China Pilot of ICOPE (Integrated Care for Older People) in Chaoyang

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1. Research background

According to the seventh census data, the proportion of people older than 65 in China has increased from 4.41% (1953) to 13.5% (2020). The increase in life expectancy is not equivalent to the extension of healthy life expectancy. The growth of overall life expectancy is slightly faster than that of healthy life expectancy, indicating that not all life extensions are healthy, accompanied by a slight increase in disabled years. Increasing health life expectancy and reducing disability and nursing burden are current strategies to cope with global aging.

In 2017, the World Health Organization issued guidelines for integrated care for older people (ICOPE) for older people in communities. The guide clearly points 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 older people; The goal of the service focuses on improving the functional capacity of older people, dealing with cognitive decline, urinary incontinence, falls, malnutrition, caregiver burden, and other problems unique to older adults; 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 older people in the community in China are still mainly outpatient services in hospitals at all levels, lacking unified health management and the concept and practice of integrated care. The implementation of integrated care in the community is conducive to effectively promoting the integration of medical care and social care, which is consistent with the purpose of the state to provide elderly care services in the community.

ICOPE model is aimed at providing people-oriented, value-based health and care services for older people throughout the life course. It needs to be comprehensively considered, designed, and implemented from the top-level design, policy guidance, payment mechanism, service capacity-building, and the management of measurable results.

In the United Nations Decade of Healthy Ageing (2021-2030), integrated care for older people is set as one of the core actions for World Health Organization. The first batch of global pilot projects of ICOPE are implemented in seven countries. The Chinese pilot was carried out by Pinetree Care Group and the Department of Geriatrics, Peking Union Medical College Hospital, in conjunction with a number of general hospitals and hundreds of community health and care service centers, with more than 2000 older people. The pilot was conducted in Chaoyang District, Beijing.

2. Research purpose

The goal of this pilot study is to evaluate the feasibility of implementing World Health Organization's ICOPE (integrated care for older people) approach in China. The main questions it aims to answer are:

1) Whether it is feasible to implement the ICOPE approach in China;

2) Whether the integrated care approach would make any difference in health outcomes and resource utilization.

For the first question, predefined parameters such as sample size, capacity building, acceptance by community-dwelling older people (participants) and care providers were examined.

3. Research methods

Prospective randomized controlled study. A total of 2000 community-dwelling older persons aged 60 and above at-risk of functional loss in Chaoyang District of Beijing are recruited and randomly assigned to the intervention group (n=500) and control group (n=1500).

3.1. Primary Outcome Measure:

Feasibility of implementing the ICOPE program in China:

1) Sample size (to successfully recruit over 2,000 participants, 500 of whom were to be categorized in the intervention group)
2) Capacity building (at least 200 primary care providers to be fully trained and deployed in the pilot program)
3) Acceptance (reach more than 90% satisfaction with the pilot by both participants and providers).

3.2. Secondary Outcome Measures:

Independence - measured by the activities of daily living (ADL) 14-questionnaire scale, to assess the participant's physical function.

Cognition - measured by mini-mental status examination (MMSE) to assess the cognitive health of the participants.

Vitality - nutrition measured by mini-nutritional assessment- short form (MNA-SF) to assess the risk of malnutrition.

Mobility - measured by short physical performance battery (SPPB) to assess the risk of declining mobility.

Psychological health - measured by geriatric depression scale-five items (GDS-5) using a short set of questions to assess possible depressive symptoms.

4. Statistical methods and sample size

4.1. Sample size calculation

At present, there is no specific local data to support the calculation of sample size.

Using all-cause death and falls as the endpoint events, based on previous literature and pre-experimental data, the percentage of decline in intrinsic ability in the community elderly population as the dependent variable ranged from 43.0% to 77.4%, and the incidence of all-cause death, falls and functional decline in the group with decline in intrinsic ability at 3-year follow-up was 16.4%, 55.3% and 64.8%, respectively, using PASS software, setting a two-sided $\alpha = 0.05$ with 90% certainty, based on the above data, it was calculated that at least 58 people with all-cause death as the endpoint event of decline in intrinsic ability, 72 people with falls as the endpoint event, and 126 people with decline in function as the endpoint event were required, considering that the population included in this study was elderly, and based on previous studies, the proportion of decline in intrinsic ability was estimated to be 70%, and considering a 5% loss of follow-up rate, at least 190 elderly people. Therefore, a total of 380 individuals were included in the intervention and control groups (intervention community and control community).

This project plans to investigate and follow up with at least 2000 older people and intervene in more than 500 cases. Combined with the sample size calculation above, this project should meet the needs of sample size.

4.2. Statistical methods:

STATA will be used to establish the database and conduct statistical analysis.

The baseline data were collected, and the corresponding statistical methods were selected according to the data type to compare the basic clinical information of patients: if the data conformed to the normal distribution, it was expressed as the mean ± standard deviation (± s),

and the independent sample t test was used for the comparison between the two groups; If the data does not conform to the normal distribution, it is expressed as the median (25th percentile, 75th percentile), and the Mann Whitney U test is used for the comparison between the two groups.

The intervention group and the control group were propensity matched, and the incidence of adverse health outcomes (all-cause death, falls, functional decline) and changes in quality of life (self-control, comparison between the two groups) were compared between the two groups.

$P < 0.05$ indicates that the difference is statistically significant.

5. Patient enrollment and exclusion criteria

5.1 Inclusion and exclusion criteria for research subjects

Inclusion Criteria:

(1) Screened as positive for intrinsic capacity declines.

(2) Decline in intrinsic capacity confirmed by in-depth assessment in any of the domains described as: MMSE < 27 (for cognition), SPPB $\leqslant$ 9 (for locomotion), MNA-SF <12 (for vitality we used nutrition as a proxy), GDS-5 $\geqslant$ 2 (for psychology we used depression as a proxy) or any vision impairment.

(3) Signed form of consent and willingly participate in the pilot study.

Exclusion Criteria:

(1) Negative results in their intrinsic capacity decline screening.

(2) Severe hearing problems as the study was conducted during COVID-19 pandemics period and relied on telecare or remote sessions of intervention.

5.2 Randomization

A random number table (1-2000 random order) was established and managed by a dedicated person (who was only responsible for informing the number). The older person who met the enrollment conditions received random numbers according to the order of the random number table. The random number divided by 3 is an integer, and the remaining 1 is the control group, and the remaining 2 is the intervention group.

6. Research process

6.1 Data acquisition and observation indicators:

(1) The elderly who met the inclusion criteria were included, and their demographic characteristics (gender, age, education, height, weight, BMI, smoking and drinking history) were recorded

(2) Assessment of intrinsic ability: according to the screening tool for integrated care for older people (ICOPE) and the people-centered assessment guide issued by WHO, there are five dimensions in total, with 1 point for each dimension. Impairment in any dimension is defined as a decline in intrinsic ability. See Case Report Form (CRF) for the rating scale of each dimension.

Cognitive dimension: Mini Mental State Examination (MMSE), with a total score of 30 points. According to the education level of the research object, whether there is cognitive dysfunction is defined. Illiteracy $\leq$ 17 points, primary school level $\leq$ 20 points, secondary school level (including technical secondary school) $\leq$ 22 points, university level (including junior college) $\leq$ 23 points. Vitality: the mini nutritional assessment short form (MNA-SF) has

a total score of 14 points. A score of 12-14 defines normal nutritional status, 8-11 indicates malnutrition risk, and 0-7 indicates malnutrition.

Psychology: the total score of the geriatric depression scale 15 item (GDS-15) is 15 points, and a score of ≥ 5 points is defined as depression (Appendix 3). Or the Zung Depression Scale (SDS) was used for evaluation. Standard score = total score × 1.25, take an integer, and a standard score > 50 points is considered as depression.

Exercise: the short physical performance battery test (SPPB), including the evaluation of sitting up test, gait speed test and balance test, has a full score of 4 points for each part, a total score of 12 points, and a score of ≤ 9 points is considered as physical function decline.

Sensory: vision assessment (do you have vision loss that affects your normal life even after wearing glasses or surgery?); Hearing assessment (do you have hearing loss that affects your daily life?). If you answer yes to either question, you have a visual impairment or a hearing impairment.

（3）Physical function assessment

Grip strength: the grip strength of the dominant hand is measured with an electronic reading table grip strength meter, and the grip distance is adjusted according to the size of the patient's hand. The one-time forced grip strength meter reaches the maximum grip strength value, and the same hand is measured twice with an interval of at least 15s, taking the best one.

Gait speed (GS): walk 4 meters at daily walking speed, time and calculate.

3-meter standing up walking test (TUGT): participants stood up from the chair, walked a distance of 3 meters, and then returned to the sitting position, walking at the daily walking speed.

Five sit up test (FRSST): without using arms (with arms crossed in front of the chest), the time required for the subject to stand up and sit down on a 47cm-tall chair for five consecutive times, counting from the sitting position and ending at the last sitting position.

Simple physical function test (SPPB): it is a comprehensive score, including three parts: the time to walk a distance of 4 meters, the time to complete the FRSST, and the ability to stand in three ways for 10 seconds (with feet, half feet, and full feet).

（4）Activities of daily living (ADL) assessment

Physical self-maintenance scale (PSMS): including 6 items such as toileting, grooming, bathing, eating, dressing, and activities, with a total of 6 points.

The Lawton instrumental activities of daily living (Lawton IADL): 8 items including using transportation, cooking, financial management, making phone calls, taking medicine, washing clothes, shopping and doing housework, with a total of 8 points.

（5）Comorbidity assessment

Charlson comorbidity index and geriatric disease cumulative score scale were used for evaluation. See the attached table for details.

（6）Frailty

Frail debilitating phenotype scale was used.

（7）Medication

Including the quantity and type of medication. The number of medications ≥ 5 was defined as polypharmacy.

6.2 Intervention methods

Intervention plan of intervention group

1) Establish an integrated care team: including integrated care managers, community doctors / competent doctors, rehabilitation specialists, and nutritionists.

2) The integrated care manager is responsible for older peoples' assessments, coordinating and integrating the care team, organizing education and supervising follow-up, and coordinating the referral and remote consultation of the superior geriatrics team according to the requirements of the community doctors.

3) Training of medical staff served by the intervention group: ① integrated care manager training, including research process introduction, comprehensive geriatric assessment, intrinsic capacity assessment, etc.; ② Integrate the relevant curriculum training of the care team to develop multi-dimensional interventions.

The principle of formulating an integrated care plan for the population with declined intrinsic capacity in the intervention group: the health management division will uniformly arrange the patient's health management plan, and organize, coordinate, implement and supervise the corresponding intervention measures.

① If the MNA-SF is less than 11 points, the risk of malnutrition should be given nutrition guidance by the dietitian according to the situation of the elderly, including oral nutritional supplements (Ensure, Yilijia SR); ② SPPB ＜ 9 points: strength training, endurance training, balance training, flexibility training (refer to "PUMCH elderly official account - elderly mobility improvement plan - Guidance and education video"); ③ If the GDS-15 score is ≥ 5, there may be depression, which should be evaluated and intervened by the community doctor. If necessary, it can be guided or referred by the psychiatrist of the superior team; ④ If MMSE is less than 24 points, community doctors further evaluate cognitive function, guide intellectual activities, and refer to the superior hospital team when necessary; ⑤ For older people with vision and hearing loss, the community doctors can develop ways to improve or adjust the compensation according to the specific situation, and the superior hospital can evaluate and see a doctor when necessary.

Control group intervention plan

In the control group, after completing the comprehensive evaluation of older people, the community doctors who did not participate in the service of the intervention group gave relevant health education according to the evaluation results.

6.3 Follow-up

Follow-up time: 3 Months, 6 Months from baseline

Follow up will be carried out through telephone, family doctor visit, medical record system review, and the ADL score, frailty scale score, and adverse health outcomes (falls, recurrent falls, severe falls, all-cause death) were recorded.

Record the time of the first fall, which can be specific to month, such as December 2020. If the person or family member can't remember clearly, they can provide the time range, such as January to June 2021.

The time and cause of all-cause death (including the direct and chronic causes of death, such as severe pneumonia and dementia) were recorded.

The intervention group with decreased intrinsic capacity will go through a comprehensive assessment. Intervention group will be re-assessed at 3 months and 6 months after baseline, while the control group will be assessed at baseline and 6 months.

7. Benefits and risks of research

7.1 Research benefits

By exploring and verifying the program process of integrated care, effectively combining community & home-based elderly care services with the health needs of the elderly, especially those who are more senior, frail and suffering from chronic diseases, we expect to provide evidence for establishing a scalable and sustainable new mode of medical and social care services.

For the elderly who receive services, we can better maintain their functional state and quality of life, improve the quality and efficiency of medical services with existing resources.

7.2 Research risks

The study is for a community-based older population with stable chronic disease and does not involve the treatment of acute diseases.

In the intervention group, the study integrated the corresponding health services, and a specially assigned person served as an "integrated care manager" to arrange the corresponding services for older patients. The intervention was mature medical and rehabilitation measures, which did not involve the use of new drugs and new devices and would not increase additional risks.

In the control group, the doctor will give health guidance according to the elderly’s assessment results, which will not have any restrictions on the existing health services for elderly patients, nor involve the use of new drugs and new devices and will not increase additional risks.

8. Quality control of the study

Personnel training shall be carried out before the implementation of the project, and special personnel shall be assigned to take charge of it.

All participating units are required to select, group, treat and follow up cases in strict accordance with the requirements of the study design. Implement the method of document management, use the scientific research record book to record the research data in detail, accurately and objectively, and ensure the authenticity, integrity, reliability and comparability of the data. The experimental data are statistically scientific, the research report is written truthfully and rigorously, and the research data are finally properly archived. Each sub center shall assign special personnel to regularly check the implementation of the project and the storage of data. And regularly report to the principal investigators.

9. Research data management and confidentiality measures

9.1 Confidentiality measures for research data

When the research results are published in academic journals, it is not allowed to disclose any information that can identify the personal identity of patients.

Each research participating unit is responsible for keeping the CRF and all other records of the study and shall not disclose the patient's privacy information to unrelated personnel; The electronic data information shall be submitted to the principal investigators of the project for scientific research analysis after desensitization (hiding personal information, such as name, ID number, address, contact information, etc.).

A special person is assigned to be responsible for data transmission and management. Data files need to be compressed and encrypted before transmission.

9.2 Management measures of research data

Each sub center shall assign a special person to be responsible for data management, including archiving, locking and keeping of CRF and other documents. Supervision of input data files and desensitization after data export. Transfer and keep relevant experimental data in strict accordance with the requirements of the pilot and restrict irrelevant personnel from contacting the research data.

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