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Feasibility study of a health education programme to improve Portfolio Diet adherence for Hong Kong adults with dyslipidemia

Dyslipidemia is a major public health challenge in Hong Kong, where raised blood cholesterol affects 51.9% of adults, and 70% remain unaware of their condition (1). Current management relies heavily on standard lifestyle advice and pharmacotherapy (such as statins), yet medications often face patient hesitancy, making effective dietary strategies crucial for reducing cardiovascular disease (CVD) risk. The Portfolio Diet is a promising dietary pattern for managing hyperlipidemia (2). It combines individual cholesterol-lowering components—viscous fibers, plant sterols, plant proteins, and nuts—which result in a mean 28.6% decrease in serum low-density lipoprotein-cholesterol (LDL-C), a result comparable to pharmacotherapy with statins (2). Because LDL-C causes atherosclerotic CVD (3), this diet leads to significant reductions in intermediate cardiometabolic risk factors demonstrated by meta-analytic evidence of trials. (4). Therefore, the dietary pattern has been recognized by multiple clinical guidelines (5-7). However, no study has been conducted to improve Portfolio Diet adherence in a non-Western population. Since local dietary habits differ from Western cohorts, culturally tailored health education is urgently needed. A feasibility study is therefore a prerequisite before implementing a full-scale randomized controlled trial (RCT) for Hong Kong's large dyslipidemia population.

Research Plan and Methods:

The proposed study will recruit **12 adults with dyslipidemia to join a 4-week health education programme**, followed by focus groups. The primary objective is to evaluate the feasibility, acceptability, and preliminary efficacy signal of the culturally adapted Portfolio Diet health education programme by understanding subjects' facilitators and barriers to dietary change to inform the design and sample size of a future full-scale RCT. We aim to demonstrate that Portfolio diet adherence can be improved in the 4-weeks health education programme, and enhance the feasibility intervention plan (e.g., the types of healthy foods to be recommended) with the involvement of participants. In the full-scale RCT, we will maintain participants' adherence for a longer period, so that the cardiometabolic health is also expected to be improved.

Settings and subject recruitment:

The proposed study will be promoted through health talks, advertisements, mass emails, and leaflets being delivered to members from the community collaborators as mentioned below. Participants will be recruited from **the Research Centre for Gerontology and Family Studies** at the Hong Kong Polytechnic University, which has a network of > 4,000 members aged ≥ 50, or participants referred by other research studies from our collaborators.

Inclusion Criteria:

1. Aged 18-65 years.
2. Chinese.
3. Borderline or high total cholesterol (TC ≥ 5.2mmol/L).

4. Overweight or obesity: BMI ≥23 kg/m2.
5. Reside in Hong Kong without travel plans for the following 12 weeks.
6. Able to maintain a regular lifestyle and eating habits throughout the study.
7. Voluntarily sign the informed consent form.

Exclusion Criteria:

1. Known alcohol, cigarette or drug abuse within the past 3 months.
2. Known liver and/or renal dysfunctions.
3. Known severe medical history (e.g., CVD, diabetes, inflammatory bowel disease,
4. cancer, psychiatric illness).
5. Participated in any interventional clinical trials within the past 3 months.

Four-week Portfolio Diet Health Education:

The health education programme will consist of **4 weekly sessions**, starting with **a group-based session** to introduce the principles of Portfolio Diet and its relationship with cardiometabolic health, followed by **3 sessions of dietary consultations by research dietitian**. The Portfolio dietary pattern to be implemented in this study will be adapted to the more commonly consumed food groups in Chinese culture. Participants in the Portfolio diet group will receive a 7-day menu in modifying their diet to meet the Portfolio dietary pattern guidelines. In brief, the diet emphasizes a daily intake target of five dietary pillars: nuts and seeds (45 g/day), plant protein from pulses and soy (50 g/day), viscous fiber (20 g/day), plant sterols (2 g/day), and plant-based fats rich in monounsaturated fatty acids (45 g/day) (8).

Focus group:

To comprehend the facilitators and barriers to dietary change from participants' perspectives, post-intervention focus group interviews will be conducted with 12 participants (6 per group) by a trained research assistant in a quiet, private meeting room at the study site. Each 1-hour session will be audio-recorded, with structured interview questions:

The structured interview guide will explore the following key domains:

- *Acceptability of the Programme:*
  How did you find the format, duration, and content of the 4-week health education sessions?
- *Dietary Changes & Practicality:*
  What were the main challenges you faced when trying to incorporate the Portfolio Diet?
- *Perceived Benefits:*
  What changes (if any) did you notice in your eating habits, confidence, or health awareness after the programme?
- *Suggestions for Improvement:*
  What aspects of the programme could be improved to make it easier for future project

implementation and how to improve Hong Kong adults' Portfolio Diet adherence in long-term?

Data collection:

Quantitative data will be collected at baseline and post-intervention (at 4 weeks) by trained research assistants. It includes:

- *Feasibility & Process Metrics:*
  Programme retention rate (percentage completing 4 weeks) and session attendance will be recorded. Completion and compliance rates of the 3-day dietary records will also be collected to evaluate participant burden, data quality, and protocol adherence.
- *Socio-demographic data:*
  To be collected at baseline: (1) age, sex, marital status, living conditions, and level of education, (2) the participants' health-related information, as well as lifestyle factors (exercise habits, alcohol drinking, and smoking status) and medical history.
- *Portfolio Diet Adherence:*
  Portfolio diet adherence will be assessed by 3-day dietary records (covering 2 weekdays and 1 weekend day of the week) completed at baseline and post-intervention. The nutrient intake of all 3-day dietary records will be analyzed by Food Processor Nutrition Analysis and Fitness software version 8.0 (ESHA Research, Salem, USA), using local foods selected from food composition tables from China and Hong Kong.

Statistical methods:

Given the pilot feasibility design and small sample size (N=12), the statistical analysis will focus on descriptive statistics and estimation to inform future sample size calculations rather than formal hypothesis testing. Continuous variables for baseline characteristics and feasibility metrics will be summarized using means ± standard deviations (or medians and interquartile ranges), while categorical variables (including retention and session attendance rates) will be expressed as counts and percentages with 95% confidence intervals (95% CI). Pre- and post-intervention changes in Portfolio Diet adherence scores and individual component intakes will be reported as mean (or median) differences alongside 95% CIs. Variance and effect size estimates derived from this trial will be utilized to perform formal sample size and power calculations for the subsequent full-scale RCT. All quantitative analyses will be performed using R (version 4.0.3).

Reference

1. Department of Health, Centre of Health Promotion. Non-Communicable Diseases Watch. Oct 2023. Available at: https://www.chp.gov.hk/files/pdf/ncd_watch_oct_2023_eng.pdf.

2. Jenkins DJA, Kendall CWC, Marchie A, Faulkner DA, Wong JMW, de Souza R, Emam A, Parker TL, Vidgen E, Lapsley KG, et al. Effects of a Dietary Portfolio of Cholesterol-Lowering Foods vs Lovastatin on Serum Lipids and C-Reactive Protein. JAMA 2003;290(4):502-10.

3. Ference BA, Ginsberg HN, Graham I, Ray KK, Packard CJ, Bruckert E, Hegele RA, Krauss RM, Raal FJ, Schunkert H, et al. Low-density lipoproteins cause atherosclerotic cardiovascular disease. 1. Evidence from genetic, epidemiologic, and clinical studies. A consensus statement from the European Atherosclerosis Society Consensus Panel. European Heart Journal 2017;38(32):2459-72.

4. Chiavaroli L, Nishi SK, Khan TA, Braunstein CR, Glenn AJ, Mejia SB, Rahelić D, Kahleová H, Salas-Salvadó J, Jenkins DJA, et al. Portfolio Dietary Pattern and Cardiovascular Disease: A Systematic Review and Meta-analysis of Controlled Trials. Progress in Cardiovascular Diseases 2018;61(1):43-53.

5. Aas A-M, Axelsen M, Churuangsuk C, Hermansen K, Kendall CWC, Kahleova H, Khan T, Lean MEJ, Mann JI, Pedersen E, et al. Evidence-based European recommendations for the dietary management of diabetes. Diabetologia 2023;66(6):965-85.

6. Pearson GJ, Thanassoulis G, Anderson TJ, Barry AR, Couture P, Dayan N, Francis GA, Genest J, Grégoire J, Grover SA, et al. 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in Adults. Canadian Journal of Cardiology 2021;37(8):1129-50

7. Grundy Scott M, Stone Neil J, Bailey Alison L, Beam C, Birtcher Kim K, Blumenthal Roger S, Braun Lynne T, de Ferranti S, Faiella-Tommasino J, Forman Daniel E, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. JACC 2019;73(24):e285-e350.

8. Glenn AJ, Lo K, Boucher BA, Vitolins MZ, Manson JE, Snetselaar LG, Kendall CW, Jenkins DJ, Liu S, Sievenpiper JL. Adherence to the Dietary Portfolio is Associated With Lower Cardiovascular Disease Risk in the Women's Health Initiative Study. Ciculation 2020;141:AP511.