

Effects of a lifestyle-related risk factor modification intervention on lifestyle changes among patients with coronary artery disease in Nepal



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ARTICLE INFO

Article history:

Received 31 March 2020

Received in revised form 21 November 2020

Accepted 24 November 2020

Keywords:

Coronary artery disease

Lifestyle

Risk factors

Randomized trials

ABSTRACT

Objective: To investigate the effect of a lifestyle-related risk factor modification intervention on coronary artery disease (CAD) patients' lifestyle changes.

Method: A randomized controlled study was conducted in Nepal. A total of 224 CAD patients (112 in each study group) were included at baseline, and 196 patients (98 in each group) completed the one-month follow-up. Patients in the intervention group (IG) received nurse-led intervention in addition to the usual care. Face-to-face and telephone interview was conducted using standard questionnaires to collect data on lifestyle-related risk factors; smoking, alcohol consumption, diet, body mass index, stress, adherence to medical therapy, and physical activity. General linear model repeated measure analysis was used to analyse the effects of the intervention.

Results: Based on self-reported data we found significant improvement in lifestyle-related risk factor habits in the IG compared with the usual care group with respect to diet ($p < 0.001$), physical activity ($p < 0.001$), medication adherence ($p < 0.001$) and stress ($p < 0.001$) at one-month follow-up.

Conclusion: Lifestyle-related risk factor modification intervention can positively influence health risk habits, even when it is less intensive but supplemented with information leaflets.

Practical implications: Nurse-led one-time intervention may successfully deliver counselling to improve healthy lifestyle among underserved CAD patients.

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1. Introduction

Coronary artery disease (CAD) is the main form of cardiovascular disease (CVD), contributing to the leading cause of death and disability worldwide [1–3]. In the past decades, CVD death rates have declined in several high-income countries but have risen in low- and middle-income countries, which contribute 80% of total CVD deaths globally [2,4]. South Asian populations

have a higher risk of CAD due to their increased exposure to risk factors and lack of prevention and control measures [5,6]. Moreover, CAD is the foremost cause of the premature death and disease burden in our country of study, Nepal, accounting for 18.7% of total deaths [3].

Previous studies have shown that the proper management of modifiable risk factors reduces the rates of sudden cardiac death, myocardial infarction, stroke, and the need for revascularization in patients with established CAD [7,8]. Earlier studies from Nepal have reported a high prevalence of lifestyle risk factors for CAD such as smoking, stress, physical inactivity, alcohol consumption, unhealthy diet, and overweight or obesity [9–11]. The burden of these modifiable risk factors is high in low- and middle-income countries; however, measures to prevent them and reduce the impact of CAD are relatively low [12]. Additionally, non-adherence

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to cardiovascular medication is outlined as a risk factor habit contributing to adverse cardiac events [13,14].

Education and motivational counselling intervention programmes have had positive impacts on patients’ knowledge, attitude and beliefs; moreover, they help to improve patients’ health by reducing CAD risk factors [15,16]. However, improving patients’ health-related risky behaviours is still a major challenge that requires significant effort [15]. An earlier study from Brazil reported that a nurse-led lifestyle counselling intervention effectively reduced cardiovascular risk in patients with CAD [17]. Another systematic review of randomized trials showed a favourable impact of nursing education and counselling interventions on secondary prevention in patients with CAD [18].

Existing knowledge on the prevention of CAD is mainly based on studies conducted in populations in high-income countries, and it is not clear to what extent these findings apply in low-income settings, especially among South Asian populations [4,19]. Most trials to date have not examined many lifestyle-related risk factors simultaneously. These lifestyle risk factors individually and also when occur together greatly impact on survival and secondary complications [20]. Thus, this study aimed to investigate the effect of seven lifestyle-related risk factor modification intervention programme on CAD patients’ lifestyle changes. The lifestyle-related risk factors considered in this study were smoking, stress, physical inactivity, alcohol consumption, unhealthy diet, overweight or obesity, and

medication adherence. We further assessed whether the intervention improved cardiovascular event rates in both the intervention group (IG) and the usual care group (UG).

2. Methods

2.1. Study design and setting

A single-centre randomized clinical trial was conducted at Sahid Gangalal National Heart Centre (SGNC) in Kathmandu, Nepal, from 1 May to 31 July 2018. Individual face-to-face structured interviews were conducted by the principal investigator to collect data at baseline. Follow-ups were conducted by telephone interview one month after the baseline data collection.

2.2. Patients and randomization

All patients aged over 18 years, who had a diagnosis of CAD confirmed by medical records, were admitted to the hospital, ability to communicate in Nepali or English language and were accessible by telephone during the follow-up period were eligible for inclusion in this study. Patients were excluded from the study if they had congenital or valvular heart diseases, high-risk cardiac conditions or impaired cognitive functions. Patients who met the above inclusion criteria and agreed to participate in the study were

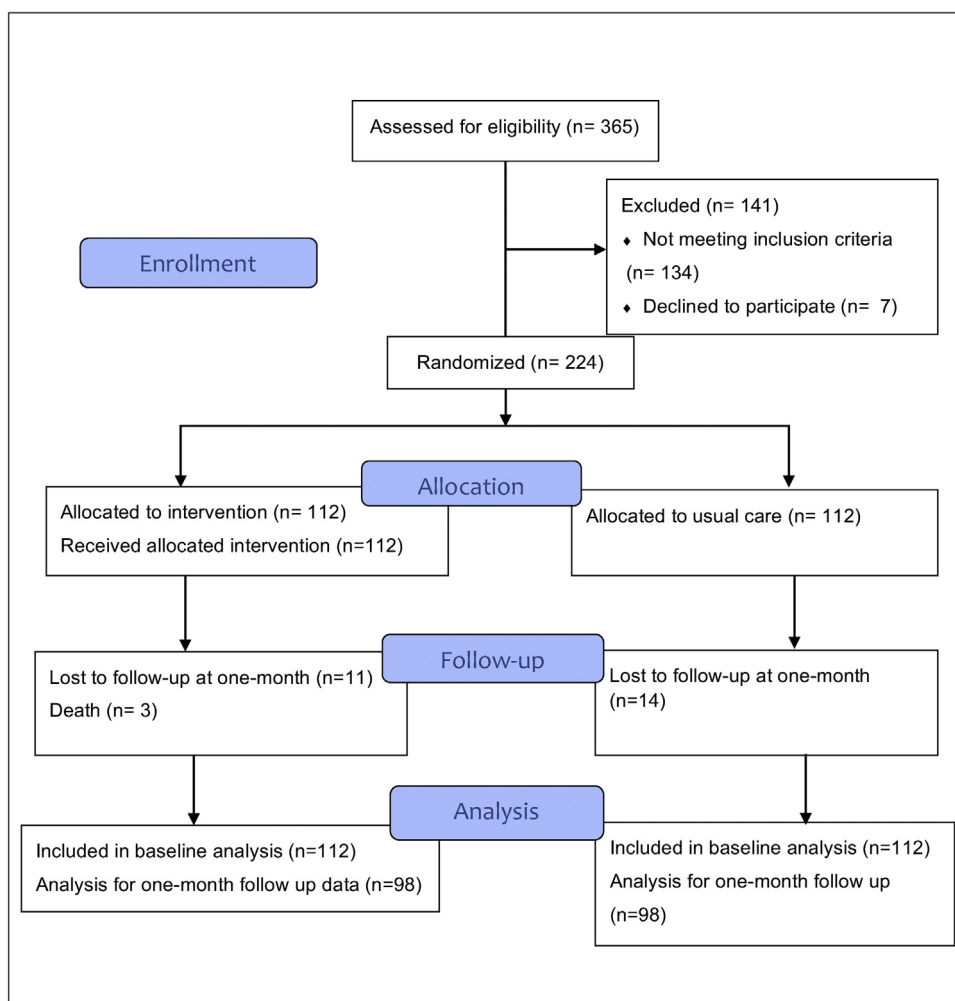


Fig. 1. Flow diagram (CONSORT) of participants through each stage of a randomized trial.

randomized using a simple randomization technique (computer-generated random numbers) into the IG and the UG in a 1:1 ratio. The random assignment of patients to either group was made after the baseline data collection.

Out of 365 patients who were screened for eligibility, 141 were excluded because they did not meet all the inclusion criteria or were unwilling to participate in the study. In total, 224 patients were included in the baseline analysis, 112 in each group. At one-month follow-up, the number of patients in each group dropped by 14 because of loss to follow-up ($n = 11$ in IG, $n = 14$ in UG) and death ($n = 3$ in IG). A total of 196 patients (98 in each group) participated in one-month follow-up with the response rate 87.5%. The details of patient recruitment are presented in a flow diagram (Fig. 1).

2.3. Sample size

Considering a power level of 0.80, an alpha level of 0.05 and an effect size of 0.37 to achieve statistically significant results, the estimated sample size was 184. The sample size was calculated using G*Power 3.1.9.2. An a priori power analysis was used with a t -test family. With an estimated attrition rate of 22%, the total sample size of the study was 224, with 112 participants in each group [21,22].

2.4. Intervention

On the day of discharge from the hospital, patients in the IG were invited along with their family members to attend a counselling session in the counselling room. The principal investigator led group counselling of three to five patients with their family members. Altogether 28 group counselling sessions were given for 112 patients in the IG. The content of the counselling was developed on the basis of previous research, recommendations issued by various heart associations that were suitable for local settings, and implicit knowledge [23–29]. The motivational counselling session lasted 45 min on average and included audio-visual material to improve patients' understanding of the counselling content. This covered aspects such as information about CAD (myocardial infarction and pharmacological, percutaneous and surgical management), lifestyle-related risk factors and their modification, and the importance of lifestyle changes. Information leaflets with pictorial description on smoking cessation, healthy diet, physical activity for cardiac health, stress management, weight management, limiting alcohol consumption and adherence to medical therapy was provided to each patient in the IG. Individual counselling was provided after the group counselling, and lifestyle goals were set for each patient in IG depending on their specific needs. The principal investigator, who is an experienced nurse with specialization in cardiac care, provided the intervention. She was the only intervener in this study, thus ensuring that every patient received the same quality of intervention in the IG. The UG patients received the usual counselling provided by the hospital, that included short verbal information about medicine use and follow-up, and short unstructured lifestyle modification counselling from the investigator.

2.5. Measurement of variables and data collection

The primary outcome variables measured in this study were smoking, alcohol consumption, diet, body mass index (BMI), stress, adherence to medical therapy, and physical activity. The standard questionnaires that were used for data collection were translated from English to Nepali, and were modified and culturally validated. Expert opinions and face validity were obtained, and the questions were pilot tested before data collection.

2.5.1. Diet

Data on diet were collected using the Cardiovascular Risk Assessment questionnaire. It consists of 10 questions, each scored on a scale of zero to 10, categorized as: low risk for a score of 0–6, medium risk for 7–13 and high risk for 14 and above [30].

2.5.2. Physical activity

The World Health Organization's (WHO) Global Physical Activity Questionnaire was used to collect data on physical activity and sedentary behaviour. The questionnaire consists of 16 items in total. Patients who achieved at least 600 Metabolic equivalent (MET) minutes of activity throughout the week, were considered physically active [31].

2.5.3. Medication adherence

The Morisky Green Levine Medication Adherence scale was used to assess adherence to medical therapy. The scale consists of four items, with scores of zero or one for yes or no responses respectively, categorised as: low adherence for a score of 0, medium adherence for 1–2 and high adherence for 3–4 [32].

2.5.4. Perceived stress

The Perceived Stress Scale was used to assess patients' stress. The questionnaire consists of 10 items, and the sum of scores for each item ranges between zero and 40, categorised as low stress for score of 0–13, moderate stress for 14–26 and high stress for 27–40 [33].

2.5.5. Smoking

In this study, current smokers were defined as patients who had smoked at least one cigarette during the previous month. Similarly, former smokers were defined as patients who had given up smoking for more than one month.

2.5.6. Alcohol use

In this study, current alcohol drinkers were defined as patients who had consumed alcohol during the previous month. Similarly, patients who had given up alcohol consumption for more than a month were defined as former alcohol drinkers.

2.5.7. BMI

BMI was calculated using the formula of weight (in kilograms) divided by height (in metres) squared. The WHO reference was used to categorize BMI [34].

The culturally validated instruments used for data collection in the study are described briefly above and have previously been reported in detail [35]. Data on socio-demographic and clinical characteristics were collected at baseline and updated during follow-up. This data included age in years, gender (male, female), ethnic group (Brahmin, Chhetri, Newar, other), religion (Hindu, other), education (uneducated, primary education, secondary education, bachelor's degree or above), work status (unemployed, employed, retired, entrepreneur, farmer), marital status (married, other), underage children (yes, no), monthly family income, residential area (Province 3, other), co-morbidity (yes, no), CAD severity (no significant stenosis or no coronary angiography performed, single vessel disease, double vessel disease, triple vessel disease or left main stenosis) and revascularization status (no revascularization, percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG)).

One-month follow-up data on lifestyle-related variables were collected using the same data collection instrument by the same investigator through a phone call. We also assessed cardiac events such as myocardial infarction, CABG, PCI or cardiac death among study patients during the follow-up. The one-to-one structured telephone interview took 20 min on average to collect follow-up

data from each patient. During the phone calls to the IG, the patients' goals were reviewed, and barriers to the implementation of a healthy lifestyle were discussed. Loss to follow-up was considered only if the patient did not answer three attempted telephone calls made at three different times.

2.6. Analysis

The descriptive characteristics of the subjects were first calculated as frequencies and percentages for the categorical variables. The continuous variables were expressed as mean and standard deviations if the data were normally distributed, and as median and interquartile ranges otherwise. The Shapiro-Wilk test and normality plots were used to check the normality of continuous variables. The differences between the groups were compared using a chi-squared test or Fisher's exact test, and a student's *t*-test or Mann-Whitney test for categorical and continuous variables respectively. General linear model (GLM) repeated measures analysis was used to investigate changes in lifestyle-related risk factor habits (as continuous variables) from baseline to one-month follow-up. The group was used as the

between-subject factor, and time as the within-subject factor. Mean values with their 95% confidence intervals and *p*-values for group, time and group*time interaction were reported. The GLM results for the variables of smoking and alcohol consumption were not reported, as the number of current smokers and current alcohol consumers was very low. The two-tailed *p*-value <0.05 was reported as a level of statistical significance. All the data analysis was performed using SPSS 23.0.

2.7. Ethics

The study was ethically approved by the Nepal Health Research Council Ethical Review Board (25/2018) and the SGNC Institutional Review Committee. All patients provided written informed consent to participate in this study.

3. Results

The baseline characteristics of the studied population stratified by study group are presented in Table 1. The mean ± SD age of patients was 59.9 ± 11.8 years, and 76% were male. Except for age

Table 1
Baseline characteristics of the study population by study group.

Characteristics	Total (n = 224)	Intervention Group (n = 112)	Usual care Group (n = 112)	P-value
Age in years (mean ±SD)	59.9 ± 11.8	61.4 ± 11.8	58.3 ± 11.6	0.050*
Gender, n (%)				0.159
Male	170 (75.9)	90 (80.4)	80 (71.4)	
Female	54 (24.1)	22 (19.6)	32 (28.6)	
Cast / Ethnic group, n (%)				0.648
Brahmin	60 (26.8)	29 (25.9)	31 (27.7)	
Chhetri	45 (20.1)	26 (23.2)	19 (17.0)	
Newar	43 (19.2)	22 (19.6)	21 (18.8)	
Others	76 (33.9)	35 (31.3)	41 (36.6)	
Religion, n (%)				0.999
Hindu	192 (85.7)	96 (85.7)	96 (85.7)	
Others	32 (14.3)	16 (14.3)	16 (14.3)	
Education, n (%)				0.570
Uneducated	62 (27.7)	27 (24.1)	35 (31.3)	
Primary education	85 (37.9)	45 (40.2)	40 (35.7)	
Secondary education	53 (23.7)	26 (23.2)	27 (24.1)	
Bachelor's degree and above	24 (10.7)	14 (12.5)	10 (8.9)	
Work status, n (%)				0.629
Unemployed	17 (7.6)	8 (7.1)	9 (8.0)	
Employed	52 (23.2)	22 (19.6)	30 (26.8)	
Retired	65 (29.0)	37 (33.0)	28 (25.0)	
Entrepreneurs	27 (12.1)	14 (12.5)	13 (11.6)	
Farmer	63 (28.1)	31 (27.7)	32 (28.6)	
Marital status, n (%)				0.999
Married	209 (93.3)	105 (93.7)	104 (92.9)	
Others	15 (6.7)	7 (6.3)	8 (7.1)	
Underage children, n (%)				0.719
Yes	37 (16.5)	17 (15.2)	20 (17.9)	
No	187 (83.5)	95 (84.8)	92 (82.1)	
Monthly family income (NPR) (Median ± IQR)	10,000 ± 16,500	15,000 ± 15,000	5000 ± 17,000	0.036*
Residential area, n (%)				0.509
Province 3	109 (48.7)	57 (50.9)	52 (46.4)	
other provinces	115 (51.3)	55 (49.1)	60 (53.6)	
Co-morbidity, n (%)				0.999
Yes	183 (81.7)	91 (81.3)	92 (82.1)	
No	41 (18.3)	21 (18.7)	20 (17.9)	
CAD Severity, n (%)				0.558
No significant stenosis/ No CAG performed	49 (21.9)	24 (21.4)	25 (22.3)	
Single vessel disease	72 (32.1)	39 (34.8)	33 (29.5)	
Double vessel disease	57 (25.5)	30 (26.8)	27 (24.1)	
Triple vessel disease / Left main stenosis	46 (20.5)	19 (16.9)	27 (24.1)	
Revascularization, n (%)				0.129
No revascularization	79 (35.3)	34 (30.4)	45 (40.2)	
PCI	123 (54.9)	69 (61.6)	54 (48.2)	
CABG	22 (9.8)	9 (8.0)	13 (11.6)	

CABG: Coronary Artery Bypass Graft, IQR: Interquartile range, NPR: Nepalese rupees.

* *p*-value <0.05 were considered statistically significant. PCI: Percutaneous Coronary Intervention.

(mean age in years: IG = 61, UG = 58, $p = 0.050$) and family's monthly income (median income in NPR: IG = 15,000, UG = 5000, $p = 0.036$), there were no statistically significant differences between the groups in the patients' basic characteristics. At one-month follow-up, the patients or their family members reported that four cardiac events (4.5%) had occurred in the IG, and 10 cardiac events (11.2%) had occurred in the UG (Table 2).

A comparison of lifestyle-related risk factors between the IG and UG at baseline and one-month follow-up is depicted in Table 3. Except for adherence to medication ($p < 0.001$), there were no statistically significant differences between the study groups at baseline. However, at one-month follow-up, five out of the seven studied lifestyle-related risk factors differed significantly between the study groups: diet ($p = 0.005$), adherence to medication ($p < 0.001$), perceived stress ($p < 0.001$), smoking ($p = 0.017$) and alcohol consumption ($p = 0.005$). We observed differences from one-month follow-up to baseline in the proportions of patients who had low dietary risk (IG, 33%; UG, 6%), low perceived stress (IG, 31%; UG, 8.1%), high medication adherence (IG, 77%; UG, 10%), former or never smoker (IG, 28%; UG, 14%) and former or never alcohol consumption (IG, 21%; UG, 1%). However, no statistically significant difference in physical activity or BMI was found between the groups at one-month follow-up.

The changes in lifestyle-related risk factor habits from baseline to one-month follow-up appear in Fig. 2. The mean diet score and stress score declined in both groups, suggesting an improvement in dietary habits and a reduction in perceived stress. However, the improvements were greater in the IG, and the effects of time and time*group interaction were both statistically significant ($p < 0.001$). The mean of total physical activity MET minutes per week increased in the IG (group*time, $p < 0.001$). The mean medication adherence score increased in both groups; however, the IG improved more from baseline to one-month follow-up (group*time, $p < 0.001$). No significant change was observed from baseline to one-month follow-up in the mean BMI for either time or time*group interaction.

4. Discussion and conclusion

4.1. Discussion

We found statistically significant differences in five of the seven studied lifestyle-related risk factor habits – diet, adherence to medication, perceived stress, smoking and alcohol consumption – between the IG and UG at one-month follow-up. The lifestyle intervention had positive effects on dietary habits, physical activity, medication adherence and perceived stress within the IG on comparison between the baseline and one-month follow-up. Cardiac events were found to be comparatively lower in the IG than in the UG. Nurse-led lifestyle-related risk factor modification intervention was effective in delivering a meaningful counselling to the patients who would not be receiving further cardiac rehabilitation care once discharged from the hospital.

Table 2
Cardiac events at one-month follow up.

Cardiac events	Intervention Group (n = 112)	Usual care Group (n = 112)
MI, n (%)	2 (2.2)	7 (7.8)
PCI, n (%)	–	1 (1.1)
CABG, n (%)	–	2 (2.2)
Cardiac death, n (%)	2 (2.2)	–
Total, n (%)	4 (4.5)	10 (11.2)

MI: Myocardial Infarction, PCI: Percutaneous Coronary Intervention, CABG: Coronary Artery Bypass Graft.

The lifestyle-related risk factor modification intervention was effective in improving the dietary habits of the IG patients in our study. Patients in both groups reported a reduction in the consumption of fried and starchy foods, sweets, sugar, tea/coffee and soft drinks. Patients also reported irregular and low consumption of fruit and fish, as these are expensive with respect to their income levels making it unaffordable to purchase for regular consumption. Contrary to this, a randomized controlled trial conducted among patients at risk of coronary heart disease (CHD) in the UK reported no significant differences between the IG and UG with respect to diet, irrespective of the number of counselling sessions the patients attended. Both groups of patients increased their consumption of fruit and vegetables and reduced their intake of fat [36]. This difference from the findings of our study was probably due to the income level of the patients, which was possibly higher in their study population in the UK than in Nepal.

We found that the mean level of total physical activity in MET minutes per week increased in the IG and decreased in the UG from their baseline values. One possible explanation for this could be that in our study, the UG patients were already more physically active than the IG at baseline, but at hospital discharge patients in both groups were advised to avoid the vigorous activity that leads to chest pain or breathlessness [37]. However, during follow-up more than three quarters of patients in the UG, and more than four fifths of patients in the IG, had 600 or more MET minutes per week. Most of the patients reported having increased their walking time by reducing their sedentary time. Consistent with our findings, an earlier study on the effectiveness of a primary healthcare-based counselling intervention on physical activity among patients with CHD risk factors reported increased physical activity among the IG, largely due to an increase in walking [36].

We found the IG adhered to medication more than the UG, although an improvement in medication adherence was found in both groups. Concurring with our finding, an earlier study that investigated the effect of nurse-led cardiovascular risk factor counselling among 201 patients with increased cardiovascular risk reported a significantly higher level of adherence to lipid-lowering medications among IG patients [38]. Similarly, a systematic review of adherence to cardiovascular medication in South Asia reported higher medication adherence in IGs than UGs, although all the intervention studies either did not have a UG or did not report the results of the UG. They reported generally low medication adherence in the South Asian region [39]. In contrast, another study on a nurse-led intervention to improve medication adherence in patients with CVD in the Netherlands reported no significant difference in adherence between the UG and the IG [40]. Most of the patients in our study reported that medication was expensive, and yet they managed to buy it by reducing their other expenses.

We found a significant improvement in self-reported measures of stress among the IG compared with the UG. An earlier study on the effectiveness of stress management among patients with acute myocardial infarction or coronary bypass surgery in a hospital in London reported significantly greater improvement in emotional well-being in the IG than the UG [41]. However, we observed a reduction in perceived stress in both groups during follow-up. This may have been because following hospitalization for CAD, the level of stress usually declines over a follow-up period [42].

We observed no impact of the intervention on BMI. This could be due to the short follow-up time. However, an earlier study to evaluate the impact of educational interventions (video and text, and only text) among 187 CAD patients found significant improvement in weight loss at six months in the group that received the video and text intervention [43].

Table 3
Comparison of lifestyle-related risk factors between groups at baseline and one-month follow-up.

Variable	Baseline		P-value	one-month follow up		P-value
	Intervention Group (n = 112)	Usual care Group (n = 112)		Intervention Group (n = 98)	Usual care Group (n = 98)	
Diet, n (%)			0.063			0.005*
Low risk	71 (63.4)	86(76.8)		94(95.9)	81(82.7)	
Medium risk	35 (31.3)	20 (17.9)		4(4.1)	17(17.3)	
High risk	6 (5.4)	6 (5.4)		–	–	
Physical activity, n (%)			0.313			0.602
MET minutes per week >= 600	73 (65.2)	81 (72.3)		79(80.6)	75(76.5)	
MET minutes per week <600	39 (34.8)	31 (27.7)		19(19.4)	23(23.5)	
Adherence to medication, n (%)			<0.001*			<0.001*
High Adherence	11 (9.8)	36 (32.1)		85(86.7)	42(42.9)	
Medium Adherence	70 (62.5)	45 (40.2)		13(13.3)	50(51.0)	
Low Adherence	8 (7.1)	9 (8.1)		–	6(6.1)	
No medication	23 (20.6)	22 (19.6)		–	–	
Stress, n (%)			0.275			<0.001*
Low stress	4 (3.6)	1 (0.9)		34(34.7)	9(9.2)	
Moderate stress	104 (92.8)	109 (97.3)		64(65.3)	87(88.8)	
High stress	4 (3.6)	2 (1.8)		–	2(2.0)	
BMI, n (%)			0.153			0.126
Underweight	6 (5.4)	7 (6.3)		4 (4.1)	7(7.1)	
Normal weight	75 (67.0)	73 (65.2)		67 (68.4)	67(68.4)	
Overweight	29 (25.8)	23 (20.5)		26(26.5)	18(18.4)	
Obese	2 (1.8)	9 (8.0)		1(1.0)	6(6.1)	
Smoking status, n (%)			0.078			0.017*
Current smoker	39 (34.8)	33 (29.5)		7 (7.1)	15(15.3)	
Former smoker	37 (33.0)	28 (25.0)		59 (60.2)	40(40.8)	
Never smoker	36 (32.1)	51 (45.5)		32 (32.7)	43(43.9)	
Alcohol consumption, n (%)			0.102			0.005*
Current Drinker	34 (30.4)	18 (16.1)		9(9.2)	15(15.3)	
Former Drinker	19 (17.0)	15 (13.4)		38(38.8)	16(16.3)	
Never Drinker	59 (52.7)	79 (70.5)		51(52.0)	67(68.4)	

* p-value <0.05 were considered statistically significant.

Although, one-month time frame is short for changes in patient’s behaviour regarding smoking cessation, increased physical activity, adherence to medication, etc., the nurse led one-time cardiac rehabilitation counselling intervention was effective for immediate positive effect on patients’ behaviours. This greater improvement on patients’ health behaviours may have been due to the fear of disease complications or death. However, we found a comparatively greater improvement in the IG.

We found a significant difference between the groups in their smoking habits at follow-up. Most of the patients who smoked at baseline reported complete cessation of smoking at one-month follow up in both groups. A similar finding was reported in a systematic review and meta-analysis of the efficacy of smoking cessation interventions among current cigarette smokers in low- and middle-income countries. Behavioural counselling and/or pharmacotherapy intervention and brief advice were reported to be effective in aiding smoking cessation in such countries [44].

Similarly, we found a significant difference between the groups in their alcohol consumption habits at one-month follow-up. A systematic review and meta-analysis of randomized trials found eight trials that reported a significant effect of a brief alcohol intervention on the reduction of alcohol consumption, while seven reported no significant effects [45]. However, in our study less, than one tenth of the IG, and less than one sixth of the UG, reported current alcohol consumption, and none of the patients in the study reported themselves to be in the harm or dependency risk group.

Higher event rates in the UG compared with the IG was found, although due to the smaller sample size there was no significant evidence to suggest that the intervention improved cardiovascular event rates. Consistent with our finding, a systematic review and meta-analysis of the effect of patient education on the management of CHD suggested that education could improve health-related quality of life, and it supported the practice of CHD

secondary prevention programmes through education interventions. However, the study concluded that its findings had insufficient power to show an effect of education on mortality and morbidity [46].

We found a higher adherence to healthy lifestyle habits in both the IG and the UG, this could be attributed to the fact that patients were aware of being participated in a study. Moreover, earlier study has reported that patients become more adherent to medication and healthy lifestyle habits after a cardiovascular event [40]. Thus, it is important to highlight that participants in the present study were patients coping with CAD, which might have made them more conscious and responsible about lifestyle changes to prevent future cardiac events. However, counselling intervention was successfully delivered to CAD patients and was supplemented with information leaflets. Participants were also positively interested in attending the counselling, receiving the pamphlet and receiving the follow-up telephone call. Pictorial descriptions in the pamphlet, especially regarding dos and don’ts, facilitated the understanding of all patients, including those with no or lower-level literacy, as reported by patients.

4.2. Limitations and strengths

The study has several potential limitations. Two different modes of data collection, at baseline (face-to-face interview) and at one-month follow-up (telephone interview) could be the limitation of the study. However, earlier studies demonstrated that face-to-face interview and telephone interview had similar measurement properties. Telephone interview is good alternative that can produce data of high-quality comparable to face-to-face mode of data collection [47–50]. Another limitation of the study could be contamination between the IG and UG, even though intervention was administered on the day of discharge from hospital to minimize

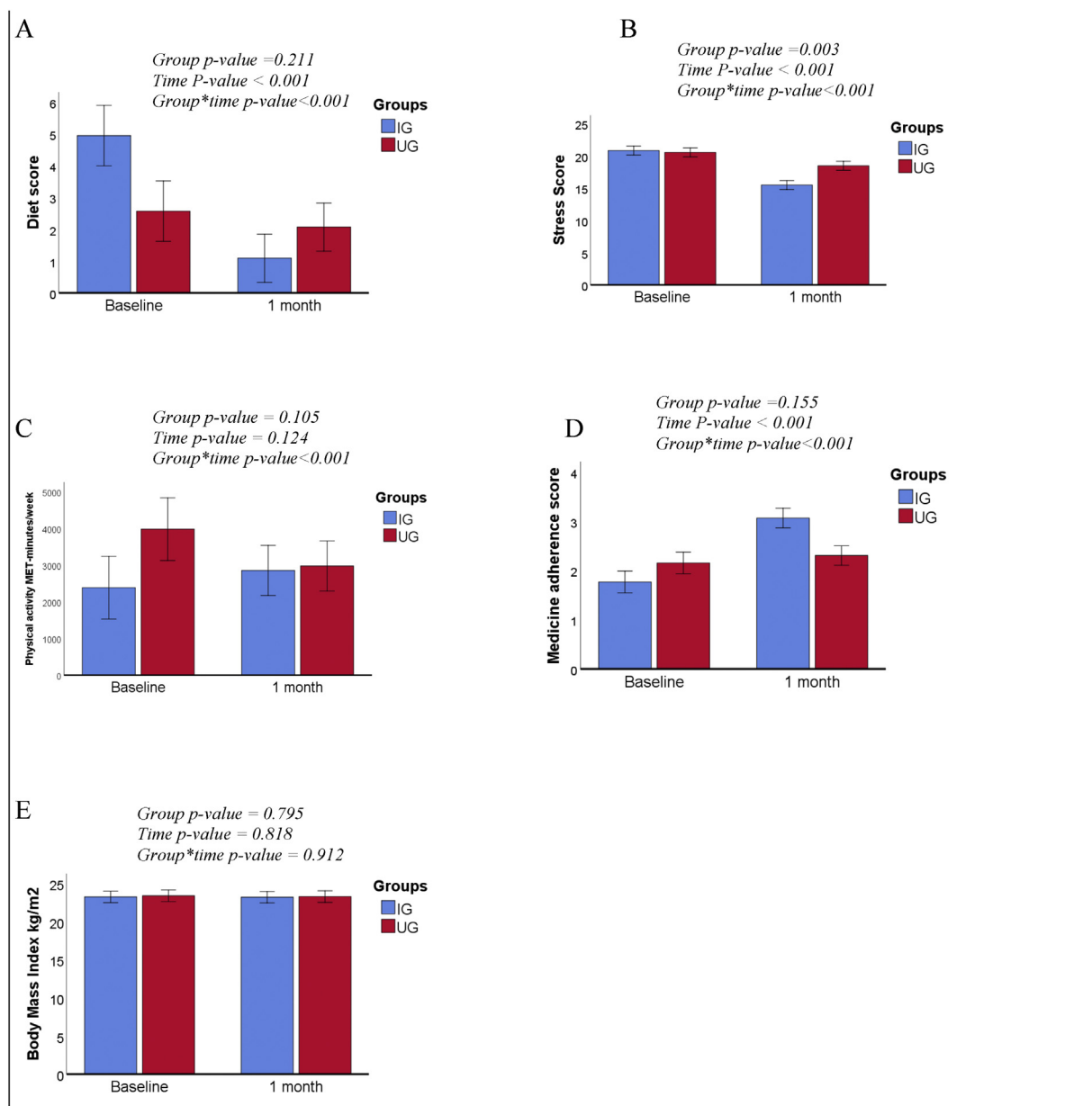


Fig. 2. (A-E) Changes in lifestyle-related risk factor habits from baseline to one-month follow-up. Error bars indicate 95% Confidence interval of mean. P-values are obtained from general linear model repeated measures analysis.

the possible contamination. We relied on self-reported data from patients, and therefore social desirability or recall bias might have partly accounted for the reported lifestyle improvements in both groups. In our study, patients were blinded for treatment allocation, however, the investigator was aware of patients receiving treatment vs controls. We therefore can't control possible bias due to investigator's probable inclination toward the IG. The effect on outcome may not be sufficiently documented due to these methodological limitations. The study result is limited to one-time intervention. Lack of medical records at follow-up is another possible limitation of the study. The generalization of study result is limited because the study was performed in a single cardiac centre in Nepal.

Despite these limitations, our study has some strengths. The high response rate (87.5%) and random control design are strengths of the study. Another strength of the study is feasibility and sustainability of the intervention, as the intervention provided is a low-cost and easy to implement in a clinical setting. The principal investigator provided

the intervention to all the participants, ensuring the same quality of intervention to every patient in the IG. This study was also the first trial to test the effectiveness of a lifestyle-related risk factor modification intervention on seven different lifestyle habits among under-studied CAD patients in Nepal.

4.3. Conclusion

The lifestyle-related risk factor modification intervention delivered by a nurse favourably affected lifestyle habits such as diet, physical activity, medication adherence and perceived stress in the IG of CAD patients after a one-month follow-up period. Since the burden of CAD is increasing globally, especially due to its increased incidence and fewer preventive measures in low- and middle-income countries such as Nepal, secondary preventive measures in addition to pharmacological and surgical therapies are a must. More counselling efforts should be implemented among

CAD patients. Further studies are recommended to investigate the long-term follow-up effects of lifestyle-related risk factor modification interventions.

4.4. Practical implications

Counselling and reading materials promote meaningful changes in health habits, which may bring health benefits among patients and minimize complications. The intervention used in this study offers guidelines to health professionals and could also be extended to CAD patients in community-based rehabilitation or home settings. More counselling and educational efforts should be targeted towards CAD patients.

Authors contribution

PG, MK and AR developed the initial protocol and design. PG prepared the content of counselling and discussed with SN for finalizing, MK and AR provided feedback. PG implemented intervention and collected data. PG, AMK and SN planned for statistical analysis. PG performed initial analysis then AMK, SN, MK and AR provided feedback. PG drafted the manuscript. All authors commented on the manuscript draft, discussed, read and approved the final manuscript.

Funding

PG was partly supported by the Finnish Cultural Foundation, Pirkanmaa Regional Fund [grant number 50181697] and Onni and Hilja Tuovisen Foundation. Funders had no role in the collection, analysis, or interpretation of the data, or in the review of the manuscript.

Declaration of Competing Interest

None of the authors report conflict of interest.

Acknowledgements

The authors sincerely thank all the participants in the study, and SGNC.

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