Participant Informed Consent

Medical research topic:	**China Pilot of ICOPE (Integrated Care for Older People) in Chaoyang**
Research Center:	Peking Union Medical College Hospital, Chinese Academy of Medical Sciences
Principal investigator:	Ninie Yan WANG, Xiaohong LIU
Informed consent version number:	2.0
Informed consent version date	September 1st, 2020
Participant name:	
Participant ID:	

Dear participant,

We would like to invite you to participate in a study entitled "China Pilot of ICOPE (Integrated Care for Older People) in Chaoyang".

Before you decide whether to agree to participate, please carefully read this informed consent form, and you can ask the researcher about your concerns. You can also ask your family, friends, or others. Once you decide to participate in the study, you would need to sign this informed consent form.

1. Research background

According to the seventh population census, the proportion of people older than 65 has increased from 4.41% (1953) to 13.5% (2020). Increasing healthy life expectancy and reducing disability and nursing burden are current strategies to cope with global aging.

In 2017, the World Health Organization issued guidelines of integrated care for older people (ICOPE) for advancing care model in communities. The guidelines clearly pointed out that it is necessary to organize all the resources that can be mobilized in the community to provide unified and integrated care services for the elderly; the goal of the service focuses on improving the functional status of the elderly, dealing with cognitive decline, urinary incontinence, falls, malnutrition, caregiver burden, and other problems unique to the elderly; It is recommended that all countries and regions refer to this guide to explore their own specific and operable model processes. At present, the health services for the elderly in the community in China are still mainly outpatient services in hospitals at all levels, lacking person-centered health management and the concept and practice of integrated care. The implementation of integrated care in the community is conducive to the effective promotion of the collection of medical care and elderly care, which is consistent with the purpose of the state to provide elderly care services in the community.

In the Decade of Healthy Ageing (2021-2030) proposed by the United Nations and the World Health Organization, integrated care for the elderly is set as a core action. The first batch of global pilot projects of the project were held in seven countries. The Chinese pilot projects are organized by Pinetree Care Group together with the Department of Geriatrics of Peking Union Medical College Hospital, in conjunction with a number of general hospitals, hundreds of community health and elderly care service institutions, and more than 2000 older people. It is implemented in Chaoyang

District, Beijing.

This study was approved by the ethics review board of Beijing Union Medical College Hospital.

2. Purpose of this study?

Initially establish a program process suitable for integrated care in urban communities in different regions of China. The community home-based elderly care service will be effectively combined with the rigid needs of the elderly with old age, frailty and chronic diseases for medical and health care services, and finally a mature, standardized, reproducible and sustainable new mode of medical and elderly care service will be established.

3. Research method

In this study, the elderly participants will be divided into intervention group and control group by researchers according to fixed rules after you agree to join the study.

Whether it is the intervention group or the control group, we will conduct a comprehensive geriatric assessment for you, collect your functional health data, and follow up your health changes and your care plan by phone.

For the intervention group, the integrated care team will formulate an individualized care plan for you according to your assessment, and the integrated care manager will implement the relevant care plan and follow up the outcomes; The integrated care manager will also arrange the corresponding health services such as nutrition guidance, rehabilitation exercise and referrals to medical team according to your needs.

In the control group, participating geriatricians or community doctors will give you corresponding health guidance and health education according to your assessment and answer any questions you might have.

4. Research process

4.1 For you to sign this informed consent before starting any research related activities.

4.2 The comprehensive geriatric assessment includes the assessment of intrinsic ability. If you have a decline in intrinsic ability, go to the next step.

4.3 You will be randomly assigned to the intervention group or the control group.

According to your assessment results, the intervention group will receive integrated care services, which will be tracked and supervised by the integrated care manager; The control group will be given health guidance and education.

4.4 The assessment should be repeated after 6 months to record the occurrence of adverse health outcomes.

5. How to end the study

The intervention study will last for 6 months. We promise to strictly protect your privacy. You can also terminate your participation in this study at any time. If you do not agree to participate, it will not affect your relationship with the health and care staff, nor will it affect their subsequent diagnosis and treatment for you. It can also be terminated at any time during the follow-up process.

6. Research benefits

In the intervention group, you can get integrated care services for free through this pilot study, so as to better improve your intrinsic capacity and maintain your health.

In the control group, you can have a more comprehensive understanding of your own health and get the corresponding health guidance for the problems found in the assessment.

7. Risks and inconveniences of research

For your personal information security in this study, we will protect the information you provide with strict technical and access control. If some of the questions we asked you in this study make you feel uncomfortable, you can refuse to answer such questions. At the same time, you can rest at any time during the assessment or intervention process. You may withdraw from this study at any time during the study.

In the intervention group, the research is to integrate the corresponding health services, and arrange the corresponding services for you by a specially assigned person as the "Integrated Care Manager". The service content is mature health and care measures, which does not involve the use of new drugs and new devices and will not bring you additional risks.

In the control group, doctors give health guidance according to your assessment results, which will not have any restrictions on your existing health services, nor involve

the use of new drugs and new devices, and will not increase your health risk.

Whether you are in the intervention group or the control group, you can conduct behaviors such as seeking medical treatment and hospitalization according to your own wishes, and the research will not impose any restrictions on your medical behaviors.

8. New information in the research process

During the course of the study, if the researcher obtains the latest important information related to the study, we will inform you in time and let you decide whether or not to continue to participate in the study.

9. Research related expenses

You do not have to bear any of the research related costs. You will not be paid for participating in this study.

10. Study related damage

This study is a pilot program of the integrated care for older people (ICOPE) as a way to better identify and respond to your health and care needs, and will not cause any harm to you.

11. How to handle my samples

Blood or body fluid samples will not be collected in the study.

12. Confidentiality system

Your health information collected from participating in this research will be kept confidential. The research results will not disclose any personally identifiable information when published in academic journals. Your corresponding research participating unit will keep all your records in this research as well as relevant hospital and office records, and no one can obtain such information without authorization. The corresponding research data, after desensitization (hiding your personal information, such as name, ID number, address, contact information, etc.), will be submitted to the principal investigators of the pilot, "Peking Union Medical College Hospital" and "Pinetree Care Group" for scientific research analysis only.

13. Possible conflicts of interest of funding sources

The cost of this study is supported by China Central Government Home- and Community-based Elderly Care Reform Grant (CYCG-20-1401).

14. Voluntary participation

Your participation is entirely voluntary. You may decide not to participate in or withdraw from the pilot at any time during the study, which will not affect your relationship with medical staff and your routine care.

15. Note to participants

Please truthfully provide the information required for the pilot. During the intervention period, please follow the integrated care plan.

16. Contact information

If you have any discomfort or have any questions about the study, you can contact the investigator:

Research Doctor	Name: Fei Lu	Tel: 18810614197

If you have any questions about your rights as a participant, you can contact the ethics committee:

Ethics Secretary	Name: Jiayue LI	Tel: 010-69156874

Thank you for reading and considering whether to participate in the study.

17. Signature page

Participant:

I confirm the following information:

（1）I have read and understood the above informed information and have enough time to consider whether to participate in the study.

（2）All my questions have been satisfactorily answered.

（3）I am willing to participate in this research and follow the research procedures.

（4）I know that I can withdraw from this study at any time without giving any reason, and my treatment or rights will not be affected.

（5）I have received a copy of the signed consent form.

（6）I agree to collect and use my samples as described above.

（7）I allow the collection and use of my personal information in this study.

（8）I know that I may be contacted in the future to obtain my permission for this research or any related sub research.

By signing this document, I agree to participate in this study according to the informed information and the statement in the consent form.

Participant name (block letters):

Participant signature: Date:

The following is limited to participants with mild cognitive impairment who need the signature of the guardian.

[the name of the participant (in block letters), the relationship between the guardian and the participant is.]

Name of guardian (in block letters): contact number:

Signature of Guardian: Date:

The following is limited to participants without reading and writing ability, and the signature of an impartial witness is required.

Name of witness (in block letters): contact number:

Signature of witness: Date:

Name of investigator / authorized person (in block letters):

Signature of investigator / authorized person: Date: