ISRCTN73836238 https://doi.org/10.1186/ISRCTN73836238

The effectiveness of two home-based interventions for older adults in managing chronic diseases

Submission date
19/10/2023

Recruitment status
No longer recruiting

Registration date
08/11/2023

Overall study status
Completed

Last Edited
02/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
As one of the regions with the highest life expectancy, an increasing number of older adults in Hong Kong are expected to live with chronic diseases at some points in their lives. The high prevalence of chronic diseases among older adults (> 60%) aggravates the demand for subsidized healthcare services and extends the already-long waiting time for such services. Therefore, effective intervention for older adults' management of their chronic diseases is becoming increasingly important to reduce the risk of developing complications of chronic diseases, and thus mitigating the pressure on healthcare system and ensuring the quality of their prolonged lifespan. Under these circumstances, this study aims to implement two home-based healthcare interventions for older adults with chronic diseases or health risks and evaluate the intervention effectiveness in improving their well-being.

Who can participate?
Older adults aged 60 years or above, residing in Hong Kong.

What does the study involve?
The study provides chronic disease management intervention for the participants based on their frailty levels. Pre-frail older adults will receive health coaching intervention whereas frail older adults with receive Buurtzorg nursing intervention. The intervention lasts for 6 – 12 weeks.

What are the possible benefits and risks of participating?
Both chronic disease management interventions are expected to enhance older adults' self-management skills to cope with their chronic conditions, to minimise complications arise from chronic diseases, to maintain their well-being, and to prevent early admission to institutional care.
The Buurtzorg nursing intervention also provide training for the caregivers of frail older adults and connects necessary community resources to maintain their functional abilities and well-being, thus promoting ageing in place.

Where is the study run from?
City University of Hong Kong

When is the study starting and how long is it expected to run for?
September 2020 to June 2025.

Who is funding the study?
The study is funded by the Bank of China (Hong Kong).

Who is the main contact?
Prof. Frank CHEN (email: youhchen@cityu.edu.hk)

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Frank Chen

ORCID ID
https://orcid.org/0000-0003-4707-9361

Contact details
Room 7251
Lau Ming Wai Academic Building
City University of Hong Kong
Hong Kong
Hong Kong
-
+852 34428595
youhchen@cityu.edu.hk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Examining the effectiveness of two home-based chronic disease management interventions for Hong Kong community-dwelling older adults: health coaching program and Buurtzorg nursing program

Study objectives
Current study hypothesis as of 17/12/2024:

Hypothesis 1: The primary and secondary outcomes are significantly improved after participation in the health coaching intervention, regardless delivered by lay health workers or health professionals.

Hypothesis 2: The improvements in primary and secondary outcomes among the participants in health coaching interventions delivered by lay health workers are comparable to those delivered by health professionals.

Hypothesis 3: The medical service utilisation and expenditure of participants in Buurtzorg nursing intervention are lesser than those receiving usual healthcare services

_____

Previous study hypothesis:

Hypothesis 1: The physical and psychosocial well-being of participants in health coaching interventions conducted by health coaches with and without healthcare license (e.g., social worker, dietitian, nurse, occupational therapist) are significantly improved.
Hypothesis 2: The improvement of physical and psychosocial well-being of participants in health coaching interventions conducted by health coaches without social work training is comparable to that conducted by health coaches with social work training.
Hypothesis 3: The medical service utilisation and expenditure of participants in Buurtzorg nursing intervention are lesser than those receiving usual healthcare services.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/09/2020, Human Subjects Ethics Sub-Committee of City University of Hong Kong (Room 2230, 2/F, Cheng Yick Chi Building, Tat Chee Avenue, Hong Kong, -, Hong Kong; +852 34426856; roger@cityu.edu.hk), ref: H002467

Study design
Multicentre interventional single-blinded randomized parallel trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Patients with any of the following health conditions, including hypertension, hyperlipidaemia, diabetes mellitus, heart diseases, chronic obstructive pulmonary disease (COPD), elevated blood pressure and/or blood glucose, central obesity, and chronic pain.

Interventions

Current interventions as of 17/12/2024:

The study involves a 12-week multicentre interventional and multi-stage multi-arm trial, aiming at examining the effectiveness of two home-based healthcare interventions — (1) health coaching intervention for pre-frail community-dwelling older adults, and (2) Buurtzorg nursing intervention for frail community-dwelling older adults — in managing chronic diseases and health risks.

All participants will be recruited form the elderly centres of the collaborating non-government organisations. Eligible participants will be assessed with a designed questionnaire in a baseline visit. Following the baseline visit, eligible participants will be stratified into two arms. Participants with satisfactory cognitive functioning (a score > 16th percentile in MoCA 5-min), low or moderate fall risk (Timed Up and Go test < 30 seconds), and without a diagnosis of dementia will be assigned to the health coaching group. Participants with impaired cognitive function (a score ≤ 16th percentile in MoCA 5-min), high fall risk (Timed Up and Go test ≥ 30 seconds), and/or a diagnosis of dementia will be assigned to the Buurtzorg nursing group. Participants in the health coaching group will be further randomised into two groups based on their age, sex, education, and number of chronic diseases: one group receiving health coaching intervention delivered by health professionals (e.g., nurses and dieticians), and another group receiving health coaching intervention delivered by lay health workers (e.g., health promotion workers and graduates in health studies). The details of each group are as below:

1. Health coaching group delivered by health professionals (HC-HP)
- Receive a 12-week face-to-face health coaching intervention aimed to enhance participants' knowledge and skills in self-managing their chronic diseases
- The intervention is delivered by health professionals
- All face-to-face sessions are conducted via home visits
- Assessments are conducted before (Time 1) and immediately after (Time 2) the intervention, respectively

2. Health coaching group delivered by lay health workers (HC-LW)
- The content and format of the health coaching intervention are the same as HC-HP group, except that the intervention is delivered by lay health workers
- Assessments are conducted before (Time 1) and immediately after (Time 2) the intervention, respectively

3. Buurtzorg nursing group (BZ)
- Receive a Buurtzorg nursing intervention conducted by trained nurses to provide direct home-based nursing care and enhance participants' healthcare network with caregiver support and community resources
- Omaha system is used to monitor their health conditions and guides the care plan
- The intervention lasts for 6 – 12 weeks depending on the participants' health assessment results
- The medical service utilisation before (Time 1) and immediately after (Time 2) the intervention is recorded

4. Individual control group (CG)
- A sample of patient data, matched with the participants' characteristics in BZ group (e.g., age, sex, medical diagnoses), will be retrieved from the Hospital Authority Data Sharing Portal
- The data includes demographics, and three-month medical service utilisation during the BZ intervention period
- No intervention is provided for CG group.

———

Previous interventions:

The study involves a 12-week multicentre interventional and multi-stage multi-arm trial, aiming at examining the effectiveness of two home-based healthcare interventions — (1) health coaching intervention for pre-frail community-dwelling older adults, and (2) Buurtzorg nursing intervention for frail community-dwelling older adults — in managing chronic diseases and health risks.

All participants will be recruited form the elderly centres of the collaborating non-government organisations. Eligible participants will be assessed with a designed questionnaire in a baseline visit. Following the baseline visit, eligible participants will be stratified into two arms. Participants with satisfactory cognitive functioning (a score > 16th percentile in MoCA 5-min), low or moderate fall risk (Timed Up and Go test < 30 seconds), and without a diagnosis of dementia will be assigned to the health coaching group. Participants with impaired cognitive function (a score ≤ 16th percentile in MoCA 5-min), high fall risk (Timed Up and Go test ≥ 30 seconds), and/or a diagnosis of dementia will be assigned to the Buurtzorg nursing group. Participants in the health coaching group will be further randomised into two groups based on their sex, chronic diseases, and health risks: one group receiving health coaching intervention conducted by health coaches with healthcare license, and another group receiving health coaching intervention by health coaches without healthcare license. The details of each group are as below:

1. Health coaching group led by social work coaches (HC-SW)
- Receive a 12-week health coaching intervention aimed to enhance participants' knowledge and skills in self-managing their chronic diseases
- The intervention is conducted by health coaches with social work training
- The intervention involves 6 face-to-face sessions and 6 telephone follow-up sessions on an alternate week basis
- All face-to-face sessions are conducted via home visits
- Assessments are conducted before (Time 1) and immediately after (Time 2) the intervention, respectively

2. Health coaching group led by non-social work coaches (HC-non-SW)
- The content and format of the health coaching intervention are the same as HC-SW group, except that the intervention is conducted by health coaches without social work training
- Assessments are conducted before (Time 1) and immediately after (Time 2) the intervention, respectively

3. Buurtzorg nursing group (BZ)
- Receive a Buurtzorg nursing intervention conducted by trained nurses to provide direct home-based nursing care and enhance participants' healthcare network with caregiver support and community resources
- Omaha system is used to monitor their health conditions and guides the care plan
- The intervention lasts for 6 – 12 weeks depending on the participants' health assessment results
- The medical service utilisation before (Time 1) and immediately after (Time 2) the intervention is recorded

4. Individual control group (CG)
- A sample of patient data, matched with the participants' characteristics in BZ group (e.g., age, sex, medical diagnoses), will be retrieved from the Hospital Authority Data Sharing Portal
- The data includes demographics, and three-month medical service utilisation during the BZ intervention period
- No intervention is provided for CG group.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 17/12/2024:

All the outcomes in health coaching groups (HC-HP and HC-LW) are assessed before (Time 1) and immediately after (Time 2) the intervention. The primary outcome measures include:
1. Patient activation is measured by the Patient Activation Measure (Judith et al., 2004).
2. Engagement in health-promoting behaviours is measured using the physical activity and nutrition subscales of the Chinese version of the short-form Health-Promoting Lifestyle Profile-II (Teng et al., 2010; Chung et al., 2023).

The utilisation of medical services in Buurtzorg nursing group and individual control group, including hospitalisation, length of stay, and emergency room visits, is recorded assessed before (Time 1) and immediately after (Time 2) the intervention.

———

Previous primary outcome measure:

All the outcomes in health coaching groups (HC-SW and HC-non-SW) are assessed before (Time 1) and immediately after (Time 2) the intervention. The outcome measures include:
1. Engagement in health-promoting behaviours is measured using the physical activity and nutrition subscales of the Chinese version of the short-form Health-Promoting Lifestyle Profile-II (Teng et al., 2010; Chung et al., 2023).
2. Self-care functional capacity is measured using the Katz's Index of ADL (Katz et al., 1963) and Lawton's Instrumental Activities of Daily Living Scale (Lawton & Brody, 1969).
3. Cognitive function is measured using the 5-min Montreal Cognitive Assessment (Wong et al., 2015).
4. Social engagement is measured using the short-form Lubben Social Network Scale (Lubben et al., 2006).
5. Loneliness is measured using the short-form UCLA Loneliness Scale (Hoghes et al., 2004; Liu et al., 2020).
6. Risk of depression is measured using the brief version of Geriatric Depression Scale (van Warwijk et al., 1995).
7. Medication-taking behaviours are measured by the Morisky Medication Adherence Scale (Morisky et al., 2008).
8. Quality of life is measured by the five-level EuroQol Five-Dimensional Questionnaire (Wong et al., 2015)
9. Risk of fall is measured by Timed Up and Go test (Podsiadlo & Richardson, 1991) and Single Leg Stance test (Kawai et al., 2018).
10. Patient activation is measured by the Patient Activation Measure (Judith et al., 2004).
11. Physiological outcomes are indicated by blood pressure, blood glucose, body mass index, and

waist circumference.
The utilisation of medical services in Buurtzorg nursing group and individual control group, including hospitalisation, length of stay, and emergency room visits, is recorded assessed before (Time 1) and immediately after (Time 2) the intervention.

Key secondary outcome(s))
Current secondary outcome measures as of 17/12/2024:

The primary outcome measures for the two health coaching groups include:
1. Risk of depression is measured using the brief version of Geriatric Depression Scale (van Warwijk et al., 1995).
2. Physiological outcomes are indicated by body mass index, and blood pressure.
For Buurtzorg nursing group, the secondary measure includes satisfaction towards intervention, which is measured by ten self-developed satisfaction items a month after the intervention.

_____

Previous secondary outcome measures:

The satisfaction towards intervention is measured using ten self-developed satisfaction items a month after the intervention.

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Aged 60 years or above
2. Community-dwelling
3. Referred by collaborating non-government organisations
4. Residing in Hong Kong
5. Able to communicate in Cantonese, Mandarin or English
6. With at least one of the following health conditions:
6.1. Hypertension
6.2. Hyperlipidaemia
6.3. Diabetes
6.4. Heart disease
6.5. Chronic obstructive pulmonary disease (COPD)
6.6. Elevated blood pressure and/or glucose
6.7. Central obesity
6.8. Chronic pain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 years

Sex
All

Key exclusion criteria
1. Aged 59 or below
2. Residing outside Hong Kong
3. Having no health conditions as listed in “Participant Inclusion Criteria”
4. Adverse home environment, such as woodlouse and/or severe hygienic problem
5. Diagnosed with mental disorder, such as schizophrenia and/or depression
6. Unstable mental conditions, such as violent tendency and/or paranoid delusion
7. Not able to communicate in Cantonese, Mandarin and English
8. Have severe hearing problem which cannot be corrected by hearing aids

Date of first enrolment
01/04/2021

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Hong Kong

Study participating centre
City University of Hong Kong
Room 5126, Lau Ming Wai Academic Building, City University of Hong Kong, 83 Tat Chee Avenue, Kowloon Tong, Kowloon
Hong Kong
Hong Kong
-

Sponsor information

Organisation
Bank of China (Hong Kong) Limited

Funder(s)

Funder type

Industry

Funder Name
Bank of China (Hong Kong) Limited

Results and Publications

Individual participant data (IPD) sharing plan
Current participant level data sharing plan:

The datasets generated and/or analysed during the current study will be available upon request from Prof. Frank CHEN (email: youhchen@cityu.edu.hk).

Previous participant level data sharing plan:

The datasets generated and/or analysed during the current study will be available upon request from Ms. Hera LEUNG (email: herleung@cityu.edu.hk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		18/12/2024	19/12/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			03/11/2023	No	No