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The effect of lifestyle intervention on clinical risk factors in patients with type 2

Preparation

Mansour Fazaa Falah Al-Hazmi
Mowafaq Ibrahim Abdullah Al-Muzaid

Abdulazim Awad Hossad Al-Hazmi

Gharam Fazaa Falah Al-Hazmi

Maslah Musabah Adhaib Al-Hazmi

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1. Mansour Fazaa Falah Al-Hazmi - Nursing Technician - mansourfa@moh.gov.sa
2. Mowafaq Ibrahim Abdullah Al-Muzaid - Physical Therapy Technician - mowafaq.my@gmail.com
3. Abdulazim Awad Hossad Al-Hazmi - Nursing Technician - aoalhazmi@moh.gov.sa
4. Gharam Fazaa Falah Al-Hazmi - Nursing Technician - Gfalhazmi@moh.gov.sa
5. Maslah Musabah Adhaib Al-Hazmi - Nursing Technician - mmhazmi@moh.gov.sa

ABSTRACT

The effect of lifestyle intervention on clinical risk factors in patients with type 2 diabetes is unclear. The aim of this meta-analysis was to evaluate the effects of comprehensive lifestyle change, such as diet, exercise, and education, on clinical markers that are risk-factors for cardiovascular disease in patients with type 2 diabetes. Methods. We searched Medline, Cochrane, EMBASE, and Google Scholar (up to August 31, 2023) for randomized controlled trials that compared standard of care (control group) with treatment regimens that included changes in lifestyle (intervention group). The primary outcome was reduction in risk factors of cardiovascular disease including body mass index (BMI), glycated hemoglobin (HbA1c), systolic blood pressure (SBP), diastolic blood pressure (DBP), high-density lipoprotein cholesterol (HDL-c), and low-density lipoprotein cholesterol (LDL-c). Results. A total of 16 studies were included in the meta-analysis. The standardized difference in means of change from baseline significantly favored the intervention compared with the control group in BMI (−0.29; 95% CI,−0.52 to −0.06, P = 0.014), HbA1c (−0.37; 95% CI, −0.59 to −0.14, P = 0.001), SBP (−0.16: 95% CI, −0.29 to −0.03, P = 0.016), DBP (−0.27, 95% CI = −0.41 to −0.12, P < 0.001). There was no difference between the intervention and control groups in HDL-c (0.05; 95% CI, −0.10 to 0.21; P = 0.503) and LDL-c (−0.14; 95% CI, −0.29 to 0.02; P = 0.092). Conclusions. The meta-analysis found that lifestyle intervention showed significant benefit in risk factors that are known to be associated with development of cardiovascular disease in patients with type 2 diabetes.

Keywords: Lifestyle Intervention Type 2 diabetes Meta-analysis

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١. منصور فزع فالح الحازمي - فني تمريض - mansourfa@moh.gov.sa
٢. موفق ابراهيم عبد الله المزيد - فني علاج طبيعي - mowafaq.my@gmail.com
٣. عبد العظيم عويد حصاد الحازمي - فني تمريض - aoalhazmi@moh.gov.sa
٤. غرام فزع فالح الحازمي - فنية تمريض - Gfalhazmi@moh.gov.sa
٥. مصلح مصبح عضيب الحازمي -فني تمريض- mmhazmi@moh.gov.sa

الملخص:

تأثير التدخل في نمط الحياة على عوامل الخطر السريرية لدى مرضى السكري من النوع ٢ غير واضح. كان الهدف من هذا التحليل التلوي هو تقييم آثار التغيير الشامل في نمط الحياة، مثل النظام الغذائي وممارسة الرياضة والتعليم، على العلامات السريرية التي تعد عوامل خطر للإصابة بأمراض القلب والأوعية الدموية لدى المرضى المصابين بداء السكري من النوع الثاني. طُرق. لقد بحثنا في Medline وCochrane وEMBASE وGoogle Scholar (حتى ٣١ أغسطس ٢٠٢٣) عن تجارب عشوائية محكومة تقارن مستوى الرعاية (مجموعة المراقبة) مع أنظمة العلاج التي تتضمن تغييرات في نمط الحياة (مجموعة التدخل). وكانت النتيجة الأولية انخفاض في عوامل خطر الإصابة بأمراض القلب والأوعية الدموية بما في ذلك مؤشر كتلة الجسم (BMI)، والهيموجلوبين السكري (HbA1c)، وضغط الدم الانقباضي (SBP)، وضغط الدم الانبساطي (DBP)، والكوليسترول الدهني عالي الكثافة (HDL-c)، والكوليسترول الدهني منخفض الكثافة (LDL-c). نتائج. تم تضمين ما مجموعه ١٦ دراسة في التحليل التلوي. كان الاختلاف المعياري في وسائل التغيير من خط الأساس يفضل بشكل كبير التدخل مقارنةً بالمجموعة الضابطة في مؤشر كتلة الجسم الاستنتاجات. وجد التحليل التلوي أن التدخل في نمط الحياة أظهر فائدة كبيرة في عوامل الخطر المعروفة بأنها مرتبطة بتطور أمراض القلب والأوعية الدموية لدى المرضى الذين يعانون من مرض السكري من النوع ٢.

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Introduction

The proportion of people with type 2 diabetes is on the rise and is a major cause of death world-wide. Type 2 diabetes is a major risk factor for vascular disease with 65% of all diabetic deaths being due to cardiovascular disease

[1]. Lifestyle characteristics, such as physical activity, diet, and stress are important factors that influence development and prognosis of type 2 diabetes

[2]. Changes in diet and increase in physical activity (walking, etc.) and exercise (running, cycling, etc.) are key components of the management of type 2 diabetes

[3], and guidelines recommend changes in these lifestyle characteristics for both prevention and management of the disease

[4]. Several systematic reviews and meta-analyses have reported the benefit of interventions aimed at improving lifestyle behaviors on disease progression and development of comorbidities (eg, vascular disease) in patients with type 2 diabetes .

However, the benefit of lifestyle changes in reducing all-cause mortality or cardiovascular disease is less clear as the findings from these analyses are inconsistent or the data are inconclusive [5–13]. To our knowledge, there have been nometa-analyses that evaluated the effect of interventions that result in multiple lifestyle changes on risk factors for cardiovascular disease in patients with type 2 diabetes. The aim of this meta-analysis was to evaluate the effects of changes in lifestyle that included dietary behavior, exercise, or physical activities on clinical markers of cardiovascular disease in patients with type 2 diabetes.

the percentage of the total variability in effect estimates among trials resulting from heterogeneity rather than chance. Random-effects models of analysis were used if heterogeneity was detected ($I2 > 50\%$). Otherwise, fixed-effects models were used. For each risk factor measure, standardized difference in means with corresponding 95%

confidence intervals (CIs) was calculated for between groups and among studies. A two sided P value

Materials and methods

1-Search strategy

We searched Medline, Cochrane, EMBASE, and Google Scholar for randomized controlled trials that compared standard care with interventions that involved changes in lifestyle. The following terms were used in the search: diabetes, cardiovascular risk, lifestyle, health education, dietary, exercise/physical activities, and behavioral intervention. Articles up to August 31, 2013 were included. Studies were excluded if they were not published in English, were not prospective randomized trials, did not enroll patients with type 2 diabetes, or did not investigate lifestyle or education programs relating to dietary behavior, exercise, or physical activities. All possibly relevant studies were also hand-searched by 2 independent reviewers and both reviewers had to agree for the study to be included. If there was disagreement, it was resolved by a third reviewer

2- Data extraction The following information or data were extracted from the included studies: the name of the first author, year of publication, study design, number of participants in each treatment group, participants' age and gender, diagnostic criteria, intervention regiment for study/control group, and results

3- Quality assessment The included studies were assessed for risk bias using the 'Risk of Bias' assessment tool, Review Manager 5.1, and recommendations for judging risk of bias provided in Chapter 8 of the Cochrane Handbook for Systematic Reviews Interventions [14].

4- Statistical analysis The primary outcome was reduction in any risk factor of cardiovascular disease including body mass index (BMI), HbA1c, systolic blood pressure (SBP), diastolic blood pressure (DBP), high-density lipoprotein-c (HDL-c), and low-density lipoprotein-c (LDL-c). BMI, HbA1c, SBP, DBP, HDL-c, and LDL-c were

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compared between participants having intensive lifestyle intervention (intervention group) and conventional intervention (control group). A χ2 based test of homogeneity was performed using Cochran's Q statistic and I2 . I2 illustrates the percentage of the total variability in effect estimates among trials resulting from heterogeneity rather than chance. Random-effects models of analysis were used if heterogeneity was detected (I2 > 50%). Otherwise, fixed-effects models were used. For each risk factor measure, standardized difference in means with corresponding 95% confidence intervals (CIs) was calculated for between groups and among studies. A twosided P value

Results

1-. Characteristics of included studies Eighty-five possible studies were identified and 18 were excluded owing to not being relevant to this analysis (Fig. 1). Of the 67 remaining studies, 51 were excluded due to being redundant with an included study, not presenting outcomes of interest, having an intervention period of 2 treatment arms. One study [15] met the inclusion criteria but was excluded because its findings, in regard to BMI, LDL-c and HDL-c changes, were not in concordance with the included studies. The inclusion of this study would have skewed the meta-analysis by increasing the discrepancy in both sensitivity and publication bias analyses (Fig. 1). A total of 16 studies were included in the meta-analysis [16–31]. The number of patients per study ranged from 23 to 2575 (Table 1). The mean (SD) age was similar across studies (range, 51.3 [1.8] to 67.3 [19]) and between the interventional and control groups (Table 1). The proportion of patients that were male ranged from 34.8% to 98%, and the lengths of the study ranged from 6 months to 8 years (Table 1). Supplementary Table S1 summarizes the change from baseline of key risk factors for all included studies.

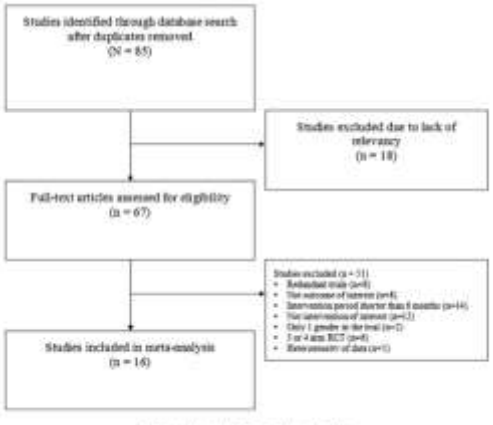

Fig. 1 - Flow chart for study selection.

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Quality assessment indicated that all 16 studies had a high risk of performance bias due to the studies not having adequate blinding of the participants and personnel (Fig. 2A and B). Six studies had high risk of bias due to risk factor assessments not being blinded [16,22–24,30,31]

2- Body mass index Eleven of the included studies reported change from baseline in BMI [18–20,22–25,27,28,30,31]. There was heterogeneity for BMI across studies (Q statistic = 71.93, I2 = 86.10%, P < 0.001); hence, a random effects analysis was applied. The standardized difference in means of change from baseline in BMI significantly favored the intervention group over the control group (standardized difference in means, −0.29; 95% CI, −0.52 to −0.06, P = 0.014.

HbA1c

All 16 studies reported data for change from baseline in HbA1c. A random effects analysis was applied owing to evidence of heterogeneity among the studies (Q statistic = 238.84, I2 = 93.72%, P < 0.001). The standardized difference in means of change from baseline in HbA1c significantly favored the intervention group compared with the control group (standardized difference in means, −0.37; 95% CI, −0.59 to −0.14, P = 0.001)

Systolic and diastolic blood pressure

Fifteen of the 16 studies reported values for SBP at baseline and following intervention [16–28,30,31] and 14 reported DBP [16–25,27,28,30,31]. There was heterogeneity across the studies in both SBP and DBP (SBP: Q statistic = 64.03, I2 = 78.13%, P < 0.001; DBP: Q statistic = 73.51, I2 = 82.32%, P < 0.001); consequently, a random effects analysis was used. The standardized difference in means of change from baseline in both SBP and DBP significantly favored the intervention (SBP: standardized difference in means, −0.16: 95% CI, −0.29 to −0.03, P = 0.016; DBP: standardized difference in means: −0.27, 95% CI = −0.41 to −0.12, P < 0.001

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LDL-c and HDL-c

Of the 16 studies, 12 reported change from baseline in LDL-c [16,17,20–23,25,26,28–31] and 13 reported change from baseline in HDL-c [16–20,22–25,28–31]. A random effects analysis was applied for both risk factors as there was evidence of heterogeneity among the studies (LDL-c: Q statistic = 48.77, I 2 = 77.45%, P < 0.001; HDL-c: Q statistic = 72.93, I2 = 83.55%, P < 0.001). The standardized difference in mean change from baseline showed no difference between groups for both HDL-c and LDL-c (HDL-c: standardized difference in means, 0.05; 95% CI, −0.10 to 0.21; P = 0.503; LDL-c: standardized difference in means = −0.14; 95% CI, −0.29 to 0.02; P = 0.092)

Sensitivity analysis and publication bias

Sensitivity analysis was performed in which the results were analyzed when one study was removed in turn for BMI and HbA1c results. The direction and magnitude of the combined estimates did not markedly change with the exclusion of individual studies, indicating that no one study dominated the findings (Fig. 4). Funnel plot analysis for publication bias found the combined effect size yielded Z values of 1.96 for BMI (P < 0.001) and −8.16 for HbA1c (P < 0.001). The Eggar's test found funnel plot symmetry, indicating there was no significant evidence of publication bias (P = 0.148 for BMI, P = 0.572 for HbA1c)

Discussion

The effect of lifestyle interventions on risk factors associated with cardiovascular disease in patients with type 2 diabetes is unclear. Only a limited number of studies have investigated this issue and they utilized a range of interventions and methodologies [16–31]. Interventions included increased physical activity, reduced caloric intake, dietary education, and counseling and education regarding treatment adherence or disease monitoring. In general, these studies indicated a benefit of lifestyle intervention on risk factors of cardiovascular disease [16–31]. However, not all findings were consistent across studies. For example, Dobrosieski et al. (2012) found

no change in blood pressure with supervised exercise [27] while, Balducci et al. (2010) found significant improvement in both systolic and diastolic blood patients with or at risk for type 2 diabetes [6,7,10,12,13]. The lifestyle interventions included an exercise and diet component and at least one other component such as smoking cessation, behavior modification, and counseling. In contrast to our study, one of the meta-analysis did not find intervention significantly improves systolic or diastolic blood pressure [7]. It also found, using sensitivity analysis, that there was improvement in HDL (mean difference, 0.04; 95% CI, 0.03–0.05) and HbA1c (mean difference, −0.71; 95% CI, −1.31 to 0–0.12) only for interventions that included pharmacotherapy [7]. In addition, these improvements did not continue past the interventional phase [7]. We did not evaluate the relationship of lifestyle intervention with pharmacotherapy or treatment duration in our analysis. Another meta-analysis specifically assessed whether resistance exercise is comparable to aerobic exercise in regard to glycemic control, blood lipids, blood pressure, anthropometric measures, health status, and adverse events [10]. Twelve

Conclusion

In summary, our meta-analysis found that lifestyle intervention which included change in diet, exercise, and education showed significant benefit in a number of risk factors which are known to be associated with cardiovascular disease in patients with type 2 diabetes. Supplementary data to this article can be found online at

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