	Types 1 and 2 diabetes HBA1c: 9.7 (1.7)	6 visits 6 months	Usual care	Good
Scott, 2004	US Primary care HMO 294	74.1 (7.5) Male (41%) NR	Older; high usage of clinic services Not applicable	24 visits 24 months	Usual care	Fair
Taveira, 2010	US Primary care VA Health system 118	64.4 (10.3) Male (95%) White (91.0%)	Type 2 diabetes HBA1c: 8.0 (1.3)	4 visits 1 month (outcomes reported at 4 months)	Usual care	Fair
Taveira, 2011	US Primary care VA Health system 88	60.8 (9.6) Male (98% White (99%)	Types 1 and 2 diabetes HBA1c: 8.4 (1.8)	9 visits 6 months	Usual care	Good
Trento, 2001	Italy Diabetes clinic University-affiliated clinic 112	61.5 (NR) Male (54%) NR	Type 2 diabetes HBA1c: 7.4 (1.4)	7-8 visits 24 months	Usual care plus individual education sessions	Fair
Trento, 2005	Italy Diabetes clinic University-affiliated clinic 62	Median 27-31 (NR) Male (60%) NR	Type 1 diabetes HBA1c: 8.7 (1.2)	15 visits 36 months	Usual care plus individual education sessions	Fair

Study	Location Setting Organization Total N	Age in Years (SD) Sex (%) Race/ethnicity (%)	Target Condition Mean Baseline HBA1c % (SD) (for Diabetes Studies)	SMA Planned Visits Study Duration	Comparator	Quality
Trento, 2010	Italy Diabetes clinic University-affiliated clinic 815	69.3 (8.4) Male (51%) NR	Type 2 diabetes HBA1c: 7.8 (1.6)	14 visits 48 months	Usual care; followup scheduled every 3 months	Good
Wagner, 2001	US Primary care HMO 707	60.7(NR) Male (53%) White (72.8%)	Types 1 and 2 diabetes HBA1c: 7.5 (NR)	8 visits 24 months	Usual care	Fair

APPENDIX H. SMA INTERVENTION COMPONENTS

Table H-1. SMA interventions: team and process components

	Clinical Team		Group		Group Visit Processes			
Study	**Clinical disciplines**	**Team continuity** **Team size**	**Closed?** **Group size**	**Family or peers allowed?**	**Individual breakouts?**	**Medication changes?**	**Visit duration (minutes)**	**Telephone contacts?**
Beck, 1997	MD, RN, and psychologists (as guest lecturers)	Specific group but rotated ≥2	Yes 8[a]	Yes	Yes	Yes	120	Yes
Bray, 2005	MD, RN, and/or others (type NR)	Yes 2	Yes 3-12	NR	Yes	Yes	120	NR
Clancy, 2003	MD, nurse practitioner, and guest presenters	Yes 2-3	Yes 19-20	NR	Yes	Yes	120	No
Clancy, 2007	MD and RN	Yes 2	Yes 6-7	No	Yes	Yes	120	No
Cohen, 2011	Pharmacist, RN, physical therapist and dietitian	Yes 4	Yes 4-6	Yes	NR	Yes	60	No
Culhane-Pera, 2005	Exercise specialist, MD, RN, and social worker	Yes 7	Yes 10-16	Yes	NR	Yes	210	NR
Edelman, 2010	Health educator, MD, pharmacist, or RN	Yes 3	Yes 7-8	No	Yes	Yes	90-120	Yes
Gutierrez, 2011	MD, pharmacist, RN, and social worker	NR 7	No NR	NR	NR	NR[b]	NR	NR
Kirsh, 2007	MD, nurse practitioner, pharmacist, psychologist, and/or RN	Yes 5	No ≤8	NR	Yes	Yes	Varied >60	NR
Levine, 2010	MD and nurse practitioner	Yes 3	Yes 25	NR	Yes	Yes	90	NR/unclear
Naik, 2011	MD	Yes ≥2	Yes 5-7	No	Yes	Yes	120	No

	Clinical Team		Group		Group Visit Processes			
Study	**Clinical disciplines**	**Team continuity** **Team size**	**Closed?** **Group size**	**Family or peers allowed?**	**Individual breakouts?**	**Medication changes?**	**Visit duration (minutes)**	**Telephone contacts?**
Sadur, 1999	Behaviorist, dietician, pharmacist, and RN	Yes 4	Yes 10-18	No	Yes	Yes	120	Yes
Scott, 2004	MD, pharmacist, RN, physical therapist, and occupational therapist	Yes ≥2	No 7.7[a]	Yes	Yes	Yes	120	No
Taveira, 2010	Dietician, pharmacist, physical therapist, and RN	Yes Unclear	Yes 4-8	Yes	NR	Yes	120	No
Taveira, 2011	Pharmacist and RN	Yes Unclear	No 4-6	Yes	No	Yes	120	No
Trento, 2001	Health educator and MD	Partial[c] 2-3	Yes 9-10	Yes	Yes	Yes	50-80	No
Trento, 2005	MD and psychopedagogist	Partial[c] 2	Yes 6-7	Yes	Yes	Yes	40-80	No
Trento, 2010	Health educator and MD	Partial[c] 2	Yes 9-10	Yes	Yes	Yes	60	No
Wagner, 2001	MD, pharmacist, and RN	Yes 3	Yes 6-10	NR	Yes	NR	60	No

[a]Group size: In these cases, a mean value rather than a range is reported in the article.
[b]Medication changes: This article did not clearly report whether medication changes were made as part of the group process; however, it is implied in that an MD and a pharmacist were usually present, and the intervention group both lowered their HbA1c and started taking more aspirin than the control group.
[c]Trento studies: The investigators relied on a pool of health providers for group intervention, which may provide patients with the possibility to see the same provider more than once—hence, team continuity is partially present.

Table H-2: SMA interventions: educational and behavioral components

Study	Leader(s) of Educational Session	Behavioral Approach	Patients Input on Topics?	Topics	Behavioral Strategies	Print Material?
Beck, 1997	MD, pharmacist, RN, or other team member	NR	No	Medication management, nutrition, physical activity	NR	Yes, generic
Bray, 2005	RN or other team member	NR	NR	Disease-specific education, medication management, nutrition	Goal-setting, personalized plan	NR
Clancy, 2003	MD, RN, or guest lecturers	NR	Yes	Disease-specific education, medication management, nutrition, physical activity	NR	NR
Clancy , 2007	MD	NR	Yes	Disease-specific education, medication management, nutrition, physical activity	NR	NR
Cohen, 2011	Pharmacist	NR	No	Disease specific education, medication management, nutrition, physical activity	Goal-setting, homework assignments, personalized care plan, self-monitoring	Yes
Culhane-Pera, 2005	RN	NR	No	Disease-specific education, medication management, nutrition, physical activity	Goal-setting, problem-solving skills	NR
Edelman, 2005	Health educator or RN	NR	Yes	Disease-specific education, medication management, nutrition, physical activity	Personalized care plan	Yes, generic
Gutierrez, 2011	Social worker	NR	NR	NR	NR	NR
Kirsh, 2007	Health psychologist	NR	NR	Disease-specific education nutrition, smoking cessation	Personalized plan	Yes, generic
Levine, 2010	MD or RN	NR	Yes	Medication management, nutrition, physical activity	NR	Yes, generic
Naik, 2011	Study clinician	NR	No	Disease-specific education, medication management	Goal-setting, personalized plan, problem-solving skills, self- monitoring	Yes, tailored
Sadur, 1999	Dietician, health behavior specialist, pharmacist, podiatrist, or RN	NR	Yes	Disease-specific education, physical activity	Personalized plan	NR
Scott, 2004	Dietician, MD, pharmacist, physical therapist, or RN	NR	Yes	Disease-specific education, medication management, nutrition, physical activity	NR	Yes tailored
Taveira, 2010	Dietician, pharmacist, physical therapist, or RN	Stages of change	No	Disease-specific education, medication management, nutrition, physical activity, smoking cessation	NR	Yes, tailored

Study	Leader(s) of Educational Session	Behavioral Approach	Patients Input on Topics?	Topics	Behavioral Strategies	Print Material?
Taveira, 2011	Nutritionist, pharmacist, or RN	Stages of change	No	Disease-specific education, medication management, nutrition, physical activity, smoking cessation	NR	Yes, tailored
Trento, 2001	MD or health educator	Patient-centered adult learning	No	Disease-specific education, medication management, nutrition, physical activity, smoking cessation	Homework assignment, problem-solving skills, self-monitoring	Yes, tailored
Trento, 2005	MD or health educator	Patient-centered adult learning	Yes	Disease-specific education, medication management, nutrition, physical activity, self-care	Homework assignment, problem-solving skills, self-monitoring	Yes, tailored
Trento, 2010	MD or health educator	Patient-centered adult learning	No	Disease-specific education, medication management, nutrition, physical activity, smoking cessation	Homework assignment, problem-solving skills, self-monitoring	Yes, tailored
Wagner, 2001	RN or other health professional	NR	No	Disease-specific education	Self-monitoring	Yes, generic

APPENDIX I. GLOSSARY

Abstract screening

The stage in a systematic review during which titles and abstracts of articles identified in the literature search are screened for inclusion or exclusion based on established criteria. Articles that pass the abstract screening stage are promoted to the full-text review stage.

Allocation concealment

The method by which randomization assignment is concealed from participants and investigators before and during the enrollment process. Common processes are central allocation (telephone or web-based, pharmacy or off-site statistician controlled randomization sequence generation and sequentially numbered, opaque, sealed envelopes. Allocation concealment concentrates on preventing selection and confounding biases, safeguards the assignment sequence *before and until* allocation, and can always be successfully implemented

Area under the curve (AUC)

The area under the receiver operating characteristic (ROC) curve. The summary receiver operator characteristic (SROC) curve and the AUC have been proposed as a way to assess diagnostic data in the context of a meta-analysis. The accuracy of a diagnostic test depends on how well the test separates the group being tested into those with and without the condition in question.

Case-control study

A retrospective, analytical, observational study often based on secondary data in which the proportion of cases with a potential risk factor are compared to the proportion of controls (individuals without the disease or condition) with the same risk factor. The common association measure for a case-control study is the odds ratio. These studies are commonly used for initial, inexpensive evaluation of risk factors and are particularly useful for rare conditions or for risk factors with long induction periods. Unfortunately, due to the potential for many forms of bias in this study type, case control studies provide relatively weak empirical evidence even when properly executed.

Case report

A description of a single case, typically describing the manifestations, clinical course, and prognosis of that case. Due to the wide range of natural biologic variability in these aspects, a single case report provides little empirical evidence to the clinician. A case report does describe how others diagnosed and treated the condition and what the clinical outcome was.

Case series

A descriptive, observational study of a series of cases, typically describing the manifestations, clinical course, and prognosis of a condition. A case series provides weak empirical evidence because of the lack of comparability unless the findings are dramatically different from expectations. Case series are best used as a source of hypotheses for investigation by stronger study designs, leading some to suggest that the case series should be regarded as clinicians talking to researchers. Unfortunately, the case series is the most common study type in the clinical literature.

ClinicalTrials.gov

A registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov provides information about a trial's purpose, location, participant characteristics, among other details.

Cochrane Database of Systematic Reviews

A bibliographic database of peer-reviewed systematic reviews and protocols prepared by the Cochrane Review Groups in The Cochrane Collaboration.

Cochran's Q test

A nonparametric statistic to test for differences in intervention effects between studies. Because the test statistic is often underpowered, the threshold for statistically significant differences in intervention effects is often set at $p<0.10$.

Cohort study

A prospective, analytical, observational study based on data, usually primary, from a followup period of a group in which some have had, have, or will have the exposure of interest, to determine the association between that exposure and an outcome. Cohort studies are susceptible to bias by differential loss to followup, the lack of control over risk assignment, and the potential for zero time bias when the cohort is assembled. Because of their prospective nature, cohort studies are stronger than case-control studies when well executed, but they also are more expensive. Because of their observational nature, cohort studies do not provide empirical evidence that is as strong as that provided by properly executed randomized controlled clinical trials.

Companion article

A publication from a trial that is not the article containing the main results of that trial. It may be a methods paper, a report of subgroup analyses, a report of combined analyses, or other auxiliary topic that adds information to the interpretation of the main publication.

Confidence interval (CI)

The range in which a particular result (such as a laboratory test) is likely to occur for everyone in the population of interest a specified percentage of the time known as the confidence level or confidence coefficient. It is an interval calculated from a study's observations used to estimate the reliability of the estimate of a parameter. The most common confidence level is 95%. For example, a confidence interval with a 95% confidence level is intended to give the assurance that, if the statistical model is correct, then taken over all the data that *might* have been obtained, the true value of the parameter will be found within the given interval 95% of the time.

Consistency

Extent to which effect size and direction vary within and across studies; inconsistency may be due to heterogeneity across PICOTS.

Cumulative Index to Nursing and Allied Health Literature (CINAHL)

A collection of medical databases of nursing and allied health literature.

Data abstraction

The stage of a systematic review that involves a pair of trained researchers extracting reported findings specific to the research questions from the full-text articles that met the established inclusion criteria. These data form the basis of the evidence synthesis.

Directness

Degree to which outcomes that are important to users of the comparative effectiveness review (patients, clinicians, or policymakers) are encompassed by trial data.

Embase

A database containing bibliographic records with citations, abstracts, and indexing derived from biomedical and pharmacological articles in peer-reviewed journals.

Exclusion criteria

The criteria, or standards, set out before a study or review. Exclusion criteria are used to determine whether a person should participate in a research study or whether an individual study should be excluded in a systematic review. Exclusion criteria may include age, previous treatments, and other medical conditions.

External validity

The extent to which clinical research studies apply to broader populations. A research study has external validity if its results can be generalized to the larger population.

Forest plot

A visual display of information from individual studies in a meta-analysis. A forest plot shows the amount of variation between the results of the studies as well as an estimate of the overall result of all the studies together. A horizontal line represents the 95% confidence interval (CI) of the "effect" observed in the studies.

Full-text review

The stage of a systematic review in which a pair of trained researches evaluates the full-text of study articles for potential inclusion in the review.

GRADE

Grading of Recommendations Assessment, Development and Evaluation (GRADE), a systematic approach to evaluating the overall body of research evidence and rating the quality of medical evidence and the strength of clinical recommendations.

Health-related quality of life (HRQOL)

Aspects of overall quality of life that can be clearly shown to affect health—either physical or mental health.

I^2

A statistic that describes the percentage (range from 0-100%) of total variation across studies due to heterogeneity between study characteristics rather than due to chance. Heterogeneity is categorized as low, moderate or high based on I^2 values of 25, 50 or 75%, respectively. It is considered an indication of consistency or inconsistency across studies in a meta-analysis.

Inclusion criteria

The criteria, or standards, set out before the systematic review. Inclusion criteria are used to determine whether an individual study can be included in a systematic review. Inclusion criteria may include population, study design, gender, age, type of disease being treated, previous treatments, and other medical conditions.

Intent-to-treat analysis

A method of analyzing results of a randomized controlled trial that includes in the analysis all cases that should have received a treatment regimen but for some reason did not. All cases allocated to each arm of the trial are analyzed together as representing that treatment arm, regardless of whether they received or completed the prescribed regimen.

Interquartile range (IQR)

A measure of the spread of or dispersion within a data set. The IQR is the width of an interval that contains the middle 50 percent of the sample, so it is smaller than the range and its value is less affected by outliers.

Meta-analysis

A way of combining data from many different research studies. A meta-analysis is a statistical process that combines the findings from individual studies.

Meta-regression analyses

An extension of meta-analysis to subgroups that allows the effect of continuous, as well as categorical, characteristics to be investigated if sufficient studies examining the same characteristics may be compared. In principle, it allows the effect of multiple factors to be investigated simultaneously. In meta-regression, the outcome variable is the effect estimate (e.g., a mean difference, etc.). The explanatory variables are characteristics of studies that might influence the size of the intervention effect.

Mixed effects

Statistical models that include both fixed (nonrandom) and random effects.

National Committee for Quality Assurance (NCQA)

A nonprofit organization dedicated to improving health care quality.

National Quality Forum (NQF)

A nonprofit organization that promotes change through development and implementation of a national strategy for health care quality measurement and reporting.

Negative predictive value (NPV)

The likelihood that people with a negative test result would not have a condition. The higher the value of the negative predictive value (for example, 99 percent would usually be considered a high value), the more useful the test is for predicting that people do not have the condition.

Nonrandomized study

Any quantitative study estimating the effectiveness of an intervention (harm or benefit) that does not use randomization to allocate units to comparison groups (including studies where "allocation" occurs in the course of usual treatment decisions or peoples' choices; i.e., studies usually called "observational"). There are many possible types of nonrandomized intervention studies, including cohort studies, case-control studies, controlled before-and-after studies, interrupted-time-series studies, and controlled trials that do not use appropriate randomization strategies (sometimes called quasi-randomized studies).

Observational study

A study in which the investigators do not seek to intervene but simply observe the course of events. Changes or differences in one characteristic (e.g., whether or not people received the intervention of interest) are studied in relation to changes or differences in other characteristics (e.g., whether or not they died), without action by the investigator. Observational studies provide weaker empirical evidence than do experimental studies because of the potential for large confounding biases to be present when there is an unknown association between a factor and an outcome.

Odds ratio

A ratio of the odds of having the outcome of interest in a group with a particular exposure, symptom, or characteristic of interest, to the odds of outcome in a group that does not have the exposure/symptom/characteristic. An odds ratio of 1 indicates that the outcome is equally likely to occur in both groups. An odds ratio of 4 indicates that the outcome is 4 times more likely to be present in the group that has the symptom or characteristic of interest, compared with the group that does not have this symptom. When outcomes are infrequent, the odds ratio is a good approximation of the risk ratio.

Outlier

An observation in a data set that is far removed in value from the others in the data set. It is an unusually large or an unusually small value compared to the others.

Patient-centered adult learning

An approach used in the professional–patient interaction. Common elements are empathic communication, acknowledgement, realistic expectations, goal negotiation, guided problem-solving, individualized strategies, and ongoing support.

PICOTS

Population, intervention, comparator, outcome, timing, setting.

Positive predictive value (PPV)

Indicates the likelihood that a person with a positive test result would actually have the condition for which the test is used. The higher the value of the positive predictive value (for example, 90 percent would be considered a high value), the more useful the test is for predicting that the person has the condition.

Precision

The degree of certainty for estimate of effect with respect to a specific outcome.

Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA)

An evidence-based minimum set of items for reporting in systematic reviews and meta-analyses.

Probability

The likelihood (or chance) that an event will occur. In a clinical research study, it is the number of times a condition or event occurs in a study group divided by the number of people being studied.

Process of care or performance measure

Quality measures used to gauge how well an entity provides care to its patients. Measures are based on scientific evidence and usually reflected in guidelines, standards of care or practice parameters.

Prospective observational study

A clinical research study in which people who presently have a certain condition or receive a particular treatment are followed over time and compared with another group of people who are not affected by the condition.

PsycINFO

An abstracting and indexing database of peer-reviewed literature in the behavioral sciences and mental health.

Publication bias

The tendency of researchers to publish experimental findings that have a positive result, while not publishing the findings when the results are negative or inconclusive. The effect of

publication bias is that published studies may be misleading. When information that differs from that of the published study is not known, people are able to draw conclusions using only information from the published studies.

PubMed

A database of citations for biomedical literature from MEDLINE, life science journals, and online books in the fields of medicine, nursing, dentistry, veterinary medicine, the health care system, and preclinical sciences.

QUADAS

Quality Assessment of the Diagnostic Accuracy Studies, a tool that uses a standard methodology to judge the quality of individual studies in a systematic review.

Quasi-experimental study

A quasi-experimental study manipulates a variable between two or more groups, but participants are not randomly assigned to groups. Quasi-experimental study designs, such as nonrandomized pre-post studies, are frequently used when it is not logistically feasible or ethical to conduct a randomized controlled trial.

Quasi-random allocation

Methods of allocating people to a trial that are not random but were intended to produce similar groups when used to allocate participants. Quasi-random methods include allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person. In practice, these methods of allocation are relatively easy to manipulate, introducing selection bias.

Randomized controlled trial

A prospective, analytical, experimental study using primary data generated in the clinical environment. Individuals similar at the beginning of the trial are randomly allocated to two or more treatment groups and the outcomes the groups are compared after sufficient followup time. Properly executed, the RCT is the strongest evidence of the clinical efficacy of preventive and therapeutic procedures in the clinical setting.

Relative risk (RR)

A comparison of the risk of a particular event for different groups of people. Relative risk is usually used to estimate exposure to something that could affect health. In a clinical research study, the experimental group is exposed to a particular drug or treatment. The control group is not. The number of events in each group is compared to determine relative risk.

Reporting bias

A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this,

systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (e.g., only outcomes or subgroups where a statistically significant difference was found).

Risk

A way of expressing the chance that something will happen. It is a measure of the association between exposure to something and what happens (the outcome). Risk is the same as probability, but it usually is used to describe the probability of an adverse event. It is the rate of events (such as breast cancer) in the total population of people who could have the event (such as women of a certain age).

Robustness score

A score developed to indicate the number of intervention components hypothesized to be associated with greater treatment effects.

Sensitivity

The ability of a test to identify correctly people with a condition. A test with high sensitivity will nearly always be positive for people who have the condition (the test has a low rate of false-negative results). Sensitivity is also known as the true-positive rate.

Shared medical appointment (SMA)

A group visit where multiple patients are seen together for followup or routine care.

Spearman's correlation

A rank correlation coefficient that is usually calculated on occasions when it is not convenient, economical, or even possible to give actual values to variables but only to assign a rank order to instances of each variable. It may also be a better indicator that a relationship exists between two variables when the relationship is nonlinear.

Specificity

The ability of a test to identify correctly people without a condition. A test with high specificity will rarely be wrong about who *does not* have the condition (the test has a low rate of false-positive results). Specificity is also known as the true-negative rate.

Stages-of-change model

A common health behavioral model consisting of these components: precontemplation, contemplation, preparation, action, and maintenance.

Standard error

The standard deviation of the sampling distribution of a statistic. Measurements taken from a sample of the population will vary from sample to sample. The standard error is a measure of the variation in the sample statistic over all possible samples of the same size. The standard error decreases as the sample size increases.

Standardized mean difference (SMD)

The difference between two estimated means divided by an estimate of the standard deviation. It is used to combine results from studies using different ways of measuring the same concept, e.g. mental health. By expressing the effects as a standardized value, the results can be combined since they have no units.

Statistical significance

A mathematical technique to measure whether the results of a study are likely to be true. Statistical significance is calculated as the probability that an effect observed in a research study is occurring because of chance. Statistical significance is usually expressed as a P-value. The smaller the P-value, the less likely it is that the results are due to chance (and more likely that the results are true). Researchers generally believe the results are probably true if the statistical significance is a P-value less than 0.05 ($p<.05$).

Strength of evidence (SOE)

A measure of how confident reviewers are about decisions that may be made based on a body of evidence. SOE is evaluated using one of four grades: (1) *High* confidence that the evidence reflects the true effect; further research is very unlikely to change reviewer confidence in the estimate of effect; (2) *moderate* confidence that the evidence reflects the true effect; further research may change the confidence in the estimate of effect and may change the estimate; (3) *low* confidence that the evidence reflects the true effect; further research is likely to change the confidence in the estimate of effect and is likely to change the estimate; and (4) *insufficient*; the evidence either is unavailable or does not permit a conclusion.

Summary receiver operating characteristic (SROC)

A data analysis approach that combines independent studies of diagnostic tests. The SROC curve and the area under the curve (AUC) have been proposed as a way to assess diagnostic data in the context of a meta-analysis.

Systematic review

A summary of the clinical literature. A systematic review is a critical assessment and evaluation of all research studies that address a particular clinical issue. The researchers use an organized method of locating, assembling, and evaluating a body of literature on a particular topic using a set of specific criteria. A systematic review typically includes a description of the findings of the collection of research studies. The systematic review may also include a quantitative pooling of data, called a meta-analysis.

Time-series study

A quasi-experimental research design in which periodic measurements are made on a defined group of individuals both before and after implementation of an intervention. Time series studies are often conducted for the purpose of determining the intervention or treatment effect.