For further information please contact:
Provider XY
Tel.: XXX – XXXXX-XXX
Mail: ines.xy@providerxy.de

Further information about the scientific study can be found at www.ines-projekt.de.

Information for Participants

Scientific study on risk of falling, fear of falling, and the benefits of smart home emergency call systems for individuals aged 70 and older[1]

Many people wish to live in their own homes for as long as possible, even at an old age, while maintaining their independence and autonomy. However, the risk of falling and the fear of falling can lead to a loss of independence and make living at home difficult or impossible.

As part of this study, funded by the Innovation Fund, your health insurance provider, participating home emergency call system providers, and Bielefeld University aim to investigate whether the use of smart home emergency call systems can improve the care for older adults living alone.

All study participants will first receive an assessment of their individual risk of falling, conducted by medical professionals via telephone. If an increased risk of falling is identified, participants will be randomly assigned to one of the following groups:

- **Group 1**:
  Participants in group 1 will take part in three written surveys, each requiring approximately 15 to 20 minutes to complete. The surveys will cover topics such as health-related quality of life, fear of falling, well-being, and general living conditions. Participants will receive a compensation of 25 euros for each completed survey.

[1]Funded by the Innovation Fund of the German Federal Joint Committee in accordance with § 92a Paragraph 1 SGB V under the project title: "INES – Efficient Initiation of Emergency Interventions Using Smart Home Emergency Call Systems for Older Adults Living Alone"; Grant Number: 01NVF21102

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- **Group 2**:
  Participants in group 2 will also take part in three written survey, each requiring approximately 15 to 20 minutes to complete. The surveys will cover topics such as health-related quality of life, fear of falling, well-being, and general living conditions. Instead of a monetary compensation, participants in this group will receive a smart home emergency call system, which consists of several innovative fall sensors for the installation at home. The system and sensors will be provided free of charge for the duration of the study.

By participating in this study, you are making an important contribution to improving the care of older adults living alone, helping them to remain in their own homes as safely and independently as possible for as long as possible. We would be delighted if you would support our initiative by taking part in the study!

Upon completion of the study, the results of the scientific evaluation will serve as a basis for decision-making to improve the range of services offered by statutory health insurance, specifically for older adults living alone. For this purpose, our study is funded by the Innovation Fund in accordance with the provisions of § 92a SGB V.

In the following sections of this document, we provide detailed information on the eligibility criteria, study procedures, and objectives, as well as an overview of the home emergency call system, data flow, data protection, the voluntary nature of participation, and your right to withdraw from the study at any time.

Rehse H, *et al. BMJ Open* 2025; 15:e092893. doi: 10.1136/bmjopen-2024-092893

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Eligibility Criteria

You are eligible to participate in the study if you meet the following criteria:

- You reside in Hamburg, North Rhine-Westphalia, or Bavaria.
- You are insured with Techniker Krankenkasse, IKK classic, AOK NordWest or AOK Bayern.
- You are living alone.
- You are 70 years or older.
- You agree to having your risk of falling assessed via telephone by the telemedicine center.
- You agree to be randomly assigned to one of the two study groups, provided that you are identified as having an increased risk of falling.
- You agree to the collection and use of your data, as described in the section "Data Flow and Data Protection."
- You sign the consent form for this study.
- If assigned to Group 2, you agree to have the smart home emergency call system permanently installed in your home for the duration of the study.

Participating in this study is voluntary. You may withdraw from the study at any time. Further details can be found in the section “Voluntary participation and withdrawal”.

Study Procedure

Further details on the project partners mentioned in this section can be found in Table 1 of the Appendix. At the beginning of the study, please carefully read this information sheet and sign the attached consent forms. Return the signed documents to the home emergency call system providers by mail using the prepaid return envelope which you received with the study materials. The "Consent Form for Telephone Contact" will then be forwarded to the Telemedicine Center of Ife Gesundheits-GmbH. Following this, medical professionals from the Telemedicine Center will contact you by telephone to conduct an interview assessing your individual risk of falling.

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Whether you are considered to have an increased risk of falling based on the telephone interview will be communicated to you directly by the Telemedicine Center at the end of the call. You will not receive any additional individual results from the study, as the data will be evaluated in a non-personalized, aggregated manner.

If the telephone interview determines that you do not have an increased risk of falling, your participation in the study will end at this point.

If you are determined to have an increased risk of falling, the Telemedicine Center will transmit your participant number (pseudonym) to Bielefeld University. There, your pseudonym will be randomly assigned to one of the two study groups. Subsequently, Bielefeld University will send your pseudonym along with your assigned group back to the home emergency call system provider, where you submitted your consent form. The home emergency call system provider will then inform you about your group assignment and the next steps.

- Participants assigned to **group 1** will receive a questionnaire by mail shortly after group assignment, as well as 12 and 21 months later. The mailing is handled by the study service provider PVS pria. You are asked to return the completed questionnaires to Bielefeld University using the prepaid envelope provided. The questionnaires do not contain any personal identifiers. Each questionnaire package includes the document „Confirmation of bank details“. Please return your bank details separately using the second prepaid return envelope provided. Once your bank details are received, PVS pria will process the payment of your compensation of 25 euros per completed survey.

- Participants assigned to group 2 will receive a smart home emergency call system from the home emergency call system provider within approximately two weeks after the telephone interview. The installation appointment will be scheduled with you by phone in advance. The system consists of a base station with a wireless transmitter in the form of a wristband and multiple innovative fall sensors. These sensors do not record any images or audio—they only detect falls. Your privacy remains fully protected. The battery-operated sensors will be installed at a height of approximately 2.10 meters in various rooms of your home, in consultation with you, using adhesive strips. The home emergency call system provider is responsible for replacing the batteries when needed. No structural modifications are required for

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installation. After the study ends, the sensors can be easily removed. In addition to testing the smart home emergency call system, you will participate in three written surveys, conducted shortly after enrollment, as well as 12 and 21 months later. The questionnaires will be sent to you by mail from our service provider PVS pria. You are asked to return the completed questionnaires to Bielefeld University using the prepaid return envelope provided. The questionnaires do not contain any personal identifiers.

Participation in the study begins with the signing of the consent form and ends after 21 months.

Aim of the Study

The aim of this study is to improve the care of older adults living at home and to help them maintain their independence and autonomy for as long as possible. To achieve this, the smart home emergency call system (INES) and its effectiveness will be evaluated in participants' home environments as part of a randomized controlled trial (RCT). This means that study participants who meet the general eligibility criteria will be randomly assigned to one of two groups (group 1: does not receive a smart home emergency call system, group 2: receives a smart home emergency call system). All study participants will continue to have full access to standard healthcare services throughout the study. The two groups will be compared on key outcomes, including hospital length of stay after an emergency admission, fear of falling, and health-related quality of life. Randomization ensures that the two groups are highly comparable in terms of known and unknown characteristics, reducing the risk of bias in the study results. This study design is considered the "gold standard" in scientific research for evaluating healthcare interventions.

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Further information about the scientific study can be found at www.ines-projekt.de.

The Home Emergency Call System INES

The sensors of the smart home emergency call system automatically detect when a person has fallen. If you experience a fall but are unable to press the emergency button yourself, the system will automatically send an emergency call via the base station to the connected emergency call center. Since the sensors are permanently assigned to specific rooms in your home, the emergency call center can identify the exact location of the fall and dispatch emergency personnel directly to that room. The response team will provide on-site first aid and take further necessary actions as required. In addition to the fall detection sensors, an emergency call can also be triggered manually at any time using the emergency button on the base station or the wrist-worn wireless transmitter. It is therefore recommended to wear the wireless transmitter as a wristband at all times.

To ensure that emergency personnel can access your home without delay in case of an emergency, you will deposit a copy of your house and apartment key with the home emergency call provider. The key will be securely stored and kept free of charge for the duration of your participation in the study. This measure saves valuable time by avoiding the need to call the fire department to force entry into your home. Additionally, it helps preventing damage to doors and eliminating potential repair costs.

The fall detection sensors do not record any personal data, create movement profiles, or capture images or audio. Their sole purpose is emergency detection. The system is designed to distinguish between humans and animals (up to 30 kg). In the event of a false alarm, the situation can be quickly clarified via the voice connection with the home emergency call center through the base station. This process does not incur any costs or disadvantages for you.

For the provision of the smart home emergency call system, the availability of emergency personnel, and the secure storage of copies of your house and apartment keys, you will enter into a separate agreement with the home emergency call system provider. If you have any questions regarding this agreement, the home emergency call system provider will be happy to assist you by phone or in a personal consultation.

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Data Flow and Data Protection

The processing of all data is carried out in accordance with applicable data protection regulations, particularly the General Data Protection Regulation (GDPR). Below, we provide information in accordance with Articles 13 and 14 of the GDPR, outlining what data is collected as part of your study participation, who collects this data, the purpose of data collection, how the collected data is protected, and how long the data will be stored. An overview of this information can be found in Table 1 in the Appendix.

All collected data will be pseudonymized. This means that identifying information (e.g., name and date of birth) will be replaced with a pseudonym (participant number). At the beginning of your study participation, the home emergency call system provider will assign you a pseudonym. To ensure that all data received by the researchers at Bielefeld University for analysis is fully protected, it will only be processed under this pseudonym. At no point will the assignment of your pseudonym to your identity be disclosed to Bielefeld University, ensuring that a direct link to your personal identity is excluded.

All data from the surveys, home emergency call system providers, and health and long-term care insurance providers is centrally collected by the trust center (OFFIS). OFFIS only receives this data in pseudonymized form and consolidates it for the purpose of scientific evaluation. As part of this process, the existing pseudonyms are replaced with new participant numbers before the data is transmitted to Bielefeld University for analysis. This additional reassignment of participant numbers further enhances data security. At no point will the assignment of the original pseudonym to your identity be disclosed to OFFIS or Bielefeld University, ensuring that your identity remains protected throughout the study.

As soon as the research objectives allow, the keys used to decrypt the pseudonyms will be permanently deleted. All data will be archived for a period of 10 years after the publication of study results by Bielefeld University and the trust center (OFFIS). After this period, the data will be irreversibly deleted. The study results will only be published in an aggregated form, ensuring that no individual participant can be identified. The entities responsible for data processing are Bielefeld University and the trust center (OFFIS). The respective health insurance providers are responsible for the provision of claims data.

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Your data is subject to strict data protection regulations and is transmitted and stored exclusively via secure, encrypted systems. All project partners have implemented technical, organizational, and personnel safeguards to ensure that only authorized individuals have access to your data. Access is granted only to the extent necessary for fulfilling project-related tasks and is protected by individual passwords. This ensures that unauthorized third parties cannot access your data.

The collected data will be stored by the respective project partners (see Table 1 in the Appendix) for a maximum period of ten years. Data storage is conducted electronically on secure servers located in Germany. After ten years, all data will be permanently deleted and cannot be recovered. At the study service provider PVS pria, data deletion will take place after four years.

The following pseudonymized data will be analyzed in the scientific evaluation of the study:

- Survey data: The surveys focus on health-related quality of life, fear of falling, well-being, and general living conditions. These data are collected and analyzed for all participants in groups 1 and 2.

- Data from the home emergency call system providers: These data include the frequency and reasons for emergency calls, the triggering event (fall sensor activation or emergency button press on the base station), and the actions taken by emergency personnel. These data are collected and analyzed only for participants in group 2. However, for participants in group 1 who use a standard home emergency call system from one of the participating providers, the frequency and reasons for emergency calls will also be collected and analyzed within the scope of this study.

- Claims data from the health insurance (for a period of 12 months prior to study participation until the end of participation): including data on medical treatments, hospital stays, medical aids, medications, outpatient and inpatient rehabilitation, and long-term care services. These data are collected and analyzed for all participants in groups 1 and 2.

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The processing of your data as part of your participation in the study is carried out based on Article 6 of the General Data Protection Regulation (GDPR). According to this regulation, data processing is lawful if the individual concerned provides consent for the processing of their personal data for one or more specific purposes. By signing the consent form, you formally agree to the processing of your data.

The processing of personal data is therefore only possible with the consent of the study participants. In the event that consent is withdrawn, any previously collected data will be deleted.

Voluntary participation and withdrawal

Participation in this study is voluntary. You may terminate your participation at any time, even after signing the consent form, without providing reasons. Choosing not to participate or withdrawing from the study (e.g., due to withdrawal of consent or loss of eligibility) will not result in any disadvantages for you. You may withdraw your consent to participate at any time in written form, verbally, or electronically by contacting your home emergency call system provider. The respective contact details can be found in Table 2 of the Appendix. Once a withdrawal request is received, the project partners will notify each other accordingly.

In the event of withdrawal, the following actions will be taken: Your pseudonymized questionnaire data will be permanently deleted. Emergency response data collected by the home emergency call system provider and claims data from your health and long-term care insurance provider will not be transmitted to the trust center (OFFIS) or Bielefeld University. If your data has already been transmitted at the time of withdrawal, the relevant data will be deleted at the trust center (OFFIS) and Bielefeld University. For participants in group 2, the components of the smart home emergency call system will be removed promptly after withdrawal.

Rehse H, *et al. BMJ Open* 2025; 15:e092893. doi: 10.1136/bmjopen-2024-092893

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Mail: ines.xy@providerxy.de

Further information about the scientific study can be found at www.ines-projekt.de.

Study participants can exercise their data protection rights by contacting the data protection officers of the respective institutions. Additionally, participants have the right to file a complaint with the relevant data protection supervisory authority if they believe that the processing of their data is unlawful. The contact details of the data protection officers and supervisory authorities of the participating institutions can be found in Table 3 in the Appendix.

Participants have the right to access their data, request corrections, request deletion of their data, restrict data processing, request data portability, object to further processing of their personal data. Furthermore, participants have the right to submit complaints to the relevant data protection supervisory authority (contact details available in Table 3 in the Appendix).

This research project has been ethically and legally reviewed and approved by the responsible ethics committee.

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Appendix

Table 1: Data Collection		
Projectpartner	**Data collection and data storage**	**Purpose**
Contact details are available from the corresponding author on reasonable request and with permission of all involved institutions.		

Table 2: Contact details for withdrawing consent			
Projectpartner	**Postal address**	**Telephone**	**Mail**
Contact details are available from the corresponding author on reasonable request and with permission of all involved institutions.			

Table 3: Contact Details of Data Protection Officers and Supervisory Authorities		
Projectpartner	**Data Protection Officers**	**Supervisory Authorities**
Contact details are available from the corresponding author on reasonable request and with permission of all involved institutions.		

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For further information please contact:
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Tel.: XXX - XXXXX-XXX
Mail: ines.xy@providerxy.de

To: Provider XY
Steet XY
00000 City

Participant-ID _____

Last name, first name _____
Date of Birth _____

Provider _____

Date _____

Health insurance ☐ AOK BY ☐ AOK NW ☐ IKK classic ☐ TK

Consent Form

for a clinical trial to investigate risk of falling, fear of falling, and the benefits of a smart home emergency call system [intelligente Notfallerkennungssysteme (INES)] in individuals aged 70 and older[1]

Consent to participation, data collection, data processing, and evaluation within the model project: "INES - Efficient Initiation of Emergency Interventions Using Smart Home Emergency Call Systems for Older Adults Living Alone"

1 DECLARATION OF PARTICIPATION

I hereby declare my consent to participate in the presented model project and its scientific evaluation. I have been informed about the model project's content, the scientific evaluation, and the data processing. **I provide this declaration voluntarily.** I have received and understood the information provided in this document and the "Information for Participants". I have had sufficient time to review these materials, ask questions, and I agree with the content.

2 CONSENT TO DATA PROCESSING

Consent to the documentation of claims data, as well as survey data. Legal basis for the data collection, processing, and storage is §92a Abs. 1 S. 3 SGB V in conjunction with § 284 Abs. 1 S. 8, 9 SGB V, Article 6(1)(a) EU-GDPR, and Article 9(2)(a) EU-GDPR. I have received the data protection information as outlined in the "Information for Participants" document, understood its contents, and consent to the described procedures.

Consent to data transmission for the evaluation

I agree to the scientific evaluation and the associated data processing as described, in pseudonymized form. I provide this declaration voluntarily. The evaluation will be conducted as explained to me and as detailed in the "Information for Participants" document, which I have received.

I consent to the transmission of my data as outlined in the "Information for Participants" document. My statutory health insurance will transmit my personal data, claims data, the home emergency call system provider will provide deployment data, and Bielefeld University will supply my survey data. These data will be pseudonymized before being sent to the trust center (OFFIS).

OFFIS will consolidate the pseudonymized data and assign a new pseudonym before transmitting the dataset to the evaluating institute (Bielefeld University). The legal basis for processing the claims data by the statutory health insurance is § 67c Abs. 2 Nr. 2 SGB X.

3 WITHDRAWAL

I may withdraw my participation and my consent to data processing at any time, without providing any reasons, in written form, verbally, or electronically by contacting my home emergency call provider (see contact details above).

The withdrawal does not affect the lawfulness of data processing carried out prior to my withdrawal based on my previous consent. Withdrawing my consent will result in immediate exclusion from the model project and further participation will no longer be possible.

_____

Date, signature of participant

[1]Funded by the Innovation Fund of the German Federal Joint Committee in accordance with § 92a Paragraph 1 SGB V under the project title: "INES - Efficient Initiation of Emergency Interventions Using Smart Home Emergency Call Systems for Older Adults Living Alone"; Grant Number: 01NVF21102

[2]Pseudonymization refers to the processing of personal data in such a way that the data can no longer be attributed to a specific individual without the use of additional information. These additional details must be stored separately and subject to technical and organizational measures that ensure the personal data is not linked to an identified or identifiable natural person (Article 4(5) EU General Data Protection Regulation (GDPR)).

For further information please contact:
Provider xy
Tel.: XXX – XXXXX–XXX
Mail: ines.xy@provider.de

Participant-ID

Consent Form

For telephone contact as part of my participation in the scientific study on risk of falling, fear of falling, and the benefits of smart home emergency call systems (INES) for individuals aged 70 and older[1]

I hereby declare

Last name	First name	Date of birth	Health insurance
Street	No.	ZIP code	City

my consent to be contacted by the telemedicine center of Ife Gesundheits-GmbH via telephone as part of my participation in the above-mentioned study. The purpose of this telephone contact is to conduct a telephone interview to assess a potential increased risk of falling.

I have been informed about the study details, data protection regulations, and data processing procedures. I have received and understood the "Information for Participants" document. I have had sufficient time to review this information and agree with its contents. I provide this declaration voluntarily.

I consent to the following:

1. Being contacted by the telemedicine center by telephone.
2. The telemedicine center collecting my data (as outlined in table 1 of the "Information for Participants") and, if a fall risk is identified, transmitting the results of the telephone interview in pseudonymized form to Bielefeld University.
3. The telemedicine center collecting my data (as outlined in table 1 of the "Information on Participants") and, if a fall risk is identified, transmitting the results of the telephone interview in pseudonymized form to the home emergency call provider with which I have enrolled in the study.

Please contact me at the following telephone number: _____

I am best reachable at the following times:

Day of the week:_____ Time:_____

Day of the week:_____ Time:_____

WITHDRAWAL

I have the right to withdraw my consent for participation and data processing at any time, without providing reasons, in written form, verbally, or electronically. Additionally, I may request the deletion of my data.

Place, Date Signature of particpant

[1]Funded by the Innovation Fund of the German Federal Joint Committee in accordance with § 92a Paragraph 1 SGB V under the project title: "INES – Efficient Initiation of Emergency Interventions Using Smart Home Emergency Call Systems for Older Adults Living Alone"; Grant Number: 01NVF21102