



**Developing and Feasibility Testing a Novel Intervention to Promote Self-management for Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes**

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## **Dedication**

*Dedicated to my MOM and DAD first, those who are real-life teachers, and they have been through a lot in their life, yet they are still the strongest woman and man I know. Although they faced many ups and downs, good and evil in their lives over 39 years, they always find a way to push forward and carry on. To their consistent help for me, my 6 sisters, 3 brothers and now for their grandchildren to live altogether by faith, love and peace. It's one of the things I admire most about them. Also, dedicated to Jordanian patients with diabetes and cardiac diseases, whose from their current challenges raised the clinical gap that began my research journey and they inspired my passion to keep moving, growing and learning during this journey.*

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## Abstract

**Background:** A quarter of the world's patients with acute coronary syndrome (ACS) reportedly have type 2 diabetes (T2D). Although self-management education and support are cornerstones in the treatment of long-term conditions, interventions to promote integrated self-management behaviours in those with T2D and ACS have not been explored nor implemented in practice. This limits such patients' quality of life significantly.

**Aim:** To develop and feasibility test a novel, integrated self-management intervention for Jordanian patients with T2D and ACS, after an acute coronary event.

**Methods:** Mixed methods sequential embedded design incorporating two phases:

- Phase One: Data from a systematic review of the literature, 17 interviews with patients and 6 focus group interviews with professionals were synthesised and used to inform the development of the novel Diabetes Cardiac Self-Management (DCSM) Intervention.
- Phase Two: Combining aspects of the Common-Sense Model of Self-Regulation, with the information sources for improving patient's self-efficacy and the teach-back educational method produced a "triple-pillared" theory-based intervention strategy and guide accurate measurement of outcomes. The application of the intervention was assessed in a non-randomised feasibility study. The intervention consisted of three in-hospital education sessions and one follow-up supportive phone call.

**Results:** Phase one data confirmed that the existing evidence on support for patients with both conditions was inadequate. Present practice did not include self-management education and support for such patients following diagnosis with ACS in Jordan. Consequently, patients' knowledge, confidence and adherence were poor. The challenges patients face in living with both conditions and their education- and support-related preferences were identified. In Phase two, 20 patients were successfully recruited over 9 weeks, with high recruitment and retention rates. The study procedures and intervention were feasible to deliver and highly acceptable to participants. Preliminary evaluation of the intervention shows promise.

**Conclusions:** In a healthcare setting in which those with two serious, long-term conditions receive no routine education or support to enable them to manage their conditions, this study has provided a foundation upon which effective interventions can be developed in future.

## Abbreviations

ACS	Acute coronary syndrome
ADA	American diabetes association
AHA	American heart association
AHEC	The area health education center
AIDS	Acquired immune deficiency syndrome
AMSTAR	Assessment of multiple systematic reviews
BHF	British heart foundation
CCU	Coronary care unit
CDC	The centers for disease control and prevention
CDSMP	Cardiac-diabetes self-Management programme
CHD	Coronary heart disease
CONSORT	Consolidated standards of reporting trials checklist
COPD	Chronic obstructive pulmonary disease
CSM-SR	Common sense model of self-regulation
CVD	Cardiovascular disease
DALYs	Disability-adjusted life years
DCSM	Diabetes cardiac self-management
DKQ	Diabetes knowledge questionnaire
DM	Diabetes mellitus
DSMQ	Diabetes self-management questionnaire
DVD	Digital video disc
ECG	Electrocardiographic
EQ-5D	EuroQol five-dimensional
ES	Educational session
HbA1c	Glycated haemoglobin
HCPs	Healthcare professionals
ICVU	Interventional cardiovascular unit
IDF	International diabetes federation
IRB	Institutional review board
KAUH	King Abdullah university hospital
LMICs	Low and middle-income countries
MeSH	Medical subject headings

MH	Ministry of health
MI	Myocardial infarction
MMAS	Morisky medication-taking adherence scale
MMSED	Mixed methods sequential embedded design
MRC	Medical research council
NHS	National health service
NSTEMI	Non-ST-elevation myocardial infarction
PBTH	Princess Basma teaching hospital
PHQ	Patient health questionnaire - depression Module
PICO	Population, intervention, comparison and outcomes
POMS	Brief profile of mood states
PPI	Patient and public involvement
PRISMA	Preferred reporting items for systematic reviews and meta-analysis
RCTs	Randomised controlled trials
RMS	Royal medical services
SEMCD	Self-efficacy for managing chronic disease
SET	Bandura's self-efficacy theory
SIGN	Scottish intercollegiate guidelines network
SPSS	The statistical package for the social sciences
STEMI	ST-elevation myocardial infarction
T1D	Type 1 diabetes
T2D	Type 2 diabetes
UA	Unstable angina
UU	Ulster University
WHO	World health organisation
YLLs	Years of life lost

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## Declarations

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## Dissemination of findings

**Some results of this study have been presented at peer reviewed international conferences and published in peer reviewed international journals.**

1. Tanash, M., Fitzsimons, D. and Coates., V. (2016) “Are interventions to promote self-management in acute coronary syndrome and type 2 diabetes effective? a systematic review”, *Abstract presentation in EuroHeartCare 2016 - Croatia, and published on European Journal of Cardiovascular Nursing*, Vol.15, No.1, P. S1 - S115.
2. Tanash, MI., Fitzsimons, D., Coates, VE. and Deaton, C. (2017), “An evaluation of the effectiveness of self-management interventions for people with type 2 diabetes after an acute coronary syndrome: a systematic review”. *Journal of Clinical Nursing*. 26, 1458-1472.
3. Tanash, M., Coates, V., Fitzsimons, D., Slater, P., Ashour and A., AL-Faouri, I., “Double trouble: developing an intervention for people with diabetes and heart disease - what professionals tell us?” (2017), *Abstract presentation in EuroHeartCare 2017- Greece, published on European Journal of Cardiovascular Nursing*, 16, S1-S100
4. Tanash, M., Coates, V., Slater, P., Fitzsimons, D. and Alshraifeen, A. “Double trouble: Implications for care and self-management interventions when patients experience type 2 diabetes post-acute coronary syndrome – qualitative study of the patient’s perspective”, *Oral presentation in EuroHeartCare 2018 -Dublin and published on European Journal of Cardiovascular Nursing*, Vol.17, No.1, P. S1–S120.

**Intended to be published in peer reviewed international journals will be named later with my supervisors:**

- Exploring the follow-up care and self-management challenges of Jordanian patients with type 2 diabetes following the acute coronary event - a qualitative study of the patients’ and their healthcare professionals’ perspectives. Will be submitted to *Patient Education and Counselling Journal*.
- What self-management education and support do patients with type 2 diabetes want after their acute coronary syndrome? a qualitative study of the patient’s perspective.
- What the important features we need to know to design "triple-pillared" theory-based self-management interventions for patients with type 2 diabetes and an acute coronary syndrome?
- Developing and initial feasibility testing of the Diabetes Cardiac Self-management (DCSM) Intervention for patients with type 2 diabetes after an acute coronary syndrome.
- Tailored of the Diabetes Cardiac Self-management (DCSM) Intervention for type 2 diabetes patients with an acute coronary syndrome - Design and development of a randomised controlled trial.



# **Chapter 1: Introduction**

## **Introduction**

This chapter provides an overview of the study. After exploring the background context, the main epidemiological data and characteristics of Acute Coronary Syndrome (ACS) and Type 2 Diabetes (T2D) are presented together with a summary of the objectives and significance of the study. The chapter concludes by presenting an overview of the outline of the thesis.

## **1.1 Background to the study**

### **1.1.1 Inspiration for the study**

As a nurse in the Coronary Care Unit (CCU) for a few years in one of the Jordanian public hospitals before starting this PhD, I worked with a significant number of patients with ACS and observed how poor management of diabetes and other cardiovascular risk factors led many patients to develop harmful cardiac problems. I observed how those patients were discharged from hospital after a few days in the CCU without fully understanding what had happened to them, having had no real education in how to deal with their health condition after they left the hospital. I observed how many of those patients and their family members left hospital uncertain, worried and feeling down due to insufficient knowledge and confidence in their ability to manage their condition.

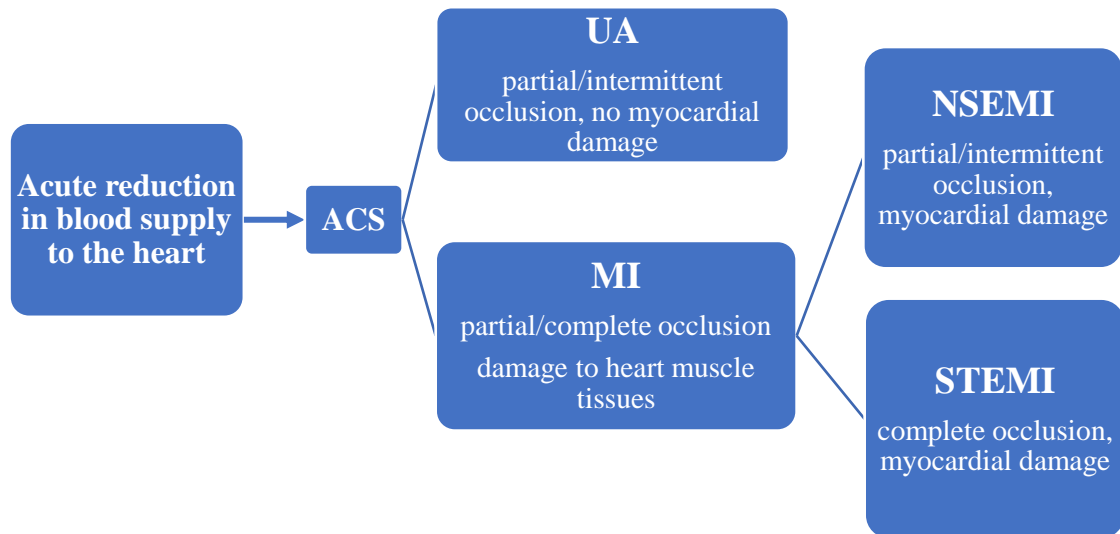
Also, I noticed that some of those patients returned to the CCU again and again with more cardiac complications, adverse outcomes due to poor management of their multiple chronic conditions, especially those who have T2D. I still remember how the condition of some of these patients deteriorated relatively shortly after their first cardiac event, becoming worse and more complicated by cardiac failure or the need to perform open heart surgery. I still remember how shocked I was when I met patients who had a record number of cardiac stents inserted into their coronary arteries over a period of only a few years following their first cardiac event, often because of repeated cardiac complications and poor health management. For example, one patient had more than 24 stents inserted over about seven years after his first cardiac event (an average of 3-4 stents each year).

I observed an association between patients with ACS and T2D and poor management of their health conditions and the tendency to ignore their modifiable risk factors such as diabetes, hypertension, smoking and non-adherence to medications, physical activities and healthy diet. I observed how many patients suffered a heart attack after a long of period of poor management and misunderstanding their diabetes and other cardiovascular risk factors, but more regrettably, they were discharged from hospital to their home without receiving real support to motivate them to make positive life changes. I wondered why this was, why they continued to neglect and mismanage their condition even after surviving a life-threatening heart attack, what their actual needs were and how I could help those patients with multiple chronic conditions. This has motivated and inspired me to work during my PhD research on a project which revolves around this problem.

### **1.1.2 What is an ACS?**

ACS is an umbrella term for conditions in which the blood supplied to the heart muscle or part of it is suddenly blocked, causing damage to its tissues. ACS includes Unstable Angina (UA) and Myocardial Infarction (MI) or “heart attack”. The latter is further classified according to electrocardiographic (ECG) changes as ST-elevation myocardial infarction (STEMI) and non-ST-elevation myocardial infarction (NSTEMI) (NICOR 2017).

The terms “heart attack” and “angina pectoris” are both widely used to describe the symptoms and clinical presentations associated with ACS. The narrowing or blockage of the coronary arteries in ACS can be sudden and either complete or partial as it can come and go (AHA 2017). Mostly, this occurs because of the slowly progressive build-up of fatty materials (atheroma) within the wall of one or more coronary arteries, often occurring without symptoms and over years, followed by a sudden restriction of the blood flow in the coronary artery and risk of formation of coronary thrombosis (blood clots within the coronary artery) or myocardial ischemia (reduction in blood supply to heart muscle and preventing it from receiving enough oxygen and nutrients). Consequently, if this ischemia continues for a long time, death of heart muscle cells can occur (Timmis 2015; AHA 2017; MFMER 2017; NICOR 2017).

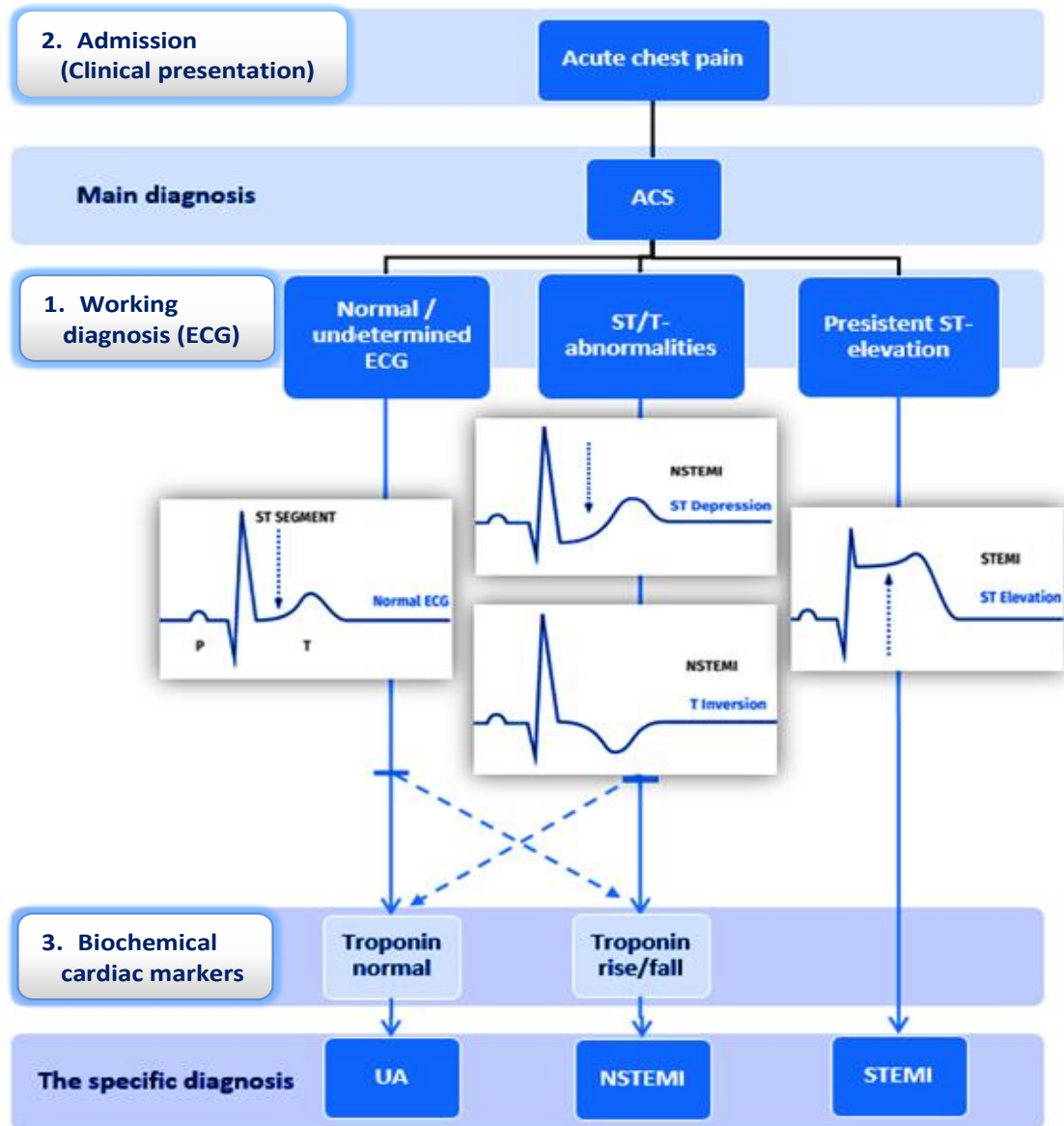


**Figure 1-1: Onset of symptoms to diagnosis patient**

The death of heart muscle cells due to a prolonged reduction of blood flow to those cells is called MI; if there is no heart muscle cells death but the heart muscles do not work properly or efficiently because of an inadequate supply of blood, it is called UA (MFMER 2017) (see Figure 1-1). However, the categorisation of ACS depends on the characteristics of three key elements: clinical presentation, biochemical cardiac markers and ECG changes (Roffi et al. 2016).

Typically, patients with ACS present to hospital with acute chest pain. Healthcare professionals use two main methods to confirm a diagnosis of ACS and to distinguish between the spectrum of diseases falling under that umbrella (Hamm et al. 2012):

1. ECG: NSTEMI and UA are associated with T-wave changes and/or ST depression/transient elevation; STEMI is associated with persistent ST elevation.
2. Cardiac Troponins: Troponin levels are very sensitive and specific indicators of myocardial injury (MI); elevated troponin levels can be used to distinguish NSTEMI from UA (see Figure 1-2).



**Figure 1-2: Diagnosing the spectrum of ACS**

## 1.2 Epidemiology of ACS

Cardiovascular disease (CVD) is the leading cause of death (Tran et al., 2017), responsible for about 46.2% of all deaths each year worldwide (WHO 2014; Tran et al. 2017). The global deaths from CVD rose by 14.5% between 2006 and 2016 to approximately 17.6 million (Naghavi et al. 2017), and this number is expected to grow to over 22.2 million by 2030 (WHO 2014). Roughly 80% of CVD deaths occur in low and middle-income countries (LMICs), with substantial mortality from coronary heart disease (CHD) (Tran et al. 2017). CHD includes angina and MI, is the most common type of CVD and the leading cause of both CVD deaths (BHF 2017) and rising in disability-

adjusted life years (DALYs) worldwide (Naghavi et al. 2017). It represents about 7 million deaths and 129 million DALYs each year and is leading cause of total years of life lost (YLLs) in 113 countries for men and in 97 countries for women. Globally, deaths from CHD increased by 19% between 2006 (7.96 million) and 2016 (9.48 million) (Naghavi et al. 2017).

An acute coronary syndrome remains the leading cause of death from CHD worldwide (AHA 2017; BHF 2017). For example, in 2012, of the 17.5 million deaths due to CVD around the world, an estimated 7.4 million (42.2%) were due to heart attacks alone (WHO 2014). In the United States, it is estimated that a heart attack occurs every 34 seconds and that every 83 seconds someone dies from a major coronary event (Mozaffarian et al. 2015). Moreover, of the 8 million patients who presented to the emergency room annually for chest pain, 20-25% are diagnosed with ACS. Of these, approximately 40% are diagnosed with UA, 40% with NSTEMI and 20% with STEMI (Amsterdam et al. 2014). Likewise, CHD is the leading cause of death in the UK; with an average of 190 people dying each day, mostly due to MI, this equates to one death roughly every 8 minutes. In the UK, there are 2.3 million people living with CHD, over 60% of whom are male. In the 1960s, more than 70% of MIs in the UK were fatal, but now at least 70% of people with an MI survive (BHF 2017).

While CHD mortality and morbidity rates vary greatly between countries, the substantial portion of the burden of CHD and ACS falls on LMICs. Furthermore, deaths from ACS occur at younger ages in LMICs than in high-income countries, and often at economically productive ages: mortality rates among adults in some LMICs are approximately double those in high-income countries, and likewise frequently affect the poor (Vedanthan et al. 2014). This burden will likely grow in the coming years as more countries make the epidemiologic transition to unhealthy habits (Seligman et al. 2016). Furthermore, many people around the world are beginning to experience a more comfortable and sedentary lifestyle, characterised by a diet high in fats and sugars, poor fitness, higher levels of tobacco and alcohol abuse (Seligman et al. 2016). The healthcare systems in many countries and particularly in LMICs are ill-equipped to prevent the problems caused by unhealthy lifestyles or to treat all the ACS, diabetes and other cardiovascular risk factors. Thus, mistreatment results from first, lack of awareness of symptoms and poor management of these conditions; second, inadequate healthcare systems that limit access to proper facilities, treatment and lifesaving medications in many

LMICs; and third, other difficulties related to the low of socioeconomic status of population of these countries (Seligman et al. 2016; Tran et al. 2017).

### **1.3 Definition of diabetes**

Diabetes mellitus (DM) refers to a number of diseases that share the common symptom of high blood glucose levels (Goldstein & Mueller-Wieland 2016). The DM consists from two main subtypes, these are type 1 diabetes (T1D), either autoimmune or idiopathic, and type 2 diabetes (T2D), attributable to insulin secretion defects, insulin resistance, or both. The T1D occurs mostly in young people and it is characterised by deficiency of insulin secretion due to destructive lesions in pancreatic  $\beta$ -cells. While the T2D, is a polygenic and heterogeneous disorder, resulting from the interaction between susceptibility genetic factors and environmental/ lifestyle factors (Goldstein & Mueller-Wieland 2016).

### **1.4 Epidemiology of diabetes**

According to the World Health Organization (WHO), CVD (46.2%), cancers (21.7%), respiratory diseases (10.7%) and diabetes (4%) were responsible for 82% of deaths from non-communicable diseases globally in 2014 (WHO 2014). Such as deaths from CVD, over three quarters of deaths from diabetes occur in LMICs, according to the International Diabetes Federation (IDF 2017a) and the WHO (WHO 2014). Diabetes incidence increased steadily over the last decades (Cheng et al. 2013) and has been classed as a global epidemic (Lorber 2014). For example, the total number of deaths and the total YLLs from diabetes both increased between 2006 and 2016 by 31.1% to 1.4 million and by 25.3% to 28.6 million respectively. The rise in the latter rate was one of the main causes of the increase in total the YLLs globally in 2016 (Naghavi et al. 2017).

As of 2017, an estimated 451 million adults around the world are living with diabetes (about 80% of whom live in LMICs), compared to 108 million in 1980. The global prevalence of diabetes has doubled since 1980, rising from 4.7% to an estimated 8.8% of the adult population worldwide in 2107 (IDF 2017a). If these trends continue, by 2045, an estimated (9.9%) 693 million adults will have diabetes (WHO 2016b; IDF 2017a).

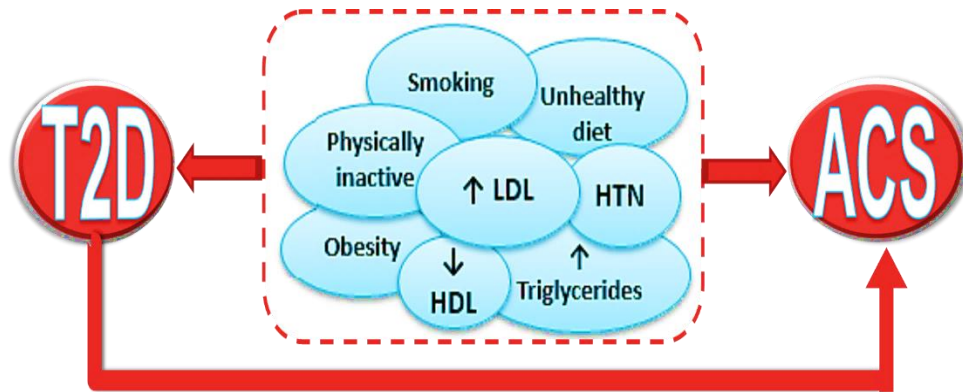
## 1.5 Links between type 2 diabetes and acute coronary syndrome

Type 2 diabetes is a chronic, metabolic disorder leading to hyperglycaemia that affects the heart and blood vessels and may cause fatal vascular complications such as MI and stroke (WHO 2015; IDF 2017b). In T2D, hyperglycaemia, or “high blood sugar” (defined as blood glucose levels greater than 7.0 mmol/L when fasting or 11.0 mmol/L, 2 hours after meals), is a result of an inadequate production of insulin and insulin resistance (the inability of the body to respond fully to insulin) (WHO 2015). T2D most often develops in people over the age of 45 and accounts for roughly 90% of all cases of DM (CDC 2016). Between a third and a half of all T2D cases globally are undiagnosed because the onset of T2D is usually slow and individuals may remain asymptomatic or hyperglycaemic for many years (WHO 2016b).

The findings from a case control study conducted in 52 countries showed that nine potentially reversible risk factors and health behaviours accounted for over 90% of MIs worldwide in both genders and at all ages in all regions of the world. These nine factors are smoking, diabetes, hypertension, dyslipidaemia, obesity, unhealthy diet, sedentary lifestyle, alcohol misuse and psychosocial factors (Yusuf et al. 2004). This result was consistent with the results of the Framingham Heart Study, a long-running research project that has provided important insight into the epidemiology and risk factors of cardiovascular disease around the world (Mahmood et al. 2014). T2D is a known cardiovascular risk factor for CHD, and poses a major public health problem. Also, poor control of T2D is a leading cause of macrovascular complications, which damage larger blood vessels and cause CHD, peripheral arterial disease and stroke, and microvascular complications, due to damage to small blood vessels and cause diabetic nephropathy, neuropathy, and retinopathy (Abdul-Ghani et al. 2017; IDF 2017a; Jelinek et al. 2017).

Compared with adults without T2D, patients with T2D have a significantly higher risk of cardiovascular mortality and morbidity and are disproportionately affected by CVD (Martín-Timón et al. 2014) and ACS (Kasteleyn, Gorter, van Puffelen, et al. 2014). The risk of CVD is 2-4 times higher in adults with T2D as in adults without T2D (White et al. 2013a). The WHO estimates that 50% of people with diabetes die of CVD, mainly from MI and stroke (WHO 2016b). In addition to the strong pathophysiological link between T2D and ACS, both conditions are associated with most cardiovascular risk factors such as high blood pressure, obesity, increasing age, poor diet and nutrition,

smoking, physical inactivity and high cholesterol (AHA 2017; IDF 2017a) (see Figure 1-3).



**Figure 1-3: Similarity in risk factors between T2D and ACS**

**Note:** **HDL:** High-Density Lipoproteins, **HTN:** High Blood Pressure, **LDL:** Low-Density Lipoproteins

Undoubtedly, the strong link between T2D and ACS exposes patients to higher risk of mortality and morbidity; for example, each year diabetes leads to 3 million CVD deaths worldwide, 75% of which occur amongst people over 30 years of age in LMICs, where detection and effective management of diabetes and CVD risk factors is constrained by resource limitations (Danaei et al. 2006). The combination of diabetes with ACS has been found to significantly decrease patients' quality of life (Wermeling et al. 2012; Uchmanowicz et al. 2013) and increases the risk of adverse outcomes after hospitalisation (Franklin et al. 2004), symptom distress and self-management difficulties (Deaton et al. 2006), readmissions to hospital for other cardiovascular complications (Saleh et al. 2012) and the risk of death at 30 days, 6 months and 1 year post cardiac event (Donahoe et al. 2007). For example, analysis of a large pool of data from randomised clinical trials that evaluated ACS therapies found that out of 62,036 patients with ACS (75% with STEMI and 25% with UA/NSTEMI), 17.1% had DM. The DM was associated with significantly higher mortality at 30 days (2.1% versus 1.1% in those without DM;  $P \leq 0.001$ ) and at 1 year (8.5% versus 5.4% in those without DM;  $P = 0.001$ ) after their cardiac event (Bahrami et al. 2008). The Global Registry of Acute Coronary Events (GRACE) conducted a multinational study of 16,116 patients hospitalised with ACS (5403 with STEMI, 4725 NSTEMI and 5988 UA). The study reported that nearly 25% of ACS patients have DM, but this rate varies considerably between countries, in some exceeding 50% (Franklin et al. 2004).



## 1.6 The Jordanian context

Jordan is an Arabic Middle Eastern country located west of Asia. One of the LMICs, Jordan has a population of 9.8 million, 52.9 % of whom are male (Government of Jordan 2017). Muslims make up approximately 97% of the country's population, Christians 2.2%, and people of other religions less than 1% (Jordan Department of Statistics 2016). The literacy rate among Jordanian adolescents is 99.1%; among adult males it is 97.9% and among adult females it is 97.4% (WHO 2017b). The official language is Modern Standard Arabic, however, English is widely understood and spoken throughout the country as it is the de facto language of various sectors such as banking, commerce, education and health; all Jordanian public schools teach English from the primary level and almost all university-level classes are held in English (CIA 2017). As of 2017, life expectancy at birth was 74.8 years (73.4 years for males and 76.3 for females) (WHO 2017b). In 2010, 14.4% of the population was living at the poverty level (World Bank Group 2010).

The Jordanian healthcare system has two main components: the public/semi-public health sector and the private health sector. There are 110 hospitals in Jordan, providing 13731 beds. The public and semi-public sector includes 48 hospitals and numerous primary health centres, accounting for 67.3% of the total hospital beds, while the private sector includes 62 hospitals (Jordan Department of Statistics 2016). The public and semi-public sector includes all hospitals of the Ministry of Health (MH), the Royal Medical Services (RMS) and two educational university hospitals: the Jordan University Hospital in Amman (the capital of Jordan) and the King Abdullah University Hospital (KAUH) in Irbid (the most densely populated city after the capital and located in the north of Jordan) (Jordan Department of Statistics 2016; Nazer & Tuffaha 2017). As in most other countries, CHD is the leading cause of mortality and morbidity in Jordan. However, only a few Jordanian hospitals have an Interventional Cardiovascular Unit (ICVU) and most of these are in Amman and within private hospitals (Eshah and Bond 2009). The long-term care facilities are still non-existent (Nazer & Tuffaha 2017). For example, there are no structured programmes for cardiovascular disease prevention or rehabilitation centers in Jordan.

In the public sector, there are only three main ICVUs, two in Amman (the Queen Alia Heart Institute and Prince Hamza Hospital) and one in the north of Jordan (KAUH) (Higher Health Council 2015). There were 18 hospital beds per 10,000 population

members in 2013, which is higher than the rates in many other countries in the region but is still suboptimal, as it is lower than the global average of 30 beds per 10,000 population (WHO 2013).

In Jordan, the healthcare sectors work independently, and there is no national electronic health records system (Nazer & Tuffaha 2017). However, in 2009 the Jordanian government undertook a step to implement a national electronic health system known as “Hakeem” to improve patient healthcare by facilitating efficiency the connect between all hospitals and healthcare centres in Jordan. Although a number of hospitals and healthcare centres have implemented this system, there are still many hospitals in which this system must be implemented according to the Electronic Health Solutions and Interventions organisation (EHSI 2017).

In Jordan, non-communicable diseases are responsible for 75.6% of all deaths; of these, 37.7% are due to CHD while 6.7% are due to diabetes mellitus (WHO 2017a). The prevalence of diabetes among Jordanian adults is estimated to be 16.8% of the population, with T2D accounting for the majority of cases (Higher Health Council 2015). Moreover, about half of diabetes cases in Jordan are undiagnosed or uncontrolled (Jordan Ministry of Health 2013). The prevalence of CVDs, diabetes and other cardiovascular risk factors among the population is high due to the spread of unhealthy eating habits and a sedentary lifestyle as a result of the dramatic changes in the socioeconomic situation in the country (Fahed et al. 2012; Musaiger & Al-Hazzaa 2012; Alkurd & Takruri 2015) and the discrepancy between the rapid pace of urbanisation and development and the slow development of the Jordanian healthcare system at both the primary and secondary care levels (Guariguata et al. 2014). Thus, these changes have contributed to the rise in risk factors for T2D and ACS, and have reduced the level of awareness and knowledge of diabetes and CVD risk factors among Jordanians (Mukattash et al. 2012). For example, the latest statistics indicate that approximately 1 in 3 Jordanian adults over 25 years of age suffers from metabolic syndrome; 35.5% of Jordanian adults are obese, 66% are overweight or obese (Al-Nsour et al. 2012; WHO 2016a), roughly 80% are physically inactive (less than 10 minutes of regular exercise/day) and only 14% of Jordanians eat healthy food ( $\geq 5$  servings of fruit and vegetable/day) (Jordan Ministry of Health 2007). Almost two fifths (38.4%) of the total population and 65.5% of males over 15 years of age reported being smokers, a rate much higher than both the global prevalence rate and that of the Eastern Mediterranean region, as well as being one of the highest rates in the world (WHO 2016a). A similar proportion (39.5%) of the adult population suffer from

high cholesterol while 56.5% have high triglycerides and 28.6% suffer from hypertension (Higher Health Council 2015).

In Jordan, the integration rate of the two conditions (ACS and T2D) is very high, as shown by previous studies. For example, Saleh et al. (2012) reported that out of 652 Jordanian patients admitted for ACS, up to 70% had glucometabolic abnormalities (44.6% had established DM and 23.8% were newly diagnosed with DM or impaired fasting glucose). Also, the study found that ACS patients with diabetes had a much higher risk of in-hospital complications, readmissions for other cardiovascular events and mortality at 6 months and 1 year than patients without diabetes. Another study conducted on 5645 patients admitted with ACS in Jordan found that 48% had diabetes (Hammoudeh et al. 2008). These rates (half or more) are close to the rate recorded in some neighbouring countries such as Saudi Arabia (Alnemer et al. 2012). Therefore, due to the high prevalence of diabetes and CHD and the combination rate of two conditions (which is double the rate reported by GRACE), the Jordanian healthcare system is currently facing a big challenge in addressing these chronic conditions and helping cardiac patients to manage their health conditions properly (Shishani 2010; Fahed et al. 2012; Musaiger & Al-Hazzaa 2012).

## **1.7 Study rationale and overview of aims**

Type 2 diabetes is associated with significantly high morbidity and mortality rates in patients with ACS (Katz et al. 2014). The immediate period after patients with diabetes have been diagnosed with ACS is associated with significant symptom distress and self-management difficulties (Deaton et al. 2006). These difficulties often are due to the complex signs and symptoms of both conditions and the many vital parameters and lifestyle changes that need to be addressed after a cardiac event (Eshah and Bond 2009). Therefore, several studies and guidelines emphasise first, the importance of improving discharge planning for all hospitalised patients with diabetes and cardiac problems; second, the need to assess patients' overall understanding of their conditions from the first day of admission; and third, the need to check patients' ability to perform self-management tasks immediately after discharge from hospital (ADA 2012; Malaskovitz & Hodge 2014). These steps are particularly needed in LMICs, where the prevalence of

these two chronic diseases and cardiovascular risks factors are high and the healthcare systems are very limited.

Integrating the management of heart diseases, diabetes and other cardiovascular risk factors is often a complex process and encompasses several regimes that patients must implement to improve the outcome of their health condition (Radhakrishnan 2012). Self-management interventions are one of the key strategies contributing to improved outcomes for patients with T2D and ACS, and that help to minimise morbidity and mortality rates (Kasteleyn et al. 2014). For example, there were many recent reviews reported that there is a sufficient evidence of effects of self-management education interventions on patients with T2D and ACS, particularly on their knowledge of the disease, psychological outcomes, lifestyle outcome and clinical outcomes such as HbA1c level (Fan & Sidani 2009; Goulding et al. 2010; van Vugt et al. 2013; Ghisi et al. 2014; Liu et al. 2017). However, to date, such interventions often lack integration and characterised by individualisation in education, which leads to mismanagement of those who have multiples chronic diseases (MFMER 2014; Liu et al. 2017), or fail to achieve their goals because they have not taken account of the actual needs and capacity of patients (Coulter 2010; Gorter et al. 2010). In Jordan, as in many other LMICs, the discharge planning and rehabilitation services for patients with diabetes and cardiac problems are rudimentary or non-existent both at the primary and the secondary care level, and providing supportive interventions for those patients during hospitalisation or immediately after discharge is logical and urgently needed (Shishani 2010; Eshah 2011; Jordan Ministry of Health 2013).

The information above indicates a strong link between T2D and ACS worldwide and in LMICs in particular. The two conditions often coexist in Jordan and they cannot be dealt with in isolation. Poor management of diabetes, cardiac problems and other cardiovascular risk factors are estimated to have caused additional morbidity and mortality risk. If diabetes and other cardiovascular risks are left uncontrolled after the cardiac event, many problems may develop, such as further cardiac complications, cardiac failure, stroke, renal failure, blindness, symptoms of distress and reduced quality of life.

Many modifiable cardiovascular risk factors contribute to the high prevalence rates of diabetes, CHD and worse health outcomes. These factors include physical inactivity, smoking, eating unhealthy food containing too much fat and sugar, inadequate intake of

vegetables and fruits, overweight and obesity, psychological stress and inadequate access to healthcare. Worldwide, detection, treatment and control of CVD and diabetes are inadequate, owing to weaknesses in health systems at the primary and secondary care level in many countries and the LMICs in particular.

There is a strong scientific evidence of the health benefits of controlling blood sugar and other cardiovascular risk factors through self-management interventions at the individual level in patients with CHD (Kasteleyn et al. 2016; Liu et al. 2017; Shi et al. 2018). Thus, integrated self-management intervention based on the needs and preferences of patients with both conditions, provided in hospital such secondary care settings and post-discharge settings, is logical and urgently needed (Liu et al. 2017). These interventions should aim to increase patients' awareness of and knowledge about diabetes and cardiac disease, motivate them to adhere to a healthy lifestyle post discharge (Eshah 2013) and help them to cope with the new challenges and difficulties that may arise after discharge from the hospital (Eshah and Bond 2009).

This study seeks to integrate the management of T2D and ACS by helping patients to increase their knowledge about both disease management, self-manage their cardiovascular risk factors and to target their modifiable risk factors soon after they diagnosis with ACS. To achieve this aim, an integrated self-management intervention must be established based on the actual needs of Jordanian patients with ACS and T2D and in line with the relevant evidence base. The core of this intervention must help those patients to prioritise and address their modifiable risk factors and improve the efficiency and effectiveness of their practice with regard to the management of their T2D and ACS together, as recommended by the many international guidelines and studies mentioned above.

## 1.8 Overall aim and objectives

The proposed study has the following aim and objectives

**Aim:** To develop a novel, integrated self-management intervention for patients with T2D and ACS and evaluate its feasibility in the Jordanian context.

### **Study objectives:**

1. To evaluate the evidence on the effectiveness of existing tailored interventions to promote self-management behaviour in patients presenting with ACS and T2D in secondary healthcare settings and post discharge from the hospital.
2. To explore the supportive care needs of patients with ACS and T2D from the perspective of the patients and their healthcare professionals (HCPs).
3. To explore the perspectives of patients and their HCPs regarding the current follow-up care provided for patients with ACS and T2D in Jordan, with the purpose of identifying their challenges, unmet needs and features that can help in the development of a new supportive intervention.
4. To develop a new supportive intervention based on the needs of Jordanian patients with T2D and ACS and in line with the relevant evidence base identified and appropriate theory.
5. To evaluate the feasibility of the newly developed intervention in the context of a single Jordanian secondary healthcare setting.

## 1.9 Outline of the thesis

This thesis consists of eight chapters. **Chapter 1** (this chapter) provides an overview of the study, including its meaning, objective and significance. **Chapter 2** provides an overview of the related literature to self-management interventions for patients with T2D and ACS, study's theoretical framework, presents the published systematic review of an evaluation of the effectiveness of self-management interventions for people with T2D and ACS and concludes by identifying the gaps in the literature. **Chapter 3** presents an overview of the study's methodological approach. **Chapter 4** describes the methods used in focus groups with HCPs and interviews with patients which were conducted in Jordan prior developing the intervention. **Chapter 5** presents Study I of the qualitative investigations. Study I is designed to explore the perspectives of HCPs regarding the

follow-up care currently provided for patients with ACS and T2D in Jordan, and to explore their opinions regarding the supportive care needs of patients with T2D and ACS. The methods and results obtained from 6 focus groups with HCPs are also outlined. **Chapter 6** presents Study II of the qualitative investigations. Study II is designed to explore the supportive care needs of patients with ACS and T2D, and their perspectives regarding the follow-up care currently provided for them in Jordan. The methods and results obtained from 17 patients are outlined. **Chapter 7** describes the methodology and procedures for developing the Diabetic Cardiac Self-Management (DCSM) Intervention for patients with both conditions, and for testing its feasibility in Jordan. **Chapter 8** presents Study III of the study. Study III presents the findings of the feasibility study. **Chapter 9** discuss the findings in light of previous research, draws together the conclusions from the above studies and summarises their strengths and limitations, before presenting a number of recommendations and implications for education, policy and practice within Jordan and the worldwide context.

## 1.10 Summary

- Globally, roughly 25% of ACS patients have T2D. However, this rate varies considerably between countries, with the rate in some LMICs reaching more than double the global rate.
- In Jordan, the proportion of cases presenting with both ACS and T2D ranges between 48-70%. In addition, the prevalence rate of all cardiovascular risk factors is high compared with that of other countries.
- The two conditions often coexist and share similar cardiovascular risk factors and many modifiable risk factors. Thus, they cannot be addressed in isolation.
- Often the coexistence of the two conditions, in addition to other cardiovascular risk factors, leads to big challenges for patients shortly after their cardiac event. These challenges mostly include difficulty in coping and managing their complex condition, emotional problems, persistent bad habits, low self-efficacy and medication adherence.
- Poor management of these challenges may expose those patients to adverse outcomes, morbidity and mortality, and reduce their quality of life.
- The subnational portion of burden of these conditions falls on LMICs such as Jordan, where the healthcare system at the primary and the secondary level is ill-equipped to prevent the problem and treat both conditions.

- Integrated intervention to promote self-management of patients is logical and urgently needed.
- The aim of this study is to develop a novel integrated self-management intervention for patients with T2D and ACS and evaluate its feasibility in the Jordanian context.

The next chapter provides an overview of the related literature and concludes by identifying the gaps in the literature.



## **Chapter 2: Literature Review**

This chapter provides a review of the available literature pertinent to this thesis and consists of three sections. The first section focuses on research related to self-management initiatives for patients with Type 2 Diabetes (T2D) and Acute Coronary Syndrome (ACS). The second section presents the systematic review of an evaluation of the effectiveness of self-management interventions for patients with T2D and ACS in secondary care settings and following discharge from hospital, that it was published (Tanash et al. 2016; Tanash et al. 2017b). The third section contains a review of the Common-Sense Model of Self-Regulation (CSM-SR) and presents the rationale for its use in this study as a framework before developing the intervention.

### **2.1 Section One – Self-management**

#### **2.1.1 Definition of Self-Management Intervention**

Self-management is a popular term for behavioural interventions and healthful behaviours used to manage a condition for those who are living with it. Self-management interventions also exemplify the complex, supportive interventions that have gradually developed over the past twenty years in the care of patients with chronic conditions such as diabetes and cardiovascular disease (Lorig & Holman 2013). Patients with a chronic condition spend only a fraction of their lives in contact with their healthcare professionals (HCPs) for treatment and counselling, whereas almost all their physical and psychological outcomes are mediated through their daily behaviour (Glasgow et al. 2003). Consequently, the management of chronic conditions requires most patients to assume a wide range of responsibilities. Whether such management requires making lifestyle changes, taking medication or undertaking preventive action, the patients, their carers or both make the day-to-day decisions about what plans or actions are to be taken (Newman et al. 2004). Hence, targeting patients' self-management behaviour is currently considered a promising approach for improving patient outcomes (McGowan 2012; Schaffler et al. 2018).

The definition of the term “self-management intervention” varied between the many studies and systematic reviews of self-management interventions. This lack of a clear and fixed operational definition may influence the conclusion of these studies and reviews. Jonkman et al. (2016) conducted a systematic review of studies containing definitions of self-management interventions and consensus meetings with self-management practitioners and research experts in order to develop an operational definition of self-management interventions. The electronic databases of EMBASE, MEDLINE, PsycINFO, CENTRAL and CINAHL were searched from January 1985 through June 2013 to retrieve publications containing definitions of self-management. Its defined as interventions that aim to equip patients with chronic diseases with the skills they need to take responsibility for and actively participate in the management of their condition. And the objective being to function optimally through the acquisition of knowledge about their condition and a combination of at least two of the following activities: medication management, stimulation of independent sign/symptom monitoring, developing the decision-making skills required for medical management, enhancing problem-solving and changing their dietary, physical activity, and/or smoking behaviour.

Glanz et al. (2015) defined self-management education interventions as comprehensive programs provided by HCPs that aim to improve clinical and psychological outcomes for patients by increasing and maintaining health behaviours. For example, along with educating patients to increase their knowledge of the disease, these programs seek to increasing other self-management behaviours such as maintaining a healthy diet, medication adherence and engaging in physical exercise, thus minimising patient morbidity or mortality (Glanz et al. 2015). Thus, both definitions are clearly combined between the acquisition of knowledge on disease management and practising self-care activities.

## **2.1.2 Self-management for patients with T2D and ACS**

### ***2.1.2.1 Effect of self-management support on patients with T2D***

Type 2 diabetes is one of the most prevalent chronic diseases globally. Patients with this condition must make a multitude of daily self-management decisions and perform self-care activities. Over the last decade, many studies have suggested that diabetes self-

management education and support provides the foundation to help patients with diabetes to navigate their self-management decisions and activities and improve their health outcomes (Norris et al. 2002; Ellis et al. 2004; Fan & Sidani 2009; Steinsbekk et al. 2012; Brunisholz et al. 2014; Chomko et al. 2016; Azam et al. 2017). Many recent health education programs have been designed to meet national or international health education standards for diabetes education (Haas et al. 2012; Tang et al. 2013), which require that programs be individualised to consider patients' current needs and health conditions (ADA 2018). However, although diabetes education and support are effective and essential for high-quality and patient-centred diabetes care, very few patients receive these services; moreover, because many patients with T2D are cared for by HCPs such as nurse practitioners, it is essential that these practitioners provide information, address psychosocial issues and concerns, support behavioural change and make appropriate referrals as needed for diabetes self-management education and support at each encounter (Funnell & Piatt 2017).

Diabetes self-management education refers to the provision by HCPs of the knowledge, skills and ability necessary for patients with diabetes to self-manage their condition. While diabetes self-management support refers to the provision of the support required for applying and sustaining the coping skills and behaviours patients need to self-manage their condition consistently (Powers et al. 2016). Often this support can be provided by HCPs and/or a variety of community-based resources such as family members. Accordingly, as both HCPs and community resources can contribute to this process of education and support, it has been recommended that HCPs and healthcare settings have the necessary resources and systematic referral processes to ensure that patients with T2D receive self-management education and support on an ongoing basis (Powers et al. 2016). It is the position of the American Diabetes Association (ADA) that all people with T2D should receive diabetes self-management education and support at diagnosis and as needed thereafter either during any hospitalisation or after discharge from hospital (ADA 2018).

Providing diabetes self-management education and/or support for patients with T2D has been shown to be cost-effective by reducing hospital admissions, readmissions (Duncan et al. 2011; Healy et al. 2013) and estimated lifetime healthcare costs due to a lower risk of complications from diabetes (Gillett et al. 2010; Brown et al. 2012; Prezio

et al. 2014). Diabetes self-management educational or supportive interventions have a positive effect on various aspects of T2D, including behavioural, psychosocial and clinical aspects. It has been reported that such programs may significantly decrease the onset and advancement of T2D complications such as coronary heart disease (Stratton et al. 2000; ACCORD 2011; Van Hateren et al. 2011), even after patients with T2D have experienced major complications such as myocardial infarction (Kelly et al. 2014). Diabetes self-management interventions may help patients with diabetes to improve their lifestyle behaviours, such as increased physical activity and decreased sedentary time (Balducci et al. 2017), adopting a healthier eating pattern and engaging in regular physical activity (Toobert et al. 2011; Siminerio et al. 2014). Other potential benefits include improving patients' quality of life (Cochran & Conn 2008; Peimani et al. 2017; Shi et al. 2018), glycaemic control (Schneider et al. 2016), healthy coping (Thorpe et al. 2013), self-efficacy and patient empowerment. Diabetes self-management interventions may also have a positive and long-lasting effect on self-care behaviours, cardiovascular fitness and metabolic health (Tang et al. 2012) and reduce the incidence of diabetes-related depression (De Groot et al. 2012; Hermanns et al. 2015; Schneider et al. 2016) and distress (Fisher et al. 2013; Dalsgaard et al. 2014; Siminerio et al. 2014).

#### ***2.1.2.2 Effect of family and peer support on self-management of patients with T2D***

Continuing T2D care requires effective self-management education and support for both patients and their family members, as the findings from different studies suggest (Gomes et al. 2017; Ebrahimi et al. 2018). For example, a systematic review was conducted by Pamungkas et al. (2017) to evaluate the impacts of diabetes self-management education that involve family members on patient health outcomes related to patient health behaviours, clinical outcomes, self-efficacy, well-being and self-management skills. Based on an appraisal of 22 intervention studies, the study found that family support increased self-efficacy and perceived support, had a positive impact on healthy diet and glycaemic control, improved patient psychological well-being and improved the health outcomes and self-management behaviours among T2D patients with uncontrolled glycaemia (Pamungkas et al. 2017). An another recent randomised control trial conducted to investigate the effects of a family-based training program on the quality of life of patients with T2D found that the quality of life of those in the experimental group (n=40) significantly improved after the patients' family members were involved in the training

program and were educated about diabetes self-management (Ebrahimi et al. 2018). These findings are consistent with those of a systemic review of randomised controlled trials conducted to evaluate the influence of family support on the clinical control of patients with T2D, which showed that there was a greater reduction in BP and HBA1c in the intervention group than in the control group (Gomes et al. 2017). Moreover, the consensus among these reviews is that family members should be directly involved in the care of patients with chronic diseases such as T2D, especially through self-management and healthcare programs (Gomes et al. 2017; Pamungkas et al. 2017; Ebrahimi et al. 2018).

Although the effectiveness of social support such as family and friends in diabetes care, and self-management education and support is evident, current practice does present some challenges, such as the lukewarm response from decision-makers towards implementing social support within diabetes care, lack of simple communication with patients and poor understanding of their actual concerns (Kadirvelu et al. 2012). In addition, poor adherence to self-care activities among patients with T2D was one of the main challenges to optimal care. For example, an appraisal of 52 studies published between 2000-2013 found that 40% of patients with T2D fail to adhere to treatment advice and the lifestyle modifications recommended by healthcare providers due to the complexity of the regimens required as well as psychological and psychosocial issues (Sapkota et al. 2015). Furthermore, the time allotted for follow-up visits with patients with T2D is often inadequate to address patients' questions about and needs in relation to self-management (Brownson & Heisler 2009).

To be effective, self-management support must be provided on a consistent basis and requires adequate provision of personnel and services, yet most current healthcare systems are often insufficiently resourced. Considering these challenges, integrating peer support into diabetes self-management education and support programs has been suggested as a promising approach which enables patients with chronic diseases to connect to other patients who have had similar experiences and thereby gain social and emotional support, which help them in the daily management of their diabetes and encourages linkages to clinical care (Riddell et al. 2012; Zhang et al. 2016).

Over the last decade, many review and research studies have been conducted about the effectiveness of the role of peer support in diabetes self-management and in promoting

health outcomes such as patient self-efficacy and quality of life (Brownson & Heisler 2009; Nettles & Belton 2010; Lynch & Egede 2011; Kadirvelu et al. 2012). For example, patients with T2D who worked with trained peers, who shared their experiences and discussed the challenges of diabetes management with those patients and encouraged them to engage in daily self-management activities, experienced a significant reduction in mean HbA1c value and significant improvement in diabetes self-management, self-efficacy and quality of life scores compared to the control group after 6 months (Peimani et al. 2017). Thus, peer support interventions can be successfully applied in diabetes self-management, especially in healthcare settings with a shortage of professionals, facilities and economic resources (Peimani et al. 2017).

### ***2.1.2.3 Adverse outcomes of diabetes and its link to ACS***

Patients with T2D have a reduced health-related quality of life compared to healthy people, especially in relation to well-being and physical functioning (Wandell 2005). Health-related quality of life also decreases in patients with T2D when other diseases co-exist, especially macrovascular diseases such as coronary heart disease and non-vascular diseases such as depression (Wandell 2005). This holds true even for T2D patients whose conditions are well-controlled (HbA1c  $\leq 5.8$  mmol/mol; total cholesterol  $\leq 5.2$  mmol/mol; systolic blood pressure  $\leq 145$  mmHg and not using insulin), whose health-related quality of life can be negatively affected, as in the findings from a cross-sectional analysis study of 2086 well-controlled T2D patients demonstrated (Wermeling et al. 2012).

Some sensitive tools are available to diagnose atherosclerotic and ischemic coronary disease, and these may help to provide incremental prognostic information which could reduce the incidence of cardiac events in patients with T2D (Upchurch & Barrett 2012). Professional guidelines for care of patients with diabetes also have suggested that those at highest risk (10-years risk  $\geq 20\%$ ) for cardiac events may benefit, yet research findings do not support widespread screening for coronary heart disease in patients with T2D (Upchurch & Barrett 2012).

A cohort study of 1.9 million people with cardiovascular diseases found that there is a strong positive association between T2D and peripheral arterial disease, non-fatal myocardial infarction, heart failure, ischaemic stroke and stable angina (Shah et al. 2015). Despite their efforts to control their disease, many patients with T2D develop ACS. This

can evoke more distress and depressive feelings in these patients, and complicate self-management of their overall condition (Kasteleyn, Gorter, van Puffelen, et al. 2014). As mentioned in the previous chapter, approximately 20%-25% of patients with ACS reportedly also have T2D (Hasin et al. 2009; Sierra-Johnson et al. 2009). Moreover, the prevalence of cardiac dysfunction may be as high as 75% in patients with T2D but is often overlooked because of complicating co-morbidities such as ACS and obesity, the initial asymptomatic nature of the disease and the lack of consensus on diagnostic criteria (Ofstad 2016).

Type 2 diabetes is strongly associated with increased risk of cardiovascular disease and cardiac dysfunction, two conditions which often co-exist and impact each other's course (Ofstad 2016). Both T2D and ACSs are often associated with cardiovascular risk factors such as obesity, low levels of physical exercise, unhealthy diet and smoking (Lakerveld et al. 2013). These cardiovascular risk factors and other clinical risk factors such as glycaemia, high blood pressure and dyslipidaemia specifically, are regularly addressed by most health education interventions provided for patients with both conditions (Lakerveld et al. 2013). Therefore, this strong association between both conditions clearly indicates that develop an integrated intervention to promote self-management behaviour and knowledge of both conditions are logical and urgently needed.

#### ***2.1.2.4 The effects of combining both conditions***

In international, prospective cohort study of patients with first myocardial infarction (MI) in countries with different socioeconomic environments, conducted to assess the long-term outcomes after MI found substantial differences in treatment and in secondary prevention interventions, including cardiac rehabilitation (Kämpfer et al. 2017). The study also found significant differences in all-cause mortality among patients from different countries. The findings showed that all-cause mortality at 3.5-year follow-up was 14.6%, 8.5% and 4.6% for patients with MI from countries with low, middle and high socioeconomic status respectively. The study suggested that there is a need to increase efforts and support to improve care and discharge planning, including in particular secondary prevention for patients with MI from countries with a low socioeconomic environment (Kämpfer et al. 2017).

Likewise, patients with T2D and ACS have an increased risk of adverse outcomes such as recurrent myocardial infarction and unstable angina, readmission, heart failure or death during follow-up (Franklin et al. 2004). This may be related to a large degree to accelerated atherosclerosis driven by inflammation (Ofstad 2016). For example, mortality at 30 days and 1 year following ACS among patients with diabetes was significantly greater than it was among patients with ACS only, either following STEMI (8.5% (ACS and DM) vs. 5.4% (ACS only)) or NSTEMI/UA (2.1% (ACS and DM) vs. 1.1% (ACS)) (Donahoe et al. 2007). Also, it has been reported that patients with ACS and T2D experienced a longer average delay from onset to hospital presentation than ACS patients without diabetes (Ting et al. 2010; McKinley et al. 2011; O'Donnell et al. 2014). Often this delay in predicting and detecting an acute coronary event was attributed to the lower sensitivity inherent in the diagnostic symptoms and tests among cardiac patients with T2D (Ofstad 2016). Despite recent therapies for patients with ACS, diabetes confers a significantly adverse outcome and prognosis, highlighting the importance of providing different care strategies to manage people with both conditions, who face particularly high risks (Donahoe et al. 2007).

A qualitative study was conducted by Ängerud et al. (2015) with 15 patients to explore their perspectives about how patients with diabetes experience the onset of MI and how they decide to seek care. Participants were interviewed within five days of their admission to hospital with MI. The findings showed that many patients did not understand that MI is a complication of diabetes and they did not see themselves as susceptible to MI, even after discharge from hospital. The authors reported that patients with diabetes are involved in a complex care-seeking process that is delayed by many obstacles such as feeling endangered and lack of awareness about their illness, its complications and the symptoms of MI, especially when they have experienced these symptoms. The study emphasised that education for patients with diabetes should include information about their increased risk of MI, the symptoms and onset of MI and the best action to take when they believe they are experiencing the symptoms of MI (Ängerud et al. 2015).

A study was conducted by Shah & Deshpande (2014) to assess the impact of diabetes on health-related quality of life in patients with coronary artery disease at 1-year follow-up after ACS by using the EuroQol five-Dimensional (EQ-5D) questionnaire. The study found that patients with ACS and diabetes reported more difficulties with usual



activities (56.9% vs. 41.3%,  $P = 0.03$ ), mobility (12.3% vs. 4.1%,  $P = 0.03$ ), anxiety/depression (33.8% vs. 14.9%,  $P < 0.001$ ) and pain/discomfort (50.8% vs. 17.8%,  $P < 0.001$ ). Furthermore, EQ-5D questionnaire utility scores were significantly lower for patients with ACS with diabetes than for those without diabetes ( $M \pm SD = 67.8 \pm 8.8$  vs.  $73.6 \pm 5.4$ ,  $P = 0.0001$ ). The poorer health-related quality of life among patients with diabetes and ACS after discharge from hospital highlights the need for individualized treatment programs to improve health outcomes among these most vulnerable people (Shah & Deshpande 2014).

Patients with T2D following ACS have been shown to experience low self-confidence, low confidence in HCPs and considerable feelings of hopelessness and fatigue (Jo Wu et al. 2008). Additionally, it has been reported that those patients with a combination of T2D and cardiovascular comorbidities such as ACS have a much lower health status, reduced physical functioning and poor well-being compared to those without cardiovascular comorbidity (Wermeling et al. 2012). Moreover, the relationship between patients with cardiac disease and their partners or close relatives may be affected negatively following discharge from hospital, as indicated by the findings from a systematic review of 20 studies which evaluated the impact of cardiac disease on the patient-partner relationship. The review indicated that both patients and their partners seemed to experience great distress, more sexual concerns, communication deficiency and concerning feelings about their relationship following the cardiac event as well as a dramatic shift in roles and responsibilities (Dalteg et al. 2011).

People who face a health threat attempt to explain their health situation by developing their own perceptions of the health threat through forming concepts about its causes, consequences, timeline and controllability (Leventhal et al. 2016). In a multilevel modelling study involving 305 patients with multimorbidity such as diabetes and heart diseases, Schüz et al. (2011) examined the influence of personal-level factors and self-efficacy on illness-specific representations and perceptions of personal and treatment control. The study showed that less self-efficacious patients are less likely to perceive their diseases as controllable by treatment and personal control, irrespective of the possible concerns these diseases could cause, and they are less able to maintain suitable self-management. Another study found that beliefs of patients about the efficacy of

treatment strongly affect adaptive behaviours such as treatment adherence in the face of chronic disease such as heart disease (Yohannes et al. 2007).

Patients with T2D may experience a decrease in health status and well-being and an increase in diabetes-related distress shortly after diagnosis with the first ACS (Kasteleyn et al. 2016). After patients with T2D have been exposed to ACS, self-management of their health condition and any complications may become more complicated as they then need to cope with two diseases, more comorbidities and risk factors all at once (Powers et al. 2016). Therefore, it has been recommended that self-management interventions are needed to optimise outcomes in relation to symptom burden, quality of life and physical function for the growing population of patients with T2D and ACS (Peterson et al. 2006). Also, as patients with T2D and ACS and their partners often lack tailored support and information on the combined effects of the two diseases from HCPs after a first ACS, they would appreciate any tailored self-management support to be provided to them shortly after discharge from hospital (Kasteleyn, Gorter, van Puffelen, et al. 2014). Such findings underpin the recommendations of the ADA (2018), which include improving the transition from hospital to home for patients with diabetes after an acute cardiac event, and providing a structured discharge plan tailored for patients with diabetes that, in addition to identifying durable medical equipment, medication reconciliation, supplies and prescriptions, includes appropriate education at the time of discharge (ADA 2018).

#### ***2.1.2.5 Importance of need for developing and implementing self-management interventions for patients with both conditions.***

Self-management education and/or support interventions play a very effective role in preventing chronic disease-related complications and are becoming more common as a structured approach to helping patients learn to better manage their chronic disease; it is also apparent that a self-management approach leads to improved acceptance of and compliance with healthier behaviours by patients with diabetes and cardiac diseases (Franek 2013). Therefore, tailored self-management interventions to reduce distress and improve self-management skills, cognitive ability and the psychological well-being of patients with T2D and ACS have been strongly recommended and are much needed.

A recent randomised controlled trial conducted in the Netherlands by Kasteleyn et al. (2016) evaluated the effectiveness of a tailored, supportive intervention approach in influencing diabetes-related distress, well-being, health status and clinical outcomes in patients with T2D after a previous diagnosis with ACS. In that study, 201 patients with T2D and ACS were successfully randomised. Those in the control group received three home visits of 45-65 minutes by a diabetes nurse at 4, 6 and 14 weeks after discharge during which the nurse explored their illness perceptions and used motivational interviewing strategies such as in-depth discussion, goal setting and homework to increase their self-efficacy. Those in the intervention group received one, roughly 15-minute telephone consultation within 3 weeks of discharge. The outcomes were measured shortly after patients were discharged from hospital (baseline time) and at 5 months (follow-up time) using three validated questionnaires for diabetes-related distress (Problem Areas in Diabetes), health status (Euroqol 5 Dimensions; Euroqol Visual Analogue Scale) and well-being (WHO Well-Being Index). The study showed that mean diabetes-related distress was low at baseline time (intervention group:  $8.2 \pm 10.1$ ; control group:  $9.2 \pm 12.4$ ) and did not change at follow-up time (intervention group:  $9.2 \pm 12.4$ ; control group:  $9.0 \pm 11.2$ ). Significant improvement was recorded in the intervention group for both baseline health status (baseline:  $69.9 \pm 17.3$ ; follow-up:  $76.8 \pm 15.6$ ;  $P < 0.001$ ) and well-being (baseline:  $58.5 \pm 28.0$ ; follow-up:  $65.5 \pm 23.7$ ;  $P = 0.005$ ). However, no improvement was recorded in the control group for either health status (baseline:  $68.6 \pm 15.9$ ; follow-up:  $69.9 \pm 16.7$ ;  $P = 0.470$ ) or well-being (baseline:  $57.5 \pm 25.2$ ; follow-up:  $59.6 \pm 24.4$ ;  $P = 0.481$ ). In regard to the clinical outcomes (HbA1c, blood pressure and cholesterol), no significant differences between baseline and follow-up times were recorded in either the intervention or the control group. Patients in both groups reported low levels of diabetes-related distress, well-being and health status after their diagnosis with ACS. Therefore, design and provision of self-management support for those patients with T2D after an acute coronary event are needed and may improve patient's health-related outcomes (Kasteleyn et al. 2016).

A recent "umbrella" review of 51 systematic reviews and meta-analyses (36 for T2D and 15 for ACS) has been conducted to identify the current evidence on health education-related interventions for patients with T2D or ACS; the review also sought to identify the content, delivery methods, setting, intensity and duration required for effective intervention with the aim of offering recommendations for educational

interventions tailored for patients with T2D and/or ACS (Liu et al. 2017). Thirty reviews (58.8%) were rated as being of high methodological quality using the Assessment of Multiple Systematic Reviews (AMSTAR) (Shea et al. 2007); the remainder were assessed as moderate.

The review consisted of 1324 relevant studies and involved more than 288,057 patients (the actual total is unavailable as 15 studies did not indicate the sample). Eight databases were searched from January 2000 through May 2016 (Liu et al. 2017). The review found that most interventions were delivered post-discharge from hospital, and that the most common HCPs providing education for patients with T2D or ACS were either nurses or multidisciplinary teams. Face-to-face educational sessions were the most frequent and efficient delivery methods, although many sessions were also delivered through follow-up telephone calls or via web contact. An average of 3.7 topics was covered in each education session and the frequency of sessions was weekly or monthly. Out of ten types of health education-related interventions used for patients with T2D, only self-management educational interventions, psychoeducational interventions, culturally appropriate health education and group medical visits were generally effective in terms of improving patient health outcomes such as HbA1c reduction and knowledge, lifestyle and psychological outcomes. Of the three main types of health education-related interventions used for patients with ACS, psychoeducational interventions and secondary prevention educational interventions, which include strategies to manage medication, promote healthy lifestyles and reduce cardiovascular complications, were generally effective in improving patient health outcomes such as quality of life and knowledge and in reducing smoking, depression and readmission due to cardiac-related complications, although there was insufficient evidence of improvement in key clinical outcomes.

The findings of the review indicate that there is a substantial amount of current evidence about the efficacy of health education interventions, their content and modes of delivery for patients with T2D or ACS. Even more interesting, however, is that none of the reviews included in this wide-ranging review focused on patients with both T2D and ACS together. Thus, there is a clear need for further rigorous investigational studies of educational interventions for patients with T2D and ACS with particular focus on their feasibility and effectiveness (Liu et al. 2017). The lack of health education interventions tailored for such patients and focused on managing both conditions, their risk factors and

complications at once, and the very limited evidence regarding the effectiveness of interventions delivered in secondary healthcare settings for patients with T2D and ACS were among the main inspirations for this study, which includes a systematic review of an evaluation of the effectiveness of self-management interventions for patients with T2D and ACS in secondary care settings and following discharge from hospital. This systematic review will be discussed in the next section of this chapter.

### **2.1.3 Impact of Health Literacy and Low Income on Self-Management of Chronic Disease**

Health literacy is defined as the degree to which persons have the capacity to obtain, process and comprehend basic health information and services needed to make suitable health decisions (Ratzan & Parker 2000). Although a high level of education or literacy does not ensure a good level of health literacy among patients with chronic diseases (Schrauben & Wiebe 2017), in general, low levels of education among people with chronic diseases are associated with poorer health, lower self-efficacy and more stress (WHO 2017). People with low education levels mostly tend to have lower incomes, socioeconomic mobility, poorer working conditions and insecure jobs, all of which contribute to adverse health outcomes (Mikkonen & Raphael 2010). Moreover, having a low education level is associated with reduced general literacy and health literacy in particular, which in turn negatively impacts on the development of self-management behaviours and skills (Mikkonen & Raphael 2010). At the patient level, often good health literacy is foundational to successful prevention and management of chronic disease (Poureslami et al. 2017).

For example, a systematic review was conducted to examine the impact of low health literacy on the use and cost of healthcare and health outcomes among adults. The review involved a search of main five databases (MEDLINE, CINAHL, PsycINFO, ERIC and Cochrane Library) as well as hand-searching for articles on health literacy published between 2003 to 22 February 2011, and for articles on numeracy published between 1966 to 22 February 2011. The review identified that low health literacy has been associated consistently with reduced medication adherence level and use of preventative health services, higher rates of mortality and hospitalization, and generally poorer health outcomes (Berkman et al. 2011).

However, a descriptive systematic review by Schaffler et al. (2018) of trials published between 2000 and 2015 evaluating the efficacy of self-management interventions in people with low health literacy or low income diagnosed with a chronic disease such as diabetes and coronary heart diseases reached a different conclusion. Of the 2976 studies retrieved, 23 were included and reviewed, ten of which reported a significant positive effect on at least one primary outcome. The review found that efficacious empowerment (self-efficacy) and disease-specific quality of life of those patients was positively affected by these interventions. Also, the review found that effective self-management interventions most often included problem-solving and taking action and/or resource utilisation. However, the efficacy of interventions did not seem to vary by format, mode of delivery, duration or whether these included people with low income and/or low health literacy. These findings indicate that further studies of high-quality, self-management interventions evaluating problem-solving in combination with resource utilization and taking action among patients with chronic diseases and low health literacy and income are needed (Schaffler et al. 2018).

Both T2D and ACS are complex and chronic conditions, each one requires patients to grasp sophisticated concepts and skills for managing their diseases (WHO 2014). Since health literacy levels can be low among middle-aged and senior adult patients, there are concerns about the impact of these low levels of health literacy on knowledge and comprehension of patients that subsequently could impact negatively on their decision making, self-management skills and treatment adherence (Speros 2009). Therefore, to promote comprehension and instil positive health behaviour changes among patients with low health literacy, nurses or HCPs need to use multiple teaching strategies and clear communication that is individualised, purposeful and demonstrates acceptance and respect when providing health education for those patients. This finding underpins the recommendations of the ADA, which emphasised the need for clear communication either directly with patients or via structured hospital discharge summaries in order to facilitate their safe transition from hospital to home and outpatient care (ADA 2018).

Another systematic review reported that there was a significant association between low health literacy and both poorer health outcomes and poor medication management (Chesser et al. 2016). This review emphasised that there is a need for a validated and standardized clinical health literacy screening tool through which to identify those

patients with chronic diseases and low health literacy, in order to help HCPs to evaluate the impact of health literacy on chronic disease management and help them use appropriate communication methods (Chesser et al. 2016).

Likewise, morbidity and mortality in many low and middle-income countries (LMICs) is associated with cardiovascular diseases, mainly coronary heart diseases in recent years, and it is estimated that about 80% of cardiovascular mortality and morbidity worldwide occurs in LMICs. Patients with chronic diseases such as T2D and ACS in LMICs are more exposed to cardiovascular risk factors such as smoking, bad diet, physical inactivity, hyperglycaemia, high blood pressure and total blood cholesterol. Therefore, a high incidence of cardiovascular disease and lower health awareness about conditions are prevalent in LMICs, and it is possible that providing behavioural and educational programs for patients with chronic diseases such as T2D and ACS may have beneficial effects on patient health outcomes (Uthman et al. 2015, 2017).

In sum, most of the studies suggested that low health literacy and low income are both associated with higher rates of chronic disease and poorer health outcomes. Interventions for improving self-management skills among low-income individuals with low health literacy may have profound effects on patient health outcomes, especially when appropriate education and communication methods are used.

A systematic review for evaluation of the effectiveness of self-management interventions for patients with T2D and ACS will now be presented in next section. This section discusses the method and key findings of this review.

## **2.2 Section Two: the systematic review**

An evaluation of the effectiveness of self-management interventions for people with type 2 diabetes after an acute coronary syndrome: a systematic review

### **2.2.1 Introduction**

As already mentioned, where T2D and ACS co-exist, these conditions generate high levels of mortality and morbidity worldwide and in the LMICs particularly. Undoubtedly, expose the patients with T2D to ACS have been found to significantly increase physical, emotionally and financially burdens for patients themselves and health services after they discharge from hospital. And the need for integrated cognitive, behavioural or educational interventions to promote self-management of patients with both conditions is logical and urgently needed.

However, tailoring self-management interventions requires assessment of the needs and abilities of the patients through initial evaluation of individual's characteristics and based on this evaluation the feedback should be more personalised. Evidence suggests that patients can be more motivated if they perceive that the intervention is relevant to their personalised condition and they believe that the intervention can enable them to achieve positive outcomes (Radhakrishnan 2012). Thus, the process of developing effective interventions could be expensive, taking both time and effort (Stellefson et al. 2008). Moreover, integrating the management of diabetes and cardiac problems is a complex and challenging process (Dunbar et al. 2015). This calls for an urgent need to justify the evidence, cost and resources utilized in developing, implementing and evaluating combined interventions for managing individuals with long-term conditions (Liu et al. 2017).

In line with current developments in intervention development and information technology, health behaviour change interventions are increasingly research based (Noar et al. 2007; Griffin et al. 2014). Healthcare professionals also believe that the health outcomes of patients with chronic diseases will improve if patients are motivated and feel involved in self-managing the complex treatment regimen (Riegel et al. 2009; Liu et al. 2017; Schaffler et al. 2018). Therefore, through this review of Randomised Controlled Trials (RCTs) "the gold standard", the primary researcher aims to evaluate the evidence



on the effectiveness of existing interventions to promote self-management behaviour for patients presenting with ACS following T2D in secondary care settings and shortly after discharge from hospital.

## **2.2.2 METHODS**

### **2.2.2.1 Search methods**

To minimise bias and encourage rigour, replication and transparency (Booth et al. 2016), a systematic process was followed during this review. Comprehensive electronic searches were conducted on six electronic databases: five bibliographic databases (Medline (Ovid SP Version), PubMed, CINAHL Plus, PsycInfo and AMED) as well as Cochrane library which is a collection of six databases including the Cochrane databases of systematic reviews and a register of controlled trials. To improve sensitivity, the search strategy was not limited by sample population (Taylor et al. 2007). However, the search in each database was limited to the empirical studies published in English language and between the period 2005-2014.

Three main keyword clusters were used related to T2D, ACS and self-management interventions. In order to discover and maximise relevant synonyms for the main keywords, a list of relevant terms for each cluster was created by reviewing the appendices of relevant reviews in the Cochrane Library and including Medical Subject Headings (MeSH) and through retrieved relevant articles had keywords noted. This process was repeated until no new keywords were recorded.

Subsequently, 27, 35 and 21 synonyms were identified and used to explore self-management intervention, ACS and T2D respectively. These keywords were categorised into three categories as illustrated in Appendix 1. To improve sensitivity, headings and subheadings for all keywords were exploded without focus a heading during the search. Abbreviations, truncation (\*,\$), wildcards (?,#), proximity searching (adjn, NEAR/n, W/n) and Boolean (and, or, not) were used as appropriate with each database to identify keywords with different spelling and terms. Final results of the search for keywords for population, intervention, comparison and outcomes (PICO) (van Loveren & Aartman 2007) were combined together by using (and). Then the results of the search were limited to adults aged 18 years or over, humans and RCTs by using validated filters with each

database such as for RCTs Cochrane Highly Sensitive Search Strategy to identify randomised trials in MEDLINE: (sensitivity and precision maximising version (2008 revision)) Ovid format was used for Medline database. Full copies of the printed searches are available from the main author. Identified duplicates were removed. Studies recommended by clinical experts and citations from studies which met the inclusion criteria were also retrieved by manually reviewed the references list of each retrieved trials to identify any other relevant studies.

#### ***2.2.2.2 Search outcome***

The initial search conducted in February 2015. In total, the search yielded the identification of 6,032 studies. Of which, 808 studies were retrieved from Medline (Ovid SP Version), 2,887 PubMed, 832 CINAHL Plus, 176 PsycInfo, 1325 Cochrane Library and only 4 from AMED. A total of 1,757 duplicates were removed. Thus, the title and abstract of 4,275 studies were screened by the primary researcher according to the PRISMA Guidelines (Moher et al. 2009) and in accordance with the following inclusion and exclusion criteria that was developed a priori of the search according to PICO format (van Loveren & Aartman 2007):

##### ***1. Population***

Male or female, aged 18 or over from all ethnicities, socioeconomic and educational backgrounds, diagnosed with T2D (established or newly diagnosed), and recently experienced coronary event with at least one of the ACS classification. However, for example, studies that included both types of diabetes (1 and 2) participants, in which the results could not be extracted for participants with T2D only, were excluded.

##### ***2. Intervention***

Interventions designed for patients with T2D following a coronary event, delivered by any healthcare professional/researcher and targeted to promote self-management and health outcomes for those patients diagnosed with diabetes and ACS in secondary care settings and/or after discharge from hospital. Studies where the target intervention was a part of complex intervention, where its effects could not be isolated were excluded.

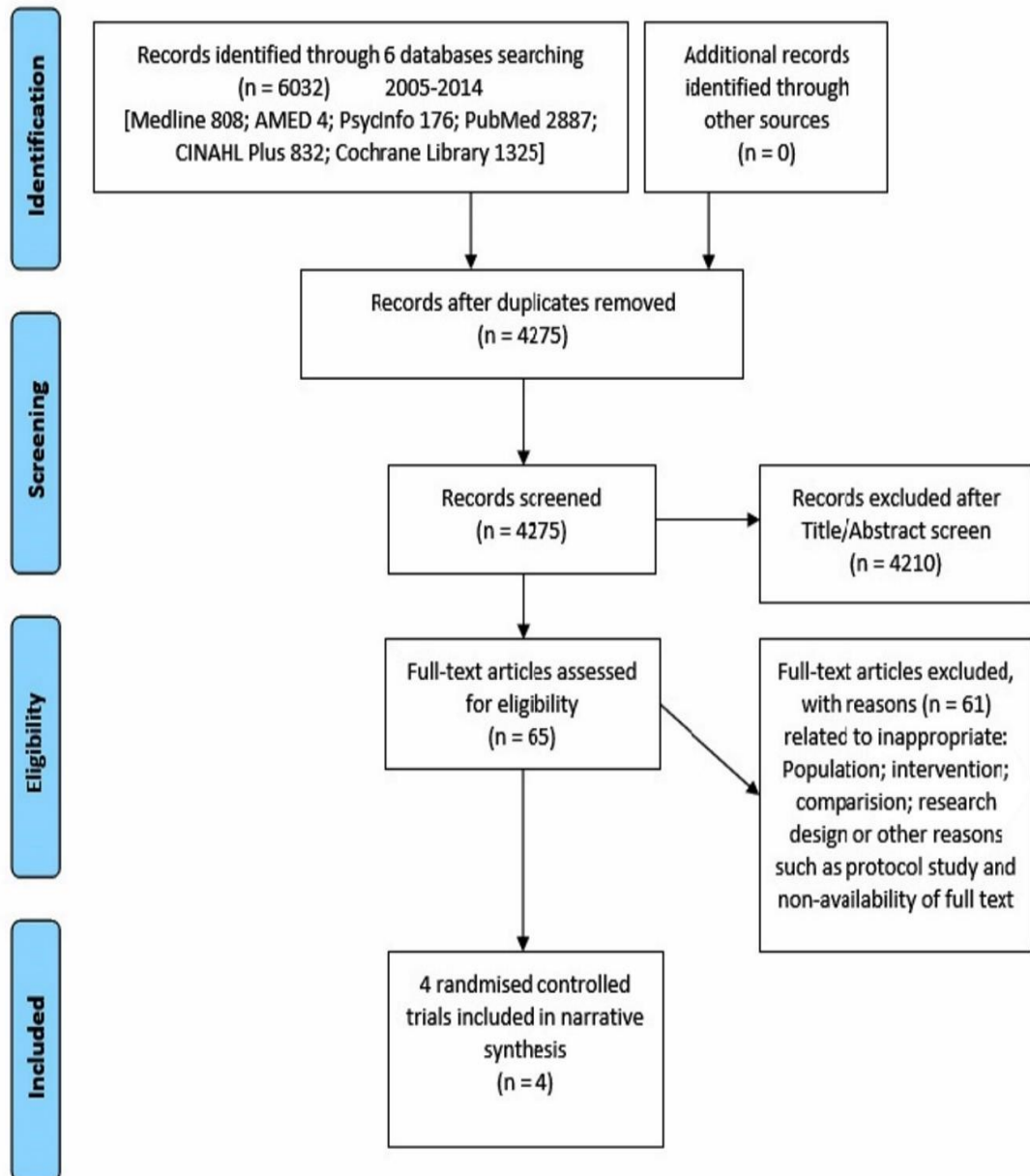
##### ***3. Comparison***

Usual care groups were compared against the groups that received usual care plus the intervention.

#### **4. *Outcomes***

Any behavioural outcome such as self-care behaviour changes, dietary control, physical activity modification and adherence to medication; clinical outcomes such as HbA1c, blood pressure and cholesterol level; or cognitive/psychological health outcomes such as self-efficacy, quality of life, knowledge and compliance level.

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Guidelines was used to structure the review and the flow of information through the four phases of the systematic review is outlined in a Figure 2-1 as recommended by Moher et al. (2015). In a stepwise refinement, approach of duplicate records, followed by title then abstract (Taylor et al. 2007; Booth et al. 2016) a total of 65 studies potentially met the inclusion criteria and 4,210 studies were excluded. Full-text articles were obtained for the remaining 65 studies and read by the primary researcher to assess eligibility. Theoretical articles, protocols, commentaries or discussion studies were excluded at this stage. In accordance with the aim of this review and PICO criteria consensus was obtained by two researchers that 4 studies met the systematic review objectives and were deemed appropriate for inclusion.

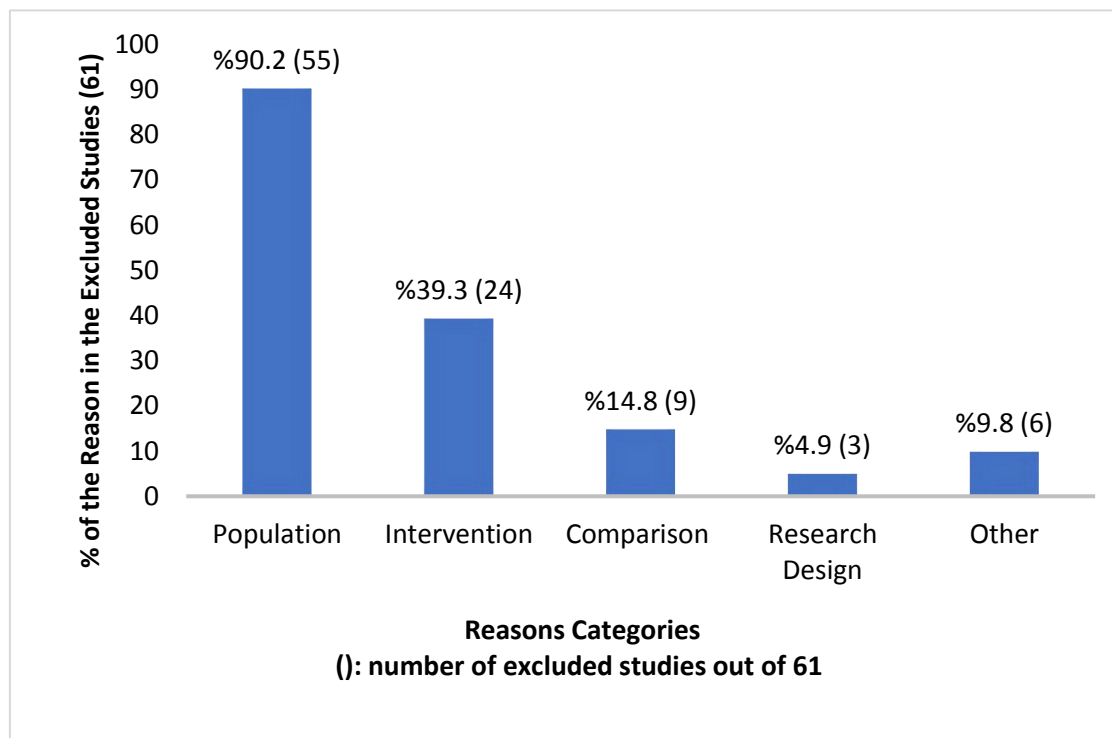


**Figure 2-1: PRISMA flow chart**

Sixty-one studies were excluded due to include each study at least one reason. The reasons for exclusion were categorised into five categories: (See Figure 2-2)

1. Inappropriate population: was the most common reason for excluding the studies. Most of excluded studies did not include participants with both conditions or did not focus on patients with diabetes post ACS.

2. Inappropriate intervention: for example, primary care interventions, not designed to be provided immediately after ACS or focused on evaluating the effects of a specific treatment such as a medication.
3. Inappropriate comparison: no control group or the control group received an alternative treatment such as a specific procedure related to medication or diet.
4. Inappropriate research design: no any related evidence of randomization.
5. Other reasons: overall 6 studies (3 protocols, 1 conference abstract, 1 unavailable full-text and 1 duplicate).



**Figure 2-2: Reasons for exclusion**

### 2.2.3 Data extraction and quality assessment

All titles, abstracts and full-texts identified were analysed according to PICO criteria by the primary researcher. The reporting quality of each included study was assessed using the Consolidated Standards of Reporting Trials checklist (25-item checklist CONSORT)

(Schulz et al. 2010). The overview of the reporting quality is shown in Table 2-1. The full CONSORT checklists for the final included studies are available in Appendix 2.

**Table 2-1: Reporting quality of the fourth studies included according to CONSORT**

	Checklist item	N	% (out of 4 studies)
<b><u>Title and abstract</u></b>	1a	2	50%
	1b	3	75%
<b><u>Introduction</u></b>			
Background and objectives	2a	4	100%
	2b	4	100%
<b><u>Methods</u></b>			
Trial design	3a	4	100%
	3b	0	0%
Participants	4a	3	75%
	4b	3	75%
Interventions	5	4	100%
Outcomes	6a	4	100%
	6b	0	0%
Sample size	7a	3	75%
	7b		N/A
Randomisation: Sequence generation	8a	3	75%
	8b	3	75%
Allocation: Concealment mechanism	9	2	50%
Implementation	10	1	25%
Blinding	11a		N/A
	11b		N/A
Statistical methods	12a	4	100%
	12b	4	100%
<b><u>Results</u></b>			
Participant flow	13a	3	75%
	13b	2	50%
Recruitment	14a	3	75%
	14b		N/A
Baseline data	15A	2	50%
Numbers analysed	16	3	75%
Outcomes and estimation	17a	4	100%
	17b		N/A
Ancillary analyses	18		N/A
Harms	19	4	100%
<b><u>Discussion</u></b>			
Limitations	20	4	100%
Generalisability	21	1	25%
Interpretation	22	4	100%
<b><u>Other information</u></b>			
Registration	23	0	0%
Protocol	24	0	0%
<b><u>Funding</u></b>	25	3	75%

The methodological quality was assessed independently by two researchers using the Scottish Intercollegiate Guidelines Network (SIGN) 13-item methodology checklist for RCTs (SIGN 2012). The SIGN quality assessment checklist was used due to its clarity, specifically designed to assess the RCTs its questions cover the dimensions of this review aim and that related to PICO, it provides overall assessment for the study in addition high inter-rater reliability. The items of SIGN checklist are especially designed to assess the methodological rigour and the internal validity by a series of statements (SIGN 2012). Based on specific indicators relating to sampling, method and data analysis, overall assessment for methodological quality was graded for each study by using following coding system ('++' for high quality study, '+' acceptable, '-' low quality and '0' unacceptable – reject). The overall grade for included RCTs illustrated in Table 2-2.

**Table 2-2: Clinical Characteristics of Identified Studies**

Name of Study	Time	Design	N	Comparison N (%)	Duration	Follow-up data	Drop-out % (n)/ reasons	Mean age ± year or (range)	Men%	SIGN Rate
(Wu et al. 2012b)	Aug 2009 - Dec 2010	RCT-2arms	30	C:13 (46.4) I: 15 (53.6)	4 weeks	4 weeks	6.66 (2) / Transfer	I: 71.5 ± 9.9 C: 62.7 ± 13	71.4	+
(Wu et al. 2012a)	NR	RCT-2arms	20	C:10 (50) I: 10 (50)	4 weeks	4 weeks	NR	NR	NR	+
(Wu et al. 2009)	Dec 2005 - July 2006	RCT-2arms	28	C: 10 (50) I: 10 (50)	4 weeks	4 weeks	28.5 (8) /NR	NR	NR	+
(Soja et al. 2007)	March 2002 – March 2003	RCT-4arms [2arms for T2D patients & 2arms for IGT patients]	68 with T2D out of 104	C/T2D: 34 (50) I/T2D: 34 (50) C/IGT: 17 (47.2) I/IGT: 19 (52.8)	1 year	3 months and at 1 year	10.29 (7) /NR	I:61.1 (43-79) C:65.7 (42-82)	65	++

**Notes:** C: control group; I: interventional group; NR: not reported; IGT: impaired glucose tolerance; N: number

All differences in scoring were discussed between the two raters and the quality rating was reached through a consensus of opinion between the raters. The key aspects from using both CONSORT and SIGN checklist were to use a well-designed extraction form which enabled accurate and complete data reporting and recording.

#### **2.2.4 Data Synthesis**

A narrative approach to the synthesis of results it was used in this review due to the methodological and outcome variations showed between the included studies. The included studies varied in criteria in terms of eligibility, intervention characteristics, the effects of the intervention and outcome results. Therefore, the extracted data could not be analysed quantitatively. Consequently, a decision was taken to provide a narrative synthesis as recommended by the PRISMA statement (Moher et al. 2015) and through followed a general framework for narrative synthesis delineated by Popay et al. (2006), with focusing on developing a preliminary synthesis of the findings of included studies, exploring relationships in the data and critical appraisal of the synthesis process which is documented within review limitations.

During this review, the primary researcher was used different techniques for developing a preliminary synthesis, including: textual descriptions of included RCTs characteristics and main results, groupings and clusters findings, tabulation, transforming data into a common rubric, and vote counting as a descriptive tool and translating data (Popay et al. 2006). So, the percentage of participants and drop-outs were calculated for each study. The summary results of the characteristics of population, intervention, outcome measures, randomisation procedure and key results were identified (see Appendix 3).

#### **2.2.5 RESULTS**

Four RCTs were identified. Two of them were pilot studies and a decision was taken to include them, as combined interventions to promote self-management behaviour for patients with T2D immediately after an acute cardiac event are underway and there is a need to consider each lesson that could be drawn from these studies even they were of a small scale or in some findings poorly reported. Understanding the key features of such studies may inform the direction in which to develop the structure and evaluate the



feasibility of combined interventions to be used in future research. The results from a total of 146 patients are presented. The four trials included and their characteristics are shown in Table 2-1.

Based on the SIGN checklist (SIGN 2012), no study had overall score low enough to warrant exclusion therefore 4 studies were included. The methodological quality of one of the identified trials was high quality (++) (Soja et al. 2007), and three were acceptable (+) (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b).

#### ***2.2.5.1 Countries and settings***

Three of identified trials were conducted in Australia and one in Denmark. All the trials took place in an acute hospital setting with most patients recruited from the department of cardiology such as a Coronary Care Unit (CCU) or cardiac rehabilitation setting. Patients in all included studies were invited to participate immediately after physiological recovery from cardiac problem.

#### ***2.2.5.2 Participants, diagnosis and study arms***

Two studies included patients who had T2D and had recovered from a coronary event without reporting any further classification about the diagnosis (Wu et al. 2009 and Wu et al. 2012a). One included patients with T2D who had recovered from ACS (32%), other coronary conditions (32%) or heart failure (36%) (Wu et al. 2012b). Three studies incorporated a two arm trial design (Wu et al. 2009; Wu et al.2012a; Wu et al. 2012b), while one incorporated four arms and included patients who had either T2D (65.4%) or Impaired Glucose Tolerance (IGT) (34.6%) and had been admitted to hospital with either ischemic heart disease (67%), congestive heart failure (7%), or had at least 3 risk factors for ischemic heart diseases (26%) (Soja et al. 2007).

#### ***2.2.5.3 Baseline data and similarity***

Sample sizes ranged from 20–68 participants. It seems most likely that the mean age of the study sample for two studies more than 60 years for both participants at control and intervention groups (see Table 2-1). The main purpose of randomisation in RCTs is to achieve interventional groups with similar baseline characteristics. To promote internal validity, assessing the significance of differences between the two groups at baseline is essential (Sedgwick 2014). Significant differences between two groups at baseline were

reported in three studies. Two of them reported no substantial difference (Soja et al. 2007; Wu et al. 2009), and one found a significant difference in gender, where the control group included only one female out of 13 participants, and this perhaps has affected the study outcome (Wu et al. 2012b). However, inadequate information about the differences in characteristics between groups at baseline were observed in these three studies, where some related and influential factors such as educational level, social classification and employment status were not taken into account. Moreover, one study did not mention any demographic data or describe the differences between the two groups at baseline (Wu et al. 2012a). Failure to use appropriate groups and assess the important differences in the composition of the study groups at baseline with regard to characteristics that could affect response to the intervention being investigated, could lead to a bias in outcomes (SIGN 2012).

#### ***2.2.5.4 Drop-out, duration of intervention and follow-up time***

Dropout rates ranged from 6% to 28% with an average of 15.15% in three studies, one study did not reported loss to follow-up (Wu et al. 2012b). The duration of the intervention was 4 weeks and the follow-up data were collected immediately after the intervention was completed in three studies (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b). While in one study the duration was 12 months and the follow-up data were collected at 3 and 12 months. (See Appendix 3) (Soja et al. 2007).

#### ***2.2.5.5 Intervention characteristics***

The intervention of two trials was a Cardiac-Diabetes Self-Management Programme (CDSMP) whose design was based on self-efficacy theory (Bandura 2004), to provide educational information aimed at developing basic skills of self-management such as monitoring blood glucose level. However, this programme seems to be more focused on the management of diabetes following cardiac event only, through focused on promoting self-management behaviours of patients to cope with diabetes after the cardiac event rather than focus to help patients to cope with diabetes and cardiac diseases together. This programme was combined with a booklet of educational concepts and fictitious patients' stories to encourage patients to think positively and apply the self-efficacy model strategies (Wu et al. 2009; Wu et al. 2012a). The same programme was used in the Wu et al. (2012b) study after being modified by adding a Digital Video Disc (DVD) depicting models of successful self-management and using trained peers to follow-up patients after

discharge. On the other hand, the Soja et al. (2007) study provided a secondary prevention programme constructed according to international guidelines such as rehabilitation of people with heart disease using Danish clinical guidelines (Rehabilitation of people with heart disease - Danish clinical guidelines 1997) and standards of medical care for patients with diabetes mellitus (Association 2001). The study used an intensified comprehensive cardiac rehabilitation programme and combined educational sessions, supervised exercise training and cooking lessons, smoking cessation, nutritional counselling, psychosocial support, physician consultations and pharmacologic therapy. Also, this programme was integrated with a diabetes module that comprised individual counselling and interactive teaching sessions.

All interventions combined at least two types of medium to deliver the components of the intervention, but were commonly delivered through in person one-to-one sessions at healthcare setting such as a CCU, a physician/outpatient clinic or the patients' home, then followed with telephone calls or text messages to deliver counselling and consultations. One study used a multimedia DVD to deliver a part of the intervention (Wu et al. 2012b). Another comprised of interactive teaching sessions (Soja et al. 2007).

A range of providers delivered the included interventions such as by only a researcher in field of CVD (Wu et al. 2009), the nurse researcher who was a highly trained registered nurse and had coronary and diabetes care experience (Wu et al. 2012a), or the nurse researcher engaged with trained peers who were former patients with similar diseases and followed-up patients by telephone calls and text messages (Wu et al. 2012b). In Soja et al. (2007) study the providers were a multi-professional team including nurses, physicians trained in cardiology and internal medicine and they were supported by specialists such as a podiatrist and ophthalmologist to provide regular surveillance for patients with T2D.

#### ***2.2.5.6 Outcome measures***

A wide variety of outcome measures were used, but no study assessed a combination of clinical, behavioural and psychosocial variables. Instruments such as questionnaires and scales were used in three studies to measure self-management outcomes (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b). One study measured the significant changes in the clinical and biomedical variables to assess the effectiveness of the intervention (Soja et

al. 2007). Data were analysed descriptively by using SPSSv18 (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b), or SASv8.2 (Statistical Analysis System) (Soja et al. 2007). In all studies statistical significance was defined as 1 or 2-sided  $P < 0.05$  (see Appendix 3).

### Psychological Outcomes

Psychological outcomes were measured at baseline and 4 weeks follow-up by the diabetes management self-efficacy scale (McDowell et al. 2005) and diabetes knowledge questions (Persell et al. 2004) in three studies (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b). One study (Wu et al. 2012a) used selected items from the subscales of Brief Profile of Mood States (POMS) (Cella et al. 1987) to assess depression and fatigue. One study (Wu et al. 2009) used mental health and vitality subscales of SF-36 version 2 (Ware et al. 2001).

Two studies reported significant improvements for experimental groups in self-management knowledge (Wu et al. 2009; Wu et al. 2012b) and only one study found a positive effect on self-efficacy of diabetes management (Wu et al. 2012a). Other variables such as depression, fatigue, mental health and vitality levels did not reveal any improvements for the experimental group.

### Behavioural Outcomes

The only behavioural outcome measured was self-management behaviour. Two studies (Wu et al. 2012a; Wu et al. 2012b) measured the self-management behaviour at baseline and 4 weeks follow-up by a Summary of Diabetes Self-care Activities (Toobert et al. 2000). This is a reliable and valid self-report questionnaire that includes items assessing the following aspects of the diabetes self-management regimen: specific diet, general diet, blood-glucose testing, exercise, smoking and foot care. However, the self-management behaviour did not record any improvement in either study, but that may be due to insensitivity of the instrument especially with the short follow-up period (at 4 weeks) in both studies. It is worth noting that no studies included a specific instrument to measure heart disease self-management.

### Clinical Outcomes

In only one study were clinical and biomedical outcomes measured at baseline, 3 and 12 months follow-up (Soja et al. 2007). The HbA1c was measured as a primary outcome to

assess if an integrated intervention would result in better glycaemic control. The differences in the mean of systolic and diastolic blood pressure, lipid control, exercise capacity and other lifestyle modifications were measured as secondary outcomes. However, after one year of use of an intensified comprehensive cardiac rehabilitation program, patients with T2D in the experimental group reported a significant improvement in the mean of HbA1c, fasting plasma glucose level, systolic and diastolic blood pressure.

#### Other Outcomes

The feasibility of the combined intervention or part of it was assessed in two studies (Wu et al. 2009; Wu et al. 2012a). In one study, the feedback from experimental patients and CCU staff on implementing the intervention revealed that it was feasible to hold the educational sessions in a CCU with follow-up at the patient's home and the provided information helped patients to improve their self-management of both conditions (Wu et al. 2009). In another one, the experimental patients and their family were encouraged to provide feedback and comments at the end of the program to assess feasibility and acceptability of incorporating the telephone calls and text-messaging as follow-up approaches. The findings indicated that using follow-up telephone support helped to resolve some patients' concerns after discharge and left a positive impression about support of health professionals for them. Regarding using reminders and reinforcing text messages to the participants and their families, data suggest some usefulness for their ongoing daily self-management, although the participants expressed a desire to receive less written information (Wu et al. 2012a).

### **2.2.6 DISCUSSION**

A key finding of this systematic review is that there were so few studies that were suitable for inclusion, as this highlights the dearth of evidence on this important clinical issue. Recently, Dunbar et al. (2015) concluded that providing an integrated self-care intervention for patients with heart failure and diabetes can significantly improve patients' quality of life, physical functioning and self-reported physical activity. The findings of this review indicated that providing a combined intervention for patients with T2D and a cardiac problem in secondary care settings and immediately after discharge from hospital is feasible and suggests these were marginally successful in promoting self-management behaviour. Although none of included studies performed an analysis for

both the clinical and psycho-behavioural outcomes together for diabetes and cardiac problems, suggesting that there is a lack of standardization for measuring outcomes of both conditions. Moreover, none of the included studies provided a sufficient clarification about the process of integrating the interventions or its components to be suitable for promoting self-management behaviours of patients with T2D and ACS together. However, there did not seem to be an association between medium, duration, providers or dose of combined interventions and intended outcomes in the included studies.

Innovative approaches such as combining the interventions with multimedia technologies or using DVD, follow-up telephones and text-messaging showed effectiveness and applicability to some extent in the included studies. Study participants and their families indicated positive feedback and quite useful experiences. However future research could focus on evaluating efficacy of using multimedia technology only as a way of testing the efficacy of separate components with the programme, and also on investigating the efficacy of using the interactive telecommunications technologies like an interactive text messaging model in conjunction with interventions designed to improve self-management for patients with both long-term conditions.

None of the four studies addressed the cost and resources used in developing and implementing the interventions. Therefore, future research should focus on assessing cost-effectiveness of combining these interventions and provide formal cost-benefits analysis for developing and implementing it. Power analyses to determine effect size were not reported. Moreover, all included studies had inadequate sample size and three of them recommended the need for a larger sample to determine the real effectiveness of its interventions (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b) Therefore, no final conclusion about the effectiveness of these interventions could be reached until a larger, sufficiently powered study is undertaken (Portney & Watkins 2009).

The results of the review should be considered carefully because some threats to the internal validity were observed within included studies. In addition to poor reporting of integration process and inadequately powered samples in above interventions, there were some issues related to inadequate assessment of validity and reliability for some intervention materials such as DVDs and educational booklets (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b), and problems with fidelity in delivering the combined interventions as a result of variability among providers where some combined

interventions or part of them were provided by different professionals or peer supporters with lack of a clear protocol or inappropriate training plan for them. Furthermore, there were a range of types of bias (selection, performance and detection) associated with the methods of the included RCTs due to lack of blinding, poor allocation and concealment mechanisms; inadequate assessment of the differences between baseline characteristics of the groups that were compared; and systematic differences between groups such as significant differences in using intensified pharmacotherapy between study groups (Soja et al. 2007) and weak consistency among intervention providers and among peer supporters (Wu et al. 2012b). Further research should take into consideration these limitations to strengthen the internal validity of a combined intervention design, thus enhancing the reliability of the subsequent results.

### **2.2.7 Limitations and implications for future research:**

- Each of the sample characteristics, cultural issues, ethical factors, beliefs and actual needs of participants in all studies were not clarified adequately, which can affect outcome and the review's transferability to international clinical practice such as in Jordan as developing country. Therefore, a clear picture of the sample characteristics and influencing factors such as illness beliefs for patients with T2D and ACS are needs to be clarified more properly before providing integrated self-management interventions.
- The search was limited by RCTs as the golden standard, six electronic databases, to a specific period (10 years) due to ongoing research and both the framework and the structural timeframe of the PhD study, English Language due to the cost of translation and for tailored interventions to be provided following ACS in secondary care settings and after discharge. This may have affected the number of studies retrieved.
- It seems most likely that the study sample in included studies were mostly elderly people and there was under-representation of female patients in all studies, although this reflects the lower number of females' patients having an ACS compared to males. However, future research design needs to provide the best

opportunity to maximise the difference/variability between the study sample to be more representative.

- Further research is warranted as only four RCTs were conducted, all of them in the developed countries. Which can affect the transferability of review findings to international clinical practice, especially developing countries. Therefore, more research needs to be done in both developed countries as well as developing countries as the rehabilitation services and discharge planning are not existed or rudimentary in these countries and the healthcare system is ill-equipped to prevent and treat the chronic diseases such as T2D and heart diseases.
- There is uncertainty about the process of integrating the components of the interventions and based on any determinants and frameworks have been guided. Therefore, further research needs to make clear how the integrated intervention stitches together the components of the intervention, and how these components enable self-management behaviours of people with T2D and ACS all at once.
- The review indicated that recruiting patients with ACS and collecting baseline data from them and offering them 2-3 short educational sessions during the time of their admission to CCU could be possible.
- Appropriate assessment points were identified to collect the follow-up data and could be applied in future studies, ranged from at 4 weeks after discharge from the hospital to 12 months. This data including biomedical markers, psychological and behavioural data.
- Feasibility studies are warranted as the cultural diversification across healthcare settings and countries are something apparent. In addition to that each recruitment capability, sample characteristics, the retention strategies, the acceptability of interventions and study procedures, and resources and tools of interventions were not identified adequately in included studies.



### **2.2.8 Relevance to this study**

At the conclusion of this systematic review, several lessons, salient factors and challenges have been identified from existing interventions and it needs to be considered in the development stage of intervention. With limited intervention designed for patients T2D and ACS and no final evidence to support effectiveness of these interventions to promote self-management behaviour for patients with both conditions, this indicates a clear need to develop interventions more appropriately for patients with both conditions in Jordanian context and further rigorous feasibility studies with them. The section is presented in the format that it was published (Tanash et al. 2017b) and can be viewed in pdf version in Appendix 4. What does this review contribute to the wider global clinical community is presented in the published paper in Appendix 4.

The theoretical framework will now be presented in next section. This section discusses the common-sense model of self-regulation and the rational for using it in this study.

## **2.3 Section Three: Theoretical framework**

### **2.3.1 The Common-Sense Model of Self-Regulation (CSM-SR)**

According to the main aim of this study, it was necessary first to understand the actual needs of those patients and their motives for change through understanding the patients' lay views of an illness in terms of living with multimorbidity post-ACS. Leventhal and his colleagues developed the CSM-SR of health and illness in the 1980s in order to understand people's illness perception and their ability and intention to perform self-management (Leventhal 1980).

Many social-cognition theories have assumed a range of attributions and beliefs to be precursors of people's health behaviour in recent decades, such as Rosenstock's health belief model (1974), the theory of planned behaviour (Ajzen 1991), transtheoretical (stages of change) model (Prochaska & DiClemente 1994) and Bandura's self-efficacy theory (1977). These theories have been used to identify the complex processes involved in mediating between health threat, pain, stressors, disability and adjustment. Each theory has its contributions and limitations for understanding the process of changing health behaviours. However, these theories have not been conclusive, as none of the individual factors studied have consistently predicted illness and health behaviours (Turk et al. 1986). This may either be due to the above theories not containing the cognitions that predict health behaviour and outcomes, or it may indicate that there were inadequacies in the research (Marteau 1993; Leventhal et al. 2016).

The CSM-SR is a theoretical framework developed to examine individuals' beliefs about their health threats (illness representations) and health behaviours (i.e. adherence to dietary and lifestyle recommendations, prescribed medication regimens and treatment advice) (Leventhal 1980; Leventhal & Steele 1984). The CSM-SR proposes that, in response to illness and other health threats, patients develop parallel cognitive representations (illness representations) and emotional representations (emotional responses to their health threat), which will influence the selection and performance of strategies to cope with that threat, and will in turn influence outcome appraisals (Leventhal 1980; Leventhal 2001). According to the CSM-SR, cognitive representation is ordered into the following five dimensions:

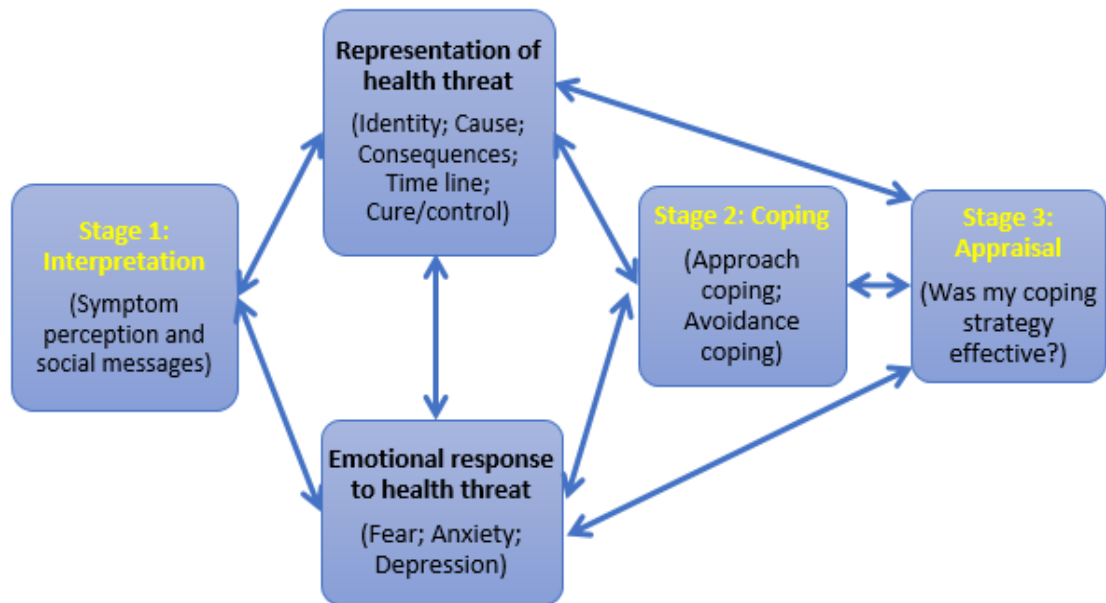
1. Identity (represents the condition and related symptoms)

2. Cause (refers to the individual's perception of what factors caused the condition)
3. Consequences (the expected effects and outcome of the condition)
4. Timeline acute/chronic (the duration of time that the individual believes their condition will last)
5. Control/Cure (the extent to which individuals believe they will control their condition through treatment, or recover from it)

Later, three further cognitive dimensions were added, which address cyclical timeline perceptions (perceptions related to fluctuation in symptoms and changeability of the condition), emotional representations (emotional perceptions related to the condition) and condition coherence (the extent to which a person has a coherent understanding of their condition) (Moss-Morris et al. 2002).

### **2.3.2 Rationale for using the CSM-SR:**

The CSM-SR is a widely used theoretical framework for understanding illness self-management, which explicates clearly the process by which patients become aware of ill health, navigate affective responses to the illness and its symptoms, create perceptions of the illness and potential treatment strategies, formulate action plans for addressing their health and integrate constant feedback on the effectiveness of the action plan and threat-progression (Leventhal et al. 2016). In other words, the CSM-SR illuminates understand what adaptations and coping strategies might need to be formed and maintained in those experiencing chronic illness. Leventhal and his colleagues propose a hierarchically organized model of an adaptive system including three main stages. These are: “representations” of the illness experience that might act as a guide, followed by “coping” responses and the performance of these, and finally “appraisal” or monitoring of the success or failure of coping strategies (Nerenz et al. 1983; Leventhal & Steele 1984) (see Figure 2-3).



**Figure 2-3: The common-sense model of self-regulation**

The CSM-SR proposes the effect of illness perception on coping behaviours and outcomes of patients with chronic illness. Furthermore, this model has been shown to be helpful in developing the interventional programs that facilitate self-management of chronic diseases (Kasteleyn, Gorter, Stellato, et al. 2014). The key concept within the CSM-SR is the idea of beliefs about illness (illness representations). These representations of illness integrate with existing schemata, enabling individuals to make sense of their symptoms and guide any coping actions (Leventhal et al. 1997).

In this study, the patient outcomes that will be assessed as secondary objectives are physiological (e.g. blood glucose and lipid profiles), behavioural (e.g. physical activity and smoking cessation) and psychological outcomes (e.g. knowledge depression and attitude). Based on the CSM-SR, these outcomes are a reflection of the coping strategies of patients with T2D and ACS, and are affected by the patients' illness representations after a diagnosis of ACS (Leventhal & Steele 1984). Thus, it was assumed that acquiring a greater understanding of the illness representations of those patients at an early stage of this study will lead to a better understanding of the patients' actual self-management needs, challenges, experiences and perceptions of their illness. Providing self-management intervention for patients at an early stage after being diagnosed with ACS

could positively change/influence the patients' illness perceptions and representations and subsequently improve their coping strategies and health outcomes, according to Leventhal et al. (2016).

The CSM-SR has a lot of similarities with other theories of problem-solving behaviour, such as the transactional model of stress and coping (Lazarus & Folkman 1984), wherein illness threat can be conceptualized as a stressful experience. However, a novel feature of Leventhal's proposition in the CSM-SR was to describe precisely the active parallel cognitive process of how individuals regulate their responses both to "illness threat" (What is this health threat? and what can I objectively do about it?) and to the individual's regulation of "emotional control" ('How do I feel about it? and what can I do to make myself feel better about it?') (Hale et al. 2007). A description of important aspects of the CSM-SR's history over 50 years of research and theoretical development makes clear the model's dynamic underpinnings, characteristics and assumptions for understanding illness self-management for patients (Leventhal et al. 2016). The CSM-SR arguably offers the best explanation for linking negative perceptions and misconceptions to behaviour and health outcomes (Goulding et al. 2010).

The benefit of using the CSM-SR with patients who are diagnosed with a chronic illness is the potential to explore sophisticated responses to an illness from several domains (Carlisle et al. 2005). Therefore, as individuals with a chronic illness like diabetes and heart disease obtain new information about their condition and evaluate their attempts to treat, moderate or cope with its effects, new illness representations are formed and develop based upon their experiences and various factors. These representations are in effect cumulative and snowball, with information being adopted, rejected or modified as necessary. Therefore, these representations are expected to be linked to the selection of coping strategies, action plans and outcomes.

### **2.3.3 The CSM-SR applications**

The CSM-SR is a useful theoretical framework for understanding coping actions and self-management behaviours and for adults, particularly in the context of chronic illnesses such as diabetes and heart disease (Cameron & Leventhal 2003). Also it having a direct influence on illness outcome (Moss-Morris et al. 1996). In a systematic review of 13

RCTs examined the effect of interventions that applied the CSM-SR as a guide on maladaptive belief change for adults with CHD. The results showed that cognitive behavioural and counselling or educational interventions can be effective in changing patients' beliefs. But the effects of changing beliefs on psychological, physiological and behavioural outcomes remain unclear (Goulding et al. 2010).

According to Leventhal et al. (1997) the emotional responses to illness appear through a number of negative feelings, mainly anxiety, depression and fear, and these emotional responses are very common in most CHD patients after suffering from ACS (Doering et al. 2010; Benyamini et al. 2013; Feng et al. 2016). In such cases, patients experience the three stages of the CSM-SR in response to such this health threat (Leventhal & Steele 1984).

The CSM-SR argues that patients are active problem-solvers in managing their health, self-monitor health-related symptoms and experiences and appraise available alternatives for responding to perceived abnormalities or threat in their health status (Grzywacz et al. 2011). Hence, an understanding of the patients' perceptions of these cognitive and emotional dimensions may determine how and why they cope with such as diabetes and heart disease and adhere to treatment instructions (Jones et al. 2015).

In 2017, a recent meta-analysis conducted by Hagger and his colleagues to evaluate the CSM-SR process in studies adopting the model in chronic illness, including T2D and ACS, examined the intercorrelations among the CSM-SR dimensions and tested the sufficiency of the CSM-SR process, in which relations between illness representations and outcomes were mediated by coping strategies. This review reported that the pattern of zero-order corrected correlations among illness representation dimensions, coping strategies (cognitive reappraisal, avoidance, emotion venting, problem-focused specific, seeking social support, problem-focused generic) and illness outcomes (disease state, distress, physical, well-being, role and social functioning) was consistent with previous analyses. Furthermore, the analyses showed that a process model included direct effects of illness representations on illness outcomes and indirect effects mediated by coping (Hagger et al. 2017). Another systematic review of the effectiveness of interventions using the CSM-SR to improve adherence behaviours for patients with chronic diseases, including adults with ACS or T2D, showed that, of nine eligible tailored interventions for self-management, six reported improvements in adherence behaviours

and three showed moderate to large effects on lifestyle recommendations and return to work (Jones et al. 2015).

In contrast, as early as 1985, a study had explored the relationship between the CSM-SR cognitive representations and adherence in patients with chronic diseases, and found there was no direct relationship between them (Meyer et al. 1985). More recently, a meta-analysis of 23 studies was conducted to explore whether cognitive representations that derived from the CSM-SR were able to predict adherence in patients with chronic diseases such as T2D and ACS. The main findings showed that the relationships between the different cognitive representations of the CSM-SR and adherence are very weak, and that the CSM-SR may not be the most appropriate model to use in predictive studies of adherence (Brandes & Mullan 2014). Therefore, Diefenbach & Leventhal (1996) have suggested that the cognitive representations of the CSM-SR are more useful for understanding the process of adherence and illness self-management than for predicting adherence. However, since then, the cognitive representations of the CSM-SR have been used to predict adherence of self-management behaviours among patients with chronic diseases in many studies. Across these studies there is no consensus about the effectiveness of cognitive representations in predicting adherence (Brandes & Mullan 2014).

Indeed, there is quite a difference between objective clinical tests that show evidence of ACS and T2D, and the experience of pain, stress or other symptoms reported by the patient. For the patient with chronic diseases, the utmost impact of the disease lies in the effect it has on their capability to live a normal daily life, and this will necessarily be the focus of their attention. Therefore, in this research it is important to develop and provide integrated intervention, firstly according to the best understanding how the perceptions, experience and impact of having two serious conditions might influence a patient's interpretation, adherence and response to it in the Jordanian context after ACS; secondly, the intervention should appreciate the multiple levels at which patients' illness representations operate and how they direct their preferences and actions for treatment and the self-management behaviours after discharge from hospital. Such this understanding may enable developing and providing an effective and culturally appropriate intervention.

For example, patients' illness representations (e.g. patients' expectations about the timeline for the effectiveness of treatment after a cardiac event) are likely to develop from the abstract level (e.g. I will feel better once I have started the treatment) to the experimental level (e.g. I have not yet noticed any difference since I started treatment), while the healthcare professional focuses on the actual (It will take three months for this treatment to start to take effect) (Leventhal et al. 2003). Therefore, the CSM-SR dimensions were used to inform the semi-structured interviews guides in Study I and II to help in understanding the cognitive and emotional representations of the study-targeted population from their perspective and their HCPs, through focusing on questions about their needs, beliefs and knowledge of T2D and ACS, the experiences and challenges of living with both conditions post-ACS, and how they self-manage their symptoms. Then, in the light of the results, the appropriate theory for guiding the intervention was revised in Chapter 7. In chapter three, the methodological design used in the study will be presented.



## **Chapter 3: Methodology**

### **Introduction**

The methodological approach used to underpin this study the mixed methods research design. This chapter provides an overview of and a rationale for this approach. A broad discussion of the mixed methods approach and paradigm is presented, including its strengths and weaknesses, before focusing on the mixed methods sequential embedded design (MMSED) and its application to this study. A visual representation of the study design and its application in the study is provided in Figure 3.1 and 3.2, to demonstrate the study's phases and the reasons behind conducting each one. The suitability of the mixed methods design in terms of its contribution to enhancing rigour, and the ethics and governance procedures undertaken are highlighted. Finally, in line with the overall aim of the study, this chapter explains how a mixed method design can contribute to knowledge and can inform policy and practice in relation to enhanced care for patients with Type 2 diabetes (T2D) and Acute Coronary Syndrome (ACS) within Jordanian and other healthcare settings.

### **3.1 Definition of mixed methods design**

Mixed methods design has become increasingly common in health research over the last two decades (Creswell & Creswell 2018). The approach involves integrating or combining both qualitative and quantitative research paradigms to draw on and complement each other's strengths and weaknesses (Bowling 2009). As defined by Johnson et al. (2007), mixed method design is a type of research design in which a researcher combines elements of qualitative and quantitative research approaches in terms of the type of data collected, the data collection and analysis procedures, and the inference techniques employed to broaden and deepen understanding and for corroborative purposes. Therefore, the term refers to any single study, series of studies or a program of several studies that combines qualitative and quantitative data (Creswell & Creswell 2018). From this definition it can be inferred that through the integration of

different research findings, a more comprehensive, balanced, informed and useful picture of the phenomena being studied is possible (Johnson et al. 2007).

### **3.2 Rationale for the use of a mixed methods design**

Taking a pragmatic approach, researchers such as offered by a mixed methods design, to choose the most suitable method(s) to achieve the aim of their research and answer its questions, rather than being constrained by one method (Creswell & Creswell 2018). The increasing popularity of mixed methods research would suggest that many researchers in health science now recognise the value of this pragmatic approach (Scott & Briggs 2009).

The overall aim of the mixed methods design is to expand and strengthen the conclusions of the study and consequently to contribute to the published literature. Ultimately, mixed methods research is about increasing knowledge and the validity of individual studies (Schoonenboom & Johnson 2017). Therefore, the design of mixed methods study should have sufficient quality (Johnson & Christensen 2017). Teddlie & Tashakkori (2009) illustrated that the main three advantages of using a mixed methods design are first, that it can help the research team to achieve research objectives that a single method or other study designs cannot; secondly, that it grants the researchers the chance to collect data from a greater diversity of perspectives; and thirdly, that interpretations and/or comparisons can be made across both qualitative and quantitative methodologies, providing more robust conclusions and contributions than would be achieved by a single method study. According to Greene et al. (1989), there are five main purposes for mixing research methods, which, also re-indicated by Greene (2007) in page 98, These are:

1. *Triangulation of research results*, which seeks convergence, corroboration and correspondence of results from various methods;
2. *Development of research results*, which seeks to use the research results from one method to help inform or develop the other method, for example, using the results of one method/phase to inform the development of sampling, designing, implementation and measurement decisions in another method/phase;

3. *Complementarity of research results*, which seeks elaboration, clarification or enhancement of the results that emerge from one research method with those which emerge from the other research method;
4. *Expansion of research results*, which seeks to extend the range of inquiry and breadth of results by using different methods for different inquiries or uncertainties;
5. *Initiation of research results*, which seeks to reshape the research questions or results from one method with the questions or results from the other method, to provide new perspectives on potential frameworks and to highlight contradictions between the results produced using different methods.

In all cases, the mixing of methods will help the research team to better answer the research questions and collect fuller and richer information than would be possible using a singular design (Schoonenboom & Johnson 2017). However, Creswell & Clark (2018) clarified that the key purpose of using mixed methods is not to seek corroboration but rather to expand understanding of results or phenomena.

### **3.3 The mixed methods paradigm**

Every mixed methods study employs methods that are associated with certain guiding principles and rules and that are selected by researchers to achieve the aim of the research systematically and appropriately. Such principles are commonly known as “paradigms” or “philosophical worldviews”. A paradigm is defined as the worldview or set of beliefs within a community of researchers and experts in the field who share a consensus about which questions are most meaningful and what procedures are appropriate for answering them (Morgan 2007).

According to (Creswell & Creswell 2018; Creswell & Clark 2018), there are four possible paradigms that are widely discussed in the literature and can be applied in mixed methods studies: postpositivism, constructivism (interpretivism), the transformative paradigm and pragmatism. The postpositivist paradigm is sometimes called “empirical science” and “positivist/postpositivist”, but the term “postpositivism” refers to the thinking that developed after the assumptions of positivism, which challenged the traditional concept of the absolute truth of knowledge (Phillips & Burbules 2000).

Postpositivism is a deterministic theory in which causes (probably), determines or influences outcomes. Therefore, the issues or ideas studied by postpositivists reflect the need to identify and evaluate the causes that influence expected outcomes, such as those found in trials and experimental studies (Phillips & Burbules 2000). The accepted approach of researchers within this paradigm generally is to begin with a theory, collect data that either supports or disproves the theory then make essential revisions and conduct additional tests; this approach is associated primarily with quantitative research and experiments (Phillips & Burbules 2000; Creswell & Clark 2018).

Constructivism, by contrast, which is often combined with interpretivism, is associated with qualitative research. Constructivist or interpretivist researchers believe that individuals seek understanding of the world in which they live and work. Researchers often rely as much as possible on the participants' perspectives of the situation or problem being studied in order to interpret or make a sense of the meanings individuals have about the world (Creswell & Creswell 2018).

Transformative paradigm assumes that research inquiry must be intertwined with politics and a political change agenda to confront social oppression at whatever levels it occurs. Therefore, research guided by this paradigm often contains an action agenda or target for reform that may change the lives of participants such as ethnic minorities and individuals with disabilities (Mertens 2014).

Finally, pragmatism is a paradigm that arises out of situations, actions and consequences rather than antecedent conditions as in the postpositivism paradigm (Creswell & Creswell 2018). According to Patton (1990), this paradigm focuses more on applications and solutions to problems or phenomena; in simple terms, its focus is on 'what works'. Researchers adopting this paradigm focus on the research problem, question and aim and use all suitable approaches available to understand the problem (Rossman & Wilson 1985). Therefore, as this philosophy underpins mixed methods research, many researchers adopt pragmatism as the best philosophical basis for mixed methods studies, stressing its value when examining research problems in the social sciences, and take a pluralistic approach to developing their knowledge about the problem (Patton 1990; Morgan 2007; Tashakkori & Teddlie 2010). Thus, the pragmatism paradigm opens the door for mixed methods researchers to use multiple research methods, different paradigms and different research assumptions, as well as different procedures of

data collection and analysis in the same study, based on whichever best meet the aim, needs and purposes of their study (Feilzer 2010; Creswell & Creswell 2018; Creswell & Clark 2018). Therefore, mixed methods studies are primarily associated with pragmatism paradigm (Tashakkori & Teddlie 2010).

In the current study, the pragmatism paradigm was adopted as the overall paradigm based on in-depth appraisal of the aim, objectives and context of the research and on best relevant evidence in the literature. The study adopted a qualitative approach within the interpretivist paradigm mainly in Phase One and employs a mixed methods experimental model with different paradigms in Phase Two. Using both qualitative and quantitative approaches under an umbrella of pragmatism philosophy allows the primary researcher to address and acquire a greater understanding of the research problem, meet the overall aim and objectives of the study and develop and feasibility test the proposed intervention systematically and based on evidence.

### **3.4 Types of mixed methods design**

Tashakkori & Teddlie (2003) demonstrated the complexity of this design by identifying around 40 types of mixed methods design with variant terminology in the literature. However, in a major contribution towards simplification, Creswell & Clark (2018) have developed four core classes of mixed methods design, these are:

- *The convergent mixed methods design* is the most common mixed methods approach, in which the researcher collects both qualitative and quantitative data on the same topic, then, after analysing them separately, combines the two and compares the results to see if the findings prove or disprove each other and to show to what extent the data converge or diverge.
- *The explanatory sequential design* involves two phases of data collection: The researcher conducts a quantitative study followed by qualitative study, and then uses the results from the first phase (i.e. the quantitative findings) to plan or build onto the second, qualitative phase. The overall intent of this design is to achieve a more in-depth understanding of the quantitative results, for example by conducting

qualitative interviews with participants after collecting survey data from them to help explain any confusing, contradictory or unusual survey responses.

- *The exploratory sequential design*, in which the researchers take the reverse approach and begin by conducting the qualitative phase to explore issues with a sample followed by a quantitative phase that can be tailored to meet the needs of the sample being studied. Often the intent of this design is to develop and test better measures for a targeted population.
- *The complex designs*, in which the design can be embedded (e.g., the mixed methods experimental design, the mixed methods case study design and the mixed methods evaluation design). This design involves more steps and procedures than are embodied in the previous three core designs (Creswell & Creswell 2018). Clark & Ivankova (2016) conceptualised a helpful framework for considering the main applications of these complex designs. These are:
  1. Intersecting a secondary method (mixed methods) within a primary quantitative or qualitative research design. In this framework, a mixed method design could be embedded as a supportive or secondary method within a primary qualitative or quantitative design (Clark & Ivankova 2016), in order to understand the participants' perspectives within the context of an experimental intervention, such as a mixed method sequential embedded design (experimental model) (Creswell & Plano Clark 2007). This is the design that is used in this study, as will be discussed later (in section 3.5).
  2. Intersecting mixed methods within another methodology. In this framework, a mixed core design could be added to other approaches to better understand the differences and similarities among different cases (Clark & Ivankova 2016). For example, the mixed methods case study design, which involves the use of one or more core designs within the framework of a single or multiple design/study (such as a case study, longitudinal research, grounded theory) could be used to develop or generate cases based on both qualitative and quantitative results and their integration (Schoonenboom & Johnson 2017).

3. Intersecting mixed methods within a theoretical framework. In this framework, a mixed methods core design could be intersected with an established theory, often in order to call for action or research (Clark & Ivankova 2016). For example, the aim of researchers who use a participatory-social justice design is to assemble evidence in the form of both qualitative and quantitative data, to give voice to participants and collaborate with them in shaping the research (Creswell & Creswell 2018).

### **3.5 Mixed methods sequential embedded design (experimental model)**

In this design, the researcher collects and analyses both qualitative and quantitative data and integrates this information within an intervention trial or experimental studies (Creswell & Creswell 2018). All imbedded design studies one of two types of data (qualitative and quantitative) plays a supplemental role within the overall design while the other type has a core role. Therefore, the qualitative data may be collected at the same time or sequentially, either at a single point in time (one phase) or at multiple points in time during the study (two phases or more) (Punch 2014), depending on the research aim and the resources available (Creswell & Creswell 2018). Also, this design allows the researcher to answer different research questions within the same study by collecting qualitative and quantitative data (Hanson 2006).

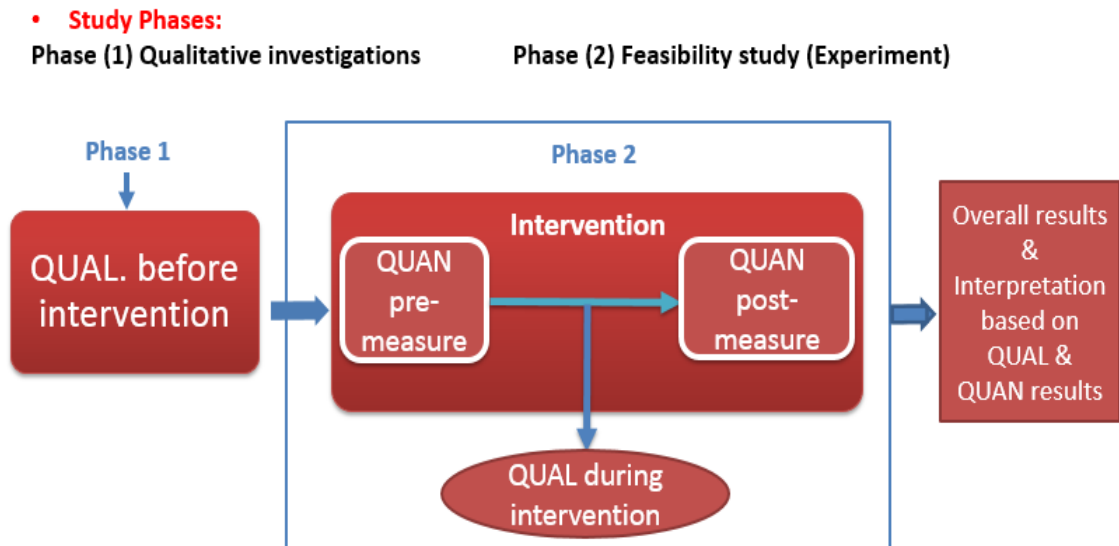
Researchers who adopt this design often add the qualitative data to the intervention trial or experiment in different ways, either before the trial/experiment begins or during or after the trial/experiment (Sandelowski 1996). The key ideas are to carry out exploration before the trial in order to embed the exploratory design before the intervention trial; to embed a convergent design during the intervention trial in order to assess the participants' experiences of the intervention; or to add an explanatory sequential design after the intervention trial in order to assess and follow up on the participants and experimental outcomes (Bryman 2016; Creswell & Clark 2018). However, the researcher should be clear and explicit about the reasons for adding the qualitative data, as the points at which the qualitative data collection and results connect to the intervention represent the integration points in mixed methods research (Creswell & Creswell 2018).

This sequential imbedded mixed methods design is very useful in research that aims to develop an intervention and test the developed intervention in the real world, where often a researcher must have qualitative information before the intervention trial to inform and shape the intervention or measures, to develop an instrument or to help in selecting the participants; sometimes this information also is needed within or after the intervention to explain the intervention results or to follow up on the experiences of the study participants with certain types of outcomes (Creswell & Plano Clark 2007).

Given the nature of the research objectives in this study, this design was deemed to be the most suitable for facilitating the development of the intervention based on the evidence and feasibility testing of this intervention in a Jordanian context. As there is a dearth of evidence to support development and implanting of self-management interventions for patients with both conditions after ACS globally (Tanash et al. 2017b) and in Jordanian context particularly. The qualitative investigations were essential before the intervention trial to identify the factors pertinent to the education and support needs for patients with T2D and ACS, this made up Phase One of the study. The qualitative data were then used to inform development of the intervention,

Feasibility testing of the newly developed intervention with a cohort of patients with T2D and ACS and within the context of a single Jordanian secondary healthcare setting using a mixed methods design made up Phase Two of the study. The complete, two-phase process is illustrated in Figure 3.1.





**Figure 3.1: The study design (mixed method sequential embedded design (Experimental model))**

**Note: Qual:** Qualitative data; **Quan:** Quantitative data

The three main criteria suggested by Teddlie & Tashakkori (2009) and Denscombe (2014) were used to outline the application of the mixed methods design to this study. These are:

1. *Implementation (sequence)*

In the MMSED-Experimental model, the researcher must decide clearly at what point in the experimental study to collect the qualitative data (i.e. before, within or after the intervention trials). This decision should be taken based on the purpose of this qualitative data (Creswell & Plano Clark 2007).

In this study, and as illustrated in Figure 3.1, the qualitative data were collected in Phase one and analysed using an interpretive approach prior to the intervention to inform the intervention content and design. In Phase two, the qualitative data were collected at two points, the first one during the intervention to explain the feasibility and acceptability results of intervention elements, the second one after the intervention to follow up on the experiences of the study participants with intervention, to evaluate their satisfaction and get their comments about the intervention elements. The rationale for conducting a feasibility study is discussed in Chapter 7.

2. *Priority (theoretical drive)*

One of the risks associated with the mixed methods design has been reported in literature, namely that one approach often becomes subordinate to the superior approach (Parahoo 2014). Therefore, Morse & Niehaus (2009) highlighted that all research should be theoretically driven. They indicated that if the theoretical drive in an investigation is focused primarily on exploration and description, it could be “qualitative” or “inductive”; if the focus is testing and prediction, the theoretical drive is “quantitative” or “deductive”.

In the case of mixed methods, there are two components, one of which corresponds to the theoretical drive of the overall investigation more than the other. This is referred to as the “core” component while the other is called the “supplemental” component. Moreover, Johnson et al. (2007) formulated that mixed methods research can have three different drives to prioritise components as follows: (1) qualitative dominant mixed methods research (qualitatively driven), (2) quantitative dominant mixed methods research (quantitatively driven) and (3) equal status, which describes research methods that fall in the area around the centre of the (qualitative-quantitative) continuum; the latter is the logic and philosophy of often mixed methods. Researchers who adopt this drive/philosophy are more likely to consider qualitative and quantitative approaches and data insights as one considers most, if not all, research questions.

Although the distinction is useful in some cases, Schoonenboom & Johnson (2017) did not recommend applying it to every mixed methods design, for several reasons. Firstly, it may decrease the rigor of the study as the supplemental component can be performed less rigorously within the study (Morse & Niehaus 2009). Secondly, it may conflict with the requirement that mixed methods design should be validated in several ways (Onwuegbuzie & Johnson 2006) and thirdly, some believe that the theoretical drive is a feature not of an overall study, but of a single research question or, more precisely, of an interpretation of a research question. For example, if a study includes multiple phases and research questions, it might include several theoretical drives (Schoonenboom 2016).

In the current study, however, although it seems that more weight is attached to the data that emerged from the core qualitative component before and during the intervention, these qualitative data informed, authenticated and provided originality for the intervention content and measures and were embedded in the pre- and post-test quantitative data collection during the intervention. Therefore, an equal status drive

(interactive) was considered, especially as the overall aim and objectives of this study are focused primarily in the area around the centre of the exploration and description (qualitative) – testing and predicting (quantitative) continuum.

### 3. *Stage of integration (relationship)*

One of the keys to a successful mixed methods study design is the effective integration of the data collected during different phases (Greene 2007). Each mixed methods study has at least one point of interface (or point of integration) at which the different types of data, either qualitative or quantitative, are brought together (Morse & Niehaus 2009; Guest 2013). Therefore, researchers employing a mixed methods design must consider how to integrate both qualitative and quantitative data during the study in a rigorous way, instead of simply mixing the components (Schoonenboom & Johnson 2017).

As Creswell & Creswell (2018) have outlined, this integration of the two databases can be (merged) as in convergent methods design, (connected by building) as in exploratory sequential design, (connected by explaining) as in explanatory sequential design or (embedded/nested) as in the complex design.

In convergent design, the two datasets are considered to be independent or separate during data collection and analysis stage (Creswell & Creswell 2018); whereby the two complete datasets from both phases are interpreted and then transformed or consolidated (Creswell & Clark 2018). In exploratory or explanatory sequential design studies, the two datasets may be connected, with one type of dataset building on or creating a need for the other, and the second-phase data cannot be collected until the first phase results are ready (Creswell & Creswell 2018).

In the embedded experimental design (experiment model), the qualitative data may be collected independently of the experiment and used to support or augment the larger design; the data may be collected before, after or even during the experiment (Creswell & Creswell 2018). For example, one dataset involving qualitative data may be imbedded or nested within the intervention design (Creswell & Clark 2018). However, in the mixed methods embedded design, it seems to be difficult to integrate the results when the two methods are used to answer different research questions or to achieve different research objectives in different phases, especially as purpose of conducting the embedded design is not to converge two different datasets collected to answer the same research question.

Therefore, those researchers who employ an embedded design can keep the two datasets of results separate in their study or even report them in separate papers (Creswell & Plano Clark 2007).

More generally, the researcher can consider mixing not only at the data analysis and results stage but also at any one or all of the following research components: the purposes of the research, research questions, methods, approach, theoretical drive and paradigm of the study, as well as the views of other researchers, participants or stakeholders (Schoonenboom & Johnson 2017). It can be useful for the researcher to consider this integration as comparing and bringing together two or more types of data on the basis of one or more purposes. For example, the integrated result could combine a qualitative description of the underlying process or intervention and a quantitatively established effect of this process or intervention (Schoonenboom & Johnson 2017).

The application of the MMSED-Experimental model and how this design added information into an interventional trial through each phase in this study is illustrated diagrammatically in Figure 3.2. The detailed advice from the Medical Research Council (MRC) Guideline for developing and evaluating complex interventions was taken into account during the study (Craig et al. 2013). This guideline helps researchers to achieve best practice by developing and testing their interventions systematically using the best existing evidence and appropriate theory, then evaluating them using a clear phased approach at the initial stages, starting with a series of feasibility and pilot studies targeting all the key uncertainties in the design and intervention, and finally moving on to an exploratory study followed by a definitive evaluation (Craig et al. 2013).

Figure 3.2 summarises the main stages of the current study, its connection to the MRC guideline stages and the main reasons for implementing each phase in the study (Craig et al. 2013). Based on the MRC guidelines, the process from the development to the implementation of the intervention in practice involves a wide range of different procedures. Therefore, according to the aim and objectives of this study, all stages of the study lie within the first two stages of the MRC guideline only. As can be seen in Figure 3.2, the study design contributes valuable information to an intervention in a different way, either before, during or after the intervention. According to Creswell & Creswell (2018), the points at which the data connect to the intervention design represent integration in this study design.

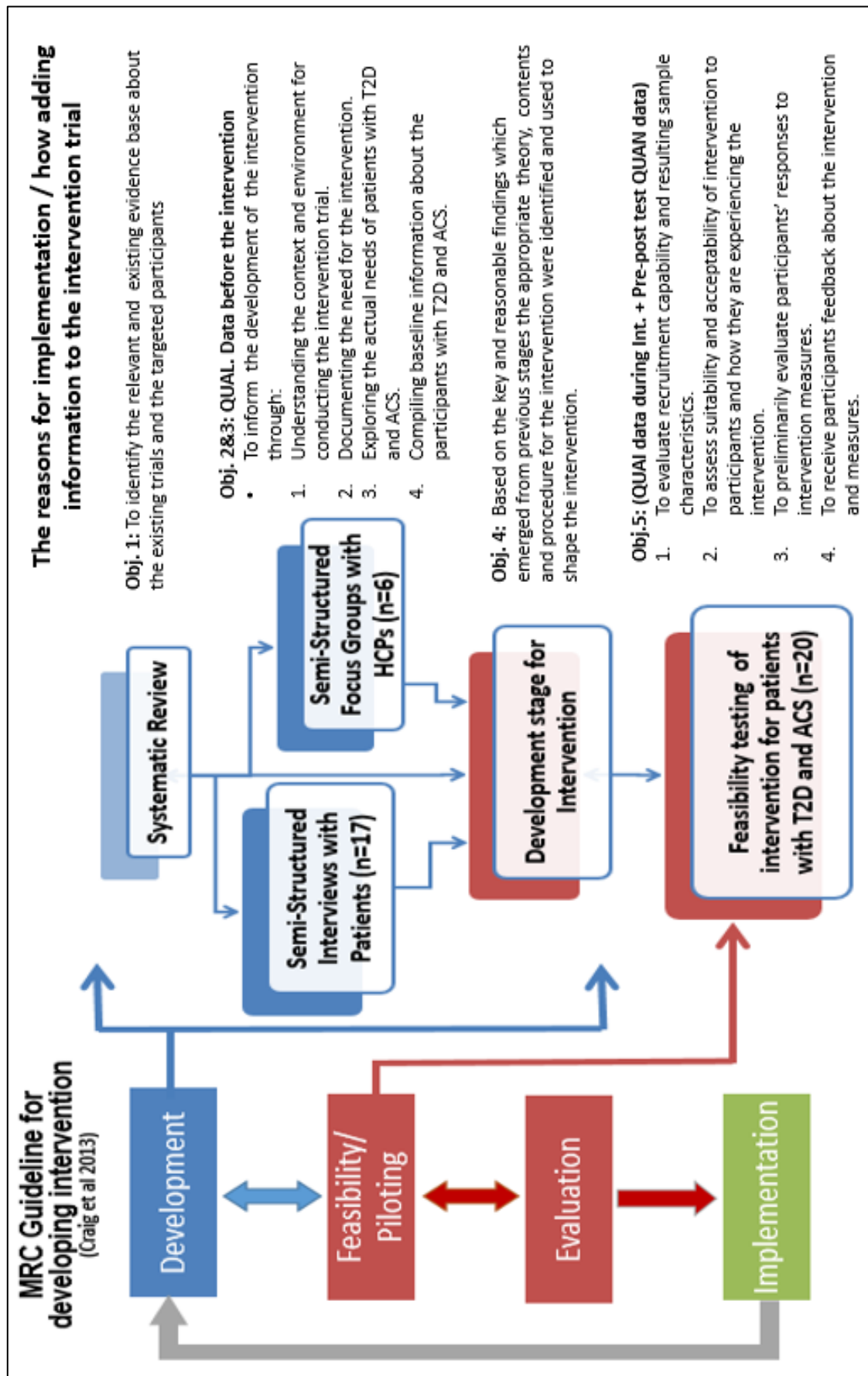


Figure 3.2: The application of the mixed methods sequential embedded design

## 3.6 Application to the Current Study

### Phase One

Phase One comprised three parts:

1. A systematic review of randomised control trials, as already covered in Chapter 2.
2. *A series of semi-structured interviews* with patients with T2D and ACS was undertaken in two Jordanian secondary care hospitals. An interpretive approach is suited to the in-depth exploration and understanding of individuals' perspectives, experiences and needs in relation to being diagnosed with T2D and ACS, and this approach has been successfully used before in a previous study with a similar population (Jo Wu et al. 2008). This is presented in Chapter 4.
3. *Six semi-structured focus groups* were undertaken with HCPs working in secondary care with patients with T2D and ACS at two Jordanian secondary hospitals. Their perspectives regarding current support and follow-up care provision for patients with both conditions were explored along with the primary needs of those patients, the challenges associated with and any suggestions for delivering education and supportive care for those patients in the context of Jordanian settings. This is presented in Chapter 4.

### Phase Two

Phase Two comprised two parts:

1. *Intervention development*: The salient factors and features identified from Phase One were used to inform the development of the intervention, mainly in terms of content and processes. The best available evidence and appropriate theory in relation to teaching methods were then used to shape the main features, elements and design of the intervention. The intervention developed through this process was then feasibility tested. This is presented in Chapter 7.
2. *Feasibility study*: A feasibility study was conducted to examine the feasibility and acceptability of the Diabetes Cardiac Self-Management (DCSM) Intervention for

a cohort of patients with ACS and T2D in the context of a single Jordanian healthcare setting. The mixed method feasibility study used qualitative data (fieldnotes and qualitative participants feedback) and quantitative data (such as response rates, retention rates, protocol completion rates, missing data rates, procedural data, pre- and post-intervention data (e.g. outcome measures and clinical data), evaluative data and others) to achieve aim of the study. Both types of data were analysed and interpreted simultaneously as a single dataset. The overall results and interpretation of this feasibility study were used to determine whether the DCSM Intervention was acceptable and appropriate for participants and whether further testing was required.

### **3.7 Suitability of this Design**

The MMSED-Experimental model obtained robust, rigorous and context-specific qualitative and quantitative data that addressed the complex issue that the study entailed: integrated self-management education and support for patients with T2D and ACS. The three benefits of using a mixed method design identified by Creswell & Creswell (2018) made this design appropriate given the aim and objectives of this research. Firstly, at a general level, this design helped the research team to explore the unique perspectives of patients and HCPs and integrated their perspectives and personal experiences into an intervention; it also helped in evaluating the feasibility and acceptability of the developed intervention and identified factors of practical relevance in a Jordanian context.

Secondly, at a procedural level, integrating the qualitative data collected before the intervention into an intervention design provided a sophisticated approach to developing a more complete understanding of the actual self-management needs of patients with both conditions in general and within the Jordanian setting in particular; it also augmented the intervention by incorporating the perspectives of patients and clinical professionals that emerged from their discussion. Likewise, both the qualitative and quantitative data integrated and interpreted in Phase Two produced a range of data about the feasibility of the intervention in real practice, including, a comprehensive understanding of the challenges of delivering the intervention in secondary healthcare settings. And helped to determine whether an intervention should be subject to further testing to ensure it is relevant to and sustainable in the intended population.

Finally, at a practical level, both Phase One and Two offered a diverse range of participants, whether patients or related stakeholders to the study, the opportunity to contribute to the study.

In general, and in Jordan specifically, there is a lack of qualitative studies concerned with the self-management behaviour of patients with T2D and ACS, coping with both conditions and their actual needs and challenges, as indicated in Chapter 2. Also, as many of combined self-management interventions for patients with both conditions are poorly described and lacked a sufficient qualitative research component (Tanash et al. 2017b). This limits our understanding of the applicability, suitability and acceptability of such interventions for the targeted patients in Jordan. Therefore, the incorporation of qualitative methods before the intervention was an attempt to inform intervention development, while their incorporation within the trial was to ensure that the researcher considers any problematic moments as well as meanings in those patients' experiences (Denscombe 2014). Using both qualitative and quantitative methods will also contextualise the findings of the research (Pluye et al. 2009) and enable intervention trial participants to provide information during the feasibility study regarding their responses to quantitative variables (Wagner et al. 2012). This design is recommended by many researcher (Cope 2015; Orsmond & Cohn 2015), and conducted in previous similar studies (Hellgren et al. 2013; Vaccaro et al. 2013; Schneider et al. 2016).

There are many challenges associated with using the MMSED. However, in this case, the main challenge of the design was its complexity and diversity, requiring the researcher to develop knowledge and refine and acquire a range of advanced skills covering both qualitative and quantitative research, including in-depth interviewing, focus group moderating skills, survey design, educational skills, qualitative analysis and using the Statistical Package for the Social Sciences (SPSS). Also, this diversity placed more demands on the researcher and added time and expense to the research project.

Another limitation of mixed methods designs suggested in the literature is that the intervention or design did not take full advantage of the richness of the qualitative data. In this study this limitation was minimised by a number of strategies which ensured the validity of the design for each phase.



### **3.8 Enhancing Rigour**

In order to enhance the validity (rigor) of the study, which in qualitative terms has been defined as trustworthiness, transferability and credibility (Guba and Lincoln 1994), an advisory group was established in Jordan at an early stage to give feedback and make suggestions on aspects of the study as it progressed, especially as there was no patient and public involvement (PPI) advisory group available in Jordan. The study advisory group included two patients elected by the researcher to represent the study's targeted patients, two physicians and a number of experts in the field working in the study's hospitals. However, during the planning and development of the study the researcher was keen to discuss the potential and importance of the research concept with them and to include their voice as much as possible in the design of the study. After completing Phase One, the researcher, met with them to discuss the clinical relevance of the findings. A number of meetings via phone call or in person with members of the group ensured that the qualitative data informed the contents and design of the intervention. These exchanges also ensured that the developed intervention met the actual needs of patients, simulated actual practice and was methodologically valid for generating and collecting the necessary data.

Two advisers/collaborators were appointed at an early stage in the study; one is an associate professor of nursing and head of nursing management in King Abdullah University Hospital (KAUH) (I.F.), and the second is the head of the Internal Medicine Department in the Ministry of Health of Jordan and Princess Basma Teaching Hospital (PBTH) (S.A.). Both of them were updated in advance about the time, location and purpose of any interviews (either with patients or with HCPs) in Phase 1 or education sessions in Phase 2, that to maintain fidelity by checking at any time the progress in setting and for emergency purpose if needed.

Additional steps were taken within each of the two phases to enhance the rigor of the study. In the Phase One, firstly, the researcher adhered to the use of a framework approach for analysing the qualitative data, which is considered to be a rigorous, appropriate and systematic approach for carrying out qualitative analysis in nursing research (Ward et al. 2013). The framework analysis approach is a systematic and scientific method that helps researchers to enhance the validity of qualitative findings by enabling them to track decisions, ensuring the original data and findings are maintained

well and a clear and organised record of all decisions is kept (Smith & Firth 2011). Secondly, to ensure the reliability and dependability of the data collected from interviewees and focus groups, all interviews and focus group discussions were conducted by the same researcher (McDougall 2000), in appropriate settings, with appropriate participants at appropriate times. Furthermore, the same guide was used for each interview and focus group discussion, using the same sequences of open-ended questions/topics that were selected to be discussed (Miles et al. 2014). These guides were also pilot-tested and revised with two patients for interviews and with a physician and a nurse for the focus groups before commencing data collection to assess the clarity and appropriateness of the open-ended questions and the relevance to the research questions and expected discussion (McDougall 2000).

Furthermore, a selection of anonymised transcripts and audio recording from the interviews and focus groups in the original language were reviewed by independent researchers within the field of cardiovascular nursing research to clarify interpretations and uncover bias as well as to discuss and review the final themes. The entire research process, including data collection, data analysis and the findings of each method, was reviewed and discussed with the study team and advisory group at various points. Through the process of meticulous refinement which has been documented, such as using dynamic spider thematic maps, the researcher supported the findings with quotations for every interpretation from at least two different participants. This technique helped to improve the study conformability and the transparency of the thematic analysis from transcripts to final themes and sub-themes.

To enhance transferability and diversity, interviewees and focus groups participants were recruited from two different settings which represented the public and the university health care sectors in Jordan (KAUH and PBTH) and selected based on the characteristics of the population and the objective of the study by using a purposive sample approach. Using this approach improve the rigor in qualitative research by reflecting the diversity within a given population, offering researchers a degree of control and minimise selection bias (Ritchie et al. 2014). With purposive sampling offers researchers deliberately seek to include “outliers” (Holloway & Galvin 2016). The researcher was also keen to provide sufficient descriptive data about the characteristics of participants, settings and related technical data to permit comparisons with samples from other studies.

In Phase Two, the validity of the intervention design and the feasibility study were enhanced by the overall design of the study itself, as the content and elements of the intervention were developed based on good evidence integrated from the findings of systematic review and the pre-qualitative phase investigations with patients and HCPs and supported with appropriate theory and teaching methods. Therefore, using a mixed methods design ensures that the intervention presented and the feasibility study conducted were rigorous and suitable for the participants, and indeed reflect the realities of the study community and practice settings (i.e. that the intervention fitted in real-world settings and culturally appropriate) by involving the perspectives of HCPs and targeted patients in meaningful ways in conceptualising and designing the feasibility research (Bowen et al. 2009). In order to maintain fidelity in the feasibility study the advisor of the study team in the KAUH (study setting) would attend random spot check education sessions provided and assessments in order to supervise the research in setting. Further validity of the components of the intervention was guaranteed through various procedures prior to commencing the feasibility test of the intervention, as will be discussed in Chapter 7.

### **3.9 Ethics and Governance Process**

Despite this research project being a low-risk, non-interventional/non-invasive procedures study, the research team recognised that doing qualitative investigations and feasibility testing for an educational intervention could cause potential participant distress and burden. All recommended strategies to minimise these issues were developed and maintained through-out all phases of the study. These strategies included: ensuring confidentiality; providing information sheets and consent forms; promoting awareness of participants that participation was completely voluntary; and assuring participants that they may choose to withdraw at any time from the study without penalty. Furthermore, all interviews, focus groups and educational sessions took place at a time convenient to the participants and in an appropriate location in the hospital. All these strategies are compliant with the Ulster University (UU) Research Governance Policy. Peer reviews provided clarity about the research protocol before submission to Ulster University's Research Governance Filter Committee and the Institutional Review Board (IRB) in Jordan. Some amendments were made based on the feedback received from these bodies. Approval was granted by the UU Committee in August 2015, from the Jordanian IRB of

KAUH in October 2015 and January 2017 for the second phase and from the IRB of Ministry of Health in November 2015.

### **3.10 Implications for Future Study**

In order to definitively evaluate and implement integrated intervention for targeted patients, a series of feasibility and efficacy pilot studies must first be conducted targeting all the key uncertainties in the intervention design and in different contexts (Craig & Petticrew 2013). Therefore, the inclusion of a global dimension to the integrated DCSM Intervention population was deemed practicable due to following points:

- The uniqueness of the participants recruited through this study,
- A systematic approach was used to develop and feasibility test the intervention using the best available evidence and appropriate theory,
- The increasing international interest in the area of developing and implementing integrated self-management interventions for patients with diabetes and heart diseases,
- The high prevalence of both diseases and their risk factors worldwide,
- The notable scarcity of published research on the perspectives of patients and HCPs ensures this research is relevant to future healthcare needs and will be basis for future research.
- The affordability of the intervention design and its apparently easy integration within secondary prevention settings and policies will require further exploration.

Some funding and dissemination of results have been successfully achieved during the study; other results will be researcher plans to disseminate as soon, as widely and as persuasively as possible. Furthermore, according to the findings of this study the previously tested intervention version should be enhanced to be delivered successfully in a different settings and context as well as to be more culturally appropriate. Also, sufficiently powered randomised control trials are required in future research in order to assess the effectiveness of intervention.

### **3.11 Summary**

In sum, a the MMSED-Experimental model was selected as the most appropriate design to achieve the overall aim of this study. In Phase One of the study, rich qualitative data were obtained from patients and HCPs to inform the intervention modelling, which was feasibility tested in Phase Two. The methods used and the results obtained from Phase One, the qualitative investigations phase, are presented in Chapter 4, 5 and 6. The methodology and results of the feasibility study from Phase Two are presented in Chapter 7 and 8.

## **Chapter 4: Qualitative Research Methods**

### **Introduction**

This chapter describes the methods used in two qualitative studies conducted before developing the intervention to achieve the second and third objectives of the study (which indicated in Chapter 1, Section 1.8). It provides a detailed description of each study methodology, including the aim and objectives of the study, its method, study design, sample, setting, data collection procedure, data management and analysis and ethical considerations.

### **4.1 Methods**

To achieve the second and third objectives of the study, two qualitative studies using an interpretative approach were conducted. In qualitative research, interviews are the most prominent data collection tool. The interview is one of the most powerful methods for understanding others in health and social care research (Morris 2015). It is also the most suitable method of accessing individuals' or professionals' perceptions, definitions of situations, meanings and constructions of reality (Punch 2014; Creswell & Creswell 2018). According to Creswell & Creswell (2018), the qualitative interview can take different forms and can be conducted face-to-face with participants, through telephone interviews, e-mail or online, or by organising interview with a number of interviewees at once (focus groups). Qualitative interviews also can vary in their degree of structure; they can be fully structured, semi-structured or unstructured, but generally, they involve a limited number of open-ended questions intended to elicit perspectives and opinions from the participants (Ritchie et al. 2014). Despite this variety in form and degree of structure, each type has different strengths and weaknesses (Punch 2014). Therefore, the type of interview selected should align with the purposes, questions and overall strategy of the research (Fontana & Frey 1994).

From a pragmatic perspective and design for this study, the qualitative interview is the best method through which to better understand another person's life, experiences and needs; it also holds value beyond the context of the direct research interaction between the participant and the researcher (Denscombe 2014). Furthermore, unlike some other qualitative data collected from such as documents or observations, the data gathered from

interviews includes participants' explicit interpretations and understanding of events (Ritchie et al. 2014). Therefore, based on the overall aim and objectives of this study, the research team concluded that using semi-structured face-to-face interviews with cohort patients with T2D and ACS and focus group interviews with Jordanian HCPs (stakeholders) are the best methods through which to achieve the objectives of the qualitative phase of the present study.

#### **4.1.1 Focus groups**

One of the key features of focus groups is that they are synergistic (Stewart & Shamdasani 2014), which means the qualitative data and insights are explicitly generated by interaction between group participants (Berg & Lune 2012). This interaction is usually generated through participants listening to each other's views and experiences, reflecting on what they hear and, in light of this, considering their own perspective further. As the discussion between the participants progresses, each individual response sharpens and becomes more refined and transfers to a deeper, more logical level (Ritchie et al. 2014).

Moreover, the focus group creates a more natural and realistic environment than that of an individual interview because participants influence and are influenced by others, just as they are when groups of individuals converse in the real world (Krueger & Casey 2014). The synergistic effect of the group setting may release information or ideas during the discussion that might not have been uncovered otherwise (Stewart & Shamdasani 2014). The focus group interview according to Parahoo (2014) is an efficient method through which to develop a comprehensive understanding of specific phenomena from a variety of perspectives. For this reason, the research team chose to conduct focus groups to explore the perspectives of HCPs because the team assumed that the interaction between participants whose disciplines, roles and characteristics differ but who share responsibility for the care of patients with T2D and ACS could lead to more in-depth insights about patient's actual needs as well as greater understanding of actual practice and the care environment (Nyumba et al. 2018) that could help to inform the development of the intervention in the next stage of the study.

Focus groups reflect the social construction and normative influences as well as the shared meanings and self-identity that ultimately represent the participants' perspective, experience and understanding of the world around them (Ritchie et al. 2014). For this

reason, the researcher (who moderated the focus groups) carefully steered the participants' discussion in order to create an environment in which the interaction between them seemed fluid and spontaneous; in addition, during sampling, the researcher sought to ensure that each participant had a specific experience of or opinion about the topic and therefore was able to contribute meaningfully to the discussion (Puchta & Potter 2004; Ritchie et al. 2014). Therefore, the focus groups were used to understand the study's phenomena and the actual context of everyday clinical practice from the point of view of current HCPs (Knudsen et al. 2012) in Jordanian secondary care. As the focus groups explicitly use participant interaction as a part of their method, when moderating the discussion, participants were encouraged to talk to one another, exchange stories, ask questions, comment on each other's experiences and express their own point of view.

Furthermore, the focus groups have been used because larger and richer data can be generated from a varied group of professionals working with patients with T2D and ACS much more quickly and at lower cost than would be the case if each were interviewed individually (Stewart & Shamdasani 2014). Focus groups can also be assembled at much shorter notice than would be required for larger and more systematic methods such as surveys (Stewart & Shamdasani 2014). According to Halcomb et al. (2007), focus groups are a very useful method of expanding existing knowledge about service provision, understanding the phenomenon being investigated and in this case, identifying actual consumer needs (i.e. those of patients with T2D and ACS) that will support the development of future self-management interventions.

#### **4.1.2 Face-to-face interviews**

Face-to-face interviews with 17 patients with T2D and ACS were conducted. These interviews were semi-structured and generally involved open-ended questions that were intended to elicit perspectives from the participants. This type of interview was very useful as the patients offered historical information about their experience (Creswell & Creswell 2018) after being diagnosed with ACS and living with two chronic conditions.

Although the researcher had a clear list of issues to be addressed and open-ended questions to be answered, the use of semi-structured interviews provided considerable flexibility in terms of the order in which the issues were considered and perhaps more important/related for each patient (Denscombe 2014). Thus, as the study was seeking to



understand the experiences and actual needs of patients, semi-structured interviews were used to allow patients to raise related issues, develop ideas, shape the content of the interview to some extent from their experience and speak more widely on the issues raised by the researcher. Furthermore, the method allows participants' responses to be explored and probed, and for topics to be covered in the order most suited to and convenient for the patient (Denscombe 2014; Creswell & Creswell 2018).

Another factor that encouraged the selecting of this method of collecting data from patients was that one-to-one interviews are relatively easy to arrange as the organiser must consider the availability of only one individual each time an interview is scheduled (Denscombe 2014). Such interviews are also relatively easy to control, as only one individual at a time needs to be guided through the interview agenda, focussing on the views, experiences, challenges and needs of a single patient, making it easier to manage and transcribe data after interviewing (Denscombe 2014).

Moreover, as each patient with T2D and ACS is a unique human being with experiences, perspectives and needs that are different from those of others, and these facts need to be deeply respected and considered when collecting data from them about their concerns and needs, one-to-one interviews were the best method to achieve this purpose (Dickert & Kass 2009; Epstein & Street 2011).

## **4.2 Design**

Qualitative research is a form of social inquiry that focuses on the way individuals or groups interpret and make sense of their experiences and the world in which they live (Flick 2014). In the other words, researchers use qualitative approaches to explore the perspectives, experiences, behaviours and feelings of people and what lies at the core of their lives (Flick 2014).

Many approaches to conducting qualitative research are described in the literature. For example, Wolcott (2009) identified 22 qualitative approaches. However, Marshall & Rossman (2014), who examined all types of approaches used by five different authors in the field of qualitative studies, found that five approaches are most common in the social and health sciences. These five approaches are: narrative, phenomenology, ethnography, grounded theory and case study (Marshall & Rossman 2014). Typically the narrative or the phenomenological approach is used to study individuals, grounded theory and case

study are primarily used to explore activities, processes, events and needs, and the ethnographic approach is used primarily to learn about the broad culture-sharing behaviour of groups or individuals (Creswell & Creswell 2018).

In the interpretive approach, interpretation of the descriptions begin as soon as the researcher engages with the phenomenon, as his/her prior background, awareness, anticipation and attention are directed toward the phenomenon (Flick 2014). This interpretation continues as the researcher carefully listens to or reads the individuals' descriptions of their experience of the phenomenon and becomes more immersed with this qualitative data. Therefore, to achieve in-depth understanding, the researcher must, to some extent, go beyond the literal meaning of the individuals' words or discussion to identify the fore-structures and thematic meanings held in the data (Mackey 2005).

In Phase One of the study, the interpretive approach was used to underpin the two parallel qualitative studies. Understanding the perspectives of patients with T2D and ACS and their HCPs requires participants to reveal their own actual experiences at the time and the environment they were in then, and in particular following their cardiac event. This approach allows either patients or their HCPs to express their own individual experience with this phenomenon and within their actual context, which brings out the actual meanings of their perceptions of their day-to-day experiences (Speziale et al. 2011) in terms of how they cope with two chronic conditions, or in case of professionals, in terms of how they deal with and care for such patients in their everyday practice.

Additionally, this approach had acknowledged benefits, as the interviewer needs less time to commence participant interviews and receives richer data because both patients and their HCPs tended to express their views, feelings and experiences more freely, comfortably and broadly when speaking to the interviewer, who was to some extent familiar with their experience and environment.

### **4.3 Sample**

Non-probability purposive sampling was used to select the sample in the both qualitative studies conducted. This technique was chosen as this technique is more consistent with study's objectives and enables the primary researcher to achieve depth of understanding of participants' perspectives (Johnson & Christensen 2017). Also, the randomization during these studies were impossible, especially with limited time, resources and

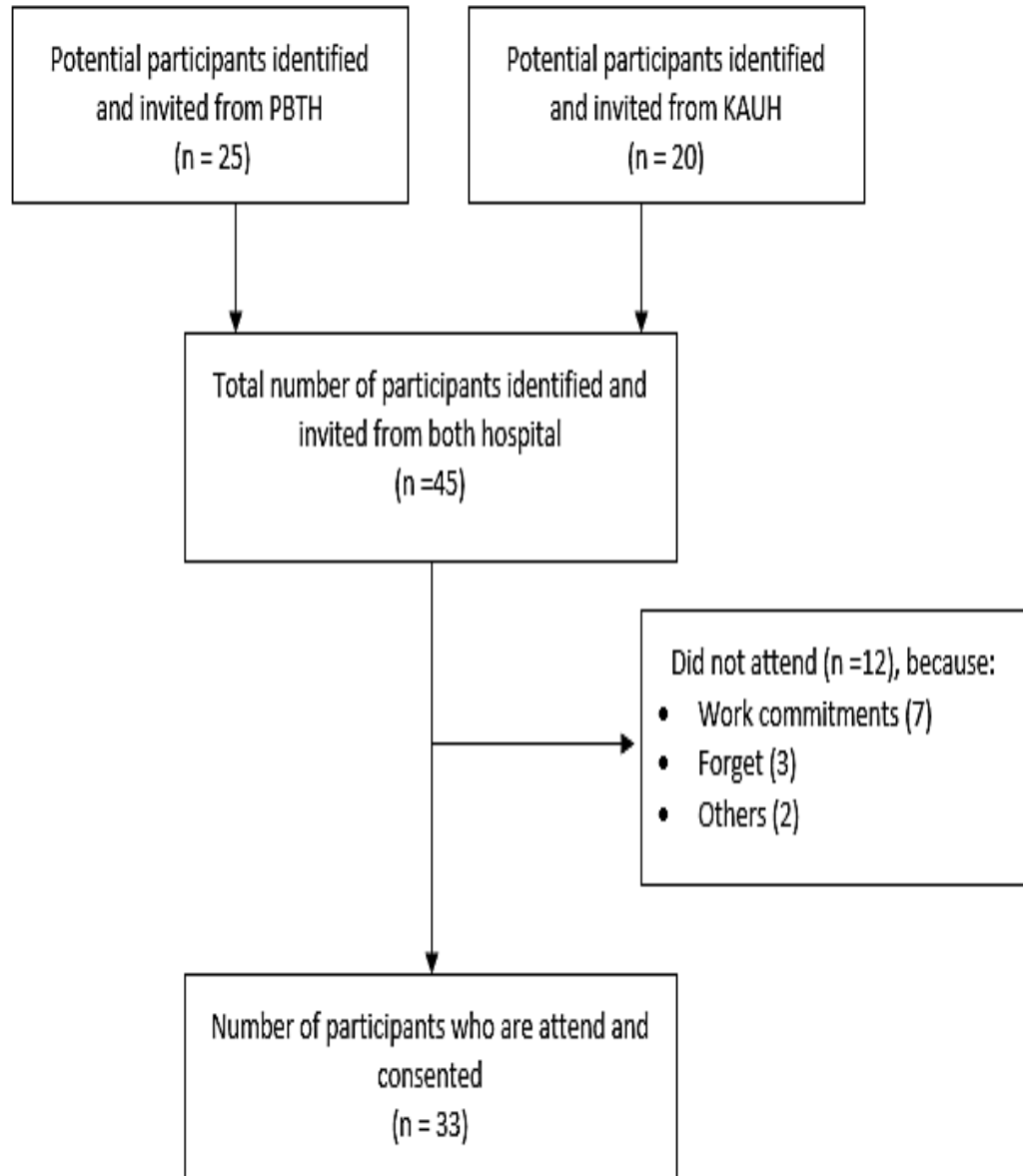
workforce (Etikan et al. 2016). In the purposive sampling, participants are selected based on study purpose and inclusion criteria with the expectation that each participant will provide rich and unique information of value to the study (Etikan et al. 2016).

The variations among participants were considered in both studies by collecting heterogeneous samples (Suen et al. 2014). The exact number of interviews was not specified prior to start of the study, but determined by the principle of theoretical saturation (Morse & Niehaus 2009). In other words, data collection continued until no new substantive information is acquired (Parahoo 2014).

#### **4.3.1 Focus groups**

Six focus groups interviews were successfully organized in January 2015 with multidisciplinary HCPs in secondary care (n = 33). Figure 4-1 illustrates the process used to recruit HCPs. All those recruited were defined as key stakeholders with regard to the patients targeted in this study, as they are in some way directly involved in the care of patients with T2D and ACS in their day-to-day experience. Focus groups were organised with participants of both genders who met the following inclusion criteria:

1. Involved in the care of patients with diabetes and cardiac diseases in secondary care settings and after discharge (i.e. cardiologists, general physicians, internal medicine physicians, head nurses in the cardiac ward, registered nurses, nursing practitioners, cardiac nurses, diabetes nurses and other professionals who may provide support or treatment for patients with ACS and T2D such as dietitians, pharma doctors, physiotherapists, occupational therapists, endocrinologists).
2. Have at least one year's experience.
3. Can converse in Arabic.
4. Have a phone number, (for organisational purpose).
5. Willing to discuss the study topic with others.
6. Willing to consent and attend the scheduled meeting (that would last between 1-2 hours) at the specific date and time.



**Figure 4-1: Flow diagram of HCP recruitment process**

### 4.3.2 Face-to-face interviews

Seventeen face-to-face semi-structured interviews were conducted during December 2015 and January 2016 with patients who were living with T2D and had experienced an ACS event at least 3-12 months before the interview (i.e. who were diagnosed with ACS and admitted to the CCU between December 2014 and August 2015). A purposive sample of men and women was recruited participants from the two main referral hospitals (KAUH and PBTH) in northern Jordan based on the inclusion and exclusion criteria outlined below.

Inclusion criteria:

1. Adults with a history of T2D and ACS within the last 3-12 months.
2. Can understand the Arabic language.
3. Physically and mentally able to participate in the study (as judged by a cardiologist).
4. Jordanian nationality.
5. Willingness to participate in an interview lasting 30-60 minutes.

Exclusion criteria:

1. Patients living outside northern Jordan.
2. Patients who also have very other serious health conditions such as cancer, COPD, physical and mental disorders.

## **4.4 Data Collection**

### **4.4.1 Focus groups**

Before recruiting participants for the focus groups, the researcher met with the study's advisors in each hospital to discuss the most appropriate time and place to hold the focus group meetings. The researcher deduced that to maximise the opportunity for interested parties to participate, the most convenient time and place to hold the focus groups for participants in KAUH are in-hospital (in any meeting room, of which there is one on each floor), during the afternoon (2-4 p.m.) and on Thursdays, as this is the last day in the working week. Consequently, the load is lighter on Thursdays than on other days because there are no cardiac out-patient clinics on Thursday evenings, which makes it more possible for the cardiologists and the internal medicine physicians to attend. In addition, the selected time is close to the time when nursing shifts rotate (usually between 4 and 5 p.m. in this hospital), enabling interested nurses to take part by arriving 2 hours before their shift begins. Moreover, medication is usually distributed to patients in hospital around 12-1 p.m., thus, provided they have no work to attend to, interested nurses can take leave from their duties for 1-2 hours to attend the focus group. Finally, staff nurses who work in the hospital's diabetes clinics complete their duties at 2 p.m. on Thursdays, and no elective cardiac catheterisations take place in the afternoon, so the professionals in cardiac departments are then relatively free.

Apart from the fact that its nurses change shifts 2-3 p.m., the study advisor in the PBTH referred to almost the same factors when recommending that focus group discussions be held in the evenings between 3 and 5 p.m., in the meeting room of hospital. They did not recommend a specific day. Subsequently, the researcher organised three focus groups in each hospital according to these recommendations and booked meeting rooms for each date.

The process of recruiting participants in each hospital began after mid of December 2015, as a rota for shifts by professionals in each department for the month of January 2016 was scheduled and published in both hospitals.

The researcher used a range of strategies to recruit the targeted participants. Firstly, the researcher advertised widely using word-of-mouth in the CCU, cardiac and diabetes clinics in each hospital and through an A4 poster that included brief information about the study, its importance, the process and the contact details of researcher, which was displayed in relevant wards such as the CCU beside the ward nurses' wall chart inviting professionals for the study. Copies of the participant information sheet (see Appendix 5) were attached to the poster. Secondly, the researcher provided participant information sheets to the study collaborators in each hospital (one cardiologist and the head nurse of the CCU and intermediate cardiac ward). They were asked to hand out the information sheets and invitation letters to participants who met the inclusion criteria.

The invitation letter described the study, explaining why the research was important, what was expected of them, noting that the discussion would be digitally recorded and assuring confidentiality. If they were interested, professionals were asked to contact the researcher directly by telephone or to leave their name and contact telephone number with the study's advisor in each hospital, who then would give their details to the researcher. At the initial contact with the researcher further information was given about the likely dates and venues for the focus group meetings to be held in their hospitals. Participants were also told they would receive a token gift (a fountain pen) for taking part and that light refreshments with fresh juices would be provided. If the potential participant was still interested, the researcher asked them which of three possible dates in January suited them best for holding focus groups in their hospital. While some potential participants confirmed that all dates suited them, some others reported that only one date suited them.

While some researchers suggest that, to promote the comfort of participants and to avoid generating power issues, each focus group should be homogeneous in terms of the experiences, age, occupation and gender of its participants (Breen 2006; Stewart & Shamdasani 2014; Carey & Asbury 2016), others advocate using a heterogeneous sample, especially in exploratory studies that are about not sensitive topics, because doing so reveals different opinions of the topic investigated and provides rich data (Hennink 2007; Liamputtong 2011; Barbour & Morgan 2017). However, according to Jayasekara (2012), who analysed the application of the focus group as a research tool in nursing research, the composition of the group should be based on the available resources, the convenience of the participants, or as Morgan & McCracken (2009) have suggested, on whatever composition of the group will best serve the purposes of the research.

Therefore, in light of the available time and resources, the convenience of the participants, the fact that the purpose of gathering was to contribute to an understanding of the issues and needs of patients rather than their own institutional power or responsibilities. And based on the principle of maximum variation of sampling, a purposeful heterogeneous sample was used.

All potential participants (KAUH=20, PBTH=25; total=45) were divided into groups based on discipline, gender and years of experience. Three focus groups were organised in each hospital, each comprised of between 5 and 10 professionals as most scholars suggest that this range is optimal for effective discussion, although smaller groups (fewer than four participants) still can be effective for exploring complex topics, particularly when the participants are experts (Morgan 1998; Morgan & McCracken 2009; Krueger & Casey 2014). Nevertheless, two additional participants to take part in each planned group were invited in case of late cancellations (Morgan 1998; Halcomb et al. 2007).

All potential participants were contacted by telephone a call or in person 1-2 weeks before the scheduled date of the meeting. Another reminder was sent by text the day before the focus group meeting to remind participants of the venue and time. The researcher's contact details were given in the message again in case further information was needed.

The signed consent forms (see Appendix 6) were collected from the participants on the day of the focus group meeting and before recording. A colleague of the researcher

helped to take notes and assisted with five of the groups; he was unable to assist with the sixth due to work commitments. Refreshments and fresh juices were provided at each meeting and each participant was given a fountain pen. The researcher mingled with the participants before the meeting began to put them at ease before the discussion. Each focus group was audio-recorded to ensure that the data accurately reflected the views of the participants. Two tape-recorders were used for backup.

The primary role of the researcher during each focus group interview was to gather data on the HCPs' views of the topics discussed. The demanding and challenging role of the researcher in the focus group method was described by Ritchie et al. (2014) as 'hybrid', as the role integrates the attributes of a moderator and a facilitator. The role requires competent communication and interviewing skills to facilitate an open and interactive discussion amongst the participants. The focus group must be moderated to ensure the confidentiality of the information provided and timekeeping and to maximise the contribution made by each participant (Tong et al. 2007). As each focus group discussion progressed, individual perspectives and differences of opinion were respected.

### *Venue for focus groups*

All the KAUH focus groups met in one of the meeting rooms of the hospital between 2 and 4 p.m. on the first, second and third Thursdays in January 2016 (as clarified in Table 5-1, next Chapter). In the KAUH, on each of 16 floors there is a meeting room available for seminars and workshops. Each room is quiet, warm and comfortable for gathering and discussion. Equipped with a round table and comfortable chairs, each room can accommodate approximately 12 individuals. The three focus groups were held in one of these meeting rooms, which was booked in advance; the room number is noted in Table 5-1, next Chapter. In short, the venues were very close, familiar and convenient both to participants who were working and to those who were not on the day of the meeting.

One of the PBTH focus groups took place in the hospital's meeting room; the other two took place in the meeting room in the office of the head nurse, which includes a suitable room for a group meeting. Both venues were very close, familiar and convenient to participants and comfortable for gathering and discussion. The first two focus groups in the PBTH were held in January 2016 from 3 to 5 p.m.; the third and final focus group meeting was conducted from 7 to 8:30 p.m. because the head nurse told the researcher a few days before the meeting date that the meeting room would not be available between 3 and 5 p.m. but would be available for use after 5 p.m. on the same day. Accordingly,

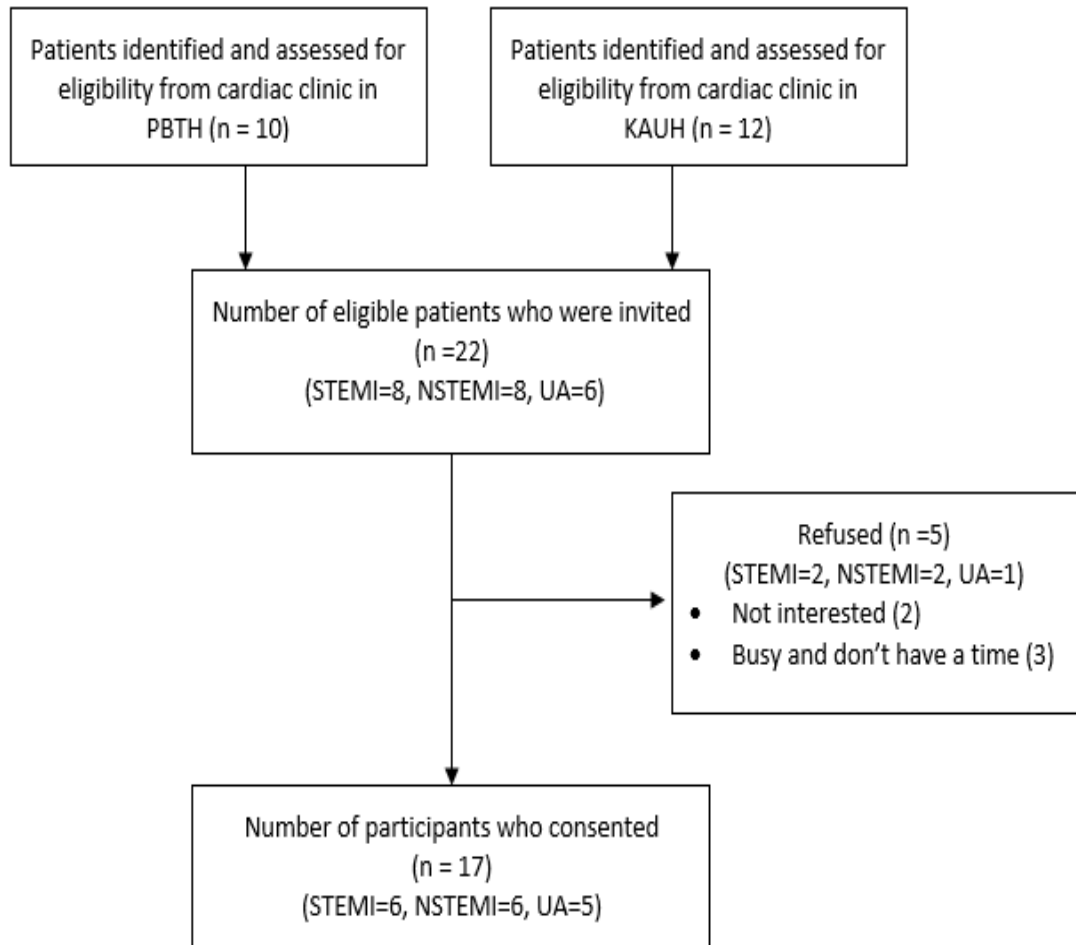


the researcher recalled all those invited to participate in this focus group to check their ability to meet later in the same day rather than cancel the meeting. Fortunately, it was possible for most of them to meet between 7 and 8:30 p.m. on the same day.

#### **4.4.2 Face-to-face interviews**

To ensure that each type of ACS was represented in the study sample, recruited patients were distributed between the three types of ACS and based on the principle of maximum variation between patient's demographic characteristics such as age, educational level and gender.

Eligible patients were identified by their cardiologist or internal medicine doctor during their follow-up visits to out-patient clinics in the selected hospitals. Based on inclusion and exclusion criteria 22 potential participants were identified by their physician and referred directly to the researcher for completion of the recruitment process. A patient's information sheet (Appendix 8) and consent form (Appendix 9) were provided to participants. From the 22 potential participants contacted by the researcher, a total of 17 took part in the study and five declined to do so (see Figure 4-2). Interviews with participants who agreed to participate directly after their follow-up visits were conducted in a suitable and quiet room within the hospital setting; a small number of participants who were busy after their follow-up visits were interviewed in their homes where they would be more comfortable and less stressed (McDougall 2000). All face-to-face interviews were conducted during the day and data was collected by using a digital recorder with the consent of the participants.



**Figure 4-2: Flow diagram of the patient recruitment process**

## 4.5 Development of interviews guide

A separate semi-structured interview guide involving a number of open-ended questions and topics related to the objectives of the studies was developed for the focus groups interviews (see Appendix 7) and for the face-to-face interviews (see Appendix 10).

During focus group interviews, following this interview guide helped the researcher ensure that the researcher took a consistent approach to initiating the discussion between participants and interacting with each group. Each meeting proceeded through the following stages: welcoming of the participants; an overview of the topic; a statement of the ground rules for the focus group; assurance of confidentiality; collection of demographic data and participant introductions; open-ended questions, beginning with the general topics and progressing to specific problems; and finally ending the meeting and thanking participants.

The interview guide for the face-to-face interviews was developed with the aim of understanding patients' responses to and experiences of living with two chronic conditions following their diagnosis with ACS, and to explore their needs and their views on how to promote their health self-management behaviours. All the questions/topics of interviews were designed to achieve study objectives, and selected based on two main pillars; the first through of reviewing of similar previous studies questions; and the second based on the three stages of the Leventhal's common-sense model for understanding people's responses to illness (representations and its five dimensions, coping stage and appraisal stage), which discussed in Chapter 2, section 2.3.1 (Leventhal et al. 2016). Face-to-face and open-ended questions were used during interviews to encourage patients to discuss in depth their own experiences of managing their two conditions (Speziale et al. 2011). Each interview lasted 30-60 minutes. All interviews began by thanking the participant for taking part in the study. The researcher then introduced the research, set the context for the proceeding discussion, reassured participants that their confidentiality would be protected, and that all data would be securely transferred and explained how findings would be reported. To achieve breadth and depth during interviews, participants were asked open-ended questions about one issue each to map territory focused on the study objectives. The researcher then used a probe technique to obtain more clarity and depth of understanding on related issues. For example, depending on the patient's response to the question, "Tell me about your experience in the CCU and following discharge from hospital after being diagnosed with a new cardiac disease in addition to diabetes", the researcher then probed for examples, clarification or further details. Prompts such as "Could you be more specific?" also were used by the researcher to obtain further detail about something relevant to the study objectives. Furthermore, the researcher used a checks technique to better understand the information patients provided and to summarise their views, for example by asking, "So, if I understand you correctly, you're saying that...". As recommended by (Denscombe 2014; Creswell & Creswell 2018), a proper ending was applied to conclude each interview.

#### **4.5.1 Pilot studies and preparation**

To improve rigour, the researcher developed the interview guide and participant information sheet first for each of the focus groups and face-to-face interviews based on the aim and objectives of the study. These materials were then revised by the research team who are experts in the area of cardiovascular and diabetes care and research, after

which the researcher arranged a pilot study to test each method. In early December 2015, three Jordanian professionals (two CCU nurses and one internal medicine physician) were contacted for a focus group interview, and two Jordanian patients with cardiac disease and diabetes were also contacted for a face-to-face interview. These pilot studies helped the researcher to refine the interview guide for each method and iron out some of the kinks before proceeding with the study sample. The pilots also helped the researcher to get a general feeling for how the face-to-face interviews and focus groups interviews would work with the expected sample. The average length of the one-to-one interview during the pilot was 44 minutes; the pilot focus group interview lasted 53 minutes. A few minor corrections to the interview guides were made following the pilot studies.

Moreover, to improve the researcher's skills, confidence and knowledge about conducting qualitative interviews and collecting rigorous qualitative data, the researcher undertook specialist training before beginning the qualitative studies (Study I and II) in the form of a 2-day course on one-to-one interviewing and focus groups at Ulster University and a 2-day course on in-depth interviewing skills delivered by the expert qualitative team at the National Centre for Social Research (NatCen), London, Britain's leading independent social research institute and experts in qualitative and quantitative social research.

## **4.6 Data Analysis**

For the researcher, qualitative data analysis was a continuous and iterative systematic process (Ritchie et al. 2014). This process commenced during the face-to-face and focus group interviews as the researcher interpreted what was being said and tried to simplify the information given by the participant(s) and explore any reference made to the topics identified. Each interview informed the next in an evolving process.

The qualitative data analysis process involved systematically transforming complex human experience and perspectives into something more useful and meaningful for others (Spencer et al. 2014). Generally speaking, the aim of analysis was the same whether analysing data from the focus groups or from face-to-face interviews. However, in the process of analysing the focus group data the researcher often sought to arrive at a group consensus during the session about the topic or issue investigated, and through the process

of analysis, the recorded opinions may change in their level of importance, as they may be expressed by one participant and then refuted by others (Breen 2006).

A number of approaches to qualitative data analysis are available, including phenomenological analysis (Svenaeus 2001), narrative analysis (Riessman 2008), the ground theory approach (Charmaz 2014) and framework analysis (Ritchie et al. 2014; Spencer et al. 2014). The latter is also known as the framework approach and the framework method. It was originally used to assess procedures and policies from the perspective of people who have experience of them (Srivastava & Thomson 2009). The framework approach was developed in the late 1980s by two researchers, Jane Ritchie and Liz Spencer, from the Qualitative Research Unit at the National Centre for Social Research in UK for use in large-scale policy research (Ritchie & Lewis 2003). However, increasingly it is being used in other areas, including health research (Elkington et al. 2004; Ellis et al. 2012; Heath et al. 2012; Gale et al. 2013) and nursing research (Swallow et al. 2011; Dullaghan et al. 2014) due to its being a straightforward analytical tool with an ability to produce clear findings and conclusions that can be related back to the primary source of data (Johnston et al. 2012).

The framework approach has been defined as a pragmatic approach for real-world investigators (Ritchie & Lewis 2003). It is not aligned with a particular philosophical, epistemological or theoretical approach, but rather it is a flexible analytical tool that can be adapted for use with various qualitative approaches that aim to generate themes and sub-themes (Gale et al. 2013). Although the approach is more commonly associated with the analysis of data from semi-structured interviews, it was designed to support analysis of data from focus groups data as well (Ritchie & Lewis 2003). For the purposes of this study, based on the recommendations recorded in the literature and following discussion with the research team, the framework approach was selected for use in this study to analyse the qualitative data from the focus groups and interviews with patients, although it is recognised that some other approaches would potentially have been valid.

The analytical process required that the raw data was transformed from data extracts from interviews or simple descriptions to more abstract themes and subthemes (Ritchie et al. 2014). This process was achieved by systematically examining and continuously interpreting the data to identify key topics which were then gradually combined into higher-order themes (Braun & Clarke 2006) which would address Objectives Two and Three of the research objectives. Although some computer-assisted software programs

such as NVivo or CAQDAS are often used in qualitative analysis, there is strong advice that such programs should be seen only as tools for managing data and not as replacements for the essential intellectual role of the researcher in qualitative analysis (Ritchie & Lewis 2003; Gale et al. 2013; Ritchie et al. 2014; Spencer et al. 2014). As Ritchie et al. (2014) reported, using a framework approach requires to a mixture of creativity and systematic searching skills, as well as a mixture of inspiration and diligent detection.

All interviews with patients and focus groups with HCPs were conducted in Arabic, audio-recorded and transcribed verbatim to Arabic and then translated into English using the back-translation technique, which will be discussed later in this chapter. This process produces large volumes of relatively complex and comprehensive qualitative data that must then be well-organized and deconstructed to reveal the meaning beneath (Van Manen 2006). Repeated listening to the audio-recordings during the transcription process and frequently engaging in focused reading of the completed transcript in both languages uncovered aspects and contextual issues that were then categorised and conceptualised, a process known as indexing and sorting features and issues in data (Ritchie et al. 2014). The researcher's field notes, which were taken after each interview and focus group meeting, were considered to be a primary form of analysis. According to Schatzman & Strauss (1973) these notes are:

“Composed of factual and reliable data, a running account of fleeting and developed interpretations and reflections and a chronicle of operational decisions made at stated times, places and circumstances”

The framework approach allows the researcher to manage unwieldy and unstructured text-based data systematically and to move easily between levels of interpretation of data without losing sight of the raw data (Spencer et al. 2014). It is considered to be an effective approach to research conducted within a limited time frame, focused on specific questions and involving a priori issues and a pre-designed sample (Srivastava & Thomson 2009) .

The framework approach has certain important features (Ritchie & Spencer 1994) which explain its use in this study. It is comprehensive meaning it allows a full review of the material collected; it is systematic, enabling the methodological management of all similar units of analysis; it is generative or grounded, meaning it is deeply based in and

driven by the original views and observations of the participants; it is dynamic, in that additions, changes and amendments can be made throughout the analytical process. It allows case analysis, enabling comparisons between and within cases and enables easy retrieval of and access to the original textual material. Finally, it is accessible to other investigators: the entire analytical process is clear and in a form that can be reviewed by people other than the primary analyst.

#### **4.6.1 Analysing qualitative data using the framework method**

The data were analysed following the seven steps of analysis which have been clearly described by Ritchie & Lewis (2003) and later by Gale et al. (2013) for analysis of each dataset separately.

##### ***1. Transcription***

Initially all focus group and face-to-face interviews were fully transcribed verbatim into Arabic and then forward-translated into English by the researcher using the back-translation technique as mentioned earlier. Each transcription therefore is assumed to be a direct reflection of the research event. In the framework approach, the content is of primary interest, so the researcher does not include conversation conventions such as pauses or other forms of nonverbal communication such as facial expressions, gestures, tone and hesitation unless they clearly change the original event or meaning into a different meaning or format (Gale et al. 2013). This process is lengthy and takes considerable efforts on the part of the researcher. However, transcribing the recordings from the interviews into both languages enabled the researcher to become more familiar with and closer the original event and the data it generated and minimised errors and omissions in the transcription process.

In focus group discussions particularly, it is always a challenge to identify the speakers. However, the researcher followed a number of strategies that helped greatly to assign/confirm the identity of the participant speaking and to clarify sentences in case of gaps. The fact that the researcher served as the moderator for all the focus groups made it much easier to identify the speaker during transcription, which the researcher performed for each interview as soon as possible after the meeting finished. Notes taken by note takers and by the researcher during the discussion also were helpful. For example, brief notes on the participants' views were tagged with the time of speech and the speaker's

characteristics (e.g. “At the 5th minute, cardiac nurse (A.A.) describes how personal culture leads to low levels of knowledge among patients about their condition using the story of one patient as an example”).

Each interview was anonymised, and the interview transcript entered on a computer using Microsoft Word. Each interview was given a numbered code. All names and other material through which individuals could be identified were removed from the transcripts. In focus groups each participant was given a code based on their specialty and a number if more than one participant in the group had the same specialty. To facilitate coding, page and line numbers were displayed in each transcript, and each was formatted using normal (2.54 cm) margins on all sides and with one line of spacing between lines and two lines of spacing between paragraphs and speakers to provide a space in which to write notes in the next stages. The anonymised transcriptions were typed and stored as a Microsoft Word file under a specific coded name. Hard copies were used in the analytical process. In addition to enhancing rigor, all these steps allowed the transcript to be edited rapidly, easily managed and manipulated and safely stored.

## ***2. Familiarisation with interviews***

Although this process is listed as the second stage according to Gale et al. (2013), this process began immediately after the face-to-face interviews and focus group meetings took place. It continued during transcription as a result of listening to the recordings and reading the transcripts. This allowed the researcher to stay close to the original sources of the data and the actual settings as well as to relive and refresh the actual experience of the participants.

At this stage, the researcher first immersed himself in the research data by reading the transcripts more than once and listening to the audio recording until he became familiar with the data, developed a sense of the data in its entirety and was able to recreate the original interviews. Secondly, the researcher gained an overview of the substantive data and identified subjects and issues of interest by writing initial notes, memos, thoughts and impressions in the margins of the transcripts and by using highlighter pens to visually index the interesting codes.

Building familiarisation with the whole data set also took considerable time. However, this stage was vital in the interpretation because it ensured that whatever labels



were developed by researcher in the subsequent stages were grounded in and supported by the original data (Spencer et al. 2014).

### ***3. Constructing an initial thematic framework***

This stage is likely to produce a mix of emergent initial themes and subthemes derived from the questions the researcher listed in the topic guides used for exploring participants' views during the interviews (Spencer et al. 2014). Thus, at this stage in the current study, after developing a list of potential topics and issues arising from each transcript for inclusion in analysis, the researcher then refined and sorted them into a set of initial themes and subthemes that gradually evolved into the initial thematic framework. At this stage, to keep the original source of each code (i.e. the initial topic or issue), each code sorted from the transcript was represented by a numerical reference written directly onto the transcript for easy identification, which was used when indexing and charting data at a later stage. Each code included either a capital "I" for interviews with patients or a capital "F" for focus groups with HCPs, the anonymised transcript number, and the page number and line number (e.g. I1:P5:L3). When coding focus group interviews, the participant's discipline was added to distinguish the speaker (e.g. CCU nurse: F1:P5:L3), and if more than one participant was from the same discipline in the same focus group, the researcher used a specific number to identify each one (e.g. CCU nurse 2: F3:P4:L3).

According to Meyer & Avery (2009), the structure, data manipulation and display features of Excel can be used for qualitative analysis. As there was no available tool that should be used with the framework approach (Ritchie & Lewis 2003), the researcher found that coding narrative text was easier and more convenient with Microsoft Word and Excel to track and cross-check data. Accordingly, all topics and issues arising from the focus group data were stored in a large, electronic table created using Microsoft Word. The Excel program was used to manage and sort data from the face-to-face interviews because of the larger number of transcripts (n=17) involved, from which so many initial themes were generated that it was difficult to expand the table in Word to accommodate them all. Thus, in addition to providing an effective audit trail during coding, using electronic programs helped make this large volume of qualitative data more accessible, manageable and more easily manipulated.

#### ***4. Indexing and sorting***

The researcher used the initial thematic frameworks to annotate and label the data (Spencer et al. 2014). Saldana (2015) refers to this process as “topic coding”. After applying a label to each chunk of data expressing similar ideas or discussing the same topic, the researcher conducted further analysis of similarly labelled data extracts. As the researcher in this study personally conducted the semi-structured interviews and the same sequence of topics was investigated in each interview, this procedure helped somewhat to produce data that was well-ordered and formed neat thematic clusters (as piles) during data analysis. By coding the data at this stage, the researcher aimed to classify the data into more specific and meaningful groups, thereby enabling the researcher to compare each group with the whole dataset systematically.

#### ***5. Reviewing data extracts***

This stage involved further refinement for crude initial thematic frameworks by reading through groups (themes) or clusters of data that had been labelled in a more precise way. Through this process the researcher tried to assess the coherence of the data extracts gathered under each theme and to determine whether they all did indeed describe the same thing, and whether if the labels given to each theme and subtheme were appropriate for the content of each group or required amendment to be more consistent with its contents.

#### ***6. Data summary and display***

This is the last step in the data management process in the framework approach, which then moves on to the mapping and interpretation of the data. During this stage of the process, the researcher summarised the data by writing a precis for each subtheme and for each transcript/each participant in the study comprised of an abstract of the speaker’s contribution to the discussion, short quotations and keywords describing the exact meaning of the original source material. These summaries were then entered on a spreadsheet and displayed as a set of matrices, by theme and by participant in the case of face-to-face interviews with patients, or by theme and by focus group in case of focus groups interviews with HCPs. Gale et al. (2013) refer to this process as “charting”. To achieve this goal, the researcher generated a matrix (case chart) on a spreadsheet for each dataset containing many cells into which the summarised data (precis) were entered by codes/themes (in columns) and cases (in rows) (see Tables 4.1 and 4.2). Each precis was entered with its numerical reference for easy identification.

There are two main methods of analysing focus group data. The first, most common method is whole group analysis; the other method is participant-based group analysis (Spencer et al. 2014). When using whole group analysis, the researcher treats the data produced by a group as a whole and the data from each group is summarised during the indexing stage in one row of the matrix. By contrast, when using the participant-based analytical method, the researcher must analyse the contributions of each participant in the group separately, and each participant's data is summarised during the indexing stage in their own row in the matrix.

Given the objectives of the focus group interviews conducted for this study and the kinds of outputs required to understand the views of the whole group. Whole group analysis was used to analyse the data from these interviews.

**Table 4-1: Matrix: Case Chart of Data from Focus Group Interviews**

Case	Theme 1	Theme 2	Theme 3	Theme 4
(F.G.1)	Precis (Dr: P4:L5) Precis (CardiacRN:P4:L8)	Precis (Cardiologist:P6:L6) Precis (DiabetesRN:P7:L2)	Precis (CardiacRN:P8:L)	Precis (Cardiologist:P8:L7) Precis (Dr: P8: L10)

**Table 4-2: Matrix: Case Chart of Data from Face-to-Face Interviews**

Case	Theme 1	Theme 2	Theme 3	Theme 4
(P1)	Precis (P4:L5)	Precis (P7:L8)	Precis (P8:L2) Precis (P8:L7)	Precis (P9:L9)

To ensure good charting data were input into the framework matrix for both types of interview, the researcher sought to strike a balance between summarising and decreasing the data on the one hand and retaining the precise original meaning and feeling of the participants' words on the other hand. This proved to be quite a challenge.

## ***7. Mapping and interpretation***

In this last stage of the framework approach, the researcher began to tease out what would become the main findings from the research (Spencer et al. 2014). This process involved a sequence of activities that can be summarised as searching for associations, concepts, patterns and explanations in each qualitative dataset with the aid of some visual displays and maps (Gale et al. 2013). In this study, the researcher used a separate file (analytic memo) to note down all his impressions, ideas and initial interpretations of the data at each stage of analysis to define concepts and map connections between themes. Having clearly identified the characteristics of and differences between the data, the researcher used a mind mapping program (XMind 8 v3.7.7) to generate semantic/spider maps of typologies that mapped the linkage between theme and subthemes. This process helped to clarify the nature of phenomena and to highlight associations within the data.

### **4.7 Translation**

The back-translation technique was used to translate the transcripts from these qualitative studies. To achieve a high level of accuracy and avoid possible errors in the translation process and to improve veracity, Chen & Boore (2010) argue that there are three main factors whose impact on the quality of translation researchers in the field of nursing must consider carefully when conducting qualitative research: the translator, back-translation, and culture and language.

In this study, in addition to the primary researcher, two-independent translators (one for the face-to-face interview transcripts and one for the focus group interview transcripts) were involved in the translation process. Both these translators were truly bilingual, meaning they were native speakers of the original language (Arabic) who spoke the target language (English) fluently and confidently. Moreover, both had extensive experience in the practical care and study of patients with T2D and ACS, having worked as cardiac nurses for an adequate period in secondary care settings in Jordan; one also had five years' experience as a CCU nurse in the UK. Both were qualified researchers in nursing sciences and cardiovascular care from the UK and had conducted qualitative research on the care of patients with cardiovascular disease in Jordan.

Like the researcher, both translators had intimate knowledge of the culture of the participants involved in the study, which helped to minimise misunderstanding and

differences in meaning between the two versions of the translations (Al-Amer et al. 2016). Thus, the researcher and the two translators who were involved in the translation process were truly bilingual professionals and sufficiently experienced, educated and familiar with the participants' language and culture, the area of study, the key concepts and the relatively formal and informal language used in the transcripts, as recommended in the literature (Bracken & Barona 1991; Chen & Boore 2010).

Back-translation is the most common and highly recommended technique for translation (Chapman & Carter 1979; Chen & Boore 2010; Santos et al. 2015). This method involved the researcher translating the final version of the transcripts in the source language (Arabic) into the target language (English), then one of the two translators translated that material from the target language back to the source language. The equivalence between the source and target versions was then evaluated by the researcher and any discrepancies were discussed between the two parties until a consensus was reached (Chapman & Carter 1979; Chen & Boore 2010). At the same time, as recommended by Al-Amer et al. (2016), the researcher stayed as close as possible to the source language and used his records and memos to resolve any discrepancies between the two versions and to minimise the potential loss of the actual meaning of the original narrative data (in Arabic) in this cross-lingual study.

## **4.8 Ethical Considerations**

Ethical approval from Ulster University's Research Governance Ethics Committee and Institutional Review Board (IRB) at KAUH and the Ministry of Health in Jordan were granted prior to commencing the study. No physical risk or harm was anticipated. However, some of potential risks and burdens for research participants were identified and the researcher adopted various strategies to minimise them.

### **4.8.1 Considerations related to informed consent**

1. Participants during this phase of the study were volunteers and part of a captive population of patients who may be in the process of receiving care and healthcare providers who are currently in service. Therefore, the researcher provided potential participants with as much information as possible before asking them to sign a consent form so that they would be able to make up their minds about

whether to take part in the study. Toward this end, information about the face-to-face interview or focus group process (whichever was relevant), the research aims and confidentiality were provided to participants either verbally or through written information sheets.

2. Potential participants were informed that their participation was entirely voluntary, and that they could choose to withdraw at any time before the data collection process was completed without comment, alteration of care (for patients), alteration of work (for HCPs) or any other penalty.
3. All potential participants initially indicated their willingness to attend an interview by giving verbal consent during their visit to their cardiologist who had access to the patient's records and knew if the patient met the inclusion criteria. All interested patients then were asked by the researcher to sign the consent form before they were interviewed.

#### **4.8.2 Considerations related to confidentiality**

The following measures were taken to guarantee participant confidentiality, anonymity and privacy:

1. Both face-to-face and focus group interviews were conducted in a convenient and very quiet room in a hospital setting.
2. Patients were given the opportunity to have the interview conducted in their own home (i.e. in a more comfortable and less stressful environment) if they preferred.
3. Participants were informed that all identifying information, including their details and consent forms, would be coded numerically and the only link between their study identification number and any identifying information would be stored in a highly secure cabinet and on a password-protected computer in Ulster University. Only the primary researcher had access to all the data and transcriptions, and these would be used for the purposes of this study only.
4. All data presented or will be presented in publications, reports and presentations in a summarised format (anonymously) so that no one will be able to identify participant from their comments or data.
5. Participants were informed that they had the right to refuse answering any question without any penalty.

6. Participants were informed that they would not be asked about anything that might violate their privacy or beliefs. The study would explore only their opinions and needs based on their personal experience.
7. Participants in the focus group interviews were asked to respect the privacy and confidentiality of other participants and their comments. And to not discuss what it happened during the focus group outside the meeting.
8. Patients were informed that all hard copies of data would be stored in a dedicated secure research room at Ulster University and eventually destroyed as per university policy.

#### **4.8.3 Considerations related to other burdens and psychological distress**

The process of interviewing patients and HCPs may give rise to some burdens, including participants' time and expenses and potential psychological distress. The following protections against these risks were undertaken:

1. As per the recommendations of the study's advisory team, the researcher selected a venue for each interview that was convenient for the participants and scheduled interviews at appropriate dates and times for the convenience of the participants. All focus group and face-to-face interviews lasted no more than 90 minutes to keep potential costs to a minimum, minimise any barriers and to accommodate the different shifts of healthcare providers.
2. The researcher avoided any uncomfortable questions that might cause harm to or upset participants, such as those related to a patient's personal issues or, in the case of healthcare providers, non-adherence to policy and guidelines. The researcher showed complete respect for all opinions and views.
3. The researcher informed all participants, and patients in particular, that they could choose to stop at any time without penalty at any stage in the interview if they became fatigued or felt discomfort or distress, and that they could be referred to their healthcare providers for support.
4. If any participant felt frustrated or distressed during a focus group meeting as a result of not having been able to express their views, the researcher sought to allay this frustration or distress by talking to them individually after the meeting.

5. To ensure that participants were fully aware of these issues during recruitment and before signing the consent form, these details were included in the study information sheets.

In addition to the above ethical considerations for participants, potential risks for the researcher when conducting an interview were also considered. These were minor and related primarily to safety issues such as driving a car, working after normal working hours and working alone, and the necessary procedures were followed to address them. When the researcher was working alone and driving a car to reach a hospital or visit a patient's home and this was considered to be a safety issue, the researcher's adviser in Jordan was notified about any planned visit, including details of when, why, where and for how long. During home visits, and especially when visiting patients after working hours, the adviser was contactable in an emergency by pressing a pre-arranged button on the researcher's mobile phone, although there was never a need to avail of this measure. The researcher had a valid driving license in Jordan during the study, complied with all national traffic laws while driving and did not drive when fatigued.

## **4.9 Summary**

Two parallel qualitative studies of individuals were conducted using the interpretive approach in an interview setting to achieve the research objectives. Six focus groups with HCPs and 17 face-to-face interviews were conducted. The purposive sampling technique was used in both studies. All interviews were digitally recorded, transcribed verbatim, translated using the back-translation technique and analysed using a framework approach (Spencer et al., 2014). The research was conducted within the framework provided by Ulster University's Research Governance Ethics Committee and the institutional review board in the Ministry of Health in Jordan and KAUH. In addition, under academic, advisory group and clinical supervision, well-recognised methods were used to ensure rigorous data and reliable findings. Chapter five presents the findings of focus groups.



## Chapter 5: Focus groups findings (Study I)

### Introduction

This chapter describes the findings from six focus group interviews conducted in the two Jordanian hospitals and discusses each of the identified themes. The location, date and duration of each group discussion are shown in Table 5-1. Each discussion lasted between 60 and 90 minutes. This phase of data gathering generated six anonymised transcripts and a data set of approximately 135 pages of narrative text.

**Table 5-1: Focus Group Schedule**

Focus Group No.	Hospital	Date	Venue	Duration (hours: minutes)
1	KAUH	07/01/2016	Floor 3C-R367	01:00
2	KAUH	14/01/2016	Floor 3C-R367	01:20
3	PBTH	16/01/2016	Floor 2-HN office	01:30
4	KAUH	21/01/2016	Floor 4D-R472	01:20
5	PBTH	24/01/2016	Floor 2-Meeting room	01:00
6	PBTH	26/01/2016	Floor 2-HN office	01:30

**Note:** PBTH: Princess Basma Teaching Hospital; KAUH: King Abdullah University Hospital; HN: Head Nurse

### 5.1 Characteristics of Participants

As shown in the below, the focus groups were comprised of healthcare professionals (HCPs) who are currently involved in the care of patients with type 2 diabetes (T2D) and acute coronary syndrome (ACS) in secondary care settings. Thirty-three participants attended six focus groups out of 45 identified and invited, with response rate was 73.3% and attendance in the six focus groups ranged from 4 to 8 participants.

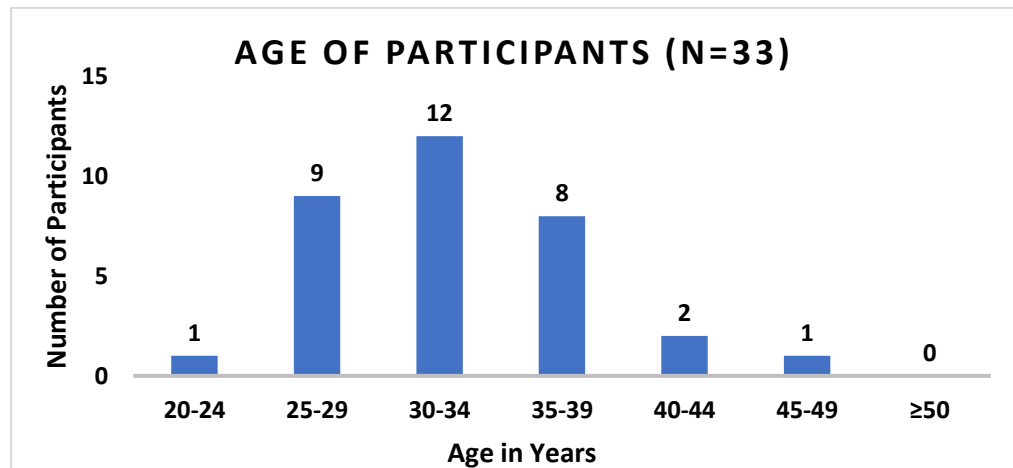
**Table 5-2: Participant characteristics, by focus group**

Characteristics	F.G.1 KAUH	F.G.2 KAUH	F.G.3 PBTH	F.G.4 KAUH	F.G.5 PBTH	F.G.6 PBTH	Overall (%~)
<b>Number of participants invited</b>	7	6	10	7	8	7	45
<b>Number of participants attended</b>	5	5	8	4	5	6	33 (73)
<b>Males</b>	5	3	7	2	2	3	22 (67)
<b>Females</b>	0	2	1	2	3	3	11 (33)
<b>Composition:</b>							
Cardiologist	1	1	1	0	1	0	4 (12)
Internal medicine dr.	1	0	1	0	0	1	3 (9)
Doctor of pharmacy	0	0	0	1	0	0	1 (3)
Head nurse	2	0	1	0	1	0	4 (12)
Registered nurse	1	3	5	1	3	4	17 (52)
Nurse Practitioners	0	0	0	0	0	1	1 (3)
Dietitian	0	0	1	1	0	0	2 (6)
Diabetes nurse	0	0	0	1	0	0	1 (3)

Although only 4 participants participated in Focus Group 4, were one was a dietitian, one a diabetes nurse, one a CCU nurse and one a doctor of pharmacy with 9, 15 and 11 years' experience respectively. As such, they can be considered expert participants who were likely to be able to talk about the research topic, particularly given the significant shortage of staff in these specialities within the Jordanian healthcare system. Focus Group 3 comprised the largest group of participants (n=8) from different disciplines, however, all the participants were involved in the discussion and the conversation reflected the true diversity of the group. In addition, the majority of participants were genuinely interested in the research and the researcher (M.T.) was able to encourage interactions between them, and he made every effort to ensure that all the participants had the opportunity to express their opinions during the discussion in order to capture the similarities and differences in their perspectives.

The 33 participants ranged in age from 24 to 48 (see Figure 5-1). Eleven (33.3%) were female and twenty-two (66.6%) were male; their median age was 32.1 years. The

highest level of education for the vast majority of participants was either a Bachelor's degree or a Master's degree. All participants described their ethnicity as Jordanian (Middle East Asian) (see Table 5-3).



**Figure 5-1: Age of participants in Study I**

Participants had between 4 and 17 years of experience in their disciplines. As was obvious during their discussion, this range of experience helped them to participate well and reflect the current situation and discuss the expected challenges. All had a role in the treatment of patients with ACS and diabetes in hospital and/or in outpatient clinics following patient discharge from hospital, however those in some disciplines, such as dietitians and pharmacists, saw no role for themselves in caring for patients following discharge.

**Table 5-3: Demographic characteristics of participants, by hospital**

	<b>PBTH</b>	<b>KAUH</b>	<b>Overall</b>
<b>Number of Focus group</b>	3	3	6
<b>Participants</b>	19	14	33
<b>Gender</b>			
Men, %	12 (63.1)	10 (71.4)	22 (66.7)
Women, %	7 (36.9)	4 (28.6)	11 (33.3)
<b>Ethnicity</b>	All Jordanian	All Jordanian	All Jordanian
<b>Age, average years <math>\pm</math>SD</b>	32.7 $\pm$ 5.3	31.3 $\pm$ 4.4	32.1 $\pm$ 4.9
<b>Higher level of education</b>			
Diploma or equivalent	1	0	1
Bachelor's degree or equivalent	12	5	17
Master's degree or equivalent	6	9	15
Doctoral degree or equivalent	0	0	0
<b>Discipline (the average years of experience)</b>			
Cardiologist	2 (6y)	2 (6y)	4 (6y)
Internal medicine doctor	2 (4.5y)	1 with 3y exp.	3 (4y)
Doctor of pharmacy	0	1 with 11y exp.	1 with 11y exp.
Head nurse	2 (20.5y)	2 (13y)	4 (16.75y)
Registered nurses	11(7.7y)	6 (5y)	17 (6.7y)
Nurse Practitioners	1 with 2y exp.	0	1 with 2y exp.
Dietitian	1 with 10y exp.	1 with 9y exp.	2 (9.5y)
Diabetes nurse	0	1 with 15y exp.	1 with 15y exp.
<b>Note: PBTH: Princess Basma Teaching Hospital; KAUH: King Abdullah University Hospital; SD: Standard deviation</b>			

## 5.2 Findings

The focus group structure was designed to maximise discussion between participants in relation to the study objectives number 2 and 3 (as indicated Chapter 1). Initial analysis of the data generated a large number of themes (n=19) and sub-themes. Through a process of summarisation, synthesis and discussion with the research team (M.T., V.C. and D.F.), these were reduced to four main themes, which are shown with their sub-themes in Figure 5-2. Each of these themes will be described in turn using descriptive and interpretive models (Krueger 1998) together with summary descriptions from the perspective of the individual participant and the study as a whole. The participants' own words in italics between quotation marks were used to illustrate the theme.

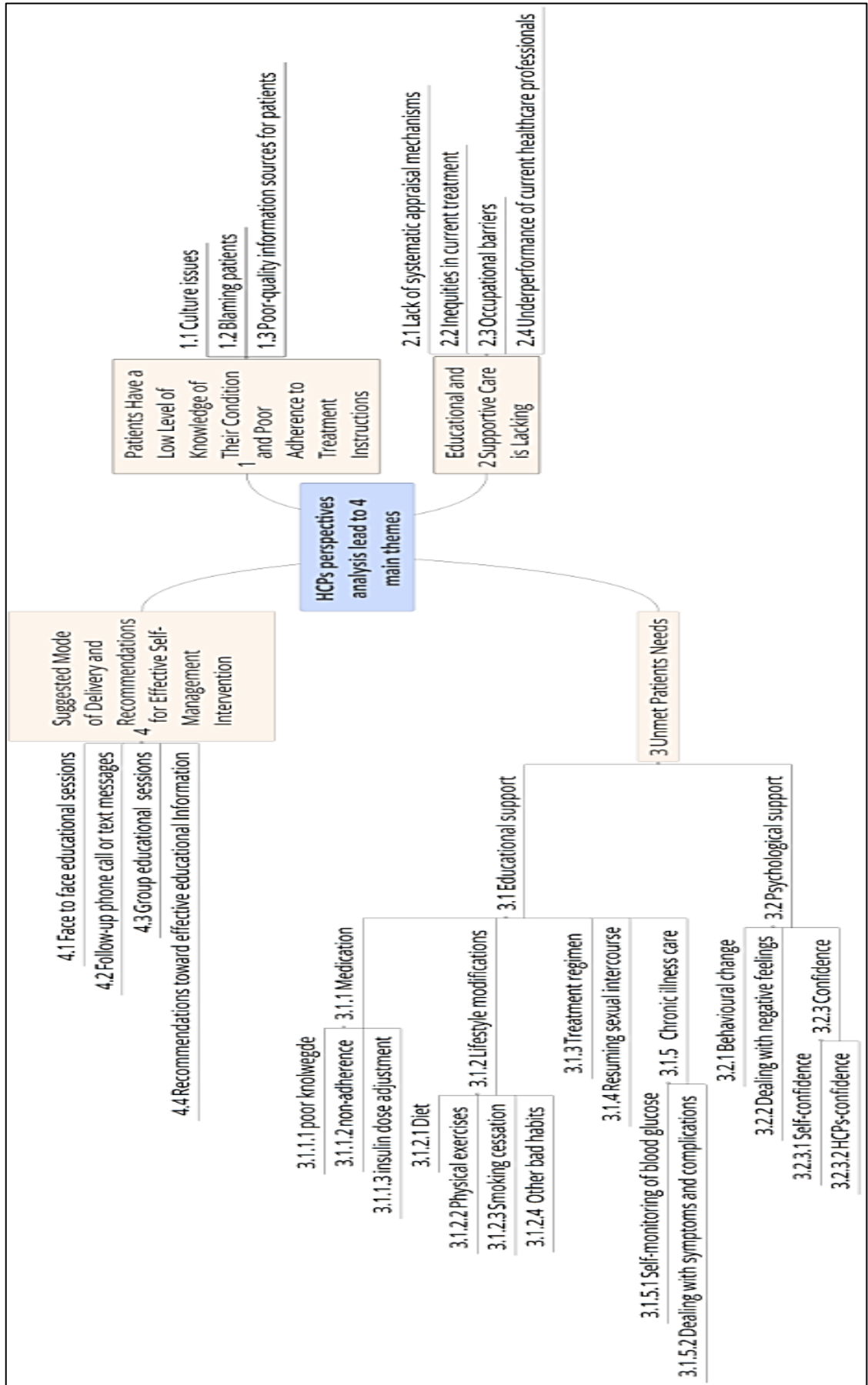


Figure 5-2: The main themes and sub-themes for all focus groups

### **5.2.1 Theme 1: Patients have a low level of knowledge of their condition and poor adherence to treatment instructions**

Considered collectively, the data from the focus groups clearly indicates that most patients with T2D and ACS know little about their conditions and their adherence to treatment instructions is poor. The participants expressed various causes for these phenomena. Having categorised all related themes, the researcher found that the participants were focused on three main subthemes (causes): cultural issues, blaming patients and poor-quality information sources for those patients.

#### **5.2.1.1 Cultural issues**

Most participants reported that the current culture in Jordan and among patients with TD2 and ACS was one of the main contributors to poor health knowledge and low adherence among those patients, as an internal medicine doctor explained:

*I think the culture of our whole community is the main reason. Our culture encourages for a lot of unhealthy foods, attitudes and misconceptions, and it is not easy for our patients to ignore it after discharge from hospital, so most of them were incapable of changing their lifestyle [...]. (Internal medicine doctor, F.1, P.17, L.15)*

Many of the participants stated that unhealthy behaviours, misconceptions and bad habits are prevalent in Jordanian society currently, which have reduced the sense of individual responsibility for health. They argued that the knowledge and adherence of many patients with diabetes and cardiac diseases are inevitably negatively affected by these cultural factors once they are discharged from hospital. One nurse described the problem as follows:

*The Jordanian health culture and patients' lifestyle outside the hospital are not encouraging. Most of those patients before they are diagnosed with cardiac disease have not engaged in physical exercise or followed a healthy diet etc. [...], so when they have an MI and are discharged from the hospital, it will be very difficult for them to change their previous attitudes, go against their surrounding culture or adhere well to our advice. (ICCU nurse, F.6, P.5, L.20)*

Some participants stated that given the ongoing lack of adequate awareness and health education about risks and treatments within Jordanian community and healthcare settings, patients with chronic diseases such as diabetes and cardiac disease will continue to suffer from the impact of these cultural factors and be unable to face the challenges arising from them after discharge from hospital. Others contended that the biggest problem these patients face when they return to their own environment after leaving hospital is the negative influence of their family and friends. Lack of appropriate family support and an unsuitable environment in home increase the burden on patients following discharge and prevent them from gaining the right knowledge about their conditions and adhering to their treatment regimen and their physician's recommendations.

*For example, when those patients visit me in the diabetes clinic, they tell me they can't follow my instructions about many things related to their diet, for example, at home or in work, because their life is strongly linked with family and friends and their typical meals are rife with all kinds of unhealthy ingredients [...]. (Diabetes nurse, F.4, P.12, L.17)*

*In all honesty, I think the patient's environment and his way of life at home [...] play a significant role in the patient's adherence and his acceptance and application of our recommendations [....]. (ICU nurse, F.5, P.8, L.1)*

In sum, participants emphasized that the cultural and social environment surrounding patients in their homes or at work affect their knowledge of their condition and adherence to treatment advice after they are discharged from hospital. These critical factors must be considered and assessed before patients are discharged from the hospital. Moreover, those patients with multimorbidity should know about these cultural issues and their impacts on their self-management behaviours, perceptions and health outcomes. Towards this end, some participants advocated involving patients' family members in educational interventions provided to patients and also educating patients about supportive strategies for dealing with cultural barriers.

#### **5.2.1.2 Blaming patients**

The focus group discussions made it clear that most participants from every discipline blame their patients for their low level of knowledge about their condition and their poor adherence to treatment instructions. Many participants in each group expressed

frustration about this and their belief that the patients themselves are primarily responsible for both.

Although most participants reported they are duty-bound to care for their patients, at the same time some reported strongly that it was not worthwhile providing educational sessions for patients with chronic conditions while they are hospitalised and they explained this view by reference to the lack of motivation and enthusiasm amongst those patients to learn about their conditions, to adhere to treatment advice or to change their negative behaviour to become healthier:

*[O]ur patients don't have any readiness to learn about their diseases or how to deal with their condition [...]. They do not show me any signs of being interested to know while I am dealing with them that motivates me to discuss their condition with them [...].* (Head nurse, F.1, P.10, L.12)

*[M]y initiative to provide health education for those patients depends on the patient himself. Sometimes he gets upset when I talk with him honestly about his condition [...]. Many don't want to know, they are not interested [...]. Sometimes the patient blatantly told me: I will eat what I want, I will continue smoking [...]. this patient doesn't give me any attention or motivation to play my role as health educator not just a physician [...].* (Cardiologist, F.2, P.23, L.9)

*[A]fter they have a cardiac event they are discharged from hospital without having the slightest intention of changing their behaviour, habits or lifestyle [...].* (ICU nurse, F.3, P.8, L.4)

Some participants expressed their frustration when describing their attempts to educate patients about their illness or to encourage them to adhere to treatment recommendations. They reported, to use their own words, that many patients preferred to stay in their comfort zone after they are discharged from hospital and are not willing to overcome the challenges they face in order to follow treatment recommendations. The participants suggested that many patients may lack self-awareness when managing their disease and low confidence in their capabilities to face the many challenges often associated with their chronic condition such as giving up smoking and tackling obesity,



changing unhealthy lifestyle and habits, and mistaken convictions and resisting negative desires:

*[M]ost of those patients here don't know much about how to deal with their multiple conditions and unfortunately, at the same time they don't want to know!! and they want to stay away from the stresses and strains of adherence to treatment regimens, thus they don't make a bold attempt to make a change against their usual lifestyle [...]. (ICCU charge nurse, F.2, P.12, L.14)*

It was interesting to note that the discussions between participants in all groups indicate that the current health education and self-empowerment training provided for patients, which, as participants have observed, is already limited, are conditional on certain behavioural indicators that patients must demonstrate to them during care. Some participants stated that they did not provide any education for patients who did not show a willingness to learn about their conditions or to how to cope with their disease well. One participant, for example, stated that care is provided only.

*if a patient has asked us and showed us he is interested in learning [...].*  
(CCU charge nurse, F.2, P.6, L.7)

Other participants discussed how patients need to show their willingness to learn by taking the initiative, for example by asking questions about their condition, listening with interest and showing respect for the advice they provide while caring for them in hospital or in out-patient clinics, to encourage them as healthcare providers to open a discussion with patients about their condition and treatment.

In sum, blaming patients for their lack of knowledge about their condition and poor adherence to their treatment regimen and a failure to use motivational strategies and communication skills to increase the willingness of patients to learn and adhere are common among HCPs and must be considered in future studies which seek to promote self-management behaviours among patients with diabetes and cardiac disease.

### **5.2.1.3 Poor-quality information sources for patients**

In general, there was consensus among participants that most patients with diabetes and cardiac disease obtain information about their condition and how to deal with its symptoms and complications from poor-quality sources, such as other patients who have

or have had the same condition or individuals with little or no relevant medical background. These individuals with no relevant medical background, may include family members, relatives, friends, colleagues or neighbours. The following responses from participants who were asked about the sources of health information for those patients, especially in the absence of health information and education provision in a healthcare setting, are illustrative:

*Mostly from the neighbours, friends or people who live around them and who are experiencing the same disease [...] sometimes they believe them more than me. (Cardiologist, F.3, P.17, L.8)*

*[F]rom talking with other patients who have the same disease in the hospital and outpatient clinics [...]. (Nurse 3, F.6, P.13, L.5)*

*From neighbours, friends or a relative's doctor, nurse or another person who has a related medical background in the family [...]. (Cardiologist, F.5, P.19, L.16)*

Some participants observed that some of those patients are empirical people who preferred to learn from their own experience with their disease and its symptoms and whose actions are based on their desires.

*I think most of them trust themselves more than others and prefer to learn from their own experience with diseases especially when no health education is provided for them after discharge from hospital and they consult their heart about their actions and follow which their heart desires or feels. (CCU Head nurse, F.5, P.19, L.18)*

*Their views are drawn from their own experience with symptoms, and most of them are going wrong [...]. (Internal medicine doctor, F.6, P.13, L.9)*

Although there is currently a lack of health education in care, some nurses reported that there are still some patients who only accept healthcare information from their primary physician.

*Many patients get their treatment information mostly from the physician and have confidence in his information only. (Dietitian, F.4, P.17, L.20)*

By contrast, a number of participants mentioned that a few of their current patients found their information on the internet, audio-visual media such as televised awareness sessions or written publications such as pamphlets which relate to their disease. Participants expressed their frustration about the poor quality of these sources, which are not evidence-based, and their concern over their patients' confidence in them. They reported that this poor-quality information impacts seriously on patients' conditions, health outcomes and trust in HCPs by exposing them to a higher level risk of following nonfactual and incorrect information which conflicts with their recommendations for proper treatment and leads to greater misunderstanding with the result that the patients' condition and health deteriorated, more adverse outcomes became more likely and the risk of readmission to hospital increased.

### **5.2.2 Theme 2: Educational and supportive care is lacking**

The second superordinate theme to emerge from the focus group interviews concerns the general lack of educational and supportive care in the Jordanian secondary and primary healthcare system currently. Most participants in all groups perceived that there is no health education or follow-up care for patients, either through the CCU and general wards in hospital or outside the hospital at outpatient clinics

*[U]nfortunately, patients with diabetes and cardiac problems are discharged from hospital with only brief information about their condition and medications, and there is no programme to meet their educational needs. Moreover, they didn't get any real health education during their hospitalisation or follow-up visits to outpatient clinics, so, honestly, with no educational services providing for those patients, their problems and sufferings from the adverse outcomes it will continue, so our care is like moving in a vicious cycle. (Cardiologist, F,3, P.9, L,11)*

An ICU nurse concurred:

*Yes, it is incomplete treatment for those patients. In short, during their hospitalization, we are mostly focused on providing clinical care for them [...]. Unfortunately, in outpatient clinics, the staff there mostly focus on renewing prescriptions of their medications and whether the patients need a new medication, no more than this. (ICU nurse, F,3, P.9, L,15)*

The focus group discussions made clear that most participants reported that a lack of educational and supportive care occurred because of the many problems in the current healthcare system. The four main reasons participants identified were (1) lack of systematic mechanisms to appraise patients' educational needs, (2) inequities in the treatment currently being provided, (3) occupational barriers and (4) the underperformance of current HCPs.

#### **5.2.2.1 Lack of systematic appraisal mechanisms**

While many physicians stated that their assessment of those patients in hospital is mostly limited to medical and clinical tests, some participants perceived that there was no established process to assess the educational needs of those patients immediately after they are diagnosed with a new chronic disease such as a cardiac event or before they are discharged from the hospital. In their view, this lack of a clear and standardised process leads firstly to the unsuccessful delegation of health education duties between HCPs.

*[There is a] lack of coordination between doctors and nurses due to the absence of a formal form/checklist summarising the patient's educational needs [which] causes a failure to identify patients' needs and provide health education for them. (ICU nurse 1, F.3, P.12, L.7)*

Secondly, having no set appraisal procedure makes it difficult to identify and prioritise the educational needs of patients with T2D and ACS in systematic way.

*We couldn't imagine what the educational needs of those patients are. Each patient has different needs from another; we only answered [the questions] the patient asked about [their condition], if he asked us [...] and most patients did not ask, and at the same time we can't offer them education about all things. (Cardiologist, F.2, P.8, L.10)*

Thirdly, these factors have eroded the perception amongst healthcare providers that providing health education for patients is part of their role.

*Currently we don't have any reminder tools to alert us about the educational needs of patients with diabetes and cardiac problems [...], so it is not our responsibility to offer education for them. However, when any of us did provide education, we did it on our own initiative [...].* (Head nurse of internal medicine floor, F.1, P.13, L.5)

Another head nurse added:

*I think we can offer education to some extent, such as if a patient needs this education urgently. But given the current work load and difficulties and in normal situations, [providing] health education for those patients is not our responsibility as nurses.* (Head nurse of ICCU, F.1, P.13, L.17)

Moreover, some participants expressed the view that the lack of systematic appraisal mechanisms for assessing and prioritising the educational needs of patients as a part of their initial assessment during hospitalization has a negative impact on patients' discharge planning, whereby cardiac patients are discharged from the CCU without a clear discharge plan or at least without successfully involving them in effective discharge planning by identifying and recording their educational needs. Subsequently, as some participants indicated, this may lead HCPs to breach their legal obligation or responsibility to address these patients' educational needs in hospital and in the follow-up time at outpatient clinics in Jordanian healthcare system.

*I support the idea to offer a specific checklist or form to be filled in shortly after the patient's admission to hospital, which would help in assessing and identifying their educational and self-management needs [...], then these identified needs should be prioritised, provided and tracked by specific healthcare professional team based on clear care plan.* (CCU charge nurse, F.1, P.14, L.3)

While a few participants indicated that they blatantly ignore the educational needs of those patients with chronic diseases in their assessment because they "don't have time

to provide it” (ICU nurse, F.5, P.7, L.9) as well as other occupational barriers that will be discussed later, one nurse emphasized that they could overcome this time issue if an evaluation form were available through which they could record the patient’s educational needs from the moment they are admitted to hospital. This evaluation form should include a comprehensive assessment to enable a better understanding of the psychological, social and economic status of patients. The patient’s educational needs would be prioritised as a list of objectives based on the importance to the patient’s health and in line with the patient’s related cofactors and the achievability of each target objective. They could then educate the patient about one or two of these educational objectives during their period of hospitalization, with the others to be followed and provided for them one after another during follow-up visits to outpatient clinics.

*[We] should take into account many considerations such as the patient’s mores, customs and traditions [...] and we should also assess the psychological and financial status of patients, because all these [factors are] changeable from one patient to another, for example, if a patient is poor he/she often has many psychological and social difficulties that need to be considered during our discussion with them [...], so I think we need to focus on these real difficulties and teach [the patient] how to deal with it appropriately by changing his lifestyle [...], so based on this initial assessment we can get a clear idea of what we have to focus on firstly in our educational objectives and recommendations. (Medical nurse 2, F.6, P.8, L.8)*

In sum, many participants across the six groups expressed concern over the lack of a systematic appraisal mechanism in current practice for assessing the educational needs of patients with chronic diseases, and they perceived that this issue was having a negative impact on the process of providing the educational and supportive information for those patients.

### **5.2.2.2 Inequities in current treatment**

Most participants in each group indicated that there is a gap in the quality of care provided, especially between the actual care they provide for patients in hospital and the standard of care that should be provided for them. Many participants described significant variations in care provided based on the patient’s age, education level and socioeconomic status. They illustrated that such variations in care among patients are common in the

current healthcare system in Jordan and have a significant influence on access to and the type of care provided for those patients. For example, one cardiologist mentioned that the referral services for counselling and educating patients about their condition could be affected by the patient's financial status:

*[I] can make referrals to a dietitian or diabetes clinic only for patients who have health insurance that covers the costs of this service, but unfortunately most health insurance available for current patients does not cover expenses such as these services. (Cardiologist, F.2, P.10, L.15)*

Another participant added:

*[T]he financial status and health insurance of most patients cover only the standard care for them post the catheterisation, which doesn't allow us to make referral for them to the diabetes clinic, ophthalmologist, diabetes foot care clinic and other such services [...], so their follow-up visits were always limited only to renewing medications, checking [the results of] clinical tests and some brief educational advice [...]. (ICCU charge nurse, F.2, P.10, L.18)*

Regarding the effect of the patient's education level on the type of health education provided, one nurse stated:

*[T]hose patients who have a low level of education or who are from a low economic status, we often don't offer health education for them in normal situations, to be honest, because such patients mostly need a lot of time to get our points and understand our instructions appropriately and its difficult for them to adhere to this advice [because] they have financial issues that restrict their ability to follow the right diet or acquire the necessary equipment such as a blood glucose monitor and test strips [...]*  
(ICU nurse 1, F.3, P.12, L.1)

Likewise, many participants expressed that patients' health outcomes and adherence to treatment recommendations after being diagnosed with diabetes and cardiac problems vary significantly based on their health insurance cover or financial status.

*[I]n our healthcare system the Glucocheck device and its strips are not covered by governmental health insurance, and most patients with diabetes haven't enough money to purchase the device and its stripes constantly [...], therefore, most patients didn't monitor their diabetes level after the cardiac event, and they also become more careless about following our instructions regarding the need to self-monitor their blood glucose [...]. (Diabetes nurse, F.4, P.10, L.10)*

Most participants stated that the education they provided for patients with diabetes and cardiac problems was often limited to inadequate information and quick advice, whether during the patient's hospitalization or at follow-up visits in the outpatient clinic.

*We offer them some short educational information but in a simple way and not in detail [...]. (CCU nurse, F.5, P.3, L.19)*

There were a number of participants who expressed that even this limited information and the referral services offered to patients with diabetes following their cardiac event are still conditional on another determinant within current practice, which is whether the patient presents with a serious need or symptom/complication. One cardiologist, for example, stated that often they provide advice for patients who have serious clinical signs of uncontrolled diabetes during their hospitalization. However, those whose clinical outcomes are acceptable, such as their blood glucose level reading at the time of hospitalisation or appointment, are not offered education. As illustrated in the following example.

*[A]ctually we provide health information based on each patient's readings. If he has acceptable glucose level, for example, it's okay, [there is] no need to provide any education. But if the patient has poorly controlled diabetes, we might educate them or refer them to a diabetes specialist doctor for education if their insurance allows it [...]. (Cardiologist, F.1, P.3, L.19)*

The same approach is taken if patients have a critical physical condition and urgently require education about something.

*[W]e didn't provide education about diet or nutrition for those patients currently receiving treatment, but we offer it only if the patient's case is*



*very critical, for example if their body mass index is more than 40, then the physician could decide to refer him to a specialist such as a dietitian [...]. (Dietitian, F.4, P.2, L.13)*

Other participants stated that patients must demonstrate an interest in education by asking questions to open discussion about their educational needs.

*[A]lthough we don't have time [...], we provide short and simple health advice only if the patient asks us [...]. (CCU charge nurse, F.1, P.24, L.15)*

*During our cursory examination of the patient, we offer some quick advice but only in relation to what he asked or was interested to know about [...]. [I]f he didn't ask, often we don't provide education or open a discussion with the patient about how to deal with disease in normal procedure. (Internal medicine doctor, F.6, P.2, L.2)*

As these testimonies clearly indicate, there are some health inequities in the treatment of patients with T2D and ACS. As a result, there is a lack of educational and supportive care in the current healthcare settings, with the consequence that many cardiac patients leave the hospital without being educated about how to manage either their new cardiac condition or their diabetes. Also, for some professionals, the decision to educate or advise patients in hospital is affected by certain unacceptable determinants, such as the patient's clinical condition alone or whether they show an interest in receiving information. Other determinants that should be considered carefully by HCPs, such as cognitive and psychological representations related to the patient's condition and their coping attitudes either before or after being diagnosed with the cardiac disease, are currently ignored.

### **5.2.2.3 Occupational barriers**

Many participants during focus group discussions reported that there were numerous occupational barriers beyond their control that prevent them from offering a sensible education and empowering care for patients with diabetes and acute cardiac problems either during their hospitalization or follow-up visits to outpatient clinics.

Although many participants perceived that providing health education and empowering care is one of their main responsibilities toward their patients, they also

stated that lack of time, heavy workloads and a massive shortage of HCPs and specialists significantly limit their ability to fulfil this responsibility.

*Clearly, we offer a little bit of health information during our morning ward round, and this is mainly because of our current workload. For example, only two doctors work during each shift in this department and we typically serve a huge number of patients, so there is not enough time for talking with each of those patients about their educational needs and explaining [things] to them [...]. If I do this with each patient, I will not be able to finish my daily duties and responsibilities. (Cardiologist, F.5, P.11, L.14)*

As many participants indicated, the size of their workload drives most of them to blatantly disregard their health education responsibilities in relation to those patients. It was interesting to note, however, that some participants, most of them nurses, mentioned that there is a lack of accountability for providing health education and other supportive care in the current healthcare system.

*Yes, we are responsible for health education and none of us deny it. However, based on our priorities in current practice, health education and all types of supportive care are outside our priorities and we offer it only if possible [...]. Also, I will be held accountable if I didn't provide medications or do physical and clinical exams, but at the same time no one will question me if I did or didn't teach patients [...]. (CCU nurse, F.3, P.11, L.17)*

Many participants stated that the barriers mentioned above have a negative impact on the actual time spent with each patient. For example, most participants, in particular the physicians, reported that, on average they generally spent 'five minutes, no more' (Cardiologist, F.5, P.11, L.9) with ACS patients each of the 2-3 times they visit them while they are in hospital, and less than 10 minutes when they see patients in the outpatient clinic following their discharge. One cardiologist, for example, stated that:

*I visit my patients daily during their hospitalisation and each visit lasts 4-5 minutes. (Cardiologist, F.2, P.7, L.12)*

Some participants expressed concern over the brevity of the time spent with patients and reported this had a significant influence on patients' knowledge about their condition, their health outcomes and their trust in them as healthcare providers, as discussed later in this chapter.

However, a few participants mentioned that the current health infrastructure of the Jordanian healthcare system is poor. For example, the number of professionals who specialise in general and diabetes-related health education, diet and rehabilitation services are very limited or in many cases non-existent, which participants reported was a significant reason why patients were not referred to specialists currently, which in turn influenced patient adherence.

*We don't have specialist people in health education, nutrition and diabetes in our hospital, so we can't refer those patients to expert professionals [...] and patients will be discharged with very limited knowledge about their condition, thus, poor adherence is something to be expected [...].*

(Internal medicine doctor, F.6, P.3, L.2)

Some participants noted that there was a massive lack of specialist clinics in current healthcare settings such as diabetes and smoking cessation clinics. In addition, a few acknowledged the urgent need to establish 'a rehabilitation centre' (Cardiologist, F.2, P.10, L.4) for those patients currently in Jordanian secondary healthcare settings who need to be served by a multidisciplinary team in order to deliver sensible care for patients diagnosed with diabetes and cardiac diseases.

#### **5.2.2.4 Underperformance of current HCPs**

It was interesting to note that some participants perceived that their own current knowledge in relation to health education and the skills required to teach patients with chronic diseases are limited and do not enable them to provide appropriate health education for patients with diabetes and cardiac diseases. They mainly attribute their underperformance to the lack of available continuous training or learning courses.

*In our hospital there are no educational sessions or awareness workshops about health education skills provided for current healthcare professions*

*to learn how to deal with those patients with multimorbidity in a professional manner [...]. (Cardiologist F.5, P.13, L,12)*

The head nurse agreed:

*Yes, we never received or rather the hospital did not offer us such training courses [...]. (CCU head nurse, F.5, P.13, L,16)*

Moreover, a few participants perceived that most current HCPs have unpersuasive communication and motivational skills, which limits their performance and confidence and impacts negatively on their patients' response to any communication with them about their condition and how to manage it well.

*I think most current healthcare staff members are very weak in communication when contacting those patients [...]. (Pharma doctor, F.4, P.6, L,15)*

*Actually, most professionals whether nurses or doctors lack the right technique or method for dealing with patients with chronic diseases [...]. [It takes a] special art and skills to open the discussion with patients and provide information for them effectively. Unfortunately, most current healthcare professionals provide that information in a non-systematic and incorrect way, therefore, the patient doesn't accept and understand the information properly and often this wrong technique proves counterproductive [...]. (Diabetes nurse, F.4, P.6, L,18)*

*[M]any current professionals have limited knowledge in terms of health education skills, and their techniques are very old and invalid for providing health information and supportive care for those patients, and sometimes make things in relation to the patient's health worse [...]. (Cardiologist, F.3, P.9, L,16).*

It was obvious from the discussion amongst participants that the underperformance of current HCPs in relation to their communication with patients who have multimorbidity

prevents them from providing health education and supportive care for those patients during their hospitalisation.

In sum, health education and supportive care for patients with diabetes and cardiac disease are lacking due to a range of factors and occupational barriers within the healthcare profession. Most patients with T2D and ACS are discharged from hospital with no assessment of their educational needs and without receiving any sensible health education about how to manage their new condition after their discharge from hospital.

### **5.2.3 Theme 3: Unmet Patient Needs**

The HCPs who took part in this study identified a wide range of needs that they believed were currently unmet for patients with ACS and T2D. These unmet needs fell into one of two sub-themes, educational support and psychological support, each of which includes a number of features.

#### ***5.2.3.1 Educational support***

Participants identified the most important topics about which those patients need to be educated during their recovery from a cardiac event, including medications, lifestyle modifications, treatment regimen, resuming sexual intercourse and chronic illness care.

##### Medication

For most participants, medication-related issues were extremely problematic for patients, especially those diagnosed with a cardiac problem. These issues varied, but can be classified into three primary types: lack of knowledge, non-adherence and insulin dose adjustment.

Many participants observed that patients with T2D and ACS do not understand the importance of taking their medication, especially cardiac drugs such as Plavix (Clopidogrel bisulfate, and antiplatelet agent), or the most common side effects of these drugs or the relevant contraindications for some drugs such as Beta-blockers which are known to disguise the symptoms of hypoglycaemia. They reported that such lack of knowledge presents a key challenge for patients in terms of managing their condition, including pharmaceutical conflicts, non-adherence and increased risk of future readmission to hospital. Moreover, there was consensus among participants that patients'

knowledge of such issues must be improved. According to one member of Focus Group 1, for example

*First of all, their knowledge of medication of both diseases is very poor [...]. Moreover, one of the main challenges that faces those patients is when they start using cardiac drugs such as Enalapril, Beta-Blockers and Angutic in addition to what they already were prescribed from drugs [...].* (Cardiologist, F.1, P.14, L.12)

A senior doctor of internal medicine added:

*[F]or the most part, those patients are not educated about their medications or condition as a whole. For example, most of those patients never distinguish between their drugs, especially the elderly patients [...]. There is some conflict between the drugs used to control the two conditions and patients need to be educated about it.* (Senior Internal Medicine doctor, F.1, P.14, L.20)

A member of Focus Group 5 explained how lack of education about the new cardiac medication frustrated patients due to the amount of medication they are required to take, which can lead to nonadherence:

*[A]fter they get a heart attack and start taking a bunch of new cardiac medications [...], managing and taking all these drugs becomes one of the main difficulties for [these patients] and many of them grow frustrated and distressed because of lack of education and stop taking it all or cancel some of it [...]; so educating them about this new medication and how to deal with it after discharge is very important.* (Charge Nurse, F.5, P.5, L.6)

Healthcare professionals identified the need for patients to adhere to their medication especially after they were discharged from hospital. They stressed that nonadherence to their medication can cause serious consequences. A senior internal medicine doctor offered this example:

*Patients need to learn how to adhere to their medication, especially the important ones [prescribed] after they experience MI such as Plavix. Patients should never stop taking it and should renew [their prescription] at least one week before they run out, because if they pause or stop taking such*

*medication for a period of time as many of our current patients often do, they will put themselves at risk of another acute MI, thrombosis or stenosis [...] so those patients need to adhere and know the consequences of non-adherence. (Senior Internal Medicine Doctor, F.1, P.16, L.2)*

Despite the vital importance of adherence, many participants stated openly that currently their patients received little or no health education in relation to their medication, including its side-effects, either in hospital or through outpatient clinics. They expressed how this can lead to distress for patients and eventually nonadherence. An example of their interaction about this issue was also reflected as quoted:

*I think as much as possible those patients should be educated about their medication, how to take it and what are the most common side-effects of using it. Actually we write their medication list when they are discharged without providing proper education and instructions, either from their doctors or the pharmacy [...]. (Internal Medicine doctor, F.6, P.12, L.1)*

*Yup! Honestly, most of those patients get lost, they become more confused and distressed when they receive more drugs than what they already have. (Nurse Practitioner, F.6, P.12, L.6)*

*Often the main problem is non-adherence because they don't know what [their medicine] is and how to take it. (ICCU nurse, F.6, P.12, L.7)*

A ward nurse expressed similar frustration with the consequences of poor education about pharmacotherapy in terms of lack of awareness and non-adherence amongst patients, and offered the following example of how improving a patient's understanding of their medication improve patient comfort and adherence:

*An uncontrolled diabetic patient that I know very well was admitted to KAUH for catheterization and coronary stenting. Before discharge he got a chance to sit with a doctor of pharmacy who taught him about all his medication and how to take them correctly. [...] The patient naturally was relieved and since then has been taking his medication regularly and has adhered well to the regimen, even though he is 73 years old. So, when the patient has good background information about his medication and understands it well, adherence will be automatic. (Nurse, F.6, P.12., L.12)*

Likewise, as insulin therapy is often an important part of the treatment for diabetes, many participants expressed concern over poor patient skills in relation to insulin dose adjustment, particularly among elderly patients. Many participants stressed the need to teach patients about the titration regimen associated with insulin use:

*Those patients urgently needed to be educated about drug dose calculation, for example, how many times they should take insulin and how much they should take. And how they should adjust the insulin dose based on actual readings of their blood sugar, particularly in the case of elderly patients.*  
(Head Nurse, F.1, P.16., L.10)

Furthermore, some expressed concern that physicians were insufficiently knowledgeable about nutrition and diabetes care in particular, with the result that they tend to misguide patients about taking insulin. According to one dietitian, for example:

*Unfortunately, because some of our doctors have a poor background in nutritional and diabetes care, they always prescribe a fixed insulin dose for their patients on the assumption that their patients will take their meals definitely and regularly, but this is totally wrong. Patients should learn how to take the insulin dose, when and on what basis, and should learn how to adjust the dose.* (Dietitian, F.4, P.2., L.9)

### Lifestyle modification

Considered collectively, the data from the focus groups clearly indicates that patients with diabetes and ACS need to be educated about lifestyle modification, with a focus on four main areas: diet, physical exercise, smoking cessation and other bad habits.

Many participants emphasized that most patients with diabetes had not been following a diabetic diet before they experienced the cardiac event, and their diet become worse after they were diagnosed with cardiac disease largely because they continued to receive no information about appropriate nutrition. As one cardiologist explained,

*I think the most difficult thing for those patients is the adherence to a diet that is appropriate for their new condition. [...] Unfortunately many of them are readmitted to hospital again and again because they are never educated about their diet.* (Cardiologist, F.5, P.5, L.1)



Other participants reported strongly that such patients also need to be aware of the consequences of not following an appropriate diet before they are discharged from hospital.

*[A]lso, as a part of the educational discharge plan for those patients. they need to learn about the consequences of bad nutrition and failure to follow a proper diet for their health. (Dietitian, F.4, P.7, L.13)*

This view was shared by a nurse practitioner:

*Diet is very important [...]. Most of these patients are obese and they need to learn immediately to lose weight by following a healthy diet. (Nurse Practitioner, F.6, P.12, L.20)*

Poor education about diet from current healthcare providers and a lack of dietitians both in hospital and in outpatient clinics after patients are discharged were identified as the main causes of this issue:

*Currently there are no dietitians and we don't have nutritionists or health education specialists in our secondary or primary healthcare settings. (Doctor, F.6, P.3, L.4)*

Some participants expressed concern over cultural attitudes within the community and suggested that the mistaken beliefs of patients themselves are one of the main obstacles to their following a healthy diet after they are discharged from hospital.

*Living healthy and following a healthy diet is not an important priority in our local community culture. (Cardiologist, F.2, P.12, L.18)*

*A patient's culture and beliefs are the main obstacles. For example, some of those patients are aware of the negative consequences of eating too much sugar and fat [...] but they never try to avoid, stop or change [...] because they always say, 'You only live once, what does it matter, everything has already been decreed by God'. (CCU nurse, F.2, P.13, L.1)*

Nevertheless, participants were mostly in agreement that encouraging patients to follow a healthy diet should be one of the main pillars of any educational intervention designed for them.

Similarly, participants in most focus groups emphasized physical exercise as one of the main lifestyle modifications these patients should be encouraged to practice regularly beginning shortly after a cardiac event. Many participants reported that practicing appropriate physical exercise should be one of the main health education priorities not only for individual patients but for society as a whole.

*I think that in general in our community, and particularly among those patients with multiple comorbidities, [...] we don't practice any healthy exercise or activity [...] and we need to be educated about it. (ICU nurse, F.3, P.14, L.1)*

However, other participants referred to a number of obstacles related to the age and gender of the patient that complicated the provision of care and advice about physical exercise:

*We should take into account the age and the gender of the patient; it may be difficult to ask an elderly patient or female patient do some exercise [...] so we mostly don't provide anything like this for them. (Cardiologist, F.1, P.16, L.18)*

The head nurse agreed:

*Yes, definitely; most women will tell you it is not possible for them to practice any physical exercise. (Head Nurse, F.1, P.16, L.22).*

This view was shared by the cardiologist in the group:

*[A woman's] husband does not allow her to go to the gym, and as you know, we are in a conservative eastern community with some cultural problems as well as a massive lack of suitable supportive sports facilities. (Cardiologist, F.1, P.17, L.1)*

In addition to the physical incapacity of elderly patients and societal constraints on eastern women, lack of appropriate leisure facilities is one of the main obstacles that limits patients' motivation to practice sports in public. Other participants stated lack of money prevented many patients from finding an alternative solution such as purchasing their own exercise equipment. However, participants in most groups acknowledged the need to encourage them to be active by providing simple, accessible alternative forms of physical exercise such as walking. Furthermore, some participants stated that by

understanding the patient's lifestyle before they are discharged from hospital, HCPs can help them to find an appropriate alternative that is compatible with the patient's lifestyle, and thereby to replace one unhealthy habit with a positive physical activity, as a diabetes nurse suggested:

*Currently there are no appropriate places available to encourage [women] to practice physical exercise outside, and when we or doctors for example advise them to buy a personal exercise device patient will say, 'I can't buy a blood glucose monitor and you ask me to buy a sports device! I can't.' [...] So we need to provide a simple solution such as walking for half an hour 3 times a week. (Diabetes nurse, F.4, P.13, L.6)*

The dietitian in the group agreed:

*Yes, many of them are obese [...]. We have to support these patients to change their bad habits through simple solutions. For example, if the patient uses a car to go to a mosque every day, then we have to encourage him to walk there instead. (Dietitian, F.4, P.13, L.15)*

The need to stop smoking was recognised as another big challenge for such patients. Participants in both main referral hospitals expressed concern that the majority of patients are unable to quit smoking after a heart attack even male or female, particularly without appropriate support and education.

One cardiologist cited findings from his recent study involving 2000 Jordanian patients. Regarding their effort to stop smoking after ACS, he noted that

*Less than 20% of patients who quit smoking after still are not smoking after one year, while around 40% of them stop only for 3-6 months after they diagnosed with ACS and up to 40% never try to quit smoking after the cardiac event. (Cardiologist, F.1, P19, L.3)*

A nurse in another group made a similar observation:

*They need to learn how to quit smoking. Most of these patients do not stop smoking after a cardiac event and many think of their cigarettes as a loyal friend that has no impact on their health. (ICU nurse, F.3, P.14, L.3)*

Although some of the HCPs who took part in this study believed that as far as educating their patients about smoking cessation, their role was limited to providing brief advice, other specialists described their frustration with this approach and its adverse impact on their patients' health. One cardiologist, for example, argued that most patients who smoke don't seem to care what happens to them (careless) and are very addicted to the nicotine in tobacco smoke and therefore cannot stop smoking after the cardiac event.

*Most of them have a lot of modifiable risk factors such as smoking [...], so for me as doctor I advise them to stop, but while a few of them respect our advice, unfortunately many reject it [...]. It is very worrying. (Cardiologist, F.2, P.6, L.21)*

Another participant reported that the failure to educate patients had exacerbated the problem:

*Actually, often we never talk with them about smoking and we don't provide them with information about smoking cessation. Consequently, at present most of them are already addicted. (Pharm-D, F.4, P.13, L.22)*

Indeed, most participants reported there was an urgent need to provide education and establish smoking cessation clinics for such patients before and after discharge from hospital. The cardiologist's views on this point are illustrative:

*To resolve this issue, they need to provide counselling programs [...]; continuing to provide only short verbal advice in hospital and outpatient clinics without any real support or educational program for those patients will never be effective (Cardiologist, F.1, P.9, L.10)*

Finally, a number of participants reported that Jordanians 'have a lot of bad habits' (Diabetes Nurses, F.4, P.12, L.1) that should be addressed as part of a general programme of lifestyle modification. Asked to elaborate on the nature of these habits, respondents focused primarily on eating habits and the factors that contribute them.

*They have irregular eating patterns, [they engage in] unregulated eating and drinking, in other words they don't take their meals at a specific time [...] and often they eat only when they have time to do so. [...] Sometimes, the nature of the patient's work [...] or having no one in their family to*

*monitor their eating or offer support perpetuates these bad habits after the patient is discharged. (Diabetes Nurse, F.4, P.12, L.3)*

Participants stated that the majority of patients' relapse into bad habits shortly after they recover from the cardiac event and as a consequence of this relapse many of them return to hospital whenever their bad habits have serious consequences for their health. In addition to the poor-quality health education currently provided as part of the follow-up care of patients diagnosed with disease as previously discussed, participants blamed this pattern of relapse on the lack of psychological or motivational support from the healthcare provider, which discourages patients from changing their bad habits after they are discharged. Other reasons participants cited included cultural practice, the uncontrolled desires of patients and the return of patients to their typical working life after being discharged from hospital, with no regard for their new health status.

#### Treatment regimen

Many participants observed that most patients have little knowledge about the treatment regimen required for effective management of chronic diseases. Some participants believed that one of the most important lessons such patients need to be aware of is that they must continue the therapy for their chronic disease for a long period of time after discharge from hospital and return to their home and working life. Currently, however, few patients realise what they need to do:

*Unfortunately, they do not understand that they have a chronic disease or the need for regular and continuing treatment. (Charge Nurse, F.2, P.24, L.1)*

*The patients didn't learn about the way to treat chronic disease or how to treat and control their diabetes for the rest of their life, to prevent their condition from becoming worse and to avoid complications (Dietitian, F.3, P.6, L.6)*

This lack of knowledge and misunderstanding about the proper treatment regimen for chronic diseases lead to non-adherence with their treatment plan. According to one ICU nurse, for example:

*Unfortunately, some [patients] never accept their disease as a chronic condition. For example, regarding their diabetes, some don't realise they*

*had a chronic condition which needs long-term treatment, so they don't take their insulin regularly and they don't follow an appropriate diet. (ICU nurse, F.5, P. 4, L.12)*

Other participants maintained that due to patients lack knowledge about their treatment regimen they can be susceptible to false remedies, fake homeopathic medicines and inaccurate cultural beliefs about the effectiveness of their treatment regimen. Also, by trusting more in the opinions of non-professionals and others' experience than the instructions of their HCPs in the hope of discovering an easier treatment plan or a quick and magical remedy for their disease.

*Many patients have told me blatantly 'I will keep eating what I want', like Massif (a high-calorie, fatty meal) and other fatty meals, 'but I will just take my lipid-regulating drugs'; [...] Many believe that taking medication alone is enough to treat their chronic condition. (Head nurse, F.1, P.18, L.6)*

*One of my patients purchased a new anti-sugar drug from Egypt after he heard from people that it can cure diabetes quickly [...] and unfortunately after he took drug X and stopped taking all his diabetes medications, he was admitted to hospital with diabetic ketoacidosis. [...] Unfortunately, many patients look for magical solutions because they do not like to have a chronic disease. (Pharm-D, F.4, P.17, L.23)*

Most participants expressed a concern over low levels of awareness of those patients about their treatment regimen for both chronic conditions, diabetes and cardiac problem. They acknowledge the need to learn them about their long-term conditions and how to live successfully with it by adhering to it treatment regimens constantly.

#### Resuming sexual intercourse:

While the vast majority of participants in all six focus groups did not say that they provided any educational information or advice about resuming sexual activity after a heart attack, a small number of participants stressed the need to educate and reassure patients about this issue, especially after they are diagnosed with another chronic cardiac condition. Specifically, patients have questions about their ability to resume sexual activity if they are well enough and these should be answered before they are discharged

from hospital. Discussing the most common complications and problems that patients experience after a cardiac event, one cardiologist said that:

*Most of them complain about shortness of breath [...] and sexual problems shortly after discharge from hospital and many feel very stressed about this.*

(Cardiologist, F.3, P.19, L.9)

A cardiologist in another focus group added:

*After they experience an MI, most men with diabetes ask me whether or not they can resume sexual intercourse, and if so, when they will be able to do*

*so.* (Cardiologist, F.2, P.25, L.3)

### Chronic illness care

Chronic illness care, which has two main components, self-monitoring of blood glucose and dealing with potential symptoms and complications after discharge from hospital, was a common thread of this sub-theme and was discussed by many participants in all six focus groups.

Many participants acknowledged the need to educate patients about how to self-monitoring their blood glucose even if they were diagnosed with diabetes a long time ago. Participants reported that successful diabetes management after a heart attack depends not only on promoting medication adherence, but also on promoting a patient's knowledge about how to read and tightly control their blood glucose levels. Participants reported this knowledge should focus on the recommended target blood glucose levels for patients with diabetes, the right time to take a reading and the importance of recording the results. The following point of view is illustrative:

*I think we have to educate each diabetic patient [...] about his diabetes before discharge [...] by providing information about what a good and bad glucose reading is and teaching him when he should take it constantly and how to record it.*

(Cardiologist, F.1, P.12, L.12)

In addition to raising patients' awareness of the importance of glucose control while recovering from a cardiac event, participants recommended providing them with supportive tools such as a table, checklist or logbook, before their discharge from hospital

to help them record their blood glucose readings and manage their blood glucose levels methodically.

*We need to encourage those patients to take regular readings of their blood glucose levels [...] and we have to develop a form or logbook to be used by our patients [...] and to use it to record all their glucose readings, keep it safe and bring this logbook with them whenever they visit us [...], which will help both of us to understand the problem and help them. (Cardiologist, F.3, P.25, L.15)*

Moreover, there was widespread agreement amongst participants in all groups that those patients with diabetes who are recovering from a cardiac event must immediately be educated about the most common symptoms and potential complications that they may encounter after they are discharged from hospital, how to avoid them and what the key strategies are for dealing with them appropriately and effectively if they occur. While some participants discussed the need to teach patients about the symptoms and potential complications, others focused on potential cardiac complications such as chest pain and another cardiac event, while others were focused primarily on complications from diabetes, such as hyperglycaemia, hypoglycaemia and lower extremities complications. In view of the seriousness of these conditions, one participant argued that:

*Before leaving the hospital, patients need to be educated about how to deal with any complications they may experience after discharge from hospital such as chest pain and how they should take Isordil immediately if they feel any chest pain; then, if the pain continues, they should go directly to the nearest ER. (CCU nurse. F.3, P.14, L.15)*

Most participants did not go into detail during the discussions when referring to the key strategies that should be suggested to patients for avoiding or dealing with each symptom and complication they mentioned. It was interesting to note, however, that the diabetes nurse and one of cardiologists, who were both very confident participants, as was evident from their contributions to the discussion within their groups, offered a number of viable strategies which they had used in their working lives. The diabetes nurse, for example, explained that:

*Often before they are discharged from hospital I encourage a diabetic patient to record his blood glucose readings every day in a specific table and if he*



*recognises an abnormal reading on any day I recommend that he write what he has eaten that day and what he has done [...]. I always encourage the patient to be involved in caring for himself and to be open with me. [...] Some of them followed my instructions and actually this procedure helped me and the patients as well to understand many things including where the real problem is, and the patient's notes is one form of evidence that I use to inform my management action. (Diabetes Nurse, F.4, P.10, L.15)*

It was obvious during participant's discussion that there was a poor knowledge in self-monitoring of blood glucose and in dealing with expected symptoms and complications among those patients with both conditions after they are discharged from hospital in particular. Improve their knowledge, skills and adherence regarding self-monitoring of blood glucose and increase their awareness about how to deal with symptoms and complications of both conditions properly are essential in any educational intervention.

#### ***5.2.3.2 Psychological support***

This sub-theme describes the main psychological needs of patients with diabetes and ACS, particularly after being diagnosed with heart disease or while recovering from heart disease. Its primary foci are first the behavioural changes that those patients need to make after being diagnosed with chronic illness; secondly dealing with the negative feelings that are often associated with chronic illness and thirdly confidence with their healthcare providers.

#### **Behavioural change**

Many participants acknowledged the need to provide immediate psychological support for patients with diabetes and ACS. All groups expressed concern about the current lack of such support for patients in acute and follow-up care. Participants were mostly in agreement that the lack of motivational strategies for behavioural change in patients with long-term conditions is one of the main reasons why patients with diabetes and ACS fail to achieve positive and sustainable behavioural change. Moreover, many participants described the frustration such patients feel and its impact on their wellbeing and quality of life:

*Our patients all want to change their behaviour for the better but unfortunately, they fail because of a lack of psychological support and motivation both in hospital and at home. For example, most smokers stop smoking for a week or so after an MI [...]. Then they get frustrated and start smoking again, unfortunately, because they lose their motivation once they are in their community, and because of the total lack of follow-up care. (ICCU charge nurse, F.2, P.25, L.5)*

Lack of psychological support is not the only challenge facing patients who have been diagnosed with two chronic diseases that may prevent them from making a behavioural change. These also include cultural attitudes, mistaken beliefs, denial of and difficulties relating to many bad habits and lifestyle changes. Participants also noted that these factors frustrate patients recovering from a heart attack and prevent them from fully committing to behaviour change after they are discharged from hospital:

*Unfortunately, patients are admitted to our hospital with ACS and then are discharged from the hospital believing it's a simple matter and without having any real intention of making any change in relation to their bad habits or adopting a healthy lifestyle that is compatible with their new condition. [...] and so they go back to smoking et cetera. (ICU nurse, F.3, P.8, L.4)*

*For patients with diabetes after ACS, it's very difficult to control their lifestyle or desires and change their habits, plus they become frustrated by and over whelmed in the number of things they have to change, so they never try or intend to change. (Head Nurse, F.1, P.18, L.2)*

That said, some participants described variations in the response of patients to the instruction to change their behaviour after a cardiac event. For example, patients without diabetes, or who are recovering from their first heart attack, and older patients ( $\geq 55$  years) are more accepting and ready to change their behaviour shortly after discharge from hospital than patients with diabetes, or with a positive history of heart attack, or middle-aged patients (36–55 years) respectively. Among the reasons participants cited for this variation are fear of having another heart attack, denial by middle-aged patients that they have an illness, and cultural practices whereby middle-aged patients are more involved with their cultural habits and committed to their lifestyle than elderly patients:

*I think the older patient is aware that if he does not change his behaviour or adhere [to his treatment plan], his condition will become worse, so he fears this, but the middle-aged patient mostly is in constant denial about his condition. (Charge Nurse, F.2, P.13, L.17)*

*Yep, mostly the elderly are more fearful as they expect to get sick at any time. (CCU nurse, F.2, P.13, L.2)*

*Younger patients always think they have the time, power and ability to live longer. (Medical nurse 1, F.2, P.14, L2)*

*I think that's because middle-aged patients are very committed to their habits, works and lifestyle, more so than elderly patients are. (Medical nurse 2, F.2, P.14, L.5)*

### Dealing with negative feelings

In addition to the immediate need to support patients to change their behaviour as they recover from a cardiac event, many participants acknowledged the need to educate patients about how to deal with negative feelings, with particular emphasis on stress, depression and denial. Participants mentioned that it is common for patients with both chronic conditions to have negative feelings, particularly during the first period after a heart attack.

Although participants did not specify strategies for dealing effectively with such feelings during group discussion, it was obvious that all had observed a strong correlation between these negative feelings and nonadherence to treatment as well as their adverse impact on patients' recovery and wellbeing.

*During the first period after they are diagnosed, most of them live in denial, so they do not adhere to our treatment plan and they refuse to change anything [...] until unfortunately some serious complications start to affect their ability to live and work well; then, they will try to adhere. (ICU nurse, F.3, P.6, L.12)*

*Such patients after discharge from hospital have a high risk of experiencing many complications such as hyper and hypoglycaemia post MI [...]. As a consequence of dealing with each of these symptoms and complications, they live in a state of constant stress and depression [...] and so they must be*

*educated about how to deal with these psychological disorders. (Diabetes nurse, F.4, P.9, L.15)*

Participants expressed that those patients are susceptible to many negative feelings, specifically with a lot of difficulties and challenges they need to deal or cope with after being diagnosed with both conditions and after discharged from hospital to home. Those patients need to have their self-confidence promoted by increasing their knowledge about strategies of dealing with these expected negative feelings, this may help them to improve their quality of life, health outcomes and adherence to treatment.

### Confidence

The focus group discussions also made clear that most participants reported that patients who are living with multiple chronic conditions and comorbidities generally lack confidence in their current healthcare providers. Participants noted that patients' confidence in their relationship with them is vitally important and its absence can be one of the main barriers to effective and sufficient communication between them and their patients, as illustrated in the following example:

*Actually, there is a crisis of confidence between us and our patients. So, for example, when I did a health education programme for them [...], unfortunately I felt that most of them didn't accept the idea and interacted with me only verbally – yah okay, yah okay – but with no commitment to adherence. (CCU nurse, F.3, P.12, L.9)*

Other participants reported that some patients had no confidence in the medical staff, laboratories or in the hospital as a whole:

*The majority of them are careless because most of those patients are not convinced about the capabilities of this hospital and those of the medical staff working here [...], and therefore also have no confidence in current laboratories or hospital care at all. (Cardiologist, F.5, P.12, L.2)*

By contrast, some participants reported that the most trusted healthcare provider is the physician, and that patients do listen to him:

*In general, the doctor is the individual our patients most trust, because here the patient believes that his doctor knows everything about him and*

*therefore he doesn't listen to other staff members. (CCU nurse, F.2, P.20, L.2)*

There was widespread agreement that lack of confidence in the relationship between healthcare providers and their patients leads to many serious problems, including nonadherence to treatment recommendations and strategies, either because they are not convinced by them or because they do not understand them, and instead blindly rely on the opinions of non-specialists for which there is no evidence:

*Many of them get their medical information from other peoples' experience [...]; unfortunately, they trust them fully, more than they trust us [...]. And unfortunately, sometimes following the suggestions of other individuals to use inappropriate treatments and stop taking their medications causes their condition to deteriorate. (Head nurse, F.1, P.23, L.2)*

Participants also described how these problems reduce patient's self-efficacy and self-esteem and gradually cause the patient's condition to deteriorate:

*For example, when one of those patients returns to hospital with diabetic ketoacidosis (DKA), [...] although we told him after he recovered to avoid fats and sweets and to be physically active and take his insulin and diabetes and cardiac medications on time [...] unfortunately he never adhered to any of this [...]. I think the problem for most of them is psychological. Lack of trust becomes like an unconscious attempt at slow suicide because of the lack of psychological support and follow-up care and loss of hope, especially among younger patients [...], most of whom find it difficult to achieve any success. (ICU nurse, F.6, P.6, L.22)*

In recognition of the danger these feelings present for patients, many participants in all groups acknowledged that there was an urgent need to teach and promote patients' confidence in themselves and in their healthcare providers. Moreover, they perceived that building their patients' confidence is certainly worth the effort as doing so will lead to better adherence to their treatment recommendations. An ICCU nurse, for example, advocated promoting patient confidence before starting to teach them and using methods appropriately tailored to the features of each individual case:

*Unfortunately, we didn't do this [...], but yep, we have to start using these methods from the outset to gain a patient's confidence, and if the patient has*

*confidence in us and in our treatment plan, his response and adherence will be good and his personal commitment will increase to change [his behaviour] and follow our guidance. (ICCU nurse, F.6, P.8, L.15).*

#### **5.2.4 Theme 4: Suggested Mode of Delivery and Recommendations for Effective Self-Management Intervention**

##### **5.2.4.1 Mode of delivery**

To determine which modes of delivery are the most appropriate for delivery of a self-management intervention for patients with T2D and ACS shortly after being diagnosed with a cardiac event, at the end of each focus group participants were asked their opinion of different modes of delivery. Three modes of delivery were suggested by the researcher: face-to-face educational sessions (FFES), phone calls and text-messages, and group educational sessions.

Most participants in each group reported strongly that FFES is the best and most appropriate method for delivering these interventions for those patients. For example, one physician stated:

*I think face-to-face educational session is the best way and more suitable with our patients' mentality, and through face-to-face sessions they will learn much more than any another method. (Internal Medicine doctor, F.1, P.22, L.3)*

Many participants expressed the view that FFES is the most effective method to teach those patients with chronic diseases about essential coping strategies and to actively involve them in the decision-making process regarding changing their behaviors. Several participants noted that most patients who are diagnosed with diabetes and cardiac disease are middle aged or elderly, therefore the FFES method is most effective because it is most able to facilitate engagement those patients by demonstrating respect for their age and experiences, making them more responsive to treatment and more actively involved in decision-making about lifestyle changes. Also, FFES allows HCPs to assess the characteristics of such patients and to develop a better understanding of their actual needs and priorities. Other participants reported that FFES was best suited to Jordanian culture, as most patients prefer to communicate with them one-to-one because they believe that

such direct communication is more respectful of their privacy and gives them the confidence to speak freely.

*Because of the culture of our community here, most patients prefer to listen directly to us and talk with us individually more than group style or to have us provide them with reading materials [...]. [T]his makes them feel more confident and respectful [...] and react to us more positively.*  
(Cardiologist, F.5, P.20, L1)

However, one cardiologist and a nurse in Focus Group 2 expressed concern about the lack of specialist professionals, capacity and time needed to provide such educational sessions for those patients in and outside the hospital, especially as the current primary and secondary healthcare settings do not have the resources for this role.

*I think it's a good idea [...], but I think should be provided by qualified professionals and these professionals should have sufficient time to provide this.* (Cardiologist, F.2, P.21, L.1)

*[C]urrently [there is] no time and no specialist workers to provide these educational sessions, and no adequate healthcare services capacity at the level of the either primary care centres or hospitals.* (CCU nurse, F.2, P.21, L.3).

Further details about the number of educational sessions that should be provided, the appropriate duration of each session and the applicability of offering such sessions to patients with ACS during their hospitalisation were discussed. Most participants expressed the view that providing educational sessions for cardiac patients during their hospitalisation would be applicable if someone were available to offer these sessions. There was no consensus among participants about either the number or duration of educational sessions that should be provided for patients in hospital, most participants in each group agreed that patients needed more than one educational session, during hospitalization or after discharge from hospital as follow-up sessions. The number of educational sessions suggested ranged between 1-4, while the ideal duration for each session ranged from 10-60 minutes, with a few participants suggesting that the duration of each session should be based on the needs and enquires of the individual patient.

Furthermore, in order to provide sensible and suitable educational sessions for both the receiver (the patient with ACS and T2D) and the provider (the healthcare professional), most participants were in agreement that the best duration of time for each educational session is ‘around 30 minutes’ (Cardiologist, F.1, P.20, L.6):

*[T]wo educational sessions, each one lasting for half an hour during the patient’s hospitalization, I think would be enough to make them aware about their condition and be suitable for the patient’s capacity and condition in CCU. (Registered Nurse 2 in CCU, F.6, P.13, L.13)*

While a few participants in each group reported that using a follow-up phone call or text messages as a mode to deliver the self-management intervention content may be effective and applicable for some patients who already are phone users, a number of participants expressed concern about some of the current obstacles that may lead to ineffectiveness or inapplicability of this method with those patients. For example, there are some technical problems in relation to the process of offering these services and the standard of these services.

*[L]ack of a central, computerised or trusted system to send texts or call patients [...]. (Dietitian, F.3, P.23, L.16)*

*The current system is ill-equipped to offer technological services to our patients; specialist professionals in related cases, quality and standardisation of information and advice and many things need to be considered carefully [...]. (Cardiologist, F.3, P.26, L.5)*

Lack of access and widespread dislike of the method among such patients are also obstacles:

*[S]ome patients do not have phones and many of them will not read their messages. (ICCU nurse F.6, P.15, L.18)*

Thirdly, the culture of current patients influences their trust in phone calls or information conveyed by text messages:



*[I]t will be unusual care for them, so many of them will stay sceptical about the information that will be provided for them [...]. (CCU nurse, F.2, P.23, L.19)*

However, some participants reported strongly that follow-up care is lacking for those patients in the current care system, and they believed that using a variety of follow-up reminder text-messages or counselling phone calls in addition to some primary educational sessions can be helpful to establish a good therapeutic relationship and promote trust confidence between the patient and their HCPs after they are discharged from hospital. Also, several participants maintained that better communication with patients could enhance their self-esteem and confidence in their ability to manage their health conditions, especially after discharge from hospital:

*I think this method will be effective in improving the relationship with them and enhancing the inner sense of confidence that they need to cope with chronic disease after they are discharged from hospital. (ICU nurse, F.3, P.23, L.18)*

Likewise, other participants in some groups expressed that systematically sending a number of short awareness or reminder text messages to patients after they are discharged from hospital these may help to improve the health outcomes and quality of life of patients who are living with multiple chronic conditions by improving their knowledge of chronic disease management, motivating them to improve their adherence to treatment instructions and to overcome the expected challenges of self-management. According to one dietitian, for example:

*[U]sing such methods will help to deliver short treatment instructions and awareness information for patients and thereby motivate them, for example, to adhere to a healthy diet or change their unhealthy lifestyle [...]. (Dietitian, F.4, P.19, L.2)*

Regarding the group educational session, a few participants in each group acknowledged the advantages associated with providing a follow-up educational group session for patients after they were discharged from hospital:

*[P]atients will be comfortable when they get a chance to discuss their problems with other patients. (CCU charge nurse, F.1, P.22, L.15)*

*[E]ach patient may benefit from other patients' experiences and coping strategies in dealing with the symptoms and difficulties of their illness [...]. (Medical nurse 3, F.6, P.16, L.15).*

While other participants reported that for group sessions to be effective, i.e. to influence patient behaviour, they must be provided by professional people and involve a role model or trained expert patient who has had a successful experience with diabetes and cardiac problems. These participants reported that this role model would play a significant role in empowering other patients by sharing his/her successful experiences and reliable information with them. However, such role models or expert patients are lacking in the current context, as several participants noted:

*[I]f we want to offer a successful structured group session we need to provide a successful role model for them, and unfortunately such expert and trained patients are currently unavailable [...]. (Diabetes nurse, F.4, P.17, L.15)*

Moreover, many participants noted that it would be quite challenging to deliver a follow-up educational group session to promote better self-management behaviours for those patients after discharge from hospital in the current context. One participant, for example, described the difficulty of managing the conversation that is likely to emerge:

*But I think it is an unworkable idea and difficult to manage, particularly with each patient having individual problems that are different from other patients' problems, and most of them have little knowledge so if anyone asks one question the discussion will be wide open and not effective as required. I think face-to-face sessions are more suitable [...]. (Diabetes nurse, F.4, P.17, L.11)*

Secondly, such sessions are difficult to organise. Because of the lack of a suitable place and time that suits all participants, especially those who work or are elderly, many will not be interested or able to attend:

*It will be nice only if it will be organised very well, [which is] not easy. I remember once we tried to hold such a group session and unfortunately most of the invited patients did not come [...]. (Head nurse, F.3, P.24, L.4)*

Another participant added:

*I think you really need to consider the time of the session and where it will be held very carefully [...], if the session's time or place are inconsistent with the patient's commitments such as work or home duties, I am sure the patient will not attend [...]. (ICCU nurse, F.3, P.25, L.1)*

Thirdly, a number of participants in three of the groups expressed that the main reasons for patients not attending will be financial. They noted that attending hospital or out-patient clinics will be financially costly and physically challenged for most patients and their families, so without providing financial incentives or making easy arrangements for patients to attend, they will not be interested.

In sum, although participants acknowledged the value of the other suggested methods for delivering self-management interventions, FFES was the method that most participants reported was more feasible and appropriate in the current context to be used to deliver this type of intervention during a patient's hospitalization or after they are discharged from hospital. However, a number of participants did mention that using other methods of delivery such as follow-up phone calls or text-messages in addition to the FFES may be helpful to establish a good therapeutic relationship between patients and their healthcare providers and may promote self-confidence, knowledge and self-management skills among patients.

#### **5.2.4.2 Recommendations toward effective information**

There was widespread agreement among participants in all groups that to provide effective self-management interventions for patients who are living with multiple chronic conditions in way that promotes their self-confidence, enhances their knowledge about both conditions and encourages greater adherence with treatment advice are required. Some features regarding the educational information that will be provided to them should be considered. Many participants acknowledged the need to pay attention to the suitability

of educational information in light of the patient's overall condition, age, educational level, culture, beliefs, socioeconomic status and preferences. For example:

*[T]he information and advice should be suitable for the patients' health condition and age as they are adults or elderly. For example, we can't ask some of them to practice physical activities shortly after they are discharged from hospital. I think the patient's capacity should be assessed before offering any information to a post-MI patient [...]. (ICU nurse, F.3, P.15, L.20)*

*To earn the confidence of the patient, we should also take into account the patient's religion and privacy concerns when we offer information, and I think the intervention provider should be neutral and respect or understand well their patient's beliefs and customs [...]. (Internal Medicine doctor, F.6, P.9, L.9)*

Some participants mentioned that information should be valuable to patients and address their actual needs. Towards that end, patients should be involved in prioritising their needs, as one participant pointed out:

*[I]nformation should be valuable for the patient, and we should take into account the patient's desires about which information they want to talk about first, [for example, if] he prefers information about his condition first, his treatment or regarding a specific thing. (Dietitian, F.3, P.16, L.4)*

Another participant mentioned that to ensure good, clear communication with patients, the provided information should be understandable.

*[I] think you have to deal with each patient based on his culture and level of education; for example, an uneducated patient may have a low level of understanding compared with those who are educated, so our information and instructions should be understandable and suitable for his cognitive capabilities, in order to provide a clear and effective message [...]. (Medical nurse 3, F.6, P.8, L.4)*

Likewise, other participants acknowledged the need to assess a patient's readiness and willingness to learn before providing any educational information or materials. These

participants assumed that the readiness of the patient to learn may have a significant influence on the patient's understanding and acceptance of and adherence with the information and advice provided after they are discharged from hospital:

*I think before providing any information or intervention for those patients, the instructor should assess the patient's willingness to receive the educational information about their condition and how to manage their conditions [...]. For example, patients who are in denial or careless may not accept or appreciate your time [or] the advice provided and will not understand the importance of this information completely [...]. (Dietitian, F.4, P.6, L.10)*

Participants in group number 4 expressed concern over the method of educational information for those patients. They reported that the educational information for patients with multimorbidity should be provided in a positive way and through collaborative learning or discussion between the patient and the health education provider. They also emphasized that, as those patients are adults, the style of teaching them should be interactive and they need to be involved in planning their care, decision making and the appraisal of their knowledge, behaviours and activities. They should not just be given orders.

*[W]e have to discuss with the patient positively about his health and what he needs to do regarding the management of their diabetes and cardiac problems, their diet and so on, and instead of telling them what to do, we have to involve them in the treatment plan and explain what they need to do in simple way. (Diabetes nurse, F.4, P.9, L.4)*

The CCU nurse added:

*Yes, the health education provider should give these adult patients their freedom to select and to find the best way of designing and assessing their action plan. (CCU nurse, F.4, P.9, L.4)*

Likewise, some participants acknowledged the need to involve a supportive person from the patient's family when providing educational information for those patients. They reported that involving family members in the educational session will help to support patients morally and physically and may improve patients' willingness to be involved in the intervention as well as their understanding of the information provided and their adherence to treatment instructions following their discharge from hospital, possibly leading to improvement in the patient's health outcome and quality of life.

*Yeah, sometimes the patient didn't accept our advice but when we involved one of his family members such as his wife or son while advising him, he interacted more positively with our advice and conversation, and the family members play an effective role in encouraging the patient to accept and follow our advice. I think involving family members sometimes is very effective, especially as we are living in the Eastern conservative society and we still have a strong relationship between family members. (Head nurse, F.3, P.22, L.9)*

*[I]nvolving one of the patient's family members in the patient's educational session will encourage the patient to control his condition and overcome his coping challenges after he is discharged from hospital. (CCU nurse, F.5, P.16, L.20)*

As most patients with diabetes and cardiac problems have many co-morbidities and challenges, some participants discussed the importance of determining which educational information is most appropriate to the patient's condition and needs. However, it was interesting to note that participants in some groups acknowledged the need to develop or use an assessment tool for prioritising patient's educational needs, such as a specifically designed form, table or checklist. Participants reported that such tools would help healthcare providers to identify a patient's educational needs regarding their conditions quickly after they are being diagnosed with cardiac problems. They could also be used to record and prioritise the identified needs, and to help involve patients in making appropriate clinical and educational decisions such as making early appropriate referrals and designing their action plan.

*I think there should be a specific checklist to be completed by the healthcare provider directly when a patient with T2D and ACS is admitted to hospital [...]. I think using such a checklist will help us to determine the educational needs of patients regarding their conditions [...]. (In charge CCU nurse, F.1, P.14, L.4)*

*I think that to activate the educational care and discharge planning for those patients in current secondary care settings, we need to develop a standard form to be compulsorily completed by healthcare providers to assess each patient's knowledge deficit regarding his health condition, medication and nutrition [...] and then identify his educational needs [and] prioritise them based on their importance and in line with the patient's preference. (Dietitian, F.4, P.18, L.5)*

Some participants further emphasised that these adult patients should be involved in the process of completing the educational assessment tool through discussion in order to understand their preferences, prioritise their educational needs and promote a sense of responsibility for their behaviours and actions.

*Assessing the educational needs of patients first by using an assessment tool like a specific form will help us to identify the patient's educational needs and detect which needs are more important for patient health. In order to achieve this, healthcare providers need to involve patients in their assessment and in completing the form and the decision-making process, and [they need to] acknowledge the patient's desire as well. (Dietitian, F.6, P.9, L.4)*

### **5.3 Summary**

This study highlighted that patients have a low level of knowledge of their both conditions and poor adherence to treatment instructions. It also highlighted the educational and supportive care is lacking and there is an urgent need for health education self-management interventions to be developed and provided for those patients into current practice. The study identified the main educational and psychological needs of those patients which could be used to inform the content of the future interventions. It also identified the appropriate teaching approaches for delivering self-management intervention for patients with T2D and ACS. In the forthcoming chapter the findings of interviews with patients will be presented.



## **Chapter 6: Findings of qualitative interviews with patients (Study II)**

### **Introduction**

This chapter describes the findings from interviews conducted with patients with type 2 diabetes (T2D) and acute coronary syndrome (ACS). The aim of this study was to explore the experiences of patients with T2D and ACS following diagnosis with ACS, with the purpose of identifying their main challenges, supportive care needs and features that can help in designing self-management intervention for patients with both conditions.

### **6.1 Characteristics of the sample**

Seventeen patients participated in the interviews, with a mean age of 53.35 years (SD = 7.26, range 39-69), of which ten were male (58.8%) and seven were female (41.2%). Most participants were married (76.4%) and either retired or unemployed (58.8%). The mean number of family members for married participants was 4.5. The mean length of stay of participants in the coronary care unit (CCU) after an ACS was 5.4 days (SD = 1.45, range 3-10 days), with a relatively small difference between the average of the length of stay for each type of ACS (5.4 days for STEMI, 6 for NSTEMI, 4.5 for UA). Some participants (n = 5), particularly those who were recruited from the Princess Basma Teaching Hospital (PBTH), reported that they were transferred to a medical ward before discharge from hospital. Those who were transferred stayed longer than those who were discharged home directly from the CCU. All participants from PBTH (n = 7) reported that they were transferred to another hospital, including a cardiac catheterisation laboratory (mostly to the King Abdullah University Hospital (KAUH)), for further medical investigation and treatment. Usually, the transfer decision was made based on the patient's health insurance and availability of beds in the host hospital (see Table 6-1).

Table 6-1: Sample characteristics of interviews

Characteristics	Number	Percentage
<b>Hospital</b>		
PBTH*	7	41.2%
KAUH**	10	58.8%
<b>Gender</b>		
Male	10	58.8%
Female	7	41.2%
<b>Marital status</b>		
Married	13	76.4%
Single	2	11.8%
Divorced	1	5.9%
Widow	1	5.9%
<b>AGE</b>		
≤40	1	5.9%
40-49	5	29.4%
50-59	8	47.1%
≥60	3	17.6%
<b>Mean age</b>	53.35 years	
<b>Higher level of education</b>		
Higher school	4	23.5%
Diploma or equivalent	7	41.2%
Bachelor's degree or equivalent	4	23.5%
Postgraduate degree	2	11.8%
<b>Employment status</b>		
Employee	7	41.2%
Unemployed	3	17.6%
Retired	7	41.2%
<b>Smoking status</b>		
Current smoker	7	41.2%
Former smoker	2	11.8%
Never smoker	8	47.1%
<b>Tried to stop smoking after ACS</b>	4	23.5%
<b>Stop smoking after ACS</b>	2	11.8%
<b>Diabetes duration</b>		
<1 years	1	5.9%
1-5 years	2	11.8%
5-10 years	3	17.6%
>10 years	11	64.7%
<b>Mean years of having T2D</b>	12.2 years	
<b>ACS duration</b>		
3-6 months	8	47.1%
6-9 months	3	17.6%
9-12 months	6	35.3%
<b>Mean months of having ACS</b>	7.88 months	
<b>Diabetes treatment</b>		
Oral	7	41.2%
Insulin	5	29.4%
Oral + Insulin	5	29.4%
<b>Experience more than one ACS</b>	4	23.5%
<b>Have Comorbidities</b>	12	70.6%
<b>Ethnicity</b>	Jordanian	100%
*Princess Basma Teaching Hospital **King Abdullah University Hospital		

It seems most likely that the study sample is well educated, with of at least 76.5% of them possessing a diploma degree or higher and only four had a secondary school education. Tobacco smokers comprised 41.2% of the sample ( $n = 7$ ), and two participants reported that they had quit smoking after being diagnosed with ACS. All participants had T2D before being diagnosed with ACS, except two participants were diagnosed with both conditions at the same time. The mean time of being diagnosed with T2D was 12.2 years ( $SD = 6.8$ , range 6 months-28 years). Although the long of period of living with diabetes among many participants it seems that most study participants depended on oral medication to manage their diabetes. Four participants (23.5%) reported they have experienced more than one acute coronary event. The mean time of being diagnosed ACS for participants since the last acute coronary event was 7.88 months ( $SD = 3.18$ , range 3-12 months). In addition, over two-thirds of the sample had comorbidities, mostly hypertension and dyslipidaemia. All participants described their ethnicity as Jordanian (Middle East Asian). The mean length of all interviews was 42.9 minutes per session ( $SD = 10.9$ , range 30-66 minutes).

## **6.2 Findings**

Following the procedure of framework analysis, numerous themes (codes) were identified during the initial analysis, and named according to the content. Initially a list of 14 themes was generated, which was subsequently reduced through the procedures of analysis to three core themes and a number of subthemes as described by study participants (see Figure 6.1).

The findings are presented within three core themes. The first theme was “Being frustrated after ACS”, the main causes of frustration were identified within this theme. The second theme was “Heath knowledge and reasonable care seekers”, which outlines the main needs of patients with two conditions following ACS. The final theme was “Willing to learn”, this theme addresses the participants’ preferences about time and location for delivering education, mode of delivery education and the style of education.

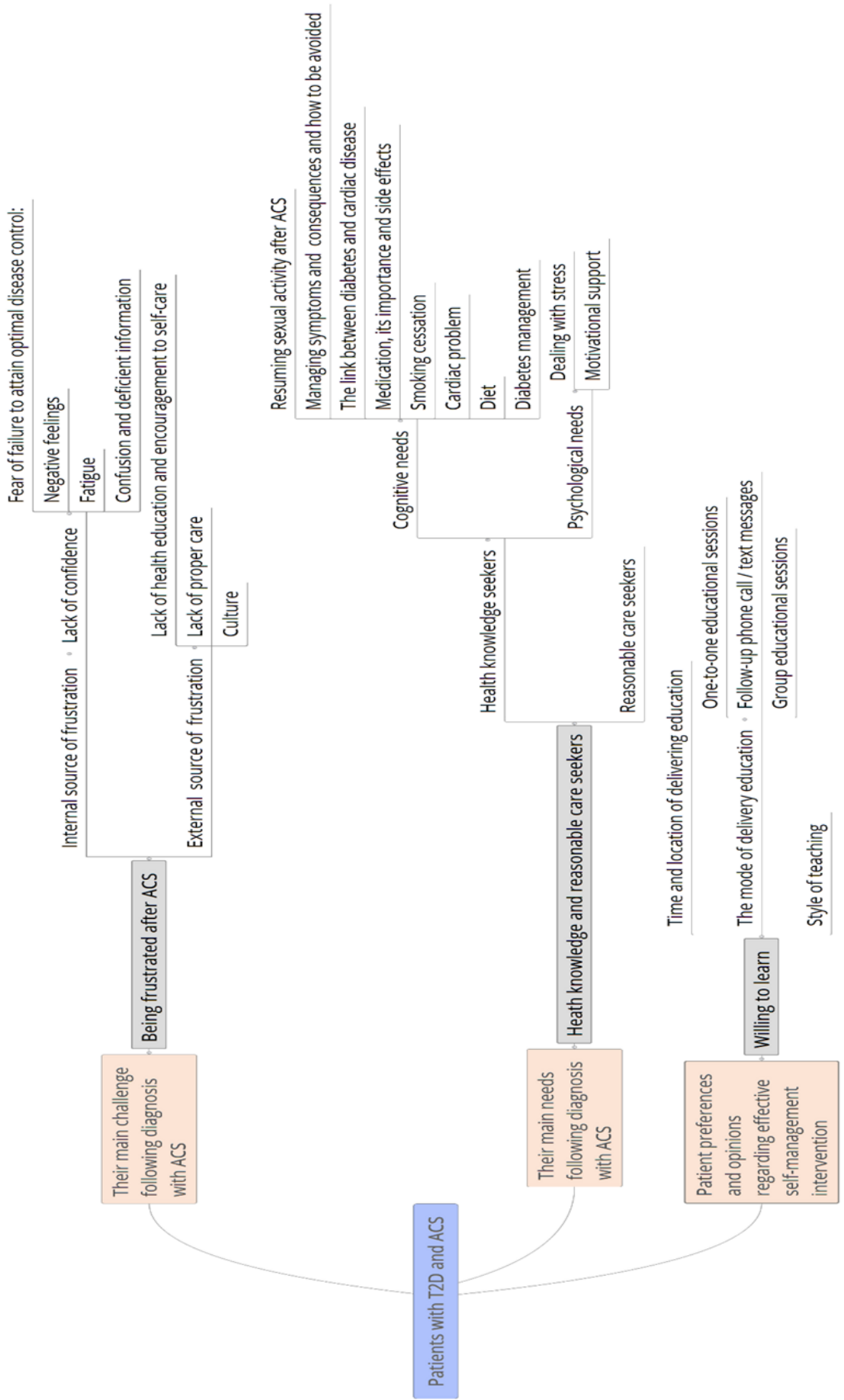


Figure 6.1: The main themes and subthemes for interviews data

In the following discussion of the qualitative findings, each of these three themes will be discussed in turn, and a number of excerpts from the data are given to prove the meaning that is attributed to each theme and subtheme. An outline of the relationship between these themes and subthemes will also be established, so that their interdependent nature may become obvious.

### **6.2.1 Theme 1: Being frustrated after diagnosis with ACS**

Most participants expressed their emotions about their daily lives after being diagnosed with T2D and ACS, the challenges about coping with their new health condition after being discharged with multiple chronic conditions. Their perspectives regarding the health care provided for them either in-hospital or during the follow-up care period after discharge from hospital were also explored.

Their admission to hospital with an acute coronary event and subsequent diagnosis with ACS in addition to the T2D challenged many of participants and their experiences portrayed their frustrations after being diagnosed with these two conditions. They reported frustrated, not only with the care they received soon after their ACS, but with the challenges they experienced after discharge from the hospital that influenced their wellbeing.

Psychologically, the sense of frustration is defined as a deep chronic sense or state of insecurity, discouragement and dissatisfaction arising from unresolved problems or unfulfilled needs (Merriam-Webster 1996) or from the perceived resistance to the fulfilment of somebody's will or goal (De Botton 2001). The data clearly indicates that there were a number of sources of this frustration for patients with T2D and ACS after diagnosis with ACS in particular. However, throughout the process of analysis data and based on the source of frustration, all the main sources were classified into two subthemes, internal or external sources of frustration. These were:

- I. Internal source of frustration
  - lack of confidence
- II. External source of frustration
  - lack of proper care and discharge procedure
  - lack of health education and empowering care
  - culture

### **6.2.1.1 Internal source of frustration - Lack of confidence**

From the interview data, it was clear that a lack of confidence played a major factor in most participants' lives, which was a source of frustration for them. There were numerous important sources of this lack of confidence among participants including:

#### **i. Fear of failure to attain optimal disease control**

Many participants expressed their fear of failure to attain optimal disease control after they were discharged from hospital. This feeling of fear was due to many of them perceiving that they would not control their diabetes and other risk factors appropriately after cardiac diseases, especially as their health condition became more complex and many factors needed to be changed or adhered to. In some cases, their fear released from their own previous failures to control their diabetes before diagnosis with ACS. However, whether their fear was released from the complexity of their new health condition or from their previous failures, their confidence to attain optimal disease control after diagnosis with ACS was significantly reduced. For example, a female patient with T2D and UA for 20 years and 6 months respectively stated:

*Since I was diagnosed with diabetes and most my readings were over than the normal levels. I tried many times to control my diabetes through sticking to a healthy diet, I tried many things, but I always stopped after a short time [...], after I got a cardiac disease and the doctor told me I need to change my lifestyle and control my diabetes, I felt much fear because I know I will not be able to control my condition with more diseases and within the same family and social circumstances that I live, I know myself I did not control my disease while my situation was less worse, and after the cardiac disease and my health become worse than before, I know it will be very difficult for me to control [...], since my heart attack until now I have not changed anything. (Pt.14, P.6, L.5).*

Another male patient, who was diagnosed with T2D, hypertension, and dyslipidaemia at the same time as admission to hospital with cardiac event (NSTEMT) reported:

*I still remember when my doctor told me I have all of these diseases together I really felt annoyed, as I did not know how to control all of these together, and frustrated as I never experienced fear like this in all my life*

*[...], so far, I did not manage these diseases well and often I can barely take my medication (Pt.10, P.1, L.6).*

ii. Negative feelings

It was interesting to note that participants live with a lot of negative feelings, restricting their confidence to control their disease. Often, such negative feelings occur because living with multiple chronic conditions, most of them are uncontrolled and many self-care activities need to be addressed. Many participants expressed their fears of living with a heart problem, fear of failure to control their disease, fear of death or deterioration and fear of the future. Furthermore, they expressed their annoyance/discouragement/depression/disappointment regarding the increased number of medications, their daily health measurements, their food and physical activity restrictions, their comorbidities to be controlled (i.e. dyslipidaemia and hypertension) and their health symptoms to be addressed after discharge from hospital. Such fears and challenges were a source of frustration for participants after discharge from the hospital and impacted negatively on their self-confidence, as many of whom their self-confidence drained quickly or gradually after ACS had to relinquish self-care activities as a result. For example, a female participant (T2D for 8 years and NSTEMI for 6 months) gradually lost her confidence after she failed many times to achieve her desired health outcome, she reported regret and frequent disappointment regarding her health and life as she reported:

*I tried many times to follow a low sugar diet to control my diabetes after my MI [...], but with increased my health problems, I have been disappointed after each attempt as I did not see any improvement in my sugar levels, so now I don't care to change any things or to stop eat this and that, because even if I eat or not my sugar level is always over 300 mg/dl, really by living with these conditions everything sucks (Pt.11, P.3, L.1).*

Another participant said:

*Shortly after I got a cardiac problem, all my psychological state changed completely to be more worse, as more than a disease to deal with, a lot of things need to be changed about my lifestyle, a long list of prohibited [...] too many measures to be taken, [...] after I discharged from hospital,*

*really many times I felt bored and frustrated especially as I could not manage my blood sugar and pressure within all these problems and under the stress I live with every day, a lot of things to stop doing or eating, a bunch of drugs to be taken, really it is hard to keep going for long run doing all these [...], so sometimes we need to be careless in order to live as others (Pt.3, P.4, L.16).*

### iii. Fatigue

All participants reported that fatigue was problematic for them after their ACS. Experiencing long-term fatigue often acted as a reminder of the severity and complexity of the condition, such fatigue always invoked negative feelings and frustrations in the participants, significantly decreasing their self-confidence to self-manage their condition. While most participants expressed that fatigue occurs because of cardiac injury, very few participants attributed this subjective feeling of tiredness to its actual physical and mental causes. Many were not aware that such poor diet, poor medication adherence, high level of sugar, lack of regular and appropriate exercises, stress and anxiety could be causes of their long-term fatigue. It was clear that participants could not distinguish between fatigue and the weakness that often occurs after they have done too much physical activity at one time, such as by working hard or walking for long period, which can be resolved by resting. The wrong interpretation of such feelings in addition to the experience of a heart attack, lead many of them to relinquish their physical activities, work and sexual activities, thereby considerably reducing the participants' quality of life by minimising their confidence to manage their condition well, as illustrated in the following examples:

*Actually, since I got a cardiac problem and I have general exhaustion in my body, this feeling restricted my movements and even my motivation to do any physical exercise [...], I remember after I was discharged from hospital I tried to walk around one kilometre back and forth daily, but I felt tired and an acceleration in my heartbeat and shortness of breath, then I totally stopped doing any physical exercise because I feared such these efforts would lead to another heart attack. However, I always feel I am tired, even if I am not doing anything [...] (Pt.2, P.6, L.4).*



Another female participant with UA for 6 months and over 2 years of dealing with poorly controlled diabetes stated:

*I have fatigue from my head to toes and this bad feeling is permanent with me since I have diabetes whether I did effort or not, it is like as I did too much work [...] some of my family members asked me to walk outside, but I always feel tired, even without any physical exercise and I feel a heaviness in my body that destroys all my interest to do any activities, I am always afraid if I walk maybe I will be more tired and my case become worse [...] (Pt.5, P.4, L.2).*

Moreover, some participants expressed that their experience of fatigue led them to be readmitted to hospital many times, because they feared that their fatigue may be the precursor to another heart attack, as illustrated in the following excerpts:

*After my MI, I feel tiredness quickly, and because of that I have been readmitted to the hospital many times, I fear always at this age I will not be able to afford more cardiac complications (Pt.7, P.3, L.1)*

There were also more consequences for fatigue on participants' physical and emotional capabilities to work or to have sex, especially those who were male, younger and employed, as illustrated in the following excerpts:

*My feeling of tiredness at all times, decreased my capability to work as before, and impact on my social interaction and sexual ability, actually this makes me a nervous person as it reduced my productivity and my financial yield (Pt.10, P.4, L.10) (Patient age was 48 years).*

*[T]his general tiredness affected me psychologically and physically, although my age is still 39 years, this feeling reduces my work productivity over than 40% [...] this feeling makes me afraid to get tired during my work and then have another heart attack, I am financially responsible about my family, I have 5 kids [...]. My willingness to have sex with my wife is almost zero [...] I feel I am not as well as before; I'm living with doubts if I will be okay! Before doing any activities [...] (Pt.9, P.4, L.17).*

iv. Confusion and lack of information

There is much confusion, lack of information and questions among participants about their condition management. This confusion causes to the participants to be more uncertain, reducing their confidence in their ability to manage their condition after an acute coronary event. Many are confused, frustrated and relinquish their self-care activities as a result, even worse, many patients have the illusion of knowledge and control:

*Honestly, I got unstable angina and I don't know what this means and how to deal with it, what causes it and why it is unstable [...], they say that there is a connection between diabetes and heart disease, because diabetes lead to increase fat and blood pressure in the body, but all thanks to god I don't have high blood pressure and in hospital they found my fat and cholesterol normal 100%, so I cannot understand how my diabetes led to heart disease, really I am confused about all of these (Pt.2, P.3, L.9).*

*Usually, I measure my glucose only if my health condition deteriorates, in this case, I take some readings but not daily, [...], for me if my sugar is 200 mg/dL (11.1 mmol/L) I consider that as good and acceptable (Pt.17, P.2, L.3).*

*A friend with heart attack told me if you will continue thinking about what you have, your condition will become worse and your emotional state will be destroyed, really he has convinced me about this, so for a long time I stop take readings of my sugar level because I believe if I keep monitoring my disease this will keep me depressed and under pressure all the time, so it is better to ignore the disease, and after my heart attack I become careless in this regard because I will not change anything [...] for me I don't like sugar so I don't need to follow a diet [...], between 200-220 mg/dL is normal sugar level and this is better than many people with diabetes such as my brother whose reaches 500 mg/dL (Pt.16, P.3, L.2).*

*I did not follow a specific diet or do physical exercises to control my condition except take my mediations and when I feel my sugar is high, I just give myself 10 or 20 gram of insulin directly and by doing this, I control my condition [...] after my heart attack nothing is changed, the*

*same difficulties and symptoms continue, but I have become lazier, frustrated and I do not have the desire to eat, I do not know why this happened to me, maybe because my heart problem or diabetes or maybe the stress, I don't know (Pt.4, P.4, L.2).* [Note: the participant used gram instead of using units to describe the amount of insulin dose, and this has also been used by other participants too].

There may be a wide range of reasons for such confusion and deficient information, but generally, they were due to poor sources of information and lack of proper health education. Participants, either before or after ACS, seemed to have many concerns and educational needs regarding their condition that need to be addressed by their healthcare professionals (HCPs), as they are initially expected after each diagnosis. However, the lack of appropriate and consistent health education either in the hospital or during follow-up visits led many to lose trust in their HCPs, becoming more reliant on their own experience or trust the information provided from other non-evidence based sources, such as other patients, friends or the internet. In both cases, there were many consequences of restricted patients' confidence and self-management activities, which will be discussed in more detail in the analysis of subsequent themes.

### ***6.2.1.2 External sources of frustration***

There were many external sources of frustration for participants. However, the main sources were: lack of health education and encouragement to self-care, lack of proper care, and culture.

#### ***i. Lack of health education and encouragement to self-care***

The most problematic source of participants' frustration was the lack of health education and encouragement to self-care. Participants expressed that their HCPs focussed on clinical care and provision of medications only for them during their treatment and interaction with patients. Furthermore, participants reported frustrated at not being able to open any educational conversations with their physicians and other HCPs about their conditions, treatments, symptoms and how to manage them whether during their hospitalisation or after at follow-up visits. The excerpts below illustrated these feelings:

*Each day during my hospitalisation with heart attack my doctors just come less 5 minutes each morning with his 10 students and trainers [...] the*

*nurses only coming from time to time to check my samples results, change some solutions and provide me with my medications, that's all, no one talked with me about my conditions ever, really it is an annoying feeling and very frustrating as you do not know what is going on around you [...]* (Pt.1, P.9, L.2).

*I really felt disappointed when I was discharged from hospital without basic information about my disease, what and how was happened to me [...]. And always the same feeling of disappointment I felt after each follow-up visit, as nothing was provided for us from our doctors regarding management of our conditions, healthy foods and you go to outpatient clinic with enthusiasm but you back to home without answers to my questions and about my health problems [...]* (Pt.13, P.5, L.2).

*[I] discharged from hospital without seeing my physician and no anyone talked with me regarding my condition [...], at follow-up visits just they told me take your medications! stop smoking! and even their advice without any smiles or feelings of care* (Pt.3, P.5, L.2).

Participants also stated that interactions with their HCPs were devoid of any encouragement to self-care during their meetings with them, whether during hospitalisation or at later follow-up visits, as evidenced in the following comments:

*We suffered from a lot of things and these need to be discussed with someone you trust in, however, yet, the physicians care and talk with us is very frustrating, no anyone gave us any type of moral support to push us forward towards the right things and adherence [...]* (Pt.12, P.5, L.6).

*Doctors and nurses, all of them, they come quickly [...] and they told you how are you today! are you okay! And always give you indications he is busy and in a hurry, unfortunately, if they answered something they answer it with brief words lacking any encouragement or motivation [...]* (Pt.6, P.5, L.14).

Such lack of health education and encouragement to self-care minimised patients' desire/intention to make positive health changes or adhere to treatment instructions after discharge from hospital.

*Although we are adult and mature people we are ignorant about this complex condition, what benefits us! and what harms us! Sometimes we know but we lack the motivation to do the needed lifestyle changes, this both ignorance and lack of motivation weakening our desire to care for ourselves [...] (Pt.13, P.7, L.9).*

ii. Lack of proper care

The second external source theme which emerged in relation to participants' frustration was the lack of proper care. Participants often wished to be treated respectfully and appropriately by their HCPs. They strongly reported that most current HCPs dealt with them in a negative way and poorly communicated with them regarding health education. It was obvious from the participants' personal experiences that many of them were grossly unsatisfied and frustrated objectively and subjectively with regard to the provided care and the way in which it was delivered during their hospitalisation and at follow-up visits in outpatient clinics. The lack of proper care, discharge planning and encouragement negatively influenced participants' confidence and willingness to look after their own health better after their acute coronary event:

*After my second follow-up visit, I felt annoyed and I stopped taking all my medications for a period of time because of the poor and provocative style of communication of doctor with me [...]. I believe a good way of dealing with patients is very effective to us emotionally, its represents two-thirds of treatment [...] (Pt.16, P.4, L.10).*

*Doctors visited while I was in hospital with heart attack not me as patient, he looked at the file and monitors and wrote his notes and medications I need and left, what do you expect from this way of care!, I am not happy about this way but nothing we can change [...] (Pt.7, P.4, L.20).*

*Nothing was provided for me about my heart attack [...], even when they provided advice to us they give it to us as orders not as advice, stop this! don't do this! Without saying why, I have to stop this or how! We are not a kid, I am 48 years, older than them, they did not talk with my in a respectful way or as should they have to do [...] (Pt.5, P.6, L.8).*

*Me as any patient in the world, I expect kindness from my doctors when they deal with me, I expect they will really care about me, my disease and my suffering after I had a heart attack, at this difficult time of my life, such this really it is touching, it enhances our self-confidence and emotional status [...] unfortunately some of the hospital staff treated me as I was an annoying guest in his/her home, so both their style in talking and characters destroyed any chance of having any useful discussion with them [...] (Pt.12, P 7., L.14).*

Participants also mentioned that there were other important aspects that contributed to their perceived lack of proper care and equal treatment to them in the current healthcare system. These affected both their physical and emotional health, precluding the provision of an appropriate educational environment for them. These aspects were lack of privacy during meetings with the HCPs either in the hospital or the clinics, the short duration of their visits and lack of reasonable services and facilities, as evident in the following excerpts:

*No privacy for patients at all in our hospital, how will I talk with my doctor or nurses with the absence of the appropriate environment, especially if they put you in a shared room [...] I think the medical staff themselves need to be educated on how to talk with patients and motivate them because they don't know (Pt.8, P.4, L.15).*

*I remember when I was in the hospital, the doctor visited me after the heart attack 2-3 times, he only came for 3-4 minutes each time, each time he asked me how I am today! How I feel! then he writes something on my file or adds one or two medicines [...] without telling me what he did or providing any information about what is happened to me [...], then he goes to another patient [...], no chance to speak with them or to ask them about your enquires (Pt.2, P.8, L.21).*

*There are no specialist clinics providing health education for us regarding diabetes, diet or smoking cessation [...] there are no educational programmes at all and there is shortage in doctors, specialists and nurses [...] (Pt.9, P.7, L.5).*

*I hope there are good healthcare providers offering us health education about our diabetes and heart attack, how to manage both diseases and teach us what should we eat and what we should not [...]* (Pt.4, P.6, L.5).

iii. Culture

During the interviews, the participants also expressed their frustration regarding the culture and the surrounding environment, and how it strongly impacted negatively on their health, lifestyle and adherence:

*Most difficulties I faced after I was discharged from the hospital was our unhealthy customs in home and outside the home, its make me feel regret about my health most the time, for example, our eating habits in home are unhealthy we eat one or two heavy meals a day, not organised, we eat too much fatty foods, sweets, we using sugar a lot in our drinks and salt in our foods, as you know rice and bread are essential in most our meals, the healthy options not available all the time. I tried many times to overcome such these customs in home or in the social events but I failed most the time, as we are firmly attached to our unhealthy culture! and eating habits and eating together style in our families and in the social events (Pt.16, P.4, L.10).*

*I felt bad many times because of this culture in which we live, it always leads me to break my commitment towards diets or stop smoking, people do not support you when you do healthy acts, for example, most of the eating habits in my family, work with colleagues and society in social events are unhealthy but the big problem you cannot stop eating with them or share life with them although you know to do this will be harmful to your health, if you are against their rules you will find many people irritated by your deeds, to avoid this, unwillingly, I acquiesced to their requests many times. (Pt.3, P.5, L.27).*

A single woman said:

*The reasons I did not practice any physical activities is that there are still some negative views towards women who are doing physically*

*activity like running outside their home and me as well I do not have that motivation to do this outside home [...], and me I cannot buy a device for running also, so I by default you will find yourself without interest or excitement to do such these activities (Pt.12, P.4, L.13).*

Another mother stated:

*We are in home eating together usually, we do not take breakfast and we eat the first meal too late [...], and may because of my commitment with my family habits and as I prepare food for them each day I did not take my insulin doses in an organised manner and as required, I am not happy about this but I can't change anything [...] (Pt.14, P.2, L.10).*

### **6.2.1.3 Summary**

The above excerpts show the internal and external sources of frustration for participants, and it is evident that frustration of patients with T2D after an acute coronary event was prevalent, representing a major challenge that led many to:

1. Lose their self-esteem and feel negative about their self and their life after discharge from the hospital with both conditions and possibly other comorbidities. Therefore, compounding these diseases with its physical and emotional symptoms, resulting in a greater negative effect on their self-esteem, minimising their ability to manage their disease well or even try new healthy things after ACS.
2. Adopt inferior coping strategies to deal with the realities of their complex condition at a pace which they feel comfortable with, including:
  - I. smoking to relive stress
  - II. Denial and non-adherence to healthy acts such as diet and checking sugar levels.
  - III. Forget the disease and conceal it from others to feel safer.
  - IV. Ignore/incorrectly responses to the disease symptoms such as taking pain relief drugs or sleep when they feel fatigued caused by disease symptoms such as high sugar levels.
  - V. Be hopelessness to control their condition because they have no future, with few years remaining to enjoy the rest of their life, seemingly no



solution to improve their complex condition as there are old with too many complications, or because they believe the problem is purely genetic.

- VI. Create new meanings or standards for their abnormal results to achieve their self-satisfaction by concealing their mistakes, such as feeling satisfied as long as the average of their abnormal sugar readings (i.e. 11 mmol/L) are less bad than other results (i.e. 21 mmol/L).
  - VII. Finally, do not engage in any physical activity because of their fear that any weakness or pain could be a precursor to another heart attack or life-threatening complications.
3. Hold some of the misbeliefs such as:
- I. All these problems are God's will and they cannot change anything; thus, they relinquish their self-care to god well.
  - II. Taking medication only is enough to control disease.
  - III. Doing household chores or job tasks are physical activities and sufficient to decrease sugar levels
  - IV. Health improvements are firmly associated with financial status and it seems impossible to make any lifestyle changes or improve health without a good financial status.
  - V. Using herbs instead of medications is better and safer to body.
  - VI. Information based on other patients' experiences is effective than information provided by professionals.
4. Subsequently, have the illusion of knowledge and control, this can backfire because it reinforces the participants' inferior coping strategies and misbeliefs, reducing their willingness to seek appropriate information about their disease management or try new strategies to control their diseases. Furthermore, it dispels underlying doubts about the wrong management for their condition and fears of their disease complications.

Understanding the internal and external sources of frustrations for those patients will allow HCPs to reflect on these sources, which negatively impact on patients' quality of life and health outcomes. Understanding these sources and working to address them can potentially improve patients' self-esteem, knowledge, and confidence in themselves

and their HCPs. It is important to note that living patients with uncontrolled diabetes and a number of comorbidities after ACS leads to mood disturbances and negative feelings, which cause an altered internal sense of those patients. Therefore, providing cognitive behavioural intervention to improve patient's self-management knowledge and skills, may be crucial for the treatment of such patients directly after ACS.

## **6.2.2 Theme 2: Health knowledge and reasonable care seekers**

### **6.2.2.1 Health knowledge seekers**

Although the participants reported different sources of their frustration, most had a desire to be knowledgeable about their health conditions and how to control their disease after discharge from hospital. From the interview data, it was clear that participants, based on their common sense as a human being, were seeking health information about their condition in different ways and according to different factors such as his/her cognitive abilities, social interactions, age and culture, as illustrated in the following excerpts:

*I tried to obtain information about my condition directly from my doctors but as long as I did not see them often to talk with them, I searched online about my case and health problems and I read what I found, each day reading something new about my disease and medications on Facebook [...], after I was diagnosed with diabetes I attempted to visit the national centre for diabetes endocrinology in Amman to learn more about diabetes and diet because they are specialists, but after two visits I stopped because was very far and I needed an appointment in advance and each visit cost much time and money (Pt.2, P.6, L.24).*

*During the four days I stayed in the hospital I have sought to get some information form the staff but I received nothing [...], so often I am trying to learn myself from my own experience to avoid eating anything make me feel bad, and I believe in taking advice from other patients with the same disease, I am always asking any patient I meet about his experience with disease and how he dealing with his problems [...], and sometimes they advise me or name some mixtures or very useful wild herbs [...], in my experience such these mixtures are better than all these*

*chemical drugs provided by doctors, really if I did not get benefits from using it definitely it will not harm me (Pt9. P.5, L.23).*

*Sometimes I read some short pamphlets or watch a medical programme on television to hear what the doctors say, if I found poster about heart disease, diabetes and its complications in the medical clinics I stop in front of it to read it, sometimes I get some important instructions [...] (Pt.11, P.4, L.18).*

*I used Google engine to search for any information I need, I love reading, also I take the advice of those who are older than me, for example, one of them advised me after I got heart attack to use the Hawthorn herb for my heart problem, I found a lot of researchers supported this, since then I drink Hawthorn in addition to my prescribed drugs and I found it good and I have advised a lot of patients to use it [...] (Pt.13. P.4, L.12).*

Three main drivers for participants to seek knowledge from sources other than their HCPs after discharge from hospital. These were, the lack of education and support for participants, increased number of complications and conflicting instructions, to be more assertive and self-reliant when interacting with other people such as their family, friends or their HCPs.

During the course of the interviews, the participants expressed a number of educational psychological needs. Often these needs were consistent with unmet needs of patients with T2D and ACS mentioned during Study I in the previous chapter. These are outlined in table below.

**Table 6-2: Cognitive and psychological needs of patients**

Theme	Subtheme / their need	Patients' statement
<b>Cognitive needs</b>	Managing symptoms and consequences and how to be avoid	<p><i>A lot of symptoms we experienced I don't know how to deal with it [...], often I feel confused and afraid when it happens because I think directly maybe it will be another heart attack or not [...] such as high and low blood sugar, chest pain and symptoms of heart attack [...]</i> (Pt.2, P.9, L.14)</p> <p><i>[I]t is important for any patient to be aware about expected consequences what he has to do to prevent such consequences and how to deal with it if its happen</i> (Pt.16, P.5, L.7)</p>
	The link between diabetes and cardiac disease	<p><i>I want to know what the connection is between both conditions, how both affect each other in my body and how increasing levels of sugar lead to angina, we hear much about diabetes only but about angina and it connection with diabetes nothing, I need to understand such this point, is it really affect! [...]</i> (Pt.4, P.6, L.15)</p>
	Medication management	<p><i>I don't know much about my drugs, I want to know why should I take all these drugs? After I was discharged from the hospital with heart problem, diabetes and hypertension I felt resentful whenever I opened the medications bag, it difficult to take it all and carry it to work [...] most of them I do not know what is it, I don't believe I need to take all these [...], since that time sometimes I just take one or two of them and when I feel nervous in home or work I did not take anything</i> (Pt.10, P.5, L.6)</p>
	Smoking cessation	<p><i>I am smoker until now, I was hoping that one of the medical staff discussed with me about how to quit smoking after my heart attack, at that time I was interested in doing it, I do not like the doctor who comes and tells me as an order "stop smoking!" and then disappears, I expected them to encourage at least and told me how I will do after 16 years of smoking, what is the appropriate way [...] I think any patient when he feels that his doctor really cares about him give him a gradual plan to stop smoking, the patient will do it or a least will reduce it [...]</i> (Pt.9, P.6, L.13)</p>

Cardiac problem	<p><i>I am interested to know more about my heart attack, what are the main causes and what is arteriosclerosis! what do I have to do to deal with this issue [...] (Pt.5, P.7, L.16)</i></p> <p><i>I think our doctors expect we know very thing about the heart disease, and we do not! We need to know about our heart disease more, its consequences, appropriate drugs and how to manage my new condition [...] (Pt.14, P.4, L.17)</i></p>
Diet	<p><i>I think the healthy diet is the important topic to be educated for all patients like me, most of us after we go back home become confused about which food and drinks are good and which are bad, I think we need to know how to choose our food and what is appropriate with our case [...] (Pt.3, P.10, L.7)</i></p> <p><i>I think my health deteriorated because of a lack of diet, but I did not get any information to understand the appropriate diet for my both conditions [...] (Pt.15, P.4, L.13)</i></p>
Diabetes management	<p><i>We live with diabetes every day and once we do something wrong, it is directly reflected on our health, I think controlling diabetes and knowing how to do this is the main key to live well after a heart attack because if the patient does not control diabetes, they will not be able to control all other things (Pt.3, P.12, L.7)</i></p>
Resuming sexual activity after ACS	<p><i>[M]y sexual activity and ability were affected and decreased to nothing! I did not know why all this happened, I was afraid to become tired and then my health deteriorate if I do sextual intercourse with my partner or if I take any sexual stimulants [...] I think most patients need to be reassured about this topic before discharged from the hospital (Pt.10, P.4, L.17)</i></p>

<b>Psychological needs</b>	Motivational support	<i>[I]t's important for patients like me to be always motivated by his healthcare provider at each visit, this non-existent currently, and more importantly to educate them how to motivate himself at home as the doctor will not be with him. I used positive and negative reinforcement with my students while I was in the school and it is effective, the healthcare providers should motivate their patient for every simple change, even if it small like a 5% decrease in sugar levels, then they should push him for more and show him the value of what he did, and also intimidate patients of the consequences of any bad behaviour or noncompliance to the plan is very important, [...] (Pt.8, P.4, L.27)</i>
	Dealing with stress	<i>I believe the psychological support is very important for patients with heart attack, I have become a nervous person and feel a lot of stress about my life and responsibility after I left the hospital, I couldn't control these feelings at home, easily I become anxious and nervous, and why I always feel this I don't know! [...] may be because everything was changed after my heart problem [...], know how to deal with these difficulties I think important. (Pt.11, P.5, L.3)</i>

Although there were many needs and topics that the patients sought to be educated about it, it was clear from the participants' extracts that they were unique individuals, with different lifestyles and priorities with regard to their needs. Most participants expressed their interest to be educated about a number of important topics, for example, the needs of those who were younger, less educated, smokers or had less comorbidities were different from those who were older, more educated, non-smokers or had many comorbidities. Therefore, understanding the patient's lifestyle and respecting his/her willingness to learn and change by involving them in prioritising their needs must be considered carefully at early stages in any cognitive or behavioural intervention for patients with multiple chronic conditions.

It was interesting that many participants perceived that their educational and psychological needs were firmly attached with the physician's roles more than other specialities as nurses. In other words, they always blamed their physicians for not providing education and support for them and did not perceive the nurses' roles in CCU or other department as a source to educate or to discuss with them about their needs in

the hospital. This indicates that may there is a status of low trust in nurses to play the role of health educators in current practice or confirming the status of lack of health education among current nurses' responsibilities in the secondary healthcare settings in general as indicated in the study one.

#### **6.2.2.2 Reasonable care seekers**

Many participants expressed their interest to obtain reasonable care from their HCPs during their hospitalisation and at follow-up visits. Sometimes participants attempted to seek this reasonable care by such showing respect and appreciation to their HCPs at most meetings and to the rules of hospital, listening carefully with their family members to them, gently trying to ask or open discussion with them about their health complaints, and arriving for their follow-up appointments in outpatient clinics early. However, participants expressed gross frustration with their treatment as discussed in theme one and with the lack of reasonable care without fair reasons. Some participants reported that such treatment was akin to medical negligence of their important needs and it lacks standardisation as treating them differently based on circumstances, such as level of health insurance, financial and social status. This was generally directed at both the healthcare system and the clinicians in Jordanian public hospitals as illustrated below:

*One month after my heart attack, I went back to the outpatient clinic to see my cardiologist, I was interested at that time to see him as I have a number of enquiries about my drugs and difficulties that I experienced [...], I came half an hour before my appointment to make sure everything was okay. Unfortunately, I was shocked as I had to wait long hours to see the doctor as a lot of patients were there at the same time, and after I entered the clinic, my cardiologist was not there, one of his junior doctors was there! Each visit I meet a different doctor, all visits mostly last for 3-5 minutes only while I am standing sometimes, during which he checks my sample tests and renews my medication list and then asked me to go to the pharmacy. I do not get a chance to ask him anything, I was exhausted from the long waiting time and the way I was treated, its made me feel weary and uninterested in talking with them because of their tedious and disrespectful process and talk, and this scenario was repeated each visit [...]. This is actually unfair treatment for us as we have serious*

*cardiac problems, they deal with us as we are patients with a cold, not as cardiac patient (Pt.1, P.9, L.20).*

*We need specialists, such as the dietitians and diabetes specialists, to talk with us in hospital, I stayed five days in the hospital after my heart attack and I did not get any consultations from specialised people in diet or diabetes [...] (Pt.12, P.6, L.9).*

*My cardiologist did not refer me to diabetes clinic because my national health insurance does not cover this service, and I have to purchase devices and diabetes test strips always and if I need a consultation regarding my diabetes I need to go to private clinic, this is unfair as my condition became more complex after heart attack (Pt.15, P.4, L.14).*

*I have two chronic diseases, there should be special programmes and periodic educational lectures provided for us and we should have access to specialist clinics and diabetes and cardiac disease specialists in our hospital to help and support us to manage our condition, our condition is not just to take drugs for 2-3 days and that's it! I want to feel that the hospital provides fair enough care and support for me [...] (Pt.6, P.9, L.6).*

### **6.2.3 Theme 3: Willing to learn**

During the course of the interviews, participants discussed their aspirations of how their health knowledge and confidence would improve and their lifestyle would change following their ACS. Participants perceived that health education, empowering care and self-management intervention were lacking for them, either during their hospitalisation or after discharge from the hospital. It was clear that the period following discharge from hospital with ACS was characterised by frustration, uncertainties and lack of knowledge and confidence for participants. However, they expressed their willingness to receive health education about how to live well with both conditions, perceiving their need for any initiatives to improve their self-care activities, quality of life and health outcomes. Three main features were discussed with participants that could help in shaping future self-management interventions for those patients.



### 6.2.3.1 Time and location of delivering education

The first important feature, which emerged in relation to participants' perspective about self-management intervention/health education, was that they often wished to receive health education immediately after their ACS. There were a variety of reasons cited for providing this at this time and during their hospitalisation including:

- I. Their curiosity about their coronary cardiac event and reassurance by minimising their uncertainties before they were discharged from hospital, such as what was the cardiac event, why it happened, how it will impact on their health and life, and how it will be managed with other diseases.
- II. Fear of heart disease, death and recurrence.
- III. Availability of time during their hospital stay, which on average was 5.4 days in CCU after their ACS.
- IV. To be given support and reassurance during their stay in hospital, but once they return home and become involved in their daily routine, they are on their own and it may be difficult physically and financially to return to the hospital for further education.
- V. Help them to gain confidence in both themselves and their HCPs to make lifestyle changes after discharge from the hospital.

These are evident in the following excerpts:

*I stayed 6 days in hospital after my heart attack, and from the second day I felt okay and I can talk freely, although I had a few of chest pains, they did not discharge me early as they wanted to make sure my cardiac enzymes were okay, I think if you provide up to one hour of health education for patient in hospital he will not feel bored and he will be very interested [...]. I think you have to focus on providing this education during patients' hospitalisation, because I am sure most patients will not return to the hospital or clinic for only health education [...] (Pt.13, P.8, L.21).*

*As you know, patients after a heart attack could experience another one or experience very serious complications lead to cause open heart surgery or possible to die, so it is very useful to prepare patients in the hospital to manage their condition well before returning to his life [...]*

*even if they get 50% of what you provide for them, it is good for them, and I'm sure such educate those patients in the hospital will wet their appetite to learn more later if you invite him to further educational programme as he reported the benefits of knowledge and may experience what they have been told, so more likely to return to discover more and more (Pt.8, P.6, L.3).*

*I encourage the provision of education for patients while they are in the hospital. I think patients need someone to talk to before discharge about their heart disease and advise them about the expected symptoms and how to manage them, about an appropriate diet and encourage and reassure them, I wished someone did this for me before I returned home (Pt.1, P.18, L.6).*

*I think we need specialists to make us aware of our condition from the first day of admission into the hospital [...], if they just come each day for 10-15 minutes to educate us about our disease this would be really very helpful [...] instead of lying on the hospital bed for 3-4 days feeling bored and sorry for themselves, we will learn something that will be of benefit after discharge [...] this will reduce our psychological thriller after heart attack and improve our spirits [...] (Pt.4, P.9, L.13).*

Implicit in each of the above examples, is the fact that most participants are willing to learn about their condition before their discharge from hospital. They reported that this could lead to improving their knowledge about how to manage their health condition and confidence either in themselves or their HCPs. Some participants also expressed that such these education sessions should be approximately half an hour, a very comfortable time period for them. Furthermore, many participants wished to continue receiving more health education and support periodically after discharge from the hospital, as they often stated they wanted follow-up sessions after discharge, such as once a month for a few months.

### **6.2.3.2 The mode of delivery education**

Different modes for teaching were discussed with participants during interviews to explore the most preferred mode for delivering self-management intervention. These

mainly included face-to-face teaching methods, structured group education sessions and the phone calls or text messages. However, there was a large proportion of participants who expressed a desire for face-to-face education sessions more than other mode of teaching. There was a variety of reasons cited for participants' preference for face-to-face mode including:

- I. More acceptable for them, whether they are held in-hospital or at home
- II. It encourages discussion style, which may more efficient and beneficial as it contributes to direct two-way communication between themselves and the HCPs.
- III. More respective of their personality, willingness and age.
- IV. More confidential and ensures privacy as they preferred to share their lifestyle, experiences, attitudes and issues freely, especially women.
- V. More understandable, and fostering their involvement in what they are learning.

*Health education is not just give me pamphlets and then see you [...], I think sitting face-to-face with patients is the most essential and important way to encourage patients to brainstorm and understand information more [...]. I hoped someone would come to me before I was discharged from the hospital to discuss my cardiac condition, medications and advise me about lifestyle changes and form a clear road map for me to follow [...]. We really miss such this [...] in regard using other ways [...], I think it's good for follow-up care, we called it in economic science the service after sale, so provide your product first for your clients, then follow them via follow-up phone calls or invitation to another session after 2-3 months [...]. (Pt.3, P.15, L.18).*

*I prefer to sit and talk with my doctor directly about my case more than other ways, if we meet as group I am sure I will not understand as much as sitting alone with my doctor. Often during the group meeting, many people want to ask and talk, especially if all are women and each one has different problems [...] honestly, I will not be able to back to the hospital to attend such group education sessions, it's difficult for me as I need one of my family members to travel with me to hospital, and I am a woman at this age I can't travel much, especially if the place far away (Pt.11, P.7, L.13).*

*I think the patient after heart attack will be happier if he receives individual sessions, and it will be more effective and motivate him to change his behaviour more than other methods, also psychologically will be more comfortable to him as you are dealing with him with respective way [...] (Pt.6, P.11, L.6).*

From participants' excerpts, it is evident that they would like any educational methods to be more centred as much as possible on themselves and their experiences, such as one-to-one educational sessions and follow-up phone calls. There may be a wide range of reasons for such perspective, but it was generally described by participants as more useful and being respectful to their time, to their physical characteristics such as age and sex, physiological factors such as their illness and lifestyle, and to their psychosocial characteristics such as their level of knowledge and financial hardship. However, there was also a willingness expressed by many participants to use other methods for teaching, such as written materials as it can be a source of knowledge and support for them, as illustrated in the following excerpt:

*I believe to use more than one method to deliver the health information [...], for me I prefer combined educational sessions with using pamphlets and books as I like to read [...], diversity in style of teaching will increase patients' desire to learn and the benefits also (Pt.13, P.8, L.13).*

Most participants expressed their interest in follow-up one-to-one sessions, either by phone calls or conducting face-to-face meetings at home or in close proximity to them after discharge from the hospital more than other methods, such as text messages and group sessions. There are many reasons for their lack of interest in the latter two methods. Often participants considered text messages as only including general health information and may not be directed to their actual needs, and the group sessions may be difficult to be organised and to achieve their actual desires as they may include a lot of discussion and side issues. Moreover, many participants expressed different conditions to attend the group sessions related to the suitability of the time and place, if there was a multi-specialist team to provide the session or not, as well as other physical and financial difficulties that could reduce their readiness to attend.

From the interview data, it was clear that many participants expressed a desire to learn directly from their HCPs and immediately after they diagnosis with ACS. They preferred to get advice and support through methods, such as one-to-one method supported with educational materials, which they perceive to be more effective for them to build their knowledge, confidence and self-esteem more quickly than other methods.

### ***6.2.3.3 Style of teaching***

As mentioned above, many participants expressed gross dissatisfaction with the way that their HCPs treating them either in-hospital or at the out-clinic, particularly with their manner, rather than with their clinical abilities. Therefore, there was also a large proportion of participants who expressed a strong desire for building supportive relationships with their HCPs. From the interview data, it was clear that the current HCPs' advice and support is usually "telling brief and quick advices/information" style. Participants expressed their frustration as they do not get an opportunity to discuss their conditions or ask questions, and their HCPs often sidestep the main issues raised by patients, disregarding their patients' willingness and perspective. Participants expressed their also disregard for their HCPs' advice and being unaccepting of their treatment instructions due to their style of dealing with them. Worse still, many participants lost trust in their HCPs, and gradually started to ignore their treatment instructions. Therefore, the style of advice and education for patients need to be carefully considered, as currently it is poor.

Many participants expressed their desire to learn through a discussion style with their HCPs (productive conversation), which allows them to express their actual needs and ask what they want, rather than just listening. Such feelings are illustrated in the following excerpts:

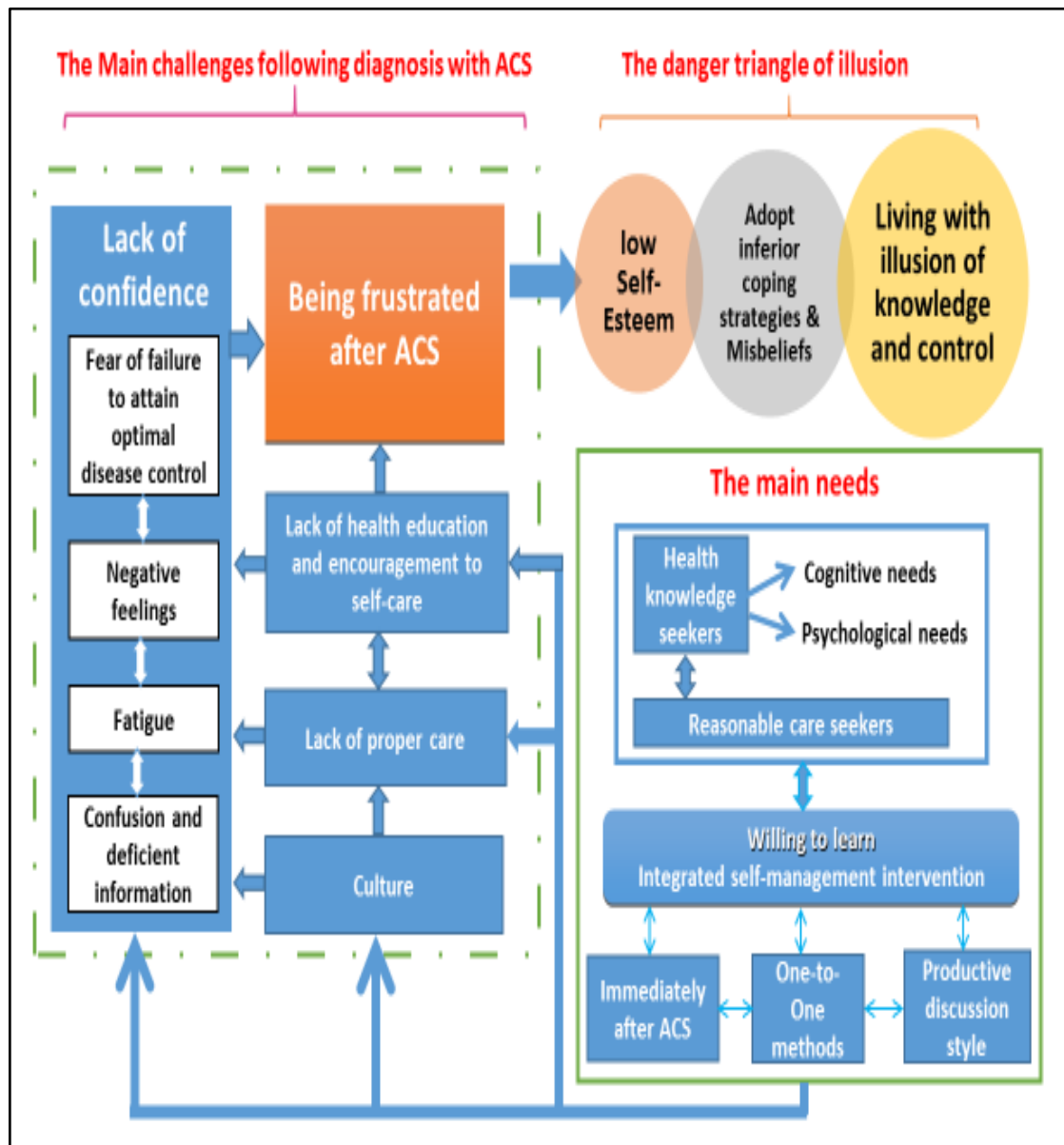
*I think our meeting with doctors should be take a discussion style between two mature parties, I should have the opportunity to ask them about what I feel and what I need to know [...], for example, if I feel a chest pain what I have to do! How do I make sure these symptoms are real! Each one of us has many questions which need to be answered [...], I am sure patients will be more comfortable, collaborative more as long as they feel that they are part of the discussion and their identity respected [...], we need to feel that our doctors and nurses care about us, smile at us, not just visit our files for signing [...]* (Pt.9, P.7, L.20).

*Any information provided for patients should be provided in a good and kind communication style, this what I like, each of us has different lives and different problems and what you provide for me may be outside of my interests [...], don't tell me: follow a diet! Take your medications! Tell me how? And tell me first what you need to know, what I usually eat in my home, I think we lack simple information and practical solutions and they miss what we really need and what we have and we can! We need a simple and applicable plan more than give me general information or a complex plan including a lot of things to do and most of them are beyond my capacities and interests [...], Do you know the real problem in the current doctors' style, they don't know what we really want from them! They do not give us the chance to tell them, and because of that, the patients are upset and their problems become worse, they deal with all their patients based on their mood and intuition [...] (Pt.12, P.8, L.1).*

From participants' excerpts, it is evident that they are interested to see some empathy from their HCPs during discussions about their condition, and to support them by know exactly what their needs and difficulties are, then helping them to resolve their issues and on their terms. It was clear that participants will be more interested and motivated to be compliant with any healthcare plan or change any behaviours if this plan or change is related to their real lifestyle as well as their physical and psychosocial realities. This can be done by facilitating a conversation style that enables disclosure their needs and interests as most of them cited. Also, sharing empathy through smiling, kindness and a simple enquiry after the patient's wellbeing would be highly appreciated by patients, and positively supporting the education process.

### 6.3 Summary and links between the themes:

To conclude, the results of these interviews demonstrate as can be seen in Figure 6.2 that:



**Figure 6.2: Proposed model of links between the themes of patients with T2D and ACS data**

- Participants experienced a lot of internal and external causes of frustration following diagnosis with ACS.
- There were many consequences of being frustrated following diagnosis with ACS for those patients, in both physical and psychological terms; of which reduction in the self-esteem of patients, adopting more inferior coping strategies and misbeliefs, and subsequently living with the illusion of knowledge and control of their diseases.

- However, most participants were knowledge seekers following diagnosis with ACS. There were many cognitive and psychological needs that required to be addressed, and these needs should be prioritised and addressed to each patient based on his/her desires and well understanding of their lifestyles, as each patient has a unique lifestyle and capability.
- Participants were reasonable care seekers following diagnosis with ACS, either during their hospitalisation or at follow-up visits. They expressed gross frustration with their current treatment and lack of reasonable care for them without fair reasons.
- Patients with T2D and ACS emphasis on need for urgent health education interventions. They considerably welcomed to provide a self-management intervention immediately after diagnosis with ACS.
- Most of them preferred to use one-to-one education sessions as core methods for teaching in such intervention. They stressed that need to focus on the educational and behavioural needs of patients themselves through facilitating a productive conversation that enables disclosure of their actual needs, prioritises and building their personal recovery plan.
- According this study findings, it seems that providing an integrated self-management for patients with T2D and ACS during their hospitalisation with ACS, and within recommended features by participants in this study could be acceptable and effective to reduce patients' frustration and improve each of patients' health knowledge, self-esteem and confidence either in themselves or in their HCPs following diagnosis with ACS.

In chapter seven, the methodology and procedures for developing and feasibility testing the study intervention for patients with T2D and ACS will be presented.



## **Chapter 7: Development of the Diabetic Cardiac Self-Management (DCSM) Intervention**

### **Introduction**

This chapter describes the methodology and procedures for developing and feasibility testing the Diabetic Cardiac Self-Management (DCSM) Intervention for patients with type 2 diabetes (T2D) and acute coronary syndrome (ACS). The appropriate evidence and theory relating to intervention development are presented followed by details of its setting, content and rigor. The methods and design of the feasibility study are then presented, together with the research questions and details of the study sample, data collection process and ethical considerations associated with the feasibility study.

### **7.1 Methods Used for Developing the DCSM Intervention**

#### **7.1.1 The overall aim**

The literature review pinpointed that patients with T2D and ACS have an increased risk of adverse health outcomes. And they share a lot of similar and modifiable lifestyle and cardiovascular risk factors. Therefore, the acute life-threatening nature of ACS requires that more emphasis should be placed on developing integrated interventions to improve self-management behaviour for patients with both conditions (Liu et al. 2017; Tanash et al. 2017b).

The findings of both qualitative studies conducted in Jordan (Study I and II) indicated that there was urgent need for a self-management intervention that would (a) minimise patients' frustration and confusion and (b) maximise their self-efficacy by improving their level of knowledge about how to cope with both conditions and by promoting their confidence, in themselves primarily but also in their healthcare professionals (HCPs). Although such interventions could not directly solve some of common physical and emotional problems those patients experiencing after diagnosis with ACS such as fatigue and negative feelings, many previous studies have indicated that when health knowledge, confidence and self-management skills of patients are improved, patients' fatigue level, negative feelings and fear of failure to attain optimal

disease control decrease significantly (Wu et al. 2012a; Wu et al. 2012b; Fisher et al. 2013; Dalsgaard et al. 2014; Siminerio et al. 2014; Hermanns et al. 2015; Kasteleyn et al. 2016; Schneider et al. 2016; Liu et al. 2017; Shi et al. 2018).

So, in order to improve patients' health knowledge, confidence as well as alter their cognitive and emotional representations after acute coronary events, studies I and II both indicated that there were many unmet cognitive and psychological needs that must be addressed for those patients. However, according to its priorities and importance the increased emphasis in the study's self-management intervention was placed on three main topics: (1) understanding cardiac disease and diabetes and the link between both diseases and its risk factors (2) lifestyle changes and the different techniques for managing their health condition; and (3) medication adherence and its importance. These educational and supportive needs for patients following their acute coronary events were consistent with unmet needs reported in many previous studies conducted in Jordan (Shishani et al. 2010; Eshah et al. 2011; Saleh et al. 2012; Jordan Ministry of Health 2013; JHHC 2015 and Mosleh et al. 2016a) and recommended at the international level (Amsterdam et al. 2014; Kasteleyn et al. 2014; Ibanez et al. 2017; Xiao-Yi et al. 2017; Zuliig et al. 2017; Liu et al. 2017 and ADA 2018).

In order to design culturally and practically appropriate intervention within Jordanian context the study's self-management intervention was designed based on patients and their HCPs preferences features and recommendations, which identified in both studies I and II.

### **7.1.2 Theoretical underpinnings for the DCSM Intervention**

Coping with acute or chronic diseases can be difficult. Current self-management interventions have shown some usefulness in helping patients with such diseases to cope and to manage the symptoms and the psychological and physical demands of their illness (Schneiderman et al. 2010; Sansom-Daly et al. 2012; Reid et al. 2013). However, there is evidence that such self-management interventions also have some significant limitations. For example, their effectiveness may be only short term (Goldbeck et al. 2014), their impact is often small (Reid et al. 2013; Arditi et al. 2016; van der Heijden et al. 2017) and their usability and efficiency in different clinical settings are also questionable (Leventhal et al. 2008). Often, such limitations occur because these interventions did not give serious

consideration to appropriate theories that describe the process of adaptation to illness (Maes & Boersma 2004). Therefore, ensuring the integration of theoretical developments in self-management and adaptation to illness is one of the most vital steps in developing efficient and effective interventions for patients with chronic diseases (Maes & Boersma 2004; Leventhal et al. 2008).

As stated in the Chapter 3 that to achieve best practice, the ideal interventions should be developed systematically by first using the best existing evidence and appropriate theoretical framework (Craig et al. 2013). The common-sense model of self-regulation (CSM-SR) was selected as the initial framework for guiding the qualitative investigations conducted in studies I and II, as indicated in Chapter 3. However, as noted in that chapter, while the CSM-SR is a well-established theoretical framework for understanding patient-related and common factors (e.g. cognitive and emotional representations and social environment) that affect patients' coping strategies and associated health outcomes (Leventhal 1980; Leventhal et al. 1997; Leventhal, Brissette, Leventhal, et al. 2003; Leventhal et al. 2016), it is less suitable for predicting adherence as reported in a recent meta-analysis study (Brandes & Mullan 2014).

The CSM-SR has mostly been used for studying the relationships between illness representations and either self-management behaviours or illness outcomes (Mc Sharry et al. 2011; Foxwell et al. 2013; Hudson et al. 2014; Dempster et al. 2015; Hagger et al. 2017). A few studies have used this theoretical model as a basis for developing self-management interventions (Karekla et al. 2018).

For example, Petrie et al. (2002) developed a brief in-hospital education intervention designed to alter MI patients' representations about their illness using the CSM-SR as a theoretical framework. The authors conducted a prospective randomized study of 65 consecutive patients with their first myocardial infarction (MI) to examine the effectiveness this intervention. Patients were assessed at three points: in hospital before and after the intervention and three months after discharge from hospital. They found that such an intervention can improve functional outcome after MI, better recovery and reduced disability. Since then, the CSM-SR has served as the basis for the design of interventions targeting several health problems, including heart disease (Broadbent et al. 2009; Lee et al. 2011) and diabetes (Tanenbaum et al. 2015).

Broadbent et al. (2009) examined also the effectiveness of a brief, in-hospital, illness perception intervention for patients with MI. One hundred and three patients with acute MI were randomised to receive either usual care or usual care plus the intervention, which consisted of three, in-hospital educational sessions with the patient each lasting up to one half hour and another one half-hour session with the patient and their spouse before the patient was discharged from the hospital. The two groups were followed up to six months. The study found that the intervention for patients with MI can improve rates of their return to work after discharge from the hospital and change their perceptions about MI. For example, at discharge the interventional group demonstrated higher a level of perceived understanding of their cardiac diseases and changes in causal attributions regarding their MI, which remained at the 6-month follow-up. They also reported a greater intention to attend cardiac rehabilitation programs, a better understanding of the health information given during hospital sessions, greater increases in physical exercise and lower anxiety about returning to work.

However, it seems that most previous interventions that used the CSM-SR as a theoretical framework focus generally on illness representations and action plans to improve outcomes of patients with cardiac disease while ignoring other important aspects of the CSM-SR, such as the role of the self-system, and almost none of these interventions have focused on motivational and pre-determined factors.

Therefore, as per the MRC guideline emphasised that best practice is to develop intervention systematically, using the best available evidence and appropriate theory (Craig et al. 2013), Bandura's self-efficacy theory (SET) (Bandura 1977), was chosen to be utilised in combination with the CSM-SR to provide direction for developing the study's intervention after the qualitative investigations conducted. In light of results of interviews conducted with "stakeholders" in study 1 and II it was found that the new intervention needs to be focused not only on altering patients' perceptions about their illness, but also on improving patient's self-efficacy after they diagnosed with ACS. The SET is a well-established theory for improving patients' beliefs of self-efficacy and it seemed to be able to promote the main features of the CSM-SR, as it will be discussed in the following.

While there are many theories explaining how to improve understanding and change health behaviour, such as Rosenstock's health belief model (Rosenstock 1974),

the theory of planned behaviour (Ajzen 1991) and the transtheoretical (stage of change) model (Prochaska and DiClemente, 1994), the SET seems to share certain concepts with CSM-SR. For instance, both theoretical models emphasise the role of patient's behaviour and action plans in achieving a more effective adaptation to illness; the role of "self" as the context in which self-regulation efforts are embedded; the importance of constant evaluation/re-evaluation processes (feedback); and the significance of experiences or programmed/habitual processes such as pre-existing behavioural patterns and previous positive and negative experiences.

Therefore, the SET probably has greater potential to impact patient behaviours than other theoretical approaches. For example, although the health belief model (Rosenstock 1974) focusses on an individual's beliefs, patients may or may not perceive themselves as needing to alter their health behaviours following diagnosis with ACS. Even if they are interested, they may or may not have the necessary knowledge and skills to persevere in changing their health behaviours. Many of these situations have been demonstrated in Studies I and II. For example, some patients did not perceive a need to change their health behaviours either because of their belief (or may misbelief) that all their problems happened by God's will and therefore were out of their control, or because of the lack of knowledge and support as confirmed was prevalent among patients with T2D and ACS.

The potential impact of The Transtheoretical (stage of change) Model (Prochaska & DiClemente 1994) is similarly limited. Although it focuses on the stages of an individual's readiness to change a health behaviour or perform a new one, it assumes that behaviour change progresses through a series of specific stages and in a linear fashion. In practice, patients may or may not be aware that they are ready to change a health behaviour or perform related tasks; they may or may not recognise a need for or be interested in changing their behaviour, or they may be aware of the illness threat and/or ready for the desired behaviour change, but they lack the confidence or motivation to initiate the change. The evidence from Studies I and II indicates that most patients with T2D and ACS following diagnosis with ACS had a low level of confidence in themselves and their HCPs primarily because of their extremely poor management of diabetes and lack of educational and supportive care. Patients' un-readiness to enact a new healthier behaviour and their lack of awareness about how to manage both conditions following diagnosis with ACS were also contributing factors.

Limitations are also evident in the theory of planned behaviour (Ajzen 1991), which focuses on the intentions of individuals to behave in certain ways. The theory assumes people always act in a rational way and based on the available information. In practice, however, even when people have the requisite knowledge and skills, they may or may not have the intention to apply them. As identified in Studies I and II, patients with ACS and T2D following diagnosis with ACS have poor knowledge and disease control and little power over their behaviours after discharge from hospital.

As reported in Studies I and II, patients' level of health knowledge varied, and often was poor. Also, the willingness of patients to adopt behaviours conducive of healthier outcomes may depend on their environment. In the context of this study, for example, patients following diagnosis with ACS experienced their recovery in three different environmental contexts: (1) the coronary care unit (CCU), (2) the intermediate/general ward and (3) the home. During their hospitalisation, patients may have less difficulty monitoring their blood glucose levels, diet, medication adherence than they do after they are discharged from the hospital. This is because during their hospitalisation, patients often rely completely on the care provided by HCPs, who constantly monitor them, routinely record their medical readings and supply appropriate meals and medication. However, after patients are discharged from the hospital to the home, they enter a different environmental context, so their performance and adherence are not guaranteed to be at the same level. Therefore, in addition to the personal and psychological aspects of patients with ACS and T2D, the theoretical framework for the integrated self-management intervention in this study should consider environmental determinants. These aspects are well-addressed in the SET, which represents the core feature of psychologist Albert Bandura's social cognitive theory (Bandura 1997).

#### **7.1.2.1 *The SET and adaptation to illness***

Self-efficacy has been defined as an individual's confidence in his/her capabilities to organise and perform the courses of action or specific behaviours required to manage prospective situations and result in beneficial outcomes (Bandura 1997). According to Bandura's Social Cognitive Theory (SCT), self-efficacy is adjustable and can have an influence on one's health status, self-motivation level and self-adherence to prescribed regimens (Bandura 1986). Individuals with higher self-efficacy towards achieving a specific task that can affect their lives have a better chance of accomplishing that task

successfully (Bandura 2001). Therefore, self-management interventions that focus on improving the self-efficacy of patients with chronic diseases are effective in improving the health and self-management-related outcomes associated with their diseases (Marks & Allegrante 2005; Hunt et al. 2012), such as improved self-management knowledge and adherence levels for patients with coronary heart disease (CHD) (Beswick et al. 2005; Maddison et al. 2015; Murphy et al. 2017; Palacios et al. 2017; Xiao-Yi et al. 2017; Zullig et al. 2017) and type 2 diabetes (Hunt et al. 2012; Gao et al. 2013). A significant relationship has been found between self-efficacy and diabetes self-management behaviour on the one hand and disease-related emotional distress on the other (Zulman et al. 2012; Gao et al. 2013). A systematic review of more than 550 high-quality studies of various interventions to support self-management shows that building self-efficacy is key to improving health-related outcomes for patients with chronic diseases (Janssen et al. 2013).

Self-efficacy theory clarifies how changing behaviour can be achieved for patients with chronic diseases by understanding and using the sources of information that influence patient's self-efficacy. According to Bandura (1977), there are four main sources of information that individuals employ to improve their self-efficacy levels, including performance outcomes, vicarious experiences, verbal persuasion and physiological feedback (self-appraisal). These terms have since been updated by Bandura (2004) to mastery experiences, social modelling, social persuasion, physical and emotional states, respectively. These new terms are used in this study.

As the findings of both Study I and Study II indicated, Jordanian patients with ACS and T2D have a low level of knowledge about and confidence in managing both conditions due to a lack of educational and supportive care either during hospitalisation or after their discharge from hospital. It seems that unless their confidence in themselves is stimulated during their hospitalisation, those patients will not be sufficiently interested in the health information provided for them or in adhering to the ongoing self-care activities for their condition. Therefore, providing an integrated intervention that aims to increase patients' level of knowledge about and confidence in self-management during their hospitalisation and after they are discharged is needed, or, to put it another way, as indicated above, maximising both their knowledge and their self-efficacy is essential to adhere to the ongoing self-care activities.

For example, in relation to the importance of improving self-efficacy in patients with cardiac disease, a systematic review was conducted in 2017 to determine the effectiveness of self-management interventions in supporting patients with CHD to improve their self-management-related outcomes and describe the essential components for effectiveness of interventions. Out of seven trials, 1321 patients with CHD included in the review recommended that interventional studies should focus on how best to increase patient self-efficacy (Palacios et al. 2017).

In accordance with the purpose of the intervention in this study, the four main sources of information for improving self-efficacy levels in combination with the CSM-SR concepts have been integrated into the intervention to enhance its effectiveness, as will be explained in the next section.

#### **7.1.2.2 *Combining the CSM-SR and SET***

In the CSM-SR conceptualisation, the illness representations of the patients are the main source of the self-regulation process involved in strategies for coping with illness and self-management behaviours (Leventhal et al. 1980). SET, on the other hand, although it theoretically puts more emphasis on the role of human motivation and behaviour than on human perceptions, also recognises the importance that patients with chronic disease often ascribe to the latter (Bandura 1997). According to Van der Bijl & Shortridge-Baggett (2002), self-efficacy represents one's belief that he or she can accomplish tasks using his or her capabilities under certain circumstances. So, the content of a patient's illness representations is likely to be dependent on information acquired during the course of his/her illness (Leventhal, Brissette & Leventhal 2003; Leventhal et al. 2007). This means that the way patients with multiple illnesses perceive and interpret their illnesses and their symptoms are dependent on illness representations on the one hand and on the contents and the directions of their self-beliefs on the other. It follows that there is a strong overlap between illness representations and the patients' general core beliefs, such as a sense of self-efficacy (Schüz et al. 2011). Thus, the first matching point between CSM-SR and SET – and therefore a necessary step towards the integration of both models within the management of chronic illnesses such as T2D and ACS – is the assessment of patients' cognitive and emotional representations about their health problems immediately following diagnosis with ACS. Towards this end, the intervention in the current study will emphasise patients' understanding of their health problem following a



cardiac event, and on the behaviours/habits they typically use to regulate it when facing a health problem.

The core principle behind the SET is that individuals are more likely to engage in actions for which they have a high level of self-efficacy and less likely to engage in those they do not (Van der Bijl & Shortridge-Baggett 2002). Moreover, people behave in ways that execute their initial self-representations and beliefs; thus, self-efficacy functions as a self-fulfilling prophecy (Gecas 2004). For example, as was shown in Studies I and II, the majority of patients with T2D and ACS have a low level of confidence, which leads them to relinquish control of their illness and self-care activities once they are discharged from the hospital. Additionally, because of their low self-efficacy, they lack the motivation to attain optimal disease control and subsequently adopt more inferior effective coping strategies, misbeliefs and live with the illusion of knowledge and control of their illnesses.

Often individuals with chronic diseases show interest in learning and performing only in those activities for which they believe they will be effective and successful (Lunenburg 2011). Therefore, as self-efficacy influences individuals' ability, willingness and motivation to learn as well as their performance, an intervention is needed that succeeds in improving patients' illness representations and their self-efficacy both together and immediately after ACS. By doing this, better self-management and decrease patients' frustration, confusion and cardiac-diabetes-related distress could be achieved.

The role of main sources of information in the designing of the study intervention will now be outlined in the following points:

1. Mastery experiences (performance outcomes)

Increasing patients' self-efficacy can be achieved by using four main sources of information. The first and most important of these are *mastery experiences (performance outcomes)* (Bandura 1977). According to Bandura, both positive and negative experiences can influence an individual's ability to learn and perform a given task. As reported in Studies I and II, most patients have poor experiences of disease control and adherence to treatment instructions either before or after diagnosis with ACS. The second integration point between CSM-SR and SET which was applied in the design of the DCSM Intervention was to discuss with patients how effectively they have coped with both positive and negative experiences, identify the main causes of their health problem and

help them understand the connection between their cognitive and emotional representations (inner factors – i.e. diabetes symptoms and illness concerns) and their adaptation behaviour (external factors – i.e. coping strategies in relation to diabetes and its symptoms).

For example, patients with T2D and ACS need to know the actual causes and risk factors behind their illness and how rigid beliefs (e.g. “my illness is God’s will and therefore out of my control”; “denial helps me to forget”; “nothing can help with my hypercalcemia”) may result in frustration. This may prevent them from making any further effort to deal with the expected symptoms related to T2D or ACS, or may cause them to lose self-esteem, engage in inferior coping strategies and develop the illusion of knowledge and control after their discharge from hospital, as shown in Study II. Because these consequences are maladaptive, they may in turn distance patients from valued activities in their lives, reducing their well-being (Hayes et al. 2011).

Studies I and II found that patients with T2D and ACS respond to painful thoughts and feelings after diagnosis with ACS by further cognitive, emotional and behavioural avoidance. Eventually, patients come to accept these negative thoughts as the only valid explanation for their condition and avoidance as the only possible coping strategy, locking them into further inaction. For example, a patient may become gripped by hopelessness or fear that they are unable to control their condition because of its complexity.

The ultimate goal of CSM-SR is to alter patient’s cognitions and appraisals in order to change their behaviour and help them adapt better to their illness. It therefore can be improved in combination with SET, which tries to change patients’ behaviour for the better by using different strategies and sources of information to improve their self-efficacy, enhance their knowledge, understand why change is important for them and to help them commit to an action plan, even in the presence of unwanted thoughts and feelings. Towards this end, several strategies including a self-appraisal, goal setting, verbal persuasion and self-monitoring were provided to help patients to alter their illness thoughts and representations or to discover a reason why it is important for them to change, to give them a sense of self-assurance and to reinforce their belief in their own efficacy.

## 2. Social modelling

The second source of information that can build one's self-efficacy is *social modelling* (Bandura 2004). This was described by Bandura (1998) as seeing other individuals who are similar to oneself (e.g., other patients who have the same illnesses) succeed through continued effort, thus raising the observer's beliefs (in this case, the patient's beliefs) that they too possess the capability to master comparable challenges. In the DCSM Intervention, patients were provided with a booklet that include real stories of patients similar to those in the study sample who had been successful in self-managing their conditions. Patients were encouraged to read these stories, which were referred to at different points in the discussion with them where appropriate. The purpose in doing so was to provide social models ("role models") showing how other patients who have similar illnesses, symptoms and difficulties can perform their self-care activities successfully. According to Bandura (1977), individuals who see that others performing a specific behaviour will persuade themselves that they also should be able to perform that behaviour to some degree. From this standpoint, in this model, patients' beliefs in their self-efficacy can be increased to enable them to expand their knowledge and develop new, positive representations by reducing the extent to which they hold maladaptive thoughts and evaluations (dysfunctional illness representations), and more importantly, encouraging their perception of their illness as controllable and certain related health goals/outcomes as achievable (curability/controllability).

Moreover, providing such role models may alter other patients' representations at an early stage in their illness, which could have an impact on their coping behaviour subsequently. For instance, role models can influence patients' expectations about the duration of cardiac-diabetes illness as a chronic disease (timeline), its impact on their physical, social and psychological well-being if not controlled (consequences), the symptoms associated with the condition (identity), the emotions generated by it (emotional representations) and the extent to which self-management can alter their condition for the better. As long as patients have positive illness representations, both their quality of life and self-management skills will increase, and their illness distress will decrease (Hagger & Orbell 2003; Petrie et al. 2007).

Thus, using mastery experiences and social modelling techniques for improving patients' beliefs of self-efficacy also helps patients to understand the relationship between

their illness representations, behaviour and outcomes. Moreover, to a certain extent it helps patients to realise that thoughts and feelings are not the only valid explanation of reality. This could help to minimise patients' frustration, their misbeliefs and the illusion of knowledge and control that most of those who took part in Study II reported.

### 3. Social persuasion

The third source of information to improve patients' beliefs of self-efficacy is *social persuasion*. According to Bandura (1998), individuals who are verbally persuaded and encouraged are more likely to make and maintain their efforts to master a given activity and incorporate their capability to do so into their daily lives. Although verbal persuasion alone is likely to have limited impact on people's self-efficacy beliefs, it is widely believed to contribute to successful self-management performance (Bandura 1986) and is used because of its ease and ready availability (Redmond 2016). Therefore, in the DCSM Intervention, patients were verbally encouraged during the education sessions, follow-up telephone call and other tools, and the style adopted in discussion with patients was that of positive encouragement. The need for this approach seemed clear in Study II, in which patients expressed extreme frustration due to lack of encouragement in their self-care activities and because of what they perceived to be unreasonable treatment. Formally incorporating this encouragement into CSM-SR-based interventions would help to improve patients' sense of the curability and controllability of their illness and enhance their positive emotional representations, thereby promoting their ability to perform (Redmond, 2016).

### 4. Self-monitoring (self-appraisal)

The fourth way to influence an individual's self-efficacy is *self-monitoring (self-appraisal)*. Individuals experience feelings from their body's outcomes and how they perceive the impact of this emotional arousal on their capability and beliefs of efficacy (Bandura 1977). According to Bandura (1998), individuals interpret their tension, fear and stress reactions as signs of inefficacy. Therefore, people who can "read" themselves well (who can 'realise' their cognitive and emotional perceptions/representations) are more able to improve their efficacy, alter their own beliefs and control their fear and uncertainty about their ability to perform the task (Bandura 1998). With regard to the process of change, the CSM-SR emphasises that achieving valued goals and changing behaviour in fact is a dynamic and ongoing process, as the SET also suggests (Leventhal

et al. 1992; Bandura 2004). As such, it entails some potential setbacks. Therefore, the patients in this study were encouraged to monitor and record their medical readings (e.g. blood glucose levels, medication use, physical activities) and their changes in their readings and behaviour as they happened and to use the gradual accomplishment of their valued goals/self-care activities as reinforcement for continuing their efforts. Over time, this technique helps patients to develop a dynamic process through which they assess their cognitive and emotional representations about their health problem as soon as they occur. Also helps patients to change the approach that they take to representing their condition and their self and reinforce their positive adaptation to illness (Leventhal et al., 2003a).

Therefore, patients were encouraged to self-monitor themselves and changes in their readings and outcomes using different strategies and multiple feedback paths. These included teaching them some self-appraisal skills for important self-care activities and providing direct feedback during the educational session and follow-up phone call about their knowledge, adherence and personal action plan. Moreover, using the teach-back method of educating patients during the intervention enabled direct feedback about patients' comprehension of illness-related information, coping strategies and treatment regimes. Thus, this method enhances the role of all sources of information for improving patients' self-efficacy.

In sum, understanding the mechanisms and consequences by which interventions may be expected to work allows for researchers to improve and refine these interventions, therefore, those designing interventions are encouraged to look for and report opportunities for improvement (Hoffmann et al., 2014). In this study, the development of the DCSM Intervention was based on integrating the knowledge and research experience gained from a well-structured model of adaptation to chronic disease, the CSM-SR (Leventhal 1980; Leventhal et al. 2016), and an evolving and efficient psychological therapy model, the SET (Bandura 1997; Bandura 2004), which may prove effective in, (1) promoting knowledge and adaptation amongst patients with T2D and ACS following a cardiac event; and (2) enhancing their well-being and health outcomes. This combination of the two models has been used effectively in several previous studies, for example, to support patients with T2D and ACS after their discharge from the hospital (Kasteleyn et al. 2014) and to change patients' perceptions after MI (Petrie et al. 2002).

However, these interventions were mostly focused on promoting illness representations and action plans and did not obviously consider or at least report the method used for teaching patients. Therefore, supporting the theoretical model of this study with a clear teaching method suitable for the characteristics and preferences of the targeted patients, such as the teach-back method that will be discussed in Section 7.2.3.7, may prove useful in achieving the best possible self-management and therapeutic outcomes for patients with T2D and ACS.

Indeed, the four sources of information for improving self-efficacy by the SET seem to be able to promote the main five features that the CSM-SR considers to be essential components of the illness-related self-regulation mechanism. These features were (1) promote the overall consistency of coping process for patients with chronic illnesses; (2) build more effective self-management goals and personal action recovery plans that consist of tangible and achievable goals and that correspond to patients' characteristics, interests and values; (3) regulate the emotions and thoughts of patients following illness; (4) convert effective illness management into newly acquired skills and habitual responses; and (5) support patients' conception of adaptation to illness as a dynamic process and emphasise the need for a continuous feedback.

Therefore, using the four mechanisms for improving self-efficacy within the SET seems suitable for stimulating the process of self-regulation, which according to the CSM-SR, is key to effective and consistent adaptation to illness and for better health outcomes (Leventhal et al. 2016). Moreover, as indicated by the findings from Studies I and II, in addition to lacking both educational and supportive care, patients with T2D and ACS face many cultural barriers following diagnosis with ACS that hinder their adaptation to illness. Therefore, using SET strategies and techniques during the CDSM Intervention would be especially helpful for those patients to face these barriers by improving their self-efficacy and self-regulation mechanism.

### **7.1.3 Contents of the DCSM Intervention**

The DCSM Intervention was a short cognitive-behavioural integrated self-management intervention designed to meet the main needs of patients with T2D and ACS. The intervention design and content were developed based on the evidence emerged from the systematic review and the qualitative studies that conducted in Jordan and according to the appropriate theoretical framework. The intervention consisted of three 20-30 minute in-hospital face-to-face educational sessions and one follow-up phone call following discharge.

In the light of the findings of the previous studies conducted, which clearly explicated the best evidence and appropriate contents and features for the intervention (e.g. mode of delivery, teaching strategies, settings and duration ...etc), the main researcher and his expert research team developed the DCSM Intervention and its contents. Then, the final version of the developed intervention was reviewed and discussed with the study advisory group in Jordan to get their feedback about the intervention and to ensure that the intervention was suitable for the targeted patients, fit with the real-world settings and culturally appropriate.

#### **7.1.3.1 Settings**

The feasibility study of the DCSM Intervention was undertaken at the King Abdullah University Hospital (KAUH) in Jordan. The KAUH is the largest teaching hospital and the only tertiary hospital in northern Jordan. The hospital has a bed capacity of 683 which can be raised to 800 in an emergency and an occupancy rate of 73.8% in 2017. The hospital has a cardiac catheterization (Cath) lab which treated 3821 patients in 2017, a coronary care unit (CCU) and an intermediate cardiac care unit (ICCU) which contain 12 beds and 24 beds, respectively. Each cardiac patient admitted to the CCU is treated in a separate room, while in the ICCU some rooms contain 2-4 beds (KAUH 2017). Eligible participants were recruited to the study from the CCU and ICCU. Follow-up phone calls also were conducted by the researcher from a comfortable room for interviewing.

#### **7.1.3.2 Ethical approval**

Ethical approval for this study was granted by the Research Governance Filter Committee and IRB Committee panel of KAUH in January 2017 (Reference Number: 13/3/3159).

### **7.1.3.3 *The facilitator***

The DCSM Intervention was implemented by the primary researcher (MT) according to the intervention's protocol, which describes in detail all the steps that must be followed each time the intervention is provided. This protocol has been revised and discussed with the research supervisory team and study advisers as appropriate before the intervention. The research team and advisers are experts and with many years of experience in different areas related to the study and the treatment patients with diabetes and cardiovascular disease. The researcher is a specialised research nurse with several years' experience in managing cardiac patients in the CCU and patients with diabetes.

### **7.1.3.4 *In-hospital educational sessions***

Three educational sessions were designed to meet the three main topics/needs of patients with both conditions, which presented above in section 7.2.1. These sessions were provided for participants over 2-3 days during their staying in the CCU. Each educational session lasted 20-30 minutes. The number, setting and duration of educational sessions were developed on the basis of a range of evidence. First, there was consensus among the HCPs in Study I regarding the importance of providing more than one education session for patients during their hospitalisation. HCPs also agreed that sessions lasting around 30 minutes would be most suitable for patients and HCPs in the CCU.

Second, the findings from Study II indicated that for Jordanian patients with T2D and ACS, the mean length of stay in the CCU after an ACS was 5.4 days (SD = 1.45, range 3-10 days), and that the most comfortable duration for each session in light of these patients' needs was about half hour. Therefore, providing up to three sessions was highly possible and recommended from a patients' perspective.

Thirdly, there was agreement between the HCPs in Study I and the patients in Study II that providing the sessions before patients were discharged from hospital was ideal for both parties. Most HCPs argued that this is the most suitable time to provide such education for patients within the current context, while patients expressed a willingness to learn in hospital and felt that this would entail fewer physical and financial burdens than holding the sessions after their discharge from hospital.

Fourthly, as reported in Studies I and II (Tanash et al. 2017a), both proper discharge planning and educational and supportive care for patients with T2D and ACS are lacking



in the current healthcare system in Jordan, which increasing patients' frustration and confusion. Providing in-hospital educational sessions could decrease their frustration and confusion and increase their knowledge and self-efficacy before their discharge from hospital.

Finally, a number of previous studies have successfully provided individual, in-hospital sessions for patients following diagnosis with ACS (Tanash et al. 2017b). For example, Broadbent et al. (2013) and (2009) provided successfully four half-hour in-hospital sessions, while other studies provided 2-3 sessions of 20-30 minutes each (Wu et al. 2011; Wu et al. 2012b).

### Session 1: General Knowledge

The first educational session (ES1) was designed to assess and improve patients' knowledge about diabetes and cardiac disease, the link between both conditions and its risk factors. Furthermore, during this session the researcher sought to aware the patient about the risk factors of both conditions and the fact that both condition share a lot of similar modifiable risk factors. According to this the patient's own thoughts about the causes of their heart attack were explored and prioritised. Thus, the session helps each patient to understand the link between both conditions, their personal risk factors and the importance of self-management in the prevention and treatment of both conditions. Moreover, improving patients' cognitive and emotional representations to self-manage their condition. Finally, the session explored the information provided in the intervention booklet about these topics (pp. 1-19) (the booklet in the English version is attached with the thesis). That in order to support the learning process and encourage patients to read related information outlined and the stories about the two role models, Ali and Fatimah (pp. 20-24).

### Session 2: Lifestyle Changes

The second educational session (ES2) was designed to help patients understand the importance of lifestyle changes to their health and help them to develop a personal action recovery plan. Towards this end, the session involved:

- a) Discussing how the patient's risk factors are associated with health behaviours and outcomes

- b) Exploring ways to reduce his/her risk of developing further health consequences (e.g. MI) and change their lifestyle.
- c) Discussing the advantages of changing unhealthy behaviours and the disadvantages of not doing so to help patients maximise the value of the changes they make and enhance their confidence.
- d) Debunking myths about the causes of heart disease and diabetes and the recovery process.
- e) Providing them with a logbook designed to facilitate self-monitoring and self-appraisal and educating them about how and why to use it (the logbook in the English version is attached with the thesis).
- f) Helping them to build up their personal action recovery plan for achieving at least one new healthier behaviour/goal, which selected on the basis of their preferences and priorities with the assistance of the newly designed logbook.
- g) Discussing the link between causal factors and the self-management plan they have developed.
- h) Exploring tips to improve their confidence in their ability to carry out their action plan after discharge from hospital.
- i) Using the information provided in the booklet regarding the top ten recommendations for reducing the risk of diabetes-related complications and further heart problems as a guide for lifestyle change.
- j) Encouraging patients to read the advice in the booklet and to use the logbook for self-monitoring.

### Session 3: Medication Adherence

The third educational session (ES3) was designed to improve medication adherence among patients and to raise their awareness of the main symptoms of diabetes and heart attack and how to deal with each of them. Towards this end, this third session involved (a) discussion of the importance of medication adherence following discharge from hospital; (b) teaching patients how to use the medication record sheet in the log-book and encouraging them to record the medications they take; (c) exploration of the diabetes management zones (green-yellow-red) used in the log-book, a tool which gives the signs and symptoms associated with each level of diabetes and the appropriate action to be taken within each zone; and (d) exploration of the symptoms of heart attack and how to deal with them appropriately, as explained in both the booklet and log-book.

#### **7.1.3.5 *Follow-up phone call***

One follow-up phone call was conducted with each patient two weeks after their discharge from hospital. The main aim of this call was to ensure that the DCSM Intervention continued after the patient discharged from the hospital to the home, and also to give patients psychological supportive and encouragement. According to Bandura's self-efficacy theory (Bandura 1986), an individual's behaviours can be influenced and changed by changing their environment. Because, the perceptions and behaviours of patients with T2D and ACS towards their self-management activities may change following their discharge from hospital, this follow-up phone call was important.

Each follow-up call involved (a) renewing the therapeutic relationship between the patient and the researcher, (b) assessment of how the patient's personal action recovery plan has progressed in terms of their performance and self-monitoring practice since their discharge from hospital and (c) discussion of the patients' concerns and any barriers related to their self-management action plan. Successful and unsuccessful self-care activities are also identified during this session. Verbal encouragement and praise are given for successful behaviour and empathy is expressed for those which have failed. The researcher then tries to identify the actual difficulties and to help the patient to set a new, attainable goal for the next period. Finally, the patient is reminded about the information in the booklet and stories of the role models.

#### **7.1.3.6 *Supportive tools needed for the DCSM Intervention***

Various supportive tools (see Figure 7-1) were given to patients during their hospitalisation to support the process of education and to improve their knowledge, confidence and adherence to their self-management recovery plan. These are detailed in turn below.



**Figure 7-1: Supportive tools used in the DCSM Intervention**

i. Booklet

A self-management booklet titled *How to Live Well with Diabetes and Heart Disease?* was developed for use in this study based on the main needs of patients with T2D and ACS that were identified during the qualitative investigations (Studies I and II). Most of the topics discussed with patients during in-hospital sessions were guided by the content of this booklet, which was designed to cover most information related to the treatment both conditions, self-management activities, coping strategies and the questions most frequently asked by patients with T2D and ACS.

The concept of the booklet was informed by the four main sources of information for improving self-efficacy (Bandura 2004). The content for this booklet was gathered from several well-known and evidence-based publications (American Heart Association 2016; British Heart Foundation 2016; Chest Heart and Stroke Scotland 2016; Northern Ireland Chest Heart and Stroke 2016; British Heart Foundation 2017). The core components of the booklet are as follows:

- I. Introduction
- II. What are coronary heart disease and diabetes?
- III. How does diabetes affect the heart?

- IV. What you can do to reduce your risk of developing further heart and health problems.
- V. Living with diabetes after a heart attack: Ali and Fatimah's stories
- VI. What drugs and treatments you might be given to treat your coronary heart disease.
- VII. How to manage your feelings and moods?
- VIII. What the warning signs and symptoms of heart attack feel like, and what to do.
- IX. Some common questions after a heart attack (housework, going back to work, sex).

The booklet is intended for both the people with both conditions, and for the people who care for them, such as their families and friends. It is sixty-eight pages in length and B5 size with normal margins. The font of the main text is 14 points or larger and black, as most patients with T2D and ACS are over 50 years and may have some sight difficulties or complications, having lived for a long period with poor diabetes control before their diagnosis with ACS. The headings and subheadings are 2 or 4 points larger than the main text and the font colour is red. The font style is Times New Roman, a type of serif font. Serif fonts are recommended because the serif makes the individual letters easier for the brain to recognize and distinguish quickly; consequently, they are generally easier to read than sans-serif fonts. Other instructions regarding the use of plain language and visuals, organisation of materials, consistent features, appearance, layout and design were considered carefully during the development and design of both the booklet and logbook in English and Arabic version. These instructions were informed by the three following guidelines:

- *Toolkit for Producing Patient Information*, which was designed by the Department of Health and includes guidance for the National Health Service (NHS) on how to produce good-quality written information for patients (DH 2003);
- *Simply Put: A Guide for Creating Easy-to-Understand Materials*, which was developed by the Centers for Disease Control and Prevention (U.S. Department of Health and Human Services) to provide practical ways to organize health information and use plain language and clear visuals, and which is particularly

useful for creating health fact sheets, brochures, booklets and other materials (CDC 2009); and

- *Guidelines for Selecting and Writing Easy-to-Read Materials*, which was developed by the Area Health Education Center (AHEC) at Ohio State University College of Medicine and discusses the use of plain language to help professionals write clear, understandable health education materials for patients and other laypeople (AHEC 2003).

These guidelines were used to ensure that the content of the booklet was readable, understandable and clear for elderly people with multiple chronic diseases; that the appropriate characters, lay language and colourful visuals were used; and to minimise the risk of patients being overwhelmed by written content.

#### ii. Logbook

The logbook was developed to help patients develop the skills of self-appraisal, self-monitoring and goal setting, and to help them determine the extent to which they have achieved mastery. The components of the logbook are as follows: (i) an introduction; (ii) a table showing the three zones for diabetes self-management (the green zone: control, the yellow zone: caution, the red zone: stop and think), the meaning of each and the actions required within each zone (ADA 2007); (iii) a figure showing the main symptoms of heart attack and what patients should do if they experience these symptoms; (iv) a medication record sheet; (v) a weekly personal self-management action plan (Coleman & Newton 2005); (vi) a 7-day blood sugar level record sheet; and (vii) a 7-day physical activity and walking diary.

This B5-sized logbook is twenty-seven pages in length, coloured, and includes this bunch of sheets for each week of a 6-week period. All instructions used in the development of the booklet were considered in developing the logbook, which is designed to encourage patients with an opportunity to record the name of their medication, and why, when and how they used it; to develop their weekly self-care goal; and to record their daily blood sugar level and physical activity. All the participants were educated about how to use the logbook through the in-hospital sessions and encouraged to record their reading after their discharge from hospital. Participants were specifically encouraged to use the blood-sugar diary sheet as a form of self-monitoring to record their daily blood sugar level each week. Patients also were encouraged to record notes related

to their diet or food taken or any barriers they experienced each day. Using the physical activity sheet, participants were encouraged to self-monitor their physical activity. The information to be recorded each day included the type, duration and time of activity, and any notes regarding the feelings, motivations or barriers they experienced.

Completing the logbook allowed patients to develop their awareness of the trend of their blood glucose levels, medication adherence, physical activities and how these trends were impacted by each other and other self-care activities, such as diet and quitting smoking (self-appraisal). The researcher also provided relevant verbal encouragement (social support) and feedback during the follow-up phone call (e.g. by reviewing the patient's average blood glucose level over the previous two weeks, discussing the patient's action and giving feedback about it).

iii. Seven-day pill box

The lack of adherence to medication among patients with T2D and ACS has been confirmed by previous studies. Many patients in Study II expressed their frustration with taking a lot of medications after diagnosis with ACS, which had led many of them to stop taking their medications or to reduce their adherence. One 7-day pill box was provided for patients at the third session and they were instructed how to use it. The box was to help patients organise their medication easily, enhance their medication adherence, and enable them to take it correctly.

iv. Engagement with family members

One of the patient's family members was invited to attend the education sessions that were provided for patients during their hospitalisation. Each patient was asked to elect a family member who was most involved in his/her life and care at home (i.e. the person who had the greatest effect on them, such as their wife, husband, daughter or son). The researcher then contacted them either personally to attend if they were available in hospital during recruitment or via a phone call.

The purpose of engaging with these family members was mainly to (a) increase their knowledge about the patient's condition, coping strategies and treatment; (b) reinforce patients' willingness to change their behaviour and adhere to their personal recovery plan after discharge from hospital; (c) help patients to prioritise their goals, identify their motivations and barriers, build effective recovery action plans and engage

in self-monitoring and self-appraisal; and (d) to reduce anxiety and panic patients and their family members may feel, which may be related to the seriousness of the patient's condition, the CCU environment and the lack of educational and supportive care which were reported in Study I. Thus, such engagement may help to improve patients' cognitive and emotional representations about illness, self-regulating and adaptation strategies after discharge by promoting the information sources for improving patient self-efficacy.

#### **7.1.3.7 *Teach-back method***

The HCPs who took part in Study I emphasised the need to engage patients in constructive and positive discussion when providing health information. They also urged practitioners to consider the suitability of the method of education in view of characteristics such as the patient's age, level of education and culture. Many Jordanian patients with both conditions are elderly adults with a wide range of experience with disease; their socioeconomic status and level of education are low and their health knowledge and adherence are poor. Moreover, Jordan is a low-middle income country whose healthcare system is ill-equipped to prevent and treat chronic diseases appropriately (Health 2013). All these factors are associated with low health literacy and self-efficacy among patients with chronic diseases (WHO 2017).

Likewise, in Study II, patients expressed frustration with the method of providing health advice or the way they have been treated by HCPs. Such frustrations influenced their desire to learn and led many of them to forget information quickly, to disregard, ignore or resist health instructions and to lose confidence in themselves and trust in their HCPs. Therefore, many patients expressed a desire to learn through productive conversation which enables disclosure of any misunderstanding by allowing them to express their actual needs and ask questions if they do not understand, rather than just listening to someone (telling brief and quick advice/information). A clear majority of patients stated that a simple communication strategy is the best method for improving their level of knowledge and self-efficacy following diagnosis with ACS either during their hospitalisation or outside the hospital.

Consequently, it was important to support the CDSM Intervention with a clear, simple education method appropriate for the context and features of the target group. The



teach-back method was used during the educational intervention sessions in an attempt to reinforce education in participants with T2D and ACS.

The teach-back method is a widely used method with which to teach people about their chronic disease and self-care management. Also known as “closing the loop” or “show me”, the teach-back method aims to increase patients’ understanding of the health advice or disease information being communicated to them during education sessions by simply asking them to repeat back the main points of the advice or instruction (Jager & Wynia 2012). The method includes a questioning technique that helps to determine what the patient has understood from the information. If the patient provides an insufficient explanation, answers incorrectly or seems to have difficulty understanding the information, the HCP can identify what information should be clarified and repeated. This process continues until the patient answers properly (Villaire & Mayer 2007b, 2007a; Shaw et al. 2012; Poureslami et al. 2017). For example, the HCP may ask such questions as “Can you please tell me what the main symptoms of MI are?” or “What can you tell others, like your wife or a colleague, about the changes in your daily diet?” However, this method is not a test of the patient’s knowledge level as much as a discussion and exploration of how well the information has been taught and what points the patient needs to be clarified or reviewed (Bradke et al. 2011). As such, this method fulfils the interests and needs of the target population identified by the findings from Studies I and II.

Research shows that 40-80% of the health information and instructions patients receive are forgotten immediately and roughly half of the health information retained is incorrect (Kessels 2003). Patients with low health literacy and low literacy are more likely to have an inferior understanding of their chronic illness (Villaire & Mayer 2007a). However, the teach-back method is useful in supporting almost all patients to understand health information, disease warning signs and treatment regimens well. Because it does not require any specific level of literacy, it allows even those with low literacy levels to actively participate and for information to be reiterated (Villaire & Mayer 2007a; Kountz 2009). Given that the findings from Studies I and II suggest there is a low level of health literacy among many patients with T2D and ACS, the teach-back method was deemed to be a suitable method for use during education sessions.

The teach-back method has been used successfully as an educational technique for HCPs to:

- a) Promote a safe transition of patients from hospital to home (Frewin et al. 2011; Kornburger et al. 2013).
- b) Improve patient satisfaction with HCPs and the healthcare system (Centrella-Nigro & Alexander 2017).
- c) Increase comprehension of discharge instructions regarding their medication, self-care and follow-up instructions in patients with low health literacy (Cutilli & Schaefer 2011; Bowskill & Garner 2012; Griffey et al. 2015).
- d) Assess and reinforce the ability of adult patients (Porter et al. 2016) and in low-income patients (Wilson et al. 2012).
- e) Improve self-monitor and knowledge retention in patients' and their family members (White et al. 2013b; Peter et al. 2015).
- f) Improve disease management and reduce hospital readmission rates for patients with chronic diseases (Howie-Esquivel et al. 2011; Dantic 2014).
- g) Increase knowledge about and adherence to diet and medications among patients with type 2 diabetes and low health literacy (Negarandeh et al. 2012).
- h) Teach patients with cardiac disease about self-care during their hospitalisation and to help them retain that knowledge following their discharge from hospital (Howie-Esquivel et al. 2011).

A systematic review was recently conducted of randomized and non-randomized trials, cohort studies, pre- and post-studies and case-control studies conducted to examine the evidence on using the teach-back method in education interventions designed to improve self-management and adherence outcomes for adult patients with one or more chronic diseases, including T2D and cardiac disease patients (Ha Dinh et al. 2016). Of the 5990 articles screened, only 12 met the inclusion criteria and were selected for analysis. Overall, the study showed that using the teach-back method achieved a significant improvement in a wide range of health care outcomes, including disease-specific knowledge, adherence and self-efficacy. There was also a positive improvement in self-care and a reduction in hospital readmission rates. Quality of life and illness-

related knowledge retention also showed improvement, although the trend was inconsistent. The review concluded that using the teach-back method to educate people with chronic illness(es) during self-management interventions will maximise patients' understanding of their illness and promote their knowledge, adherence, self-care skills and self-efficacy (Ha Dinh et al. 2016).

Therefore, the teach-back method was used to explain information clearly, check patients understanding and improve patient-provider communication. During the study's sessions the ten elements of competence for using teach-back effectively were applied:

1. Use a caring tone of voice and attitude.
2. Display comfortable body language and make eye contact.
3. Use plain language.
4. Ask the patient to explain back, using their own words.
5. Use non-shaming, open-ended questions.
6. Avoid asking questions that can be answered with a simple yes or no.
7. Emphasize that the responsibility to explain clearly is on you, the provider.
8. If the patient is not able to teach back correctly, explain again and re-check.
9. Use reader-friendly print materials to support learning.
10. Document use of and patient response to teach-back.

#### **7.1.4 Application of the four information sources in the DCSM Intervention**

Examples of the application of the DCSM Intervention activities in each session and their relationship to the four sources of self-efficacy information are provided in Appendix 13. Further details of the DCSM Intervention activities are provided in Appendix 12.

#### **7.1.5 Translation of The DCSM Intervention materials**

Due to time constraints and limited resources, the booklet and the logbook were translated from English into Arabic using the "single" one-way translation method. However, to

ensure the translated materials were culturally and linguistically appropriate, a number of steps were taken as per the recommendations outlined in '*Toolkit Guidelines for Culturally Appropriate Translation*' (CMS 2012) and *Simply Put: A Guide for Creating Easy-to-Understand Materials* (CDC 2009):

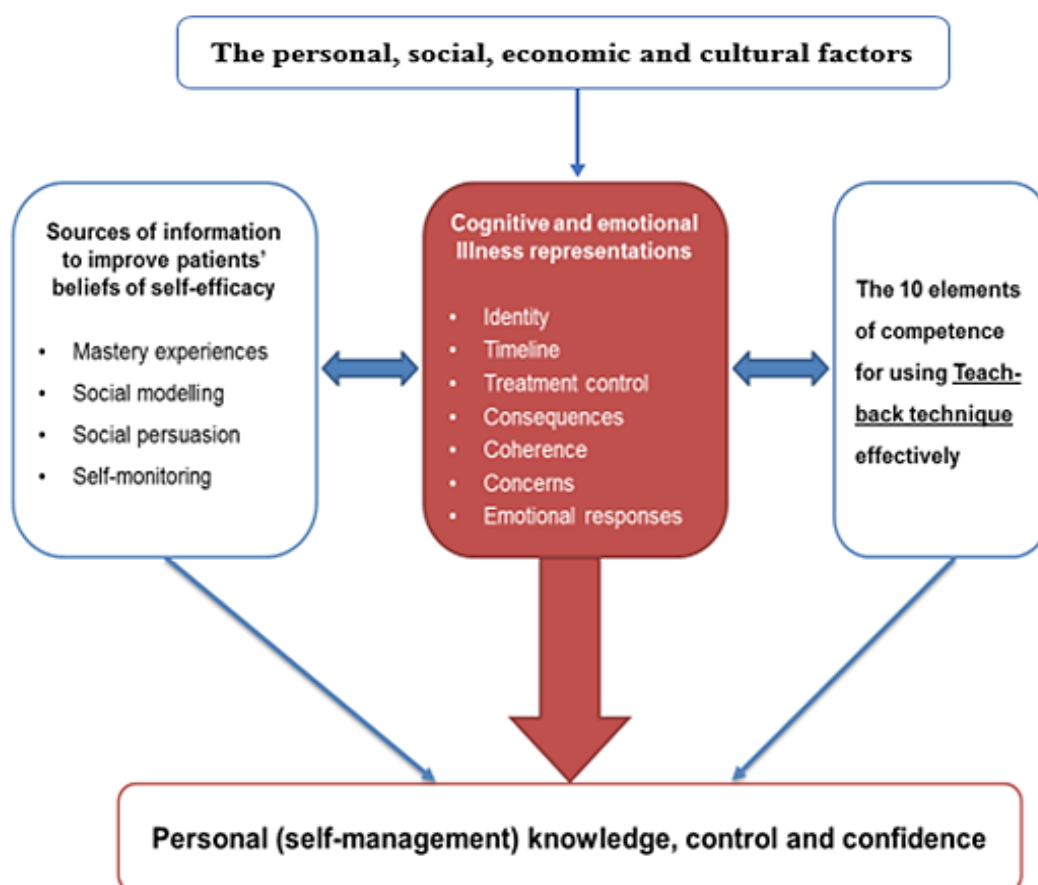
1. The terminology used in the English language version of the booklet were reviewed with reference to the plain language thesaurus for health communications developed by the Centers for Disease Control and Prevention's National Center for Health Marketing (CDC, 2009) to help HCPs and researchers make health information clear and easy to understand. The medical terms found in health information literature can be confusing. This thesaurus suggests plain language equivalents to medical terms, references and phrases that HCPs often use. Examples of terms from the first draft of the booklet that were replaced with plainer/clearer terms are displayed in Appendix 14.
2. After the English-language versions were reviewed by the research supervisors, who have extensive experience of managing patients with diabetes and cardiac disease, the booklet and logbook were carefully translated into Arabic by the primary researcher who is familiar with the target audience, their values, customs, health beliefs and cultural perspectives. Furthermore, the primary researcher is a native speaker of the target language, with experience in the care of patients with diabetes and cardiac diseases in Jordan. And having conducted the qualitative investigations and transcribed and analysed the data. During the translation process, literal translations were avoided, and the active voice was used to improve readability. A wide range of phrases, expressions and terms used by the target audiences were used. This flexible approach was adopted to produce more culturally appropriate material and to make sure the translation was done for meaning.
3. The initial Arabic translation was carefully reviewed by two different bilingual researchers and two clinical professionals who are familiar with the management of both conditions, and the cultural and linguistic patterns of the intended patients in Jordan. In response to their feedback, further changes were implemented including, for example, using Arabic rather than English numbers and measuring units, using words rather than signs (e.g. "less than" instead of < and "greater

than” instead of >), replacing some terms with others more suitable for the target population (e.g. “medical review”/“مراجعته طبيّة” rather than “doctor visit”/“زيارة الطبيب”, “sport exercises”/“تمارين رياضيّة” rather than “physical activity”/“أنشطة رياضيّة”).

4. Two Jordanian patients with diabetes and cardiac disease reviewed the forms and materials to assess and improve their validity and readability. The patients were asked if the information was clear and easy to understand, if any words or parts were difficult to read or understand or otherwise confusing in any way and if anything was offensive or unhelpful. Overall, both patients provided positive feedback and felt the material was very clear and useful. However, they did provide very few minor comments which were then addressed as appropriate. For example, one patient asked how to record the drugs they took on the medication record sheet. Although patients will receive instruction on this during Session 3, to address this concern, an example was added to the first row of the sheet to illustrate how to record drugs (see the logbook, page 4).
5. After working on reviewers’ feedback, both the booklet and the logbook were reviewed by an independent, bilingual, linguistic professional with good writing skills in Arabic who is familiar with the culture and language patterns of the intended patients in Jordan. This person served as an editor and proof reader, reviewing the quality of the translation to ensure it was polished and error-free.
6. After the translation and consultation stage a separate package of materials was printed in each language. The single language format has chosen for several reasons. Firstly, the targeted patients are familiar only with Arabic; secondly the format is simple, very flexible, and readers generally like it, finding it less intimidating than dual-language formats that cover the same information twice. Finally, it is a common choice for formatting translated material (CMS 2012).

### 7.1.6 Summary

Informed by the evidence from relevant previous studies and drawing on the most appropriate theories and methods of teaching for this target population, this study hypothesises that a CDSM Intervention that succeeds in increasing patients' knowledge and self-efficacy will lead to improvement in patients' illness representations about the management of both conditions after diagnosis with ACS. Subsequently, the intervention lead to improve self-management behaviour, confidence and a decrease in diabetes- and cardiac-related confusion, frustration and distress. The theoretical framework for the current study is explained in Figure 7-2 and Figure 7-3 below.



**Figure 7-2: The theoretical model of the impact of self-efficacy and the teach-back method in relation to the person's representations**

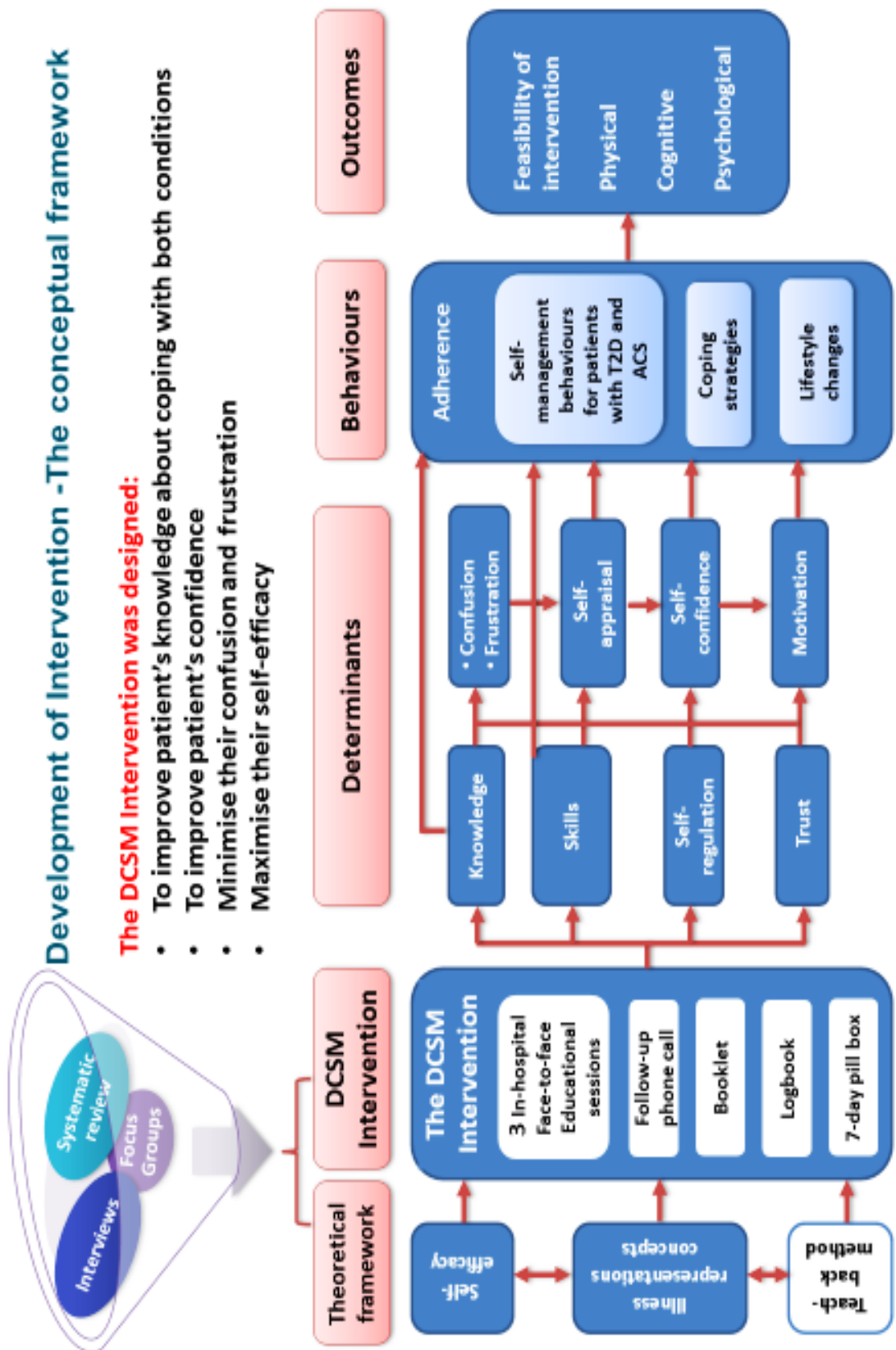


Figure 7-3: The DCSM Intervention theoretical framework

## **7.2 Feasibility testing the DCSM Intervention**

### **7.2.1 Design**

Lack of clarity about how the intervention functions will lead to inconsistency in the research results (Hrisos et al., 2008) and inefficiency in translating these results into practice, resulting in the failure of the intervention (Hrisos et al., 2008; Michie et al., 2008; Noar et al., 2008). Even the most well-designed study can develop unexpected problems with recruitment, retention, acceptance or methodology. Possibly the best strategy for achieving an effective study design is the completion of a feasibility study prior to the initiation of a larger-scale trial (Cope 2015). As the DCSM Intervention was the first in the history of Jordanian healthcare practice to be designed for delivery to patients with T2D and ACS, there was a certain degree of uncertainty regarding the feasibility of the study procedures and design. Therefore, following development of the intervention, a feasibility study was conducted to:

- a) Evaluate recruitment capability and the characteristics of the resulting sample.
- b) Assess the suitability and acceptability of the intervention to participants.
- c) Enable a preliminary evaluation of the participants' response to the intervention measures.
- d) Receive participants' feedback about the intervention and measures.

A mixed methods design was adopted for this feasibility study to measure its primary and secondary outcomes. Further details about the outline questions have been used to test the feasibility of the DCSM Intervention are available in Appendix 15, which was developed on the basis of the overall aim and theoretical framework of the current study and in accordance with the main objectives and guiding questions associated with most feasibility studies (Tickle-Degnen 2013; Orsmond & Cohn 2015).

### **7.2.2 Sample size**

As this was a feasibility study, a formal sample size calculation may not be appropriate (Lancaster et al. 2004; Thabane et al. 2010; Billingham et al. 2013). Feasibility studies are not expected to involve large samples and in fact are often based on samples which are small and without adequate power to perform statistical hypothesis testing (Tickle-Degnen 2013; Orsmond & Cohn 2015). That said, the sample should be representative of



the target study population and large enough to provide useful information about the aspects that are being assessed for feasibility (Thabane et al. 2010; Orsmond & Cohn 2015). In a comprehensive article, in which she evaluated the samples used in pilot and feasibility studies for their adequacy in providing estimates precise enough to meet a variety of possible aims, Hertzog (2008) asserted that using samples as small as 10-15 participants per group in feasibility studies can be sufficient.

The outcomes of most feasibility and pilot studies should be measured with descriptive statistics and qualitative analysis, and by reporting the basic data related to the feasibility of both the intervention and the administrative and physical infrastructure (Tickle-Degnen 2013). However, as no available dataset included the number of eligible patients admitted to the CCU in the study setting, the sample size of the study was estimated according to the pre-consultations conducted with two cardiologists, one senior CCU nurse and one head nurse of CCU in the study setting. Those HCPs were asked the following questions:

1. How realistic and obvious are the eligibility criteria?
2. How easy are the intended patients to identify?
3. How willing would they be to be recruited?
4. What is the expected recruitment rate for one week, approximately?
5. What is the expected refusal rate?

The HCPs reported that many patients who are admitted to the CCU with ACS have diabetes and most would be interested in participating in the study, the exceptions being those who experience a serious complication after their cardiac event or the very elderly. They confirmed that potential recruits could be identified by the physicians and senior shift nurses who are in charge of the CCU, as they have access to patients' records and know if a patient meets the inclusion criteria of the feasibility study. Regarding the expected recruitment number for intended patients, the HCPs estimated that 3-4 patients (male and female and different type of ACS) could be recruited each week. Informed by this advice, it was decided that approximately 20 participants could be recruited in 6 weeks. A purposive sampling was used. The participants were selected based on the study purpose and criteria with the aim to maximise variations and provide unique and rich information of value to the feasibility study (Suen et al. 2014).

### 7.2.3 Non-prepuberty sampling

Researchers can either choose probability sampling or non-probability sampling as a basis for selecting their sample from the targeted population. While the probability sampling relies on use of random selection to get more representative sample, the non-probability sampling does not operate on the principle of random selection to the sample and are used when researchers find it undesirable or difficult to choose the sample on basis of randomisation. However, the later approach can still retain the aim of generation a representative sample according to the purpose of the study (Denscombe 2014). Non-randomised feasibility study was used during this study because the following reasons:

- a) As this was the first time for implementing the DCSM Intervention in Jordanian secondary care setting. There was not sufficient information about the study subjects and their availability to undertake probability sampling (i.e. no clear information about who much the inclusion and exclusion criteria will be suitable with current population and how many subjects make up the targeted population).
- b) According to the pre-investigation conducted about the availability of targeted population, and within the available and limited time to run the feasibility study in this PhD study, it was not feasible to include a sufficiently large number of participants in the study by using probability sampling.
- c) As the research on captive participants who are under-treatment in the CCU and referral to the study based on the judgment of their treatment team, it was exceedingly difficult and unethical to do random allocation.
- d) The purpose of the study was to focus on feasibility testing the intervention nor to assess the effectiveness of the intervention. So, using a purposive sample with non-randomised techniques to select eligible participants from the population was more appropriate for the purpose of the study.
- e) It was impractical within this PhD study to do random allocation due time consuming, high cost and less convenience for the participants, HCPs, and the researcher within the limited resources.

### 7.2.4 Participants

Participants were recruited between 22 April 2017 and 23 June 2017 in accordance with the inclusion and exclusion criteria (below). Both sets of criteria were developed on the

basis of the most relevant evidence drawn from a review of the literature and the systematic review. Discussions with expert researchers and clinical professionals in the area of managing patients with ACS and T2D also were conducted, including two researchers in the field of cardiovascular diseases, specialist CCU nurses, a cardiologist and an internal medicine specialist.

#### Inclusion criteria

- Male and female patients.
- Aged 18 or older.
- Recruited from the coronary care unit (CCU) in a participating hospital.
- Having ACS (STEMI, NSTEMI and UA).
- Having a medical diagnosis of T2D.
- Having medical and psychiatric stability as judged by the treatment team in the hospital / CCU.
- Having the verbal and cognitive capacity to engage in the intervention.
- Being able to read and write in Arabic.
- Having a mobile phone or landline telephone during the study (phone access).
- Willing to consent.

#### Exclusion criteria

- Patients with terminal illnesses such as cancer, AIDS (Acquired Immune Deficiency Syndrome) and leukaemia.
- Patients with congestive heart failure, chronic obstructive pulmonary disease (COPD) or chronic pain.
- Patients with dementia or other significant cognitive impairment.
- Patients with serious visual or physical impairment.
- Patients who are transferred for open-heart surgery or to another hospital, or who will be discharged to home from the CCU after one day.

### 7.2.5 Recruitment

Potential participants were identified by the cardiologist, the internal medicine doctor or the senior cardiac nurse who were in charge of the CCU during the study period in the KAUH. All three have access to patients' records and direct contact with the patients themselves and therefore were able to examine a patient's medical history and assess whether or not someone with ACS admitted to the CCU met the inclusion criteria of the study. Both the inclusion and exclusion criteria were delivered to and discussed with them together with the protocol and procedure of the study in advance of recruitment. A brochure was displayed on the wall chart in the nurses' station in the CCU to remind the CCU medical team about the study whenever they registered a new case on the chart. Using an eligibility sheet (Appendix 16) to aid their assessment, any of the medical team who deemed a patient to be eligible to participate introduced the study to the patient verbally, providing a brief overview to assess their interest.

Once HCP had obtained initial verbal consent from potential participants, all interested patients were then referred to the primary researcher, who contacted them personally to provide more information about the study, to distribute the participant information sheet (Appendix 17), which provides additional details about participation, and a consent form (Appendix 18), and to answer any questions the patient had to their satisfaction. Once potential participants had sufficient time for reflection and discussion with their family if needed, a time was arranged with them to gain their informed consent in writing. It was emphasised that because they were volunteering to participate in the study, they were free to withdraw at any time without affecting their medical care and without having to provide any reason unless they chose to do so. Once the patient consented, they were given a brief, 10-15-minute outline of the DCSM Intervention prior to the first education session. The primary purpose of this engagement is to build a caring and therapeutic relationship with the patient and their family before starting the intervention, to explain its objectives and procedures, to encourage one of the patient's family members to attend the education sessions, to arrange a suitable time for the first education session and to provide the patient with the self-administration questionnaire and the booklet.

## 7.2.6 Data collection

Several data were collected during the study to assess the feasibility of intervention as well as to assess any improve on of participants in their knowledge, behaviour and clinical outcome, which related to the both conditions. All these data collected in this study were selected based on its linkage to the study theoretical framework and the expected outcomes which discussed in previous similar studies.

### 7.2.6.1 *Participant characteristics*

After receiving a participant's consent, all relevant information from their medical record (e.g. type of ACS) was collected with the assistance of the patient's treatment team. Other demographic data (e.g. age, marital status, work status, smoking status, level of physical activity, co-morbidities, etc.) were collected through a questionnaire (Appendix 19) at baseline (T1).

### 7.2.6.2 *Instruments*

All outcomes measures were assessed at two time-points. Pre-intervention (baseline) data was collected in hospital, directly after patients gave their consent (T1). Post-intervention data were collected at the hospital outpatient clinic 4-6 weeks after the patient was discharged from the hospital (T3). Although many of these scales are in the public domain, the permission to use these scales in the feasibility study were obtained directly via email from the responsible author(s). This survey has six components:

1. *Diabetes Knowledge Questionnaire (8-items) (DKQ)*. Developed to assess self-management knowledge of diabetes (Persell et al. 2004), this instrument has been used in various studies (Wu et al. 2009; Wu et al. 2012b) and has been shown to provide good validity and reliability (Persell et al. 2004).
2. *Diabetes Self-Management Questionnaire (DSMQ)*. Developed to assess self-care behaviours associated with glycaemic control, this (16-item instrument is reliable, valid and efficient. Based on theoretical considerations and the process of empirical improvement, it covers several aspects of self-management, including glucose management, dietary control, physical activity and health-care use (Schmitt et al. 2013).

3. *Patient Health Questionnaire (PHQ-9) Depression Module*. Often used to measure and monitor the severity of depression and response to treatment (Kroenke et al. 2001), this multipurpose instrument is valid, brief and useful in clinical practice. It can be quickly completed by the patient and scored by the clinician. Also, the instrument can be administered repeatedly, enabling it to capture improvement in or deterioration of depression in response to treatment. Moreover, it can be used as a case identification instrument for measuring the severity of depression in patients with CHD (Haddad et al. 2013).
4. *Acute Coronary Syndrome (ACS) Response Index*. This valid questionnaire was used to measure participants' knowledge, attitudes and beliefs regarding the symptoms of and responses to ACS. It is comprised of 33 items, of which 21 relate to knowledge (alpha 0.82), 5 relate to attitude and 7 relate to beliefs (alpha 0.76) (Riegel et al., 2007).
5. *Self-efficacy for Managing Chronic Disease (6-items) (SEMCD-6)*. Used to assess disease self-efficacy, this validated instrument covers several areas that are common to most long-term diseases: symptom control, emotional functioning, role function and communicating with physicians (Lorig et al. 2001).
6. *Morisky Medication-Taking Adherence Scale (4-items) (MMAS-4)*. The Morisky Scale was used to assess participants' adherence to their medication. It is a good self-reported measure of medication-taking behaviour and is widely used in different kinds of studies. Cronbach's alpha was 0.83 (Morisky et al. 1986).

#### **7.2.6.3 Clinical data**

Blood pressure, blood glucose and lipid levels were collected from the patient's profile at T1 and T3. The patient's body mass index. The body mass index also was collected at T1 to help characterise the sample.

#### **7.2.6.4 Lifestyle changes goals checklist**

Patients prioritised and selected their self-management goals either from a list of goals provided in the booklet or from the figure of target practice model in the logbook, which was used during the second education session to guide conversations with the patient about goal-setting and help them develop a personal action plan before being discharged.

Two weeks after discharge, during the follow-up phone call and at T3 (4-6 weeks), patients' progress in relation to their personal action recovery plan was assessed. Patients were asked simple questions designed to determine the extent to which they had implemented lifestyle changes and also to explore what was stopping them from achieving their goals and to help them plan small steps which would enable them to achieve their goals or build new goals. All notes about these questions were documented by the researcher on the intervention protocol form for each patient in preparation for analysis.

#### **7.2.6.5 *Acceptability and suitability***

The acceptability and suitability of the intervention were measured by assessing the results of a 17-item satisfaction evaluation form (Appendix 20), which was designed to evaluate the participant's views on the acceptability and suitability of various aspects of the DCSM Intervention. Participants were asked to rate the usefulness and clarity of the information provided, the assessment sessions and the phone calls and the quality of the teaching style. Participants also were given the opportunity to expand on any problem they had experienced with any element of the intervention.

This form includes 13 questions to be answered using a 5-point Likert scale (1 = Not At All; 2 = Somewhat; 3 = Moderately; 4 = Quite A Bit; 5 = Very Much), Of these, six concern the education sessions and four relate to the follow-up phone calls. Another two ask participants to rate the extent to which they found the program useful and enjoyable, and one concerns the quality of the facilitator. A further two simple questions ask participants whether they prefer attending education sessions or receiving phone calls. The form also encourages participants to give their feedback on the delivery and content of the intervention by responding to four open-ended questions about the education sessions, phone call, the facilitator and method of teaching, and how to improve the intervention.

An independent nursing researcher contacted all those participants who completed the intervention by phone at T3 and completed a form for each. All completed forms were returned to the researcher for analysis. Study adherence was monitored throughout the intervention procedure by documenting outcome measures at the assessment points, including the rate of response to the questionnaire, any assistance they received when filling out the questionnaire and the time required to complete it. The patient's rate of compliance with their weekly personal goals, building new goals and self-reporting of

self-care activities such as physical activity, and recording blood glucose levels were also documented to track the extent to which elements of the intervention were acceptable and appealing to study participants and compatible with their daily routine.

#### **7.2.6.6 Feasibility**

To evaluate the feasibility of the study, careful records and fieldnotes were kept throughout the test period. These focused on dealing with participants, providing the DCSM Intervention, collecting data and evaluating participants' responses to intervention measures. In relation to dealing with participants, several information was recorded such as:

- a) The evaluation of recruitment capability.
- b) The recruitment process and its challenges, including recruitment, refusal, retention and attrition rates.
- c) The process of recruiting participants' family members and its challenges.
- d) The characteristics of the participants.

In relation to the aspects of the DCSM Intervention, many data were recorded throughout the study, including such as:

- a) The length of time for each session.
- b) Challenges, procedures and the extent to which each of these aspects of intervention and the outcome measures were suitable, feasible and acceptable to participants.
- c) Other environmental and technical factors

Finally, preliminary evaluation of the participants' response to the measurement scales were also recorded. Further details about the feasibility data are available in Appendix 15.

#### **7.2.7 Strategies for improving recruitment and retention rates**

To improve recruitment and retention rates during the feasibility study, several strategies were introduced. These are informed by previous investigation findings and consultation with the study advisory group. They include:



1. Participants were recruited during the patients' stay in the CCU and immediately after their condition stabilised following the acute coronary event. According to the recommendations emerged from of Studies I and II, this is the optimal time and location for recruitment, and has been implemented successfully in similar studies, as evidenced by the findings from the systemic review (Tanash et al. 2017b) and in Eshah (2013), for example, who successfully recruited Jordanian patients with ACS in CCU and provided pre-discharge education session on ACS patients' lifestyles.
2. Because the CCU adopts a shift work system and to meet ethical regulation requirements and maximise recruitment rates, multiple recruitment approaches (e.g. brochure, word of mouth, phone contact) and recruiters were used in the study setting. As it has been recommended by many previous studies (Miyamoto et al. 2013; Befort et al. 2015; Young et al. 2015).
3. The recruiters were adequately informed and continually reminded about the feasibility study. This approach was adopted due to constraints in time of the patients' staying in hospital and the researcher considered that the HCPs had many commitments and care responsibilities that could lead them to forget to refer patients to the study.
4. Face-to-face meetings between the researcher and patients and their families helped to establish trust and a positive relationship between them and raise awareness patients about the study procedure, expected benefits, costs, risks and time commitment required.
5. Clear, simple, plain language was used to convey the research information and explain the meaning of consent to potential participants.
6. All the study materials were written and translated as appropriate for their intended audience and according to the guidelines discussed previously.

7. Assistance was available to help participants fill out the questionnaire and to provide additional information on request, if needed, while emphasising that all answers were from the patient's point of view.
8. The current healthcare procedures followed to treatment patients with ACS in Jordanian setting were carefully considered when intervention designed. For example, to minimise the burden on participants and the researcher the follow-up data were collected from patients during their follow-up visits to outpatient clinics, which typically took place 4-6 weeks after the patient's discharge from hospital. In addition, some of existing available data were utilized such as the clinical data from the participants' records.
9. The time at which sessions were provided in hospital was considered carefully to avoid clashes with the timing of routine treatment, meals and visiting hours and also to accommodate patient preference. The option of providing two sessions in a single day if the patient were able and willing also was considered to minimise the risk of the patient being discharged from the hospital early and missing one of the face-to-face sessions.
10. More than one telephone number was recorded for each patient, if available, to minimise the risk of losing contact with them after their discharge from hospital.
11. Text messages were used to remind patients about scheduled follow-up phone calls and outpatient clinic meetings.
12. Timely feedback and positive encouragement were provided during sessions to encourage patients to remain in the study.
13. Several other measures were taken to prevent participants from feeling overwhelmed or burdened by the study. These were discussed throughout Chapter 8.

## **7.2.8 Ethical considerations**

### **7.2.8.1 *Informed consent***

Those who took part in this phase of the study were volunteers and part of a captive population (i.e. patients who may be in the process of receiving care). Therefore, sufficient information about the study was provided to potential participants either verbally or in the form of a detailed written information sheet (Appendix 17). Potential participants were given sufficient time for reflection and discussion with their families before being asked to sign a consent form. They were informed that their participation was entirely voluntary and that they were free to choose to withdraw at any time before the data collection phase was complete without explanation, and without incurring any alteration in their care or any other penalty. Only those who were physically and mentally able to give informed consent were recruited.

### **7.2.8.2 *Confidentiality***

The confidentiality of all information through which participants could be identified (e.g. their name, phone number) was guaranteed. Towards this end, also when scheduling intervention sessions or collecting data, the patient's privacy and convenience were carefully considered.

All data collected, including patients' personal details and consent forms, were coded numerically, and the only link between the study identification number and participants' identifying information was stored in a highly secure cabinet and on a password-protected computer. Only the primary researcher had access to all the data, which was used only for the purposes of this study. Participants were informed about this process. Participants were informed that they had a right to refrain from answering any question, and that they would not be questioned about anything that might violate their privacy or beliefs.

All data were analysed on a secure drive and later stored in a secure, dedicated research room at Ulster University. All data collected in the course of this study will be destroyed, as per university policy, after ten years. All study findings will be disseminated and presented in related peer reviewed journals and conferences anonymously.

### **7.2.8.3 *Burdens and psychological distress***

In addition to the above the ethical considerations, consideration was given to any additional burdens, psychological distress or potential harm that could be caused to either the participants or the researcher. To mitigate the risk of such burdens, all education sessions were designed to last no more than 30 minutes, and their time and location were arranged at the convenience of the participant. The nurse or doctor with direct responsibility for the participant was informed before any in-hospital education session was provided, to confirm that the patient's condition was stable and that they were able to meet and to minimise any risk.

Any uncomfortable questions that might cause harm or upset for participants, such as those related to personal issues, were avoided. Furthermore, participants were informed before each session that they could choose to stop at any time and at any stage without penalty if they became fatigued or felt discomfort or distress, and that they could be referred to their healthcare providers for support.

The potential risks for the researcher during this study were minor. For example, the researcher was at some risk of hospital infection while providing the intervention. To minimize this risk, the CCU policy regarding standard precautions for infection control was considered and applied carefully. The primary researcher was familiar with these precautions due to his clinical experience and having conducted research on knowledge of and compliance with standard precautions for infection control among nurses in the same setting while studying for his Master's degree.

The researcher often worked alone, drove a car to reach the hospital or outpatient clinic and worked after hours and at different times (morning, evening and night). All these were identified as risk factors. To mitigate these risks, the researcher's adviser in the study setting was informed about his progress and any planned visits; the researcher also held a valid Jordanian driving license, complied with all national traffic laws and did not drive when feeling fatigued or in case of an emergency.

### **7.2.9 Summery**

The DCSM Intervention was designed according to the best available evidence and study's theoretical framework. The intervention consists of three in-hospital half-hour education sessions and one half-hour follow-up phone call two weeks after hospital discharge. Participants were followed up to 6 weeks. A mixed methods design was implemented to measure the primary and secondary outcomes of the feasibility study. In chapter eight, the findings of the feasibility study will be presented.

## **Chapter 8. Findings from the Feasibility Study (Study III)**

### **Introduction**

The main objectives of this study were to evaluate the feasibility and acceptability of a newly developed self-management intervention in the context of a Jordanian healthcare setting. In this chapter, the results of the feasibility study will be presented. The three main areas of feasibility that will be discussed are: participants, the Cardiac-Diabetes Self-Management (DCSM) Intervention and the preliminary evaluation of participants' responses to intervention measures.

### **8.1 Participants**

When considering the participants of the study, there are three main areas that must be examined: the recruitment and retention of participants to the study, and the characteristics of the study sample.

#### **8.1.1 Evaluation of recruitment capability**

##### ***8.1.1.1 The recruitment process and its challenges***

In the feasibility study of the DCSM Intervention, the recruitment target was 20 participants with acute coronary syndrome (ACS) and type 2 diabetes (T2D) within 6 weeks from a Coronary Care Unit (CCU) in the King Abdullah University Hospital (KAUH). However, during the period considered, the researcher enrolled and received consent from only 14 participants, and recruiting this number was challenging within this specific period. Subsequently, the period for enrolment was extended by three weeks to a total of nine weeks to achieve the target number of participants for this feasibility study (see Table 8-1). However, the eligibility criteria for participants were not changed at that stage because they were suitable and clear.

Initially, two senior members of the cardiac nursing and two clinicians in the KAUH were meant to contact the researcher when a potential patient was identified. However, it soon became apparent that ward staff were not remembering to contact the researcher when a potential patient was admitted. It is difficult to know why this was the case, but

perhaps that happened because they were busy with their work commitments and priorities related to patient care when suitable patients were admitted. Their shift work may have led them to forget ongoing studies, or the study might not have been a priority for them as they were volunteers and were not being paid to identify eligible patients for the study.

During the first few weeks of the feasibility study, the opportunity to refer a few potential participants to the study was lost because the ward staff did not refer them to the researcher. This was due to the ward staff not referring them to the researcher during the first 24 hours of their hospitalisation or stabilisation. This delay was often related to delay in the diagnosis process and receipt of results of some diagnostic tests such as the Troponin T test or uncertainty over whether the patient had diabetes; sometimes it related to the process of referring suitable patients to the researcher. For example, two of the potential participants were referred to the researcher shortly before they were discharged from hospital. Recruiting them was not possible as there was insufficient time to complete the consent process and to collect pre-intervention data and provide them the educational sessions. Diagnosis of another two potential participants was delayed due to the ward staff having other clinical priorities. These factors limited the rate of recruitment in the first three weeks of the feasibility study relative to the number of patients who were eligible to be recruited to the study, as can be seen in Table 8-1.

**Table 8-1: Participants recruited from 22 April to 23 June 2017**

Week	W1	W2	W3	W4	W5	W6	W7	W8	W9	Total
<b>Date</b>	22 - 28 Apr	29 Apr - 5 May	6 - 12 May	13 - 19 May	20 - 26 May	27 May - 2 Jun	Extended period			9 weeks
						3-9 Jun	10-16 Jun	17-23 Jun		
<b>Admit</b>	3	4	5	4	3	5	3	3	2	32
<b>Refer</b>	2	3	3	4	3	4	3	3	2	27
<b>CABG</b>	0	0	0	1	0	1	0	0	0	2
<b>Decline</b>	1	1	0	0	1	0	0	1	1	5
<b>Recruit</b>	1	2	3	3	2	3	3	2	1	20

**Notes:** W: Week; CABG: Coronary artery bypass grafting

In an attempt to improve the recruitment process and minimise the number of late referrals to the study, the researcher attended the KAUH daily to check the wards. Also from time to time, the researcher reminded the ward staff about the inclusion criteria of the study and the need to contact him as soon as possible when a suitable patient was identified, both by word-of-mouth and via a brochure which was placed on the wall chart of the nurses' office in the CCU.

During the period 23 April 2017 to 23 June 2017, 32 potential individuals were admitted to the KAUH with ACS and T2D, of whom 27 potential patients were referred and invited to participate in the study (see Table 8-1). Roughly two-thirds of these participants were admitted directly to the CCU of the KAUH through the emergency room of hospital; the others were transferred from another hospital within the same governorate (Irbid governorate) to the KAUH after having been diagnosed with one of the ACS categories based on the medical evaluation of their electrocardiogram (ECG) and cardiac biomarkers.

The probability of transferring patients with ACS from other hospitals to the KAUH had been anticipated before the feasibility study was conducted, as noted in previous chapter. However, the study found that two key issues impacted on the eligibility of participants who are transferred from other hospitals to the KAUH:

1. Many of the transferred patients were excluded from the study having been admitted to the KAUH as non-acute cases awaiting elective cardiac catheterization. In most cases, the transfer process for these patients had been delayed by several days, weeks or months in some cases after the actual cardiac event. Often such delays occurred as a result of circumstances related to the patient's health insurance, the patient's health condition, the unavailability of inpatient beds in the CCU of the KAUH at the time of their cardiac event, or poor staff coordination between the two hospitals.
2. In a few cases, the treatment plan for the participant who had given consent was changed shortly after their hospitalization when their condition became more critical. For example, the treatment plan for two participants who already had been transferred from another hospital and were recruited to the study before they underwent cardiac catheterisation changed to open-heart surgery after their catheterisation. Consequently, the number of those eligible to participate in the study was reduced when those participants were excluded from the study. The treatment plan for patients



with ACS is likely to change after catheterisation, which may affect their eligibility to continue in the study.

#### ***8.1.1.2 Recruitment, refusal, retention and attrition rates***

Of the 27 potential participants invited to participate in the study, 22 (81.5%) agreed to participate and were enrolled. This high rate of agreement could represent excellent acceptability for this self-management intervention within the sample population. However, two patients who previously agreed to take part in the study were excluded when their cardiologist decided they needed open-heart surgery. This left 20 patients who gave their consent and successfully completed the initial assessments within the first 36 hours of their admission during the pre-intervention assessment (T1). The final recruitment rate was estimated as 74.1%.

As can be seen in Table 8-2, the assessments were completed at two main points in time. During the first assessment (T1), pre-intervention data were collected in hospital and directly after patients gave their consent. Data were also collected post-intervention (T3), in the hospital outpatient clinic 4-6 weeks after the patient was discharged. Follow-up phone calls were made two weeks after the patient was discharged from hospital (T2), during which some data were collected about the participant's healthy lifestyle goals by asking participants to what extent they have met their goals.

In summary, 22 participants agreed to take part in the study, two of whom were subsequently excluded (open-heart surgery). Most participants (90%; n=18) completed both T1 and T2, and 85% (n=17) successfully completed the post-intervention assessment (T3). Thus, the study reported a high retention rate (85%).

**Table 8-2: Drop-out rate and stage of drop out**

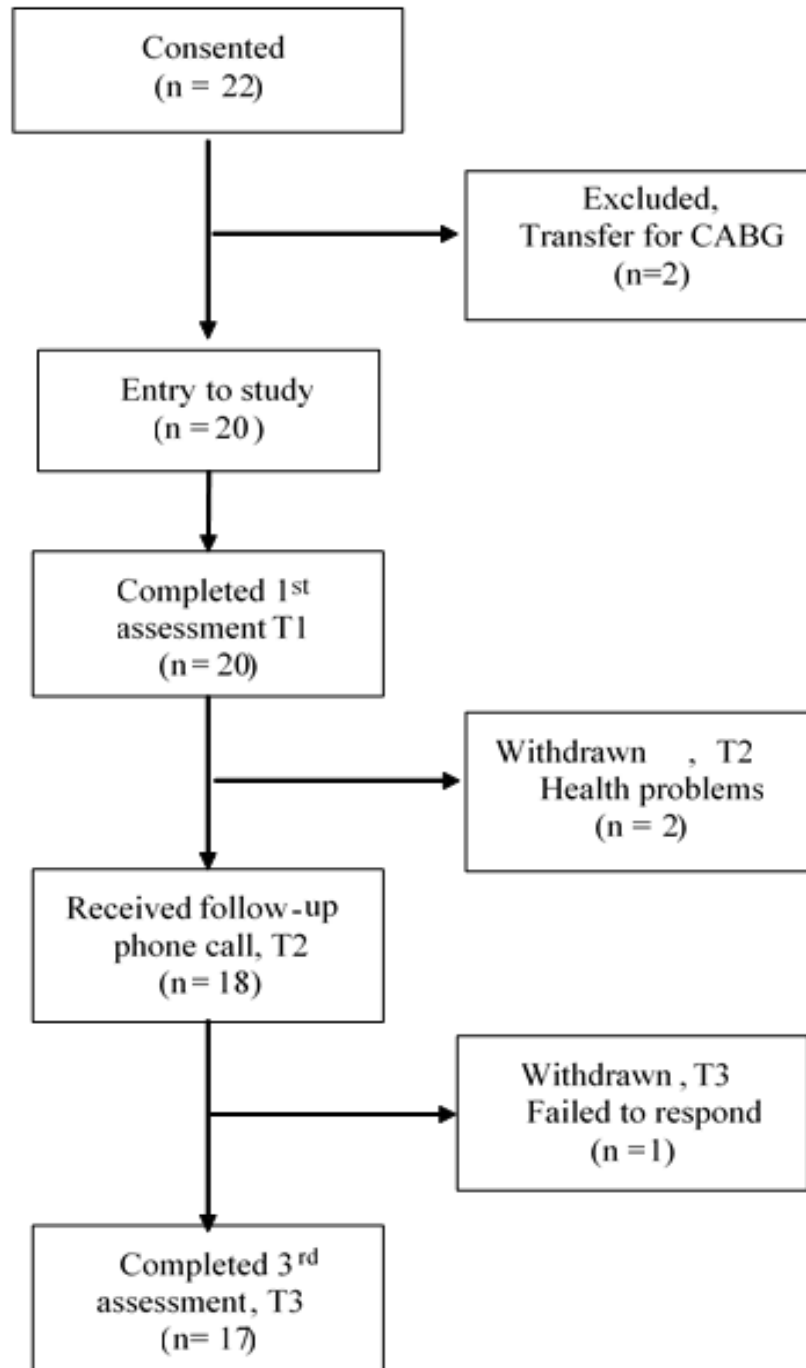
	Number of patients
<b>Identification</b>	27
<b>Declined</b>	5
<b>Accepted but excluded after they transferred to CABG</b>	2
<b>Consent received</b>	20
<b>Completed pre-intervention data (T1)</b>	20
<b>Completed 1st session F-F</b>	20
<b>Completed 2nd session F-F</b>	20
<b>Completed 3rd session F-F</b>	19 (17: F-F; 2: P.Call)
<b>Completed follow-up phone call (T2)</b>	18
<b>Completed intervention and post-intervention data (T3)</b>	17 (85%)
<b>Dropped out/Withdrawn</b>	3 (15%)

**CABG:** Coronary artery bypass grafting; **F-F:** Face-to-face; **P.Call:** Phone call; **T1:** 1<sup>st</sup> assessment; **T2:** 2<sup>nd</sup> assessment, 2 weeks after discharge; **T3:** final assessment, 4-6 weeks after discharge.

The researcher spent time with each potential patient and his/her family members within 36 hours of their admission at T1 explaining why they were selected and outlining the method and impact of the study. An information sheet for participants of the feasibility study (Appendix 17) was offered to each patient, who then was given some time to discuss their participation with their family. Upon reflection, and following discussion with their family, five patients decided not to proceed with the study, giving a refusal rate of 18.5%. Three of these stated that they were feeling discomfort and physical pain and they did not have the energy to receive educational sessions in hospital. One asked the researcher if he could participate later, but this was not possible due to the short length of time the patient had spent in hospital and the study objectives required that the feasibility of offering the educational sessions for patients with ACS during their hospitalisation be examined. Another one felt that he had sufficient knowledge about his condition and was not in the mood to talk about his illnesses or read the materials explaining the study.

With regard to the attrition rate, only three participants (15%) were lost before follow-up between T1 and T3 after their discharge from hospital. Of the three who withdrew, two did so before they completed the follow-up phone call due to further health

problems that led to a deterioration in their health and readmission to hospital, and one could not be contacted for a final assessment. as can be seen from Figure 8-1.



**Figure 8-1:Flow chart of participant inclusion process (Engagement with participants)**

**Note:** CABG: Coronary artery bypass grafting; T1: 1<sup>st</sup> assessment; T2: 2<sup>nd</sup> assessment, 2 weeks after discharge; T3: final assessment, 4-6 weeks after discharge

The study reported a small attrition rate (15%). Among the reasons for this are that the DCSM Intervention had been conducted and the main data collected within the structure of the hospital, the total time span of the study was short, the DCSM Intervention was well designed to be relevant to the target participants, the researcher was available to check the wards daily and flexible strategies were followed during the study to maximise retention. All these factors could increase the willingness of individuals to remain in the study.

### ***8.1.1.3 The process of retaining study participants***

The initial appointment for the follow-up call was arranged with each participant before they were discharged from hospital. However, in order to maximise retention, the researcher used a systematic method for scheduling appointments and maintaining contact with participants and monitoring cohort retention. The researcher used a monthly tablet calendar for scheduling appointments during the study. Multiple contact details for each participant were obtained before their discharge from hospital, including details for someone residing with the participant if available. The researcher provided reminders about scheduled appointments and other study-related activities to all participants. For example, one day before appointments, each participant received a reminder via a text message or phone call. In most cases, the final in-hospital educational session was offered on the last day of the participant's hospitalisation; therefore, at the end of each third session participants were reminded of their out-patient follow-up plan. Likewise, at the end of each follow-up phone call, the researcher double-checked the participant's out-clinic appointment/visit date, discussed with the participant when and where they were able to meet in the hospital out-clinic, then made a decision based on their preference.

Most patients with ACS experienced some physical and emotional difficulties during their hospitalisation, such as anxiety about their condition, pain or discomfort after their cardiac catheterization at the insertion site (where the catheter is put into the body) or due to having to lie flat and still for a prolonged period (approximately 4-8 hours). Such difficulties placed a burden on participants and limited the time available for educational sessions.

However, to minimise the burden on participants during the study, the researcher offered a range of appointment times for each of the three in-hospital educational sessions (i.e. early morning, noon, evenings) and when the participant's condition was stabilised. For example, the researcher found that providing an educational session early morning (around 8am) suited many participants and helped in avoiding busy times as there were no visitors, ward staff completed change shifts and the morning medicines round was done. In addition, a certain degree of flexibility was applied in scheduling the follow-up phone calls (morning, noon, evenings, weekends or working days, provided they were conducted within 2-3 days of the study target time) and the out-clinic visit (before or after the doctor's appointment). Moreover, the researcher showed empathy towards participants' personal situation when scheduling or cancelling appointments and always tried to involve them in deciding suitable times for appointments. To encourage them to attend the educational sessions appointments also, the researcher explained the potential benefits of participation to the participants' family members and he tried to keep them as up-to-date as possible about the educational sessions.

Eighteen participants successfully received follow-up telephone call 14 days after discharge (see Figure 8-1). Of these, seven participants (35%) postponed a scheduled call at least once to another time on either the same day or the next day. Often this was due to the patient being preoccupied when first called. While men were more flexible about when they were called, most women were preferred to schedule a phone call between 10 a.m. and 12 noon. However, at the beginning of each appointment, the researcher routinely asked the participant if it was a good time to talk or proceed with the educational session. This step was taken to show respect for the participant's willingness to take part in the study, to strengthen the researcher's relationship with them, to ensure they were comfortable during the appointment and to help them receive the information and give a positive reinforcement. Although the systematic and fixable strategy was used for participant contact, we found that their other factors must be considered before contacting participants, such as the patient's beliefs and culture in general.

None of the participants directly expressed concern about the timing of their appointments. However, some female participants seemed to be most comfortable with appointments scheduled at noon time. This may have been to avoid any conflict with their customs and beliefs, given that eastern women would not be comfortable receiving a phone call or visit from a foreign man in the evening. Similarly, another cultural issue was impacted on time of follow-up phone call session, some participants were recruited

to the study during Ramadan, one of the five fundamental pillars of Islam, during which the majority of Muslims worldwide observe an absolute fast from dawn to sunset consuming no food or drink and avoiding conjugal relationships and smoking (Chamsi-Pasha & Chamsi-Pasha 2016). Although ACS and other chronic illness patients are exempt from religious observation (Al-Munajjid 2010; Chamsi-Pasha et al. 2014; Al-Munajjid 2016) and this was explained to participants before discharge by their physician and the intervention provider, two participants insisted on fasting for a few days of Ramadan after their discharge from hospital. These individuals asked to postpone their follow-up phone call appointments until 2-3 hours after Iftar, the main meal during Ramadan, which takes place shortly after sunset. However, in order to maximise retention, some factors (e.g. culture and customs) must be considered carefully in the early stages of any future studies, such as using male and female researchers, understanding well the characteristics and culture of the target population, identifying the optimal timeframe for running the intervention and avoiding as much as possible any religious or cultural occasions.

#### ***8.1.1.4 The process of recruitment of participants' family members and its challenges***

When recruiting participants for the feasibility study, the researcher was keen to recruit one member of the patient's family to attend the educational sessions provided for participants in the hospital. As can be seen from Table 8-3, in the case of three participants, no family members were invited because the participant was unwilling to involve them, either because they were busy, as one participant explained, or because of other factors related to family dynamics, according to the other two participants. Respect for the participants' unwillingness to involve their families and a desire not to interfere in their personal lives were important at this early stage of the study, but at the same time this did reduce the number of individuals from the participants' families who could be invited.

Seventeen family members were identified and invited verbally, either by using word of mouth in hospital during the recruitment process (n=13), or through a phone call with them after receiving their contact details from the patient during T1 (n=4). They invited as volunteer/supporter to their patients with the right to not participate and withdraw at

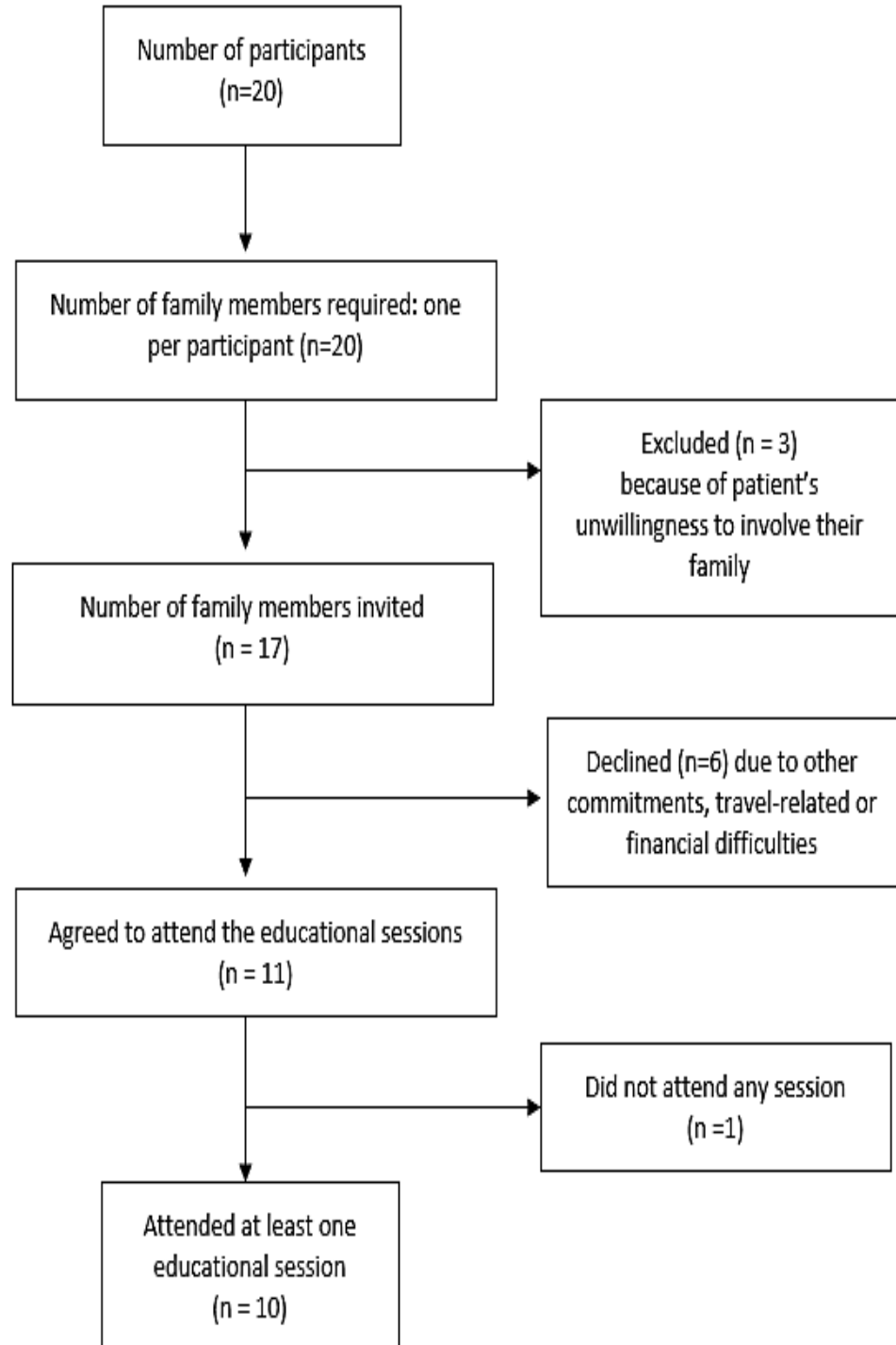
any time without penalty or impact care of their patients were considered and explained for them.

Also, the researcher explained to participants and their family members why they had been invited to the session and how their attendance might benefit the patient's health. Out of 17 family members invited, only 11 individuals agreed to attend the educational sessions, giving a response rate of 64.7%. Of these, eight were female (73%) and three were male (27%).

**Table 8-3: Characteristics of patient family members invited to educational sessions**

Characteristics	Number	Percent
<b>Invited:</b>	17	
<b>Form of invitation:</b>		
<b>Word-of-mouth in hospital</b>	13 (9 accepted)	76.5%
<b>Via phone call</b>	4 (2 accepted)	23.5%
<b>Agreed to attend:</b>	11	64.7%
<b>Gender</b>		
<b>Male</b>	3	27.3%
<b>Female</b>	8	72.7%
<b>Relationship to patient:</b>		
<b>Spouse</b>	5	45.5%
<b>Husband</b>	1	9.1%
<b>Wife</b>	4	36.4%
<b>Son</b>	2	18.2%
<b>Daughter</b>	3	27.3%
<b>Mix (different persons during sessions)</b>	1	9.1%
<b>Number of sessions attended:</b>		
<b>None</b>	1	9%
<b>1 or 2 sessions (partial attendance)</b>	9	82%
<b>3 sessions (complete attendance)</b>	1	9%

Six of the 17 family members who were invited to attend declined the invitation. Most of these appreciated the idea of attending, but nevertheless either gently refused or implied that they were unable to attend, often because of commitments at work or at home, or because daily travel to the hospital was physically or financially difficult. In addition, the daughter of one participant initially accepted the invitation but did not attend any sessions. Ultimately ten family members attended at least one educational session, as shown in Figure 8-2.



**Figure 8-2: Flow chart of family member inclusion process**

Although all those who accepted the invitation to attend expressed interest in and appreciation for the opportunity initially, the majority attended only one or two of the three sessions provided for participants; only one person attended all three sessions. Both recruiting and retaining family members of patients with ACS to attend three educational



sessions in the hospital environment were a big challenge, and need to be considered carefully in future studies. Providing some form of financial or non-financial incentive, such as a taxi fare or an inexpensive token of appreciation for attendees at each session could improve their recruitment and retention rate.

In addition to transportation difficulties and commitments at home, there are five key issues with regards to the feasibility of recruiting patients' family members and retaining them to attend every session:

1. The dates for the educational sessions were not fixed at the time participants were recruited, due to the unpredictable circumstances of patients in the CCU. For example, such patients sometimes developed unforeseen complications and often received unexpected visitors, given that most visitors were found to be non-compliant with hospital policy with regard to visiting times. Whatever the reason for doing so, however, rescheduling the appointment had a negative impact on attendance by the participant's family members.
2. Some patients were unwilling to involve a family member due to issues within the family.
3. Roughly half of enrolled family members were spouses, which may have contributed to the rate of attrition, given that, in the absence of their partners, they became more responsible for the family.
4. The structure of the feasibility study required that three educational sessions were provided within, on average, 2-3 days of the participant's cardiac event. This, plus the relatively short hospital stays of these patients, meant that the researcher had very little time in which to schedule appointments and had to seize the opportunity when the participant's condition allowed, even if this meant that the educational session was held without the participant's family member being present.
5. There was no clear, systematic or standard method to contact family members. Between 8 and 18 hours before each follow-up session, the researcher sent a reminder by text message to most of the recruited family members with the date and time of the next session. The best way to communicate with some individuals, by contrast, was through the patients themselves; this was especially true of younger patients.

However, the short notice provided about the time of next session might not have given them enough time to attend the sessions.

Thus, these factors may have decreased the willingness of family members to continue attending sessions, and significantly reduced their response and retention rates. Without new or additional arrangements for enrolling them, future researchers are likely to continue to have difficulty in enrolling and retaining them at an appropriate rate.

### **8.1.2 Characteristics of the study participants**

Examining the characteristics of the feasibility study sample is important for determining whether the intervention is relevant to the study participants (Orsmond & Cohn 2015). The inclusion criteria were adult patients, aged 18 or older, recruited from the coronary care unit (CCU) in participating hospitals; having ACS (STEMI, NSTEMI and UA); having a medical diagnosis of type 2 diabetes; having medical and psychiatric stability determined by the treatment team in hospital; having the verbal and cognitive capacity to engage in the intervention; being able to read and write in Arabic; and having a mobile phone or landline telephone during the study. Exclusion criteria were patients with terminal illnesses such as cancer, AIDS (Acquired Immune Deficiency Syndrome) and leukaemia; patients with congestive heart failure, chronic obstructive pulmonary disease (COPD) or chronic pain; patients with dementia or other significant cognitive impairment; patients with serious visual or physical impairment; patients who were transferred for open-heart surgery or to another hospital, or were discharged home from the CCU after one day.

As can be seen in Table 8-4, the participants recruited for this feasibility study were more likely to be male (65%), and the majority were diagnosed with a heart attack (80%, NSTEMI and STEMI). The mean age of all participants was  $58.65 \pm 7.51$  years; 65% of participants were less than 60 years old. Most participants were married (85%) and either retired or unemployed (70%). It seems most likely that the study's sample educated, as at least 65% of them had earned a college degree or higher and only two had a secondary school education or less. More than half earned a monthly income of less than 500 Jordanian Dinar (around 550 Pounds Sterling), meaning that the annual income for 55% of participants ( $n=11$ ) was less than the Gross National Income (GNI) in Jordan while the annual income of the remaining participants ( $n=9$ ) was roughly the same at the GNI in

Jordan. According to the World Bank Group (2016), the value of GNI per capita in Jordan was roughly £6,800.

**Table 8-4: Characteristics of study participants**

Category	Frequency	Overall %
<b>Gender</b>		
Male	13	65
Female	7	35
<b>Type of ACS</b>		
STEMI	8	40
NSTEMI	8	40
UA	4	20
<b>Age</b>	58.65 ± 7.51 years	
40-49	2	10
50-60	11	55
61 or older	7	35
<b>Material status</b>		
Married	17	85
Widowed	3	15
<b>Employment status</b>		
Working full time	3	15
Self-employed	2	10
Unemployed	3	15
Retired	11	55
<b>Smoking Status</b>		
Current smoker	8	40
Ex-smoker (for more than 6 months)	6	30
Never smoked	6	30
<b>Mean number of cigarettes</b>	29.37 ± 10.83 cigarettes	
<b>Level of education</b>		
Less than high / secondary school	2	10
High / secondary school	5	25
College, diploma or associate degree	7	35
Bachelor's degree or higher	6	30
<b>Monthly Income</b>		
Less than 500 JD (£530)	11	55
Between 500-1000 JD (£530-£1060)	9	45
<b>Physical Activity per week</b>		
Do not practice	14	70
Less than recommended (Moderate)	5	25
Moderate (moderately vigorous activity 30 min, 3-5 times per week)	0	0
More than recommended (Moderate)	1	5

<b>Healthy Diet / Foods</b>		
Not committed	15	75
Committed	5	25
<b>Mean Body Mass Index (BMI)</b>	$27.9 \pm 2.7 \text{ kg/m}^2$	
<b>Family History of Premature CVD</b>	15	75
<b>Medical History</b>		
DM	20	100
HTN	13	65
Dyslipidaemia	12	60
<b>Previous MI or UA</b>	9	45
<b>Diabetes History</b>		
0-3 years	3	15
4-7 years	8	40
8-15 years	6	30
More than 15 years	3	15
<b>Type of DM medication</b>		
Insulin	1	5
Tablets	13	65
Both	6	30
<b>Mean number of medications</b>	$7.1 \pm 1.93 \text{ medications}$	
<b>Participant in cardiac or diabetes program</b>	0	0

**Note:** CVD: Cardiovascular diseases; DM: Diabetes mellitus; JD: Jordanian Dinar (one JD equals 1.41 US Dollar); HTN: Hypertension.

The overall fitness of study participants was relatively poor. Tobacco smokers comprised 40% of the sample, consuming on average of  $29.37 \pm 10.83$  cigarettes per day. Many participants were overweight ( $n=13$ ) or obese ( $n=5$ ), and the mean body mass index (BMI) of all participants was  $27.9 \pm 2.7 \text{ kg/m}^2$ . Participants were prescribed a mean of  $7.1 \pm 1.93$  medications. Moreover, none of the participants reported engaging in the recommended level of physical activity (30 minutes of moderately vigorous activity, 3-5 times a week). Indeed, 70% rated their physical activity level as not doing any physical activities, 25% engaged in less than the recommended level and only 5% ( $n=1$ ) exceeded the recommended level. Over two-thirds of participants stated that they were not committed to a healthy diet/healthy food. Likewise, reported hypertension (65%), dyslipidaemia (60%), family history of premature cardiovascular diseases (CVD) (75%) and a previous diagnosis of ACS (45%) were prevalent in the sample. Although nine participants had experienced ACS prior to their admission to hospital and the vast majority had had T2D for four years or more, none of them had participated in a

rehabilitation or education programme related to either condition. Such a high prevalence of cardiovascular risk factors and poor level of fitness amongst the study participants and the lack of an education and rehabilitation programme clearly indicate their need for integrated self-management interventions such as the DCSM Intervention.

In summary, the eligibility criteria for participants in the feasibility study were sufficient and relevant to the target population and feasible for use in future studies. Recruitment and retention of participants after they experienced an ACS in the CCU was not found to be challenging, and the offer of 2-3 educational sessions during their hospitalisation was generally well received. These findings suggest that patients could be open to a hospital-based, integrated self-management intervention such as the CDSM Intervention and that achieving an appropriate recruitment and retention rate in a larger pilot or efficacy study was feasible. However, the level of difficulty in enrolling and retaining participant's family members to attend all three in-hospital educational sessions was surprising, and suggests that enrolling members of the participant's family to attend education sessions shortly after a cardiac event as part of a hospital-based education intervention may not be feasible. Without new or additional arrangements for enrolling them, such as holding follow-up educational sessions with patients and their families in the patient's home or adopting a new retention strategy such as those described above, it is likely to remain difficult to enrol and retain family members at an appropriate rate in future studies.

## **8.2 Diabetic-Cardiac Self-Management Intervention**

The second element of the feasibility study to be considered is that of the DCSM Intervention itself. It is important to assess the extent to which the intervention and outcome measures were suitable and acceptable to participants. The DCSM Intervention elements that were used in the feasibility study were described in detail previously in Chapter 7, but in brief, the intervention was mainly designed to improve participants' knowledge about their health condition and to enhance their self-efficacy. The intervention was delivered by the researcher, who is a specialised research nurse with experience in managing cardiac patients in the CCU and patients with diabetes. The elements of the DCSM Intervention that participants received are shown in Table 8-5.

**Table 8-5: The elements of the DCSM Intervention**

Element	Number	Mean time $\pm$ SD (minutes)	Range (minutes)
<b>ES1 (General Knowledge)</b>	20	28.2 $\pm$ 5	20-40
<b>ES2 (Lifestyle Changes)</b>	20	31.3 $\pm$ 4.7	22-40
<b>ES3 (Medication Adherence)</b>	19 (17 F-F, 2 P.Call)	21.9 $\pm$ 3	18-30
<b>Follow-up phone call (Reinforcement)</b>	18	21.4 $\pm$ 3.9	18-32
<b>Booklet and Logbook</b>	20	<b>(see attached materials with thesis)</b>	
<b>7-Day Tablet Sorter Box</b>	20	<b>(see Appendix 21)</b>	

**Note:** ES: Educational session; F-F: Face-to-face; P.Call: Phone call; SD: Standard deviation

Table 8-5 shows that 17 participants (85%) successfully completed three face-to-face educational sessions during their hospitalisation. All participants received the first two educational sessions of the intervention successfully during their hospitalisation. However, it was a challenge to offer the third session face-to-face for some participants. In the case of three participants, their short length of stay in hospital (less than 3 days) made it impossible to deliver the ES3 to them in hospital. However, the researcher did manage to cover the third session on medication adherence via a phone call with two of them within the first 3 days of their discharge from hospital. One participant, however, did not complete the third session because he had a pain and needed to relax as he mentioned, or could be other reasons led to this need to be considered (e.g. time of calling shortly after discharging or the mode of delivering the session).

Despite the unique, fast-paced and stressful environment of the CCU, providing the DCSM Intervention within that environment and in the hospital overall was applicable and simple to organise and carry out. When the feasibility study began, the researcher was keen to provide one educational session per a day for participants during their hospitalisation in order to minimise the burden on the participants. However, it soon become apparent that this was not possible in all cases due to the short time some patients spent in hospital. Therefore, in order to maximise the retention of participants and minimise as much as possible discrepancies between participants in relation to the number of sessions they received in hospital, the research team decided to be more flexible and test the possibility of offering two sessions in the same day whenever time and the

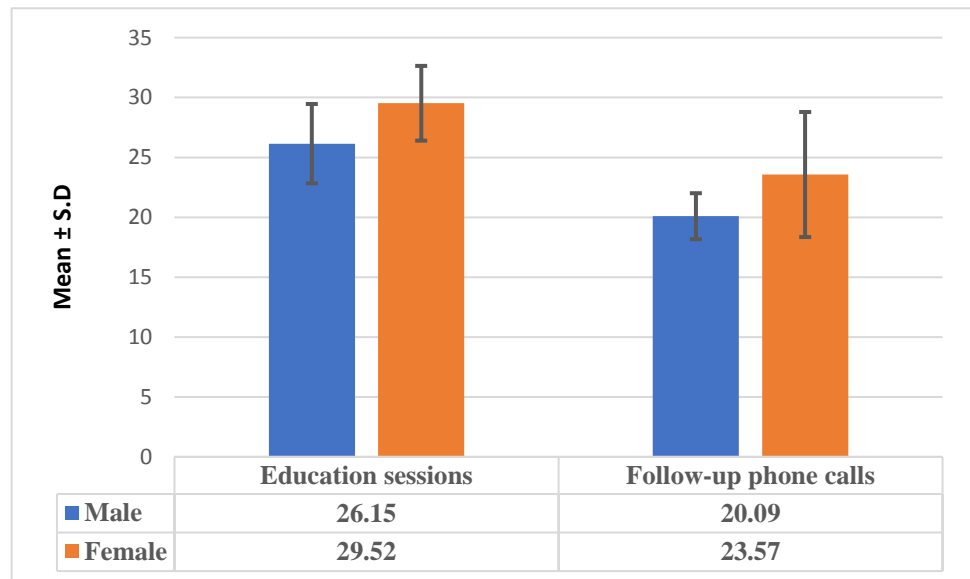
patient's capacity allowed, by providing one session in the morning and the other in the evening.

One-third of participants received the last two educational sessions on the same day, at two different times. The findings indicate that most participants had the time and the capacity to complete two educational sessions in the same day, provided the time interval between the two sessions was not less than 8 hours. None of the participants who received two sessions in the same day expressed any concern about this. Indeed, this strategy was found to be feasible and acceptable from the participants' perspective. It was also found to maximise retention, as 85% of participants successfully completed three sessions before their discharge from hospital. While this could be a useful strategy for any future efficacy studies, it is worth mentioning that it did place a considerable burden on the researcher by increasing his work commitments and the amount of time he was required to spend at the hospital. If more than one researcher/professional had been used, it might have been possible to reduce the burden on the intervention provider.

As can be seen in Table 8-5, the mean length of all three educational sessions provided for participants in hospital was  $27.33 \pm 3.56$  minutes. The mean length of each session was  $28.2 \pm 5$  minutes (ES1),  $31.3 \pm 4.7$  minutes (ES2) and  $21.9 \pm 3$  minutes (ES3). The mean length of the follow-up phone calls made to all participants was  $21.44 \pm 3.85$  minutes (range 18-32 minutes). The mean length of ES2, which concerned lifestyle changes, was relatively longer than the mean length of both ES1 and ES3 (concerning medication adherence), which had the shortest mean length ( $21.9 \pm 3$  minutes). The number of participants who received an educational session that lasted more than 30 minutes was 6 (ES1), 11 (ES2) and 1 (ES3). However, the length of most education sessions and follow-up phone calls fell within the average time allocated for each session in the DCSM Intervention guide (20-30 minutes).

Although the length of each appointment varied slightly from one participant to another depending on the characteristics of the participant and the type of appointment, both the mean length of all educational sessions and the mean length of all follow-up calls differed significantly by gender, as determined by a one-way ANOVA test ( $p$  value of  $<0.05$ ). There were no significant differences by any other demographic aspects. As can be clearly seen from the clustered bar chart in Figure 8-3, the mean length was higher for women than for men for both the educational sessions and the follow-up phone calls.

Overall, the vast majority of participants felt that they received a lot of useful information about their illnesses and about the development of self-management skills before their discharge from hospital. Only one felt that he had not received highly important input. Also, at the end of the intervention, the researcher asked all participants whether the length of the education sessions and phone calls had been comfortable, acceptable and reasonable. All agreed that this was the case. Moreover, they reported that they also enjoyed the sessions and they had been happy to be involved.



**Figure 8-3: Mean length of appointments by gender**

All participants received an information pack as part of ES1 from the researcher that included a booklet, a logbook and a medication box. They were encouraged to read and use these materials during all their appointments. No participants expressed any concern about this. They all appreciated these materials, which they found to be very clear, well designed, comprehensible and useful, helping them to develop their knowledge about both ACS and T2D and to manage their conditions.



### 8.2.1 The acceptability and suitability of the DCSM Intervention

The acceptability and suitability of the DCSM Intervention was assessed through participants' responses to the assessment form (Appendix 20) at T3 and other indicators of the participants' engagement in the study. All participants who completed the study were asked to respond frankly to the questions on the assessment form. An independent nursing researcher contacted all those participants by phone. As can be seen from Table 8-6, this form included 13 questions with a 5-item Likert scale, two simple preference testing questions and four open-ended questions about each main element. These questions were designed to measure the acceptability and suitability of elements of the intervention, the usefulness and clarity of the information provided and the quality of the teaching style and also to give participants the opportunity to expand on any related issues they felt had been problematic. Out of the 17 participants who completed the feasibility study, 16 successfully completed the intervention assessment form.

**Table 8-6: Response to the acceptability assessment form**

Element	Focus of questioning	Very much	Quite a bit	Somewhat	A little bit	Not at all
<b>Educational sessions</b>	Comfortability	8	8	0	0	0
	Understandable input	13	3	0	0	0
	Satisfaction with the style of teaching	10	6	0	0	0
	Effectiveness in enhancing your knowledge and improving your health	13	2	1	0	0
	Effectiveness in promoting your confidence and ability to control your conditions	10	4	2	0	0
<b>Follow-up phone calls</b>	Comfortability and convenience	8	6	2	0	0
	Effectiveness in enhancing your health-related knowledge	7	4	4	1	0
	Effectiveness in promoting your self-confidence to control your disease	3	7	6	0	0
	Effectiveness in promoting your psychological wellbeing	9	2	5	0	0
<b>Overall</b>	Useful	11	5	0	0	0
	Enjoyable	10	5	1	0	0

<b>Booklet and logbook</b>	Comprehensible and effective in developing your health-related knowledge	9	3	4	0	0
<b>Intervention Provider</b>	Quality and goodness	11	4	1	0	0

All the participants were very positive regarding the elements of the intervention and felt happy to participate. No one expressed any concern about participating or raised any issues regarding the safety of the intervention procedures or tasks. A clear majority of participants agreed that the intervention was acceptable, that they had received a lot of useful information and had had benefitted in several ways.

All participants were told to feel free to give their frank comments regarding each part of the intervention. Out of 16 who successfully completed the intervention assessment form, 14 participants made comments about the educational session. Of these, eight felt that they were useful and had increased their level of knowledge about their illnesses. For example, one male participant stated:

*[I]t was useful, and I feel happy to be involved [...] it was very helpful to me, I got a chance to correct a lot of misinformation about my previous condition [the patient had a DM for over 8 years] and I have learned how should I deal with my new condition probably after hospitalisation [...].*  
(Male, P4)

A further four participants reported that the sessions helped reduce the mental and emotional pressures they experienced after their cardiac event, such as anxiety, stress, uncomfortable feelings and worries. For example, one participant explained:

*[R]eally it was a great a great relief to find somebody to talk to about your concerns at that time, about your needs. At that time, I was very anxious and stressed [...], he helped me to relieve many of the emotional worries and stressors I had [...].* (Male, P19)

There was widespread agreement among participants that the approach of the intervention was satisfactory. For example, many stated that the educational sessions were “excellent” “good”, “useful” and “well organized” and that their length was “comfortable”. Some participants suggested that educational sessions should be provided regularly after their discharge from hospital. They expressed no reservations about where

these sessions were held (i.e. in the hospital, at their home or in a healthcare center) or the form of these sessions (i.e. one-to-one or a group session). Other participants suggested that incorporating visual materials such as videos and pictures into the sessions or sending regular reminders by text would motivate them to adhere to the treatment and increase their knowledge.

In relation to the follow-up phone calls, most participants felt that they were very useful, and they appreciated and were grateful for the phone call. None raised any issues about follow-up phone calls. Nine participants reported that they were willing to continue to receive calls from time to time, for example, once a month. Although all participants received reminders by text message on the day before their follow-up phone call appointments, two participants asked to be reminded via a phone call as they did not always read the text messages.

One of the main objectives of the follow-up phone calls was to reinforce the participants' self-confidence. Four participants reported that the follow-up phone calls helped to enhance their self-confidence. They expressed happiness at having a chance to frankly discuss their health condition with a trusted professional, which had helped to minimise their health-related difficulties and encouraged them to continue to manage their health condition.

*[I]t was good to talk with someone. I trusted him, he knows my condition and he tried to encourage me and support me. I really felt confident after the phone call to manage my cardiac condition and control my diabetes more [...]. (Female, P2)*

*[I]t was quite interesting to find someone who asked about me and about my health. I really appreciated that. I spoke to him freely regarding my concerns at that time and he guided and encouraged me well to achieve my goals [...]. (Female, P7)*

None of the participants expressed any concerns regarding the intervention provider, his gender or his style of communication. Most appreciated his efforts and expressed their admiration for his teaching style, which they described as “simple”, “clear”, “enjoyable” and “comfortable”, and his treatment of them, which they described as “respectful”, “polite”, “indulgent” and “kind”. This positive feedback suggests that the teach-back method applied in the DCSM Intervention was a clear, simple, suitable and acceptable

method for participants and feasible to be used in future studies, as shown by the following quote:

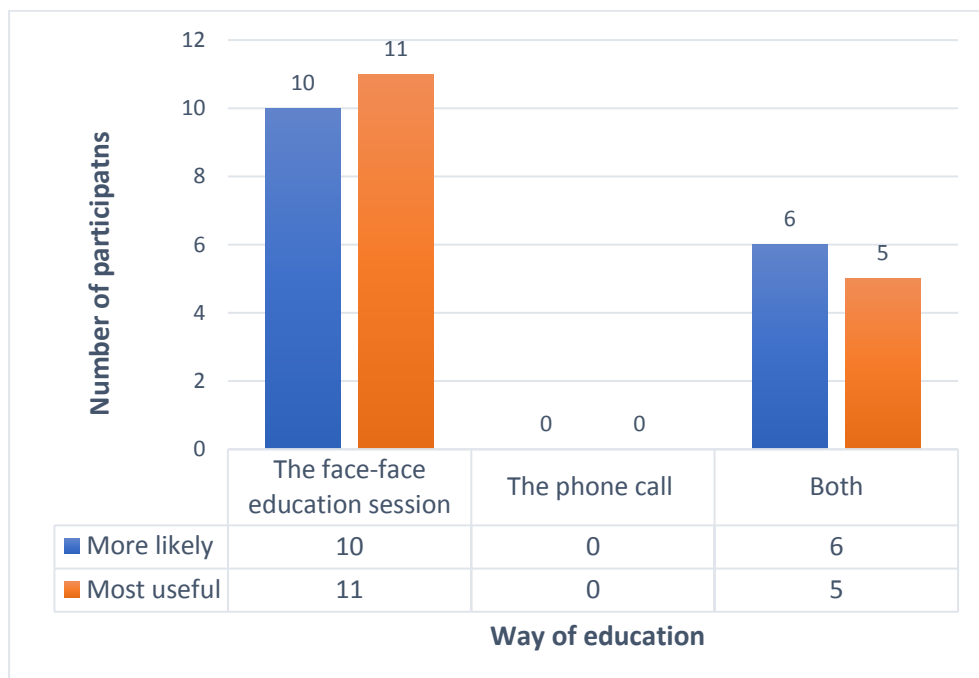
*He [the intervention provider] was brilliant. It was good to find someone who could listen to me and treat me well. I really felt much better and psychologically at ease after each talk with him and I believe that helping the patient to feel more comfortable which is the half of the remedy. (Male, P3)*

As can be seen from Table 8-6, the vast majority of participants felt that both the education sessions and the follow-up phone calls were “very much” or “quite a bit” comfortable, understandable, enhanced their knowledge about ACS and T2D and promoted their self-confidence to manage their condition after discharge from hospital. It was obvious that the degree of participants’ satisfaction with the educational sessions involved more than the follow-up phone calls, as indicated in the Table 8-6. However, if face-to-face and semi-structured educational sessions had been used after discharge, it might have been possible to increase participants’ level of knowledge, self-efficacy and satisfaction. If more follow-up phone calls had been provided, then participants’ satisfaction and the benefits of the session may also have increased.

Overall, roughly two-third of the participants felt that the DCSM Intervention was very enjoyable and useful; the rest felt that it was quite a bit enjoyable and useful. None felt that the DCSM Intervention was only a little bit or not useful or enjoyable. All participants were very positive regarding the written material, which they felt was comprehensible and useful in promoting their health knowledge. None expressed any concerns about it. Some participants stated that they had read the booklet more than once and that they browsed through it from time to time. All participants were asked to assess whether the intervention provider was good at providing the intervention. All participants agreed “very much” (69%), “quite a bit” (25%) or “somewhat” (6%) that he was good.

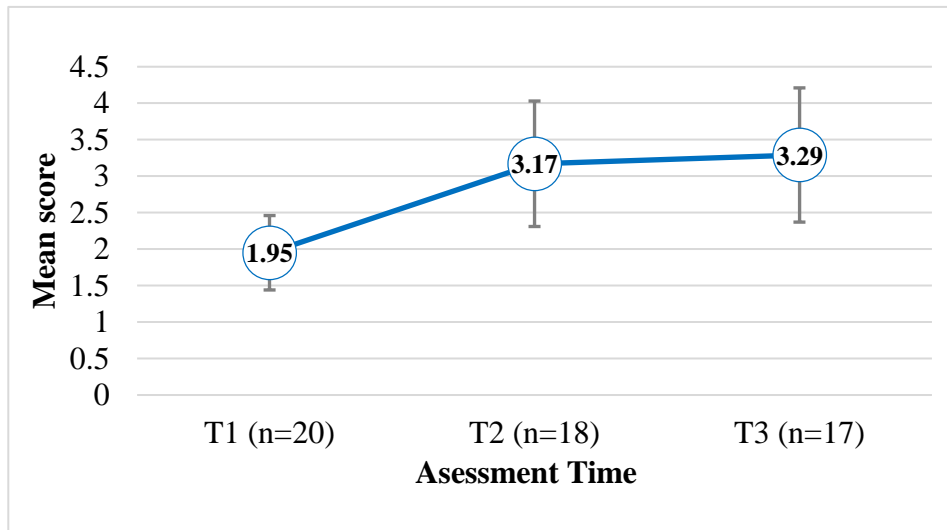
All participants were asked to choose which method of education they preferred and which they found most useful. As can be seen in Figure 8-4, for each method of education, there was a clear relationship between the number of participants who preferred that method and the number of participants who felt that way was most useful to them. An approximately equal number of participants felt that the face-to-face educational sessions were preferable and most useful. By contrast, no one preferred the phone calls as a method

of education alone or felt they were more useful than the face-to-face educational sessions; however, an approximately equal number of participants liked both methods of education and felt that both were useful. It was obvious from this chart that all participants preferred the face-to-face educational sessions and felt they were more useful than phone calls, although they had no reservations about using the phone calls in addition to or in support of the face-to-face educational sessions. In other words, all participants preferred the one-to-one sessions as the primary method of education in these self-management interventions.



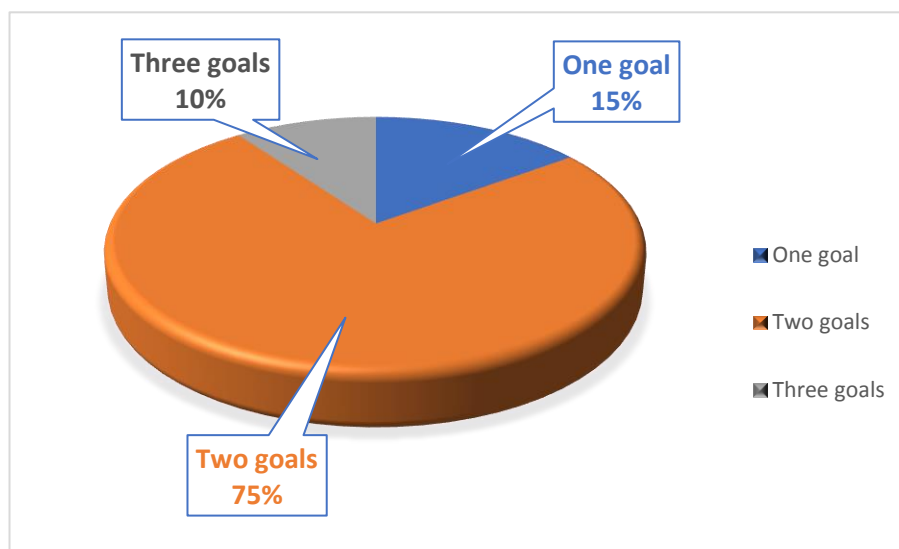
**Figure 8-4: Participant preferences for mode of delivering education**

In addition to a retention rate of 85%, participants were found to have engaged well in the activities/tasks of the DCMS Intervention after they were discharged from hospital. For example, most participants were adhering well to the healthy lifestyle change goals that were developed with them during ES2. The mean number of lifestyle change goals made by participants in hospital was  $1.95 \pm 0.51$  (range: 1–3 goals for each), and this average increased positively over the period of the study. As shown in Figure 8-5, the mean number of goals that participants were working on at T2 and T3 were  $3.17 \pm 0.86$  (range: 2-5 goals),  $3.29 \pm 0.92$  (range: 2-5 goals), respectively; both averages were greater than the mean number of goals at T1. This positive improvement may indicate that the intervention elements and tasks were acceptable and appealing to study participants and fit with their daily life activities.



**Figure 8-5: Number of lifestyle changes was selected by participants in hospital**

As can be seen in Figure 8-6, 85% of participants (n=17) selected two or more lifestyle change goals to discuss ES2 before their discharge from hospital. These findings suggest that it is feasible to teach participants how to develop a plan for lifestyle change and manage their chronic diseases before they are discharged from hospital, and that the DCSM Intervention procedure was suitable and acceptable for this purpose.



**Figure 8-6: Mean number of lifestyle change goals that selected by participants to be achieved during the study**

Table 8-7 shows a degree of variation in the lifestyle change topics/goals selected and prioritised for discussion by participants during ES2 from a list of topics related to the self-management of chronic diseases (as shown in Log-Book). Also, their willingness to change and to develop a new goal increased over time. Of the eight participants who smoked, all prioritised the goal of “stopping or reducing smoking” at T1. Two weeks after their discharge from hospital (T2), five participants had stopped smoking completely and three had reduced the number of cigarettes they smoked considerably. At T3, three of those who had quit were still not smoking and reported that the strategies they had learned during the DCSM Intervention were effective. Two of them had found it difficult to stay off cigarettes and therefore had changed his goal to reduce the number he smoked significantly. Another one participant did not complete the final assessment (T3). Two participants who had reduced the number of cigarettes they smoked considerably at T1 and T2 had maintained this goal at T3. Only one had resumed smoking.

**Table 8-7: Progress towards lifestyle change goals selected by participants**

Goals	T1 (n=20) Participants ranking of selected goals in order of importance as of ES2				T2 (n=18)	T3 (n=17)
	1 <sup>st</sup> goal	2 <sup>nd</sup> goal	3 <sup>rd</sup> goal	Total		
	<b>Stopping or reducing smoking</b>	8	0	0	8	8
<b>Planning and doing regular exercise</b>	4	7	1	12	9	11
<b>Eating a balanced diet</b>	5	5	0	10	12	11
<b>Checking and controlling blood sugar level</b>	3	4	2	9	10	13
<b>Adhering to medication regimen</b>	0	1	0	1	18	16

Only one participant selected medication adherence as a topic to be discussed during ES2. However, after receiving education about the importance of medication adherence and receiving tablet sorter boxes during ES3, all participants (100%) at T2 and 94% of them at T3 identified adherence to their medication as one of their goals for managing their chronic diseases.

Overall, participants’ positive feedback reflected their satisfaction with the DCSM Intervention elements and the intervention approach taken in teaching and motivating

them. Their positive response also indicates that the DCSM Intervention approach was acceptable and appealing to most participants, and that the information and activities provided were clear, useful and appropriate for the participants needs and did not place an intolerable burden on them.


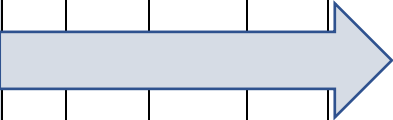
### **8.3 Preliminary evaluation of participants' responses to intervention measures**

As previously noted, many researchers contend that evaluating the outcomes of feasibility studies is inappropriate and only possible in a large pilot or efficacy study (Billingham et al. 2013). They argue that evaluation is inconsistent the objectives of feasibility studies, whose small sample size means they have low statistical power, increasing the probability of misrepresentative significance testing, thereby leading to Type I and II errors (i.e. false positive results and false negative results, respectively). However, some argue that the researchers must still conduct a preliminary evaluation of the participants' response to the intervention to determine whether proceeding with the intervention is advisable and promising (Orsmond & Cohn 2015). Although this study sample was small (n=20) for doing a significant testing, many scholars, for example, have recommended that 12 participants per group are acceptable in the studies where the friability testing, the precision about the mean and variance and regulatory considerations are the rationale for doing it (Julious 2005).

Therefore, to assess whether the DCSM Intervention shows promise for patients with ACS and T2D, the researcher examined scores on pre- and post-intervention testing measures in the DCSM Intervention study and reviewed qualitative feedback from participants. Data from these outcome measures were collected during the two main assessments (T1 and T3), as shown in Table 8-8. Six validated measures were utilised and various clinical data was collected (i.e. random blood glucose, blood pressure and lipid profiles). Lipid profiles produce four results: total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides.



**Table 8-8: The DCSM Intervention outline**

		W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12	W13	W14	W15					
		22-28 Apr	29 Apr- 5 May	6-12 May	13-19 May	20-26 May	27 May – 2 Jun	3-9 Jun	10-16 Jun	17-23 Jun	24-30 Jun	1-7 Jul	8-14 Jul	15-21 Jul	22-28 Jul	29 Jul-4 Aug					
First Assessment ( T1 )		<ul style="list-style-type: none"> <li>❖ <b>3 one-to-one educational sessions in hospital (20-30 mins each)</b></li> <li>❖ <b>Consent form</b></li> <li>❖ <b>Pre-intervention Data:</b></li> <li>❖ <b>Questionnaire:</b> <ol style="list-style-type: none"> <li>1. Demographic data (15 items)</li> <li>2. Diabetes knowledge Q (8 items)</li> <li>3. Diabetes self-management Q (16 items)</li> <li>4. Patient health Q – depression model (9 items)</li> <li>5. ACS Response Index Q (knowledge, attitude, beliefs) (33 items)</li> <li>6. Self-efficacy for managing chronic disease (6 items)</li> <li>7. Morisky medication adherence Q (4 items)</li> </ol> </li> <li>❖ <b>Clinical data</b> (BMI, average of blood glucose test, BP and lipid profile levels).</li> </ul>																			
	T2				<ul style="list-style-type: none"> <li>✓ Follow-up phone call after 2 weeks (20-30 mins)</li> <li>✓ 2 weeks – questions re. lifestyle change goals</li> </ul>																
Third Assessment ( T3 )						<ul style="list-style-type: none"> <li>✓ Post-discharge data (4-6 weeks after patient’s discharge)</li> <li>❖ <b>Questionnaire:</b> <ol style="list-style-type: none"> <li>1. Diabetes knowledge Q (8 items)</li> <li>2. Diabetes self-management Q (16 items)</li> <li>3. Patient health Q – depression model (9 items)</li> <li>4. ACS Response Index Q (knowledge, attitude, beliefs) (33 items)</li> <li>5. Self-efficacy for managing chronic disease (6 items)</li> <li>6. Morisky medication adherence Q (4 items)</li> </ol> </li> <li>❖ <b>Clinical data</b> (average of blood glucose test, BP and lipid profile levels)</li> <li>❖ <b>6 weeks – questions re. lifestyle change goals.</b></li> <li>❖ <b>Intervention evaluation form</b> (collected by another researcher)</li> </ul>															

### 8.3.1 Data management

Data was managed and analysed statistically using the Statistical Package for the Social Sciences (SPSS) for Windows, Version 24. Data were coded numerically and entered into the SPSS dataset. The researcher then double-checked all entered data for verification purposes. A further data check was conducted by running frequency distributions of all variables to detect missing, outlying and invalid values. As the data entry and verification were both conducted by the researcher, any inconsistency in data entry was minimised. After checking the data, the score, mean, range and category of data were computed for each scale and subscale as appropriate. Because the distribution of data is one of main factors that influence the selection of statistical testing methods (McCrum-Dardner, 2008), the distribution of the data from each measure was examined for abnormalities before testing began.

To check if the data were normally distributed, i.e. bell-shaped and symmetrical about the mean, the distribution of interval-scale data for this sample was examined using numerical methods such as the Shapiro-Wilk test of normality ( $p > 0.05$ ) and Skewness and Kurtosis, and graphical methods such as Histograms and Normal Q-Q Plots. Next, statistical evidence was gathered to determine whether the mean difference between paired assessments (at baseline (T1) and after participating in the DCSM Intervention (T3)) was significantly different from zero. A Paired Samples t-test for continuous data that were normally distributed was then run, together with a nonparametric Wilcoxon Signed-Ranks test for continuous data that were not normally distributed. Statistical significance was based on p value of 0.05 or less.

### **8.3.2 Preliminarily evaluation of participants' clinical outcome**

All clinical data for the feasibility study were collected from hospital records. The ward staff were the only individuals with access to participants' files. Therefore, all clinical data involved in the feasibility study was taken from hospital records under ward staff supervision while maintaining all those conditions on which ethical approval for the study was granted. Baseline data was collected based on the readings from blood samples taken on the first morning of the participants' hospitalization and before they received the DCSM Intervention. Readings of blood sugar and lipid profile levels at T3 were collected from hospital records of blood samples taken one day before the participants first visited their physician; these samples were drawn in the morning and after an overnight fast. Post blood pressure levels were taken when participants visited their physician clinic, which is part of a hospital's outpatient department, 4-6 weeks after their discharge from hospital.

All clinical data at T3 were collected successfully by the researcher for those who completed the study (n=17). However, a lipid profile was not conducted for 7 of the 17 participants. This was due to non-attendance by those participants before their appointment with their physician. Thus, the blood sugar levels of those patients were measured using a clinical kit available at the physician clinic, but their lipids were reported as missing data. Therefore, to minimise missing data and inconsistencies in the data, future studies may need to recommend a commercial kit to measure participants' clinical data such as plasma glucose, HbA1c, plasma insulin and lipids.

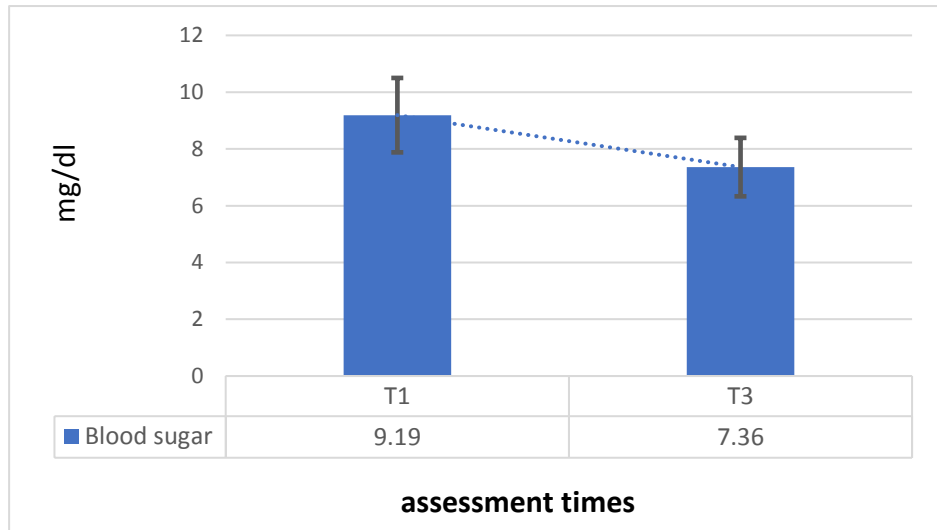
All clinical data were normally distributed, as the value of the Shapiro-Wilk test was greater than  $p=0.05$  for all data, the histogram of all data was approximately symmetrical or moderately skewed, and a normal Q-Q plot was indicated for all data. A Paired t-test therefore was used to compare paired means of clinical data and assess if there were any significant changes.

As can be seen in Table 8-9, there was a significant average difference between the pre-and post-intervention scores for each of blood sugar level, total cholesterol level and triglycerides level. No significant average differences were found between pre- and post-intervention scores for each of systolic and diastolic BP, HDL or LDL.

**Table 8-9: Pre-/post-intervention comparison of clinical data after receiving the DCSM Intervention for 6 weeks**

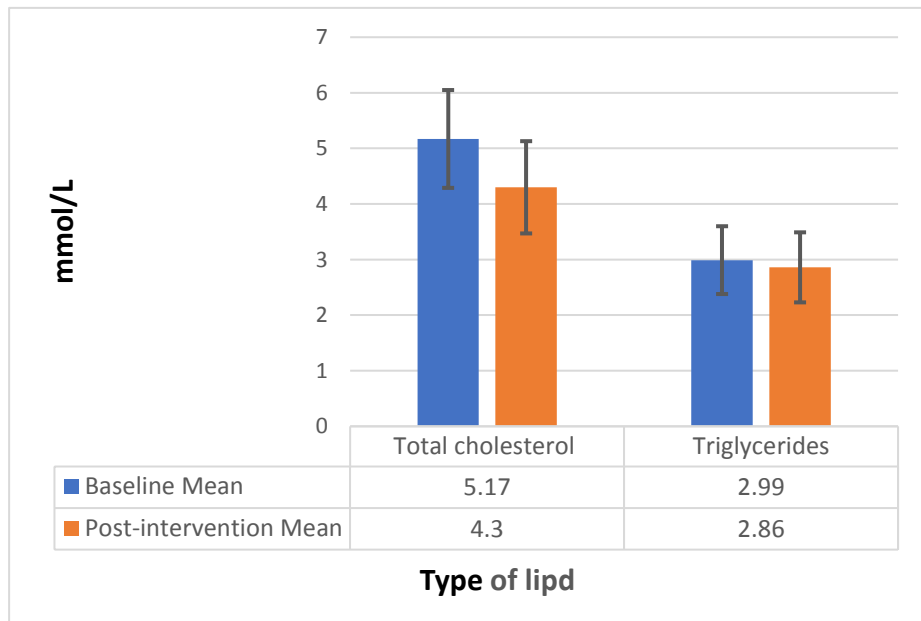
	Baseline data (T1)				Post-intervention data (T3)				sig
	N	Mean $\pm$ SD	Min	Max	N	Mean $\pm$ SD	Min	Max	
<b>Blood sugar</b>	20	9.19 $\pm$ 1.31	6.18	11.3	17	7.36 $\pm$ 1.03	5.9	9.5	0.00*
<b>Systolic BP</b>	20	144 $\pm$ 15.05	121	190	17	136.53 $\pm$ 12.45	110	160	0.102
<b>Diastolic BP</b>	20	87 $\pm$ 7.73	71	100	17	86.76 $\pm$ 4.16	80	83	0.724
<b>Total cholesterol</b>	20	5.17 $\pm$ 0.88	3.9	6.95	10	4.3 $\pm$ 0.61	3.3	5.1	0.001*
<b>HDL</b>	20	0.79 $\pm$ 0.19	0.55	1.2	10	0.83 $\pm$ 0.1	0.7	1	0.371
<b>LDL</b>	20	3.69 $\pm$ 0.79	2.5	5.65	10	3.1 $\pm$ 0.48	2.5	4	0.081
<b>Triglycerides</b>	20	2.99 $\pm$ 0.83	1.7	5	10	2.86 $\pm$ 0.63	2.1	3.9	0.027*

Table 8-9 shows significant improvements in mean fasting glucose levels of participants ( $t_{16} = 6.362$ ;  $p = 0.001$ ), which dropped significantly from baseline ( $9.19 \pm 1.31$  mmol/dl) to 4-6 weeks ( $7.36 \pm 1.03$  mmol/dl). The vast majority of participants reported that they had poorly controlled diabetes and a weekly average glucose level that would be considered uncontrolled (fasting blood sugar  $> 7.8$  mmol/L) at baseline. As all participants were encouraged before discharged from the hospital to record their blood sugar levels in the logbooks that had been offered to them and they had learned about how to compute their weekly average, about half of those who received a follow-up phone calls after two weeks of discharging ( $n=8$ ) reported that their average weekly glucose reduced by more than 20%. At 4-6 weeks (T3), around two-thirds had reduced their average weekly glucose levels by more than 20% (see Figure 8-7).



**Figure 8-7: Pre-/post-intervention comparison of glucose mean after receiving the DCSM Intervention for 6 weeks**

Figure 8-8 shows that the mean total cholesterol ( $t_9 = 4.611$ ;  $p = 0.001$ ) and triglycerides ( $t_9 = 2.647$ ;  $p = 0.027$ ) changed significantly over time.



**Figure 8-8: Pre-/post-intervention comparison of significant lipid mean changes after receiving the DCSM Intervention for 6 weeks**

The prevalence of the cardiovascular comorbidities among those in the study sample was high. All participants had T2D, 60% had hypertension and 65% had dyslipidaemia; for this reason, it was important to explore changes in clinical outcomes. Although this feasibility study was a short-term study with only a small sample size, the DCSM Intervention appeared to be especially effective in helping participants manage their illnesses and their cardiovascular comorbidities because the mean fasting glucose, total cholesterol and triglycerides levels dropped significantly for most participants from T1 to T3.

### **8.3.3 Preliminarily evaluation of participants' response to scales**

The mean time required for all participants to complete the questionnaire in T1 was 24.55 ± 2.79 minutes, ranging between 20 to 30 minutes, which was longer than was expected before the study. Where the survey was tested in the prior face validity study which conducted with two patients with both conditions and indicated that the 92-item questionnaire could be completed in 15-20 minutes.

The questionnaire was fully completed by 20 participants during the initial assessment (T1) and by 17 participants during the third assessment (T3). However, six participants (30%) expressed some difficulty understanding how to answer some items on the questionnaire. Most difficulties were reported in relation to the scale of Self-efficacy for Managing Chronic disease 6-items (Lorig et al. 2001). To use this scale, the respondent must consider the extent to which they feel confident about managing their symptoms and disease on 10 subscales for each item. However, this issue was resolved as soon as the participants received some clarification from the researcher about the process of answering questions.

In the third assessment (T3, 4-6 weeks after discharge) the average time taken to complete all items was reduced to approximately 15 minutes by excluding 15 items of demographic data, thereby reducing the total number of items to 77. The speed of completion may also have been due to the increasing familiarity of participants with the questionnaire format. Participants had no major difficulty completing the questionnaire in a timely manner and returned completed questionnaires with very little missing data.

However, due to the physical or emotional challenges of the patient's condition within the first 36 hours of a cardiac event, as noted above (Section 8.1.1.3), it is worth

mentioning that some participants needed assistance to complete the questionnaire at T1. Only nine (45%) participants were capable of completing the questionnaire by themselves. Other participants either needed supervision to complete the questionnaire or benefited from having the questions read aloud to them. For example, seven (35%) participants received help to fill in the questionnaire from a family member; another four (20%) participants got help from the researcher himself. In all cases, however, the researcher explicitly stated, both verbally and in the cover page of the questionnaire, that all answers should be given from the point of view of the patient and not that of the person who is helping them.

However, using a t-test (p value of  $<0.05$ ), the mean time spent completing the questionnaire was tested to determine if there were any significant variations between groups of related demographic variables, such as ACS type, gender, level of education, employment status and how the questionnaire was completed. The mean time spent completing the questionnaire by all participants during the two assessments was not significantly different between groups of demographic variables, as determined by the one-way ANOVA test.

The choice of outcome measures and the rationale for choosing them was described in the previous chapter. This section will outline the results obtained at T1 and T3 and compare the frequencies and mean scores of the pre- and post-intervention data in relation to the following six outcome measures:

1. Diabetes Knowledge Questions (DKQ)
2. Diabetes Self-Management Questionnaire (DSMQ)
3. Patient health questionnaire (PHQ-9) depression module
4. Acute Coronary Syndrome (ACS)-Response index
5. Self-efficacy for managing chronic disease 6-items (SEMCD-6)
6. Morisky medication-taking adherence scale (MMAS)

Seventeen participants completed all the above instruments at T1 and T3. The nonparametric Wilcoxon Signed-Ranks test was used to compare the pre- and post-intervention means for all instruments. This was due to the integration of the small sample size with the presence of the non-normality distribution of some items as it rather were highly skewed to the right or left.

### 8.3.3.1 Diabetes Knowledge Questions (DKQ)

Diabetes knowledge was measured by using the validated instrument, the DKQ. The frequency with which correct responses were given to these questions increased after respondents received the DCSM Intervention. As Table 8-10 indicates, the mean score on the 8-items knowledge scale for all participants increased 1.65 points at T3.

**Table 8-10: Overall outcome measures**

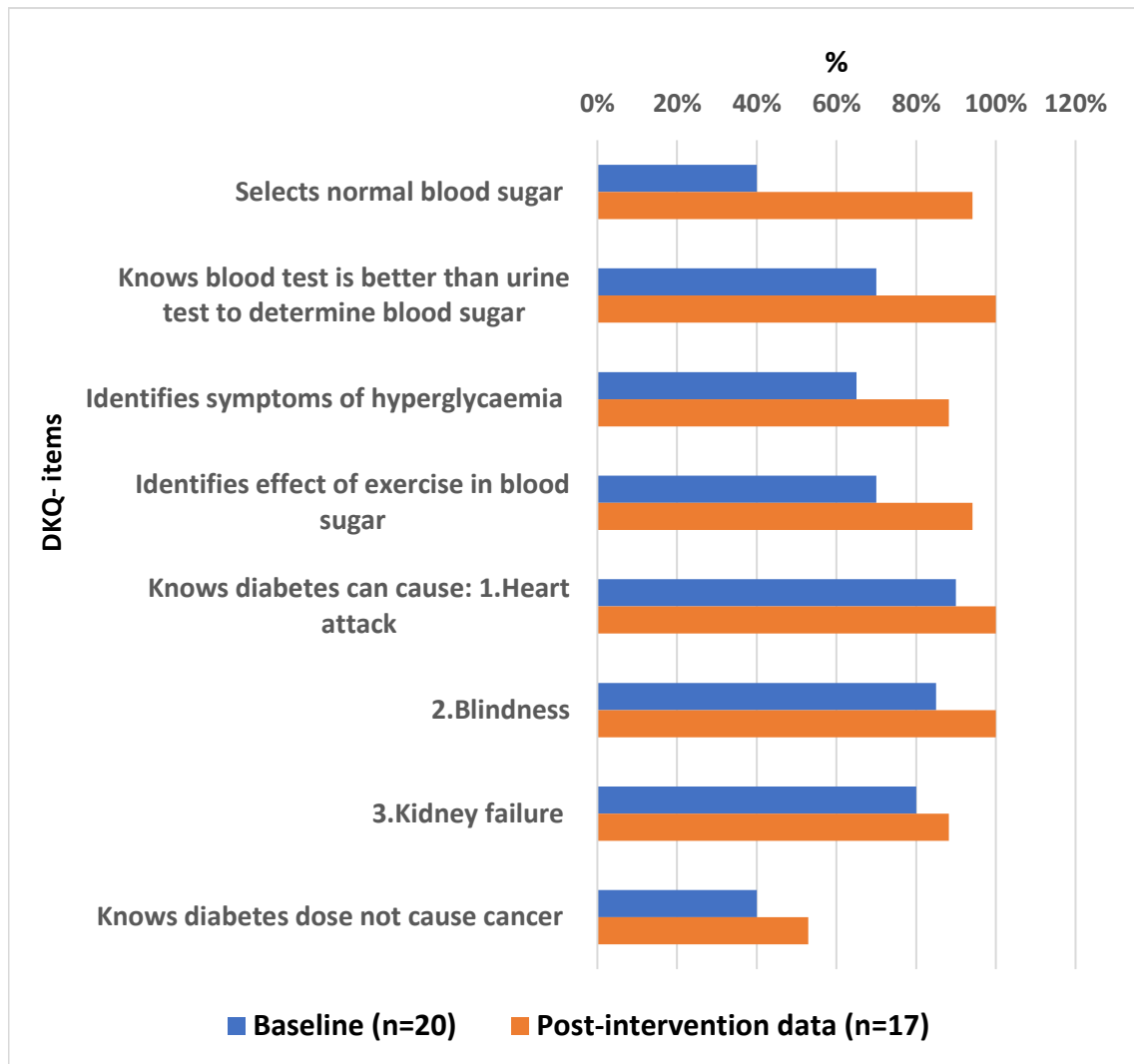
<u>Measures</u>		Scale range	Baseline T1 (SD)	Post-Intervention Data T3 (SD)	Change	Significance
<b>Diabetes Knowledge Questions (DKQ)</b>		0-8	5.65 (2.11)	7.3 (0.8)	+1.65	sg
<b>Diabetes Self-Management Questionnaire (DSMQ), (Sum Scale)</b>		0-10	4.06 (1.76)	7.62 (0.9)	+3.56	sg
<b>Subscales (DSMQ)</b>	Glucose management (GM)	0-10	3.84 (2.24)	7.92 (1.35)	+4.08	sg
	Dietary control (DC)	0-10	3.63 (2.32)	7.11 (1)	+3.48	sg
	Physical activity (PA)	0-10	3.27 (3.27)	6.67 (2.04)	+3.4	sg
	Health-care use (HCU)	0-10	6.08 (2.08)	8.63 (1.92)	+2.55	sg
<b>Patient health questionnaire (PHQ-9) depression</b>		0-27	11.71 (4.48)	8.06 (1.9)	-3.65	sg
<b><u>The Acute Coronary Syndrome (ACS)-Response index:</u></b>						
<b>1. ACS-Knowledge</b>		0-21	12.65 (2.03)	17.12 (2.61)	+4.47	sg
<b>2. ACS-Attitude (Sum Scale)</b>		5-20	9.53 (3.62)	16.94 (1.34)	+7.41	sg
<b>Subscales ACS-</b>	ACS-Attitude re. symptoms recognition	3-12	6.18 (2.53)	10.18 (1.88)	+4	sg
	ACS-Attitude re. help-seeking	2-8	3.35 (1.54)	6.76 (1)	+3.41	sg
<b>3. ACS-Beliefs (Sum Scale)</b>		7-28	20.12 (2.85)	25.12 (1.83)	+5	sg
<b>Subscales ACS-Beliefs</b>	ACS-Beliefs re. expectations	4-16	11.76 (1.95)	15 (1.32)	+3.24	sg
	ACS-Beliefs re. action	3-12	8 (1.7)	10.12 (1.17)	+2.12	sg



<b>Self-efficacy for managing chronic disease 6-items (SEMCD)</b>	6-60	28 (9.11)	39.82 (4.2)	+11.82	sg
<b>Morisky medication-taking adherence scale (MMAS)</b>	0-4	2.47 (1.33)	0.47 (0.51)	-2	sg

All participants appeared to understand all the questions and to answer them fully. However, occasionally it was necessary to reinforce that “don’t know” was a valid answer and to recommend that participants select this answer if they were unsure. This was clarified through both the verbal and written instructions given to participants prior to completing the questionnaire. A number of participants were found to choose “don’t know” as their answer to some questions, and the frequency ratio for this answer reached 30% of participants in response to one question at T1. Therefore, it is recommended to include this in verbal and written instructions prior to completing to the questionnaire in future studies, as some participants may feel they must choose an answer even when they were not sure.

At T1, most participants knew that diabetes could cause coronary heart disease, blindness or renal diseases (90%, 85% and 80%, respectively), but only 40% knew diabetes could not cause cancer. Only 40% correctly identified normal blood sugar, 65% correctly identified the symptoms of hyperglycaemia, and 70% identified the effect of exercise on blood sugar. The frequency of correct responses to the pre- and post-intervention knowledge questions is depicted in Figure 8-9.



**Figure 8-9: Frequency of correct responses to diabetes knowledge questions**

### 8.3.3.2 *Diabetes Self-Management Questionnaire (DSMQ)*

The DSMQ consists of 16 items covering different aspects of diabetes self-management. In addition to a ‘Sum Scale’ (SS) score based on all 16 items that measures the patient’s overall capacity for self-care, scores were calculated for four subscales: ‘Glucose Management’ (GM) (5 items), ‘Dietary Control’ (DC) (4 items), ‘Physical Activity’ (PA) (3 items) and ‘Health-Care Use’ (HU) (3 items). Participants rated the extent to which each answer applied to them using a 4-point Likert scale from 0 (“does not apply to me”) to 3 (“applies to me very much”). Items scores were summed and transferred to scores ranging from 0 to 10 for each of SS and the 4 subscales. A high score on the DSMQ scales represents more desirable self-management behaviour. Table 8-10 shows that the mean

scores of the pre- and post-intervention test for the DSMQ sum scale and the four subscales all improved following the DCSM Intervention. The mean score of the DSMQ sum scale increased 3.56 points at T3. The mean score for the GM, DC, PA and HU subscales increased at T3 by 4.08, 3.48, 3.4, 2.55 points at T3, respectively.

Table 8-11 provides an overview of the 16 questions of the DSMQ and shows the increase in the overall scores for each question. The responses provided by participants after receiving the DCSM Intervention reflect their better understanding of self-management and the proper use of healthcare facilities, as evidenced by the increase in value from the pre- to the post-intervention scores. However, there is room for improvement also on some subscales, such as dietary control and physical activities.

Question 16 asks participants to select the response that most describes them in relation to the statement, “My diabetes self-care is poor”. At T1, only 15% of participants (n=3) chose the response, “Does not apply to me”, whereas 53% of participants gave this response at T3. Thus, like the subjective information that participants provided following the DCSM Intervention, their answers to the DSMQ indicate that they had a better grasp of their diabetes diagnosis and how to manage the disease.

The DSMQ was completed with only one answer missing at T1 (Question 6). However, because the DSMQ includes 7 items that are formulated positively and 9 that are inversely formulated, some participants reported that some items were repeated, only in reverse (i.e. negatively worded). For example, Question 3 assessed the participant’s adherence to appointments with healthcare professionals, while Question 7 assessed the participant’s avoidance of appointments with healthcare professionals. As a consequence, during the initial assessment, some participants found the questionnaire (DSMQ) tiresome or tricky, especially those who were more educated, who felt that they were answering the same questions twice.

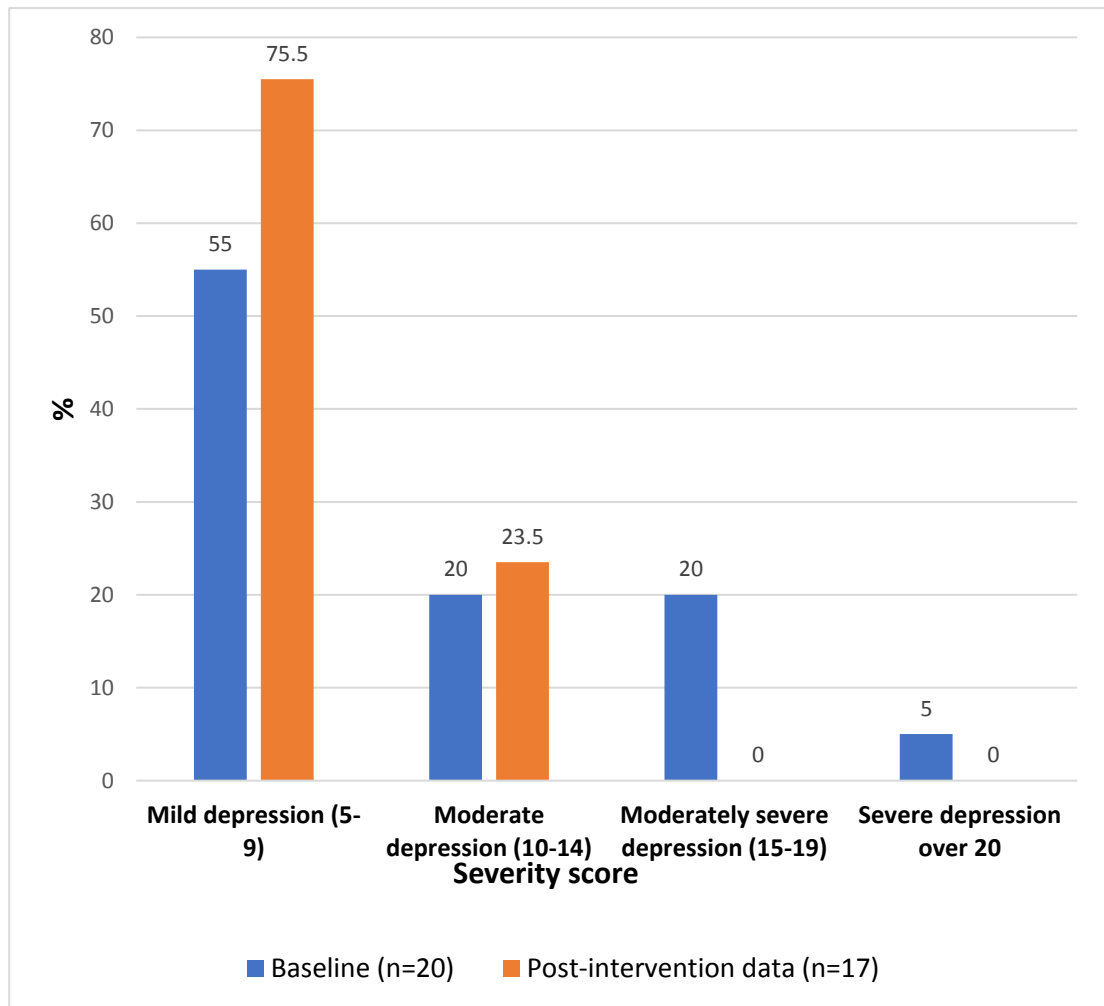
**Table 8-11: Response to the Diabetes Self-Management Questionnaire items**

Subscale	Items	Item	Time	Applies very much	Applies to a considerable degree	Applies to some degree	Does not apply
Glucose management	1	<b>Check blood sugar levels with care and attention</b>	T1	1 (5%)	7 (35%)	4 (20%)	8 (40%)
			T3	7 (41.2%)	9 (52.9%)	1 (5.9%)	0 (0%)
	4	<b>Take diabetes medication as prescribed</b>	T1	6 (30%)	5 (25%)	4 (20%)	5 (25%)
			T3	12 (70%)	5 (29.4%)	0 (0%)	0 (0%)
	6*	<b>Record blood sugar levels regularly</b>	T1	2 (10%)	1 (5%)	1(5%)	15 (75%)
			T3	3 (17.6%)	10 (58.8%)	4 (23.5%)	0 (0%)
	10	<b>Do not check blood sugar levels frequently enough</b>	T1	4 (20%)	9 (45%)	3 (15%)	4 (20%)
			T3	0 (0%)	3 (17.6%)	8 (47.1%)	6 (35.3%)
	12	<b>Forget to take / skip diabetes medication</b>	T1	5 (25%)	9 (45%)	2 (10%)	4 (20%)
			T3	0 (0%)	1 (5.9%)	3 (17.6%)	13 (76.5%)
Dietary control	2	<b>Choose food to easily achieve optimal blood sugar</b>	T1	5 (25%)	5 (25%)	3 (15%)	7 (35%)
			T3	11 (64.7%)	6 (35.3%)	0 (0%)	0 (0%)
	5	<b>Occasionally eat lots of sweets / high-carb foods</b>	T1	3 (15%)	12 (60%)	2 (10%)	3 (15%)
			T3	0 (0%)	4 (23.5%)	7 (41.2%)	6 (35.3%)
	9	<b>Follow specialist's dietary recommendations</b>	T1	4 (20%)	1(5%)	3 (15%)	12 (60%)
			T3	7 (41.2%)	10 (58.8%)	0 (0%)	0 (0%)
13	<b>Sometimes have real 'food binges'</b>	T1	11 (55%)	7 (35%)	1(5%)	1 (5%)	
		T3	1 (5.9%)	10 (58.8%)	5 (29.4%)	1 (5.9%)	
Physical activity	8	<b>Do physical activity to achieve optimal sugar levels</b>	T1	3 (15%)	0 (0%)	2 (10%)	15 (75%)
			T3	3 (17.6%)	10 (58.8%)	3 (17.6%)	1 (5.9%)
	11	<b>Avoid physical activity, although good for diabetes</b>	T1	7 (35%)	8 (45%)	3 (15%)	2 (10%)
			T3	2 (11.8%)	1 (5.9%)	8 (47.1.8%)	6 (35.3%)
15	<b>Skip planned physical activity</b>	T1	6 (30%)	7 (35%)	3 (15%)	4 (20%)	
		T3	2 (11.8%)	2 (11.8%)	10 (58.8%)	3 (17.6%)	
Health-care use	3	<b>Keep recommended doctors' appointments</b>	T1	3(15%)	8 (40%)	7 (35%)	2 (10%)
			T3	9 (52.9%)	8 (47.1%)	0 (0%)	0 (0%)
	7	<b>Avoid diabetes-related doctors' appointments</b>	T1	2 (10%)	9 (45%)	3 (15%)	6 (30%)
			T3	1 (5.9%)	1 (5.9%)	2 (11.8%)	13 (76.5%)
14	<b>Should see medical practitioner(s) more often</b>	T1	2 (10%)	3 (15%)	6 (30%)	9 (45%)	
		T3	0 (0%)	2 (11.8%)	7 (41.2%)	8 (47.1%)	
16	<b>Diabetes self-care is poor</b>	T1	10 (50%)	7 (35%)	0 (0%)	3 (15%)	
		T3	1 (5.9)	2 (11.8%)	5 (29.4%)	9 (52.9%)	

### ***8.3.3.3 The patient health questionnaire (PHQ-9) depression module***

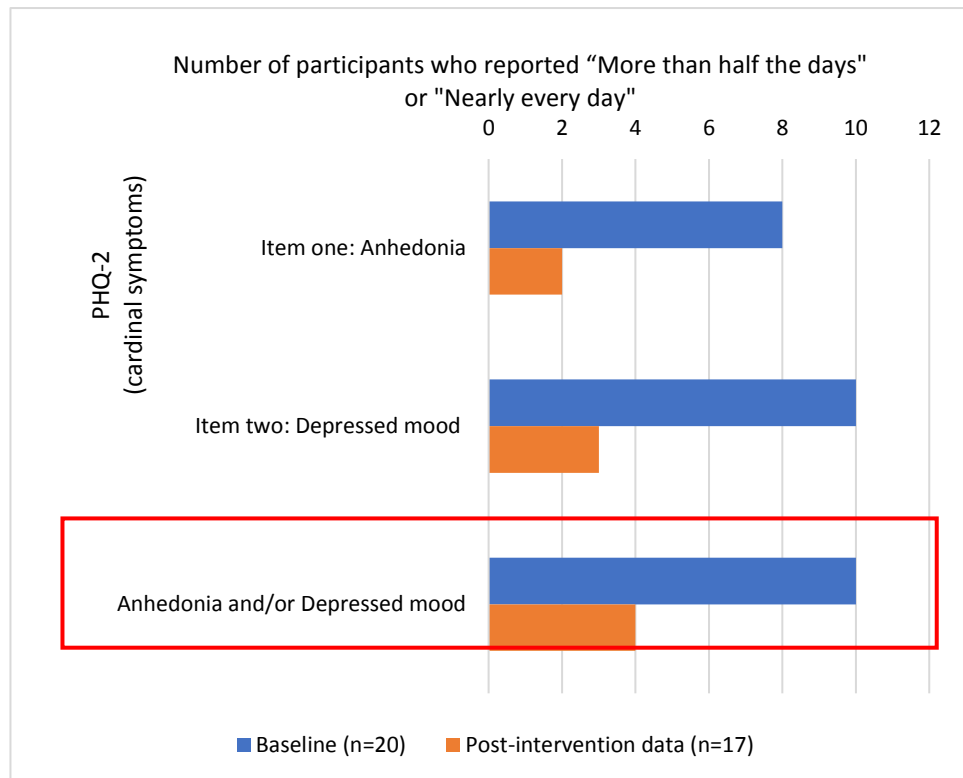
The PHQ-9 is a self-rating instrument for depression. Participants were asked to rate how often each of nine symptoms occurred in the past two weeks from 0 to 3, where 0 indicates “not at all”, 1 “several days”, 2 “more than half the days” and 3 “nearly every day”. The PHQ-9 was administered without difficulty to all participants and was answered fully at both T1 and T3. The PHQ-9 has been used in this study only to monitor the severity of depression and response to the DCSM Intervention. The total scores computed based on the sum of the 9 item scores, with a potential range of 0-27. The mean PHQ-9 score was  $11.71 \pm 4.48$  at T1 and  $8.06 \pm 1.9$  at T3. The positive change between the two assessments was -3.65 (see Table 8-10).

All participants who completed the form during both assessments selected “Not at all” in response to the question about suicidal ideation. As shown in Figure 8-10, participants were generally more depressed at baseline and in many cases their scores decreased over the period from T1 to T3. At T1, over half of participants (n=11) had mild depression or minimal symptoms of depression, while three-quarters of participants (n=13) had mild levels of depression at T3. However, it is important to note that nine participants (45%) presented with scores greater than nine at T1, while only 4 (23.5%) did so at T3. This level of depression would be treated as clinically significant. At T1, 20% of participants (n=4) had moderately severe levels, and 5% (n=1) had severe levels of depression. Of these five participants, three had reduced their score to moderate levels and two scored less than nine at T3. In addition, one participant developed significant depression over the course of the study, reporting “moderate depression levels” at T3. However, no participants had moderately severe or severe levels of depression at T3.



**Figure 8-10: Change in depression score**

However, it is important to note that of the 20 participants who completed the PHQ-9 at T1, only ten (50%) reported experiencing at least one cardinal symptom of anhedonia or depressed mood on more than half the days in the preceding two weeks, while at T3, only 23.5% of participants (n= 4 of 17) reported experiencing at least one cardinal symptom (see Figure 8-11). Thus, half the participants at T1 and over three-quarters of participants at T3 did not achieve a positive value (more than half the days in the preceding fortnight) for at least one of the first two cardinal symptoms (PHQ-2) of the PHQ-9, and therefore were ineligible to complete either the full PHQ-9 to future studies that use the PHQ-9 to screen for depression or make a tentative diagnosis.



**Figure 8-11: Frequency of responses to cardinal symptoms**

#### **8.3.3.4 Acute Coronary Syndrome (ACS)-Response index**

The ACS Response Index measures three key factors, namely knowledge, attitudes and beliefs about ACS. Overall, the ACS Response Index took the longest time to complete, but was the more interesting part of the assessment for participants as it directly related to their cardiac event during the study. All items were understandable and answered fully without difficulty.

##### **Knowledge subscale of ACS response index**

The mean score on the knowledge scale (range 0 to 21) was  $12.65 \pm 2.03$  (60.2%  $\pm$  9.7%) at T1 and  $17.12 \pm 2.62$  (81.5%  $\pm$  12.5%) at T3. The positive change in mean scale between the two timepoints was 4.47 (21.28%). Using a score of 70% (14.7 out of 21) or higher on the knowledge scale as a cut-off point, 20% (4 of 20 participants) at T1 and 70.6% (12 of 17 participants) at T3 were identified as having a higher level of knowledge about ACS symptoms.

As shown in Table 8-12, exploring the participants' knowledge of individual symptoms revealed that at T1, all participants associated chest pain/pressure/tightness and chest discomfort with symptoms of a heart attack. This was followed by shortness of

breath/difficulty breathing (95%), sweating (85%) and arm/shoulder pain (85%). There was a very high incidence of failure to recognize some of the less common symptoms, such as back pain (35%), dizziness and light-headedness (40%), jaw pain (25%), nausea and vomiting (45%), neck pain (45%) and heartburn/indigestion/stomach problems (35%). The inclusion of distracter symptoms led a significant number of participants to incorrectly identify lower abdominal pain (75%), arm paralysis (75%), headache (30%), numbness/tingling in arm or hand (80%) and slurred speech (70%) as heart attack symptoms.

**Table 8-12: Correct responses regarding ACS symptoms**

<b>Symptom</b>	<b>The correct answer</b>	<b>T1 (out of 20) N (%)</b>	<b>T3 (out of 17) N (%)</b>
Lower abdominal pain	No	14 (70)	15 (88.2)
Arm pain/shoulder pain	Yes	17 (85)	17 (100)
Arm paralysis	No	5 (25)	10 (58.8)
Back pain	Yes	7 (35)	13 (76.5)
Chest pain/pressure/tightness	Yes	20 (100)	17 (100)
Chest discomfort	Yes	20 (100)	17 (100)
Cough	No	13 (65)	13 (76.5)
Dizziness, light-headedness	Yes	8 (40)	14 (82.4)
Headache	No	14 (70)	14 (82.4)
Heartburn/indigestion/stomach problems	Yes	7 (35)	10 (58.8)
Jaw pain	Yes	5 (25)	11 (64.7)
Loss of consciousness/fainting	Yes	12 (60)	16 (94.1)
Nausea/vomiting	Yes	9 (45)	13 (76.5)
Neck pain	Yes	9 (45)	10 (58.8)
Numbness/tingling in arm or hand	No	4 (20)	13 (76.5)
Pale, ashen, loss of colour	Yes	14 (70)	15 (88.2)
Palpitations/rapid heart rate	Yes	14 (70)	17 (100)
Shortness of breath/difficulty breathing	Yes	19 (95)	17 (100)
Slurred speech	No	6 (30)	13 (76.5)
Sweating	Yes	17 (85)	16 (94.1)
Weakness/fatigue	Yes	13 (65)	16 (94.1)



By T3, all participants associated arm pain/shoulder pain, chest pain/pressure/tightness, chest discomfort, palpitations/rapid heart rate and shortness of breath/difficulty breathing with symptoms of a heart attack. The frequency of correct responses for other heart attack symptoms also improved significantly, while a smaller number of participants incorrectly identified distractor symptoms as heart attack symptoms. These findings indicate that the level of knowledge about ACS symptoms among most participants improved after they received the DCSM Intervention.

### **Attitude subscale of ACS response index**

As shown in Table 8-10, the mean score on the attitude scale was  $9.53 \pm 3.62$  at T1 and  $16.94 \pm 1.34$  at T3 (range 5–20). The positive change between the two assessments was +7.41 in the overall mean scores, +4 in the mean scores of symptoms recognition subscale and +3.41 in the mean scores of help-seeking subscale. Table 8-13 shows that while only 20% of participants at baseline were “very sure” or “pretty sure” that they would know if they themselves were having a heart attack, all participants (100%) at T3 were very sure or pretty sure that they would. Only 15% at T1 were confident that they could differentiate between a heart attack and other medical problems, but this rose to 70.6% at T3. Likewise, the percentage of participants who were pretty sure or very sure that they could get help for themselves if they thought they were having a heart attack was increased from 15% at T1 to 82.4% at T3.

**Table 8-13: Responses to the attitude section of the ACS response index**

Attitude	Very sure		Pretty sure		A little sure		Not at all sure	
	N (%)		N (%)		N (%)		N (%)	
	T1	T3	T1	T3	T1	T3	T1	T3
Recognize heart attack in someone else	2 (10)	8 (47.1)	2 (10)	7 (41.2)	7 (35)	2 (11.8)	9 (45)	0 (0)
Recognize heart attack in yourself	2 (10)	15 (88.2)	2 (10)	2 (11.8)	12 (60)	0 (0)	4 (20)	0 (0)
Tell difference between heart attack and other medical problems	1 (5)	4 (23.5)	2 (10)	8 (47.1)	12 (60)	5 (29.4)	5 (25)	0 (0)
Get help for someone else if they were having a heart attack	0 (0)	10 (58.8)	2 (10)	5 (29.4)	8 (40)	2 (11.8)	10 (50)	0 (0)
Get help for yourself if having a heart attack	1 (5)	8 (47.1)	2 (10)	6 (35.3)	6 (30)	3 (17.6)	11 (55)	0 (0)

### **The beliefs subscale of ACS response index**

Table 8-10 shows that the mean score on the beliefs scale was  $20.12 \pm 2.85$  at T1 and  $25.12 \pm 1.83$  at T3 (range 7-27), indicating a significant change of +5 between the two timepoints. The mean scores on the expectation subscale and the action subscale were positively improved also. As can be seen from Table 8-14, at both T1 and T3, nearly all the participants stated that they would go to hospital right away if they were experiencing chest pain for more than 15 minutes, or if they were having chest pain and were not sure if it was a heart attack, or if they just thought they were having a heart attack. At T1, over 30% stated that they would be embarrassed to go to the hospital if they mistakenly thought they were having a heart attack, while only 11.8% gave this response at T3. However, most participants at both T1 (80%) and T3 (64.7%) would prefer someone to drive them to the hospital than have an ambulance come to their home. While 45% at T1 agreed if they thought they were having a heart attack would wait until they were very sure before going to the hospital, none of the participants agreed with this statement at T3. The complete range of responses to the beliefs scale is summarised in Table 8-14.

**Table 8-14: Responses to the beliefs section of the ACS response index**

Beliefs	Strongly agree		Agree		Disagree		Strongly disagree	
	N (%)		N (%)		N (%)		N (%)	
	T1	T3	T1	T3	T1	T3	T1	T3
If chest pain >15 minutes, I should go to hospital ASAP.	8 (40)	16 (94.1)	12 (60)	1 (5.9)	0 (0)	0 (0)	0 (0)	0 (0)
I'd be embarrassed to go to hospital if I thought I was having heart attack but was not.	0 (0)	1 (5.9)	7 (35)	1 (5.9)	8 (40)	1 (5.9)	5 (25)	14 (82.4)
If I thought I was having a heart attack, I would wait until I was very sure.	2 (10)	0 (0)	7 (35)	0 (0)	6 (30)	4 (23.5)	5 (25)	13 (76.5)
If I thought I was having a heart attack, I would rather have someone drive me to hospital than call an ambulance.	14 (70)	4 (23.5)	2 (10)	7 (41.2)	3 (15)	2 (11.8)	1 (5)	4 (23.5)

Because of the cost of medical care, I would want to be absolutely sure I was having a heart attack before going to the hospital.	3 (15)	0 (0)	8 (40)	1 (5.9)	6 (30)	5 (29.4)	3 (30)	11 (64.7)
If having chest pain and not sure if it is a heart attack, I should go to hospital.	7 (35)	16 (94.1)	11 (55)	1 (5.9)	2 (10)	0 (0)	0 (0)	0 (0)
If I thought I was having a heart attack, I would go to hospital right away.	12 (60)	17 (100)	8 (40)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

### 8.3.3.5 *The Self-Efficacy for Managing Chronic Disease 6-Item Scale (SEMCD)*

Participants had some difficulty completing the SEMCD. The SEMCD requires more explanation than the other activities, particularly during the initial assessment, as it requires participants to consider their confidence in relation to a set of items about managing their disease and its symptoms, then choose a number from a 10-step Likert scale ranging from 1 to 10 for each item, where 1 represents “not at all confident” and 10 represents “totally confident”. Although the instructions for answering the items were clarified in writing, some participants found it difficult to understand the process. However, this issue was quickly resolved by additional, verbal explanation from the researcher. All scales were answered without any missing data by all participants except for one at T1, who give no answer to two items. however, the scale was included because the SEMCD scale allowing a maximum of two missing item responses.

As can be seen in Table 8-10, the overall mean of the SEMCD was  $28 \pm 9.11$  at T1 and  $39.82 \pm 4.2$  at T3, with values ranging between 6 and 60. Table 8-15 shows that participants were less confident at T1. The mean self-efficacy scores increased from a less than moderate position of 4.53 out of 10 to 6.64 out of 10 at T3, representing a 21.1% rise between the two time points.

**Table 8-15: Means [standard deviation (SD)] for items on the Self-Efficacy for Managing Chronic Disease 6-Item Scale**

Items	T1 (n=20) Mean (SD)	T3 (n=17) Mean (SD)
How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?	5.1 (1.48)	6.29 (1.53)
How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?	4.6 (2.56)	6.76 (1.39)
How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?	4.75 (2.1)	6.65 (1.5)
How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?	4.35 (1.95)	6.06 (1.52)
How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?	4.15 (2.01)	6.82 (1.85)
How confident are you that you can do other things besides just taking medication to reduce how much your illness affects your everyday life?	4.25 (1.94)	7.24 (1.99)
Overall mean out of 10	<b>4.53</b>	<b>6.64</b>

### 8.3.3.6 *Morisky Medication-Taking Adherence Scale: 4 items (MMAS)*

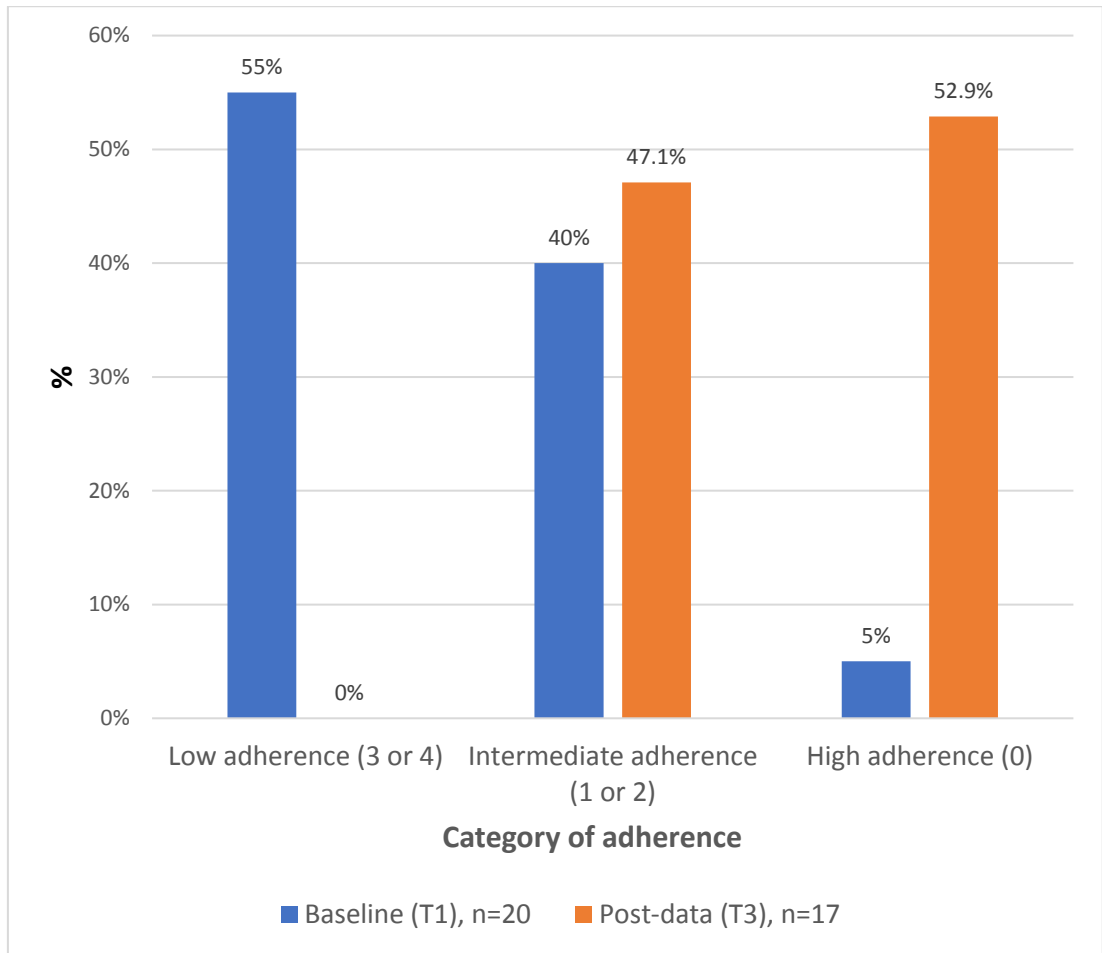
The MMAS was completed easily and answered fully by the participants. The scale took less than a minute to be complete. The mean score for the medication adherence scale was  $2.47 \pm 1.33$  at T1 and  $0.47 \pm 0.51$  at T3 (range 0-4) (see Table 8-10), indicating a higher level of medication adherence by patients after they received the DCISM Intervention. In terms of the frequency distribution of the MMAS items, 90% of participants at T1 answered that they forget to take their medicines, whereas only 41.7% did so at T3. Likewise, intentionally, over half of participants at T1 were sometimes careless about taking their medicines, or had stopped taking their medicine either when they felt better or if they felt worse when they took it, whereas at T3 almost none of the participants approved of these behaviours (see Table 8-16).

**Table 8-16: Responses to medication adherence scale.**

Items	T1 (n=20)		T3 (n=17)	
	YES n (%)	NO n (%)	YES n (%)	NO n (%)
Do you ever forget to take your medicine?	18 (90)	2 (10)	7 (41.7)	10 (58.8)
Are you careless at times about taking your medicine?	12 (60)	8 (40)	0 (0)	17 (100)
When you feel better, do you sometimes stop taking your medicine?	10 (50)	9 (45)	0 (0)	17 (100)
Sometimes if you feel worse when you take your medicine, do you stop taking it?	13 (65)	6 (30)	1 (5.9)	16 (94.1)

The MMAS provides information on behaviours associated with low medication adherence amongst participants. As can be seen in Table 8-16, at T1, most participants were both unintentionally and intentionally nonadherent. Some of their responses indicate behaviours related to forgetfulness and carelessness while others indicate a conscious decision to stop taking their medication when they felt better or because they felt worse when they took it. By contrast, at T3, most participants were adherent, and of those who were not, most were unintentional and almost none were intentional.

According to Morisky et al. (1986), there are three categories of adherent patients: low adherence patients with score of 3 or 4, intermediate adherers with a score of 1 or 2, and high adherers with a score of 0. By these standards, the present study population included 55% low adherers, 40% intermediate adherers and only 5% high adherers at T1, whereas at T3, all participants were either high adherers (53%) or intermediate adherers (47%), as shown in Figure 8-12.



**Figure 8-12: Suggested revision: Medication adherence by study participants at T1 and T3**

**8.4 Conclusion:**

The study was designed to examine the feasibility and acceptability of the DCSM Intervention for patients with ACS and T2D in the context of a Jordanian healthcare setting. The feasibility study was successful in its aim of examining the DCSM Intervention for 20 participants in one of main referral hospital in Jordan. Information gathered within the feasibility study has shown that recruitment and retention of participants after they experienced an ACS in the CCU was not found to be challenging, and the provider of 2-3 educational sessions during their hospitalisation and one follow-up phone calls 2 weeks after they are discharged from hospital were acceptable and generally well received.

In sum, the DCSM Intervention designed to meet the needs of patients with diabetes and ACS, specifically in the in the period following an acute cardiac event, was feasible

to deliver in the CCU and continued to be carried out at home by phone call, acceptable and appealing to most target population, and beneficial in terms of improving patient's health knowledge about coping with both conditions and patient's self-efficacy to control their disease.

Chapter nine presents the discussion of the findings of the feasibility study, which amalgamated with previous study findings to provide the foundation for the development of the main implications to education, policy, practice and research. Also, will present the strength and limitations of each study, will make recommendations for policy, practice and education, and final conclusion.

## **Chapter 9: Discussion and Conclusion**

### **Introduction**

This chapter compares and contrasts the findings from the feasibility study with previous research and the literature on the promotion of self-management knowledge and behaviour for those with type 2 diabetes (T2D) and acute coronary syndrome (ACS). The factors influencing the DCSM Intervention, the procedures followed, and the methods used to conduct the study are discussed, together with the strengths and limitations and the strategies which could be employed in future studies to control for limitations. In the final section, the implications of the study for nursing education, practice, research and policy are discussed, and recommendations are presented for future research.

### **9.1 The Need for the Study**

In order to implement policy and healthcare change, large efficacy studies (e.g., fully-powered Randomised Control Trails (RCTs)) are needed. To conduct full RCTs, large and sufficient amounts of physical and financial resources are required. Therefore, the Medical Research Council (MRC) guidelines (Craig et al. 2013) have recommended that conducting trials and gathering robust preliminary data at the early stages from pilot and feasibility studies are essential. The results of the investigations conducted during Phase 1 of this study emphasised that there is urgent need to develop and feasibility test an integrated self-management intervention for patients presenting with ACS and T2D at both international and local levels in Jordan.

Globally, approximately, 20-25% of patients (Hasin et al., 2009; Bradshaw et al., 2006) and 48-70% of Jordanian patients (Hammoudeh 2008; Saleh et al. 2012; Jordan Ministry of Health 2013) with ACS were reported to have diabetes. The two conditions are strongly pathophysiologically linked (Ofstad 2016) and share many modifiable cardiovascular risk factors (Lakerveld et al. 2013; ADA 2018). Moreover, patients with both conditions have an increased risk of morbidity and mortality (Franklin et al. 2004; Ofstad 2016; Lettino et al. 2017) and a longer average delay between the onset of symptoms and hospital stays (Ting et al. 2010). However, there is a dearth of evidence from interventions around the world which are designed to promote self-management for patients with both conditions following acute coronary events (Liu et al. 2017; Tanash et al. 2017b) and none at all in Jordan.



The systematic review of randomised controlled trials (RCTs) outlined in Chapter 2 provided a contemporary perspective using existing evidence of the effectiveness of integrated self-management interventions for this high-risk patient group (Tanash et al. 2017b). The evidence compiled from this review and the findings from Studies I and II support recent international clinical guidelines such as those issued by the American Diabetes Association (ADA) (ADA 2018), the International Diabetes of Federation (IDF) (IDF 2017) and the European Society of Cardiology (ESC) (Ibanez et al. 2017). These indicate that theoretically-based, integrated self-management interventions for patients with both conditions immediately after diagnosis with ACS, delivered through individualised educational sessions and supported by multiple cognitive and behavioural strategies, are most likely to improve patients' self-management knowledge, behaviours and health outcomes.

Moreover, data from the qualitative explorations with Jordanian patients and their HCPs verify that both patients and HCPs embrace the idea of developing and providing interventions that promote self-management education and support for patients with both conditions in secondary healthcare settings. However, in order for the newly developed intervention in this study to inform practice in healthcare settings, this intervention needed to demonstrate feasibility and promising findings (Craig and Petticrew, 2013).

## **9.2 Findings from the Feasibility Study**

The results from Chapter 8 suggest that the DCSM Intervention is feasible, acceptable and beneficial in terms of improving patients' health knowledge in relation to coping with both conditions and their self-efficacy to control disease. In the following section, the key findings, recommendations and limitations of the DCSM Intervention study will be discussed. The findings have been grouped into three main areas: recruitment capability and resulting sample characteristics, the design of the DCSM Intervention and its effects on patients' health outcomes.

### **9.2.1 Recruitment capability and resulting sample characteristics**

#### ***9.2.1.1 Recruitment and retention rates for participants***

The DCSM Intervention study successfully recruited 20 participants within 9 weeks. With a recruitment rate of 74.1% and only a 15% drop-out rate, there was a high rate of retention among participants (85% over approximately 6 weeks). This is in keeping with

the patient recruitment and retention rates reported by previous interventions that have provided education and collected data in hospital and post-discharge settings. For example, the recruitment rate for a pre-discharge education intervention provided for Jordanian patients with ACS was 90% (Eshah 2013); two interventions for New Zealand patients with ACS reported rates of 82% (Broadbent et al. 2013) and 89% (Broadbent et al. 2009) respectively. Previous retention rates have ranged from 94.4% over four weeks (Wu et al. 2012b), to 90.2% over three months (Broadbent et al. 2009) to 89.7% over one year (Soja et al. 2007).

Recruitment (76%) and retention (68.3%) rates were somewhat lower when the health education intervention was provided, and data collected in patients' homes (Kasteleyn et al. 2016). Likewise, retention rates were lower for less intensive educational interventions, such as Broadbent et al. (2013) study that provided only one in-hospital, 30-minute, nurse-led computerised Predict CVD-Diabetes session for patients with ACS, with a retention rate of 55.6%. These findings suggest that the intensity of the intervention, early provision of face-to-face education sessions and collecting data within healthcare settings (e.g. hospital and outpatient clinics) are associated with increased engagement by patients with the intervention. One explanation for this may be that such features strengthen the patient-provider relationship, and increase benefits, while reducing the cost and burden of the intervention for patients.

One of the main challenges to establishing this point is that there is a dearth of evidence about integrated self-management interventions for patients with T2D and ACS, as most previous studies have been poorly reported (Kasteleyn et al. 2014; Liu et al. 2017; Tanash et al. 2017b). Therefore, direct comparison with other similar studies is difficult. Furthermore, the rates of recruitment and retention of subjects vary significantly depending on (1) the inclusion and exclusion criteria used (e.g., only elderly people); (2) the strategy for recruiting subjects, which are often not reported or well considered; and (3) other factors related to environmental variables such as the prevalence of potential participants and the place and time of recruitment.

For example, in this study, the King Abdullah University Hospital (KAUH) was the only public hospital with an interventional cardiac unit which serves more than a million citizens in the northern area of Jordan (KAUH 2017). The number of individuals with both conditions is very high within the Jordanian population (is double the global

rate, as mentioned above) (Hammoudeh 2008; Saleh et al. 2012). Thus, the prevalence of targeted participants was high in the study setting. Likewise, the scarcity of health education in Jordan created an urgent need amongst those patients for educational and supportive care in Jordan (Eshah 2011; Saleh et al. 2012; Eshah 2013; Health 2013; Tanash et al. 2017a). Their high degree of willingness to learn, as indicated by the findings from Study II, in addition to the effective strategies applied in this study to maximise the recruitment and retention of participants, enabled the researcher fairly quickly recruit the sample required. Over 9 weeks the average recruitment rate was 2.2 participants/week and a retention rate of 85% until the intervention was complete. In other studies, the rate was much lower (0.5-2.1 participants/week) and the recruitment period much longer (34-94 weeks) (Soja et al. 2007; Wu et al. 2009; Wu et al. 2012b; Kasteleyn et al. 2016). Thus, the data clearly indicates that the study intervention was both needed and appealing to Jordanian patients with ACS and T2D in secondary healthcare settings.

#### ***9.2.1.2 Recruitment and retention rates for the family members***

Recruitment and retention of family members was problematic in this study. Of the 17 family members invited, 10 (58.8%) attended at least one in-hospital session. Whilst the practical and theoretical evidence for the important role family members play in supporting self-management and promoting positive health outcomes is clear (Lisa et al. 2018), only one (9%) attended all three sessions in this study. As indicated in Chapter 8 (Section 8.1.1.4), such non-attendance was primarily due to physical or financial difficulties. Other possible explanations include the fact that many patients want to be more assertive and self-reliant when interacting with their family as indicated in Study II. Other possible reasons may be a lack of awareness among patients and their families about the link between family support and the successful management of chronic diseases (Gibbons et al. 2014; Reinares et al. 2016) poor communication amongst family members (Checton et al. 2012), or lack of understanding of the ways in which a chronic condition affects families (poor family adaptability) (Brittain et al. 2010).

On the other hand, data from Studies I and II of this study affirms that participants remained strongly attached to their family's lifestyle (i.e. eating habits) after discharge and this was one of the main reasons why they abandoned their self-care activities. Therefore, as a recent systematic review highlighted, meaningful engagement with families in clinical practice is important, together with a sharper focus on the nurse's contribution in supporting patients' families (Deek et al. 2016). Furthermore, the

engagement of family members in education programs has been found to increase understanding of self-management information and skills and, in turn, improve family functioning (Lee et al. 2017). , Further research to improve their willingness to engage in self-management interventions across acute and community settings and to adapt to the challenges they face over time is worth considering.

Without some additional arrangements, future studies are likely to continue to have difficulty enrolling and retaining family members at an appropriate rate. These arrangements may include financial incentives, provision of travel expenses, designing one or more follow-up education sessions in the patient's home to facilitate their involvement, using Smartphone applications for communications, and inviting family members to attend just one session specifically designed to discuss the recovery plan developed with the patient and their role in its implementation. Another option explored by Broadbent et al. (2009) is to record all the in-hospital sessions with the patient and then give the recording to the patient and their family to listen to later.

### ***9.2.1.3 Refusal rates***

The participant refusal rate was 18.5%. The main reason for declining were feeling pain and discomfort. However, feelings of discomfort, being anxious and very tired are to be expected in the first 1-2 days after an ACS (Chest Heart and Stroke Scotland 2016). Refusal rates in previous studies with the same population ranged from 11.2-24% for some similar reasons (Broadbent et al. 2009; Broadbent et al. 2013; Eshah 2013; Kasteleyn et al. 2016). The treatment plan for some patients with ACS is likely to change as their circumstances become more complicated or their condition deteriorates after catheterisation (e.g., they need open-heart surgery), affecting their eligibility to continue in the study. In this study, this led to the exclusion of two patients (7.4%) who had given consent shortly after their hospitalization; 6.7% and 6.9% of eligible patients were excluded for these reasons in two previous studies (Broadbent et al. 2009; Wu et al. 2012b). Such factors should be considered carefully when developing the inclusion and exclusion criteria for participants in future studies. That said, the high recruitment and retention rates of Jordanian patients with both conditions indicates that the study recruitment procedures and the intervention was generally acceptable and appealing to these patients.

#### ***9.2.1.4 Eligibility criteria***

The eligibility criteria for participants were clear, sufficient, relevant to the target population in this study and feasible for use in future studies. The mean age of the study sample was  $58.65 \pm 7.51$  years. Other Jordanian studies including patients with ACS reported a lower mean age. Eshah (2013), for example, reported a mean age of  $48.4 \pm 12.07$  years; and (Mosleh et al. 2016b) report that it was  $50.9 \pm 13.9$  years. However, these means were considerably younger than the mean age of patients with ACS from the Netherlands ( $65.8 \pm 9.5$  years) (Kasteleyn et al. 2016) and Australia ( $71.5 \pm 9.9$  years) (Wu et al. 2012b).

Moreover, the overall fitness of patients was relatively poor in different phases of this study. A similarly poor level of fitness was found in comparable patients in previous Jordanian studies. For example, 40% of the sample in the feasibility study was composed of current and heavy tobacco smokers, 60% had hypertension and 65% had dyslipidaemia. Similar rates or higher were also reported in some recent Jordanian studies in which comparable subjects were recruited (Eshah 2013; Mosleh et al. 2016b; Mayyas et al. 2017). These rates of cardiovascular risk factors were much higher than those reported in studies in developed countries (Soja et al. 2007; Wu et al. 2012b; Kasteleyn et al. 2016).

There are a number of possible explanations for these poor rates. These include firstly, the high prevalence of T2D, ACS and cardiovascular risk factors among Jordanian adults. Secondly, the ill-equipped nature of the Jordanian healthcare system to prevent and treat these risks and diseases (Alkurd & Takruri 2015; Higher Health Council 2015; WHO 2016). Thirdly, a lack of awareness about rehabilitation or education programmes across acute and community settings, as confirmed by the data from the two phases of this study; and fourthly, the low socioeconomic status of people in low and middle-income countries (LMICs) (Seligman et al. 2016; Tran et al. 2017). All these factors clearly and poignantly indicate the urgent need for the study intervention and for further research in the field of integrated self-management interventions for this high-risk patient group. This would constitute a crucial step towards improving current practice in Jordan and promoting self-management knowledge and behaviours as well as health outcomes among patients with both conditions.

Recruiting participants with T2D was not a big challenge in this study, as most of the ACS cases admitted to the CCU already had T2D. This may be explained by the same factors explained above. For example, both Mosleh et al. (2016b) and Eshah (2013) reported that about half of their ACS patients recruited had diabetes. However, other studies have reported that 20-30% of Jordanian patients with CHD and no history of diabetes were found to have high blood glucose levels on admission with ACS (Al-Nsour et al. 2012; Jordan Ministry of Health 2013). Therefore, those newly diagnosed with T2D at admission with ACS may need to be considered in future interventions.

Although the recruitment rate in this study was sufficient according to the current criteria, several inquiries have been received from clinicians about the eligibility of patients with T2D who were admitted to the hospital for elective cardiac catheterization and stenting, whom they indicated also would benefit from the study intervention. The condition of those patients is more stable than that of the acute cases, and their capacity to receive longer education sessions may be higher. However, they are less available in hospital after catheterisation as they are usually discharged 12 to 24 hours after the catheter is removed. Therefore, further research is required to develop new mechanisms for educational provision within the limited period in which patients are hospitalised, such as combining two education sessions for delivery at one time or on the same day. However, overall, the sample members appeared to have characteristics that were consistent with that reported in the research literature, and Studies I and II, describing patients with ACS and T2D who would be appropriate participants in the DCSM Intervention.

#### ***9.2.1.5 Willingness of HCPs and patients***

Most ward staff working in the CCU agreed to refer participants to the DCSM Intervention. Their support was crucial in improving the recruitment and retention rate. As their positive and proactive opinion on the importance of receiving education about living well with both conditions influenced their patients and maximised their motivation and willingness to participate. It was observed that the current ward staff and patients with T2D and ACS were extremely receptive to the study intervention.

The majority of patients stated that their reasons for consenting were to improve their health knowledge and wellbeing. The fact that they wanted to aid this research in changing the unreasonable current practice and to help future patients was also reported.

Such personal and altruistic motives are typically reported as reasons for participation in healthcare interventions. (Ssali et al. 2017), for example, found that the desire to improve health and wellbeing or to reduce burdens' are the most common reasons given for participation in health interventions, together with a willingness to help other patients or to contribute to a "greater good" (McCann et al. 2010).

This evidence also highlights the importance of improving current discharge plans and the referral process to cardiac and diabetes self-management programs. Many Jordanian researchers have highlighted the urgent need to prepare and certify specialist nurses to serve as health educators in hospital for patients with chronic diseases (Shishani 2010; JHHC 2015; Mayyas et al. 2017). This was also reported in Study I among HCPs as a practical solution to the current lack of education and supportive care.

With regard to patients with cardiac diseases, Tawalbeh (2018) emphasised that cardiac educational programs should be urgently adopted in Jordanian secondary care settings to improve patients' knowledge and self-care behaviours. Eshah (2013) recommended that cardiac nurses must be educated and enabled to provide an effective discharge plan, including health education for patients with ACS before they are discharged. These data are important as they demonstrate the vital role of giving immediate health education to ACS survivors and its importance for the patient's health outcomes. Also, it promotes the possibility of translating the study intervention into real practice by involving and training CCU nurses to deliver the intervention.

## **9.2.2 The DCSM Intervention Design**

### ***9.2.2.1 Development process***

Many studies have reported that the development of education programs for patients with T2D and ACS should carefully consider the actual needs of the targeted population and to what extent the contents of the intervention are culturally appropriate (Brown et al. 2013; Choi et al. 2016; Creamer et al. 2016). In this study, the design of the DCSM Intervention was informed by the key findings of Studies I and II and the existing evidence (see Table 9-1). Other factors (e.g., the timeframe of the PhD study and available resources) were also considered in this feasibility study and served to limit certain modifiable features, such as the duration of the delivery and follow-up period for data collection. However, the intervention was appropriately established according to the best

evidence and theoretical framework. Moreover, the feasibility and outcomes of the intervention indicate that the intervention was promising and established a solid foundation for future efficacy studies that include, for example, further follow-up sessions and a longer follow-up period for data collection.

**Table 9.1: Recommendations of self-management interventions for patients with T2D and ACS**

Features	Systematic review of RCTs (Tanash et al. 2017b)	Recent umbrella review (Liu et al. 2017) and other related literature	Pre-qualitative investigations (Studies I and II)
<b>Theoretical approach</b>	SET and recommendations of local and international guidelines.	SCT (including SET), HBM and empowerment theory (e.g., empowerment behavioural change model).	Should help to improve patients' knowledge, confidence and self-efficacy.
<b>Behavioural strategies</b>	Goal setting, health education and consultation.	Goal setting, health education.	Multi cognitive and behavioural strategies help to minimise patient confusion and frustration and maximise their knowledge and self-efficacy.
<b>Educational content</b>	Glycaemic control, lifestyle changes, exercise training, cooking lessons, smoking cessation, nutritional counselling, psychological support, medications.	Behavioural change (such as smoking cessation), cardiovascular risk factors, diet, exercise, glycaemic control, medication, psychosocial issues, self-management.	Overview of both diseases, risk factors, lifestyle changes, self-management skills, medication adherence.
<b>Expected provider</b>	Nurse, trained peers, multidisciplinary team.	Nurse or multidisciplinary team.	Nurse, specialist, multidisciplinary team.
<b>Teaching strategies</b>	Multi strategies including two or more of the following: face-to-face teaching; written materials; digital materials; follow-up phone call and text messages; telephone consultation.	Face-to-face support; written materials; telephone contact or mixed.	Face-to-face support as an essential feature, integrated with other supportive strategies (e.g., follow-up phone calls and written materials).
<b>Teaching format</b>	One by one or mixed.	One by one or mixed.	One by one preferably.
<b>Contact hours</b>	At least 30 minutes per session.	More than 30 minutes per week.	Between 20-30 minutes per session time.



<b>Duration of intervention</b>	At least 4 weeks.	At least 6 months.	Open until patient's saturation point.
<b>Duration of follow-up</b>	At least 4 weeks.	At least 12 months.	Open until patient's saturation point.
<b>Settings</b>	Inpatient (e.g., CCU), patient's home and post-discharge settings.	Inpatient and post-discharge settings.	During hospitalisation and/or post-discharge settings.
<b>Note:</b> <b>HBM:</b> health belief model; <b>SCT:</b> social cognitive theory; <b>SET:</b> self-efficacy theory.			

Using appropriate theories for designing self-management interventions may positively influence the effectiveness of the intervention (Craig & Petticrew 2013; van Vugt et al. 2013). In this study, theories were selected primarily on the basis of the purpose of the intervention (Ramadas et al. 2011). Two common and dynamic psychological theories that have proven to be key factors for understanding illness self-management and the control of chronic conditions are central to the current intervention. As discussed in Chapter 7, the intervention was developed by combining the Common-Sense Model of Self-Regulation (CSM-SR) (Leventhal et al. 2016), and Self-Efficacy Theory (SET) (Bandura 1977). By matching various aspects of the CSM-SR with the four main sources of self-efficacy, as well as the elements of competence for effective use of the teach-back to teach patients, a “triple-pillared” integrated self-management intervention was produced. To our knowledge, this is the first interventional study for patients with T2D and ACS using this clear and comprehensive framework to improve patients' illness representations and self-efficacy after ACS. This provides a clear foundation on which future intervention can be developed.

In accordance with the study framework and the recommendations of effective self-management interventions for patients with both conditions (Goulding et al. 2010; Aldcroft et al. 2011; Liu et al. 2017), the DCSM Intervention used multiple cognitive behavioural strategies to meet the needs of patients and maximise effectiveness. Using such strategies is often effective in changing maladaptive illness beliefs of patients with ACS (Goulding et al. 2010; Aldcroft et al. 2011), T2D (van Vugt et al. 2013; Powers et al. 2016) and both conditions (Liu et al. 2017). In this study it has been found that using these strategies helped participants to engage with the intervention, thereby improving acceptability and retention rates.

As indicated in Studies I and II, the targeted population had low levels of health literacy, and each patient was unique and needed to be involved in prioritising their needs and planning their goals. For these reasons the teach-back method (Jager & Wynia 2012) was an appropriate teaching method. Using this method helped patients to improve their health knowledge and confidence in their ability to control their conditions. What's more, their satisfaction with this style of teaching was obvious. The effectiveness of using the teach-back method with patients with chronic disease has been widely reported (Griffey et al. 2015; Ha Dinh et al. 2016; Centrella-Nigro & Alexander 2017). However, no previous similar trial has determined the method of teaching or how to provide information for patients with T2D and ACS (Soja et al. 2007; Wu et al. 2011; Wu et al. 2012a; Wu et al. 2012b; Wu et al. 2015; Kasteleyn et al. 2016). Lack of using clear and appropriate teaching method was also obvious in the majority of the existing self-management interventions for patients with T2D or ACS (Liu et al. 2017).

Compared with previous similar interventions, the contents, framework, strategies and method of teaching in the DCSM Intervention were all developed systematically and based on evidence. According to MRC guidelines (Craig & Petticrew 2013), this method of development often contributes to the effectiveness of programs designed to improve patients' self-management knowledge and behaviour in practice.

#### ***9.2.2.2 Feasibility setting***

Many internal and external factors can affect the construction, validity, implementation and results of RCTs (Spieth et al. 2016). The main purposes of a feasibility study are to build the foundation for the planned intervention study and to ensure that its implementation is practical and reduces threats to the validity of the study's outcomes (Tickle-Degnen 2013). The findings from the feasibility testing of the DCSM Intervention in a single Jordanian healthcare setting suggest that it is highly appropriate and acceptable for application in future studies. This study established a solid foundation and evidence for understanding the context in which future interventions can take place. Also, it helped to identify some uncertainties, such as involving a family member in the in-hospital education sessions.

However, a feasibility study is not designed to generate definitive results therefore the effectiveness of the DCSM Intervention still must be tested in a RCT study.

Conducting RCTs are widely recognised as the most reliable method of assessing the effectiveness of an intervention as they minimise the risk of confounding factors affecting the findings (Akobeng 2005). It is also considered the gold standard for clinical research (Sullivan 2011). Therefore, as the DCSM Intervention is designed to recruit patients with two serious conditions from a complex healthcare setting (CCU), pilot testing of RCT of the DCSM Intervention is recommended as a first step towards conducting a full-scale RCT. Also, this will inform procedures (e.g., randomisation and blinding) for both the control and the interventional group, and enable the determination of effect sizes for use in sample-size calculations in any future full-scale RCTs (Feeley et al. 2009; Day et al. 2015).

### ***9.2.2.3 Duration of intervention and timing of follow-up assessment***

The duration of the DCSM Intervention was short (less than one month). This was quite similar to that of some previous interventions (Wu et al. 2009; Wu et al. 2011; Wu et al. 2012b) and longer than that of others, which only offered education for patients with ACS during their hospitalisation (Petrie et al. 2002; Broadbent et al. 2009; Broadbent et al. 2013; Eshah 2013). Both Soja et al. (2007); Kasteleyn et al. (2016) provided longer educational interventions of 5 months and 12 months, respectively. Feedback from participants in this study indicates a great interest for additional follow-up support sessions in the period after the study intervention.

A systematic review of seven health education interventions involving a total of 536 patients with ACS found that those lasting at least six months resulted in the most significant improvements in primary outcomes such as smoking cessation, knowledge levels and behavioural changes (Aldcroft et al. 2011). For patients with T2D, systematic reviews have reported that health education programmes lasting more than six months also produced larger effects for all primary outcomes (e.g., HbA1c, knowledge levels) (Fan & Sidani 2009; Saffari et al. 2014). Therefore, to achieve and assess their effectiveness, health interventions with a longer duration and additional follow-up sessions over a period of at least 6 months must be considered in future RCTs.

Ensuring sufficient follow-up assessments of outcomes was important to assess to what extent the DCSM Intervention was promising. In this study, follow-up data were collected 4-6 weeks after participants were discharged from hospital. As in various previous studies (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b), patients showed

improvements at this point. Also, during this time period, patients with ACS in Jordan attend their first visit with their cardiologists in an outpatient clinic, which makes collecting post-intervention data more achievable.

However, Liu et al. (2017) have recommended that the follow-up period for health education interventions for patients with ACS and T2D be at least 12 months. Therefore, in order to evaluate the long-term effectiveness of the DCSM Intervention in any future efficacy study, sufficient time for follow-up assessment will be necessary, as the self-care activities and behavioural changes must be integrated into the everyday life of the patient to maximise its benefits.

#### ***9.2.2.4 In-hospital education provision***

In this study, 85% of participants successfully completed three in-hospital sessions. This is indicative of a feasible approach, which could be smoothly integrated into clinical practice in the Jordanian healthcare system, for example by training nurses to provide the education for patients in hospital. As indicated in Studies I and II, educational and supportive care is lacking for patients with T2D and ACS both in hospital and post-hospitalisation (e.g., no rehabilitation centres) due to many functional and occupational barriers. The results from the two phases of this study show a high prevalence of risk factors among patients, indicating a poor level of knowledge of and adherence to the management plan for their condition either before and after developing ACS. These were confirmed in many previous studies in Jordan (Eshah 2011; Al-Nsour et al. 2012; Jordan Ministry of Health 2013; Mosleh et al. 2016a).

However, providing the DCSM Intervention during patients' hospitalisation helps to increase their knowledge and confidence to adhere to a healthy lifestyle after discharge. The improvements reported in this study regarding adherence to a healthy lifestyle are consistent with the results of previous in-hospital health interventions provided for patients with ACS in Jordan (Eshah 2013) and other countries (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b; Broadbent et al. 2013), which also emphasised that nurses must be educated and prepared to invest in the education of patients with ACS prior to discharge.

Recent reviews of the literature found that health education-related interventions that are delivered primarily in inpatient and post-discharge settings (e.g., in hospital and

cardiac or diabetes centres) were effective (Liu et al. 2017; Tanash et al. 2017b). Conducting the intervention within clinical settings mostly minimises the difficulties associated with enrolling participants at an appropriate rate (Orsmond & Cohn 2015) and may lessen the financial and other burdens on patients in LMICs (Schaffler et al. 2018). That said, the implementation of the DCSM Intervention during patients' hospitalisation in the CCU and its outcomes are likely to have been influenced by two main factors: the characteristics of the intervention provider and the study environment.

#### Characteristics of the intervention provider

According to Sidani & Braden (2013), nursing interventions could be influenced by the personal characteristics (e.g., gender, age, interpersonal style and communication skills) and the professional characteristics (e.g., knowledge, speciality and level of competence) of the provider. Therefore, the characteristics of the provider (detailed in Chapter 7, Section 7.2.3.3) of the DCSM Intervention mostly contributed to the implementation of the DCSM. The staff on the ward in the CCU (e.g., the clinician and senior cardiac nurse) who helped in recruiting and securing the consent of participants and those who treated them during their hospitalisation in the CCU during the intervention period may also have had an influence on participants' understanding, health behaviours and outcomes.

For example, although each participant was informed verbally and in writing that their participation was completely voluntary, they still may have felt pressure to take part in the study and reluctant to refuse. As they were under treatment they may have felt vulnerable. As long as the future intervention is non-RCT and not home-based, the same recruitment approaches can be applied. However, recruiting and retention of patients to control groups in future RCTs, or to interventions that include follow-up visits and data collection in patients' home, could be a new challenge influenced by the characteristics of the intervention provider(s). These uncertainties must be pilot tested in the Jordanian context in future studies.

Although none of the participants expressed any concerns regarding the provider's gender, using both male and female providers in future studies is still recommended to maximise the recruitment and retention of participants and to keep the intervention culturally appropriate for a larger sample. This is especially important for female participants (given the conservative Eastern culture of the target population) if the intervention is extended to include follow-up home visits. This issue was discussed

among HCPs in Study I, and they recommended involving male and female nurses within the multi-disciplinary team.

As Table 9.1 shows, most previous similar interventions were provided by specialist nurses in diabetes or heart disease, either by one person or by a group of different educators. However, nurses and multidisciplinary teams that include different specialists (e.g., dietitians) were the most frequent providers of self-management interventions for patients with T2D and/or ACS and were also the most frequently recommended. However, due to poor reporting of providers' characteristics in previous interventions and variations between studies in relation to the characteristics and number of providers involved, there is no clear evidence as to whether having one or more than one provider delivering the intervention is more effective for patients with T2D and ACS. This conclusion has been reported in different systematic reviews and meta-analyses (Loveman et al. 2008; Liu et al. 2017). Therefore, the number and characteristics of the intervention providers must be considered and researched in future studies. Also, to minimise variation among providers within the same study, their training should be standardised in future RCTs.

#### Study environment (setting)

The DCSM Intervention was conducted in either the CCU or the Intermediate CCU and participants received a follow-up telephone call while they were in their home. The health outcomes of the participants could have been influenced by these environments. For example, the environment in the CCU may have influenced participants' blood glucose and pressure levels both during hospitalisation.

While in hospital, participants are often offered healthy foods which adhere to the principles of a "no-added salt", "sugar-free" and "low fat" diet; they may also be receiving intensive intravenous insulin therapy. These factors may impact on patients' blood glucose and pressure levels. Moreover, the control of these measures may not continue in the participant's home. This depends on their level of adherence to their personal action recovery plan after they are discharged from the hospital, which includes eating healthy foods, taking their medication, being physical active and other self-management activities. It also depends on their health conditions, particularly if they experience any complications, such as infection or distress, after being discharged. Thus, more attention to the different settings may need to be considered in future interventions.

Due to the physical, emotional and technical features of the CCU environment, the time available for education, and the cognitive and physical capacity of participants to receive education, were limited. For example, the mean length of all three in-hospital sessions provided for participants in the DCSM Intervention was  $27.33 \pm 3.56$  minutes. This is largely consistent with many previous studies which have provided in-hospital education sessions for patients with ACS and T2D (Broadbent et al. 2009; Wu et al. 2009; Wu et al. 2012a; Broadbent et al. 2013). However, none of the previous studies faced challenges related to patients' ability or to the environment of CCU to provide up to three half-hour in-hospital sessions. This study offers clear evidence on the applicability of providing self-management education sessions for patients with ACS within a CCU environment.

However, in this study, the length of most educational sessions provided in hospital and follow-up telephone calls was within the average time allocated for each appointment (20-30 minutes). This aspect of the design accords with the recommendations in the literature and with the findings from Studies I and II. This length was found to be acceptable, reasonable and well-matched to the participants' capacity while in hospital. For example, 85% of participants managed to select 2-3 lifestyle change goals and prioritised them to be discussed and planned in hospital sessions. Most achieved a positive improvement in relation to these goals after they were discharged from hospital, and their willingness to develop a new goal increased over the course of the study. This may indicate that the duration and the amount of contact with the patients while in hospital and within the first month after discharge were acceptable, reasonable and in line with their capacity.

#### ***9.2.2.5 Teaching format***

It was obvious from their responses that all the participants preferred the face-to-face education sessions, which they felt were more useful and comfortable than other modes of delivery. This preference is consistent with the findings from Studies I and II. Face-to-face education sessions are the most common delivery mode of education for patients with ACS and T2D (Liu et al. 2017). They are also more effective in enhancing patients' health knowledge and blood glucose regulation than other or mixed delivery modes (Fan & Sidani 2009; Ricci-Cabello et al. 2014). This preference may be explained by the findings from Studies I and II, which indicated that the face-to-face format facilitates

productive conversation, enables patients to ask questions and disclose their needs, maximising their engagement, and respects their identity as responsible adults.

However, some participants reported that the follow-up telephone calls also helped to enhance their self-confidence, minimise their health-related difficulties and encouraged them to continue to manage their diseases. These findings are consistent with those of previous studies in which face-to-face education sessions were provided as the primary mode of delivery and then followed-up with telephone calls or home visits (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b). Using telephone calls or individualised counselling to deliver education for patients with ACS and T2D has proven very effective in many interventions (Liu et al. 2017). For example, Kotb et al. (2014) reported that telephone-based health education was effective for minimising anxiety and depression, hospitalisation rates, smoking and blood pressure in patients with T2D and ACS. Therefore, increasing the number of monthly one-to-one follow-up sessions could be a way to extend the duration of the DCSM Intervention and maximise patients' outcome in future research.

Overall, the positive feedback from participants reflected their satisfaction with the education delivery modes employed in the DCSM Intervention. This indicates that the intervention approach was acceptable and appealing to most participants and that the information and self-management skills provided were useful, met their needs and did not place an intolerable burden on them. Therefore, these modes of delivery are recommended for use in future interventions with the same target population. Other delivery modes (e.g., group education sessions, home visits and online services) also may be suitable, as reported in Studies I and II, but should be carefully considered in terms of the availability of physical and financial resources and appropriate facilitators.

#### **9.2.2.6 Booklet and log-book**

Previous researchers have reported that specifically designed booklets, checklists, leaflets and diary logs are effective and very useful tools for encouraging patients to increase their health knowledge, self-confidence, self-appraisal and monitoring skills (Wu et al. 2012b; Mélanie et al. 2017; Vooradi et al. 2018). The response from participants to both the booklet and log-book used in this study was very positive as indicated in Chapter 8. Therefore, these tools could contribute to future studies in Arab countries as they have been well designed, translated and used by the study participants. Many clinicians



expressed great interest in using these tools with their patients with T2D and ACS, particularly given the current occupational obstacles (e.g. lack of time for health education) in the Jordanian healthcare system.

#### **9.2.2.7 Educational content**

Several reviews have emphasised that the educational content of any self-management intervention should be based on the actual needs of patients and be culturally appropriate (Brown et al. 2013; Choi et al. 2016; Creamer et al. 2016). Towards this end, the findings from Studies I and II helped inform the content of the DCSM Intervention as discussed in Chapter 7.

An average of 3-4 topics were discussed with participants at each session. Patients found the educational contents of the intervention and the sequence in which they were delivered very acceptable and appealing. This may be explained by the person-centred approach used in developing and delivering the intervention contents, which is consistent with recent recommendations regarding the contents of effective self-management interventions for patients with T2D and ACS (Liu et al. 2017; Tanash et al. 2017b; ADA 2018a).

Moreover, patient characteristics such as age, cognitive abilities, hospital and home environment, socio-economic background and cultural sensitivities were considered, as these factors influence knowledge and promote health behaviour change in patients with ACS (Ghisi et al. 2014) and T2D (Hawthorne et al. 2010; Attridge et al. 2014; Creamer et al. 2016).

The content of the DCSM Intervention was designed to involve participants in prioritising their needs, identifying their risk factors, lifestyle change goals and developing their personal recovery plan. In this sense, it is consistent with a similar, previous intervention (Kasteleyn et al. 2016), but distinguished from many others which prioritised one condition over the other and were more standardised in relation to patients' lifestyle goals (Wu et al. 2009; Wu et al. 2012a; Wu et al. 2012b; Eshah 2013). However, because the contents of existent interventions vary, there is no clear evidence of their effectiveness on self-management outcomes or on recruitment and retention rates for patients with T2D and ACS. Further review is required to assess this matter.

### 9.2.3 Effects on health outcomes

#### 9.2.3.1 Measures and clinical data

Participants had no difficulty in completing measures in a timely manner and returned the completed measures either at baseline (T1) or post-intervention (T3) with very little missing data. However, roughly half needed assistance in completing the measures at T1. For example, 30% of the participants filling out the 6-item scale of 'Self-efficacy for Managing Chronic Disease' (Lorig et al. 2001) received some clarification about how to answer the questions. This difficulty in answering the questions using this scale required that the primary researcher to be on hand to clarify the process when necessary. Therefore, it may be worth modifying the scale to make it easier to understand or appoint a representative nurse to help patients to record the study measures and assist with data collection in future studies.

On average, participants required  $24.55 \pm 2.79$  minutes (77 items + 15 items of demographic data) to complete the questionnaire at T1 and roughly 5 minutes less at T3. Although many previous studies have used a similar number of items or more, and have collected data both in and outside hospital, none have reported the time needed to complete the questionnaire or any challenges faced by participants when filling in the questionnaire in the CCU before the intervention (Wu et al. 2012a; Wu et al. 2012b; Eshah 2013). One study, designed to collect baseline data in the patients' homes three weeks after their hospital discharge, used a questionnaire that took an hour to complete; this was one of the main reasons for the high dropout rate in the study (Kasteleyn et al. 2016). However, to minimise the anticipated burden on patients who have consented to participate and to sustain willingness to participate in future studies, it is recommended that the length of the questionnaire be further reduced.

The baseline data were collected within the first 36 hours of the participants' admission (T1). Thus, their scores may have been affected by their physical and emotional condition of participants after diagnosis with another serious condition (ACS). Patients with ACS are generally under-diagnosed and under-treated at T1, and many studies have confirmed that levels of depression and anxiety (Meneghetti et al. 2017), lipid profiles (Balci 2011; Shrivastava et al. 2015), and glucose (Deedwania et al. 2008; ADA 2018) can change during acute illnesses like ACS, which could significantly increase or influence the levels recorded. Therefore, in order to gauge the stability of the measures and to assess the actual effectiveness of the DCSM Intervention in the long term, multi-

assessment times (e.g., at baseline, at 1, 6 and 12 months after hospitalisation) are needed in future efficacy trials.

Half the participants at T1 and over three-quarters of participants at T3 did not achieve a positive value for at least one of the first two cardinal symptoms the Patient Health Questionnaire (PHQ-2) to screen for depression of the nine items of the PHQ-9 and therefore were ineligible to complete the full PHQ-9. Therefore, to minimise the burden on such patients in future studies, it is recommended that the first two cardinal symptoms of the PHQ-9 be used as an initial screen for detecting a positive PHQ-2 response, which would trigger completion of the full nine-item PHQ-9. This method of initial screening using the PHQ-2 has been validated in prior studies involving medical patients (Whooley et al. 1997) and patients with ACS (Frazier et al. 2014) and is recommended as an accurate tool for screening patients with ACS by the American Heart Association Board (Lichtman et al. 2008; McGuire et al. 2013). Clear guidance for filling in this measure should be provided if it is to be used in future studies.

### ***9.2.3.2 Knowledge development and psychological change***

Although this study mainly focused on the feasibility and acceptability of the intervention, cognitive and behavioural change was always an integral part of the design and implementation of the intervention. The inclusion of some cognitive and behavioural elements in the DCSM Intervention is extremely important for the evaluation of self-management interventions with patients with T2D and ACS (Brown et al. 2013; Ghisi et al. 2014; Kasteleyn et al. 2014; Liu et al. 2017).

Overall, across all scales used in the study, a similar picture emerged of positive improvements between T1 and T3 in relation to the level of patient knowledge about both conditions; diabetes and cardiac self-management skills; depression level; self-efficacy to manage their disease; and medication adherence. While some of these positive improvements were reported in previous similar studies, others were not. This can be a good indication that the DCSM Intervention is promising. This result may be explained by the fact that the DCSM Intervention was developed systematically and in accordance with the patients' actual needs and in line with clear theoretical framework and appropriate method of teaching. Furthermore, by using multiple educational and supportive techniques during the intervention. such as goal settings, stories, counselling and written materials.

For example, of three previous trials with similar subjects which evaluated the participants' level of diabetes knowledge, depression, self-efficacy of diabetes management and diabetes self-care activates in pre- and post-self-management intervention at four weeks, only two reported significant improvements among interventional groups in relation to diabetes knowledge (Wu et al. 2009; Wu et al. 2012b), and only one reported a significant improvement in self-efficacy of diabetes management (Wu et al. 2012a). Other variables showed no improvement. These three RCTs involved small samples (20-30 participants) and many researchers acknowledge that an underpowered sample size may generate Type I errors (false positive results) and Type II errors (false negative results) (Kraemer et al. 2006). Furthermore, it is worth noting that the contents of all three interventions focussed chiefly on diabetes management and did not provide adequate information about heart disease self-management for patients after ACS. These factors may have significantly influenced the findings of these interventions.

Another recent RCT which used three in-home education sessions (focusing on patients' illness perceptions and using motivational interviewing to increase their self-efficacy) for patients with T2D after first ACS showed that only the health status scores and well-being of participants significantly improved five months after discharge. Other variables, such as depression, anxiety, self-efficacy, self-management and illness perception for both diseases, showed no significant improvement (Kasteleyn et al. 2016). This result may be explained by that the DCSM Intervention was developed based on the best evidence and appropriate theoretical framework.

In sum, due to the very limited studies with findings similar to those of this study, and variations in the type of study as discussed above it is difficult to compare their findings or to determine their relative effectiveness. Therefore, further rigorous reviews and experimental studies with patients with both conditions are needed.

## **9.3 Contribution to knowledge**

### **9.3.1 The systematic review**

The recently published systematic review described in Chapter 2 (Tanash et al. 2017b) assessed the evidence on the effectiveness of existing RCTs in a field that is growing and still very limited. The evidence compiled in this review informs current clinicians,

researchers and funders that there is a serious dearth of evidence to support the effectiveness of intergraded interventions in promoting self-management of patients with T2D and ACS. Although conducting a systematic reviews of complex interventions can be problematic, as the methodology of how to find, review and combine data from complex intervention trials is not yet fully standard and developed (Petticrew 2003). And due to the variation in the way interventions are delivered (Herbert and Bo 2005). This systematic review identifies the relevant, existing evidence base by informing literature about up to date similar RCTs “gold standards”, providing a detailed account of each intervention, classifying the variant forms of the complex interventions, in terms of the mode of delivery, components of the interventions, theoretical frameworks used and other characteristics of interventions, as well as reporting the evaluation methods and findings of interventions appropriately. The review informs future researches about structures and processes, deficiencies and specific aspects of long-term conditions management, specifically, management of patients with T2D and ACS in the secondary healthcare settings.

However, this review supports the view that theoretically-based, integrated self-management interventions delivered in multiple modes in the hospital following an acute coronary event and in post-discharge settings are likely to be feasible and generate positive outcomes related to patients’ knowledge, self-efficacy and clinical outcomes. The review also suggests that such interventions could be delivered by nurses and multidisciplinary teams and that follow-up should take place at 4 weeks, 3 and 12 months. In addition, cognitive-behavioural interventions that teach self-management are more likely to be feasible and effective for patients with T2D and ACS. However, the content of the included trials lacked integration, as they focused on the management and associated risk factors of one disease or the other rather than both. This may significantly reduce the effectiveness of intervention provided for patients with both conditions. This indicates a clear need for further rigorous experimental studies in which the content of the intervention is focused on both conditions at once.

### **9.3.2 Qualitative investigations (Studies I and II)**

There has been very little research on the views of Jordanian patients with ACS in relation to their learning needs (Eshah 2011; Mosleh et al. 2016a). These few quantitative studies that have been conducted are descriptive and concluded that information about wound

care after catheterisation and medication are the most essential learning needs for those patients. However, these studies were limited to using only the Patient Learning Needs Scale (Bubela et al. 1990) to identify the learning needs of patients with ACS; and they have not focused on the actual needs of patients who have diabetes and heart diseases. Thus, this limits patients' perspective significantly about their actual needs and preferences to manage patients with both conditions effectively.

This study is the first conducted in Jordan to explore the perspectives of patients with T2D and ACS and their current HCPs regarding the supportive care needs of those patients and the follow-up care currently provided for them. These two studies encourage for the immediate involvement of patients in an integrated cognitive-behavioural self-management interventions following an acute coronary event. The results of interviews with "stakeholders" prior design the DCSM Intervention will help future studies also to determine the exact and appropriate content, elements and theoretical context of self-management education and support interventions delivered at hospital and home after patients with T2D diagnosis with ACS to help this high-risk group of patients to cope with both conditions. The findings support the recommendations of the international guidelines and associations (e.g. IDF, ADA, AHA and WHO) to improve discharge planning and the transition from the hospital to home for patients with T2D and ACS.

The findings of qualitative investigations inform that patients with T2D and ACS have numerous and diverse educational and supportive needs and enquires about coping with both multiple long-term conditions (specifically, about diabetes and heart disease) and its effective treatment, which may be difficult to address within the current context of a typical and limited Jordanian treatment and poor follow-up care. Finally, the findings add to the limited evidence about the experience of living with T2D and ACS following a cardiac event, the currant cultural challenges and the organisational and policy deficiencies. However, to manage both conditions adequately and effectively, the findings provide robust qualitative evidence and an in-depth, real-world understanding of the factors and features that helped in the development of new innovative efforts and integrated self-management interventions are need to enable patients and their HCPs to recognise, articulate and response to such needs effectively and in timely manner. The results, can influence how HCPs manage and provide education for patients with multiple comorbidities after ACS by identifying the patients' preferences in regard such as an

appropriate mode of delivery of education, style of education and time of providing education.

### **9.3.3 Development and feasibility testing of the DCSM Intervention**

The study developed a novel integrated self-management intervention for patients with both conditions in a systematic way and according to the well-understanding the actual needs and desires of those patients and in line with perspectives of their HCPs, other stakeholders and an appropriate theoretical framework, this may enable the DCSM Intervention to move forwards to be evaluated by conducting more pilot studies targeting the rest of uncertainties within the Jordanian context. This is the first intervention to take place in Jordan that focused on managing both conditions simultaneously following ACS. This study also developed new, reliable and evidence-based supportive tools (a booklet and log-book) and translated them into Arabic, enabling their use in future Arabic interventional studies with patients with both conditions.

The feasibility testing of the DCSM Intervention contributed to professional knowledge in terms of clinical practice and to that of researchers in the field of the management of adults with diabetes and heart disease. The findings from this study provide evidence of the feasibility and acceptability of the DCSM Intervention in the Jordanian secondary healthcare context. Also, it provides researchers and professionals with important information about all aspects of the development, evaluation and implementation of the intervention in a Jordanian context before they commit to major investments in terms of money, resources and time required for large-scale RCTs. Thus, this study identified elements and effective strategies that reduce threats to such interventions, maximise recruitment and retention rates and build a solid foundation upon which effective RCTs and treatment can be developed in future practice within health care systems.

The Consolidated Standards of Reporting Trials checklist (CONSORT), which is an evidence-based, minimum set of recommendations for facilitating critical appraisal, reporting and interpretation of RCTs (Schulz et al. 2010). Although, this study was non-randomised feasibility study and some items of CONSORT checklist have not discussed such as randomisation procedures, but it has clearly identified many of the 25 principles/items of the checklist such as background and objective, participants,

intervention and outcomes ...etc. Therefore, to minimise or avoid systematic error and bias, and to design, conduct, and report future RCTs appropriately such as CONSORT statement needs to be considered at an early stage of the development of RCT of the DCSM Intervention (Moher, Hopewell and et al. 2010).

#### **9.4 Embracing Systems Theory**

Using systems theory, silos and lack of the integration of care between the various HCPs, HCPs and their patients and between different conditions, care services, environments can be addressed. Which can also help in identifying an overarching goal to address the fragmentation of care and enhance patient care and outcomes (Cordon 2013). Systems theories help to understand and look at the components of the system and its interactions between each other, within the context of the larger system (Anderson 2017).

Any healthcare system has various levels of complexities and stakeholders (e.g. decision makers, organisations and HCPs) who are shape the way in which health care is provided to society. It involves several levels of care, from delivering prevention care, to palliative care. These healthcare systems are complex, and also those patients with multi long-term conditions are living with complex condition and systems (Anderson 2017).

In Jordan, the healthcare system ill-equipped to prevent and treat chronic conditions affectively (Higher Health Council 2015 and WHO 2016). It was obvious that the current practice and professionals have created fragile silos and diverse clinical foci when caring patients with T2D and ACS in clinical settings (Liu et al. 2017). This may cause lack of impact of treatment for those patients (Tanash et al. 2017, Coulter 2010). Or may reflect development, evaluation or implementation failure of interventions (Craig et al. 2013).

For example, as reported in the study I and II there are a lack of connection between patients with T2D and ACS and their HCPs in an appropriate and timely manner. The self-management education and support are lacking in both primary and secondary care settings. There are a number of health inequalities in current care of those patients. It also there is a poor of coordination of care, as no effective communication between HCPs and no systematic appraisal mechanisms for identifying, prioritising and addressing patients' needs systematically. On the other hand, there is some of cultural problem between HCPs, such as the physicians tend to have the dominant view.



Furthermore, it was obvious that there is fractures in Jordanian healthcare systems and delivery of care for those patients, which allow those patients to “fall through the gaps” in care- for example, primary/secondary care services, preventive and curative services, and professionals. Also, often current practice addressing each condition in isolation from another after ACS (Liu et al. 2017 and Tanash et al. 2017). Therefore, by continue caring these long-term conditions in isolation, and without integrating of care for those patients as “a whole case”, according to “patient-centred” approach and within “a whole system” may current practice will continue suffering from the collapse of the patient’s treatment recovery plan, and causing more complexity, confusion and frustrations for patients. According to Kodner and Spreeuwenbur (2002) reported that without integration at various levels of the health systems and care services, all parts of health care performance can suffer. For example, patients get confused, frustrated and lost, needed care fail to be delivered, or are delayed, patient satisfaction and quality of care decline, and the potential for cost-effectiveness diminishes.

Although the DCSM Intervention was feasible, acceptable and shows promise, still a number of pilot studies which will be targeted a number of the key uncertainties in design and evaluation of the intervention, as well as in the implementation process within Jordanian context are urgently needed. Therefore, to support translation of the DCSM intervention into routine practice successfully, using systems-theory-based and well-structured integration model as a framework at early future studies is crucial.

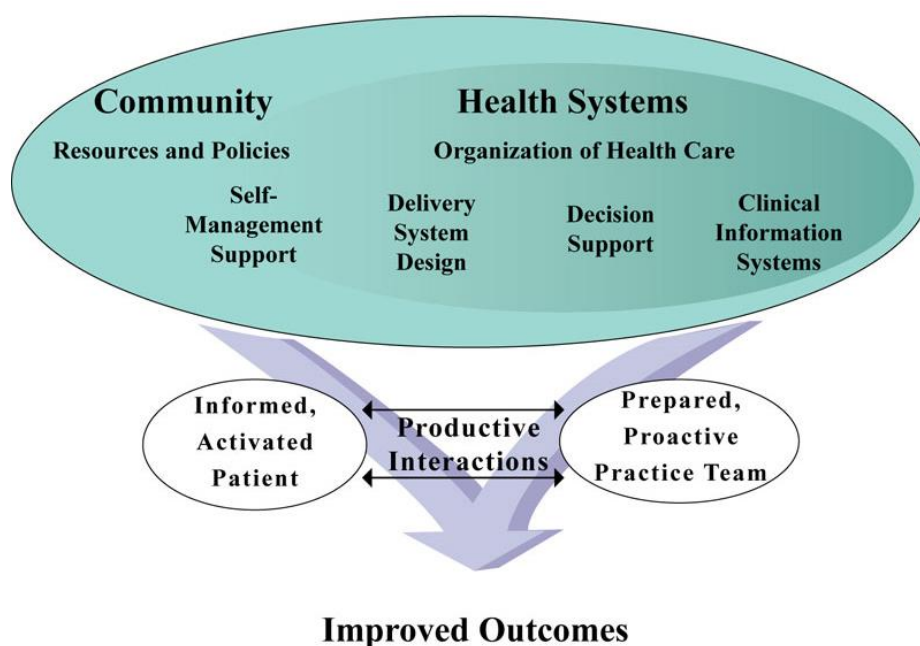
There are a various theories and contemporary conceptual models in each specific filed of since developed from the worldviews of the early philosophers and well-understanding systems and systems thinking. In field of the treatment of the long-term conditions, some countries and researchers have developed various models aimed to provide better integration care for people such as diabetes mellitus and cardiovascular diseases (Cordon 2013).

The chronic care model (CCM) is one of the most well-structured and widely applied integrated care models (Wagner 1998), used to provide a holistic framework for the organisation of health systems and meet needs of patients with long-term conditions. Which are widely documented to have a positive impact on patient outcomes, quality of care and cost savings (WHO 2016). It consists of six main domains as can be seen in

Figure 9.1. which summarizes the basic elements for improving care in health systems at the community, organization, practice and patient levels.

In Jordanian context, the prevalence of cardiac disease, diabetes, other cardiovascular risk factors are high and rising. The current healthcare system and management of these long-term conditions within a “Whole system” have many of deficiencies which need to be considered in designing future studies of assessment the DCSM Intervention. The main of these deficiencies are:

- Lack of care coordination among HCPs.
- The current HCPs do not follow established practice guidelines.
- Lack of planned care and self-management education and support for patients to manage their illnesses effectively.
- Lack of active follow-up to ensure the best outcomes.
- The HCPs inadequately trained to meet patients’ needs and provide reasonable care.



**Figure 9.1: The chronic care model**

developed by (Wagner 1998)

In this study, it seems that the DCSM Intervention focused mainly on improving self-management support domain (system). However, as there is overlapping between the CCM domains and the targeted population are patients with long-term conditions,

changes must be made at all levels of systems to be efficient and catalysts to achieve the changes that needs to happen at the level of the health care system.

Therefore, to overcome these deficiencies the DCSM Intervention needs to help in transformation of Jordanian health care, from a reactive system - responding mainly when an individual is sick with ACS and T2D as example - to proactive system and focused on keeping an individual as healthy as possible after hospital discharge. Moreover, helps in improving integrated care in health systems at the community, organization, practice and patient levels. To do this, **first, in regard the self-management support domain**, an Interdisciplinary specialist care team need to be established to provide the DCSM Intervention. Thus, empower and prepare patients to manage their illness and health care. The members of the team need to be valuable, unified as a team, and identify as a team an overall clinical goal for the patient. The members of the interdisciplinary team need to be trained on using effective self-management education and support strategies that include assessment patient's needs, goal-setting, motivational interviewing, action planning, problem-solving and follow-up care. The team need to use effective arrangements to support patients and family engagement in patient's self-care recovery plan. **Second, in regard the community domain**, the intervention team need to help patients to identify effective community programs/initiatives/activities/practices for Jordanian patients and encourage them to participate in it. **Third, in regard the health system domain**, there is need to promote effective leadership and improvement strategies within all levels of the healthcare system by create a collaborative culture that emphasises team working and the delivery of patient-centred care and highly co-ordinated. **Fourth, in regard the delivery system design domain**, there is urgently need to define roles, responsibilities and distribute tasks among HCPs and the intervention team members, provide care and self-care strategies that patients understand and that fits with their cultural and their socioeconomic status, use planned interactions between the HCPs and patients to support evidence-based care, ensure regular follow-up by the care team through providing planned follow-up phone calls and home visit sessions. **Fifth, in regard the decision support**, embed and share evidence-based guidelines and information with patients to encourage their participation, promote best practice, support care co-ordination across care services and decrease unwarranted variations or gaps in care, also there is need to integrate specialist expertise (e.g. dilatations and diabetes specialists) as possible and primary care. **Six, in regard the clinical information systems**, there is need to promote information technology that

supports the delivery of the DCSM Intervention “integrated care”, and share information of self-education and support with patients and HCPs to coordinate care, especially via the shared electronic medical record.

It’s often hard to attribute outcomes to specific interventions (Craig et al. 2013). However, to assess whether the future DCSM Intervention will be implemented as planned and to explore possible explanations for the outcomes a number of the measure outcomes need to be collected at different multi assessment pointes (baseline, 1 month, 6 months and 1 year). These outcomes include such validated clinical, cognitive and behavioural measures as that used in the feasibility study during this study, quality of life outcomes, evaluation outcomes, interviewing stakeholders, hospital/emergency admissions rates, feasibility and acceptability outcomes.

## **9.5 Strengths of the Study**

The methodology used in this novel study was unique on three levels. Firstly, it involved a specific and robust systematic review to identify relevant evidence about existing RCTs. This review was able to theoretically inform understanding of the related factors and the mechanisms of change underpinning existing interventions. Classifying the various forms of intervention from the data available in published studies is often a challenge (Craig & Petticrew 2013). Although there is limited research in this area, this review could be maintained and updated to inform best practice by accessing the evidence that becomes available in the future.

Secondly, no previous Jordanian study has attempted to explore the supportive care needs of patients with both conditions or the current follow-up care provided for them from the perspective of patients and their HCPs. The participants recruited in both qualitative studies were from two different main referral hospitals in Jordan (a public and a university hospital), and the professionals who took part in the focus groups were experts representing eight disciplines with many years of experience in the management of patients with T2D and ACS. The rigor and trustworthiness of the data were ensured. Thus, both studies provide an in-depth insight into the real-world challenges and unmet needs that patients with both conditions experience on a daily basis after diagnosis with ACS. These data establish a sound foundation to understand the current Jordanian context in regard to those living with both conditions.

Thirdly, the intervention developed in this study based on the best available evidence and appropriate theory and teaching methods. The process was systematic and rigorously conducted in terms that were compatible with recent methodological and practical recommendations and took account of the constraints on developing and evaluating complex interventions. In addition, the educational contents of the intervention and its evaluated outcomes focused on both conditions. A mixture of qualitative and quantitative methods was used to evaluate the feasibility of the intervention. This offered a clear picture with regard to the intervention process, the estimated outcomes and the anticipated confounders in future studies.

## **9.6 Limitations**

Along with the above strengths of the study, a number of limitations should be considered. Those which relate to the systematic review are presented in Chapter 2, Section 2.2.7.

### **9.6.1 Qualitative investigations (Studies I and II)**

All data were collected in Arabic and was then translated into English using a back-translation process. This process was time-consuming and required considerable effort. For example, although rigorous attention was paid to the quality of the translation, some thoughts expressed by the participants may not be adequately conveyed in English. As it was not possible to return the transcripts to all the participants for validation due to time and physical constraints, this may have limited the reporting and rigour of the data. Although having benefitted from some in-depth training courses on qualitative interviewing and analysis, the primary researcher was a novice interviewer. Consequently, he may not have obtained the most in-depth descriptions from the participants about their perspectives, needs or experiences in terms of managing both conditions within the limited time of interviews.

### **9.6.2 Development and feasibility testing the DCSM Intervention**

Although rigorous attention was paid during the process of developing the intervention, it cannot be determined whether changes reported were due to the research intervention per se or to other extraneous variables to which the participants may have been subjected during and after hospitalisation.

Bias may also have been introduced by the use of a self-report questionnaire. As the relationship between the researcher and the participants developed during the intervention, patients may have given the answers they thought the researcher most desired, and this may have led them to offer responses that were less than accurate. This could have an impact on the reliability of the findings.

The duration of delivery and the follow-up period were both short and the latter was limited to one assessment point due to limited resources and the restricted timeframe for this doctoral study.

## **9.7 Recommendations**

The following recommendations are proposed to improve the care of patients with T2D and ACS, highlight areas for improvement in current policies and protocols and help in determining the direction of future health educational interventions.

### **9.7.1 Recommendations for clinical practice**

- Future self-management education and support should focus on treating both chronic conditions and other risk factors with the same degree of importance.
- Before discharging patients from hospital following cardiac events, patients' knowledge, attitude and experience with regard to the management of their long-term conditions should be assessed, and their educational needs prioritised at subsequent reviews. Accordingly, patients should be informed about the self-management of both conditions, and its impact on their daily life in a systematic way (e.g. through the provision of education sessions), in the presence of a family member chosen by the patient if possible. The information provided should be documented consistently in the patient's case notes, or by using a specifically-designed checklist, for use by professionals in future consultations.
- A specified health education professional (e.g. a self-care nurse) should be appointed in cardiac units and centres to provide effective self-management education to patients and their families. This professional should be educated and qualified as a

health educator and have the motivation and skills necessary to provide evidence-based individualised education (Ibanez et al. 2017). This will help to integrate self-management into everyday practice.

- Promote using productive conversations that encourage patients to disclose their needs is needed in clinical practice.
- Innovative effective tools and strategies should be developed to improve understanding of self-management among professionals, patients and carers, for example by developing patient- and family-oriented booklets such as the one used in this study with practical and clear information on coping with both conditions, as well as booklets containing practical information for professionals on how to educate patients about self-management.
- The self-management education and support needs of patients should be identified during their hospitalisation. Together, patients and their healthcare professional(s) should develop a personal self-management plan as soon as they are diagnosed with a chronic disease. This plan should be systematically reviewed and developed over time according to well understanding patient's characteristics and lifestyle.
- Patients should be made aware of the resources and facilities available for ongoing support and education and should be able to access the best option(s) to meet their self-management needs.

### **9.7.2 Recommendations for policy**

- National health strategies and awareness-raising campaigns should be actioned to include the provision of health education services (e.g. rehabilitation centres and referral services) and self-management programmes for all patients with diabetes and coronary heart disease, and such provision should be embedded into clinical practice in secondary care settings, regardless of their socioeconomic status.
- In Jordan, there is an urgent need to involve patients and expert professional representatives in future reviews of national health guidelines and in future research

into the management of chronic diseases to ensure that their perspectives are incorporated, and in order to achieve a patient-centred approach.

- Organisational policies on health education and the management of patients with heart disease and diabetes should be simple, clear and accessible to all professionals. These policies should place greater emphasis on enabling professionals through the provision of the best and most culturally appropriate health education skills and tools.

### **9.7.3 Recommendations for professional education**

- Self-management education and support must be a higher priority in care. The necessary training and facilities should be provided to enable current HCPs to achieve this.
- Encouraging productive discussions regarding self-management education and support for patients, prioritising their needs and planning their goals is highly important. Toward this end, professionals need the necessary training (e.g. the art of communication with patients needing self-management education and support) to access essential knowledge and develop appropriate skills, as well as all the logistic support (e.g. time, place and tools) to educate and support patients effectively are needed to be provided for them.
- The healthcare system must be enhanced via a coordinated interprofessional approach incorporating ongoing communication between HCPs and patients/families in relation to self-management education and support.

## **9.8 Implications for Research**

The following implications for further research are based on the findings of this study:

- Review of the published literature highlights that very little is known about the patients' perspective on coping with both conditions or their associated educational and psychological needs, particularly in LMICs. In-depth exploration of their views on how their needs can be met effectively is required.



- Further systematic reviews are needed to assess the effectiveness of health education-related interventions for patients with T2D and ACS. Such a review should aim to identify optimal features for use in the development of self-management interventions for those patients.
- There is a need to explore how to activate patient, professional and public involvement in the implementation of research and in designing self-management interventions in a Jordanian context, in order to inform relevant guidance with regard to best practice.
- Further studies are needed to explore the needs and experiences of professionals, including any barriers they have encountered, in providing self-management education and support to patients with T2D and ACS in primary and secondary care settings.
- Further quantitative and qualitative investigations should be conducted about the self-management educational and supportive needs of patients with both conditions.
- There is a need for further rigorous experimental studies involving patients with T2D and ACS, starting with a series of feasibility and pilot studies targeting each of the uncertainties and confounders in the design, and within different contexts, before moving on to a larger exploratory study.
- Full-scale RCTs with a longer delivery time (at least 6 months) and duration of follow-up (at least 12 months) are needed to assess the effectiveness of the DCSM Intervention in different settings.

## **9.9 Conclusion**

This study contributes new knowledge to the field. In terms of achieving best practice, it develops a novel and integrated self-management intervention for patients with T2D and ACS in systematic way, using the best available evidence and appropriate theoretical approaches and teaching method. Currently in Jordan those with the serious long-term conditions of type 2 diabetes and acute coronary syndrome do not receive routine education or support to enable them to manage their conditions when discharged. The feasibility study presented in this thesis provides a sound foundation on which healthcare provision to optimise health and well-being of those with these conditions can be developed.

## List of Appendixes

### Appendix 1: Search Terms used in the Search Strategy

	<b>Self-management intervention</b>	<b>Acute coronary syndrome</b>	<b>Type 2 diabetes</b>
<b>Alternative terms (Synonyms)</b>	Self-care; Rehabilitation; Self-Monitoring ; Self Administration ; Activities of Daily Living; Health Education; Patient Education; Patient Participation; Patient compliance; patient adherence; health promotion; Behaviour therapy; Health behaviour; Program evaluation; Modification; Life style/ Interventions or changes; Psychosocial/treatment or therapy or intervention; Self-efficacy; Health care quality; Risk management; Manage risk; Risk care; Care risk; Reduction intervention; Risk prevention	ACS; Angina Pectoris; Heart attack; Heart disease; Cardiac disease; Vascular disease; Coronary disease; Coronary heart disease; CHD; Cardiovascular disease ; CVD; CV; Myocardial infarction; Acute myocardial infarction; Myocardial ischemia ; MI; AMI; Unstable coronary; Unstable angina; Acute angina; Microvascular angina; ST segment elevation myocardial infarction; STEMI; non-ST segment elevation myocardial infarction; NSTEMI; Coronary thrombosis; Acute coronary; Heart infarction; Arteriosclerosis / Atherosclerosis; Cardiac arrest; Macrovascular disease; Microangiopathy/ Microvascular disease/ small vessel disease	Non-insulin dependent diabetes mellitus; NIDDM; Type 2 diabetes mellitus; Type II diabetes mellitus; T2DM; T2D; TIIDM; TIID; Insulin resistance; Hyperinsulinemia; Glucose intolerance; Diabetic; Glycaemic /Glycemic; Hyperglycemia /Hyperglycaemia /Hyperglycaemic /Hyperglycemic; High blood glucose; Blood sugar; Uncontrolled glucose; Abnormal glucose level

## Appendix 2: Reporting quality according to CONSORT

Section/Topic	Item No	Checklist item	Reported on page No				
			1 <sup>st</sup> study	2 <sup>nd</sup> study	3 <sup>rd</sup> study	4 <sup>th</sup> study	Number of studies reported (Total %)
1 <sup>st</sup> Study : (Wu et al. 2012b), 2 <sup>nd</sup> Study: (Wu et al. 2012a), 3 <sup>rd</sup> Study: (Wu et al. 2009), 4 <sup>th</sup> Study: (Soja 2007)							
Title and abstract	1a	Identification as a randomised trial in the title	345	...	...	321	2 (50%)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	345	...	396	321	3 (75%)
Background and objective	2a	Scientific background and explanation of rationale	346	395	396-397	321-623	4 (100%)
	2b	Specific objectives or hypotheses	346	395	397	623	4 (100%)
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	346	395	397	624	4 (100%)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	...	....	....	....	0 (0%)
Participants	4a	Eligibility criteria for participants	347	395	...	623	3 (75%)
	4b	Settings and locations where the data were collected	347	395	...	623	3 (75%)

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	347	395	397	624	4 (100%)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	348	396	397-398	626	4 (100%)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	....	...	....	...	0 (0%)
sample size	7a	How sample size was determined	347	...	397	623	3 (75%)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	...	...	...	...	N/A
<b>Randomisation:</b>							
Sequence generation	8a	Method used to generate the random allocation sequence	346	...	397	623	3 (75%)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	346	...	397	624	3 (75%)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	347	...	...	625	2 (50%)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	348	...	...	...	1 (25%)

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	...	...	...	...	N/A
	11b	If relevant, description of the similarity of interventions	...	...	...	...	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	347	396	397	626	4 (100%)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	347	396	397	626	4 (100%)
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	348	...	397-398	626	3 (75%)
	13b	For each group, losses and exclusions after randomisation, together with reasons	348	...	...	263	2 (50%)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	346	...	397	623	3 (75%)
	14b	Why the trial ended or was stopped	...	...	...	...	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	349	...	...	623	2 (50%)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	349	...	397	626	3 (75%)

Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	349	396	397	626	4 (100%)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	...	...	...	...	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	...	....	....	...	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	350	396	398	626	4 (100%)
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	350	397	398	626	4 (100%)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	...	...	...	327	1 (25%)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	350	396- 397	398- 399	626- 627	4 (100%)
<b>Other information</b>							
Registration	23	Registration number and name of trial registry	.....	...	...	...	0 (0%)
Protocol	24	Where the full trial protocol can be accessed, if available	....	...	...	....	0 (0%)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	351	397	399	....	3 (75%)

### Appendix 3: The summary of the characteristics of included studies

Study & Purpose	Population	Intervention	Outcome measures	Randomisation	Key results
<p><b>1. (Wu <i>et al.</i> 2012b)</b></p> <p><b><u>Purpose</u></b>  <b>Determine whether incorporation of patient peer supports in a cardiac-diabetes self-management program lead to greater improvement in self-efficacy, knowledge and self-management behaviour of those patients</b></p>	<p><u>Inc. criteria</u>            ≥18 years; T2D; admitted to CCU with a critical cardiac event; had mobile phone and able to read and speak English language.</p> <p><u>Exc. criteria</u>            Unable to read and speak English language; or critically ill, unconscious or on respiratory ventilation.</p> <p><u>Sample size</u>            30 patients</p> <p><u>Main diagnosis</u>            ACS = 9 (32%)            Heart failure = 10 (36%)            Other Cardiac conditions = 9 (32%)</p>	<p><u>Includes</u>            1<sup>st</sup>week: 3 face-to-face educational sessions +DVD in CCU            2<sup>nd</sup>week: 1 followed-up telephone call, and 2 text messaging reminders            At 3<sup>rd</sup> &amp; 4<sup>th</sup>week: follow-up telephone.</p> <p><u>Providers:</u>            Main researcher+ trained peers</p> <p><u>Framework</u>            Self-efficacy theory</p> <p><u>Setting</u>            CCU + patient's home</p> <p><u>Country</u>            Australia</p>	<p>1. Self-efficacy            2. Self-management behaviour            3. Self-management Knowledge</p> <p><u>Analysis:</u>            Descriptive, Using SPSS v18.            -P&lt;0.05</p>	<p><u>Allocation</u>            Table of random numbers.</p> <p><u>Concealment</u>            sealed, numbered, opaque envelopes</p> <p><u>Implementation</u>            Not reported</p> <p><u>Blinding</u>            No</p>	<p><u>Similarity</u>            - No significant difference between the 2 groups for material status, diagnoses, age, knowledge, self-efficacy and self-care behaviour levels at baseline outcomes.            - Only a significant difference for gender (Control group:12male/ 1 female and Interventional group: 8male / 7 female).</p> <p><u>Findings</u>            - Mann–Whitney U-tests indicated a significantly higher level of knowledge (Z=1.9, P=0.05) for the interventional group.            - No significant difference (P&gt;0.05) between the two groups for self-efficacy and self-care behaviour.</p> <p><u>Limitations</u>            - Small sample size            - Intervener effects (trained research nurse).            - Consistency between research staff and training of peers (lack of detailed training manual).            - Insufficient number of training sessions for peer supporters thus, low in familiarity with the process of supporting patients.            - Insensitivity of tools            - Short follow-up period</p>

<p><b>2. Wu et al. 2012a</b>  <b><u>Purpose</u></b>  <b>Pilot test feasibility of the cardiac-diabetes self-management program incorporating telephone and text-messaging as follow-up approaches</b></p>	<p><u>Inc. criteria</u>  Patients with T2D and cardiac conditions who recovered from the initial critical cardiac event; physically stabilised; ready to receive information and participate in discussion about their ongoing care</p> <p><u>Exc. criteria</u>  Not reported</p> <p><u>Sample size</u>  20 patients</p> <p><u>Main Diagnosis</u>  T2D and critical cardiac event</p>	<p><u>Includes</u>  1<sup>st</sup>week: 3 face-to-face educational sessions + educational booklet in CCU  2<sup>nd</sup>week: follow-up telephone call  3<sup>rd</sup>&amp;4<sup>th</sup>week: follow-up text-messages</p> <p><u>Provider:</u>  The nurse researcher (highly trained RNs)</p> <p><u>Framework</u>  Self-efficacy theory</p> <p><u>Setting</u>  CCU</p> <p><u>Country</u>  Australia</p>	<p>1. Self-management behaviour  2. Self-efficacy  3. Quality of life indicators of fatigue and depression.  4. Diabetes Knowledge</p> <p><u>Analysis</u>  Descriptive, Using SPSS v18.  - P&lt;0.05</p>	<p>Mechanism of both allocation, concealment and implementation are not reported</p> <p><u>Blinding</u>  No</p>	<p><u>Similarity</u>  - Overall, demographic and baseline data are not reported, the only data provided were about the mean score of self-efficacy for each group (around 125 of 200).</p> <p><u>Findings</u>  - Significant improvements for the experimental groups in self-efficacy (the mean about 175 of 200 for the interventional group and 140 for control group at T2).  - No significant improvements for each of knowledge, self-care behaviour, fatigue and depressed levels.  - Slight improvement without significance, in level of self-care behaviour.  - Feedback and comments of participants and their family indicated that follow-up telephone helped to resolve some of patients' concerns, and felt that they were supported by health professional. And the text-messaging reminders provide some usefulness toward continuing their daily self-management activities such as compliance with medication and diet.</p> <p><u>Limitations</u>  - Small sample size  - Poor reporting  - Insensitivity of tools  - Short follow-up period</p>
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<p><b>3. Wu et al. 2009</b>  <b><u>Purpose:</u></b>  <b>develop and pilot test a cardiac–diabetes self-management program using an experimental design.</b></p>	<p><u>Inc. criteria</u>  Patients admitted to CCU with cardiac problem and have T2D; physically stabilised.</p> <p><u>Exc. criteria</u>  Not reported</p> <p><u>Sample size</u>  28 patients</p> <p><u>Main Diagnosis</u>  Not reported</p>	<p><u>Includes</u>  1<sup>st</sup>week: 3 educational sessions in CCU  2<sup>nd</sup>week: 1 home visit  3<sup>rd</sup>&amp;4<sup>th</sup>week: follow-up phone calls</p> <p><u>Provider:</u>  The main researcher</p> <p><u>Framework</u>  Self-efficacy theory</p> <p><u>Setting</u>  CCU + patents home.</p> <p><u>Country</u>  Australia</p>	<p>1. Mental health and vitality.  2. Diabetes Knowledge  3. Self-Efficacy  4. Feasibility of intervention.</p> <p><u>Analysis</u>  Descriptive, Using SPSS v18.  - P&lt;0.05</p>	<p><u>Allocation</u>  computer-generated table of random numbers</p> <p><u>Concealment</u>  Not reported</p> <p><u>Implementation</u>  Not reported</p> <p><u>Blinding</u>  No</p>	<p><u>Similarity</u>  No significances found in gender, material status and disease data between the 2 groups.</p> <p><u>Findings</u>  - Significant improvements in knowledge levels (from mean score 4 at T1 to 7 at T2) and no significant improvement in self-efficacy.  - The feedback and comments of patients and staff indicated that the programme is feasible to implement in CCU with follow up at home. Because it provided viable information to promote patients’ self-management behaviours. And the staff showed their interest in this intervention to providing more appropriate care to the patients.</p> <p><u>Limitations</u>  - Small simple size  - Insensitivity of tools  - Short follow-up period</p>
<p><b>4. Soja et al. 2007</b>  <b><u>Purpose:</u></b>  <b>Evaluate if an integrated approach of treatment would result</b></p>	<p><u>Inc. criteria</u>  Had T2D and Impaired glucose tolerance (IGT); Patients admitted with ischemic heart disease, congestive heart failure, or high-risk cardiovascular patients</p>	<p><u>Includes</u>  The first six weeks: patient education, supervised exercise training (90 minutes of training twice a week), nutritional counseling,</p>	<p>Clinical, biochemical and medication outcomes</p> <p><u>Analysis</u></p>	<p>Allocation, concealment and implementation all not reported</p> <p><u>Blinding</u>  No</p>	<p><u>Similarity</u>  The randomization was well balanced with no statistical difference at baseline between the two groups.</p> <p><u>Findings</u>  - Patients with T2D in the intervention group attained a significantly greater mean</p>

<p><b>in a better glycemic control and improve clinical outcome.</b></p>	<p>with at least 3 classic risk factors.</p> <p><u>Exc. criteria</u> Severe noncardiovascular disease, New York Heart Association stage IV, unstable patients awaiting revascularization, severe abuse of alcohol and sedatives, dementia patients</p> <p><u>Sample size</u> Overall in the study 201 patients, with T2D 68 patients</p> <p><u>Main Diagnosis:</u> Ischemic heart disease (67%); Congestive heart failure (7%); At least 3 risk factors for ischemic heart disease (26%).</p>	<p>supervised cooking lessons on location, smoking cessation, psychosocial support including a 24hr telephone line, pharmacologic therapy, and risk factor management supported by a minimum of consultations by a physician after 3, 6, and 12 months; The program integrated with diabetes module (3 interactive teaching sessions of 2.5 hr each with in-depth information of self-care principles involving symptoms of peripheral arterial insufficiency, diabetic neuropathy, nephropathy, and retinopathy.</p> <p><u>Provider:</u></p>	<p>The SAS (version 8.2, SAS Institute, Cary, NC) statistical package - 2-sided P &lt;0.05</p>	<p>reduction in HbA1c, fasting plasma glucose, and blood pressure (diastolic &amp; systolic) than those in the control group.</p> <p>- By the end of the study, patients with T2D in intervention group received a more intensified pharmacotherapy than those in the control group such as angiotensin converting enzyme inhibitor–angiotensin II receptor, antagonist (ACEI/ARA) and metformin.</p> <p><u>-Limitations:</u> - It is not possible to evaluate which is the most important among the components in the combined risk factor management program. - There was a difference in pharmacotherapy treatment between the 2 study groups. - Focus on clinical and biomedical outcome only</p>
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		Multi-professional health team  <u>Framework</u> Several International guidelines <u>Setting:</u> University Hospital <u>Country</u> Denmark			
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## Appendix 4: PDF of systematic review



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REVIEW

## An evaluation of the effectiveness of self-management interventions for people with type 2 diabetes after an acute coronary syndrome: a systematic review

Mu'ath Ibrahim Tanash, Donna Fitzsimons, Vivien Coates and Christi Deaton

**Background.** Type 2 diabetes is highly prevalent in patients with acute coronary syndrome and impacts negatively on health outcomes and self-management. Both conditions share similar risk factors. However, there is insufficient evidence on the effectiveness of combined interventions to promote self-management behaviour for people with diabetes and cardiac problems. Identifying critical features of successful interventions will inform future integrated self-management programmes for patients with both conditions.

**Objectives.** To assess the evidence on the effectiveness of existing interventions to promote self-management behaviour for patients presenting with acute coronary syndrome and type 2 diabetes in secondary care settings and postdischarge.

**Design.** We searched MEDLINE, PubMed, CINAHL Plus, PsycInfo, Cochrane Library and AMED for randomised controlled trials published between January 2005–December 2014. The search was performed using the following search terms of 'acute coronary syndrome', 'type 2 diabetes' and 'self-management intervention' and their substitutes combined.

**Results.** Of 4275 articles that were retrieved, only four trials met all the inclusion criteria (population, intervention, comparison and outcome) and were analysed. Overall, the results show that providing combined interventions for patients with both conditions including educational sessions supported by multimedia or telecommunication technologies was partially successful in promoting self-management behaviours. Implementation of these combined interventions during patient's hospitalisation and postdischarge was feasible. Intervention group subjects reported a significant improvement in self-efficacy, level of knowledge, glycated haemoglobin, blood pressure and fasting glucose test. However, there are many threats have been noticed around internal validity of included studies that could compromise the conclusions drawn.

**Conclusion.** With limited research in this area, there was no final evidence to support effectiveness of combined interventions to promote self-management

### What does this article contribute to the wider global clinical community?

- Clinicians need to be aware that the processes of validating the contents of combined interventions for patients with diabetes and cardiac problems are poorly described to date and there is a limited evidence base to work from, so integrated interventions need to be further developed and tested.
- Opens researchers' eyes to critical features and limitations of existing combined interventions designed for patients with T2D and ACS. And, there is also an importance of combining technology with high-quality self-management interventions for patients with multiple chronic conditions that may contribute to effective health outcomes such as reduce a rehospitalisation, mortality and morbidity rates.
- Further research is needed to develop robust combined self-management interventions including an evaluation of cost-effectiveness of implementing such interventions.

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behaviour for patients with type 2 diabetes and acute coronary syndrome. Sufficiently powered, good quality, well-conducted and reported randomised controlled trials are required.

**Key words:** caring intervention, coronary heart disease, heart disease, intervention, randomised controlled trials, self-care, self-management, type 2 diabetes

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## Introduction

Type 2 Diabetes (T2D) is a metabolic disorder, leading to hyperglycaemia and vascular complications such as stroke and myocardial infarction (MI) (WHO 2015). Where T2D and MI coexist, these conditions generate high levels of mortality and morbidity worldwide; for example, 52% of fatalities of patients with T2D are related to cardiovascular disease (CVD) (Morrish *et al.* 2001). Recently, because of the relentless increase in incidence of diabetes worldwide (Yiling *et al.* 2013), it has been classed a global epidemic (Lorber 2014), affecting about 381.8 million (8.3%) adults; this number is expected to nearly double by 2035 (International Diabetes Federation 2013). However, despite patients' efforts to control their diabetes, data indicate that many will be faced with a CVD, mainly an acute coronary event (Kasteleyn *et al.* 2014). The strength of the pathophysiological link between both conditions means they share many associated risk factors contributing to increasing the risk of developing both conditions, such as hyperglycaemia, obesity, lack of physical activity, hypertension and high cholesterol (American Heart Association 2013).

The global registry of acute coronary events conducted a multinational prospective study of 16,116 patients hospitalised with an acute coronary syndrome (ACS) (5403 with ST-elevation MI, 4725 non-ST-elevation MI and 5988 unstable angina). The study reported that one in four patients with ACS suffered from diabetes (Franklin *et al.* 2004). In another recent national study conducted in Jordan and Saudi Arabia, the prevalence of diabetes in patients with ACS was more than a half (Alnemer *et al.* 2012, Saleh *et al.* 2012, Hammoudeh *et al.* 2013). Undoubtedly, the combination of both conditions considerably decreases patients' quality of life (Wermeling *et al.* 2012, Uchmanowicz *et al.* 2013) and increases the risk of adverse outcomes (Franklin *et al.* 2004), symptom distress and self-management difficulties (Deaton *et al.* 2006), readmissions to the hospital for other cardiovascular events (Saleh *et al.* 2012), and increased risk of mortality at 30 days and one year post-ACS event (Donahoe *et al.* 2007).

Several studies and guidelines emphasise the importance of improving discharge planning for all hospitalised patients with diabetes and cardiac problems beginning from the first day of admission through assessment of the patients' overall understanding of their conditions and checking their ability to perform self-management tasks immediately after discharge (American Diabetes Association 2012, Malaskovitz & Hodge 2014). Management of ACS and T2D are often complex and encompass several regimens that the patients have to implement to improve outcomes of their condition (Radhakrishnan 2012), and there is a potential for conflicts between these two treatment regimens that may compromise adherence (Cha *et al.* 2012). Self-management interventions are one of the key strategies contributing to the improvement of patients' outcomes, minimising their morbidity and mortality risks (Kasteleyn *et al.* 2014). However, such interventions, up to the present, have generally lacked integration and individualisation despite T2D and ACS sharing similar risk factors (Mayo Clinic 2014), so a combined intervention that meets the needs of this growing population would be logical and urgently needed.

To date, there is no particular definition of 'self-management intervention'. Based on current literature, Galdas *et al.* (2015) describe a self-management intervention as any intervention primarily tailored to develop cognitive and behavioural abilities and capabilities of patients to manage their conditions effectively through providing different types of support, training and education. However, tailoring such interventions requires assessment of the needs and abilities of the patients through initial evaluation of individual's characteristics, and based on this evaluation, the feedback should be more personalised. Evidence suggests that patients can be more motivated if they perceive that the intervention is relevant to their personalised condition and they believe that the intervention can enable them to achieve positive outcomes (Radhakrishnan 2012). Thus, the process of developing effective interventions could be expensive, taking both time and effort (Stellefson *et al.* 2008). Moreover, integrating the management of diabetes and cardiac problems is a complex and challenging process

(Dunbar *et al.* 2015). This calls for an urgent need to justify the evidence, cost and resources used in developing, implementing and evaluating combined interventions for managing individuals with long-term conditions.

In line with current developments in intervention development and information technology, health behaviour change interventions are increasingly research based (Noar *et al.* 2007). Healthcare professionals also believe that the health outcomes of patients with long-term conditions will improve if patients are motivated and feel involved in self-managing the complex treatment regimen (Noar *et al.* 2007, Riegel *et al.* 2009). Therefore, through this review of randomised controlled trials (RCTs) 'the gold standard', the authors' aim was to evaluate the evidence on the effectiveness of existing interventions to promote self-management behaviour for patients presenting with ACS following T2D in secondary care settings and shortly after discharge from hospital.

## Methods

### Search methods

Comprehensive electronic searches were conducted on MEDLINE (Ovid SP Version), PubMed, CINAHL Plus, PsycInfo, Cochrane Library and AMED and limited to the studies published in the English language and the period 2005–2014. The search was undertaken in February 2015.

Three main keyword clusters were used related to T2D, ACS and self-management interventions. To discover relevant synonyms for the main keywords, a list of relevant terms for each cluster was created by reviewing the appendices of relevant reviews in the Cochrane Library and including Medical Subject Headings. Subsequently, 27, 35 and 21 synonyms were identified to explore self-management intervention, ACS and T2D, respectively, and are presented in Table 1. Headings and subheadings for all keywords were exploded without focusing a heading during the search. Abbreviations, truncation (\*,\$), wildcards (?,#), proximity searching (*adjn*, *NEAR/n*, *W/n*) and Boolean (*and*, *or*, *not*) were used as appropriate with each database to identify keywords with different spelling and terms. Final results of the search for keywords for population, intervention, comparison and outcomes (PICO; van Loveren & Aartman 2007) were combined together using (*and*). Then, the results of the search were limited to adults aged 18 years or over, humans and RCTs using validated filters with each database such as for RCTs Cochrane Highly Sensitive Search Strategy to identify randomised trials in MEDLINE: (sensitivity and precision maximising version (2008 revision)). Ovid format was used for MEDLINE database. Full copies of the printed searches are available from the main author. Identified duplicates were removed. Also, references lists of retrieved trials were manually reviewed to identify any other relevant studies.

**Table 1** Alternative terms for key words

	Self-management intervention	Acute coronary syndrome	Type 2 diabetes
Alternative terms (Synonyms)	Self-care; Rehabilitation; Self-Monitoring; Self Administration; Activities of Daily Living; Health Education; Patient Education; Patient Participation; Patient compliance; patient adherence; health promotion; Behaviour therapy; Health behaviour; Program evaluation; Modification; Life style/ Interventions or changes; Psychosocial/treatment or therapy or intervention; Self-efficacy; Health care quality; Risk management; Manage risk; Risk care; Care risk; Reduction intervention; Risk prevention	ACS; Angina Pectoris; Heart attack; Heart disease; Cardiac disease; Vascular disease; Coronary disease; Coronary heart disease; CHD; Cardiovascular disease;CVD; CV; Myocardial infarction; Acute myocardial infarction; Myocardial ischemia; MI; AMI; Unstable coronary; Unstable angina; Acute angina; Microvascular angina; ST segment elevation myocardial infarction; STEMI; non-ST segment elevation myocardial infarction; NSTEMI; Coronary thrombosis; Acute coronary; Heart infarction; Arteriosclerosis/ Atherosclerosis; Cardiac arrest; Macrovascular disease; Microangiopathy/Microvascular disease/Small vessel disease	Non insulin dependent diabetes mellitus; NIDDM; Type 2 diabetes mellitus; Type II diabetes mellitus; T2DM; T2D; THDM; TIID; Insulin resistance; Hyperinsulinemia; Glucose intolerance; Diabetic; Glycaemic/Glycemic; Hyperglycemia/Hyperglycaemia/ Hyperglycaemic/Hyperglycemic; High blood glucose; Blood sugar; Uncontrolled glucose; Abnormal glucose level

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### Search outcome

In total, the search yielded the identification of 6032 studies. Of which, 808 studies were retrieved from MEDLINE (Ovid SP Version), 2887 PubMed, 832 CINAHL Plus, 176 PsycInfo, 1325 Cochrane Library and only four from AMED. A total of 1757 duplicates were removed. Thus, the title and abstract of 4275 studies were screened by the main author in accordance with the following inclusion and exclusion criteria that were developed *a priori* of the search according to PICO format (van Loveren & Aartman 2007).

### Population

Male or female, aged 18 or over from all ethnicities, socioeconomic and educational backgrounds, diagnosed with T2D (established or newly diagnosed), and recently experienced coronary event with at least one of the ACS classification. However, for example, studies that included both types of diabetes (1 and 2) participants, in which the results could not be extracted for participants with T2D only, were excluded.

### Intervention

Interventions designed for patients with T2D following a coronary event, delivered by any healthcare professional/researcher and targeted to promote self-management and health outcomes for those patients diagnosed with diabetes and ACS in secondary care settings and/or after discharge from hospital. Studies where the target intervention was a part of complex intervention, where its effects could not be isolated, were excluded.

### Comparison

Usual care groups were compared against the groups that received usual care plus the intervention.

### Outcomes

Any behavioural outcome such as self-care behaviour changes, dietary control, physical activity modification and adherence to medication; clinical outcomes such as HbA1c, blood pressure and cholesterol level; or psychological health outcomes such as self-efficacy, quality of life, knowledge and compliance level.

A total of 4210 studies were excluded in accordance with our criteria. Full-text articles were obtained for the remaining 65 studies and examined in more depth by the main author. Sixty-one studies were excluded, and some of these studies that were excluded included more than one reason. The reasons for exclusion were categorised into inappropriate in: Population (90.2%, did not include both conditions

or did not focus on patients with diabetes post-ACS); Intervention (39.3%, for example primary care interventions, not designed to be provided immediately after ACS or focused on evaluating the effects of a specific treatment such as a medication); Comparison (14.8%, no control group or the control group received an alternative treatment such as a specific procedure related to medication or diet); Research design (4.9% no evidence of randomisation); and other (9.8%/6 studies: three protocols, one conference abstract, one unavailable full-text and one duplicate). See Fig. 1.

The preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Guidelines was used to structure the review, and the flow of information through the four phases of the systematic review is outlined in a Fig. (2) as recommended by Moher *et al.* (2015).

### Data extraction and quality assessment

All titles, abstracts and full-texts identified were analysed according to our criteria by the main author. The reporting quality of each included study was assessed using the Consolidated Standards of Reporting Trials checklist (25-item checklist CONSORT) (Schulz *et al.* 2010). The reporting quality is shown in Table 2. The CONSORT checklists for the final included studies are available from the main author. The methodological quality was assessed independently by the main and second author using the Scottish Intercollegiate Guidelines Network (SIGN) 13-item methodology checklist for RCTs (Scottish Intercollegiate Guidelines Network 2012). The items are especially designed to assess the internal validity by a series of statements. Based on responses, overall assessment for methodological quality was reported using following coding system (++) for high-

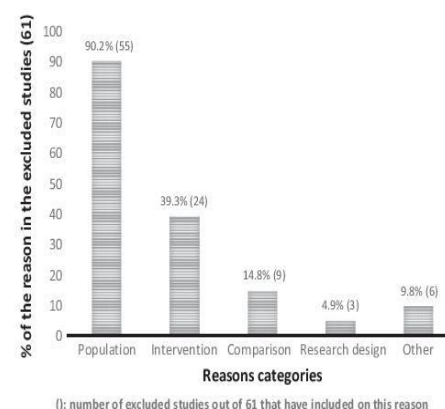


Figure 1 Reasons for exclusion.

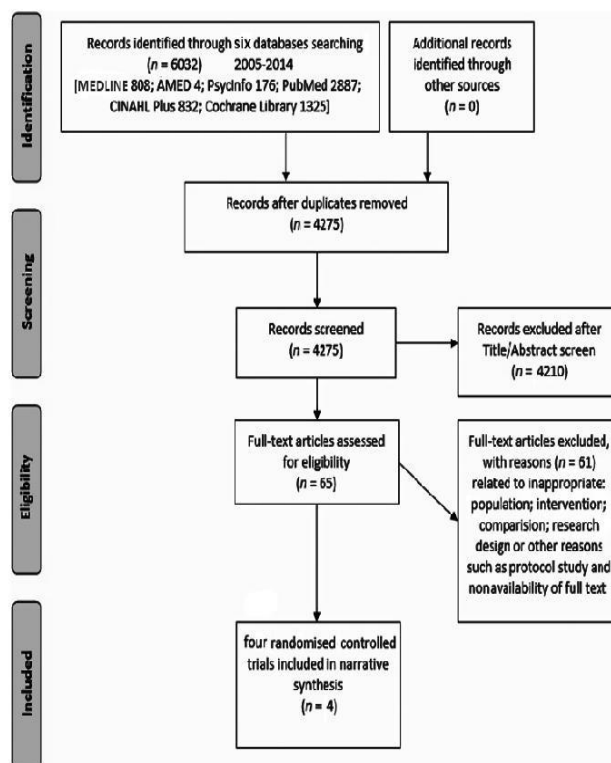


Figure 2 PRISMA flow chart.

quality study, + acceptable and 0 low quality). All differences in scoring were discussed between the two raters, and the quality rating was reached through a consensus of opinion between the raters.

### Data synthesis

The included studies varied in criteria in terms of eligibility, intervention characteristics and outcome results; therefore, the extracted data could not be analysed quantitatively. Consequently, a decision was taken to provide a narrative synthesis as recommended by the PRISMA statement (Moher *et al.* 2015). The percentage of participants and dropouts were calculated for each study. The summary results of the characteristics of population, intervention, outcome measures, randomisation procedure and key results were identified. A summary of the studies characteristics is shown in Table 3.

### Results

Four RCTs were identified. Two of them were pilot studies, and a decision was taken to include them, as combined

interventions to promote self-management behaviour for patients with T2D immediately after an acute cardiac event are underway and there is a need to consider each lesson that could be drawn from these studies even they were of a small scale or poorly reported. Understanding the key features of such studies may inform the direction in which to develop the structure and evaluate the feasibility of combined interventions to be used in future research. The results from a total of 146 patients are presented. The four trials included, and their characteristics are shown in Table 4.

Based on the SIGN checklist (Scottish Intercollegiate Guidelines Network 2012), the methodological quality of one of the identified trials was high quality (++) (Soja *et al.* 2007), and three were acceptable (+) (Wu *et al.* 2009, 2012a,b).

### Countries and settings

Three of identified trials were conducted in Australia and one in Denmark. All the trials took place in an acute hospital setting with most patients recruited from the department of cardiology such as a coronary care unit (CCU) or cardiac



Table 2 Reporting quality according to CONSORT

Description	Checklist item	N	%	
Title and abstract	1a	2	50	
	1b	3	75	
Introduction				
	Background and objectives	2a	4	100
		2b	4	100
Methods				
	Trial design	3a	4	100
		3b	0	0
	Participants	4a	3	75
		4b	3	75
	Interventions	5	4	100
	Outcomes	6a	4	100
		6b	0	0
	Sample size	7a	3	75
		7b	N/A	
	Randomisation: Sequence generation	8a	3	75
		8b	3	75
	Allocation: Concealment mechanism	9	2	50
	Implementation	10	1	25
	Blinding	11a	N/A	
11b				
Statistical methods	12a	4	100	
	12b	4	100	
Results				
	Participant flow	13a	3	75
		13b	2	50
	Recruitment	14a	3	75
		14b	N/A	
	Baseline data	15A	2	50
	Numbers analysed	16	3	75
	Outcomes and estimation	17a	4	100
		17b	N/A	
	Ancillary analyses	18	N/A	
	Harms	19	4	100
	Discussion			
Limitations		20	4	100
Generalisability		21	1	25
Interpretation	22	4	100	
Other information				
	Registration	23	0	0
	Protocol	24	0	0
Funding	25	3	75	

rehabilitation setting. Patients in all included studies were invited to participate immediately after physiological recovery from cardiac problem.

#### Participants, diagnosis and study arms

Two studies included patients who had T2D and had recovered from a coronary event without reporting any further classification about the diagnosis (Wu *et al.* 2009, 2012a). One included patients with T2D who had recovered from ACS

(32%), other coronary conditions (32%) or heart failure (36%) (Wu *et al.* 2012b). Three studies incorporated a two-arm trial design (Wu *et al.* 2009, 2012a,b), while one incorporated four arms and included patients who had either T2D (65.4%) or impaired glucose tolerance (IGT) (34.6%) and had been admitted to hospital with either ischaemic heart disease (67%), congestive heart failure (7%), or had at least three risk factors for ischaemic heart diseases (26%) (Soja *et al.* 2007).

#### Baseline data and similarity

Sample sizes ranged from 20–68 participants. The main purpose of randomisation in RCTs is to achieve interventional groups with similar baseline characteristics. To promote internal validity, assessing the significance of differences between the two groups at baseline is essential (Sedgwick 2014). Significant differences between two groups at baseline were reported in three studies. Two of them reported no substantial difference (Soja *et al.* 2007, Wu *et al.* 2009), and one found a significant difference in gender, where the control group included only one female of 13 participants, and this perhaps has affected the study outcome (Wu *et al.* 2012b). However, inadequate information about the differences in characteristics between groups at baseline was observed in these three studies, where some related and influential factors such as educational level, social classification and employment status were not taken into account. Moreover, one study did not mention any demographic data or describe the differences between the two groups at baseline (Wu *et al.* 2012a). Failure to use appropriate groups and assess the important differences in the composition of the study groups at baseline with regard to characteristics that could affect response to the intervention being investigated could lead to a bias in outcomes (Scottish Intercollegiate Guidelines Network 2012).

#### Dropout, duration of intervention and follow-up time

Dropout rates ranged from 6–28% with an average of 15.15% in three studies, one study reported loss to follow-up (Wu *et al.* 2012b). The duration of the intervention was 4 weeks, and the follow-up data were collected immediately after the intervention was completed in three studies (Wu *et al.* 2009, 2012a,b). While in one study, the duration was 12 months and the follow-up data were collected at 3 and 12 months. (Soja *et al.* 2007). See Table 3.

#### Intervention characteristics

The intervention of two trials was a Cardiac-Diabetes Self-Management Programme (CDSMP) whose design was

Table 3 The summary of the characteristics of included studies

Study & Purpose	Population	Intervention	Outcome measures	Randomisation	Key results
<p>1 Wu <i>et al.</i> (2012b)</p> <p>Purpose Determine whether incorporation of patient peer supports in a cardiac-diabetes self-management program (CDSMP) lead to greater improvement in self-efficacy, knowledge and self-management behaviour</p>	<p><i>Incl. criteria</i> ≥18 years; T2D; admitted to CCU with a critical cardiac event; had mobile phone and able to read and speak English.</p> <p><i>Exc. criteria</i> Unable to read and speak English; or critically ill, unconscious or on respiratory ventilation.</p> <p><i>Main diagnosis</i> ACS = 9 (32%) Heart failure = 10 (36%) Other Cardiac conditions = 9 (32%)</p>	<p><i>Includes</i> 1st week: 3 face-to-face educational sessions +DVD in CCU 2nd week: 1 followed-up telephone call, and 2 text messaging reminders At 3rd &amp; 4th week: follow-up telephone.</p> <p><i>Providers</i> Main researcher+ trained peers</p> <p><i>Framework</i> Self-efficacy theory</p> <p><i>Setting</i> CCU + patient's home. Australia</p>	<p>1 Self-efficacy 2 Self-management behaviour 3 Self-management Knowledge</p> <p><i>Analysis</i> Descriptive, Using spss version 18. <math>p &lt; 0.05</math></p>	<p><i>Allocation</i> Table of random numbers. <i>Concealment</i> sealed, numbered, opaque envelopes <i>Implementation</i> NA <i>Blinding</i> No</p>	<p><i>Similarity</i></p> <ul style="list-style-type: none"> <li>No significant difference between the 2 groups for material status, diagnoses, age, knowledge, self-efficacy and self-care behaviour levels at baseline outcomes</li> <li>Only a significant difference for gender (CG:12M/1F and IG: 8M/7F)</li> </ul> <p><i>Findings</i></p> <ul style="list-style-type: none"> <li>Mann-Whitney U-tests indicated a significantly higher level of knowledge (<math>Z = 1.9, p = 0.05</math>) for the IG</li> <li>No significant difference (<math>p &gt; 0.05</math>) between the two groups for self-efficacy and self-care behaviour</li> </ul> <p><i>Limitations</i></p> <ul style="list-style-type: none"> <li>Small sample size</li> <li>Intervener effects (trained research nurse)</li> <li>Consistency between research staff and training of peers (lack of detailed training manual)</li> <li>Insufficient number of training sessions for peer supporters thus, low in familiarity with the process of supporting patients</li> <li>Insensitivity of tools</li> <li>Short follow-up period</li> </ul>

Table 3 (continued)

Study & Purpose	Population	Intervention	Outcome measures	Randomisation	Key results
<p>2 Wu <i>et al.</i> (2012a)</p> <p><b>Purpose</b></p> <p>Pilot test feasibility of the GDSMP incorporating telephone and text-messaging as follow-up approaches</p>	<p><b>Incl. criteria</b></p> <p>Patients with T2D and cardiac conditions who recovered from the initial critical cardiac event; physically stabilised; ready to receive information and participate in discussion about their ongoing care</p> <p><b>Exc. criteria</b></p> <p>Not reported</p> <p><b>Main Diagnosis</b></p> <p>T2D and critical cardiac event</p>	<p><b>Includes</b></p> <p>1st week: 3 face-to-face educational sessions + educational booklet in CCU</p> <p>2nd week: follow-up telephone call</p> <p>3rd &amp; 4th week: follow-up text-messages</p> <p><b>Provider</b></p> <p>The nurse researcher (highly trained RNs)</p> <p><b>Framework</b></p> <p>Self-efficacy theory</p> <p><b>Setting</b></p> <p>CCU</p> <p>Australia</p>	<p>1 Self-management behaviour</p> <p>2 Self-efficacy</p> <p>3 Quality of life indicators of fatigue and depression</p> <p>4 Diabetes Knowledge</p> <p><b>Analysis</b></p> <p>Descriptive, Using spss version 18.  <math>p &lt; 0.05</math></p>	<p>Mechanism of both allocation, concealment and implementation are not reported</p> <p><b>Blinding</b></p> <p>No</p>	<p><b>Similarity</b></p> <ul style="list-style-type: none"> <li>Overall, demographic and base line data are not reported, the only data provided were about the mean score of self-efficacy for each group (around 125 of 200)</li> </ul> <p><b>Findings</b></p> <ul style="list-style-type: none"> <li>Significant improvements for the experimental groups in self-efficacy (the mean about 175 of 200 for the IG and 140 for CG at T2)</li> <li>No significant improvements for each of knowledge, self-care behaviour, fatigue and depressed levels</li> <li>Slight improvement without significance, in level of self-care behaviour</li> <li>Feedback and comments of participants and their family indicated that follow-up telephone helped to resolve some of patients' concerns, and felt that they were supported by health professional. And the text-messaging reminders provide some usefulness toward continuing their daily self-management activities such as compliance with medication and diet.</li> </ul> <p><b>Limitations</b></p> <ul style="list-style-type: none"> <li>Small sample size</li> <li>Poor reporting</li> <li>Insensitivity of tools</li> <li>-Short follow-up period</li> </ul>

Table 3 (continued)

Study & Purpose	Population	Intervention	Outcome measures	Randomisation	Key results
3 Wu <i>et al.</i> (2009) Develop and pilot test a Cardiac-Diabetes Self-Management Program (CDSMP) using an experimental design	<i>Inc. criteria</i> Patients admitted to CCU with cardiac problem and have T2D; physically stabilised. <i>Exc. criteria</i> Not reported <i>Main Diagnosis</i> Not reported	<i>Includes</i> 1st week: 3 educational sessions in CCU 2nd week: 1 home visit 3rd & 4th week: follow-up phone calls <i>Provider</i> The main researcher <i>Framework</i> Self-efficacy theory <i>Setting</i> CCU + patients home, Australia	1 Mental health and vitality 2 Diabetes Knowledge 3 Self-Efficacy 4 Feasibility of intervention <i>Analysis</i> Descriptive, Using spss version 18. $p < 0.05$	<i>Allocation</i> computer-generated table of random numbers <i>Concealment</i> NA <i>Implementation</i> NA <i>Blinding</i> No	<i>Similarity</i> • No significances found in gender, marital status and disease data between the 2 groups <i>Findings</i> • Significant improvements in knowledge levels (from mean score 4 at T1 to 7 at T2) and no significant improvement in self-efficacy • The feedback and comments of patients and staff indicated that the programme is feasible to implement in CCU with follow up at home. Because it provided viable information to promote patients self-management behaviours. And the staff showed their interest in this intervention to providing more appropriate care to the patients <i>Limitations</i> • Small sample size • Insensitivity of tools • Short follow-up period

Table 3 (continued)

Study & Purpose	Population	Intervention	Outcome measures	Randomisation	Key results
4 Soja et al. (2007) Purpose Evaluate if an integrated approach of treatment would result in a better glycemic control and improve clinical outcome	<i>Inc. criteria</i> Had T2D and IGT; Patients admitted with ischemic heart disease, congestive heart failure, or high-risk cardiovascular patients with at least 3 classic risk factors. <i>Exc. criteria</i> Severe noncardiovascular disease, New York Heart Association stage IV, unstable patients awaiting revascularization, severe abuse of alcohol and sedatives, dementia patients <i>Main Diagnosis</i> Ischemic heart disease (67%); Congestive heart failure (7%); At least 3 risk factors for ischemic heart disease (26%)	<i>Includes</i> The first six weeks: patient education, supervised exercise training (90 minutes of training twice a week), nutritional counseling, supervised cooking lessons on location, smoking cessation, psychosocial support including a 24hr telephone line, pharmacologic therapy, and risk factor management supported by a minimum of consultations by a physician after 3, 6, and 12 months; The program integrated with diabetes module (3 interactive teaching sessions of 2.5 hour each with in-depth information of self-care principles involving symptoms of peripheral arterial insufficiency, diabetic neuropathy, nephropathy, and retinopathy. <i>Provider</i> Multi-professional health team <i>Framework</i> Several International guidelines <i>Setting</i> University Hospital Denmark	Clinical, biochemical and medication outcomes <i>Analysis</i> The sas (version 8.2, SAS Institute, Cary, NC, USA) statistical package 2-sided $p < 0.05$	Allocation, concealment and Implementation all not reported <i>Blinding</i> No	<i>Similarity</i> <ul style="list-style-type: none"> <li>The randomization was well balanced with no statistical difference at baseline between the 2 groups</li> </ul> <i>Findings</i> <ul style="list-style-type: none"> <li>Patients with T2D in the IG attained a significantly greater mean reduction in HbA1c, fasting plasma glucose, and blood pressure (diastolic &amp; systolic) than those in the CG</li> <li>By the end of the study, patients with T2D in IG received a more intensified pharmacotherapy than those in the CG such as angiotensin converting enzyme inhibitor-angiotensin II receptor, antagonist (ACEI/ARA) and metformin</li> </ul> <i>Limitations</i> <ul style="list-style-type: none"> <li>It is not possible to evaluate which is the most important among the components in the combined risk factor management program</li> <li>There was a difference in pharmacotherapy treatment between the 2 study groups</li> <li>Focus on clinical and biomedical outcome only</li> </ul>

Table 4 Clinical Characteristics of identified studies

Name of Study	Time	Design	N	Comparison N (%)	Duration	Follow-up data	Dropout % (n)/reasons	Mean age $\pm$ year or range	Men%	SIGN Rate
Wu <i>et al.</i> (2012b)	August 2009– December 2010	RCT-2 arms	30	C:13 (46.4) I: 15 (53.6)	4 weeks	4 weeks	6.66 (2)/transfer	I: 71.5 $\pm$ 9.9 C: 62.7 $\pm$ 13	71.4	+
Wu <i>et al.</i> (2012a)	NR	RCT-2 arms	20	C:10 (50) I: 10 (50)	4 weeks	4 weeks	NR	NR	NR	+
Wu <i>et al.</i> (2009)	December 2005– July 2006	RCT-2 arms	28	C: 10 (50) I: 10 (50)	4 weeks	4 weeks	28.5 (8)/NR	NR	NR	+
Soja <i>et al.</i> (2007)	March 2002– March 2003	RCT-4 arms [2 arms for T2D patients & 2 arms for IGT patients]	68 with T2D out of 104	C/T2D: 34 (50) I/T2D: 34 (50) C/IGT: 17 (47.2) I/IGT: 19 (52.8)	1 year	3 months and at 1 year	10.29 (7)/NR	I:61.1 (43–79) C:65.7 (42–82)	65	++

C: control group; I: interventional group; NR: not reported; IGT: impaired glucose tolerance; N: number.

based on self-efficacy theory (Bandura 2004), to provide educational information aimed at developing basic skills of self-management such as monitoring blood glucose level. This programme was combined with a booklet of educational concepts and fictitious patients' stories to encourage patients to think positively and apply the self-efficacy model strategies (Wu *et al.* 2009, 2012a). The same programme was used in the Wu *et al.* (2012b) study after being modified by adding a digital video disc (DVD) depicting models of successful self-management and using trained peers to follow-up patients after discharge. On the other hand, the Soja *et al.* (2007) study provided a secondary prevention programme constructed according to international guidelines such as rehabilitation of people with heart disease using Danish clinical guidelines (Danish Heart Foundation and Danish Society of Cardiology 1997) and standards of medical care for patients with diabetes mellitus (American Diabetes Association 2001). The study used an intensified comprehensive cardiac rehabilitation programme and combined educational sessions, supervised exercise training and cooking lessons, smoking cessation, nutritional counselling, psychosocial support, physician consultations and pharmacologic therapy. Also, this programme was integrated with a diabetes module that was comprised of individual counselling and interactive teaching sessions.

All interventions combined at least two types of medium to deliver the components of the intervention, but were commonly delivered through in person one-to-one sessions at healthcare setting such as a CCU, a physician/outpatient clinic or the patients' home, then followed with telephone calls or text messages to deliver counselling and consultations. One study used a multimedia DVD to deliver a part of the intervention (Wu *et al.* 2012b). Another was comprised of interactive teaching sessions (Soja *et al.* 2007).

A range of providers delivered the included interventions such as by only a researcher (Wu *et al.* 2009), the nurse researcher who was a highly trained registered nurse and had coronary and diabetes care experience (Wu *et al.* 2012a), or engaged with trained peers who were former patients with similar diseases and followed up patients by telephone calls and text messages (Wu *et al.* 2012b). In Soja *et al.* (2007) study, the providers were a multiprofessional team including nurses, physicians trained in cardiology and internal medicine and they were supported by specialists such as a podiatrist and ophthalmologist to provide regular surveillance for patients with T2D.

### Outcome measures

A wide variety of outcome measures were used, but no study assessed a combination of clinical, behavioural and

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psychosocial variables. Instruments such as questionnaires and scales were used in three studies to measure self-management outcomes (Wu *et al.* 2009, 2012a,b). One study measured the significant changes in the clinical and biomedical variables to assess the effectiveness of the intervention (Soja *et al.* 2007). Data were analysed descriptively using SPSS version 18 (Wu *et al.* 2009, 2012a,b) or SAS version 8.2 (Statistical Analysis System; Soja *et al.* 2007). In all studies, statistical significance was defined as one- or two-sided  $p < 0.05$  (see Table 3).

#### Psychological outcomes

Psychological outcomes were measured at baseline and 4 weeks follow-up by the diabetes management self-efficacy scale (McDowell *et al.* 2005) and diabetes knowledge questions (Persell *et al.* 2004) in three studies (Wu *et al.* 2009, 2012a,b). One study (Wu *et al.* 2012a) used selected items from the subscales of Brief Profile of Mood States (POMS) (Cella *et al.* 1987) to assess depression and fatigue. One study (Wu *et al.* 2009) used mental health and vitality subscales of SF-36 version 2 (Ware *et al.* 2001).

Two studies reported significant improvements for experimental groups in self-management knowledge (Wu *et al.* 2009, 2012b), and only one study found a positive effect on self-efficacy of diabetes management (Wu *et al.* 2012a). Other variables such as depression, fatigue, mental health and vitality levels did not reveal any improvements for the experimental group.

#### Behavioural outcomes

The only behavioural outcome measured was self-management behaviour. Two studies (Wu *et al.* 2012a,b) measured the self-management behaviour at baseline and 4 weeks follow-up by a Summary of Diabetes Self-care Activities (Toobert *et al.* 2000). This is a reliable and valid self-report questionnaire that includes items assessing the following aspects of the diabetes self-management regimen: specific diet, general diet, blood glucose testing, exercise, smoking and foot care. However, the self-management behaviour did not record any improvement in either study, but that may be due to insensitivity of the instrument especially with the short follow-up period (at four weeks) in both studies. It is worth noting that no studies included a specific instrument to measure heart disease self-management.

#### Clinical outcomes

In only one study were clinical and biomedical outcomes measured at baseline, 3 and 12 months follow-up (Soja *et al.* 2007). The glycated haemoglobin A1c (HbA1c) was measured as a primary outcome to assess whether an

integrated intervention would result in better glycaemic control. The differences in the mean of systolic and diastolic blood pressure, lipid control, exercise capacity and other lifestyle modifications were measured as secondary outcomes. However, after one year of use of an intensified comprehensive cardiac rehabilitation programme, patients with T2D in the experimental group reported a significant improvement in the mean of HbA1c, fasting plasma glucose level, systolic and diastolic blood pressure.

#### Other outcomes

The feasibility of the combined intervention or part of it was assessed in two studies (Wu *et al.* 2009, 2012a). In one study, the feedback from experimental patients and CCU staff on implementing the intervention revealed that it was feasible to hold the educational sessions in a CCU with follow-up at the patient's home and the provided information helped patients to improve their self-management of both conditions (Wu *et al.* 2009). In another one, the experimental patients and their family were encouraged to provide feedback and comments at the end of the programme to assess feasibility and acceptability of incorporating the telephone calls and text-messaging as follow-up approaches. The findings indicated that using follow-up telephone support helped to resolve some patients' concerns after discharge and left a positive impression about support of health professionals for them. Regarding using reminders and reinforcing text messages to the participants and their families, data suggest some usefulness for their ongoing daily self-management, although the participants expressed a desire to receive less written information (Wu *et al.* 2012a).

## Discussion

A key finding of this systematic review is that there were so few studies that were suitable for inclusion, as this highlights the dearth of evidence on this important clinical issue. Recently, Dunbar *et al.* (2015) concluded that providing an integrated self-care intervention for patients with heart failure and diabetes can significantly improve patients' quality of life, physical functioning and self-reported physical activity. The findings of this review indicated that providing a combined intervention for patients with T2D and a cardiac problem in secondary care settings and immediately after discharge from hospital is feasible and suggests these were marginally successful in promoting self-management behaviour. Although none of included studies performed an analysis for both the clinical and psycho-behavioural outcomes together for diabetes and cardiac

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problems, suggesting that there is a lack of standardisation for measuring outcomes of both conditions. However, there did not seem to be an association between medium, duration, providers or dose of combined interventions and intended outcomes in the included studies.

Innovative approaches such as combining the interventions with multimedia technologies or using DVD, follow-up telephones and text-messaging showed effectiveness and applicability to some extent in the included studies. Study participants and their families indicated positive feedback and quite useful experiences. However, future research could focus on evaluating efficacy of using multimedia technology only as a way of testing the efficacy of separate components with the programme, and also on investigating the efficacy of using the interactive telecommunications technologies like an interactive text-messaging model in conjunction with interventions designed to improve self-management for patients with both long-term conditions.

None of the four studies addressed the cost and resources used in developing and implementing the interventions. Therefore, future research should focus on assessing cost-effectiveness of combining these interventions and provide formal cost-benefits analysis for developing and implementing it. Power analyses to determine effect size were not reported. Moreover, all included studies had inadequate sample size and three of them recommended the need for a larger sample to determine the real effectiveness of its interventions (Wu *et al.* 2009, 2012a,b). Therefore, no final conclusion about the effectiveness of these interventions could be reached until a larger, sufficiently powered study is undertaken (Portney & Watkins 2009).

The results of the review should be considered carefully because some threats to the internal validity were observed within included studies. In addition to poor reporting of integration process and inadequately powered samples in above interventions, there were some issues related to inadequate assessment of validity and reliability for some intervention materials such as DVDs and educational booklets (Wu *et al.* 2009, 2012a,b), and problems with fidelity in delivering the combined interventions as a result of variability among providers where some combined interventions or part of them were provided by different professionals or peer supporters with lack of a clear protocol or inappropriate training plan for them. Furthermore, there were a range of types of bias (selection, performance and detection) associated with the methods of the included RCTs due to lack of blinding, poor allocation and concealment mechanisms; inadequate assessment of the differences between baseline characteristics of the groups that were compared; and systematic differences between groups such as significant

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differences in using intensified pharmacotherapy between study groups (Soja *et al.* 2007) and weak consistency among intervention providers and among peer supporters (Wu *et al.* 2012b). Further research should take into consideration these limitations to strengthen the internal validity of a combined intervention design, thus enhancing the reliability of the subsequent results.

## Relevance to clinical practice

At the conclusion of this systematic review, several lessons and challenges have been identified from existing combined interventions designed to promote self-management behaviour and health outcome for patients with T2D and ACS that needs to be considered in future research. There is limited research in the area of developing integrated self-management interventions for patients with multiple chronic conditions in general. There are even fewer papers testing these interventions by RCTs, recognised as the gold standard evaluation design, before translation to practice. As such, it is unsurprising that there was no final evidence to support effectiveness of combined interventions to promote self-management behaviour for patients with T2D and ACS. Despite the increasing prevalence of people living with more than one chronic condition, we continue to treat and manage each one separately. There is a dearth of evidence to support people who are living with both these conditions. There is an urgent need to develop robust programmes that address this area of clinical practice.

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## Contributions

MT, DF and VC contributed to conception, design, data extraction and analysis and drafted this article; MT contributed to search databases, article acquisition and screening for inclusion, and critically revised this article; CD contributed to manuscript preparation and revised this article; and all authors have approved this version and agree to be published.

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## Conflicts of interest

The authors declare that they have no conflict of interests.



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## Appendix 5 : PIS for focus groups with HCPs



### Participant Information Sheet for Focus Group

### ورقة معلومات المشترك في مجموعة التركيز

**Dear colleague:** You are being invited to take part in a research study that is part of my PhD thesis. Before you decide whether or not you wish to take part, please take time to read the following information about the purpose and procedures of the study carefully and discuss it with others if you wish. If you need further information please do not hesitate to contact me. Thank you for your time and effort.

**Study Title:** Developing and Feasibility Testing a Novel Intervention to Address the Supportive Care Needs of Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes.

**If you would like further information about this study please feel free to contact:**

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**عزيزي الزميل:**  
أنت مدعو للمشاركة في دراسة بحثية هي جزء من رسالتي للدكتوراة. قبل أن تتخذ القرار للمشاركة، يرجى أخذ الوقت لقراءة المعلومات التالية حول هدف إجراء الدراسة وإجراءات المشاركة بعناية ومناقشتها مع الآخرين إذا كنت ترغب في ذلك. إذا كنت بحاجة إلى مزيد من المعلومات يرجى عدم التردد في الاتصال بي و شكرا لك على وقتك وجهدك

**عنوان الدراسة:**  
تطوير وفحص جدوى برنامج جديد لثلية احتياجات الرعاية الداعمة للمرضى الأردنيين الذين يعانون من متلازمة الشريان التاجي الحادة والسكري النوع الثاني.

إذا كنت بحاجة إلى مزيد من المعلومات حول الدراسة يرجى عدم التردد في الاتصال علي:

الباحث:  
معاذ إبراهيم طنناش

البريد الإلكتروني:

[Tanash-m@email.ulster.ac.uk](mailto:Tanash-m@email.ulster.ac.uk)

رقم الهاتف:

JO/  
00962798752251  
UK/  
00447593965921

### **What is the purpose of the study?**

The study is part of my thesis. Overall, the study aims to develop and evaluate the feasibility and acceptability of a novel supportive care intervention for patients with Type 2 diabetes and acute coronary syndrome in the context of Jordanian secondary healthcare settings.

ما هو الغرض من هذه الدراسة؟  
الدراسة هي جزء من رسالتي. بشكل عام، تهدف الدراسة إلى تحديد احتياجات المرضى الأردنيين الذين يعانون من أمراض القلب التاجية ومرض السكري بشكل متزامن، أيضا نريد تطوير وتقديم برنامج رعاية داعمة لتحسن الرعاية الذاتية لدى المريض بناء على احتياجات المريض الفعلية أولاً وبما يتناسب مع آراء مقدمي الرعاية الطبية ثانياً، وبعد ذلك سنقوم بدراسة جدوى تقديم هذا البرنامج المطور إلى هؤلاء المرضى.

**Why have you been chosen?** You have been chosen to participate in this study because, firstly, you are one of the current healthcare providers who are involved in the care of patients with diabetes and a cardiac problem in Jordanian secondary care settings and after discharge. Secondly, you fulfil the necessary criteria required for this study. The criteria are:

1. Professional who are involved in the care of patients with diabetes and cardiac diseases in secondary care settings and after discharge, such as cardiologist, physicians, nurses, practitioners , dietitian and diabetes nurses, pharma doctor.
2. At least 1 years' experience.
3. Can converse in Arabic
4. Willing to consent and attend 1-2hr meeting.

**Do you have to take part?** No, but your participation would be sincerely appreciated. Taking part in the study is entirely voluntary.

**If I decide to take part in the study, what will happen to me?** If you agree to take part in the study, you will be asked to sign the attached consent form and return it on the day of meeting. You will be involved in a focus group interview that will be held at a time and place that is convenient time for you within January 2016 (such as in a quiet room at your work place). The focus group interview will be audio recorded. The session will last approximately 1 hour. The session will be run by Mu'ath Tanash and maybe there will also be someone present to take notes during your discussion. The session will be recorded by using audio recording device. During the session the researcher will ask non-directive, open-ended questions to explore your perspective of the current follow-up supportive care process in Jordanian secondary care settings and your opinion of supportive intervention needs for patients with diabetes and cardiac problems, as well as of the study intervention, particularly around delivery and acceptance, and suggestions for improving the proposed intervention. We will also explore the challenges you face when delivering supportive intervention for patients with T2D and ACS in Jordanian health settings.

لماذا تم اختيارك للمشاركة في هذه الدراسة؟ لقد تم اختيارك للمشاركة في هذه الدراسة لأنه، أولاً، أنت واحد من مقدمي الرعاية الصحية الحاليين الذين يشاركون في رعاية المرضى الذين يعانون من مرض السكري ومشاكل في القلب في مستشفيات الرعاية الثانوية الأردنية وبعد الخروج منها. ثانياً، أنت تفي بالمعايير اللازمة لهذه الدراسة، والمعايير هي:

1. إحدى مقدمي الرعاية الذين يشاركون في رعاية المرضى الذين يعانون من السكري النوع الثاني ومشكلة القلب في مرافق الرعاية الثانوية وبعد الخروج منها (أخصائي/ مقيم أمراض قلب أو باطني ، رئيس ترميز، ممرض قانوني، ممرض مشارك، طبيب علم، و "أخصائي الحميات / علاج الطبيعي/ علاج الوظيفي / الغدد الصماء وسكري")
2. لديك سنة خبرة على الأقل.
3. قدر على المخاطبة والنقاش بلغة العربية.
4. على استعداد للموافقة ولحضور الاجتماع لفترة 1-2 ساعة فقط

هل يجب المشاركة؟ لا، ولكن مشاركتكم سيكون موضع تقدير واحترام. المشاركة في هذه الدراسة هي تطوعية تماما.

ماذا سيحدث لي إذا قررت المشاركة بالدراسة؟

إذا وافقت على المشاركة في الدراسة، سوف يطلب منك التوقيع على استمارة الموافقة المرفقة في يوم المشاركة. وسوف تكون المشاركة في لقاء مجموعة التركيز الذي سيعقد في الوقت والمكان المناسبين بالنسبة لك في شهر يناير 2016 (مثل في غرفة هادئة في مكان عملك). سوف يتم تسجيل مقابلة مجموعة التركيز صوتياً. وستستمر المقابلة تقريبا ساعة واحدة. ستدار المقابلة من قبل الباحث معاذ طنّاش وربما سيكون هناك أيضا شخص للمساعدة في تدوين الملاحظات أثناء مناقشتكم. ستسجل المقابلة باستخدام جهاز تسجيل الصوت. خلال المقابلة الباحث سيشرح بعض الاسئلة الغير توجيهيه و العامه لإستكشاف وجهة نظرك ونظر زملائك حول عملية الرعاية الداعمة والمتابعة المحلية المقدمه في مرافق الرعاية الثانوية الأردنية للمرضى الذين يعانون من السكري و من امراض القلب وسنأخذ رأيك حول إحتياجات هؤلاء المرضى وسبل تحسين الرعاية المقدمه لهم. سنبحث أيضا التحديات التي تواجهكم عند تقديم برامج الرعاية التوعيه والتثقيفيه الداعمة لمرضى السكري من النوع الثاني والذين يعانون من مشاكل قلبيه في مرافق الرعاية الصحية الأردنية.

**What will happen to the information that you give?** Before starting the session, the investigator will ask all participants to respect the confidentiality of the group. All information you provide will be analysed confidentially and will only be used for the research purposes of this study. Each consenting participant will be identified by a study number. All data collected and participant consent forms will be coded numerically and the only link between the study identification number and participants' identifying information will be stored in a highly secure cabinet at Ulster University and secured on a password-protected computer. Only the main researcher will have access to the data. The final results of the analysed information may be published, but all personal data will be completely removed prior to publication, as required under data legislation.

**Will you benefit directly from this research study?** There might be no direct benefit for you; however, your participation might help current issues regarding self-management of diabetes and cardiac problems to be better understood in a systematic way in Jordanian healthcare settings, and this understanding may well contribute to changing healthcare services for the better in Jordan. The quality of care for patients with diabetes and cardiac problems could also be improved.

**What if something goes wrong?** Normally, answering the study questions should cause you no harm. However, if problems occur, you can contact the researcher who will try to help you to deal with the situation.

**Who has reviewed the study?** This study has been reviewed and approved by the Research Ethics Committee of the School of Nursing, Ulster University, Northern Ireland, UK. And ethics committee in each King Abdullah University Hospital and Jordanian Ministry of Health.

**Thank you for taking time to read this information**

ماذا سيحدث للمعلومات التي تقدمها؟

قبل بدء المقابلة، سوف يطلب الباحث من جميع المشاركين احترام سرية المجموعة وراء المشاركين الآخرين. وسيتم تحليل كل المعلومات التي تقدمها بسرية ولن تستخدم إلا لأغراض البحث في هذه الدراسة. وسيتم تحديد كل مشارك بالدراسة من خلال رقم معين. جميع البيانات التي يتم جمعها واستمارات الموافقة للمشاركين التي تم ترميزها عددياً سيتم تخزينها في خزانة آمنة وسريه في جامعة أولستر وعلى جهاز كمبيوتر محمي بكلمة مرور. فقط الباحث الرئيسي سيتمكن من الوصول إلى البيانات. يمكن نشر النتائج النهائية للبحث في احدى المجالات العلمية المحكمة، ولكن سيتم إزالة كافة البيانات الشخصية للمشاركين تماما قبل نشرها، كما يتطلب بموجب التشريعات والقوانين للمحافظة على البيانات.

هل سوف تستفيد مباشرة من هذه الدراسة البحثية؟

قد لا تكون هناك فائدة مباشرة عائدة عليك. ولكن، مشاركتكم قد تساعد في حل القضايا الراهنة بشأن الإدارة الذاتية للمرضى الذين يعانون من مرض السكري ومشاكل في القلب. ومشاركتكم ستساهم في فهم القضايا والاحتياجات على نحو أفضل وبطريقة منهجية، وهذا الفهم قد يسهم كذلك في تغيير خدمات الرعاية الصحية لنحو أفضل في الأردن. وبالتالي تحسين نوعية الرعاية المقدمة للمرضى الذين يعانون من مرض السكري ومشاكل في القلب.

ماذا لو حدث خطأ ما؟

الإجابة على أسئلة الدراسة لن يسبب لك أي ضرر. ومع ذلك، في حالة حدوث مشاكل أو لديك أي استفسار، يمكنك الاتصال بالباحث الذي سيحاول مساعدتك وسيقوم بالتعامل مع المشكلة أو الحلة.

من هم الذين راجعوا هذه الدراسة؟

لقد روجعت هذه الدراسة وتمت الموافقة عليها من قبل لجنة البحوث الأخلاقية في كل من جامعة أُلستر البريطانية، وزارة الصحة الاردنيه ومستشفى الملك عبد الله المؤسس الجامعي.

شكراً لوقتكم للنظر في هذه الدعوة للمشاركة في الدراسة

## Appendix 6: Consent form for focus groups participants

### Participant Consent Form for Focus Group

**Study Title:** Developing and Feasibility Testing a Novel Intervention to Address the Supportive Care Needs of Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes.

**Please read each of the following statements, then sign the form:**

- I confirm that I have received verbal and written information about the aim, process and sequence of the study.
- I have read the participant information sheet and I understand it. I have had the opportunity to ask questions regarding the study and I have obtained adequate answers.
- I have received the information sheet and I will be given a copy of the consent form.
- I understand that I am not directly benefiting by taking part in this study.
- I had sufficient time to consider my participation.
- I agree to the session being audio recorded.
- I agree to maintain the confidentiality of the information discussed by all participants and the researcher during the focus group session.
- I agree to respect the privacy of fellow participants and not repeat what is said in the focus group to others.
- I confirm my participation in the study is entirely voluntary and I am free to withdraw from the study at any time without giving any reason.
- I understand that any research data may be reviewed by the University's supervisors or other responsible individuals from Ulster University, UK. I give permission to these individuals to obtain sight of my personal records while maintaining strict confidentiality.
- I understand my responsibilities as a study participant. I hereby declare that I will participate in the above study.

**Participant name:** \_\_\_\_\_ **Date:** \_\_\_/\_\_\_/\_\_\_ **Signature:** \_\_\_\_\_

**Researcher name:** Mu'ath Tanash (+962 798752251 / E: [Tanash-m@email.ulster.ac.uk](mailto:Tanash-m@email.ulster.ac.uk) )

**Date:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

## Appendix 7: Interviews guide - Study I

### Semi-Structured Focus Group Guide

**Study topic:** Developing and Feasibility Testing a Novel Intervention to Address the Supportive Care Needs of Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes.

During the session the investigator will seek to achieve the following objectives:

1. To explore the supportive care needs of patients with ACS and T2D from the perspective of their healthcare professionals.
2. To explore the perspectives of healthcare professionals regarding the current follow-up care provided for patients with ACS and T2D in Jordan, with the purpose of identifying their challenges, unmet needs and features that can help in the development of a new supportive intervention.

### Introduction (part 1):

First of all, the investigator will welcome the participants and thank them for coming to take part in the study. Before starting the session, the investigator will:

- Ensure that the place is comfortable and secure for participants and that there will be no disturbances during recording the session.
- Introduce himself, his work, and the note-taker.
- Ask participants an informal question such as 'how is your work going?'
- Inform participants about the topics that will be discussed during the session and who will participate in the focus group, as per the following:
  1. I am going to ask you some questions. This does not have to be done in any particular order but I do want everyone to take part in the discussion. I ask that only one person speak at a time.
  2. Feel free to treat this as a discussion and respond to what others are saying, whether you agree or disagree. I am interested in your opinions and whatever you have to say is fine because there are no right or wrong answers. I am just asking to get your opinions based on your own personal experience. I am here to learn from you.
  3. You have a right to refrain from answering any particular question if you want.
  4. Once I start recording I will not use anyone's full name and could you please do the same.
- Reassure participants about maintaining confidentiality of the research data and treating their answers as confidential. All data collected, participants' details and consent forms will be coded numerically and the only link between the study identification number and participants' identifying information will be stored in a highly secure cabinet and secured on a password-protected computer. Only the main researcher will have access to the data and transcriptions which will be used for the purposes of this study only. All information about the study results will be published anonymously.
- Inform participants of the duration of the session and that the session will be recorded by using a tape recorder. Notes will be taken because we are interested in recording all their comments.
- Request participants to respect the privacy of other participants and not repeat what is said in the focus group to others outside the group.
- Inform participants that their discussion may help to improve current follow-up care services for patients with diabetes and cardiac problems.

- Ask the participants if they have any questions about the study or about the session procedures before starting the recording.
- Ask participants to complete the demographic data sheet and sign the consent form.

### **Introduction (part 2):**

- I will start the tape recorder now.
- After all participants have taken a seat around the table, starting on my right I will ask each participant to introduce him or herself (using the first name only), their specialty and number of years' experience.

### **Topics of interview:**

#### **Perspective:**

- ✦ The first thing that I would like you to discuss is your perspective of current follow-up supportive care processes provided for patients with diabetes and ACS in Jordanian settings after they have experienced one type of acute coronary syndrome and immediately after discharge from hospital.
  1. To start, how would you describe the current follow-up supportive care services for patient with diabetes and ACS in the Jordanian healthcare system?
  2. Are the current follow-up supportive care services in Jordanian secondary settings meeting the needs of patients with diabetes and cardiac problems?
  3. In addition to drug treatment, can you tell us about what supportive care services you provide for these patients during hospitalization and immediately after discharge?
  4. Did you receive any training courses or participate in workshops to help you to provide comprehensive treatment or support interventions for these patients during hospitalization or after discharge?
  5. How could you improve the treatment to provide effective supportive care intervention/information for patient with diabetes and ACS?



### **Opinions and suggestions:**

✚ Now, we'd like to discuss your opinions of patients' needs and any difficulties you encounter.

1. Based on your experience, what do you think are the most important needs of patients with diabetes and ACS, and how can we better help them to promote their self-management behaviour and motivate them to adhere to a healthy lifestyle post discharge?
2. If you had a chance to speak to Jordanian health policy makers, what are the things you would want to tell them in order to help meet the needs of patients with diabetes and ACS?
3. If you could design the perfect support intervention for patients with diabetes and ACS, what would it look like?
4. What are the obstacles to the implementation of supportive interventions for these patients?

✚ The last thing that I'd like to discuss with you today is your opinions and suggestions about providing educational interventions for patients with diabetes and acute coronary syndrome, including face-to-face educational sessions for patients during hospitalization and after as a follow-up, follow-up phone call, supportive care awareness text-messages and group educational sessions.

1. To what extent do you think this will be effective?
2. What are the obstacles that you would expect to implementation for each method?
3. What are your suggestions and recommendations about providing such an intervention?

### **Ending:**

- We have now reached the end of our session and these were all the questions I wanted to ask. If anyone would like to add anything else or has any final thought about our topic that they have not had a chance to share, please do so now.
- Tell participants what will happen to the data following the session ("to provide more assurance about confidentiality") and how the information might be used to improve current health services for patients with diabetes and cardiac problems.
- Stop recording.
- Thank the participants for coming and sharing their opinions. Say that I hope they have enjoyed the discussion today.

## Appendix 8: PIS for interviews with patients – Study II



### Participant Information Sheet for Interview

**Dear Patient:** You are being invited to take part in a research study that is part of my PhD thesis. During the interview, the researcher will ask you about your perspective regarding the current supportive care process, your educational and supportive needs and your experience of living with Type 2 diabetes and a cardiac problem. Before you decide whether or not you wish to take part, please take time to read the following information about the purpose and procedures of the study carefully and also discuss it with others if you wish. If you need further information, please do not hesitate to contact me or my supervisor. Thank you for your time and effort.

**Study Title:** Identifying Supportive Care Needs for Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes: Developing and Evaluating a Novel Intervention.

**If you would like further information about this study please feel free to contact:**

<p><b>Research student:</b>            Mu'ath Tanash            PhD student at Institute of Nursing and Health Research (INHR)            Ulster University – School of Nursing            Newtownabbey            BT37 0QB            UK            E-mail: Tanash-m@email.ulster.ac.uk            Mobile: +44 7593965921            Work: +44 2890368355</p>	<p><b>Research Supervisor:</b>            Professor Donna Fitzsimons            Ulster University - School of Nursing            Newtownabbey            BT37 0QB            UK            E-mail d.fitzsimons@ulster.ac.uk            Telephone +44 28 90366619</p>
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**What is the purpose of the study?** The study is part of my thesis, leading to a PhD degree in nursing science. Overall, the study aims to develop and evaluate the feasibility and acceptability of a novel supportive care intervention for patients with Type 2 diabetes and acute coronary syndrome in the context of Jordanian secondary healthcare settings.

**Why have you been chosen?** You have been chosen to participate in this study because, firstly, you have been admitted to hospital with a diagnosis of one of the acute coronary events and you have Type 2 diabetes. Secondly, you fulfil the necessary criteria required for this study. The criteria are:

1. Adults with a history of T2D and ACS within the last 3-12 months.
2. Can understand the Arabic language.
3. Physically and mentally able to participate in the study (as judged by a cardiologist).
4. Jordanian nationality.
5. Willingness to participate in an interview lasting 30-60 minutes.

**Do you have to take part?** No, but your participation would be sincerely appreciated. Taking part in the study is entirely voluntary. It is up to you whether or not to take part. If you change your mind, you can withdraw at any time without giving a reason and this will not affect your rights or care in any way.

**What are the study procedures?** If you agree to take part in the study, you will be asked to sign the attached consent form and then you will be asked to participate in a face-to-face interview, which will last 30-90 minutes. This interview will be conducted by Mu'ath Tanash who will arrange it at a time and place that is convenient for you (such as in a quiet room in hospital or in your home). The interview will be audio recorded and before starting you will be asked to complete the demographic data sheet. During the interview, the researcher will explore the perspectives of patients with Type 2 diabetes and acute coronary syndrome regarding the current follow-up supportive care process in Jordanian secondary care settings, your experience of living with both conditions and then will identify patients' needs and opinions of a new supportive intervention.

**What will happen to the information that you give?** All information you provide will be analysed confidentially and will only be used for the research purposes of this study. All consenting participants will be identified by a study number. All data collected and participant consent forms will be coded numerically, and the only link between the study identification number and participants' identifying information will be stored in a highly secure cabinet and secured on a password-protected computer. Only the main researcher will have access to the data. The final results of the analysed information may be published, but all personal data will be completely removed prior to publication, as required under data legislation.

**Will you benefit directly from this research study?** There might be no direct benefits for you, but conducting the study might well contribute to improving the quality of care in the future for patients with diabetes and cardiac problems in Jordan.

**What will happen to the research findings?** The findings of this study will be presented and reported anonymously and will be part of the researcher's PhD thesis. Additionally, findings may be published in healthcare journals and presented at national and international conferences, as well as being used for written publications in peer-reviewed journals. Findings will be made available to participants at the end of the study if they are interested in knowing the outcomes of this study. If you wish to receive information about the research findings, please contact me.

**What if something goes wrong?** Normally, answering the research questions should cause you no harm. However, if problems occur, you can contact the researcher who will try to help you to deal with the situation.

**Who has reviewed the study?** This study has been reviewed and approved by the Research Ethics Committee of the School of Nursing, Ulster University, Northern Ireland, UK.

**Thank you for taking time to read this information**

**Mu'ath Tanash**

## Appendix 9: Consent form for patients - Study II



### Participant Consent Form for Interview

**Study Title:** Identifying Supportive Care Needs for Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes: Developing and Evaluating a Novel Intervention.

**Please read each of the following statements, then tick  $\checkmark$  in all the boxes that apply:**

- I confirm that I have received verbal and written information about the aim, process and sequence of the study.
- I have read the participant information sheet and I understand it. I have had the opportunity to ask questions regarding the study and I have obtained adequate answers.
- I have received the information sheet and I will be given a copy of the consent form.
- I understand that I am not directly benefiting by taking part in this study.
- I had sufficient time to consider my participation.
- I agree to the interview being audio recorded.
- I confirm my participation in the study is entirely voluntary and I am free to withdraw from the study at any time without giving any reason.
- I understand that any research data may be reviewed by the University's supervisors or other responsible individuals from Ulster University, UK. I give permission to these individuals to obtain sight of my personal records while maintaining strict confidentiality.
- I understand my responsibilities as a study participant. I hereby declare that I will participate in the above study.

**Participant name:** \_\_\_\_\_ **Date:** \_\_\_/\_\_\_/\_\_\_ **Signature:** \_\_\_\_\_

**Researcher name:** Mu'ath Tanash (P: +44 7593965921 / E: [Tanash-m@email.ulster.ac.uk](mailto:Tanash-m@email.ulster.ac.uk) )

**Date:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

## Appendix 10: Interviews guide- Study II

### Semi-structured Interview Guide

**Study topic:** Developing and Feasibility Testing a Novel Intervention to Address the Supportive Care Needs of Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes.

During the interview the investigator will seek to achieve the following objectives:

1. To explore the supportive care needs of patients with ACS and T2D
2. To explore the perspectives of patients regarding the current follow-up care provided for them in Jordan, with the purpose of identifying their challenges, unmet needs and features that can help in the development of a new supportive intervention.

#### Introduction:

**Aim: To introduce the research and set the context for the proceeding discussion.**

First of all, the investigator will thank the participant for taking part in the study. Then, before starting the interview, the investigator will:

- Ensure that the place is comfortable and secure for participants and that there will be no disturbances during the interview.
- Introduce self and Ulster University.
- Introduce the study: what is about and who it is for.
- Talk through key points:
  - length of interview
  - Interview like a discussion, although specific topics to cover
  - No right or wrong answers, your views are important
  - Participation is voluntary and right to withdraw
  - Recording interview so can listen and for accuracy
- Reassure participants about confidentiality, anonymity, secure transfer of data, how findings will be reported.
- Ask participants to **sign the consent form**.
- Any questions they may have. (SART RECORDING)

#### Background and personal circumstances:

**Aim: To introduce the respondent and highlight any key background issues that might influence their experience and needs.**

- Age; household circumstances (whether live alone or with others)
- Main daytime activity (with working or not, details)
- Smoking (details)

#### Experiences and needs:

**Aim: To explore patients' experience of having both diseases; their needs and how coping with both disease symptoms.**

1. **Past medical history** (diabetes and cardiac problem);
  - How long?
  - When you found out you had two conditions, how did that feel?
2. What is your **understanding** of your illness (for both)?
3. What has been your **experience of managing the two diseases?**
4. Are there any aspects that are **difficult** for you?
  - If so, how are you coping with these?
1. What are the **most common symptoms** you have experienced after you were discharged from hospital with both conditions?
  - How do you manage the symptoms of the two diseases?
2. Where are you getting information to help you manage your symptoms and difficulties?
3. Based on your experience of living with two diseases, what do you think patients with both conditions **need to receive in hospital and immediately after discharge** to improve their health? (why and how)
4. Is there anything about diabetes or the cardiac problem **that you would like to know or understand** since you have been diagnosed with both conditions but have not been able to find the answer to?
5. What **information sources** are most important in shaping your perception of managing the two diseases?
6. What **motivates** you to manage the two diseases effectively?

#### **Perspectives:**

**Aim: to explore patient's perspective about supportive care services/interventions they received**

1. Can you tell us about **any supportive care services you have received** regarding your condition during hospitalization and after your discharge?
  - If there is, what **type** of program? What are **the benefits, disadvantages**, and who provides it?
  - If not, why or what are **the obstacles?**
2. How would you **describe the existing supportive care services** for patients with diabetes and cardiac problems in the Jordanian healthcare system?
3. How **effective** is the healthcare providers' treatment you received during hospitalization or after your discharge to promote managing the two diseases?
4. Did you **receive any supportive interventions/programs to** help you manage the diseases during hospitalization or after your discharge?

#### **Opinions and suggestions:**

**Aim: to get respondent's ideas for how improve existing supportive care and promote their health behaviour for**

1. In addition to any drug treatment you have received, **what support do you think could promote health behaviour** for patients with diabetes and cardiac problems, **motivate them to adhere to a healthy lifestyle** and help them in managing the two diseases?

2. What do you **know** about the **self-management/self-care program** for diabetes and cardiac problems?
3. How can the existing supportive care process/treatment be improved? What are your **suggestions**?
4. What type of **program/information** do you think should be provided for patients with diabetes and cardiac problems in hospital or after discharge? And who to provide it?
5. What is your **opinion** about providing health education program for patients with diabetes and cardiac problems?
  - How to be provided (which mode of delivery most appropriate, from whom..., in which style), When should be provided and what should be included?

**Ending:**

- We have reached the end of our session – is there anything else you would like to add?
- Tell participants what will happen to the data following the interview (“reassurance about confidentiality and anonymity of reporting data”) and how the information will be used to improve current health services for patients with diabetes and cardiac problems.
- Check if they want to be informed of findings
- Stop recording.
- Thank the participants for their time and for sharing their experience.

**Appendix 11: The Arabic version of the materials of the DCSM Intervention**

All the materials in the Arabic language which used in the intervention (questionnaire, study booklet and log book etc) can be submitted if needed by contacting the primary researcher via email or phone:

**Mu'ath Tanash**

**E-mail:** [Tanash-m@ulster.ac.uk](mailto:Tanash-m@ulster.ac.uk)  
[mmuuaatth@yahoo.com](mailto:mmuuaatth@yahoo.com)

**Work:** +44 2890368355

**Mobile:** +44 7593965921



## Appendix 12: The DCSM Intervention activities

### In-hospital educational sessions

#### Objectives:

At the end of this educational sessions, it is expected that patients will be able to:

1. Understand their new condition, connection between diabetes and cardiac disease, most related signs and symptoms, and how to live healthy with both conditions.
2. Set-up attainable goals about one or two lifestyle changes.
3. Follow the techniques of self-monitoring.
4. Improve their medication adherence.
5. Answer their questions and concerns.
6. Enhance their self-confidence and self-awareness.

Session	Activates	Time	Comments
<p><b><u>Pre- sessional meeting</u></b></p> <p><b>Expected overall time:</b> About 15 mins</p>	<p>The researcher will:</p> <ol style="list-style-type: none"> <li>1. Introduce himself and the program for patient.</li> <li>2. Keep always using a caring tone of voice and attitude, comfortable body language, make eye contact and plain language.</li> <li>3. Explain the procedure of research program.</li> <li>4. Outline the objectives of educational program to the patients and their family.</li> <li>5. Encourage the family member to attend the educational sessions and inform them about important of their role in helping the patient.</li> <li>6. Collect consent form.</li> <li>7. Arrange a time for the first session</li> <li>8. Provide the questionnaire.</li> <li>9. Give patient the booklet for reading when be capable.</li> <li>10. Collect baseline data.</li> </ol>		
<p><b><u>First session</u></b></p> <p>General Knowledge</p> <p><b>Expected overall time:</b> About 25-30 mins</p>	<ol style="list-style-type: none"> <li>1. Assess the <b>patients' baseline understanding</b> before providing any information, by asking definite and open-ended questions to know what they need to know or to do, in a caring way, for example: <i>Could you tell me what you know about diabetes?</i> <i>Do you think there is a connection between diabetes and your cardiac event?</i></li> <li><b><u>Definition</u></b></li> <li>2. Explain what the heart attack and diabetes are?</li> </ol>	<p><b>2 mins</b></p> <p><b>3 mins</b></p>	

	<ol style="list-style-type: none"> <li>3. Discuss what are the <b><u>connection</u></b> between both diseases and how poor control of diabetes affect the heart and blood vessels? <b>5 mins</b></li> <li>4. Discuss about the <b><u>risks of</u></b> coronary heart disease and symptoms of <b><u>poor control</u></b> of diabetes. <b>5 mins</b></li> <li>5. Explain for patient <b><u>things they need to know</u></b> clearly by using plain language and without using medical jargon or vague terms. <b>5mins</b></li> <li>6. Try to <b><u>emphasize</u></b> one to three key points and check patient's understanding through using <b><u>teach-back</u></b>, and if needed, will re-explain and check <b><u>again</u></b>. <b>5 mins</b></li> <li>7. Researcher will use information in the program booklet to support learning and <b><u>encourage them to read</u></b> it. And encourage to read the <b><u>stories</u></b> of Ali and Fatimah <b>2 mins</b></li> <li>8. Encourage patient to ask questions. <b>2 mins</b></li> <li>9. Arrange a time for the second session</li> </ol>	
<p><b><u>Second session</u></b></p> <p>Lifestyle Changes</p> <p><b>Expected overall time:</b></p> <p>About 30 mins</p>	<ol style="list-style-type: none"> <li>1. Discuss with patient <b><u>how to reduce risk</u></b> of developing further heart and health problems? And how to they can <b><u>self-management</u></b> improve their chronic conditions? <b>1+2</b></li> <li>2. Based on program booklet, in simple language, present a list of different <b><u>lifestyle change</u></b> topics (such as; smoking, diet and physical exercise) and <b><u>prioritise</u></b> them based on importance to patient's health and their preference. <b>15 mins</b></li> <li>3. Then, will ask patients to select one or two of the most important topics to discuss in the today session. <b>3+4</b></li> <li>4. Researcher will use elements of <b><u>teach back</u></b> method to <b><u>improve patients' knowledge, understanding value of change</u></b> and confidence about their selected topics. <b>5 mins</b></li> </ol>	

	<p>5. Researcher will help patients to build up their personal <b><u>action plan</u></b> for achieving new healthy behaviour.</p> <p>6. Researcher will assess patient's confidence to carry out his/her action plan after discharge, by asking them: how confident are you in your ability to carry out your action plan after discharge, on a <b><u>scale of 0 to 10</u></b>, with 0 being extremely low confidence and 10 extremely high? If patient's confidence less than 7, the researcher will discuss with patient about how to modify the plan until the patient has a confidence level of 7 or more.</p> <p>7. <b><u>Encourage to take notes for their action to change</u></b> after discharge from hospital, that to understand success and barriers, by such as <b>using logbook sheet related to the glucose monitoring and walking diary.</b></p> <p>8. <b>Encourage patient to read</b> in booklet more how to reduce risk and how to self-management their chronic conditions.</p> <p>9. Arrange a time for the third session</p>	<p>5+6 5 mins</p> <p>7+8 5 mins</p>	
<p><b><u>Third session</u></b></p> <p>Medication Adherence</p> <p><b>Expected overall time:</b></p> <p>About 25-30 mins</p>	<p>1. Use elements of teach back method to enhance patients' knowledge regarding their <b>medications and the importance of adherence</b> to medication regimen.</p> <p>2. Use teach back to confirm patient understanding of using medication, for example, by asking patient: <i>I always ask my patients to repeat things back to make sure I have explained them clearly, so I would like you to tell me <b>how you are going to take the medicines</b> that we talked about today?... or: When you discharge to home, and one of your family ask you what the nurse said to you regarding your medication, what will you tell them?</i></p> <p>3. If the patient answers were wrong on inadequate, the researcher will</p>	<p>10 mins</p> <p>5 mins</p>	

	<p>explain the matter again to ensure the patient completely understand the matter.</p> <p>4. <b>If needed</b>, the researcher will <b>write down</b> the important instructions for the patients in simple and understandable language.</p> <p>5. Teach patients about using <b>medication record sheet and medication box</b> and encourage them to record their taken medications.</p> <p>6. Teach patient about <b>diabetes and heart zones</b> for management (a traffic light tools), that presented in the logbook.</p> <p>7. Teach patient about symptoms of heart attack and how to deal with it appropriately.</p>	<b>5 mins</b>	
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### Follow-up phone call

#### Objectives:

At the end of this follow-up phone call, it is expected that patients will be able to:

1. Get more support by using reinforce techniques.
2. Continue to present the activates and techniques of self-management for lifestyle changes and medication adherence by assessing and supporting patient's plan for self-management.
3. Get social support to understanding barriers and help to solve their problems and get encouragement to set more attainable objectives.
4. Reduces some of their concerns.

Topics	Activates	Expected Time	Comments
<b>Greeting</b>	<p>Warm up relationship with patients:</p> <ol style="list-style-type: none"> <li>1. saying hello, dear sir/madam .....my name is ....., I am the PhD student in the Ulster University. Do you still remember me? How are you today?</li> <li>2. Today, I would like to continue discuss with you about your health condition, it may need <b>20-30 mins</b>, it's that fine?</li> </ol>	<b>1 mins</b>	
<b>Assessment</b>	<ol style="list-style-type: none"> <li>1. Lead patient to describe the activates of self-management after discharge from hospital. By asking Such as: <i>tell me about your experience of managing your condition at home?</i></li> <li>2. Encourage patients to express their <b>concerns and barriers</b> they have</li> </ol>	<b>3 mins</b>	

	<p>related to their self-management action plan of their health condition after discharge from hospital. By asking:</p> <p><i>tell me about your experience of conducting your action plan to achieve your goal at home? Any concerns or difficulties about this? if yes please give me more details</i></p> <p>3. Encourage patients to freely talk about their performance during last two weeks to observe how much they did and how successful they are from their record and talking.</p>	<p>3 mins</p> <p>4 mins</p>	
<b>Identify the successful and failure self-management activities and solving problems that faced patient</b>	<ol style="list-style-type: none"> <li>1. Identify most patient's problem related to practice self-management activities or to physical condition.</li> <li>2. Advice patient how to solve problem or to visit her/his doctor if needed.</li> <li>3. If patient have achieved positive behaviour changes and doing well, the researcher will provide verbal encouragement and praise</li> <li>4. If patient have not archived positive behaviour changes, the researcher will provide empathy and try understanding why and will discuss with patients to help them to set a new attainable goal for next weeks.</li> </ol>	10 mins	
<b>Remind patients about the information in the booklet and stories of successful models</b>	<ol style="list-style-type: none"> <li>1. Encourage patients to re-reading information in the booklet again and remind them about the models regarding successful looking after himself or herself.</li> </ol>	2 mins	
<b>Reinforcement</b>	<ol style="list-style-type: none"> <li>1. Provide positive verbal reinforcement of benefits and impotent of self-management to their health and quality of life.</li> <li>2. Answer patient's questions.</li> </ol>	2 mins	
<b>Finally</b>	Set up a time for next meeting to collect some data.	1 mins	

### Appendix 13 : Application of the four information sources in the DCSM Intervention activates

Activities	Source of information
<b>Session 1 (in-hospital)</b>	
1. Establish relationship with the patient	
2. Briefly assess the patient's baseline understanding of their condition (diabetes and cardiac disease).	•Appraisal: ME
3. Explain the definition of both conditions and discuss the relationship between them and how poor control of diabetes affects the heart and blood vessels.	•Appraisal: ME
4. Discuss the main cardiovascular risk factors and clarify that both conditions share many modifiable risk factors.	•Appraisal: ME
5. Discuss the main symptoms and consequences of poor control of diabetes and cardiac disease.	•Appraisal: ME
6. Discuss the two role models in the booklet (Ali and Fatima); persuade the patient of the benefits of self-management and explain that despite the challenges of living with diabetes and cardiac disease, both models were successfully living with both conditions.	•Appraisal: ME •Model: SM •Verbal persuasion: SP
7. Provide the family member who attends the session with information about the intervention and inform them about the importance of self-management behaviour and how to encourage and help the patient with their self-care activities.	•Social support and verbal encouragement: SP
<b>Session 2 (in-hospital)</b>	
1. Discuss how the patient can reduce their risk of developing further heart and health problems and manage their chronic conditions in home	•Appraisal: ME
2. Encourage the patient to set attainable health objectives and help them to prioritise their goals and build a weekly personal action plan for learning new behaviour.	•Goal setting: ME •Social support: SP
3. Assess the patient's confidence to carry out their action plan after discharge.	•Self-appraisal: SA •Feedback: SA
4. Discuss how the patient can reduce their risk of developing further heart and health problems and manage their chronic conditions in home	•Self-monitoring: ME •Self-appraisal: SA
5. Encourage the patient to read the booklet for more information about how to reduce risk factors and improve their self-management skills	•Appraisal: ME •Verbal persuasion: SP
<b>Session 3 (in-hospital)</b>	

1. Discuss the importance of adhering to the medication regimen, particularly the relationship between adherence and health outcomes	•Appraisal: ME
2. Use the teach-back method to confirm the patient's understanding of using medications.	•Appraisal: ME •Feedback: SA
3. Teach the patient how to use the medication record sheet in the log book and the 7-day pill box. Encourage them to record the medications they take and use the box to manage their medications.	•Verbal encouragement: SP
4. Teach the patient about diabetes zones for management (a traffic light tool, in the logbook) and assess their diabetes readings and know the appropriate action for each case.	•Self-appraisal: SA
5. Teach the patient about the heart attack symptoms and the appropriate actions that need to be taken.	
<b>Follow-up phone call (2 weeks after discharge)</b>	
1. Ask the patient to describe their thoughts, experiences and feelings about self-management.	•Feedback: SA
2. Identify any problems or concerns the patient has about self-managing their condition and/or their personal action plan and solve these problems.	•Social support: SP
3. Discuss the patient's self-monitoring and identify their feelings about it and problems they have experienced.	•Feedback: SA
4. Provide verbal encouragement and praise for positive achievements. If the patient has not achieved positive behavioural changes, provide empathy and try to understand the obstacles and help them to set a new attainable goal for the next week.	•Social support: SP •Feedback: SA •Goal setting: ME
5. Set goal(s) for the next week	•Goal setting: ME
6. Remind the patient about the role models in the booklet.	•Model: SM
7. Remind the patient about the information in the booklet and encourage them to re-read it.	•Verbal encouragement: SP •Appraisal: ME
8. Remind the patient about using the logbook to record and monitor their behaviours.	•Self-appraisal: SA
9. Answer the patient's questions.	•Social support: SP
<b>Supportive tools</b>	
1. Booklet.	•Appraisal: ME •Model: SM
2. Logbook and 7-day pill box organiser.	•Self-monitoring: ME •Self-appraisal: SA

<p><b>3. Attending family member.</b></p> <p>- Encourage the patient's family member to take part in the discussion during education sessions, to read the booklet, encourage and persuade the patient to change their behaviour, to help the patient to develop and review their weekly personal action plan, and to help the patient adhere to their medication.</p>	<p>•Social support and verbal encouragement: SP</p>
<p><b>Teach-back method</b></p>	
<p><b>1. Clearly explain what the patient needs to know by using plain language and without using medical jargon or vague terms.</b></p> <p><b>2. Use elements of the teach-back method after each point of discussion to encourage the patient to emphasise 1-3 key points related to topic of discussion and then check their understanding. If further explanation is needed, provide it.</b></p> <p><b>3. Encourage patients to ask questions and express their concerns rather than just listen.</b></p> <p><b>4. Use elements of the teach-back method to improve the patient's knowledge and understanding of the value of change and boost their confidence in their ability to change ( in relation to their goals and medication adherence, for example).</b></p>	<p>•Social support and verbal encouragement: SP</p> <p>•Feedback: SA</p>
<p><b>ME:</b> Mastery experiences; <b>SM:</b> Social modelling; <b>SP:</b> Social persuasion; <b>SA:</b> Self appraisal</p>	



**Appendix 14: Example of terms from first draft of booklet have been changed to more plain terms**

<b>Term</b>	<b>Plain language</b>
<b>Adhere to medications</b>	Stick to medications regime as prescribed
<b>You're not allergic to aspirin</b>	Your body does not reaction to aspirin by sneezing, hives or forming a rash for example.
<b>Assess</b>	Evaluate
<b>Assist</b>	Help
<b>Avoid</b>	Do not
<b>Benefit</b>	Help
<b>Cardiologist</b>	Heart doctor
<b>Cardiovascular</b>	Heart and blood vessels
<b>Coronary heart diseases</b>	Heart disease
<b>Circulation</b>	Flow the blood though the body
<b>Health condition/ your condition</b>	A medical problem, an disease, an illness
<b>Continue to</b>	Keep on, still, remain
<b>Control</b>	Manage, have power over, take care of
<b>Decrease</b>	Lower, drop
<b>Detection</b>	Figure out
<b>Develop</b>	Create
<b>Diabetes</b>	Elevated sugar in the blood
<b>Display on</b>	Show on
<b>Effect</b>	Make, result
<b>Enhance</b>	Improve
<b>Episode</b>	Event, attack or brief time
<b>Experience</b>	Have, feel, go through
<b>Risk factors</b>	The causes or something that increases your likelihood of getting a disease
<b>Fatigue</b>	Weak feeling of the whole body
<b>Frequent</b>	Common, often
<b>Glucose</b>	Sugar
<b>Immediately</b>	Right away
<b>Increase</b>	Raise
<b>Kidneys</b>	Organ that filters blood
<b>Maintain</b>	Keep, take care of
<b>Manage</b>	Control, watch, take care of
<b>Medicine/medication</b>	Drugs
<b>Mg</b>	Milligram
<b>Pharmacist</b>	Druggist
<b>Regarding</b>	About
<b>Significant</b>	Big, important
<b>State</b>	Tell, say
<b>Temporary</b>	Short, brief
<b>Ulcer</b>	Open sore

## **Appendix 15: Primary and secondary outcome that need to be evaluated during the feasibility study**

### **Primary outcomes**

#### **1: Evaluation of recruitment capability and resulting sample characteristics**

Aim: to determine whether the DCSM Intervention would be applicable, acceptable and successful in Jordanian context. These data may help us evaluate the feasibility of the proposed recruitment plan and procedures.

- a. Number of potential participants refereed, recruited and refused to take part?
- b. Can we recruit appropriate participants according to the study inclusion and exclusion criteria?
  - We proposed to recruit and collect data from 20 patients with T2D and ACS within 6 weeks
- c. Exploring challenges to recruit patients into study?
- d. What are the recruitment and refusal rate for both patients and their family member? Why they participated or refused to participate?
- e. How feasible and suitable our eligibility criteria? (is it clear and sufficient or too restrictive).
- f. Examining the sample characteristics of the study participants it consistent with the range of expected characteristics as informed by previous research and literature. (to determining whether the intervention is relevant to the study participants).

#### **2: Evaluate and refinement of data collection procedure and outcome measures.**

- a. How appropriate are the data collection procedure and outcomes measures for the intended participants and for purpose of the study? (understandable for patients, appropriates the amount of data collection, does the patients have the capacity to complete the data, missing data...etc)

#### **3: Evaluate of acceptability and suitability of intervention and study procedure.**

- a. Are the study procedures and intervention suitable for and acceptable to participants?
- b. Satisfaction and usefulness, which will be assessed by using the evaluation form with Likert scales. The form asks the patients about their satisfaction and usefulness of intervention elements. The form encourages them to give their feedback about the intervention elements and the way of providing the intervention. This evaluation form should be collected by independent researcher after the intervention via phone.
- c. Assess retention and adherence rate to study procedures, intervention attendance and engagement, time, capacity, understanding of procedures and intervention, burdens.
- d. Other issue such as safety and adverse events?

#### **4: Evaluation of resources and ability to manage and implement the study and intervention.**

- Equipment needs, training and skills, administrative capacity, ethics, time to conduct the study.

**Secondary outcome****5: Preliminary evaluation of participant responses to intervention measures**

Aim: to assess if the intervention will achieve any positive improvement for participants or not, and to determine whether proceeding is advisable, or does the intervention show promise of being successful with the intended population?

Examine the qualitative and quantitative data of participant responses to intervention:

**a. Suggested cognitive and psychological outcome**

1. Diabetes Knowledge Questionnaire (8-items)
2. Diabetes Self-Management Questionnaire (DSMQ)
3. Patient Health Questionnaire (PHQ-9) Depression Module
4. Acute Coronary Syndrome (ACS) Response Index
5. Self-efficacy for Managing Chronic Disease (6-items) (SEMCD-6)
6. Morisky Medication-Taking Adherence Scale (4-items) (MMAS-4)

**b. Clinical outcome**

Blood pressure, blood glucose and lipid profile levels

## Appendix 16: Eligibility screening form



**Patient record number:**

**Date:**

	Yes	No
<b>Inclusion Criteria:</b>		
• Male and female patients.		
• Aged 18 or older.		
• Having ACS (STEMI, NSTEMI and UA).		
• Having a medical diagnosis of T2D.		
• Having medical and psychiatric stability as judged by the treatment team in the hospital / CCU.		
• Having the verbal and cognitive capacity to engage in the intervention.		
• Being able to read and write in Arabic.		
• Having a mobile phone or landline telephone during the study (phone access).		
• Willing to consent.		
<b><i>If YES has been answered for above questions, please complete the following:</i></b>		
<b>Exclusion Criteria:</b>		
• Patients with terminal illnesses such as cancer, AIDS (Acquired Immune Deficiency Syndrome) and leukaemia.		
• Patients with congestive heart failure, chronic obstructive pulmonary disease (COPD) or chronic pain.		
• Patients with dementia or other significant cognitive impairment.		
• Patients with serious visual or physical impairment.		
• Patients who are transferred for open-heart surgery or to another hospital, or who will be discharged to home from the CCU after one day		

If all inclusion criteria of the study answer by “Yes” and all exclusion criteria by “No”. So, the patient is meeting the inclusion and exclusion criteria of the DCSM Intervention and need to refer him/her to the primary researcher by contacting him directly on his contact details (See down) or give the form to senior shift nurse in CCU

**Mu’ath Tanash**

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## Appendix 17: Participant Information Sheet for Feasibility Study



### Participant Information Sheet for Feasibility Study

**Dear Patient:** You are being invited to take part in a research study that is part of my PhD thesis. During the feasibility study, in addition to the same treatment and nursing care that you would normally receive, you will be involved in the study program which designed to promote self-management knowledge and behaviour for the patient with diabetes and cardiac disease. The researcher (Mu'ath Tanash) will provide for you educational sessions while you are in hospital and one follow-up phone call session after 2-3 weeks of discharge from the hospital. This educational intervention will focus on your needs and knowledge as a patient with diabetes and, recently, also a cardiac problem. This may help you to promote self-management of your new health condition and it also may improve your health behaviour and adherence with medical advice. Finally, the researcher will collect some data from you before and after the intervention in order to assess the feasibility and acceptability of the program.

Before you decide whether or not you wish to take part in this study, please take time to read the following information about the purpose and procedures of the study carefully and also discuss it with others if you wish. If you need further information, please do not hesitate to contact me or my supervisor. Thank you for your time and effort.

**Study Title:** Identifying Supportive Care Needs for Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes: Developing and Evaluating a Novel Intervention.

**If you would like further information about this study please feel free to contact:**

<p><b>Research student:</b>            Mu'ath Tanash            PhD student at Institute of Nursing and Health Research (INHR)            Ulster University – School of Nursing            Newtownabbey            BT37 0QB            UK            E-mail: Tanash-m@email.ulster.ac.uk            Mobile/ UK: +44 7593965921            Mobile/ JO: +962 798752251</p>	<p><b>Research Supervisor:</b>            Professor Donna Fitzsimons            Ulster University - School of Nursing            Newtownabbey            BT37 0QB            UK            E-mail d.fitzsimons@ulster.ac.uk            Telephone +44 28 90366619</p>
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**What is the purpose of the study?** The study is part of my PhD thesis, leading to a PhD degree in nursing science. Overall, the study aims to develop and evaluate the feasibility and acceptability of a novel supportive care intervention for patients with Type 2 diabetes and acute coronary syndrome in the context of Jordanian secondary healthcare settings.

**Why have you been chosen?** You have been chosen to participate in this study because, firstly, you were admitted to hospital with a diagnosis of one type of acute coronary event

and you have Type 2 diabetes. Secondly, you fulfil the necessary criteria required for this study. The criteria are:

- Aged 18 or older.
- Having heart attack
- Having a medical diagnosis of type 2 diabetes.
- Having medical and psychiatric stability as judged by the treatment team in the hospital.
- Having the verbal and cognitive capacity to engage in the intervention.
- Being able to read and write in Arabic.
- Having a mobile phone or landline telephone during the study (phone access).
- Willing to consent.

**Do you have to take part?** No, but your participation would be sincerely appreciated. Taking part in the study is entirely voluntary. It is up to you whether or not to take part. If you change your mind, you can withdraw at any time without giving a reason and this will not affect your rights or treatment in any way.

**What are the study procedures?** If you agree to take part in the study, you will be asked to sign the attached consent form. In addition to some medical and demographic data that will be taken from your medical file in hospital, the investigator will ask you to complete a questionnaire before starting the interventional sessions (it will take approximately 15-20 minutes). The questionnaire will assess your knowledge; self-care behaviour; self-efficacy; medication adherence, depression level and beliefs regarding both conditions. The investigator will then provide you with the supportive intervention and this will include the following:

- Three educational sessions face to face while you are in the hospital. The main components will focus on your knowledge of both conditions, lifestyle changes and skills of self-management, and medication adherence. Each session will last around 30 minutes.
- One follow-up call after 2-3 weeks of discharge from the hospital. During this session will discuss your condition and your progress of self-care, will give you an appropriate psychological support and encouragement, will guide you to resolve your issue. The session will last around 20-30 minutes.

Finally, around one month after your discharge from hospital, the investigator will telephone you to arrange a meeting with you (such as in hospital when you visit your doctor in the outpatient clinic) to complete the questionnaire again and to collect some data from your file.

**What will happen to the information that you give?** All information you provide will be analysed confidentially and only used for the research purposes of this study. All consenting participants will be identified by a study number. All data collected and participant consent forms will be coded numerically and the only link between the study identification number and participants' identifying information will be stored in a highly secure cabinet and secured on a password-protected computer at Ulster University. Only

the main researcher will have access to the data. The final results of the analysed information may be published, but all personal data will be completely removed prior to publication as required under data legislation.

**Will you benefit directly from this research study?** There are no direct benefits for participants, but patients may well improve their knowledge and self-management skills relating to their condition. Participants may well make less use of urgent and acute secondary care services as a result of becoming more aware of their health condition. However, if any serious issues arise at any stage concerning patients that may impact on their health or safety, patients will be encouraged to discuss such issues with their healthcare providers as soon as possible.

The final findings of the study may well contribute to improvement of the quality of care in the future for patients with diabetes and cardiac problems in Jordan, and it may well be a unique opportunity to contribute to development of secondary prevention strategies in the Jordanian healthcare system.

**What will happen to the research findings?** The findings of this study will be presented anonymously and will be part of the researcher's PhD thesis. Additionally, findings may be published in healthcare journals and presented at national and international conferences, as well as being used for written publications in peer-reviewed journals. Findings will be made available to participants at the end of the study if they are interested in knowing the outcomes of the study. If you wish to receive information about the research findings, please contact me.

**What if something goes wrong?** Normally, providing the educational intervention or answering the questionnaire should not cause you any serious harm. However, if problems occur, you can contact the researcher who will try to help you to deal with the situation.

**Who has reviewed the study?** This study has been reviewed and approved by the Research Ethics Committee of the School of Nursing, Ulster University, Northern Ireland, United Kingdom. Also it approved by the Institutional Review Board of King Abdullah University Hospital, Jordan.

**Thank you for taking time to read this information**

**Mu'ath Tanash**

**Appendix 18: Participant Consent Form for Feasibility Study****Participant Consent Form for Feasibility Study**

**Study Title:** Identifying Supportive Care Needs for Jordanian Patients Presenting with an Acute Coronary Syndrome and Type 2 Diabetes: Developing and Evaluating a Novel Intervention.

**Please read each of the following statements, then tick  $\surd$  in all the boxes that apply:**

- I confirm that I have received verbal and written information about the aim, process and sequence of the study.
- I have read the participant information sheet and have understood it. I have had the opportunity to ask questions regarding the study and I have obtained adequate answers.
- I understand that the researchers will hold all information and data collected during the study securely and in confidence and that all efforts will be made to ensure that I cannot be identified as a participant in the study and I give permission for the researchers to hold relevant personal data.
- I understand that I am not directly benefiting by taking part in this study.
- I understand that the researchers involved in this study need to have access to my medical file through the medical team. I give permission to these individuals to have access to my records to get related data to the study (e.g. demographic data, blood glucose level, blood pressure and lipid profile).
- I confirm my participation in the study is entirely voluntary and I am free to withdraw from the study at any time without giving any reason.
- I give permission to be contacted by the researcher via telephone calls/text message
- I understand that any research data may be reviewed by the University supervisors or other responsible individuals from the research team. I give permission to these individuals to obtain sight of my medical records while maintaining strict confidentiality.
- I understand my responsibilities as a study participant. I hereby declare that I will participate in the above study.

**Participant name:** \_\_\_\_\_ **Date:** \_\_\_/\_\_\_/\_\_\_ **Signature:** \_\_\_\_\_

**Researcher name:** Mu'ath Tanash (P: +962 798752251 / E: [Tanash-m@email.ulster.ac.uk](mailto:Tanash-m@email.ulster.ac.uk))

**Date:** \_\_\_\_\_

**Signature:** \_\_\_\_\_



**Appendix 19: A self-administered questionnaire for participants in the feasibility study**



**Questionnaire**

Patient code number

*First, I would like to take this opportunity to thank you for taking part in our study.*

**Completing the questionnaire:**

This questionnaire lasting approximately 20-25 minutes to complete. For each question please clearly choosing one answer by using a black or blue pen. Don't worry if you make a mistake; simple cross out the mistake and again choose the correct answer.

**Questions or Help:**

If you have any question about the study or have any queries about the questionnaire please do not hesitate to ask or contact the researcher, he will be available to help you if needed. However, the answers should be given from your point of view not the point of view of the person who is helping.

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Hypertension       Diabetes       Hyperlipidemia or high cholesterol

**13. Have you ever had a heart attack or unstable angina?**

Yes       No

**14. How long have you lived with diabetes?**

0– 3 years       4– 7 years  
 8– 15 years       More than 15 years

**15. Which type of medication you take to manage your diabetes?**

Insulin       Tablets       Both

**16. Have you ever attended (either completely or partially) any course or health educational program about managing your diabetes or cardiovascular disease?**

Yes       No

.....

❖ **Part one: Select and circle the correct answer**

**17. What is a normal blood sugar?**

(A) 70–126      (B) More than 126–200      (C) Greater than 200      (D) Don't know

**18. Blood sugar can be checked with a blood sample or a urine sample. How do these two tests compare?**

(A) Blood test is better      (B) Urine test is better  
(C) They are about the same      (D) Don't know

**19. If someone with diabetes feels thirsty, tired, and weak, it usually means their blood sugar is?**

(A) High      (B) Low      (C) Don't know

**20. When someone with diabetes exercises, their blood sugar?**

(A) Goes up      (B) Goes down      (C) Stays the same      (D) Don't know

**21. Can diabetes cause heart attacks?**

(A) Yes      (B) No      (C) Don't know

**22. Can diabetes cause cancer?**

(A) Yes      (B) No      (C) Don't know

**23. Can diabetes cause blindness?**

(A) Yes      (B) No      (C) Don't know

**24. Can diabetes cause kidney failure?**

(A) Yes

(B) No

(C) Don't know

❖ **Part two: The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 4 weeks, please specify the extent to which each statement applies to you.**

**25. I check my blood sugar levels with care and attention.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**26. The food I choose to eat makes it easy to achieve optimal blood sugar levels.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**27. I keep all doctors' appointments recommended for my diabetes treatment.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**28. I take my diabetes medication (e. g. insulin, tablets) as prescribed.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**29. Occasionally I eat lots of sweets or other foods rich in carbohydrates.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**30. I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter).** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**31. I tend to avoid diabetes-related doctors' appointments.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**32. I do regular physical activity to achieve optimal blood sugar levels.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me**33. I strictly follow the dietary recommendations given by my doctor or diabetes specialist.** Applies to me very much Applies to me to a consider-able degree Applies to me to some degree Does not apply to me

**34. I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control.**

Applies to me very much                       Applies to me to a consider-able degree

Applies to me to some degree                       Does not apply to me

**35. I avoid physical activity, although it would improve my diabetes.**

Applies to me very much                       Applies to me to a consider-able degree

Applies to me to some degree                       Does not apply to me

**36. I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets).**

Applies to me very much                       Applies to me to a consider-able degree

Applies to me to some degree                       Does not apply to me

**37. Sometimes I have real ‘ food binges’ (not triggered by hypoglycaemia)**

Applies to me very much                       Applies to me to a consider-able degree

Applies to me to some degree                       Does not apply to me

**38. Regarding my diabetes care, I should see my medical practitioner(s) more often**

Applies to me very much                       Applies to me to a consider-able degree

Applies to me to some degree                       Does not apply to me

**39. I tend to skip planned physical activity**

Applies to me very much                       Applies to me to a consider-able degree

Applies to me to some degree                       Does not apply to me

**40. My diabetes self-care is poor**

Applies to me very much                       Applies to me to a consider-able degree

Applies to me to some degree                       Does not apply to me



**Part four: The following questions ask about your health and your perceptions about heart attack symptoms. The study investigators would be grateful if you would answer all of the questions in each section.**

### **1. Knowledge Subscale**

**Please circle “0” if you think the symptom is not a symptom of a heart attack or “1” if you think the symptom is a symptom of heart attack.**

	<b>No</b>	<b>Yes</b>
<b>1.</b> Lower abdominal pain	0	1
<b>2.</b> Arm pain or shoulder pain	0	1
<b>3.</b> Arm paralysis	0	1
<b>4.</b> Back pain	0	1
<b>5.</b> Chest pain/pressure/tightness	0	1
<b>6.</b> Chest discomfort (heaviness, burning, tenderness)	0	1
<b>7.</b> Cough	0	1
<b>8.</b> Dizziness, lightheadedness	0	1
<b>9.</b> Headache	0	1
<b>10.</b> Heartburn/indigestion/stomach problem	0	1
<b>11.</b> Jaw pain	0	1
<b>12.</b> Loss of consciousness/fainting	0	1
<b>13.</b> Nausea/vomiting	0	1
<b>14.</b> Neck pain	0	1
<b>15.</b> Numbness/tingling in arm or hand	0	1
<b>16.</b> Pale, ashen, loss/change of color	0	1
<b>17.</b> Palpitations/rapid heart rate	0	1
<b>18.</b> Shortness of breath/difficulty breathing	0	1
<b>19.</b> Slurred speech	0	1
<b>20.</b> Sweating	0	1
<b>21.</b> Weakness/fatigue	0	1

## 2. Attitudes Subscale.

Next are some questions about some statements of attitude. Please circle “1” for not at all, “2” for a little sure, “3” for pretty sure, and “4” for very sure.

22. How sure are you that you could recognize the signs and symptoms of a heart attack in someone else?

1	2	3	4
not at all	little sure	pretty sure	very sure

23. How sure are you that you could recognize the signs and symptoms of a heart attack in yourself?

1	2	3	4
not at all	little sure	pretty sure	very sure

24. How sure are you that you could tell the difference between the signs or symptoms of a heart attack and other medical problems?

1	2	3	4
not at all	little sure	pretty sure	very sure

25. How sure are you that you could get help for someone if you thought they were having a heart attack?

1	2	3	4
not at all	little sure	pretty sure	very sure

26. How sure are you that you could get help for yourself if you thought you were having a heart attack?

1	2	3	4
not at all	little sure	pretty sure	very sure

## 3. Beliefs Subscale.

Next are some questions about some statements of opinions. Please circle “1” for strongly agree, “2” for agree, “3” for disagree, and “4” for strongly disagree.

27. If I have chest pain that doesn’t stop after 15 minutes, I should get to the hospital as soon as possible

1	2	3	4
strongly agree	agree	disagree	strongly disagree

28. I would be embarrassed to go to the hospital if I thought I was having a heart attack but I wasn’t.

1	2	3	4
strongly agree	agree	disagree	strongly disagree

29. If I thought I was having a heart attack, I would wait until I was very sure before going to the hospital.

1	2	3	4
strongly agree	agree	disagree	strongly disagree

30. If I thought I was having a heart attack, I would rather have someone drive me to the hospital than have an ambulance come to my home.



1	2	3	4
strongly agree	agree	disagree	strongly disagree

31. Because of the cost of medical care, I would want to be absolutely sure I was having a heart attack before going to the hospital.

1	2	3	4
strongly agree	agree	disagree	strongly disagree

32. If I'm having chest pain and I'm not very sure if it's a heart attack, I should go to the hospital .

1	2	3	4
strongly agree	agree	disagree	strongly disagree

33. If I thought I was having a heart attack, I would go to the hospital right away .

1	2	3	4
strongly agree	agree	disagree	strongly disagree

.....

**Part five: Please select one answer on each following question:**

**1. Do you ever forget to take your medications?**

Yes                       No

**2. Do you ever have problems remembering to take your medications?**

Yes                       No

**3. When you feel better, do you sometimes stop taking your medications?**

Yes                       No

**4. Sometimes if you feel worse when you take your medications, do you stop taking it?**

Yes                       No

**Part six: we would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time**

1. How confident do you feel that you can keep the fatigue caused by your disease from interfering with the things you want to do?

not at all										totally	
confident	1	2	3	4	5	6	7	8	9	10	confident

2. How confident do you feel that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

not at all										totally	
confident	1	2	3	4	5	6	7	8	9	10	confident

3. How confident do you feel that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

not at all										totally	
confident	1	2	3	4	5	6	7	8	9	10	confident

4. How confident do you feel that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

not at all										totally	
confident	1	2	3	4	5	6	7	8	9	10	confident

5. How confident do you feel that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?

not at all										totally	
confident	1	2	3	4	5	6	7	8	9	10	confident

6. How confident do you feel that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

not at all										totally	
confident	1	2	3	4	5	6	7	8	9	10	confident

**Thank you very much for your time  
Mu'ath Tanash**

**Appendix 20: Evaluation Form**

<b>About the follow-up phone call, answer the following questions?</b>				
<b>Was the phone call convenient for you?</b>				
1 Not at all	2 A little bit	3 Somewhat	4 Quite a bit	5 Very much
<b>Do you think the phone call was effective in enhancing your health knowledge?</b>				
1 Not at all	2 A little bit	3 Somewhat	4 Quite a bit	5 Very much
<b>Do you think the phone call was effective in boosting your confidence to control the disease?</b>				
1 Not at all	2 A little bit	3 Somewhat	4 Quite a bit	5 Very much
<b>Do you think the phone call was effective in enhancing your psychological comfort?</b>				
1 Not at all	2 A little bit	3 Somewhat	4 Quite a bit	5 Very much
<b>Any comments or suggestions about using phone calls with the patient (such as, about the time, duration, number of times, content...etc)</b> ..... ..... ..... ..... ..... .....				
<b>Overall the intervention</b>				
<b>In general, did you find the program useful?</b>				
1 Not at all	2 A little bit	3 Somewhat	4 Quite a bit	5 Very much
<b>In general, did you find the program interesting?</b>				
1 Not at all	2 A little bit	3 Somewhat	4 Quite a bit	5 Very much
<b>Which mode of delivery did you like more?</b>				
<input type="checkbox"/> In-hospital sessions	<input type="checkbox"/> Follow-up phone call			<input type="checkbox"/> Both
<b>Which mode of delivery you found it useful more?</b>				
<input type="checkbox"/> In-hospital sessions	<input type="checkbox"/> Follow-up phone call			<input type="checkbox"/> Both
<b>Finally, do you think the provider of the program was good in providing the health information and support?</b>				

1 Not at all	2 A little bit	3 Somewhat	4 Quite a bit	5 Very much
<p><b>Comments or suggestions about the mode of delivery of the intervention or about the intervention provider:</b></p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>				
<p><b>How we can improve the health education program for patients with diabetes and heart disease?</b></p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>				

Thank you

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