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EZZAT AHMED AL-ADAWY, R.M.M.

2022

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The incidence of metabolic syndrome amongst a group of migrants to Qatar employed in Hamad Medical Corporation 24 months postmigration: A prospective longitudinal observational cohort study

Rana Moustafa Mahmoud Ezzat Ahmed Al-Adawy

The incidence of metabolic syndrome amongst a group of migrants to Qatar employed in Hamad Medical Corporation 24 months post-migration: A prospective longitudinal observational cohort study study

Rana Moustafa Mahmoud Ezzat Ahmed Al-Adawy

A thesis submitted in partial fulfilment of the requirements of Robert Gordon University for the degree of Doctor of Philosophy

This research programme was carried out in collaboration with Hamad Medical Corporation (HMC); Qatar University (QU)

Sep 2022

"It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is most adaptable to change"

Charles Darwin

Abstract

Over the past two decades, the International Organisation for Migration highlighted the increasing proportion of international migration from 2.8% (150 million in 2000) to 3.5% (272 million in 2020) of the total world population. In 2019, the Labour Force Survey conducted by the Planning and Statistical Authority in Qatar estimated that migrants represented 91% of the total population in Qatar. Several studies have investigated the effect of migration on migrants' health, particularly relating to metabolic syndrome (MetS) development. A major limitation is that most studies researched migration to Western counties such as the USA, Canada, and Europe. The results and conclusions of these studies may not be generalisable to Qatar hence there is a gap in the literature. In addition, there was a lack of synthesis of the specific roles, activities, and impact of pharmacists in relation to MetS. The overall aim of this project was to explore the role of pharmacists in screening, prevention, and management of MetS.

The first phase was a longitudinal observational cohort study. The study aimed to investigate the effect of migration to Qatar on new MetS incidence amongst initially MetS-free migrants who were also employed at Hamad Medical Corporation (HMC), 24-months post residing in Qatar. The unique study design controlled for ethnic origin risk factors and attributed the MetS incidence to the migration process itself. The incidence of MetS amongst the initially MetS-free migrants rose to 17.0% during Qatar's two years of residence. Consuming medications that might induce MetS was the key determinant of MetS and increased the risk by 6-fold.

The increase in MetS incidence shown in phase 1 indicated a need to alleviate the effect of migration on MetS risk among migrants. A systematic review of the pharmacists' role in MetS screening, prevention and, management was conducted as the second phase of the PhD project. Ten studies were included in the review, and the settings included community pharmacies, primary health centres, inpatient and outpatients' clinics. Patient groups ranged from paediatrics with risk

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factors, adults with co-morbid conditions and psychiatric patients. Integration of the pharmacist within the multidisciplinary team, an easy referral process and accessibility of service were potential facilitators. Inadequate funding was the key barrier. The limited number of studies describing pharmacist input in MetS provides some evidence of positive outcomes of screening and management as part of collaborative practice.

The finding of both the longitudinal study and the systematic review were taken into account to recommend a bespoke pharmacist model of care to screen, prevent and manage MetS amongst Qatar's migrants. The scope is to utilise pharmacists' skills as medication experts to alleviate adverse medication effects on MetS. This is of particular relevance as medications inducing MetS was a key determinant of MetS identified amongst Qatar's migrants.

This study provides evidence about the impact of migration to the Middle East in new-onset MetS incidence. Assessment and follow-up of these migrants in terms of MetS and the elements will generally improve health status, control risk factors, and result in a less likelihood of longer-term consequences and an enhanced quality of life. This study will guide policymakers within the Ministry of Public Health and HMC in implementing preventative measures to combat MetS among migrants and develop strategies for early warning systems.

In conclusion, the unique study design of the prospective study has added to the knowledge about the effect of migration to Qatar as part of the Middle East on MetS development. In addition, the systematic review has added robust evidence about pharmacists' competence in MetS screening, prevention, and management. Further research is recommended to examine the suggested pharmacist model of care around MetS in Qatar.

Keywords: Metabolic syndrome, incidence, Qatar, migrants, 24-months postmigration, determinants.

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External output

Peer-reviewed publications:

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at: <u>http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CR4201808986</u> 2

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Oral and poster presentations:

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Al-Adawi RM, Stewart D, Ryan C, Tonna A. Systematic review of pharmacist input to metabolic syndrome screening, management and prevention. *5th Qatar international pharmacy conference QIPC.* Qatar; Feb 2019. (Poster presentation)

Al-Adawi RM, Stewart D, Ryan C, Tonna A. Systematic review of pharmacist input to metabolic syndrome screening, management, and prevention. *The European Association of Hospital Pharmacists*. Spain: Mar 2019. (Oral presentation)

Al-Adawi RM, Prabhu KS, Stewart D, Ryan C, Abdel Aziz H, Eledrisi M, Ibrahim MIM, Uddin S, Tonna A. The effect of migration on the development of metabolic syndrome in a group of migrants to Qatar. *CUDOS CONGRESS 2019 "Current Understanding in Diabetes, Obesity, and Related Disorders"*. Qatar: Nov 2019. (Poster presentation)

Al-Adawi RM, Stewart D, Ryan C, Tonna A. Systematic review of pharmacist input to metabolic syndrome screening, management and prevention. *CUDOS CONGRESS 2019* "*Current Understanding in Diabetes, Obesity, and Related Disorders*". Qatar: Nov 2019. (Poster presentation)

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Al-Adawi RM, Stewart D, Ryan C, Tonna A. A systematic review of pharmacists' input in the screening, management and prevention of metabolic syndrome. *Qatar Health 2021*. Qatar: 20-23 Jan 2020. (Poster presentation)

Al-Adawi RM, Prabhu KS, Stewart D, Ryan C, Abdel Aziz H, Eledrisi M, Ibrahim MIM, Uddin S, Tonna A. The effect of migration on the development of metabolic syndrome in a group of migrants to Qatar. *The Fourth Qatar Diabetes,*

Endocrinology and Metabolic Conference (QDEM-4). Qatar: Feb 2020. (Poster presentation)

Al-Adawi RM, Prabhu KS, Stewart D, Ryan C, Abdel Aziz H, Eledrisi M, Ibrahim MIM, Uddin S, Tonna A. Is there a role for the pharmacist in screening for metabolic syndrome?. *European Journal of Hospital Pharmacy*. 2020;27: A95. (Poster presentation, published abstract)

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Al-Adawi RM, Prabhu KS, Stewart D, Ryan C, Abdel Aziz H, Eledrisi M, Ibrahim MIM, Uddin S, Tonna A. The effect of migration on the incidence of new-onset metabolic syndrome amongst a group of migrants to Qatar. *Qatar University Health Research Symposium. Qatar*: Nov 2020. (Oral presentation)

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Forward

This thesis represents my PhD project, conducted on a part-time basis, initiated in Oct 2016 and completed in February 2022 at Robert Gordon University, Aberdeen, UK. During the last four years, I have been investigating the effect of migration to the Middle East on migrant's health concerning MetS development. In addition, I have also been exploring the potential role of pharmacists in screening prevention, and management of MetS.

I obtained my Bachelor's degree in Pharmaceutical Science from Al-Mansoura University in Egypt and graduated with a strong standing in 2007. I got my Master's degree in clinical pharmacy from Queen's University, Belfast, UK, in 2012 with commendation. After, I have worked as an investigator and co-investigator in many research projects to improve my research experience and sharpen my skills, with particular interest in endocrine and diabetes. Currently, I am working as a clinical pharmacist at the leading national health service institution in Qatar, Hamad Medical Corporation.

Being a migrant to Qatar was the inspiration to shed some light on migrants' health and positively impact their health outcomes whilst also contributing towards saving the healthcare resources of Qatar.

It was a real learning experience. Throughout my PhD journey, I have been learning a lot about research from the intensive courses provided by the university, the continuous constructive feedback from my supervisory team and the support of fellow research students. All this guided my development as a researcher. Additionally, I was fortunate enough to present the abstracts of this project at several national and international conferences and network with people from different regions across the world, which have further enhanced my learning experience. Unfortunately, we lost considerable opportunities during the COVID-19 outbreak. The abstract was accepted at several national and international conferences and forums that unfortunately were cancelled due to the initial COVID-19 outbreak. In due course, the online platforms solved this issue, and all conferences were held virtually.

The results of this project will positively impact the health of migrants to Qatar and the Middle East. Pharmacist participation in screening and prevention of MetS would serve the Qatar national vision 2030 to attain better health and accessible, cost-effective healthcare.

Thesis structure

A prospective longitudinal research design and a systematic review were chosen to pursue this doctoral project and were presented in five chapters as follows.

Chapter 1 provides an overview of metabolic syndrome, complications and burden, in addition to outlines about Qatar, the health sector, the migrants' population in Qatar, and the evolving role of pharmacists beyond the confined role in dispensing areas.

Chapter 2 provides an overview of paradigms, methodologies and methods used to describe research focusing on application to this doctoral project. A justification of the selected approaches concerning the study objectives and outcomes is provided in this chapter, along with each methodology's potential advantages and limitations.

Chapter 3 describes the first study of this PhD project, the prospective longitudinal observational cohort study that aimed to explore the incidence of MetS, components and risk factors in a population of HMC migrants over time. The detailed methods, research team responsibility and findings are discussed in the chapter.

Chapter 4, the second study of this PhD project, was an original systematic review that aimed to critically appraise, synthesise, and present the available evidence on the pharmacists' input in the screening, prevention, and management of MetS. The protocol was developed following the PRISMA-P statement and published in the International Prospective Register of Systematic Reviews in Health and Social Science PROSPERO. This review's findings provide evidence of positive outcomes of pharmacist input in MetS screening and management as part of collaborative practice.

Chapter 5 summarises the aim and key findings of each phase of this project, designates the novelty of the research idea, compares the findings with the literature, describes the relevance to the local scene, outlines the potential impact and discusses potential future research.

Abbreviations

\$	United States dollar
AACE	American Association of Clinical Endocrinologists
АНА	American Heart Association
AHA/NHLBI	American Heart Association and the National Heart, Lung, and
	Blood Institute
AOR	Adjusted odds ratio
APA	American Psychiatric Association
ASHP	American Society of Hospital Pharmacist
BG	Blood Glucose
BMI	Body Mass Index
BP	Blood Pressure
CAP	College of American Pathologists
CHD	Coronary Heart Disease
CONSORT	Consolidated Standards of Reporting Trials
COREQ	The consolidated criteria for reporting qualitative studies
DBP	Diastolic blood pressure
DM	Diabetes Mellitus
DRPs	Drug Related Problems
EBM	Evidence-based medicine
EGIR	European Group for the study of Insulin Resistance
EQUATOR	Enhancing the QUAlity and Transparency Of health Research
FBG	Fasting Blood Glucose
FIFA	Fédération Internationale de Football Association
GCC	Gulf Corporate Council
HbA1c	Glycated Haemoglobin
HDL-C	High-Density Lipoprotein Cholesterol
НМС	Hamad Medical Corporation
Ht	Height
HTN	Hypertension
IDF	International Diabetes Federation
IPA	International Pharmaceutical Abstracts

IQR	inter-quartile ratio			
IRB	institutional review board			
IT	Information Technology			
JCI	Joint Commission International			
MARE	Metabolic Syndrome and Arteries Research			
MDT	Multidisciplinary Team			
MEDLINE	Medical Literature Analysis and Retrieval System Online			
MetS	Metabolic Syndrome			
MRC	Medical Research Council			
MSc	Master of Science			
NCEP/ATP III	National Cholesterol Education Program/Adult Treatment Panel III			
NHS	National Health Strategy			
OR	Odds ratio			
PI	Principal Investigator			
PICO	Population, Intervention, Comparator and Outcomes			
POC Point-Of-Care				
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses			
PRISMA-P	Preferred Reporting Items for Systematic Review and Meta-Analysis			
	Protocols			
PROSPERO	International Database of the Prospectively Registered Systematic			
	Review in Health and Social Science			
QNV	Qatar National Vision			
RA	Research Assistant			
RCT	Randomised Controlled Trials			
RGU	Robert Gordon University			
SBP	Systolic blood pressure			
SD	Standard Deviation			
TG	Triglycerides			
UKRI	UK Research Innovation			
USA	United States of America			
WC	Waist Circumference			
WHO	World Health Organization			

Wt Weight

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Chapter 1: Introduction

Chapter 1: An overview of Metabolic Syndrome

1.1 Definitions of Metabolic Syndrome

The American Heart Association (AHA) considers metabolic syndrome (MetS) as a global epidemic (1,2), where it affects about one-quarter of the world's adult population and is a significant cause of morbidity and mortality (3,4). This syndrome includes the most commonly occurring chronic diseases of diabetes mellitus (DM), hypertension (HTN) dyslipidemia and obesity, yet is underdiagnosed and underrated by physicians (2,5). Over the years, there have been several attempts to define MetS. As early as 1988, Reaven described the coexistence of cardiovascular risk factors including DM, HTN and dyslipidemia with suggestions that insulin resistance was the key risk factor. This was known as "syndrome X" (6). One year later, the definition was modified by Kaplan, and central obesity was introduced to the definition, now termed "deadly quarter" (7).

In 1998, the World Health Organization (WHO) was the first international organization to define MetS. Insulin resistance was proposed as the main element to diagnose an individual with MetS (8). The European Group for the study of Insulin Resistance (EGIR) later modified the definition, where the cutoff value of triglycerides (TG) increased from \geq 1.7 to 2 mmol/L and waist circumference (WC) replaced both body mass index (BMI) and waist/hip ratio (9) (Table 1.1).

In 2002, the National Cholesterol Education Program/Adult Treatment Panel III (NCEP/ATP III), expanded the definition to include five criteria, with patients considered to have MetS if they have three of these five criteria (10). This definition was updated in 2003 by the American Association of Clinical Endocrinologists (AACE) (11) and further updated again by the NCEP/ATP III in 2005 (12) (Table 1.1).

In the absence of a universally well-accepted definition, the International Diabetes Federation (IDF) published the consensus-developed worldwide definition of MetS in 2006 (Table 1.1). Central obesity and insulin resistance were

2

acknowledged as important causative factors for MetS (3). In 2009, the IDF task force reviewed the definition, and the interim statement was published. The updated criteria define a person as having MetS if there are any three out of the following five elements; HTN, DM, elevated TG, low High-density lipoprotein cholesterol (HDL-C) or central obesity, without obesity being an essential diagnostic element (Table 1.1) (13). Of note, this is still the current definition with no further updates.

Parameters considered in definition	WHO 1998 (8)	EGIR 1999 (9)	NCEP/ATPIII 2002 (10)	AACE 2003 (11)	NCEP/ATPIII 2005 (12)	IDF 2006 (3)	IDF harmonised criteria 2009 (13)
Essential	Insulin resistance (in top 25.0% of the laboratory specific reference range) *; glucose ≥ 6.1 mmol/L; 2-hour glucose ≥ 7.8 mmol/L	Insulin resistance or fasting hyperinsulinemia (in top 25.0% of the laboratory specific reference range) *		High risk of insulin resistance or BMI ≥25 kg/m ² or WC ≥102 cm (men) or ≥88 cm (women)		WC ≥94 cm (men) or ≥80 cm (women)	
Number of abnormalities	And ≥2 of:	And ≥2 of:	≥3 of:	And ≥2 of:	≥3 of:	And ≥2 of:	≥3 of:
Glucose (mmol/L)		6.1 to 6.9	≥6.1	≥6.1; ≥2-hour glucose 7.8	≥5.6 or drug treatment for elevated blood glucose	≥5.6 or diagnosed diabetes	≥5.6 or drug treatment for elevated blood glucose
HDL- cholesterol (mmol/L)	<0.9 (men); <1.0 (women)	<1.0	<1.0 (men); <1.3 (women)	<1.0 (men); <1.3 (women)	<1.0 (men); <1.3 (women) or drug treatment for low HDL-C	<1.0 (men); <1.3 (women) or drug treatment for low HDL-C	<1.0 (men); <1.3 (women) or drug treatment for low HDL-C
Triglycerides (mmol/L)	≥1.7	≥2.0 or drug treatment for dyslipidemia	≥1.7	≥1.7	≥1.7 or drug treatment for elevated triglycerides	≥1.7 or drug treatment for high triglycerides	≥1.7 or drug treatment for high triglycerides
Obesity	Waist/hip ratio men >0.9 or Women >0.85 or BMI ≥30 kg/m ²	WC Men ≥94 cm or Women ≥80 cm	WC Men >102 cm or Women >88 cm		WC Men ≥102 cm or Women ≥88 cm		WC: population- and country-specific definitions (See Table 1.2)
Hypertension (mmHg)	≥140/90	≥140/90 or drug treatment for hypertension	≥130/85	≥130/85	≥130/85 or drug treatment for hypertension	≥130/85 or drug treatment for hypertension	≥130/85 or drug treatment for hypertension

Table 1.1 Evolution of metabolic syndrome definition by different organisations.

* Insulin resistance measured by insulin clamp, which administers IV insulin and glucose infusion with frequent blood glucose monitoring (14-16).

Abbreviations: WC, Waist circumference; BMI, Body Mass Index; HDL-cholesterol, High-Density Lipoprotein-cholesterol.

Country/ethnic specific values for WC, as advocated by IDF in 2006 and retained in IDF 2009 revision, are given in Table 1.2.

Country/ethnic group		Waist circumference (as measure of central obesity)
Europids	Male	≥ 94 cm
	Female	≥ 80 cm
South Asians	Male	≥ 90 cm
	Female	≥ 80 cm
Chinese	Male	≥ 90 cm
	Female	≥ 80 cm
Japanese	Male	≥ 90 cm
	Female	≥ 80 cm
Ethnic South and Central	Use South Asian recommendations until	
Americans	more specific data are available	
Sub-Saharan Africans	Use European data until more specific data are available	
Eastern Mediterranean and Middle East (Arab) populations	Use European data until more specific data are available	

Table 1.2 Country/ethnic-specific values for waist circumference (3).

The harmonised IDF criteria advocated for adapting country/ethnic-specific values of WC measurements rather than fixed numbers as described in NCEP/ATP III (13) (Table 1.1 and 1.2). The harmonised IDF criteria have been used as the criteria of choice to estimate prevalence and incidence of MetS in the Middle East and Mediterranean region in several studies (17,18). Indeed, in the past decade, the harmonised IDF MetS criteria has been the most widely quoted in the literature as a tool to diagnose MetS (17-22). In summary, the harmonised IDF criteria define patients as having MetS if they have any three out of the following five elements (DM, HTN, high TG, low HDL-C, or central obesity), without considering the central obesity an essential element (13). This definition was adopted throughout this thesis.

1.2 Pathogenesis

MetS pathogenicity is attributed to a combination of genetic predisposition, excessive calorific intake, and sedentary lifestyle, leading to abdominal obesity and insulin resistance. These attributed factors provoke DM, HTN, and dyslipidemia via several biochemical pathways, eventually leading to MetS (23,24). Additionally, some specific types of medicines may influence the development of MetS, for example, antidepressants, thiazide diuretics, βeta-blockers, thiazolidinediones, and oral contraceptives (25).

1.3 Risk factors

1.3.1 Non-modifiable risk factors

The non-modifiable risk factors for MetS are ethnic group, age, family history, hormonal changes, fatty liver, polycystic ovary disease and sleep apnea (23).

1.3.2 Modifiable risk factors

In addition to the modifiable clinical factors articulated earlier (e.g. DM, HTN, dyslipidemia and obesity), there are others which merit further description and consideration. There is some evidence that psychological factors of anger, stress, anxiety, and sleep deprivation may also increase the risk of MetS (26,27).

Moreover, accumulating evidence has linked migration and immigration to MetS and its individual elements (DM, HTN, high TG, low HDL-C and central obesity) (28-33).

Several studies have explored the process by which immigration and migration increase the risk of MetS. This was found to be multifactorial and factors included are acculturation and acculturation stress (34-38), urbanization (39,40), westernization (41-46), leisure time physical activity (47) and migration period (30,48-51). These factors are discussed in greater detail in section 1.7.

1.4 Prevalence of MetS

According to IDF, MetS affects one-quarter of the world's population, doubling the risk of coronary heart disease, increasing the risk of mortality secondary to coronary heart disease threefold and increasing the risk of developing Type 2 DM fivefold in those not already affected. MetS has become a global concern due to its increasing prevalence as a result of rising obesity (3).

Data from a National Health and Nutrition Examination Survey in the United States of America (USA) estimated the prevalence of MetS in a cohort of more than 50,000 adults. Over 24 years, data indicated an increase in MetS prevalence from 1988 to 2012 (Figure 1.1), which is expected to further increase due to growing obesity and increased life expectancy (21).

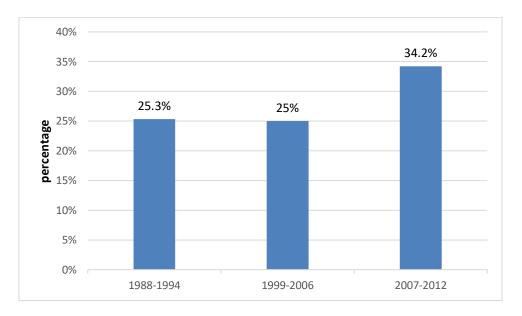


Figure 1.1 MetS prevalence in the USA over years (21).

Data from the Metabolic Syndrome and Arteries Research (MARE) Consortium, examined more than 34,800 participants from ten European countries and one cohort from the USA, showing a 24.3% overall prevalence of MetS, that increased directly with age advancement. Figure 1.2 illustrates the breakdown of MetS prevalence in Europe and the USA. MetS prevalence in the USA was lower than in most European countries. However, it should be noted that the author acknowledged the small sample size and unrepresentative samples as limitations of the study. (52) (Figure 1.2).

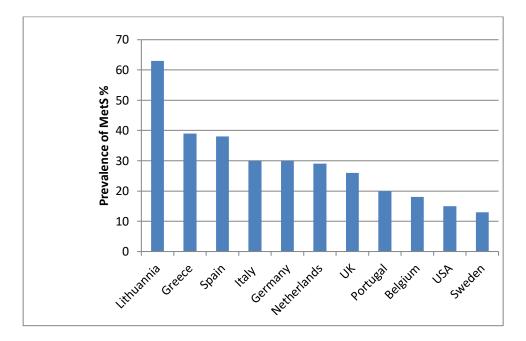


Figure 1.2 Prevalence of MetS in the USA and Europe (52).

Prevalence figures of MetS are also high in the Middle East, estimated at around 16.0% in Saudi Arabia (3), 36.0% in Iran (53) and 33.0% in Kuwait (54). Several studies have researched the prevalence of MetS in Qatar. Using the IDF criteria, the prevalence was 34.0% for Qatari nationals, (55), increasing to 46.0% amongst obese Qatari nationals (56). Adopting NCEP/ATP III criteria, a recent cross-sectional survey conducted in 2020 showed that the MetS prevalence amongst Qatar population (nationals and migrants) was 48.8%, while the prevalence specifically amongst Qatari nationals was 43.0% (57). The individual elements of MetS have also been studied with prevalence data for the Qatari population. The following figures were reported: 17.0% for DM, 19.0% for HTN, 35.0% for obesity and 22.0% for hypertriglyceridaemia. Notably, almost three quarters of participants (71.3%) were not engaged in vigorous physical activity, and more than 90.0% were eating less than five portions of fruit or vegetables per day (58,59).

1.5 Complications and consequences

As described earlier, MetS has serious consequences in terms of morbidity, mortality, and economics. MetS can predispose the individual to higher cardiovascular disease and stroke risks (60) increase Type 2 DM fivefold (3) and increase the risk of various cancers (61). Notably, it may also increase the risk of nonalcoholic fatty liver and the most severe form, nonalcoholic steatohepatitis (62,63), which in turn can progress to liver hepatocellular carcinoma (64), one of the leading causes of cancer death in the USA (65). MetS raises the possibility of developing preeclampsia in pregnancy (66) and is also linked to a decline in cognitive function in older people (67-69).

A systematic review of 30 clinical studies, which included data from over 60,000 individuals, supported the association between MetS and decreased quality of life, particularly in women and obese patients (70). A metaanalysis of 20 studies confirmed the relationship between MetS and hypogonadism (71).

1.6 Burden of MetS and the complications

MetS increases the risk of heart disease, DM, and cancer (3) which are accompanied by devastating economic consequences. As demonstrated in Figure 1.3, in 2017 the National Vital Statistics Reports in the USA showed that heart disease and cancer as the leading causes of mortality which may be direct consequences of MetS (72). In 2020, the AHA endorsed stroke and heart disease fact sheet that the direct cost (medical expenditure) and the indirect cost (loss productivity/mortality) of cardiovascular disease were estimated to be \$213.8 billion and \$351.3 billion annually respectively (73).

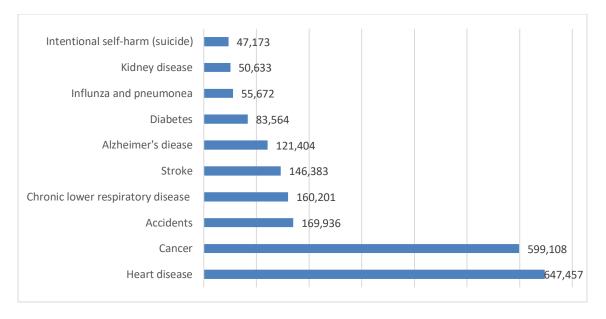


Figure 1.3 Deaths per leading cause of mortality in the USA in 2017 (72).

Similarly, MetS increases the risk of Type 2 DM fivefold (3), which imposes a substantial economic burden on patients, society, and healthcare system. In the USA in 2017, the total direct and indirect cost of DM was estimated to be \$327 billion (74).

Moreover, each individual element of the MetS was attributed to an annual increment in the total healthcare cost of about 25.0% per each additional MetS risk factor (75). When compared to those without MetS, the annual healthcare cost for MetS patients was 4.5 times higher (76). Several studies have reported an additional increment in the indirect economic burden in the form of disability costs, productivity loss, occupational dysfunction and increasing health and pharmacy costs (76-80).

As discussed earlier, MetS increases the risk of cancers, which is considered to be the second leading cause of death in the USA (72) (Figure 1.3). In 2012, the burden of MetS related cancer was assessed in a study undertaken in South Korea. The estimated cost of MetS related cancer in South Korea was \$124.5 million for direct medical expenditure and \$75.3 million for the indirect burden, for example, loss of productivity and death (81).

1.7 Migration and MetS

Globalisation has increased the rate of migration and movement for different purposes such as economic, professional, or due to conflicts. Consequently, health-related problems associated with migration are a worldwide concern. Literature links migration to increased incidence of MetS and the individual elements of HTN, DM and obesity (28-30,82).

One of the attributed events is the acculturation stress, defined as stress generated amongst migrants due to legal status, language conflict, feelings of loneliness, financial situation or discrimination, which may negatively affect physical, psychological and social health (34,83-85). As described in the literature, migrants from sub-Saharan Africa reported a higher rate of development of Type 2 DM compared to natives. The native rural Ethiopian population has a 1.0% risk of diabetes. However, on migration to Israel, the risk of Type 2 DM increased to 3.6% despite similarity in genetic characteristics (34).

In addition, urbanisation was found to affect the development of MetS in migrants (29,47,86). Several studies have argued that the higher the levels of urbanisation, industrialisation and economic growth in the destination country, the greater the risk of developing cardiovascular disease and Type 2 DM. This has been attributed to the changes in diet, lifestyle and physical activity (42,43,46,87). Moreover, factors of increased calorific intake and decreased energy expenditure have been widely discussed in other studies (44,45,88). Accumulating evidence from three systematic reviews and meta-analyses highlighted an inverse relationship between the level of leisure time physical activity (any physical activity take place in free time) and the risk of MetS development (89-91).

The time spent by migrants away from their original home country required to develop MetS or one of the core five elements is still relatively unknown

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and undocumented. No clear cutoff points have been reported in the literature. Some studies stratified the population into groups, from zero to more than 15 years-post migration, for assessing MetS or its elements (28,34,92). Compared to South Asian migrants who lived in the USA for less than 15 years, migrants who spent more than 15 years were at a significantly higher risk of cardiovascular diseases. (28). Another study showed that Taiwanese women who lived in Australia for more than five years had a higher risk of developing insulin resistance, obesity and deranged liver enzymes, compared to those who lived in Australia for less than five years (93). On the other hand, some studies have argued that changes in MetS elements (e.g. blood pressure (BP), insulin resistance and lipid derangements) can be affected following periods as short as one-year post residing in the destination country (30,50,51).

Migration is defined as temporary movement to a country to find work; immigration is usually associated with moving to a country to permanently live there (94). This distinction is not always made in the literature. Others also consider immigration to include rural to urban movement within the same country. In the context of Qatar, migration is likely to be more relevant, and consequently, the term "migration" has been adopted for use throughout this thesis.

1.8 Role of pharmacist in patients' care

Historically the pharmacist's role was confined to medication dispensing areas. This has evolved, and healthcare systems tend to utilise the knowledge and experience of pharmacists towards improving patient care (95).

As early as 1990, pharmaceutical care was first described by Hepler and Strand, who extended the pharmacist's responsibilities beyond the dispensing role to a patient-centred care process that aims to decrease the preventable medication-related morbidity, mortality, length of hospital stay and foster the quality of life (96). In a further statement published by the American Society of Hospital Pharmacist (ASHP) in 1993 and reviewed in 1998, pharmaceutical care was further expanded to cover two main elements; the first element addressing medications and medication-related problems and the second patient-centred care (97). Subsequently, the perspective of the profession has transformed from pure medication dispensing to a more comprehensive patient-centred care, supported by postgraduate training and qualifications (98).

Pharmacists can collaborate in the medical care of MetS. Pharmacists could host MetS screening and educational campaigns, to raise awareness about MetS as a silent syndrome. Additionally, they may identify the at-risk population and those who need medical attention. Moreover, pharmacists have a role in educating MetS patients about their medications, foster medication adherence, and augment patients' abilities to self-monitor BP, blood glucose (BG) and weight (Wt). Pharmacists may also have a role in emphasizing the role of non-pharmacological interventions in modifying MetS risk factors, for example, a healthy diet and exercise (99).

In collaboration with physicians or independently, pharmacists have shown their ability to manage the separate elements of MetS. Many studies have provided evidence of pharmacist interventions benefit in DM (100-102), HTN (103,104), dyslipidemia (105,106), and obesity (107,108). According to a review undertaken by Harvard Business School, pharmacists' extensive medication knowledge, along with the capability to access laboratory results, apply clinical protocols and modify medications empowered pharmacists to extend their support to the physicians to provide integrative healthcare and improve patients quality of care (109).This contemporary service development resulted in curbing healthcare cost especially amongst complicated cases with polypharmacy (110).

1.9 Relevance to Qatar

This research was undertaken in Qatar; hence, the following section provides background information about Qatar. Qatar is a peninsula located in the central Northeast coast of the Arabian Gulf and has 536 kilometres of coastline. Saudi Arabia is the only country that shares land border at the southern area (111) (Figure 1.4). Qatar recorded a vast improvement in peace and security domain, and was ranked by the Institute for Economics and Peace as the 31st ahead of 132 countries in global peace (112) and considered the wealthiest country in the region per-capita with high oil and gas reserves (113).

Doha is the capital city of Qatar located on the Eastern coast of the Arabian Gulf, more than half of the nation's population are located in Doha and its suburb, where most of the governmental, cultural and economic activities are concentrated (111).

Arabic is the official language; the English language is widely spoken due to the open culture and diversity of nationalities. Qatar is an Islamic country; Islam is the base of its cultures and law. However, Qatar maintains religious freedom; many of the migrants are believers of Christianity, Hinduism, and Buddhism (111).

The terrain in Qatar is generally flat desert in nature, and the weather is hot and humid most of the year (range from 22 degrees Celsius in winter to 45 degrees Celsius in summer), most days are sunny, rainy occasionally in the winter (111).



Figure 1.4 The Gulf Corporate Council (GCC) map (114).

Qatar is one of six countries comprising the Gulf Corporate Council (GCC); these countries are Qatar, Kingdom of Saudi Arabia, United Arab Emirates, Sultanate of Oman, Kuwait, and Kingdom of Bahrain. They share similar geographical characteristics, hot weather, Arabic culture, and habits. This union was created in 1981 to advance their economies (115).

Qatar will host the "Fédération Internationale de Football Association" (FIFA) world cup 2022, and the infrastructure has been built or is still under construction for this event. This has created a substantial work opportunity and attracted many professional and low-skilled labourers to Qatar resulting in the dramatic increase to the Qatari population recently.

Qatar public transportation and infrastructure underwent a major overall evolvement by launching the rail, new highways, expanding the healthcare facilities in addition to building 12 iconic stadiums. Qatar invested in these projects, which will sustain beyond staging FIFA world cup 2022 (116). In the last decade, Qatar has witnessed massive evolution in multiple areas, which created a lot of job opportunities, and attracted people from different regions of the world with various backgrounds. The population in Qatar has grown significantly over the past 27 years, to reach 2.8 million in 2019 from 250,00 in 1950 (Figure 1.5). Of note, about 94.0% of Qatar's workforce and 91.0% of the total population are migrants. 64.0% of Qatar newborns are foreigners (117,118). It is worth mentioning that about 21.8% of the migrant population in Qatar are from India, 12.5% from Nepal, 12.5% from Bangladesh and about 17.6% are from other Arab countries, including Egypt, Syria, Lebanon, Jourdan, Palestine and Sudan (Figure 1.6), with variable educational attainment as illustrated in Figure 1.7 (117).

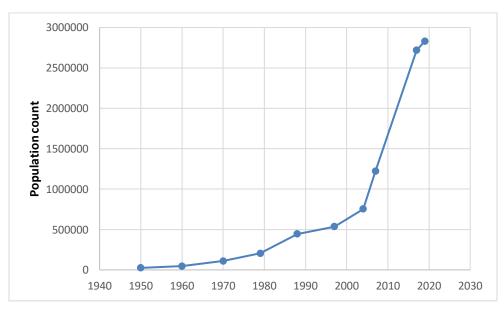


Figure 1.5 The evolution of Qatar's Population (119,120).

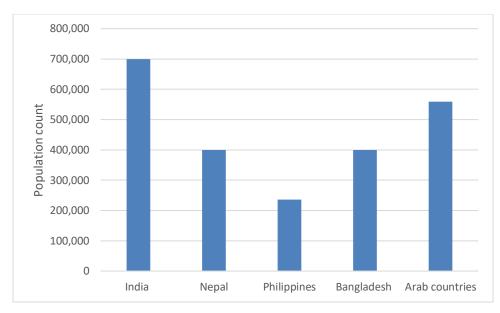


Figure 1.6 Population of Qatar migrants by nationalities (133).

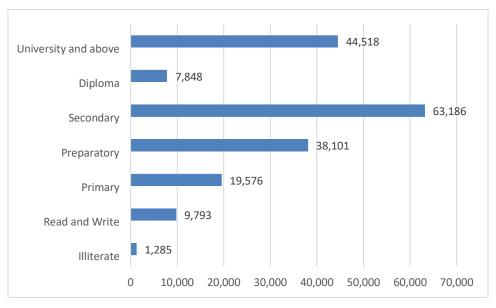


Figure 1.7 Migrant population by educational attainment (117).

1.9.1 Qatar National vision (QNV) 2030, health focus

In 2008, the Qatar National Vision 2030 was launched, mapping the road for the prosperous future of the country in both economic and social aspects. This vision encourages galvanising the power of all the governmental, private sectors, the society and Qatar citizens toward prosperity while maintaining the Islamic and Arabic identity.

The Qatar National Vision 2030 is based on four pillars: human, social, economic, and environmental development pillars (Figure 1.8). The human development pillar comprises three outcomes: well-educated generations, physically and mentally healthy population and skilled and inspired workforce. The health-related outcome aims to establish world-standard high-class integrated healthcare that is affordable, accessible, and comprehensive. It also aims to foster public health, "prevent diseases and epidemics" and pursue high-quality research to meet the national healthcare needs (121).

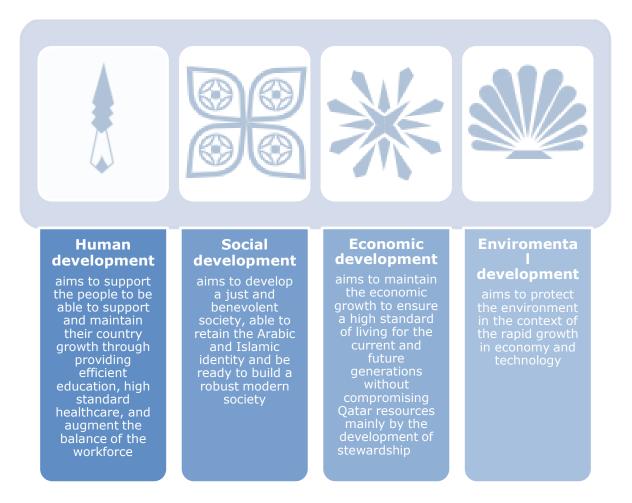


Figure 1.8 Qatar National Vision 2030 pillars (121).

1.9.2 National Health Strategy (NHS)

To aspire ambitious health-related goals, Qatar National Vision 2030 set forth the framework for a multiphasic long-term outcome plan; the National Health Strategy 2011-2016, followed by National Health Strategy 2018-2022. The initial strategy described the health developments that resulted in; increased healthcare capacity, a comprehensive, accessible primary healthcare, an integrated e-health system throughout the health sector, a well-governed health research, a proactive health promotion that aimed to disease prevention and early detection, and world-class healthcare. The National Health Strategy 2011-2016 attained fundamental reforms to the health system among the pre-defined seven goals, through 38 successful projects and over 200 fruitful outcomes (122,123).

This was further carried on by an updated strategy launched in 2018. The health challenges were highlighted to galvanise the efforts to achieve the triple aimed therapy; better health, better care, and better value (Figure 1.9) (122). Transforming healthcare to more patient-centred care was believed as an essential demand to follow the global vision (Figure 1.10).

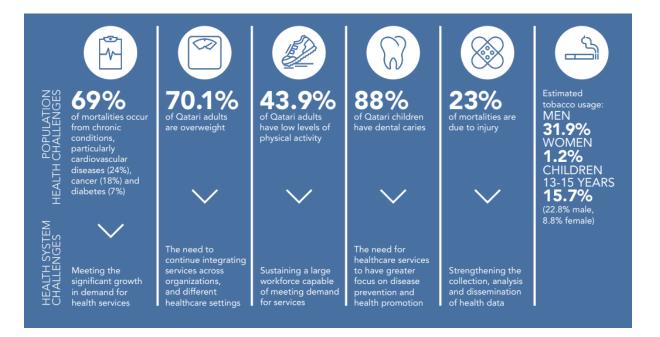


Figure 1.9 The healthcare sector challenges in Qatar 2018-2022. (Source Ministry of public health 2018) (122).

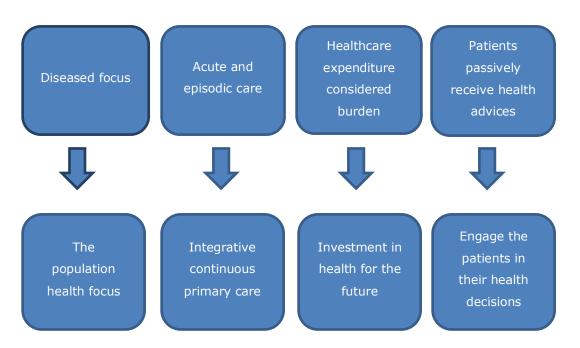


Figure 1.10 The transition of healthcare vision. (Source Ministry of public health 2018) (122).

The following figure summarises the National Health Strategy triple goals in the context of the Qatar National Vision 2030 health-related outcomes, the seven priority-populations in addition to the five system-wide priorities (Figure 1.11).

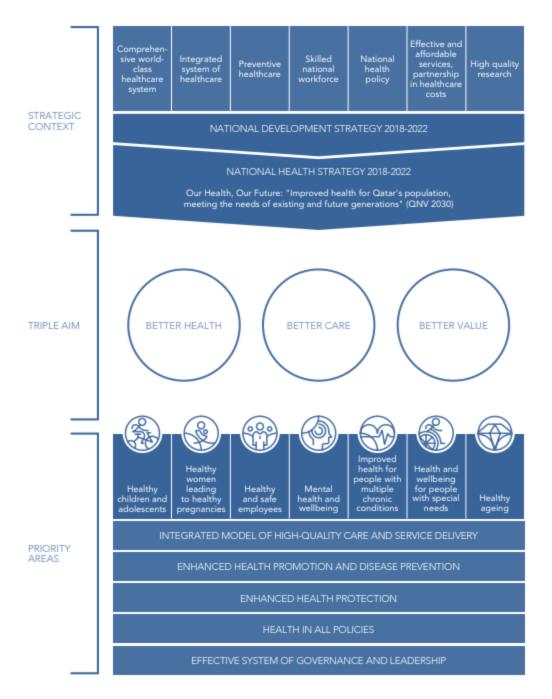


Figure 1.11 The health sector priorities and focus areas. (Source Ministry of public health 2018) (122).

1.9.3 History and demographics of the health sector

Qatar has a well-established and advanced healthcare system, including; 4 medical commission centres, 30 primary health centres, and Hamad Medical Corporation (HMC) in addition to private clinics and medical facilities with appropriate geographical distribution based on the population density (124) (see Table 1.3). HMC is a governmental academic non-profit provider of secondary and tertiary healthcare consisting of 20 facilities, including nine specialised hospitals, three general hospitals in addition to ambulance service, home healthcare and skilled nursing facilities. In 2011, HMC was the first institution out of the USA to have the Joint Commission International (JCI) accreditation for all its facilities, demonstrating global healthcare excellence (125) (see Table 1.3). HMC sponsors several residency and fellowship programs and is affiliated with two medical schools in Qatar, Weil Coronail and Qarar University (117).

HMC is the leading healthcare provider in Qatar, due to the geographical distribution of its facilities in the country. HMC is a governmental healthcare institution providing free medical services to the Qatari national population and subsidises healthcare services to migrants (117). The Ministry of Public Health 2017 reported that patients load is about 75.0% concentrated at HMC (126), with 1,474,614 outpatient visits, 326,740 admissions and 1,117,675 emergency department visits reported during 2017 (127). Hence, meeting the ambitious national vision, Qatar has expanded the healthcare facilities to address the demand on health sectors as illustrated in Tables 1.3 and 1.4.

Table 1.3 Comparing the number of hospitals, health centres, clinics and pharmacies in Qatar in 2015 and 2018 (124).

Hospitals, Health centres, clinics and pharmacies	Number of facilities 2015	Number of facilities 2018
Governmental hospitals and nursing facilities	10	20
Private hospitals	4	6
Healthcare centres	22	30
Paediatric emergency centres	5	5
Hamad General Hospital outpatient clinics	9	53
Medical commission	3	4
Sports medical centres	1	1
Qatar petroleum clinics	22	19
Private sector clinics	642	490
Private pharmacies	414	327
Private laboratories & X-rays	62	54

Table 1.4 The list of hospitals and the corresponding number of beds in Qatar 2015 and 2018 (124).

The hospital	Number of beds	Number of
	2015	beds 2018
Hamad General Hospital	600	663
Ruhmailah hospital	588	243
Surgery centre	0	354
Al Amal Hospital	66	61
Al Khor Hospital	122	113
Heart Hospital	116	114
Al Wakrah Hospital	269	326
Cuban Hospital	81	72
Aspetar	20	50
Naufar	28	127
Communicable disease Centre CDC	0	65
Psychiatry hospital	0	77
Women wellness and research centre	0	167
Qatar Rehabilitation institute	0	167
Ambulatory care centre	0	15
Hazm Mebaireek general hospital	0	118
Enaya specialized care centre	0	134
Residential community	0	75
Muather compound	0	24
Sidra medicine	0	394
Private hospitals	254	358
Total	2,462	3,535

1.9.4 Prevalence of MetS amongst native Qatar's citizens

In an attempt to construct a country-specific definition of MetS, Al-Thani et al. conducted a national health survey amongst native Qatari citizens in 2012 that employed the WHO STEPwise questionnaire for chronic non-communicable diseases. This survey revealed that cut-off points of WC \geq

102cm for men and ≥ 94cm for females are the core determinants of the other MetS elements amongst adult Qataris. Accordingly, the estimated prevalence of MetS was lower when compared to the one calculated with the harmonised IDF criteria (28.0% (n=699) vs 37.0% (n=924) respectively). However, amongst those who were not known to have any medical illnesses, 16.5% of the native Qatari population were diagnosed with MetS, and a significant correlation of MetS prevalence with advancing age was highlighted (128). Additionally, the results of the questionnaire revealed that 16.8% of the study population were diabetics, 32.0% were hypertensive, 9.0% had high LDL-C, 15.8% had high fasting TG, and 37.0% of the female population had low HDL-C and 49.2% of males (129).

An earlier published study by Musallaum et al. reported comparable MetS prevalence utilising the NCEP/ATP III and IDF criteria. The prevalence was estimated to be 26.4% and 34.0%, respectively, amongst native Qataris. Age, obesity, and diabetes were found to have a significant relation with the increasing prevalence of MetS (55).

Furthermore, amongst obese native Qatari citizens (BMI >30kg/m²), Ismail established, in a randomised cross-sectional study, that 46.3% (n=63) were diagnosed with MetS according to the IDF MetS criteria. Similarly, both diabetes and advanced age were significantly associated with increased risk of MetS (56).

A recent cross-sectional study estimated the prevalence of MetS among people who visited the primary healthcare centres in Qatar during 2017, the NCEP/ATP III criteria. The study revealed a prevalence of MetS amongst native Qatari citizens (43.0%) (57) higher than that reported earlier in 2008 (26.4%) using the same criteria (55).

Growing obesity amongst adults and children is a worldwide concern. In 2016, the WHO global obesity report declared an increasing obesity and

overweight prevalence by 3-fold amongst adults and by more than 4.5-fold amongst children (aged 5-19 years) since 1975 (130). Likewise, the world health survey conducted in Qatar, among children (2-19 years), from 2006 to 2016 revealed that the prevalence of being overweight had increased by more than 3-fold from 12.6% to 43.0%, and obesity increased from 16.1% to 21.5% (129,131).

In 2015, the Ministry of Public Health statistical authority defined low physical activity, overweight and chronic non-communicable diseases as healthcare challenges. About 1 in 5 adult Qataris had low physical activities, and 5 in 7 were identified as overweight (BMI> 25 to 29.9Kg/m2), 69.0% of native Qatari citizens died from chronic non-communicable diseases (Figure 1.7) (122).

1.9.5 Migrants' health in Qatar and GCC

When compared to the native Qatar citizens (43.0%), MetS prevalence was higher amongst Qatar's migrant groups from South Asia 50.7%, North Africa 50.7% and Western Asia 46.8% who showed higher odds of developing MetS (OR 1.73, OR 1.8 and OR 1.17 respectively) (57).

Growing evidence highlights a high rate of non-communicable diseases amongst migrants to the Gulf region. A scoping review reported the prevalence of chronic non-communicable diseases amongst South Asian migrants (India, Bangladesh, and Pakistan) to the Gulf (Qatar, United Arab Emirates, Saudi Arabia, Oman, Kuwait, and Bahrain) (132). Four studies were included in the review, the reported figure for HTN prevalence was 30.5%, DM ranged from 9.0%-16.7% and pre-DM was 30.3%. Of the included studies in the review, a cross-sectional study compared Indian migrants to Indians living in India. The prevalence of HTN amongst Indian migrants to the Gulf was higher by 25.9% (p>0.05). The Indian migrants' risk of HTN development was higher than the non-migrant group (OR=3, 95% CI 1.83-4.94). The review asserted that the longer the duration of migration to the destination country, the higher the risk of chronic noncommunicable disease (132). In the context of Qatar migrants' health, the South Asian population represents 39.0% (1.25 million) of the migrant population in Qatar (120,133).

A growing body of evidence has highlighted the high rate of MetS elements (DM, HTN and obesity) amongst migrants to the Gulf region and specifically to Qatar. However, the association with migration to the Middle East could not be concluded as these studies design focused on the prevalence of MetS rather than the incidence. Therefore, this study is vital to address the gap literature and evaluate the relationship between the incidence of MetS and the elements and migration to Qatar.

1.10 The importance of this study in Qatar

Many studies have assessed MetS status among native Qataris (55,56). However, there is a paucity of data about non-Qatari residents upon arrival and following the initial years of residency in Qatar. This study is relevant to Qatar due to the growing migrant population within Qatar, which in 2019 represented 94.0% of the workforce and 91.0% of the total population (117) (Figure 1.12), and is expected to expand over the coming decades (119,120).

Of greater relevance to Qatar is the evidence which links migration and immigration to increased risk of MetS and the individual elements (28-33,134).

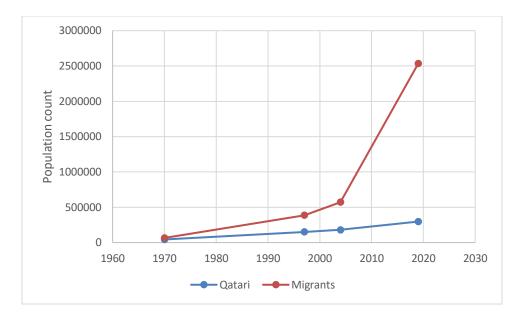


Figure 1.6 Qatar population including national Qatari and migrant population over years (120,133).

The intent of this project was to bridge the gap in the literature about MetS incidence among migrants to Qatar. Additionally, this study will address the individual and regional factors associated with the development of MetS in migrants of Qatar. This will guide the creation of an action plan compatible with the lifestyle in Qatar specifically and the Middle East generally.

While management of MetS, the associated elements and the subsequent complications are of great importance, there is a dire need to act proactively to disease prevention. In line with Qatar National Health Strategy 2018-2022, *"enhancing disease prevention and health promotion"* is one of the five system-wide priorities outlined by the Ministry of Public Health to achieve better health and save healthcare resources' expenditure on preventable non-communicable disease. The National Health Strategy highlights growing obesity, reduced physical activities, and an increasing rate of non-communicable chronic diseases as healthcare challenges (Figure 1.7) (122).

The cardiovascular complications secondary to MetS can be prevented by 80.5% and 82.1% in men and women respectively, by optimising the BP and

the lipid profile (135). In addition, lifestyle interventions, including physical activity and adopting a healthier diet, were found to be valuable measures improving deranged metabolic parameters and ameliorate the cardiovascular complications (136-140).

Therefore, early detection and prevention of MetS can significantly impact health status with associated direct and indirect economic benefits. MetS is, therefore, an essential issue for the population of Qatar with an impact on health, healthcare utilisation, economy and society. This project will address some of these challenges by screening migrants for MetS which leads to early diagnosis, treatment, and prevention of complications that will decrease the demand on the healthcare sector and save resources.

Screening of migrants moving to Qatar is a significant health promotion initiative to a group of population which constitutes the vast majority of the population in Qatar (117). Further research on MetS and its elements in Qatar's population is warranted to develop interventions to decrease and ultimately prevent MetS.

1.11 Aim and objectives

The overall aim of this doctoral project is to explore the role of pharmacists in screening, prevention, and management of MetS. The specific objectives are:

1- To estimate the incidence of the MetS in a random group of migrants coming to Qatar.

2- To identify the factors potentially associated with increased MetS development amongst Qatar's migrants.

3- To critically appraise, synthesise, and present the available evidence on the role of pharmacists in screening, prevention, and management of MetS.4- To consider all research findings to recommend a pharmacist-led modelof-care for the prevention and early detection and management of MetS.

Chapter 2: Methodology

2. Introduction to the chapter

This chapter provides an overview of paradigms, methodologies and methods used to describe research focusing on application to this doctoral project. The approach was aligned with the positivist paradigm and quantitative methodology in the primary research of the doctoral project. The methodology included a cross-sectional survey embedded within the longitudinal observational cohort study. A systematic review followed. A justification of the selected approaches concerning the study objectives and outcomes is provided in this chapter, along with each methodology's potential advantages and limitations.

2.1 Philosophical paradigms

2.1.1 Paradigms used in research

A paradigm is a pattern, concept or theoretical framework applied to address and understand a subject at a particular time. The four main paradigms used in research are discussed, compared and summarised (Table 2.1). Table 2.1 Description of the four main paradigms used in research.

Paradigms	Description
Positivism	Usually concerned with science and called the scientific method.
	This paradigm assumes that gained knowledge already exists despite what is known about it.
	Knowledge can be quantified, reproducible by other researchers if they follow the same procedures of data collection and analysis.
	The theory is universal, and generalisability can be assumed (141).
Constructivism	Usually concerned with understanding the subjective social reality.
	Knowledge in this area cannot be quantified and varies depending on the point of view of different people.
	The researchers are an integral part of the researched social reality, interact with the study population to allow extensive comprehension of their point of view and create the thematic data (141,142).
Critical theory	Also known as transformative, collaborative, and participatory action (143).
	This paradigm arose in response to concern about the political and social justices and aimed to develop a political reform agenda.
	The research focus includes discrimination, empowerment, oppression, and other social issues.
	The participants are encouraged to collaborate in reforming the future (144).
Pragmatism	Resulted from the conflict between the two contradictory paradigms; the positivist and constructivist (145).
	Advocates a multi-pragmatic approach to comprehend the researched idea completely.
	Suggests that the researched idea is affected by the social, political, financial, and historical context (144,145).

2.1.2 Quantitative vs qualitative methodologies

Quantitative and qualitative research are two different methodologies used for conducting research. Quantitative research deals with numerical data and statistical analysis, aiming to generalise facts. The qualitative research deals with words and gist of the research subject, aiming for theme conception. They differ in many things, including; philosophy, aim, researcher's role, design, data collection, data analysis, and reported data forms (144,146) (Table 2.2).

Table 2.2 Comparison between qualitative and quantitative methodologies (144,146).

	Quantitative	Qualitative
Main paradigm	Positivism	Constructivism
Research aim	Discover the fixed reality,	Construct the variable,
	generalisability, study the	dynamic reality
	cause and effect, and	interpretation,
	make infers and	understanding and
	predications.	contextualisation.
The researcher's role	Detached from the	Integrated with the
	researched subjects.	researched subjects.
Design	Observational,	Naturalistic, non-
	interventional,	experimental.
	experimental.	
Data collection	Data collected by	Data collected by the
	measuring the research	researcher's observation,
	subject and using	interviews, and focus
	structured instruments.	groups.
Data analysis	Data analysed by	Data analysed by themes.
	statistical analysis.	
Form of data report	Numerical indices and	Words.
	graphs.	

2.1.3 Research paradigms and methodologies appropriate for this research

The primary research aim in this doctoral project was to explore the incidence risk of MetS, elements, and risk factors in a population of HMC migrants over time. The quantitative (longitudinal observational cohort) methodology has been considered the most appropriate methodology to address the aim and the objectives, with an embedded cross-sectional survey as a part of the data collection.

The quantitative methodology with the positivism paradigm was adopted, which embraces direct observation of the existing reality and quantifies tangible outcomes. Observing migrants' MetS parameters over time helped to explore the effect of migration to the Middle East on MetS new incidence, explain the relationship and the associated factors through quantitative approaches. This aligns with the positivism paradigm; since this research is reproducible, other researchers conducting the same research will have similar results, which can be generalised to the general migrant population.

Aligned with the quantitative methodology, applying the longitudinal cohort study design, the aim and objectives of this study were addressed by obtaining quantitative measurements (metabolic parameters) at two different time points; at baseline and after exposure to the potential risk factor (two years post-migration to the Middle East). Cohort studies could be single or double cohort groups. In the single cohort studies (similar to this study), the group of participants who did not develop the outcome of interest at the end of the study (participants who did not develop MetS post-migration) act as the internal controls (147). The association between baseline measures or characteristics and the outcome of interest can be drawn statistically (147).

MetS elements are quantitative, and therefore the numerical nature of the data implies that qualitative methodologies were not suitable. In addition, it is impractical for the researchers to integrate with participants to observe them over two years to identify any changes in their health. Additionally, qualitative methods would give more opinions and views rather than facts. The subjective opinions and personal perceptions would not help to address the research aim and objectives in determining the association or determinants (144).

Moreover, to better understand the relationship between the dependent and independent variables (the direction and the magnitude), a cross-sectional survey was embedded as part of the data collection. The WHO STEPwise questionnaire was opted to address the research objectives (3 and 4) rather than the qualitative approaches (structured or non-structured interviews or focus groups) due to the potential risk for social desirability, especially when sharing their details and lifestyle, which might be inconvenient and hinder the participants from giving the accurate answers. (144).

2.2 Quantitative approach of the primary research

2.2.1 Philosophical considerations

As per Lincoln and Guba, each paradigm is made up of four elements; ontology, epistemology, axiology, and methodology (148). Table 2.3 describes the philosophical assumptions underpinning the quantitative research paradigm adopted in the primary research of this doctoral project.

Philosophical assumptions	Question	Characteristics	Implications for practice
Ontology	What is the nature of reality?	Reality is objective and already exists regardless of our knowledge about and waiting to be discovered.	Researcher infers the knowledge from reality in the presence of proper reasoning.
Epistemology	What is the stand of the researchers about the researched knowledge?	Data about the knowledge is independently collected	Researcher uses overt or covert observation.
Axiology	What is the role of value?	Research is value-free and unbiased.	Researcher describes the facts.
Methodology	What is the process of research?	Research is deductive, begins with broad ideas to be narrowed down.	Researcher can verify or refute the initial hypothesis.

Table 2.3 Philosophical considerations in quantitative research (144).

2.2.2 Approaches in quantitative methodologies

The primary approaches associated with the quantitative methodologies are illustrated in Table 2.4.

Table 2.4 Quantitative research	approaches	(147).
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Methodology	Description
Randomised controlled trials	Random selection and allocation of the participants is secured. Includes the manipulation of the independent variable(s) and the observation of the dependent variable(s). Considered as a robust and reliable research design in which most of the external factors are controlled (149).
Cohort studies	Identifies a group of people who are disease-free at baseline. Follow them up after exposure to the suspected risk factor, over time, until the outcome of interest occurs. Several outcomes can be investigated simultaneously. Suitable to study rare exposure. Relatively, large sample size is required. Time-consuming, until the outcome happens without intervention, and susceptible to participant dropout.
Case-control studies	Identifies a group of people with the outcome of interest at baseline. A comprehensive history about the exposure to the risk factor(s) is taken. The best method to study diseases that occur after prolonged exposure to the risk factor. Suitable to investigate rare conditions. Relatively, small size is required. Cannot determine cause and effect, or the chronological order of events. Susceptible to recall and observation bias (retrospective data recalling by participants and observational bias by the researcher).
Survey-based studies	Used to draw inferences from a small study population to the extended general population. Not suitable to determine the cause and effect.

As discussed in Chapter 3, the primary research aimed to explore the incidence risk of MetS, elements and risk factors in a population of HMC migrants over time. Considering that manipulating the independent factor (migration to the Middle East) is unrealistic, randomised controlled trials

(RCTs) were deemed unsuitable. Alternatively, the migration process has been happening as a natural exposure. Hence, the longitudinal cohort methodology was considered the most appropriate within the quantitative methodologies to address the research aim. Moreover, the feasibility and the availability of the pre-existing pre-employment check-up informed the methodology selection.

The longitudinal cohort observational methodology has the advantage of feasibility, determining the incidence risk of MetS amongst migrants to Qatar (the outcome of interest) and the association with the risk factors by calculating risk ratio. At the same time, the cross-sectional survey was chosen to determine the association between new-MetS incidence risk and lifestyle characteristics.

2.2.3 Sampling techniques in quantitative research

Every piece of research asks questions about specific populations. The entire group of people targeted by the research question is called "population". However, due to feasibility and practical reasons, it is impossible to study the entire population. Hence, a smaller, approachable, reachable, and representative group of people are selected from the general population termed "sample" (150). The relationship between the general population and the study sample is illustrated in Figure 2.1.

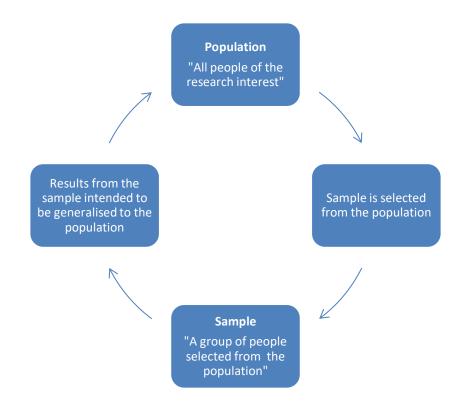


Figure 2.1 The relationship between the general population and the study sample (150).

Sampling of the population could be undertaken either by probability or nonprobability techniques. Unlike non-probability, probability sampling is characterised by random sampling of the population, in which each member of the population has an equal chance of participating in the study. Additionally, it provides a more representative sample and greater ability to generalise the results to the general population (143). Table 2.5 presents the methods and characteristics of sampling included in each technique. Table 2.5 Sampling techniques and characteristics (151).

	Probability	Non-probability
Methods of sampling	Random sampling Systematic random sampling Stratified random sampling Cluster random sampling Quota random sampling Multi-stage sampling	Convenience sampling Snowball sampling Purposive sampling
Characteristics	Commonly used in the positivism paradigm Suitable for conclusive studies Objective Empirical/Practical Scientific Quantitative Representative	Commonly used in the constructivism paradigm Suitable for exploratory studies Not reflecting the general population Qualitative Unrepresentative Less cost Timesaving

A simple and stratified random sampling of non-Qatari employees was the initially proposed sampling technique, following stratifying them into groups based on their jobs, to have a more representative sample. However, as described in Chapter 3, an insufficient number of non-Qatari new employees was detected during the pre-specified study period due to the national government strategy that enforces increasing the number of national (Qatari) employees within the governmental and private sectors. In order to expedite the recruitment process and maximise the sample enrolled, the non-probability convenient sampling was employed instead. All eligible migrants (as per inclusion and exclusion criteria) who joined HMC and had pre-employment examinations undertaken during the six months between 1st of July and 31st of December 2017 were invited to participate in the screening. The identified MetS-free participant-migrants from the screening process were contacted and recruited for the prospective follow-up study; two years post-residency in Qatar.

2.2.5 Statistical analysis

Two types of statistical analysis applied to the research. The first is descriptive statistical analysis, used to summarise data practically and straightforwardly. The frequency and percentages are used to describe the categorical data, while the mean \pm standard deviation (\pm SD) or the median \pm inter-quartile ratio (\pm IQR) are used to summarise the continuous data (152).

The second is inferential statistical analysis, which applied to interpret the outcomes and draw a conclusion from the sample to the general population (152).

The most statistical tests applied to evaluate data distribution are the Kolmogorov-Smirnov test and the Shapiro-Wilk test. According to the data normality, either parametric or non-parametric tests will be applied. The commonly used inferential statistical analyses are described in Table 2.6 (153).

Data type	2 groups (independent)	≥3 groups (independent)	2 related samples	≥3 related samples
Continuous normally distributed (parametric)	t-test	One-Way ANOVA	Paired t-test	Repeated measures ANOVA
Continuous, skewed (non- parametric)	Mann-Whitney U test	Kruskal-Wallis	Wilcoxon signed ranks test	Friedman test
Ordinal	Mann-Whitney U test	Kruskal-Wallis	Wilcoxon signed ranks test	Friedman test
Nominal	Chi-square or Fishers exact	Chi-square or Fishers exact	McNemar's test	Cochrane Q

Table 2.6 Commonly applied statistical tests (154).

The statistical analysis plan of the primary research of this doctoral project is discussed in greater detail in Chapter 3. The one-Way ANOVA, Wilcoxon signed rank and Chi-square tests were used in this research. Further justification is found in Chapter 3.

2.3 Robustness in quantitative research

2.3.1 Introduction

Quantitative research robustness is usually evaluated by reliability and validity. Reliability is about the consistency of the repeatedly measured parameters and reflects to which extent the scale or instrument is free from error (151). Validity in research is about how accurate the measures are, and this typically describes the internal validity. In comparison, external validity is about the generalisability of the results to the general population (151). There are many threats to validity and reliability in quantitative research. The following table (2.7) illustrates the common sources of bias and error in research.

Table 2.7 The most common types of bias in quantitative research (151,155).

Bias	Definition
Sampling bias	Originated from the participants' selection or allocation method, including recruiting from a single geographical point, or sharing common characteristics that might influence the results. The discrepancy in the population's equal probability to participate in the study resulted in an unrepresentative sample.
Subject bias (definition of the inclusion criteria)	Unclear definition or incomplete set of data required for the inclusion criteria to enroll participants in the study.
Observation period	The length of the observation period from baseline to follow-up. Too short duration maybe not enough to develop the outcome of interest.
Acquiescence response set bias	Participants tend to agree with the given statements rather than endorse disagreement.
Measurement decay	Deterioration of the measuring process, instrument, or device by the time.
Non-response bias	Non-response bias in cross-sectional design and withdrawal bias in the longitudinal cohort researches are potential sources of bias. The characteristics of the participants and the results might deviate from the actual values.
Observer bias	Observer background and perceptions may influence the observations.
Social desirability bias	The tendency of the participants to answer the questions positively to impress others.
Reactive effect (awareness of being studied)	The participants' response is influenced by being studied, being more interested in the researched topic, or wanting to impress the researcher.
Recall bias	The ability of the participants to recall events or data related to the researched topic.
Selection bias	Inconsistency between the sample and general population characteristics.

2.3.2 Quality control measures for this doctoral research

The potential types of bias and the measures taken to alleviate these are highlighted in Chapter 3. A summary of the measures taken to minimize these potential types of bias is presented in Table 2.8. Table 2.8 Potential types of bias and the measures taken to minimize them.

Source of bias	Measures to overcome
Acquiescence response set bias	No statements to agree or disagree with in the WHO STEPwise questionnaire. A quantitatively oriented questionnaire comprises objective questions about facts.
Social desirability bias	The questionnaire was anonymous to reduce the participant tendency to answering the ideal expected answers.
Measurement decay	The devices utilised to measure the weight, height, and blood pressure undergo regular inspection and planned periodic maintenance to ensure the quality and accuracy of the utilities as per HMC policies (156).
Non-response bias	Handouts explaining the importance of the study were distributed to the participants to minimise the non- response bias in the cross-sectional design and withdrawal bias in the longitudinal cohort research.
Observer bias	The objective nature of the question eliminated observer background and perceptions.

The potential threats to the external validity in the primary research of this doctoral project were related to considering a sample of convenience (sampling bias), utilising already existing data at baseline screening (subject bias), and the relatively short follow-up period (2-year) (observation bias). The potential threats to the external validity and the measures applied to alleviate these threats were discussed thoroughly in Chapter 3.

2.4 Literature review

2.4.1 Introduction

Evidence-based medicine (EBM) is governed by finding the best evidence to implement it in practice for patient care. The hierarchy of evidence informs the healthcare practitioners about the strength and level of evidence (157). The accepted pyramid of evidence locates the highest level of evidence at the top and the lowest at the bottom. Meta-analysis and systematic reviews of randomised controlled trials are at the top of the pyramid (Figure 2.2) (157).

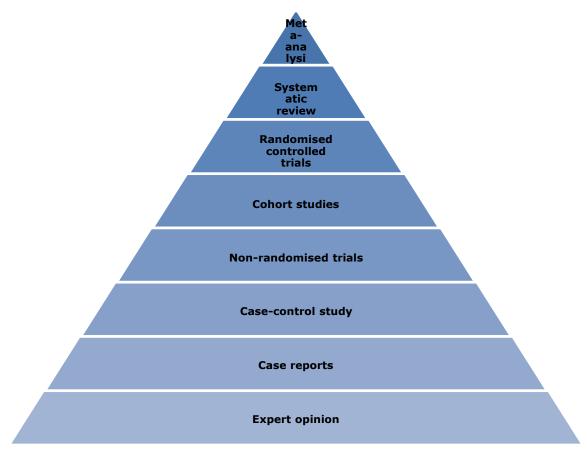


Figure 2.2 Hierarchy of evidence (158,159).

A literature review is defined as an extensive review of the available literature related to the researched topic. Conducting a literature review is essential to:

- Provide a preliminary insight about what have been already done.
- Identify the gap in literature and approaches to focus research questions.
- Set the foundation of further research and a benchmark to compare the results of various studies (152).

2.4.2 Types of literature reviews

While the types of literature reviews vary, the following Table (2.9) describes the most common types of review articles.

Table 2.9 Types of literature review (152).

Review type	Description				
Literature review	A summary of the available literature covering a particular topic does not have				
	to be comprehensive—the data presented narratively, texts, tables, and				
	charts.				
Scoping review	A preliminary search aimed at identifying the availability of sufficient published				
	and ongoing studies to conduct a systematic review.				
Mapping review/	A map of the quality and quantity of the relevant literature of the research				
	topic informing the feasibility to commence with a systematic review or				
systematic map	primary research.				
Meta-analysis	A quantitative combination of the numerical results of several studies				
	statistically to estimate the overall results. Conventional study designs and				
	outcome measures are essential to combine the results.				
Qualitative systematic	A synthesis of the evidence from the qualitative studies. Results in the				
review/ qualitative	generation of new theory and an in-depth understanding of a phenomenon.				
evidence synthesis					
Systematic review	A synthesis and appraisal of the evidence, following methodological guidelines.				
Umbrella review	An overarching review compiling the evidence from different systematic				
	reviews to answer the research question.				

2.4.3 Review types applied in this doctoral project

A general literature review was conducted initially through Google Scholar to identify the current evidence and categorise the gap in the literature on the role of pharmacist around MetS. This was followed by a scoping review of the central databases in the field, including; Cochrane Library of Systematic Reviews and Meta-analysis and the International Database of the Prospectively Registered Systematic Review in Health and Social Science (PROSPERO) using the terms 'pharmacist' and 'metabolic syndrome'. The search yielded no related published or ongoing systematic reviews of the role of the pharmacist around MetS. Using the same terms, a search in Medline identified a body of primary literature sufficient for a systematic review. Of note, the identified studies were of different methodologies (RCTs and observational studies), which put this systematic review at the top of the hierarchy of evidence just below the systematic review of RCTs.

As presented in Chapter 4, a systematic review was conducted to address the identified gap in the literature and synthesise the evidence of the pharmacist's input in screening, managing, and preventing MetS and determining the impact of such input. In order to establish evidence and make recommendations for the pharmacist to intervene in the MetS discipline, it was crucial to appreciate the impact of the pharmacist's role in MetS, describe the available care models, and comprehend the facilitators and barriers of the implementation of such new service.

Given the identified heterogeneity in the identified studies regarding the study designs, aims and objectives, outcomes and MetS criteria, pursing meta-analysis was considered unsuitable. A systematic review was deemed feasible to synthesis the evidence about the pharmacist's role around MetS. The detailed method, outcomes and conclusion are described thoroughly in

Chapter 4.

2.5 Summary of the research design applied to this project

This chapter represents several methodological approaches along with the corresponding methods. The following schematic diagram (Figure 2.3) illustrates the designs employed at each phase of this project.

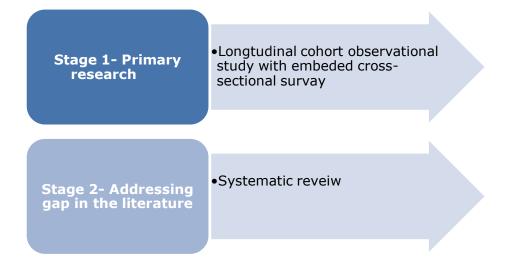


Figure 2.3 Schematic diagram of the research designs applied in this project.

Chapter 3: A prospective, longitudinal, observational cohort study

CHAPTER 3: A prospective, longitudinal, observational cohort study to assess the effect of migration on the development of metabolic syndrome in a group of migrants to Qatar

3. Introduction to the chapter

As discussed in Chapter one, MetS is a cardiovascular risk that has been increasingly recognised as an adverse health outcome as a consequence of migration to Western countries such as USA, Canada and Europe (28,44,92). There is, however, a paucity of data about the incidence of MetS related to migration to the Middle East. This is of particular relevance given the exceptionally high rates of migration to the Middle East over the last few decades. Data from Qatar Planning and Statistical Authority indicates that migrants represent about 94% of the workforce and 91% of the total population (117). This chapter presents the aim, objectives, methods, and results of the prospective, longitudinal study in which migrants to Qatar were screened for MetS at baseline (within three months of arrival to Qatar) and followed up 24months post residence.

In addition to the experienced academic supervisory team, the research team included two researchers and a research assistant. The responsibilities of each member are described in this chapter.

The overall aim and objectives of this research were developed and refined since submission of the initial proposal in October 2017 to both Robert Gordon University (RGU) and HMC Institutional Review Board (IRB). Literature review and discussions with the supervisory team influenced this development. Figure 3.1 describes the evolution of the aim and the objectives, with a brief justification.

3.1 Aim and objectives

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The original

Aim

Explore the incidence of MetS, components and risk factors in a population of HMC *immigrants* over time.

Objectives

Phase one – baseline (within 3 months of arrival), routinely collected data 1. To determine the prevalence of MetS among

new *immigrants* who came to Qatar in 2013.

The Mets-free individuals will then be the subjects of study in phase two. Phase two – 7 years post-baseline.

2. To determine the incidence of MetS and MetS components amongst these individuals *seven* years post-arrival in Qatar.

3. To compare those with MetS, MetS components and healthy *immigrants* at follow-up regarding variables of demographics and behaviours relating to modifiable risk factors.

4. To identify predictors of MetS and MetS components.

The term "migrant" replaced "immigrant" as it was deemed to describe the expatriate situation more accurately in Qatar where population movement is primarily for economic reasons {{279

Objective 1: "to identify and describe" replaced "to determine the prevalence", to produce significant epidemiological data, a large sample size would be required, which was unlikely over the projected timescale.

Objective 2: The length of stay in Qatar was amended to two years instead of seven years, due to feasibility and availability of the data.

After evolution

Aim

Explore the incidence of MetS, components and risk factors in a population of HMC *migrants* over time.

Objectives

Phase one – baseline (within 3 months of arrival), routinely collected data

1. Identify and describe MetS-free migrants who have been residing in Qatar for less than three months.

These individuals will then be the subjects of study in phase two. Phase two - 24 months post-baseline.

2. To determine the incidence of MetS and MetS components amongst these individuals *24 months* post-arrival in Qatar.

 To compare those with MetS, MetS components and healthy *migrants* at follow-up regarding variables of demographics and behaviours relating to modifiable risk factors.
 To identify predictors of MetS and MetS components.

Figure 3.1 The evolution of the aim and objectives of the prospective longitudinal observational cohort study

3.2 Methods

3.2.1 Research team

In addition to the academic supervisory team, the research team consisted of the doctoral student (the research lead), the principal investigator (PI) and the research assistant (RA). Given that the PI and the doctoral student were affiliated with the funding body, HMC has funded an RA post with a research budget to facilitate the completion of the project within the funding period without compromising the quality of both the research and the primary responsibilities of HMC researchers.

The RA received appropriate training and supervision on the standard methods for obtaining the physical measurements described in Table 3.1, in addition to training on assisting patients in undertaking the questionnaire. Table 3.1 describes the responsibilities/roles of each member of the research team. Table 3.1 Research team responsibilities/roles.

Team member	Responsibilities/roles					
The doctoral student	Study conceptualization; design; study administration and execution,					
(research lead)	study population inclusion /exclusion development, assess inclusion/					
	exclusion criteria, determine eligibility, subject selection, available for					
	audit and inspection, clinical follow-up, concept/interpretation of data,					
	overseeing data collection, overseeing data analysis, validation of the					
	profiling data, directly supervise the RA, literature review, manuscript					
	writing, overall study responsibility for the study at the site and					
	preparing progress reports and documents required for ethics					
	annually. Moreover, responsible for initial and final drafting of outputs					
	such as journal papers and conference abstracts.					
Research assistant	Obtain informed consent form, collection of lab results, collection vital					
(RA)	signs, obtain measurements, and obtain the questionnaire from					
	participants and data entry.					
The principal	Secure funding, study administration and execution and regulatory					
investigator (PI)	binders and documents maintenance.					
Supervisory team	The supervisory team consisted of Dr. Antonella Tonna the principal					
	supervisor, and Prof. Derek Stewart and Prof. Cristin Ryan the second					
	supervisors.					
Local Advisors	The local advisory team consisted of Dr Eledris, senior internal					
	medicine consultant at HMC, Hani Abdelaziz, pharmacy supervisor at					
	HMC and Mohamed Izham, Professor of Social & Administrative					
	Pharmacy at Qatar University.					

3.2.2 Research design

As described in Chapter 2, the prospective longitudinal observational design nested with an embedded cross-sectional survey was determined to be the most appropriate to address the research objectives. A quantitative approach was considered most appropriate to research the effect of migration on MetS incidence over time. This project was conducted over two phases. The initial phase involved screening for eligible participants, by reviewing the electronic medical profiles (Cerner[®]) of migrants who had moved to Qatar (July to December 2017) and had resided in Qatar for up to 3 months, as described below (Figure 3.2). Migrants with normal metabolic parameters were invited for rescreening 24-months post-migration and, parameters repeated. Those with abnormal metabolic parameters were counselled or referred for medical review and excluded from follow-up.

The second phase comprised a prospective follow-up of the migrants screened at Phase 1 who had normal metabolic parameters at baseline. Rescreening was conducted 24 months after the baseline implying that this was at least 24 months post-migration to Qatar (July to December 2019), as illustrated in Figure 3.3.

Phase 1 (3.2.5) mainly utilised existing data from the pre-employment medical check-up after obtaining the written consent. Of note, within HMC the pre-employment medical check-up is a standard essential process for all new employees to confirm fitness to undertake their anticipated roles whilst minimizing risk to themselves and others. This process is mandatory for all HMC staff, locals, and migrants, within three months of arriving in Qatar and prior to commencing employment.

Currently, this examination includes medical history, physical examination, general health screening for human immunodeficiency virus infection, hepatitis B virus, hepatitis C virus, syphilis and tuberculosis. There is also screening for chronic diseases including DM, HTN and dyslipidaemia, in addition to BMI and smoking status. All results are documented in the electronic medical profile system (Cerner[®]).

3.2.3 Settings

This study was conducted within HMC facilities, the national health service provider in Qatar. As described in Chapter 1, HMC is a JCI-accredited, non-profit organisation which comprises 20 facilities; nine specialized hospitals, three general hospitals in addition to the ambulance service, home healthcare, skilled nursing facilities and pre-employment/staff clinics where the standard preemployment examinations of all new employees are usually conducted. More than 25,000 employees of considerable ethnic diversity work in HMC, with employees having migrated from more than 90 countries (160).

3.2.4 Data collection tools

A data collection tool was developed and piloted among 10 participants, with pilot data excluded from the main study (Appendix 3.1). The following data were extracted from the electronic medical record at baseline and follow-up: socio-demographic information, physical measurements, and biochemical measurements of blood glucose and lipid profile (TG and HDL-C).

The WHO STEPwise characterised any changes in lifestyle as part of the migration process. This validated questionnaire was developed to aid the surveillance of risk factors trends within and between countries (161) and comprises eleven core domains. Participants were requested to answer each question relating to lifestyle habits at baseline and 24-months post-migration.

The questionnaire has core and expanded elements; however, only the core elements were collected to address the research aim of this study. The questionnaire was either self-completed or administered by the RA, depending on the participants' preferences (Appendix 3.2). The self-administered questionnaire was provided as an option for participants who desired to maintain anonymity. The RA-administered questionnaire ensured participants understood the questions correctly and overcame the issue of illiteracy (151). The likelihood of missing questions was also reduced. However, all the participants in this study chose to undertake the questionnaire with the assistance of the RA.

The questionnaire comprises 3 steps: step 1 (demographic information & behavioural measurements), step 2 (physical measurements), and step 3 (biochemical parameters). Step 1 questions included; demographics (sex, age, marital status, educational level, and occupation), behavioural measurements to addresses cardiovascular risk factors (tobacco use, alcohol consumption, diet and physical activities) and comorbidities (DM, HTN, dyslipidaemia and heart

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disease). Step 2 included questions about physical measurements including; Wt, height (Ht), WC and BP. Step 3 questions included biochemical measurements of blood glucose and lipid profile (TG and HDL-C) which were retrieved by the RA from the electronic medical profile. Question types were categorical (answer with yes or no), ordinal (rank the answer) and ratio scale (the respondents provided measurable answers) (162) (Appendix 3.2).

3.2.5 Phase 1

Inclusion and exclusion criteria

Inclusion Criteria

Adults aged 18 – 65 years New migrants to Qatar, within three months of their arrival Migrants who joined HMC workforce within the 6-month recruitment period from July to December 2017

Exclusion Criteria

Pregnancy

All Qatari or GCC citizens (due to the cultural, ethnic and economic similarities) Former residents of GCC countries (due to the cultural and economic similarity between GCC countries)

Study population

The study population comprised migrants employed at HMC, where all new employees are subjected to a pre-employment medical examination. Following ethical approval (Appendix 3.3), the pre-employment staff clinic provided contact details for employees who joined HMC from 01 July to 31 December 2017. The population was not restricted to health professionals and included a range of professional and labour groups including engineers, accountants, HR personnel, secretaries, social workers, clerks, catering, farmers, drivers, housekeepers, and construction workers.

Sample size

Given that the staff clinic received about 125 new employees per week, the proposed sample for initial screening was 1300 migrants. It was anticipated that recruitment would be achieved in 3-4 months with the aim of recruiting 289 MetS-free migrants, as per calculated sample size for Phase 2 (please see section 3.2.6).

Recruitment

The RA approached potential participants via telephone and provided study information. If interested, an appointment was booked at which further information was provided; those agreeing to participate were asked to sign the written consent form at the time or were given one week to consider participation and sign the form. Written consent was also obtained to permit accessing their electronic medical profiles (Cerner[®]). A leaflet describing the study processes and potential benefits of participating in the research was provided to minimise the drop-out rate (Appendix 3.4).

Permission was also sought to be contacted by the RA at 24 months for participation in the follow-up study (assuming they satisfied Phase 2 inclusion/exclusion criteria and were MetS-free at baseline). A standard telephone script, approved by the medical research centre, was adhered to in all telephone calls (Appendix 3.5).

Data collection

The doctoral student filtered the list of potential participants as per Phase 1 inclusion and exclusion criteria. The RA obtained the socio-demographics (age, gender, ethnic origin, occupation, marital status, and data about former residency in Qatar or other GCC countries) during the consent-signing meeting.

Data collection at baseline comprised extraction of pre-existing data (that were routinely measured by HMC pre-employment/staff clinic). The RA extracted the data from the electronic medical profile (Cerner[®]) and data collection was repeated in a 50% random sample by the doctoral student to confirm reliability. The data extracted were outlined in Table 3.2.

Parameters	Description				
Demographics	Sex, age, ethnic origin.				
Social history	Marital status, occupation, level of education, history of residing				
	within the GCC region and date of joining HMC.				
Data related to MetS	TG, HDL-C, HbA1c, BP, WC, Wt, Ht and BMI.				
(laboratory tests and physical examination)	Diagnosis of MetS described in section 3.2.8.				
Medical history	A history of DM, HTN, cardiovascular disease or dyslipidaemia.				
Medication history	Any antihypertensives, antihyperglycemics, antidyslipidaemic				
	medication, obesity treatment or any treatment that have been				
	proven to induce metabolic syndrome (antihypertensive agents,				
	e.g. β Blockers and diuretics; endocrine, e.g. corticosteroids,				
	danazol growth hormone, oral contraceptives and				
	thiazolidinediones; neurologic/psychiatric agents, antipsychotics,				
	antidepressants and antiepileptics; miscellaneous agents, e.g.				
	immunosuppressant agents, niacin, protease inhibitors and				
	retinoids (163).				

Table 3.2 Data collected at Phase 1 (Appendix 3.1).

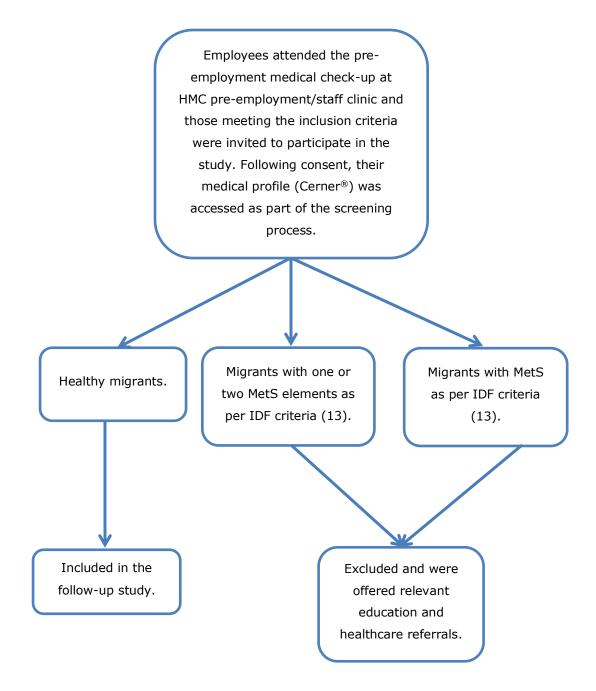


Figure 3.2 Flow diagram recruitment for Phase 1.

3.2.6 Phase 2

In Phase 2, participants screened in Phase 1 and found to be MetS-free were followed-up.

Inclusion and exclusion criteria

Inclusion criteria

Migrants identified as MetS-free at Phase 1 who had been living in Qatar for the past 24 months and were in HMC employment

Exclusion criteria

Migrants with one or two MetS elements or with MetS as per IDF criteria as identified in Phase 1 (13).

Study population

All identified MetS-free participants who consented from Phase 1 were enrolled in Phase 2 of the study (the prospective follow-up).

Sample size

In the literature MetS rates amongst migrants range from 17.0-39.0%, with the majority of studies reporting 20.0-30.0% (164-168). Using an estimated rate of $25.0\pm5\%$, the study sample size was calculated to be 289 participants, with a precision of 5.0% and 95.0% CIs (169).

Recruitment

The RA contacted the eligible participants during July to December 2019.

Data collection

Data collection for the second Phase was prospective. The participants were contacted by the RA to remind them to attend any HMC laboratory, and to book an appointment to complete the WHO STEPwise questionnaire and to obtain physical measurements (Wt, Ht, BMI, BP, and WC). Laboratory results were extracted from the electronic medical profiles (Cerner[®]), and reliability again confirmed. The follow-up laboratory tests were fasting TG, fasting blood glucose (FBG), HDL-C and HbA1c.

The following table summarises the parameters collected both at baseline and follow-up and gives the standardised method used to measure each parameter.

Table 3.3 Details of parameters collected, and methods used.

Measurement	Description				
measurement					
Height (cm)	Using a drop-down measuring tape fixed on the wall, after asking the participant to remove his/her shoes, standing straight ahead.				
Waist circumference (cm)	Using a non-stretch measuring tape, located correctly on the top of the hip bone, surrounding the abdomen, and passing on the umbilical. The participant was asked to stand straight and not to hold his/her breathe.				
Weight (Kg)	Using a digital weighing scale. The participant was asked to stand tall and remove his/her shoes and any bulky items.				
Body Mass Index (BMI) (kg/m ²)	BMI (kg/m ²) was calculated by dividing weight in kg by the square of height in meter.				
Blood pressure (mmHg)	The lowest of three separate reading using calibrated zero mercury sphygmomanometer, after at least ten minutes of resting, sitting properly on a chair with a straight back, legs on the floor and arm supported at the level of the heart was recorded as the blood pressure measurement.				
Blood sample	A blood sample for FBG, HbA1c, TG and HDL-C was taken by appropriately qualified personnel as per HMC protocol. The samples were sent to the HMC central laboratory for blood analysis for fasting lipid panel and blood glucose (170).				
The World health organisation (WHO) STEPwise approach to noncommunicable disease risk factor surveillance (STEPS) (162) (Appendix 3.2)	The questionnaire was administered once at follow-up. Parameters obtained from participants about MetS risk factors at baseline (retrospectively) and post 24 months of residence in Qatar, to determine any change in lifestyle. The physical activity data were presented in the results as either meeting the WHO criteria for physical activity or not. The WHO advocates that adults aged 18- 65 years to maintain 150 mins per week moderate physical activates, or 75 mins per week vigorous activity or an equivalent combination. The moderate activities include walking, cycling, or doing household work. The vigorous activities were defined as those requiring more oxygen consumption including but not limited to; swimming, jumping, and weightlifting (171). Data regarding diet intake collected in the questionnaire were summarised and presented as either meeting WHO recommendation for diet or not. To have a healthy lifestyle, WHO advocates consuming at least five portions of fruit and vegetables per day (172).				

The overall study process during the follow-up period (Phase 2) is outlined in Figure 3.3.

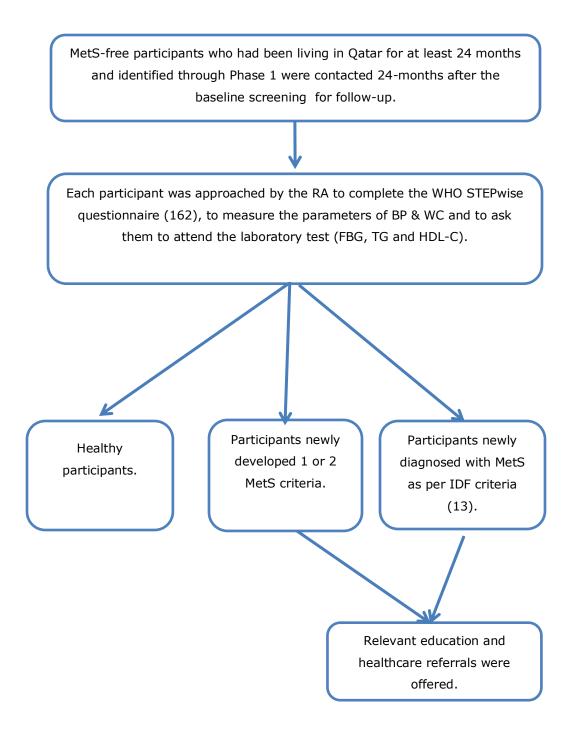


Figure 3.3 Flow diagram of Phase 2.

A summary of the process in chronological order at both Phase 1 and Phase 2 of the study are described in Figure 3.4.

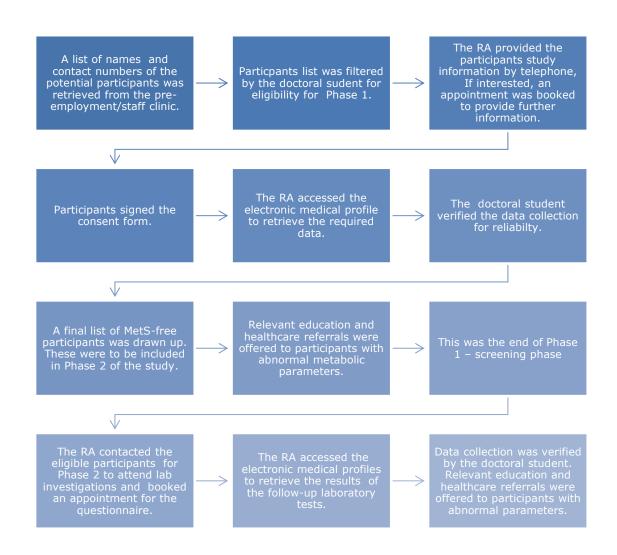


Figure 3.4 Flow chart summarising the research process.

3.2.7 Governance

The protocol was prepared and submitted for ethical review at both RGU and HMC IRB in October 2017. The proposal was approved by the School of Pharmacy and Life Sciences, RGU (S97) (Appendix 3.6) and HMC – IRB (IRGC-03-NI-17-070) (Appendix 3.3).

Each participant was coded with a unique study identification number on all data collection documentation, and throughout data analysis. A list linking this code to the patient identifier was kept in a separate locked cabinet with restricted access to the PI and the doctoral student. All computer files were password protected. All data collection documentation will be retained for at least five years post-study completion, to permit future regulatory authority audit.

The blood samples were collected as per HMC laboratory management protocol by a qualified health care provider, nurse, phlebotomist, or technologist. After confirmation of patient identifications, sample tube labelling was done in the presence of each patient (173). The collected samples were handled and transferred as per infection control standards, to the central area of receiving and processing specimens (174). During the sample collection, any adverse event (pain at the sight of the injection, itching or petechial defined red spots under the skin) was reported systematically per HMC phlebotomy adverse reaction protocol (173).

Based on HMC protocol for reporting laboratory critical test results/values, any detected critical values by laboratory personnel were conveyed to the pertinent clinician for urgent action, documentation in the patient's electronic profile (Cerner[®]) is mandatory (170).

As illustrated earlier, any participants identified with one or more elements of MetS throughout the study were provided with referrals to medical outpatient clinics, to participate in early detection and management of MetS and its complications as illustrated in Figures 3.2, 3.3 and 3.4. to ensure high-standard patient-centred care.

3.2.8 Diagnosis of MetS

At both Phases 1 and 2 the diagnosis of MetS and the elements was determined based on the interim statement of the IDF in conjunction with the National Heart, Lung, and Blood Institute (NHLBI), the American Heart Association (AHA), the World Heart Federation, the International Atherosclerosis Society and the International Association for the Study of Obesity (13). This definition was adopted for this study (Table 3.4).

Table 3.4 Updated criteria for clinical diagnosis of Metabolic Syndrome (2009) (13).

MeasureCategorical Cut PointsPatients were diagnosed as having MetS if they had any three out of the following five elements			
Elevated WC	Population and country-specific definitions (Table 3.5)		
Elevated TG	≥1.7 mmol/L or on drug treatment for elevated triglycerides		
Reduced HDL-C	<1.0 mmol/L in males <1.3 mmol/L in females or on drug treatment for reduced HDL-C		
Elevated BP	Systolic BP≥130 and/or diastolic BP≥85 mm Hg or on antihypertensive drug treatment in a patient with a history of hypertension		
Elevated FBG	≥5.5 mmol/L or on drug treatment of high glucose		

*Abbreviations: WC, Waist Circumference; TG, Triglycerides; HDL-C, High-Density Lipoprotein Cholesterol; BP, Blood Pressure; FBG, Fasting Blood Glucose.

Country/ethnic specific values for waist circumference are given in Table 3.5.

Table 3.5 Country/ethnic-specific values for waist circumference (3).

Country/ethnic group		Waist circumference (a measure of central obesity)			
Europids	Male ≥ 94 cm				
	Female	≥ 80 cm			
South Asians	Male	≥ 90 cm			
	Female	≥ 80 cm			
Chinese	Male ≥ 90 cm				
	Female ≥ 80 cm				
Japanese	Male ≥ 90 cm				
	Female ≥ 80 cm				
Ethnic South and Central Americans	Use South Asian recommendations until more specific data are available.				
Sub-Saharan Africans	Use European data until more specific data are available.				
Eastern Mediterranean and Middle East (Arab) populations	Use European data until more specific data are available.				

3.2.9 Data entry and analysis

Data collected were entered into Microsoft Excel[®] by the RA, then exported to SPSS[®] Version 26 (IBM Corp. Released 2015. IBM statistical analysis for windows. Version 26. Armonk, NY: IBM Corp) for further analysis, with expert input from a statistician. The approach to statistical analysis was mapped to each research objective, as described.

Objective one: *Identify and describe MetS-free migrants who have been residing in Qatar for less than three months.*

Descriptive statistics were used to describe the characteristics of the MetS-free migrants at baseline before exposure to migration.

Objective two: Determine the incidence of MetS and MetS components amongst these individuals 24 months post-arrival in Qatar.

The incidence of new MetS-development was determined by applying the incidence rate formula (175).

Incidence rate risk= $\frac{\text{Number of new MetS cases during the study period}}{\text{Number of participants who completed the follow-up}} \times 100$

The incidence of each element of MetS was determined by employing the incidence rate formula (175).

 $\label{eq:Incidence} \mbox{Incidence rate risk} = \frac{\mbox{Number of new elements of MetS during the study period}}{\mbox{Number of participants who completed the follow-up}} \times 100$

Descriptive statistics were used to describe the characteristics of the participants at follow-up 24-months post-migration (2019).

Data normality was tested for the metabolic parameters applying Kolmogorov-Smirnov test, which revealed normal distribution of the data.

The paired sample t-test was used to compare means of continuous variables (means of; BP, FBG, HDL-C and TG) of the same group of migrants at baseline (2017) and follow-up (2019).

Objective 3: Compare those with MetS, MetS components and healthy migrants at follow-up regarding variables of demographics and behaviours relating to modifiable risk factors.

Association between incidence of MetS or the elements (1 or 2 elements) with the categorical parameters (age, gender, ethnic group, occupation, marital status, smoking status and meeting WHO criteria for physical activities and diet) was tested using Pearson Chi-square test.

Wilcoxon Signed Rank test was applied to compare between related groups (baseline and 24-months after migration) for skewed numerical data. The vigorous and moderate activities of migrants at baseline, and follow-up were compared. Association with the normally distributed parameters was tested using One-Way ANOVA.

Objective 4: Identify predictors of MetS and MetS components.

Significant variables from the univariate analysis were utilised to construct the multiple univariate logistic regression model to determine any association with MetS incidence. All p-values presented were two-tailed, and p-values <0.05 was considered as statistically significant.

3.3 Results

This section describes the results of both Phase 1 and 2. During the study period, 1379 employees joined HMC with diverse nationalities (Qataries and migrants) and a wide range of occupations, of whom 1084 were successfully contacted. Following access to the individual electronic medical profile, 205 participants were identified as having no element of MetS and were included in the follow-up. Seven participants became pregnant and were excluded from follow-up, and 38 partially completed the laboratory follow-up (Figure 3.5).

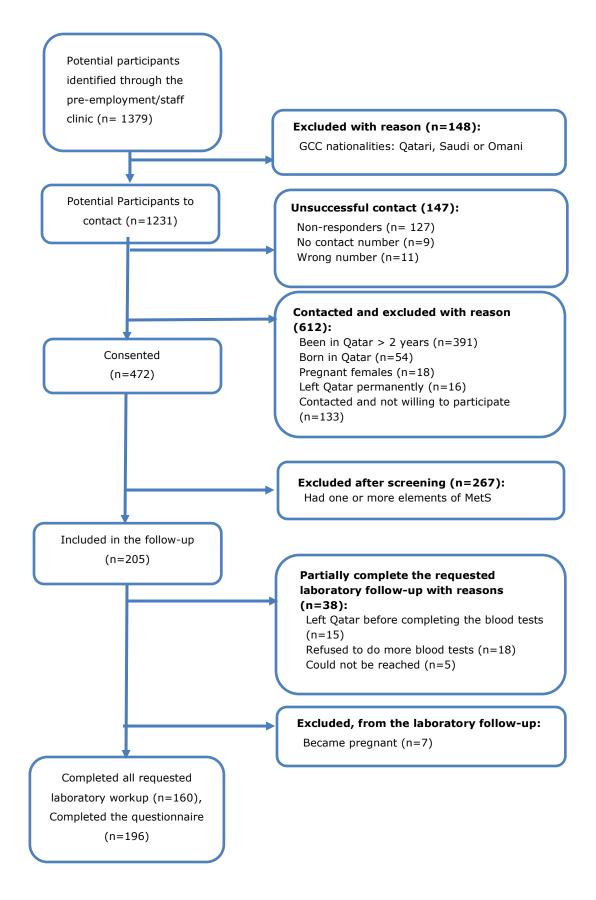


Figure 3.5 Participant flow at screening and follow-up.

3.3.1 Characteristics of the study population screened for recruitment

A total of 472 participants were successfully screened as part of Phase 1 of the study. The mean age was 32.3 (\pm 5.7) years, 70.3% (n=332) were males, 60.0% (n=283) were married, and 82.6% (n=390) came from Asia. Most of them were employed as nurses (65.0%, n=307), and the majority were of graduate-level (78.2%, n=369), as shown in Table 3.6.

Table 3.6 Demographic characteristics of the 472 participants screened for recruitment.

Characteristic	Values %(n)
	32.3 ± 5.7^{4}
Age (years) Gender	52.5 ±5.7
	70.2 (222)
Male	70.3 (332)
Female	29.7 (140)
Ethnic origin	
Arabs	5.9 (28)
Asian	82.6 (390)
Africans	1.7 (8)
Europeans	5.5 (26)
Others*	4.3 (20)
Marital status	
Married	60.0 (283)
Single	39.2 (185)
Divorcee	0.8 (4)
Education	
Below bachelor's degree	0.6 (3)
Graduate (Bachelor & Diploma)	78.2 (369)
Postgraduate (Master and above)	21.2 (100)
Occupation	
Doctors	14.2 (67)
Nurses	65.0 (307)
Allied healthcare ^c	17.2 (81)
Others**	
Uniers	3.6 (17)

 $^{\text{¥}}$ ± represents standard deviation (SD).

*Other included: North Americans, South Americans, Australians- Oceanians.

^c Pharmacists, pharmacy technicians, psychologists, audiologists and speech language pathologists; physical therapists, occupational therapists and respiratory therapists, imaging specialists, nutritionists and dietitians ^{**}Other occupations included: clerk, engineer, Information Technologist (IT) and healthcare aides.

MetS and related parameters amongst the screened population

The screening results of the 472 participants utilising the pre-existing data of the new migrants to Qatar as HMC employees at baseline showed that more than half of them had at least one element of MetS (56.6%, n=267). One in seven (14.8%, n=70) participants had elevated systolic blood pressure (SBP) >130 mmHg, and one in ten (9.7%, n=46) had high diastolic blood pressure (DBP) >85 mmHg.

One in four participants (25.0%, n=118) had HDL-C below the target (< 1 mmol/L in male and <1.3 mmol/L in female). Also, about half of the participants (47.8%, n=226) had central obesity, as shown in Table 3.7.

Table 3.7 Metabolic parameters of the 472 screened potential participants for recruitment.

MetS status and elements	Values %(n)
MetS elements	
Zero elements	43.4 (205)
1 or 2 elements	39.6 (187)
3 or more	17.0 (80)
SBP mmHg [¥]	122.4 ± 11.0
DBP mmHg [¥]	73.9 ± 9.2
HbA1c% [¥]	5.2 ± 0.5
TG mmol/L [¥]	1.4 ± 0.9
HDL-C mmol/L [¥]	1.2 ± 0.3
WC cm [¥]	90.9 ±10.3
Wt Kg [¥]	73.0 ± 14.6
BMI kg/m ^{2¥}	26.0 ± 4.1
Abnormal metabolic parameters	Values %(n)
SBP ≥ 130 mmHg	14.8 (70)
DBP≥ 85 mmHg	9.7 (46)
HbA1c>5.6%	7.2 (34)
TG ≥ 1.7 mmol/L	22.0 (104)
HDL-C <1 mmol/L for males or <1.3 mmol/L for females	25.0 (118)
WC ≥90 cm for male and ≥80 cm for females [#]	47.8 (226)
Known to have DM	0.4 (2)
Known to have HTN	1.9 (9)

Abbreviations: MetS, Metabolic Syndrome; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; FBG, Fasting Blood Glucose; HbA1c, Glycated haemoglobin; TG; Triglycerides; HDL-C, High-Density Lipoprotein Cholesterol; WC, Waist Circumference; Wt, Weight; BMI, Body Mass Index; DM, Diabetes Mellitus; HTN, Hypertension.

 $^{\text{*}}$ ± represents standard deviation (SD).

[#] Except for Europid males \geq 94 cm, please refer to table 3.4.

3.3.2 Results related to the objectives

Objective 1: Identify and describe MetS-free migrants who have been residing in Qatar for less than three months.

Of the 205 MetS-free participants identified at baseline, 153 (74.6%) were males, and 166 (81.0%) came from Asia. The majority were healthcare providers, largely nurses (n= 136, 66.3%). Most of them (n=181, 92.3%) were non-smokers and met the WHO criteria for physical activities (n=183, 93.4%) (Table 3.8).

Table 3.8 Characteristics of the 205 MetS-free participants at baseline within 3 months of arrival to Qatar (2017).

Characteristic	Values %(n)
Age (years)	31.2 <u>+</u> 5.2 [¥]
Gender	
Male Female	74.6 (153) 25.4 (52)
	23.1 (32)
Ethnic origin Arabs	8.8 (18)
Asian	81.0 (166)
Africans	2.4 (5)
Europeans Others*	3.4 (7) 4.4 (9)
Marital status Married	49.9 (100)
Single	48.8 (100) 50.2 (103)
Divorcee	1.0 (2)
Education	
Below bachelor's degree	1.5 (3)
Graduate (Bachelor & Diploma)	77.0 (158)
Postgraduate (Master and above) Occupation	21.5 (44)
Doctors	13.7 (28)
Nurses	66.3 (136)
Allied healthcare	15.1 (31)
Others**	4.9 (10)
Smokers (n= 196) ^c	24(1)
Yes No	2.1 (4) 92.3 (181)
Missing	5.6 (11)
Alcohol consumers	
Yes No	NA
Mean (SD) number of days fruit consumed in a week (days/week)	3.8 ±2.3 days/week [¥]
Mean (SD) number of servings of fruits consumed on average per day	1.32 ± 0.7 serves/day [*]
Mean (SD) number of days vegetables consumed in a week (days/week)	4.7 \pm 2.2 days/week [¥]
Mean (SD) number of servings of vegetables consumed on average per day	1.6 ± 0.7 serves/day [¥]
Median (IQR) number of mins of moderate activities per week	1800 (540-2850) min [¶]
Median (IQR) number of mins of vigorous activities week	120 (0-300) min [¶]
Met WHO criteria for moderate activity (n= 196) $^{\circ}$	00.0 (175)
Yes No	89.3 (175) 9.2 (18)
Missing	1.5 (3)
Met WHO criteria for vigorous activity (n= 196) ^c	
Yes	54.6 (107)
No Missing	42.3 (83) 3.1 (6)
Met the WHO criteria for physical activity (vigorous or moderate) (n=	(*/
196) ^c	02 4 (102)
Yes No	93.4 (183) 6.6 (13)
Met WHO recommendations for diet baseline (n= 196) c	()
Yes	5.1 (10)
No Abbreviations: WHO World Health Organisation	94.9 (186)

Abbreviations: WHO, World Health Organisation. [¥] ± represents standard deviation (SD).

*Other included: North Americans, South Americans, Australians- Oceanians.

**Other occupations included: Clerk, engineer, IT and Aides.

[¶]Median and IQ range reported due to data skewness.

 $^{
m c}$ Out of the 205 participants, only 196 completed the questionnaire

Objective 2: Determine the incidence risk of MetS and MetS components amongst these individuals 24 months post-arrival in Qatar.

At follow-up, 160 of the 205 participants completed all the requested laboratory workup and physical measurements (the five elements of MetS). The incidence risk of new-onset MetS during the 24-months of residing in Qatar was 17.0% (n=27/160, 95% CI; 11.0%-23.0%); 81.0% (n=129/160) of participants developed at least one element of MetS. Only 19.0% (31/160) of participants were still MetS free 24-months post-migration (Table 3.9).

Table 3.9 The incidence risk of MetS amongst migrants post 24-months migration to Qatar (n=160).

Metabolic parameters	Incidence risk % (n)	95% CI (%)
Zero element of MetS	19.0 (31)	14.0-26.0
1 element of MetS	33.0 (52)	25.0-40.0
2 elements of MetS	31.0 (50)	24.0-39.0
3 or more elements of MetS	17.0 (27)	11.0-23.0

As shown in Table 3.10, at follow-up more than half of the participants developed central obesity (56.5%, n=108/191, 95% CI; 49.0%-64.0%), 33.5% (n=56/167, 95% CI; 26.0%-41.0%) developed elevated glycaemic parameters (either abnormal FBG, HbA1c or on DM medications), while 33.0% (n=65/197, 95% CI; 27.0%-40.0%) developed HTN (elevated SBP, DBP or on antihypertensive medications), and 18.7% (n=31/166, CI; 13.0%-26.0%) had new-onset hypertriglyceridaemia.

Metabolic parameters (n) [¥]	Values %(n)	95% CI (%)
HTN SBP \geq 130 mmHg (n=197) DBP \geq 85 mmHg (n=197) SBP \geq 130 mmHg or DBP \geq 85 mmHg or on antihypertensive medications (n=197)	19.3 (38) 13.7 (27) 33.0 (65)	14.0-26.0 9.0-19.0 27.0-40.0
DM, pre-DM FBG > 5.5 mmol/L or on medications (n=169) FBG > 5.5 mmol/L or HbA1c > 5.6% or on medications (n=167) FBG > 5.5 mmol/L or HbA1c > 6.5% or on medications (n=167)	26.6 (45) 33.5 (56) 3.6 (6)	20.0-34.0 26.0-41.0 1.0-8.0
Dyslipidaemia TG ≥1.7 mmol/L (n=166) HDL-C <1 mmol/L for males or <1.3 mmol/L for females (n=165) HDL-C <1 mmol/L for males or <1.3 mmol/L for females or TG ≥1.7 mmol/L or on medications (n=166)	18.7 (31) 9.7 (16) 30.7 (51)	13.0-26.0 6.0-15.0 22.0-37.0
Obesity WC ≥90 cm for male and ≥80 cm for females [*] (n=191) WC above the range [*] or on obesity medications (n=192)	56.5 (108) 56.8 (109)	49.0-64.0 49.0-64.0

Table 3.10 The incidence risk of the MetS elements 24-months post-migration.

*WC \geq 90 cm for male and \geq 80 cm for females except for Europid males \geq 94 cm, please refer to table 3.4. *The number of the participants vary between the parameters, due to the availability of the data. 38 have partially completed the laboratory workup, while 160 have completed them all.

All metabolic parameters were statistically significantly raised at follow-up from baseline except for SBP (Table 3.11). FBG values were not compared because these were not available for all participants at baseline, since baseline data were part of an existing routine medical check-up.

Abbreviations: MetS, Metabolic Syndrome; HTN, Hypertension; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; DM, Diabetes Mellitus; FBG, Fasting Blood Glucose; HbA1c, Glycated hemoglobin; TG; Triglycerides; HDL-C, High-Density Lipoprotein Cholesterol; WC, Waist Circumference.

Metabolic parameter (n) ^c	Baseline (2017) [¥]	Follow-up (2019) [¥]	t-value [¶]	df	p-value*
SBP mmHg (n=196)	119 ±9.3	120 ±12.0	-1.73	195	0.085
DBP mmHg (n=197)	71 ±9.0	75 ±10.0	-4.90	196	<0.001
HbA1c % (n=166)	5.1 ±0.3	5.4 ±0.3	-13.90	165	<0.001
TG mmol/L (n=166)	1 ±0.4	1.2 ±0.7	-4.56	165	<0.001
HDL-C mmol/L (n=165)	1.29 ±0.3	1.34 ±0.3	-3.15	164	0.002
WC cm (n=192)	84.2 ±5.5	88.4 ±6.9	-12.05	191	<0.001

Table 3.11 Comparison of the metabolic parameters at baseline and follow-up.

Abbreviations: SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; HbA1c, Glycated Heamoglobin; TG, Triglycerides; HDL-C, High-Density Lipoprotein Cholesterol.

 $^{
m c}$ The number of the participants vary between the parameters, due to the availability of the data. 38 have partially completed the laboratory workup, while 160 have completed them all.

 $^{\text{*}}$ ± represents standard deviation (SD).

[¶] Paired Sample t-test test-value

*Paired Sample t-test.

Of the 205 eligible participants, 196 (95.6%) completed the STEPwise questionnaire 24-months post residing in Qatar. Most were non-smokers (n=174, 88.8%) and met the WHO criteria for physical activities (n=179, 91.3%). The lifestyle parameters at 24-months post-migration are given in Table 3.12. The mean times spent in vigorous and moderate activities at follow-up dropped by 50% compared to baseline (p=0.001 for both, Wilcoxon Signed Rank test). However, at follow-up, the reduced moderate and vigorous physical activity levels were not associated with MetS incidence (p=0.792, p=0.680 respectively, Pearson Chi-Square test, Table 3.13). Table 3.12 The modifiable risk factors of the participants two years postmigration to Qatar (n=196).

Lifestyle parameters	Values% (n)			
Smokers				
Yes	11.2 (22)			
No	88.8 (174)			
Missing	0			
Alcohol consumers	0			
Yes	41.8 (82)			
No	58.2 (114)			
Mean (SD) number of days fruit consumed in a week	$4.4 \pm 2.3 \text{ days/week}^{\text{x}}$			
(days/week)	4.4 ±2.5 days/week			
Mean (SD) number of servings of fruits consumed on average	1.25 ±0.6 serves/day [¥]			
per day	1.25 ±0.0 serves/day			
Mean (SD) number of days vegetables consumed in a week	4 ±2.3 days/week [¥]			
(days/week)	4 ±2.5 days/week			
Mean (SD) number of servings of vegetables consumed on	1.25 ± 0.6 convoc/day¥			
	$1.35 \pm 0.6 \text{ serves/day}^{\text{X}}$			
average per day Modian (IOD) number of mine of moderate activities	1410 (419 2400) min-			
Median (IQR) number of mins of moderate activities Median (IQR) number of mins of vigorous activities	1410 (418-2400) mins [¶]			
Median (IQR) number of mins of vigorous activities Met WHO criteria for moderate activity	60 (0-240) mins [¶]			
-	0.47(1.00)			
Yes	84.7 (166)			
No	15.3 (30)			
Missing	0			
Met WHO criteria for vigorous activity	42.0 (86)			
Yes	43.9 (86)			
No	51.0 (100)			
Missing	5.1 (10)			
Met the WHO criteria for physical activity (vigorous or moderate) Yes	01 2 (170)			
	91.3 (179)			
No Met WHO recommendations for diet	8.7 (17)			
Yes	2 5 (5)			
No	2.5 (5) 97.5 (191)			
Medications that can induce MetS	97.5 (191)			
Yes (see details below)	17.9 (35)			
No	82.1 (161)			
Breakdown of medications consumed by participants that may	02.1 (101)			
induce MetS				
Anticonvulsant (gabapentin)	5.1 (10)			
β-Blockers	3.1 (6)			
Short course steroid (≤3 weeks)	2.1 (4)			
Steroid course (>3 weeks)	1.5 (3)			
Thiazide diuretic and steroid	1.5 (3)			
Retinoid	1.1 (2)			
OCPs	0.5 (1)			
Antidepressants	0.5 (1)			
Antiepileptic medications	0.5 (1)			
β-blocker+ antidepressants	0.5 (1)			
β-blocker+ OCPs	0.5 (1)			
β-blocker +OCPs+ antidepressant	0.5 (1)			
β -blocker + thiazide diuretic + antidepressant	0.5 (1)			
Abbreviations:OCPs, oral contraceptives.	\-/			

Abbreviations:OCPs, oral contraceptives.

 * ± represents standard deviation (SD).

[¶]Median and IQ range reported due to data skewness.

Objective 3: Compare those with MetS, MetS components and healthy migrants at follow-up regarding variables of demographics and behaviours relating to modifiable risk factors.

Per protocol analysis was applied to the following analysis. Hence, only participants who had completed the follow-up work-up were included in the analysis. There was a significant association between male gender and developing MetS (Chi-square = 13.4, df= 4, p=0.01). Additionally, administration of medications that potentially induce MetS was significantly associated with increased risk of MetS or the elements (Chi-square = 16.9, df= 4, p=0.002) compared to those not taking such medications (Table 3.13). Age was not compared as most participants were of a similar age (mean age 31.2 ± 5.2 years). Ethnic groups, marital status, education, occupation, diet, and exercise had no statistically significant effect on incidence of new-onset MetS. Of note, no patients were identified as having five elements of MetS at the end of the 24 months. Table 3.13 Comparison of migrants with 1,2, 3 and 4 elements of MetS and MetS-free migrants 24 months postmigration to Qatar regarding variables of demographics and the modifiable risk factors (lifestyle variables) $(n=160)^{\circ}$.

	No MetS %(n)	1 element of MetS %(n)	2 elements of MetS %(n)	3 elements of MetS %(n)	4 elements of MetS %(n)	Test value	df	P-value
Gender Male Female	64.5 (20) 35.5 (11)	73.1 (38) 26.9 (14)	86.0 (43) 14.0 (7)	100 (18) 0	55.6 (5) 44.4 (4)	13.4	4	0.01*
Ethnic group Arabs Asians Africans European Others*	6.5 (2) 90.3 (28) 0 3.2 (1)	7.7 (4) 78.8 (41) 1.9 (1) 5.8 (3) 5.8 (3)	10.0 (5) 74.0 (37) 6.0 (3) 4.0 (2) 6.0 (3)	5.6 (1) 94.4 (17) 0 0 0	$0\\88.9(8)\\0\\11.1\%(1)$	11.3	16	0.788*
Marital status Married Single Divorced	22.6 (7) 71.0 (22) 6.4 (2)	48.1 (25) 50.0 (26) 1.9 (1)	50.0 (25) 50.0 (25) 0	61.1 (11) 38.9 (7) 0	55.6 (5) 44.4 (4) 0	10.2	8	0.254*
Education Below bachelor's degree Graduate (Bachelor, Diploma) Postgraduate (Master and above)	6.4 (2) 83.9 (26) 9.7 (3)	0 80.8 (42) 19.2 (10)	0 72.0 (36) 28.0 (14)	0 77.8 (14) 22.2 (4)	0 66.7 (6) 33.3 (3)	12.7	8	0.123*
Occupation Doctors Nurses Allied healthcare providers Others**	6.5 (2) 70.9 (22) 16.1 (5) 6.5 (2)	11.5 (6) 71.2 (37) 15.4 (8) 1.9 (1)	12.0 (6) 58.0 (29) 24.0 (12) 6.0 (3)	11.1 (2) 83.3 (15) 0 5.6 (1)	22.2 (2) 66.7 (6) 0 11.1 (1)	11.5	12	0.489*
Medication that might induce MetS Yes No	19.4 (6) 80.6 (25)	13.5 (7) 86.5 (45)	12.0 (6) 88.0 (44)	27.8 (5) 72.2 (13)	66.7 (6) 33.3 (3)	16.9	4	0.002*
Number of days fruit consumed in a week [¥] (days/week)	4.2±2.3	4.3±2.3	4.3 ±2.3	4.7 ±2.3	3.8 ±2.6	0.26	4	0.905 [€]
Mean (SD) number of servings of fruit consumed per day [¥] (serves/day)	1.3 ±0.8	1.3 ±0.5	1.2 ±0.6	1 ±0.4	1.2 ±0.4	0.93	4	0.448 ^c
Number of days vegetables consumed per week [¥] (days/ week)	3.6 ±1.9	4 ±2.2	4 ±2.5	4.9 ±2.4	4.1 ±2.8	0.85	4	0.493 [€]
Number of servings of vegetables consumed per day [¥] (serves/day)	1.3 ±0.6	1.4 ±0.6	1.3 ±0.5	1.4 ±0.5	1.4 ±0.5	0.39	4	0.811€

Met WHO recommendation for moderate activity (≥ 150 min/week) Yes No	88.2% (30) 11.8% (4)	86.3% (44) 13.7% (7)	80.0% (40) 20.0% (10)	88.2% (15) 11.8% (2)	88.9% (8) 11.1% (1)	4.67	8	0.792*
Met WHO recommendation for vigorous activity (≥ 75 min/week) Yes No	37.5% (12) 62.5% (20)	48.0% (24) 52.0% (26)	46.9% (23) 53.1% (26)	57.9% (11) 42.1% (8)	30.0% (3) 70.0% (7)	5.70	8	0.680*
Met WHO criteria for moderate or vigorous activity Yes No	93.7% (30) 6.3% (2)	92.3% (48) 7.7% (4)	86.0% (43) 14.0% (7)	88.2% (15) 11.8% (2)	100% (9) 0	7.81	8	0.452*

^an=160 since this includes participants where full laboratory work out was available.

*Pearson Chi-Square test.

[€]One-Way ANOVA test.

 4 ± represents standard deviation (SD).

*Other nationalities included: North Americans, South Americans, Australians- Oceanians.

**Other occupations included: Clerk, engineer, IT and Aides.

Objective 4: Identify predictors of MetS and MetS components.

Univariate logistic regression analysis was undertaken to identify the determinants of MetS. Consuming medications that potentially induce MetS (Such as anticonvulsants, β blockers and steroids) was associated with a 4-fold higher risk of MetS (unadjusted OR 4.4, 95% CI; 1.74-10.92, p=0.001). Multiple logistic regression analysis was used to adjust for gender and physical activities (moderate and vigorous, baseline, and follow-up). Consuming medications that potentially induce MetS was found to be associated with a 6-fold risk of MetS (AOR 6.3, 95% CI; 2.27-17.73, p<0.001) (Table 3.14).

Table 3.14 Logistic Regression analysis for factors associated with MetS development at 24 months post migration (n=160) ².

		<u>Univariate</u>	logistic regres	<u>ssion</u>	<u>Multiple</u>	e logistic regres	<u>ssion</u>
Variable	MetS % (n)	Unadjusted OR	95% CI	p-value	Adjusted OR	95% CI	p-value
Gender Male Female	17.9% (22) 13.5% (5)	1.4 1 (reference)	(0.48-3.98)	0.534	3 1 (reference)	(0.76-11.85)	0.116
WHO for moderate activities at baseline met (2017) Yes No	17.5% (25) 6.7% (1)	2.9 1 (reference)	(0.37-23.60)	0.285	4.4 1 (reference)	(0.37-52.74)	0.242
WHO for vigorous activities at baseline met (2017) Yes No	18.7% (17) 13.4% (9)	1.5 1(reference)	(0.62-3.56)	0.379	0.9 1 (reference)	(0.31-2.87)	0.939
WHO for vigorous activities at follow-up met (2019) Yes No	17.3% (23) 12.5% (3)	1.5 1 (reference)	(0.40-5.32)	0.561	0.9 1 (reference)	(0.21-4.70)	0.996
WHO for moderate activities at follow-up met (2019) Yes No	16.4% (12) 16.7% (14)	0.9 1 (reference)	(0.42-2.29)	0.969	1.2 1 (reference)	(0.41-3.32)	0.764
Taking medications that induce MetS Yes No	36.7% (11) 11.7% (15)	4.4 1 (reference)	(1.74-10.92)	0.001	6.3 1 (reference)	(2.27-17.73)	<0.001

[¥] Total number of participants included in the analysis equals 160, however; any single missing value in the participants data, the whole data related to that participant were excluded.

In summary, these results indicate that migration to Qatar is associated with new incidence of MetS of 17.0% (n=27/160, 95% CI; 11.0%-23.0%), within 24months of migration. The most common metabolic abnormality was central obesity in 56.5% (n=108/191, 95% CI; 49.0% - 64.0%) followed by the abnormal glycaemic parameters in 33.5% (n=56/167, 95% CI; 26.0%-41.0%) of the participants. When compared to females, MetS was more common amongst males (p=0.01). Participants receiving medications that potentially induce MetS are 6-fold more likely to develop MetS (AOR=6.3, 95% CI; 2.27-17.73, p<0.001).

Exploratory analysis:

An additional exploratory analysis was done to explore and assess MetS differences between males and females. However, the findings may not be conclusive due to the imbalance in numbers recruited between males and females, where males represented 74.6% (153) of the total population.

The incidence risk of MetS and the overall number of elements were comparable between males and females. However, the incidence risk of the individual elements of MetS varied between genders. For example, the incidence risk of HTN and elevated TG were significantly higher among males (p=0.010 and p=0.007, respectively). However, the incidence risk of low HDL-C was significantly higher amongst females (p=0.020) (Table 3.15).

Incedince risk	Male % (n)	Female % (n)	p-value	df
MetS status	18.1 (23/127)	10.8 (4/37)	0.292	1
1 element of MetS	30.6% (38/124)	38.9% (14/36)	0.087	
2 elements of MetS	34.7% (43/124)	19.4% (7/36)		
3 elements of MetS	18.5 (23/124)	11.1 (4/36)		3
DM/pre-DM(FBG > 5.5 mmol/L or HbA1c > 5.6% or on medications)	34.1 (44/129)	31.6 (12/38)	0.772	1
HTN (high SBP, or DBP or on medications)	37.7 (57/151)	17.4 (8/46)	0.010	1
High TG	22.9 (30/131)	2.9 (1/35)	0.007	1
Low HDL-C	6.9 (9/130)	20.0 (7/35)	0.020	1
Central obesity*	53.7 (80/149)	66.7(28/42)	0.134	1

Table 3.15: MetS incidence risk among males and females.

* WC \geq 90 cm for male and \geq 80 cm for females except for Europid males \geq 94 cm or on medications, please refer to table 3.4

Compared to females, males had lower physical activity levels defined as not meeting WHO physical activity (150 mins per week moderate physical activities, or 75 mins per week vigorous activity or an equivalent combination) (94.2% vs 80.4%, p=0.0001). Likewise, alcohol consumption was significantly higher among males than females (49% vs 19.6%, p=0.0001). However, females tended to utilise medications that induce MetS more than males (26.5% vs 14.4%, p=0.05) (Table 3.16).

MetS risk factor	Male %(n)	Female %(n)	p-value	df
Smoking	13.4 (20/149)	4.3(2/46)	0.089	1
Alcohol consumption	49 (73/149)	19.6 (9/46)	0.0001	1
Did not meet WHO criteria for Diet at follow-up 2019	94.2 (145/154)	80.4% (41/51)	0.003	1
Did not meet WHO criteria for physical activity at follow-up 2019	8.7 (13/149)	8.7 (4/46)	0.995	1
Using medication that might induce MetS	14.4 (22/153)	26.5 (13/49)	0.05	1

Table 3.16: MetS risk factors among males and females

3.4 Discussion

3.4.1 Summary of the key findings

This study aimed to determine the incidence of MetS and the elements and characterise the potential risk factors amongst a group of HMC migrants who have been residing in Qatar for 24 months. Key study findings are that among migrants with normal metabolic parameters at baseline, 17.0% (95% CI; 11.0%-23.0%) developed MetS during the 24-months residence in Qatar, with around 81.0% (95% CI; 73.8%-86.0%) developing at least one element of MetS, most commonly central obesity. Administration of medications that potentially induce MetS increased MetS risk by 6-fold.

3.4.2 Interpretation of the findings

This is the first study that sought to determine the incidence of MetS, the elements and the related risk factors amongst a group of migrants to Qatar.

Studies have explored migrant's health by three approaches. First, comparing between different migrant groups together and comparing them to the native population of the host country (164,176-179). Both comparisons explore the role of ethnic variation rather than the migration process itself. Second, studies that compared groups of migrants of exact origin at different host countries, which explored the effect of socio-economic factors (180-183). Third, studies comparing migrants with their counterparts living in their home country, which control for the ethnic or genetic predisposition and blame the migrant process itself for MetS development (168,184,185). The last approach deemed to be the most relevant to the current study, and the results can be compared to the current study. While all previous approaches focused on the prevalence rather than the incidence, the alternation in migrates health to migration process itself. The current study determined the incidence of MetS amongst the same group of migrants at baseline and 24-months post migration. The genetic predisposition and race

variation are controlled, and the only changing variable is the migration and the associated lifestyle modifications.

In the current study, the incidence of MetS amongst initially MetS-free Qatar migrants rose to 17.0% during the 24-months in Qatar. Likewise, Van der Linden reported high MetS prevalence among Ghanaian migrants to Europe, compared to their counterparts in Ghana (ranged from 31.4% to 38.4% vs 8.3% respectively) (168). Thus, both studies highlighted that migrants are at increased risk of MetS development.

In this study, more than half of the study population developed central obesity during the 24-months residence in Qatar due to reduced physical activities and diet with fewer fruit and vegetable portions, as highlighted in the analysis of survey data. In a systematic review of 39 cross-sectional studies, Goulão et al. highlighted the positive association between obesity prevalence and length of stay in the host country (186,187). Migration was associated with weight gain, which directly increased with the duration of migration. Similar to the findings of the current study, a recent study conducted amongst Qatar migrants in 2020 also highlighted that male migrants were more likely than female to develop MetS (57). Central and South American male migrants to Washington tended to develop MetS more than female migrants (165). This variation was attributed to the sex hormones that make men more prone to develop central obesity and subsequent insulin resistance (188,189).

Regarding the sociodemographic parameters, previous studies have shown the MetS-protective effect of being unmarried (single, divorced or widow), having high education, occupation levels and consuming diets rich in fruits and vegetables (128,190,190-198). Other studies have also highlighted the variation of MetS prevalence with ethnic groups (57,199), being most marked in South Asian migrants. Conversely, the current study showed no association between occupation, education, marital status, ethnic origin and diet with MetS incidence. However, the limited sample size and lack of ethnic variability (81.0% were Asians) could explain these differences.

The WHO advocates maintaining at least 150 mins/week of moderate activities or 75 mins/week of vigorous activity or a mixture of them as a healthy lifestyle. As a worldwide accepted criterion, the WHO recommendations were adopted in this study to evaluate the level of physical activity. Although, the mean time of moderate and vigorous activity from baseline to follow-up reduced by 50% (p<0.001 for both), the logistic regression yielded a non-significant correlation between reduced physical activity level at follow-up and MetS incidence. In contrast, two national-based health surveys in South Korea, and China have reported MetS prevalence inversely correlated with physical activity (200,201).

Compared to migrants not receiving any medications that alter the metabolic parameters, migrants consuming any of these medications were at increased risk of MetS by six-fold. The most commonly reported medications in the current study were anticonvulsants, β blockers, steroids, and diuretics. Several previous studies have confirmed these adverse metabolic effects with proposed mechanisms including promotion of weight gain, fat disposition in the visceral area, subsequent impaired glucose tolerance, and insulin resistance (202-205). Caution should be exercised when prescribing these medications with periodic monitoring of the metabolic parameters (206).

3.4.3 Strengths

There are numerous strengths to this study. While all previous studies focused on MetS prevalence at one time-point, this is the first study to screen migrants for MetS at baseline and determine the incidence 24-months post-migration. Hence, the current study associates MetS-incidence to the migration process itself and the subsequent lifestyle modification. In addition, this is the first study to assess MetS and potential determinants amongst migrants to the Middle East and the Gulf. A validated and well-established questionnaire (WHO STEPwise) was used to address lifestyle modifications (162) (Appendix 3.2).

Moreover, several measures were adopted to maximise reliability and validity, to minimise bias and promoting robustness. A key strength is that the quantitative

approach was adopted as the most appropriate to answer the study objectives. By applying descriptive, inferential and association statistics, conclusions were generated from numerical values. Data collection documentation was piloted to ensure comprehensiveness and feasibility. The objectivity of the data extraction tool eliminates potential observer bias.

The prospective design of the follow-up study ensured that all required parameters were available. Baseline and follow-up laboratory tests were performed at HMC laboratories accredited by the College of American Pathologists (CAP) in 2014 and reaccredited in 2018. Noteworthy, blood sampling was conducted at HMC laboratories by adequately trained personnel, under aseptic techniques following a standardised infection control protocol (174). The blood samples were handled and stored as per the HMC laboratory management protocol (170). The devices utilised to measure Wt, Ht, and BP underwent regular inspection and planned periodic maintenance to ensure the quality and accuracy (156). This reduced any potential measurement decay bias. Finally, a leaflet describing the study's process and benefits was provided to reduce any attrition throughout the study.

3.4.4 Limitations

There are limitations; hence the study findings should be interpreted with caution. These include the relatively low participation rate, resulting in the study size being below the calculated sample estimation. In addition, there are potential issues of generalizability beyond the study setting. Notably, most of the population were Asian, and almost all had a medical background. Baseline questionnaire data may also be subject to recall bias and the follow-up period of two years was relatively short. In addition evidence indicates that a more extended migration period may be associated with higher MetS prevalence (28).

3.4.5 Implication for future research and for clinical practice or policy

This study provides evidence about the impact of migration to the Middle East in new-onset MetS incidence. Assessment and follow-up of these migrants in terms of MetS and the elements will generally improve health status, control of risk factors, less likelihood of longer-term consequences and enhanced quality of life. This study will guide policymakers within the Ministry of Public Health and HMC in implementing preventative measures to combat MetS among migrants and develop strategies for early warning systems. This section will be considered in detail in the Chapter 5.

3.5 Conclusion

There is limited evidence about the incidence of MetS and the elements postmigration, particularly in the Middle East. Migrants to Qatar particularly males, were at increased MetS incidence during 24-months of migration. Consuming medications that potentially induce MetS was a significant determinant. These factors should be the subject of prospective intervention studies.

Chapter 4: Systematic Review

Chapter 4: A systematic review of pharmacist input to metabolic syndrome screening, management, and prevention

4. Introduction to the chapter

To date, most evidence on healthcare professional input to MetS management has centred on physicians and nurses (207). While these roles are well-defined, there is less evidence supporting pharmacist involvement in MetS management. There is potential for pharmacists to apply their expert medication knowledge and clinical skills to enhance the care of patients who are at risk of or have established MetS. There is evidence of positive impact relating to pharmacist input to specific MetS risk factors including the management of Type 1 and 2 DM (208), HTN (209,210), weight loss in obesity (211,212) and reduction in cardiovascular disease related hospitalization and mortality (213). Growing evidence has suggested that pharmacist-physician collaborative multidisciplinary care approach in many disciplines is best practice (214). This will support achieving the aim of better population health, better patient experience and low per capita cost (215).

A preliminary search of the Cochrane Library of Systematic Reviews and Metaanalysis and the International Database of the Prospectively Registered Systematic Review in Health and Social Science (PROSPERO) using the terms, 'pharmacist' and 'metabolic syndrome', yielded no related published or ongoing systematic reviews. A search in Medical Literature Analysis and Retrieval System Online (MEDLINE) using the same terms identified a body of primary literature sufficient for a systematic review to be undertaken.

4.1 Aim of the review

The aim of this systematic review was to critically appraise, synthesise, and present the evidence on pharmacists' input to the screening, prevention, and management of MetS. Specific objectives were to:

To determine the types of pharmacist input reported in the studies

To determine the impact of the reported input To characterise the populations who could benefit most from the input To identify the facilitators and barriers to the effective implementation of pharmacist input.

4.2 Ethics approval

The IRB of the Medical Research Centre at HMC in Qatar confirmed that no ethics approval was required to undertake this review.

4.3 Method

4.3.1 Protocol development

The systematic review protocol was developed based on the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 guidance (216) and registered in the International Prospective Register of Systematic Reviews (PROSPERO) (Appendix 4.1) (217).

4.3.2 Inclusion and exclusion criteria

The standard systematic review PICO (population, intervention, comparator, and outcomes) approach was employed (218).

Type of participants

All studies irrespective of population groups were included in the review.

Type of interventions

All pharmacist activities in the screening, prevention, or management of MetS were included.

Type of comparator

All studies were included whether or not there was a control group.

Type of outcome

All studies which had outcomes relating to assessing the pharmacists' input to the screening, management, and prevention of MetS were included.

The outcomes were diverse: comparisons of different models of pharmacist input in MetS; descriptions of the process of development of the models; and the clinical outcomes of such interventions.

Types of studies to be included

All studies were included irrespective of design. The initial search indicated that the first relevant article was published in 2008; hence, all studies published between 2008 and March 2020, in the English language were included.

4.3.3 Exclusion Criteria

Grey literature was excluded due to the potentially limited information to permit quality assessment, and difficulties in searching and retrieval (219).

4.3.4 Search strategy and data sources

The electronic search strategy was guided by the "Peer Review of Electronic Search Strategies" (PRESS) checklist (220). An initial search of MEDLINE and Cumulative Index to Nursing and Allied Health Literature (CINAHL) was conducted, using keywords of 'pharma*' AND 'metabolic syndrome' to identify further keywords and search terms. The search string then applied to MEDLINE, CINAHL, Cochrane, International Pharmaceutical Abstracts (IPA) and Google Scholar was {'Metabolic syndrome*' OR 'syndrome x' OR 'Insulin resistance syndrome*' OR 'Dysmetabolic syndrome*' OR "Hypertriglyceridemic waist*' OR 'Obesity syndrome*' OR 'Metabolic Cardiovascular Syndrome' OR 'Reaven Syndrome X' OR 'Atherothrombogenic syndrome'} AND 'Pharm*'. The reference lists of all identified articles were hand searched to identify any further relevant articles. Attempts were made to contact corresponding authors where data were missing or incomplete.

4.3.5 Quality assessment and data extraction

Eligible studies were assessed for quality using standardised quality assessment tools, the Cochrane bias assessment tool and the National Heart, Lung and Blood Institute (NHLBI) quality assessment tools (221,222). Quality assessment using these tools was undertaken independently by two reviewers, with any disagreements resolved by discussion and referral to a third reviewer if necessary. RCTs were deemed of good quality if all criteria were of low bias risk as judged by the assessor, fair if the study had one high bias risk or two uncertain bias criteria, and poor if two or more high or uncertain bias criteria (221).

A data extraction tool was developed by adapting and customizing the "Data collection form for intervention review – RCTs and non-RCTs" from the Cochrane Collaboration (223). Information was extracted by two independent reviewers.

4.3.6 Data synthesis

Given the lack of homogeneity of study aims, participants and outcome measures, a narrative approach to data synthesis was undertaken, using text and tables aligned to each of the review objectives.

4.4 Results

4.4.1 The results of the search process

The initial search yielded 39,430 studies. For feasibility and practical reasons, the 39,430 articles were screened initially for titles only and this excluded 39,363 irrelevant titles. Abstract screening excluded a further 53. Of the 14 remaining studies, four were excluded from the full-text review. No additional studies were identified through the bibliography review. Of the ten studies included in the following stages, four were RCTs, four were cross-sectional design, one a before-and-after study and one was a quality improvement project (Figure 4.1).

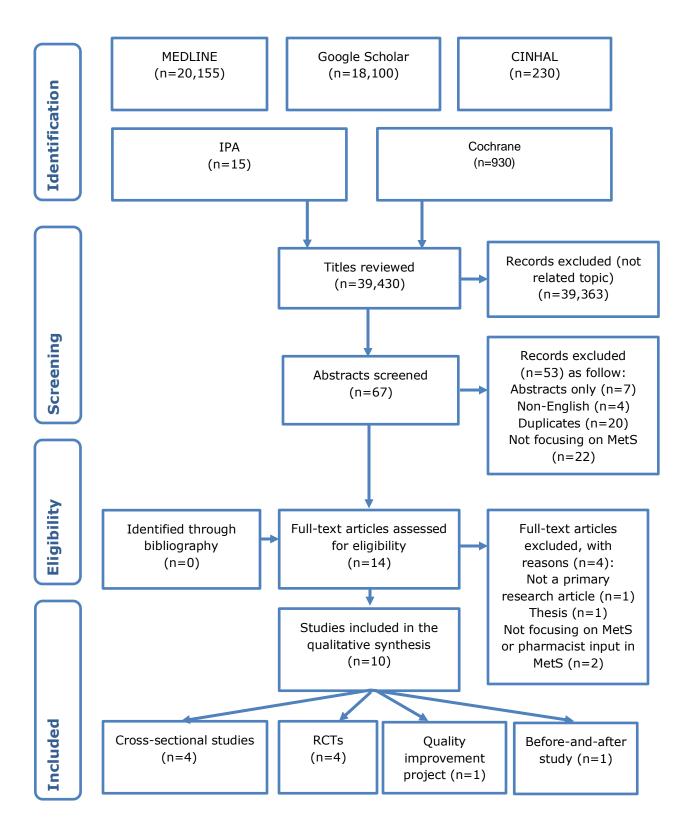


Figure 4.1 Flow diagram of the literature review process.

4.4.2 Quality assessment

Quality assessment of all included studies is reported in Tables 4.1-4.2. The RCTs had low bias for the primary outcome measures (Table 4.1). The key limitation of the cross-sectional studies was the absence of a rationale for, or calculation of, sample size (Table 4.2). The overall potential risk of bias of the before-and-after study was assessed to be low. Restricting the assessment to a single time point (measuring the outcome once after the outreach visits) and single hospital ward (the study was held in a psychiatric ward of the hospital) were key study limitations (Table 4.2).

	Hammad et al. 2011 (224)	Plaster et al. 2012 (225)	Schneiderhan et al. 2014 (226)	Azevedo et al. 2017 (227)
Random sequence generation (selection bias)	L	L	L	L
Allocation concealment (selection bias)	L	L	L	L
Blinding of participants and personnel (performance bias)	NA	NA	NA	NA
Blinding of outcome assessment (detection bias)	L	L	L	L
Incomplete outcome data (attrition bias)	L	L	L	L
Selective outcome reporting? (reporting bias)	L	L	L	L
Other bias	L	L	L	L
The quality rating	Good	Good	Good	Good

Table 4.1 Quality assessment of randomised controlled trials studies (221).

L: Low risk, H: High risk, NA: Not applicable, U: unclear.

Table 4.2 Quality assessment of cross-sectional studies (222), and before-andafter (pre-post) studies with no control group (222) respectively.

Cross-sectional studies	Schneiderhan et al. 2009 (228)	Olenak and Calpin 2010 (229)	Benavides et al. 2011 (230)	Via-Sosa et al. 2014 (231)	Kjeldsen et al. 2013 (232)
			1		
1. Was the research question or objective in this paper clearly stated?	Y	Y	Y	Y	
2. Was the study population clearly specified and defined?	N	Y	Y	Y	
 3. Was the participation rate of eligible persons at least 50%? 4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants? 	CD Y	CD Y	Y Y	CD Y	
5. Was a sample size justification, power description, or variance and effect estimates provided?	N	N	N	Y	
6. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	Y	Y	Y	Y	
Before-and-after (pre-post) studies					
1. Was the study question or objective clearly stated?					Y
2. Were eligibility/selection criteria for the study population prespecified and clearly described?					Y
3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?					Y
4. Were all eligible participants that met the prespecified entry criteria enrolled?					CD
5. Was the sample size sufficiently large to provide confidence in the findings?					CD
6. Was the test/service/intervention clearly described and delivered consistently across the study population?					Y
7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?					Y
8. Were the people assessing the outcomes blinded to the participants' exposures/interventions?					N
9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?					NA
10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes?					Y
11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?					N
12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?					N

Y: Yes, N: No, NA: Not applicable, CD: cannot determine.

4.4.3 Data extraction

Most of the studies (n=7) were conducted in South and North America, with two in Europe and one in the Middle East. A total of 1728 participants were included, with sample size ranging from 17 to 650. The four RCTs evaluated the impact of pharmacist contribution in MetS management versus conventional care. One before-and-after study assessed the impact of a pharmacist outreach visit to implement a MetS screening program in a hospital ward. The four cross-sectional studies mainly assessed the usefulness or the implementation of pharmacist-led MetS screening. The quality improvement project evaluated the patient load before and after expansion of the metabolic clinic, with special focus on the type of pharmacist input. Table 4.3 describes the study findings in relation to the review objectives.

	Aim/objectives, as	-	Results	Population	Ma	ain findings related to t	he reviews' obje:	ectives
Author, year, country	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
Schneiderhan et al., 2009, Minnesota (228)	"To assess the usefulness of a metabolic risk screening program, including point-of-care (POC) glucose testing, to quantify baseline metabolic risk in outpatients receiving antipsychotics"	Retrospective cross-sectional	Of 92 patients screened 65 (71%) had one MetS parameter and 40 (43%) had 2. No significant difference reported between parameters irrespective of antipsychotic. No results presented for POC testing	Adult outpatients receiving antipsychotic medications	Piloted MetS risk screening clinic to identify rates of metabolic abnormalities Developed a MetS screening tool for patients treated with antipsychotic agents Communicated relevant information and recommendations to patients and patient's psychiatrist	Earlier detection of Mets through pharmacist-led screening program (71% with at least 1 MetS parameter) Earlier intervention by providing proper education to the patients and relevant healthcare referral	Females receiving antipsychotics with a BMI > 30kg/m ² of African American origin	Facilitators:Being a part of and havinga defined role in themultidisciplinary teamAppropriate clinic set-upincluding facilities forreferral, clinic logisticsAvailability of resources,such as POC devices. Thelatter is of particularimportance when dealingwith psychiatric patientsBarriers:Difficult behaviours ofpsychiatric patients

Table 4.3 Description of studies included in the systematic review, in relation to the SR objectives.

.5	Aim/objectives, as	c	Results	Population	Ма	ain findings related to t	he reviews' obj	ectives
Author, year, country	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
	"To implement a		Baseline screening	239	Baseline screening for	Earlier detection of	The	Facilitators:
	comprehensive		indicated that	volunteers	MetS and	Mets through the	prevalence of	Community pharmacy
	screening for MetS that		86 (36%) had MetS.	over 18 years	Framingham 10-year	pharmacist-led	MetS was	setting placing the
	could be duplicated in		Using Framingham	of with no	risk assessment	screening program	higher in older	pharmacist in an excellent
ê	other community		risk assessment, 20	history of	Provision of	Earlier intervention by	adults aged	position to provide a
(229)	pharmacy settings,		(8.3%) ware at high	CHD	educational lifestyle	providing education to	49.9 ± 17	screening service
ia (determine the		risk of CHD (≥20		intervention at	the patients and	years and	Effective communication
van	prevalence of MetS in	λpn	10-year risk of CHD)		baseline for all	relevant healthcare	those with DM	with physicians
syl	our local community,	ll st			patients	referral (58%	or pre-DM	Patient engagement and
Pennsylvania	determine the 10-year	iona	87% with MetS self-		Provision of screening	discussed their results		ownership of their health
č	risk of developing	cross-sectional study	reported lifestyle		results to the	with a physician)		Availability of POC devices
2010,	coronary heart disease	SS-S	changes following		physician			Effective advertising of
	(CHD) in patients with		education provided		Assessing uptake of			screening service
Calpin.,	MetS, and determine	ive	by the pharmacist		lifestyle modifications			
Cal	the effectiveness of an	rospective			suggested by a non-			Barriers:
and	education provided by	ros	No further details		validated			Financial costs of
ak a	the pharmacist to		were provided		questionnaire			consumables
Olenak	encourage patients to							
ō	make lifestyle changes"							

	Aim/objectives, as	_	Results	Population	Μ	lain findings related to	the reviews' obj	ectives
Author, year, country	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
, 2011, Cameron (230)	"To evaluate the role of a clinical pharmacist (CP)-in screening children and adolescents for components of the MetS"	cross-sectional study	Of the 25 participants who completed the study 1 (4%) had 3 parameters of MetS, 7 (28%) had two components, and 9 (36%) had only one Treatment recommendations were made for 17	High-risk children aged 10-18 years old, of Mexican American origin in a rural ambulatory health centre	Assessing the participants for each component of MetS Educating the participants about exercise Providing the paediatrician with screening results and management recommendations	Early detection of MetS and the components in a paediatric population (68% with at least 1 MetS parameter) Enhance the early management of MetS through the provision of treatment recommendation to the physicians	Paediatric patients with components or risk factors of MetS like obesity, first- degree family history of DM or acanthosis nigricans	Facilitators: Previous experience in pharmacist running of a screening clinic Effective collaboration with the physicians Barriers: Financial costs of staff and consumables Rural areas and lack of access to healthcare
Benavides et al.,		Prospective, c	(68%) participants and communicated to the paediatrician. All were non- pharmacological interventions			Increase the patient's knowledge and awareness of MetS Prevent the progression of the disease to overt HTN and DM Referrals to physician and dietitian for further assessment		provision Lack of consensus on MetS definition in children and adolescents

2	Aim/objectives, as	c	Results	Population	Ма	ain findings related to t	he reviews' obje	ectives
Author, year, country	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
Hammad et al., 2011, Jordan (224)	"To describe the clinical benefits of a physician- clinical pharmacist collaboration in achieving better glycemic control and better lipid and BP measurements in patients with metabolic syndrome as defined by NCEP/ATP III guidelines"	RCT non-blinded	Of the 199 participants, when comparing the control group to the intervention group, 22 (24.7%) vs 43 (39.1%), respectively (p=0.032) were shifted from the MetS to none-MetS status. There was a significant reduction in TG, and BP in the intervention group compared to the control group. 308 pharmacist interventions were provided to	High-risk patients identified at family medicine outpatient clinics	Recruit the identified patients with suspected MetS Interview patient prior to the appointment with the physician Develop individualised care plans in collaboration with physicians Provide medication and lifestyle modification education with handouts Provide recommendations to start new treatment and laboratory monitoring Provide patient follow- up	Improve MetS status amongst the participants in the intervention group by 39.1% Improve the elements of MetS in the intervention group including TG reduced by 15 mg/dL more than in the control group (p=0.029) Improve BP reduction was significantly higher in the intervention group (SBP 12.2 ± 20 mmHg and DBP 7.2 ± 12.6 mmHg (p=0.049) Increase the patient's	Patients with hypertension and high triglycerides	Facilitators:Effective collaboration withthe physicians in assessingand managing MetSLogistical issues associatedwith clinic siteEngaging the patient andencouraging ownershipand adherenceEffective patient follow-upBarriers:Lack of availability ofresources includingpharmacist timeLack of the formalintegration of the MetSscreening andmanagement protocolswithin the health system
			patients and physicians		ч р	knowledge and awareness of MetS		

.5	Aim/objectives, as	E	Results	Population	Ma	ain findings related to t	he reviews' obj	ectives
Author, year, country		Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
Plaster et al., 2012, Brazil (225)	"To determine the impact of a pharmaceutical care program in a sample of public outpatients with MetS"	RCT non-blinded	96 (80%) out of 120 participants had MetS. At baseline, drug- related problems (DRPs) were identified relating to efficiency, safety and necessity. At follow up, all were improved. Improvement in the intervention group was found in all the measured parameters after 6 months from baseline. This was statistically significant for almost all parameters	Diabetic patients with MetS identified at outpatient community health centres	Baseline assessment to obtain the demographical data and identify any DRP Provide pharmaceutical interventions targeting the proper medications use and lifestyle modifications Inform the physicians of the pharmacist interventions	A significant reduction in coronary heart disease (22±2 to 14±2%; p<0.01). 83 % resolution and 100 % improvement of the DRPs and optimization of drug treatment Increase the medications adherence indicated indirectly by the improvement of the clinical outcomes Improve BP -13±3 mmHg (p<0.05) Increase weight reduction -2.6±1 kg in the intervention group	Diabetic, hypertensive obese patients	Facilitators: Effective collaboration with the physicians Being a part of the multidisciplinary team (MDT) and having a defined role Adequate financial resource Applying a pre-defined pharmaceutical framework (Dáder method) <u>Barriers:</u> Limiting the community health centre pharmacist role to dispensing Lack of resource including staff and consumables

	Aim/objectives, as	E	Results	Population	M	ain findings related to t	he reviews' obje	ectives
Author, year, country	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
Kjeldsen et al., 2013, Denmark (232)	"To evaluate the effect of outreach, visit by clinical pharmacists to support the implementation of screening of MetS at a psychiatric ward"	Before-and-after study	Improvement in utilisation of MetS screening sheets by 45% (from 34 (36%) to 91 (81%), P<0.001), Better documentation of screening values 24 (26%) to 91 (81%) (p<0.001) and better identification of MetS (9.3 (10%) vs 50 (45%), p<0.001)	205 Patients over 18 years with schizophrenia or affective disorders, in a psychiatric ward for at least 10 days and on antipsychotic s or mood- stabilizing medicines were included in the study (93 before the outreach visit and 112 after)	Auditing physician adherence to appropriate documentation Holding a weekly conference with the physicians and nurses to discuss the audit results Providing patient- specific recommendations	Successful implementation of a psychiatric hospital- based screening program indicated as follows: Increase utilization of the screening sheets by 45% Improve the quality of the screening by 55% Earlier detection of antipsychotic induced MetS by 35% Earlier management of the identified MetS cases amongst hospitalized psychiatric patients	Adult hospitalised patients receiving antipsychotics or mood- stabilizers	Facilitators: Availability of appropriate documentation with audit for compliance Effective collaboration with the MDT, with a defined role Barriers: Difficult behaviours of the psychiatric patients Lack of proper communication and/or documentation with the general practitioners in the community health centres Unavailability of the IT software to facilitate documentation and

5	Aim/objectives, as	c	Results	Population	M	he reviews' obje	ectives		
Author, year, country	Author, year, country country study design Study design				Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS	
Via-Sosa et al., 2014, Spain (231)	"The main aim of the study was to determine the prevalence of pre- MetS, the secondary aims were to study the presence of other cardiovascular risk factors and determine patients' cardiovascular risk"	Cross-sectional, descriptive study	Among the 650 screened participants, 124 (21.9%) had pre- MetS. Of the study population; 319 (49.1%) were hypertensive, 262 (40.3%) had abdominal obesity, 179 (27.5%) had high FBG, 131 (20.1%) had high TG and 109 (16.8%) had low HDL-C. 27% had not been previously diagnosed with dyslipidemia or hypertension	18-65-year- old adults who visited 23 community pharmacies to check for MetS risk factors	Screen of participants for pre-MetS and cardiovascular risk factors including patient interviews and measurement of appropriate metabolic parameters	Earlier detection of MetS through pharmacist-led screening program (27% never diagnosed with HTN or dyslipidemia)	Men Older adults (age >53 years old) with BMI > 25 kg/m ² Sedentary lifestyle (less than 30 min regular activity 4 to 5 times per week)	Facilitators: Community pharmacy setting placing the pharmacist in an excellent position to provide a screening service Available resource such as POC devices Barriers: Lack of financial support including that for staff and consumables	

	Aim/objectives, as	E	Results	Population	the reviews' obj	ectives		
Author, year, countrv	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
Schneiderhan et al., 2014, Minnesota (226)	" To determine the percentage of subjects taking antipsychotic agents who meet the criteria for MetS at baseline using POC test results. Secondary objectives included the following (1) evaluate the effectiveness of the prevision by pharmacist comprehensive medication management services regarding their ability to reduce the mean difference in number of MetS risk parameters based on POC test resulted at 6 and 12 months and (2) evaluate the overall impact of psychiatric medication therapy on MetS"	RCT non-blinded	At baseline of 120 participants screened, 106 (88.3%) had dyslipidemia, 63 (52.5%) were hypertensive and 27 (22.5%) were diabetic. No significant difference in MetS parameters between groups at 6 months and 12 months. No significant difference reported between parameters irrespective of antipsychotic	Patients 18 years and over, taking antipsychotic medications recruited from three community mental health clinics who had never been reviewed by a pharmacist	Baseline assessment of MetS risk factors amongst patients receiving antipsychotic medications Assessment of the safety and effectiveness of the prescribed medications Follow up of patients at regular intervals Provision of the interpretation of POC test results, care plans, and recommendations to the physician	Earlier detection of MetS through pharmacist-led screening program allowing earlier management Potential decrease drug induced MetS amongst psychiatric patients receive antipsychotics	Psychiatric patients who are receiving antipsychotics	Facilitators: Availability of the POC devices particularly due to the challenging behaviour of psychiatric patients Being a part of the MDT with a defined role Barriers: Challenging behaviours of psychiatric patients Lack of financial support including that for staff and consumables

							ted to the reviews' objectives						
Author, year,	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS					
Azevedo et al. 2017, Brazil (227)	"To evaluate the effectiveness of home pharmaceutical interventions in Brazilian primary care patients with MetS"	RCT non-blinded	63 patients with MetS were enrolled in the study. 64.5% (n=49) of pharmacists' interventions were educational and behavioural orientation. 26.3% (n=20) involved physician requesting review, and 9.2% (n=7) of the cases were referred to the physician for further assessment. After 6 months follow-up, the intervention group showed a significant reduction of BP by 8%, TG by 18.7%, DRPs by 59% and adherence increment by 18.2%	Adult patients aged 18 years and over diagnosed with MetS within 30 days	Baseline assessment of both groups Monthly follow-ups of the intervention group, including the following activities: Reviewing medications, identification of DRPs that might decrease the adherence and resolving them Provide education about administration and storage Diet and lifestyle recommendations Identify any unaddressed medical problem	Improve the management of MetS and the individual components (reduction of BP by 8%, TG by 18.7%) Foster medication adherence by 18.2% Decrease the DRPs by 59%	Older patients with MetS mean age 62 years particularly if (low income and low educational level)	Facilitators: Collaboration with MDT Applying standardized care pharmaceutical care plan (45) The settings of home visits Barriers No identified barriers					

	Aim/objectives, as		Results	Population	Ma	ectives		
Author, year, country	described by the author(s)	Study design			Description of pharmacist input	Impact of the identified input	Population who would benefit most from input	Facilitators and barriers to the effective implementation of MetS
	To evaluate the number		The initial pilot clinic	Adults	Baseline assessment s	Potential improvement	Adults on a	Facilitators:
	of pharmacologic		had 40 referrals, of	diagnosed	for MetS	in management of	secondary	Appropriate clinic set-up
	pharmacists		them 25 were	with MetS	Ordering and	MetS in psychiatric	generation	including facilities for
	interventions, assess		followed up. The	and on a	monitoring lab	patients on second	antipsychotic	referral, clinic logistics
\sim	the number of		new expanded clinic	second-	investigations	generation	with average	Effective advertising of
Palm Beach (233)	nonpharmacologic		received 28 referrals	generation	Made required	antipsychotics	age 58 years,	screening service via in-
i i i i i i i i i i i i i i i i i i i	interventions, and	ъ	with 17 followed up.	antipsychotic	medications		male gender,	service presentation
eac	compare the patient		Twenty-five		adjustments to the		smokers and	Authority of pharmacist to
8	load post expansion	Quality improvement project	pharmacological		doses of psychiatric		not formally	initiate medications and
Palr	to the pilot	t pr	(initiate new		medications and,		active	order labs
st	implementation of the	nen	medications or dose		diabetes, hypertension			Availability of appropriate
West	metabolic clinic.	ver	adjustment) and 33		and dyslipidemia			documentation
15,		brc	nonpharmacological		medications			Effective follow-up
201		۲ تا	interventions (diet		Educating participants			
ole		Ialit	and exercise) were		about diet and healthy			
Ganzer, Nicole		Ŋ	made. Three		lifestyle, and referred			<u>Barriers</u>
er,			referrals to national		to the national			Lack of adherence to the
anz			weight loss program		program for weight			clinic follow-up
Ü			and 1 referral to		loss			Lack of awareness of this
			smoking secession		Advising patients to			service in the community
			were offered by the		stop smoking and			Difficult behavior of
			pharmacists		referral to smoking			psychiatric patients
					secession clinic			

4.5 Data synthesis

Review objective 1: Description of pharmacist input

Study settings were community pharmacies (229,231) ambulatory outpatient clinics (family medicine, community health centres and psychiatric clinics) (224-226,228,230), pharmacist outreach visits to psychiatric patients in a hospital ward setting (232) and as part of a home healthcare service (227).

The pharmacist input was described in all the studies with varying levels of detail provided. Pharmacist screening of participants for MetS against validated criteria was described in eight studies (224-226,228,230-232) with screening results communicated to the relevant physician (228,230). In two studies, screening of other CV risk factors, using the Framingham risk assessment tool, was additionally reported (229,231). Various approaches to participant recruitment were described: clinic referral-based recruitment in three studies (228,233), appointment booking following appropriate advertisement in the media and the surrounding clinics (229), recruiting walk-ins to the community pharmacy (231) or through pharmacist patient history review (224). Two studies did not clearly report the recruitment process (225,226).

All RCTs described the baseline assessment of all patients with regular follow-up of the intervention arm, with both baseline and follow up conducted by the pharmacist (224-227). The pharmacist attended the clinic appointment along with the physician in one study (224) and documented and communicated a plan to the physician in three studies (225-227). In two studies, pharmacists also provided recommendations relating to laboratory testing and the need to prescribe new medications for undiagnosed conditions (224-227,233). Lifestyle modification recommendations were provided by the pharmacist in five studies (224,225,227,228,233), with only one of these measuring related outcomes using a nonvalidated questionnaire at three to six months (229) (Table 4.3).

Review objective 2: Impact of pharmacist role in MetS

Eight studies aimed to determine the impact of the pharmacist input. In the studies focusing on screening, the percentage of the newly diagnosed participants with MetS was reported. These participants would not have been diagnosed if the pharmacy screening service not been available (228,230,231). Patients were followed-up by referral (228), or by communicating the relevant clinical parameters to the physician (229,230). One study demonstrated an improvement in the quality and quantity of documentation completed by physicians relating to MetS screening (232). No further patient follows up was reported in one study (231).

The impact in MetS management in collaboration with the multidisciplinary team (MDT) was measured in four RCTs and one cross-sectional study, with improvement of anthropometric and metabolic parameters being the primary outcome measures (224-227). Additionally, determination of patient medication adherence was reported in one study (227). All but one study reported positive impact in terms of: achieving MetS parameter goals, reverting to non-MetS status, improved medication adherence and self-reported improved lifestyle modification. The study conducted in a psychiatric outpatient clinic failed to show significant improvement in metabolic parameters after the 12 months study period (226).

Review objective 3: The beneficiary population

Adults with comorbidities of MetS elements such as DM, HTN, dyslipidemia and obesity were included in five studies (224,225,227,231,233). Psychiatric patients receiving antipsychotic medications were targeted in three studies (226,228,233), since these medications are associated with significant weight gain (67). One study included children and adolescents at high-risk of MetS, with a first-degree family history of type 2 DM, obesity or acanthosis nigricans (230), due to the potential link to underlying insulin resistance (234,235). Healthy volunteers were the subjects of one study (229) (Table 4.3).

Review objective 4: Facilitators and barriers

None of the studies specifically aimed to determine the facilitators and barriers to pharmacist input. Consequently, data relating to facilitators and barriers were extracted by the reviewers. Throughout all studies, the most commonly identified facilitator was effective communication, documentation and appropriate setting for MDT referrals, in addition to active collaboration with the MDT where each member of the MDT had a defined role (Table 4.4). Lack of funding for reimbursement of pharmacist time, purchasing consumables and other resources such as information technology (IT) software was the most common barrier identified to the effective implementation of the pharmacist-led activity. Challenging behaviour of psychiatric patients was reported as a barrier in all studies involving psychiatric patients (Table 4.4).

	Schneiderhan et al, 2009 (228)	Olenak and Calpin, 2010 (229)	Benavides et al, 2010 (230)	Hammad et al, 2011 (224)	Plaster et al, 2012 (225)	kjeldsen et al, 2013 (232)	Via-Sosa et al, 2014 (231)	Schneiderhanet al, 2014 (226)	Azevedo et al. 2017 (227)	Ganzer, Nicole 2015, (233)	Total
Facilitators											
Collaboration with MDT with a defined role for each member	\checkmark				V	V		V	\checkmark		5
Effective communication/ documentation and referral	\checkmark	\checkmark		\checkmark	\checkmark						8
to the MDT	V	v	v	v	v	V			v	v	0
Appropriate setting / easy accessibility		\checkmark		\checkmark			\checkmark		\checkmark	\checkmark	5
Patient engagement in the therapeutic plan		\checkmark		\checkmark							2
Positive experience with pharmacist-led activity			\checkmark								1
Pharmaceutical framework adaptation					\checkmark				\checkmark		2
Effective follow-up		\checkmark		\checkmark					\checkmark	\checkmark	4
Effective funds including POC, advertising	\checkmark	\checkmark			\checkmark		\checkmark	\checkmark			5
Privilege to prescribe medications and order labs										\checkmark	1
Barriers											
Difficult behaviour of psychiatric patients	\checkmark					\checkmark		\checkmark		\checkmark	4
Lack of funding for consumables, staff, and IT software		\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark			7
Rural area and lack of healthcare access			\checkmark								1
No consensus on the clear MetS definition for			\checkmark								1
paediatrics											
Lack of formal integration of protocols in the				\checkmark							1
healthcare system											
Restricting the pharmacist to dispensing					\checkmark						1
Improper documentation and ineffective						\checkmark					1
communication with physicians											

Table 4.4 The facilitators and barriers of effective implementation of pharmacist input in MetS.

4.6 Discussion

This is the first published systematic review focusing specifically on pharmacist input in MetS. This review identified ten studies, four of which were RCTs. The most frequently reported inputs were in screening and in management, with prevention-related activities described in one study. The main population studied was adults with comorbidities putting them at higher risk of developing MetS. Beneficial impacts were described in terms of earlier diagnosis, potentially earlier intervention, and improvement in the MetS parameters. Successful integration with the MDT, effective communication and accessibility of the community pharmacies were most likely facilitators towards the implementation with lack of funding the most likely barrier.

This review adhered to best practice in conducting and reporting a systematic review, as described in "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) (236) (Appendix 4.1). The wide range of patient populations reported in the studies may enhance the generalisability of findings to at-risk populations. The main review limitation was restricting the review to papers published in English, resulting in four studies not being included. While the quality of the studies was generally good, reporting could be enhanced by encouraging the authors to adopt robust reporting criteria such as those recommended by the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network (237,238).

This systematic review has identified limited evidence upon which to inform the best practice of pharmacist input to MetS. The evidence base is derived from ten studies, only four of which were RCTs. Of the ten studies, there was marked variation in the aims and the models of care delivered, which significantly limits any potential for data pooling. Indeed, only four studies provided a comprehensive description of pharmacist interventions in terms of defined activities, training, processes, documentation, outcomes to be recorded and follow-ups.

A pharmacist-based intervention around MetS could be argued to be a complex intervention as defined by the UK Medical Research Council (MRC) which defines a 'complex intervention' as one with several interacting components, involving different behaviours and variability in outcomes (239). The MRC complex intervention framework has four stages of development, feasibility/ pilot testing, evaluation, and implementation. It is worth noting that none of the ten studies in this systematic review included all these stages, with deficiencies around the development, feasibility, and pilot testing stages. Ideally, the interventions should be developed and informed by evidence base in the literature (e.g. a systematic review), consider the theoretical basis for the intervention (e.g. behaviour change theory) and involve all stakeholders in development. Interventions developed according to this system are more likely to be successful compared to those developed pragmatically (239,240). There is also a lack of consideration of the MRC framework in the primary studies included in previous systematic reviews describing pharmacists input to managing MetS elements such DM (241), HTN (209), obesity (211) and cardiovascular risk factors (242). Despite the absence of application of the MRC framework, this review has provided some evidence of the benefit of the pharmacist input, particularly in the screening for and management of MetS. There were positive outcomes of earlier diagnosis, referrals to the pertinent physician and reaching the MetS parameter goals.

Obese adults with chronic comorbid conditions and paediatrics with risk factors were identified in this review to be among the beneficiary populations. These findings concur with at-risk populations highlighted by international organizations. The AHA and NHLBI underpin obesity and prediabetes as the main risk factors to develop MetS, in addition to other risk factors such as a sedentary lifestyle, atherogenic diet and older age (140). This was further supported by the IDF communication consensus worldwide definition of MetS in 2006. Central obesity and insulin resistance were defined as the most potent risk factors to develop MetS, in addition to other risk factors such as ageing, genetic predisposition, sedentary lifestyle, proinflammatory status and hormonal

changewood (3). Hence, prioritizing the at-risk population is logical and would be recommended, especially at the initial phase of implementing pharmacist-led activity with limited resource and experience.

Additionally, patients receiving antipsychotic medications were recognized by the American Psychiatric Association (APA) as at-risk population for development of MetS due to the strong association with weight gain, dyslipidemia and hyperglycemia, and emphasized the importance of regular screening and monitoring of MetS (243). This supports the fact that psychiatric patients were also among the beneficiary populations identified in this review. The challenges facing the implementation of the pharmacist within the collaborative service involving different specialities, including mental health, are common. While the nature of the conditions and the interventions are varied, the need for effective collaboration remains. The findings of a systematic review of 18 studies reporting the facilitators and barriers to the implementation of collaborative practice in mental health were in line with the findings of the current review. To successfully implement a new collaborative service, Wood, and colleagues emphasised the importance of adopting a multidisciplinary approach in mental health, including a pharmacist, maintaining effective communications, applying structured care plans and sustaining active patient's follow-up. On the other hand, the readiness of the organisations and staff for implementation and lack of knowledgeable, self-confident staff, adequate supervision and resources were the more pronounced barriers reported by Wood et al. (244).

A meta-synthesis of 29 qualitative studies categorized the influencing factors (facilitators and barriers) of implementing an advanced pharmacist run patient centred service into four categories; the patients' factors, the interpersonal communication factors, organizational and community factors (245). Among the most prominent factors enhancing implementation of advanced pharmaceutical services were easy accessibility of the service, sufficient resources for information technology (IT) programmes, educational materials, service promotion, staff incentives, effective collaboration and communication and a predesigned protocol

to define the role of each member of the team. The lack of these factors was barriers to implementation of the services (245). This is similar to findings in this reported systematic review, for example, organizational factors such as limited resources were also a barrier to implementation of pharmacist input to MetS; the interpersonal communication factors such as effective collaboration and communication with other healthcare providers were considered a facilitator, and specific patient factors including the challenging behaviour of psychiatric patients was a barrier to the practical implementation (Table 4.4).

The findings of this review are consistent with several published systematic reviews that have suggested that the MDT-pharmacist collaboration is the best model of care and facilitated the pharmacist's role in screening and management of patients with MetS. Showande et al. confirmed the effectiveness of collaborative pharmacist management of Type 1 and Type 2 DM with 41 RCTs included in a systematic review and meta-analysis (241). Similarly, in an earlier published systematic review by Altowaijri et al. across different settings (inpatient, outpatients and community pharmacies), pharmacist involvement with the MDT in secondary prevention of cardiovascular diseases was associated with better control of the cardiovascular risk factors and improvement in the clinical outcome (242).

Of paramount importance, emerging studies have suggested strategies to overcome the barriers to the implementation of collaborative pharmacist service. A meta-synthesis of 29 qualitative studies as well as the collaborative practice agreement issued by the national center for chronic disease prevention and health promotion, both has advocated utilizing evidence-informed practice along with seeking support from a leading champion in the field were suggested to alleviate the organisational and staff reluctance toward the implementation of new collaborative services. A multidisciplinary approach with engaging patients and their families was recommended to increase the readiness of the staff and patients to accept the pharmacist service. Emphasizing the potential long-term healthcare cost reduction secondary to the pharmacist collaboration and having more than one source of funding and cutting unnecessary expenses were suggested to overcome the financial barrier (246,247).

4.7 Conclusion

The limited number of studies describing pharmacist input in MetS provides some evidence of positive outcomes from screening and management as part of collaborative practice. Further work is required to provide more robust evidence of effectiveness and cost-effectiveness, while considering key barriers, to enable integration within standard practice.

Chapter 5: Discussion

Chapter 5: Discussion

5. Introduction to the chapter

This chapter describes the evolution of the doctoral research aim and objectives, restates the key findings of each study phase, describes the interpretation of the research program's findings, originality, potential impact, dissemination plan, and suggestions for future research.

5.1 The evolution of the research

During this PhD journey, the research aim and objectives evolved, and the skills of the PhD student as a researcher sharpened and developed with every step. As a result, considerable progress was made in gaining a deep understanding and application of research methodology, governance, academic writing, and presentation skills. The guidance and feedback from the experienced supervisory team was a cornerstone to this progress. Furthermore, constructive peer reviewers' comments as part of various submissions have improved the nature of the work. In addition, attending courses and workshops, and presenting at several national and international conferences enriched the experience. These provided further opportunities to discuss findings with other researchers.

The original aim of this doctoral research, "*To explore the role of pharmacists in screening, prevention and management of MetS",* remained the same throughout the study. However, the specific research objectives were refined as the research progressed, and this was also informed by the comprehensive literature review presented in the early chapters.

Of note, the original final objective, "*To pilot a pharmacist-led clinic focused on the screening, management, and prevention of MetS*", was considered not to be feasible within the timescale of the doctoral research hence was revised. In addition, initiating a highly novel service within any healthcare institution, including HMC, is complex and typically involves many stages of approval from internal and perhaps external bodies. There were also likely to be significant resource implications in terms of staffing, equipments, and consumables. The final objective was therefore revised as "*To consider all research findings to*"

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recommend a pharmacist-led model-of-care for the prevention, and early detection, and management of MetS" (Figure 5.1).

The overall doctoral research

aim and objectives

The original

The overall aim of this doctoral research is to explore the role of pharmacists in screening, prevention, and management of MetS. The specific objectives are:

- 1- To estimate the incidence of the MetS in a random group of *immigrants* coming to Qatar.
- 2- To identify the factors potentially associated with increased MetS development amongst Qatar's *immigrants*.
- 3- To critically appraise, synthesise, and present the available evidence on the role of pharmacists in screening, prevention, and management of MetS.
- 4- To pilot a pharmacist-led clinic, focused on the screening, management, and

After evolution

The overall aim of this doctoral research is to explore the role of pharmacists in screening, prevention, and management of MetS. The specific objectives are:

- 1. To estimate the incidence of the MetS in a random group of *migrants* coming to Qatar.
- 2. To identify the factors potentially associated with increased MetS development amongst Qatar's *migrants.*
- 3. To critically appraise, synthesise, and present the available evidence on the role of pharmacists in screening, prevention, and management of MetS.
- 4. To consider all research findings to recommend a pharmacist-led model-of-care for the prevention, early detection, and management of MetS.

Figure 5.1 The evolution of the aim and objectives of the doctoral research.

As discussed in Chapter 3, the aim, and objectives of the first study (prospective longitudinal observational cohort study) were slightly modified (Figure 5.2). One of the initial study objectives was "*To determine the prevalence of MetS among new immigrants who came to Qatar in 2013*". However, to have clinically meaningful epidemiological data, it is necessary to have large sample sizes (248). Unfortunately, as described in Chapter 3, the sample size was smaller than initially anticipated (205 migrants). Therefore, this objective was amended as "*To identify and describe MetS-free migrants who have been residing in Qatar for less than three months*", where MetS prevalence among migrants to Qatar on arrival as a baseline was reported rather than epidemiological data.

Throughout the research," migrant" replaced the term "immigrant" to describe more accurately the expatriates in Qatar, since migrant is "a person who moves to a new area or country to find work or better living conditions", an immigrant by comparison is "a person who comes to live permanently in a foreign country" (249). The prospective longitudinal observational study aim and objectives

The original

A. Aim

The overall study aim is to explore the incidence of MetS, components, and risk factors in a population of HMC *immigrants* over time.

B. Objectives

Phase one - baseline, (within 3 months of arrival), routinely collected data

1. To determine the prevalence of MetS among new *immigrants* who came to Qatar in *2013*.

The Mets-free individuals will then be the subjects of study in phase two.

Phase two – 7 years post-baseline

2. To determine the incidence of MetS and MetS components amongst these individuals *seven* years post-arrival in Qatar.

3. To compare those with MetS, MetS components and healthy *immigrants* at follow-up regarding variables of demographics and behaviours relating to modifiable risk factors.

4. To identify predictors of MetS and MetS components.

After evolution

A. Aim

The overall study aim is to explore the incidence of MetS components, and risk factors in a population of HMC *migrants* over time.

B. Objectives

Phase one – baseline (within 3 months of arrival), routinely collected data

1. To identify and describe MetS-free migrants who have been residing in Qatar for less than three months.

These individuals will then be the subjects of study in phase two.

Phase two - 24 months post-baseline

2. To determine the incidence of MetS and MetS components amongst these individuals *24 months* post-arrival in Qatar.

3. To compare those with MetS, MetS components and healthy *migrants* at follow-up regarding variables of demographics and behaviours relating to modifiable risk factors.

4. To identify predictors of MetS and MetS components.

Figure 5.2 The evolution of the aim and objectives of the prospective longitudinal observational cohort study.

As described in Chapter 4 and described briefly in section 5.2.2, the systematic review was the second step in the doctoral research to synthesise the evidence regarding the pharmacist's role in MetS.

The aim and objectives remained the same throughout, as illustrated in Figure 5.3.

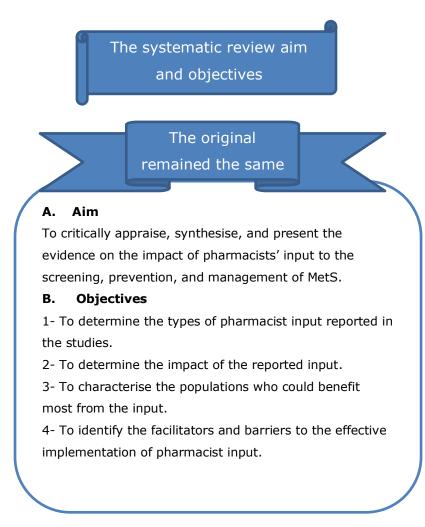


Figure 5.3 The systematic review aim and objectives.

5.2 Key findings

5.2.1. Study 1: The prospective longitudinal observational cohort study This study addressed the first two objectives of the doctorate research. MetS screening of migrants to Qatar at baseline revealed that more than half (53.4%, n=205) were MetS-free and eligible for enrolment in the follow-up phase of the study. During the 24-months of residence in Qatar 17.0% (n=27/160, 95% CI 11.0%-23.0%) of the initially MetS-free migrants developed MetS, and 81.0% (n=129/160) developed at least one element of MetS. The most common single element of MetS was central obesity (56.5%, n=108/191, 95% CI 49.0%-64.0%) as defined by IDF criteria (13). All metabolic parameters were raised significantly at follow-up from baseline, except for SBP (see Table 3.10). Male gender and receiving medications that potentially induce MetS were identified as risk factors for MetS (Chi-square value=13.4, df=4, p=0.01 and Chi-square value=16.9, df=4, p=0.002 respectively). However, after controlling for gender and moderate and vigorous physical activities in the regression analysis, only consuming medications that potentially induce MetS increased the odds of MetS incidence amongst migrants to Qatar six-fold (AOR 6.3, 95% CI; 2.27-17.73, p<0.001).

5.2.2. Study 2: Systematic review

This study addressed the third objective of the doctorate research. As described in Chapter 4, the systematic review aimed to critically appraise, synthesise, and present the evidence on the impact of pharmacists' input on the screening, prevention, and management of MetS. Ten studies were included in the systematic review; four were RCTs, four were cross-sectional studies, one was a before-and-after study, and one was a quality improvement project.

Most studies focused on pharmacists' input to MetS screening and management. Screening primarily involved diagnosing patients with MetS based on one of the approved MetS criteria and communicating metabolic parameters to physicians. Management of MetS described pharmacists collaborating with the MDT members by suggesting dose adjustment, alternative therapy, laboratory followup, discontinuing unnecessary medications, and providing medications and lifestyle modifications education. A positive impact of pharmacist intervention was reported in all studies regardless of the stage of the patient journey, including achieving normal metabolic parameter values, reverting to a non-MetS status, and improved medication adherence. The populations studied were paediatrics with risk factors, adults with comorbidities and psychiatric patients. Integration of the pharmacist within the MDT, an easy referral process and accessibility of the service were potential facilitators, with inadequate funding being the key barrier. The studies describing pharmacist input to MetS provided outcomes of screening and management as part of collaborative practice. The current systematic review, along with the previous systematic reviews about pharmacist managed chronic diseases (Cardiovascular disease, HTN, DM, obesity, dyslipidemia) (107,209,242,250), have identified a potential new role for pharmacists in Qatar and beyond.

5.2.3 The suggested future pharmacist intervention:

This section addresses the fourth objective of this doctoral research. The findings from the prospective study and the systematic review suggest the potential for a pharmacist-led model of care to combat MetS amongst Qatar migrants. The prospective study shows that migration to the middle east, including Qatar, is associated with new MetS incidence. Providing that the migrant population represent the majority of Qatar's population (91%), hence, MetS among migrants is of great importance.

Research findings from the prospective study and the systematic review have been considered and combined to suggest a future pharmacist intervention that is likely to meet the requirements of migrants to Qatar.

The systematic review has informed that pharmacists are competent to perform MetS screening in different settings. Additionally, the collaboration with physicians in the management of MetS in the outpatient clinic was superior management by physicians only.

Models of care have been described in the literature driven by pharmacists. These include screening of HTN and DM in the community pharmacies, with risk factor assessment and motivational lifestyle education (101, 103). Moreover, collaborative management of DM and HTN was described in the literature in different settings. These include pharmacist review of patients before a physician appointment with documentation of recommendations (100), and independent appointments with the pharmacist who implement recommendations following approval from the relevant physician (102). Both have been shown to be effective with rapid achievement of the target levels of BG or BP.

In the light of this evidence, a suggested model of care to address the local needs in Qatar is being put forward as follows: A pharmacist-led MetS screening of migrants is conducted at their first healthcare encounter in Qatar, which is the medical commission centre. Additionally, the pharmacists will educate the migrants about adopting a healthier lifestyle and making healthy choices for themselves and their families, with a facilitated referral system to the second step. The screening will include investigating taking a medical history and conducting MetS screening based on the latest approved MetS criteria. It is aimed for the screening to be conducted within three months of migrants landing in Qatar.

The pharmacist will refer migrants with MetS or the elements as identified through the screening process to a specialised pharmacist-physician collaborative MetS management clinic within the primary health centres. A pharmacist will assess migrants with MetS prior to the physician's visit. Migrants will be assessed for MetS parameters and agreed therapy goals set. Moreover, the current medications will be assessed for appropriateness (indications, dose, duration, administration, drug-drug interaction, drug-food interaction, adverse drug reaction, renal or hepatic dose adjustment, therapeutic drug monitoring) and any recommendations made to the relevant physician. Finally, a medication therapy management clinic run by a pharmacist is suggested to manage MetSfree migrants who are consuming medications that have the potential to induce MetS. This has been identified in prospective study as the main predictor of MetS among Qatars' migrants. As the medications experts, pharmacists will utilise their skills to introduce measures to minimise adverse drug reactions while maintaining the therapeutic benefit of the medications regimen. The measures include recommendations for alternative drug management, dose adjustment, adjuvant therapy, therapeutic monitoring and non-pharmacological intervention (Figure 5.4).

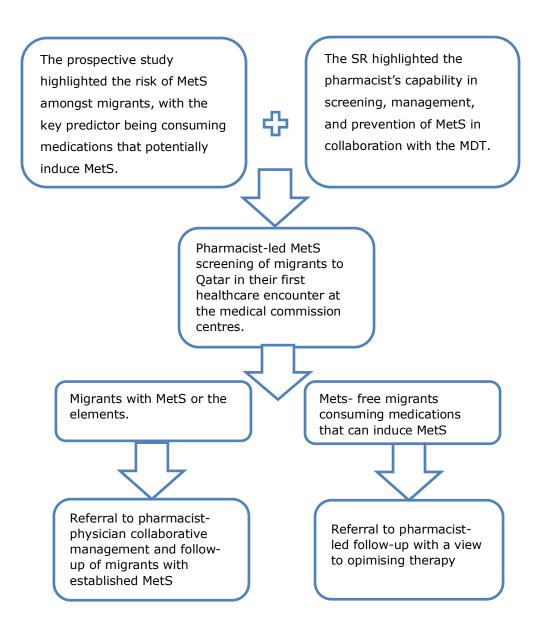


Figure 5.4 A suggested pathway for a pharmacist-led intervention based on findings of this research

5.3 Interpretation of findings

5.3.1 Relevance of findings to the local scene

This doctoral research aligns with the National Health Strategies (2011-2016 and 2018-2022) and Qatar National Vision 2030 (Figure 5.5). As described in Chapter 1, Qatar National Vision was developed in 2008 with a set of goals to enhance Qatar prosperity by 2030 (121). As part of this vision, the National Health Strategy defined seven priority populations highlighted as vulnerable.

These are children and adolescents, women of childbearing age, workforce, people vulnerable to mental illness, people with comorbid conditions, people with special needs, and the older population.

The prospective longitudinal observational cohort study focused on two of these seven populations. The first population is the "workforce", where the migrant population represents 94.0% of Qatar's workforce (117). They were screened for MetS at baseline upon arrival to Qatar with a follow-up 24-months later. The second population group, "people with comorbid conditions", were represented by migrants identified with MetS at baseline and follow-up phases of this study. All identified migrants with deranged metabolic parameters were referred to physicians for further management, ensuring earlier intervention and improvement in health outcomes in the medium and long term.

Additionally, this project addressed one of the five goals set by the National Health Strategy 2018-2022 (122) (see Figure 1.9), enhancing health promotion and disease prevention (Figure 5.5). The prospective longitudinal observational cohort study enhanced health promotion by screening migrants for MetS at baseline and follow-up. Both allowed early detection and intervention with improved management of MetS, leading to better health of migrants and ultimately less demand for acute healthcare in the future. This would relieve burden on the healthcare sector, identified in the National Health Strategy 2018 -2022 as a challenge that required proactive intervention (122). Furthermore, the results emphasised the importance of galvanising efforts of the different organisations and the society to prevent disease and support health promotion (Figure 1.7).

The systematic review supports pharmacists' participation in achieving the goals set forth by the NHS (122). The systematic review findings highlighted the potential future role of pharmacists in screening and prevention of MetS, which could increase the health literacy and awareness of MetS and its risk factors amongst the migrant populations. As part of the health promotion programme, pharmacists can assist migrants to take control of their health to prevent noncommunicable diseases, including MetS.

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This intervention may also be relevant to Qatari citizens since evidence indicates a high prevalence of MetS among native Qatar citizens. In 2012, the STEPwise questionnaire was administered in Qatar, with the estimated MetS prevalence amongst the general native Qatar population being 37.0% (128). In a more recent cross-sectional study among native Qatar population who visited primary health centres in 2020, the estimated prevalence of MetS was 43.0% (57). Hence, it is wise to expand the proposed pharmacist-led screening and collaborative management to the non-migrant population. Pharmacist-led MetS screening could occur in community pharmacies with good geographical distribution and easy accessibility by the general population. Pharmacists would provide education about MetS risk factors, prevention measures and complications. A facilitated referral system could be granted to the allocated pharmacies to ensure safe and reliable transition of care of MetS-affected population to the specialised pharmacist-physician MetS clinics in the primary health centres. The complicated cases with multiple comorbid conditions could be referred to similar clinics in outpatient department of the secondary healthcare facilities.

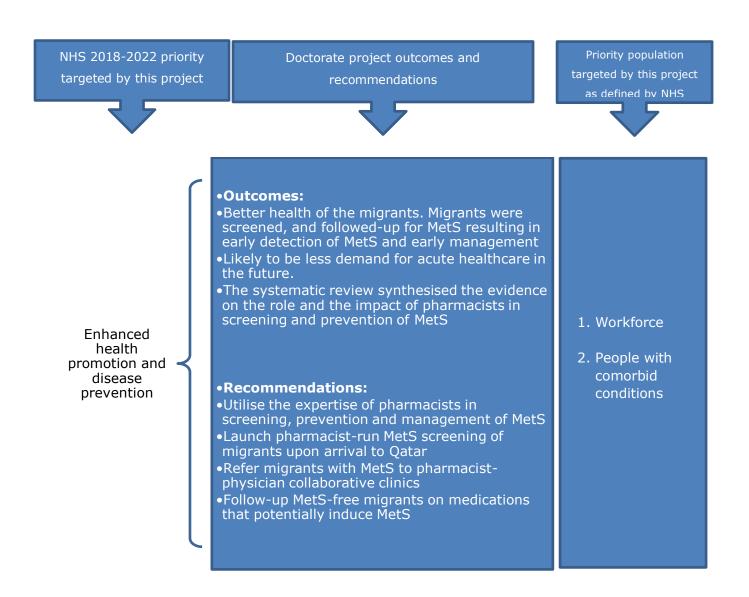


Figure 5.5 The outcomes of the doctoral research in line with QNV 2030.

5.3.2 Comparison to the literature

The first study in this doctoral research, the prospective longitudinal observational cohort study, together with previous studies, highlighted that migrants are at risk of MetS (164,168). While this project focused on determining the incidence risk of MetS amongst a group of initially MetS-free migrants to Qatar, all other studies focused on the prevalence with varied designs. Van Der Linden et al. compared the MetS prevalence of the Ghanaian migrants with their counterparts in the home country. Controlling for race and

genetic disposition factors, MetS prevalence was attributed to the migration process and associated lifestyle modifications (168). Kim, Y.J et al. compared MetS prevalence between migrants to South Korea and the native population. The study design considered the genetic predisposition, ethnic origin, lifestyle modification, and lack of adaptation at the new country as MetS risk factors (164). The authors concluded that migration had negatively impacted migrants' health and increased their risk of MetS.

The prospective longitudinal study screened migrants at baseline and followed them up two years later. This allowed the identification of migration's effect on migrant's health and characterised the determinants. The ethnic origin and genetic disposition were controlled by comparing the same migrants before and after migration. Therefore, changes in MetS incidence risk were attributed to the migration process itself and the subsequent lifestyle alteration. The unique design of this study limited the ability to compare the findings with the literature.

The doctoral research study showed that the males tended to have a higher incidence risk of MetS. Consuming medications that can adversely affect the metabolic parameters increased the odds of MetS six times (AOR 6.3, 95% CI 2.27-17.3, p<0.001). Pharmacists screening migrants for MetS, with appropriate follow-up, and education about MetS consequences and preventative measures are proposed as a potential solution to alleviate the effect of migration on health.

The systematic review was the first published to highlight the positive impact of the pharmacist's role focusing specifically on MetS screening and management. Likewise, a positive impact was demonstrated by an earlier systematic review and meta-analysis of 45 studies that explored pharmacist impact on hyperlipidaemia. This showed a significant reduction in lipid parameters (TG, LDL-C) when compared to the control group achieved by providing patient education and medication adjustment through a pharmacist and primary physician collaboration. The setting was diverse, including community pharmacies, health centres and hospital settings (105). This finding was further supported by a randomised controlled trial in 24 community pharmacies comparing pharmacist-nurse versus conventional management of HTN. The collaborative pharmacist-nurse management included BP measurement and documentation in a pocket card, lifestyle modification reinforcement, and communicating recommendations to the primary physicians (104). This provides evidence that pharmacist participation in the management of MetS and other chronic diseases is related to better disease management.

5.4 Originality of the research

5.4.1. Novelty of design, concepts and ideas

There are several aspects of this doctoral research that constitute an original contribution to knowledge and advance evidence.

The prospective longitudinal observational cohort study with an embedded crosssectional survey exploring the incidence risk and determining the predictors of MetS amongst a group of migrants is the first in the Middle East. Additionally, this is the first study to determine the incidence risk of MetS among migrants rather than prevalence. This enabled a direct link between the incidence risk of the new-onset MetS to the migration process and the subsequent lifestyle modifications. As described in Chapters 2 and 3, several measures were taken to promote the research quality and minimise the threats to validity and reliability (251). Of note, the prospective longitudinal observational cohort study was published in a high impact factor, peer reviewed journal (251).

The systematic review protocol was registered in the International Database of Prospectively Registered Systematic Reviews in Health and Social Care (PROSPERO) (217). The systematic review itself was conducted according to best practice. The systematic review protocol and systematic review were reported aligned with the Preferred Reporting Items for Systematic Review and Meta-analysis Protocols and Reviews (PRISMA-P & PRISMA) to enhance quality (216,236). Moreover, the systematic review paper was published in a relatively high impact factor, peer-reviewed journal (252).

5.5 Future work

This doctoral research may lead to further follow-up research, mainly to provide evidence on the outcomes of pharmacists' input to MetS management and prevention.

5.5.1 Study 1: A randomised trial to determine the effectiveness of a pharmacist-physician collaborative MetS-management compared with conventional physician intervention among patients with MetS.

Research aim:

The purpose of this trial is to compare pharmacist-physician collaborative management of MetS to the conventional management by physicians only.

Research hypothesis:

This study will test the hypothesis that pharmacist-physician collaborative management of MetS yields improvement in MetS parameters and reverting to non-MetS status, compared to physician care only.

Research philosophy:

This study aligns with a positivist philosophical paradigm given its objectivity in studying reality, involving collecting and analysing numerical data in relation to the study hypothesis.

Methodology and methods:

A randomised, parallel open labelled trial will be conducted in HMC outpatient clinics in Qatar. Patients diagnosed with MetS through the internal medicine outpatient clinics at HMC, according to the harmonised IDF criteria or any updated criteria (13), will be invited to participate. The sample size calculation will be based on the published number of participants who reverted to the non-MetS status at the follow-up reported in the literature. In an RCT, Hammad et al. reported the percentage of the MetS patients who reverted to non-MetS status after six months of pharmacist-collaborative intervention (39.1% vs 24.0% for those who received standard care) (224). Assuming a similar percentage (39.0%) and 10.0% follow-up lost, a total of 300 participants (150 in each arm) is required to achieve 80.0% power, two-sided p-value= 0.05 and effect size= 14.4 (253).

Patients will be randomised utilising a computerised system into two groups to receive the pharmacist-physician collaborative intervention or physician care in a

1:1 ratio. Pharmaceutical care includes comprehensive medication review for appropriateness (indication, dose, adverse drug reactions on metabolic parameters), setting therapy goals, and engaging patients in their therapeutic plan. Moreover, pharmacists will assess patients' adherence, suggest dose adjustment or alternative therapies, assess the laboratory results, and correlate these with the therapy goals, and also focus on non-pharmaceutical therapy (education about healthy lifestyle). Pharmacists will communicate their recommendations to the physicians. The metabolic parameters for the intervention group will be monitored every three months over the 12-month study period. The control group will be monitored biannually as per the standard follow-up plan for stable patients.

The study will be an open labelled randomised trial due to the inappropriateness of blinding participants, pharmacists, or physicians. It is impractical to hide the physicians' or the pharmacists' identities; moreover, the more frequent follow-up visits in the intervention arm cannot be masked. However, the outcome assessors will be blinded to the allocation of the participants.

The outcome measures will be MetS status and the change of the metabolic parameters from baseline. The harmonised IDF MetS criteria or any updated criteria (13) will be applied to assess the change in MetS status and the elements throughout the study. Descriptive and inferential statistics will be applied to compare the change of MetS status and parameters between the two arms from baseline to follow-up after testing data normality. The study will be reported following the Consolidated Standards of Reporting Trials (CONSORT) statement (254).

5.5.2 Study 2: Pharmacist led medications management of MetS-free patients on medications that potentially induce MetS: A randomised, open-label trial.

Research aim:

This study aims to evaluate the effectiveness of pharmacist medication management in preventing MetS among MetS-free patients consuming medications that potentially induce MetS.

Research hypothesis:

This study tests the hypothesis that pharmacist medication management may prevent MetS development among MetS-free patients who consume medications that potentially induce MetS.

Research philosophy:

This study aligns with the postpositivist philosophical paradigm. The collected data are objective and are metabolic parameters gathered to inform whether pharmacists' medication management is effective.

Methodology and method:

A quantitative approach of a randomised, parallel, open-label methodology is appropriate to address the research aim. MetS-free adults receiving medications that potentially induce MetS, identified from the internal medicine outpatient department, will be randomly assigned using a computerised system, either to receive pharmacists' medication management in addition to the conventional care or to receive conventional care only (regular follow-up in medicine outpatient clinics). Sample size to have 80.0% power, p-value=0.05 and effect size =0.5, will be calculated based on the literature findings of the impact of pharmacist-led medication management of MetS or its elements.

A pharmacist interview will be booked in the community pharmacy settings with reasonable geographical distribution (each participant will be assigned to the nearest pharmacy). The pharmacist will introduce measures to alleviate the medication's adverse effect on the metabolic parameters while ensuring the desired therapeutic benefit. These measures include proposing dose adjustment or switching to other alternative medications with less adverse metabolic effects and reinforcing non-pharmacological interventions in adopting a healthy lifestyle. The recommendations will be communicated to the relevant physician. Metabolic parameters will be measured at baseline and every six months over the 2-year study period. Over time, the change in MetS status will be assessed and compared between groups to indicate the pharmacists' medication management impact in preventing MetS.

Inferential analysis will compare the metabolic syndrome status and the metabolic parameters between the intervention and the control groups. The study will be reported following the Consolidated Standards of Reporting Trials (CONSORT) statement (254).

5.5.3 Study 3: Qualitative interviews with pharmacists exploring their views and experiences in MetS screening, prevention and management: nested interviews within the first two studies.

Research aim:

This research intends to explore the pharmacists' experiences in MetS prevention and management from the perspective of those who participated in previously proposed studies 1 and 2.

Research philosophy:

A phenomenological philosophical paradigm is the most suitable for addressing the research aim given the subjectivity in exploring views and real-life experiences of pharmacists involved in service delivery.

Methodology and method:

A qualitative methodology will be employed using semi-structured interviews with pharmacists who participated in the above-described RCTs. All members of the research team will receive training in conducting qualitative interviews, as required.

Purposive sampling will be employed. All pharmacists who participated in service delivery will be approached via telephone to invite them to participate in a 30-minute interview, arranged at their workplace and a suitable time. The semi-structured interview will be piloted to promote credibility and clarity of the open-ended questions. Field notes will be taken at the time of the interview. The interview will be audio recorded to enable the research team to transcribe, code and categorise the data into themes. Themes will be derived from the data collected from the participants and sorted into categories; each category will be coded with the most representative word from the participants' perspective.

Interpretative phenomenological analysis will be applied to provide a thorough description of the pharmacist experience in managing and preventing MetS in different settings. Feedback provided by the participants will help reflect and refine the implementation process of the pharmacist-run models described in the two previous studies (255).

The consolidated criteria for reporting qualitative studies (COREQ) will be applied to ensure the high quality of reporting this study (256).

5.6 Impact of the research

UK Research and Innovation (UKRI) defines impact as "*the demonstrable contribution that excellent research makes to society and the economy*" (257). When evaluating impact, the UKRI advocates focus on answering three questions; Who will benefit from the research? How will they benefit? What action will the research team take to make the beneficiary population likely to benefit from the research? Figure 5.6 demonstrates the pathways to impact, as suggested by UKRI.

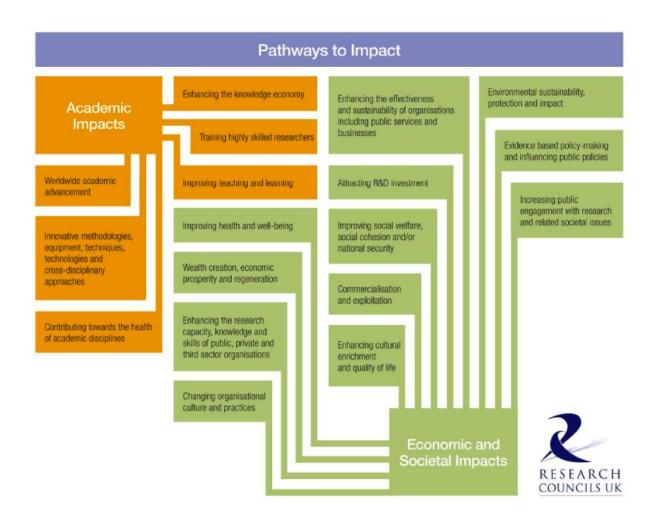
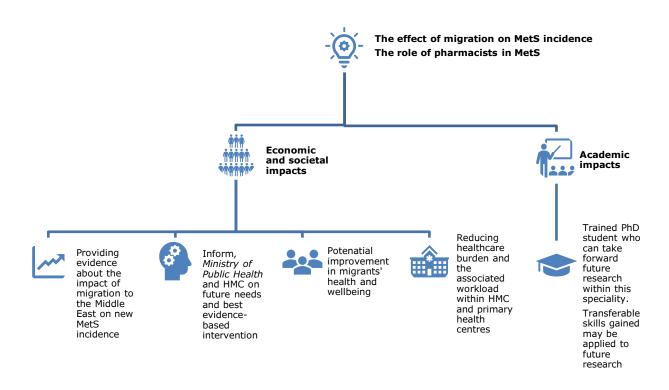


Figure 5.6 Pathways to impact (257).

The pathway to the impact of this project mapped according to the UKRI is summarised in Figure 5.7.



Abbreviation: MetS, Metabolic syndrome; HMC, Hamad Medical Corporation

Figure 5.7 Pathway to the potential impact mapped as per UKRI.

5.6.1 The potential multilevel impact of this doctoral research

Academic impact on the PhD student

The PhD student gained training and experience in various research methodologies, guided by the supervisory team, as well as gaining expertise in specific project subject area. As a result, there will be a long-term impact on capacity and capability for future research (Figure 5.7).

<u>Impact on migrants working within HMC and general migrant population</u> This doctoral research provides evidence about the impact of migration to the Middle East on new-onset MetS incidence. Therefore, it can impact migrants' health and wellbeing in the short, medium to long term. Assessment and regular follow-up of these migrants in terms of MetS and the elements will lead to earlier detection and management of MetS, DM, HTN, dyslipidaemia and obesity. As a result, there is likely to be an improvement in health status generally, control of risk factors, less likelihood of longer-term consequences such as cardiovascular disease, stroke, DM, and enhanced quality of life (Figure 5.7).

This study will guide policymakers within the Ministry of Public Health and HMC in implementing preventative measures to combat MetS among migrants and develop strategies for early warning systems (Figure 5.7). Moreover, it will assist in achieving the goals set forth by Qatar National Vision 2030 (121) and other national strategies including the National Health Strategies 2011-2016 and 2018-2022 (258). These strategies aim to maintain a healthy society, where migrants constitute about 94.0% of the workforce in Qatar and 91.0% of the total population (117).

One outcome of the research could be initiating additional services by the medical commission centres, for example, launching pharmacist-led MetS screening within the first three months of the migrant's arrival to Qatar in medical commission centres settings. Additionally, this could include providing an orientation program to the migrants, provided by pharmacists in the community pharmacy setting, to inform them of the benefits of adopting a healthy lifestyle to avoid the unfavourable consequences of MetS. Also, migrants with MetS could be referred to specialised MetS clinics run by pharmacists in collaboration with physicians.

Impact on the organisation - HMC

Health care systems, including primary care centres and HMC, will benefit by applying preventative measures, leading to reductions in the healthcare burden and associated workload (Figure 5.7). In addition, the preventive initiatives will optimise resources, raise the standards of care, and enhance healthcare and health-related outcomes. The publication of study findings will raise researchers' profiles within HMC and Qatar, generally.

Finally, given the cultural similarities and importance of migration in Qatar and other Middle Eastern countries, it is likely that the findings will be applicable beyond Qatar.

5.7 Conclusion

This doctoral research has addressed the literature gap and identified an association between migration to the Middle East and the incidence risk of MetS. Consuming medications that potentially induce MetS further increases the risk of MetS amongst migrants by six-fold.

This project included one of the highest levels of evidence, a systematic review, that underpinned the positive impact of pharmacist input in screening, prevention, and management of MetS among a wide range of populations in different settings. In addition, the systematic review results provide the foundation for pharmacists' skills as medication champions in the health promotion programs against MetS in Qatar, amongst migrants as an at-risk population.

As consuming medications that potentially induce MetS was identified as a determinant of MetS in this study, pharmacist targeted medications management of patients on any of these medications is suggested. This aims to optimise the therapeutic regimen, maximising benefit while minimising the adverse metabolic effect of the consumed medications.

On completion of this doctoral research, the outputs have resulted in MetS being more recognised as a health hazard amongst migrants to Qatar. Pharmacists were identified as potential healthcare experts to participate in screening, prevention, and management of MetS. Pharmacist-physician collaborative practice is proposed to manage migrants identified with MetS. Further research based on the MRC evaluation framework is warranted to systematically develop, evaluate, implement, and refine the proposed service.

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Appendices

Appendix 3.1: Data collection sheet

The effect of migration on the development of Metabolic Syndrome in a group of immigrants to Qatar

Patient Details Collection Sheet

Patient Name:
HC Number:
Visa Number:
Patient Code:
Contact number:
Job title:
Age:
Gender:
Nationality:



IRGC-03-NI-17-070 Validity: 25 01 2021 - 24 01 2022 E-stamped 26 Jan 2021

WHO STEPS Instrument (Core and Expanded)



The WHO STEPwise approach to noncommunicable disease risk factor surveillance (STEPS)

World Health Organization 20 Avenue Appia, 1211 Geneva 27, Switzerland



For further information: www.who.int/ncds/steps

STEPS Instrument

Overview	
Introduction	This is the generic STEPS Instrument which countries will use to develop their tailored instrument. It contains the:
	CORE items (unshaded boxes)EXPANDED items (shaded boxes).
Core Items	The Core items for each section ask questions required to calculate basic variables. For example:
	 current daily smokers mean BMI.
	Note: All the core questions should be asked, removing core questions will impact the analysis.
Expanded items	The Expanded items for each section ask more detailed information. Examples include:
_	use of smokeless tobaccosedentary behaviour.
Guide to the	The table below is a brief guide to each of the columns in the Instrument.

columns

Column	Description	Country Tailoring
Question	Each question is to be read to the participants	• Select sections to use.
		• Add expanded and optional questions as desired.
Response	This column lists the available response options which the interviewer will be circling or filling in the text boxes. The skip instructions are shown on the right hand side of the responses and should be carefully followed during interviews.	 Add country-specific responses for demographic responses (e.g. C6). Change skip question identifiers where necessary.
Code	The column is designed to match data from the instrument into the data entry tool, data analysis syntax, data book, and fact sheet.	This should never be changed or removed. The code is used as a general identifier for the data entry and analysis.



WHO STEPS INSTRUMENT FOR NONCOMMUNICABLE DISEASE RISK FACTOR SURVEILLANCE

<INSERT COUNTRY NAME>

Survey Information

Location and Date	Response	Cod	de
Cluster/Centre/Village ID		11	
Cluster/Centre/Village name		12	
Interviewer ID		13	
Date of completion of the instrument	لــلــا لــلــا لــلــا dd mm year	14	

Consent, Interview Language and Name		R	esponse	Code
Concert has been read and obtained	Yes	1		15
Consent has been read and obtained	No	2	If NO, END	15
	English	1		
Interview Lenguage [Incort Lenguage]	[Add others]	2		16
Interview Language [Insert Language]	[Add others]	3		10
	[Add others]	4		
Time of interview				17
(24 hour clock)			hrs mins	17
Family Surname				18
First Name				19
Additional Information that may be helpful				
Contact phone number where possible				I10

Step 1 Demographic Information

CORE: Demographic Information		
Question	Response	Code
Sex (Record Male / Female as observed)	Male 1 Female 2	C1
What is your date of birth? Don't Know 77 77 7777	dd mm year	C2
How old are you?	Years	C3
In total, how many years have you spent at school and in full- time study (excluding pre-school)?	Years	C4

Step 1 Behavioural Measurements

CORE: Tobacco Use						
Now I am going to ask you some questions about tobacco use.						
Question	Response Code					
Do you currently smoke any tobacco products, such as	Yes 1					
cigarettes, cigars or pipes?		T1				
(USE SHOWCARD)	No 2 If No, go to T8					
Do you currently smoke tobacco products daily?	Yes 1	Т2				
bo you currently shoke tobacco products daily?	No 2	12				
How old wars you when you first started amplying?	Age (years)	T3				
How old were you when you first started smoking?	Don't know 77 L If Known, go to T5a/T5aw	15				
Do you remember how long ago it was?	In Years	T4a				
(RECORD ONLY 1, NOT ALL 3)	OR in Months	T4b				
Don't know 77	OR in Weeks	T4c				

		DAILY↓ WEEKLY↓	
	Manufactured cigarettes		T5a/T5aw
On average, how many of the following products do you	Hand-rolled cigarettes		T5b/T5bw
smoke each day/week?	Pipes full of tobacco		T5c/T5cw
(IF LESS THAN DAILY, RECORD WEEKLY)	Cigars, cheroots, cigarillos		T5d/T5dw
(RECORD FOR EACH TYPE, USE SHOWCARD)	Number of Shisha sessions		T5e/T5ew
Don't Know 7777	Other	If Other, go to T5other, else go to T6	T5f/T5fw
	Other (please specify):		T5other/ T5otherw
During the past 12 months, have you tried to stop smoking ?	Yes No	1 2	Т6
During any visit to a doctor or other health worker in the past 12 months, were you advised to quit smoking tobacco?	Yes No No visit during the past 12	1 If T2=Yes, go to T12; if T2=No, go to T9 2 If T2=Yes, go to T12; if T2=No, go to T9 3 If T2=Yes, go to T12; if T2=No, go to T9	Τ7
In the past, did you ever smoke any tobacco products? (USE SHOWCARD)	Yes No	1 2 If No, go to T12	Т8
In the past, did you ever smoke daily ?	Yes No	1 If T1=Yes, go to T12, else go to T10 2 If T1=Yes, go to T12, else go to T10	Т9

CORE: Alcohol Consumption		
The next questions ask about the consumption of alcohol.		
Question	Response	Code
Have you ever consumed any alcohol such as beer, wine, spirits or [add other local examples]?	Yes 1	A1
(USE SHOWCARD OR SHOW EXAMPLES)	No 2 If No, go to A16	
Have you consumed any alcohol within the past 12 months?	Yes 1 If Yes, go to A4	A2
	No 2	
	Yes 1 If Yes, go to A16	

Have you stopped drinking due to health reasons, such as a negative impact on your health or on the advice of your doctor or other health worker?	No	2 If No, go to A16	A3
During the past 12 months, how frequently have you had at least one standard alcoholic drink?	Daily 5-6 days per week 3-4 days per week 1-2 days per week	1 2 3 4	A4
(READ RESPONSES, USE SHOWCARD)	1-3 days per month Less than once a month Never	5 6 7	
Have you consumed any alcohol within the past 30 days ?	Yes No	1 2 If No, go to A13	A5
During the past 30 days, on how many occasions did you have at least one standard alcoholic drink?	Number Don't know 77	If Zero, go to A13	A6
During the past 30 days, when you drank alcohol, how many standard drinks on average did you have during one drinking occasion? (USE SHOWCARD)	Number Don't know 77		A7
During the past 30 days, what was the largest number of standard drinks you had on a single occasion, counting all types of alcoholic drinks together?	Largest number Don't Know 77		A8
During the past 30 days, how many times did you have six or more standard drinks in a single drinking occasion?	Number of times Don't Know 77		A9
	Monday		A10a
During each of the past 7 days , how many standard drinks did	Tuesday		A10b
you have each day?	Wednesday		A10c
(USE SHOWCARD)	Thursday		A10d
	Friday		A10e
Don't Know 77	Saturday		A10f
	Sunday		A10g

CORE: Alcohol Consumption, continued

I have just asked you about your consumption of alcohol during the past 7 days. The questions were about alcohol in general, while the next questions refer to your consumption of homebrewed alcohol, alcohol brought over the border/from another country, any alcohol not intended

Question	Res	ponse	Code
During the past 7 days , did you consume any homebrewed alcohol, any alcohol brought over the border/from another	Yes	1	A11
country, any alcohol not intended for drinking or other untaxed alcohol?	No	2 If No, go to A13	ATT
	Homebrewed spirits, e.g. moonshine		A12a
On average, how many standard drinks of the following did you consume during the past 7 days ?	Homebrewed beer or wine, e.g. beer, palm or fruit wine		A12b
[INSERT COUNTRY-SPECIFIC EXAMPLES]	Alcohol brought over the border/from another country		A12c
(USE SHOWCARD) Don't Know 77	Alcohol not intended for drinking, e.g. alcohol-based medicines, perfumes, after shaves		A12d
	Other untaxed alcohol in the country		A12e

CORE: Diet The next questions ask about the fruits and vegetables that you usually eat. I have a nutrition card here that shows you some examples of local fruits and vegetables. Each picture represents the size of a serving. As you answer these questions please think of a typical week in the last year. Question Response Code In a typical week, on how many days do you eat fruit? Number of days D4

In a typical week, on how many days do you eat fruit ?	Number of days	If Zero days, go to D3	D1
(USE SHOWCARD)	Don't Know 77		
How many servings of fruit do you eat on one of those days?	Number of servings		20
			D2
(USE SHOWCARD)	Don't Know 77		
In a typical week, on how many days do you eat vegetables?	Number of days		D3
(USE SHOWCARD)	Don't Know 77	If Zero days, go to D5	
How many servings of vegetables do you eat on one of those	Number of servings		D4
			UT
days? (USE SHOWCARD)	Don't know 77		

Dietary salt

With the next questions, we would like to learn more about salt in your diet. Dietary salt includes ordinary table salt, unrefined salt such as sea salt, iodized salt, salty stock cubes and powders, and salty sauces such as soy sauce or fish sauce (see showcard). The following questions are on adding salt to the food right before you eat it, on how food is prepared in your home, on eating processed foods that are high in salt such as *[insert country specific examples]*, and questions on controlling your salt intake. Please answer the questions even if you consider yourself to eat a diet low in salt.

How often do you add salt or a salty sauce such as soy sauce	Always	1	
to your food right before you eat it or as you are eating it?	Often	2	
	Sometimes	3	D5
	Rarely	4	00
(SELECT ONLY ONE)	Never	5	
	Don't know	77	
	Always	1	
	Often	2	
How often is salt, salty seasoning or a salty sauce added in	Sometimes	3	D6
cooking or preparing foods in your household?	Rarely	4	20
	Never	5	
	Don't know	77	
How often do you eat processed food high in salt? By	Always	1	
processed food high in salt, I mean foods that have been altered	Often	2	
from their natural state, such as packaged salty snacks, canned	Sometimes	3	
salty food including pickles and preserves, salty food prepared at a	Rarely	4	D7
fast food restaurant, cheese, bacon and processed meat [add	Never	5	
country specific examples].	Don't know	77	
	Far too much	1	
	Too much	2	
	Just the right amount	3	D8
How much salt or salty sauce do you think you consume?	Too little	4	50
	Far too little	5	
	Don't know	77	

CORE: Physical Activity

Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person.

Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment. *[Insert other examples if needed]*. In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.

Question	Response	Code
Work		

Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like <i>[carrying or lifting heavy loads, digging or construction work]</i> for at least 10 minutes continuously?	Yes 1 No 2 <i>If No, go to P 4</i>	P1		
In a typical week, on how many days do you do vigorous- intensity activities as part of your work?	Number of days	P2		
How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : minutes	P3 (a-b)		
Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking [or carrying light loads] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If No, go to P 7	P4		
In a typical week, on how many days do you do moderate- intensity activities as part of your work?	Number of days	P5		
How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : minutes	P6 (a-b)		
Travel to and from places				
The next questions exclude the physical activities at work that you have already mentioned. Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship. <i>[Insert other examples if needed]</i>				
Do you walk or use a bicycle (<i>pedal cycle</i>) for at least 10 minutes continuously to get to and from places?	Yes 1 No 2 If No, go to P 10	P7		
In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days	P8		
How much time do you spend walking or bicycling for travel on a typical day?	Hours : minutes	P9 (a-b)		

CORE: Physical Activity, Continued				
Question	Response	Code		
Recreational activities				
The next questions exclude the work and transport activities	that you have already mentioned.			
Now I would like to ask you about sports, fitness and recrea	tional activities (leisure), [Insert relevant terms].			
Do you do any vigorous-intensity sports, fitness or recreational	Yes 1			
(leisure) activities that cause large increases in breathing or		P10		
heart rate like [running or football] for at least 10 minutes	No 2 If No, go to P 13			
continuously?				
In a typical week, on how many days do you do vigorous-		P11		
intensity sports, fitness or recreational (leisure) activities?	Number of days			
		P12		
How much time do you spend doing vigorous-intensity sports,	Hours : minutes			
fitness or recreational activities on a typical day?	hrs mins	(a-b)		
Do you do any moderate-intensity sports, fitness or recreational	Yes 1			
(leisure) activities that cause a small increase in breathing or		P13		
heart rate such as brisk walking, [cycling, swimming, volleyball]	No 2 If No, go to P16	110		
for at least 10 minutes continuously?	100 Z 11 NO, 90 10 F 10			
In a typical week, on how many days do you do moderate-				
intensity sports, fitness or recreational <i>(leisure)</i> activities?	Number of days	P14		
How much time do you spend doing moderate-intensity sports,		P15		
fitness or recreational (leisure) activities on a typical day?	Hours : minutes			
	hrs mins	(a-b)		

EXPANDED: Physical Activity			
Sedentary behaviour			
The following question is about sitting or reclining at work, at	t home, getting to and from places, or with friends including time spent	sitting at a	
desk, sitting with friends, traveling in car, bus, train, reading, playing cards or watching television, but do not include time spent sleeping.			
[INSERT EXAMPLES] (USE SHOWCARD)			
How much time do you usually spend sitting or reclining on a		P16	
typical day?	Hours : minutes hrs mins	(a-b)	

CORE: History of Raised Blood Pressure		
Question	Response	Code
Have you ever had your blood pressure measured by a doctor or other health worker?	Yes 1 No 2 <i>If No, go to H6</i>	H1
Have you ever been told by a doctor or other health worker that you have raised blood pressure or hypertension?	Yes 1 No 2 If No, go to H6	H2a
Were you first told in the past 12 months?	Yes 1 No 2	H2b
In the past two weeks, have you taken any drugs (medication) for raised blood pressure prescribed by a doctor or other health worker?	Yes 1 No 2	H3
Have you ever seen a traditional healer for raised blood pressure or hypertension?	Yes 1 No 2	H4
Are you currently taking any herbal or traditional remedy for your raised blood pressure?	Yes 1 No 2	H5

CORE: History of Diabetes				
Have you ever had your blood sugar measured by a doctor or other health worker?	Yes No	1 2	If No, go to H12	H6
Have you ever been told by a doctor or other health worker that you have raised blood sugar or diabetes?	Yes No	1 2	If No, go to H12	H7a
Were you first told in the past 12 months?	Yes No	1 2		H7b
In the past two weeks, have you taken any drugs (medication) for diabetes prescribed by a doctor or other health worker?	Yes No	1 2		H8
Are you currently taking insulin for diabetes prescribed by a doctor or other health worker?	Yes No	1 2		H9
Have you ever seen a traditional healer for diabetes or raised blood sugar?	Yes No	1 2		H10
Are you currently taking any herbal or traditional remedy for your diabetes?	Yes No	1 2		H11

Question	Respons	se	Code
Have you ever had your cholesterol (fat levels in your blood)	Yes	1	
measured by a doctor or other health worker?	No	2 If No, go to H17	
Have you ever been told by a doctor or other health worker the	nat Yes	1	ŀ
you have raised cholesterol?	No	2 If No, go to H17	
Were you first told in the past 12 months?	Yes	1	ŀ
	No	2	
In the past two weeks, have you taken any oral treatment	Yes	1	
(medication) for raised total cholesterol prescribed by a doctor or other health worker?		2	
Have you ever seen a traditional healer for raised cholestero	2 Yes	1	
		2	
Are you currently taking any herbal or traditional remedy for	Yes	1	
your raised cholesterol?	No	2	

CORE: History of Cardiovascular Diseases			
Have you ever had a heart attack or chest pain from heart	Yes	1	
disease (angina) or a stroke (cerebrovascular accident or incident)?	No	2	H17
Are you currently taking aspirin regularly to prevent or treat heart	Yes	1	
disease?	No	2	H18
Are you currently taking statins	Yes	1	
(Lovastatin/Simvastatin/Atorvastatin or any other statin) regularly to prevent or treat heart disease?	No	2	H19

CORE: Lifestyle Advice

Question	Response	Code
During the past 12 months, have you visited a doctor or other health worker?	Yes 1 No 2 If No and C1=1, go	
During any of your visits to a doctor or other health worker in the pas (RECORD FOR EACH)	t 12 months, were you advised to do any of the following?	
Quit using tobacco or don't start	Yes 1 No 2	H20a
Reduce salt in your diet	Yes 1 No 2	H20b
Eat at least five servings of fruit and/or vegetables each day	Yes 1 No 2	H20c
Reduce fat in your diet	Yes 1 No 2	H20d
Start or do more physical activity	Yes 1 No 2	H20e
Maintain a healthy body weight or lose weight	Yes 1 No 2	H20f
Reduce sugary beverages in your diet	Yes 1 If C1=1 go to M1 No 2 If C1=1 go to M1	H20g

CORE (for women only): Cervical Cancer Screening

The next question asks about cervical cancer prevention. Screening tests for cervical cancer prevention can be done in different ways, including Visual Inspection with Acetic Acid/vinegar (VIA), pap smear and Human Papillomavirus (HPV) test. VIA is an inspection of the surface of the uterine cervix after acetic acid (or vinegar) has been applied to it. For both pap smear and HPV test, a doctor or nurse uses a swab to wipe from inside your vagina, take a sample and send it to a laboratory. It is even possible that you were given the swab yourself and asked to swab the inside of your vagina. The laboratory checks for abnormal cell changes if a pap smear is done, and for the HP virus if an HPV test is done.

	Yes	1	
Have you ever had a screening test for cervical cancer, using any of these methods described above?	No	2	CX1
	Don't know	77	

Step 2 Physical Measurements

Question	D		O a a la
Question	Resp	onse	Code
Interviewer ID			M1
Device ID for blood pressure			M2
	Small	1	
Cuff size used	Medium	2	M3
	Large	3	
Des dise 4	Systolic (mmHg)		M4a
Reading 1	Diastolic (mmHg)		M4b
	Systolic (mmHg)		M5a
Reading 2	Diastolic (mmHg)		M5b
	Systolic (mmHg)		M6a
Reading 3	Diastolic (mmHg)		M6b
During the past two weeks, have you been treated for raised	Yes	1	
blood pressure with drugs (medication) prescribed by a doctor or other health worker?	No	2	M7
CORE: Height and Weight			
	Yes	1 If Yes, go to M 16	M8
For women: Are you pregnant?	No	2	IVIO
Interviewer ID			M9
	Height		M10a
Device IDs for height and weight			M10b
	Weight		
Height	in Centimetres (cm)		M11
Weight	in Kilograms (kg)		M12
If too large for scale 666.6			
CORE: Waist			
Device ID for waist			M13
Waist circumference	in Centimetres (cm)		M14
	()		

Step 3 Biochemical Measurements

CORE: Blood Glucose		
Question	Response	Code
During the past 12 hours have you had anything to eat or drink, other than water?	Yes 1 No 2	B1
Technician ID		B2
Device ID		B3
Time of day blood specimen taken (24 hour clock)	Hours : minutes	B4
Fasting blood glucose [CHOOSE ACCORDINGLY: MMOL/L OR MG/DL]	mmol/l L mg/dl L	B5
Today, have you taken insulin or other drugs (medication) that have been prescribed by a doctor or other health worker for raised blood glucose?	Yes 1 No 2	B6
CORE: Blood Lipids		
Device ID		B7
Total cholesterol [CHOOSE ACCORDINGLY: MMOL/L OR MG/DL]	mmol/l mg/dl	B8
During the past two weeks, have you been treated for raised cholesterol with drugs (medication) prescribed by a doctor or other health worker?	Yes 1 No 2	В9
CORE: Urinary sodium and creatinine		·
Had you been fasting prior to the urine collection?	Yes 1 No 2	B10
Technician ID		B11
Device ID		B12
Time of day urine sample taken (24 hour clock)	Hours : minutes	B13
Urinary sodium	mmol/l	B14
Urinary creatinine	mmol/l [[]	B15

Appendix 3.3: HMC IRB approval letter

5/13/2018



INSTITUTIONAL REVIEW BOARD HAMAD MEDICAL CORPORATION DOHA-QATAR

Dr. Kirti Sathyananda Prabhu				
Graduate Registered Nurse (CF)	Email: irb@hamad.qa Tel: 00974-40256410			
	HMC-IRB Registration: SCH-HMC-020-2015			
HAMAD MEDICAL CORPORATION	IRB-MoPH Assurance: MOPH-A-HMC-020			
Doha-Qatar				
APPROVAL NOTICE				
Protocol No. :	IRGC-03-NI-17-070			
Protocol Title :	The effect of migration on the development of Metabolic Syndrome in a group of immigrants to Qatar			
QNRF/Other Reference Number :	NA			
Date of HMC-IRB Approval :	15 February 2018			
Date of Letter Issued :	04 March 2018			
Review Type :	Expedited			
Decision :	Approved			
Approved HMC Enrollment :	400 (2000 Screening)			
NPRP Grant Holder :	NA			

The IRB has reviewed the submitted documents of the above titled research and approval for the study has been granted. The list of approved document(s) is attached.

IRB oversight expires 12 months from the date of approval indicated above. It is the responsibility of the Investigator to ensure timely renewal of study oversight. Progress reports for continuing review must be approved prior to expiration date therefore, submissions must be received by the IRB 60 to 90 days prior to the expiration date.

Requested Resolutions: None

Any resolutions submitted must include a letter indicating that the submission is a follow up request by the IRB; this will ensure that resolutions are processed appropriately and in a timely manner.

Please note; this approval only covers HMC, you may also need approvals from other institutions involved in your study. You should not start your study until all of these have been obtained.

If you have any questions or need additional information, please contact IRB at the above mentioned email address or telephone number.

As part of PI's responsibilities, all research activities must be recorded in Cerner's medical records per visit for each subject involved in the study.

Important Note: The list of your responsibilities as Principal Investigator is attached to this letter.



Sincerely,				
Chairman of Institut	tional Review Board:			
24	Hamowich Waterout Hannauch Constant Constant States of the Constant States		Date:	
DOCUMENTTYPE	DOCUMENTNAME	LANGUAGE	NOOFPAGES	VERSIONNO
Data Collection Sheet	IRGC-03-NI-17-070_DataCollectionSheet_Eng_26- FEB-18_1Pages_80972.pdf	English	1	V1.0
Research Protocol	IRGC-03-NI-17-070_ResearchProtocol_V1.0_04- MAR-18_38Pages_80992.11_26-FEB- 18_38Pages_80992.pdf	English	38	V1.0
Data Collection Sheet	IRGC-03-NI-17- 070_DataCollectionSheet_Eng_V1.0_26-FEB- 18_2Pages_80999.3_26-FEB-18_2Pages_80999.pdf	English	2	V1.0
Data/ Material Transfer Agreement	MRC-01-17- 172_Data/MaterialTransferAgreement_Eng_V0.1_30- OCT-17_5Pages_82939.doc	English	5	V1.0
Interview/ Script	IRGC-03-NI-17-070_Interview/Script_Eng_V1.0_26- FEB-18_1Pages_248397.2_26-FEB- 18_1Pages_248397.pdf	English	1	V1.0
Research Consent Form	IRGC-03-NI-17- 070_ResearchConsentForm_Eng_V1.0_26-FEB- 18_6Pages_248425.2_26-FEB- 18_6Pages_248425.pdf	English	6	V1.0
Questionnaire/ Survey	IRGC-03-NI-17- 070_Questionnaire/Survey_Eng_V1.0_26-FEB- 18_12Pages_248439.2_26-FEB- 18_12Pages_248439.pdf	English	12	V1.0
Interview/ Script	IRGC-03-NI-17-070_Interview/Script_Ara_V1.0_26- FEB-18_1Pages_264983.1_25-FEB- 18_1Pages_264983.pdf	Arabic	1	V1.0
Research Consent Form	IRGC-03-NI-17- 070_ResearchConsentForm_Ara_V1.0_26-FEB- 18_6Pages_264999.1_25-FEB- 18_6Pages_264999.pdf	Arabic	6	V1.0
Questionnaire/ Survey	IRGC-03-NI-17- 070_Questionnaire/Survey_Ara_V1.0_26-FEB- 18_12Pages_265015.1_25-FEB- 18_12Pages_265015.pdf	Arabic	12	V1.0

5/13/2018



Hamad Medical Corporation

Institutional Review Board

Email: irb@hamad.qa Tel: 00974-40256410 HMC-IRB Registration: SCH-HMC-020-2015 IRB-MoPH Assurance: MOPH-A-HMC-020

Responsibilities of the Principal Investigator:

As the Principal Investigator of this research project, you are ultimately responsible for:

- · Protecting the rights, safety and welfare of research subjects
- Following the IRB-approved protocol (application and any materials submitted with it; e.g. only research team members
 designated to obtain consent on the scheme of delegation should only do so and no other personnel)
- Maintaining confidentiality of the subjects by not sharing Patient Identifiable Information outside HMC Facility
- Maintaining privacy of the subjects by performing research related procedures on subjects in private settings
- Reporting serious adverse events and serious unanticipated problems to the HMC-IRB and the other relevant compliance entities of HMC within 7 days of knowing about it
 - "Serious Adverse Event" (SAE) is any adverse event temporally associated with the subject's participation in
 research (whether or not considered related to the subject's participation in the research) that meets any of the
 following criteria:
 - results in death;
 - is life-threatening (places the subject at immediate risk of death from the event as it occurred);
 - requires inpatient hospitalization or prolongation of existing hospitalization;
 - results in a persistent or significant disability/incapacity;
 - results in a congenital anomaly/birth defect; or
 - any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and
 may require medical or surgical intervention to prevent one of the other outcomes listed in this definition
- Keeping the source documents (i.e. Cerner's medical records) updated regarding the enrollment of the patient, the MRC study number and study related procedures for each subject involved in the study
- Using only HMC-IRB stamped documents at HMC facilities while conducting the research. Those documents might have other institution's IRB stamp if applicable
- Following the requirements of HMC HRP policies, especially with regard to obtaining prior approval of changes to the research, reporting events or new information, progress reports before the expiry of the IRB approval by 60-90 days and final reports.
- · Making sure that no study procedures should be conducted after the expiry date of the ethical (IRB) approval
- · The conduct of the study team with regards to all of the above

Sincerely,

M. Hannowich Dr. Natharmedi Harmadalth Is Constant, Barmitiky Materia 1845

Signature:

Dr. Mohammed Hammoudeh

Chairman Institutional Review Board

Hamad Medical Corporation

Appendix 3.4 Research written consent form

م_ؤسـســة حـمــد الـطـبيــة Hamad Medical Corporation حة · تعليم · بحوث HEALTH · EDUCATION · RESEARCH 1. Title of research The effect of migration on the development of Metabolic Syndrome in a group of immigrants to Qatar 2. Principal Investigator Dr. Kirti. S. Prabhu, Interim Translational Research Institute, AHS, HMC 3. Why are we inviting you to join this research? The investigator and colleagues at Hamad Medical Corporation (HMC) in collaboration with Robert Gordon university (RGU), Aberdeen, United Kingdom and Qatar university (QU), Doha, Qatar, are conducting this research. We are inviting you to join because you have migrated to Qatar from another country other than GCC. We are interested in learning more about lifestyle modification and food habit changes that have occurred after your migration and whether these changes have any impact on your metabolic parameters. As part of routine investigation for newly joined employees your demographic profile, anthropometric measurement and various blood parameters were analysed. After taking consent from you we shall analyse your preexisting data from Cerner.If you met our all our pre-defined criteria you will be informed about same and will be called for follow-up at the end of two year. 4. What should you know about this research?

- Research will be explained in detail to you
- Participating in this research will be entirely your decision.
- You can contact us any time if you have any doubts or need any clarification regarding this research.
- You may change your decision at any point of time
 - We will not hold your decision against you

5. Who can you talk to?

If you have questions or concerns, or if you think the research has hurt you, talk to the research team at: If you have questions or concerns, or if you think the research has hurt you, talk to the research team at:

- Dr. Kirti. S. Prabhu, Post-Doctoral Research Scientist at iTRI, Academic Health System (33956548)
- Dr. Rana Moustafa, clinical pharmacist at Hamad General Hospital (55554563)
- If you have questions about your rights as a volunteer, or you want to talk to someone outside the researchteam, please contact:

HMC Institutional Review Board (HMC-IRB) Chair at 5554 6316

 HMC-IRB Office at 4025 6410 (from Sunday to Thursday between 7:00am-3:00pm) or email at irb@hamad.ga

6. Why are we doing the research?

Various studies that have been published in the past have proven that lifestyle modification indeed severely affects the metabolic parameters leading to chances of developing cardiovascular and diabetes related problems at youngage. So far, no data or studies have been done on immigrants in Qatar working at Hamad General Hospital (HGH) orat any private firms and therefore we would like to conduct this research.

7. How long will the research take?

You will be in the research for 2 years from date of signing consent. During this time, you will be called once at the end oftwo year for a follow up which will last around 30-45 minutes.

8. How many people will take part?

We plan to screen around 2000 participants will be approached (at staff clinic or through telephone) and consented so as to obtain data from medical records out of which hopefully 400 would fit our set criteria and be followed up

9. What happens if you take part?

Staff clinic: All participants (employees) visiting staff clinic for completing pre-employment checkup formality will becontacted and study in detail will be explained to them. Further, they will also be informed that if they agree their data obtained during pre-employment check-up will be accessed using Cerner. Participants willing to enroll for studywill be asked to sign consent form which will be done only after IRB approval. If we are not able to meet any participants in staff clinic due to time constraint their HC number will be taken from staff clinic for contacting them.

ITRI- As mentioned earlier due to time constraint if we are not able to meet participants they will be contacted via telephone and briefly study will be explained to them. If they are interested, they will be asked to visit i-TRI, building320, Hamad medical city wherein study in detail will be explained.

Phone calls will be done at the initial stage if incase we were not able to meet subject/s in staff clinic and then after2 years from data of enrollment.

If you agree to join, the study team will ask you to do the following:

- You will be asked to complete a questionnaire. If you require assistance with completing the questionnaire, research assistants will be available to help with this.
- This will include; demographics (sex, age, marital status, educational level and occupation), comorbidities for the candidate and family (DM, HTN, dyslipidemia and heart disease) behavioral measurements (tobacco use, alcohol consumption, diet and physical activities) in addition to physical and biochemical measurements, it include some categorical questions (to answer with yes or no) ordinal questions (rank the answer) and ratio scale questions (the respondents have to provide measurable answers)
- We will obtain blood samples from all subjects. (2 Blood samples 5 mL each in different tubes one for HbAIC and other for lipid profile. Both will be collected at same time) These will be obtained at 2 years post landingin Qatar and joining HMC
- We will obtain physical measurements for blood pressure, weight and height and waist circumference and compare to baseline data that was measured 2 years ago.

All the medical data collected during the period of two years will be used only for research purpose.

Role of Collaborators:

Robert Gordon university (RGU), Aberdeen, United Kingdom- As this is part of PhD work, in order to cross verify dataobtained from study (only if required) data sheet with coded information will be shared.

Qatar university (QU), Doha, Qatar: As statistical analysis will be done in Qatar University, we will share data incoded form with them.

10. Could the research be bad for you?

- You will not have any sort of serious adverse events from participating in this study.
- The only risk is slight discomfort during blood collection Slight pricking sensation at the insertion of the needle, or slight bruising might occur once blood samples are obtained.

11. Could the research be good for you?

We cannot promise any direct benefit to you or to others from you joining this research.

However, possible benefits could be that You will benefit from assessment and regular followup in terms of metabolic parameters (possibility of diabetes, heart issues etc.) and the components, will lead to earlier detection and management of Diabetes, Hypertension, obesity. The study might help you with improvements in health statusgenerally, reduction in risk factors, less likelihood of longer-term consequences such as coronary heart disease, stroke and diabetes, and enhanced quality of life. During this course if we encounter any participant with abnormal results, they will be informed about it and if needed will be referred to staff clinic

Your concerns will be addressed more frequently as compared to someone who is not a part of the study.

Potential benefits for others include:

The findings of the study will help us better manage health of immigrant's patients in the future and reduce the risksand severity of cardiovascular and diabetic incidences in the Qatari and non-Qatari population.

12. What happens to information about you?

Information collected from you during course of study will be secured. Information will be coded, and this particularcode will help us to identify you in our records. We will not identify you personally in any reports or publications about this research.

We cannot guarantee complete secrecy, but we will limit access to information about you. Only people who have aneed to review information will have access. These people might include:

- Members of the research team and other representatives whose work is related to the research or toprotecting your rights and safety
- Representatives of the Qatar Ministry of Public Health and Medical Research Centre-HMC, HMC-IRB whomake sure the study is done properly and that your rights and safety are protected
- Your doctors and nurses

Your blood samples will be kept and used in Hamad Medical corporation, Qatar only. We may use any leftoverstored samples for future research.

At the end of the study, all forms with your name or other identifying information will be stored in a locked facility atHMC for a period of at least 3 years. Only the study investigator or study staff members assisting the investigator will have access to these forms. Afterfive years, the forms will be destroyed.

Only certain study investigators who are working directly with the study data will have the master code that links your name with the code number. This master code will be kept in a secure location at Hamad medical corporation.

During the study, your samples will be kept and used at HMC in Qatar only. We would like to keep any samples leftover at the end of the study for a period of 5 years for future research.

We will store these leftover samples with a link to your identity. Leftover samples might be shared with researcherswho were not part of this study. This research might include genetic research.

Samples that we share with other researchers won't include information that identifies you. If you change your mind about the research or about letting us use your samples, we won't be able to get back any samples that wehave shared with other researchers.

You may join this study even if you do not allow this future use. You can mark your choice at the end of this form. Ifyou do not allow storage of your samples, we will destroy the sample at the end of the study.

Data generated from study will be shared with below mentioned universities.

Robert Gordon university (RGU), Aberdeen, United Kingdom- As this is part of PhD work, in order to cross verifyresults obtained from study (only if required) data sheet with coded information will be shared.

Qatar university (QU), Doha, Qatar: As statistical analysis will be done in Qatar University, we will share data incoded form with them.

13. What if you don't want to join?

You can say no and we will not hold it against you.

14. What if you join but change your mind?

You can stop participating at any time and we will not hold it against you. If you withdraw consent and stopparticipating, we will not use your data. All collected samples and data will be destroyed.

15. What else should you know?

This research is funded by Medical Research Centre, Hamad Medical Corporation, Doha, Qatar. If you are injured as a direct result of research procedures, contact the investigator and appropriate care will be made available at HMC. If you seek care outside of HMC, such care will be at your expense. Compensation is notavailable in case of injury.

The investigator or sponsor may stop the study or take you out of the study at any time, even if you would like tocontinue.

16. Additional Choices

We plan to use data from this study in other projects in the future. This might include sharing the data with other researchers. Although we will keep a link between your identity and the data about you we will not provide that linkto anyone we share the data with.

Information from analyses of your samples and medical information will be put into databases along with

information from other volunteers. This will help researchers around the world.

These databases will not include your name, telephone number or other information that directly identifies you.

In Section 12, we explained that we would like to use your samples for future research. Please indicate your choiceby initialing the appropriate line below:

_I ALLOW storage and use of my samples for future research.

_I **DO NOT ALLOW** storage or use of my samples for future research.

We would like your permission to contact you about participating in future studies. You may still join this studyeven if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

_YES, you may contact me

_NO, you may NOT contact me

Signature Page for Capable Adult
Volunteer
I voluntarily agree to join the research described in this form.
Printed Name of Volunteer
Signature of Volunteer Date
Person Obtaining Consent
 I document that: I (or another member of the research team) have fully explained this research to the volunteer. I have personally evaluated the volunteer's understanding of the research and obtained their voluntaryagreement.
Printed Name of Person Obtaining Consent
Signature of Person DateObtaining Consent
Witness (if applicable)
l document that the information in this form (and any other written information) was accurately explained to thevolunteer, who appears to have understood and freely given Consent to join the research.
Printed Name of Witness
Signature of Witness Date

Dear sir/madam,

We are contacting you for our research purpose which you had agreed to be part of. We would like to have an appointment with you whenever you are free as we need to ask you few questions and have your demographic profile and anthropometric measurement. Please let us know your convenient time.

Appendix 3.6: RGU approval letter



SCHOOL OF PHARMACY & LIFE SCIENCES Robert Gordon University Sir Ian Wood Building Garthdee Road Aberdeen AB10 7G1 United Kingdom Tel: 01224 262500/2800 www.rgu.ac.uk

5 March 2018

Dear Rana

Re.: The effect of immigration on the development of Metabolic Syndrome in a group of immigrants to Qatar

The School Research Ethics Committee has assessed your application and the overall decision is that there are no ethical issues with your project.

I can now confirm that you are able to proceed with your research and any further ethics applications.

Should there be any amendments to this project during the research we would advise you to consult with the convener of the ethics committee as to whether a further ethical review would be required.

We wish you success with your project.

Regards

11.

Dr Colin Thompson Convener of the School Ethics Review Panel



Appendix 4.1: The systematic review protocol (PROSPERO).

6/16/2020 https://www.erd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018089862&ID=CRD42018089862 PROSPERO NHR National Institute for Health Research International prospective register of systematic reviews The impact of pharmacists' input on the screening, management and prevention of metabolic syndrome Rana Al Adawi, Antonella Tonna, Derek Stewert, Cristin Rayan, Mohsen Eledrisi, Hani Abdelaziz Citation Rana Al Adawi, Antonella Tonna, Derek Stewert, Cristin Rayan, Mohsen Eledrisi, Hani Abdelaziz. The impact of pharmacists' input on the screening, management and prevention of metabolic syndrome. PROSPERO 2018 CRD42018089862 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42018089862 **Review question** To critically appraise, synthesise, and present the available evidence on the impact of pharmacists' input on the screening, prevention and management of metabolic syndrome (MetS). Specific aims 1- To determine the types of pharmacist interventions reported in the studies. 2- To describe the impact of the identified interventions as reported in the studies. 3- To identify the facilitators and barriers to the effective implementation of pharmacist interventions in the screening, prevention and management of MetS. 4- To characterise the populations who could benefit most from the interventions. Searches A thorough search and appraisal of the current published literature regarding the impact of pharmacists' interventions on the screening, prevention and management of MetS will be carried out. An exploratory search has indicated that the first relevant article was published in 2008, and hence, all studies published from 2008 onwards in the English language will be included. The search will be conducted electronically, using medical subject headings (MeSH), and will involve the following databases; MEDLINE, CINAHL, IPA and The Cochrane Library. Additional search strategy information is available in the attached PDF document (link provided below). Types of study to be included All studies, irrespective of their design, will be included. Condition or domain being studied Metabolic syndrome screening, management and prevention, in which there is pharmacist involvement, and the impact of the pharmacists' input. Participants/population Inclusion criteria: all studies irrespective of the population groups involved will be included in the review. Exclusion criteria: none. Intervention(s), exposure(s) Any intervention involving pharmacist input into the screening, prevention or management of MetS will be included. https://www.erd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018089862&ID=CRD42018089862

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Comparator(s)/control

Comparisons of the impact of the interventions with or without pharmacist input, if the data is available. All studies will be included whether or not there is a control group.

Main outcome(s)

Assessment of the impact of pharmacists' input on the screening, management and prevention of metabolic syndrome.

The outcomes are likely to be diverse and may include the following: comparisons of different models of pharmacist input in MetS, descriptions of the process of development of the models, and the clinical and economic outcomes of such interventions.

Additional outcome(s)

None.

Data extraction (selection and coding)

Two reviewers will independently review the titles and abstracts of the studies identified in the searches, and the full texts of articles identified as being potentially eligible for inclusion will again be reviewed by two reviewers independently, and decisions made regarding inclusion/exclusion. Any disagreements over the eligibility of articles will be resolved by consultation with a third reviewer, and the included and excluded studies will be documented as per PRISMA guidelines.

Data will then be extracted from the studies selected for inclusion using a customised data extraction form which will be developed before the data extraction process begins. It is expected to include: study title, date, country, duration, population characteristics, mode of the interventions, study design, methodology, the primary and secondary outcomes, subgroup analysis and any other findings which address the study objectives.

Risk of bias (quality) assessment

The quality of the eligible studies will be critically appraised and assessed using standardised quality assessment tools appropriate for the type of study, as follows:

Randomised controlled trials: the Cochrane bias assessment tool.

Observational studies (case-control and cohort studies): the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) checklist.

Qualitative studies: the COREQ (COnsolidated criteria for REporting Qualitative research) bias assessment tool.

Bias will be assessed by two reviewers independently, with any disagreements be resolved by discussion with a third party.

Strategy for data synthesis

A descriptive synthesis of the results from the included studies will be undertaken, which will allow for an analysis of the evidence regarding the impact of pharmacist input into the screening, prevention and management of MetS, the available pharmacist models of care, and the clinical outcomes in relation to the MetS.

A narrative description and tabulation will be presented for each study, and comparisons and contrasts within and between studies in terms of populations, settings, methods, interventions, outcomes, subgroup analyses or post hoc analyses, facilitators and barriers will also be made.

Analysis of subgroups or subsets

Subgroup analyses will be carried out to explore the reported roles of pharmacists across different countries and geographical regions.

Data from qualitative and quantitative studies will be aggregated and described using a narrative approach.

Contact details for further information

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Rana Moustafa Al Adawi rahmed4@hamad.qa

Organisational affiliation of the review

Hamad Medical Corporation Robert Gordon University www.hamad.qa

www.RGU.ac.uk

Review team members and their organisational affiliations

Dr Rana Al Adawi. Harnad Medical Corporation Dr Antonella Tonna. Robert Gordon University Professor Derek Stewert. Robert Gordon University Dr Cristin Rayan. Trinity College Dr Mohsen Eledrisi. Harnad Medical Corporation Dr Hani Abdelaziz. Harnad Medical Corporation

Type and method of review

Intervention, Prevention, Systematic review

Anticipated or actual start date

01 April 2018

Anticipated completion date

31 December 2018

Funding sources/sponsors

None

Conflicts of interest

None specified. None known

Language

English

Country Ireland, Qatar, Scotland

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Community Pharmacy Services; Delivery of Health Care; Disease Management; Humans; Mass Screening; Metabolic Syndrome; Pharmaceutical Services; Pharmacies; Pharmacists; Primary Prevention; Professional Role

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Date of registration in PROSPERO 07 March 2018

Date of first submission

04 March 2018

6/16/2020

Stage of review at time of this submission

The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

07 March 2018

PROSPERO

This information has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. The registrant confirms that the information supplied for this submission is accurate and complete. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

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