Tampere University

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Effect of Intervention on Lifestyle Changes among Patients with Coronary Artery Disease in Nepal

A Randomized Controlled Trial

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ACADEMIC DISSERTATION
To be presented, with the permission of
the Faculty of Social Sciences
of Tampere University,
for public discussion in the Yellow Hall F025
of the Arvo building, Arvo Ylpön katu 34, Tampere,
on 19 December 2022, at 12 o'clock.

ACADEMIC DISSERTATION
Tampere University, Faculty of Social Sciences
Finland

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Cover design: Roihu Inc.

ISBN 978-952-03-2673-9 (print)
ISBN 978-952-03-2674-6 (pdf)
ISSN 2489-9860 (print)
ISSN 2490-0028 (pdf)
http://urn.fi/URN:ISBN:978-952-03-2674-6

Carbon dioxide emissions from printing Tampere University dissertations have been compensated.

PunaMusta Oy – Yliopistopaino
Joensuu 2022

ACKNOWLEDGEMENTS

This thesis is completed with the help and patience of some very important persons to whom I'm indebted and forever grateful. This study was carried out at the Faculty of Social Sciences, Tampere University in Finland.

First and foremost, I express my sincere gratitude to my supervisors adjunct professor Anja Rantanen and professor Marja Kaunonen for their continuous support and guidance. Without their patience, motivation, and support for grant application, this work would not have been completed on time. My sincere gratitude goes to adjunct professor Subas Neupane who agreed to be in the follow-up group of my thesis. He has guided and motivated me throughout my PhD journey. I am indebted for his immense support, and valuable time throughout the study period. I am also grateful to professor Katja Joronen and university instructor Anna-Maija Koivisto, who agreed to be in the follow-up group of my thesis and provided their insightful feedback regarding my work.

I sincerely thank Sahid Gangalal National Heart Center, Kathmandu, Nepal, and to all the participants in this study. I am grateful to the Tampere University, Pirkanmaa Regional Fund of Finnish Cultural Foundation, The Finnish National Agency for Education grant, Onni ja Hilja Tuovisen Säätiö, City of Tampere publishing grant who supported financially for this work.

I am thankful to my opponent adjunct professor Päivi Kankkunen from University of Eastern Finland. I am also thankful to professor Hannele Turunen, University of Eastern Finland, and adjunct professor Marita Koivunen, University of Turku for pre-examining my thesis. I am grateful for the insightful feedback they have provided on my thesis.

My sincere thanks go to all faculty members, lecturers and staffs of Tampere University who have directly and indirectly supported me throughout my study.

My gratitude goes to Prakash KC PhD., who guided me from the scratch, motivated, supported, and inspired me throughout this long process. I sincerely thank him from the bottom of my heart for everything. I am grateful to my friend Sushmita Katuwal PhD, who was always there to support me whenever a felt low in my both professional and family life. I am thankful to adjunct professor Tarja Kinnunen, Seetu K.c., Pabitra Basnet PhD, Kalpana Bastola PhD, Kishor Hadkhale PhD, Deependra Singh PhD, Chandra Prajapati PhD, Satu Katri, Tuija Rasku PhD, and Zhifei Liu who have directly or indirectly motivated me in many ways for my professional growth and to complete my PhD thesis.

I am thankful to all my Nepalese community in Finland, who were there to share my happiness and my sorrow. You all are more than an extended family to me.

I am eternally grateful to my parents, my father Purna Prasad Gaudel and my mother Narayani Gaudel for everything. It is their dream to see me graduating PhD, I owe them my everything. I would like to extend my gratitude to my in-laws, my brothers, and their little kids for their continuous motivation and admiration. I would like to thank my extended family and relatives in Nepal who have always showered their love and blessings.

Finally, I am everlastingly grateful to my husband Bishwa Prasad Subedi, who has always supported, motivated, loved, and cared for me unconditionally. You are my greatest power, my inspiration, my best friend, and everything to me. Completing this study and growing up a baby would not be this easy without your full support and dedication to us. We are blessed with a baby girl, Aanvi Subedi, she is an angel to us, and another little bundle of joy is on his way. You both are far more important than anything else can ever be and I love you.

ABSTRACT

Coronary artery disease (CAD) is the leading cause of mortality and disability worldwide. Unhealthy lifestyles are responsible for the high prevalence of CAD, especially among the South Asian population. Existing knowledge on the prevention of CAD is mainly based on studies conducted among populations in high-income countries. It is important to assess the effectiveness of interventions to improve healthy lifestyles in populations in low-income settings such as Nepal. The main aim of the study is to gain insight into the prevalence of modifiable risk factors and to investigate the effect of a nurse-led lifestyle modification intervention among patients with CAD. This study investigates unhealthy diet, physical inactivity, perceived stress, overweight or obesity, nonadherence to medication, smoking, and alcohol consumption. The first objective of the study was to evaluate the prevalence of lifestyle-related risk factors among patients with CAD (Phase I). The second and third objectives were to evaluate the effect of a lifestyle modification intervention on CAD patients' lifestyle changes at one-month (Phase II) and six-month after the intervention (Phase III).

A cross-sectional study was conducted to evaluate the prevalence of lifestyle-related risk factors among CAD patients (n=224). A pre-test post-test control group experimental research design was used to evaluate the effect of the lifestyle modification intervention on CAD patients' adherence to lifestyle changes. Baseline data were collected from CAD patients at the National Heart Center, Kathmandu, Nepal. At baseline, individual face-to-face structured interviews were conducted between May 1 and July 31, 2018. Follow-up data were collected by telephone interview, one-month and six-month after the baseline data collection. Patients were randomly selected into the group and usual care group using a simple random sampling technique. Seven lifestyle-related risk factors were included in this study, and culturally validated instruments were used to collect data on each of the lifestyle risk habits. Group counseling was given to patients (n=112) and their family members. The content of the counseling intervention was developed based on an extensive literature search and recommendations issued by different heart associations. The theoretical basis of the intervention was Imogene King's theory of goal attainment.

The findings of the study, based on self-reported data, showed a high prevalence of multiple lifestyle-related risk factors among the studied patients, with stress being the most prevalent and current alcohol consumption the least. Male patients and patients with a high income had higher odds of being in the medium- and high-risk groups respectively. Except for adherence to medication, there were no statistically significant differences between the study groups at baseline. However, at one-month follow-up, five of the seven lifestyle-related risk factors differed significantly between the study groups: diet, adherence to medication, perceived stress, smoking, and alcohol consumption. A general linear model repeated measure analysis showed a greater improvement in lifestyle-related risk factor habits in the intervention group compared with the usual care group, the effects of time*group interaction were statistically significant for dietary habits, physical activity, medication adherence, and perceived stress at one-month and six-month follow-ups. All seven lifestyle-related risk factors differed significantly between the study groups at the six-month follow-up.

The generalizability of the study's results is limited because the study was performed in a single cardiac center in Nepal. Because there is an increased incidence of CAD 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. Counseling interventions delivered successfully by a nurse may improve healthy lifestyles among underserved CAD patients. Counseling and reading materials promote meaningful changes in health habits, which may bring health benefits to patients and minimize complications. More counseling and educational efforts should be targeted toward CAD patients.

TIIVISTELMÄ

Sepelvaltimotauti (CAD) on johtava kuolleisuuden ja työkyvyttömyyden aiheuttaja maailmanlaajuisesti. Epäterveelliset elämäntavat ovat syynä sepelvaltimotaudin suureen esiintyvyyteen erityisesti Etelä-Aasian väestössä. Nykyinen tieto sepelvaltimotaudin ehkäisystä perustuu pääasiassa korkean tulotason maiden väestön keskuudessa tehtyihin tutkimuksiin. On tärkeää arvioida terveellisten elämäntapojen parantamiseksi tehtyjen interventioiden vaikutusta pienituloisissa väestöryhmissä, kuten Nepalissa. Tämän väitöskirjan tarkoituksena on tutkia useiden elämäntapaan liittyvien riskitekijöiden muuttamiseksi tehdyn ohjausintervention vaikutusta sepelvaltimotautia sairastavilla potilailla. Riskitekijöinä ovat epäterveellinen ruokavalio, fyysinen passiivisuus, koettu stressi, ylipaino tai lihavuus, lääkityksen noudattamatta jättäminen, tupakointi ja alkoholin käyttö. Tutkimuksen ensimmäisen vaiheen tarkoituksena oli arvioida elämäntapaan liittyvien riskitekijöiden esiintyvyyttä potilailla. Toisen ja kolmannen vaiheen tarkoituksena oli arvioida kehitetyn ohjausintervention vaikutusta potilaiden elämäntapamuutoksiin kuukauden (vaihe II) ja kuuden kuukauden (vaihe III) seurannassa.

Poikkileikkaustutkimuksessa arvioitiin elämäntapaan liittyvien riskitekijöiden esiintyvyyttä potilaiden keskuudessa. Ohjausintervention vaikutusta potilaiden sitoutumiseen elämäntapamuutoksiin arvioitiin koe-kontrolliryhmissä ennen-jälkeen seurannassa. Aineistot kerättiin potilailta National Heart Centerissä, Katmandussa, Nepalissa. Lähtötilanteen aineisto kerättiin yksilöhaastatteluina, jotka tehtiin 1.5.–31.7.2018. Seurantatiedot kerättiin puhelinhaastattelulla kuukauden ja kuuden kuukauden kuluttua lähtötilanteen tietojen keruusta. Osallistujat jaettiin satunnaisesti koeryhmään ja tavanomaista hoitoa saavaan kontrolliryhmään yksinkertaisella satunnaisotantatekniikalla. Tähän tutkimukseen sisältyi seitsemän elämäntapaan liittyvää riskitekijää, josta kustakin kerättiin tietoa kulttuurisesti validoiduilla mittareilla. Interventio toteutettiin ryhmäohjauksena, jota annettiin potilaille (n=112) ja heidän perheenjäsenilleen. Intervention sisältö kehitettiin laajan kirjallisuushaun ja sydänjärjestöjen antamien suositusten pohjalta. Intervention teoreettinen perusta oli Imogene Kingin teoria tavoitteen saavuttamisesta.

Tutkimustulokset osoittivat tutkimukseen osallistuneilla useiden elämäntapaan liittyvien riskitekijöiden esiintyvyyden, joista stressi oli yleisintä ja tutkimuksen aikainen

alkoholinkäyttö vähäisintä. Lähtötilanteessa ei koe- ja kontrolliryhmien välillä ollut merkitseviä eroja lukuun ottamatta lääkityksen noudattamisessa. Kuukauden seurannassa viisi seitsemästä elämäntapaan liittyvästä riskitekijästä erosi kuitenkin merkitsevästi koe- ja kontrolliryhmien välillä: ruokavalio, lääkityksen noudattaminen, koettu stressi, tupakointi ja alkoholinkäyttö. Yleinen lineaarinen malli (GLM) toistetuille mittauksille osoitti koeryhmässä verrattuna kontrolliryhmään merkitsevää parannusta elämäntapaan liittyvissä riskitekijöissä; ajan ja ryhmän yhdysvaikutus oli tilastollisesti merkitsevä ruokavalion, fyysisen aktiivisuuden, lääkityksen noudattamisen, ja koetun stressin kannalta yhden ja kuuden kuukauden seurannassa. Kaikki seitsemän elämäntapaan liittyvää riskitekijää erosi merkitsevästi koe- ja kontrolliryhmien välillä kuuden kuukauden seurannassa.

Tutkimustulosten yleistettävyys on rajallista, koska tutkimus tehtiin yhdessä sydänkeskuksessa Nepalissa. Koska sepelvaltimotaudin ilmaantuvuus lisääntyy ja ennaltaehkäiseviä toimenpiteitä on vähemmän alhaisen ja keskitulotason maissa, kuten Nepalissa, toissijaiset ehkäisevät toimenpiteet ovat lääkinnällisen ja kirurgisten hoitojen lisäksi välttämättömiä. Sairaanhoitajan onnistuneesti toteuttama ohjausinterventio voi parantaa palveluja vähän saavien sepelvaltimotautia sairastavien potilaiden terveitä elämäntapoja. Ohjaus ja kirjalliset materiaalit edistävät mielekkäitä muutoksia terveystottumuksiin ja voivat tuottaa terveyshyötyjä potilaille ja minimoida komplikaatioita. Sepelvaltimotautia sairastaville potilaille tulisi suunnata aiempaa enemmän ohjausta ja koulutusta.

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ABBREVIATIONS

AMI	acute myocardial infarction
BMI	body mass index
CABG	coronary artery bypass graft
CAD	coronary artery disease
CHD	coronary heart disease
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CVD	cardiovascular disease
DM	diabetes mellitus
GLM	general linear model
HRQL	health-related quality of life
ICD	International Classification of Diseases
IG	intervention group
IHD	ischemic heart disease
MI	myocardial infarction
n	number (of cases, sample size)
PCI	percutaneous coronary intervention
POR	prevalence odds ratio
QOL	quality of life
RCT	randomized controlled trial
UG	usual care group
WHO	World Health Organization

ORIGINAL PUBLICATIONS

The dissertation is based on the following articles, which are referred to in the text by their Roman numerals.

I Gaudel, P., Kaunonen, M., Neupane, S., Joronen, K., Koivisto, A.-M., & Rantanen, A. (2019). Lifestyle-related risk factors among patients with coronary artery disease in Nepal. *Scandinavian Journal of Caring Sciences*, *34*(3). https://doi.org/10.1111/scs.12784

II Gaudel, P., Neupane, S., Koivisto, A.-M., Kaunonen, M., & Rantanen, A. (2021). Effects of a lifestyle-related risk factor modification intervention on lifestyle changes among patients with coronary artery disease in Nepal. *Patient Education and Counseling*, *104*(6). https://doi.org/10.1016/J.PEC.2020.11.030

III Gaudel, P., Neupane, S., Koivisto, A.-M., Kaunonen, M., & Rantanen, A. (2021). Effects of intervention on lifestyle changes among coronary artery disease patients in Nepal: A six-month follow-up study. *Nursing Open, 9*(4). https://doi.org/10.1002/nop2.1212

 The summary contains some unpublished results.

1 INTRODUCTION

Cardiovascular diseases (CVDs) are the leading cause of disease burden in the world, resulting in 9.14 million deaths worldwide in 2019 (Roth et al., 2020). Coronary artery disease (CAD), also known as coronary heart disease (CHD) or ischemic heart disease (IHD), is the main form of CVD. It is a pathologic process affecting the coronary arteries. A buildup of plaque in the coronary arteries causes a narrowing or blockage of the arteries that supply oxygen-rich blood to the heart. This results in symptoms such as chest pain, shortness of breath, discomfort, or myocardial infarction (MI) leading to death (King et al., 2020). CAD has been consistently ranked as the number one cause of morbidity and mortality worldwide (Vos et al., 2017). The global prevalence of CAD is rising; the current rate of 1655 per 100,000 is expected to rise beyond 1845 by the year 2030 (Khan et al., 2020; Vos et al., 2017).

CVDs are the main type of noncommunicable disease that cause death at the ages of 30–69 years, and 85% of these deaths are estimated to occur in low-and middle-income countries (World Health Organization, 2021). South Asian populations have a higher burden of CAD compared with other ethnicities globally (Dimovski et al., 2019). CAD is an emerging epidemic in low- and middle-income countries including Nepal (Gaziano et al., 2010; Maskey et al., 2003). An analysis of Global Burden of Disease data from 2017 show that CAD contributed to 16.4% of total deaths and 7.5% of disability-adjusted life years in Nepal (Bhattarai et al., 2020). According to data published by the World Health Organization (WHO), 34,167 deaths in Nepal—that is, 20.53% of the country's total deaths—were attributed to CAD in 2018 (WHO, 2022). A study conducted around two decades earlier in Nepal reported a 40-fold increase in the incidence of acute myocardial infarction (AMI) in the previous 30 years (Maskey et al., 2003) and, the CAD cases have been rising continuously to date (Bhattarai et al., 2020).

An unhealthy lifestyle may show up in people as high blood pressure, raised blood glucose, or raised blood lipids. These metabolic risk factors can lead to CAD and premature death associated with it (Gaziano et al., 2010; World Health Organization, 2021). The European Survey of Cardiovascular Disease Prevention and Diabetes V survey, which included 8261 patients from 27 countries, revealed that an unhealthy lifestyle adversely impacts metabolic risk factors in spite of a high use of cardioprotective medications. The study also showed that a large majority of coronary patients have unhealthy lifestyles (Kotseva et al., 2019). Unhealthy lifestyles such as decreased consumption of fruit and vegetables, low physical activity, high levels of stress, tobacco consumption, and other psychosocial factors are reported to be responsible for the high prevalence of CAD among the South Asian population (Gaziano et al., 2010; Nair et al., 2012). Previous studies from Nepal have also shown that unhealthy lifestyle habits such as smoking, unhealthy diet, low physical activity, stress, harmful use of alcohol, and obesity and overweight are prevalent CAD risk factors among the studied populations (Dhungana et al., 2018, 202; Khanal et al., 2018). These unhealthy lifestyle habits are associated with a high incidence of CAD and secondary complications (Dhungana et al., 2018; Dimovski et al., 2019).

Despite the abundance of evidence that adopting a healthy lifestyle can decrease the burden of CVD, CAD is still the number one cause of death in developing and industrialized nations. It is important to modify unhealthy lifestyles to make a significant impact on preventing the progression of CAD and reversing existing disease (Roberts et al., 2005; Roth et al., 2020). Interventions that focus on adherence to healthy lifestyles and drug therapies are essential and should be implemented at the patient level with the use of education and personalized approaches (Gupta et al., 2019). A systematic review of randomized trials of nursing interventions for secondary prevention in patients with CAD and heart failure demonstrated that nursing interventions had a beneficial impact on secondary CAD prevention (Allen et al., 2010).

Previous studies have shown that lifestyle interventions significantly improve cardiac risk factors to prevent or reverse CAD. However, these studies were predominantly conducted among Western populations, and it is not clear to what extent the findings apply to South Asian populations (Chow et al., 2015; Dod et al., 2010; Hardcastle et al., 2013). Studies report a lack of evidence related to the

sustained and longer-term impact of interventions on changing health behaviors (Allen et al., 2010; Jepson et al., 2010). Jepson and colleagues have suggested assessing the effectiveness of different interventions across different populations to address health inequalities (Jepson et al., 2010). It is of prime importance to focus on reducing risk factors associated with CAD by finding and adopting low-cost interventions in low-resource settings such as Nepal. The prevention of CAD involves lifelong adherence to a healthy lifestyle and medication (Gupta et al., 2019). Thus, culturally acceptable, feasible, and sustainable interventions to reduce common modifiable risk factors are essential to reduce disease complications and deaths.

There is a large gap in the initiation of interventions to encourage the uptake of lifestyle-changing behaviors among CAD patients. It is important to assess the prevalence of lifestyle-related risk factors and the effectiveness of lifestyle counseling in bringing about healthy lifestyle changes across different populations. This study addresses the gap in the literature on the prevalence of lifestyle-related risk factors and the effectiveness of interventions in bringing about lifestyle changes among an under-studied population. The study provides added insights on the prevalence of seven lifestyle-related risk factors among patients diagnosed with CAD. The seven lifestyle behaviors considered in this study are unhealthy diet, physical inactivity smoking, medication nonadherence, perceived stress, alcohol consumption, and overweight or obesity. The study aimed to investigate the effect of a nurse-led lifestyle modification intervention on these seven lifestyle-related health risk behaviors simultaneously. Implementing an effective, low-cost, widely available, sustainable, and feasible approach to improve the adoption of healthy lifestyles among underserved patients at the highest risk of cardiovascular events is a great challenge. Therefore, this study sets out the implications for nursing practice, nursing education, and future research.

2 REVIEW OF THE LITERATURE

Literature searches were undertaken during each phase of the study. The literature reviews were updated with newer publications. Literature was sought systematically using CINAHL, PsycINFO, ScienceDirect, PubMed, and the reference lists of relevant previous studies. The searches were limited to recent literature (i.e. from the last 15 years) with full-text availability and published in English. Older literature sources were also used in some instances.

2.1 CAD overview

CAD is a condition that occurs when the arteries that supply oxygen and nutrients to the heart muscle are narrowed or blocked by the buildup of a fatty material called plaque. Depending on the number of coronary arteries with atherosclerotic involvement, CAD is categorized as single-vessel disease, double-vessel disease, or triple-vessel disease. CAD is categorized as nonobstructive CAD if ≤50% diameter stenosis occurs in the coronary artery. There are two main coronary arteries, namely the left main coronary artery and the right coronary artery. The left main coronary artery divides into the left anterior descending artery and the circumflex artery. Blood supply to the front of the left side of the heart is done by left anterior descending artery and blood supply to the outer side and back of the heart is done by the circumflex artery. The right coronary artery divides into smaller branches such as the right posterior descending artery and the acute marginal artery, and it supplies blood to right side of the heart. The left main coronary artery and right coronary artery together supply blood to the septum (middle) of the heart.(Burke, 2016; White, 2016)

2.1.1 Pathogenesis of CAD

The deposit of plaque in the artery's inner walls starts from a very young age, and it takes years or decades to manifest as CAD in individuals. This process of

plaque buildup inside the arteries is called atherosclerosis, meaning hardening of arteries. Various risk factors such as increasing age, male gender, unhealthy lifestyle, family history, and genetic factors contribute to plaque buildup inside the arteries. Plaque consists of cholesterol, fatty substances, waste products, calcium, and fibrin (a clot-making substance). The buildup of plaque narrows the coronary arteries, thus reducing blood flow, which results in reduced oxygen supply to the walls of the heart. The lack of blood supply to the heart muscle deprives the cardiac cells of sufficient oxygen and nutrients, leading to ischemia. Due to the narrowed arteries, the heart pumps harder to deliver oxygen-rich blood to the body, which may result in symptoms such as chest discomfort, chest pain (angina), or shortness of breath. If the blood flow is restricted completely or almost completely, the heart muscle starts to die, causing MI or sudden cardiac death. In some patients, MI can be the first sign of CAD. If a blood clot in a coronary artery breaks and moves to the brain, it can cause a stroke (brain attack). The risk of long-term damage increases with each minute spent without treatment for this disease. (Burke, 2016; Wenger, 2002; White, 2016)

2.1.2 Descriptive epidemiology

In the 10th revision of the International Classification of Diseases (ICD-10), IHDs (I20–I25) are classified as angina pectoris (I20), AMI (I21), subsequent MI (I22), certain current complications following AMI (I23), other IHD (I24), and chronic IHD (I25)(ICD-10 Version:2016).

CAD is the topmost cause of mortality globally (Malakar et al., 2019; Nowbar et al., 2019). The incidence of CAD increases with age, and CAD is more common in men than women. According to the most up-to-date epidemiological data from the Global Burden of Disease study, the global prevalence of CAD is around 126 million, which is approximately 1.7% of the world's population (Vos et al., 2017). Although age-adjusted rates show a decrease in the incidence of the disease, an increased number of cases is estimated due to population aging (Khan et al., 2020; Vos et al., 2017).

Khan et al., (2020) evaluated epidemiological trends in IHD globally. Their study found that IHD had been the leading cause of mortality and disability globally for more than two decades, while age-standardized rates showed a decreased

prevalence of IHD in all regions over time, with greater prevalence in South Asia. Rates of mortality and disability differ between countries and have improved in high-income countries in the last few decades. This improvement in mortality may be due to effective preventive measures and treatments for the acute phase of disease. However, the incidence of CAD may also increase in developed countries in the near future due to immigration, population aging, and increased sedentary behavior (González, 2014; Ralapanawa et al., 2021).

Early detection of arterial damage and plaque buildup with the latest technology has provided important insights into disease patterns and effective treatments, thus reducing disability and mortality. Unfortunately, projections of CAD in developing countries are still alarming. A lack of adequate data about disease and risk factor levels in many developing countries has caused difficulty in the exact estimation of epidemiological data (González, 2014; Ralapanawa et al., 2021). South Asians have a higher burden of CAD. Both nonimmigrant and immigrant South Asians around the world have high levels of CAD compared with other ethnicities (Ahmed et al., 2018).

2.1.3 Clinical characteristics and management of CAD

The most common symptoms of CAD include chest discomfort, which is also called angina. Angina is described as discomfort that spreads to or can only be felt in the left shoulder, arms, neck, back, or jaw. Often patients describe angina as heaviness, tightness, pressure, aching, burning, numbness, fullness, squeezing, or a dull ache that does not subside with rest or a change of position. Other clinical characteristics include tiredness, dizziness, lightheadedness, nausea, or weakness. The symptoms of heart attack may slightly differ in women, including symptoms such as discomfort or pain in the shoulder, neck, abdomen and/or back, feelings of indigestion or heartburn, unexplained anxiety, or cold sweats. Symptoms of CAD may appear after light physical activity such as walking upstairs, or sometimes even at rest. Sometimes a heart attack/MI is the first sign of CAD. Clinical manifestations of CHD present 10–20 years later in women than in men (Burke, 2016; Wenger, 2002; White, 2016).

CAD is managed with lifestyle changes, medication, or interventional procedures such as stenting, angioplasty, or coronary artery bypass graft (CABG) surgery.

Untreated CAD leads to complications such as heart attack, heart rhythm problems, heart failure, cardiogenic shock, sudden cardiac arrest, and death. CAD patients' survival and quality of life (QOL) has increased with advancements in health care facilities and recent technologies. However, CAD still presents a large medical and economic burden throughout the world. The outcomes of the disease could be further improved with lifestyle change along with medical management (Bauersachs et al., 2019).

2.1.4 Lives of CAD patients

The QOL of patients living with CAD differs across countries and patient groups. However, lower health-related quality of life (HRQL) estimates have been found in patients with MI and among patients who suffer from recurring CAD events. Patients' lifestyle risk factors habits seem to be an important determinant of HRQL (Smedt et al., 2013). A cross-sectional study conducted in Iran investigated QOL and related factors among 200 women with CAD. The study revealed average levels of overall QOL among study participants, with some domains that needed to be improved (Ghasemi et al., 2014). A follow-up study to assess gender differences in the evolution of HRQL after a coronary event was carried out among 112 men and 63 women with AMI or unstable angina. Based on follow-up data from 55 men and 25 women at three months, and 35 men and 12 women at six months, the study found a higher frequency of rehospitalization and revascularization in women; however, men had progressed favorably in most of the physical dimensions during the follow-up period. Decreased HRQL in men was determined by worse mental health and anginal frequency; in addition to these, a history of the disease and revascularization were the variables that determined decreased in HRQL in women (Dueñas et al., 2011).

Another previous study evaluated the HRQL of patients with CHD and ischemic heart failure. The study found a negative correlation between anxiety and depression and HRQL. The results also demonstrated that anxiety was mainly correlated with patients' symptoms, rather than with their history of MI (Moryś et al., 2016).

2.2 Risk factors for CAD

Individuals with CAD have many risk factors. Some risk factors can be modified, but not others. Risk factors that are nonmodifiable include older age, male gender, genetic factors, and a family history of heart disease (Hajar, 2017). These conventional risk factors cannot be controlled or modified. Risk of developing CAD can be reduced by changing modifiable risk factors, but CAD cannot be completely prevented. The risk factors that can be modified or controlled are diabetes, high blood pressure, high blood cholesterol levels, smoking, overweight or obesity, lack of physical activity, unhealthy diet, stress, and harmful use of alcohol (Gaziano et al., 2010; Hajar, 2017b; Kotseva et al., 2019). Managing diabetes, blood pressure, and cholesterol with lifestyle changes and/or medication is important. Healthy individuals with a prevalence of genetic, environmental, or lifestyle risk factors are at high risk of CAD occurrence in the near future (Malakar et al., 2019).

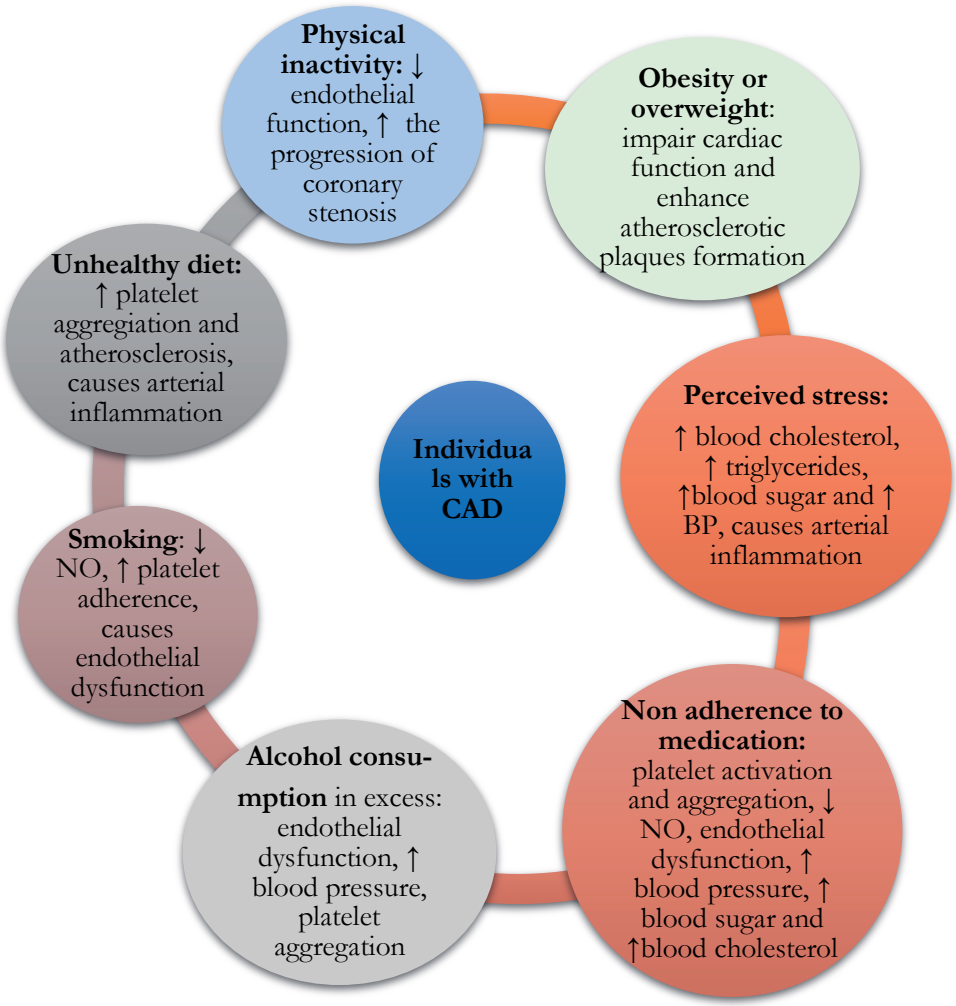


Figure 1. Lifestyle-related risk factors and possible mechanisms of CAD

2.2.1 Unhealthy diet

It is crucial to improve overall diet quality and macronutrient sources in order to reduce the global burden of CVD. To achieve better cardiovascular health, a healthy overall dietary pattern that emphasizes quality and healthy sources of fats and carbohydrates is recommended (Pan et al., 2018). Plant-based nutrition with a minimal intake of animal products can restore the ability of the heart's endothelial cells to produce nitric oxide, which can stop or reverse CVD (Esselstyn, 2017). Similarly, consumption of fruit, vegetables, and fish has been shown to be inversely associated with CAD. It is recommended that people should consume green and yellow vegetables, fruit, soy products, and fish at least twice a week (Saita et al., 2014). A study by Gupta et al. (2019) emphasizes an increased intake of whole grains, vegetables, fruit, legumes, nuts, fish, and soy products. This study further suggests the importance of lowering the intake of saturated fats and replacing them with unsaturated fats, avoiding processed foods and trans fat, minimizing the intake of refined carbohydrates and sugar, having a high intake of plant-based foods, and lowering animal-source foods to maintain cardiovascular health. An earlier meta-analysis included participants from 10 prospective cohort studies to generate evidence on the association between the WHO's dietary recommendations and mortality from CVD. The results of the study showed that a healthy diet was significantly associated with a reduction in CVD mortality in elderly populations in southern Europe and the United States (Jankovic et al., 2015). Many epidemiological studies have reported promising effects of a healthy diet on the prevention and reversal of atherosclerotic disease (Esselstyn, 2017; Gupta et al., 2019; Pan et al., 2018; Saita et al., 2014).

Esselstyn et al. (2014) followed 198 patients who had been counseled to choose plant-based nutrition for a mean of 3.7 years. Patients were advised to take whole grains, legumes, lentils, vegetables, and fruit as a major proportion of their daily diet. They were encouraged to take flaxseed as an additional source of omega-6 and omega-3 essential fatty acids. Patients were also advised to avoid added oils, processed foods, excess salt, and sugary foods. The study found a reduction in the recurrent cardiac event rate among patients who maintained plant-based nutrition. Nutritional intervention can prevent or even reverse the progression of atherosclerotic changes among individuals.

Antioxidants, vitamins C and E, carotenoids and polyphenols (found in green and yellow vegetables), and n-3 polyunsaturated fatty acids (found in fish) help with reduced platelet aggregation, lower triglyceride, plaque stabilization, and atherosclerosis-preventive effects. However, the exact mechanism by which antioxidant foods help to prevent atherosclerotic diseases is still unknown (Saita et al., 2014).
A systematic review and pooled analysis of prospective cohort studies and randomized controlled trials (RCTs) found that vegetables, nuts, and Mediterranean and high-quality dietary patterns had a strong protective association with CHD. Intake of trans-fatty acids and foods with a high glycemic index was found to have harmful effects on cardiac health (Mente et al., 2009).

2.2.2 Physical inactivity

Physical activity effectively reduces cardiovascular events and increases the life expectancy of individuals. It plays an important role in the pathogenesis of CAD. It improves endothelial function, halts the progression of coronary stenosis, and improves arterial blood supply (Winzer et al., 2018). Physical inactivity and a sedentary lifestyle are major risk factors for CVD (Roberts et al., 2005). A systematic review and meta-analysis quantifying the association between physical activity and CVD and diabetes found that an increase in physical activity—from being inactive to achieving the recommended physical activity level of 150 minutes of moderate-intensity aerobic activity per week—was associated with a 23% lower risk of CVD mortality and a 17% reduction in CVD incidence. This study suggested that moving from inactivity to a small amount of physical activity offered the greatest gain for health (Wahid et al., 2016).

The Pure prospective cohort study recruited participants from 17 countries, which included high-income (n=3), middle-income (n=10), and low-income (n=4) countries. Individuals aged 35–70 years with no preexisting CVD were invited to participate in the study. The participants' physical activity was assessed using the International Physical Activity Questionnaire. A total of 141,945 participants completed the questionnaire, and the analysis was limited to 130,843 participants without preexisting CVD. The findings of the study revealed that both recreational and nonrecreational physical activity was associated with a lower risk of cardiovascular events and mortality in individuals from low-income,

middle-income, and high-income countries. Higher physical activity rates were associated with much lower risk, and even walking for 30 minutes on most days of the week had substantial benefits. Increasing physical activity is a simple and low-cost approach that is applicable globally to reduce deaths and CVD (Lear et al., 2017).

A study that surveyed 1746 CAD patients at baseline and after two years' follow-up in Oulu, Finland, found that leisure-time physical activity reduced the risk of cardiac death among CAD patients. The study also reported that even a minor increase in physical activity from sedentary behavior affected cardiac mortality (Lahtinen et al., 2018). However, physical inactivity is increasing in developing countries, due to progressive shifts of lifestyle toward more sedentary patterns (Roberts et al., 2005).

2.2.3 Smoking

Smoking is a strong risk factor for CAD, and for fatal or nonfatal recurrences. Interventions for smoking prevention and early smoking cessation are a must to improve overall cardiovascular health. Cigarette smoke and its constituents cause vascular dysfunction. Smoking causes reduced nitric oxide and endothelial dysfunction, increases the adherence of platelets, and exacerbates the inflammatory environment, all of which leads to atherogenic vessel wall changes. Smoking cessation is vital to reverse damage that has already occurred in the vascular walls and to prevent CVDs caused by smoking (Messner et al., 2014). All patients with CAD must be advised to stop smoking (Hajar, 2017). A systematic review and meta-analysis of low cigarette consumption and the risk of CHD and stroke reported that there is no safe level of smoking for CVD. Another meta-analysis of the association between cigarette consumption and CHD based on 141 cohort studies showed that the relative risk of coronary artery disease from smoking one cigarette per day was 1.48 for men and 1.57 for women, and from smoking 20 cigarettes per day was 2.04 for men and 2.84 for women (Hackshaw et al., 2018). Smoking was significantly associated with CAD, and a dose-response relationship was identified between pack-years of smoking and CAD (Ning et al., 2019). Smoking cessation is related to lower risk of heart disease, although a significantly elevated risk of CAD persists for up to 20 years following smoking cessation (Ning et al., 2019).

2.2.4 Medication nonadherence

Nonadherence to cardiovascular medication is often the dominant risk factor for CAD that increases the risk of adverse cardiac events, including mortality (Levy et al., 2018; Leiden et al., 2014). Adherence to medication is highly important to effectively manage CAD and prevent secondary complications. Failure to adhere to CAD medication can be both intentional and unintentional. Low adherence to medication has been found in studies conducted among South Asians. Interventions that aim to improve medication adherence in this population are critical (Volgman et al., 2018). A systematic review of the impact of medication adherence on CAD outcomes and costs was conducted by Bitton et al. (2013). A total of 25 high-quality studies were included in this systematic review. Most of the studies included focused on aspirin, statins, and antihypertensive medications. The results revealed that higher medication adherence significantly improved CAD outcomes in the study populations. The study further showed a 10.1–17.8% health cost reduction between high and low medication-adherent patients.

Achieving high rates of medication adherence is very challenging. Medications are often expensive and may have side effects. In addition, lifestyle factors may make adherence difficult. Adherence to medication is typically lower among patients with chronic conditions compared with those with acute conditions. Methods to improve adherence have involved a combination of behavioral interventions and the provision of educational information about the patient's disease condition and the importance of medication (Osterberg et al., 2005). Various interventions can be used to increase patients' adherence to secondary prevention medicine after an MI. Patient education provided by health care professionals in person or by telephone is one effective approach to improve medication adherence (Levy et al., 2018).

Gehi et al. (2007) prospectively evaluated the risk of cardiovascular events associated with medication adherence in patients with stable CHD. A total of 1015 patients from the Heart and Soul study were followed for 3.9 years. Of these patients, 8.2% reported nonadherence to medication, and 14.4% developed cardiovascular events. The study found that adherent patients were less likely than nonadherent patients to develop cardiovascular events such as recurrent CHD, MI, or stroke.

2.2.5 Perceived stress

Stress causes an abnormal activation of the sympathetic nervous system, which plays an important role in increasing the risk of CAD. Long-term stress increases levels of cortisol, which can increase blood cholesterol, triglycerides, blood sugar, and blood pressure. Stress also promotes plaque buildup in the arteries by causing arterial inflammation (Fioranelli et al., 2018). A case-control study by Yang and colleagues included 178 male patients with young CAD as cases (≤55 years) and 181 non-CAD individuals as controls. In this study, perceived stress status was assessed by the Perceived Stress Scale, and levels of epinephrine and norepinephrine were also measured. The study found that Perceived Stress Scale scores were correlated with levels of epinephrine (correlation (r)=0.45) and norepinephrine (r=0.41). The study further suggested the development of multiple approaches to increase coping responses to severe stress and for the prevention of CAD (Yang et al., 2015). A systematic review and meta-analysis of perceived stress and its association with incident CHD based on six prospective observational cohort studies (n=118,696) yielded an aggregate risk ratio of 1.27 (95% confidence interval (CI), 1.12–1.45) for the magnitude of the relation between incident CHD and high perceived stress. The study suggested a moderately increased risk of incident CHD among individuals with high perceived stress (Richardson et al., 2012).

2.2.6 Alcohol consumption

The effect of alcohol consumption on cardiovascular health is complex. Low to moderate ethanol consumption may have a positive effect on endothelial function, whereas high levels of alcohol may impair it. Low- to moderate-risk drinking is usually defined as one or two standard drinks per day, and heavy drinking is defined as the consumption of four or more standard drinks per day. A systematic review and meta-analysis revealed that low to moderate alcohol consumption lowered hypertension risk among women, whereas heavy drinking of >20g ethanol per day increased hypertension risk in both men and women (Briasoulis et al., 2012). Studies on the effect of alcohol consumption (particularly red wine) on various CVDs and mortality have reported that a light to moderate intake of alcohol is associated with a lower risk of CAD, heart failure, and cardiovascular mortality. Except in individuals with severe liver disease, low

alcohol intake may be of benefit. Previous studies report that heavy consumption of alcohol has deleterious cardiovascular outcomes, including increased mortality (Goel et al., 2018; Klatsky, 2015; Song et al., 2018).

Potential benefits of moderate red wine consumption have been suggested in previous studies. The alcoholic and polyphenolic components of wine contribute to cardiovascular health protection, mainly through antioxidant properties and lipid-regulating and anti-inflammatory effects (Golan et al., 2019; Liberale et al., 2019). The possible mechanisms behind alcohol's effects on CAD protection include raising high-density lipoprotein, reducing low-density lipoprotein oxidation in blood vessel walls, lowering fibrinogen, lowering the risk of type II diabetes mellitus (DM), possibly by reducing insulin resistance, and increasing cardiac myocytes. Low to moderate alcohol use (<20mM) increases endogenous nitric oxide synthase expression and nitric oxide production in the aortic vascular wall. This helps to regulate vascular tone and has a protective effect in the cardiovascular system by preventing platelet aggregation and adhesion. A high level of alcohol (>29mM) may cause alterations in nitric oxide availability, decreased endogenous nitric oxide synthase expression leading to endothelial cell dysfunction and plaque buildup in arteries, disruption of arterial-vascular function, and body fluid imbalances (Briasoulis et al., 2012; Leong et al., 2014; Piano, 2017).

Whitman et al. (2017) conducted a longitudinal analysis to determine the effect of alcohol abuse on the incidence of cardiac diseases among California residents who were above 21 years old. A total of 14,727,591 patients were included in the analysis, 268,084 of whom (1.8% of the study population) had an alcohol abuse diagnosis. The study found that alcohol abuse was associated with increased risk of atrial fibrillation, MI, and congestive heart failure to a similar degree to other well-established risk factors. The study suggested that alcohol in excess is cardiotoxic, and thus efforts to mitigate the excess use of alcohol are important to deliver meaningful reductions of CVD. Interestingly, the Interheart case-control study, which included observations from 52 countries, revealed that although moderate alcohol use may protect against MI in most populations, this may not be generalizable to populations across different geographical regions, especially South Asian populations. The study's results suggested that South Asians living outside South Asia may have a reduced risk of MI with moderate alcohol consumption. However, the protective effect of low to moderate alcohol

use was not seen in South Asians living in South Asia (Leong et al., 2014). This difference may be attributable to the type and pattern of alcohol use and various other environmental and cultural factors.

2.2.7 Overweight

Overweight and obesity are independent risk factors for CVDs, particularly heart failure and CHD (Lassale et al., 2018; Logue et al., 2011; Thomsen et al., 2014). The exact mechanisms connecting excess body mass and CAD are not clear. The adipose tissue that produces pro-inflammatory cytokines may impair cardiac function and enhance atherosclerotic plaque formation.

Maintaining a healthy weight is essential for primary prevention of CAD. Contrary to this, some studies suggest a potentially protective effect of obesity among individuals when it co-occurs with CAD. It is assumed that excess body mass is equally important in secondary prevention settings. Some previous studies and meta-analyses have shown overweight CVD patients to have a better prognosis than patients with lower body mass with the same CVD. This phenomenon, known as the obesity paradox, is not completely understood. The protective mechanisms behind obesity and CVD remain unknown. Obese individuals have increased fat mass and lean mass, and this increased lean mass may improve their cardiorespiratory fitness (Carbone et al., 2019; Lavie et al., 2016, 2018).

An RCT was conducted among 6595 moderately hypercholesterolemic men with no history of diabetes or CVD in Scotland. The study participants were followed up for 15 years. The results showed that the risk of nonfatal CVD events was similar across all body mass index (BMI) categories. However, the risk of fatal CAD events increased among obese individuals (Logue et al., 2011). A prospective study followed 37,674 apparently healthy young men for angiography-proven incident CHD through the staff periodic examination center of the Israeli army's medical corps. Over approximately 17.4 years of mean follow-up, 327 incident cases of CHD were documented in the study population. The patients' BMI was measured at regular intervals during the study period. The results showed that elevated BMI during both adolescence and adulthood was associated with CHD. The study concluded that BMI at young ages is an

independent predictor of CHD, suggesting that body mass has long-term consequences (Tirosh et al., 2011).

2.3 Importance of lifestyle changes for CAD risk reduction

A healthy lifestyle reduces the risk of CAD compared with an unfavorable lifestyle. A population-based cohort study included a total population of 26,323 from the Malmö Diet and Cancer Study with 18 years of prospective follow-up. The study revealed that a favorable lifestyle was associated with a 44% lower risk of CAD compared with an unhealthy lifestyle (Dimovski et al., 2019). A study of people aged 40–80 years in Nepal showed that smoking, harmful use of alcohol, insufficient intake of fruit and vegetables, low physical activity, and overweight and obesity were common risk factors in a rural Nepalese population. The study additionally reported that 98% of the study population (n=345) had at least one risk factor, 63% had at least three risk factors, and 2% had six risk factors (Khanal et al., 2018). The adoption of healthy lifestyles and preventive strategies is important for the management of life-threatening CVD (Malakar et al., 2019). Lifestyle changes reduce CVD morbidity and mortality. Long-term adherence to healthy lifestyle changes maximizes the health benefits to the individual. However, interventions targeting lifestyle changes result in initial behavioral changes but are not able to achieve long-term behavioral maintenance (Artinian et al., 2010).

2.4 Prevention of CAD

Primary prevention includes measures to prevent the onset of disease. Promoting a healthy lifestyle throughout the life course to prevent the onset of CVD is a primary prevention measure. Secondary prevention involves identifying risks of disease, detecting disease, and making early interventions to manage the disease. Tertiary prevention involves the management of disease symptoms and the prevention of disease complications once the disease has become established in the individual. Thus, lifestyle changes such as meeting physical activity recommendations, improving dietary habits, taking regular medication for DM, hypertension, or cholesterol if indicated, quitting the use of tobacco, maintaining a healthy weight, and avoiding stressors are crucial for primary, secondary, and

tertiary prevention (Jepson et al., 2010). Lifestyle counseling to maintain healthy lifestyle habits should be provided to prevent CVDs. Socioeconomically disadvantaged individuals should be assessed for potential barriers to access to a heart-healthy diet and prescribed medications. Adults should be assessed for psychosocial stressors, access to facilities for physical activities, body size perception, and adherence to treatment for DM and hypertension. Individuals' social and cultural influences on the maintenance of healthy lifestyles should also be assessed, and appropriate counseling should be provided. Health care professionals should prioritize primary prevention strategies, help individuals/patients reduce their risk of CAD, and encourage them to adhere to healthier lifestyle changes (Arnett et al., 2019; Magnani et al., 2018). The substantial decrease in CAD deaths in high-income countries such as the United States is very likely explained by an increase in primary and secondary prevention efforts, as well as the effective treatment of hospitalized patients with acute MI(Dalen et al., 2014). This strategy is especially lacking in low-to-middle-income countries such as Nepal, which may have contributed to the rise in the CVD burden in recent years (Ahmed et al., 2018).

Patients living with CAD are at risk of subsequent ischemic events as a result of atherosclerosis progression. Secondary and tertiary prevention is important for the management of symptoms and the prevention of cardiovascular complications such as recurrent MI, stroke, or sudden cardiac death. These preventive strategies help patients to maintain physical health and QOL after CAD (Dimovski et al., 2019; Ghimire et al., 2018).

Comprehensive risk factor management plays a key role in improving CAD patients survival, maintaining the highest levels of health, reducing recurrent coronary events, and reducing the need for revascularization. Patients living with CAD should be encouraged to adhere to their medical treatment regimen to control DM, hypertension, and cholesterol. Along with medication adherence, patients should be encouraged to develop self-management skills to maintain a healthy lifestyle and behavior modifications (Fioranelli et al., 2018). Patients' mental health is an important aspect of CAD prevention, and therefore patients should be facilitated to develop skills for stress reduction. Poor adherence to secondary prevention of CAD could lead to a greater risk of disease complications and mortality in the long term (Kulik et al., 2015; Smith et al., 2011). The current study therefore focuses on helping patients to achieve healthy

lifestyle-related risk factor modifications by mean of a counseling intervention for secondary and tertiary prevention of CAD.

2.5 Patient counseling

Counseling and supportive interventions to improve the QOL of people living with CAD is crucial, especially among individuals with low socioeconomic status (Ghasemi et al., 2014). It is important to individualize the content of interventions and rehabilitation programs to improve the HRQL of patients living with CAD (Dueñas et al., 2011). A review of systematic reviews of the effectiveness of interventions to change six health behaviors revealed that some interventions were effective in achieving behavioral change. The study showed that individual counseling was one of the effective interventions. The review emphasized studies that assessed the differential effectiveness of interventions across different populations (Jepson et al., 2010). Patient education provided by physicians, pharmacists, or nurses, and follow-up performed either in person or by telephone, had promising effects on improved medication adherence (Levy et al., 2018). An RCT of CAD patients from southern Brazil comprised 74 patients, 38 in the intervention group and 36 in the control group. The IG received nurse-led individual lifestyle counseling sessions, and the control group received standard medical advice. The study found that at one year of follow-up, there was a significant between-group difference for weight (Saffi et al., 2014). A systematic review on the effects of health coaching on adult patients with chronic diseases concluded that healthcare professionals plays important role in promoting healthy behavior among adults with chronic disease. Furthermore, the review emphasized that patient education motivates change in their lifestyle and improves home-based self-care among patients (Kivelä et al., 2014).

The theoretical basis of the intervention in this dissertation draws on Imogene King's theory of goal attainment. This theory aligns with the nursing process to assist individuals and families to mutually set goals, and to explore and agree on the means to achieve those goals (Alligood, 2010). A systematic review of the effectiveness of nursing interventions based on King's theory found that goal

attainment theory was commonly applied in articles in both educational and clinical fields. The review recommended that King's conceptual system and the theory of goal attainment could be used in different situations to enhance patients' compliance, improve their QOL, and reduce complications in patients (Balasi et al., 2021). King's theory focuses on the interaction with the patient to set mutual goals according to the patient's needs, explore possible means, and agree the means to achieve the goals. Thus, King's theory encompass concept of this study and it seems to translate well to the intervention process used.

2.6 Effects of interventions on lifestyle changes

A review of systematic reviews reported findings on the effectiveness of interventions to change health behaviors that included unhealthy eating, physical inactivity, smoking, and alcohol misuse. The study included 103 reviews that focused on interventions to change existing unhealthy behaviors. The results revealed that individual counseling was one of the most effective interventions to improve health behaviors. The authors of the study concluded that some interventions were effective in achieving behavioral change (Jepson et al., 2010). All patients with CAD should have access to a program delivered by health care professionals. These programs should address all aspects of lifestyle and adherence to cardioprotective medication to improve patients QOL and reduce the risk of recurrent cardiovascular events (Kotseva et al., 2019). Certain interventions, such as financial incentives and peer pressure, were not found to be effective in improving patients adherence to medication after MI. Interventions such as technological monitoring and encouragement seemed to be promising but dependent on patient engagement. Other interventions, such as medication reminders via text message, were found to be effective if patients were required to respond. However, multifaceted interventions that involved a combination of different interventions appeared to be successful in all patients (Levy et al., 2018)

An earlier systematic review of randomized trials demonstrated the beneficial impact of nursing interventions on the management and prevention of complications among patients with CAD or heart failure. The study revealed the beneficial impact of nursing interventions on lifestyle habits including physical activity, dietary intake, cigarette smoking, and weight loss. However, the

interventions' frequency, duration, intensity, components, sustainability, and cost-effectiveness remained unknown (Allen et al., 2010). Saffi et al., (2014) conducted a randomized clinical trial to evaluate the effect of systematic, nurse-led individual lifestyle counseling sessions on the reduction of 10-year cardiovascular risk scores. A total of 74 CAD patients from a tertiary care center in southern Brazil completed the one-year follow-up assessment. The intervention comprised information on cardiovascular risk factors, physical activity, smoking cessation, dietary control, and the management of weight, blood pressure, blood sugar, and lipid profiles. In addition, the study included Morisky's four-item medication adherence scale. The findings showed that the nurse-led lifestyle counseling intervention effectively reduced cardiovascular risk scores (Saffi et al., 2014). Another recent study on the effect of a nursing intervention on the secondary prevention of coronary heart disease revealed that a well-developed nursing intervention could improve the health behaviors and outcomes of CHD patients (Shen et al., 2021). Similarly, a randomized controlled trial examined effectiveness of nurse-led self-mangement programme for CHD patients among 144 Chinese patients. The study result showed that over six months self-management behaviors and health outcomes were improved significantly in the intervention group (Jiang et al., 2020). An RCT conducted by Hardcastle et al. (2013) with a 12-month post-intervention follow-up assessed the effectiveness of a motivational interviewing intervention on weight loss, physical activity, and CVD. A total of 334 patients, completed the baseline assessment and the findings revealed that the MI intervention led to significant improvements in walking and cholesterol at 12 months. The study further suggested that a low-intensity counseling intervention was effective in bringing about long-term changes in some health-related outcomes, especially for patients with elevated levels of cardiovascular risk factors at baseline.

2.7 Justification for the present study

The CAD burden is continuing its decades-long rise globally. This emphasizes the urgent need to implement effective interventions to achieve reductions in CAD related disability and mortality (Roth et al., 2020). However, the optimal combination of intervention components to improve outcomes in patients with

CAD is unknown (Allen et al., 2010). Thus, research in this area of cardiovascular nursing remains crucial. Exposure to cardiovascular risk factors and their clustering is common in the Nepalese population, which indicates the need for interventions to reduce high-risk behaviors, which could help to reduce the future burden of CAD (Ghimire et al., 2018; Khanal et al., 2018). The burden of CAD limits the sustainable development of a low-to-middle-income country such as Nepal. The lifestyle behaviors of the population in Nepal differ in many respects from those in other countries, especially high-income countries. Therefore, interventions conducted in other cultural settings may not be applicable to this population. Better data are needed on the effectiveness of low-cost sustainable interventions with regard to multiple risk factors in different study populations. There remains a large gap between identifying an effective intervention and delivering it to patients who have limited access to health care facilities. Thus, in the current study we seek to address the gap in the literature on the effectiveness of counseling interventions with regard to seven different lifestyle behaviors among patients with limited access to health care facilities. A summary of the literature is presented in Figure 2.

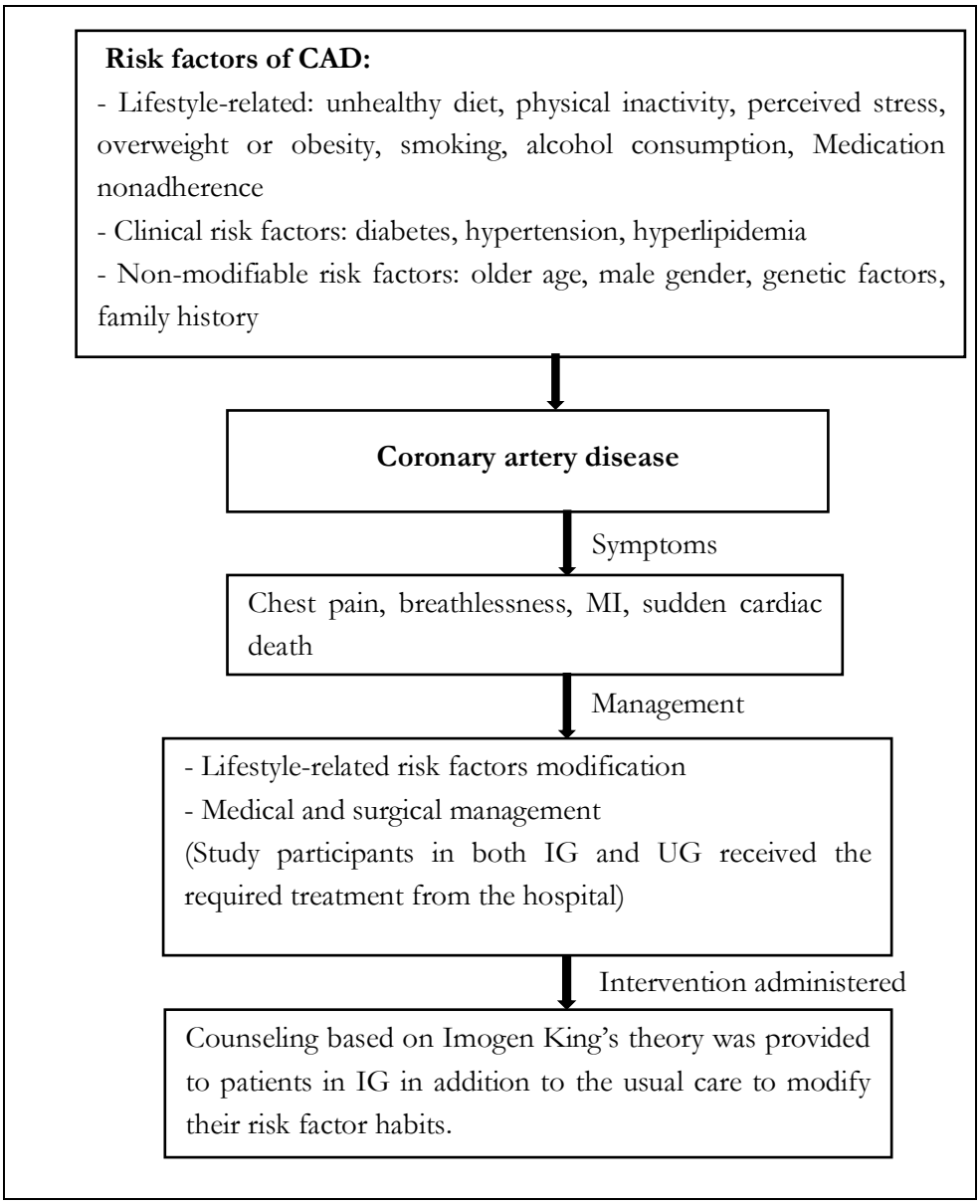


Figure 2. Summary of literature

3 AIMS OF THE STUDY

The *purpose* of this study is to describe the prevalence of modifiable risk factors and to investigate the effect of a lifestyle modification intervention on adherence to a healthy lifestyle among patients with CAD.

The *main aim* of the study is to gain insight into the prevalence of modifiable risk factors and to investigate the effect of a nurse-led lifestyle modification intervention among patients with CAD. The overall aim is to enable patients with CAD to adhere to healthy lifestyle changes. An examination of these lifestyle habits provides a comprehensive understanding of the impact of the intervention in terms of bringing about positive lifestyle changes and reducing complications of CAD.

The *specific research questions* are the following:

1. What is the prevalence of lifestyle-related risk factors among patients with CAD? (Article I)
2. What is the effect of a lifestyle modification intervention on CAD patients' lifestyle changes one-month after the intervention? (Article II)
3. What is the effect of a lifestyle modification intervention on CAD patients' lifestyle changes six-month after the intervention? (Article III)
4. What is the effect of a nurse-led short counseling intervention on lifestyle-related risk factor changes among CAD patients? (Summary)

The *hypothesis* of the study is as follows:

> An intervention focusing on lifestyle-related risk factors (unhealthy diet, physical inactivity, medication nonadherence, perceived stress, obesity or overweight, smoking, and alcohol consumption) improves healthy lifestyle changes in patients with CAD.

4 METHODS

4.1 Study design and setting

The overall study was divided into three phases. In Phase I, a cross-sectional study was designed to assess the prevalence of lifestyle-related risk factors among patients living with CAD. The results of the study are presented and published in Article I. In Phase II, a randomized controlled study was conducted to assess the effect of the intervention at one-month follow-up. The results of the study are presented and published in Article II. In Phase III, six-month follow-up data were collected and analyzed to assess the intermediate-term effect of the intervention. The results of the study are presented and published in Article III.

The study was conducted at a national cardiac center in Kathmandu, Nepal. The majority (42.4%) of patients admitted to the hospital have CAD, comprising approximately 3750 patients per year (Annual Report 2018). Patients diagnosed with CAD at the hospital were assessed for eligibility to be included in the study. The inclusion criteria were age over 18 years, clinical diagnosis of CAD, ability to communicate in Nepali or English, accessibility by telephone, and willingness to participate voluntarily. Patients with congenital or valvular heart diseases, serious medical or surgical conditions, high-risk cardiac conditions, and hearing, speaking, or cognitive problems were excluded from the study. A summary of the study population and design is presented in Table 1.

Table 1. Summary of study population and design

	Article I	**Article II**	**Article III**
Purpose	To assess the prevalence of lifestyle-related risk factors	To assess the effect of the intervention at a one-month follow-up	To assess the effect of the intervention at a six-month follow-up
Study design	Cross-sectional study	Randomized controlled trial	Randomized controlled trial
Study population	224 patients with CAD	196 (98 in each group)	184 (93 in IG and 91 in UG)
Method of data collection	Face-to-face interview	Telephone interview	Telephone interview
Data-collection	May-July 2018 (Baseline)	June-August 2018	November 2018-January 2019
Follow-up time	-	One-month after intervention	Six-month after intervention
Outcome variable	unhealthy diet, physical inactivity, perceived stress, medication nonadherence, obesity or overweight, smoking, alcohol consumption	unhealthy diet, physical inactivity, perceived stress, medication nonadherence, obesity or overweight, smoking, alcohol consumption	unhealthy diet, physical inactivity, perceived stress, medication nonadherence, obesity or overweight, smoking, alcohol consumption

4.2 Sample size calculation

It was hypothesized that there would be a relative improvement in healthy lifestyle habits among the IG compared with the UG at the follow-ups. For α=5%, power of 80%, and effect size of 0.37, the sample size required to detect this difference was 92 per arm. After we took account of an estimated attrition rate of 22% for adequate power, the sample size was 112 per arm. An a priori power analysis was used with a t-test family to calculate the sample size (Iestra et al., 2005; IJzelenberg et al., 2012).

4.3 Participants

A total of 365 patients with a diagnosis of CAD based on ICD-10-CM Sections I20–I25 were screened for eligibility from the list of patients. A total of 141 patients were excluded: 134 did not meet the inclusion criteria, and seven declined to participate in the study. In total, 224 eligible CAD patients were included in the baseline analysis. After the baseline survey, patients were randomized into the IG and UG in a 1:1 ratio using a simple randomization technique. Of the 224 patients included in the baseline analysis, 112 were randomized into each group. Only 196 patients, 98 from each group, participated in the study at one-month follow-up. Fourteen patients dropped out of each group at one month due to loss to follow up (n=11) and death (n=3) in the IG, and loss to follow-up (n=14) in the UG. At the six-month follow-up, 93 patients participated from the IG and 91 from the UG. Patients dropped out due to loss to follow-up (n=5 in each group) and death (n=2 in the UG). The response rate at one-month follow-up was 87.5%: a total of 196 out of 224 patients responded to the follow-up call and questionnaire at one month. Of these 196 patients, 184 responded at the six-month follow-up, leading to a response rate of 93.9%. The overall response rate of the study population was 82.1%: from 224 patients at baseline, a total of 184 patients responded at the six-month follow-up. The details of patient enrollment, follow-up, and loss to follow-up are provided in Figure 3.

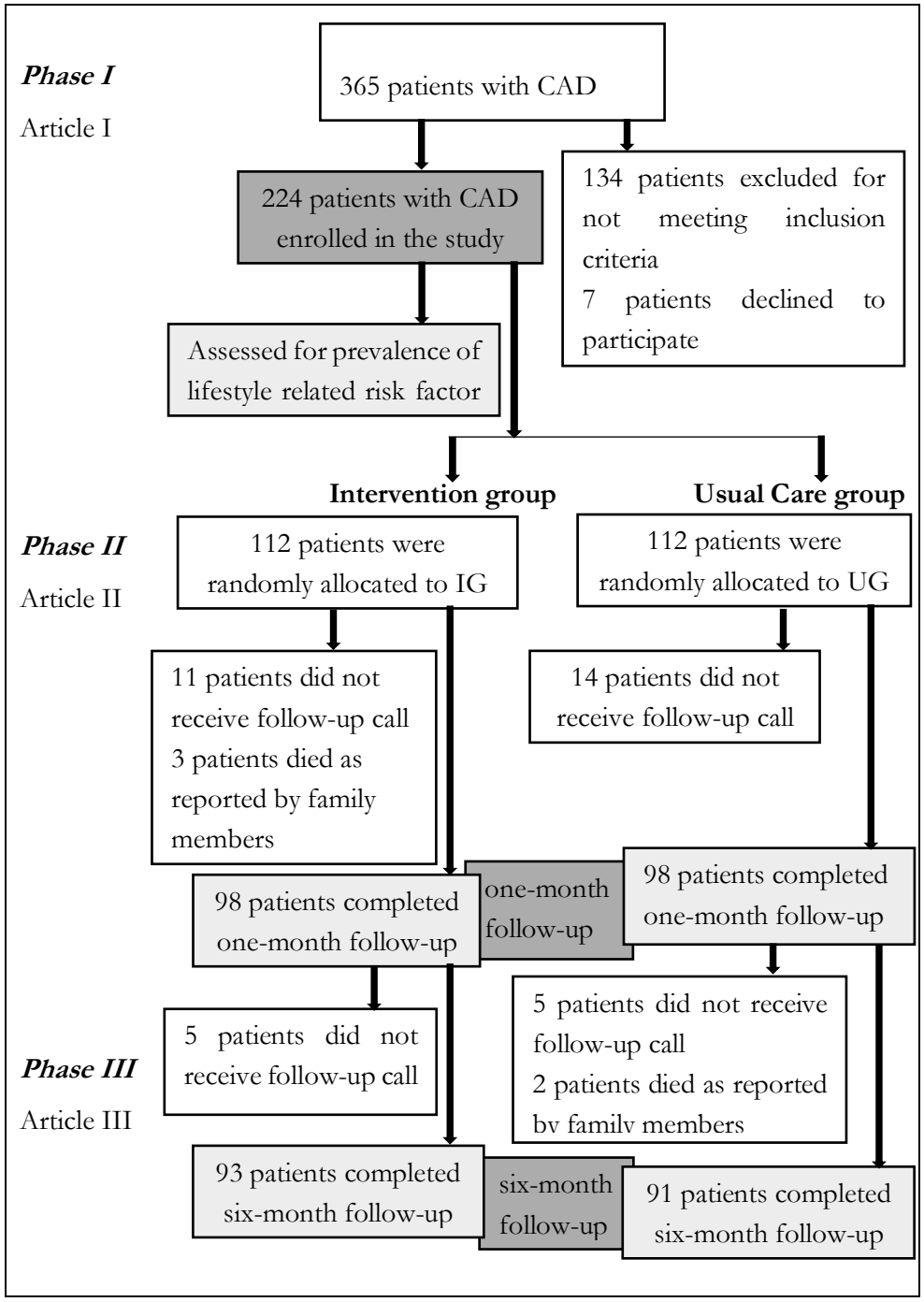


Figure 3. Study samples

4.4 Intervention

King's goal attainment theory (King, 1992) concentrates on how the goals of the client are attained through nurse-client transactions. This study focused on perception, the means of the exploration, interactions, transactions, goal setting, and feedback.

Perception: Perception is each person's representation of reality. In the present study, the investigator's perception was that lifestyle risk factor modification among patients with CAD would lower the risk of fatal heart attack, stroke, and hospital readmission. This perception was developed from the literature review, expert opinions, and experience of caring for patients with CAD. Patients' perceptions of the disease were influenced by factors such as age, gender, religion, caste, education, marital status, residential area, number of underage children, occupation, family income per month, duration of present illness, and other chronic disease.

Means of exploration: To assess information at baseline, structured interviews among patients with CAD was conducted on both IG and UG using the same standard questionnaire regarding diet, physical activity, adherence to medical therapy, perceived stress, smoking, and alcohol consumption. Available data on patients' recent histories of heart attack, stroke, hospital readmission, and medications was also obtained.

Interactions: The investigator interacted with patients with the aim of modifying their lifestyle risk factor habits. Both investigator and patients made judgments, took action, and reacted.

Transactions: The investigator and patients mutually identified their goals, that is, adherence to healthy lifestyle changes. Group and individual counseling were administered, and the investigator provided informational leaflets to patients to help them achieve their goals.

Action: Actions in the present study included group counseling for three to five patients and their family members and individual patient-centered counseling in IG. In addition, printed materials on lifestyle risk factor modification were provided to patients in IG.

Reaction: Reaction is the effect of action. Reaction was assessed by the administration of a standard questionnaire among CAD patients in both groups, and by gathering available data on patients' recent lifestyle habits and recent histories of heart attack, stroke, and hospital readmission during follow-up at one-month and six-month after intervention.

Goal achievement: A comparison of the lifestyle habits of patients with CAD in the IG and UG at baseline and during follow-ups helped to establish whether the goals had been achieved or not.

Feedback: Participants in the IG gave positive responses and were willing to attend the intervention and receive follow-up calls. However, patient feedback was not evaluated in this study.

In this study, the intervention consisted of counseling in a group of three to five patients with their family members, followed by individual counseling. Patients in the IG were invited into the counseling room to attend a counseling session with their family members. Counseling was provided on the day of discharge from hospital to minimize possible contamination between the IG and UG. During the counseling sessions, the investigator had a discussion with the patient and their family, and goals were set mutually to achieve the outcomes desired by the patient. Audiovisual material was used to explore the means to achieve the goals during the counseling, and each counseling session lasted roughly 45 minutes on average.

To develop the content of the intervention, the study team discussed the informational requirements of Nepali cardiac patients. The principal investigator drafted the content of the counseling and the leaflets, and then revised that content based on comments from the study team. The counseling content was prepared in both English and Nepali versions; however, only the Nepali version was used in this study. Experts from Nepal including a cardiologist, cardiac surgeon, and nurse specialist evaluated the face and content validity of the

proposed intervention in the Nepali context. It was important to check the extent to which the planned intervention would be valid and was likely to be effective among the target population. The experts suggested minor revisions, based on which a few sentences were modified. The content of the intervention was read and approved by experts in the field. The intervention included optimum information for the patients' requirements, in simple language to ease the understanding of patients with little or no knowledge about the disease. The content of the counseling intervention was developed based on recommendations issued by various heart associations and the findings of previous research (Eckel et al., 2014; Esselstyn, 2017; Jankovic et al., 2015; Lahtinen et al., 2018; Nishtar, 2002; Olendzki et al., 2006; Societies, 1998). The intervention was administered by the principal investigator to all 112 patients in the IG in their local language (Nepali). The leaflets were provided to patients after the counseling sessions; the information in the leaflets was illustrated and enhanced by simple informative pictures. During the counseling session information about the disease, the medical and surgical management of CAD, the importance of adherence to medication, and the adoption of healthy lifestyle behaviors to manage and prevent disease complications was provided. Patients in the UG received the usual care as well as short unstructured counseling regarding lifestyle modification. The content of the intervention addressed during the counseling is briefly described in the following subsections.

4.4.1 Information about the disease

Patients were given information about symptoms of CAD, how the disease progresses, the pharmacological, percutaneous, and surgical management that is available, and the importance of lifestyle changes to prevent complications.

4.4.2 Diet

Patients were advised to eat plenty of fresh fruit and vegetables, a variety of whole grain products, lean meat, fish, peas, beans, low-fat dairy products, and fiber-rich food. Patients were encouraged to avoid sweets and limit their salt intake. Patients were advised to limit the use of saturated fats and trans fats, and to replace these with monounsaturated fat and omega-3. Patients were advised

to avoid foods with empty calories (such as ice cream, cookies, cake, and pizza), as they do not provide any nutrition to the body.

4.4.3 Physical activity

Patients were advised to perform physical activity such as walking, jogging, cycling, swimming, gardening, or other moderate-intensity exercises on a regular basis. The importance of exercise to reduce symptoms, improve myocardial perfusion, lower high cholesterol and high blood pressure, improve blood sugar, and maintain a healthy weight was explained. The importance of replacing sedentary behavior with some physical activity was emphasized. Patients were encouraged to exercise for at least 30 minutes a day, at least five days a week. Patients were advised to start with low-impact aerobic activity to minimize the risk of musculoskeletal injury. Patients were taught to monitor their pulse at rest and during exercise, and to terminate the exercise if any warning signs or symptoms occurred.

4.4.4 Maintaining a healthy weight

Patients were encouraged to maintain a healthy weight by doing regular physical activity and adopting a healthy diet. Patients were taught to keep track of their weight by measuring their BMI. Patients were encouraged to keep their BMI between 18.5 and 24.9 kg/m^2.

4.4.5 Smoking and alcohol consumption

The life-threatening effect of smoking was explained to patients. Tips were given on how to quit smoking. Patients were encouraged to set a date on which to give up smoking, and to stick to their decision. Patients were informed that the craving would go away slowly as the nicotine faded from the body, and the first six weeks after quitting smoking would be harsh. Chewing gum, eating hard candy, making phone calls, squeezing a stress ball, and taking deep breaths were suggested as ways to distract themselves when cravings arose during the quitting process. Patients were informed about other behavioral therapy, supportive therapy, and some other validated cessation treatments, including medical

treatments. Tips were given for family members to support and encourage patients to quit smoking, such as offering them distraction during cravings, not nagging, lecturing, or scolding them, not criticizing them, and not offering them any form of tobacco. Patients were also advised to avoid drinking alcohol, or if they did drink it to do so in moderation.

4.4.6 Perceived stress

Patients were taught that in stressful situations, our body releases hormones (such as cortisol and adrenaline), which leads to high blood pressure, arterial damage, irregular heart rhythm, and a weakened immune system. Stress can increase the risk of adverse cardiac events such as heart attack and stroke, so patients were given suggestions for effective stress management. Patients were given tips to manage stress such as identifying the cause of stress, accepting things they cannot change, sharing their feelings, practicing gratitude, doing exercise, sleeping well, doing something they enjoyed every day, laughing at least once a day, maintaining a positive attitude, meditating, practicing mindfulness, doing deep breathing exercises, eating a healthy diet, and avoiding unhealthy habits.

4.4.7 Medication adherence

Patients were advised to take the medication the doctor had prescribed and stick to their treatment regimen. Patients were informed that high adherence improves health outcomes and reduces recurrent MI and mortality.

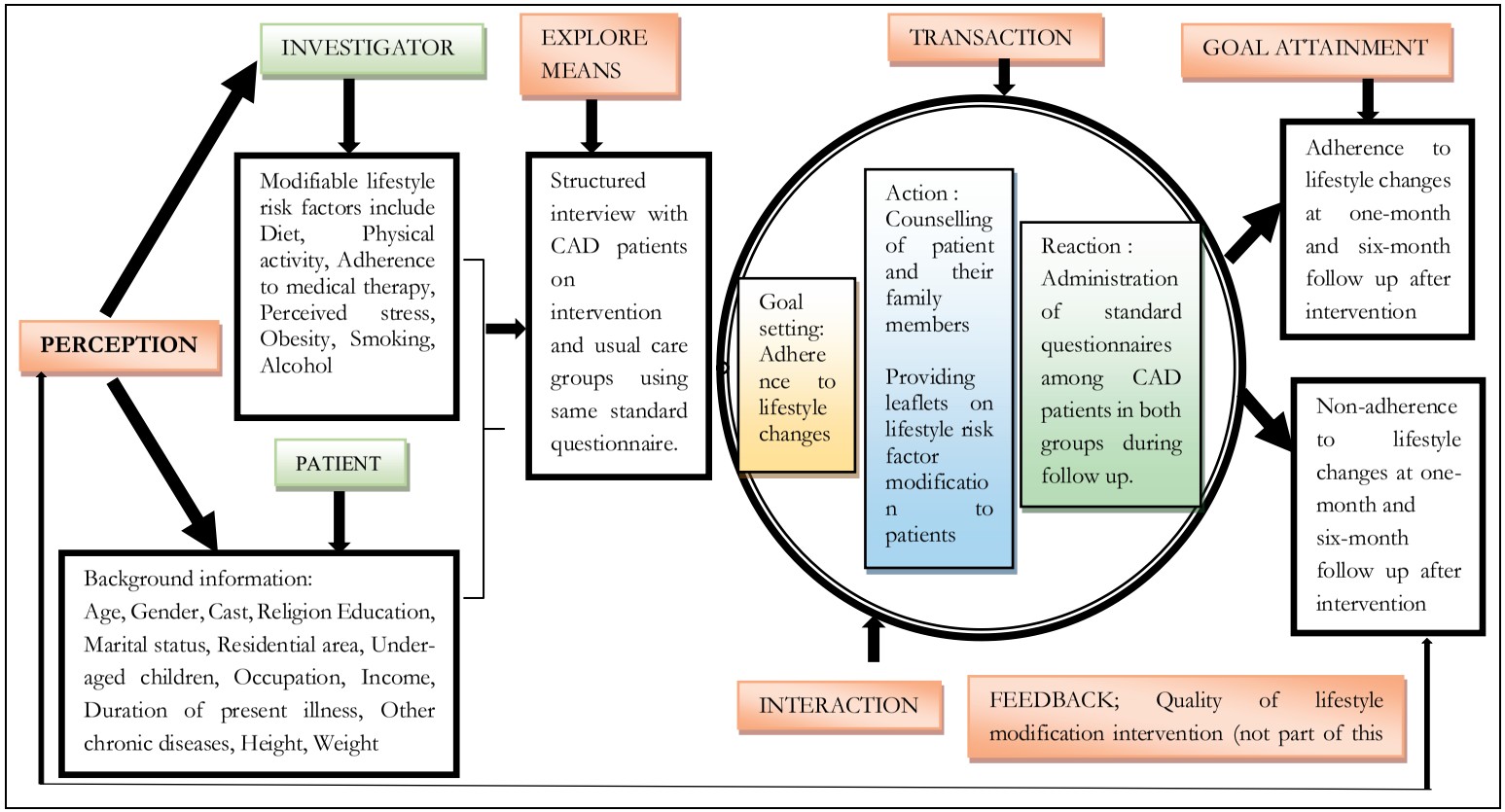


Figure 4. Conceptual framework for the intervention, modified Imogen King's Goal Attainment Theory

4.5 Study variables and instruments

The sociodemographic variables included in this study were 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 provinces).

The health-related variables included were comorbidity (yes, no), CAD severity (no significant stenosis or no coronary angiography performed, single-vessel disease, double-vessel disease, triple-vessel disease, left main stenosis), and revascularization status (no revascularization, percutaneous coronary intervention (PCI), CABG).

The main study outcome variables were multiple lifestyle-related risk factors, namely, diet, physical activity, perceived stress, overweight/obesity (BMI), smoking, alcohol consumption, and adherence to medication.

Standard instruments were selected to collect data on the multiple lifestyle variables based on extensive literature review. Instruments were used depending on the purpose of the research, quality of the instruments, affordability, reliability, and cultural acceptability of the items used in the instruments by the study population. The same questionnaire was used to collect data at all three time points: baseline, one-month and six-month follow-up. The instruments are presented in Table 2.

Table 2. Instruments for measuring lifestyle-related risk factors of CAD patients

Measured variables	Instrument	Dimensions	Items	Scale /Score	Catagories
Diet	Cardiovascular risk assessment questionnaire (Diet section)(Limited, 2018)	food habits	10	each item has four responses, with different scoring ranging from -10 to 10.	low risk group (-19 to 6), medium risk group (7 to 13) high-risk group (≥14)
Physical activity	Global Physical Activity Questionnaire of World Health Organization (World Health Organization, n.d.)	assess information on three domains: Work, travel to and from places, recreational activities	16	the sum of the total MET minutes of activity computed for each setting using equation that uses response codes from P1 -P16	patients who achieved at least 600 metabolic equivalent (MET) minutes throughout the week were considered physically active and those who achieve <600 MET minutes throughout the week were considered physically inactive group
Medication adherence	Morisky Green Levine Medication Adherence Scale (Morisky et al., 1986)	assess patient's adherence to prescribed medications	4	each yes response score '0' and no response score '1'	high adherence (3-4 score), medium adherence (1-2 score), low adherence (0 score)

Perceived stress	Perceived stress scale (Cohen et al., 1983)	assess patient's feelings and thoughts	10	4-pont likert scale (0=never, 1=almost never, 2-sometimes, 3-fairly often, 4=very often) Total scores range from 0 to 40 with higher score indicating higher perceived stress	low stress (0-13 score), moderate (14-26 score) high stress (27-40 score)
Smoking	The Fagerstrom Test for Nicotine Dependence (Heatherton et al., 1991)	assess smoking and nicotine dependency	6	score range from 0 to 3 depending on the response to items	high nicotoine dependency (6 or > score) low to moderate nicotine dependency (5 or <)
Alcohol consumption	Alcohol screening questionnaire, AUDIT (Babor et al., 2001)	identify healthy alcohol use and alcohol dependence	10	each response to the item has a score ranging from 0 to 4. All response scores are added for a total score, that correlates with a zone of use	four Zones: I-Low risk, II-Risky, III-Harmful and IV-Dependent

Body Mass Index	WHO reference (World Health Organization, 2000)	calculated based on patient's weight in kilograms divided by square of the body height in meters			underweight (BMI<18.5) normal weight (BMI 18.5-24.9) overweight (25-30) obesity (>30)

4.6 Data collection

The questionnaires were pilot tested after we had obtained expert opinions and face validity. The instrument was pilot tested among 10% of the study population. Based on the findings of the pilot study, some minor linguistic changes were made to two items in the Alcohol Use Disorders Identification Test questionnaire. Data on demographics, clinical variables, and baseline lifestyle-related risk factors were collected through face-to-face interviews. An electronic self-reported questionnaire was used to collect the data. Two links with same content/questionnaire were created separately for the IG and UG so that the data entered for different groups were available on separate Excel spreadsheets. The electronic form was used to ease the data entry process and minimize manual data entry errors. The questionnaire consisted of instruments to collect data on lifestyle-related risk factors. In addition, it included items concerning background and health-related characteristics. The same baseline instruments were administered by the same investigator through a phone call to collect data at the follow-ups. A telephone interview during follow-up was the only feasible option to collect data from patients scattered across different geographical regions. The telephone interviews took 20 minutes on average. A patient was considered lost to follow-up only if three attempted telephone calls made at three different times received no response from the patient.

4.7 Ethical considerations

Ethical principles were followed during each phase of the study including the study design, methods, data collection, and other relevant aspects (Doody et al., 2016; Modi et al., 2014). The study was ethically approved by the Institutional Review Committee of the hospital in Nepal. The hospital granted permission to implement the intervention and conduct the study after reviewing the data collection tools and content of the intervention. Additionally, ethical clearance from the Nepal Health Research Council Ethical Review Board (25/2018) was obatined. Permission to use the standard questionnaires in this study was obtained from the copyright holders. The original source is appropriately acknowledged with the appropriate bibliographical reference in Articles I–III

and in the summary. All study participants were informed of the nature of the study and their right to withdraw at any time without any adverse effects. Informed written consent to participate in the study was obtained from all the patients that participated. The confidentiality of the data was maintained. Data is stored securely and is currently available from the corresponding author. The patients in the UG received standard care from the hospital and unstructured short verbal counseling from the investigator. Throughout the study process, the principal investigator and co-authors had no conflict of interest.

4.8 Statistical analysis

Descriptive characteristics of the study population were expressed as frequencies and percentages for categorical variables. The continuous variables were presented as mean and standard deviations when data were normally distributed, and as median and interquartile ranges for data with nonnormal distribution. The Shapiro-Wilk test was used to check the normality of the data. Differences between the categorized groups were compared using a chi-squared test or Fisher's exact test. A student's t-test or Mann-Whitney test was used to compare differences between the groups with continuous variables. The two-tailed p-value <0.05 was taken as the level of statistical significance (Polit, 2011). All data analyses were conducted using Statistical Package for the Social Sciences version 27.0.

In Article I, the prevalence of lifestyle-related risk factors was presented as frequencies and percentages. Three risk groups—low (one or two risk factors), medium (three risk factors), and high (four to seven risk factors)—were categorized based on the number of risk factors present. To estimate the prevalence odds ratios (PORs) with 95% CIs for the risk groups with the study population's sociodemographic characteristics, we used multinomial logistic regression (Hosmer et al., 2013).

In Articles II and III, a general linear model (GLM) repeated measure analysis was used to analyze the intervention's effect on patients' lifestyle-related risk factor habits at one- and six-month follow-up. The group was used as the between-subject factor, and time as the within-subject factor. Risk factor habits were used as continuous variables, and mean values with their 95% CIs and p-

values for group, time, and group*time interaction were reported. Since the number of current smokers and alcohol consumers were very small, we did not report the GLM results for the variables of smoking and alcohol consumption (Polit, 2011).

5 RESULTS

5.1 Characteristics of the study population

Of the 365 patients assessed for eligibility for this study, a total of 224 participants were identified for enrollment. Thus, a total of 224 patients were included in the data analysis in Phase I (Article I, Table 2). Of these study participants, 76% were male, and the majority of participants were aged 51–60 years (30%). In total, 38% of participants had a primary education, 30% had retired work status, and 93% were married. Participants' median family income was 10,000 Nepali rupees (84 United States dollars). In total, 82% of participants had comorbidity, 32% had single-vessel disease, and 55% had undergone PCI. There were no statistically significant differences between the groups' baseline characteristics except for family income (Article II, Table 1). A total of 93 patients participated in the IG and 91 in the UG at six-month follow-up. No statistically significant differences between participants were found in the follow-up, except for family income (Article III, Table 1).

No differences in background characteristics between the groups was found during follow-up, indicating that loss to follow-up had no effect on the distribution of participants between groups. Both groups lost participants to follow-up in similar ways.

5.2 Prevalence of risk factors

At baseline, patients with one or two risk factors (33%) were categorized as the low-risk group, those with three risk factors (36%) as the medium-risk group, and those with four to seven risk factors (31%) as the high-risk group. The greatest number of male participants were in the medium-risk group (40%), whereas the greatest number of female participants were in the low-risk group (46%).

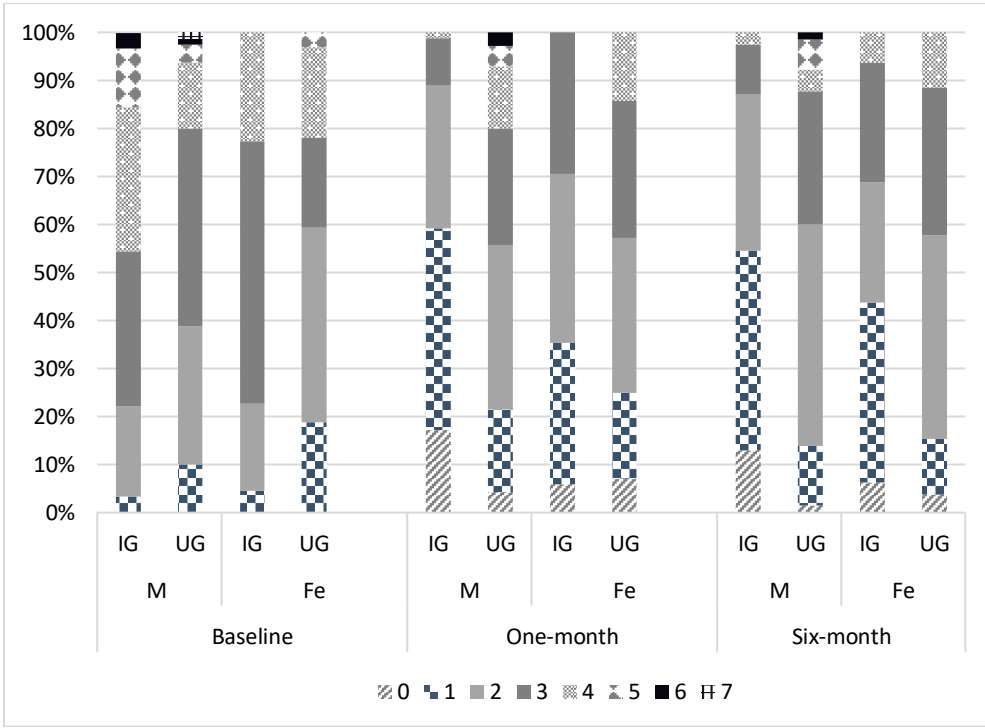
The majority of participants (97%) reported having perceived stress, followed by medication nonadherence (59%), smoking (32%), physical inactivity (31%),

unhealthy diet (30%), overweight or obesity (28%), and alcohol consumption (23%) (Article I, Figure 1). The majority of patients in this study had clustering of three risk factors (36%), followed by clustering of two (25%), four (22%), five (7%), and six or seven (2%) risk factors. A total of 8% of patients reported having only one risk factor at baseline (Article I, Figure 2).

Prevalence odds ratios were calculated using the low-risk group as the reference group. Significant differences between risk groups in gender, marital status, and having underage children was found (Article I, Table 4).

5.3 Number of lifestyle risk factors in study groups stratified by gender

The distribution of the number of risk factors between groups among male and female participants from baseline to six-month follow-up is presented in Figure 5. The clustering of risk factors among women was slightly lower than among men in both groups at baseline. In men, up to seven risk factor habits were clustered, whereas the highest clustering for women was five risk factors. All participants had at least one risk factor at baseline; however, at one-month and six-month follow-up, the number of patients with no risk factor habits had increased.



IG: Intervention group, UG: Usual care group, M: male, Fe: female, number of risk factors are numbered from 0 to 7

Figure 5. Number of risk factors between groups stratified by gender

5.4 Prevalence of lifestyle-related risk factor habits in study participants

Stress was the most prevalent risk factor in both groups at baseline. Overweight or obesity and alcohol consumption were the least prevalent risk factors in the IG and UG respectively at baseline. Both groups had improved their risk factor habits at one month. The improvement between baseline and one-month follow-up was higher compared with the improvement between one-month follow-up and six-month follow-up. However, greater improvement had been achieved in the IG than in the UG at both follow-up time points.

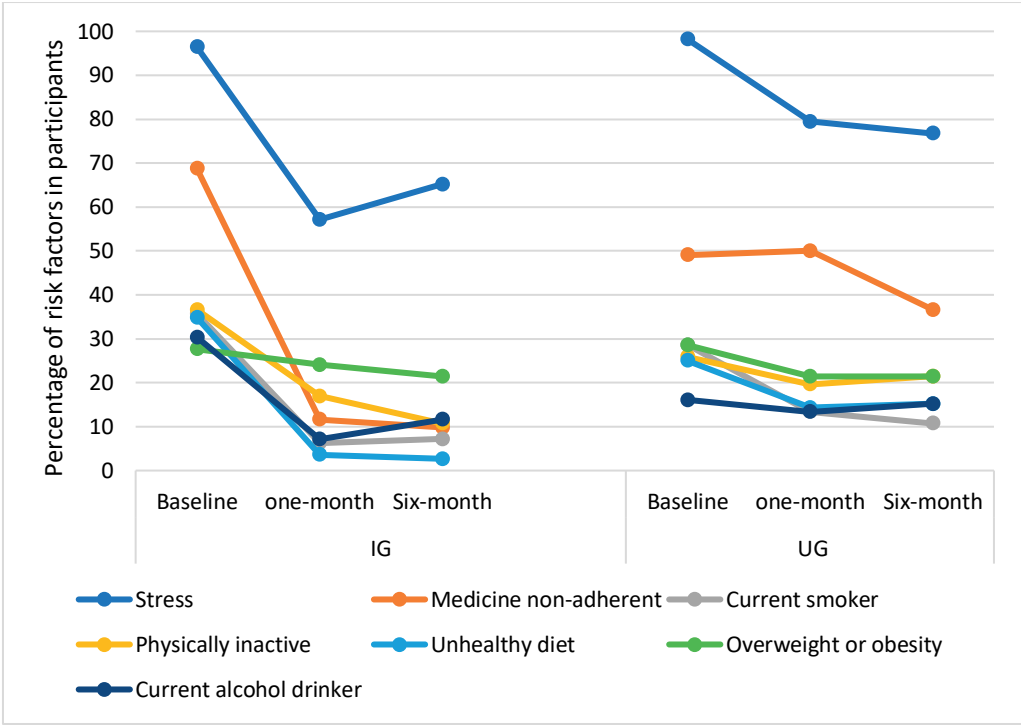


Figure 6. Pattern of lifestyle-related risk factors between groups

5.5 Cardiac events

Based on self-reported data from patients or their family members, four cardiac events had occurred in the IG at one-month follow-up, and one cardiac event had occurred in the IG at six-month follow-up. Similarly, 10 and six cardiac events had occurred in the UG at one-month and six-month follow-up respectively.

Table 3. Cardiac events at one and six-month follow up

Cardiac events	**One-month** (Phase II)		**Six-month** (Phase III)	
	IG (n=100)	**UG (n=98)**	**IG (n=93)**	**UG (n=93)**
MI, n (%)	2 (2.2)	7 (7.8)	1 (1.1)	4 (3.7)
PCI, n (%)	-	1 (1.1)	-	-
CABG, n (%)	-	2 (2.2)	-	-
Cardiac death, n (%)	2 (2.2)	-	-	2 (1.9)
Total, n (%)	**4 (4.5)**	**10 (11.2)**	**1 (1.1)**	**6 (5.6)**

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

5.6 Lifestyle-related risk factors: between-group comparison

Lifestyle-related risk factors did not differ significantly between the groups at baseline, except for adherence to medication ($p<0.001$). However, five risk factor habits and all seven studied lifestyle-related risk factors differed significantly between the groups at one-month and six-month follow-up respectively (Article III, Table2). Improvements in reported dietary habits, perceived stress, and medication adherence were found in both groups at one-month follow up. However, greater improvement was seen in the IG. Physical activity levels had improved significantly in the IG at one-month follow-up (Article II, Figure 2). At six-month follow-up, significant improvements in reported dietary habits, perceived stress, physical activity, adherence to medication, and BMI in the IG compared with the UG was found (Article III, Figure 2). A greater improvement in lifestyle habits was observed between baseline and one-month follow-up in both groups, compared with the one-month to six-month follow-up time.

However, BMI had improved significantly only at six-month follow-up in the IG (Article III, Figure 2).

5.7 Summary of study findings

This study found a high prevalence of lifestyle-related risk factors among the studied population. Every patient had at least one lifestyle-related risk factor, and a clustering of three risk factors was the most common (Article I). When the groups were stratified by gender, the clustering of risk factor habits was slightly higher in men than in women (Figure 5). Risk factor habits had improved in both groups (IG and UG) at the follow-ups; however, a greater improvement was found in the IG. A greater change in healthy lifestyle habits was found between baseline and one month compared with the change between one-month and six-month (Figure 6). Comparatively more cardiac events had occurred in the UG than in the IG at one-month and six-month follow-up (Table 2). GLM repeated model analysis showed greater improvements in reported dietary habits, perceived stress, physical activity, and adherence to medication in the IG compared with the UG at one-month follow-up (Article II). At six-month follow-up, a statistically significant effect of group-by-time interaction was found for diet, adherence to medication, physical activity, and perceived stress (Article III). The nurse-led, low-intensity lifestyle counseling intervention had significantly improved lifestyle habits in the IG compared with the UG at the follow-ups. A summary of the study findings is presented in Figure 7.

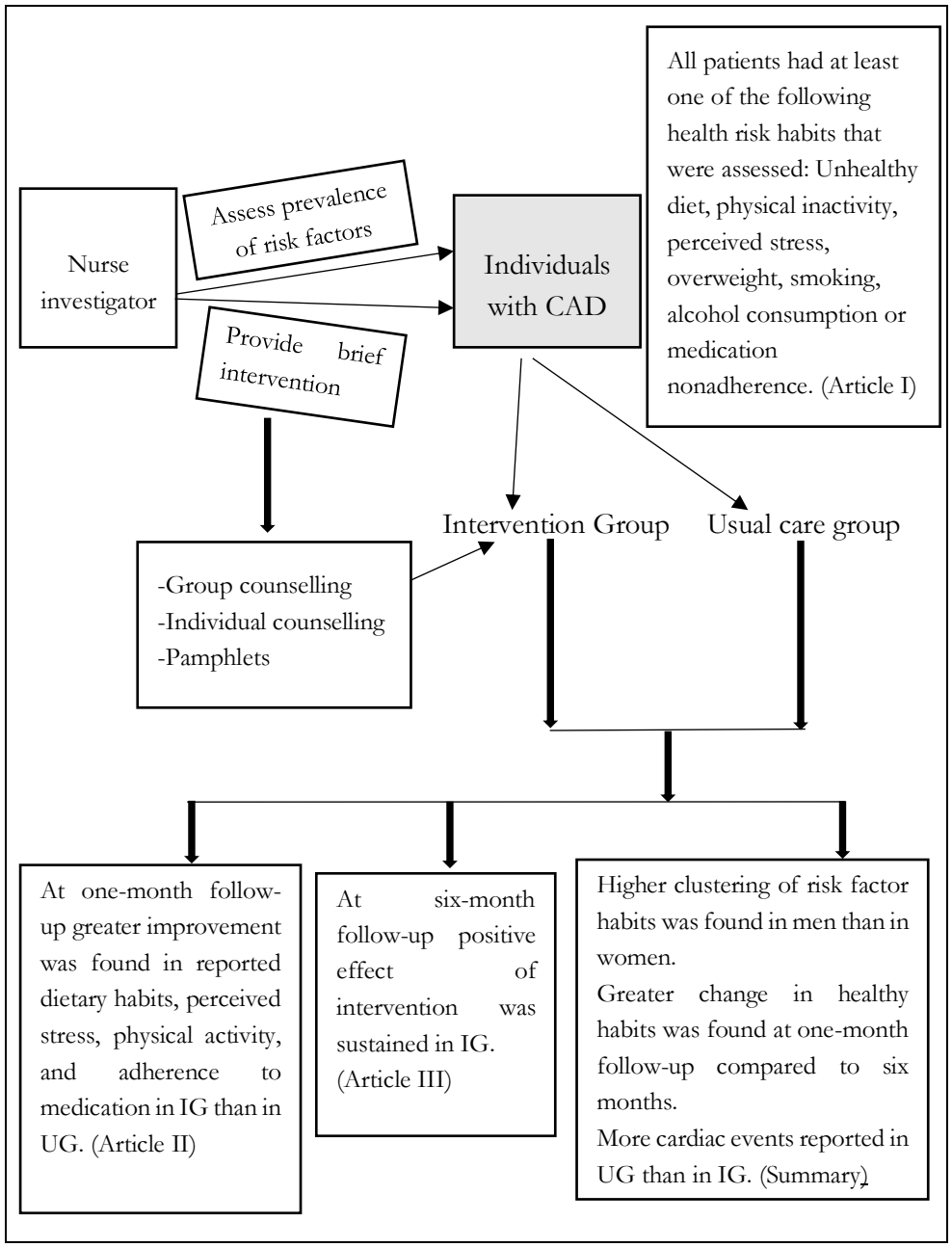


Figure 7. Summary of study findings

6 DISCUSSION

6.1 Discussion of main findings

The present study's findings showed that the majority of study participants had multiple lifestyle-related health risk behaviors (Article I). There is previous little research on the prevalence of unhealthy behaviors and the effectiveness of counseling interventions to bring about healthy lifestyle changes among CAD patients, especially in South Asia, including Nepal (Chow et al., 2015; Dod et al., 2010; Hardcastle et al., 2013). The findings of this study corroborate the findings of some earlier studies that reported a high prevalence of CAD risk factors among study participants (Dhungana et al., 2018; Ghimire et al., 2018; Khanal et al., 2018; Pieris et al., 2014). These studies reported high alcohol and tobacco use, overweight and obesity, fast food and soft drink consumption, low physical activity, and low fruit and vegetable consumption among their participants. These earlier studies were conducted among adolescents in municipalities in different districts in Nepal. In addition to the previously studied lifestyle-related risk factors, the present study also investigated perceived stress and medication adherence among CAD patients. This study's results revealed that perceived stress was the most prevalent risk factor, and nonadherence to medication was the second most prevalent risk factor, followed by smoking, physical inactivity, unhealthy diet, overweight or obesity, and alcohol consumption (Article I). Some previous studies found that both acute and chronic psychological stress contributed to mechanisms underlying cardiac events such as endothelial dysfunction and myocardial ischemia (Merz et al., 2002; Wirtz et al., 2017). The WHO and previous studies have included stress as a major nontraditional risk factor (Merz et al., 2002; Eckel et al., 2014; Wirtz et al., 2017). In the study of nonadherence to cardiovascular medications, Leiden et al. (2014) reported that nonadherence was often the dominant risk factor in poor health outcomes. Thus, we addressed perceived stress and medication adherence along with diet, physical activity, overweight or obesity, smoking, and alcohol consumption in the present study.

A nurse-led one-time intervention was found to be effective in the modification of lifestyle-related risk factors (Articles II and III). This study result is consistent with findings from previous RCTs and systematic reviews (Aminde et al., 2018; de Waure et al., 2013; Dod et al., 2010; Jepson et al., 2010; Sargent et al., 2012; von Gaudecker R., 2017). These studies found that behavioral change interventions reduced unhealthy lifestyle-related risk factors or promoted healthy behaviors. These studies included different health-related behaviors such as healthy eating, physical exercise, smoking, alcohol misuse, weight management, and stress management. Furthermore, like the present study these studies reported on the effectiveness of interventions to bring about healthy lifestyle changes in the short term (one month) or the longer term (one year or more). The studies were conducted among populations in high-income countries. The studies investigated one or two lifestyle habits, and they did not assess multiple simultaneous risk factors. However, the present study focused on an overall change in unhealthy lifestyle behaviors to prevent secondary complications and recurrent MI or death among CAD patients.

In the present study, a one-time nurse-led intervention was found to be effective at one-month follow-up, and its effectiveness was sustained at six-month follow-up (Articles II and III). Similarly, a previous study by McKinley et al. (2009) showed that a relatively short education and counseling intervention improved knowledge, attitudes, beliefs, and responses to acute coronary syndrome symptoms in individuals with CHD. Contrary to our findings, a study by S. Hardcastle et al. (2008) reported that multiple sessions of client-centered counseling reduced CHD risk factors. Their findings showed that patients who had more sessions had a greater reduction in risk factors, but a short intervention had no effect on behavior modification. This difference from our study findings is likely due to differences in the selection of study participants. The present study comprised patients with CAD, whereas the study by S. Hardcastle et al. (2008) only included participants who exhibited at least one CVD risk factor such as excess weight, hypertension, or hypercholesterolemia.

A greater improvement among the IG in reported dietary habits, perceived stress, physical activity, and medication adherence was obtained at the follow-ups in the present study. These findings corroborate previous studies (Chakhssi et al., 2018; Hardcastle et al., 2013; LIN et al., 2010; Momeni et al., 2016; Shrestha et al., 2020; Taitel et al., 2012). On the other hand, Hardcastle et al. (2008) reported that a

counseling intervention did not change participants' diet compared with a control group. The intervention in their study included nutritional information plus five face-to-face counseling sessions with a registered dietitian. The effectiveness of the intervention in our study may be attributable to the fact that our participants had recently experienced life-threatening cardiovascular events due to CAD, whereas the participants in the study by Hardcastle et al. (2008) had either excess weight, hypertension, or hypercholesteremia. During follow-ups, patients in both groups reported a reduction in their consumption of unhealthy items such as fried and starchy foods, sweet soft drinks, and others. Patients reported an increased intake of homegrown vegetables but an inability to afford fruit and fish due to their low-income levels. A previous study from Nepal also reported that some participants did not consume fruit and vegetables due to their low purchasing capacity (Ghimire et al., 2018).

Patients in IG reported an improvement in perceived stress, and this finding is in line with findings from previous studies (Chakhssi et al., 2018; Momeni et al., 2016). Patients reported high stress at baseline but less stress during follow-ups. High perceived stress among study participants at baseline may have been due to hospitalization, sudden onset of MI, or repeated occurrences of life-threatening MI. At the follow-ups, the patients in our study reported that they now became less upset when unexpected things happened; most patients reported that they very often felt they were able to control the important things in their lives, and they felt nervous or stressed only sometimes.

At the follow-ups, patients in the IG reported that they were physically active. The mean level of physical activity in metabolic equivalent minutes per week had increased in the IG at the follow-ups. In contrast, Hardcastle et al. (2013) reported that a motivational interviewing intervention had an inadequate effect on physical activity. However, their study results showed the effectiveness of a counseling intervention among study participants who were at high risk of CVD. Similarly, a systematic review by Lin et al. (2010) showed mixed effects of low-intensity physical activity counseling interventions among study participants. In the present study, most patients' physical activity came either from their work or from brisk walking. Patients in the IG reported an increase in their leisure time physical activity, such as continuous brisk walking for at least 10 minutes. Patients in both groups reported that they did not do recreational activities such as sports or fitness. A systematic review by Beenackers et al. (2012) showed that

people occupying high socioeconomic positions were more physically active during their leisure time compared with those in low socioeconomic positions. Occupational physical activity was more prevalent among those in lower socioeconomic positions (Beenackers et al., 2012). Low levels of recreational physical activity during leisure time among our study participants may be partially attributed to the fact that our participants had low socioeconomic status compared with participants included in studies in high-income countries.

Patients in the IG reported a higher adherence to medication than the UG at one-month and six-month follow-up. In contrast to this finding, a previous RCT conducted at a single center in the Netherlands found no effect of intervention on behavioral change strategies to improve medication adherence in patients with CVD. The intervention program consisted of a nurse-based intervention providing structured information and motivational counseling, and a personalized website to visualize cardiovascular risk levels. The study's findings showed a higher adherence in the UG than in the IG (Sieben et al., 2019). The structured usual care applied as part of the usual care program to all cardiovascular patients in the given setting may have resulted in the high medication adherence of both groups in the study. However, our study findings are consistent with the findings of previous studies from the Midwestern United States (Taitel et al., 2012) and Nepal (Shrestha et al., 2020). Both of those studies reported that a brief counseling intervention improved medicine adherence and persistency compared with a comparison group. In the present study, patients in both groups reported that nonadherence was particularly due to forgetfulness about taking their medication.

No effect of the intervention on BMI was obtained at one-month follow-up. However, at six-month follow-up, patients in the IG reported they had achieved a decrease in body weight, reaching a statistically significant difference. The lack of impact of the intervention on BMI at one month may be due to the short follow-up time. The present finding is in line with the results of a previous study on the impact on health literacy of an educational intervention for patients living with CAD. The study reported an improvement in health behaviors leading to significant improvements in weight loss at six-month follow-up in the group that had received video and text interventions (Eckman et al., 2012).

Patients in both groups reported improvements in smoking habits at the follow-ups compared with the baseline. However, a greater improvement was seen among IG patients. IG patients who smoked at baseline reported either a complete cessation of smoking or a reduction in the number of cigarettes smoked per day at the follow-ups. In line with our findings, a previous systematic review on individual behavioral counseling for smoking cessation reported that when pharmacotherapy was not offered to any of the participants, face-to-face individual counseling from a health care worker was more effective for smoking cessation (Lancaster et al., 2017). Another systematic review and meta-analysis of the efficacy of smoking cessation interventions in low- and middle-income countries also revealed the benefit of minimal interventions such as brief advice compared with the usual care in aiding smoking cessation (Akanbi et al., 2019).

Patients in the IG reported improvements in alcohol consumption habits at the follow-ups compared with the baseline. Patients who consumed alcohol at baseline reported either complete abstinence or a reduction in the amount of alcohol consumed during follow-ups. In line with our findings, a previous review of reviews by Jepson et al. (2010) reported on the effectiveness of counseling interventions to change health behaviors for mild to moderate alcohol consumption. In contrast to this study's finding, an RCT on the effectiveness of psychological treatments for alcohol use disorder delivered by community-based counselors in Nepal reported no significant effect of the intervention on alcohol use reduction (Jordans et al., 2019). The variance between the abovementioned study and this study may be due to the variation in the included participants. In the other study, the participants had been diagnosed with alcohol use disorder; in the present study, more than half of participants reported that they had never drunk alcohol, and most of those who did consume alcohol reported only mild to moderate alcohol consumption levels.

A comparatively greater number of cardiac events had occurred in the UG at one-month and six-month follow-up in this study. Due to the smaller sample size and lack of medical data, and because the study is based on self-reported data from patients or family members, there is no evidence to suggest that the intervention improved the rate of cardiovascular events. This study's findings corroborate those of a systematic review and meta-analysis of RCTs, which assessed the effects of education on mortality, morbidity, health care costs, and HRQL in people with CHD. The results yielded weak evidence to suggest that

education reduced mortality and cardiac morbidity outcomes. However, the systematic review did reveal that education could improve HRQL and decrease health care costs. The authors of the review supported the continuation of education as an intervention for CHD secondary prevention (Brown et al., 2013).

As expected, an intervention that focused on lifestyle-related risk factor habits improved healthy lifestyle changes among CAD patients, thus confirming our study's hypothesis. These results support the evidence that patients' adherence to healthy lifestyles increases with a nurse-administered brief education and counseling intervention. Health care policymakers and hospital administrators should be aware of the importance of patient education to ensure adherence to healthy lifestyle behaviors. There was a gap in patients' knowledge about the importance of lifestyle changes. Most patients had neglected healthy behaviors, and some patients reported that they had been unaware that their lifestyle constituted cardiovascular risk behavior; this was also reported by participants in a previous study (Ghimire et al., 2018). Nurse educators should be made available for each patient, to assess the individual patient's needs and make problem-solving plans. Steps must be taken to ensure that every patient receives a good quality of education based on evidence-based practice.

6.2 Validity and reliability of the study

Validity and reliability are determined by the quality of the quantitative method, design, instruments, and data analysis employed in a particular study. Validity defines the extent to which concepts are accurately measured in a quantitative study. Reliability refers to the consistency, stability, and repeatability of the measures obtained (Polit, 2014).

In Phase I, a descriptive study was designed to investigate the prevalence of lifestyle-related risk factors. In Phases II and III of this study, a new intervention was out to compare it against existing usual care. Choice of research design is important to produce valid and reliable evidence, so we used a randomized controlled design (Polit, 2014). Consolidated Standards of Reporting Trials (CONSORT) criteria were used to ensure the adequate reporting of the RCT. The design, analysis, and interpretation of the trial was reported using a 25-item checklist and a flow diagram from the CONSORT statement (Borglin et al.,

2010; Zwarenstein et al., 2008). To measure the effectiveness of an intervention—that is, whether the intervention works in a usual care setting—one should design a pragmatic trial. In this way, if the intervention's effectiveness is established, the study results will be applicable and generalizable to patients in a real setting that are similar to the participants in the trial. The study design must control for all possible sources of extraneous variation that may affect the study results. The present study considered the randomization and potential biases described in the extended CONSORT statement. However, no blinding was used, since limited resources meant that it was not practical or feasible to do so. Nonetheless, at the time of enrollment, neither the participants nor the researcher knew to which group each participant would be assigned.

Homogeneity between the IG and UG was obtained for most sociodemographic variables, but not all. There was a three-year difference in the mean age of patients between the IG and UG, and a 9% difference in the number of male participants in the two groups. Almost 13% more patients had had PCI in the IG. The IG also exhibited fewer prognostic measures such as older age. These differences in baseline characteristics between the groups was the result of chance. The differences may have had some effect on the study's results regarding the effectiveness of the intervention. We include this as an important limitation of the study.

Appropriate instruments were chosen to measure each lifestyle variable in the study. After permission had been obtained from the original creators of the instruments, they were translated from English to Nepali and back translation was done. Cultural and content validation of the instruments was obtained from the experts. Instruments had previously been validated, and there was evidence of their use in different situations among different sample groups. However, the diet questionnaire was obtained from the Metagenics company, which had designed it for use in their clinics, and it had not been validated. The questionnaires consisted of self-reported items, which were pre-tested to evaluate the validity and feasibility of the instruments and their use in the Nepali context. Preliminary feedback related to the study items was obtained from participants in the pilot study. Based on their comments and a statistical and inferential analysis of their responses, minor linguistic changes were made to some items. To avoid any bias the data from the pre-test were not included in the main study.

All participants received the intervention from the same investigator, which helped to ensure the consistency of the intervention. Structured interviews were conducted, and the same investigator asked a standard set of questions to all the participants in a uniform way, thus reliability of conducting interviews was maintained. The principal investigator provided the face-to-face intervention and called the patients for follow-up, which further helped to ensure consistency. The research protocol was carefully planned, standardized, and executed, thus controlling for performance bias (Borglin et al., 2010). The study was carried out with a small sample from a single hospital in Nepal; hence, the study's findings cannot be generalized to the larger population.

One strength of this study is that it focused on the number one cause of death and disability globally and was conducted among an under-studied population in Nepal. Another strength of the study is its simultaneous examination of multiple lifestyle-related risk factors among CAD patients, which has rarely been done in previous studies. In addition, internationally evaluated standard tools were used to assess each lifestyle behavior among the study participants. The random control design and the high response rate (one-month 87.5%, six-month 82.1%) among study participants is another strength. Another important strength of the study is the sustainability and feasibility of the intervention. The intervention is easy to implement at low cost in a clinical setting. The intervention was administered by the principal investigator to all the participants in the IG, ensuring the same quality of intervention for all. To our knowledge, this is the first study to assess the effect of an intervention on seven different lifestyle-related risk factors among CAD patients in Nepal.

The study results were based on self-reported data from participants. This may have led to the underreporting of unhealthy behaviors, due to social desirability bias. It may also have led to recall bias in both study groups. These are potential limitations of the study. To address recall bias, we used direct versus indirect questions and proxy subjects in addition to patients. At baseline, data were collected using face-to-face structured interviews; however, during follow-ups we collected data through telephone interviews. The use of these two different methods of data collection may be another limitation of the study. However,

earlier studies have demonstrated that telephone interviews can produce data of high quality, comparable to the face-to-face mode of data collection (Canning et al., 2018; da Silva et al., 2014). Another limitation may be cross-contamination between the study groups; however, to minimize possible contamination, the intervention was administered to the IG on the day of discharge. The study was not blinded, which may have caused bias due to the investigator's probable unconscious inclination toward the IG. The study was conducted in a single center with a relatively small sample, and thus the generalizability of the results is limited.

6.3 Conclusions

This study provides a descriptive summary of the prevalence of lifestyle-related risk factors among CAD patients in Nepal. The study's findings show a high prevalence of lifestyle risk factors among CAD patients, which indicates inadequacies in the current health strategy.

This study offers notable evidence of the effects of a nurse-led one-time intervention in bringing about multiple lifestyle changes among CAD patients. This is the first intervention study to assess seven lifestyle-related risk factor habits simultaneously among CAD patients in Nepal. The positive effects of the nurse-led intervention at one-month and six-month follow-up indicate that the counseling intervention (supplemented with informational leaflets) developed in this study can help to change CAD patients' lifestyle-related risk factor habits. Seven lifestyle-related risk factors; unhealthy diet, physical inactivity, perceived stress, medication nonadherence, overweight or obesity, smoking, and alcohol consumption were studied simultaneously in the present study. This study adds valuable information to the current research evidence and builds an important foundation on which nurses and health care mangers can develop strategies for patient education and counseling by setting individual lifestyle goals.

6.4 Implications for nursing practice, management, education, and research

The results of the present study are encouraging and offer the following implications for practice, management, education, and future research.

Implications for practice and management

- Health care professionals/nurses need to be aware of the high prevalence of lifestyle-related modifiable risk factors in patients with CAD.
- An effective intervention based on evidence-based knowledge needs to be planned to modify patients' health risk behaviors.
- The intervention needs to be implemented as part of routine care, to reverse disease progression and prevent secondary complications.
- Nursing/health care managers must focus on creating opportunities for staff to update their knowledge and skills so that they can educate patients and their family members regarding healthy lifestyle modifications in their working area.
- Patients should be offered systematic support and information about the importance of adopting a healthy lifestyle during each hospital visit, and through telephone conversations when a direct visit to the hospital is not feasible.

Implications for education

- Nurses should have opportunities for continuous education and training that is evidence-based.
- Nursing education should address the topic of patient education. Patient education about disease and possible complications motivates patients to modify their unhealthy lifestyle behaviors.

Implications for research

- Future studies should examine the effect of interventions to assess longer-term changes in lifestyle-related risk factors among patients, using longitudinal study designs.
- There is a lack of research that explores multiple lifestyle-related risk factors simultaneously. More evidence is needed in this area, especially from low- and middle-income country settings.
- Studies need to be carried out to investigate the cost-effectiveness, feasibility, and sustainability of interventions in terms of reducing health care costs and rates of cardiac events and rehospitalization.
- More extensive and longer-term experimental research among larger populations is recommended to confirm and generalize the effectiveness of the intervention for lifestyle modification.

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8 APPENDIX

Appendix Table: Studies on lifestyle factors and CAD risk

Risk factors studied	Author, year	Study design	No. of cases	Results	Effect size
Diet	Esselstyn, 2017	RCT	198	Whole food and plant-based nutrition with minimal intake of animal products can eliminate future cardiac events and can also reverse atherosclerosis.	Patients who were adherent to plant-based nutrition had a reduced number of cardiac events compared to non-adherent patients. Almost 99% of patients who were adherent to dietary intervention did not have any major cardiac events (use ref).
	Mente et al., 2009	Systematic review (pooled analysis)	29209 (prospective cohort studies) 7204 (RCTs)	Intake of vegetables, nuts, fruits, fish, whole grains and fiber have valid associations with CHD.	The pooled analysis of cohort studies showed that consumption of fish (relative risk [RR], 0.81 [0.70-0.92]), fruits (0.80 [0.66-0.93]), nuts [0.70 [0.57-0.82]], vegetables (0.77 [0.68-0.87]), whole grains (0.81 [0.75-0.86]) were associated with significantly lower risk of CHD.

Physical activity	Wahid et al., 2016	Systematic review and Meta-analyis	3,439874	Improvement in health can be gained by doing a small amount of physical activity rather than staying inactive	An increase from being inactive to achieving recommended Physical activity levels was associated with a lower risk of CVD mortality by 23%, CVD incidence by 17%, and T2DM incidence by 26% (relative risk [RR], 0.77 [0.71-0.84]), (RR, 0.83 [0.77-0.89]), and (RR, 0.74 [0.72-0.77]), respectively, after adjustment for body weight. (need to paraphrase)
	Lear et al., 2017	Prospective Cohort study	168,916	Increasing recreational and non-recreational physical activity lower the risk of mortality and CVD events.	Compared with low physical activity moderate and high physical activity were associated with a greater reduction in mortality (hazard ratio 0·80, 95% CI 0·74–0·87 and 0·65, 0·60–0·71; p<0·0001 for trend), and major CVD (0·86, 0·78–0·93; p<0·001 for trend).
	Lahtinen et al., 2018	Cohort study? / longitudinal	1,746	Any amount of leisure-time physical activity reduces risk of cardiac death in patients with stable CAD.	Patients who remined inactive and became inactive had 4.9 (95% CI 2.4 to 9.8, p <0.001) and 2.4-fold (95% CI 1.3 to 4.5, p <0.01) risk of cardiac death compared to patients who were at least irregularly active.
Smoking	Hacksh aw et al., 2018	Systematic review and meta-analysis	5,66 million	There is no safe level of smoking for cardiovascular disease. Smoking as less as one cigarette per day also	The pooled relative risk for CHD among men and women was 1.48 (95% CI 1.30-1.69) and 1.57 (95% CI 1.29 – 1.91) for smoking one cigarette per day and 2.04 (95% CI 1.86 – 2.24)

		of cohort studies		carries greater risk of developing CHD.	and 2.84 (95% CI 2.21 – 3.64) for smoking 20 cigarettes per day respectively.
	Ning et al., 2019	Community-based cohort study (with nearly 3 decades of follow-up)	13,355	A dose-response relationship exists between pack years of smoking and CHD outcome. The elevated risk of CHD persists for up to 20 years after smoking cessation. Smoking prevention and early smoking cessation are crucial for overall cardiovascular health.	Compared with current smokers, smoking cessation for <5 years had a Hazard ratio of 0.77 (95% CI 0.63-0.93) and smoking cessation for ≥ 30 years had a Hazard ratio of 0.47 (95% CI 0.39-0.56) for CHD.
Medica-tion adher-ence	Corrao et al., 2011	Cohort study	242,594	Patients who followed antihypertensive drug therapy had a reduced risk of cardiac events compared to patients who had discontinued at least one episode of treatment.	Compliance with antihypertensive medications had a 37% reduced risk of cardiovascular outcomes (95% CI 34-40%)
	Gehi et al., 2007	Prospective study	1015	The risk of cardiovascular events is 2-fold greater in self-reported medication	Self-reported medication nonadherence increases the risk of cardiovascular events (hazard ratio, 2.3; 95% CI, 1.3-4.3)

				nonadherent patients with stable CHD.	
Stress	Yang et l., 2015	Case-control study	352,	High perceived stress was found to be the independent risk factor for CAD in young Chinese male patients after adjustment for multiple cardiovascular risk factors.	Perceived stress was independently correlated with CAD in young patients (OR, 1.81;95%CI, 1.23-2.66). The perceived stress score was correlated with levels of epinephrine (r=0.45) and norepinephrine (r=0.41).
	Richar dson et al., 2012	Systematic review and Meta-analysis	118,696	Risk of incident CHD, that is new diagnosis of, hospitalization for, or mortality secondary to CHD is associated with high perceived stress.	A risk ratio of 1.27 (95% CI, 1.12-1.45) for the magnitude of the relation between high perceived stress and incident CHD was found.

Alcohol consu-mption	Briasoulis et al., 2012	Systematic review and Meta-analysis	227,656	The risk of hypertension increases with heavy alcohol consumption in both males and women. Low to moderate alcohol consumption has shown a decreased risk of hypertension among women but there is a trend toward increased risk in men.	Compared with nondrinkers, men with alcohol consumption <10 g/d had an increased risk of hypertension (relative risk [RR], 1.03; 95% CI, 0.94-1.13) whereas heavy alcohol consumption of > 30 g/d had a significantly increased risk (RR, 1.77; 95% CI, 1.39-2.26). The protective effect of alcohol consumption of < 10 g/d was found among women (RR, 0.87; 95% CI, 0.82-0.92), however heavy alcohol consumption of <30 g/d had a significantly increased risk of hypertension in women (RR, 1.19; 95% CI, 1.07-1.32).
	Whitman et al., 2017	Longitudinal study	14,727,591	Alcohol abuse increased the risk of cardiac diseases, demonstrating that alcohol in excess is cardiotoxic.	Excess alcohol consumption was associated with an increased risk of myocardial infarction (hazard ratio 1.45; 95% CI, 1.40-1.51)
Overw-eight	Logue et al., 2011	Randomized controlled trial	6082	The risk of fatal CHD events is high among obese men.	Compared to participants with BMI 25-27.4 kg/m^2 the risk of fatal CHD events was increased in men with BMI 30-39.9 kg/ m^2, after adjusting for age, sex, and statin treatment hazard ratio (HR) is 1.75 (95% CI 1.12 to 2.74) and after adjusting for known CVD risk factors and deprivation HR is 1.60 (95% CI 1.02 to 2.53)

	Tirosh et al., 2011	Prospective study	37, 674	Elevated BMI during adolescence and adulthood is an independent predictor of CHD.	Elevated adolescent BMI was a significant predictor of angiography-proven CHD (hazard ratio 5.43; 95% CI, 2.77-10.62). High BMI during adolescence and adulthood were independently associated with CHD (p=0.048 for interaction).

PUBLICATION 1

Lifestyle-related risk factors among patients with coronary artery disease in Nepal

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Scandinavian Journal of Caring Sciences 2020;34: 782-791
doi:10.1111/scs.12784

Lifestyle-Related Risk Factors Among Patients with Coronary Artery Disease in Nepal

Abstract

Background: Coronary artery disease (CAD) is the leading cause of death and morbidity globally. South Asia, including Nepal, has higher risks for CAD due to relatively higher exposures to risk factors. This study evaluated the prevalence of lifestyle-related risk factors and the associations of risk factors with socio-demographic variables among CAD patients.

Methods: A cross-sectional study was conducted among CAD patients (n=224) admitted to a national heart centre in Nepal. Data on dietary habits, smoking, alcohol consumption, stress, physical activity, overweight or obesity, and adherence to medication were collected using standard questionnaires. The numbers of risk factors were categorised into three groups (1–2= low, 3= medium, 4–7=high). Data analysis was performed by cross-tabulation and multinomial logistic regression. Prevalence odds ratios (POR) and their 95% confidence intervals (CIs) were used as the measure of the associations.

Results: The prevalence of risk factors among patients varied from 23% to 97%, with stress being the most prevalent, and current alcohol consumption the least. The majority of study patients had multiple lifestyle-related risk factors. Male patients (POR for medium vs. low 2.83; 95% CI 1.3, 6.18) and patients with high incomes (POR for high vs. low 2.53; 95% CI 1.10, 5.83) had higher odds of being in the medium- and high-risk group respectively.

Conclusions: Lifestyle-related risk factors were highly prevalent among CAD patients. Various socio-demographic variables were associated with the risk groups. Intervention studies on lifestyle risk factor modifications among this target group are recommended.

Keywords: Coronary artery disease, risk factors, lifestyle, patients

Introduction

Coronary artery disease (CAD) is one of the major cardiovascular disorders, resulting in complete or partial blockage of the arteries that provide oxygen and nutrients to the heart (1). CAD, also known as coronary heart disease, has been consistently ranked as the number one cause of death and disability globally (2-5). Cardiovascular diseases account for 17.9 million deaths annually, representing 31% of all global deaths (5). Although deaths from cardiovascular disease have declined considerably in high-income countries in the past few decades, CAD remains a leading cause of morbidity and mortality worldwide (3, 5, 6).

More than three quarters of deaths from cardiovascular disease take place in low- and middle-income countries (5). Due to both pathophysiological and life course-related risk factors, South Asians have a higher risk for CAD (7). CAD is the leading cause of death in Nepal, accounting for 18.7% of total deaths (2).

Previous literature shows that cigarette-smoking, physical inactivity, obesity or overweight, unhealthy diet, excessive alcohol, excessive stress, diabetes, hypertension and high blood cholesterol are established risk factors for cardiovascular events (8, 9). However, there are few studies on cardiovascular risk factors conducted in Nepal. One study conducted in a tertiary hospital setting in Nepal reported that patients' modifiable risk factor habits were stress, sedentary lifestyle, fatty diet and smoking (10). A community-based cross-sectional study in Nepal reported that the lifestyle-related risk factors for cardiovascular diseases were smoking, alcohol consumption, insufficient fruit and vegetable intake, insufficient physical activity, and obesity (11). An earlier study showed that proper management of these modifiable risk factors reduced sudden cardiac death rates, myocardial infarction, stroke, and the need for revascularisation (12). In addition, adherence to cardiovascular medication is another main factor in risk reduction for adverse cardiac events, including mortality (13, 14). Although several studies have reported on risk factors for CAD, most of these studies do not report on the prevalence of lifestyle-related risk factors among patients diagnosed with CAD. To our knowledge, the literature remains sparse in this area, especially for low- and middle-income countries. It is important to monitor lifestyle-related risk factors, along with strategies for disease prevention and management, in order to improve patients' prognosis and hence reduce the burden of CAD. In this study, we aimed to investigate the prevalence of lifestyle-related risk factors, and to examine the associations of risk factors with socio-demographic variables among CAD patients.

Methods

Study design and participants

A cross-sectional study was conducted to evaluate the prevalence of lifestyle-related risk factors among CAD patients. CAD patients diagnosed by physicians (ICD-10-CM Section I20–I25) were checked systematically on the list of patients admitted to the Sahid Gangalal National Heart Centre (SGNHC) in Kathmandu, Nepal between 1 May and 31 July 2018. In total, 224 CAD patients were included in the study. Patients who met the following criteria were included: aged over 18 years, clinical diagnosis of CAD, ability to communicate in Nepali or English, and accessible by telephone. Patients with congenital heart disease, valvular heart diseases, high-risk cardiac conditions and impaired cognitive functions were excluded. Standard questionnaires, which were in English, were translated and checked for content validation in Nepali. The Nepali version of the questionnaire was pretested among 10% of the total study population before data collection. Individual face-to-face structured interviews were conducted to collect the data, taking approximately 25 minutes for each patient. The data were collected using computer/mobile-assisted online questionnaire forms, to avoid possible errors and ensure the quality of the data. Written informed consent was obtained, and the confidentiality of information provided by patients was ensured.

Measurement of variables

Lifestyle-related risk factors

Seven lifestyle-related risk factors were included in this study: unhealthy diet, physical inactivity, non-adherence to medication, perceived stress, overweight or obesity, smoking, and alcohol consumption (Table 1). Three risk groups were created based on combinations of the seven studied risk factors: patients with one or two risk factors were in the ‘low-risk’ group, patients with three were ‘medium risk’, and patients with four to seven were ‘high risk’. Clinical data on CAD severity, co-morbidity and revascularisation were obtained from hospital records. Culturally validated standard instruments were used to collect data on each of the lifestyle risk habits.

- Dietary habits: data on diet were collected from the diet section of the cardiovascular risk assessment questionnaire (15). The questionnaire consists of 10 questions, each measured on a scale of 0–10, with a score for each option. Three risk groups were then defined based on the scores: low risk for a score of -19 to 6, medium risk for 7 to 13, and high risk for 14 and above (15).

- Physical activity: the Global Physical Activity Questionnaire was used to collect information on three settings for physical activity and sedentary behaviour (16): activity at work, travel to and from places, and recreational activities. In total, 16 items were included on the questionnaire, and the metabolic equivalent (MET) minutes of activity for each setting were computed. World Health Organization (WHO) recommendations on physical activity for health were said to be met if a patient achieved at least 600 MET minutes throughout the week through activity during their work, transport and leisure time (16).
- Medication adherence: the Morisky Green Levine Medication Adherence Scale was used to assess adherence to medical therapy. This is a four-item scale with yes or no responses, coded in the data as 0 or 1. In the analysis, the four items were summed to form a scale of 0–4, categorised into three groups: low adherence for a score of 0, medium adherence for a score of 1–2, and high adherence for a score of 3–4 (17).
- Perceived stress: the Perceived Stress Scale was used to assess stress by asking about the patients' feelings and thoughts. It consists of 10 questions, each with five possible responses (never, almost never, sometimes, fairly often, very often). The total score was calculated by summing the 10 items, categorised as low (scores of 0–13), moderate (14–26) and high (27–40) perceived stress (18).
- Body mass index (BMI): BMI was calculated as weight in kilograms divided by height in metres squared, and sorted into four categories using the WHO standard classification for BMI (19). The four categories were underweight (BMI <18.5), normal weight (BMI 18.5–24.9), overweight (BMI 25–30) and obese (BMI >30).
- Smoking: patients who had smoked at least one cigarette during the previous month were defined as current smokers. Patients who had given up smoking for more than one month were defined as former smokers. The nicotine dependency of current smokers was measured using the Fagerstrom Test for Nicotine Dependence. In total, six items are included in the questionnaire, each measured on a scale of 0–3. Based on the total sum score, nicotine dependency was classified into two groups: low to moderate nicotine dependency for a score of 5 or less, and high nicotine dependency for a score of 6 or more (20).
- Alcohol use: patients who had consumed alcohol during the previous month were categorised as current alcohol drinkers. Patients who had given up consuming alcohol for more than one month were defined as former alcohol drinkers. The Alcohol Use Disorders Identification Test was used to collect information on patients' alcohol use. It consists of 10 questions, with a 0–4 response score for each question. The responses were summed, and

the total score was categorised into four zones: zone I (low risk) for a score of 0–3 for women and 0–4 for men; zone II (risky) for a score of 4–12 for women and 5–14 for men; zone III (harmful) for a score of 13–19 for women and 15–19 for men; zone IV (dependent) for a score of 20+ for both men and women (21).

Socio-demographic variables

The socio-demographic variables included in this study were: age in years (<51, 51–60, 61–70, 71+), 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 in Nepalese rupees (NPR) (<5000, 5000–20000, >20000), residential area (provinces 1 and 2, province 3, provinces 4 and 5, other).

Clinical variables

CAD severity was divided into four categories: no significant stenosis or no coronary angiography performed; single-vessel disease; double-vessel disease; triple-vessel disease or left main stenosis. Co-morbidity was divided into two groups: yes or no. Revascularisation status was divided into three categories: no revascularisation; percutaneous coronary intervention; coronary artery bypass graft.

Statistical analysis

The patients' descriptive characteristics and prevalence of lifestyle-related risk factors were presented as frequencies and percentages for categorical variables. The continuous variables were expressed as mean ± standard deviation when the data were normally distributed, and median and interquartile range otherwise. The normality of the data was tested using the Shapiro-Wilk test. Differences between the categorised risk groups with regard to the descriptive characteristics of the study population were compared using a chi-squared test or Fisher's exact test. Multinomial logistic regression was applied to estimate the prevalence odds ratios (PORs) with 95% confidence intervals (CIs) of the risk groups with the study population's socio-demographic characteristics. The low-risk group was used as the reference group, and the PORs were calculated for medium vs. low and high vs. low. The two-tailed p-value <0.05 was used as a level of statistical significance. All the statistical analyses were performed using Statistical Package for Social Sciences (SPSS) version 23.0 for Windows (IBM Corporation, Armonk, NY, USA).

Results

The socio-demographic and clinical characteristics of the study population are presented in Table 2. The mean age of patients was 59.9 years, and 76% were male. The distribution of lifestyle-related risk factors among patients with CAD is depicted in Table 3. Of the study population, 5% had a high dietary risk and 25% had a medium dietary risk. Likewise, 31% were physically inactive. The median sedentary time per day was 360 minutes. Only 8% of the study population had low medication adherence, and more than half (51%) had medium medication adherence. The majority (95%) had moderate perceived stress. Of the total patients, only 5% were obese, 23% were overweight, and 6% were underweight. Almost one third (32%) were current smokers, 12% were chewing tobacco users, and almost one quarter (23%) were current alcohol drinkers. Figure I shows the prevalence of lifestyle-related risk factors in the study population, in descending order. The most prevalent risk factor was stress (97%), followed by non-adherence to medication (59%), smoking (32%), physical inactivity (31%) and unhealthy diet (30%). Overweight or obesity (28%) and current alcohol consumption (23%) were the least prevalent lifestyle-related risk factors among the studied patients.

Figure II shows the distribution of lifestyle-related risk factors in the study population. Every patient had at least one lifestyle-related risk factor. Patients with three of the seven risk factors were the commonest (36%), followed by those with two (25%) and four risk factors (22%). Only a few (<1%) had all seven risk factors, whereas 8% had only one risk factor.

Table 4 shows the prevalence of risk factors among the study population by socio-demographic characteristics. No statistically significant difference between the risk groups was found according to socio-demographic variables, except for gender, marital status and having underage children. More female participants (46%) had a low risk, whereas more male participants (40%) were in the medium-risk group. Table 5 shows the association of the risk groups with socio-demographic characteristics from the multinomial logistic regression analysis. Male patients had higher odds of being in the medium-risk group (POR for medium vs. low 2.83; 95% CI 1.3, 6.18) compared with their female counterparts. Married patients had lower odds than others of being in the high-risk group compared with the low-risk group (POR for high vs. low 0.18; 95% CI 0.04, 0.88). Similarly, compared with patients with no underage children, those with underage children had lower odds of being in the medium-risk group compared with the low-risk group (POR for medium vs. low 0.15; 95% CI 0.05, 0.45). Patients with higher incomes (NPR >20000) had higher odds of being in the high-risk group than patients with low incomes (POR for high vs. low 2.53; 95% CI 1.10, 5.83).

Discussion

We investigated the prevalence of seven different lifestyle-related risk factors among patients with CAD. The central finding is that the majority of the studied patients had multiple lifestyle-related risk factors. Among the individual risk factors, the majority had moderate to high perceived stress, were non-adherent to medication, and had a history of smoking, with almost one third being current smokers. Similarly, almost one third of patients were physically inactive and had a dietary risk, one quarter were overweight or obese, and more than one fifth were current alcohol consumers. The multivariable model showed a significant association of the number of risk factors with gender, marital status, underage children and monthly income.

We found a high prevalence of multiple lifestyle-related risk factors among CAD patients in our study. More than two thirds of the studied patients had three or more risk factors, with almost 36% having three lifestyle-related risk factors, and 25% at least two risk factors. Similar findings have been reported in previous studies. A study on the prevalence of risk factors for CAD among patients in Oman reported that patients with four risk factors were the commonest (22). A study conducted in the community in Eastern Nepal reported that approximately one third of subjects had more than one risk factor (23). A further study on the clustering of lifestyle-related risk factors among the general adult population in the Netherlands reported that about 20% of subjects had at least three lifestyle risk factors (24). However, most of the previously reported studies have not investigated as many as seven different lifestyle-related risk factors among CAD patients.

We found a prevalence of medium to high dietary risk among one third of the studied patients, which is lower than the reported findings of earlier studies (23, 25, 26). However, most of these previous studies investigated either the consumption of fruit and vegetables or dietary fat among the general population, whereas our study included the consumption of fruit, vegetables, fish, starchy/fatty foods, and sweetened and caffeinated beverages to investigate dietary risks among CAD patients. Despite the use of a large range of dietary items in our study, this risk prevalence was relatively low.

In our study population, almost one third did not meet WHO recommendations on physical activity for health. In line with our findings, an earlier cross-sectional study on cardiovascular risk factors in Nepal reported that 21% of participants had insufficient physical activity (11). Most of the patients in our study indicated that they were involved in occupational physical activity, very few were active while travelling to and from places, and almost none performed recreational leisure-time physical activities other than brisk walking. Previous studies have shown that regular high-

frequency exercise and physical activity increases myocardial perfusion and muscle function, which subsequently reduces the further progression of atherosclerosis in patients with CAD (27-29).

We found that only a small group of patients were highly adherent to medication in our study. This might be attributed to patients' carelessness about the regular intake of medicine, or to their feeling better when they stop taking medicine or worse when they do take medicine. It has previously been shown that non-adherence to medication leads to adverse outcomes among patients with CAD (30).

We found that the majority of patients in our study had moderate perceived stress. Perceived stress may be related to ill health such as chest pain, hospitalisation, and the financial burden of treatment. Previous studies have shown that even brief episodes of mental stress may cause endothelial dysfunction, resulting in the progression of atherosclerosis (31). We found obesity and overweight (BMI ≥25) among 28% of our study patients, this is similar to earlier findings reported in Eastern Nepal, which found a BMI ≥25 among 33.6% of the study population (23). However, a study in a peri-urban community Kathmandu reported a BMI ≥25 in 60% of its study population (11). These variations might be due to the availability and affordability of a healthy diet or fast food, and may also be due to work-/travel-related physical activity among study participants in different regions of Nepal.

We observed smoking among 32% of the studied patients, which corroborates the findings of earlier studies in Nepal (11, 23). A large proportion of participants in our study were former smokers (29%), which possibly suggests the increasing trend of smoking cessation among CAD patients. It has been demonstrated that smoking is strongly associated with the development of CAD and the severity of coronary stenosis (32, 33).

We found that 23% of our study patients were current alcohol drinkers, whereas more than three fifths never drank alcohol. In line with our findings, an earlier cross-sectional study on cardiovascular risk factors in Nepal reported that 29% of study participants were alcohol consumers (11). A dose-response meta-analysis of prospective studies reported that alcohol consumption in moderation (<36 grams per day) is associated with a reduced risk of CAD (34).

We found that married patients had lower odds of being in the high-risk group. This finding concurs with an earlier study among Dutch people, which reported that the number of risk factors was lower among married people than among those with no partner (24). We found that the number of lifestyle-related risk factors was higher among males than females, which contradicts an earlier finding in Oman that females had more risk factors (22). The difference might be due to the fact that the two studies were conducted in different settings with different cultural backgrounds. We

found patients with underage children were less likely to have high-risk factors. This finding could be due to the younger age of our study patients (23% were aged ≤50 years) and their busy working lives due to their responsibilities for underage children. To our knowledge, no previous study has examined the association between having underage children and the number of lifestyle-related risk factors among CAD patients.

We found patients with higher incomes had higher odds of being in the high-risk group than those with low incomes. Contrary to this, a cross-sectional study conducted among CAD patients in northern Jordan reported that patients with high monthly incomes had a higher adherence to healthy lifestyles (35). Our result may be attributed to the higher-income group's purchasing power to buy cigarettes, soft drinks and fast food. Moreover, the higher-income group in our study was mostly white-collar workers, which is suggested to be a physically inactive group, as they spend a high number of work hours sitting and have less leisure-time physical activity (36, 37). Overall, our findings suggest a higher prevalence of unhealthy lifestyle habits among CAD patients, which exposes them to the risk of future cardiovascular events.

Strengths and limitations

An important strength of this study is that it concerns a leading cause of death globally, and was conducted among an under-studied South Asian population. Another strength is our study's use of face-to-face structured interviews with patients, which offered opportunities for clarification and strengthened the response rate. In addition, we examined seven lifestyle-related risk factors among patients simultaneously, using internationally evaluated standard tools, which is rare in previous studies.

Despite these strengths, our study has several limitations. The information was collected from a single centre with a relatively small sample size, due to the limited available resources. A similar study could be conducted with a larger sample size to produce greater reliability in the study results. Social desirability bias might have caused the under-reporting of unhealthy behaviours. This bias was addressed by using direct vs. indirect questions, and with the use of proxy subjects in addition to patients. Moreover, the association of the number of risk factors with various socio-demographic factors was cross-sectional, limiting causal inference from the findings.

Conclusion

We found a high prevalence of a number of lifestyle-related risk factors among CAD patients. The most prevalent risk factor was stress, and alcohol consumption was the least prevalent. Male gender, marital status, underage children and monthly income were significantly associated with risk groups. The assessment of lifestyle-related risk factors provides evidence of risk patterns and helps to identify major issues to be addressed to prevent secondary complications. Furthermore, intervention studies focusing on lifestyle-related risk factor modifications in particular groups are recommended.

Declaration of conflict of interest

The authors declare that there is no conflict of interest.

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Table 1: Lifestyle-related risk factors

Variable	Definition	Questionnaire
Unhealthy diet	Moderate to high risk score (score of 7 or above)	Cardiovascular Risk Assessment Questionnaire(1)
Physical inactivity/ sedentary behaviour	Not meeting WHO recommendations on physical activity for health (MET minutes per week <600)	Global Physical Activity Questionnaire(2)
Non-adherence to medication	Low to medium adherence score (score of 0-2)	Morisky Green Levine Medication Adherence Scale(3)
Perceived stress	Moderate to high stress (score of 14-40)	Perceived Stress Scale(4)
Obesity or overweight	BMI ≥30 kg/m^2 as obese; BMI 25-30 kg/m^2 as overweight	WHO standard classification; BMI formula to calculate obesity(5)
Smoking	Has smoked at least 1 cigarette in previous month	Fagerstrom Test for Nicotine Dependence(6)
Alcohol consumption	Has consumed alcohol in previous month	AUDIT(7)

WHO: World Health Organization. MET: metabolic equivalent. BMI: body mass index. AUDIT: Alcohol Use Disorders Identification Test.

Table 2: Socio-demographic and clinical characteristics of study population (n=224)

Characteristics	n (%)
Age in years	
≤50	52 (23.2)
51-60	67 (29.9)
61-70	63 (28.1)
≥71	42 (18.8)
Gender	
Male	170 (75.9)
Female	54 (24.1)
Ethnic group	
Brahmin	60 (26.8)
Chhetri	45 (20.1)
Newar	43 (19.2)
Other	76 (33.9)
Religion	
Hindu	192 (85.7)
Other	32 (14.3)
Education	
Uneducated	62 (27.7)
Primary education	85 (37.9)
Secondary education	53 (23.7)
Bachelor's degree or above	24 (10.7)
Work status	
Unemployed	17 (7.6)
Employed	52 (23.2)
Retired	65 (29.0)
Entrepreneur	27 (12.1)
Farmer	63 (28.1)
Marital status	
Married	209 (93.3)

Other	15 (6.7)
Underage children	
Yes	37 (16.5)
No	187 (83.5)
Monthly family income (NPR)	
<5000	92 (41.1)
5000-20000	76 (33.9)
>20000	56 (25.0)
Residential area	
Provinces 1 & 2	52 (23.2)
Province 3	109 (48.7)
Provinces 4 & 5	51 (22.8)
Other	12 (5.3)
Co-morbidity	
Yes	183 (81.7)
No	41 (18.3)
CAD severity	
No significant stenosis/no CAG performed	49 (21.9)
Single-vessel disease	72 (32.1)
Double-vessel disease	57 (25.5)
Triple-vessel disease/left main stenosis	46 (20.5)
Revascularisation	
No revascularisation	79 (35.3)
PCI	123 (54.9)
CABG	22 (9.8)

NPR: Nepalese rupees. CAD: coronary artery disease. CAG: coronary angiography. PCI: percutaneous coronary intervention. CABG: coronary artery bypass graft.

Table 3: Distribution of lifestyle-related risk factors among study population (n = 224)

Variables	n (%)
Diet	
Low risk	157 (70.1)
Medium risk	55 (24.6)
High risk	12 (5.4)
Physical activity (n, %)	
MET minutes per week ≥600	154 (68.8)
MET minutes per week <600	70 (31.3)
Adherence to medication	
Low adherence	17 (7.6)
Medium adherence	115 (51.3)
High adherence	47 (21.0)
No medication	45 (20.1)
Stress	
Low stress	6 (2.7)
Moderate stress	213 (95.1)
High stress	5 (2.2)
BMI	
Underweight	13 (5.8)
Normal weight	148 (66.1)
Overweight	52 (23.2)
Obese	11 (4.9)
Smoking status	
Current smoker	72 (32.1)
High nicotine dependence	*22 (9.8)*
Low to moderate nicotine dependence	*50 (22.3)*
Former smoker	65 (29.0)
Never smoked	87 (38.8)
Chewing tobacco consumption	

Yes	26 (11.6)
No	198 (88.4)
Alcohol consumption	
Current drinker	52 (23.2)
I Low risk	*6 (2.7)*
II Risky	*41 (18.3)*
III Harmful	*3 (1.3)*
IV Dependent	*2 (0.9)*
Former drinker	34 (15.2)
Never drunk alcohol	138 (61.6)

MET: metabolic equivalent minutes. BMI: body mass index.

Table 4: Prevalence of numbers of risk factors by socio-demographic characteristic

Characteristics	Total sample (n=224)	Low-risk group: 1 or 2 risk factors (n, %)	Medium-risk group: 3 risk factors (n, %)	High-risk group: 4-7 risk factors (n, %)	p-value
Age, classified					0.245
≤50	52	17 (32.7)	12 (23.1)	23 (44.2)	
51-60	67	24 (35.8)	27 (40.3)	16 (23.9)	
61-70	63	19 (30.2)	26 (41.3)	18 (28.6)	
≥71	42	15 (35.7)	15 (35.7)	12 (28.6)	
Gender					0.028*
Male	170	50 (29.4)	68 (40.0)	52 (30.6)	
Female	54	25 (46.3)	12 (22.2)	17 (31.5)	
Caste/ethnic group					0.990
Brahmin & Chhetri	105	35 (33.3)	38 (36.2)	32 (30.5)	
Other	119	40 (33.6)	42 (35.3)	37 (31.1)	
Religion					0.821
Hindu	192	65 (33.9)	67 (34.9)	60 (31.3)	
Other	32	10 (31.3)	13 (40.6)	9 (28.1)	
Education					0.135
Uneducated & primary education	147	54 (36.7)	54 (36.7)	39 (26.5)	
Secondary education & above	77	21 (27.3)	26 (33.8)	30 (39.0)	
Work status					0.874
Unemployed	82	27 (32.9)	31 (37.8)	24 (29.3)	
Employed	142	48 (33.8)	49 (34.5)	45 (31.7)	
Marital status					0.045*
Married	209	73 (34.9)	76 (36.4)	60 (28.7)	
Others	15	2 (13.3)	4 (26.7)	9 (60.0)	
Underage children					0.001*
Yes	37	20 (54.1)	4 (10.8)	13 (35.1)	

No	187	55 (29.4)	76 (40.6)	56 (29.9)	
Income (NPR)					0.115
<5001	92	37 (40.2)	34 (37.0)	21 (22.8)	
5001-20000	76	22 (28.9)	29 (38.2)	25 (32.9)	
>20000	56	16 (28.6)	17 (30.4)	23 (41.1)	
Residential area					0.230
Province 3	109	36 (33.0)	34 (31.2)	39 (35.8)	
Other	115	39 (33.9)	46 (40.0)	30 (26.1)	

NPR: Nepalese rupees. p-value <0.05 statistically significant.

Table 5: Association of risk groups with socio-demographic characteristics from multinomial logistic regression analysis

Characteristics	**POR, 95% CI for risk groups**	
	Medium vs. low	**High vs. low**
Age (years)		
≤50	1	1
51-60	1.59 (0.63-4.00)	0.49 (0.20-1.20)
61-70	1.94 (0.75-4.99)	0.70 (0.29-1.72)
≥71	1.42 (0.51-3.96)	0.59 (0.22-1.58)
Gender		
Female	1	1
Male	2.83 (1.3-6.18)	1.53 (0.74-3.17)
Caste/ethnic group		
Brahmin & Chhetri	1	1
Newar & others	0.97 (0.51-1.82)	1.01 (0.52-1.95)
Religion		
Others	1	1
Hindu	0.79 (0.33-1.94)	1.03 (0.39-2.69)
Education		
Uneducated or primary education	1	1
Secondary education or above	1.23 (0.62-2.46)	1.98 (0.99-3.96)
Work status		
Unemployed	1	1
Employed	0.89 (0.46-1.71)	1.06 (0.53-2.09)
Marital status		
Other	1	1
Married	0.52 (0.93-2.93)	0.18 (0.04-0.88)
Underage children		
No	1	1
Yes	0.15 (0.05-0.45)	0.64 (0.29-1.41)

Monthly family income (NPR)		
<5001	1	1
5000-20000	1.43 (0.69-2.95)	2.00 (0.91-4.39)
>20000	1.16 (0.51-2.64)	2.53 (1.10-5.83)
Residential area		
Others	1	1
Province 3	0.80 (0.43-1.51)	1.41 (0.73-2.72)

POR: prevalence odds ratio. CI: confidence interval. NPR: Nepalese rupees. Categories of some variables merged to provide sufficient data for analysis, e.g. ethnic group, education, work status and residential area.

Figure I: Prevalence of lifestyle-related risk factors in study population, in descending order

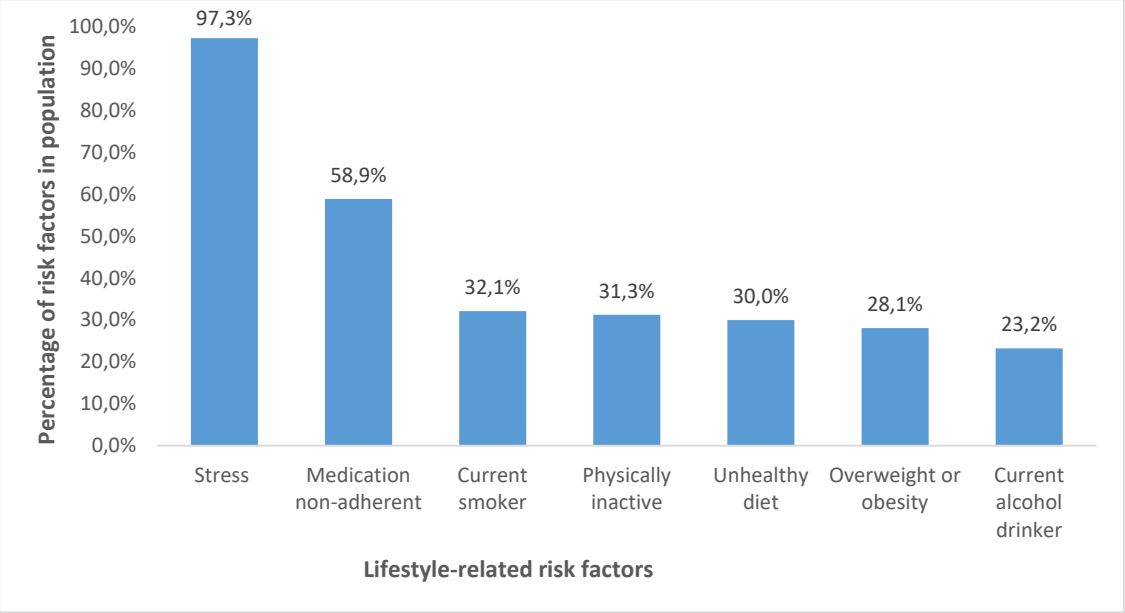
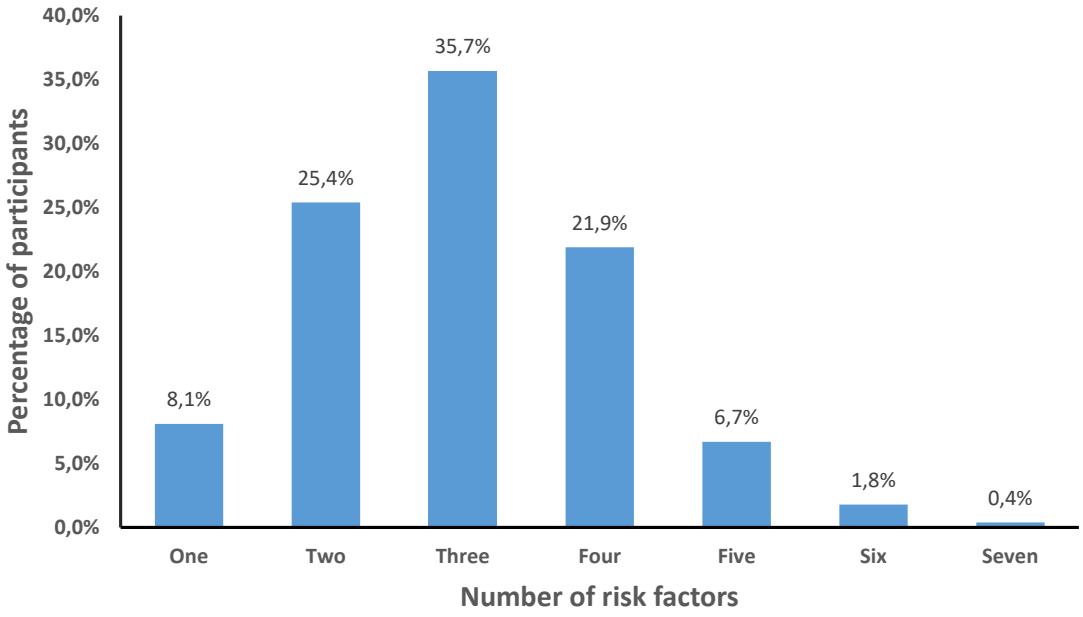


Figure II: Distribution of numbers of lifestyle risk factors in the study population


40,0%
35,0%
30,0%
25,0%
20,0%
15,0%
10,0%
5,0%
0,0%
Percentage of participants
8,1%
25,4%
35,7%
21,9%
6,7%
1,8%
0,4%
One
Two
Three
Four
Five
Six
Seven
Number of risk factors

PUBLICATION 2

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

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Patient Education and Counseling 2021; 104: 1406-1414
doi:10.1016/j.pec.2020.11.030

Patient Education and Counseling 104 (2021) 1406–1414

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

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.

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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https://doi.org/10.1016/j.pec.2020.11.030

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

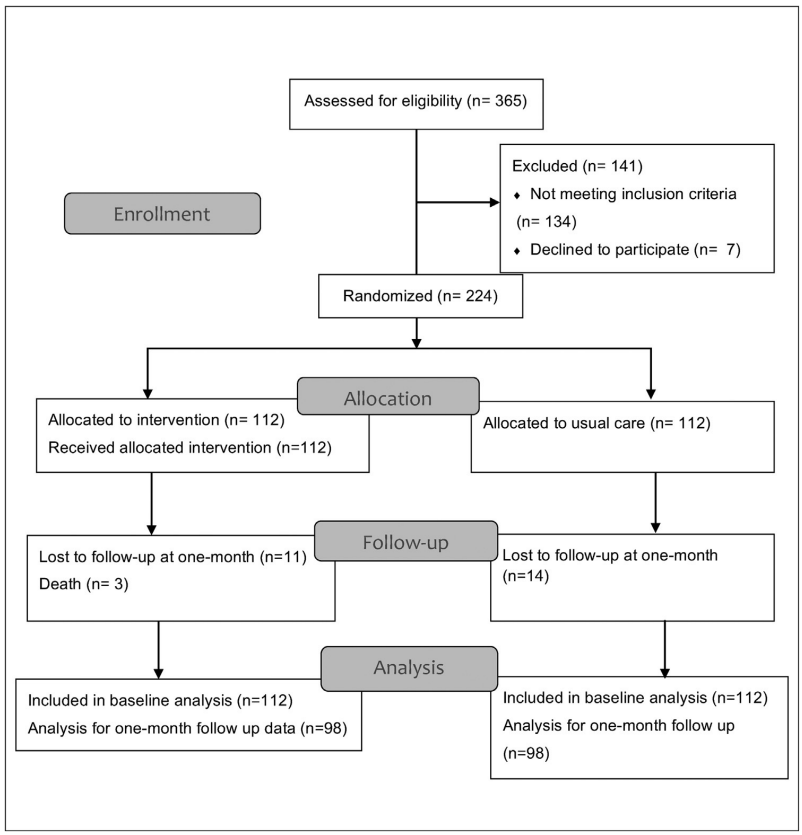

Fig. 1. Flow diagram (CONSORT) of participants through each stage of a randomized trial.

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 -19−6, 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 (%)				
Yes	183 (81.7)	91 (81.3)	92 (82.1)	0.999
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			one-month follow up		
	Intervention Group (n = 112)	Usual care Group (n = 112)	P-value	Intervention Group (n = 98)	Usual care Group (n = 98)	P-value
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

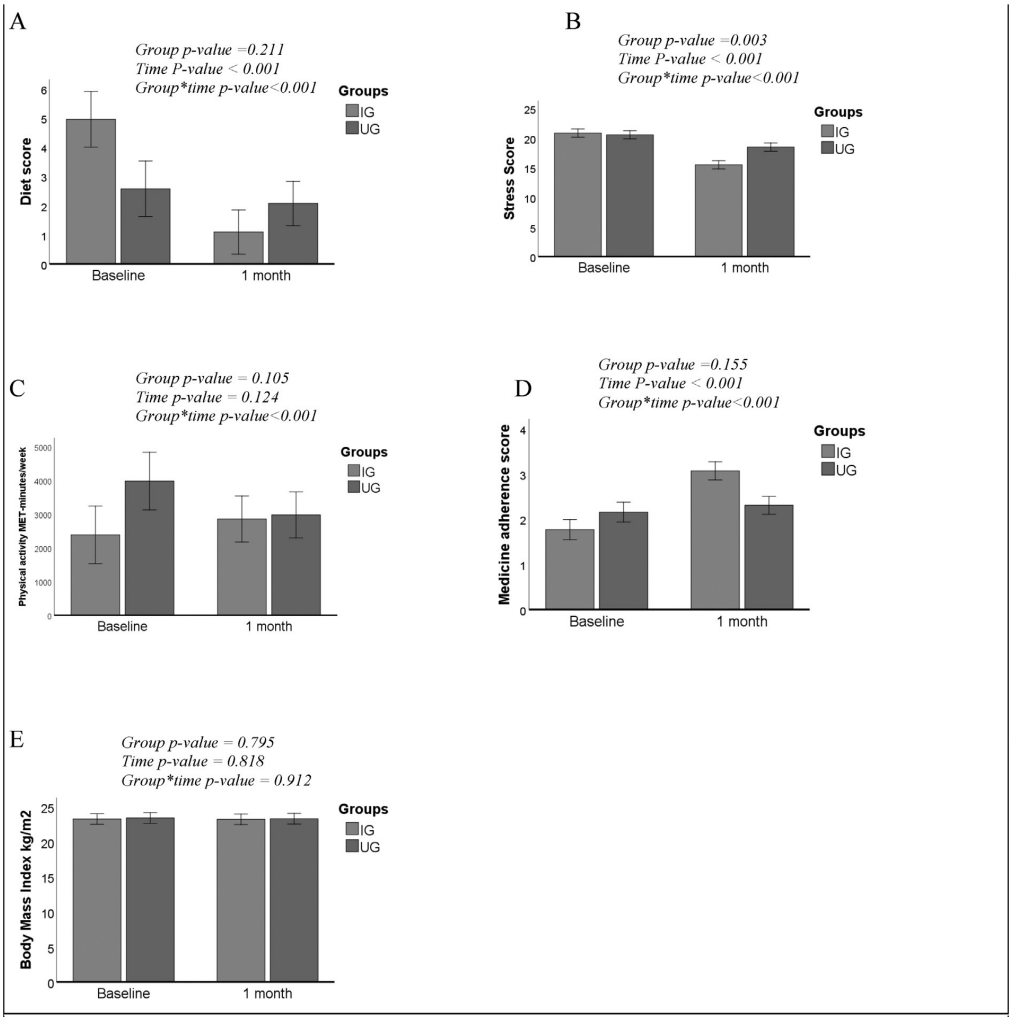

Fig. 2. (A-E) Changes in lifestyle-related risk factor habits from baseline to one-month follow-up. Error bars indicate 95% Confidence interval of mean. P-values are obtained from general linear model repeated measures analysis.

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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PUBLICATION 3

Effects of intervention on lifestyle changes among coronary artery disease patients: A 6-month follow-up study

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NursingOpen 2022; 9: 2024-2036
doi: 10.1002/nop2.1212

Received: 12 January 2022 | Revised: 17 March 2022 | Accepted: 3 April 2022

DOI: 10.1002/nop2.1212

RESEARCH ARTICLE

NursingOpen Open Access WILEY

Effects of intervention on lifestyle changes among coronary artery disease patients: A 6-month follow-up study

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Funding information
Pramila Gaudel was supported by the Finnish Cultural Foundation, Pirkanmaa Regional Fund (grant number 50201302). The funding source had no role on the study design, data analysis or interpretation of the data collection.

Abstract

Aim: The main aim of the study was to investigate the effects of a nurse-led lifestyle-related risk factor modification intervention on multiple lifestyle behaviours among coronary artery disease patients over six months.

Design: A pre-test post-test control group design was conducted in a single clinical centre in Nepal.

Methods: A total of 224 eligible patients were randomly assigned to either the usual care group or the intervention group at baseline. The lifestyle intervention consisted of a brief counselling session supplemented with informational leaflets. Standard questionnaires were used to collect self-reported data from patients on multiple lifestyle behaviours: diet, physical activity, adherence to medication, stress, body mass index, smoking and alcohol consumption. General linear model repeated measure analysis was used to estimate the effect of intervention.

Results: A statistically significant effect of study group-by-time interaction for diet, adherence to medication, physical activity, and perceived stress was found at 6-month follow-up. Overall, greater improvement in lifestyle habits was found in the intervention group compared with the control group at 6-month follow-up.

KEYWORDS
coronary artery disease, effects of intervention, lifestyle, risk factors

1 | INTRODUCTION

Coronary artery disease (CAD) is the most common form of cardiovascular disease, responsible for 16% of the world's total death (WHO, 2020). CAD is the leading cause of premature death and remains a major cause of disability adjusted life years (DALYs) globally (Roth et al., 2020; WHO, 2020). Since 2000, CAD-related death has been increased globally but especially in low- and middle-income countries (LMICs) (WHO, 2020). More than 80% of cardiovascular disease deaths were in LMICs, and most cases are reported at an early age compared with high-income countries (Bowry et al., 2015). LMICs like Nepal are in the midst of a health crisis, resulting largely from limited preventative measures, unhealthy lifestyle choices and increased exposure to risk factors (Bhattarai et al., 2020; Gaziano et al., 2010). CAD is the number one cause of death in Nepal, accounting for 20.5% of the total deaths (WHO, 2021).

Clinical Trial Registration: The study is not registered in any Clinical trial registry. The study was designed in 2017 and was implemented immediately after that.

Diabetes, hypertension and dyslipidaemia are known to be major cardiovascular risk factors. These risk factors are strongly influenced by lifestyle habits (Mozaffarian et al., 2008). The latest EUROASPIRE V survey has reported that the basic lifestyle habits are fundamental risk factors for cardiovascular disease that require more emphasis and focus (Kotseva et al., 2019; Mozaffarian et al., 2008). South Asian population have a higher prevalence of risk factor habits regardless of their residence in South Asia or otherwise (Ahmed et al., 2018; Gaudel et al., 2020; Ghimire & Dhungana, 2018; Khanal et al., 2018). Diet low in whole grains, vegetables and fruits, smoking, alcohol consumption and low physical activity are the lifestyle choices of people in Nepal which are leading risk factors for CAD, contributing to higher incidence of CAD and unacceptable numbers of premature deaths (Bhattarai et al., 2020; Ghimire & Dhungana, 2018).

Interventions for the secondary prevention of CAD is a current priority. Medical and surgical interventions are proven to reduce the incidence of major cardiovascular events among people living with CAD. However, lifestyle risk factors modification is also one of the most effective methods used to regress atherosclerosis among CAD patients (Kotseva et al., 2019; Maniar & Bittner, 2015; Mozaffarian et al., 2008). Adherence to medical management in addition to following healthy lifestyle habits is crucial for secondary prevention of CAD (Hajar, 2017; Kotseva et al., 2019). We may prevent cardiac events or reverse the condition by providing education, counselling and support to patients about healthy lifestyle changes (Dod et al., 2010; von Gaudecker, 2017; Maniar & Bittner, 2015). Similarly, a systematic review of 28 studies on the effect of nurse-delivered lifestyle interventions, revealed positive results of intervention on various outcomes such as weight, dietary behaviours, physical activity and patient satisfaction (Sargent et al., 2012). However, effect of intervention on multiple lifestyle-related risk factors among CAD patients are rarely studied in South Asia. A study conducted among CAD patients in Nepal showed that nurse-led educational intervention improved patients' knowledge of cardiac rehabilitation (Shrestha et al., 2020). Given that there exists a gap in the available literature on how intervention and positive lifestyle changes are connected. Assessing the effectiveness of lifestyle counselling across different populations is important to address health inequalities (Jepson et al., 2010). There is a need to focus on implementing cost-effective interventions against all risk factors to improve outcome in patients with CAD especially in LMICs (Aminde et al., 2018; Khanal et al., 2018; Roth et al., 2020).

In this study, we pursue to address the gap in the literature on effectiveness of low-cost intervention on multiple lifestyle behaviours among patients with limited access to healthcare facility. The lifestyle habits assessed in this study were smoking, unhealthy diet, low physical activity, stress, harmful use of alcohol, obesity or excess weight and medication adherence. We earlier reported the short-term effect of intervention on lifestyle-related risk factors among CAD patients (Gaudel et al., 2021). In this study, we aimed to evaluate both the short- and long-term effect of a nurse-led brief counselling intervention on multiple lifestyle-related risk factors at 1-month and 6-month follow-ups among patients living with CAD in Nepal.

2 | METHODS

2.1 | Study design and setting

A pre-test post-test control group design was used in this study. The study was conducted on in-patient wards of a National Heart Centre, in Kathmandu, Nepal. The baseline survey was conducted from May 2018 to July 2018 and the follow-up data were collected from November 2018 to January 2019.

2.2 | Study participants and randomization

Patients with physician diagnosed CAD were checked systematically on the list of patients admitted at a national heart centre, between May and July 2018. A total of 365 patients with CAD, admitted at a hospital were screened for eligibility, 134 patients were excluded for not meeting the inclusion criteria and seven eligible patients declined to participate in the study. In total, 224 eligible patients were enrolled and randomized into intervention group (IG) and usual care group (UG) in a 1:1 ratio using computer-generated random number sequence after the baseline survey. The sample size was calculated using a priori power analysis with a *t*-test family. To achieve statistically significant results a power level of 0.80, an alpha level of 0.05 and an effect size of 0.37 were considered, with and estimated attrition rate of 22%, the total sample size of the study was 224 (Iestra et al., 2005; IJzelenberg et al., 2012; Polit, 2014). The inclusion criteria included patients aged over 18 years, admitted with a medical diagnosis of CAD, who were able to communicate in Nepali or English, accessible by telephone and willing to voluntarily participate. Patients with a serious medical and surgical condition, those with hearing, speaking and cognitive problems were excluded from the study.

2.3 | Intervention

Counselling in a group of three to five patients with their family members was administered, followed by individual counselling. Patients in IG were invited to attend a counselling session along with their family members on the day of discharge from the hospital. Counselling was given in a separate room of the hospital. Audio-visual material was used for counselling and each session lasted about 45 min on average, with 40 min of minimum and 50 min of maximum time per session. Each participant in the IG received single group counselling session which was followed by an individual counselling to set lifestyle goals for each patient depending on their specific needs. Informational leaflets with pictorial descriptions were given after the counselling session. The intervention was administered to all 112 patients in IG in their local language by the principal investigator, who has received specialized education in cardiovascular nursing. Patients in UG received the usual care and a short session of unstructured counselling for

lifestyle modification. Patients in IG were given detailed information about the symptoms of CAD, how the disease progresses, what pharmacological, percutaneous and surgical management techniques are available, and the importance of lifestyle changes to prevent complications.

The content of the counselling intervention including leaflets were developed based on the informational requirements for Nepali cardiac patients. The study team discussed the content for counselling and leaflets and agreed to include pictorial description. Principal investigator drafted content of counselling and leaflets and revised based on comments from the study team. Nepali version of the content was sent to expert in Nepal including cardiologist, cardiac surgeon and a nurse specialist for the face and content validity in Nepali context. Content validity was important check point to evaluate the extent to which proposed intervention could be valid and probably to be effective in the target population of the intervention. Minor revision in few sentences were made based on expert's suggestion. Information included was optimum as per patient's requirement, simple language was used to ease understanding of patients with little or no knowledge about disease. Aim of counselling was to help patients to know more about their health, care, treatment, importance of adopting healthy lifestyle and ways to modify lifestyle-related health risk factors. Information was illustrated and enhanced by using simple informative pictures. Guidelines for writing patient information leaflets were followed.(Eckel et al., 2014; Esselstyn, 2017; Jankovic et al., 2015; Lahtinen et al., 2018; Nishtar, 2002; Olendzki et al., 2006; Second Joint Task Force of European & other Societies, 1998) (Box 1).

2.4 | Measurement of variables and data collection

Following standard questionnaires were used to collect data on lifestyle variables: a cardiovascular risk assessment questionnaire (Limited, 2018), The Global Physical Activity Questionnaire (Prevention of Noncommunicable Diseases Department, 2018), Morisky Green Levine Medication Adherence Scale (Morisky et al., 1986) and The Perceived Stress Scale (Cohen et al., 1983). Questionnaires were translated from English to Nepali language and expert opinion and cultural validation were obtained. The questionnaires were pilot tested before data collection.

The principal investigator interviewed patients using questionnaires on seven different lifestyle variables. Information about socio-demographic and clinical variables was also obtained from interview. Baseline data were collected by face-to-face interviews, follow-up data were collected using the same questionnaire by the same investigator through a phone call. A telephone interview was the only feasible option in this study to collect follow-up data from patients who do not visit hospital often and were distributed in different geographic regions. To collect data from each patient using the structured telephone interview took 20 min on average. Patients were considered lost to follow-up only if they do not respond to three attempted telephone calls made at three different times. Brief description of questionnaires that were used to collect data on lifestyle variables at all three time points (baseline, 1-month follow-up and 6-month follow-up) is given below.

2.4.1 | Diet

A cardiovascular risk assessment questionnaire was used to collect data on diet. The questionnaire consists of 10 questions, each scored on a scale of −10 to 10. Based on the score, risk groups were defined as low (−19 to 6), medium (7 to13) and high risk (≥ 14) (Limited, 2018).

2.4.2 | Physical activity

Data on patients' physical activity level and sedentary behaviour were collected using the Global Physical Activity Questionnaire. The questionnaire consists of 16 items about activity during work, transport and leisure time. Metabolic equivalent (MET) minutes of activity were computed depending on the patient's response. Patients were considered physically active if they achieved 600 MET minutes throughout the week (Prevention of Noncommunicable Diseases Department, 2018).

2.4.3 | Medication adherence

Adherence to medication was assessed using the Morisky Green Levine Medication Adherence Scale. The scale consists of four items, each item was scored as zero or one. Based on scale of 0–4, three groups were categorized: low adherence for a score of 0, medium adherence for 1–2 and high adherence for 3–4 (Morisky et al., 1986).

2.4.4 | Perceived stress

The Perceived Stress Scale which consists of 10 items, was used to assess the patient's stress. The total score was calculated by summing the items and the sum of scores for each item ranged between zero and 40. Perceived stress was categorized as low for score of 0–13, moderate for 14–26 and high for 27–40 (Cohen et al., 1983).

2.4.5 | BMI

BMI was calculated based on the measurement of weight and height (weight/height^2). The WHO reference was used to categorize BMI into 4 categories: underweight, normal weight, overweight and obese (WHO, 2018).

BOX 1 Examples of content of the lifestyle-related intervention addressed during counselling

Diet
- Eat plenty of fresh fruit, vegetables, a variety of whole grain products, lean meat, fish, peas, beans, low-fat dairy products and fibre-rich food.
- Avoid sweets and limit salt intake.

Physical Activity
- Exercise at least 30 min a day, at least 5 days a week. Regularly perform physical activities like walking, jogging, cycling, swimming, gardening and other moderate-intensity exercises.
- Monitor pulse at rest and during exercise and terminate exercise if any warning signs or symptoms occur.

Excess weight or Obesity
- Maintain a healthy weight by doing regular physical activity and by consuming healthy diet.
- Keep track of healthy weight by measuring BMI.

Smoking
- Set a date to give up smoking and stick with the decision. Cravings go away slowly as nicotine in the body fades, and the first 6 weeks after quitting smoking will be harsh, so stay motivated.
- Chewing gum, eating hard candy, making a phone call, squeezing a stress ball, taking deep breaths can be helpful distractions from cravings during the quitting process.

Alcohol Consumption
- Avoid drinking alcohol or if you drink make sure it is in moderation.
- Excessive alcohol use contributes to high blood pressure and may damage heart muscle, leading to heart failure.

Perceived Stress
- Identify the causes of stress and accept the things that cannot be changed.
- Try sharing feelings, practicing gratitude, doing exercise, sleeping well, laughing at least once a day, maintaining a positive attitude, meditating, practicing mindfulness, doing deep breathing exercises.

Medication Adherence
- Take medication regularly and stick with the treatment regimen.
- High medication adherence reduces recurrent myocardial infarction and mortality.

2.4.6 | Smoking and alcohol use

In this study, patients who had smoked at least one cigarette or had consumed alcohol during the previous month were defined as current smokers and current alcohol drinkers, respectively. Former smokers and former drinkers were defined as patients who had given up smoking or alcohol consumption for more than one month, respectively.

Socio-demographic and clinical variables

The variables included were age in years, gender (male and female), ethnic group (Brahmin, Chhetri, Newar and others), religion (Hindu and others), education (uneducated, primary education, secondary education, bachelor's degree or above), work status (unemployed, employed, retired, entrepreneur, farmer), marital status (married and others), underage children (yes and no), monthly family income, residential area (province 3 and other provinces), co-morbidity (yes, no), CAD severity (no statistically 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 and coronary artery bypass graft). Data on these variables were collected at baseline and updated during follow-ups.

2.5 | Ethical consideration

Ethical approval for the study was obtained from the Nepal Health Research Council Ethical Review Board (25/2018) and from the hospital under study. Patients were informed about the nature of the study and their right to refuse consent or withdraw at any time during the study without any adverse effect was explained. Informed written consent was obtained from all the participants.

2.6 | Statistical analysis

Descriptive statistics were calculated and presented as means, standard deviations for continuous variables, percentage and frequencies for categorical variables. We compared differences between the study groups using chi-squared test or Fisher's exact test, and a Student's *t*-test or Mann–Whitney test for categorical and

continuous variables, respectively. To analyse the intervention's effect on lifestyle-related risk factor habits at 1- and 6-month, a general linear model (GLM) repeated-measures analysis was used. We used the group as the between-subject factor, time as the within-subject factor and risk factor habits as continuous variables for the analysis. We reported mean values with their 95% confidence intervals (CIs) and p-values for group, time and group × time interaction. The GLM repeated measures analysis results for the smoking and alcohol consumption variables were not reported, as there were few cases of current smoker and alcohol consumer. A *p*-value of <.05 for the two-tailed test was considered as the level of statistical significance. All data analysis was conducted using SPSS 23.0.

3 | RESULTS

A total of 224 participants (112 in each group) with CAD were enrolled at baseline, 196 participants (98 in each group) were retained at 1-month follow-up and 184 participants (93 in IG and 91 in UG) were retained at 6-month follow-up and included in the data analysis (Figure 1). Baseline characteristics of the study participants by study group are presented in Table 1. The mean age of participants was 60.0 (*SD* = 11.8) years, and 77% were male.

Among lifestyle factors, no statistically significant difference between the groups was found at baseline, except for adherence to medication (p <.001; Table 2). At 1-month follow-up significant difference between the groups was found for diet (p =.005), adherence to medication (p <.001), perceived stress (p <.001), smoking (p =.017) and alcohol consumption (p =.005).

At 6-month follow-up all the seven studied lifestyle-related risk factors differed significantly between the study groups: diet (p =.001), physical activity (p =.026), adherence to medication (p <.001), perceived stress (p <.001), BMI (p =.013), smoking (p =.012) and alcohol consumption (p =.021).

Effects of the intervention on lifestyle-related risk factor changes over the 6-month study period are given in Figure 2. GLM repeated measures analysis indicated improvement in reported dietary habits, physical activity, adherence to medication and perceived stress at follow-ups in IG compared with UG. A steep decline indicating improvement in dietary habits and perceived stress was observed from baseline to 1-month follow-up in both groups. Similarly, a steep improvement was observed in physical activity at follow-ups in IG; however, a steep decline was observed in UG compared with baseline. A steep improvement in adherence to medication was observed from baseline to 1-month follow-up in IG, while from one month to six months the improvement was less in both groups. Nevertheless, a steep decline indicating improvement in BMI was observed from one month to six months for IG. Overall, greater improvement was found in the IG, and the effects of time and time × group interaction were statistically significant for diet (p <.001), adherence to medication (p <.001), and perceived stress (p <.001). A statistically significant increase in the mean total physical activity MET minutes per week (group * time, p =.002) was observed at 6-month follow-up in IG.

The number of lifestyle-related risk factors between study groups at different time points appear in Figure 3. At baseline, all the patients reported at least one lifestyle-related risk factor. At 1-month and 6-month follow-ups, there were patients having no risk factor habits. Patients having only one or two risk factors have increased in number in both groups. Similarly, patients having clustering of more than two risk factor habits has decreased in follow-up compared with baseline. At 1-month follow-up, 15% of patients in IG and 5% of patients in UG reported no risk factor habits; at 6-month follow-up, 12% of patients in IG and 2% of patients in UG reported no risk factor habits.

4 | DISCUSSION

We found that the one-time nurse-led counselling intervention supplemented with information leaflets had an impact in improving lifestyle-related risk factor habits of CAD patients in both short and long term. We studied multiple lifestyle-related risk factor habits simultaneously. The results show a positive effect of the intervention on dietary habits, physical activity, medication adherence and perceived stress in IG at follow-ups compared with UG. We found a statistically significant reduction in the number of lifestyle-related risk factor habits in IG at the 1-month and 6-month follow-ups compared with UG. There were not any changes in the methods and study outcomes after the study commenced.

A statistically significant improvement in patient reported dietary habits was found from baseline to follow-ups in IG in our study. Our findings are consistent with the results of a systematic review (LIN et al., 2010) on behavioural counselling to prevent cardiovascular disease by promoting healthy diets in adults. That study suggests that even low-intensity dietary counselling results in a moderate increase in healthy dietary habits like increased fruit and vegetable intake and a decrease in dietary fat intake (LIN et al., 2010). Similarly, another study from Western Nepal reported a positive impact of educational intervention on lifestyle modification, such as limited salt intake and avoiding fatty foods, among hypertensive patients (Sharma et al., 2014).

Based on patients self-reported data, we found that the mean level of physical activity in MET minutes per week significantly increased in IG at follow-ups. Almost 87% of patients in IG and 74% of patients in UG self-reported being physically active, as their mean level of total physical activity in MET minutes per week was ≥600 at the 6-month follow-up. In contrast to our findings, a previous study by Hardcastle et al. (2013) reported an inadequate effect of a motivational interviewing intervention on physical activity, as the participants did not meet 600 MET minutes per week for total physical activity. Nonetheless, the study showed the effectiveness of a counselling intervention for patients with a particularly high risk of cardiovascular disease. Similarly, a systematic review reported mixed effects of low-intensity physical activity counselling interventions (LIN et al., 2010). These differences were plausible due to the differences in the selection of the participants. The present study

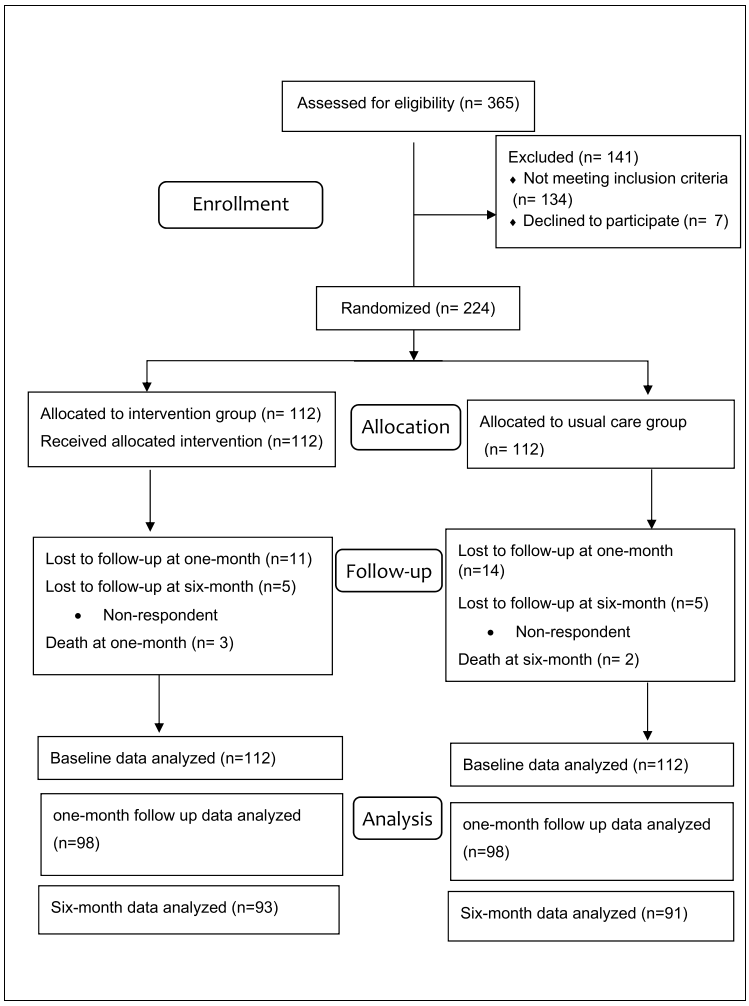

FIGURE 1 Flow diagram (CONSORT) of participants through each stage of the study

comprised patients with CAD in contradict to the participants who only exhibit CVD risk factor in the study by Hardcastle et al., (2013). And the systematic review by LIN et al., (2010) excluded the interventions that targeted persons with known cardiovascular disease or combination of its risk factors.

Patients in IG reported to have achieved a decrease in body weight during the follow-ups, reaching statistical significance at the 6-month follow-up. IG and UG did not differ at 1-month follow-up; however, the difference became statistically significant at 6-month follow-up. We found only 15% of patients in IG and 20% of patients in UG were overweight at the 6-month follow-up. In contrast to our findings, a previous randomized controlled trial reported that a motivational interviewing intervention had no improvements in BMI at 12 months of post-intervention. Yet, the study has reported a statistically significant improvement in BMI between baseline and six months among obese and hypercholesteraemic patients who were at high risk of cardiovascular disease (Hardcastle et al., 2013). The reason for improvement in BMI in our study could be due to patients in our study were at increased risk of getting cardiovascular event due to recent MI or hospitalization due to CAD.

Patients reported higher adherence to medication at 1-month and 6-month follow-ups in both study groups compared with baseline, with statistically significant increase in adherence among IG compared with UG. In concurrent with our finding, a previous retrospective cohort study conducted at Midwestern USA reported that patients who had a brief face-to-face counselling session demonstrated greater medicine adherence and persistency than a comparison group (Taitel et al., 2012). Similarly, another study from Nepal among older hypertensive patients reported that counselling intervention improved medication adherence among patients (Shrestha et al., 2019).

Patients in both groups reported greater reduction in perceived stress at 1-month follow-up than at 6-month follow-up. However, a statistically significant decrease in perceived stress was found in

TABLE 1 Background characteristics of the retained population at 6-month follow-up

Characteristics	Total ($n = 184$)	Intervention Group ($n = 93$)	Usual care Group ($n = 91$)
Age in years (mean ±*SD*)	60.0 ± 11.8	60.9 ± 11.9	59.1 ± 11.8
Gender, *n* (%)			
Male	142 (77.2)	77 (82.8)	65 (71.4)
Female	42 (22.8)	16 (17.2)	26 (28.6)
Cast/Ethnic group, *n* (%)			
Brahmin	50 (27.2)	23 (24.7)	27 (29.7)
Chhetri	38 (20.7)	23 (24.7)	15 (16.5)
Newar	34 (18.5)	18 (19.4)	16 (17.6)
Others	62 (33.6)	29 (31.2)	33 (36.2)
Religion, *n* (%)			
Hindu	160 (87.0)	80 (86.0)	80 (87.9)
Others	24 (13.0)	13 (14.0)	11 (12.1)
Education, *n* (%)			
Uneducated	48 (26.1)	19 (20.4)	29 (31.9)
Primary education	72 (39.1)	38 (40.9)	34 (37.4)
Secondary education	43 (23.4)	23 (24.7)	20 (21.9)
Bachelor's degree or above	21 (11.4)	13 (14.0)	8 (8.8)
Work status, *n* (%)			
Unemployed	12 (6.5)	6 (6.5)	6 (6.6)
Employed	46 (25.0)	19 (20.4)	27 (29.7)
Retired	55 (29.9)	32 (34.4)	23 (25.3)
Entrepreneurs	22 (12.0)	13 (14.0)	9 (9.9)
Farmer	49 (26.6)	23 (24.7)	26 (28.5)
Marital status, *n* (%)			
Married	172 (93.5)	89 (95.7)	83 (91.2)
Others	12 (6.5)	4 (4.3)	8 (8.8)
Underage children, *n* (%)			
Yes	28 (15.2)	15 (16.1)	13 (14.3)
No	156 (84.8)	78 (83.9)	78 (85.7)
Monthly family income (NPR) (Median±IQR)	10,000 ± 17,000	15,000 ± 16,000	5,000 ± 17,000
Residential area, *n* (%)			
Province 3	93 (50.5)	49 (52.7)	44 (48.4)
Other provinces	91 (49.5)	44 (47.3)	47 (51.6)
Co-morbidity, *n* (%)			
Yes	152 (82.6)	77 (82.8)	75 (82.4)
No	32 (17.4)	16 (17.2)	16 (17.6)
CAD Severity, *n* (%)			
No significant stenosis/No CAG performed	40 (21.7)	21 (22.6)	19 (20.8)
Single vessel disease	58 (31.5)	34 (36.6)	24 (26.4)
Double vessel disease	47 (25.6)	24 (25.8)	23 (25.3)
Triple vessel disease/Left main stenosis	39 (21.2)	14 (15.0)	25 (27.5)
Revascularization, *n* (%)			
No revascularization	57 (31.0)	25 (26.9)	32 (35.2)
PCI	107 (58.1)	61 (65.6)	46 (50.5)
CABG	20 (10.9)	7 (7.5)	13 (14.3)

Abbreviations: CABG, coronary artery bypass graft; IQR, interquartile range; NPR, Nepalese rupees; PCI, percutaneous coronary intervention.

TABLE 2 Comparison of lifestyle-related risk factors between groups at baseline, 1-month and 6-month follow-ups

Variable	Baseline			1-month follow-up			6-month follow-up		
	Intervention Group (n = 112)	Usual care Group (n = 112)	p-value	Intervention Group (n = 98)	Usual care Group (n = 98)	p-value	Intervention Group (n = 93)	Usual care Group (n = 91)	p-value
Diet, n (%)									
Low risk	71 (63.4)	86 (76.8)	.063	94 (95.9)	81 (82.7)	.005*	90 (96.8)	74 (81.3)	.001*
Medium risk	35 (31.3)	20 (17.9)		4 (4.1)	17 (17.3)		3 (3.2)	16 (17.6)	
High risk	6 (5.3)	6 (5.3)		–	–		–	1 (1.1)	
Physical activity, n (%)									
MET minutes per week ≥600	73 (65.2)	81 (72.3)	.313	79 (80.6)	75 (76.5)	.602	81 (87.1)	67 (73.6)	.026*
MET minutes per week <600	39 (34.8)	31 (27.7)		19 (19.4)	23 (23.5)		12 (12.9)	24 (26.4)	
Adherence to medication, n (%)									
High	11 (9.8)	36 (32.1)	<.001*	85 (86.7)	42 (42.9)	<.001*	82 (88.2)	50 (54.8)	<.001*
Medium	70 (62.5)	45 (40.2)		13 (13.3)	50 (51.0)		10 (10.7)	38 (41.8)	
Low	8 (7.1)	9 (8.1)		–	6 (6.1)		1 (1.1)	3 (3.4)	
No medication	23 (20.6)	22 (19.6)		–	–		–	–	
Stress, n (%)									
Low stress	4 (3.6)	1 (0.9)	.275	34 (34.7)	9 (9.2)	<.001*	20 (21.5)	5 (5.5)	<.001*
Moderate stress	104 (92.8)	109 (97.3)		64 (65.3)	87 (88.8)		73 (78.5)	84 (92.3)	
High stress	4 (3.6)	2 (1.8)		–	2 (2.0)		–	2 (2.2)	
BMI, n (%)									
Underweight	6 (5.4)	7 (6.3)	.153	4 (4.1)	7 (7.1)	.126	–	3 (3.3)	.013*
Normal weight	75 (67.0)	73 (65.2)		67 (68.4)	67 (68.4)		79 (84.9)	65 (71.4)	
Overweight	29 (25.8)	23 (20.5)		26 (26.5)	18 (18.4)		14 (15.1)	18 (19.8)	
Obese	2 (1.8)	9 (8.0)		1 (1.0)	6 (6.1)		–	5 (5.5)	
Smoking status, n (%)									
Current smoker	39 (34.8)	33 (29.5)	.078	7 (7.1)	15 (15.3)	.017*	8 (8.6)	17 (18.7)	.012*
Former smoker	37 (33.0)	28 (25.0)		59 (60.2)	40 (40.8)		55 (59.1)	35 (38.5)	
Never smoker	36 (32.2)	51 (45.5)		32 (32.7)	43 (43.9)		30 (32.3)	39 (42.8)	
Alcohol consumption, n (%)									
Current Drinker	34 (30.4)	18 (16.1)	.102	9 (9.2)	15 (15.3)	.005*	12 (12.9)	15 (16.5)	.021*
Former Drinker	19 (16.9)	15 (13.4)		38 (38.8)	16 (16.3)		32 (34.4)	15 (16.5)	
Never Drinker	59 (52.7)	79 (70.5)		51 (52.0)	67 (68.4)		49 (52.7)	61 (67.0)	

Abbreviation: MET, metabolic equivalent.

*p-value <.05 were considered statistically significant.

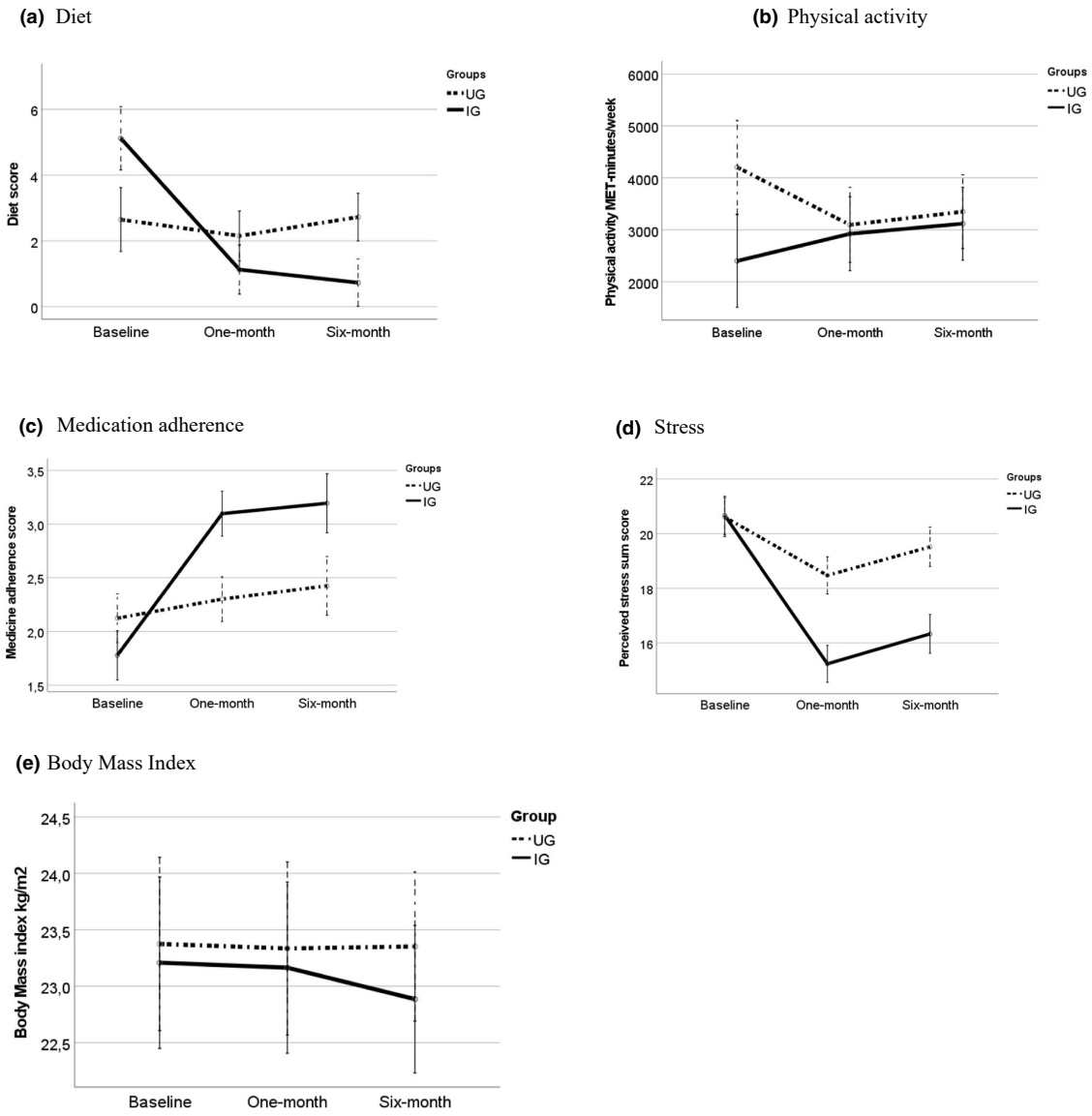

FIGURE 2 (a–e) Changes in lifestyle-related risk factor from baseline to 6-month follow-up. Error bars indicate 95% Confidence interval of mean from general linear model repeated measures analysis. Abbreviations: IG: Intervention Group, UG: Usual care Group

IG compared with UG at both follow-ups. In line with our finding, previous studies reveal that interventions aimed at raising positive feelings, cognitions or behaviours are effective in reducing participants' perceived stress (Chakhssi et al., 2018; Momeni et al., 2016).

We found that smoking habits differed significantly between the groups at follow-ups. Less than one-tenth of patients in IG and more than one-sixth of patients in UG reported to be current smokers at 6-month follow-up. Comparatively, fewer patients in IG than in UG self-reported as current smokers at follow-ups. A similar finding was reported in a systematic review on individual behavioural counselling for smoking cessation: face-to-face individual counselling from a healthcare worker for smoking cessation was more effective at 6-month follow-up when pharmacotherapy was not offered to any participants (Lancaster & Stead, 2017).

A statistically significant difference between the groups in their alcohol consumption habits were found at follow-ups. Comparatively fewer patients self-reported as current alcohol drinkers in IG than in UG. In contrast to our findings, a previous study conducted in Nepal on the effectiveness of counselling on alcohol consumption delivered by community-based counsellors, reported no significant

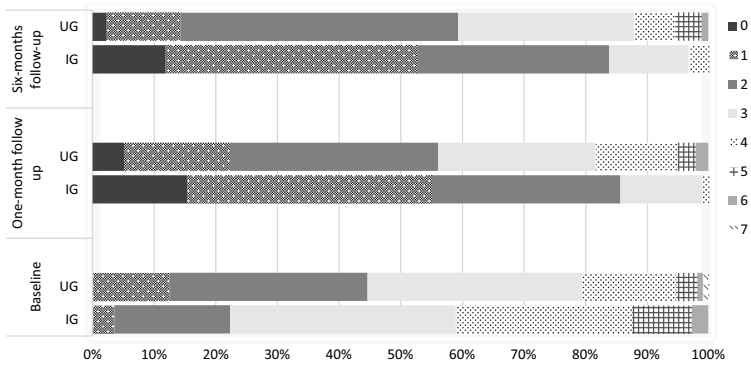

FIGURE 3 Number of lifestyle-related risk factors between study groups at baseline, at 1-month and at 6-month follow-ups. Abbreviations: IG: intervention group, UG: usual care group, number of risk factors are numbered from 0 to 7

effect in the intervention group when compared to control group participants (Jordans et al., 2019). This variance could be attributed to the fact that Jordans et al., (2019) included participants who were diagnosed with alcohol use disorder, but in our study >50% of the study participants reported to have never drunk alcohol and only <5% reported harmful or dependent use of alcohol in the baseline survey (Gaudel et al., 2020). A previous review of reviews on the effectiveness of interventions in changing health behaviours reported that counselling intervention for alcohol use is most successful in changing health behaviours for mild-to-moderate alcohol consumption or binge drinking of participants (Jepson et al., 2010).

We found a reduced total number of lifestyle-related risk factor habits in both groups during 1-month and 6-month follow-ups; however, a greater reduction was found in IG than UG. There were not any changes in the methods and study outcomes after the study commenced. Our participants' reasons for adopting healthy lifestyle habits could be their perception of being unhealthy. People tend to adopt lifestyle changes to improve their health, usually after they fall sick (Lakerveld et al., 2008). In agreement with our finding, previous studies on the effect of lifestyle counselling interventions have reported that interactively implemented patient-centred lifestyle counselling improves the adherence to healthier lifestyle habits (von Gaudecker, 2017; Jepson et al., 2010; Sargent et al., 2012). A steeper and more positive trend at 1-month than at 6-month follow-up in this study could be due to participants' initial enthusiasm for change immediately after their hospital visit.

4.1 | Strengths and limitations

The randomized control study design and use of multifaceted standard data collection questionnaires are the strengths of the study. The intervention was given by a nurse investigator, ensuring the same quality of intervention to every patient in the IG. Another strength of the study is the use of feasible and sustainable intervention that is easy to implement and adopt in a clinical setting.

Our study had some limitations. Self-reported data from participants might have caused social desirability or recall bias in both the study groups. We did not use matched randomization technique to randomize the study patient in our study. This may have created apparent imbalances between the groups in some variables at baseline which is one of the limitations of the study. Lack of double blinding could have caused unconscious inclination of the investigator towards IG. Possible contamination between IG and UG could be another study limitation, although the intervention was administered on the day of discharge from hospital to minimize contamination between groups. Using a telephone interview method for the follow-up data collection could be another study limitation. However, telephone interviews can produce high-quality data comparable to face-to face interviews (Canning et al., 2018; da Silva et al., 2014). The generalizability of this study's findings is limited due to the small sample size from a single cardiac centre.

4.2 | Implications for nursing practice

Lifestyle intervention as delivered by a nurse improved lifestyle habits in patients with CAD. Providing effective lifestyle intervention is crucial to bring about healthy lifestyle changes among CAD patients. A modest improvement of lifestyle habits has sustainable effects in reducing cardiovascular events. The prevalence of lifestyle risk factors among CAD patients highlights the inadequacies of the current health strategy. Thus, lifestyle counselling interventions for patients with CAD should be incorporated by nurses as a part of routine health care.

4.3 | Conclusion

The one-time nurse-led brief lifestyle counselling intervention supplemented with pictorial information leaflets significantly improved the lifestyle habits of CAD patients. The counselling intervention was effective even when multiple lifestyle-related risk factors, in terms of dietary habit, physical activity, perceived stress, overweight/obesity, smoking, alcohol consumption and adherence to medications were addressed simultaneously. Thus, more research should be focused on lifestyle risk factors and effective interventions to change them. This study reported the effects of intervention at 6-month

follow-up, a further study to address the long-term impact of intervention in a larger population is recommended.

ACKNOWLEDGEMENTS

We sincerely thank Sahid Gangalal National Heart center and all the participants in the study.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Pramila Gaudel: Conceptualization, methodology, formal analysis, investigation, writing original draft, project administration, writing – review and editing and funding acquisition. Subas Neupane: Conceptualization, methodology, formal analysis, supervision, validation and writing – review and editing. Anna-Maija Koivisto: methodology, validation, formal analysis. Marja Kaunonen: Conceptualization, methodology, supervision, validation, project administration and funding acquisition. Anja Rantanen: Conceptualization, methodology, supervision, validation, project administration and funding acquisition.

ETHICAL APPROVAL

Ethical approval for conducting study was obtained from the corresponding country's national health research council and also from the hospital's ethical board.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Gaudel, P., Neupane, S., Koivisto, A.-M., Kaunonen, M., & Rantanen, A. (2022). Effects of intervention on lifestyle changes among coronary artery disease patients: A 6-month follow-up study. *Nursing Open*, *9*, 2024–2036. https://doi.org/10.1002/nop2.1212