

Efficacy of non-pharmacological interventions in controlling type 2 diabetes in patients of African descent: A systematic review

Takira Glasgow¹, Liz Cheek², Naji Tabet^{1*}

¹Postgraduate Medicine, Division of Medical Education, Brighton and Sussex Medical School, Brighton, UK

²Computing, Engineering and Mathematics, University of Brighton, Brighton, UK

Email: *n.t.tabet@brighton.ac.uk

Received 10 March 2013; revised 11 April 2013; accepted 12 May 2013

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ABSTRACT

Purpose: The purpose of this review is to systematically assess the potential effectiveness of targeted educational and other non-pharmacological interventions on diabetes control in populations of African descent in developed countries. Such information can inform intervention strategies and highlight evidence-based approaches to deal with this significant problem in this population. **Methods:** A systematic review and a meta-analysis of random controlled trials and cohort studies evaluating the influence of education and other non-pharmacological interventions on HbA1C concentrations in patients of African descent with diabetes. A comprehensive search of PubMed, EMBASE, CINAHL, ZETOC, SIGLE databases was carried out. **Results:** Although nine studies (8 randomised controlled trials and 1 cohort study) met the inclusion criteria, relevant HbA1C data were available for 6 of the studies for the subsequent meta-analysis. Heterogeneity of meta-analysis was high ($I^2 = 92\%$), the random effects pooled standard mean difference favoured the intervention -0.66 ($-1.15, -0.17$), $p = 0.009$. After sensitivity analysis, I^2 remained moderate to high at 69%. The random effects pooled standard mean difference continued to favour the intervention -0.48 ($-0.81, -0.16$), $p = 0.009$. **Conclusion:** There is evidence supporting the efficacy of educational and other non-pharmacological interventions in diabetes control in populations of African descent in English speaking developed countries. This conclusion is tempered by the significant heterogeneity of selected interventions and paucity of high quality research in the target population.

*Corresponding author.

Keywords: Diabetes; Education; African Descent; Non-Pharmacological Intervention; HbA1C

1. INTRODUCTION

Estimates by the WHO demonstrate the scope of the diabetes challenge: 438 million people world-wide will have diabetes by 2030, and one in three Americans will have the disease by 2050 [1,2]. The prevalence of diabetes is much higher among populations of African descent in developed countries. In the USA, for example, African Americans are twice as likely to be diagnosed with diabetes (prevalence of 11.8%) and a third of cases are undiagnosed. Further, among African Americans type 2 diabetes accounts for 90% to 95% of all cases [3]. In the UK, it was estimated that the African Caribbean population had a prevalence of diabetes three times greater than the general population in 2006 [4].

Alongside the high prevalence of diabetes among patients from African ancestry in developed countries, increased complication rates are also reported. In the US, the National Health and Nutrition Examination Survey (NHANES) 1971-1992 prospective analysis of the amputation rates of a 14,407 cohort concluded that African American participants (2199 in number) underwent 2.8 times more amputations compared to their white counterparts [5]. Feinglass and colleagues further stated that males of African ancestry were 1.7 times more likely to experience primary and repeat amputations [6]. Likewise, the prevalence of diabetic retinopathy and macular oedema was also higher in participants from African ancestry with diabetes (36.7% and 11.1% compared to 24.8% and 2.7% among white, and 25.7% and 8.9% among Chinese patients respectively) [7]. In a different study Gulliford and colleagues determined that the prevalence of sight-threatening diabetic retinopathy was 15.2% in

Africans, 14.7% in African-Caribbean and 9.4% in white Europeans. The data which were collected in three South London boroughs during an 18-month period suggested that retinopathy is not only more prevalent but also more severe in those with African ancestry [8].

Particular group characteristics may influence the management of diabetes among patients of African descent. These include the adherence to medication [9], health beliefs and cultural bias [10-14], health numeracy [15], access to health care and insurance issues [16-18], and socio-economic status [19]. Self-management practices in patients of African descent and other ethnic populations in developed countries were reviewed and it was concluded that there was lack of education, understanding and communication at the patient level and cultural differences or lack of cultural sensitivity at provider levels [20,21]. Chin and colleagues reported on effectiveness of interventions to reduce racial disparities in health care [22]. The most effective interventions were found to be multifaceted programmes aimed simultaneously at patient provider and health organisation. Culturally tailored quality improvement programmes based on cultural “leverage” showed improvement in patient empowerment for self-care, decreased barriers of access to physicians and improved cultural sensitivity by health care providers. Peek *et al.* [23] reviewed diabetes care interventions in multiple ethnic groups such as Hispanics, African Americans, Americans of Caribbean origin, Native American, Asian American and Pacific Islanders. The most effective interventions were noted to be culturally tailored, individual education with peer support and improvements to health care systems [23]. Hawthorne *et al.* [24] reviewed the literature in relation to the effectiveness of culturally appropriate health education for type 2 diabetes in patients of African descent and other ethnic groups. The authors reported improvement of mean difference in HbA1c at 3 and 6 months post-intervention, but not at 12 months. However, heterogeneity in the education and follow-up methods made interpretation of the benefits difficult to interpret.

A large number of people of African and Caribbean descent live in developed countries such as the USA and the UK. Such individuals have specific characteristics which may differentiate them from other ethnic and racial groups, and also have a high rate of type 2 diabetes. Therefore, it is important to review the effectiveness of targeted non-pharmacological interventions on diabetes control in this population. Such information is essential to establish the value of such programs and to inform the design of future care strategies. The effectiveness of these interventions will be assessed by their ability to reduce blood glucose levels in the target population. The goal is to compare the interventions with control or usual care.

2. METHODOLOGY

2.1. Search Strategy

Databases (PubMed, Embase, CINAHL, ZETOC, NHS evidence, Clinical trials.gov and SIGLE) were searched using the combined search terms “type 2 diabetes” and/or “intervention” and “black” or “African” or “Caribbean”. In addition, references of the journals and reference text books were consulted. The searches were done between November and December 2010, May to June 2011 and between September 24th and October 6th 2011 (**Figure 1**).

2.2. Selection Criteria

The population of interest was adult participants of African descent in developed countries which includes “African-Americans”, “African-Caribbean”, “Non-Hispanic blacks” and “self-described blacks”. Studies were restricted to those published in English from the developed

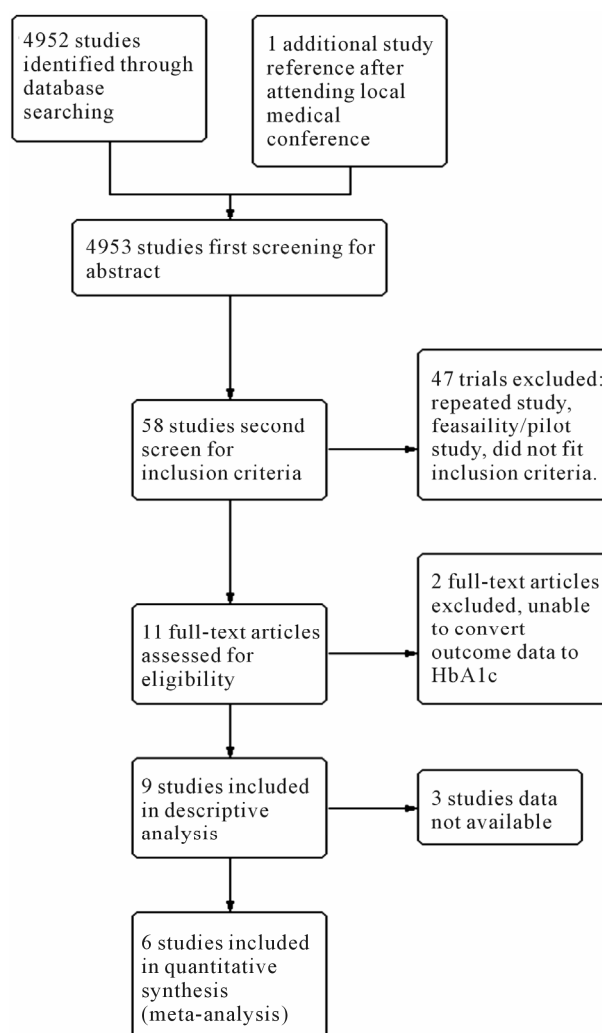


Figure 1. Flow chart screening process.

English speaking countries such as the USA and the UK. The interventions of interest were non-pharmacological including educational programs. The primary outcome of interest was a measure of difference in HbA1C with the standard deviation.

2.3. Inclusion Criteria

This included randomised controlled trials (RCTs) or prospective cohort studies published between January 1st 1995 and October 6th 2011. The participants, males or females, had type 2 diabetes according to the WHO criteria and were 18 years or older (adults). Trials including participants with diabetes under age 18, persons with type 1 diabetes, known LADA, MODY and those with gestational diabetes were excluded. Also excluded, were interventions in which less than 90% of participants were of African descent. Feasibility studies for an intervention were also excluded, but pilot studies were included if the outcome data were appropriate, and if the study was not duplicated.

2.4. Quality Assessment

Critical appraisal checklists were adapted from Cochrane Collaboration tool for assessing risk of bias and the quality of each study. Information from all included studies was extracted and tabulated. Where data were insufficient for a particular study, authors were contacted for clarification.

2.5. Data Extraction

Data were extracted using a RevMan data collection form according to the selection criteria, and subsequently analysed. The information extracted included the study information (author and year), participant characteristics and number of participants recruited. The duration of intervention was 6 months where possible. Drop-outs, as well as type of intervention and duration of the intervention/study duration were also extracted with every effort to minimise missing data. The outcome measures of HbA1C difference were calculated for each trial before synthesising the data.

2.6. Data Analysis

Standardised mean difference was used to describe the data. The mean difference for the intervention and the control were calculated separately and the standard deviation within the groups calculated for missing data. The effect size calculated was from the net difference in mean HbA1C between the intervention and the control groups. Hedges unbiased estimate was used to correct the overestimated value of the mean difference in studies with small sample sizes. Sd (within) was calculated from

$\text{sq root } \left\{ \frac{(n_1-1)S_1^2 + (n_2-1)S_2^2}{n_1+n_2-2} \right\}$ [25].

RevMan software was used for Meta-analysis of HbA1C results. Testing for heterogeneity in the data by the chi-square test and Forest plot of the trials was included in the review. RevMan statistics were also confirmed by calculation.

3. RESULTS

Initially 4952 studies were identified through database searches of PubMed, CINAHL, Embase, and one additional from a local conference. Of the 58 potential studies for inclusion only 9 met inclusion criteria and were subsequently included in the systematic review with 8 being controlled trials. The characteristics of included studies are tabulated below (**Table 1**). A Pre-test post-test longitudinal study was included because this study was randomised and had two groups—a control and experimental group, resembling a RCT [26]. A control intervention time series study, a cohort study, was also included [34].

3.1. Characteristics of Included Studies

All of the studies were comparisons of interventions within an African American population and the effectiveness at improving outcomes including HbA1C. The length of trials ranged from 6 months to 36 months. The sample participant sizes ranged from 64 to 4138 with mean age of 56 - 62 years. Participants were either all or at least 94% African Americans. All selected studies were from the USA. There were over 64% females in every group. The studies took place in urban African American communities, with the exception of Skelly *et al.* and Anderson-Loftin *et al.*, which were located in rural southeast and South Carolina. Control groups included a 2 × 2 factorial design [31] and a three group experimental design [33]. The studies were of an intervention compared to usual care, conventional care or minimal intervention. Comparisons between the intervention and control group baseline group characteristics were not statistically different within each study. The one exception was that of Anderson-Loftin *et al.* [27].

In one trial [29] HbA1C was not the primary outcome and in the remaining trials, HbA1C was not the only outcome measured; BMI/weight, lipids and blood pressure were other outcomes measured in the remaining trials. Methods used to measure the unit of the outcome HbA1C varied and included high pressure liquid chromatography, Glycaffin column method, immunoturbidimetric method, and glucometer; none of the methods accounted for haemoglobin variants. HbA1C was measured in % mg/dl; IFCC mmol/mol units were not found in the literature. Proportion of patients reaching target HbA1C was only reported in few studies so this was

Table 1. Characteristics of included studies [26-34].

Study	Participants	Method	Intervention	Outcome
A randomised controlled trial (RCT) of weight reduction and exercise for diabetes management in older AA subjects Agurs-Collins, 1997	Overweight AA n = 64 age 55 to 79; intensive care (IC): 62.4 +/- 5.9, usual care (UC): 61 +/- 5.7; 66% female (F) in IC, 88% F in UC; urban hospital DC. Recruited from GP/dm clinics, private practice	Participants classified by medication, randomly assigned by statistician. 85% completed 6 month visit, attrition 15%	Intensive: First 3 months: 12 weekly group sessions of 8 to 10 nutrition/exercise, 1 individual dietcounseling session, 6 biweekly group 3 months. Usual care: 1 individual session, 6 biweekly group or 1 class and 2 mailings	At 3 months HbA1C -1.6%; At 6 months—net mean difference 2.4% +/- 1.8% p < 0.01
Soul food light. Culturally competent diabetes education Anderson-Loftin, W., 2005	97 adult AA duration 1 year, data collection at 6 months. Age Intervention (int) 58.9 +/- 10.1, age control (ctrl) 55.7 +/- 12.1. 78, 75% F. Rural South Carolina small medically underserved	Longitudinal pre-test, post-test design. Random assignment by computer generated table of random #. Attrition 22%, 44% control (significant) RA id # was blinded to group assignment	IC: culturally sensitive 4 weekly 90 min classes in diet, 5 monthly 1hr peer-prof discussion groups—telephone follow-up weekly. UC: referral to a traditional 8 hr diabetes class optional attendance. (mean 4.8 classes) research assistant (RA) call at 3 months	Int group 7.5 +/-1.6 Ctrl 8.3 +/- 2.6. At 6 months int: 7.0 +/- 1.1 p = 0.518, ctrl 8.0 +/- 2.8. No significant diff, however A1c was low in experimental group at baseline (floor effect)
A patient-centric provider assisted diabetes telehealth self-management intervention for urban minorities Carter, E.L., 2011	74 total, 27 lost, 26 treatment group, 21 control group. AA > 18 years in median age 56. Duration 9 months. 64% F. Washington DC, primary care practice, inner city.	Adequate sequence generation by random numbers table. Attrition 27/74 (36%)	Telehealth intervention: self management module biweekly 30 min video conference, health education, social network versus patient health care provider	Baseline A1C 8.9 “Significant association between participation and A1C of 7% or below.”
The effects of nurse care manager (NCM) & community health worker (CHW) team on diabetic control, emergency department (ED) visits & hospitalizations among urban AA with type 2 diabetes Gary, 2009	Duration 24, 36 months. 542 randomly assigned AA, mean age 58, 73% F. Community-university affiliated, low income urban population	Technicians blinded to intervention assignment. Attrition 8%; 92% completing 24 month visit. Blinded observers collected data at baseline and 24 months	Intensive: minimal plus individual culturally tailored care provided by NCM & CHW used evidence based clinical algorithm with feedback to PCP. Minimal: lay health educator reminder by telephone every 6 months	HbA1C Mean difference (d) (final minus baseline) intensive -2.0 +/- 1.7; d minimal -0.08 +/- 1.93
The effect of a diabetes education coping skills training and care intervention on psychological and psychosocial outcomes in black women with type 2 diabetes. Melkus, 2010	109 black American women. Duration 10/11 weeks with follow-up of 2 years. Age 48 +/- 10 years. Location polyclinic centre adjacent to school of nursing in urban southern New England community	Adequate sequence generation computer randomised. Attrition rate 29%, blinding unclear, incomplete data addressed	Intervention:#52 11 weekly group sessions; first 6 culturally relevant diabetes self-management training; 5 coping skills training Conventional care: #57 Community hosp based grp diabetes educational classes and grp follow-up Q&A for 10 weeks. 1 to 5 diabetes ed, 6 to 10 diabetes discussion	Baseline completers: 8.1 +/- 2.1; control grp 8.3 +/- 2.2, intervention group 8.0 +/- 2.1. At 6 months control 7, experimental 7.2
An endocrinologist supported intervention aimed at providers improves diabetes management in a primary care site. Phillips, 2005	Intervention for residents. 4138 patients with type 2 diabetes average 59 years, 67% female; 94% AA average duration 3 years (15 month average). BMI 33 kg/m ² . Baseline A1C 8.1%. Grady Medical Clinic Georgia, urban indigent population	Randomised with 2 x 2 factorial design to control or manage both 2 endocrinologist supported interventions, Blinding	Computerised decision support reminders that provided individual recommendations for management at time of visit. Face to face feedback q 2 weeks. Compared outcomes to non-intervention primary care sites within same health system	Change in A1C 0.6%, final 7.46% w/feedback & reminder. Change in A1C 0.2% final 7.84% p < 0.02 in control grp. Over 2 yr final A1C 7.5% vs 8.2% p < 0.001

Continued

A RCT of church based self-management program for AA with type 2 diabetes. Samuel-Hodge, 2009	24 churches in central NC Feb 01 to Aug 03. Duration 8, 12 months. Specific intervention: 13 churches, 117 Minimal intervention: 11 churches, 84. Mean age 59, A1C 7.8% BMI 35 kg/m ² (87% or 174 patients), 64%F	Randomisation by opening next envelope from set of sequentially numbered sealed envelopes containing study group assignment as determined by random # generation by statistical consultant using a PC. Attrition 13%	Church-based, culturally appropriate, self mx education. Specific interv: 8 month intensive phase 1 individual counselling, 12 group sessions, monthly phone contact, 3 encouragement postcards, 4 month reinforcement Minimal: standard educational pamphlets by mail	At 8 months mean diff 0.4% (95% CI) p = 0.009; 0.5% (95% CI) p < 0.001 in a larger model adjusting for additional variables
Controlled trial of nursing interventions to improve health outcomes of older AA women with type 2 diabetes. Skelly, A.H., 2009	180 AA females >55 years without co-morbidities type 2 diabetes > 1 yr A1C > 7%. Duration 3, 6, 9 months. Rural areas of south-east, living below poverty line. Recruited from health centres, department clinics, primary care	RCT three grp experimental design. Study assignments in sealed envelopes. RA blind to study assignment. Retention at 9 months 90.6%; 9.4% attrition	Symptoms focused diabetes intervention individual teaching at home with telephone booster 2 weekly over 12 wks versus attentional control (focus on "how to" weight management & diet skills training) 4 × 60 minute bimonthly visits	Baseline 8.44 +/- 1.63 symptom intervention, 8.11 +/- 1.61 weight management and diet control. At 6 months 7.85 intervention and 7.95 weight control. Booster not included.
Self management support in "real world" settings. An empowerment based intervention. Tang, 2010	77 AA with type 2 diabetes. 69% F. Duration 6, 12 months. Mean age 61. Michigan, recruitment by newspapers, flyers, health centre, church	Attrition rate 13% CONTROL-INTERVENTION COHORT STUDY Control intervention time series design	Intervention: weekly DSMS groups optional & support over 24 weeks. 6 months attentional control, 6 months Lifelong management intervention sessions. Control: weekly newsletters	Change in A1C control 0.31 versus -0.68 (intervention) p < 0.01 "significant reduction in A1C compared to control group."

abandoned for meta-analysis.

The trials mainly targeted patient education. One study focused on exercise and dietary self-management. There were no multi-component interventions. The interventions used both individual or group designs—3 group interventions, 4 individual and 2 mixed interventions. There was one provider intervention and 8 patient interventions; the trial interventions used the expertise of diabetes educators, nurses, community health workers, lay health educators and counselors and, less often, physicians.

3.2. Quality of the Studies Selected

A total number of 3329 participants at baseline were divided into the intervention and control groups. Patients lost to attrition varied between 8% and 23% - 44%; for the latter there was a baseline difference between the intervention and control groups; all of the studies commented on attrition or addressed incomplete data. Using the modified Cochrane Collaboration tool for quality score, allocation concealment was described in one study [27], blinding in four studies [27,29,31,33], and adequate sequence generation in four [27,30,32,33]. Two studies were considered high quality, 6 studies were considered fair quality and 1 study considered inadequate/poor quality (Table 2).

Relevant HbA1C data were available for six of the

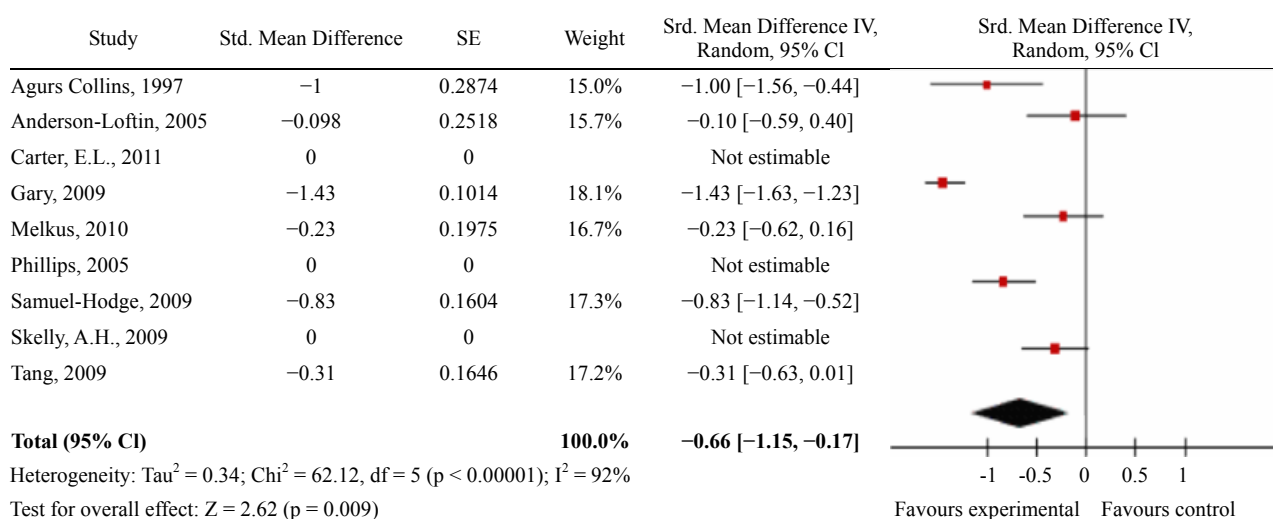
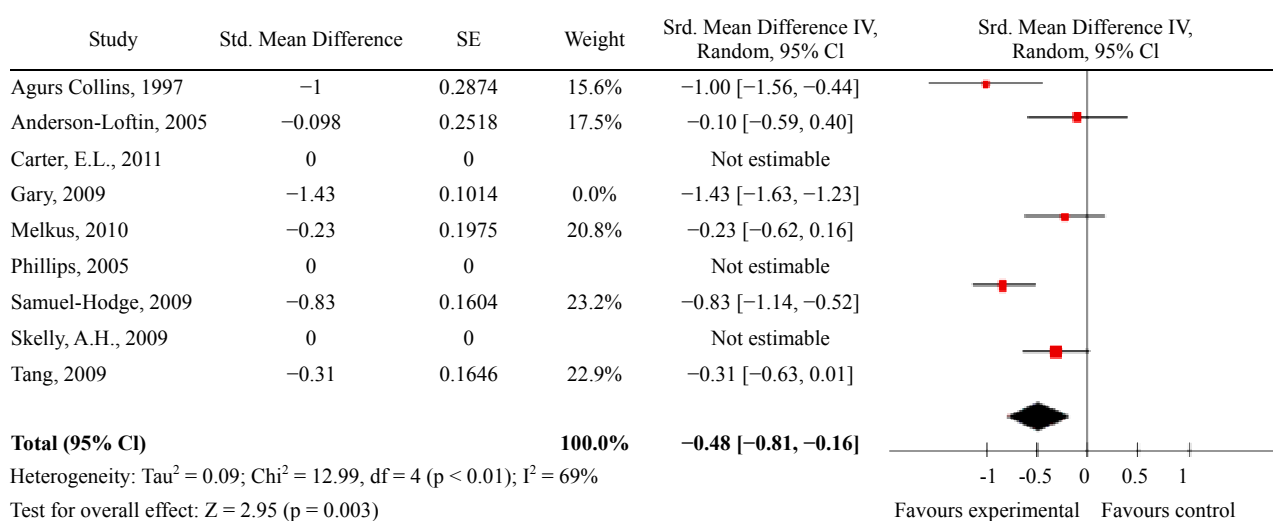
studies for meta-analysis. The effect measure of standardised mean difference of the random effects model is presented in the forest plot below (Figure 2). The pooled results reveal high heterogeneity, that is, $I^2 = 92\%$ of the variation between the studies is due to heterogeneity $p < 0.00001$; most of the observed variance is real, indicating that these studies are too different to compare. The random effects pooled standard mean difference favoured the intervention $-0.66 (-1.15, -0.17)$. The test for overall effect produced a $p = 0.009$. Sensitivity analysis was done with removal of Gary study (Figure 3). This study was an outlier with weight of 18.1% (42.9% in the fixed method analysis) with sample size over 200 in each study arm; the other studies had samples sizes that were more comparable. After sensitivity analysis the heterogeneity was moderate to high $I^2 = 69\%$ $p < 0.01$. The Chi-square test was still greater than the degrees of freedom at 12.99 versus 5 indicating heterogeneity. The random effects pooled standard mean difference still favoured the intervention after sensitivity analysis $-0.48 (-0.81, -0.16)$. Also after sensitivity analysis the test for overall effect produced a $p = 0.009$.

4. DISCUSSION

In this systematic review and meta-analysis non-pharmacological care interventions specifically directed at populations of African descent appear to significantly

Table 2. Quality table for the included studies.

Study	Random Sequence generation	Allocation concealment	Blinding of researcher	Blinding of participant	Attrition/ In-complete data addressed	Total
Agurs-Collins, 1997	Low risk	unclear	unclear	unclear	Low risk	Fair quality
Anderson-Loftin, 2005	Low risk	Low risk	Low risk	unclear	Low risk	High quality
Carter, E.L., 2011	Low risk	unclear	unclear	unclear	Low risk	Fair quality
Gary, 2009	unclear	unclear	Low risk	unclear	Low risk	Fair quality
Melkus, G., 2010	Low risk	unclear	unclear	unclear	Low risk	Fair quality
Phillips, L.S., 2005	unclear	unclear	Low risk	unclear	Low risk	Fair quality
Samuel-Hodge, 2009	Low risk	Low risk	unclear	unclear	Low risk	Fair quality
Skelly, A.H., 2009	Low risk	Low risk	Low risk	unclear	Low risk	High quality
Tang, T.S., 2009	unclear	unclear	unclear	unclear	Low risk	Poor quality

**Figure 2.** Forest plot of results before sensitivity analysis.**Figure 3.** Forest plot of results after sensitivity analysis.

influence the concentrations of HbA1C compared to controls or usual practice. However, the conclusion of this review is likely to be influenced by the heterogeneity encountered in selected studies which undoubtedly limit the interpretation of the data. The heterogeneity encountered can be explained by the varied interventions, duration of interventions, differences in participants and differences in methods of HbA1C measurement. Although the duration of the interventions in the review was heterogeneous, improvements in glycaemic control were achievable under such circumstances. Further, the conclusion of this review is in line with previously published work showing the effectiveness of culturally tailored interventions [23]. Chin *et al.* [22] reported on the effectiveness of nurse-led programmes, but there was only one such programme in that review. The duration of the studies in this review is also relevant because long-term effectiveness of a trial wanes without reinforcement, and attrition also tends to decrease with the ability of a study to maintain interest and motivation. In addition, there is the possibility of successful follow-up for at least two years [29,30].

This systematic review has several limitations. Firstly, the interventions included in the systematic review were U.S. studies hence generalisability to other countries and scenarios may be limited, but nevertheless the review does give an indication of utility of targeted educational and other non-pharmacological interventions. Secondly, there was failure to comment on participant blinding and allocation concealment in 6 of the 9 selected studies, leading to selection and performance biases. Although attrition was accounted for in all studies, attrition rate was high in three of these (Carter—36%, Anderson-Loftin—22% - 44%, Melkus—29%). Thirdly, publication bias leads to overestimation of intervention effect, or errors in reported effects. Grey literature was searched to decrease the possibility of bias, but this search yielded no results. Finally, the HbA1C measurement method varied between studies and although the major haemoglobinopathies of sickle cell variants are unlikely to alter measurements in populations with mean age of 56 to 62, this must be considered for the younger age groups in the general population for future research. In addition, anaemia, polycythaemia and B12 deficiencies affecting the red blood cells, affect HbA1C measurement and this was neither mentioned, nor factored into outcomes in any of the included studies.

Notwithstanding the limitations of this systematic review, there is now some indication that targeted educational and non-pharmacological interventions are worthwhile in the African ancestry population with diabetes. Hence, it is hoped that the review can impact local practice by highlighting the importance of motivating and empowering patients in their communities through ap-

propriate interventions to complement and indeed enhance pharmacological ones. Additional well designed and powered trials are still needed to shed further light on this issue but non-controversial strategies based on current best practice can be useful and need to be implemented.

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ABBREVIATIONS

RCTs: Randomised Controlled Trials;

WHO: World Health Organisation;

LADA: Latent Autoimmune Diabetes of Adulthood;

Mody: Maturity Onset Diabetes of the Young