Information Sheet for Study Participants (Family member)

Equal or Over 18 Years of Age

Information Sheet consists of 2 parts:

Part 1 Information sheet for study participants

Part 2 Volunteer research agreement form

Part 1

Research project title: **Effectiveness of the Individual and Family Health Literacy Enhancement Program Among Older persons with Physical Multimorbidity**

Research Team: **Mrs. Jun Shan**

Institute: **Faculty of Nursing, Chiang Mai University**

Research Funding: **No sponsor**

You are being invited to take part in this study because you **are the person who is living with older persons with hypertension and type 2 diabetes and meet the following criteria: aged 18 and over; physical independence and cognitive intact; be willing to participate in the study.** The **140** participants who meet these criteria are needed for this study and will be selected together with the older persons from **XinChengQiao community and ChengDong community. All eligible participants together with older persons will be randomly assigned into the same experimental and same control group.** Before you decide to take part in this study, please take your time in reading this information sheet to make sure that you understand what you will be asked to do as part of this study. You are welcome to discuss this study with someone that you know and trust before you make your decision. If you have any questions regarding this study, please feel free to ask the research staff.

Again, your decision making to participate this study is completely voluntary. You can refuse to participate in this study or withdraw from this study at any time without informing any reason.

Your rights to medical care or any existing care you are receiving will not be affected if you decide not to be in this study.

Information related to this study

Older persons are more likely to have multimorbidity simultaneously as the number of chronic diseases increases with age. Physical multimorbidity which means the co-occurrence of two or more chronic physical conditions is the most common pattern and the most prevalent chronic physical disease pair is hypertension and diabetes mellitus in Chinese older persons. Effective management and control of coexisting hypertension and type 2 diabetes requires diligent daily self-management. Effective self-management will help older persons achieve blood pressure and blood sugar goal, reduce the incidences of cardiovascular diseases and mortality, and reduce the risks of nephropathy and retinopathy, which furtherly decrease treatment burden and symptom burden; improve health status; reduce hospitalization; and improve their quality of life.

Older persons often encountered more challenges for self-management because of the complexity of chronic conditions (long duration, slow progression and unpredictable); and vulnerability (poor literacy and numeracy skills, limited function, hearing or vision limitations) associated with aging. Older persons often find it difficult to self-manage symptoms, complex therapeutic routines, subsequently resulting in higher symptom burden and treatment burden. Thus, older persons need support from their family which plays a key role in self-management. And health literacy of individual and family has been identified as a stronger factor influencing self-management since it is the basic skill for better self-management. Older persons often had lower education level and age-related physiological

changes such as short-term memory loss and decreased capacity to process and remember new information, lead to not understanding the importance of therapeutic regimes and low adherence. Thus, this study is to develop a novel educational program providing logical and organized information for individuals and families to increases their comprehension and memory of health information, as well as health maintenance skills to enhance individual and family health literacy, improve self-management behaviors of older persons with hypertension and type 2 diabetes, which is helpful for controlling blood pressure and blood sugar, preventing complications, and subsequently decrease treatment burden and symptom burden, improve their quality of life.

Study design

An experimental design will be designed to determine the effectiveness of individual and family enhancement program among older persons with physical multimorbidity.

Participant Responsibilities

(1) Responsibilities for participants in the control group:

You will attend each process of usual care provided by physician and nurses for older persons, which consists of physical examination, regular treatment protocol, patient education and telephone follow-up by community nurses.

You will be asked to fill out the Demographic Data Form. Completing the questionnaire should take around 5 minutes.

(2) Responsibilities for participants in the experimental group:

You should also receive the individual and family health literacy enhancement program, involving of 8 sessions of educational courses that will be led by the researcher. Each session will be lasted for 2 hours with 1 intermittent break, and it will be held twice a week with 10 participants per group. The contents of the program include disease-related knowledge such as pathophysiology, symptoms, treatments, and specifics (patient-centered

information) of hypertension and type 2 diabetes, and health maintenance skills such as self-management skills (goal setting, action planning, self-monitoring, problem solving; and relaxation techniques), role of the family in the self-management. Practicing self-management skills will be included in the program.

You will be asked to fill out the Demographic Data Form. Completing the questionnaire should take around 5 minutes.

Duration that participant will join in this study

(1) The duration for you in experimental group is about four weeks, including attending 8 sessions of educational courses (twice one week, and each session will be lasted for 2 hours with 1 intermittent break), and will be asked to fill out questionnaires twice. Completing each questionnaire should take around 5-10 minutes.

(2) The duration for you in control group is about four weeks, including physical examination (once every two weeks), regular treatment protocol, patient education and telephone follow-up once every week (each time will be lasted half an hour), and will be asked to fill out questionnaires twice. Completing each questionnaire should take around 5-10 minutes.

Possible risks or uncomfortable events from this study and how the study will minimize or avoid these risks

If you are in the interventional group, you will receive the individual and family health literacy enhancement program including attending 8 sessions of education. Each session of the program will last for 2 hours which may make you feel tired and boring. During the process, the researcher will (1) use multiple medias for education, such as PPT and video including vivid and dynamic images to attract participants' attention; and multiple activities such as situational dialogues and practice; (2) create comfortable environment and provide some snacks and beverages; (3) take a break during the education. In addition, if you feel

uncomfortable or unwilling to attend the following sessions, you have the right to refuse or withdraw from the study at any time during the study.

Considering the situation of Covid-19, possible risk is the coronavirus transmission. Some prevention measures will be taken to prevent the transmission of Covid-19 as following: (1) Taking temperature and Health Green Code will be required before they enter the community activity center, only with normal temperature will be allowed to participate in each session; (2) You will be required to wash hands using alcohol gel and wear masks throughout the process; (3) You will be arranged to keep the safe social distance during the education; and (4) Following the local prevention regulations.

If you are in the control group, you will also attend patient education and telephone follow-up once every week (each time will be lasted half an hour) which may make you feel tired and boring. We will use simple and understandable language to attract your attention and make you easy to understand your family member's diseases. If you feel uncomfortable or unwilling to attend, you have the right to refuse or withdraw from the study at any time during the study. Regarding the situation of Covid-19, possible risk is the coronavirus transmission. The health care providers, you and your family members will be required to keep normal temperature and have green health code. Besides, washing hands using alcohol gel and wearing masks are necessary throughout the whole care process. Other local prevention regulations will be followed.

Anticipated benefits to study participants

Direct/indirect benefits. You will obtain health related knowledge to improve the understanding of your diseases and treatments. Some self-management skills (goal setting; action planning; self-monitoring; problem solving, and relaxation techniques to manage emotions) will be obtained from the study. All may enhance your health literacy to improve your abilities to self-manage hypertension and type 2 diabetes, prevent complications,

decrease treatment burden and symptoms, and furtherly improve your quality of life in the future.

In case of withdrawal during the study, your rights to medical care or any existing care they are receiving will not be affected.

Data Protection and Confidentiality

All information collected about you in this study will be collected in the form of documents or electronic data files or both forms. This information will be kept confidential from those who do not have the right to know your information. There is only a study staff who will have access to your information. However, the Research Ethics Committee and the persons who have the authority to oversee this study will be able to access your information to review study information and the research process. You have a legal right to access your personal information. If you wish to use this right, please inform study staff. Any benefits from this study will provided as allowed by the regulations of Chiang Mai University.

Data collection will be divided into two parts: Information from the study and personal data that identifies you by linking with the code. The data from the study will be identified as code and kept at the researcher's personal computer in encrypted files and will be destroyed after the study is completed and the study findings have been published in the Journal for 3 years. Preserved in such period, there may be a need to confirm the accuracy of the information after the study or to repeat the analysis to confirm the validity.

How the information will be used and shared with anyone

The study data will be used to summarize and report without reference to your name or anything that will indicate you. However, some journals may require the provision of individual data to be recorded in public databases for other researchers to access. Please be assured that the data that is shared will not appear as an individual identifier or link to you.

Cost or compensation from participating in the study

This study provides no payment, but a gift (an oil-control pot) will be given as compensation for your time for attending the program. If you have an illness or injury due to your participation in the study, the researcher will help you to visit the doctors and be responsible for caring for you.

If you have any question about this study, please contact

Research contact person (s)

1. Name: Jun Shan

Address: 19 QiXiu Road, faculty of nursing, Nantong University, ChongChuan district, Nantong City, Jiangsu Province, China

Phone Number: (+86) 13862825206

If you have any questions about your rights before or during participating in this study, please contact the Research Ethics Committee, Faculty of Nursing, Chiang Mai University. Tel. 66-53-936080 (Office hours) or Fax. 66-53-894170

Conflicts of interest associated with this study [ ] Yes [√] No

Part 2

Volunteer Research Agreement Form

My name is Mr/Mrs/Miss.....agrees to participate in the study on Effectiveness of the Individual and Family Health Literacy Enhancement Program Among Older Persons with Physical Multimorbidity

I have already been given information and explanation about this study thoroughly. Also, I have been given an opportunity to have any questions and received answers clearly. I have enough time to read and understand the information sheet for the study participants carefully and receive enough time to decide whether to participate in this study.

I acknowledge that I can refuse independently to participate in this study. During the participation in this study, I can withdraw from this study at any time without affecting family members' receiving the usual care provided by the community healthcare providers. I will receive any new information that is related to or impacts this study which may affect my decision to take part in the study.

I acknowledge that the researcher will keep my personal information as confidential, only be disclosed in the form of a summary of the study, and practice things that do not harm to my body or my mind throughout this study. The researcher certifies that if there is any danger from such study I will be fully cared for.

By signing this form, I did not waive any legal rights which I should have, and after signing, I will a copy of information sheet and volunteer research agreement form (1 copy).

Signature of study participant.....Day/Month/Year.....

Signature of a person who requests agreement from study participants (or the investigator)

.....Day/Month/Year.....

Information Sheet for Study Participants (Older Persons)

Equal or Over 18 Years of Age

Information Sheet consists of 2 parts:

Part 1 Information sheet for study participants

Part 2 Volunteer research agreement form

Part 1

Research project title: **Effectiveness of the Individual and Family Health Literacy Enhancement Program Among Older persons with Physical Multimorbidity**

Research Team: **Mrs. Jun Shan**

Institute: **Faculty of Nursing, Chiang Mai University**

Research Funding: **No sponsor**

You are being invited to take part in this study because you **are the person who is 60-80 years old and having been diagnosed with hypertension and type 2 diabetes at least 6 months. You are physical independence and cognitive intact, having at least a family member who is willing to participate in the study.** The **140** participants who meet these criteria are needed for this study and will be selected from **XinChengQiao community and ChengDong community for data collection. All eligible participants will be listed in a randomization list. Recruited participants will be randomly assigned into the experimental and the control group by permute block design procedure according to the randomization list. In this study, the sample size is 140 persons. 70 eligible participants will be recruited in each community.**

Before you decide to take part in this study, please take your time in reading this information sheet to make sure that you understand what you will be asked to do as part of

this study. You are welcome to discuss this study with someone that you know and trust before you make your decision. If you have any questions regarding this study, please feel free to ask the research staff.

Again, your decision making to participate this study is completely voluntary. You can refuse to participate in this study or withdraw from this study at any time without informing any reason.

Your rights to medical care or any existing care you are receiving will not be affected if you decide not to be in this study.

Information related to this study

Older persons are more likely to have multimorbidity simultaneously as the number of chronic diseases increases with age. Physical multimorbidity which means the co-occurrence of two or more chronic physical conditions is the most common pattern and the most prevalent chronic physical disease pair is hypertension and diabetes mellitus in Chinese older persons. Effective management and control of coexisting hypertension and type 2 diabetes requires diligent daily self-management. Effective self-management will help older persons achieve blood pressure and blood sugar goal, reduce the incidences of cardiovascular diseases and mortality, and reduce the risks of nephropathy and retinopathy, which furtherly decrease treatment burden and symptom burden; improve health status; reduce hospitalization; and improve their quality of life.

Older persons often encountered more challenges for self-management because of the complexity of chronic conditions (long duration, slow progression and unpredictable); and vulnerability (poor literacy and numeracy skills, limited function, hearing or vision limitations) associated with aging. Older persons often find it difficult to self-manage symptoms, complex therapeutic routines, subsequently resulting in higher symptom burden and treatment burden. Thus, older persons need support from their family which plays a key

role in self-management. And health literacy of individual and family has been identified as a stronger factor influencing self-management since it is the basic skill for better self-management. Older persons often had lower education level and age-related physiological changes such as short-term memory loss and decreased capacity to process and remember new information, lead to not understanding the importance of therapeutic regimes and low adherence. Thus, this study is to develop a novel educational program providing logical and organized information for individuals and families to increases their comprehension and memory of health information, as well as health maintenance skills to enhance individual and family health literacy, improve self-management behaviors of older persons with hypertension and type 2 diabetes, which is helpful for controlling blood pressure and blood sugar, preventing complications, and subsequently decrease treatment burden and symptom burden, improve their quality of life.

Study design

An experimental design will be designed to determine the effectiveness of individual and family enhancement program among older persons with physical multimorbidity.

Participant Responsibilities

(1) Responsibilities for participants in the control group:

You will receive usual care by physician and nurses during the experimental period. The usual care consists of physical examination, regular treatment protocol, patient education and telephone follow-up by community nurses.

You will be asked to fill out 5 questionnaires at the beginning of the usual care, including the Demographic Data Form; the Chinese version of Functional Communication Critical Health Literacy (FCCHL); Chinese version of Partners in Health (PIH) Scale; the Chinese version of Treatment Burden Questionnaire (TBQ); the simplified Chinese version of Memorial Symptom Assessment Scale Short Form (MSAS-SF-SC). At the end of usual

care, you need to complete one questionnaire (Chinese version of FCCHL). Besides, at 8 weeks after the usual care, you need to complete one questionnaire (Chinese PIH) and to complete two questionnaires (Chinese version of TBQ and MSAS-SF-SC) at 12 weeks after the usual care. Completing each questionnaire should take around 5-10 minutes.

(2) Responsibilities for participants in the experimental group:

You will receive the individual and family health literacy enhancement program, involving of 8 sessions of educational courses that will be led by the researcher. Each session will be lasted for 2 hours with 1 intermittent break, and it will be held twice a week with 10 participants per group. The contents of the program include disease-related knowledge such as pathophysiology, symptoms, treatments, and specifics (patient-centered information) of hypertension and type 2 diabetes, and health maintenance skills such as self-management skills (goal setting, action planning, self-monitoring, problem solving; and relaxation techniques). Practicing self-management skills will be included in the program.

You will also be asked to fill out 5 questionnaires at the beginning of the intervention, including the Demographic Data Form; Chinese version of FCCHL; Chinese version of PIH; Chinese version of TBQ; MSAS-SF-SC. At the end of the intervention, you need to complete one questionnaire (Chinese version of FCCHL). In addition, at 8 weeks after the intervention, the participants need to complete one questionnaire (Chinese PIH) and to complete two questionnaires (Chinese version of TBQ and MSAS-SF-SC) at 12 weeks after the intervention. Completing each questionnaire should take around 5-10 minutes.

Duration that participant will join in this study

(1) The duration for you in experimental group is about four weeks, including attending 8 sessions of educational courses (twice one week, and each session will be lasted for 2 hours with 1 intermittent break), and will be asked to fill out questionnaires twice. Completing each questionnaire should take around 5-10 minutes.

(2) The duration for you in control group is about four weeks, including physical examination (once every two weeks), regular treatment protocol, patient education and telephone follow-up once every week (each time will be lasted half an hour), and will be asked to fill out questionnaires twice. Completing each questionnaire should take around 5-10 minutes.

Possible risks or uncomfortable events from this study and how the study will minimize or avoid these risks

If you are in the interventional group, you will receive the individual and family health literacy enhancement program including attending 8 sessions of education. Each session of the program will last for 2 hours which may make you feel tired and boring. During the process, the researcher will (1) use multiple medias for education, such as PPT and video including vivid and dynamic images to attract participants' attention; and multiple activities such as situational dialogues and practice; (2) create comfortable environment and provide some snacks and beverages; (3) take a break during the education. In addition, if you feel uncomfortable or unwilling to attend the following sessions, you have the right to refuse or withdraw from the study at any time during the study.

Considering the situation of Covid-19, possible risk is the coronavirus transmission. Some prevention measures will be taken to prevent the transmission of Covid-19 as following: (1) taking temperature and Health Green Code will be required before you enter the community activity center, only with normal temperature will be allowed to participate in each session; (2) you will be required to wash hands using alcohol gel and wear masks throughout the process; (3) you will be arranged to keep the safe social distance during the education; and (4) following the local prevention regulations.

If you are in the control group, you will receive usual care including physical examination (once every two weeks), regular treatment protocol, patient education and

telephone follow-up once every week (each time will be lasted half an hour) which may make you feel tired and boring. We will use simple and understandable language to attract your attention and make you easy to understand your diseases. If you feel uncomfortable or unwilling to accept the usual care, you have the right to refuse or withdraw from the study at any time during the study. Regarding the situation of Covid-19, possible risk is the coronavirus transmission. The health care providers and you will be required to keep normal temperature and have green health code. Besides, washing hands using alcohol gel and wearing masks are necessary throughout the whole care process. Furthermore, other local prevention regulations will be followed.

Anticipated benefits to study participants

Direct/indirect benefits. You will obtain health related knowledge to improve the understanding of your diseases and treatments. Some self-management skills (goal setting; action planning; self-monitoring; problem solving, and relaxation techniques to manage emotions) will be obtained from the study. All may enhance your health literacy to improve your abilities to self-manage hypertension and type 2 diabetes, prevent complications, decrease treatment burden and symptoms, and furtherly improve your quality of life in the future.

In case of withdrawal during the study, your rights to medical care or any existing care you are receiving will not be affected.

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How the information will be used and shared with anyone

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Cost or compensation from participating in the study

This study provides no payment, but a gift (an oil-control pot) will be given as compensation for your time for attending the program. If you have an illness or injury due to your participation in the study, the researcher will help you to visit the doctors and be responsible for caring for you.

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Research contact person (s)

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Phone Number: (+86) 13862825206

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Conflicts of interest associated with this study [ ] Yes [√] No

Part 2

Volunteer Research Agreement Form

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I acknowledge that the researcher will keep my personal information as confidential, only be disclosed in the form of a summary of the study, and practice things that do not harm to my body or my mind throughout this study. The researcher certifies that if there is any danger from such study I will be fully cared for.

By signing this form, I did not waive any legal rights which I should have, and after signing, I will a copy of information sheet and volunteer research agreement form (1 copy).

Signature of study participant.....Day/Month/Year.....

Signature of a person who requests agreement from study participants (or the investigator)

.....Day/Month/Year.....

研究对象知情同意书（家庭成员）

大于等于 18 岁

知情同意书包括两部分：

第一部分 研究对象知情页

第二部分 自愿同意书

第一部分

研究项目题目： 个人及家庭照顾者健康素养强化项目在老年生理多重病症患者中的应用效果

研究团队： 单 君

单位： 清迈大学护理学院

研究基金： 无

您被邀请参加本次研究，主要是因为您与患有高血压和 2 型糖尿病的老年人生活在一起，并符合以下标准:18 岁及以上；具有自理能力，认知完整；愿意参与本研究。本研究需要符合标准的 140 名参与者（老年人和家庭成员各 70 名），并将与新城桥社区和城东社区的老年患者一起被纳入研究对象。所有符合条件的研究对象将被随机分配到相同的实验组和对照组。

在您决定参加本次研究之前，请仔细阅读本知情同意书，以确保您了解本次研究将要求您做哪些工作。在您做出决定之前，欢迎您与您了解和信任的人讨论这项研究。如果您对本次研究有任何疑问，请随时向研究人员询问。

再次强调，您参与这项研究的决定是完全自愿的。您可以不告知任何理由，随时拒绝参加本次研究或退出本次研究。

如果您决定不参加本次研究，您获得医疗护理或您正在接受的任何现有护理的权利将不会受到影响。

与本研究相关的信息

老年人更有可能同时并发多种疾病，因为慢性疾病的数量随着年龄的增长而增加。生理多重病症是指两种或两种以上的慢性生理疾病同时发生。它是最常见的一种多重病症模式。而中国老年人最普遍的慢性生理疾病模式是高血压合并糖尿病。有效管理和控制并存的高血压和 2 型糖尿病需要日常自我管理。有效的自我管理将有助于老年人实现良好的血压和血糖目标，降低心血管疾病的发病率和死亡率，降低肾病和视网膜病变的风险，从而进一步降低治疗负担和症状负担;改善健康状况;减少住院治疗;提高生活质量。

由于慢性病的复杂性(持续时间长、进展缓慢和不可预测)，老年人在自我管理方面往往面临更多挑战;以及与衰老相关的脆弱性(读写能力和计算能力差、功能有限、听力或视力受限)。老年人往往难以自我管理症状，治疗过程复杂，容易导致症状负担和治疗负担加重。因此，老年人需要家庭成员的支持，这在自我管理方面起着关键作用。个人和家庭的健康素养被认为是影响自我管理的一个强有力的因素，因为它是较好自我管理的基本技能。老年人的教育水平往往较低，与年龄相关的生理变化，如短期记忆丧失和处理和记忆新信息的能力下降，导致不了解治疗方案的重要性和低依从性。因此，本研究拟开发一种新颖的教育方案，为个人和家庭成员提供具有逻辑性和组织性的疾病相关信息，以提高个人和家庭成员对健康信息的理解和记忆，提高老年人和家庭成员的健康素养，提高高血压和 2 型糖尿病患者的自我管理行为，从而有效

控制血压和血糖，预防并发症，减轻患者的治疗负担和症状负担，提高患者的生活质量。

研究设计： 实验性研究（随机对照实验）

研究对象职责

(1) 对照组参与者的职责

你在研究期间将接受医生和护士的常规治疗和护理。常规诊治包括体格检查、常规治疗方案、健康教育和社区护士电话随访。

我们会要求你填写一般资料表，完成问卷大约需要 5 分钟。

(2) 实验组参与者的职责

你将接受个人和家庭成员健康素养强化方案，包括由研究者实施的 8 期健康教育课程。每节课持续 2 小时，中间休息 1 次（10 min），每周 2 次，每组 10 人。内容包括高血压、2 型糖尿病的病理生理学、症状、治疗方法、针对每个患者的特定信息等疾病相关知识，自我管理技能(目标设定、行动计划、自我监测、问题解决;和放松技巧)。该项目也包括自我管理技能的练习。

我们会要求你填写一般资料表，完成问卷大约需要 5 分钟。

研究对象参与本研究的时间

(1) 实验组：你参与的时间约为 4 周，包括参加 8 期教育课程 (每周 2 次，每次 2 小时，中间休息 1 次)。

(2) 对照组：你参与的时间也为 4 周，包括体检 (每两周 1 次)、常规治疗方案、患者健康宣教及电话随访(每周 1 次，每次半小时)。

本研究可能出现的风险或不舒服的事件，以及本研究将如何减少或避免这些风险

如果你在干预组，你将接受个人和家庭成员健康素养强化方案，包括参加 8 期健康教育课程。每节课程将持续 2 小时，可能会让你感到疲劳和无聊。在此过程中，研究者将 (1) 使用多种教学媒体，如 PPT、视频等，其中包含生动、动态的图像，以吸引参与者的注意力; 以及情景对话和练习等多项活动; (2) 营造舒适的环境，并提供一些零食和饮料; (3) 健康教育课程期间休息。此外，如果您感到不舒服或不愿意参加以下活动，您有权在活动期间的任何时候拒绝或退出本次研究。

考虑到 Covid-19 的情况，可能的风险是冠状病毒传播。为防止新冠病毒传播，将采取以下预防措施: (1)进入社区活动中心前，需进行体温测量，并出示绿色健康码，每节课只允许体温正常的人参加; (2) 你在进入社区活动中心前应使用酒精凝胶洗手，并全程佩戴口罩; (3)在健康教育过程中，你应保持安全社交距离;(4) 遵守当地预防规定。

如果你在对照组，你将参与患者健康宣教及电话随访(每周 1 次，每次半小时)。这可能会让你觉得无聊或疲劳。我们会用简单通俗易懂的语言来吸引你的注意，让你更能了解你家庭成员的疾病。如果你感到不舒服或不愿意接受常规护理，你有权在研究期间的任何时刻拒绝或退出研究。就新冠肺炎疫情而言，可能存在的风险是新冠病毒传播。进行常规护理的医护人员和你将被要求保持正常体温以及苏康码绿码，具有 48 小时核酸阴性报告。此外，在整个护理中，要求使用酒精消毒剂洗手和戴口罩。并严格遵循当地防疫的相关要求。

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理情绪)。所有这些都可以提高您的健康素养，提高您自我管理高血压和 2 型糖尿病的能力，预防并发症，减少治疗负担和症状负担，并进一步提高您未来的生活质量。

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参与研究的费用或补偿

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如果您有任何问题，请联系：

研究联系人：

1. 姓名: 单 君

地址: 中国江苏省南通市崇川区启秀路 19 号 南通大学医学院（护理学院）

联系电话: (+86) 13862825206

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与本研究相关的利益冲突 [ ] 是 [√] 否

第二部分

研究自愿同意书

我的名字是：_____同意参与该研究：个人及家庭照顾者健康素养强化项目在老年生理多重病症患者中的应用效果。

我已经获得这项研究的详细信息和解释。此外，我也有机会提出任何问题，并得到明确回答。我有足够的时间仔细阅读和了解研究对象的知情书，并有足够的时间来决定是否参与这项研究。

我知道我可以自主拒绝参与这项研究。在参与该项研究期间，我可以随时退出这项研究，而不影响接受社区卫生保健人员提供的常规护理。我将收到任何与本研究相关或影响该研究的新信息，这些信息可能会影响我参加本研究的决定。

我知道研究人员将对我的个人信息保密，只会以研究成果的形式公开，并且在整个研究过程中，采取的做法对我身心无害。研究人员表示，如果在参与该研究中出现任何危险，我将会得到充分照顾和护理。

签署此表，我并没有放弃我应该享有的任何法律权利，签署后，我将获得一份研究对象知情和自愿同意书(1 份)。

研究对象签名:_____年/月/日_____.

研究者签名: _____年/月/日_____.

研究对象知情同意书（老年患者）

大于等于 18 岁

知情同意书包括两部分：

第一部分 研究对象知情页

第二部分 自愿同意书

第一部分

研究项目题目： 个人及家庭照顾者健康素养强化项目在老年生理多重病症患者中的应用效果

研究团队： 单 君

单位： 清迈大学护理学院

研究基金： 无

您被邀请参加本研究，主要是由于您是被确诊为高血压合并糖尿病的老年患者（60-80 岁），且确诊时间至少 6 个月以上。具有自理能力且认知完整，而且有至少一名家庭成员愿意参与本项研究。本研究共需 140 名参与者，南通新城桥社区和城东社区符合标准的患者及家属将被纳入本研究。且所有符合标准的参与者将被列在一个随机列表中。将招募的参与者按照随机列表，通过排列块设计程序，随机分为实验组和对照组。本研究样本量为 140 人，因此，每个社区将招募 70 名符合条件的参与者。

在您决定参加本次研究之前，请仔细阅读本知情同意书，以确保您了解本次研究将要求您做哪些工作。在您做出决定之前，欢迎您与您了解和信任的人讨论这项研究。如果您对本次研究有任何疑问，请随时向研究人员询问。

再次强调，您参与这项研究的决定是完全自愿的。您可以不告知任何理由，随时拒绝参加本次研究或退出本次研究。

如果您决定不参加本次研究，您获得医疗护理或您正在接受的任何现有护理的权利将不会受到影响。

与本研究相关的信息

老年人更有可能同时并发多种疾病，因为慢性疾病的数量随着年龄的增长而增加。生理多重病症是指两种或两种以上的慢性生理疾病同时发生。它是最常见的一种多重病症模式。而中国老年人最普遍的慢性生理疾病模式是高血压合并糖尿病。有效管理和控制并存的高血压和 2 型糖尿病需要日常自我管理。有效的自我管理将有助于老年人实现良好的血压和血糖目标，降低心血管疾病的发病率和死亡率，降低肾病和视网膜病变的风险，从而进一步降低治疗负担和症状负担;改善健康状况;减少住院治疗;提高生活质量。

由于慢性病的复杂性(持续时间长、进展缓慢和不可预测)，老年人在自我管理方面往往面临更多挑战;以及与衰老相关的脆弱性(读写能力和计算能力差、功能有限、听力或视力受限)。老年人往往难以自我管理症状，治疗过程复杂，容易导致症状负担和治疗负担加重。因此，老年人需要家庭成员的支持，这在自我管理方面起着关键作用。个人和家庭的健康素养被认为是影响自我管理的一个强有力的因素，因为它是较好自我管理的基本技能。老年人的教育水平往往较低，与年龄相关的生理变化，如短期记忆丧失和处理和记忆新信息的能力下降，导致不了解治疗方案的重要性和低依从性。因此，本研究拟开发一种新颖的教育方案，为个人和家庭成员提供具有逻辑性和组织性的疾病相关信息，以提高个人和家庭成员对健康信息的理解和记忆，提高老年人和家庭成员的健康素养，提高高血压和 2 型糖尿病患者的自我管理行为，从而

有效控制血压和血糖，预防并发症，减轻患者的治疗负担和症状负担，提高患者的生活质量。

研究设计： 实验性研究（随机对照实验）

研究对象职责

(1) 对照组参与者的职责

你在研究期间将接受医生和护士的常规治疗和护理。常规诊治包括体格检查、常规治疗方案、健康教育和社区护士电话随访。

在常规治疗和护理前，我们会要求你填写 5 份问卷，包括患者一般资料表; 中文版功能性沟通评判健康素养(FCCHL); 中文版 PIH 量表; 中文版治疗负担问卷(TBQ); 中文版纪念症状评估简表(MSAS-SF)。常规治疗和护理结束后需要完成一份问卷（中文版功能性沟通评判健康素养，FCCHL），另外，在结束后的第 8 周需要完成一份问卷（中文版 PIH 量表），在结束后的第 12 周需要完成两份问卷(中文版治疗负担问卷，TBQ; 中文版纪念症状评估简表，MSAS-SF)，且完成一份问卷大约需要 5-10 分钟。

(2) 实验组参与者的职责

你将接受个人和家庭成员健康素养强化方案，包括由研究者实施的 8 期健康教育课程。每节课持续 2 小时，中间休息 1 次（10 min），每周 2 次，每组 10 人。内容包括高血压、2 型糖尿病的病理生理学、症状、治疗方法、针对每个患者的特定信息等疾病相关知识，自我管理技能(目标设定、行动计划、自我监测、问题解决;和放松技巧)。该项目也包括自我管理技能的练习。

在干预开始前，我们也会要求你填写 5 份问卷，包括患者一般资料表; 中文版功能性沟通评判健康素养(FCCHL); 中文版 PIH 量表; 中文版治疗负担问卷(TBQ); 中文版纪念症状评估简表(MSAS-SF)。干预结束后需要完成一份问卷（中文版功能性沟通评判

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研究对象参与本研究的时间

(1) 实验组：你参与的时间约为 4 周，包括参加 8 期教育课程(每周 2 次，每次 2 小时，中间休息 1 次)，并填写 2 次问卷。完成每一份问卷大约需要 5-10 分钟。

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研究联系人：

1. 姓名: 单 君

地址: 中国江苏省南通市崇川区启秀路 19 号 南通大学医学院（护理学院）

联系电话: (+86) 13862825206

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我知道我可以自主拒绝参与这项研究。在参与该项研究期间，我可以随时退出这项研究，而不影响接受社区卫生保健人员提供的常规护理。我将收到任何与本研究相关或影响该研究的新信息，这些信息可能会影响我参加本研究的决定。

我知道研究人员将对我的个人信息保密，只会以研究成果的形式公开，并且在整个研究过程中，采取的做法对我身心无害。研究人员表示，如果在参与该研究中出现任何危险，我将会得到充分照顾和护理。

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