A nurse-led lifestyle intervention using mobile application versus booklet for adults with Metabolic Syndrome- Protocol for a randomized controlled trial

INTRODUCTION

Metabolic syndrome (MetS) is defined as a cluster of cardio metabolic risk factors: diabetes and prediabetes, abdominal obesity, high cholesterol and high blood pressure (The international Diabetes federation, 2017). According to the new International Diabetes Federation (IDF) definition, a person with MetS must have central obesity (defined as waist circumference with ethnicity- specific values) plus any two of the following factors or be receiving related treatment such as raised triglycerides, reduce HDL cholesterol, raised blood pressure or have been previously diagnosed hypertension or raised plasma glucose or previously diagnosed with type 2 diabetes (The international Diabetes federation, 2017). The rising prevalence in metabolic syndrome has led to widespread concerns in all populations (Saklayen, 2018). The prevalence of MetS has been increasing, with prevalence of 24% to 78% in the western population (Mottillo et al., 2010) and about 15% to 36 % in the Asia pacific region, including Australia, Singapore, Japan , Korea and China (Gu et al., 2005; Ranasinghe, Mathangasinghe, Jayawardena, Hills, & Misra, 2017). Clients with Metabolic syndrome will have higher chance of developing diabetes, prediabetes, and cardiovascular disease if not well treated. These patients, if obese, take little physical exercise or have poor glycemic control, further increase their risk of cardiovascular events and stroke (Butnoriene et al., 2015). In addition, MetS patients also perceived a high level of stress and decrease QoL (Butnoriene et al., 2015; Gheshlagh, Parizad, & Sayehmiri, 2016;Vetter et al., 2011). The formulation of effective strategies and programmes that can address the challenges of the growing prevalence of metabolic syndrome become a priority of government health policy and healthcare strategies here and in many other countries (Bassi et al., 2014).

Life style modification such as staying physically active and performing regular exercise is always recommended as important because regular physical exercise can increase insulin sensitivity, improve good cholesterol levels (HDL), and reduce blood pressure, body weight, and cardiovascular risk factors (Centers of Disease and

Prevention, 2018; The international Diabetes federation, 2017; Pettman et al., 2008; Vetter et al., 2011; Wu, Hwang, Chen, & Chuang, 2011). According to WHO recommendation, it is beneficial for an adult to perform moderate intensity activity such as brisk walking exercise at a rate of 5 to 6 km/h (with moderate intensity) for at least 30 minutes per day, 5 days per week. Moderate intensity activity can be expressed as 50% to 70% of maximum heart rate (220 minus age). It has been well reported that regular physical exercise can strengthen muscle, improve blood circulation and mood and maintain physical and psychological wellbeing (Pettman et al., 2008; WHO 2018). Therefore, there is a great need to develop the educational intervention/ programme for life style modification for the clients.

During the past decade, e-health technology, the use of information and communication technologies for health has proved to be an effective mode of delivery of educational intervention (World Health Organization, 2017; Azar et al., 2016; Jahangiry, Montazeri, Najafi, Yaseri, & Farhangi, 2017; Neville, O'Hara, & Milat, 2009; Oh et al., 2015; Petrella, Stuckey, Shapiro, & Gill, 2014; Whitehead & Seaton, 2016). Hence, there is a need to further explore any application for the future development of e-health or any strategies to increase the physical exercise and promote wellbeing.

BACKGROUND

Metabolic syndrome (MetS) is prevalent with high risks of developing into diabetes, prediabetes, and cardiovascular disease if not well treated (Kaur, 2014; Lao et al., 2014). Life style modification includes diet and exercise regulations especially staying physically active and performing regular exercise is always recommended as important to lose weight and calorie intake (Bassi et al., 2014; Gallo-Villegas et al., 2016; Gomez-Huelgas et al., 2015; Ranasinghe, Mathangasinghe, Jayawardena, Hills, & Misra, 2017; Seligman et al., 2011). Previous studies have reported various modalities of life style intervention on MetS management including educational programme with educational sessions and counselling, on-site educational intervention and exercise supervision (Chang, Chen, Chien, & Lin, 2016; Kim. C, Kim, D, & Park, 2011; Nanri et al., 2012; Oh et al., 2010; Zhang et al., 2016) and home-based Life Style Interventional Programme (LIP) for MetS patients (Wu et al., 2011; Wang, Chair, &

Wong, 2017). In these programme, nurses played an important role in education and encourage patients to participate in lifestyle modification, reducing the risk factors of MetS (Harris & Smith, 2014; Wang et al., 2017). By setting a systematic and achievable goal, patients are more willing to accept and change behaviour. Nurses' continuous monitoring and provide reinforcement is essential for the successful Lifestyle Intervention Programs (LIPs) (Kaur, 2014; Wang et al., 2017). For example, a recent research have demonstrated that an Lifestyle Intervention Programme (LIP) consisting of one educational session supplemented by a LIP booklet was effective on body weight reduction, decreasing depression and improving quality of life (Wang et al., 2017). However, most previous studies are limited by high labour resource and thus are transferrable to limited numbers of patients only (Chang et al., 2016; Kim et al., 2011; Nanri et al., 2012; Wang et al., 2017; Wu et al., 2011; Zhang et al., 2016).

Studies reported the great potential of internet- and mobile phone-based mHealth educational interventions to support patients with chronic diseases (e.g., cardiovascular disease, diabetes heart failure) to promote disease self- management (Azar et al., 2016; Jahangiry et al., 2017; Petrella et al., 2014; Whitehead & Seaton, 2016; Wong, Chair, Leung, Sit and Leung, 2018; World Health Organization, 2011). 'eHealth' or mHealth refers using mobile computing, communication technologies to improve access to health information, improve the access to routine, and emergency health services, and provide diagnostic services and other functions (World Health Organization, 2011). Recent studies have proven the efficacy of eHealth/mHealth technologies as effective modes of client support. However, these studies are limited to insufficient evidence on the theoretical framework which guide intervention and unclear of its comprehensive effect on total exercise, self-efficacy for exercise, cardiovascular endurance and stress level (Azar et al., 2016; Jahangiry et al., 2017; Oh et al., 2015; Petrella et al., 2014; Whitehead & Seaton, 2016). In addition, there is limited evidence to compare the effects of the Lifestyle intervention programme using mobile application versus booklet as most of the available studies only examine the effect on e-health intervention/ programme versus usual care (Azar et al., 2016; Jahangiry et al., 2017; Oh et al., 2015; Petrella et al., 2014) or booklet versus usual care (Wang et al., 2017). More empirical studies are required.

Considering the effectiveness of a Lifestyle Intervention Programme (Wang et al., 2017), the advantages of e-health programmes for patients, the widespread use of the

smart phone among adults (Census and Statistical Department, 2015) and the growing number of adults with MetS (The international Diabetes federation, 2017; Mottillo et al., 2010; Ranasinghe et al., 2017), we plan to integrate a self -developed mobile application into the existing Lifestyle Intervention programme (LIP) and comparing the effect of the use of this LIP (using MetS app vs booklet) on total exercise, cardiometabolic risk factor profile, cardiovascular endurance and perceived stress level for Chinese adults with MetS in Hong Kong. This empirical study will further add evidence to examine which approaches (app versus booklet) is more superior so that effective strategies may be planned.

THE STUDY

Aims

This study aims to test the effectiveness of a Lifestyle Intervention Programme (LIP) using MetS app versus a booklet on various outcomes in term of body weight, total exercise, cardio metabolic risk factors, and cardiovascular endurance, psychological outcomes (perceived stress scale and exercise self-efficacy) for MetS adults in the Hong Kong community.

Objectives

Across 24 weeks, we would like to compare the effectiveness of the Life style Intervention programme among App group or Booklet group or control group on :

1. Body weight (primary outcome) ;
2. Exercise outcomes: total amount of exercise, as measured by the Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ) ;
3. Improvement in any two of cardiometabolic risk factors profile (waist circumference, body mass index, blood pressure, cholesterol (HDL), triglycerides, and blood glucose level);
4. Cardiovascular endurance (measured by the Three- minute Step Test);
5. Stress level as measured by the Chinese Version of the Perceived Stress Scale (PSS-10);
6. Exercise self-efficacy as measured by the Chinese version of the Self-Efficacy for Exercise scale (SEE-C)

Design / Methodology

Study design: A parallel group 1:1:1 randomized controlled trial with three arms, namely, MetS app group (App Group), booklet group and the control group will be

employed to examine the of a Lifestyle Intervention Programme (LIP) on various outcomes for MetS adults in the community. Figure 1 shows the flowchart of the study.

Randomization and allocation concealment

In each study community centre, the eligible clients will be randomly assigned to the either App Group or Booklet Group or the Control group. The allocation sequence was computer-generated with a ratio of 1:1:1 and prepared by a statistician before commencement of the study. Each allocated sequence has been written in a small card and placed in a sealed envelope. The envelope will be opened after the client complete the baseline questionnaire. Then the research assistant will inform the client about the intervention allocation and follow-up procedure. The health care team and the research assistant who collected data will be blind to the group allocation.

Subjects and setting

Data will be collected from six community centres for the adults. The demographic profile of the members and the setting are similar to minimize the cluster effect. Each centre provides many health promotion activities to residents living nearby.

Inclusion criteria

The inclusion criteria are those:

1. Ethnic Chinese client who has a smart phone and able to read Chinese.
2. Adult age 18 or over
3. MetS Clients with central obesity (male >90 cm , female > 80cm) plus two items of the followings :

- Raised triglycerides ≥ 150 mg/dL (1.7 mmol/L) or specific treatment for this lipid abnormality
- Reduced HDL cholesterol < 40 mg/dL (1.03 mmol/L) in males < 50 mg/dL (1.29 mmol/L) in females or treatment for this lipid abnormality

- Raised blood pressure systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg or treatment of previously diagnosed hypertension (HT)

4. Raised fasting plasma glucose (FPG) ≥ 100 mg/dL (5.6 mmol/L), or previously diagnosed type 2 diabetes (DM)

Exclusion criteria

Clients with physical, mental, visual, or cognitive impairments with regular medical follow-ups and treatment, and those who have musculoskeletal disorders or other disabling diseases that may limit the practice of walking exercise/ brisk walking exercise will be excluded. Clients who received prescribed drug for weight reduction will be excluded.

Sample size

According to the meta-analysis (Mateo, Granado-Font, Ferré-Grau, & Montaña-Carreras, 2015) in 2015, the effect size of using mobile apps as compared to printed material or counselling on the changes in body weight is 0.19 and the study of Wang et al. (2016) reported the effect size of the LIP programme as compared to usual care on body weight is 0.17. Using a repeated measures design with 3 time points, variance of body weight as 11.27, the correlations between body weight at baseline and 1 month (T1) is 0.8 and a decay rate of 0.8 at 3 months (T2), 96 patients in each group will be needed to achieve a statistical power of 80% at the 5% significance level and to detect a significant time x treatment interaction effect. Further based on our attrition rate of our pilot study is about 10.53 % -18.5% for both app and booklet group at 3 months, and our similar intervention studies in Chinese population reported 15% -19% (Wang et al., 2017; Wong, Chair, Leung, Sit, & Leung, 2018) and therefore assuming a 20% attrition rate, a total of 120 patients per group (i.e. 360 in total) is needed to be recruited for this study.

Intervention material and theoretical framework of the app design:

The front page of the app (Figure 2) will include colourful icons to direct the participant to i) the educational area, which defines MS and provides tips regarding a healthy diet, exercise and healthy life style ii) a health member area, with blood pressure, cholesterol, body weight and glycaemic level data; iii) a record of daily exercise and set goals. The content of booklet is the same as in the app group. The

major component of the LIP booklet consists of fact of metabolic syndrome, advice of diet, exercise, medication, life style and stress management.

The Life style intervention programme (LIP) design is grounded on self-efficacy theories and the health beliefs model (Bandura, 1997; Janz, Champion & Strecher, 2002). In line with previous studies of e-health educational intervention development (Oh et al., 2015), the LIP knowledge platform, a construct of the health beliefs model regarding perceived susceptibility, severity, benefits and barriers, will provide facts about metabolic syndrome, its risk factors and the effects of regular physical exercise on health. In addition, tips of diet and exercise plan will be provided. The members' area and interactive platform of the MetS app will further apply the 'cues to action' and 'enhancing self-efficacy' constructs of the health beliefs model and enable self-action and self-monitoring related to individual need and health problems, exercise records, body weight and blood pressure. Accordingly, the app will motivate the participants and enhance their self-efficacy in terms of healthy behaviour of life style, self-monitoring and maintenance of blood pressure and exercise. To arouse interest and fidelity of the app intervention, fifteen messages with encouraging words has been designed and app group participant will receive one automatic health message daily. In addition, the alert /feedback feature in red colour and relevant advice will be provided if necessary.

Intervention protocol

All subjects will continue their prescribed medical treatments if any. At the intervention day, a nurse will provide a 30-min LIP educational talk to all participants. They will also be advised to perform brisk walking exercise at a rate of 5 to 6 km/h (with moderate intensity) for at least 30 minutes per day, 5 days per week that is about 2.5 to 3 km (about six laps of the running track /standard football field). A systematic review by Lin et al. (2014) reported that the duration of Life modification programme of five included trials ranged from four to 24 weeks, and durations of at least 12 weeks significantly improved the outcomes. In this regards, the whole study last for 24 weeks but the additional measure will be added within the first 12 weeks in order to enhance fidelity and sustainability of the intervention.

App Group: Participants will receive the MetS mobile application (MetS app)

instalment and briefing by a research assistant after the educational talk. During the study period, they will be able view the knowledge content in their own smart phone. In addition, a membership area provides individual support of self- health monitoring, goal setting for their exercise plan and exercise record.

Booklet Group: The participants will receive a Hong Kong version LIP booklet to take home and use for 24 weeks. LIP booklet has been developed by the team to fit the life style for Chinese population (Wang et al. 2017).

Control Group: The participants will receive a placebo health leaflet. The health leaflet is related to the general health information of exercise practice, which is supplied by the Department of Health, Hong Kong. The leaflet is commonly distributed to the public for health promotion. For the ethical reason, those control group participants are freely to receive the LIP booklet after completion of the study at 24 weeks.

Procedure of data collection

All eligible clients will be screened by simple health assessment (waist circumference and health history screening) and approached by the research assistant (RA1). Eligible clients will be invited to join the study with a signed written consent after explanation. Baseline data (T1) will be collected by the RA1. The eligible participants will be randomly allocated to either the control group or App group or booklet group according to randomization process. All participants will receive intervention according to the protocol. Different dates will be planned for different groups for all follow-ups respectively to avoid contamination of the subjects as well as blinding to the assessor as far as possible.

In all follow-ups, the trained RA2 who is blind to group allocation will perform the physical assessment for the participants. All participants will be asked to fill in and return the questionnaire to the locked box at the reception desk of the community centre. The participants will complete the baseline questionnaire before randomization (T0), and then they will complete the follow-ups at week 4 (T1), week 12 (T2) and week 20 (T3) after intervention. A structured questionnaire will be used to collect data.

The primary outcome

Body weight will be measured using the same electronic weight scale in the community centres or research office.

Secondary outcomes

i) Total physical exercise will be quantified with a modified version of the GSLTPAQ (Godin, 2011; Godin & Shephard, 1985). The patients will be instructed to indicate the amount of exercises undertaken and rank the exercises in the order of difficulty (strenuous, moderate, or mild). The total score will be calculated. This scale had previously been widely used and shown to have good psychometric properties with acceptable test–retest reliability (ranging from 0.62 to 0.81), and correlated with maximum oxygen consumption, treadmill time and other similar physical activity questionnaires (Godin, 2011).

ii) Chinese version of Self-Efficacy for Exercise (SEE-C)

The SEE-C scale consists of nine items, and responses are given on a scale of 0–10 scale. The sum of the responses to all nine items yields the final composite score ranging from 0–90. The SEE-C has been proved reliable with good psychometric properties (a Cronbach's alpha of 0.75) for Chinese adults (Lee et al., 2009; Wong et al., 2018).

iii) Cardiovascular endurance test.

Three -minute step test aims to test the client's cardiovascular functional endurance after exercise across the age span and gender. A participant steps on and off of a 12-inch high bench / or stair for 3 minutes. Their pulse is then taken while the participant remains standing. Compare the heart rate with the table according to the age and gender to determine the fitness within a range of 7 scores from excellent to good, above average, average, below average, poor and very poor (Bohannon, Bubela, Wang, Magasi, Gershon, 2011).

iv) Perceived stress scale (PSS-10)

Ten self-report items measure the degree to which situations in one's life are appraised as stressful and the current levels of stress experienced in the last month. Summative scores range from 0 to 40, with higher score indicating higher stress levels. These scores have been used as outcome measures of experienced levels of stress. This scale has been used in Chinese cardiac patients with good psychometric properties (Leung, Lam, Chan, 2010).

v) Demographic, clinical and MetS risk factors profile

Demographic data (age, gender, and occupation, educational level), medical problems, (health problems, drug use, recent hospitalization) will be collected at baseline. Medical consultation, complications and admission, MetS app usage or LIP booklet usage will be collected at all follow-ups. MetS risk factor profile (waist circumference, systolic and diastolic blood pressure, LDL cholesterol, and HDL cholesterol, and triglycerides, blood sugar level), body mass index, blood pressure and body weight will be collected at baseline and T4 (week 20) by the trained RA . Blood samples will be taken by using a finger stick using auto-analyser and the participants are asked to have 8 hours fasting. The Waist circumference is measured by a trained RA with a tape (cm) at the midpoint between the top of the iliac crest and the lower margin of the last rib in the standing position at the end of several consecutive natural breaths

Planned data analysis

To minimize subject contamination, different dates of follow-ups will be assigned to different groups. To minimize researcher bias and ensure good blinding to the assessors, research assistant, RA1 who are responsible for data collection will be blind to the group allocation. They will receive a briefing and training session for data collection and blood taking by using the finger-stick method and use the auto blood analysers. All questionnaires will be distributed to the individual participant and asked to return own questionnaire into the locked box after physical assessment by RA1. Inter-rater reliability of the data collection procedures among the research assistants has been examined in the pilot study.

Data will be entered and analysed using SPSS version 23. Demographic data will be summarized, with frequency and percentage for categorical variables, whereas mean and standard deviation for continuous variables. Group difference at baseline will be

compared using Chi-square tests for categorical variables and ANOVA for continuous variables.

To compare the mean changes in the continuous outcome variables including body weight, total exercise, weight circumference, BMI, self-efficacy in exercise, perceived stress level among the three groups with the intention-to-treat principle and generalized estimating equation (GEE) models, will be applied. Post-hoc pairwise comparisons of the changes in the outcome variables across the three study groups will be performed to compare the effectiveness of Apps to Booklet, Apps to control and Booklet to control respectively. All the tests are two-sided and a p-value < 0.05 will be considered statistically significant.

Ethical consideration

Ethics approval and permission has been obtained from the study university and the selected community centres. RCT registration has been obtained at ClinicalTrials.gov Protocol Registration system (https://clinicaltrials.gov/). The registration number is ClinicalTrials.gov ID: NCT03778788. Eligible clients will be invited to join the study with a signed written consent after explanation and ample time for consideration. Clients are voluntary, well informed about the purpose, nature and procedure of the study. A written informed consent will be obtained from each participant and they will be free to refuse to any assessments, and withdraw from the study at any time. Furthermore, anonymity and confidentiality of the data collected will be closely monitored.

Regarding the safety of the subjects during the intervention, the research team will monitor the progress to check if there is any problems happen during the intervention period such as discomfort in brisk walking.

Validity and reliability

All the selected measures are all validated with good reliability and validity with Cronbach's alpha > 0.7 and have been adopted in the local context. For example, total physical exercise with a modified version of the GSLTPAQ has been widely used in many studies with good reliability (Godin, 2011; Godin & Shephard, 1985). Chinese

version of Self-Efficacy for Exercise Perceived Stress Scale have been adopted and used in the local context with good psychometric properties (Lee et al., 2009; Wong et al., 2018; Leung, Lam, Chan, 2010). Any difference in baseline characteristics between groups will be accounted for in the statistical analysis.

DISCUSSION

Life style modification is important for those clients with metabolic syndrome to improve the condition of obesity and prediabetes, decrease risk of diabetes, lipaemia and hypertension as these risks may be amenable to lifestyle intervention. This project has theoretical, research, and practical significance. This study will contribute to evidence-based practice by testing the effectiveness of a life style intervention programme using a MetS app versus a booklet and the control group for MetS adults. It may determine a causal relationship between LIP with a Mets app and LIP with a booklet on body weight, total exercise, cardio metabolic risk factors, cardiovascular endurance, and psychosocial outcomes for MetS adults. This study will further add evidence to examine which approaches (app or booklet) is more superior to the others so that effective strategies may be planned. In addition, more empirical studies to examine a longer term effect are recommended to examine the sustainability of the intervention as most of the previous studies measure the outcomes within twelve weeks only. In our study, the new evidence of a longer term effect (up to twenty weeks) will be provided.

The results will support the continuity of care for MetS clients in the community. If the MetS App is effective, it can be promoted to the population on a larger scale to reduce MetS risks with limited human resource. In terms of novelty of the app design, this app is designed underpinned by theoretical framework with advanced technology such as automatic message and reminder/positive feedback to motivate the clients to initiate and maintain their healthy life style such as exercise.

From a clinical perspective, the MetS app is important for those clients with obesity and prediabetes, increased risk of diabetes, lipaemia and hypertension as these risks may be amenable to lifestyle intervention. A Lifestyle Intervention Programme with support of a MetS app could improve or reverse the condition of MetS, result in good exercise maintenance that will be beneficial in reducing cardio-

metabolic risk profile and promoting psychological wellbeing. Nurses are at the best position to provide support and promote healthy life style and exercise maintenance and conduct evaluation in these programme. Such intervention may be another means of enhancing the partnership between health care professionals and patients with metabolic syndrome. The findings will provide insight for the healthcare team as well as the government or policy makers with a most effective mean for health promotion strategies and services in the community.

Limitations

There are several potential limitations in this study. Subject recruitment may be challenging because most of the potential participants attending the community are those older adults or elderly. We may not be able to avoid participation bias as the participation to the study is voluntary. More strategies are required to attract the working adults with metabolic syndrome to join the study. The attrition rate may be high due to the long follow-ups up to 24 weeks. More measures may be considered to remind the participants for follow up or engage in the study.

Conclusion

Metabolic syndrome is a common health problem associated with heightened risk of cardiovascular disease and the risks are potentially amenable to lifestyle intervention. This study will address both research and clinical gap to identify which approaches (app or booklet) is more superior to the others so that effective strategies may be planned for the clients with metabolic syndrome. The findings is important to clinical implications in terms of potentially labour saving and can be widely use in a large scale in the community setting if the intervention (using app) has been proven effective and likely of community impact.

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