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Assessing the effectiveness and cost-effectiveness of a smart home emergency call system: study protocol for a randomised controlled trial in Germany

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ABSTRACT

Introduction Falls can lead to serious health-related consequences in the older population. If an emergency occurs within the home environment of an older person living alone, the initiation of emergency care can be delayed, leading to even worse outcomes for this population. Smart home emergency call systems (HECSs) can detect falls and automatically trigger an emergency alarm, potentially reducing time to emergency care and improving outcomes. The INES (Intelligentes NotfallErkennungsSystem—smart emergency detection system) study is a prospective randomised controlled trial conducted in three German federal states that aims to investigate the effectiveness and cost-effectiveness of a smart HECS.

Methods and analysis Following a telephone interview, individuals aged 70 years or older, living alone, at risk of falling and willing to participate are included in the study. Participants are assigned to one of two groups depending on their previous use of a HECS. Based on the sample size calculation, the study aims to recruit n=498 participants already using a standard HECS (group A) and n=1378 participants who have not used a HECS before (group B). Within both groups, participants are randomised into the intervention arm (IA) and control arm (CA). The IA receives a smart HECS during the 21-month follow-up period. In addition to a standard HECS with a base station and a wearable radio transmitter, the smart HECS includes sensors that can detect falls and automatically trigger an alarm. The primary outcome assessed will be the days spent in the hospital after an emergency admission. Secondary outcomes include the utilisation of healthcare services and their total costs, progression of care dependency, fear of falling (Falls Efficacy Scale—International), health-related quality of life (EQ-5D-5L) and well-being (ICEpop CAPability measure for Older people).

Ethics and dissemination The design and conceptualisation of the INES study were approved by the ethics committee of the Hamburg Medical Association on 26 June 2023 (2023-101032-BO-ff). Results of the INES study will be published in peer-reviewed articles.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ First randomised controlled trial to evaluate the effectiveness and cost-effectiveness of smart home emergency call systems in Germany.
⇒ Multicentre trial with centres in three different German regions.
⇒ Findings could support health policy decision-makers.
⇒ Study is not blinded due to feasibility reasons.

Trial registration number Deutsches Register Klinischer Studien, German Clinical Trials Register DRKS00031408. Registered on 28 June 2023.

INTRODUCTION

In Germany, approximately 1.8 million people experience fall accidents annually. Among those aged 65 years and older (65+), the majority of these accidents (54.3%) occur at home.[1] At the same time, the number of single-person households in the German general population has increased by 46% since 1991, with more than one-fifth of the whole population now living alone.[2] Additionally, the number of people aged 65+ has increased by 6.7 million since 1991.[3] These demographic shifts have resulted in over 6 million people aged 65+ living alone in Germany in 2023.[4] When older individuals living alone experience an emergency, such as a fall at home, they may be unable to call for help. In this case, emergency care can only be initiated after the person is discovered by neighbours, family members or other caregivers. The amount of fall-related injuries that require hospitalisation increases with age and affects approximately one-third (33.7%) of the German population aged 65+.[1] Delays

in initiating an emergency call are associated with a greater risk of health-related complications.[5 6]

Common injuries from falls include head and neck trauma, sprains or tears in muscles, ligaments and tendons,[7 8] as well as fractures. Especially fractures of the hip or femoral neck are associated with morbidity and mortality.[8 9] Besides physical impairments, fear of falling is a frequent consequence leading to avoidance of physical activity, which in turn causes or exacerbates a decline in muscle strength and mobility and a reduction in social activities. This is accompanied by a reduced health-related quality of life (HRQoL), mood disorders, social isolation and an increased risk of recurrent falls.[10 11] Current research indicates that these recurrent falls often result in hospital readmissions and increased utilisation of healthcare services, thereby placing a significant burden on healthcare systems.[12]

The increasing number of people living alone and the ageing population emphasise the relevance of developing care concepts tailored to these demographics. In light of demographic shifts and the severe consequences of falls, innovative approaches are needed to support seniors living alone to remain in their familiar environment. Therefore, age-appropriate assistive technologies (ambient assisted living, AAL) offer the potential to reduce the need for assistance for the older population and enable them to live at home independently.[13]

One example of AAL is home emergency call systems (HECSs). Standard HECSs consist of a wearable radio transmitter with an emergency button and a base station. If a person experiences an emergency at home and presses the emergency button, a voice connection to the emergency staff of the HECS provider is established through the base station. The situation is assessed, and emergency personnel are alerted to provide further care if needed.[14] HECSs contribute to enhancing the sense of security and extending the time a person is able to live at home independently[15] while also reducing the length of stay following a hospital admission and improving the quality of life.[16] Standard HECSs require a high level of user compliance, as the wearables need to be worn at all times to initiate an emergency call.[17] Studies show that in certain situations that are potentially prone to accidents (eg, in the shower or at night), wearables are often not worn.[15] Even when the wearable is worn during an emergency, people often do not use it due to confusion or because they are simply unable to do so.[17]

In addition to regular HECSs, smart HECSs have cameras or sensors, either wearable or non-wearable, that can detect falls and automatically initiate an emergency call.[18] Especially those systems using non-wearable sensors help mitigate the problem of low user compliance. There is an extensive body of literature on technological research on this type of fall detection; however, there is a lack of clinical trials evaluating these technologies.[18] A study indicates that smart HECSs are perceived as useful for individuals with mild cognitive impairment or dementia, as well as for their caregivers. However, a delay in nursing home admission or a reduction in the care needed could not be shown.[19] Furthermore, findings on other potential benefits, such as a reduction in fear of falling or hospitalisation rates, remain inconclusive in the existing literature.[18] A feasibility study has also highlighted the challenges of installing a reliable smart HECSs in real-world homes, which differ significantly from laboratory conditions. These findings underscore the lack of evidence from clinical trials and field studies.[20]

Despite the growing interest in smart HECSs, the effectiveness and cost-effectiveness of smart HECSs have not yet been evaluated in a randomised controlled trial (RCT).

METHODS

Objectives

The primary objective of this study is to evaluate the effectiveness of INES (Intelligentes NotfallErkennungsSystem—smart emergency detection system), a smart HECS technology. The use of an INES is hypothesised to result in a faster initiation of emergency care for older individuals who experience falls at home, thereby reducing the health-related consequences of emergency events. Specifically, it is expected that the use of an INES will lead to a reduction in the length of hospital stay after emergency admission compared with a standard HECS. Further objectives of this study encompass the evaluation of the development of healthcare service utilisation, HRQoL, well-being, fear of falling, progression of care dependency and the cost-effectiveness of the intervention.

Study setting and trial design

4 SHIs (statutory health insurances) and 4 HECS providers are participating in the study, situated in three German federal states (Bavaria, Hamburg and North Rhine-Westphalia). The INES study is a prospective RCT consisting of two groups. Group A comprises participants with a pre-existing standard HECS, whereas participants in group B are not prior users of a HECS. Group A aims to compare the new form of care using an INES with the current standard of care using a standard HECS to demonstrate the benefits of adding an INES to standard care (treatment as usual (TAU)=standard HECS). Group B aims to compare the new form of care using INES with the standard care without a HECS. The results of group B are therefore useful for determining whether participants who did not have a HECS before (TAU=no HECS) can benefit from an INES system. Both groups are independent of each other, and within each group, participants will be randomly assigned to the intervention arm (IA) or control arm (CA) using stratified block randomisation, aiming for an equal size of both arms. The participating HECS providers are used as strata. Participants randomised into the IA receive an INES for 21 months, while participants in the CA do not receive any intervention. The intervention period begins on 1 August 2023 and ends on 28 February 2026. The relatively long

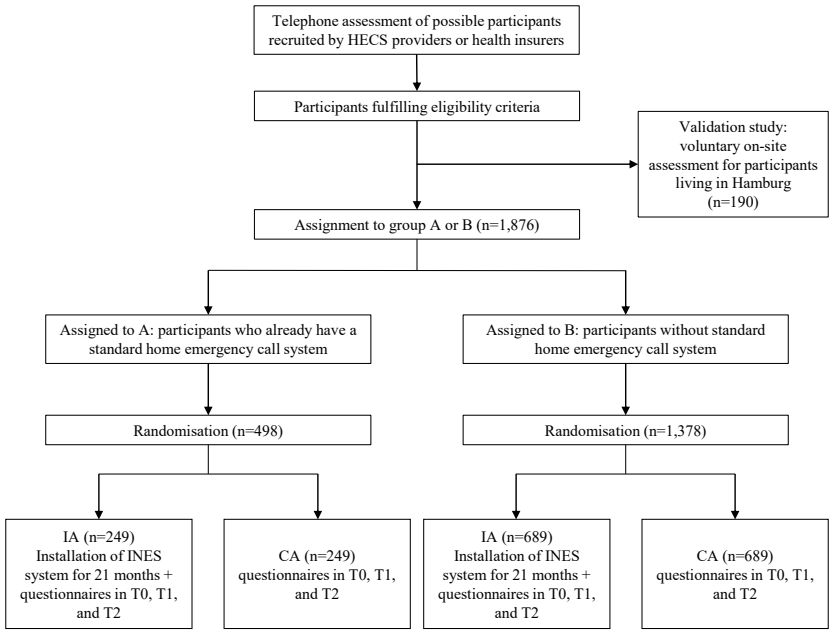

Figure 1 Participant timeline. A figure showing the course of the study for participants in groups A and B for both study arms (IA and CA). CA, control arm; HECS, home emergency call system; IA, intervention arm; INES, Intelligentes NotfallErkennungsSystem.

follow-up period of 21 months has been chosen based on the average number of emergency calls the HECS providers are receiving. This ensures capturing a sufficient number of emergency events to include in the data analysis. All participants (IA and CA) are asked to fill out questionnaires at study inclusion (T0), after 12 months (T1) and 21 months (T2), as shown in figure 1.

Eligibility criteria and recruitment

The study population comprises individuals insured by participating health insurers, aged at least 70 years and living alone. Sheltered or assisted living arrangements are not considered inpatient care facilities and are therefore not a reason for exclusion. A further criterion is an elevated risk of falling, determined through a telephone interview carried out by trained medical staff. The telephone interview will include the 12-item Stay Independent Questionnaire, as recommended by the US Centers for Disease Control and Prevention in their accident prevention campaign, Stopping Elderly Accidents, Death and Injuries.[21] A score of 4 or higher on the questionnaire indicates an increased risk of falling. Additionally, individuals who score below 4 but report having experienced at least one fall in the past 12 months are also classified as having an increased risk. In order to validate the questionnaire's use, participants of the Hamburg region will be invited to attend a geriatric evaluation, including medical history, medication use and a geriatric assessment. Mobility will be assessed using the Short Physical Performance Battery[22 23] and the Timed Up and Go Test.[24] Details on this subpart of the project will be published elsewhere.

Additionally, participants must live in one of the three above-mentioned federal states. Further inclusion and exclusion criteria are listed in table 1.

Recruitment begins on 1 July 2023 and concludes on 31 March 2024. Recruitment for group A is carried out by the HECS providers contacting their existing customers who use standard HECSs. For group B, participating health insurers contact those customers who may be eligible for enrolment in the study and refer those who are interested in participating in the study to the corresponding regional HECS provider. Potential participants receive additional information and a declaration of consent from their HECS provider, which needs to be signed prior to enrolment. The participant consent form can be found in online supplemental materials 1 and 2.

Intervention

Participants allocated to the IA receive an INES from the designated HECS provider. An INES comprises three key components: (1) a base station and a corresponding radio transmitter incorporated in a wristband, (2) smart fall sensors and (3) a voice-panic detector (VPD). The base station establishes connectivity between the home environment and the emergency call centre of the HECS provider. The stationary fall sensors can detect falls through radar technology and a

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Groups A and B	
► 70 years and older. ► Living alone in the target region. ► Increased risk of falling, assessed by a telephone interview. ► Written consent for the study.	► Living in an inpatient care facility. ► No increased risk of falling. ► No legally valid consent to participate in the study (possible). ► Insufficient knowledge of the German language. ► Not insured with one of the participating health insurers. ► Requirements of the home environment not met (eg, larger pets).
Group A	
► Provision of standard HECS by one of the participating providers (self-payer/covered by care insurance).	
Group B	
► No previous provision of standard HECS.	

A list of all inclusion and exclusion criteria for participants in groups A and B of the study.
HECS, home emergency call system.

machine learning-based algorithm. The VPD is an additional device serving as an audio and voice extension. It is equipped with a pull cord, an emergency button and a voice detector capable of initiating an emergency call by voice command. The main advantages of an INES compared with a standard HECS include the ability to detect falls and trigger an emergency call, even in scenarios where the individual is not wearing the wristband or is unable to activate the emergency button, alongside continuous availability for use and the ability to distinguish between humans and smaller animals (see exclusion criteria, table 1).

The following criteria are defined for the successful installation of an INES:

1. Standard configuration: a base station, a wristband, an average of five sensors in the defined rooms (living room, bedroom, bathroom, hallway and kitchen) and a VPD.
2. Modified configuration (if site-specific conditions at home do not permit a standard configuration): a base station, a wristband, an average of five sensors in at least three of the five defined rooms (living room, bedroom, bathroom, hallway and kitchen) and a VPD.

The predefined five rooms are covered as comprehensively as possible with the available sensors (maximum of eight and an average of five sensors per participant). A modified configuration will be implemented if on-site conditions do not allow for the standard configuration (eg, the floorplan of an apartment does not contain all defined rooms or has very small rooms). In individual cases, it may be useful to equip additional rooms that are frequently used. Any deviations from the standard configuration are in accordance with the aforementioned criteria, ensuring sensor placement in at least three of the five defined rooms, with a maximum of eight sensors and an average of five sensors per participant. Documentation of individual participant equipment is ensured by the HECS providers.

If an emergency call is triggered by an INES, a voice connection between the participant's home and the emergency call centre is established to assess the necessity of on-site assistance. If required, emergency personnel from the HECS provider are alerted and proceed to the participant's home. After an on-site assessment, the emergency personnel initiates appropriate measures and alert emergency services if needed. To ensure quick access to the participant's home in emergency cases, the HECS providers safely store a spare key for the front door.

Outcomes

Primary outcome

Hospital length of stay after emergency admission

The primary outcome is defined as the average hospital length of stay in days following an emergency admission. This measure is derived from SHI claims data. The underlying hypothesis (H_1) posits that the mean hospital length of stay after an emergency admission is reduced among participants of the IA (π_i), due to the use of an INES, compared with participants of the CA (π_c). The corresponding null hypothesis (H_0) posits that the mean hospital length of stay after an emergency admission in the IA is greater than or equal to that in the CA.

$$H_0: \ \pi_i \geq \pi_c$$
$$H_1: \ \pi_i < \pi_c$$

Secondary outcomes

Secondary outcomes aimed at providing supplementary insights into the effectiveness of an INES are outlined below. For patient-reported outcomes, such as fear of falling, HRQoL and well-being, standardised instruments available in the German language and suitable for the study population are used. An overview of the instruments

Table 2 Enrolment, intervention and assessment schedule of the INES study

	Study period				
			Postallocation		
Timepoint	Enrolment	Allocation	At study inclusion (T0)	12 months after inclusion (T1)	21 months after inclusion (T2)
Enrolment:					
Consent	X				
Telephone interview	X				
Allocation		X			
Interventions:					
INES (IA)			◆—	—	—◆
Assessments:					
Fear of falling (FES-I)[25 26]			X	X	X
HRQoL (*EQ-5D-5L*)[27]			X	X	X
Well-being (ICECAP-O)[28]			X	X	X

Overview of the time schedule for the enrolment, intervention and assessments carried out during the course of the study. This table refers to item 13 of the SPIRIT checklist.
FES-I, Falls Efficacy Scale—International; HRQoL, health-related quality of life; IA, intervention arm; ICECAP-O, ICEpop CAPability measure for Older people; INES, Intelligentes NotfallErkennungsSystem; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials.

used and the timing of the assessments is presented in table 2.

Fear of falling

Assessment of the outcome is conducted at three points in time using the Falls Efficacy Scale—International (FES-I). The FES-I consists of 16 items measuring concerns associated with various activities and falls.[25 26]

HRQoL and well-being

These outcomes are measured at three points in time for all participants using the EQ-5D-5L and ICEpop CAPability measure for Older people (ICECAP-O). The EQ-5D-5L is a generic questionnaire to measure HRQoL. The instrument comprises five dimensions with five response levels and is supplemented by the EQ Visual Analogue Scale.[27] ICECAP-O is used to measure capability in older people for economic evaluations with a focus on measuring well-being rather than health.[28]

Utilisation of healthcare services after hospital discharge

This outcome is determined based on SHI claims data, including information on inpatient and outpatient services, pharmaceuticals, remedies and aids and inpatient and outpatient rehabilitation, among others.

Total cost of healthcare utilisation

This outcome is determined based on SHI claims data. Healthcare resource utilisation and total healthcare costs are evaluated for both the IA and CA over the 21-month follow-up period. Costs for the intervention are also assessed for the IA.

Progression of care dependency

Progression of care dependency is defined as at least one initial application for a level of nursing care or an application for an upgrade to a higher level. The outcome is determined across all participants over the entire follow-up period.

Sample size and randomisation

G*Power (V.3.1.9.7) was used to estimate sample sizes and perform a power analysis.[29] Given the differentiation into two distinct groups, separate calculations of sample sizes were necessary. Due to a lack of evidence regarding the effects of INES on hospital length of stay after an emergency admission and similar outcomes, the calculation of the sample size was based on a preliminary analysis of claims data from a participating health insurer. This analysis indicated that insured individuals aged 70 years and above, using a standard HECS and presumably living alone, exhibit an average hospital length of stay of 9.5 days after emergency admission. However, the number of potential participants in both groups is constrained by the number of telephone interviews that could be conducted rather than solely by the number of eligible individuals identified in the claims data. Therefore, sample size estimation is based on assumptions about the effect size (Cohen's d). Assuming an effect size of d=0.25 and a power of 80%, a sample size for group A of 398 is required. For group B,

a lower effect size of d=0.15 is assumed. With a power of 80%, the calculated sample size is 1102. Accounting for an anticipated dropout rate of 20% in both groups, a final sample size of 498 for group A and 1378 for group B was determined.

Participants from both groups will independently be randomised into the IA or CA. In the randomisation process, groups A and B are block-randomised, stratified by each HECS provider, with blocks of sizes 2, 4 and 6 being randomly selected multiple times. This approach mitigates the impact of potential recruitment problems on the success of randomisation. The evaluating institute conducts the randomisation process and forwards the results to the HECS providers. Since the randomisation process is carried out at an independent institute, it is ensured that all individuals involved in the enrolment of participants and implementation of the intervention have no ability to influence the randomisation process or predict its outcomes. An automated process was employed to read in reported ID numbers from newly included participants after telephone assessment on a weekly basis, followed by an automated assignment of ID numbers to the next available appropriate list positions based on group and HECS provider specifications. Randomisation is carried out using the statistical software R (V.4.2.1)[30] with the additional package 'blockrand'.[31]

Data collection and management

Primary data are collected using paper-based surveys. To enhance retention in the CA over the 21-month follow-up period, participants receive a €25 reimbursement per survey. This incentive is aimed at compensating CA participants for being excluded from receiving an INES. Reminders are sent to participants if the surveys are not returned within 4 weeks. Claims data will be provided by the participating SHIs, while the HECS providers supply deployment data from the smart HECSs. To control for adverse effects, these data contain information on all initiated alarms, including reasons and actions taken for each alarm.

Data collection, analysis and storage are carried out in compliance with relevant data protection regulations. An independent trust centre is responsible for consolidating data from various sources (primary data, claims data from health insurers and deployment data from HECS providers) before the pseudonymised data are forwarded to the evaluating institute to prevent the identification of individual participants. To further ensure data security, all data will be encrypted. Access to the final dataset is limited to the trust centre and the evaluating institute.

Data analysis

Data analysis is conducted based on the aforementioned outcomes obtained from the collected data employing an intention-to-treat approach. Therefore, data from all participants who provided consent and did not withdraw will be evaluated according to their initial group assignment. Analyses will be performed separately for both groups. The descriptive analysis incorporates absolute and relative frequencies of participants' baseline characteristics and outcomes alongside measures of central tendencies and dispersion (eg, median, variance and SD). Following the descriptive analyses, further statistical analyses are performed to analyse primary and secondary outcomes. Potential mean differences between IA and CA with regard to the primary outcome are analysed using appropriate statistical methods (eg, t-test). Depending on the properties of the primary outcome, corresponding regression models (eg, generalised linear models) are estimated. This allows for the consideration of covariates (eg, age, morbidity and, if applicable, parameters from deployment data from the HECS providers). Model quality will be evaluated through residual analysis. SHI claims data from the 12 months preceding the follow-up period will be included in the analysis. It is assumed that the primary outcome will include a substantial number of zero counts, as most participants will not experience an emergency admission and will not be hospitalised. Given these properties of the primary outcome, an appropriate 2-stage regression model (eg, Hurdle model[32 33]) will be employed. Those models enable the separate modelling of the probabilities of hospitalisation following an emergency admission in the first stage and the days spent in hospital for all participants who experience an emergency admission in the second stage.

For the health economic evaluation, healthcare resource utilisation and the total costs of healthcare services for IA and CA will be considered. Additionally, intervention costs are considered for the IA. If the intervention is found to be beneficial but more expensive than TAU, the incremental cost-effectiveness ratio will be calculated. Sensitivity analyses are carried out to assess the robustness of the evaluation and the assumptions made.

The latest version of the open source software R (with suitable extension packages) will be used for statistical data processing and analysis. The analysis of SHI claims data is conducted according to the Good Practice of Secondary Data Analysis guidelines,[34] the recommendations of the Memorandum on Methods for Health Services Research[35] and the standards of the German Society for Evaluation.[36]

Ethics and dissemination

The conceptualisation was approved by the ethics committee of the Hamburg Medical Association on June 26, 2023 (2023–101032-BO-ff). Ethical considerations, including participant consent, data protection and study integrity, have been carefully addressed to ensure compliance with relevant regulations. Results of the INES study will be disseminated through peer-reviewed publications and conference presentations to contribute to the existing body of literature on smart HECSs and their impact on health outcomes.

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination of this study. This is mostly due to financial and organisational constraints and is one of the limitations of the study.

Harms

The intervention is not expected to cause any major harm to the participants. Participants in the IA receive a detailed explanation of the INES, with a particular focus on the VPD and the sensors. The sensors do not record any personal data, pictures or sounds, and consent to participate in the study can be withdrawn at any time, resulting in the deinstallation of the INES systems in the IA.

In the event of a false alarm, the situation can be clarified via the voice connection with the emergency personnel from the HECS providers without any further costs or disadvantages for the participants. If sensors fail to detect a fall, emergency calls will not be triggered automatically. In this case, an emergency call needs to be made manually, as it would be the case without a HECS.

DISCUSSION

Falls and comparable accidents occurring at home are significant health concerns for older people living alone. With an ageing population and a rising number of single-person households, there is a growing need for new approaches that enable individuals to remain in their own homes for as long as possible. Smart HECSs represent one promising solution in providing improved care for this population. To the best of our knowledge, this is the first RCT evaluating the effectiveness and cost-effectiveness of smart HECSs in Germany. While research on the underlying technologies of sensor-based fall detection is extensive, evidence from clinical trials on smart HECSs' impact on health outcomes and cost-effectiveness remains scarce. This study aims to address this gap by generating evidence on whether these smart systems are superior compared with standard HECSs or no HECSs in reducing the hospital length of stay after emergency admission in the older population at risk of falling.

One limitation of our study is the lack of blinding of HECS providers and participants. This may introduce bias as HECS provider staff can influence subsequent care decisions following an emergency call. Blinding of the participants was not possible for ethical reasons, as non-functioning smart HECSs could lead to a false sense of security in case of emergency. Furthermore, the study did not include patient and public involvement in its design and conduction, which could have provided valuable insights from the target population's perspective.

If the usage of smart HECSs proves to be beneficial, integration into SHI coverage may be pursued. By generating new evidence on the effectiveness and cost-effectiveness of smart HECSs, this trial could support decision-makers in the process, ensuring broader access. The results of this study are not only useful for the German healthcare system but will also be valuable for other countries with a comparable demographic profile facing similar challenges within the healthcare system caused by the ageing population.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Hamburg Medical Association (2023-101032-BO-ff). Participants gave informed consent to participate in the study before taking part. The conceptualisation and design of the INES study were approved by the ethics committee of the Hamburg Medical Association on 26 June 2023 (2023–101032-BO-ff). Ethical considerations, including participant consent, data protection and study integrity, have been carefully addressed to ensure compliance with relevant regulations. Results of the INES study will be disseminated through peer-reviewed publications and conference presentations to contribute to the existing body of literature on smart HECSs and their impact on health outcomes.

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