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Meta-analysis of the effectiveness of chronic care management for diabetes: investigating heterogeneity in outcomes

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Abstract

Purpose The study aims to support decision making on how best to redesign diabetes care by investigating three potential sources of heterogeneity in effectiveness across trials of diabetes care management.

Methods Medline, CINAHL and PsycInfo were searched for systematic reviews and empirical studies focusing on: (1) diabetes mellitus; (2) adult patients; and (3) interventions consisting of at least two components of the chronic care model (CCM). Systematic reviews were analysed descriptively; empirical studies were meta-analysed. Pooled effect measures were estimated using a meta-regression model that incorporated study quality, length of follow-up and number of intervention components as potential predictors of heterogeneity in effects.

Results Overall, reviews ($n = 15$) of diabetes care programmes report modest improvements in glycaemic control. Empirical studies ($n = 61$) show wide-ranging results on HbA1c, systolic blood pressure and guideline adherence. Differences between studies in methodological quality cannot explain this heterogeneity in effects. Variety in length of follow-up can explain (part of) the variability, yet not across all outcomes. Diversity in the number of included intervention components can explain 8–12% of the heterogeneity in effects on HbA1c and systolic blood pressure.

Conclusions The outcomes of chronic care management for diabetes are generally positive, yet differ considerably across trials. The most promising results are attained in studies with limited follow-up (<1 year) and by programmes including more than two CCM components. These factors can, however, explain only part of the heterogeneity in effectiveness between studies. Other potential sources of heterogeneity should be investigated to ensure implementation of evidence-based improvements in diabetes care.

Introduction

Traditional models of care, developed to react to acute episodes of illness, are not sufficiently equipped to deal with complex chronic diseases, such as diabetes mellitus [1,2]. Widespread quality deficiencies exist, including fragmentation, insufficient adherence to evidence-based practice guidelines and limited follow-up of patients over time [3–7]. As a result, the outcomes of diabetes care – in terms of effectiveness, disease control and patient satisfaction – are often inadequate. In response to these problems, new strategies of providing diabetes care are being introduced in many countries around the world. These strategies are as diverse as the health care systems in which they are implemented and include such concepts as case management, integrated care and care

coordination [8–10]. Perhaps best known internationally are disease management and the chronic care model (CCM), both of which were introduced first in the United States. The CCM was adopted by the World Health Organization as an evidence-based guide for improvement in the four basic elements necessary for the provision of high-quality chronic care: self-management support, delivery system design, clinical information systems and decision support [11,12].

Despite the inherent logic and appeal of chronic care management – that is, better care today will result in better health and less expensive care in the future – coming to strong conclusions regarding effectiveness has proven difficult [13–16]. The existing evidence base is limited and flawed by a high level of statistical heterogeneity, that is, variation in measured effects [17–23]. Variation in nomenclature contributes considerably to this variability in outcomes across studies, as do differences in methodology [24,25]. It is, however, especially the inherently multi-component nature of chronic care management that presents evaluators (and particularly systematic reviews) with challenges. Previous research has shown that differences between studies in the number and combination of included intervention components complicate the pooling of data that is so crucial to evidence-based medicine [26].

In recent years, some authors have cautioned against the impulse to widely implement innovative but unproven care strategies, which might waste resources and even have adverse effects on patients' health [14,16,27]. To prevent this, it is crucial that we revisit the current body of literature and elucidate the existing heterogeneity in effectiveness. The present review addresses this issue by synthesizing the international literature on diabetes care management and, subsequently, assessing the extent to which differences in outcomes between studies of diabetes care management can be explained by differences in either of three factors: (1) methodological study quality; (2) length of follow-up; and (3) number of included intervention components according to the CCM. Study quality is investigated because this has been criticized in diabetes research [25] and including good and poor quality trials in a systematic review may increase heterogeneity of estimated effects across trials [28,29]. Length of follow-up is important to complex multi-component interventions such as chronic care management because the required behavioural, organizational and cultural changes need time to come about [13]. Hence, studies with a short follow-up period may either over- or underestimate effects [30]. The number of components included in an intervention is investigated as a potential cause of heterogeneity in results because the CCM assumes that more comprehensive programmes will attain more promising effects [11,12]. Meta-analysis and meta-regression will be used to determine the pooled effects of diabetes care management programmes on different endpoints as well as to investigate the three potential sources of heterogeneity described previously. The aim of the review is to support the understanding of and decision making about how best to redesign diabetes care.

Methods

Literature search

We combined medical subject headings (*patient care team*; *patient care planning*; *primary nursing care*; *case management*; *critical pathways*; *primary healthcare*; *continuity of patient care*; *guidelines*; *practice guideline; disease management*; *comprehensive healthcare*; and *ambulatory care*) and text words (*disease state management*; *disease management*; *integrated care; coordinated care*; and *shared care*) related to chronic care management with the MeSH term *diabetes mellitus* to search the databases Medline, CINAHL and PsycInfo for English-language systematic reviews published between 1995 and 2011. The references from each of the included reviews were hand searched for potentially relevant empirical studies.

Study inclusion and data extraction

We included any systematic review or empirical study that focused on: (1) diabetes mellitus as the main condition of interest; (2) adult patients as the main receivers of the interventions; and (3) interventions consisting of at least two components of the CCM [11–13]. Case reports and expert opinions were excluded, as were studies that did not report on any relevant outcome measure. Three members of the research team (AE, LL, LS) independently screened citations and abstracted included reviews and studies using separate structured data entry forms. Disagreements were resolved by consensus.

Assessing sources of heterogeneity

Based on the existing literature, we *a priori* identified three potential sources of heterogeneity in effects: methodological quality [25,28,29], length of follow-up [13,30] and number of included intervention components [11,12]. We used the validated HTA-DM instrument to classify studies as demonstrating either low (<50 points), moderate (50 to 69 points) or high quality (70 to 100 points) [31]. The use of quality scales in systematic reviews has been criticized, particularly as a means to exclude or assign weights to trials [28,29], yet we applied a tailor-made, validated instrument and used this solely to categorize studies according to their quality. Length of follow-up was measured in months. For the purpose of meta-analysis, this variable was dichotomized (<1 year, ≥1 year); in the meta-regression, length of follow-up was included as a continuous variable (number of months). To group diabetes care programmes according to the four basic elements of the CCM, we followed the coding method of Zwar *et al*. [32], using the most recent description of the model's components by Wagner *et al*. [12]

Statistical analyses

Data collected from the reviews were analysed descriptively; data from empirical studies were in addition meta-analysed with the Review Manager (version 5.0.2; The Cochrane Collaboration). An *a priori* decision was made to meta-analyse the two most frequently measured clinical outcome indicators (HbA1c and systolic blood pressure) and the single most reported indicator of process (guideline adherence). To account for baseline differences between groups in clinical outcomes, the mean changes from baseline to follow-up were compared. Variances of changes were rarely reported, in which case they were assumed to be equal to one-half of the sum of the variances of the baseline and follow-up measures [33]. Missing standard deviations were

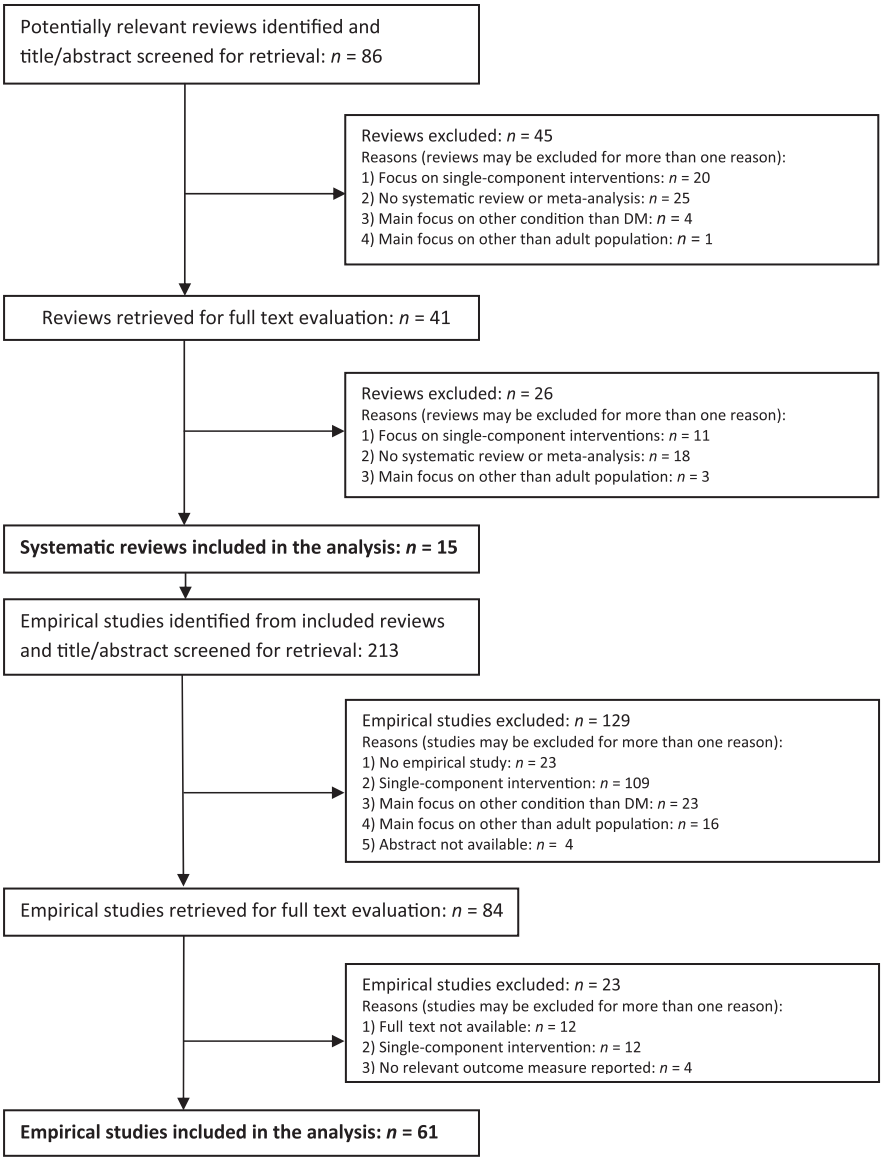

Figure 1 Study in/exclusion flowchart. DM, diabetes mellitus.

calculated by using reported 95% confidence intervals (CIs) or *P* values [34] or, if such estimations were impossible, requested from the authors. In case of no response, the studies were excluded from the meta-analysis.

Given the heterogeneity between studies' results, we used the random-effects meta-analysis model of DerSimonian and Laird [35] to calculate pooled mean differences and 95% CIs in HbA1c and systolic blood pressure. This model was also used to determine the pooled relative ratios (RRs) and 95% CIs for guideline adherence. The I^2 statistic was calculated to quantify the heterogeneity between studies on the basis of the chi-squared (χ^2) test and its degrees of freedom [34]. A univariable meta-regression model (Proc Mixed, SAS Version 9.2, SAS Institute Inc., Cary, NC, USA) was fitted to estimate the extent to which covariates on the study level can explain the differences between studies in measured effects [36,37]. For this purpose, the effects of the empirical studies were weighted by the inverse variance weight formulas. RRs were logarithm transformed [38]. All covariates – that is, study quality, length of follow-up and number of intervention components – were entered into the regression model as continuous variables. The level of heterogeneity explained was expressed as the percentage change in τ^2 (between-study variance) following separate inclusion of the covariates.

Results

Fifteen systematic reviews [17–23,26,33,39–44] (eight of which included a meta-analysis) and 61 empirical studies [45–105] met all inclusion criteria (Fig. 1). The number of studies included in the reviews varies from 5 to 58, with a median of 20. The set of empirical studies included 41 randomized controlled trials, 6 controlled clinical trials, and 4 before-after studies. The remaining 10 trials were observational studies.

Findings from systematic reviews

The reviews (Supporting Information Table S1) synthesize evidence on a wide variety of strategies for diabetes care, ranging from disease management and case management to telemonitoring, specialist nurse interventions, and shared care. Common aspect of the programmes is their strong focus on improving glycaemic control to prevent diabetes-related complications such as hypoglycaemia. The outcomes reported in the reviews vary, but some frequently measured variables are HbA1c ($n = 13$), blood pressure ($n = 9$) and quality of life ($n = 5$). Overall, the reviews draw positive conclusions about effectiveness, although improvements in glycaemic control are often modest.

Findings from empirical studies

Of the 61 empirical studies (Supporting Information Table S2), 39% scored high on methodological quality, 56% scored moderate and 5% scored poor. Length of follow-up varied from 3 to 48 months, with a median of 12 months. Forty-two studies (69%) reported a follow-up of 12 months or more. Twenty-one studies evaluated chronic care management programmes with two CCM components, 19 evaluated programmes with three components and 21 evaluated programmes with four components. The most frequently included components of the CCM were delivery system design (DSD; $n = 52$) and self-management support (SMS; $n = 49$), followed by clinical information systems (CIS; $n = 47$) and decision support (DS; N = 35). The 21 programmes consisting of two CCM components favoured a combination of SMS and DSD (43%), whereas the 19 three-component interventions most commonly combined SMS, DSD and CIS (53%).

Although the operationalization of the CCM components differed between studies, some general trends can be identified. SMS most frequently took the form of patient education and regular follow-up by diabetes nurse educators. DSD often consisted of the introduction of multidisciplinary care teams or the involvement of pharmacists, case managers and/or nurse specialists in the care for diabetes patients. CIS were mainly telemonitoring systems but also computerized patient databases, shared patient records and reminder systems. DS was offered through the implementation of diabetes guidelines as well as medication algorithms. Most interventions aimed to improve glycaemic control by supporting self-management, reducing fragmentation and/or providing evidence-based care. In general, control groups continued to receive usual care from their primary care physicians, although some were also given access to educational materials (Supporting Information Table S2). The two clinical outcomes measured most frequently were HbA1c ($n = 60$) and systolic blood pressure ($n = 34$), whereas guideline adherence was measured most regularly as a process indicator ($n = 19$). These three variables were meta-analysed (Table 1).

Glycated haemoglobin (HbA1c)

All but one study [79] assessed HbA1c levels ($n = 60$), although some [62,69,82,103] reported the fractions of patients accomplishing a certain level of glycated haemoglobin at study end [e.g. <53 mmol mol^{-1} (7.0%)] rather than the actual values. These studies were excluded from the meta-analysis, as were those for which missing data could not be estimated nor retrieved [50,59, 63,64,78,89,99,104].

Overall, the pooled effect estimate ($n = 48$) shows that chronic care management for diabetes results in a statistically significant reduction in HbA1c of 5 mmol mol^{-1} (0.5%), compared with (mostly) usual care [95% CI: −7 to −3.5 mmol mol^{-1} (−0.6 to −0.3%)]. Subgroup analyses (Table 1) reveal that, apart from low-quality studies ($n = 1$), all subgroups of studies have a significant positive effect on HbA1c. The most notable improvements are attained by three component programmes, studies with a follow-up of less than 12 months and moderate quality studies. The overall as well as the subgroup analyses show strong heterogeneity (I^2 ranging from 71 to 87%). Meta-regression demonstrates no significant effect of study quality, length of follow-up or number of intervention components on the reduction of HbA1c (Table 1), although correcting for the latter covariate does result in an 8% reduction in statistical heterogeneity.

Systolic blood pressure

More than half ($n = 34$) of the studies included in this review assessed systolic blood pressure [45,48,53–56,58,60,61,64,65, 67–70,72,73,75–77,79,84–86,88–90,93,95–98,100,102]. Excluded from the meta-analysis were studies reporting the fractions of patients achieving a certain level of systolic blood pressure rather than the actual values at follow-up and studies for which variances of changes could not be estimated nor retrieved [48,64,65,68,69,89,90,96,102].

The meta-analysis ($n = 25$) demonstrates a statistically significant overall reduction in systolic blood pressure of 2.8 mmHg (95% CI, −4.7 to −0.95) in the intervention groups as compared with the control groups. Subgroup analyses show that two component interventions and studies with a follow-up of less than 1 year are not associated with a significant reduction in systolic blood pressure. Moderate heterogeneity exists between studies in terms of measured effects ($I^2 = 68\%$). Meta-regression demonstrates no significant effect of study quality, length of follow-up or number of intervention components on the reduction of HbA1c (Table 1), although correcting for the latter covariate does result in a 12% reduction in statistical heterogeneity.

Guideline adherence

About one third of the included studies ($n = 19$) uses providers' adherence to evidence-based guidelines as an indicator of process and compares the extent to which intervention and control patients received recommended medical procedures over specific periods of time (usually 12 months) [47,52–55,60,62,64,67,69,79, 80,86,89–91,100,103,104]. As the content of the diabetes guidelines used in the chronic care management programmes differs considerably, the two most uniformly and frequently measured recommendations were meta-analysed (Table 1). These concern the yearly provision of one eye examination ($n = 10$) and one foot examination ($n = 10$).

The meta-analysis for eye examinations [60,62,69,80,86,89, 90,100,103,104] provides a pooled RR of 1.88 (95% CI, 1.46 to 2.42), indicating a significantly greater probability of yearly eye screenings in the intervention groups. The likelihood for patients to receive a yearly foot exam is 111% higher in the intervention groups ($n = 10$; RR 2.11, 95% CI: 1.55 to 2.86) [54,60,62,69, 80,86,89,90,103,104]. Subgroup analyses, which were possible

Table 1 Results of the meta-analysis and meta-regression

	No. of studies	No. of participants	Mean difference (95% CI; I^2)	Explained heterogeneity (*P*)
HbA1c [mmol/mol (%)]	**48**	**11 457**	**–5 (–0.5) [–7, –3.5 (–0.6, –0.3); 80%]**	
Study quality				1% (*P* = 0.68)
Low quality	1	56	–2 (–0.2) [–9, 4 (–0.8, 0.4); NA]	
Moderate quality	26	5 174	–6 (–0.6) [–9, –3.5 (–0.8, –0.3); 82%]	
High quality	21	6 227	–4 (–0.4) [–6, –2 (–0.6, –0.2); 77%]	
Length of follow-up				0.5% (*P* = 0.66)
<1 year	19	2 097	–7 (–0.6) [–9, –4 (–0.9, –0.3); 71%]	
≥1 year	29	9 360	–4 (–0.4) [–6, –2 (–0.6, –0.2); 83%]	
Number of components				8% (*P* = 0.22)
2	19	4 697	–4 (–0.3) [–6, –1 (–0.55, –0.1); 71%]	
3	13	1 667	–8 (–0.7) [–13, –3 (–1.2, –0.3); 87%]	
4	16	5 093	–4.5 (–0.4) [–7, –2 (–0.6, –0.2); 75%]	
SBP (mmHg)	**25**	**7 719**	**–2.8 (–4.7, –0.9; 68%)**	
Study quality				1.5% (*P* = 0.68)
Low quality	0	0	Not estimable	
Moderate quality	11	3 099	–2.7 (–5.0, –0.4; 54%)	
High quality	14	4 620	–3.0 (–5.9, –0.1; 76%)	
Length of follow-up				5% (*P* = 0.42)
<1 year	5	593	–3.4 (–7.0, –0.25; 18%)	
≥1 year	20	7 126	–2.7 (–4.8, –0.6; 72%)	
Number of components				12% (*P* = 0.20)
2	9	2 860	–0.6 (–4.6, 3.4; 83%)	
3	5	809	–3.3 (–6.1, –0.5; 3%)	
4	11	4 050	–4.4 (–6.8, –2.0; 57%)	
	No. of studies	**No. of participants**	**Relative ratio (95% CI; I^2)**	**Explained heterogeneity (*P*)**
Yearly eye examination	**10**	**6 232**	**1.88 (1.46, 2.42; 95%]**	
Study quality				11% (*P* = 0.2758)
Low quality	1	1 644	1.58 (1.44, 1.74; NA)	
Moderate quality	5	3 387	3.04 (1.67, 5.55; 97%)	
High quality	4	1 201	1.20 (1.05, 1.37; 52%)	
Length of follow-up				21% (*P* = 0.1185)
<1 year	0	0	Not estimable	
≥1 year	10	6 232	1.88 (1.46, 2.42; 95%)	
Number of components				7% (*P* = 0.3727)
2	0	0	Not estimable	
3	7	4 989	2.13 (1.56, 2.91; 96%)	
4	3	1 243	1.45 (0.87, 2.43; 94%)	
Yearly foot examination	**10**	**6 818**	**2.11 (1.55, 2.86; 98%)**	
Study quality				1% (*P* = 0.7341)
Low quality	1	1 644	7.91 (5.98, 10.46; NA)	
Moderate quality	5	3 387	1.94 (1.30, 2.91; 97%)	
High quality	4	1 787	1.64 (1.14, 2.35; 95%)	
Length of follow-up				49% (*P* = 0.0032)
<1 year	0	0	Not estimable	
≥1 year	10	6 818	2.11 (1.55, 2.86; 98%)	
Number of components				1% (*P* = 0.7360)
2	1	769	1.27 (1.09, 1.48; NA)	
3	6	4 806	2.80 (1.72, 4.55; 98%)	
4	3	1 243	1.55 (0.97, 2.49; 94%)	

CI, confidence interval; I^2, statistical heterogeneity (%).

for number of components and study quality, demonstrate that only three component programmes attain statistically significant improvements in the rates of yearly foot and eye examinations. Meta-regression does not, however, show significance for either of these covariates, which implies that they cannot explain the heterogeneity between studies (I^2 ranging from 52 to 98%). Variation in length of follow-up, included in the meta-regression as a continuous variable (i.e. number of months), explains 49% of the heterogeneity in effects on foot screening ($P = 0.003$), yet cannot explain variability with regard to effects on eye examinations ($P = 0.12$).

Discussion

In line with previously conducted systematic reviews in this field, our meta-analysis suggests that chronic care management programmes have positive effects on the processes and outcomes of diabetes care. However, the empirical studies underlying our analysis differ considerably in both the directions and sizes of measured effects. Diversity in study quality does not appear to explain this statistical heterogeneity, although few of the trials included in our analysis were categorized as having low quality (which might be a consequence of our strategy of searching for empirical studies via systematic reviews). Variety in length of follow-up explains 49% of the variability across trials in effects on providers' adherence foot screening guidelines ($P = 0.003$). In terms of effects on clinical outcomes, the positive impact of chronic care management appears to diminish with increased length of follow-up, although the differences between subgroups are not statistically significant. Given that the positive effects of education on patients' self-management behaviour – and, thus, their glycaemic control – are difficult to maintain over time [106–108], short studies might overestimate effectiveness. Variety in the number of intervention components elucidates 8 to 12% of the diversity between studies with regard to measured changes in HbA1c and systolic blood pressure. Three and four component interventions attain stronger – though not significantly stronger – effect estimates than do two component strategies. This finding conforms to the presumption of the CCM that changes must be made in multiple areas in order to considerably improve the quality and outcomes of diabetes care [11,12]. Relatively few trials evaluated diabetes care programmes that integrated all CCM components, even despite the relatively long existence of and strong scientific support for this model [11–13]. This might very well limit the effects of chronic care management on patient outcomes.

As far as we are aware, this study is the first meta-analysis of chronic care management for diabetes that attempts to explain statistical heterogeneity by assessing differences in methodological quality, length of follow-up and number of intervention components according to the CCM. Shojania *et al*. [26] conducted a meta-analysis of diabetes care strategies with adjustment for effects of study size and mean baseline HbA1c value: these factors reduced statistical heterogeneity by approximately 50%. More recently, Pimouguet *et al*. [44] assessed the effect of various patient characteristics and disease management features on changes in HbA1c concentration. The authors found that disease management programmes are more effective for patients with poor glycaemic control (baseline HbA1c > 8.0%). Moreover, treatment adjustment (i.e. the ability of disease managers to start or modify medical treatment) and patient education were identified as effective features of disease management. In line with our results, Pimouguet *et al*. [44] also found that shorter studies report more promising effects on glycaemic control than do longer studies, although this difference did not achieve statistical significance.

Other reviews have also attempted to answer the question 'what is most effective?' [16,17,21], but their results are divergent and questionable, as there is a lack of clear terminology in the area of chronic care management. Hence, fundamentally different interventions share the same moniker, which may obscure important information concerning their working mechanisms, especially when they differ in effectiveness [24]. The potential causes of heterogeneity included in our analyses were selected on the basis of the available evidence. Nonetheless, the variation in effect sizes across trials is likely to be caused by other study-level factors, such as differences in study design, target population and implementation context. The degree of integration between intervention components might also be an important cause of statistical heterogeneity, as the CCM assumes that programmes in which elements are strongly interrelated result in better outcomes than programmes in which elements are more loosely coupled [11,12].

Our study used an extensive search strategy following the internationally accepted definition of chronic care management [109] and was conducted on the basis of combined expertise from five research institutes. Nevertheless, some limitations should be noted. First, it can be questioned whether the HTA-DM instrument [31] – the only relevant and tested instrument for assessing the quality of studies evaluating chronic care management – allows for proper scoring of items that bias the effect of interventions for diabetes, as it focuses primarily on the quality of reporting. Further validation of a quality instrument for studies evaluating complex interventions, such as chronic care programmes, is needed. Second, the care received by intervention as well as control patients is often poorly described, which makes comparisons between studies difficult and complicates the mapping of intervention components to the CCM. In addition, many studies exhibit a paucity of descriptive detail – standard deviations and *P* values are rarely reported – which necessitates either the use of estimates or exclusion from the analyses. Finally, the outcomes of our review are restricted to those effect measures used most frequently in the existing evidence on diabetes care management, whereas others – such as patients' health-related quality of life, self-efficacy and satisfaction with care – may be equally or even more important [110–113].

More research is needed to understand and support decision making on how best to redesign the care for patients suffering from diabetes. Coming to strong and consistent conclusions about the impact of chronic care management necessitates a clear framework of the mechanisms underlying various strategies and their expected effects. The latter should be measured with adequate length of follow-up and linked logically with an intervention's aims and components as well as the underlying theory driving the anticipated behaviour change in both patients and care providers. Moreover, evaluation efforts must be based on proper understanding of the characteristics of disease management programmes (i.e. scope, content, dose, context) and the populations that specific interventions target (i.e. disease type, severity, case-mix) [114]. Elucidating heterogeneity in this manner allows for more in-depth and disentangled insights into the effects of chronic care management and aids in answering the vital question of 'what works best for whom' in diabetes care.

Competing interests

The authors report no conflicts of interest

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1 Overview of systematic reviews.
Table S2 Overview of empirical studies.

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