INFORMED CONSENT FORM

Study Document | Cover Page

Official Title of the Study	Development and Application of Early-Warning and Precision-Intervention Technologies for Decline in Intrinsic Capacity among Older Adults
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Sponsor / Funder	Zhejiang University International Institute of Health Medicine
Ethics Committee	Human Research Ethics Committee, The Fourth Affiliated Hospital of Zhejiang University School of Medicine

This cover page is provided for the ClinicalTrials.gov study-document submission. The Informed Consent Form that follows is the ethics-approved Version 1.0 dated 19 August 2026; its content is unchanged. The NCT number has not yet been assigned because the registration record is still under review.

Informed Consent Form for Research Participants

Dear Sir or Madam,
We invite you to take part in the scientific research project "Development and Application of Early-Warning and Precision-Intervention Technologies for Decline in Intrinsic Capacity among Older Adults." Before you decide whether to participate, please read the following information carefully. It is intended to help you understand the content of this study, why the study is being conducted, and the potential benefits, risks, and discomforts it may involve for you.
The following is an introduction to this study:

1. Research Background

As people age, memory, walking ability, mood, energy, vision, and hearing may gradually decline. In the early stages these changes are often difficult to detect, and by the time they become apparent they have already affected daily life. With devices such as smart wristbands and ambulatory blood pressure monitors, it is now possible to record bodily changes over the long term; combined with artificial-intelligence analysis, this offers the prospect of detecting early signs of such decline and providing personalised health guidance. However, these technologies are not yet sufficiently mature. How to integrate the data, how to make accurate predictions, and how to deliver advice suited to each individual all require further research. This project aims to develop such an intelligent health management system and to verify, in the community setting, whether it can genuinely help older adults maintain physical function and reduce illness.

2. Purpose of the Study

This study aims to track changes in physical function among older adults over the long term using wearable devices and questionnaires, to identify the key indicators that provide early warning of decline in intrinsic capacity, to establish a risk prediction model, and to develop an artificial-intelligence-assisted personalised health guidance system. It will ultimately be verified through a community-based trial whether the system can help older adults delay functional decline and reduce adverse events such as falls and hospitalisation.

3. Procedures of the Study

3.1 Inclusion criteria

- Age ≥60 years;
- Residence in the community for ≥6 months;
- Clear consciousness, able to cooperate with assessments and device operation (individuals with mild memory decline may complete the procedures with assistance from a family member);
- Voluntary participation with a signed consent form.

3.2 Exclusion criteria

- Severe cognitive impairment or mental illness, rendering cooperation impossible;
- Severe disease of the heart, lungs, liver, or kidneys, or terminal-stage cancer;

- Broken or infected skin making device wearing unsuitable;
- Any other circumstances considered by the researcher to be unsuitable for participation.

3.3 Study process and duration

Your total participation in this study will last approximately 12 months. The main procedures are as follows:

Enrolment assessment: after you sign the consent form, the research staff will use a questionnaire to understand your basic health status and will assess your memory, walking ability, mood, nutrition, vision, and hearing. A wearable device (such as a wristband or an ambulatory blood pressure monitor) will be fitted, which will continuously record your daily activities, heart rate, blood pressure, sleep, and related information for approximately 7 consecutive days.

Routine monitoring: during the study, you will wear the wearable device as instructed. The device collects data automatically and will not interfere with your normal life.

Random allocation: this study groups participants at the community level. The community to which you belong will be randomly assigned to either the "intervention group" or the "control group."

If you are in the intervention group: you will use the intelligent health management platform developed in this study to receive personalised health advice on diet, exercise, and cognitive training via your mobile phone or tablet, and you will interact with the AI health coach.

If you are in the control group: you will receive routine community-based elderly health management services.

Scheduled reassessment: at months 3, 6, and 12, you will return to the community health service centre to complete the follow-up assessment, the content of which is similar to that at enrolment (questionnaire, device wearing, etc.).

End of the study: your participation ends after completion of the 12-month assessment. Your data will be identified by a code rather than your name and will be used solely for scientific analysis.

3.4 What you will be required to do if you participate

If you meet the eligibility criteria and voluntarily agree to participate, you will take part in the study according to the following steps:

- Provide truthful information about your personal details, medical history, and current health status;
- Cooperate with the various questionnaire assessments and physical function tests (such as walking and grip strength tests);
- Wear the wearable device as instructed, taking care to protect it from water and to charge it, so as to avoid damage;
- If in the intervention group: carry out daily health management according to the advice delivered by the platform, use the AI health coach regularly, and report faithfully on how well you have followed the advice;
- If in the control group: continue to receive routine community health services and attend the scheduled reassessments as notified.

4. Potential Benefits of Participating in This Study

During the study you will receive physical function assessments related to this research (such as tests of memory and mobility) to enable us to collect data; some participants will have the opportunity to experience the investigational AI health monitoring tools. Please note that the primary purpose of this study is scientific exploration. Assessment results are for research use only, do not constitute a clinical diagnosis or treatment advice, and cannot be guaranteed to improve your health. There may be no direct benefit to you.

5. Possible Adverse Reactions, Risks, and Precautions

The procedures of this project will be carried out strictly in accordance with clinical standards. Nevertheless, the following discomforts or risks may arise during the study, and are disclosed here:
This is a non-invasive observational and interventional study and the overall risk is low. However, the following discomforts or risks may still occur during the study:

- *Risks related to exercise guidance:* when exercising according to the platform's recommendations, muscle soreness or a risk of falls may occur. Before exercise we will assess your physical condition and prescribe an exercise plan suited to you. We advise gradual progression and attention to environmental safety during exercise; stop immediately if any discomfort occurs.
- *Risks related to device wearing:* when wearing the portable multimodal data-collection device, some participants may experience mild skin discomfort, pressure marks, or an allergic reaction to the adhesive materials on the neck. This is usually relieved by removing the device. If persistent discomfort occurs, the research staff will adjust the usage plan or suspend device use as appropriate.

Other discomforts may occur during the study. Please report them to your researcher immediately; he or she will manage the discomfort you experience. We hereby undertake to minimise the probability of the risks and adverse consequences described above.

6. Costs

This study entails no additional costs.

7. Compensation and Compensation for Injury

Should an adverse event occur during the clinical study and be confirmed as genuinely related to this study, the researchers will, in accordance with the provisions of the relevant laws or guiding principles of the People's Republic of China, provide for the costs of diagnostic and treatment related to the research damage and grant corresponding financial compensation.

8. Alternative Options

If you do not participate in this study, you may continue with your normal life as usual.

9. Confidentiality of Your Personal Information

Information relating to your participation in this study will be recorded in the research records/case report forms. All examination results appearing in original medical records (including personal data, laboratory slips, etc.) will be kept fully confidential within the bounds permitted by law. Your name will not appear in the report forms; only the code assigned to you at the time of enrolment will appear. Any research summaries, articles, or public publications will likewise refer only to your code, where necessary.
Where required, the drug regulatory authority, the ethics committee, or the funding body of the project may inspect participants' study materials in accordance with the relevant provisions. However, without permission, they will not use such materials for any other purpose nor disclose them to any other organisation.

10. Must You Take Part in This Study?

Whether you participate in this study is entirely at your discretion, and you may decline to take part.
At any time during the study, you have the right to withdraw. If you choose to withdraw, your health entitlements outside this study will not be affected, nor will you be subject to discrimination or unfair treatment on this account.
Your physician or the researcher may, in the interests of your wellbeing, terminate your participation in this trial at any time.
If you withdraw from the trial for any reason, you may be asked about the reasons for withdrawal. If the physician considers it necessary, you may also be required to undergo laboratory tests and a physical examination. You may refuse, and will not be subject to discrimination or unfair treatment on this account.

11. Ethics Committee

If you have any questions about this study, you may contact the person in charge of this study; the telephone number is given below.
If you have any dissatisfaction or suggestions during the study, please contact the Human Research Ethics Committee of the Fourth Affiliated Hospital of Zhejiang University School of Medicine.
Telephone: 0579-89935006 **Email:** jigoulunli_zy4y@163.com
Please retain this document.

12. Statement of Consent

1. I have read this informed consent form, and the person responsible for the project has given me a detailed explanation of the purpose, content, risks, and benefits of this trial.
2. I have discussed and asked questions about this study, and I am satisfied with the answers.
3. I have had sufficient time to make my decision.
4. I voluntarily consent to participate in the scientific research described in this consent form, and I agree that my research data may be used for publication of this study.
5. I consent to representatives of the drug regulatory authority, the ethics committee, or the funding body of the project inspecting my research materials.
6. I will receive a copy of the informed consent form that has been signed and dated.

Ultimately, I have decided to consent to participate in this trial.
I confirm that I have read and understood the informed consent form for this study, that I voluntarily accept the treatment methods described in this study, and that I consent to the use of my medical data for publication of this study.
Participant signature:Contact:Date:
Legal representative signature (if required):Relationship to the participant:
Contact:Date:
Witness (if required):Contact:Date:
I confirm that I have explained the detailed circumstances of this study to the participant, including his or her rights and the potential benefits and risks, and that I have provided him or her with a signed copy of the informed consent form.
Researcher signature:Date:
Researcher contact: