

# Effectiveness of Community Health Worker interventions in Type 2 Diabetes care: a systematic review and meta-analysis of randomized controlled trials

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## Abstract

**Background:** Given the rising prevalence of type 2 diabetes, associated comorbidities, and healthcare costs, it is crucial to explore new models of care. This study evaluates the benefits of Community Health Worker interventions to improve glycemic control in type 2 diabetes and aims to identify characteristics of interventions that contribute to their effectiveness.

**Methods:** This review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. A systematic review of the literature and meta-analysis was performed. The protocol was published on Prospero (CRD42024498110). Searches were conducted in Medline, Embase, CINAHL, and Scopus until August 2025. Randomized controlled trials on CHW interventions for type 2 diabetes were included, with no restrictions on population or country. Studies involving type 1 diabetes, prediabetes, nurse/pharmacist/GP interventions, or follow-up under six months were excluded. Studies that did not compare to (enhanced) usual care or did not quantify HbA1c changes as an outcome measure as well as single-arm studies were excluded.

Study characteristics were extracted from each article by LES and cross-verified by SH. Pooled estimates were calculated using a random-effects meta-analysis using Stata (StataCorp LLC). Subgroup analyses, meta-regression and sensitivity analyses were conducted to explore heterogeneity. Quality was appraised utilizing the Effective Public Health Practice Project tool by three authors (LES, AM, SH). Certainty of the evidence was assessed with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.

**Findings:** A total of 40 eligible studies were identified with a total of 9,606 participants, 4,988 in the control group and 4,618 in the intervention group. Weighted average age was 63 and 74% of participants were women. Three studies were excluded from the meta-analysis because of insufficient data. We estimated an effect size of -0.39 (95% CI -0.48, -0.31,  $p < 0.001$ ) reduction HbA1c. Subgroup and sensitivity analyses found no significant variation in effect size based on study duration, uncontrolled baseline HbA1c, socioeconomic status, country income level, program intensity CHW role, integration in primary care, comparator, study quality, co-intervention. Effect size in Hispanic populations was significantly greater although this subgroup analysis may be underpowered.

**Interpretation:** This study provides strong evidence that CHW interventions improve care for people with type 2 diabetes. The effects appear consistent across a range of settings, suggesting generalizability. Future research should focus on standardizing CHW training, evaluating long-term outcomes, and optimizing implementation strategies.

**Funding:** There were no sources of funding.

## Introduction

By 2050, over 1.31 billion people are projected to have diabetes, with marginalized groups disproportionately affected.<sup>1 2</sup> Although incidence rates have remained stable, improved survival means more individuals are living longer with the disease, leading to increased complications and rising healthcare costs.<sup>3</sup> Notably, type 2 diabetes (T2DM) is the most expensive chronic condition in the U.S., accounting for one in every four healthcare dollars.<sup>4</sup> Therefore, there is an urgent need for effective and sustainable management strategies to improve long-term care and alleviate pressure on health systems.

To address care delivery gaps for chronic diseases, the World Health Organization (WHO) advocates for task-sharing models, which shift away from fragmented, hospital-based care toward community-driven approaches.<sup>5</sup> These models improve health outcomes, system responsiveness, and efficiency by ensuring continuous, accessible, and patient-centered care.<sup>5</sup> There is consensus that evolving disease patterns, technological advancements, and global health worker shortages require a balanced mix of skills and personnel for effective health system performance.<sup>4,5</sup> A review by an EU Expert Panel found that task-shifting among healthcare professionals enhances care quality and reduces costs without negatively impacting health outcomes.<sup>5</sup>

One such approach is the integration of Community Health Workers (CHWs) into primary healthcare. A community health worker is a local individual who delivers essential health services within their community. They are considered informal health workers and are generally not formally trained like a nurse or doctor but are trained to support health initiatives and improve well-being within their community.<sup>6</sup> Advantages of CHWs include their facilitation of culturally sensitive care and overcoming linguistic barriers, often bridging a gap towards hard-to-reach population.<sup>6,7</sup> Food insecurity, poor nutrition, communication barriers and economic hardship drive disparities in T2DM. Community health workers (CHWs) can help bridge this gap, offering person-centered care where traditional care falls short.<sup>8</sup>

Hartzler et al. outlined three main roles i.e. health services, health education and care coordination, and six functions i.e. self-management, behavioural, informational, social support, medication management or resource linking, for CHWs.<sup>9,10</sup> Detailed roles and functions of CHWs are described in **Error! Reference source not found.**

CHW intervention programs have proliferated in recent decades, particularly benefiting vulnerable populations.<sup>6</sup> A 2015 meta-analysis by Palmas et al. included only US-based studies with a follow-up period of at least 12 months. The analysis included only 13 studies and reported a modest reduction in HbA1c with CHW interventions.<sup>11</sup> The study applied a narrow definition of CHWs and did not examine factors that might enhance effectiveness.<sup>11</sup> Since then, many RCTs have been published, with several reporting positive outcomes. As terms like peers, lay caregivers, and promotores vary across regions, we use a broad definition to capture all CHW interventions globally. We aim to contribute to this literature by including studies that had a follow-up period of at least six months and without any country restriction. We conducted a systematic review and meta-analysis to evaluate the effectiveness of CHW interventions compared to usual care in improving glycemic

control among adults with T2DM, while also examining program features associated with greater impact and expanding the geographic and intervention scope.

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## METHODOLOGY

A systematic review and meta-analysis were performed, adhering to the Cochrane Handbook for Systematic Reviews of Interventions.<sup>12</sup> The protocol was published on Prospero (CRD42024498110). Ethics approval was not required for this study as stated by the Research Ethics Committee of the London School of Hygiene and Tropical Medicine

### Search strategy and selection criteria

We searched Medline, EMBASE, CINAHL, and Scopus from inception of the databases until 13<sup>th</sup> of August 2023 for randomized controlled trials reporting influence of CHW interventions on glycemic control. The search was later updated to incorporate studies from August 2023 until August 2025. In addition, reference lists of the included articles were screened. A librarian was consulted to develop the search strategy. The full search strategy is available in the appendix. (**Error! Reference source not found.** and **Error! Reference source not found.**)

The selection process was conducted independently by two investigators (LES, SH). Conflicts were resolved through discussion between LES and AM. PICOST criteria can be found in the appendix (**Error! Reference source not found.**). Only randomized controlled trials were included. Studies with participants under the age of 18 or those with type 1 diabetes or prediabetes were excluded. The definition of profile and role of CHWs were employed to recognize interventions that may not have been explicitly labeled as Community Health Worker (CHW) interventions but essentially aligned with the same concept. This has led to the inclusion of articles describing CHWs as lay leaders, promotores, health care navigators, trained peer educators. Studies were excluded if interventions were delivered by registered nurses, physicians, or pharmacists. However, if the intervention was delivered by a CHW and only supervised by a nurse, the study was not excluded. If a CHW used a digital health tool the study was not excluded. Studies were only included if they compared the CHW intervention to usual care.

In diabetes care, disease control is measured by glycated hemoglobin (HbA1c), a marker closely associated with the microvascular and macrovascular complications of diabetes. A level of HbA1c  $\geq 6.5\%$  (48mmol/mol) is generally used as diagnostic threshold for diabetes<sup>13</sup>. Studies that did not quantify HbA1c changes as outcome measure were excluded. RCTs with a follow-up period of less than six months were excluded to reduce the influence of short-term fluctuations in HbA1c values as HbA1c reflects average glucose over three months and may not fully capture intervention effects at just three months.<sup>14</sup> There were no restrictions on language. The studies were excluded from the meta-analysis if they did not report endpoint data or any measure of variability.

## Data extraction and quality appraisal

Data was extracted and organized according to Cochrane's Handbook of Systematic Reviews by LES. SH independently cross-verified the extracted data. The analysis and interpretation were conducted by LES, AM and RM.<sup>12</sup>

First, study characteristics including country, setting, and duration were collected. Secondly, population details including age, baseline HbA1c, ethnicity, gender, income level were extracted. Data on racial/ethnic background and socioeconomic hardship were extracted to reflect disparities between local communities and healthcare systems populations. Study populations were considered socioeconomically disadvantaged if their income fell below the national median, their educational attainment was low, and/or they lived in areas of high deprivation. Intervention specifics were extracted, detailing intervention and control group descriptions, CHW roles, CHW training, integration into primary healthcare, intensity, contact hours, and duration. Intensity was classified as low (0-2 elements), moderate (3-4 elements), or high (5-6 elements), based on Viswanathan et al, with "elements" defined as one-on-one interactions, face-to-face meetings, sessions lasting an hour or more, spanning over three months, involving six or more interactions, and utilizing tailored materials.<sup>15</sup> Finally, effect sizes with precision and significance were extracted.

The quality of all selected studies was assessed using a modified version of the Effective Public Healthcare Panacea Tool (EPHPP). The modified tool can be found in the supplements (**Error! Reference source not found.**). This tool consisted of eleven criteria grouped into seven categories: external generalizability, randomization, allocation, blinding, data collection and follow-up, intervention integrity, and effect size with selective reporting.<sup>16</sup> Data collection and follow-up were merged into one category compared to the original EPHPP tool. The appraisal process was conducted by LES with a secondary screening shared between AM and SH. Low generalizability was indicated by a participation rate below 40% or focus on a specific subpopulation. We considered allocation to be biased when there were significant differences in unadjusted baseline characteristics. Bias due to lack of blinding of the participants was categorized as moderate. Retention was considered poor when fewer than 60% of participants were successfully followed up. Substantial co-interventions were seen as high risk of bias. Analysis was considered weak if data was not adequately reported or missing data not appropriately imputed. Overall rating followed EPHPP guidelines.<sup>16</sup> The study quality was rated "weak" overall if two or more categories were weak, "moderate" if one category was weak, and "strong" if no categories exhibited high risk of bias.<sup>16</sup> Weak studies were included, as per Eysenbach's rationale that high attrition studies still inform future research on self-management interventions.<sup>17</sup> Evidence certainty was evaluated using the GRADE approach.<sup>18</sup>

## Data analysis

### *Effect size calculation*

Baseline and endpoint means and standard deviations (SDs) were used as input data. Intervention effects were taken from final assessment. Missing summary statistics were computed per Cochrane Handbook guidelines.<sup>12</sup> (**Error! Reference source not found.**) If follow-up, standard deviation or variation measures were not supplied, they

were calculated from reported mean difference and variation. If a study did not report values of endpoint means, but rather a graph to visually reflect change, the mean and confidence intervals were estimated based on this graph.<sup>19</sup> If a study did not report endpoint variation, but only significance level for within group change, the p-value was equated with significance level used (e.g.  $p < 0.05$  would become  $p = 0.05$ ) and subsequent t-inverse test was performed.<sup>20–24</sup> Studies lacking effect size or precision measures were excluded from the quantitative analysis ( $n=3$ ).<sup>25–27</sup> Missing data was not imputed.

### *Meta-Analysis*

Effectiveness expressed by reduction HbA1c was pooled using a random-effects model with significance level set at  $p < 0.05$ . Analyses were performed in Stata (StataCorp LLC) using the metan package with methodological heterogeneity assessed using Stata's  $I^2$  statistic, 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively.<sup>28</sup>

We explored heterogeneity through several sub-group analyses and meta-regression. First, we compared treatment effects between studies with  $< 12$  months of follow-up and those with  $\geq 12$  months. Next, we conducted a subgroup analysis based on whether the study restricted to a population with uncontrolled T2DM at baseline, i.e.  $HbA1c \geq 8\%$ . We then examined heterogeneity in treatment effect by ethnic/racial background and by socioeconomic status. Next, we investigated heterogeneity by national income level, using the World Bank classification of high-income countries (HICs) versus low- and middle-income countries (LMICs). Moreover, heterogeneity by CHW intervention intensity, comparing high-intensity CHW programs to those of moderate and low intensity was investigated. Additionally, we explored the impact of CHW interventions across different CHW roles, including health service delivery, health coaching, and care coordination, as well as their integration into primary care. Finally, we explored heterogeneity based on comparator group, differentiating between usual care and enhanced usual care. Meta-regression subsequently examined the correlation between baseline HbA1c and effect size. Sensitivity analyses addressed low-quality studies, co-intervention and differentiated between peer/lay/promotores-labeled interventions and CHW-labeled interventions. Cumulative meta-analysis was conducted to evaluate temporal trends and establish stability of the estimate. A leave-one-out analysis was done to investigate the influence of each study on the overall effect-size estimate and to identify influential studies. Publication bias was assessed using funnel plots, Egger's test and Galbraith Plot.

## **Funding**

There was no funding source for this study.

## Results

The search and selection process details are provided in the Prisma Flowchart in Figure 1. The search took place from inception of the databases until August 2023 and identified 1374 of which 186 full reports were assessed and 31 were included. Five more were identified through manual searches. A subsequent update from January 2023 to August 2025 identified 355 records. 35 full reports were assessed, and four articles met eligibility criteria. Overall, 40 studies were included and 37 were included in the meta-analysis. A list of excluded articles can be found in appendix. (eTable 7 and eTable 8)

The analysis included 9,606 participants, comprising 4,988 in the control group and 4,618 in the intervention group. Weighted average age was 63 and 74% of participants were women. Out of forty studies, thirty-one were conducted in the US<sup>19–21,23,25,26,29–53</sup>, with others located in Australia (n=2)<sup>22,54</sup>, the UK (n=1)<sup>24,55</sup>, Canada (n=1), the Philippines (n=1)<sup>56</sup>, India (n=1)<sup>57</sup>, India and Pakistan (n=1)<sup>58,59</sup>, Nepal (n=1)<sup>27</sup>, and South Africa (n=1). Twenty-seven studies targeted ethnic or racial minority populations<sup>19–23,26,29–32,35,37–50,52,54</sup>, and twenty-four were socioeconomically disadvantaged<sup>20,23,24,26,29–34,36–38,41–45,47,48,50,51,54,56</sup>.

Ten studies restricted to participants with uncontrolled diabetes at baseline (HbA1c >8%<sup>60</sup>)<sup>21,29,34,36,37,40,42,54,58</sup>, while other simply included patients with a T2DM diagnosis. Comparators were usual care or enhanced usual care<sup>30,35,37,39,40,47,48,51,52,61</sup> defined as additional telephone calls, mails with educational materials or a single educational session. Detailed description of enhanced usual care per study can be found in the appendix (**Error! Reference source not found.**). Study durations ranged from 6 to 24 months.

Delivery methods of CHW-provided care varied, with interventions delivered face-to-face, via telephone, or through digital platforms, often incorporating cultural activities like cooking classes and religious events. Eight out of nine studies outside of the U.S. and three U.S. studies used labels other than 'CHW' to describe the intervention that is essentially aligned with CHW interventions. Instead, they use labels such as lay individuals, peer leaders, or promotores. Terminology and intervention descriptions are elaborated on in the appendix (eTable 10 and eTable 11).

Contact hours ranged from 4 to 60 and intensity from low to high. Sixteen studies integrated CHWs into the primary healthcare team. CHW roles were stratified based on Hartzler et al.'s framework in service delivery (e.g. sugar measurement) (n=5), care coordination (n=14), and health education (n=37).<sup>9</sup> Within the health education group, most CHW interventions focused on short-term diabetes self-management education. Due to the limited contribution of service delivery interventions and overlap between health coaching and care coordination, CHW roles were categorized into (1) health coaching and (2) a combination of health coaching and care coordination for subsequent data analysis.<sup>9</sup> CHWs received training tailored by the study team rather than following established guidelines. Sixteen studies included co-interventions, i.e. digital health tools (n=6)<sup>29,31,41,50,57,58</sup>, nurse assistance (n=6)<sup>19,38,45,47,48,53</sup> Details on study stratification including CHW roles and functions are in Table 1 and the appendix (eTable 12).

## Effect of CHW interventions on HbA1c change

Three studies were excluded from the quantitative analysis due to insufficient data.<sup>25,26</sup> The CHW intervention results in a mean difference of  $-0.39$  HbA1c (95% CI  $-0.48, -0.31$ ;  $I^2=17.33\%$ ) compared to usual care, resulting from pooling thirty-seven studies. (Figure 2)

### *Subgroup analyses and meta-regression*

Table 2 summarizes the results from the sub-group analyses. There was no significant difference in the primary outcome based on the duration of follow-up ( $p=0.50$ ), although less heterogeneity across studies was observed in the  $<12$  months group (**Error! Reference source not found.**). No statistically significant differences were demonstrated between inclusion of only uncontrolled T2DM at baseline or all T2DM patients ( $p=0.65$ ) (**Error! Reference source not found.**) or between socioeconomically disadvantaged or diverse populations ( $p=0.65$ ) (eFigure 3), or between HIC or LMIC ( $p=0.94$ ) (**Error! Reference source not found.**). Furthermore, no statistically significant differences were demonstrated when CHW interventions were stratified into low, middle or high intensity ( $p=0.83$ ) (**Error! Reference source not found.**) or between health education and care coordination combined with health education ( $p=0.29$ ) (**Error! Reference source not found.**), or integration into primary health care ( $p=0.30$ ) (**Error! Reference source not found.**). Lastly, subgroup analysis for comparator group did not show significant difference in effect size compared to usual care or enhanced usual care ( $p=0.41$ ) (**Error! Reference source not found.**). Moreover, meta-regression for baseline HbA1c showed no significant difference in effect size depending on baseline HbA1c ( $p=0.88$ ). (eFigure 9). The only subgroup analysis demonstrating a significant difference in effect size was among racial and ethnic minorities, with a stronger effect observed in the U.S. Hispanic population ( $p=0.01$ ; eFigure 10), although this subgroup may have been underpowered due to the limited number of studies within each subgroup.

### *Sensitivity analyses*

Sensitivity analysis showed no significant impact from excluding low-quality studies ( $p=0.61$ ) (**Error! Reference source not found.**) or from excluding studies with co-interventions ( $p=0.69$ ) (**Error! Reference source not found.**), or studies with intervention labeled as other than CHWs ( $p=0.86$ ) (**Error! Reference source not found.**). Leave-one-out analyses showed no material change when any single study was excluded, indicating the results were not driven by any one study. (**Error! Reference source not found.**). Cumulative meta-analysis observed consistent effect sizes since 2014 (**Error! Reference source not found.**).

### *Publication bias*

Although a Galbraith plot (eFigure 16) suggests potential small-study effects as most studies exhibit low precision, the Egger test did not indicate significant publication bias and funnel plot (**Error! Reference source not found.**) showed no evidence of asymmetry ( $\beta_1 = 0.25$  (SE =  $0.631$ ),  $p = 0.69$ ).

## Quality Appraisal

Of forty studies included in the analysis, nine were assessed as high quality, twenty as moderate quality, and eleven as low quality. Studies were assessed as low quality primarily due to high drop-out rates without data imputation. Only seven studies had

unrestricted populations, while most focused on sub-populations.<sup>25,27,47,53,55,58,59</sup> All studies randomized adequately and seven blinded assessors.<sup>24,32–34,37,40,51</sup> Most studies (n=23) adjusted for baseline differences.<sup>20,22–24,26,27,31,32,37–42,44,45,47,49,52,53,55,58,59</sup> Retention was generally high ( $\geq 80\%$ ), though four studies had follow-ups below 60%, rated as weak.<sup>20,26,48,59</sup> Thirteen studies reported co-interventions.<sup>19,29,31,38,41,43,45,47,48,50,53,57,58</sup> Only eighteen studies adhered to the intention-to-treat principle and imputed missing data.<sup>23,26,27,30–35,37–40,46,47,51,53,59</sup> Precision was generally moderate. Detailed overview can be found in the supplementary appendix (eTable 13 and eTable 14).

## **GRADE**

Studies were assessed with the GRADE approach.<sup>18</sup> Overall, 25 studies showed high certainty of evidence. Ten studies were rated with moderate certainty because of identified risk of bias concerns or risk to external validity and five were rated low because of a combination of the above. Assessment can be found in the appendix. (eTable 15)

## Discussion

This systematic review and meta-analysis demonstrate that CHW interventions significantly improved glycemic control in patients with T2DM. Although potentially underpowered, subgroup analyses showed no statistically significant differences in effect size across study duration, uncontrolled baseline HbA1c, country income level, program intensity, CHW role, integration in primary health care, comparator group, co-interventions, delivery by individuals not explicitly labeled as 'CHW' or study quality. The racial/ethnic minority subgroup analysis indicates a stronger effect in U.S. Hispanic populations, though it may be underpowered. Meta-regression showed that CHWs were effective across varying levels of diabetes severity. These findings indicate the broad applicability of CHW interventions since the inclusion of a CHW in the care team alone seems to improve health outcomes.

CHW interventions lowered HbA1c by 0.39 compared with usual care which falls within the minimal clinically important difference for diabetes management (0.3–0.5%).<sup>62</sup> This range, supported by the American Diabetes Association, acknowledges that while small HbA1c fluctuations ( $\pm 0.3\%$ ) may reflect assay variability, reductions of 0.3% or greater are clinically meaningful.<sup>63</sup> Landmark studies such as the UKPDS and DCCT have demonstrated a continuous, curvilinear relationship between HbA1c and microvascular complications, with no clear lower threshold. These findings highlight that even modest reductions in HbA1c significantly decrease the risk of retinopathy, nephropathy, and neuropathy, particularly when lowering levels from high to moderate ranges.<sup>62,64</sup> Although the absolute benefit is greatest in individuals with higher baseline HbA1c, smaller decreases still confer substantial risk reduction.<sup>62,64</sup> Moreover, real-world evidence shows that each 0.2% HbA1c decline is associated with meaningful improvements in treatment intensification and goal attainment, emphasizing the clinical significance of even small improvements in glycemic control.<sup>65</sup> Our findings suggest that CHWs may be more effective in Hispanic populations. However, the subgroup analysis may be underpowered, so this effect cannot be generalized to other vulnerable groups. Nonetheless, the intervention might be particularly useful in the U.S. Hispanic population because CHWs provide culturally sensitive care and break down language barriers, bridging a gap towards underserved populations.<sup>6,7</sup>

CHW interventions in type 2 diabetes mellitus consistently yield modest but significant reductions in hemoglobin A1c (HbA1c), typically around -0.21 to -0.5, as demonstrated in meta-analyses such as Palmas et al. (2015) and recent real-world studies in Hispanic populations.<sup>11,66</sup> These reductions are smaller than those achieved by first-line pharmacologic agents like metformin, which typically lower HbA1c by about 1 in clinical trials, but are comparable to the incremental reductions seen when diabetes medications are initiated in real-world observational cohorts, where HbA1c decreases range from -0.3 to -1 depending on baseline glycemic control and population characteristics.<sup>67</sup> Importantly, CHW interventions have shown incremental HbA1c improvements even among participants already on diabetes medications, without the adverse events commonly associated with pharmacologic therapy, such as hypoglycemia or gastrointestinal side effects.<sup>68</sup>

This study suggests that CHW care is broadly effective, although the specific factors driving this success are not fully understood. One possible explanation is the impact on treatment adherence, as supported by the study of Nguyen et al., who found that adherence improves when there is ethnic/racial concordance between patients and healthcare providers, particularly in cardiovascular disease interventions like smoking cessation.<sup>69</sup> Community health workers (CHWs) are effective in addressing gaps in diabetes care related to social determinants of health, including linguistic and cultural barriers, food insecurity, and housing instability.<sup>6</sup> This study found that glucose control is more pronounced when CHWs provide care coordination that includes connecting patients to social resources, rather than focusing solely on diabetes self-management, although these results were not statistically significant ( $p=0.09$ ). This aligns with prior evidence that care coordination addressing social needs can improve clinical outcomes, but the magnitude of HbA1c reduction may be modest and sometimes not reach statistical significance.<sup>70</sup> Lastly, CHWs are ideally placed to mitigate the consequences of global health workforce shortages, which are estimated at ten million in 2030, and disproportionately affect Asia and Africa.<sup>71</sup> Due to the limited number of studies from Asia and Africa we did not conduct subgroup analyses by geographic region. Future studies should address this gap.

The definition of Community Health Workers (CHWs) in this analysis was broadened to recognize interventions that, while not explicitly labeled as CHW programs, align with the core functions and competencies. This approach led to the inclusion of interventions delivered by lay leaders, promotores, health care navigators, and trained peer educators, reflecting the diversity of terminology across global settings. Although these terms are not strictly synonymous, their inclusion was justified by the substantial overlap in intervention content and delivery. CHWs and peer supporters often come from the same communities and receive culturally tailored training, but differ in scope.<sup>72</sup> CHWs typically address broader social needs and work within care teams, while peers focus on self-management support, often outside formal health systems.<sup>73 72</sup>

Conclusively, building on prior research, this study confirms the robust effectiveness of CHWs in improving glycemic control for individuals with T2DM and highlights their potential to reduce disparities and enhance diabetes outcomes.

## Limitations of the Current Evidence

Several limitations need to be acknowledged. First, we acknowledge the clinical heterogeneity across studies. We explored this by subgroups analysis and meta-regression which found that these aspects did not significantly influence the results, except for racial/ethnic background. According to Cochrane guidelines, at least ten studies per subgroup are needed for reliable results.<sup>12</sup> Most subgroups analyses met this criterion except for racial/ethnic background, baseline glycemic control, country income level, and co-interventions. Second, variations in context and health care financing influence healthcare delivery and accessibility may skew findings, particularly due to the dominance of U.S. studies ( $n=31$ ). Additionally, most studies were conducted in HICs suggesting the need for further research in resource-constrained settings. Next some studies did not adhere to the intention-to-treat principle and had high dropout rates which might inflate the results. Co-interventions in some studies further complicate the results and financial incentives for follow-up attendance for participants may have inflated retention rates. However, sensitivity

analyses suggest that excluding lower-quality studies does not substantially change the overall conclusions. Future research should focus on standardizing CHW training, evaluating long-term outcomes, and optimizing implementation strategies.

Preprint not peer reviewed

## Conclusion

Given the escalating prevalence of T2DM, its associated comorbidities, and persistent socioeconomic disparities, the development of innovative care models is imperative. This review synthesizes evidence from randomized controlled trials evaluating CHW interventions for T2DM management. Across studies, CHW involvement was associated with statistically and clinically meaningful improvements in glycemic control. These benefits were consistent regardless of intervention duration, baseline glycemic control, socio-economic status, country income level, program intensity, CHW role, integration with primary care, comparator group, study quality, co-interventions or intervention specifics with a potentially greater effect in underserved marginalized communities. Collectively, CHW interventions consistently lead to clinically significant reductions in HbA1c, reinforcing their importance in comprehensive diabetes management.

## **Contributor statement contributions**

The conceptualization of the study was led by LES in collaboration with RM. The literature search was carried out by LES and RM, with support from a librarian at the London School of Economics. Study selection was performed by LES and SH, with any conflicts resolved through discussion between LES and AM. Data collection was undertaken by LES and cross-checked by SH. Quality appraisal was conducted by LES, with a secondary screening shared between AM and SH. Data analysis was carried out by LES in collaboration with RM. The original draft was written by LES and subsequently reviewed and edited by RM and AM. Visualisation was completed by LES. There was no funding source.

# Acknowledgments

## Funding / Support

The work was not funded

## Data sharing statement

The data used in this meta-analysis were derived from publicly accessible databases, including Medline, Embase, CINAHL, and Scopus. The datasets included in this study can be obtained upon request.

## Conflict of interest

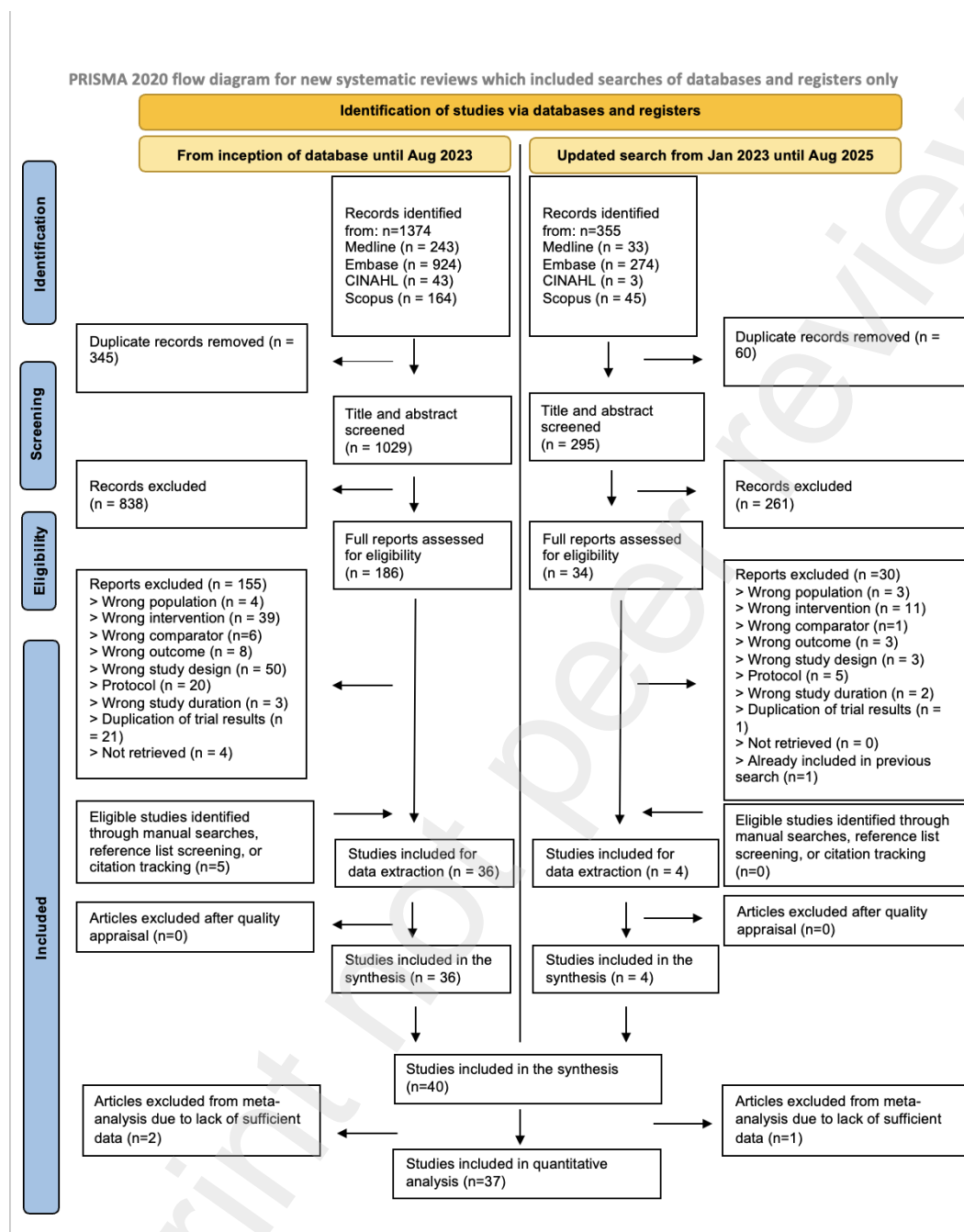
We declare no competing interests. Conflict of interest form can be found in the appendix (p 47-54).

## AI statement

ChatGPT (OpenAI) was used solely for the purposes of rephrasing text and correcting spelling and grammar. No AI-generated content was used for data analysis, interpretation, or original writing beyond language refinement. All AI-assisted outputs were carefully reviewed and verified to ensure accuracy.

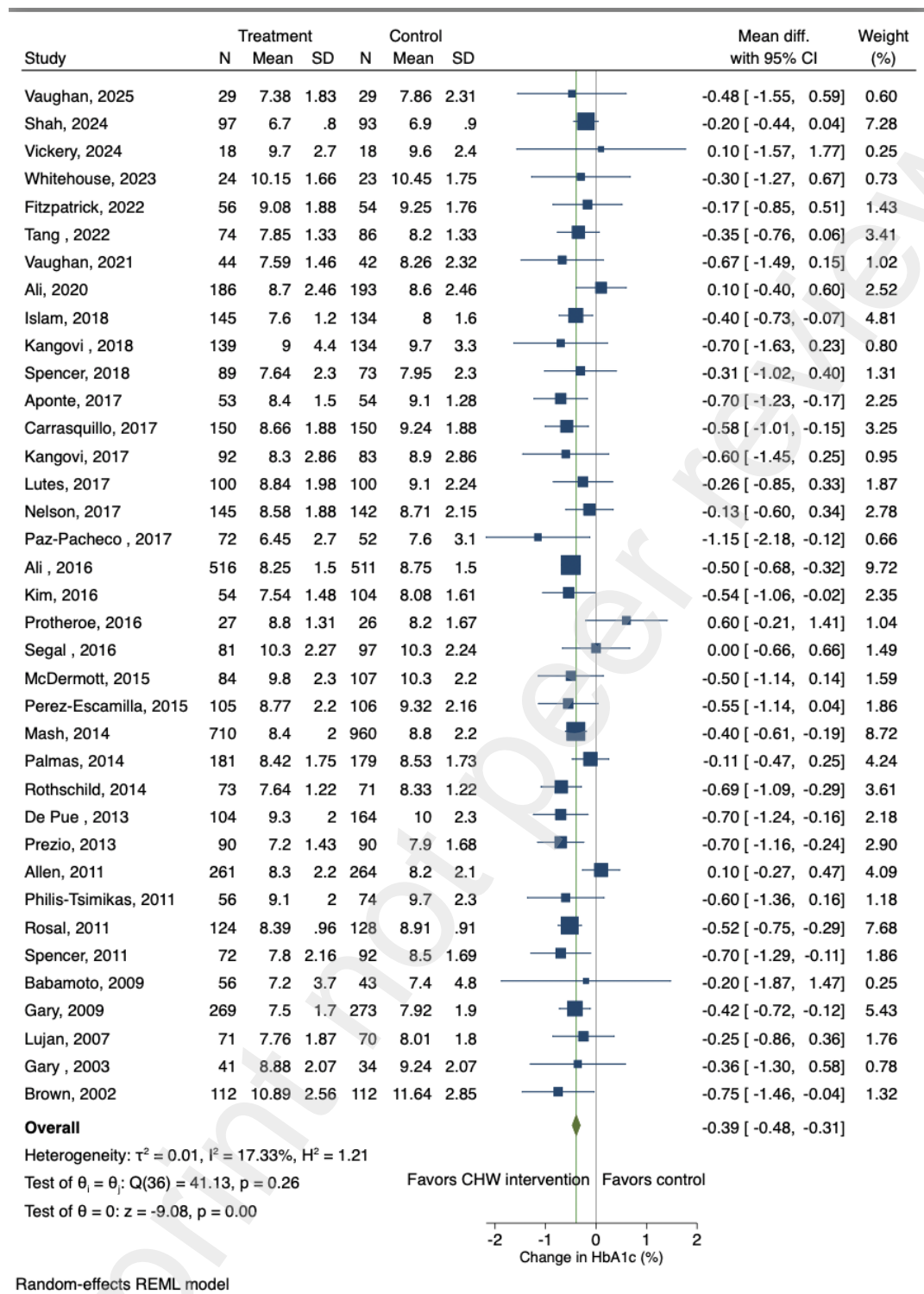
# Figures

Figure 1 Prisma flowchart: search results



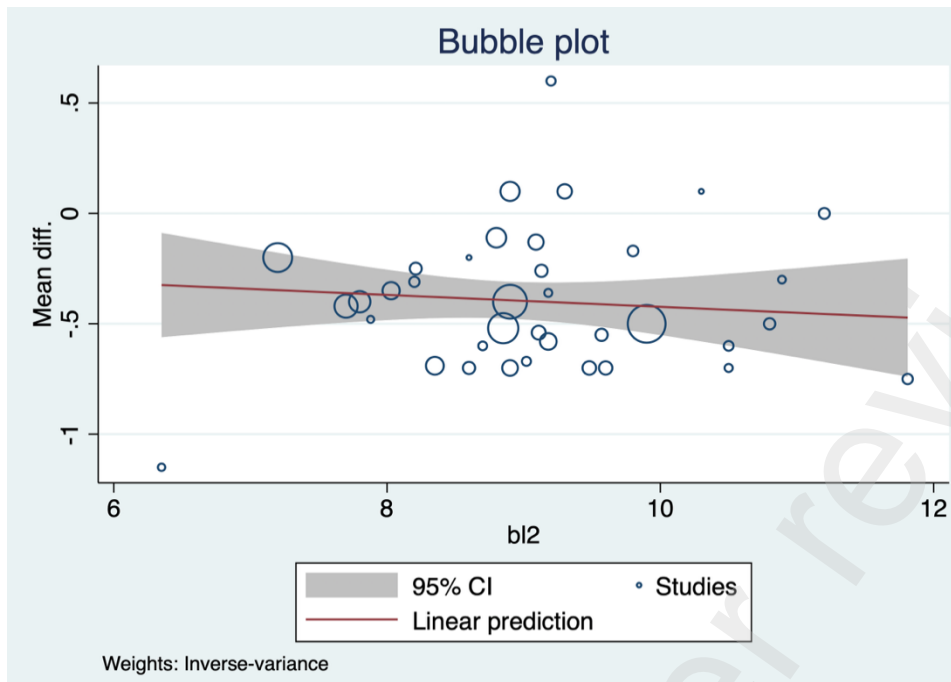
\*5 articles were identified through manual searches, reference list screening, or citation tracking <sup>22,33,34,41,59</sup>

Figure 2: Forest plot effectiveness against usual care (n=37)



Each square represents the point estimate of mean HbA1c (%) change for an individual study, with the size of the square proportional to the statistical weight of that study. The diamond at the bottom of the plot represents the pooled mean difference in HbA1c, with its width corresponding to the 95% confidence interval for the overall effect. For Carrasquillo (2017) and Gary (2003), means were imputed since only mean differences were reported. The meta-analysis was conducted using mean differences, while the means shown in the plot are study averages.

Figure 3: Bubble plot displaying metaregression results. Effect size depending on baseline HbA1c %.



## Tables

Table 1 Study Characteristics

	General Study characteristics				Functions CHW (Hartzler)					
	Country/ Region	n. tot (control/ intervention)	Racial/ethnic minority	Socioeconomic status	Self-management	Behavioural modification	Educational support	Social Support	Resource linking	Medication
<b>Cluster 1: Care coordination and health coaching (n=14)</b>										
Vaughan, 2025	US, Texas	58 (29/29)	Hispanic	Disadvantaged	✓	✓	✓	✓	✓	✓
Whitehouse, 2023	US, Philadelphia	150 (50/50)	N/A	Disadvantaged	✓	✓		✓	✓	
Fitzpatrick, 2022	US, Oregon Washington	110 (54/56)	African American, Hispanic	Diverse	✓			✓	✓	
Tang, 2022	Canada, British Columbia	196 (98/98)	N/A	Diverse	✓			✓	✓	
Kangovi, 2018	US, Philadelphia	273 (134/139)	N/A	Disadvantaged	✓	✓		✓	✓	
Kangovi, 2017	US, Philadelphia	302 (152/150)	N/A	Disadvantaged	✓	✓		✓	✓	
Carrasquillo, 2017	US, Florida	300 (150/150)	Hispanic	Disadvantaged	✓	✓	✓	✓	✓	✓
Ali, 2016	India, Pakistan	1146 (571/575)	N/A	Diverse	✓	✓				
Segal, 2016	Australia	193 (106/87)	Indigenous community	Diverse	✓				✓	
McDermott, 2015	Australia	213 (113/100)	Aboriginal community	Disadvantaged	✓	✓	✓	✓	✓	✓
Pérez-Escamilla, 2015	US, Connecticut	211 (106/105)	Hispanic	Disadvantaged	✓	✓	✓		✓	
Palmas, 2014	US, New York	360 (179/181)	Hispanic	Diverse		✓	✓		✓	
De Pue, 2013	American Samoa	268 (164/104)	N/A	Diverse	✓	✓	✓			
Prezio, 2013	US, Texas	180 (90/90)	Hispanic	Disadvantaged	✓	✓	✓		✓	
Gary, 2003	US, Maryland	75 (34/41)	African American	Disadvantaged	✓	✓	✓	✓	✓	
<b>Cluster 2: Health coaching (n=28)</b>										
*Paudel, 2025	Nepal	481 (243/238)	Diverse	Diverse	✓	✓	✓			
Shah, 2024	US, Georgia	190 (93/97)	South Asian	East	Diverse	✓	✓	✓	✓	
Vickery, 2024	US	36 (18/18)	80% African American		Disadvantaged	✓	✓	✓	✓	
Vaughan, 2021	US, Texas	89 (45/44)	Hispanic	Disadvantaged	✓	✓				
Ali, 2020	India	404 (208/196)	N/A	Diverse	✓					
Spencer, 2018	US, Michigan	222 (73/89)	Hispanic	Diverse	✓	✓	✓	✓		
Islam, 2018	US, New York	336 (160/176)	Bangladeshi	Diverse	✓	✓	✓			
Lutes, 2017	US, North Carolina	200 (100/100)	African American	Diverse	✓	✓				
Aponte, 2017	US, New York	180 (60/60)	Hispanic	Diverse			✓			
Nelson, 2017	US, Washington	287 (142/145)	N/A	Disadvantaged	✓					
Paz-Pacheco, 2017	the Phillipines	155 (70/85)	N/A	Disadvantaged	✓	✓	✓			
Kim, 2016	US, Washington DC/Baltimore	250 (104/54)	Korean Americans	Diverse	✓	✓	✓	✓		

<i>Protheroe, 2016</i>	The UK	76 (37/39)	N/A	Disadvantaged	✓	✓	
<i>Mash, 2014</i>	South-Africa	1570 (860/710)	N/A	Diverse		✓	✓
<i>Rothschild, 2014</i>	US, Illinois	144 (71/73)	Hispanic	Diverse	✓		✓
<i>*Forjuoh, 2014</i>	US, Texas	196 (95/101)	Diverse	Diverse	✓	✓	
<i>Allen, 2011</i>	US, Maryland	525 (264/261)	80% African American	Diverse		✓	✓
<i>Spencer, 201</i>	US, Michigan	164 (92/72)	57 % African-American	Diverse	✓		✓
<i>Rosal, 2011</i>	US, Massachusetts	252 (128/124)	Hispanic	Disadvantaged	✓	✓	✓
<i>Philis-Tsimakis, 2011</i>	US, California	207 (103/104)	Hispanic	Disadvantaged	✓	✓	
<i>Gary, 2009</i>	US, Maryland	542 (273/269)	African American	Disadvantaged			✓
<i>Babamoto, 2009</i>	US, California	189 (60/75)	Hispanic	Disadvantaged	✓	✓	✓
<i>*Sixta, 2008</i>	US, Texas	131 (68/61)	Hispanic	Disadvantaged	✓	✓	
<i>Lujan, 2007</i>	US, Texas	149 (74/75)	Hispanic	Disadvantaged	✓		
<i>Brown, 2002</i>	US, Texas	252 (126/126)	Hispanic	Disadvantaged	✓		✓

\*not included in the quantitative analysis due to insufficient data

**Table 2: Subgroup analyses and sensitivity analyses**

Intervention characteristic		Mean difference (CI)	P value
Study duration	≥12 months (n=22)	-0.40 (95% CI: -0.51, -0.28; I <sup>2</sup> =25.95%)	P=0.8
	<12 months (n=15)	-0.38 (95% CI: -0.51, -0.25; I <sup>2</sup> =7.14%)	
Uncontrolled T2DM at baseline (HbA1c % <8%) as inclusion criterion	HbA1c > 8% at baseline (n=9)	-0.43 (95% CI: -0.59, -0.27; I <sup>2</sup> =12.87%)	P=0.58
	All T2DM patients (n=28)	-0.38 (95% CI: -0.48, -0.28; I <sup>2</sup> =20.72%)	
Racial and ethnic background	African American (n=3)	-0.38 (95% CI: -0.64, -0.12; I <sup>2</sup> =00.00%)	P=0.01
	African American and Hispanic (n=2)	-0.46 (95% CI: -0.98, 0.05; I <sup>2</sup> =24.84%)	
	African American and North American (n=2)	0.10 (95% CI: -0.26, -0.46; I <sup>2</sup> =00.00%)	
	American Samoan (n=1)	-0.70 (95% CI: -1.24, -0.16; I <sup>2</sup> =.%)	
	Bangladeshi in the US (n=2)	-0.27 (95% CI: -0.46, -0.07; I <sup>2</sup> =00.00%)	
	British (n=1)	0.60 (95% CI: -0.21, 1.41; I <sup>2</sup> =.%)	
	Hispanic (n=14)	-0.51 (95% CI: -0.64, -0.38; I <sup>2</sup> =00.00%)	
	Indian (n=1)	0.10 (95% CI: -0.40, 0.60; I <sup>2</sup> =.%)	
	Indian and Pakistani (n=1)	-0.50 (95% CI: -0.68, -0.32; I <sup>2</sup> =.%)	
	Indigenous Australian community (n=2)	-0.26 (95% CI: -0.75, 0.23; I <sup>2</sup> =11.15%)	
	Korean (n=1)	-0.54 (95% CI: -1.06, -0.02; I <sup>2</sup> =.%)	
	North American (n=5)	-0.33 (95% CI: -0.60, -0.06; I <sup>2</sup> =00.00%)	
	Phillipino (n=1)	-1.15 (95% CI: -2.18, -0.12; I <sup>2</sup> =.%)	
	South-African (n=1)	-0.40 (95% CI: -0.61, -0.19; I <sup>2</sup> =.%)	
Socioeconomic status	Disadvantaged (n=23)	-0.42 (95% CI: -0.55, -0.28; I <sup>2</sup> =20.55%)	P=0.65
	Diverse (n=14)	-0.38 (95% CI: -0.48, -0.27; I <sup>2</sup> =19.38%)	
Country income level	HIC (n=33)	-0.39 (95% CI: -0.49, -0.29; I <sup>2</sup> =17.86%)	P=0.94
	LMIC (n=4)	-0.40 (95% CI: -0.63, -0.17; I <sup>2</sup> =50.16%)	
Intensity of the intervention	High (n=15)	-0.40 (95% CI: -0.56, -0.24; I <sup>2</sup> =38.35%)	P=0.92
	Medium (n=12)	-0.39 (95% CI: -0.54, -0.24; I <sup>2</sup> =0%)	
	Low (n=10)	-0.42 (95% CI: -0.54, -0.31; I <sup>2</sup> =0%)	
Role of CHW	Health coaching (n=23)	-0.35 (95% CI: -0.46, -0.23; I <sup>2</sup> =30.63%)	P=0.09
	Health coaching and care coordination (n=14)	-0.49 (95% CI: -0.62, -0.37; I <sup>2</sup> =0%)	
Integration in primary healthcare system	Integrated in the primary health care system (n=12)	-0.45 (95% CI: -0.62, -0.27; I <sup>2</sup> =5.01%)	P=0.50
	Not integrated in the primary health care system (n=25)	-0.38 (95% CI: -0.48, -0.28; I <sup>2</sup> =24.19%)	
Comparator group	Usual care (n=27)	-0.45 (95% CI: -0.54, -0.37; I <sup>2</sup> =0.00%)	P=0.09
	Enhanced usual care (n=10)	-0.29 (95% CI: -0.46, -0.11; I <sup>2</sup> =36.99%)	
Metaregression	Baseline HbA1c %	--0.27 (95% CI: -0.11, 0.06; I <sup>2</sup> =15.40%)	P=0.54
Quality of the study	Strong (n=89)	-0.244 (95% CI: -0.68, -0.20; I <sup>2</sup> =46.61%)	P=0.61
	Moderate (n=20)	-0.36 (95% CI: -0.47, -0.25; I <sup>2</sup> =18.91%)	

	Weak (n=11)	-0.44 (95% CI: -0.60, -0.29, I <sup>2</sup> =0.00%)	
Co-intervention	Digital Health Tool (n=5)	-0.46 (95% CI: -0.60, -0.33; I <sup>2</sup> = 0.00%)	P=0.56
	Nurse assistance (n=6)	-0.42 (95% CI: -0.69, -0.15; I <sup>2</sup> = 50.04%)	
	No co-intervention (n=25)	-0.37 (95% CI: -0.47, -0.28; I <sup>2</sup> =4.18%)	
Delivery by individuals not explicitly labeled as CHWs	CHW (n=27)	-0.40 (95% CI: -0.51, -0.28; I <sup>2</sup> =20.08%)	P=0.79
	Other (n=10)	-0.42 (95% CI: -0.52, -0.31; I <sup>2</sup> =17.33%)	

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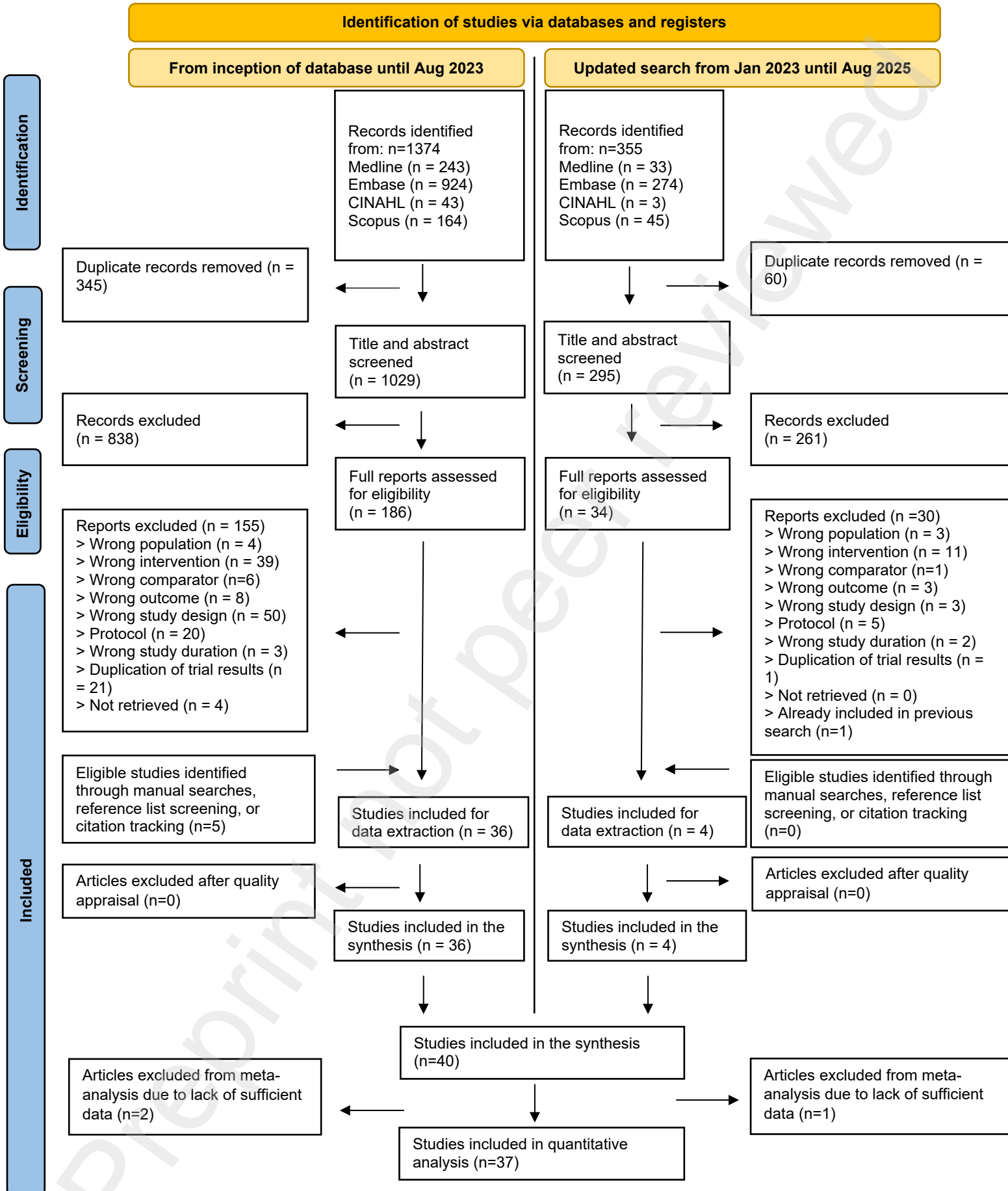
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PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only



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