# Feasibility and Initial Efficacy of Home-Based Cardiac Telerehabilitation— A Pilot Study

by

Zhonghan Li

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## AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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# Abstract

**Background:** Cardiovascular Disease (CVD) is the top health problem all over the world, including China. Home-based rehabilitation after cardiac surgery has been shown to be beneficial. In our study, a clinical study has been carried out to investigate the feasibility and effectiveness of using emergent mobile and information technology to deliver monitoring and feedback function in Home-Based Cardiac Telerehabilitation program (HBCTR). The main purpose of this study is to assess the feasibility and acceptance of the HBCTR program in low risk patients post Percutaneous Coronary Intervention (PCI). The secondary purpose is to assess the initial efficacy of the HBCTR program.

**Method:** A single-blinded parallel two-arm Randomized Controlled Trial (RCT) has been conducted at the First Affiliated Hospital of Shantou University Medical College, China. A total of 24 post PCI patients were recruited and randomly divided into two equal groups. The control group (Usual Care (UC) program) received paper-based CVD educational booklets and biweekly outpatient review. The experiment group (HBCTR program) carried out outdoor walking/jogging exercise with real time physiological monitoring along with CVD education materials. Feasibility and acceptance of the HBCTR program were evaluated by using an acceptance questionnaire, a satisfaction questionnaire, patients' adherence evaluation, system abnormalities analysis, and safety evaluation. The effectiveness of this program was measured by using 6 Minutes Walking Test (6MWT), Fagerstrom Test for Nicotine Dependence (FTND), Cardiac Depression Scale (CDS)), and SF-36 Health Survey.

**Results:** A total of 53 respondents completed the HBCTR patient acceptance questionnaire, and 22 participants completed the RCT. One experiment group participant withdrew, and one control group participant lost contact during the RCT. 67.9% of participants deemed the HBCTR program acceptable due to real time exercise monitoring and emergency alert function. Features including real time exercise monitoring and emergency alerts are attributed to the high acceptance of the HBCTR program. The HBCTR program is perceived to allow patients to exercise in a safer and more independent manner compared to the UC method, and 81.8% of participants (n=9) felt satisfied with the HBCTR program. The average adherence rates of HBCTR in terms of exercise trainings, self-reporting, and medication intake are 92.9%, 88.4%, and 90.0% respectively. No serious adverse event was reported in the study; Out of the 184 exercise trainings the HBCTR remote monitoring system had only 7(3.8%) temporary system failures. After the six- week intervention, both groups resulted in statistically significant improvements in SF-36 physical component summary (PCS), SF-36 mental component summary (MCS), 6MWT, FTND,

DASI, and CDS. Furthermore, patients in the experimental group had better improvements compared to patients in the control group in PCS scores in SF-36 (HBCTR: $\Delta 12.5 \pm 7.8$ vs UC: $\Delta\ 4.6 \pm 5.7$), DASI (HBCTR: $\Delta 0.7 \pm 0.5$ vs UC: $\Delta\ 0.3 \pm 0.4$), and 6 MWT (HBCTR: $\Delta 45.5 \pm 17.4$ vs UC: $\Delta 27.6 \pm 14.7$).

**Conclusion:** The proposed HBCTR program is feasible and safe for low-risk post PCI patients. Although improvements were observed in both groups, the physical indicators of PCS and 6MWT of HBCTR patients exceeded those of the UC patients. The patients in the HBCTR program showed high satisfaction and decreased fears in performing rehabilitation exercise "at home" with remote monitoring. With this decreased fears in exercise, the adherence among the HBCTR patients was high which resulted in their benefit physical outcomes. Future study with multiple centers and a large-scale randomized controlled trial can be carried out to further assess the efficiency of the HBCTR program in long term. Cost analysis also can be added into the further study to compare the cost effective between HBCTR and traditional center-based CR.

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# Chapter 1

# Introduction

Cardiovascular Disease (CVD) is the number one cause of death in China and worldwide. The World Health Organization (WHO) reported that in 2012, 17.5 million people died from CVD (World Health Organization, 2014). There were approximately 230 million CVD patients in China in 2008, and, annually, it kills approximately 3 million Chinese (Hu et al., 2012). Data published by the Public Health Agency of Canada shows that 29% of all deaths in Canada resulted from CVD in 2008 (Statistics Canada, 2011).

Percutaneous Coronary Intervention (PCI) has been widely used to treat CVD. For post-PCI patients, Cardiac Rehabilitation (CR) has been recommended as a standard intervention procedure from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR, 2013). CR is an effective intervention for post-PCI patients because it decreases the chances of hospital re-admissions and reduces cardiovascular morbidity and mortality; it also improves functional capacity and quality of life through physical activity and secondary prevention education (Piepoli et al., 2010; Heran et al., 2011). Furthermore, CR can improve outcomes of surgery, and lower a range of risk factors for cardiovascular conditions (Ades, 2001; Taylor et al., 2004).

Despite the large body of evidence showing the benefits of CR, more than 70% of cardiac patients are still not eligible to participant in any form of rehabilitation in many counties (Kotseva et al., 2009). This is even more the case in developing countries, such as China (Liu, Dai, Cheng, Guo, 2006). Home-Based Cardiac Rehabilitation (HBCR) is considered as an alternative to center-based or hospital-based CR, which aims to increase patient participation, especially among older people, disabled people or rural populations. In addition, HBCR has been proven to be as effective as hospital-based CR in terms of clinical outcomes (Taylor, Dalal, Jolly, Moxham, Zawada, 2010).

CR in China is mainly limited to early mobilization and on-site physical exercises, and a very low proportion of patients are eligible for such CR programs (Thompson & Yu, 2007). Many cardiac patients cannot attend CR programs for a variety of reasons, including financial difficulties, disease limitations, limited healthcare facilities and transportation.

A new type of HBCR, Home-Based Cardiac Telerehabilitation (HBCTR), has been defined as an application of telecommunication technology in HBCR for the purpose of long-distance monitoring and providing timely communication between CR professionals and patients (Wen, Yeh, Chang, & Lee,

2008). Compared to conventional outpatient CR, HBCTR programs may improve rehabilitation services for cardiac patients in terms of reducing care costs by remote monitoring of patients, allowing rehabilitation professionals to track and supervise multiple patients without geographical constraints, enhancing the patients' adherence rate by carrying out rehabilitation routines in a familiar and convenient environment, and expanding the reach of rehabilitation programs.

A variety of home monitoring devices have been used for patients' self-management and health promotion in CR, such as Heart Rate (HR) meters, Electrocardiogram (ECG) monitors and video conferencing (Scalvini et al., 2013; Worringham et al., 2011; Piotrowicz et al., 2010; Piotrowicz et al., 2014).

The proposed HBCTR system consists of sensors, smartphones, servers and the Internet. Based on automatically collected participants' physiological and activity signals, as well as self-reported data, the care team is able to provide nearly real-time or periodical feedback to participants. The pilot study was a single-centre, parallel-group, randomized controlled trial comparing: (i) usual medical care with; (ii) a HBCTR program for low risk patients post PCI in the First Affiliated Hospital of Shantou University Medical College, China. Measurements were obtained at the baseline and at the end of the six-week intervention. The main goal of this pilot study was to explore: (1) the acceptance and feasibility of the HBCTR programs by using the HBCTR acceptance questionnaire, the HBCTR satisfaction questionnaires, patients' adherence evaluation, a system abnormalities analysis and safety evaluation; and (2) the initial efficacy of the HBCTR program in low risk patients after PCI in terms of exercise capacity, modifying risk factors and quality of life.

# Chapter 2

# Literature Review

## 2.1 Cardiovascular Disease and Percutaneous Coronary Intervention

Cardiovascular Disease (CVD) is defined as a series of disorders of the heart and blood vessels, including coronary heart disease, cerebrovascular disease and peripheral arterial disease. CVD is the leading cause of death globally (World Health Organization, 2014). Not only does it result in high mortality, but the significant financial burden of CVD is a global issue. American Centers for Disease Control and Prevention (2014) estimated the cost of CVD globally to be approximately 863 billion USD, and that it will increase 22% to 1.044 trillion USD in 2030.

Percutaneous Coronary Intervention (PCI), also called coronary angioplasty or angioplasty with stent, is a non-surgical treatment which uses transcatheter technology to dredge narrow or even an occlusion of the coronary artery lumen in order to improve myocardial blood flow perfusion, thus decreasing heart-related chest pain (angina), and increasing the functionality for patients (Braunwald, Zipes, Libby, 2005). PCI has been widely used to treat coronary heart disease. In 2003, American PCI cases already reached 900,000, which surpass the number of Coronary Artery Bypass Grafting (CABG) cases (Braunwald, et al 2005). In China, the cases of PCI have also been increasing rapidly, and reached 180,000 cases in 2008 (Hu et al., 2012). Although PCI is a low risk intervention for cardiac patients, they also need high quality rehabilitation and secondary prevention to achieve optimal outcomes.

## 2.2 Traditional Cardiac Rehabilitation after PCI

Cardiac Rehabilitation (CR) is defined by the American Heart Association (AHA) (2014) as "a medical process which provides cardiac patients with beneficial interventions so that patients can recover by their own efforts and attain physical, psychological and social independence." The target population of CR is the patients who are recovering from acute myocardial infarction, CABG, PCI or heart failure.

CR is an essential component of secondary prevention for CVD and post PCI patients. It consists of a series of complex interventions including patient assessment, physical activity counselling, exercise training, diet/nutritional counselling, weight control management, lipid management, blood pressure monitoring, smoking cessation and psychosocial management. Like all post-PCI, the aims of CR are managing and decreasing risk factors of CVD (Piepoli et al., 2010; Balady et al., 2007; Perk et al., 2012).

Traditionally, outpatient CR programs are performed for patients through group-based exercise sessions, one to three times per week, and supplemented with self-education material. The duration of

outpatient CR programs varies from 4 to 24 weeks depending on each patient's health status (Kavanagh, 2007; Taylor et al., 2010; Scott, Lindsay, Harden, 2003). CR usually can be divided into three or four phases. **Table 1** shows these phases (Gonzalez, Cuccurullo, Jafri, Luciano, 2004).

**Table 1 Phases of Cardiac Rehabilitation**

| | |
|---|---|
| Phase I (Inpatient Period) | This phase of rehabilitation can last from two days to seven days depending on the patient's health condition. During the acute inpatient hospitalization, this stage of rehabilitation includes patients' assessments, early education, initial mobilization and a discharge plan. |
| Phase II (Immediate Outpatient Period) | This stage is the most closely monitored phase of rehabilitation. The duration of this stage is determined by the patient's risk level and monitoring needs. Medical personnel teach patients how to do rehabilitation and supervise exercise training. |
| Phase III and Phase IV (Intermediate and Maintenance Periods) | The third stage of CR is an extended outpatient period which can be divided into two sub-stages: intermediate and maintenance. The intermediate stage follows the Immediate Outpatient period. Patients still participate in CR programs without close monitoring. Phase IV is a lifetime period, when patients maintain their lifestyle changes for the long term. |

Systematic reviews of randomized controlled trials of CR programs show that the total and cardiac mortality were reduced by 20% and 27% respectively through CR (Stone, Arthur, Suskin, 2009; Taylor et al., 2004). Furthermore, CR has been proven to modify CVD risk factors, facilitate the maintenance of an independent lifestyle, and decrease further cardiac events (Fletcher et al., 2001; Stone, Cyr, Friesen, 2001; Balady et al., 2007; Piepoli et al., 2010). Although CR brings many benefits to patients, barriers and drawbacks of outpatient CR programs cannot be ignored. The Canadian Heart Health Strategy and Action Plan (2009) published that only approximately 34% of patients are eligible to participate in CR in Canada.

The challenges are twofold: low program participation and limited medical resources (Carlson, Johnson, Franklin, Vander, 2000). Geographical barriers are always a major reason for low attendance in many countries (Leung, Brual, Macpherson, & Grace, 2010; Echeverri, 2007; Brual, et al., 2010). The physical limitations of patients restrict their ability to drive any long distance. Additionally, psychological factors (depression and anxiety) also affect the potential candidates attending the CR program, and some candidates choose not to attend group-based CR programs because they have difficulty exercising in a

group setting even though they may benefit from positive physiological changes (Taylor, Barber, McIntosh, & Khan, 1998; Lane, Carroll, Ring, Beevers, & Lip, 2001; Yohannes, Yalfani, Doherty & Bundy, 2007). Other barriers which affect attendance in CR programs include safety concerns, time loss and financial hardship. Furthermore, limited medical resources include insufficient number of well-trained CR physicians and not all healthcare (rehabilitation) centers want to or can afford the space, personnel and equipment.

CR program services face additional requirements that address cardiac patients' problems (Kavanagh, 2007). A CR program needs no less than one month of regular exercise with costly healthcare facilities and well-trained professional staff. The sustainability of CR programs is at risk, especially in light of the high costs of care resources (Karunanithi & Sarela, 2009). This problem is more acute in China where there are both limited medical resources and a large population.

## 2.3 Home-Based Cardiac Rehabilitation

"Home-based" CR (HBCR) is a structured CR program which implements medical practices for cardiac patients in a non-hospital setting. "Hospital-based or center-based" CR programs are hosted either in a hospital or medical centre setting. Cochrane (2010) has shown that there is no significant difference in effectiveness between HBCR and centre-based CR of Coronary Heart Disease (CHD) patients with respect to quality of life, risk factors, mortality and morbidity over short periods (3-12months).

The main benefit to implementing HBCR is to provide more access and options for cardiac patients. A HBCR program allows the patient to perform physical rehabilitation in a familiar and comfortable environment. Patients are no longer required to spend a long time commuting to rehabilitation centers (Xia, Asif & Zhao, 2013). Accordingly, the adherence rate of rehabilitation will increase. These benefits of HBCR can, in turn, encourage physicians to prescribe more physical rehabilitation to patients. As a result, HBCR can help patients to return to normal life faster and maintain a healthy lifestyle for the long run.

Patients usually undergo initial risk assessment and basic training for HBCR for several days prior to being discharged from a hospital or medical centre. The risk assessment is one of the essential components of CR programs after PCI, which include clinical history, physical examination and stress testing. The purpose of risk assessment is to assess participants' capacity for exercise and educational needs for HBCR (Piepoli et al., 2010). After the risk assessment, patients participate in training sessions and learn about precautions for HBCR (Gordon et al., 2002; Arthur et al., 2002; Carlson, Johnson, Franklin, Vander, 2000).

The length and type of a HBCR program vary based on a patient's needs and a rehabilitation center's resources. The National Heart Foundation of Australia & Australian Cardiac Rehabilitation Association (NHFAACRA) (2004) recommended that HBCR programs usually begin from discharge until the initial goal is achieved, typically from 4 to 12 weeks. HBCR generally includes educational counselling and individual guidance services.

The educational counselling component introduces the basic knowledge of CR to patients, including the heart structure and function, the effects of heart disease and surgery, the benefits of doing a CR program, the risk factors for heart disease, and secondary prevention (e.g. physical activity counselling, diet/nutritional counselling, weight control management, lipid management, blood pressure monitoring, smoking cessation, psychosocial management and diabetes).The educational counselling also provides CR education to patients with behaviour change and maintenance strategy, returning to work, emergency planning for home, guidelines for activities at home, and management of symptoms (Piepoli et al., 2010; NHFAACRA, 2004).

Although HBCR programs have been used for many years, the different types of HBCR are still evolving. In the past, a nurse usually connects with patients by telephone, mail or home visits on a regular basis to provide some structured educational materials. This form of HBCR programs usually does not provide real-time physiological monitoring and professional guidance to patients; therefore, patients are required to visit the clinic center to get feedback from the medical professionals (Haskell et al., 1994; Gordon et al., 2001; Vale, Jelinek, Best, Santamaria, 2002; Vale et al., 2003; Lewin, Robertson, Cay, Irving, Campbell, 1992). Healthcare providers in many countries (Australia, Canada, Italy, New Zealand and UK) have used the Heart Manual (Heart Manual, 2008) to educate patients and enable them to self-administer the HBCR (Lewin et al., 1992). However, one of the biggest challenges of the HBCR is the lack of effective objective information for physiological indicator monitoring and the lack of a medical team's timely customized individual feedback to patients. The challenge not only increases cardiac patients' safety concerns about exercise, but also limits the clinical management from health personnel (Worringham, Rojek, & Stewart, 2011).

With the development of telecommunication, mobile technology has the potential to overcome barriers of monitoring and safety issues. HBCTR is a modern method of performing HBCR, and is defined as managing and performing HBCR programs with remote technology, which includes telemonitoring (often involving sensors), telesupport (e.g. supports from nurses and coordinators), telecoaching (support and instruction for exercise training) and teleconsulting (Winters, 2004). The main difference between HBCTR and HBCR is that HBCTR employs mobile phones, wireless wearable

devices and Internet services to monitor and facilitate communication between health personnel and patients. **Table 2** shows the comparison between center-based CR, conventional HBCR and HBCTR.

**Table 2 Comparison between center-based CR, conventional HBCR and HBCTR**

| Type | Protocol | Advantages | Disadvantages |
|---|---|---|---|
| **Hospital-based or center-based" CR** | CR professionals implement CR for patients in a hospital or rehabilitation center. | 1. On-site exercise with close monitoring<br>2. Timely instructions | 1. Low participation<br>2. Time loss<br>3. Financial hardship |
| **HBCR** | Patients do CR in a non-hospital setting.<br>A nurse usually connects with patients by telephone, mail or home visits on a regular basis to provide some structured educational materials | 1. High participation and adherence<br>2. Patient is able to perform physical rehabilitation in a familiar and comfortable environment | 1. Lacks objective physiological monitoring<br>2. No timely customized feedback |
| **HBCTR** | CR professionals implement CR with mobile technology, including remote monitoring and regular health guidance. | 1. Patients physiological monitoring<br>2. Timely customized instructions | 1. Costly devices<br>2. Complex operation |

Researchers have used modern communication technology to establish a variety of monitoring systems or customized feedback functions in HBCTR and to test their feasibility and adherence in post cardiac surgery patients (Piotrowicz & Piotrowicz, 2011; Piotrowicz et al., 2010; Piotrowicz et al., 2014; Varnfield et al., 2014; Jaworek & Augustyniak, 2011). A study conducted by Mattila et al. in 2009 made use of a HR monitor and Smartphone technology to collect and analyze the data when a patient exercises. Worringham et al. (2011) demonstrated the feasibility of a system using a Smartphone, ECG and Global Positioning System (GPS) for remotely monitoring exercises. They monitored the one-lead real time ECG, HR and walking speed when patients walked outside.

Many studies reported that HBCTR programs are not only safe, but also have high adherence and good satisfaction for post cardiac surgery patients (Scalvini et al., 2009; Scalvini et al., 2013; Maric, Kaan, Ignaszewski, Lear, 2009; Mortara et al., 2009; Varnfield et al., 2014; Piotrowicz et al., 2010). Neither death nor serious adverse events have been reported in HBCTR programs (Smart et al., 2005; Piotrowicz et al., 2010; Piotrowicz et al., 2014).

Studies have shown that the adherence to telerehabilitation programs is better than that in conventional outpatient CR programs (Smart, Haluska, Jeffriess, Marwick, 2005; Piotrowicz et al., 2010; Varnfield et al., 2014). Regular communication between care team and patients in telerehabilitation

programs generally result in a better understanding of patients' needs and concerns. Some HBCTR programs have an alert or warning function. In this warning function, when abnormal signs (e.g. tachycardia) are detected, the system alerts and notifies medical personnel immediately via Short Message Service (SMS) (Piotrowicz et al., 2014).

Recently, a study reported that a Smartphone-based home care model with activity monitoring not only improved the CR adherence but also was effective as traditional CR in terms of physiological and psychological health outcomes (Varnfield M et al, 2014). One form of a HBCTR study used synchronized videoconferencing to manage exercise training for patients (Scalvini et al., 2013; Scalvini, Zanelli, Comini, Tomba, Troise, Giordano, 2009).

However, with the exception of synchronized videoconferencing, all other HBCTR programs do not combine health monitoring with fast customized guidance to patients, so a nurse or physiotherapist needs to make home visits to provide revised exercise advice for patients. Furthermore, the HBCTR program with synchronized videoconferencing requires costly devices. In order to make a more convenient, flexible, cost effective and reliable HBCTR program which combines health monitoring and customized feedback, a new remote HBCTR model should be established.

### 2.3.1 Physical Activity

Before prescribing exercise training for a HBCTR participant, a stress test is performed to gather valuable diagnostic and cardiopulmonary information about a patient. An exercise stress test is also used to evaluate the patient's exercise capacity after CR programs (Pina, Balady, Hanson, Labovitz, Madonna, Myers, 1995). The modified Bruce protocol (Hill &Timmis, 2002) or 6 Minutes Walking Test (6MWT) (Fiorina et al., 2007) are commonly used for such purposes.

Exercise prescription is usually designed based on a patient's exercise stress test outcome. The objective of exercise training is mainly to maintain a certain amount of exercise time and intensity. The European Association of Cardiovascular Prevention and Rehabilitation recommends 3-5 training sessions per week and 30–60 minutes per session at 55–70% of the maximum HR (Piepoli et al., 2010). The expected energy consumption should be more than 1500 kcal/week.

The customization of a HBCTR program may include exercise type, frequency (times/week), intensity (target heart rate, Borg Rating of Perceived Exertion (RPE)), and duration (minutes) to achieve exercise goals (Smith et al., 2006). Exercise types include stretching, walking, jogging, dancing, doing Tai Chi, swimming, or cycling. The exercise intensity is monitored by the target HR and RPE. The target HR range is a patient's 55–70% of the maximum HR. The American Association of Cardiovascular and

Pulmonary Rehabilitation (AACPR) recommends RPE levels for CR exercise to be between 12-16, but most HBCR programs prefer to select more conservative levels, from 11 to 15 (Carlson, Johnson, Franklin, Vander, 2000).

### 2.3.2 Vital Signals Monitored During HBCTR Program

Ideally, HBCTR will monitor HR, continuous or intermittent ECG, blood pressure (BP), RPE and exercise reactions to ensure patient safety.

#### 2.3.2.1 Heart Rate & Blood Pressure

Heart rate is a common indicator of a patient's cardiac status during a CR program (Lusignan et al., 2000). The NHFAACRA (2004) recommends that HR be monitored as a critical parameter to evaluate candidate's health condition pre- and post-activity. In all rehabilitation programs, especially in HBCTR programs, patients are required to measure their HR, and report the data to doctors regularly (Smart, Haluska, Jeffriess, Marwick, 2005). BP is another indicator monitoring a person's cardiac status during a CR program (Artinian, Washington, Templin, 2001). The AACVPR (2013) recommends that a patient's BP should be measured before and after the rehabilitation exercise.

#### 2.3.2.2 Exercise Reactions (Signs and Symptoms)

It is important for patients to recognize angina or myocardial ischemia symptoms in CR programs, especially during exercise training. Angina or myocardial ischemia symptoms especially if associated with physical activity, include pressure, tingling, pain, heaviness, burning, numbness in the chest, jaw, neck, or arms, light-headedness, dizziness, or fainting, shortness of breath, rapid heartbeat or palpitations (Braunwald et al., 2005).

#### 2.3.2.3 Electrocardiography (ECG)

According to guidelines of NHFAACRA (2004) and AACVPR (2013), ideally, ECG can be a major physiological parameter for the assessment of patients' health status during CR programs. Although continuous ECG is not necessary for low-risk patients according to AACPR guidelines (2004), direct supervision and real-time ECG monitoring are still commonly used to facilitate HBCTR for patients (Wenger, 2008). Some HBCTR programs used one-lead ECG devices to monitor and record the heart activity data (Scalvini et al., 2013; Scalvini et al., 2009). These ECG devices increase CR adherence and performance for participants (Kmill, Sherrington, Third, 2007).

When adequate equipment is used, ECG monitoring for exercise training is regarded as significant: arrhythmia or other important ECG abnormalities can be found without delay, and exercise

prescription can be adjusted depending on monitoring results. As a result, the confidence of patients when engaged in independent activities will increase (AACVPR, 2013). Therefore, ECG has been used to provide protection for candidates in outpatient CR programs (Kouidi, Farmakiotis, Kouidis, Deligiannis, 2006).

#### 2.3.2.4 Rating of Perceived Exertion (RPE)

RPE is a measurement of the perceived exertion in exercise or sports, and it is often used to monitor the exercise intensity in CR programs (AACVPR, 2013; Borg, 1998). Because physical exertion has a linear correlation with HR and ventricular oxygen consumption, RPE is used to monitor exercise progress and intensity during exercise training (Mezzani et al., 2012). Furthermore, RPE, as an adjunct to HR, is a reliable indicator to assess cardiac patients regardless of whether they take beta blocker medications or not (Hartzell et al., 1986; Dunbar et al., 1992; Eston & Connolly, 1996). The common scale for RPE is the RPE Borg scale, which ranks exercise intensity from 6 (no exertion at all) to 20 (maximal exertion). The RPE Borg scale table is presented in **Appendix A**.

## 2.4 Current State of Cardiac Rehabilitation in China

In China, the concept of CR still is not well recognized, though CVD is a top cause of death and disability. To our knowledge, there is no HBCR program in mainland China and formal outpatient CR programs are only available in large metropolitan public hospitals (e.g. Beijing, Shanghai) or advanced private hospitals. After being discharged, patients have very limited CR opportunities. In most rural areas, patients are discharged without any form of rehabilitation.

There is little opportunity for patients to attend outpatient CR programs because they are few in number, and the model of CR programs is not comprehensive. Hong Kong has well-established CR programs which are run by a team of CR professionals (i.e. two cardiologists, a rehabilitation physician, four cardiac rehabilitation nurses, two physiotherapists, two occupational therapists, a clinical psychologist, a dietician, and a research assistant) (Yu et al., 2000; Yu et al., 2004). However, by contrast to mainland China, most CR programs are run by a nurse whose CR education focuses on early mobilization by providing leaflets and booklets to patients (David & Yu, 2007). Most outpatient CR programs usually operate two times per week for 12 weeks. Some programs have regular follow-up for three to six months. Nevertheless, there is no Chinese national standard for CR programs. A few studies have focused on early mobilization and exercise in CR instead of a comprehensive CR program involving psychosocial counselling and risk factor education (David & Yu, 2007).

The reasons for these problems include very limited medical resources, a high patient-to-doctor ratio, and a lack of well-trained professional rehabilitation professionals. In addition, doctors usually lack enthusiasm for promoting CR compared with cardiac surgeries and drug therapies in many hospitals. Furthermore, there is also a lack of demand resulting from a poor understanding of rehabilitation among cardiac patients. The limited CR programs are operated differently across each hospital depending on a particular hospital's priority and the available resources. Meanwhile, based on a global mobile phone snapshot in 2013, the fact that 89% of Chinese people own a mobile phone and 66% own a smartphone demonstrates that the potential to reach a large population with mobile health interventions is very high. In view of the national population with its limited medical resources but high ratio of smartphone ownership, a more convenient, flexible and reliable HBCTR program with smartphone should be established in China.

## 2.5 Technology in HBCTR

A variety of information and communication technologies are used in HBCTR in order to monitor patients and provide them with help in a timely manner without any geographical barrier (Health Canada, 2013). Many studies have evaluated the possibility of using telemonitoring technology and devices in CR programs. The most commonly applied infrastructure in relevant studies consists of the three main components: patient module, care team module and communication technology. The patient module is a set of rehabilitation equipment (e.g. sensors and smartphone) which monitor patients' health indicators from a long distance. Different monitoring devices are used to collect particular physiological parameters for analysis and evaluation in different HBCTR programs. The HBCTR programs usually use HR or even ECG monitors and Smartphones to collect and analyze data when patients do exercise (Mattila, Ding, Mattila, Särelä, 2009; Worringham et al., 2011; Wen et al., 2008; Goh et al., 2006). The available remote monitoring equipment is shown in **Table 3**.

**Table 3 Different Types of Remote Monitoring Equipment**

| Name | Monitoring indicators | Equipment | Advantages | Disadvantages |
|---|---|---|---|---|
| **UCARE RG 10(Android), Micor sens, China** | 1. Real time ECG signal<br>2. HR<br>3. Walking speed<br>4. Exercise types (walking, running, standing)<br>5. GPS | A chest strap with a sensor, a smart programmed smartphone | 1. Real time ECG and HR monitoring<br>2. Automatic alert function<br>3. Compatible with most Android phones | 1. High cost ($600) |
| **BioHarness 3, Zephyr ,US** | 1. HR & R-R Interval<br>2. Breathing Rate<br>3. Posture<br>4. Activity Level<br>5. Peak Acceleration<br>6. Speed & Distance | Exercise clothes with sensors | 1. Comprehensive exercise monitoring | 1. No automatic alert<br>2. Very high cost ($1300) |
| **Heart Rate watch, alpha, Mio, US** | 1. Average and max HR<br>2. Calories burned<br>3. Total exercise time | Heart Rate watch | 1. Real-time HR monitoring without chest strap<br>2. Low cost ($200) | 1. No ECG monitoring<br>2. Only compatible with iPhone & Samsung |
| **Alive Heart and Activity Monitor, AUSTRALIA** | 1. Single-lead ECG<br>2. HR<br>3. GPS-based speed and location | Detector with sensors | 1. Real-time data monitoring (ECG, heart rate, heart rate, and GPS) | 1. No automatic alert or warning function |

In the second component (care team module), well-trained healthcare coordinators or doctors provide personalized rehabilitation recommendations to candidates according to the contents of monitoring report. The care team also is allowed to review and check users' health activity history records. Web-based interface or smart phone application are the common tools used by care team to perform their work (Sufi et al., 2006; Korsakas et al., 2006; Braecklein et al., 2005).

Communication technology is the third component which is used to facilitate communication between the patients and doctors. A variety of communication protocols and available devices have been tested in different studies. In the patient unit, data are transmitted through Bluetooth. Critical signals in physiological parameters trigger mobile devices to send messages through GSM, GPRS, 3G, or 4G networks. Meanwhile, relevant signals are sent to the care team module through the networks (Worringham et al., 2011; Karunanithi et al., 2009; Sha et al., 2008; Hung & Zhang, 2003).

## 2.6 Outcomes

CR programs can be evaluated according to three categories of criteria; namely exercise capacity, modified risk factor, and quality of life.

### 2.6.1 Exercise Capacity

The benefits of physical activity for cardiac patients have been shown in many guidebooks and systemic reviews (NHFAACRA, 2004; AACVPR, 2013; Taylor et al., 2004; Rees et al., 2004; Smart et al., 2004; Piepoli et al., 2010). Exercise training not only relieves patients' activity-related symptoms and exercise capacity, but also builds their confidence to return to society both physiologically and psychologically (Perk et al., 2007; Jolliffe et al., 2001; Taylor et al., 2004).

According to statistics published by the Cochrane Database of systemic review, all-cause mortality, death rates, and relative risk of CVD are reduced effectively through exercise-based CR (Jolliffe et al., 2001). Accordingly, as a core parameter of CR, exercise capacity is reported in almost all trials. The Duke Activity Status Index (DASI) is a self-administered questionnaire to measure a patient's peak oxygen uptake and it has been widely accepted as an indicator of a patient's exercise capacity (Hltaky et al., 1989). The 6 Minutes Walking Test (6MWT) is also a standard functional test of exercise capacity to demonstrate the physical outcome for cardiac patients (Fiorina et al., 2007).

### 2.6.2 Modifiable Coronary Risk Factors

As mentioned before, one of the CR program goals is to modify and manage the risk factors of CVD. CR programs are expected to change a patient's potential risk factors, including body weight, psychological factors (e.g. depression), smoking behaviour, and blood pressure level (Piepoli et al., 2010).

#### 2.6.2.1 Body Weight

Body weight is a basic factor in CR programs. There is a positive linear relationship between the Body Mass Index (BMI) and all-cause mortality (Whitlock et al., 2009). Many guidelines, including AHA/AACVPR, recommend using BMI and waist circumference as parameters for measuring body weight (Smith et al., 2006).

Guideline to Prevention and Control Obesity in Chinese Adults (2003) confirms that the BMI value is a reliable indicator for Chinese people. Waist-hip ratio (WHR), the ratio of waist and hip, is another important indicator to determine central obesity. Accordingly, BMI and WHR are used to evaluate the weight management of a HBCR program.

#### 2.6.2.2 Psychological Outcomes

Psychological outcomes are evaluated in CR programs because a high prevalence of depression is reported among cardiac patients (Sullivan et al., 1999; Steffens et al., 1999; Gonzalez et al., 1996; Burker et al., 1995).

The Cardiac Depression Scale (CDS) is a valid and reliable screening questionnaire to measure depression in cardiac patients (Hare & Davis, 1996). It is a short self-rating questionnaire which consists of 26 items (7-point scale) relating to sleep disturbance, anhedonia, uncertainty, mood, cognition, hopelessness, and inactivity. The template of the CDS can be found in **Appendix B**. The CDS offers a responsive and sensitive instrument to measure depression among cardiac patients, and it is highly appropriate for clinical use (Wise, Harris, Carter, 2006). The results of other studies provide further evidence showing the reliability and validity of the CDS for cardiac patients (Birks, Roebuck, Thompson, 2004; Ski, Thompson, Hare, Stewart, Watson, 2012). Furthermore, Wang et al (2008) reported that the Chinese version of the CDS is a valid and reliable disease-specific measurement of depression levels for Chinese-speaking cardiac patients.

#### 2.6.2.3 Blood Pressure

Controlling blood pressure is a significant goal in CR programs because hypertension is a risk factor of CVD. Many guidelines, including AHA/AACVPR, recommend that blood pressure should be assessed as part of outcomes of CR programs (Smith et al., 2006; Piepoli et al., 2010). In addition, 7 trials, which were included in a Cochrane study (Taylor et al., 2010), reported that there is no significant difference in both systolic blood pressure (SBP) and diastolic blood pressure (DBP) between home- and centre-based CR programs.

#### 2.6.2.4 Smoking Behaviour

Smoking behaviour should be evaluated before and after CR programs since tobacco cessation consulting is one of the components in CR programs (Piepoli et al., 2010). The Fagerstrom Test for Nicotine Dependence (FTND) is a commonly used questionnaire to test the level of nicotine dependence in smokers (Heatherton, Kozlowski, Frecker, Fagerstrom, 1991). The FTND questionnaire, a revised version of the FagerStrom Tolerance Questionnaire (FTQ), has proved to be more reliable (Pomerleau, Carton, Lutzke, Flessland, Pomerleau, 1994). Many studies have shown that FTND is a valid and reliable tool used in both experimental programs and clinical applications (Dijkstra, Tromp, 2002; Etter, Duc, Perneger, 1999; Fagerstrom, Schneider, 1989; Payne, Smith, McCracken, McSherry, Antony, 1994; Pomerleau et al., 1994). Although both home- and centre-based CR programs can reduce tobacco dependence, there is no statistically significant difference between these two types of CR programs (Taylor et al., 2010).

### 2.6.3 Health-Related Quality of Life

To measure health-related quality of life (HRQoL) of patients in CR programs, a number of standardized questionnaires can be used, including the Nottingham Health Profile (Hunt et al., 1980), the Short-Form 36 (SF36) (McHorney, Ware, Raczek, 1993), the Interpersonal Support Evaluation List (ISEL) (Cohen & Hoberman,1983; Cohen, Mermelstein, Kamarck, Hoberman,1985), and EuroQol (EQ-5D) (Rabin, de Charro, 2001).

A 36-item Short Form Survey (SF-36) is a commonly-used self-administered questionnaire for evaluating the general health-related quality of life in cardiac patients (Smith et al., 2006; Piepoli et al., 2010). Many research results have shown the SF-36 is a valid, reliable assessment method to measure the patients' quality of life in CR programs (Stewart, Hays, Ware, 1988; Bunker, Kotz, McBurney, McCrae, 1997). The SF-36 consists of 36 questions in two categories: a physical composite score (PCS) and a mental composite score (MCS) (Ware, 1993). A Cochrane systemic review used SF-36 to assess the quality of life between home- and centre-based CR programs, and they reported both home- and centre-based CR programs are able to improve patients' quality of life compared to their baseline (Taylor et al., 2004).

# Chapter 3

# Methods

## 3.1 Design

The pilot study was a single-centre, parallel-group, randomized controlled trial comparing (i) usual medical care with (ii) a HBCTR program for low-risk patients post PCI in the First Affiliated Hospital of Shantou University Medical College, China.

Measurements were obtained at the baseline and at the end of the six- week intervention period. The study was approved by the First Affiliated Hospital of Shantou University Medical College Ethics Committee (**Appendix C**) and the University of Waterloo Research Ethics Board (**Appendix D**). The proposed study flow of patients was designed according to the Consolidated Standards of Reporting Trials (Moher, Schulz, Altman, 2001). A brief design flow chart is shown in **Figure 1**.

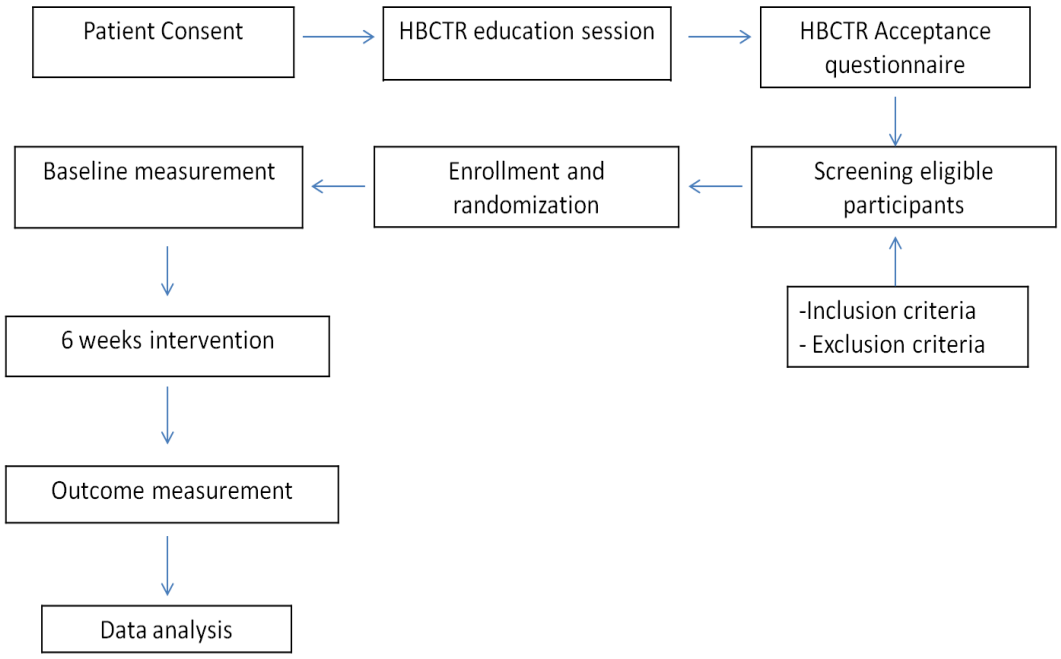



**Figure 1 Study Design**

**The main outcome** was to assess acceptance and feasibility of the HBCTR program for study participants by using the HBCTR acceptance questionnaire, the HBCTR satisfaction questionnaires, a patients' adherence evaluation, a system abnormalities analysis and a safety evaluation.

**The secondary aim** of the study was to assess the initial efficacy of the HBCTR program in terms of exercise capacity, modifying risk factors and quality of life.

## 3.2 Sample

For this study, we recruited post-PCI patients with low-risk diagnostic criteria (as defined in the AACPR Risk Stratification Criteria for Cardiac Patients (Williams, 2001) and the Chinese Association of Rehabilitation Medicine Cardiovascular Committee Risk Stratification Criteria for Cardiac Patients (Liu & Chen, 2006)) from the 1st Affiliated Hospital of Shantou University Medical College. Shantou is a typical medium-sized Chinese city with 5.3 million citizens in a geographical area of 2064 $km^2$. The 1st Affiliated Hospital of Shantou University Medical College is a Class A tertiary comprehensive public hospital which has 2242 employees and 1800 beds. We chose to do this study in Shantou and that hospital in particular because it can represent proportionately the Chinese population and the characteristics of large public Chinese hospitals.

We included patients:

- Post PCI patients within 12 months
- Living with at least one other person in the household who acts as a caregiver or guardian
- Age 40-75 years old
- Able to accept and follow the medical team's instruction.
- Willing to perform exercise
- Able to read Chinese and speak Mandarin
- Presence of functional capacity of ≥5 Metabolic Equivalent (METs).
- Presence of normal hemodynamics during exercise testing and recovery (e.g. appropriate increases and decreases in heart rate and systolic blood pressure with increasing workloads and recovery)
- Resting ejection fraction ≥ 50%

Exclusion criteria where patients who met one or more of these conditions were excluded included:

- Undergone previous Coronary Artery Bypass Graft Surgery (CABG)
- Peri-PCI complications
- Recurrent resting pain
- Age >75
- Presence of diabetes
- Renal issues
- Malignancy

- A history of cerebrovascular accident
- Severe liver or kidney damage or cognitive impairment, aphasia, mental disorder or inability to inspection and treatment
- Unstable angina
- Complex ventricular dysrhythmias during exercise testing or recovery

## 3.3 Procedure

### 3.3.1 Recruitment and Randomization

The HBCTR coordinator assisted attending physicians at the cardiac clinic to screen and enroll participants. Patient consent (**Appendix E**) was obtained at the start of the study.

Interested individuals who had undergone PCI were directed to a study coordinator to participate in a HBCTR Acceptance Questionnaire study. The HBCTR Acceptance Questionnaire (**Appendix F**) was designed based on the current HBCR survey results (Piepoli et al., 2010; Larizza et al., 2014; Larizza et al., 2012; Boise et al., 2013; Wild, Boise, Lundell, Foucek, 2008; Demiris et al., 2004) to investigate patients' perception toward the HBCTR program and to select potentially eligible participants for the proposed clinical trial. Before patients completed the HBCTR Acceptance Questionnaire, our program coordinator provided each patient with an HBCTR education session and demonstrated how to use the home-monitoring system.

After patients have agreed to participate in the HBCTR clinical study, a research cardiologist screened the candidates' eligibility by diagnoses, medical history, past interventional procedures, laboratory tests, symptoms, signs, risk factors, medication history, family history, functional capacity and other issues.

The Duke Activity Status Index (DASI) was used to provide a rough estimate of a patient's peak oxygen uptake. Participants were instructed to complete the questionnaire to confirm that the participant's exercise capacity was larger than 5 Metabolic Equivalent of Energy (METs). The DASI table is presented in **Appendix- J.**

A total of 24 eligible participants were randomly assigned to the control group (usual care) or the experiment group (HBCTR) at a 1:1 ratio via the random allocation sequences generated from SAS software (SAS Institute Inc., Cary, NC, USA). Although participants could not be blinded to their treatment allocation, research assessors were blinded to intervention allocation.

### 3.3.2 Measurement

A Research Assistant (RA) scheduled an appointment with the participants to measure their characteristics and baseline indicators after participants were discharged, which included demographic data, clinical examination, Body Mass Index (BMI), DASI, SF-36 Health Survey, FTND, and CDS. The clinical observation flowchart is shown in **Table 4**, which lists the indicators evaluated at baseline and at 6 weeks.

During the enrolment phase, some outcomes of participants' baseline indicators were already recorded, including medical history, DASI, BMI, and the HBCTR acceptance questionnaire. A RA guided participants to evaluate other baseline indicators, including 6MWT, SF 36 Survey, FTND and CDS.

#### 3.3.2.1 Functional Capacity Measurement

The functional capacity was measured with a 6MWT in the measured hospital ward corridor with markers placed at 50 meters. Patients were instructed to perform a six-minute shuttle walk test as far as possible, but not to run or jog. The 6MWT standardized protocol is shown in **Appendix G**.

#### 3.3.2.2 Quality of Life and Risk Factors Measurement

A SF-36 Health Survey (**Appendix H**) was used to evaluate the general health-related quality of life for participants. Higher scores are indicative of better quality of life. The FTND questionnaire (**Appendix I**) was used to test the level of nicotine dependence in participants. The CDS is a valid and reliable screening questionnaire to measure depression in cardiac patients.

After a six-week intervention, rehabilitation outcomes of the participants' in both control and experiment groups were measured by FTND, CDS, 6MWT, DASI, SF-36 Health Survey, a safety evaluation, a system abnormalities analysis, an adherence evaluation, and the HBCTR Satisfaction Questionnaire (**Appendix K**).

**Table 4 Clinical Observation Flowchart**

| Stage | Select the candidate, Baseline measure | Intervention period |
|---|---|---|
| **Visit** | 1 | 2 |
| **Timeline** | -2~0W | 6W±2d |
| Informed Consent | √ | |
| Inclusion/Exclusion Criteria | √ | |
| Demographic Data | √ | |
| Clinical Examination | √ | |
| Duke Activity Status Index | √ | √ |
| HBCTR Acceptance Questionnaire | √ | |
| Body mass index (BMI) | √ | |
| Waist-hip ratio (WHR) | √ | |
| SF-36 Health Survey | √ | √ |
| Fagerstrom Test for Nicotine Dependence (FTND) | √ | √ |
| Cardiac Depression Scale (CDS) | √ | √ |
| Safety evaluation of cardiac rehabilitation | | √ |
| System abnormalities Analysis | | √ |
| Adherence evaluation | | √ |
| HBCTR Satisfaction Questionnaire | | √ |

√ means measure and record the indicator at that time period

- Body Mass Index (BMI) = Weight (kg) / height $^{2}$ (m)
- Waist-Hip-Ratio (WHR) = Waist / hip

## 3.4 Interventions

### 3.4.1 Usual Care Group

The participants who were randomly assigned into the usual care (UC) group received the current post PCI care, which involved a paper-based CVD educational booklet and a biweekly outpatient review according to the Chinese Ministry of Health clinical pathway (2009). The educational booklet was designed based on guidelines of NHFAACRA and AACVPR, which includes the following sections: the heart structure and function, the effects of heart disease and surgery, the benefits of doing a CR program, the risk factors for heart disease, and secondary prevention including physical activity counselling, diet/nutritional counselling, weight control management, lipid management, blood pressure monitoring, smoking cessation, psychosocial management and diabetes management. The educational booklet also provides information about behaviour change and maintenance, returning to work, emergency planning for home, guidelines for activities at home, and management of symptoms. The guidelines for activities in the educational booklet were aimed at encouraging patients to do the exercises. Participants in the usual care group were also encouraged to keep track of their activity data on a weekly calendar (Appendix L) and return the calendars to their physicians when they attended the hospital to do their outpatient review. The outpatient physicians were then able to provide a basic physical check-up, refill any prescriptions and suggest additional exercises.

### 3.4.2 HBCTR Group

Participants in the HBCTR group were recommended to complete outdoor walking/jogging no less than three times per week for six weeks with real-time physiological monitoring, and they were also provided with the same CVD educational booklet as the UC group to manage lifestyle and risk factors.

Prior to discharge, all participants in both groups were instructed to learn how to recognize abnormal symptoms or signs, such as pressure, tingling, pain, heaviness, burning, numbness, light-headedness, dizziness, fainting, shortness of breath, rapid heartbeat or palpitations, especially if associated with physical activity. Participants were also educated to measure and report their health indicators, such as blood pressure (by electronic sphygmomanometer), HR, and Borg Rating of Perceived Exertion (RPE).

In addition, all participants were instructed to slow down exercise immediately or to not start exercise when the following circumstances occur (NHFAACRA, 2004; AACVPR, 2013): 1) the monitoring system display alerts or warnings (only for HBCTR group); 2) systolic BP before or during exercise is higher than 200mmhg or diastolic blood pressure is higher than 110mmhg; 3) exercise RPE is

beyond 15; 4) Appearance of restrictive symptoms or signs, such as angina, chest tightness, shortness of breath, palpitations, dizziness, syncope, paleness, sweating and other symptoms before or during exercise.

All participants were required to check their health condition (e.g. fatigue, dyspnoea, angina symptoms, upset, BP, HR, medications used and any problems related to exercise training) before exercise training to ensure they are healthy enough to do exercise. If no contraindications occurred, patients were able to start their training session. HBCTR participants switched on their wearable device (sensor) during their exercise. The sensor automatically measured their real time ECG, maximum and average heart rate, activity level, energy consumption, exercise time and walk/jogging speed.

Exercise training in the HBCTR program was tailored according to each patient's DASI outcome. The target of the exercise training was 3-5 training sessions per week with a length of 30 minutes at 55–70% of the Maximum Heart Rate (MHR) at the onset of symptoms for each session (RPE scale for CR exercise is approximately 11 to 15) (Piepoli et al., 2010). (MHR)= 220-age (the equation MHR=164 - 0.7*age was substituted for patients using beta-blocker).

Each exercise session was divided into three periods: a warm-up period, exercise period and cool down period. The participants were instructed to start an exercise activity with a warm-up period by doing low-intensity warm-up exercises for 5-10 minutes, such as stretching and walking. During the following exercise period, patients did exercises at ±10% of the target HR fluctuations for about 15-20 minutes. During the cool-down period, low-intensity exercises allowed patients to recover for 10 minutes to prevent their cardiac output from decreasing suddenly. However, each exercise plan changed to match individual interests and health status. When an adverse response (sign or symptom) was reported during exercise, the exercise prescription plan (intensity, duration, frequency, and modalities) was changed by the care team (physical therapists) to reflect the therapeutic response.

Participants in both groups were provided with a weekly calendar (Appendix L) to keep track of their individual health data. The information provided to participants included things such as exercise date, type and duration, mean and max heart rate, blood pressure, RPE range, exercise reactions and occurrence of any adverse event (restrictive symptoms or signs that might appear, such as angina, chest tightness, shortness of breath, palpitations, dizziness, syncope, paleness, or sweating) and intake of any heart-related medication (if applicable) or use of any health care services (such as hospital admission or outpatient clinic).

### 3.4.3 The HBCTR Remote Monitoring System

The HBCTR program needs to use appropriate technology such as sensors, smartphones, servers, and the Internet to implement real time monitoring and fast feedback functions. Accordingly, the remote monitoring system (**Figure 2**) consisted of a belt strap with a sensor (Ucare RG10, http://www.microsenstech.com), a smartphone with an application, servers and a web portal. Participants wore the sensor and turned on the application on their smartphone when they started to do exercise training. **Figure 3** shows how a participant would wear a sensor.

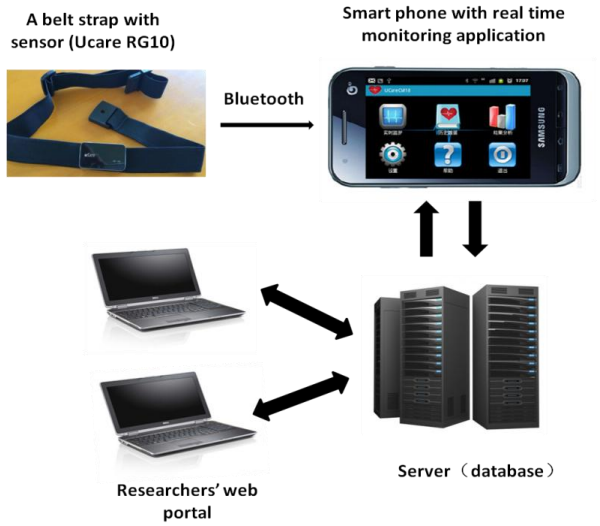



**Figure 2 Components of Remote Monitoring System** **Figure 3 Sensor and Smartphone**

The sensor (Ucare RG 10) and the smartphone with the rehab app were used to attain real time monitoring and record participants' physiological indicators when they did exercises. When a patient would start to do exercises, he/she would open the rehab app on his/her smartphone and click the "start" button; then real-time monitoring would begin using the remote monitoring system (Ucare RG10, MicroSens Ltd, China). The system monitored and recorded the participant's ECG, maximum and average HR, type of activity, energy consumption, activity duration (including the start and end times), walking/jogging speed and the Global Positioning System (GPS) location. The participants could observe their real-time walking/jogging speed, continuous ECG, HR, duration and type of activity on the main page of the rehab app on their smartphone when they exercised. They could also check the history of their health data in the rehab app, which included average and maximum HR, energy consumption, and activity duration.

The warning and emergency call functions were embedded in the mobile devices to enable the patients to slow down or stop exercising before the symptoms worsen or call for emergency help by pressing the button on the device if one or more of the following occurs: (i) clinically significant ECG changes are detected; (ii) data connection is interrupted; (iii) a patient's HR exceeds target HR range; or (iv) a patient falls down. Concurrently, the smartphone showed warning information and alerts using audible voice warnings. For example, if an arrhythmia was to be detected by the mobile devices, the smartphone would automatically send an emergency message to the care team. In practice, either two RAs or one research nurse would be on duty to receive a patient's emergency call or message and would transfer the call/message to the care team to facilitate the patient receiving prompt personalized feedback.

An example of customized feedback by the care team for an arrhythmia participant would be to immediately call the participant and warn them to slow down their exercise and check whether they have any angina signs or symptoms (e.g. light-headedness, dizziness, fainting, shortness of breath, rapid heartbeat or palpitations). At the same time, the care team would advise the patient to continue monitoring closely their physiological indicators and symptoms while reassuring them in order to ease any nervousness they may be experiencing.

A central server received and stored the patients' rehabilitation data, and through a web portal, the care team professionals were able to monitor a patient's real-time ECG and GPS location when he/she exercised, and were able to review a patient's health data history (i.e. ECG, maximum and average HR, exercise time and duration, type of exercise and abnormal data report). From the abnormal data report, the care team could replay a patient's abnormal ECG and determine the time and duration of the event. **Figure 4** shows the main page of the care team's view of the web portal.

Based on the sensor monitoring data and participant's self-evaluation, the care team would send an updated exercise prescription and any precautions to the HBCTR participant via weekly messages. Appendix M is the template for a 1-6 week exercise prescription.

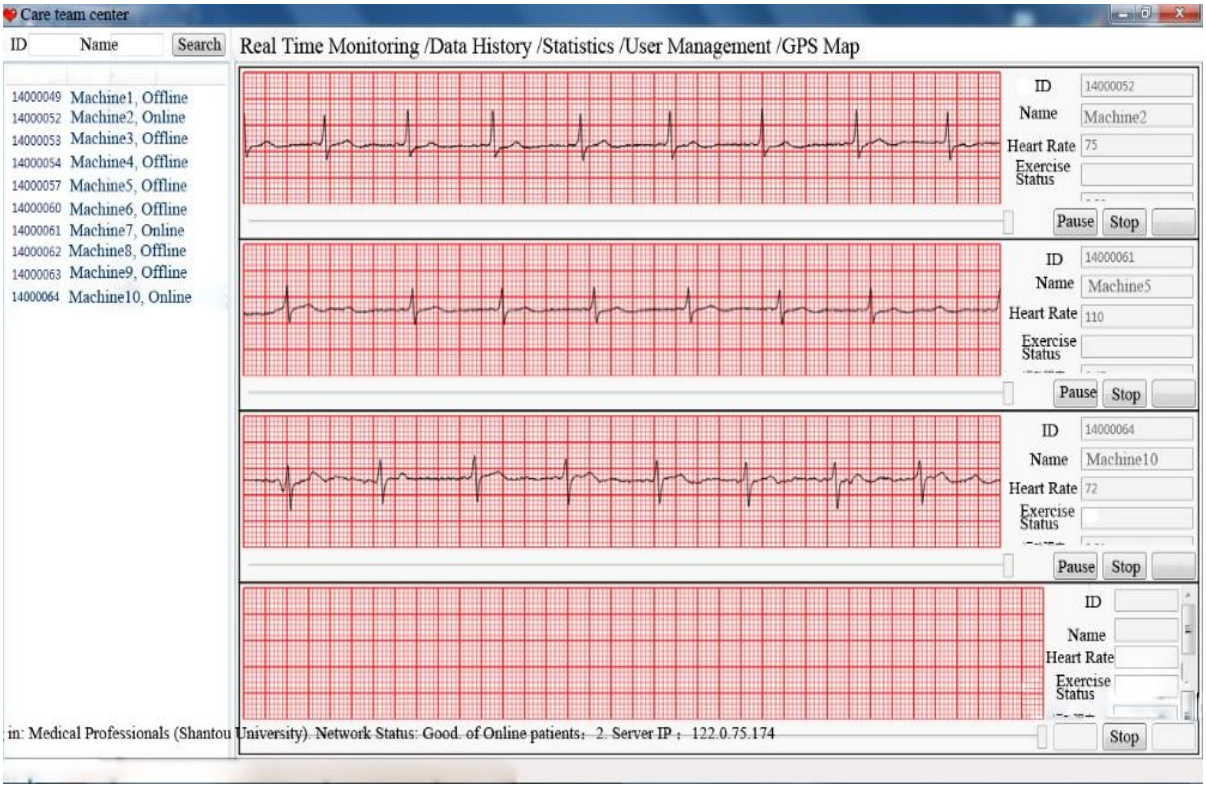



**Figure 4 The main page of the web portal**

## 3.5 Data Analysis

Continuous variables were expressed as number, percentage, mean and standard deviation. The homogeneity of baseline data in demographic and clinical difference was compared using two-sided t-test for continuous variables and chi-square test for categorical variables. One way repeated measures analysis of variance (ANOVA) were used to examine if there is a statistically significant change between baseline and 6 weeks in 6MWT, SF-36, BMI, CDS, and FTND respectively for the UC group and the HBCTR group. Change scores were calculated as 6-week score minus baseline score, and one way ANOVA was used to identify the significance level of these change scores between the UC group and the HBCTR group to detect differences in the improvement of 6MWT, SF-36, BMI, CDS, and FTND outcomes. P-value was considered significant if $<0.05$. A descriptive analysis was performed for subjective data, which included HBCTR acceptance questionnaire and the HBCTR satisfaction questionnaire.

# Chapter 4

# Results

Of the 65 patients screened for eligibility for this study, 53(81.5%) agreed to participate in the HBCTR acceptance survey, and 24 (36.9%) were enrolled in the clinical study. 12 participants were randomly assigned to the control group (usual care) and 12 to the experiment group (HBCTR). One participant in the experiment group withdrew due to personal reasons, and one participant in the control group lost contact. The planned flow chart is illustrated in **Figure 4**.

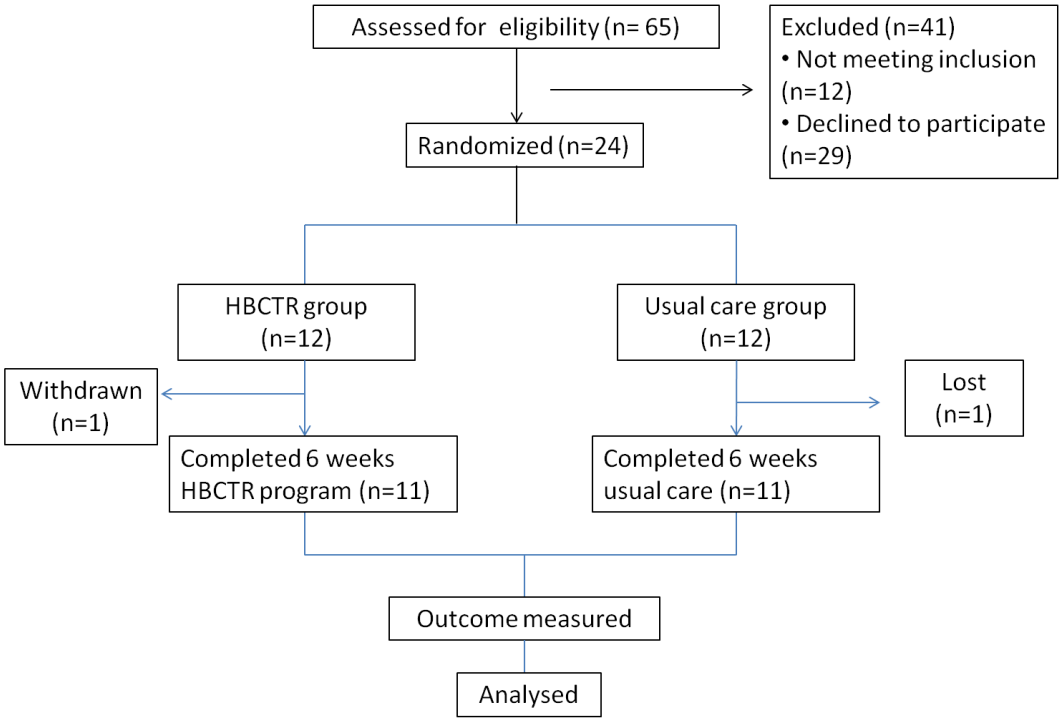



**Figure 5 Flow Chart**

Participants' baseline characteristics and outcome variables are presented in **Table 5**. No statistically significant differences were found in both groups.

**Table 5 Participant Baseline Characteristics**

| | HBCTR (n=11) | Usual medical care (n=11) | P-value |
|---|---|---|---|
| **Mean age ±SD (year)** | 59.6±10.1 | 57.5±7.8 | 0.85 |
| **Gender (n,%)** | | | 0.53 |
| Male | 9 (81.8%) | 10(90.9%) | |
| Female | 2(18.2%) | 1(9.1%) | |
| **Educational level** | | | 0.60 |
| Primary or less (0~6 years) | 2(18.2%) | 4(36.4%) | |
| Middle School (7~9 years) | 2(18.2%) | 2(18.2%) | |
| High school or above(>9 years) | 7(63.6%) | 5(45.4%) | |
| **Employment status** | | | 0.67 |
| Not working | 6(54.6%) | 5(45.4%) | |
| Working | 5(45.4%) | 6(54.6%) | |
| **Annual income ($)** | | | 0.90 |
| <3000 | 1(9.1%) | 1(9.1%) | |
| 3000~6000 | 4(36.4%) | 5(45.4%) | |
| >6000 | 6(54.5%) | 5(45.4%) | |
| **Living place** | | | 0.67 |
| City | 6(54.6%) | 5(45.4%) | |
| Countryside | 5(45.4%) | 6(54.6%) | |
| **Distance to hospital** | | | 0.81 |
| <5km | 2(18.2%) | 1(9.1%) | |
| 5-20km | 3(27.3%) | 3(27.3%) | |
| >20km | 6(54.5%) | 7(63.6%) | |
| **Self-care ability** | | | 0.61 |
| Completely self-care | 8(72.7%) | 9(81.8%) | |
| Partly self-care | 3(27.3%) | 2(18.2%) | |
| **The number of cardiac stents** | | | 0.86 |
| One | 2(18.2%) | 3(27.3%) | |
| Two | 5(45.4%) | 4(36.4%) | |
| Three or more | 4(36.4%) | 4(36.4%) | |
| **Myocardial infarctions** | | | 0.86 |
| First | 4(36.4%) | 5(45.4%) | |
| Second | 4(36.4%) | 4(36.4%) | |
| Third | 3(27.3%) | 2(18.2%) | |
| **Exercise time/day** | | | 0.86 |
| <30min | 5(45.4%) | 4(36.4%) | |
| 30-60min | 4(36.4%) | 4(36.4%) | |
| >60min | 2(18.2%) | 3(27.2%) | |
| Smoking | 5(45.5%) | 6(54.6%) | 0.67 |
| **Hypertension** | 6(54.6%) | 6(54.6%) | 1.0 |
| **High cholesterol** | 2(18.2%) | 1(9.1%) | 0.53 |
| **BMI (Mean ±SD)** | 25.17±3.65 | 23.77±3.05 | 0.34 |

## 4.1 Acceptance and Feasibility (Primary Outcome Measures)

The HBCTR acceptance questionnaire, HBCTR satisfaction questionnaires, patients' adherence evaluation, a system abnormalities analysis, and a safety evaluation were used to assess the acceptance and feasibility of the HBCTR program for study participants.

### 4.1.1 Acceptance and Satisfaction Questionnaire of HBCTR program

At the start of the study, a total of 53 patients who underwent PCI completed the 7-item questionnaire to evaluate the acceptance of the HBCTR program. The results are presented in **Table 6**. Among the 53 respondents, only 5.7% had ever heard of cardiac rehabilitation, but after the HBCTR information session, 67.9% were willing to participate.

In terms of the reasons for acceptance, the participants selected: enhanced safety and independence (44.4%), having the automatic and emergency alert function (16.6%), the ability to self-monitor physical conditions daily (22.2%), having regular professional instructions (5.6%), receiving timely help when needed (8.3%) and providing assurance to family members (2.8%). Reasons for refusal to participate were: operation too cumbersome (41.2%), concerns for safety (35.3%), no need for CR (11.8%), unreliable technology (5.9%), inaccurate monitoring information (5.9%) and breach of privacy (0%).

For the five basic components of cardiac rehabilitation, i.e. physical activity counseling, psychological counseling, diet/nutrition counseling, exercise training and risk factors management, the average and standard deviation of the five-point scale mean scores were calculated and shown in the answer of **Question 2 (rank how strongly you are willing to receive the five components on a scale of 1-5) in Table 6**. The management of risk factors and diet/nutrition counseling factors received the highest scores of $4.81 \pm 0.48$ and $4.23 \pm 0.90$, respectively. This was followed by the exercise training guidance ($3.91 \pm 0.78$) and physical activity consultation ($3.81 \pm 1.01$) factors. The patient psychological counseling factor received the lowest score of $1.90 \pm 0.88$.

When it comes to choosing the most important factor that may impact the home monitoring systems, 32% of respondents thought the affordability of the system was the most significant factor. This was followed by the feasibility of the system (15%), simple operation of sensor (13%), being able to monitor exercise indicators (13%) and system understanding (9%). No respondent considered privacy issues as the most important factor (0%).

**Table 6 HBCTR Patient Acceptance Questionnaire (N=53)**

| Questions | Average scores or answers |
|---|---|
| 1. Do you know you need to do cardiac rehabilitation after your PCI surgery? | Yes = 3(5.7%)<br>No =50 (94.3%) |
| 2. Please rank how strongly you are willing to receive the following interventions after surgery on a scale of 1-5, from not interested to very interested:<br>i) Physical activity counselling<br>ii) Psychological counselling<br>iii) Diet / Nutrition counselling<br>iv) Exercise training guide<br>v) Risk factors management (weight, blood pressure, blood lipids, blood glucose and smoking) | Mean score $\pm$ SD<br><br>i) $= 3.81 \pm 1.01$<br>ii) $= 1.90 \pm 0.88$<br>iii) $= 4.23 \pm 0.90$<br>iv) $= 3.91 \pm 0.78$<br>v) $= 4.81 \pm 0.48$ |
| 3. Do you believe HBCTR will benefit you now and into the future? | A. Definitely will = 38 (71.7%)<br>B. Probably will = 11 (20.7%)<br>C. Don't know = 3 (5.7%)<br>D. Probably won't = 1 (1.9%) |
| 4. Do you want to participate in the HBCTR program if you are eligible? | A. Yes = 36 (67.9%)<br>B. No = 17 (32.1%) |
| 5. Which aspect do you think you can benefit most from HBCTR (the reason of acceptance)? | A. Making life safer and more independent = 16 (44.4%)<br>B. Being able to self-monitor activity = 8 (22.2%)<br>C. Receiving timely help when needed = 3 (8.3%)<br>D. Having regular professional instruction =2 (5.6%)<br>E. Providing assurance to family members =1(2.8%).<br>F. Having automatic emergency alert = 6(16.6%) |
| 6. Which factor are you most concerned with regarding the HBCTR program? (the reason of rejection)? | A. Unreliable technology = 1(5.9%)<br>B. Too cumbersome operation = 7 (41.2%)<br>C. Concerns for safety =6 (35.3%)<br>D. Inaccurate monitoring data =1(5.9%) |

| | |
|---|---|
| | E. Breach of privacy = 0<br>F. No need for CR= 2 (11.8%) |
| 7. Please choose the most impactful of the following factors that may hinder the implementation of HBCTR. | A. Affordable =17(32.1%)<br>B. Understanding of mobile devices =5(9.4%)<br>C. Simple operation of sensor =7(13.2%)<br>D. Feasibility of the system =8(15.1%)<br>E. Real time monitoring function =7(13.2%)<br>F. Personalized service =1(1.9%)<br>G. Automatic emergency alert =4 (7.5%)<br>H. Usability of devices =1(1.9%)<br>I. Non-invasive intervention =3(5.7%)<br>J. Protecting Data Privacy =0 |

After the 6-week HBCTR intervention, a total of 11 patients in the HBCTR group completed the HBCTR satisfaction questionnaire and reported high satisfaction (4.55±0.82). The majority of respondents believed that the HBCTR program is robust (4.73±0.47) and easy to use (4.64±0.67). All respondents thought that the HBCTR program decreased their fears in exercise and most of them felt more confident in self-managing their conditions over the entire period of the HBCTR program than before (4.55±0.82). The majority of participants felt the HBCTR system helped them communicate with their doctors (4.64±0.50), helped their caregivers to look after them (4.82±0.40) and improved their quality of life (4.64±0.81). Furthermore, most patients believed that the instructions from the care team were clear (4±0.63), and among all the participants, 81.8% thought the real-time monitoring was the most useful function in the HBCTR program, and rest (18.2%) chose the automatic warning/alert as the most significant function. The result details are presented in **Table 7**.

**Table 7 HBCTR Patients Satisfaction Questionnaire (N=11)**

| Questions | Average scores or answers |
|---|---|
| 1. Are you satisfied with the HBCTR program? (Negative to positive score 1 to 5) | 4.55 ±0.82 |
| 2. Do you think the HBCTR program is easy to use? (Negative to positive score 1 to 5) | 4.64 ±0.67 |
| 3. Do you think the HBCTR program is robust? (Negative to positive score 1 to 5) | 4.73 ±0.47 |
| 4. Do you feel the HBCTR program decreases your fears to exercise after surgery? (Negative to positive score 1 to 5) | 5 ±0 |
| 5. Do you feel more confident in self-managing your conditions than before? (Negative to positive score 1 to 5) | 4.55 ±0.82 |
| 6. Do you think the HBCTR system helped you to communicate with your doctors? (Negative to positive score 1 to 5) | 4.64 ±0.50 |
| 7. Were the instructions from the care team clear enough for you? (Negative to positive score 1 to 5) | 4 ±0.63 |
| 8. Which part of the system is the most useful?<br>A. Real time physiological monitoring<br>B. Customized feedback<br>C. Emergency call function<br>D. Automatic alert<br>E. Timely communication with doctors<br>F. None | A=81.8%<br>D=18.2% |
| 9. Do you think the HBCTR program improved your quality of life? (Negative to positive score 1 to 5) | 4.64 ±0.81 |
| 10. Do you think the HBCTR program helped your caregiver look after you? (Negative to positive score 1 to 5) | 4.82 ±0.40 |
| 11. Will you recommend the HBCTR to others? (Negative to positive score 1 to 5) | 4.82 ±0.40 |

### 4.1.2 Adherence Evaluation

From our recruitment effort of 53 patients, 45.3% (n=24) participated in the program, and a total of 22 participants completed the 6-week study. One participant in the experiment group withdrew due to personal reasons and one participant in the control group lost contact.

HBCTR adherence was defined as the percentage of participants who carried out the HBCTR program. It can be divided into three adherence rate categories: HBCTR exercise, self-reporting, and medication intake. The three calculation formulas are shown in **Table 8**. The HBCTR exercise adherence rate was assessed based on the exercise data in the HBCTR system records. The other two adherence rates

were assessed based on patients' weekly reports. For instance, the patients should have performed the exercises three times per week for six weeks. In this case, 11 patients completed the project equaling a total of 198 exercises. Similarly, self-reporting should have resulted in a total of 198 reports. Medication should have been taken daily by the 11 patients over the six weeks for a total of 462 times. The average adherence rates of HBCTR exercise, self-reporting and medication intake are 92.9%, 88.4% and 90.0%, respectively. The details are shown in **Table 9**.

**Table 8 Three Adherence Rates Calculation Formulas**

| |
|---|
| HBCTR exercise adherence rate = $\frac{\#\text{ of times patients did exercise}}{\#\text{ of times patients should do exercise}(3*6*11)} * 100\%$ |
| Participants self-reporting adherence rate = $\frac{\#\text{ of times patients did self-reporting}}{\#\text{ of times patients should do self-reporting}} * 100\%$ |
| Medication adherence rate = $\frac{\#\text{ of times patients took medication}}{\#\text{ of times patients should take medication}} * 100\%$ |

**Table 9 HBCTR Program Adherence Summary**

| | |
|---|---|
| Remote rehabilitation exercise training adherence rate | # of times patients should do exercise: 198<br># of times patients did exercise: 184<br>adherence rate = 92.9% |
| Participants self-reporting adherence rate | # of times patients should self-report:198<br># of times patients did self-report:175<br>adherence rate = 88.4 % |
| Medication adherence rate | # of times patients should take medication: 462<br># of times patients took medication: 416<br>adherence rate = 90.0 % |

### 4.1.3 System Abnormalities Analysis and Safety Evaluation

During 184 exercise sessions (6,532 minutes) in HBCTR, four participants experienced a total of seven temporary system failures in seven exercise sessions. The monitoring sensor detected a total of 22 abnormalities for the remaining exercise sessions (19 occurrences of HR above the maximize target HR in five patients and three asymptomatic arrhythmia in two patients). The details are shown in **Table 10**. Participants were alerted by the mobile system to take a break from exercising given the potential risks. The participants who experienced the abnormalities received the care team's feedback promptly. Upon following the care team's instructions to slow down exercising, all of their physiological indicators went back to the normal range. The participants who had an inoperable sensor switch button or broken USB port received a replacement from the care team. The hanging in the app was corrected by rebooting the Smartphone.

**Table 10 HBCTR System Abnormalities and Safety Evaluation Summary**

| Abnormal health data | Percentage of exercise training sessions (N=184) | Description |
|---|---|---|
| **HR above maximize target** | 10.3% | 19 times HR above maximize target occurred for average 1.1 minutes in 5 patients (Participant A, B, D, G and J). The average HR above target HR is about 134. |
| **Arrhythmia** | 1.6% | 3 times asymptomatic arrhythmia occurred for average 6.8 minutes in 2 patients (Participant B and H). |
| **Temporary system failures** | 3.8% | 1 time sensor switch button failure, 2 times sensor USB broken and 4 times Smartphone APP down |

HR: Heart rate; USB: Universal Serial Bus; APP: application

Adverse Events (AE) are defined as any unfavorable signs, symptoms, or health status changes during the study intervention (FDA Expert Working Group, 2007). No serious adverse event occurred in either group as a result of the exercise training. Three patients in the HBCTR group experienced a total of four adverse events: three asymptomatic arrhythmia events were indicated on the remote ECG monitoring sensor and one minor skin reaction to the sensor electrodes was reported. The UC group reported two events in two patients: backache due to heavy housework and shortness of breath due to inadequate warming up activities.

## 4.2 Effectiveness (Secondary outcome measures)

### 4.2.1 Within-group analysis

One-way repeated measures ANOVA was used to examine the changes from baseline to 6 weeks in both groups regarding on 6MWT, SF36, DASI, FTND and CDS. The following variables improved significantly in 6 weeks compared to baseline in both groups: 6MWT (distance), SF36 (PCS, MCS), FTND and CDS (p-values <0.05). No significant Borg RPE score changes were observed in both groups' patients in 6 weeks compared to baseline. Compared to baseline, the participants in HBCTR group had better DASI in 6-weeks (p-values <0.05), but there was no effect in UC group. **Table 11** summarizes the effectiveness of both groups' interventions on modified risk factors measured by FTND and CDS, functional capacity measured by performance on the 6MWT and DASI, and quality of life measured by SF-36 Health Survey between baseline and 6 weeks.

**Table 11 Effectiveness in the HBCTR group and the UC group between baseline and 6-weeks**

| Variable | HBCTR group (n=11) | | | UC group (n=11) | | |
|---|---|---|---|---|---|---|
| | Baseline | 6-week | P- value Baseline vs 6 –week | Baseline | 6-week | P- value Baseline vs 6 -week |
| **SF 36** | | | | | | |
| PCS | 53.4 ±13.7 | 66.1 ±9.7 | P<0.05 | 54.4 ±11.3 | 58.2 ±12.1 | P<0.05 |
| MCS | 61.6 ±11.9 | 70.3 ±8.0 | P<0.05 | 61.1 ±13.7 | 65.9 ±13.2 | P<0.05 |
| **6MWT** | | | | | | |
| Distance(m) | 373.5 ±38.4 | 418.5 ±37.5 | P<0.05 | 377.8 ±29.9 | 405.5 ±31.4 | P<0.05 |
| Borg RPE post test | 11.0 ±2.3 | 10.5 ±2.0 | NS | 10.82 ±2.6 | 10.73 ±2.4 | NS |
| **DASI** | 6.1 ±0.7 | 6.8 ±0.9 | P<0.05 | 6.2 ±0.7 | 6.5 ±0.6 | NS |
| **FTND** | 2.8 ±3.5 | 0.8 ±1.5 | P<0.05 | 3.1 ±3.2 | 1.9 ±2.8 | P<0.05 |
| **CDS** | 74.6 ±20.5 | 54.5 ±17.8 | P<0.05 | 76.8 ±21.0 | 55.9 ±24.2 | P<0.05 |

* Values are Mean (SD). SF 36- 36-item Short Form Survey, PCS-Physical Component Summary, MCS-Mental Component Summary, 6MWT- 6 Minutes Walking Test, DASI- Duke Activity Status Index, FTND- Fagerstrom Test for Nicotine Dependence, CDS- Cardiac Depression Scale.

### 4.2.2 Between-group analysis

There were no statistically significant differences in clinical outcomes (6MWT, SF36, FTND, CDS and DASI) between the two groups at baseline (p-values > 0.05). However, after the 6-week intervention, the improvement in SF 36 PCS, DASI, and 6 MWT distance in the HBCTR group was significantly greater than those in the UC group. Analysis demonstrated no statistically significant difference for the two groups in improvement of MCS, RPE, FTND, CDS from baseline to 6 weeks. **Table 12** shows the results of improvements in 6 weeks compared to baseline on 6MWT (distance), SF36 (PCS, MCS), FTND and CDS in both groups (p-values <0.05).

**Table 12 The difference in improvements between HBCTR group and UC group**

| Variable | HBCTR 6 weeks values- baseline values | UC 6 weeks values- baseline values | P-Value |
|---|---|---|---|
| **SF 36** | | | |
| PCS | 12.5 ±7.8 | 4.6 ±5.7 | P<0.05 |
| MCS | 8.7 ±8.9 | 4.9 ±4.5 | NS |
| **6MWT** | | | |
| Distance(m) | 45.5 ±17.4 | 27.6 ±14.7 | P<0.05 |
| Borg RPE post test | -0.6 ±0.9 | -0.1 ±0.8 | NS |
| **DASI** | 0.7 ±0.5 | 0.3 ±0.4 | P<0.05 |
| **FTND** | -2.0 ±2.93 | -1.2 ±1.7 | NS |
| **CDS** | -20.1 ±4.5 | -21.0 ±9.1 | NS |

* Values are Mean (SD). SF 36- 36-item Short Form Survey, PCS-Physical Component Summary, MCS-Mental Component Summary, 6MWT- 6 Minutes Walking Test, DASI- Duke Activity Status Index, FTND- Fagerstrom Test for Nicotine Dependence, CDS- Cardiac Depression Scale.

# Chapter 5

# Discussion

In conventional telerehabilitation programs, medical personnel cannot provide fast customized feedback to patients, and to date there has been no literature showing the successful implementation of real-time functional monitoring combined with personalized feedback in HBCTR programs. With the rapid advent of mobile and wearable technology, the possibility of mobile technology being utilized in health promotion and home-based health programs is being looked to as a possible way of addressing these gaps.

To our knowledge, our HBCTR is the first program in the world to put real-time physiological monitoring functions combined with customized feedback into practice. This pilot project is an example of emerging tele-health that involves a multidisciplinary team using mobile technology to extend rehabilitation service to patients at home. This model is also the first HBCR with remote health monitoring carried out in China. The benefits are 1) the hospital-based or center-based rehabilitation team can remotely monitor patients' key health indicators and progresses while the remote sensors and apps on smart phones provide individual customized feedback to patients; 2) clinicians can provide timely customized feedback to patients; 3) patients are highly motivated and confident to conduct self-improvement activities; and 4) patients' achieved better physical outcomes.

We demonstrated that patients can use the remote monitoring sensor effectively to automatically measure their real-time ECG, maximum and average heart rate, activity level, energy consumption, exercise time and walk/jogging speed. The results from this study indicate that the program delivery, educational material, mobile technology and communication mechanisms are appropriate to the Chinese culture and healthcare systems.

This study provides insight into the attitude of providers and participants about the use of technology in HBCR programs. From this we can begin to understand the determinants of a successful home-based rehabilitation program in terms of the serviceability, reliability and adaptability of mobile health programs. The knowledge obtained from this study could also promote the use of mobile health technology in other disease prevention and management programs. In addition, the acceptance questionnaire is the first HBCTR attitude survey conducted on a Chinese population. The results may provide guidance on how the HBCTR program should be designed and deployed in China.

## 5.1 Safety of HBCTR in post PCI patients

The pre-exercise assessment, real-time monitoring, emergency alert function and post-exercise prescription adjustment by the care team were put in place to ensure participants' safety. The study results showed that the proposed HBCTR program was safe in cardiac patients with PCI as we expected. We observed that no serious adverse event happened during this study and only minor adverse events occurred in both groups. For instance, during a total of 184 exercise sessions in the HBCTR program, only three asymptomatic arrhythmia were seen within two patients (1.6%). We did not find any arrhythmia incidence reported in conventional CR in other studies because CR patients are usually not monitored by ECG. Thus, we cannot compare the HBCTR arrhythmia incidence to conventional CR arrhythmia incidence. However, another HBCR study confirmed that heart failure patients did not develop arrhythmia requiring treatment within their program (Piotrowicz, Jasionowska, Banaszak, Gwilkowska, Piotrowicz, 2012).

Supervised exercise with remote monitoring in CR programs has been proved safe and high reliable in many HBCTR programs (Piotrowicz et al., 2010; Piotrowicz et al., 2014; Varnfield et al., 2014; O'Connor et al., 2009). Neither death nor other serious adverse events happened as a result of participating in these home-based telerehabilitation programs. Piotrowicz et al (2014) reported that few minor adverse events occurred during telerehabilitation, such as 5.3% patients developing minor skin reactions because of the electrodes.

Furthermore, one study even confirmed that the home based telerehabilitation is safe among high-risk patients if they are remotely monitored and supervised training is provided to them under strict observation by the care team, and if effective cooperation between the telerehabilitation team and the patients is established (Piotrowicz et al., 2010). One possible concern is monitoring system failures during exercise training. Even with a reasonable low incidence (7 system failures in 184 exercise training totaling 6532 minutes), these failures should still be decreased by improving the quality and reliability of the sensors and mobile applications. This will further allow us to provide effective telerehabilitation to patients.

## 5.2 Acceptance and Satisfaction of the HBCTR Program

Although there are surveys on patients' attitudes towards tele-health programs (Boise et al., 2013; Demiris et al., 2004; Larizza et al., 2012; Larizza et al., 2014; Wild et al., 2008), to the best of our knowledge, the acceptance survey in this study is the first to assess post-PCI patients' willingness to participate in the HBCTR program and identify factors that could affect their attitude. We designed the

acceptance and satisfaction questionnaire to investigate Chinese cardiac patients' attitudes and experiences toward HBCTR.

From the acceptance questionnaire, we know that after having a better understanding of the HBCTR program, the majority of participants (92%) felt confident with it, despite the fact that very few (5.7%) had heard about CR before. Furthermore, the mean scores from patients' interests in the five components of CR were relative high, which indicates that cardiac patients are willing to be trained to utilize the proposed HBCTR. From **Table 6**, it is clear that patients had a strong desire to receive HBCTR education, which included risk factor management, diet/nutrition counseling, physical consultation, and exercise training guidance. Interestingly, the psychological counseling was chosen as the least important factor among the five components of the CR program, which demonstrates that psychological well-being was not deemed to be important to Chinese cardiac patients.

Participants reported that the most motivating factors to participate in the HBCTR were the following: improvement of safety and independence in life (44.4%); ability to self-monitor physical conditions (22.2%); and having automatic and emergency alert function (16.6%). This finding indicates that patients are enthusiastic about the proposed HBCTR program. The main unfavorable reasons included: difficult to operate (41.2%), concerns for safety (35.3%) and unnecessary CR protocol (11.8%). About 35.3% of participants did not accept HBCTR because of its cumbersome operation and safety concerns. However, their concerns could be overcome with better education about the HBCTR. Notably, no participant was concerned about personal privacy violation, which is very different from attitudes among patients in other western counties (Larizza M. F.,et al, 2013; Linda Boise et al,2013; Katherine Wild et al,2008; Melanie Larizza et al.,2012).

There are ten possible affecting factors on implementing HBCTR program (Details are shown in **Question 7, Table 6**). The system affordability is considered as a dominant factor of implementing HBCTR program (32%). This may be due to the medical system in China, with no general coverage for rehabilitation service. The other possible affecting factors are follows: feasibility of the system (15%), simple operation (13%), physiological indictors monitoring function (13%) and system understanding (9%).

From the results of the HBCTR satisfaction questionnaire, we know that the majority of respondents were satisfied with the HBCTR program, and they believed the monitoring devices were robust and easy to use. In our study, the HBCTR program not only enhanced participants' confidence to exercise after a cardiac event and PCI, but also helped them to communicate with their doctors, helped participants' caregivers in looking after them, and improved their health related quality of life. Despite

patients carrying out rehabilitation far from our medical centre (i.e. at home or walking outside), they felt safe due to remote real-time monitoring and the emergency alert function. Accordingly, HBCTR program plays an important role in making patients' lives more independent and exercise safer.

The results of HBCTR acceptance and satisfaction questionnaire showed that participants were adherent to and satisfied with the HBCTR program. These results are similar to findings found in Piotrowicz studies (Piotrowicz et al., 2010; Piotrowicz et al., 2014), which also reported that home-based telerehabilitation had good acceptance and high adherence in cardiac patients. In Piotrowicz's study (2014), each patient was able to use the monitoring device without others help. Moreover, 98.7% of patients reported operating the device easily or very easily, and 93.3% of patients felt telerehabilitation stimulate their desire to do exercise.

The adherence evaluation demonstrates that HBCTR program received high adherence rate on participants' exercise trainings (93%), self-report (88%) and medication intake (90%). These rates are close to a similar cardiac telerehabilitation study (Varnfield et al., 2014), which has 80% uptake rate, 94% adherence rate, and 80% completion rate. Another telerehabilitation study, Piotrowicz's study (2014), also reported that a total of 94.7% of the patients were adherent to the telemonitoring walking. The high adherence reflected that patients feel confident and satisfied with telerehabilitation program, which led to better physical capacity outcome compared to the control group who received usual care. A Cochrane systematic review reported that three interventions can effectively promote patients' adherence to CR: customized medical professionals' counseling, patients' activity planning and activity self-monitoring (Karmali, Davies, Taylor, Beswick, Martin, Ebrahim, 2014). Thus, it is reasonable that the participants in this study actively adhered to the HBCTR program because the program included all three successful interventions.

Although HBCTR participants are confident and satisfied with the program and the increases in their exercise safety and life independence are seen, it is still necessary to simplify the HBCTR system operation, decrease cost, and provide patients with comprehensive education about its safety and operation in order to enhance patients' experience and improve clinical outcomes.

## 5.3 Effectiveness of HBCTR program

After the six- week intervention, we observed statistically significant improvement in both groups' participants in almost all outcomes (6MWT, SF36, FTND, CDS and DASI). These results showed that both of the HBCTR and usual care improved participants' physical and psychosocial outcomes. Moreover, the HBCTR program resulted in a significant improvement compared to usual care in all

physical indictors (6MWT, DASI, and physical component summary in SF36). The difference in physical improvement may come from the difference of exercise intensity between two groups. We found that the confidence of HBCTR patients increased when they engaged in independent activities with remote monitoring and rehabilitation exercise, and this increased confidence contributed to good adherence with the HBCTR program. Martin et al reported that higher CR adherence result in better improved outcomes. Accordingly, the good adherence of the HBCTR program consequently led to improved physical outcomes.

However, there is no statistically significant difference between two groups in terms of psychological outcomes improvement, as the psychological education delivering model was not changed in HBCTR program compared to usual care. Chinese patients and doctors usually only focus on physiological health and ignore psychological well-being. The results of HBCTR acceptance questionnaire also demonstrated that the psychological counseling received the lowest acceptance among Chinese cardiac patients. In order to overcome the psychological issue, patients should be provided with better education about psychological health and care providers with psychology training should be encouraged to participate in the multi-disciplinary team offering CR.

Since the proposed HBCTR is a new model CR, and no study reported the outcome of current Chinese post PCI usual care, it is difficult to compare our program's effectiveness to other studies in a similar setting. However, based on a systematic review and meta-analysis (Jolly, Taylor, Lip & Stevens, 2006), HBCTR had better outcomes than usual care in exercise capacity, total cholesterol, anxiety and depression. The exercise capacity of patients in the HBCR group is improved by 0.44 METS compared to usual care, which is close to the results (0.4 METS) in our study.

## 5.4 Strengths and Limitations

This study is not only a successful attempt at the implementation of comprehensive exercise real time monitoring combined with personalized feedback in HBCTR programs, but also provides information on participants' attitude about the use of technology in HBCTR programs. This type of HBCTR may simplify the traditional phases of CR and develop a new model of CR phase, which includes three periods (i.e. inpatient, close home monitoring and long- term home monitoring). This new model of CR may help patients to start CR earlier, and enroll in the program longer to achieve the optimal outcome. These findings contribute to guide the effectiveness of methods to utilize mobile technology into CR programs.

The limitations include: 1. our study is a pilot single centre trial with small sample size, therefore the results cannot be generalized; 2. Although HBCTR is reported as a cost-effective manner, we did not

compare the cost between the two interventions; 3. Although the proposed HBCTR program incorporated almost all core components of CR, the comments of smoking cessation and return to work are not built into a Smartphone platform for this study. 4. The study does not track the exercise behavior and adherence rate among patients in UC group. Accordingly, it cannot answer whether HBCTR had better adherence than UC or not. 5. The medication adherence evaluation is based on patients self-reporting, we do not record whether they just take some or all medications.

# Chapter 6

# Conclusion and Future Directions

The HBCTR program is a feasible, safe, and well-accepted intervention with good adherence and effectiveness in low-risk post PCI patients. After a six- week intervention, both the HBCTR and the usual care groups' patients had better physical and psychological outcomes. However, the HBCTR patients had significantly better physical indicators (PCS and 6MWT) than the usual care. Although the majority of cardiac patients are not familiar with CR, they accepted the HBCTR program willingly after having a better understanding of the intervention.

Although our study showed that HBCTR is feasible, safe and has initial efficacy, it still needs further research to determine its effectiveness through a large-scale RCT. Furthermore, long-term effectiveness of HBCTR should be compared with center-based CR or other types of HBCR. A follow-up is usually conducted at the 6-month mark to evaluate whether the patient has maintained the lifestyle and behavior changes implemented after HBTC intervention (Varnfield et al., 2014; Swedberg, Wolf & Ekman, 2011; Chaudhry et al., 2010). The duration of the HBCTR intervention was not long enough to determine the basic CR core indicators such as blood lipid, BMI and heart rate variability. In the future study, those indicators should be included to reflect long-term physiological and psychological changes.

Although HBCTR is reported as a cost-effective intervention, this study didn't include a cost analysis module due to limited resources. The cost is one of the determinants that impact the successful adoption of HBCTR, and cost analysis of HBCTR should be carried out in future studies, as well as the cost comparison between HBCTR and center-based CR program. Next steps include a study examining the adherence in UC and medications use in HBCTR, as well as the analysis of the difference between UC and HBCTR adherence and medications use in CR programs. Since Canada is also facing similar challenges in implementing CR programs as China, including low program participation, low doctor-patient ratio and high financial burden, HBCTR can also be examined in Canadian setting to explore acceptance, feasibility and effectiveness of HBCTR within this population.

# Appendix A

# Borg Rating of Perceived Exertion

**Instructions for Borg Rating of Perceived Exertion (RPE) Scale**

While doing physical activity, we want you to rate your perception of exertion. This feeling should reflect how heavy and strenuous the exercise feels to you, combining all sensations and feelings of physical stress, effort, and fatigue. Do not concern yourself with any one factor such as leg pain or shortness of breath, but try to focus on your total feeling of exertion.

Look at the rating scale below while you are engaging in an activity; it ranges from 6 to 20, where 6 means "no exertion at all" and 20 means "maximal exertion." Choose the number from below that best describes your level of exertion. This will give you a good idea of the intensity level of your activity, and you can use this information to speed up or slow down your movements to reach your desired range.

Try to appraise your feeling of exertion as honestly as possible, without thinking about what the actual physical load is. Your own feeling of effort and exertion is important, not how it compares to others. Look at the scales and the expressions and then give a number.

The Borg scale is simple to understand and very user-friendly. However, to use it effectively, it is necessary to adhere to the standard guidelines in measuring perceived exertion. These guidelines are:

1) It should be clear to either the client, patient, or athlete that perceived exertion is a method to determine the intensity of effort, strain, and/or discomfort that is felt during exercise;

2) The range of sensations must correspond to the scale. For example, number 6 should be made in reference to the feelings during rest, whereas number 20 should refer to the maximal level of exertion;

3) Either the RPE should be made specific to the overall body perception or the perception derived from a certain anatomical region of the body such as chest, arms and/or legs. Typically, individuals interested in monitoring the stress of a workout use RPE ratings.

4) It is important to know that when rating one’s perception of exertion there is no right or wrong answer for the rating. However, the individual must clearly understand the meaning of the descriptors, so careful explanation of the scale is necessary before using.

| | |
|---|---|
| **6** | **No exertion at all** |
| **7** | |
| | **Extremely light (7.5)** |
| **8** | |
| **9** | **Very light** |
| **10** | |
| **11** | **Light** |
| **12** | |
| **13** | **Somewhat hard** |
| **14** | |
| **15** | **Hard (heavy)** |
| **16** | |
| **17** | **Very hard** |
| **18** | |
| **19** | **Extremely hard** |
| **20** | **Maximal exertion** |

Number 9 corresponds to "very light" exercise. For a healthy person, it is like walking slowly at his or her own pace for some minutes. 13 on the scale is "somewhat hard" exercise, but it still feels OK to continue. 17 "very hard" is very strenuous. A healthy person can still go on, but he or she really has to push him- or herself. It feels very heavy, and the person is very tired. 19 on the scale is an extremely strenuous exercise level. For most people this is the most strenuous exercise they have ever experienced.

Adapted from Borg, G. (1970). Perceived exertion as an indicator of somatic stress. Scandinavian Journal of Rehabilitation Medicine, 2(2), 92-98

# Appendix B

## Cardiac Depression Scale (CDS)

This questionnaire consists of a number of statements about the way you feel **at present**.

Next to each statement there is a rating scale from 1 to 7 for you to indicate how much you agree or disagree with the statement "Strongly disagree 1 2 3 4 5 6 7 Strongly agree"

Please indicate how strongly you agree or disagree with each statement by circling one of the numbers on the scale. THERE ARE NO RIGHT OR WRONG ANSWERS

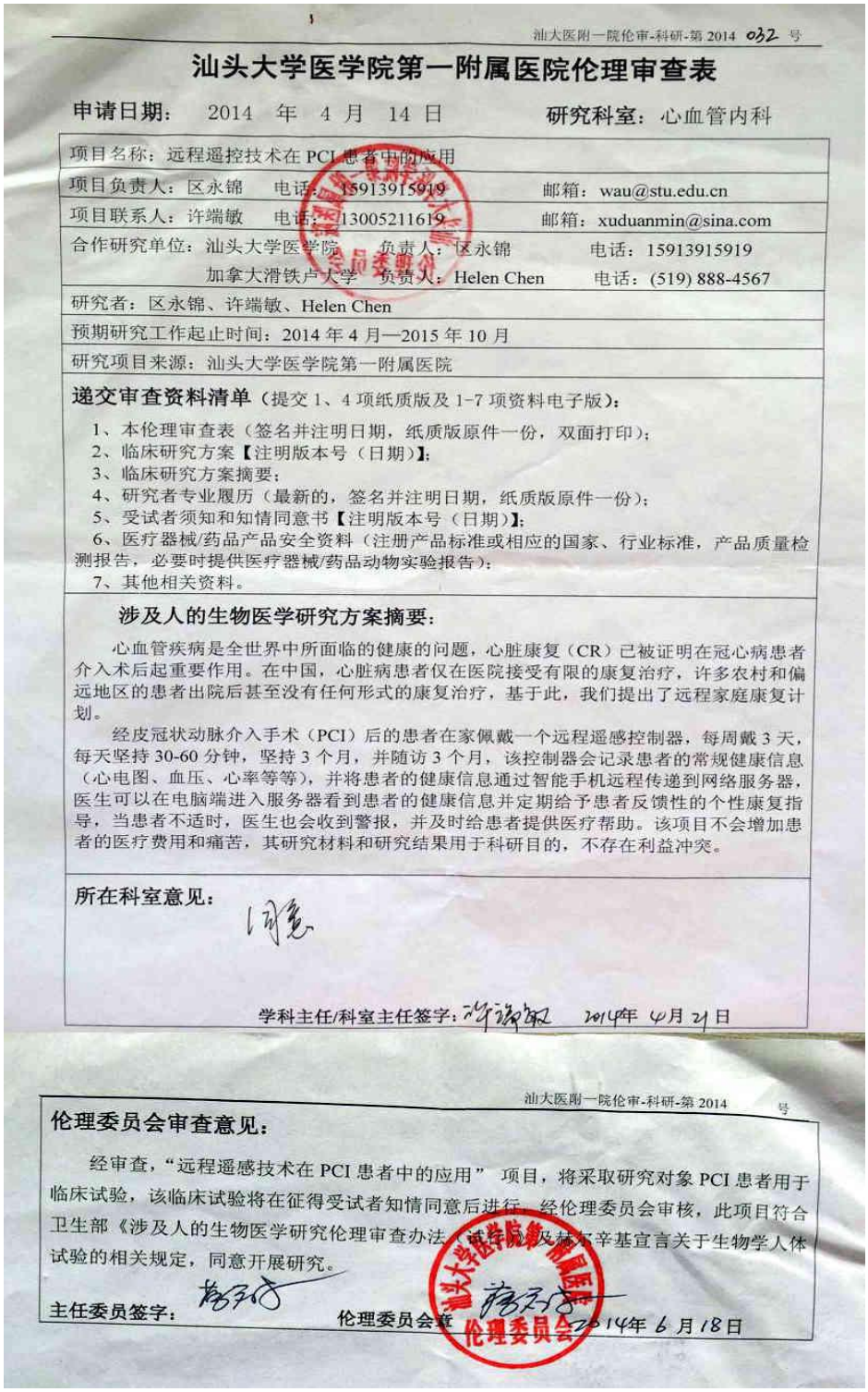
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1. I have dropped many of interests and activities… | 1<br>None dropped | 2 | 3 | 4 | 5 | 6 | 7<br>All dropped |
| 2. My concentration is as good as it ever was… | 1<br>Very poor Concentration | 2 | 3 | 4 | 5 | 6 | 7<br>Excellent Concentration |
| 3. I can't be bothered doing anything much… | 1<br>Keen to do Things | 2 | 3 | 4 | 5 | 6 | 7<br>can't be bothered |
| 4. I get pleasure from life at present…. | 1<br>No pleasure | 2 | 3 | 4 | 5 | 6 | 7<br>Great pleasure |
| 5. I am concerned about the uncertainty of my health… | 1<br>Not concerned | 2 | 3 | 4 | 5 | 6 | 7<br>very concerned |
| 6. I may not recover completely... | 1<br>Will recover Completely | 2 | 3 | 4 | 5 | 6 | 7<br>will not recover |
| 7. My sleep is restless and disturbed… | 1<br>Not restless | 2 | 3 | 4 | 5 | 6 | 7<br>very restless |
| 8. I am not the person I used to be… | 1<br>Just the same | 2 | 3 | 4 | 5 | 6 | 7<br>completely different |
| 9. I wake up in the early hours of the morning and cannot get back to sleep... | 1<br>Never wake | 2 | 3 | 4 | 5 | 6 | 7<br>always wake |
| 10. I feel like I am living on borrowed time... | 1<br>Unlimited Time | 2 | 3 | 4 | 5 | 6 | 7<br>very much on borrowed time |
| 11. Dying is the best solution for me... | 1<br>No solution | 2 | 3 | 4 | 5 | 6 | 7<br>best solution |
| 12. I feel in good spirits… | 1<br>Very poor Spirits | 2 | 3 | 4 | 5 | 6 | 7<br>excellent spirits |
| 13. The possibility of sudden death worries me... | 1<br>Not at all | 2 | 3 | 4 | 5 | 6 | 7<br>very worried |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 14. There is only misery in the future for me... | 1<br>No misery | 2 | 3 | 4 | 5 | 6 | 7<br>only misery |
| 15. My mind is as fast and alert as always... | 1<br>Slow and Inattentive | 2 | 3 | 4 | 5 | 6 | 7<br>very fast and alert |
| 16. I get hardly anything done... | 1<br>Everything Done | 2 | 3 | 4 | 5 | 6 | 7<br>nothing done |
| 17. My problems are not yet over... | 1<br>All problems Over | 2 | 3 | 4 | 5 | 6 | 7<br>still major problems |
| 18. Things which I regret about my life are bothering me... | 1<br>Absolutely No regrets | 2 | 3 | 4 | 5 | 6 | 7<br>great regrets |
| 19. I gain just as much pleasure from my leisure activities as I used to... | 1<br>No pleasure at all | 2 | 3 | 4 | 5 | 6 | 7<br>very great pleasure |
| 20. My memory is as good as it always was... | 1<br>Very poor Memory | 2 | 3 | 4 | 5 | 6 | 7<br>excellent memory |
| 21. I become tearful more easily than before… | 1<br>Not at all Tearful | 2 | 3 | 4 | 5 | 6 | 7<br>very easily tearful |
| 22. I seem to get more easily irritated by others than before... | 1<br>Never Irritated | 2 | 3 | 4 | 5 | 6 | 7<br>very easily irrtated |
| 23. I feel independent and in control of my life... | 1<br>No Independence | 2 | 3 | 4 | 5 | 6 | 7<br>completely independent |
| 24. I lose my temper more easily nowadays... | 1<br>Never lose Temper | 2 | 3 | 4 | 5 | 6 | 7<br>lose it very easily |
| 25. I feel frustrated... | 1<br>Not at all Frustrated | 2 | 3 | 4 | 5 | 6 | 7<br>extremely frustrated |
| 26. I am concerned about my capacity for sexual activity... | 1<br>No concern at all | 2 | 3 | 4 | 5 | 6 | 7<br>Grave concern |

# Appendix C

# The First Affiliated Hospital of Shantou University Medical College

# Ethics Approval



汕大医附一院伦审-科研-第 2014 032 号

## 汕头大学医学院第一附属医院伦理审查表

**申请日期：** 2014 年 4 月 14 日　　**研究科室：** 心血管内科

| |
|---|
| 项目名称：远程遥控技术在 PCI 患者中的应用 |
| 项目负责人：区永锦　电话：15913915919　邮箱：wau@stu.edu.cn |
| 项目联系人：许端敏　电话：13005211619　邮箱：xuduanmin@sina.com |
| 合作研究单位：汕头大学医学院　负责人：区永锦　电话：15913915919<br>加拿大滑铁卢大学　负责人：Helen Chen　电话：(519) 888-4567 |
| 研究者：区永锦、许端敏、Helen Chen |
| 预期研究工作起止时间：2014 年 4 月—2015 年 10 月 |
| 研究项目来源：汕头大学医学院第一附属医院 |

**递交审查资料清单**（提交 1、4 项纸质版及 1-7 项资料电子版）：

1、本伦理审查表（签名并注明日期，纸质版原件一份，双面打印）；
2、临床研究方案【注明版本号（日期）】；
3、临床研究方案摘要；
4、研究者专业履历（最新的，签名并注明日期，纸质版原件一份）；
5、受试者须知和知情同意书【注明版本号（日期）】；
6、医疗器械/药品产品安全资料（注册产品标准或相应的国家、行业标准，产品质量检测报告，必要时提供医疗器械/药品动物实验报告）；
7、其他相关资料。

**涉及人的生物医学研究方案摘要：**

心血管疾病是全世界中所面临的健康的问题，心脏康复（CR）已被证明在冠心病患者介入术后起重要作用。在中国，心脏病患者仅在医院接受有限的康复治疗，许多农村和偏远地区的患者出院后甚至没有任何形式的康复治疗，基于此，我们提出了远程家庭康复计划。

经皮冠状动脉介入手术（PCI）后的患者在家佩戴一个远程遥感控制器，每周戴 3 天，每天坚持 30-60 分钟，坚持 3 个月，并随访 3 个月，该控制器会记录患者的常规健康信息（心电图、血压、心率等等），并将患者的健康信息通过智能手机远程传递到网络服务器，医生可以在电脑端进入服务器看到患者的健康信息并定期给予患者反馈性的个性康复指导，当患者不适时，医生也会收到警报，并及时给患者提供医疗帮助。该项目不会增加患者的医疗费用和痛苦，其研究材料和研究结果用于科研目的，不存在利益冲突。

**所在科室意见：**

学科主任/科室主任签字：　2014年 4月 21日

汕大医附一院伦审-科研-第 2014　号

**伦理委员会审查意见：**

经审查，“远程遥感技术在 PCI 患者中的应用” 项目，将采取研究对象 PCI 患者用于临床试验，该临床试验将在征得受试者知情同意后进行。经伦理委员会审核，此项目符合卫生部《涉及人的生物医学研究伦理审查办法》试行版及赫尔辛基宣言关于生物学人体试验的相关规定，同意开展研究。

**主任委员签字：**　**伦理委员会章**　2014年 6 月 18 日

# Appendix D

# Ethics Approval from University of Waterloo Research Ethics Board

**UNIVERSITY OF WATERLOO**

**OFFICE OF RESEARCH ETHICS**

**Notification of Ethics Clearance of Application to Conduct Research with Human Participants**

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| | |
|---|---|
| **Faculty Supervisor:** Helen Chen | **Department:** Health Studies & Gerontology |
| **Faculty Supervisor:** Ian McKillop | **Department:** Health Studies & Gerontology |
| **Student Investigator:** Zhonghan Li | **Department:** Health Studies & Gerontology |
| **Collaborator:** William Au | **Department:** Shantou University Medical College |

**ORE File #:** 19983

**Project Title:** Feasibility and Initial Efficacy of Home-Based Cardiac Telerehabilitation A Pilot Study

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*This certificate provides confirmation the above project has been reviewed in accordance with the University of Waterloo's Guidelines for Research with Human Participants and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. This project has received ethics clearance through a University of Waterloo Research Ethics Committee.*

***Note 1**: This ethics clearance is valid for one year from the date shown on the certificate and is renewable annually. Renewal is through completion and ethics clearance of the Annual Progress Report for Continuing Research (ORE Form 105).*

***Note 2**: This project must be conducted according to the application description and revised materials for which ethics clearance has been granted. All subsequent modifications to the project also must receive prior ethics clearance (i.e., Request for Ethics Clearance of a Modification, ORE Form 104) through a University of Waterloo Research Ethics Committee and must not begin until notification has been received by the investigators.*

***Note 3**: Researchers must submit a Progress Report on Continuing Human Research Projects (ORE Form 105) annually for all ongoing research projects or on the completion of the project. The Office of Research Ethics sends the ORE Form 105 for a project to the Principal Investigator or Faculty Supervisor for completion. If ethics clearance of an ongoing project is not renewed and consequently expires, the Office of Research Ethics may be obliged to notify Research Finance for their action in accordance with university and funding agency regulations.*

***Note 4**: Any unanticipated event involving a participant that adversely affected the participant(s) must be reported immediately (i.e., within 1 business day of becoming aware of the event) to the ORE using ORE Form 106. Any unanticipated or unintentional changes which may impact the research protocol must be reported within seven days of the deviation to the ORE using ORE form 107.*

Maureen Nummelin, PhD
Chief Ethics Officer

OR
Julie Joza, MPH
Senior Manager, Research Ethics

Oct 3/14
Date

# Appendix E

## The information-consent letter

**Title of Project:** Feasibility and Initial Efficacy of Home-Based Cardiac Telerehabilitation (HBCTR) program- A pilot study

**Primary Investigator:** 1. Helen Chen, University of Waterloo, helen.chen@uwaterloo.ca, 5198884567 X32131
2. William W. Au, Shantou University Medical College, wau@stu.edu.cn, 86-754-88900279

**Co-investigators:**

1. Dr. Duanmin Xu, First Affiliated Hospital of Shantou University Medical College, dxu@ stu.edu.cn,
2. Dr. Chang Chen, First Affiliated Hospital of Shantou University Medical College, cchen@ stu.edu.cn,
3. Dr. Jilin Li, First Affiliated Hospital of Shantou University Medical College, cchen@ stu.edu.cn,
4. Dr. Lan Chen, First Affiliated Hospital of Shantou University Medical College, clan@ stu.edu.cn,
5. Nurse Yan Xiong, First Affiliated Hospital of Shantou University Medical College, xyan@ stu.edu.cn,

**Students or Trainees**: Zhonghan Li, University of Waterloo, z363li@uwaterloo.ca, 13815441047
Jiaying Fang, Shantou University Medical College, Fjiaying@stu.deu.cn, 18511502563

**Sponsors:** 1. University of Waterloo, 2. Mitacs Globalink Research Award, 3. Shantou University Medical College, 4. First Affiliated Hospital of Shantou University Medical College

**Introduction**

You are being invited to participate in a Home-Based Cardiac telerehabilitation (HBCTR) program, which is a collaborative research study between Canadian University of Waterloo and Shantou University Medical College. We have outlined the study here, and will discuss it with you. Please read this information carefully. Ask questions about anything that you want to know more about.

**Why is this research being done?**

Home-Based Cardiac Rehabilitation (HBCR) is an effective and convenient intervention for post-PCI (Percutaneous coronary intervention) patients because it decreases the chance of secondary hospital admissions and reduces cardiovascular morbidity and mortality; it improves functional capacity and

quality of life through physical activity and secondary prevention education. For post-PCI patients, cardiac rehabilitation (CR) has been recommended as a standard intervention procedure from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR). With telemedicine developing, telerehabilitation brings us an opportunity to implement HBCR at a long distance. However, no literature has shown the feasibility and effectiveness for Chinese people.

**What is the purpose of the study?**

In this study you will receive a HBCTR program by using emergent mobile and information technology to monitor your health data when you are exercising. The purpose of the pilot study is to assess the acceptability, feasibility and initial efficacy of the proposed cardiac rehab program. Our team wants to investigate (1) how you accept HBCTR program (2) whether the HBCTR devices and software are reliable and effective; (3) whether the program can improve your clinical outcomes after six weeks HBCTR intervention.

We need to do a really large study to achieve this goal. The current pilot study will recruit 20 to 24 post PCI patients in the first Affiliated Hospital of Shantou University Medical College. It will be the first step in finding out if it is feasible to do a really large study. The current study will also help us understand whether exercise can improve function and quality of life for patients after PCI.

**Who is eligible for this project?**

**Inclusion criteria**

- Post PCI patients within 12 months
- Live with at least one other person in the household
- Age 40-75 years old
- Able to accept and follow the medical team's instruction.
- Able to perform exercise
- Able to read Chinese and speak Mandarin
- Presence of functional capacity of ≥5 METs.
- Presence of normal hemodynamics during exercise testing and recovery (e.g. appropriate increases and decreases in heart rate and systolic blood pressure with increasing workloads and recovery)
- Resting ejection fraction ≥ 50%

Exclusion criteria

Patients exhibiting any 1 of these are excluded:

- Undergone previous Coronary artery bypass surgery (CABG)
- Peri-PCI complications
- Recurrent resting pain
- Age >75
- Presence of diabetes
- Renal issues
- Malignancy
- A history of cerebrovascular accident
- Severe liver or kidney damage or cognitive impairment, aphasia, mental disorder or inability to inspection and treatment
- Unstable angina
- Complex ventricular dysrhythmias during exercise testing **or** recovery

**What will your responsibilities be if you decide to take part in the study?**

You will be asked to participate in one visit to the first Affiliated Hospital of Shantou University Medical College at the beginning of the study, and one study visit at the end of the study, which is six weeks later. The study visit will take approximately two to three hours, and will include the assessments listed below. If you cannot complete an assessment, or do not wish to, you can still remain in the study. The only assessments that are mandatory are the Duke Activity Status Index, demographic data and medical history at the start, to confirm that you are eligible to participate.

*Study assessments during study visits at the start:*

- First of all, you will be provided by the research nurse or RA with a HBCTR Acceptance Questionnaire to learn the most attractive and most concerning aspect of the HBCTR program for you at the start of the study.
- The Duke Activity Status Index is a self-administered questionnaire that measures your functional capacity. It can be used to get a rough estimate of a patient's peak oxygen uptake to confirm your exercise capacity is larger than 5 METs (Metabolic Equivalent of Energy). The MET is a physiological measure expressing the exercise intensity and is defined as the rate of energy

consumption during a specific physical activity to a reference metabolic rate, set by convention to 3.5 ml $O^2$ $kg^{-1}$ $min^{-1}$. The MET of 5 is about you can walk at a 6.4km/h rate on level ground: (5 - 6 mets) or Washing vegetables, cooking (4-5METs). The study cardiologist will conduct the Duke Activity Status with you about one month after your PCI

- A demographic assessment that includes assessing your height, weight, sex, age, smoking and drinking behavior, your education, social economic class, independent living ability and social circumstances. The study research assistant (RA) will be responsible for conducting this assessment with you.
- The team doctor at your site, their delegate, or the research assistant will review your medical record in the hospital database to obtain your diagnosis, previous physical examination findings, history of symptoms, PCI history, exercise history, family history, drug History and your healthy inspection outcome, such as: (1) Conventional blood test +blood type, Conventional Urine test + Ketones, Conventional Stool test+ Fecal occult blood. (2) Liver and kidney function, electrolytes, glucose, lipids, serum markers of myocardial injury, coagulation, infectious disease screening (hepatitis B, hepatitis C, HIV, syphilis, etc.). (3) Chest X-ray, electrocardiogram, echocardiogram, blood pressure and assessment of myocardial ischemia (low-risk, non-emergency revascularization).The purpose of reviewing your these medical record is to ensure you are eligible for inclusion criteria and excluded exclusion criteria, for example, your resting ejection fraction is $\geq$ 50%, and you do not have complex ventricular dysrhythmias or peri-PCI complications.
- You will be asked to do rehab exercises three days a week, 20-30 minutes per day, for six weeks.

*Other assessments during study visits at the start and 6 weeks later:*

- You will be provided by the research nurse or RA with a Cardiac Depression Scale (CDS), which is a valid and reliable screening questionnaire to measure depression in cardiac patients.
- If still smoking after PCI, you will be provided by the research nurse or RA with a Fagerstrom Test for Nicotine Dependence (FTND), which is a commonly-used questionnaire to test the level of Nicotine dependence in smokers.
- You will be provided by the research nurse or RA with a 36-item Short Form Survey (SF-36), which is a commonly-used self-administered questionnaire for evaluating the general health-related quality of life in cardiac patients.

- You will be provided by the physical therapist with a six minute walking test, which is a simple measure of functional exercise capacity for clinical trials with cardiac patients.
- You will be provided by the research nurse or RA with a HBCTR Satisfaction Questionnaire after the six weeks intervention period.
- You will be provided with weekly calendars to keep track of your exercise date, type and time, mean and max heart rate, blood pressure, Borg Rating of Perceived Exertion (RPE)range, self-feeling and whether you have had an adverse event (Restrictive symptoms or signs appear, such as angina, chest tightness, shortness of breath, palpitations, dizziness, syncope, pale, sweating before or during exercise) and whether you are taking your heart-related medication (if applicable) or used any health care services(go inpatient or outpatient due to any disorder).
- You will be contacted by one of the research RAs bi-weekly to see how you are doing, and whether you have had any uncomfortable symptom or concerns. A phone number will be provided so that you can report any exercise, heart or other health problems.

Everyone in the study will be provided with post PCI rehab care. All participants will be asked to visit the study cardiologists and rehab doctors in hospital at the start and six weeks later. All participants can ask for study cardiologists to visit their home over the six weeks study period if necessary. Once you complete the first study visit in the hospital, you will be randomly assigned to one of two groups. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor can choose what group you will be in.

Everyone participant has 50% percentage chance going to Group 1 (HBCTR program group) and 50% percentage chance going to Group 2(usual care group).Participants in Group 1 will be given a Home-Based Cardiac Telerehabilitation (HBCTR) program. The program includes real time functional monitoring with remote sensor, customized exercise prescription and cardiovascular disease (CVD) education materials. The remote wearable system (Figure 1) is a commercially produced device (Ucare RG10, MicroSens Ltd, China, http://www.microsenstech.com), which consists of a belt strap with sensor and a programmed smart phone. The system can help you record routine vital signs and will delivery this information to doctors. The system enables the study doctors to monitor your health information and regularly give feedback to guide your exercise prescription. The remote sensor is linked with a cell phone via bluetooth and will deliver your data to your doctor through a phone signal. You can read the rehabilitation guide on your smart phone. You will be taught by study RA how to use the monitoring system.

The customized exercise prescription will be tailored to each individual's ability and will include aerobic and strength training to be performed at least three times weekly. The CVD education materials will include information outlining recommendations for your dietary intake, physical activity, smoking cessation, CVD education counselling, lipid-lowering therapy, blood pressure, weight loss and exercise therapy.

Figure 1: remote wearable system (sensor and smart phone)

Participants in Group 2 will receive current hospital cardiac rehab after PCI (usual care), which includes CVD educational booklets and outpatient review bi-weekly. The CVD educational booklets are same as Group 1. The outpatient review will check your health status, refill your medication and discuss your health or other topics. You also will receive tailored exercise guidance. Six weeks later, you will be asked not to disclose what group you are in to the research assistant performing assessments.

To promote your safety and gain benefit, you must give priority to regular participation and adherence to the prescribed intensity, duration, frequency, progression, and type of activity. To achieve best possible care:

DO NOT

- Withhold any information pertinent to symptoms from any staff member.
- Exceed your target heart rate.
- Exercise when you do not feel well.
- Exercise within 1 hour after eating or using tobacco products or alcohol.
- Use extremely hot water during showering after exercise (avoid sauna, steam bath, and similar extreme temperatures.
- Competitive sport which you cannot control the exercise intensity.

- Adjust the exercise program by yourself. If you want to change the exercise treatment (which includes duration, intensity and frequency), inform to your doctor in time.

DO

- Report any unusual symptoms that you experience before, during, or after exercise.
- Follow, without, exception ALL recommendations made by staff concerning the limits of exercise, weight control, or health related activities which you may be encouraged to do and document by recordings.
- Warm-up exercises like stretching is needed at the beginning and end of each exercise training
- Exercise in a comfortable condition. If patients feel chest discomfort occurs, overworked, pain, excessive shortness of breath, nausea, dizziness, blurred vision, or any other associated symptoms, stop to exercise and connect research team immediately.
- Do exercise training in the comfortable temperature. Avoid doing exercise under very humid and hot weather
- Ensure freely access to drink water when doing exercise.
- Check your BP and HR before each exercise training in order to make sure these indicators are in normal range.( when being charged, cardiologists would tell you your blood pressure and heart rate normal range. Before their exercise regimen, you can check by your electronic sphygmomanometer)

**What are the possible benefits of the study for me and/or society?**

We will provide you with the results of your assessments at the end of the study, so that you can see how you did and how you recover within the six weeks. You will be provided a feedback letter after the program. If you are interested in receiving more information regarding your exercise and health, the research team will give you a summary of this information. Participation in the rehabilitation program may help to evaluate which activities or habitat you may safely engage in during your daily life. Potential of benefits from cardiac rehab include increasing exercise capacity, health quality of life and modifying risk factors. If you were in Group 1, you are allowed to keep the sensor and smart phone for 6 weeks and they have to be returned at the end of the 6 week study. No assurance can be given that the rehabilitation program will realize the potential benefits, although considerable evidence improvement is usually achieved. Our study will be a first step in providing more evidence about the safety and effectiveness of cardiac rehab for post PCI patients in China.

**What are the possible risks and discomforts?**

There is a potential for exercise-related changes to occur during the assessments or exercise, such as muscle soreness and changes in blood pressure and heart rate. Any physical exercise or performance-based test is associated with a risk of falls or cardiovascular complications. We aim to minimize the risks by having the exercise prescription done by a physical therapist, and by having training for our staff.

We are asking you to do the cardiac rehab exercise training for the duration of the study. There exists the possibility of certain changes occurring during rehab exercise. These include abnormal blood pressure, fainting, irregular, fat, or slow heart rhythm. Every effort will be made to minimize those risks by provision of appropriate supervision (real time vital signs monitoring with automatic alarm function and available emergency call) during exercise. Emergency call and equipment and trained personnel are available to deal with unusual situations that may arise. If you are concerned you can discuss the risks with your physician.

**What information will be kept private and confidential?**

Your data will not be shared with anyone except with your consent or as required by law. All personal information will be removed from the data and will be replaced with an ID code. All you health data collected during this study will be retained for 7 years in a database in Network Information center of Shantou University Medical College, Shantou, China, to which only researchers associated with this study have access. The system is highly secure, and it encrypts the data and protects it with a password that is only known by the research team. Paper and electronic records will be retained for 7 years after the study is complete. All anonymized forms and study data will be stored in a locked office or on a password-protected online database. Only the research team (doctors, research coordinator and research RA) will have access to the data. Some of the data may be examined by students doing thesis projects or research internships, but your name or other identifying information will not appear with the data. Data stored at the University of Waterloo will be secured in accordance with University of Waterloo policies available at http://ist.uwaterloo.ca/security/policy/.

Information about you will be obtained from your health records held at Network Information center of Shantou University Medical College for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the University of Waterloo or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published or presented in a variety of forums. The results will be presented in such a way that you cannot be identified, except with your permission.

**Can I end my participation early?**

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you volunteer to be in this study, you may withdraw at any time. You can opt out of only some parts of the study, or withdraw altogether. We will not withdraw previously collected data unless you request that we do. If you decide to withdraw from the project, please notify a member of the research team.

**Will I be paid to participate in the study?**

You will be paid 50 Yuan (9 dollars) to reimburse part of your parking or bus transportation costs for travel to study visits.

**What happens if I have a research-related injury?**

If you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigators, institutions and/or sponsors from their legal and professional responsibilities. If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

If you have any urgent medical problem, heart attack (injury) that is related to your participation in this study or have any questions, concerns or would like to speak to the study team for any reason please call:

Day Emergency Number: Dr. Jilin Li at phone: 13592852807

This project has been reviewed by, and received ethics clearance through, the First Affiliated Hospital of Shantou University Medical College Research Ethics Board. If you have any comments or concerns resulting from your participation in this study, contact them at 88369014 by phone.

This project has also been reviewed by, and received ethics clearance through, a University of Waterloo Research Ethics Committee. If you have any comments or concerns resulting from your participation in this study, you can contact Dr. Maureen Nummelin, Director, Office of Research Ethics at (01)519-888-4567 ext. 36005 or by email at maureen.nummelin@uwaterloo.ca.

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**Consent of Participant**

I have read the information presented in the information letter about the study, *Feasibility and Initial Efficacy of Home-Based Cardiac Telerehabilitation (HBCTR) program- A pilot study*, being conducted by (Dr. William W. Au) and colleagues or I have had it read to me in a language that I understand. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I requested. I understand the purposes, procedures and risks of the research described in the project.

I am aware that I may withdraw from the study without penalty at any time by advising the researchers of this decision.

With full knowledge of all foregoing, I agree, of my own free will to participate in this study. I have been advised that I will receive a signed copy of this form.

Name of Participant

_____

Signature of Participant Date

_____ _____

Person obtaining consent:

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

Name, Role in Study Signature Date

# Appendix F

## The HBCTR Acceptance Questionnaire

1. Do you know you need to do cardiac rehabilitation after your PCI surgery?

   A. Yes, I know  B. No, I don't know

2. Please rank how strongly you are willingly to receive the following interventions after surgery on a scale 1-5 from not interested to very interested. (Piepoli et al., 2010)

| Important component of CR | No interested Very interested<br>1 2 3 4 5 |
|---|---|
| Physical activity counselling | |
| Psychological counselling | |
| Diet / Nutrition counselling | |
| Exercise training guide | |
| Risk factors management (weight, blood pressure, blood lipids, blood glucose, and smoking) | |

3. Do you believe HBCTR will benefit you now and into the future?

   A. definitely will  B. probably will  C. don't know  D. probably won't  E. definitely won't

4. Do you want to participate in the HBCTR program if you are eligible?

   A. Yes, I do  B. No, I don't

5. Which aspect do you think you can benefit most from HBCTR (the reason of acceptance)?

   A. Make life (exercise) safer and more independent
   B. Being able to self-monitor activity condition daily
   C. Receiving timely help when needed
   D. Having regular professional rehabilitation instruction
   E. Providing assurance to family members
   F. Having automatic emergency alert
   G. Others_____

6. What factor are you most concerned with regarding to HBCTR program (the reason of rejection)?

   A. Unreliable technology
   B. Too cumbersome operation
   C. Concerns for safety
   D. Inaccurate monitoring data
   E. Data (Privacy) may leak
   G. Not necessary to do cardiac rehabilitation.
   H. Others_____

7. Please choose the most impactful of the following factors that may hinder the implementation of HBCTR.

| Affecting Factors of home monitoring systems |
|---|
| A. Affordable (including software, hardware, installation, use, maintenance costs) |
| B. A comprehensive understanding of the system (advantages and disadvantages) |
| C. Simple operation of sensor |
| D. Feasibility of the system |
| E. Monitoring health indictors during exercise |
| F. Personalized service (exercise prescription, health guidance) |
| G. Access to send an alert to doctors or family members |
| H. Usability of devices |
| I. Non-invasive intervention |
| J. Protecting Data Privacy |

Designed from:

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# Appendix G

## Protocol for 6 Minute Walk Assessment

1. **Equipment** – rolling distance marker and stopwatch.
2. **Exclusion criteria** – Patients with musculoskeletal problems that preclude them from walking such as intermittent claudication, paralysis, pain and psychiatric problems that would contribute to decreased walking performance. Uncontrolled angina, hypertension, recent history of cardiac dysrhythmia, or other forms of heart disease may also preclude testing.
3. **Protocol** –
    - **a.** Prior to the first walk; resting HR, BP, ECG will be recorded
    - **b.** Walks should take place at least two hours following a meal
    - **c.** Patients will be asked to walk from end to end of the walking track, covering as much ground as possible in 6 minutes
    - **d.** The 6 minute walk should be carried out on a quiet indoor hallway that is at least 100 ft in length.
    - **e.** Three walks should be carried out with at least 15 minutes of rest between each test or on separate days.
    - **f.** The following instructions will be given to patients: " The purpose of this test is to find out how far you can walk in 6 minutes. You will start from this point (indicate marker at one end of the course) and follow the hallway to the marker at the end, then turn around and walk back. When you arrive back at the starting point, you will go back and forth again. You will go back and forth as many times as you can in the six minute period. If you need to, you may stop and rest. Just remain where you are until you can go again. However, the most important thing about the test is that you cover as much ground as possible during the six minutes. I will tell you the time and I will let you know when the six minutes are up. When I say 'stop', please stand right where you are". Subjects will then be asked to repeat the gist of the instructions to validate understanding.
    - **g.** During the walks, the following words of encouragement will be provided at 30 second intervals: "you're doing very well", "keep up the good work", "good work", "you're doing fine".
    - **h.** Patients are told when 2,4 and 6 minutes (Stop) have elapsed.
    - **i.** The longest distance walked of the three trials will be recorded as 6MDW, although all distances will be documented.
    - **j.** Immediately following completion of the walking test, patients will be asked to rate their level of perceived exertion and HR, BP and ECG will be recorded. Total distance walked will also be determined for future comparisons.

American Thoracic Society (2002). Guidelines for the Six-Minute Walk Test. American Journal of Respiratory and Critical Care Medicine. 166:1, 111-117.

# Appendix H

## SF-36 Health Survey

Instructions for completing the questionnaire:

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

Patient Name: _____ Date: _____

1. In general, would you say your health is:

- o Excellent
- o Very good
- o Good
- o Fair
- o Poor

2. Compared to one year ago, how would you rate your health in general now?

- o Much better now than a year ago
- o Somewhat better now than a year ago
- o About the same as one year ago
- o Somewhat worse now than one year ago
- o Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

- o Yes, limited a lot.
- o Yes, limited a little.
- o No, not limited at all.

b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?

- o Yes, limited a lot.
- o Yes, limited a little.
- o No, not limited at all.

c. Lifting or carrying groceries.

- o Yes, limited a lot.
- o Yes, limited a little.
- o No, not limited at all.

d. Climbing several flights of stairs.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

e. Climbing one flight of stairs.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

f. Bending, kneeling or stooping.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

g. Walking more than one mile.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

h. Walking several blocks.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

i. Walking one block.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

j. Bathing or dressing yourself.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down the amount of time you spent on work or other activities?

- Yes
- No

b. Accomplished less than you would like?

- Yes
- No

c. Were limited in the kind of work or other activities

- Yes
- No

d. Had difficulty performing the work or other activities (for example, it took extra time)

- Yes
- No

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a. Cut down the amount of time you spent on work or other activities?

- Yes
- No

b. Accomplished less than you would like

- Yes
- No

c. Didn't do work or other activities as carefully as usual

- Yes
- No

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

7. How much bodily pain have you had during the past 4 weeks?

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

a. did you feel full of pep?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

b. have you been a very nervous person?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

c. have you felt so down in the dumps nothing could cheer you up?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

d. have you felt calm and peaceful?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time

- None of the time

e. did you have a lot of energy?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

f. have you felt downhearted and blue?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

g. did you feel worn out?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

h. have you been a happy person?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

i. did you feel tired?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

b. I am as healthy as anybody I know

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

c. I expect my health to get worse

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

d. My health is excellent

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

# Appendix I

## Fagerstrom Test for Nicotine Dependence (FTND)

1. How soon after you wake up do you smoke your first cigarette?

- After 60 minutes (0)
- 31-60 minutes (1)
- 6-30 minutes (2)
- Within 5 minutes (3)

2. Do you find it difficult to refrain from smoking in places where it is forbidden?

- No (0)
- Yes (1)

3. Which cigarette would you hate most to give up?

- The first in the morning (1)
- Any other (0)

4. How many cigarettes per day do you smoke?

- 10 or less (0)
- 11-20 (1)
- 21-30 (2)
- 31 or more (3)

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?

- No (0)
- Yes (1)

6. Do you smoke even if you are so ill that you are in bed most of the day?

- No (0)
- Yes (1)

Scoring

0-2 Very low dependence 3-4 Low dependence 5 Medium dependence

6-7 High dependence 8-10 Very high dependence

Adapted from Heatherton, T.F., Kozlowski, L.T., Frecker, R.C., Fagerstrom, K.O. (1991). The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. *British Journal of Addictions*; 86:1119-27.

# Appendix J

## Duke Activity Status Index

The Duke Activity Status Index is a self-administered questionnaire that measures a patient's functional capacity. It can be used to get a rough estimate of a patient's peak oxygen uptake.

| Item | Activity | Yes | No |
|---|---|---|---|
| 1 | Can you take care of yourself (eating, dressing, bathing or using the toilet)? | 2.75 | 0 |
| 2 | Can you walk indoors such as around your house? | 1.75 | 0 |
| 3 | Can you walk a block or two on level ground? | 2.75 | 0 |
| 4 | Can you climb a flight of stairs or walk up a hill? | 5.50 | 0 |
| 5 | Can you run a short distance? | 8.00 | 0 |
| 6 | Can you do light work around the house like dusting or washing dishes? | 2.70 | 0 |
| 7 | Can you do moderate work around the house like vacuuming, sweeping floors or carrying groceries? | 3.50 | 0 |
| 8 | Can you do heavy work around the house like scrubbing floors or lifting and moving heavy furniture? | 8.00 | 0 |
| 9 | Can you do yard work like raking leaves weeding, or pushing a power mower? | 4.50 | 0 |
| 10 | Can you have sexual relations? | 5.25 | 0 |
| 11 | Can you participate in moderate recreational activities like gold, bowling, dancing, doubles tennis, or throwing a baseball or football? | 6.00 | 0 |
| 12 | Can you participate in strenuous sports like swimming singles, tennis, football, basketball, or skiing? | 7.50 | 0 |

Duke Activity Status Index= $\sum values\ of\ all\ 12\ items$

Maximum value : 58.2

Minimum value : 0

Estimated peak oxygen uptake in mL/min = $(0.43 \times DASI) + 9.6$

Adapted from Hltaky MA Boineau RE et al. A brief self-administered questionnaire to determine functional capacity (The Duke Activity Status Index). Am J Cardio. 1989; 64: 651-654

# Appendix K

## HBCTR Patients Satisfaction Questionnaire

**1. Are you satisfied with the HBCTR system?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Completely satisfied | | Neutral | | Not at all satisfied |

**2. Do you think the HBCTR system is easy to use?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Very easy | | Neutral | | Very hard |

**3. Do you think the HBCTR program is Robust?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Very easy | | Neutral | | Very hard |

**4. Do you feel the HBCTR program decreases your fears in exercise after surgery?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Strongly agree | | Neutral | | Strongly disagree |

**5. Do you feel more confident in self-managing your disorders than before?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Strongly agree | | Neutral | | Strongly disagree |

**6. How many times have you ever stopped your rehabilitation exercise due to technical problems?**

A. 0 B.1-2 C. 3-4 D more than 5

**7. Do you think the system helped you to communicate with your doctors?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Very clear | | Neutral | | Very unclear |

**8. Were the instructions from the research team clear enough for you?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Very clear | | Neutral | | Very unclear |

**9. Which part of the system is the most useful?**

A. Real time physiological monitoring B. Customized feedback C. Emergency call

D. Automatically warning E. Communication with the medical staff F. None

**10. Do you think the HBCTR program improved your quality of life?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Very much | | As usual | | Much worse |

**11. Do you think the HBCTR program helped your caregivers look after you?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Very much | | As usual | | Much worse |

**12. Will you recommend the HBCTR to others?**

| 5 | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| Of course | | I don't know | | Of course not |

# Appendix L

## Weekly record card

Participant Code:

Target HR range: RPE range:

Problems since last session:

Exercise prescription:

# of cigarettes/w:

Body weight:

| date | comment | mins | meds | Warn-up | Resting HR | Resting BP | Ex:mean & Max HR | Post-ex BP | RPE range | Self feeling |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

Medication records:

**Weekly recorded report**

| # of System failures and reasons | |
|---|---|
| Safety Evaluation | 1. Number of exercises stop and reasons:<br>2. Severity (mild, moderate, severe):<br>3. The relationship between the intervention (definitely related, probably related, may be relevant, may be irrelevant, and certainly irrelevant):<br>4. Duration (start and end date, or whether existing at last check):<br>5. Whether they are serious adverse events: |
| Remote rehabilitation exercise training adherence rate | # of times of patients should do exercise:<br># of times of patients did exercise:<br>adherence rate = % |
| Participants self-report adherence rate | # of times of patients should self-report:<br># of times of patients did self-report:<br>adherence rate = % |
| Medication intake adherence rate | # of times of patients took medication:<br># of times of patients should take medication:<br>adherence rate = % |

# Appendix M

## 1-6 weeks exercise prescription sample

| Weeks after discharge | Exercise prescription sample |
|---|---|
| 1 | Stretch exercise 5mins, comfortable walking 10mins; Tai Chi 10 mins. If you feel little uncomfortable, slow down or rest for a while, cool down walking 10 mins.<br>Target heart rate: 80-100 RPE= 9-12 |
| 2 | Stretch exercise 10 mins, walking 20 mins; Light weight exercising (barbells and dumb-bells) 5 mins; If you feel little uncomfortable, slow down or rest for a while; cool down walking 10 mins.<br>Target heart rate: 80-110 RPE= 10-14 |
| 3 | Stretch exercise 5mins; Light weight exercising (barbells and dumb-bells) 5mins, walking 15 mins; jogging 5 mins; cool down walking 10 mins.<br>Target heart rate: 80-110 RPE= 11-14 |
| 4 | Stretch exercise 5mins; walking 10 mins; jogging 10 mins; cool down walking 10 mins.<br>Target heart rate: 80-115 RPE= 11-14 |
| 5 | Stretch exercise 5mins; jogging 25 mins; callisthenic exercise 10 mins; cool down walking 10 mins.<br>Target heart rate: 80-115 RPE= 11-15 |
| 6 | Stretch exercise 5mins; jogging 20 mins; callisthenic exercise 10mins; cool down walking 10 mins.<br>Target heart rate: 80-120 RPE= 11-15 |

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