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The effectiveness of a home-based interactive e-health educational intervention for middle-aged coronary heart disease (CHD) adults in improving total exercise, adherence rate, exercise efficacy and outcomes: a study protocol doe a randomized controlled trial (RCT)

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Background

Coronary Heart Disease (CHD) is the leading cause of death globally and locally. In Hong Kong, CHD exhibits an increasing incidence among middle-aged adults (age 40-60. (Hospital Authority, 2011; World Health Organization, 2014)

Secondary preventive strategies (e.g. good lipid control, performing physical activity, making healthy dietary choices) are suggested to be effective means of self-management of CHD. (Conn et al., 2007)

Low exercise adherence has been observed among CHD patients.(Conn et. Al., 2009; Woodard & Berry, 2001)

Behavior change in exercise and diet choice is a challenging long-term process!!

Background

So, What should we do to support CHD clients for self- health management and also improve their exercise adherence and total exercise ?





Background

E-health Technology has been proven as effective modes of client support. Many studies demonstrated that e-health intervention (internet and mobile phone-based interventions) or home based educational intervention have been successfully used to support chronic disease clients for health management and secondary prevention in the community.

(Jackson, Bolen , Brancati et al., 2006; Murray , Burns , See et al., 2005; Neville , O'Hara , Milat , 2009)

A number of studies have reported significant positive effects of e-health interventions on physical activity and health outcomes (Neville et al, 2009,Wang et al, 2012).

Background

- E-health refers to the use of medical informatics, public health and businesses, involving the health services and information delivered by or enhanced through the Internet and related technologies. (Oh et al., 2005)
- E-health technology has shown effectiveness in improving exercise adherence, while self-monitoring have been found to enhance self-efficacy. (Oiu, Sun & Xue, 2012. (Oiu, Sun & Xue, 2005 ; Wang , Sereika, & Chasens ER, 2012)
- Advantages of E-health technology as a mode of educational intervention are:[17]
  - Cost-effectiveness
  - Flexibility
  - Accessibility



- However, most E-health programs lack personal interaction.

(Steele, Mummery, Dwyer, 2008; Tse ,Choi,Leung, 2008)

Project Aims

- Develop a highly interactive E-health educational intervention (e-HEI).
- Determine the effectiveness of the home-based e-HEI program for middle-aged patients with CHD.
- In specific, to examine:
  - the effect of total exercise, exercise efficacy and exercise adherence rate
  - the change in risk factor profile
  - the change in health related quality of life and psychological outcomes





Hypotheses

- Five specific hypotheses are listed below:
- CHD patients receiving e-HEI when compared to those in the control group would demonstrate :
- (i) **improved amount of exercise time**, as measured by the Godin–Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ) across six months;
- (ii) **enhanced exercise efficacy** as measured by the Chinese version of the Self-Efficacy for Exercise (SEE-C) across six months;
- (iii) **improved exercise adherence rate** across six months;
- (iv) **controlled risk factor profile** in terms of blood pressure, cholesterol, triglycerides, and glycemic control across 12 months; and
- (v) **improved health-related quality of life** in terms of physical and psychological outcomes, as measured by the Chinese (HK) version of the Health Survey Questionnaire (SF-12) and the Chinese Hospital Anxiety and Depression (HAD) Scale across six months.

Study Design

- Prospective parallel randomized controlled trial
- Data will be collected from the specialist clinics of two regional hospitals in Hong Kong.
- Patients who satisfied the inclusion and exclusion criteria will be invited to the study.
  - Inclusion criteria:
    - Chinese adults who attends regular follow-up treatments for their CHD problems
    - Aged 30-65
    - Can use and access internet at home
  - Exclusion criteria:
    - Patients with physical, mental, visual, cognitive impairments
    - Patients with contra-indications to walking

Sample Size

- Sample size is calculated based on primary outcome of physical exercise, clinical significance, and the results of our recently completed pilot study.
- Estimated effect size (Cohen's d) from the pilot study was 0.29.
- It is estimated that 175 patients in each group will be needed to achieve a statistical power of 80%, at 5% significant level of a two-tailed pooled t-test.
- As 15% attrition rate was observed in our pilot study at 3-months follow up, and further assuming a 20% attrition rate at 6-months follow up; 438 patients will be recruited for the study.



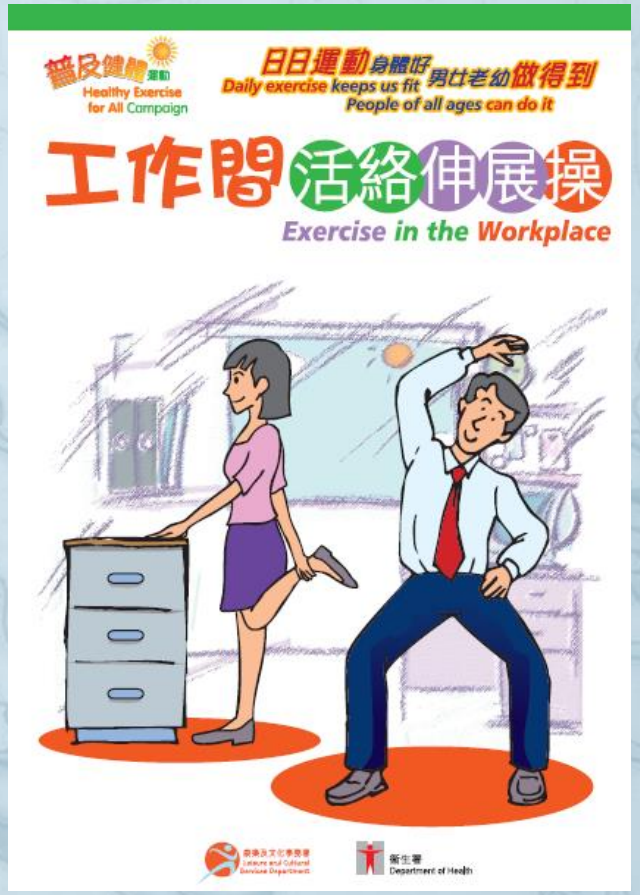
Randomisation

- The allocation sequence has been computer-generated by a statistician, blinded to investigators, randomising patients with a ratio of 1:1 by using blocked randomization method with block size four.
- A small card indicating the group assignment has been placed in opaque sealed envelopes. The envelopes will be opened by the research assistant after the patients have completed the baseline questionnaires.

Intervention: Control Group

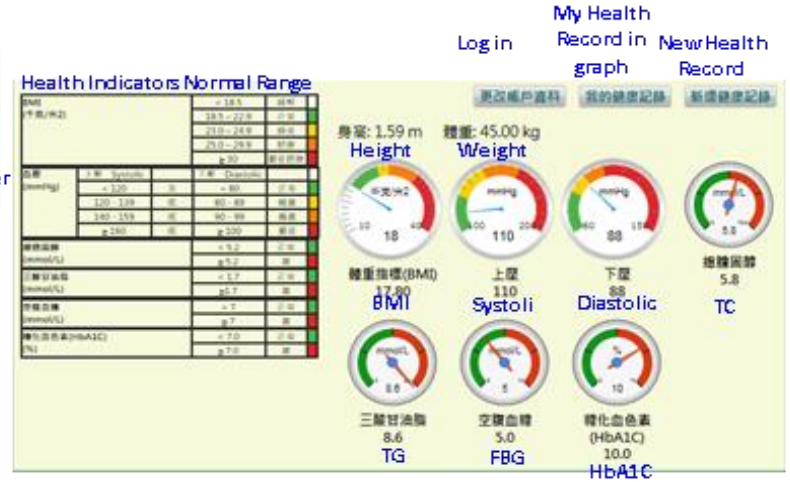
- All participants in the control group will receive routine usual care comprised usual medication and an educational leaflet about CHD.





Intervention: Intervention Group







e-health web link
(http://ehealth.nur.cuhk.edu.hk)

- e-health web aims to support clients' exercise monitoring and health record.
- This study was approved by the Ethical Research Committee of the study hospital and university.

- http://ehealth.nur.cuhk.edu.hk/CUNursing/cuna.do?action=summaryExercisePage

Intervention : Intervention Group

- usual care + **additional individualized educational intervention**
- The content of the e-HEI link is based on the health belief model.
- e-HEI link: http://ehealth.nur.cuhk.edu.hk

Content of e-health link :

- knowledge related to CHD and measures to modify risk factors.
- The members' area _safe, individualized and interactive platform for :
- Exercise record ;
- Health record (body weight, blood pressure, blood sugar level, lipid profile etc.)
- All participants will in the intervention group will also be prescribed to perform additional walking exercise, with each session lasting 30 minutes, for at least 5 times per week.
- Demonstration of e-HEI link and members' area will be conducted.

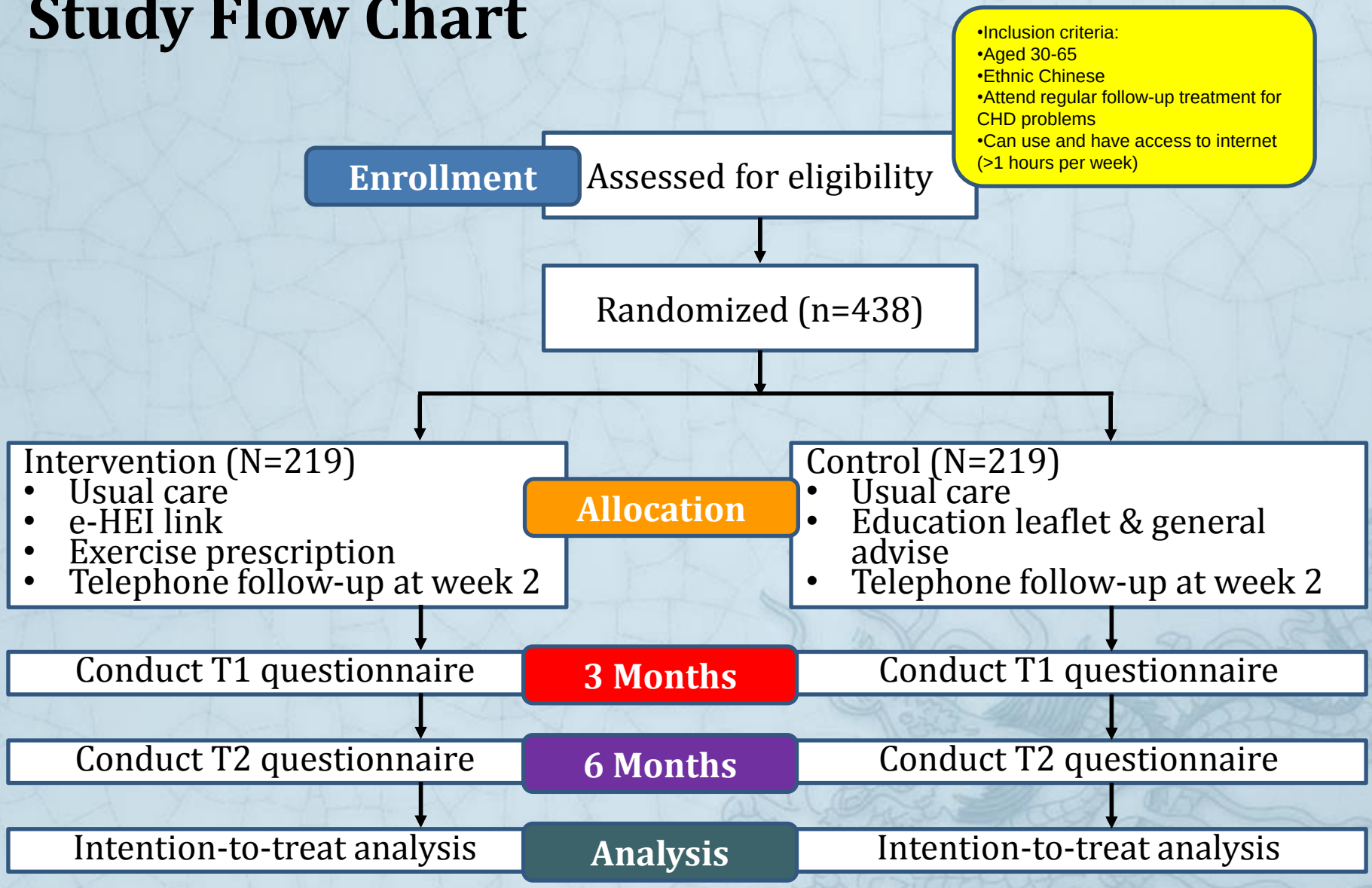
Intervention : Follow-up

One telephone follow-up intervention- to all participants a week after initial contact.

The reminder calls aims to assess the patients' usage of the web link for the intervention group; while a causal talk related to other health-related lifestyle practices for the control group. The time for telephone follow up is about 10-15 minutes .

- Fidelity of intervention has been maintain by same dosage of educational session and telephone follow up _ same staff and same assigned time interval.

Study Flow Chart



Outcome measures: Primary Outcomes

- Two consecutive (3-months and 6 months) follow-ups will be arranged and conducted for all participants.
- A structured validated questionnaire will be used for data collection .
- **Total physical exercise**
  - Godin-Shepherd Leisure Time Physical Activity Questionnaire[20]
  - The scale measures how often per week and how long per session have they performed strenuous, moderate and mild exercise outside their work duties. (Godin and Shephard , 1985)
  - Weekly frequencies of strenuous, moderate, and light activities are multiplied by 9, 5, 3 METs respectively. Total weekly leisure activity is calculated in arbitrary units by summing the products of the separate components.
  - This scale has been shown to have good psychometric properties. (Jacobs, Ainsworth , Hartman , 1993 ; Sallis , Buono , Roby , *et al* , 1993)

Outcome measures: Secondary Outcomes

- Exercise efficacy:Chinese version of self-efficacy for exercise (SEE-C)
  - 9 items with responses on a 0-10 scale
  - Proven to be reliable and good psychometric properties (α=0.75) (Resnick & Jenkins 2000; Lee, Perng & Ho, 2009)
- Exercise adherence
  - Frequency and time interval of exercises will be retrieved from web record
  - Compliance rate of >75% is regarded as good adherence (Leung CM, Wing YK, Kwong PK, *et al.*,1999)
- Anxiety and depression
  - Chinese version of HAD scale
  - 14 items on a 4-point likert scale
  - Psychometrics properties were satisfactory among Chinese patients (Leung CM, Wing YK, Kwong PK, *et al.*, 1999)

Outcome measures: Secondary Outcomes

- Quality of life
  - Chinese (HK) version of Health Survey Questionnaire (SF-12)
  - Consists of 12 questions that are summarized into a physical component (PCS) and mental component score (MCS).
  - SF-12 was translated into Chinese and validated in Hong Kong with good psychometric properties. (Lam, Tse, & Gandek , 2005).
- Demographic and clinic data
  - Age, gender, and occupation will be collected
  - Medical problems, cardiac risk factor profile (systolic and diastolic blood pressure, LDL cholesterol, HDL cholesterol, and triglycerides), blood sugar level, HbA1C, body weight and BMI will be retrieved from patients' medical records.

Data Analysis

- Data will be analyzed using SPSS and EQS
- Baseline characteristics between two groups will be compared by Chi-square or Fisher exact test for categorical variables; and t-test or Mann-Whitney test for continuous variables.
- Generalized linear models with adjustments for demographic and other potential confounding variables will be used to compare the mean changes in the in total physical exercise, self-efficacy in exercise, cardiovascular risk profile, anxiety and depression, and health-related quality of life over time between the two groups.
- All the tests are two-sided and a p-value < 0.05 will be considered statistically significant.

Ethical consideration

- The study was approved by the University and Hospital Ethics Committee.
- Registration : Clinicaltrials.gov Identifier : NCT02350192

Current status of the study

- The study has received grant support from the Health and Medical Research Fund granted by the Food and Health Bureau of the Hong Kong Government.
- The project has begun in June 2013 and data collection has been completed in mid July 2015.

- Ehealth_Baseline_Preliminary_Tables presented US.docx



Strengths and limitations of this study protocol

- This RCT study contributes to evidence-based practice by testing the effectiveness of an interactive e-Health link for patients with CHD.
- The study has been designed to meet the criteria for high-quality non-pharmacological RCTs with randomization, multicenter participation, blinded assessment during data collection, and analysis with a good sample size.
- However the study will be limited to a single-blinded design that the intervener knows the grouping allocation due to the nature of the intervention.

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