Plan Overview

A Data Management Plan created using HKUL DMPTool

Title: Nurse-led Primary Healthcare Intervention Model in Women's Health Management in Hong Kong

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Project abstract:

Introduction: Achieving comprehensive primary healthcare for women is critical in improving health outcomes, curbing expenses, and fostering equity. The current study aims to evaluate the effectiveness of a nurse-led risk-based women's health intervention, and to develop an evidence-based model to strengthen primary healthcare for Hong Kong females.

Methods: A total of 1212 eligible female residents aged 45-64 will be enrolled. A stepped-wedge cluster randomized controlled trial with continuous recruitment will be conducted. The trial will consist of four consecutive phases with transition period. Three social service organizations each

will be randomized to an allocation sequence. All will begin with control and end in intervention exposure. Participants allocated to the intervention condition will receive a nurse-led risk-based 5As intervention at baseline, 1-, 3-, and 6-month. The control participants will receive general lifestyle modification advice for women at baseline, 3- and 6-month.

The primary outcome is participants' medical resource utilization at 3-month follow-up. Secondary outcomes include health confidence, self-management, quality-of-life, condition-specific (menopausal-related vasomotor symptoms, urinary incontinence, depression and anxiety; osteoporosis; breast cancer, cervical cancer, colorectal cancer; hypertension) risk assessments at follow-ups using validated instruments. Within- and between-group effect, and intra- and inter-cluster effects over time, as well as the qualitative interviews will be analyzed.

Discussion: This study will provide evidence on the effectiveness, feasibility and acceptability of the nurse-led risk-based PHC model targeting women's health management. Such model would have great potential in promoting preventive care, encouraging health screening and resource utilization, empowering female population in self-care, contributing to the health improvements in women, and strengthening the primary healthcare system.

Start date: 11-01-2024

End date: 04-30-2027

Last modified: 01-09-2025

Nurse-led Primary Healthcare Intervention Model in Women's Health Management in Hong Kong

Data Collection

What data will you collect or create?

Personal data from clinical research (i.e. IRB approved) will be collected. Given the considerable volume of data generated, it will be stored in the project internal server and backed up. For the data, both numbers and texts will be collected. Durinig analysis, some data will be directly comparable, while others will be involved in additional calculations and processing before analysis. Software RStudio 2024.12.0+46 will be used for data analysis. Data containing personal ID information will be encrypted and will not be shared to any third parties. The software allow long-term access to the data analysis by the analyst. No existing data can be reuse.

How will the data be collected or created?

The data will be collected from the web portal and from interviews from a total of 1728 participants at multiple timepoints.

Documentation and Metadata

What documentation and metadata will accompany the data?

Research project researcher will help manage the datasets. For each data input, its title, property, characteristic, source participants, date and time of collection will be clearly recorded. The raw data collected will be in excel format, accessible among researchers and analyst of the project internal team during the analysis. A readme.txt file will be accompanied with the data for methodological, analytical, procedural, and data content/property details.

Ethics and Legal Compliance

How will you manage any ethical issues?

Ethical approval was obtained from IRB. Consents will be obtained every time before any type of data collection take place. Individual participants will not be directly identifiable from the datasets to be used for analysis.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

The research team owns the data. The raw data will be encrypted and securely stored, inaccessible to the third parties. Only the researchers of the project will be permitted to access to raw data and/or study record.

Storage and Backup

How will the data be stored and backed up during the research? i. e. until stored in the final location (e.g. on your password protected laptop)?

The data will be stored in the project internal server with sufficient storage and without any conflict of interests to related funders and organizations, backed up in external hard drive locked with keys in project PIs, and recover by the research project team internal IT expert. Back up will happen every time new input happened. The server requires permission from the project administrators for access, and requires username and password to login. The collected personal information, research data, and all relevant documents will be kept for 7 years after the study has been completed.

How will you manage access and security?

The server requires permission from the project administrators for access, and requires username and password to login. The external hard drive will be safely stored with key possessed by the project PIs. The Only the researchers of the project will be permitted to access to raw data and/or study record. All data transferring work will be conducted by trained researcher of the project internal team, and training on data privacy and safety is delivered to all colloborators.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Approved by the IRB, the collected personal information, research data and all relevant documents will be kept for 7 years post trial completion. Publications and research outcome sharing shall be made, therefore, all data in relation to these are considered important thus kept for a period of 7-year before cleaning.

What is the long-term preservation plan for the dataset?

Documentation will be accompanied with data in long-term preservation. Data will be held in the HKU DataHub. Budgets and effort were planned for this process.

Data Sharing

How will you share the data?

Long-term encrypted research data will be made available to those authorities with clearly stated concerns towards the content, analysis, and interpretation of the raw data. The data will be made available in a period of 7-year post trial completion. For anyone who may concern, they may directly contact the research PI for relevant inquiries.

Are any restrictions on data sharing? If yes, Why?

Upon data sharing, non-disclosure agreement need to be obtained to avoid inappropriate use of data. No identifiable personal information will be shared given the consideration of privacy and confidentiality.

Responsibilities and Resources

Who will be responsible for data management?

One of the researchers will be responsible for data management plan implementation and amendments, and ensuring it is reviewed. Project PI will be responsible for controlling the access of data. Internal IT staff will offer technical support during back-up and recovery. All collaborators have no objection to the data ownership by research team, and no objection to the DMP.

What resources will you require to deliver your plan?

Trainings is involved in better emphasizing the DMP. Experts will deliver training contents to all research staff on data managements.