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Behavioral trials in the Arab Gulf States: A scoping review

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Abstract

The leading chronic conditions in Arab Gulf States are modifiable by lifestyle change. Available evidence suggests a paucity of experimental studies on these conditions. We aimed to review the published randomized controlled trials on behavioral modification in the Arab Gulf States. Three databases (PubMed, Embase, and Cochrane) were searched for related keywords, and the records were screened for eligible studies; data were abstracted on trial characteristics (e.g. publication year, study population, primary outcome, intervention, control, follow-up, and outcome results), and a quality assessment of the trials was made. A total of 16 trials were eligible; 50% did not provide sample size calculation, and 31% did not designate a primary outcome. A majority of the trials did not explain randomization or allocation concealment (50%), did not blind outcome assessors (69%) or adopt an intention-to-treat analysis (56%); and 82% of trials found a significant intervention effect. More behavioral trials should be conducted overall and specifically for conditions for which there are no trials (e.g. respiratory tract infection and road injury).

Keywords

Behavioral, intervention, randomized controlled trials, Arabs, Gulf

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Introduction

Arab Gulf States, home to over 93 million people, include seven nation states: Saudi Arabia, Bahrain, Qatar, Kuwait, Oman, United Arab Emirates, and Iraq. As major producers of petroleum, these countries, except Iraq, belong to the world's high-income countries, and their citizens enjoy a relatively affluent life (gross national income per person per year is $41,932).[1]

The major causes of death in these high-income Arab countries are non-communicable diseases and road injuries.[2] For example, in 2010, the top five contributors of death were ischemic heart diseases (18.4%), road injuries (11.9%), stroke (11.5%), lower respiratory tract infection (4.9%), and diabetes (4.3%).[2] A significant portion of these deaths could be averted if the population prevalence of risk factors (e.g. obesity, unhealthy diet, physical inactivity, and smoking) were reduced.

The picture becomes clear if Saudi Arabia, the largest and the most populated of the Arab Gulf States, is taken as an example. Almost 29% of Saudis are obese (body mass index $\geqslant 30\,kg/m^2$), and its prevalence is higher among women than men (33.5% vs 24.1%).[3] Only a small percentage of the Saudi population meets the dietary recommendation for fruits (5.2%) and vegetables (7.5%).[4] One-third of its population (aged $\geqslant 15$ years) is completely physically inactive, and only 12% meet the recommended level of moderate physical activity (30 min, 5 days a week); inactivity is higher among women and the educated.[5] A large percentage of the population engages in tobacco consumption; around 12.2% are current smokers (21.5% of men and 1.1% of women) and another 4.3% are shisha (or water pipe) smokers (7.3% of men and 1.3% of women).[6] More than half of Saudis (55.8%) are either borderline or overtly hypertensive, and slightly less than half (45%) of those who take anti-hypertensive medication have their blood pressure controlled.[7] The

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prevalence of risk factors in other Gulf States is more or less similar to those in Saudi Arabia.[8–10]

A multi-pronged approach—from policies to programs to information dissemination—is necessary to reduce the level of modifiable risk factors in the population. A critical component of that approach is to develop interventions that help people adjust their unhealthy behaviors. Many interventions on healthy eating and exercise, weight management, smoking prevention, medication adherence, or road safety have been developed and tested elsewhere in the world, particularly in the West.[11–16] However, they need to be assessed in Gulf States for their effectiveness and applicability. Experimentation with interventions also enables local researchers to adapt the interventions and make them culturally appropriate and acceptable to the Arabs.

An interventional study that uses the randomized controlled trial (RCT) design produces the most unbiased estimate on the efficacy of the intervention; and it does so through the control of confounding factors and minimization of bias.[17] Unfortunately, the current evidence points to inadequate research, both in terms of quantity and quality, from Arab Gulf States. Bibliometric indicators (e.g. number of publications in high-impact journals, citation frequency, and h-index) show that these countries are lagging behind not only Western countries but also regional countries like Turkey and Israel.[18] In addition, an overwhelming majority of research from Arab Gulf States is cross-sectional, and only a tiny percentage is experimental. For example, only 3% and 5% of all research studies from Saudi Arabia in the fields of cardiovascular diseases and diabetes, respectively, were experimental in nature.[19,20]

With the backdrop of a high prevalence of non-communicable diseases and their associated risk factors in Arab Gulf States, it is timely to do a scoping review of experimental studies, specifically RCTs. The specific objectives were to (1) identify types of behavioral interventions, (2) assess the quality of published trials, and (3) detect areas where behavioral trials have not yet been conducted. The review findings will likely provide a macro-level picture of interventional studies for policy-makers, funders, and local researchers alike to identify priority areas for research.

Methods

Parent study

The data used in this review are part of an ongoing larger bibliometric study on RCTs in the Arab Gulf States. The eligibility criteria for inclusion in the parent study were (1) published study that used a RCT design, (2) conducted in one of the Arab Gulf States, (3) published before 31 December 2018, and (4) written in English. Four senior medical students searched three databases—PubMed, Embase, and Cochrane—for eligible trials. The search terms for PubMed were ((((((“Saudi Arabia”[MeSH]OR“Bahrain”[MeSH])OR“Kuwait”[MeSH]) OR “Qatar”[MeSH]) OR “United Arab Emirates”[MeSH]) OR “Oman”[MeSH]) OR “Iraq”[MeSH]) AND “Clinical Trial”[Publication Type]. The Medical Subject Heading (MeSH) and country name were also used in Cochrane for the search and “randomized clinical trials” was chosen as a filter. For Embase, “clinical trials” AND country name were used after choosing multi-field search.

PubMed, Embase, and Cochrane produced 431, 921, and 293 records, respectively. Research assistants read the study titles carefully, removed duplicates (n = 292), and screened out those that did not meet the inclusion criteria (n = 1114; animal study, observational studies, review, studies not conducted in the Arab Gulf States, and so on).

Review study on behavioral trials

The interventions of 176 eligible RCTs from the parent study were assessed for their nature. Trials that tested a drug, surgical procedure, prosthesis, or educational material were excluded (n = 160), leaving 16 trials, where the intervention included a behavioral component, the focus of this review (Figure 1).

Data charting process

From each included study, data were abstracted on (1) authors’ names, (2) publication year, (3) title, (4) sample size, (5) study population, (6) intervention name, (7) type of control, (8) primary outcome(s), (9) follow-up duration, (10) main results, and (11) significance of main results. If the trial did not specify a primary outcome, it was recorded as “not designated.”

Initially, one co-author (A.Y.I.) charted the data of the included trials. They were reviewed independently by the lead and senior authors (N.S. and J.S.). Any discrepancy was resolved through discussion and consensus among the authors.

Critical appraisal of trials

The items of appraisal criteria were based on the Jadad Scale[21] and the Cochrane Collaboration Risk of Bias Tool (CCRBT).[22] Each trial was assessed based on (1) whether the sample size calculation (and/or power calculation) was provided, (2) whether randomization was explained (i.e. how it was done, for example, use of random number tables or computer software), (3) whether allocation concealment was explained (e.g. use of sealed envelopes or conducted by a third party), (4) whether outcome assessors were blinded to group assignment, since blinding of participants is not feasible for behavioral trials, and (5) whether an intention-to-treat analysis was adopted or primary outcome effect.

Data analysis

Trial characteristics, along with main outcome results, were tabulated. In addition, indicators of study quality were summarized. Finally, the interventions used in these trials were identified and were categorized under broad themes.

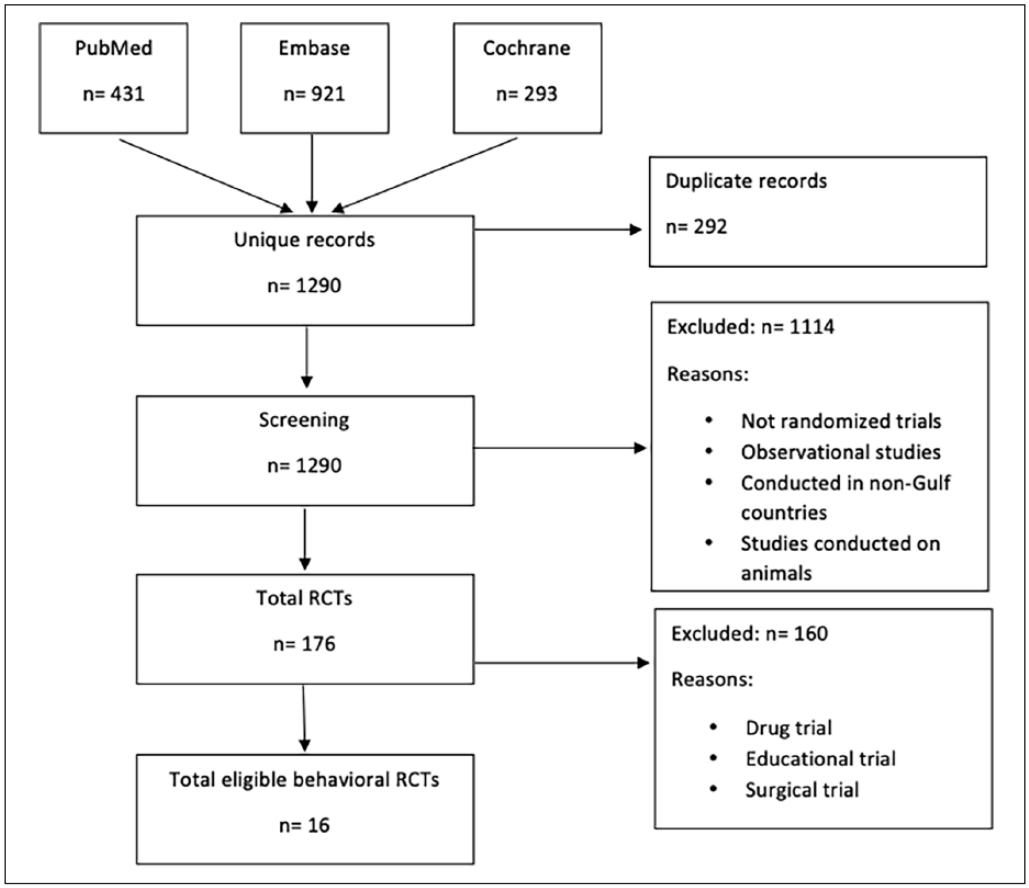

Figure 1. Flowchart for the eligibility of trials.

Results

General trial characteristics

The search resulted in 16 behavioral RCTs published between the years 2010 and 2018;[23–38] seven were from Saudi Arabia, three from the United Arab Emirates, and two each from Oman, Qatar, and Kuwait (Table 1). There were no trials from Bahrain or Iraq. One-third of the trials (31%) had a sample size below 100. A majority of the trials (62.5%) were conducted with a patient population. The studies tested different types of interventions: 50% diet plus physical activity, 18% diet only, 6% physical activity only, and 12.5% smoking cessation. In 31% of the studies, no primary outcome was mentioned but a group of outcomes were reported. A majority of the studies (68.5%) followed the participants for 6 months or longer; significant intervention effect was reported by 82% of the trials (Table 1).

Quality assessment of the trials

Half of the trials (50%) did not provide a sample size calculation. A similar proportion (50%) did not explain how randomization was conducted. The majority of the trials (69%) did not explain how concealment of group allocation was ensured. No information was provided regarding if outcome assessors were blinded to participants' group assignment in 69% of the trials. An intention-to-treat analysis was not followed or mentioned in 56% of the trials (Table 2).

Description of interventions

Diet only. Three trials evaluated dietary interventions, and each of them used a different approach. In one trial, participants were encouraged to restrict carbohydrates to 20%–25% of total daily energy intake. Another trial tailored dietary advice to each individual diabetic patient, and one study targeted calorie restriction with low-caloric foods such as fruits and grains.[23,25,30] Irrespective of the nature of the intervention, all three reported significant improvements in the outcomes (e.g. body weight, HbA1c level, and psoriasis severity score).

Physical activity only. The intervention was delivered in three individual consultations (pedometers + messaging) to encourage participants to reach the goal of 150 min of moderate or 75 min of vigorous activity per week.[38] It produced a significant increase in self-reported physical activity after 12 months compared to standard care (mean group difference: +447.4 MET/min/week).

Table 1. Study characteristics of behavioral randomized controlled trials conducted in the Arab Gulf States (n = 16).

No.	Author(s)	Location	Population	Sample size	Intervention	Control	Primary outcome	Follow-up duration	Result
1	Al-Sarraj et al.[23]	UAE	Adults with metabolic syndrome	39	Carbohydrate restriction diet	Carbohydrate restriction diet for 6 weeks, then the American Heart Association diet for 6 weeks	Not designated	3 months	Significant reduction in body weight, trunk fat, triglyceride, and total cholesterol
2	Mutwalli et al.[24]	Saudi Arabia	Coronary arteries bypass graft (CABG) surgery patients	49	Home-based cardiac rehabilitation program (three sessions plus phone counseling)	Standard hospital care	Not designated	6 months	Significant improvement in quality of life in the intervention group. Group differences for other outcomes were not possible to determine
3	Al-Shookri et al.[25]	Oman	Diabetic patients	170	Practice guidelines nutritional care (three sessions)	Usual nutritional care	HbA1c	6 months	Significant reduction in HbA1c in the intervention group
4	Abd El-Kader et al.[26]	Saudi Arabia	Obese children with asthma	80	Diet + exercise + medical treatment	Medical treatment only	Not designated	2 months	Significant decrease in TNF-α, IL-6, IL-8, and leptin, and an increase in adiponectin in intervention group
5	Mohamed et al.[27]	Qatar	Diabetic patients	430	Diabetes, lifestyle, and exercise counseling sessions (n = 4) plus educational booklet	Educational booklet on diabetes only	HbA1c, fasting glucose, lipid profile, albumin/creatinine ratio, BMI and blood pressure	12 months	Significant reduction in HbA1c, fasting glucose, BMI, and albumin/creatinine ratio in the intervention group
6	Youssef[28]	Saudi Arabia	Patients	502	SMS appointment reminders	No reminder	Non-attendance rate	N/A	Non-attendance was significantly lower in intervention group
7	Boodai et al.[29]	Kuwait	Obese adolescents	82	Six group discussion sessions for decreasing sedentary behavior, increasing activity and improving diet	Referral to primary care	Change in BMI z-score	6 months	No difference in change in BMI z-score between groups
8	Al-Mutairi and Nour[30]	Kuwait	Overweight and obese adults with psoriasis on biologic therapy	262	Calorie-restricted diet personalized by a dietitian	Usual diet	Psoriasis Area and Severity Index (PASI) score	6 months	Significant improvement in the PASI score in the intervention group
9	Abdi et al.[31]	UAE	Diabetic patients	35	Behavioral lifestyle program (eight sessions)	Standard care	HbA1c	12 months	Significant reduction in HbA1c in the Intervention group
10	Abd El-Kader and Saiem Al-Dahr[32]	Saudi Arabia	Obese inactive postmenopausal women	103	Aerobic exercise on treadmill and diet regimen	No intervention	Not designated	3 months	Intervention more effective in decreasing TNF-α, IL-6, CRP, ICAM-1, VCAM-1, and PAI-1: Ac
11	Al-Haj Mohd et al.[33]	UAE	Diabetic patients	446	Education on medication adherence (one session) and weekly phone calls	Standard patient education	Adherence level	6 months	Intervention more effective to improve adherence to medication
12	Mohammed et al.[34]	Saudi Arabia	Adolescent	1416	Video peer-led anti-smoking program with activities (five sessions)	Usual care without anti-smoking content	Not designated	6 months	Intervention increased negative attitude toward smoking and lowered intentions to start smoking
13	Alghamdi[35]	Saudi Arabia	Obese adults	140	Lifestyle intervention affecting diet, exercise, and behavioral techniques followed by six visits with message reminders	One health education session	Significant weight loss (⩾5% of original body weight)	3 months	Intervention participants significantly more likely achieved weight loss
14	El Hajj et al.[36]	Qatar	Adult smokers	314	Adaptive pharmacist-based counseling with nicotine replacement therapy (four sessions, each 30 min)	Brief pharmacist-based counseling with nicotine replacement therapy (one session, 5 min)	Self-reported continuous abstinence	12 months	No significant difference in smoking cessation
15	Alfawaz et al.[37]	Saudi Arabia	Pre-diabetic adults	294	Arm 1: Intensive lifestyle modification by phone (diet and exercise) Arm 2: General advice plus metformin	General advice	Full MetS score—summary of component score	12 months	Full MetS score decreased significantly among Arm 1 and Arm 2 participants
16	Alghafri et al.[38]	Oman	Inactive diabetic patients	232	Consultations by dietitians on physical activity + pedometers + WhatsApp messages	Usual care	Change in physical activity (MET.min/week)	12 months	Significant increase in physical activity in the intervention group

BMI: body mass index; CRP: C-reactive protein; HbA1c: glycated hemoglobin; ICAM-1: inter-cellular adhesion molecule; IL-6: interleukin-6; IL-8: interleukin-8; MET: metabolic equivalent; MetS: metabolic syndrome; PAI-1:Ac: plasminogen activator inhibitor-1 activity; TNF-α: tumor necrosis factor-alpha; UAE: United Arab Emirates; VCAM-1: vascular cell adhesion molecule.

Table 2. Quality assessment of behavioral randomized controlled trials conducted in the Arab Gulf States (n = 16).

No.	First author, year	Sample size calculation provided (yes/no)	Randomization explained (yes/no)	Allocation concealment explained (yes/no)	Outcome assessors blinded (yes/no/can't tell)	Intention-to-treat analysis (yes/no)
1	Al-Sarraj et al.[23]	No	No	No	Can't tell	Can't tell
2	Mutwalli et al.[24]	No	No	No	Can't tell	Can't tell
3	Al-Shookri et al.[25]	Yes	Yes	No	Can't tell	Can't tell
4	Abd El-Kader et al.[26]	No	No	No	Can't tell	Can't tell
5	Mohamed et al.[27]	No	No	No	Can't tell	Yes
6	Youssef[28]	Yes	Yes	Yes	Yes	Yes
7	Boodai et al.[29]	Yes	Yes	Yes	Yes	Yes
8	Al-Mutairi and Nour[30]	No	No	No	Can't tell	Can't tell
9	Abdi et al.[31]	Yes	Yes	No	Can't tell	Yes
10	Abd El-Kader and Saiem Al-Dahr[32]	No	No	No	Can't tell	No
11	Al-Haj Mohd et al.[33]	No	Yes	No	Can't tell	Can't tell
12	Mohammed et al.[34]	Yes	No	No	Can't tell	No
13	Alghamdi[35]	Yes	Yes	Yes	No	Yes
14	El Hajj et al.[36]	Yes	Yes	Yes	Yes	Yes
15	Alfawaz et al.[37]	No	Yes	Yes	Can't tell	No
16	Alghafri et al.[38]	Yes	No	No	Yes	Yes

Physical activity and diet in combination. Out of eight trials that used a combination intervention of physical activity and diet, two did not specify the behavioral targets for diet and physical activity.[27,29] One trial specified the physical activity goal as 30 min of daily walking but did not specify dietary goals.[24] The dietary goals in the remaining five trials included calorie and carbohydrate restriction,[31,35] calorie restriction only,[26,32] or fat restriction with an increase in fiber.[37] The physical activity goals of these combination trials included 30 min of moderate activity, five times per week,[31,32,35] >5000 pedometer steps per day,[37] or aerobic training (30 min, four times per week).[26] All the trials that used a combination intervention strategy reported significant outcome effect except one;[29] the outcomes tested were quality of life, inflammatory markers (n = 2), HbA1c (n = 2), weight loss, and metabolic syndrome score.

Smoking prevention/cessation. One intervention included peer-led video sessions on smoking refusal, peer pressure, self-efficacy enhancement, and smoking alternatives, which were delivered to adolescents in schools.[34] The second intervention was counseling delivered by pharmacists on smoking cessation and nicotine replacement therapy.[36] The school-based intervention significantly increased negative attitudes toward smoking and lowered intentions to initiate smoking, while the pharmacist-led intervention did not make a difference in smoking cessation.

Medication adherence. The intervention was a 30-min educational session about diabetes and its medication, followed by weekly phone calls for 3 months to motivate the participants to adhere to treatment and to overcome obstacles to adherence.[33] Adherence increased significantly as a result of the intervention.

Patient attendance. The intervention was SMS reminders to patients attending the outpatient department for their follow-up visit, which significantly increased the attendance.[28]

Discussion

The volume of behavioral trials originating from the Arab Gulf States is low, given that the predominant burden of disease in this region comes from conditions that are amenable to lifestyle modification (e.g. diabetes, obesity). This low volume is congruent with other studies that showed that approximately 95% of trials originate from Europe, North America, and Australia.[39] Given that some of the Arab countries (e.g. Saudi Arabia, Bahrain) spend a quarter of their healthcare budget to treat diabetes, it is unfortunate that more behavioral trials were not conducted to test interventions with an aim to either reduce incidence of diabetes among high-risk population (e.g. obese or physically inactive adults) or reduce the complications among diabetic patients.[40] One potential explanation is that Arab nations do not have a long history of clinical research.[41]

The trials in this review were missing critical information, such as sample size calculation (50%) or designation of primary outcome (31%). These percentages are radically higher than the corresponding percentages from trials in developed countries (missing information in <5% of trials).[39] Sample size is critical to assess whether the trial is sufficiently powered to detect a difference.[42] When a primary outcome is not designated a priori and there are multiple outcomes assessed,

the investigators can manipulate the focus of the results toward significant findings.[43]

The risk of bias was likely high in most of these behavioral trials, given that randomization was not explained, allocation concealment of group status was not ensured, outcome assessors were not blinded, and an intention-to-treat analysis was not adopted. One casualty of trials with high-risk bias is that they are more likely to yield significant results. The result that 82% of the trials reported a significant intervention effect is in line with the evidence that trials from developing countries are more likely to report significant results than trials from developed countries.[41]

This review, to our knowledge, is the first attempt to compile and characterize interventional trials from the Arab Gulf States. It relied on elaborate search terms, multiple databases (i.e. increased sensitivity), and screening of search records (i.e. increased specificity) to obtain the included studies. Another strength of this review is the quality assessment of trials, which has identified the weaknesses of the existing trials and may benefit prospective researchers with their future trial designs. This review is limited by the fact that it may have missed the trials that were published in non-indexed journals and those that are currently underway and/or unpublished.

Recommendations

In general, more behavioral trials need to be undertaken in this region, particularly to address those conditions that are major public health issues, such as obesity, physical inactivity, and smoking. In addition, there are important health conditions and leading causes of death, such as road traffic injuries, respiratory tract infections, and vitamin D deficiency, for which no trials have been conducted. A number of effective interventions (e.g. hand washing or meditation/exercise for respiratory infection and area-wide traffic calming for road traffic injuries)[44–46] have been tested in other countries and could be adapted to the sociocultural needs of this region.

Future trials should select the study population judiciously. For example, the largest burden of obesity in the Arab Gulf States lies in the adult age group;[47] however, most of the available trials on obesity were tested on children, adolescents, or patients.[26,29,30]

In future trials, researchers should choose an objective assessment of the primary outcome whenever it is feasible. For example, proper monitoring of physical activity is essential, but it was measured objectively in only three of the studies.[26,32,38]

Researchers should strategize beforehand to prevent significant loss to follow-up of trial participants. They could consider strategies such as having a run-in period, sending electronic reminders, and providing incentives to complete follow-up assessments. In this review, loss to follow-up was so large in a few trials that it made the study results questionable,[27,35] and in other trials, loss to follow-up could not be assessed because the reporting was unclear.[24,33]

Researchers should take advantage of modern technology in their intervention designs. For example, use of smartphone apps, social media, and tracking devices have shown to be effective modes for delivering interventions, particularly in physical activity trials.[48–50]

Researchers should opt for larger, multi-center trials instead of single-center trials. Single-center trials often produce an inflated effect size, which leads to a significant intervention effect that is not reproducible in multi-center trials.[44]

Conclusion

The volume of behavioral trials (n = 16) is small compared to a geographical area with over 93 million people. The quality of these trials is questionable, since they are weak on methodological rigor and comprehensiveness of reporting. Effort should be made to conduct more trials of improved quality as a whole and specifically for conditions that are major contributors of death in this region but for which there are currently no available trials.

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