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Empowering healthy lifestyle behaviour through personalised intervention portfolios using a healthy lifestyle recommender system to prevent and control obesity in older adults: pilot study protocols from the HealthyW8 project

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ABSTRACT

Introduction Obesity prevalence has increased globally, imposing a significant burden on individuals and societies. Innovative solutions are, therefore, essential to mitigate its impact.

Methods and analysis This protocol outlines the framework of seven independent European pilot studies conducted in Bulgaria, Germany, Luxembourg and Spain, under the EU-Horizon HealthyW8 project. These studies aim to evaluate as primary outcomes feasibility, usage patterns (adherence) and user satisfaction of the Healthy Lifestyle Recommender System (HLRS), a personalised digital tool designed to promote healthy lifestyles through tailored physical activity and meal recommendations, considering emotional aspects. The seven pilot trials will collectively include 240 (around 30 participants/trial) older adults (≥65 years) with overweight (body mass index (BMI) 25.0–29.9 kg/m^2) over a 3-month period. As a recruitment mitigation strategy, we will extend the age range to include individuals aged ≥55 years and those with normal weight (BMI 18.5–24.9 kg/m^2). Other parameters collected include anthropometric measurements, questionnaires to survey lifestyle (alcohol and tobacco consumption, sleep quality), dietary patterns (food frequency questionnaire and 24-hour recall) and emotional well-being, as well as data collected from wearable devices (smartwatch, accelerometer) to track 24-hour activity patterns. Additionally, two pilot studies will collect blood, urine, saliva (only one partner) and stool samples to explore biomarkers of inflammation, oxidative stress, gut microbiome and circulating miRNAs.

Expected outcomes It is hypothesised that participants will use the HLRS consistently enough to assess its feasibility and impact. The findings will contribute to planning and executing long-term trials focused on health outcomes and enhance understanding of the multimodal nature of obesity risk and its comorbidities. This protocol facilitates comparisons across studies in diverse cultural and contextual settings, offering insights into how personal

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Innovative eHealth strategy: the study aims to improve health behaviours by using mobile apps with nudges and gamification features to increase user engagement.
⇒ Broader health impact assessment: the usability and adherence of the Healthy Lifestyle Recommender Solution system in older adults across four European countries will be assessed, while examining multiple obesity-related risk factors, including diet, physical activity and inflammation.
⇒ Comprehensive health monitoring: it combines novel biomarkers (eg, salivary proteomics, gut microbiota, microRNAs) with conventional methods (eg, clinical analysis, diet and physical activity) to evaluate the effects of the intervention.
⇒ Methodological variation: while the execution of the pilot studies varies and is adapted to specific contexts and countries, the methodological assumptions, target population characteristics and core questionnaires are harmonised across all trials.
⇒ Study limitations and mitigations: although the study lacks a control group, rigorous design and transparent reporting minimise bias and enhance the validity of the findings.

and environmental factors influence the implementation and effectiveness of the HLRS.

Ethics and dissemination Ethical approval has been obtained in each country independently. Dissemination efforts will prioritise high-impact journal publications.

Trial registration number NCT07011368.

INTRODUCTION

The demographic transition has led to a significant increase in the older adult population, which is expected to rise by 21% globally by 2050.[1] This poses a major public health challenge due to the growing burden of non-communicable diseases (NCDs), comorbidities and increasing healthcare costs.[2 3] A major concern among older adults is obesity, that is, excessive fat deposits that impair health (body mass index (BMI) ≥30 kg/m^2).[4] In Europe, approximately one in five adults over 60 years suffers from obesity.[5] High prevalence rates have been reported in Southern Europe, including Spain (40.1% in women and 32.5% in men aged ≥65 years)[6] and Portugal (39.2% among adults aged 65–84 years).[7]

Obesity is associated with cardiovascular disorders (eg, stroke, coronary disease and hypertension), type 2 diabetes mellitus,[8–10] reduced physical activity (PA) and function, lower quality of life and increased disability and nursing home admissions.[11] Several factors contribute to obesity risk, including poor eating habits, reduced caloric needs and physical inactivity.[11] However, body composition, especially visceral body fat, is also critical.[12] Persons with adequate body weight but with abdominal obesity (≥88 cm for women and ≥102 cm for men), or a high waist-to-hip ratio (>0.85 for women and >0.90 for men) may be at increased risk for frailty, including disability, falls, fractures, hospitalisation and death.[13] Additionally, sarcopenic obesity, characterised by high BMI combined with a decline in skeletal muscle mass and strength, is a risk factor for cardiovascular and metabolic diseases,[14–16] with a global prevalence of 11% in 2021.[14]

Regarding nutrition, older adults face challenges, including reduced food intake and appetite, malabsorption, impaired sensory perception (taste, smell and vision), and difficulties with swallowing and digestion.[17] Barriers to improving diet quality include established food behaviours,[18] emotional imbalances,[19] limited financial resources,[20] food insecurity, cultural factors,[21 22] social isolation and low food literacy.[23] Effective nutritional interventions include nutrition education and counselling by qualified dietitians, promotion of healthy dietary patterns and encouragement of nutrient-dense foods such as pulses, vegetables, fruits, nuts, whole grains and low-glycaemic index foods.[24]

PA levels among older adults are often below recommendations.[25] The WHO recommends >150 min/week of moderate-intensity aerobic activity, along with muscle-strengthening exercises on two or more days to enhance cardiorespiratory and muscular fitness.[26] Regular PA improves mental health, sleep quality, muscle mass and energy expenditure, thereby reducing the risk of obesity and NCDs.[27] When developing PA interventions for older adults, key considerations include promoting social interactions (sharing the experience with others), emphasising the benefits of PA, minimising time and financial burden and choosing familiar and accessible locations.[28] Walking is a particularly suitable activity, as it is affordable, accessible and easily integrated by promoting device-assisted walking or pedometer-based interventions.[29]

eHealth interventions represent a promising strategy to overcome barriers and facilitate implementation proposals aimed at improving diet and PA. These interventions offer scalable, cost-effective and personalised solutions.[30 31] Digital technologies, such as web applications, wearable devices and mobile health (mHealth) applications, can promote healthier lifestyles through personalised recommendations, goal setting, nudging/gamification and monitoring.[32] When combined with lifestyle interventions, digital technologies have shown positive effects in older adults, including increased PA, prevention of muscle mass loss, reduced fat intake, enhanced fruit and vegetable consumption and improvements in body weight, fasting plasma glucose and lipid profile.[33] However, the success and cost-effectiveness of digital public health interventions depend on understanding users' health priorities and acceptance of these technologies.[34] Barriers to adoption include sociodemographic factors (low education) and economic factors (low income) as well as health-related factors, such as impaired vision, hearing loss, motor and cognitive deficits,[35] and broader life circumstances.[36] Though numerous digital obesity prevention apps are available, many have important limitations, including (a) time-consuming food logging/monitoring requirements; (b) unsuitability for older adults unfamiliar with mobile apps; (c) limited focus on either diet or PA (moderate-to-vigorous intensity); (d) lack of consideration of cultural, socioeconomic, environment contexts; (e) insufficient long-term engagement features such as nudging; (f) and inadequate integration of psychological and emotional aspects.[37 38]

This background has inspired the creation of several pan-European projects funded by the EU Horizon Calls (https://cordis.europa.eu/project/id/101080645), including the HealthyW8 project.[39] HealthyW8 aims to implement a recently developed Healthy Lifestyle Recommender Solution (HLRS), a digital intervention integrating mobile applications to address diet, PA, psychological and behavioural aspects, sleep and emotional well-being. The HLRS was developed through scoping and systematic reviews[40 41] and participatory design workshops conducted across nine EU countries,[42 43] ensuring personalised interventions. A key strength of HealthyW8 is its approach to overcoming current eHealth limitations by engaging individuals with low motivation for healthy lifestyles through nudges and gamification strategies. The intervention is based on the Health Action Process Approach, which distinguishes motivational and volitional phases of behaviour change[44] and supports

tailored feedback, goal setting and self-monitoring. The HLRS aims to enhance both initiation and maintenance of healthy behaviours.

The project also incorporates novel biomarkers to assess intervention effects and obesity risk, including salivary proteomics,[45 46] gut microbiota[47] and microRNAs,[48] alongside conventional endpoints such as blood plasma[49] and dietary assessment through questionnaires.[50–52] The HealthyW8 pilot studies aim to establish a comprehensive framework for addressing obesity and related comorbidities. This article describes the combined protocols designed to evaluate, as primary objectives, the feasibility, usage patterns (adherence) and user satisfaction with the HLRS among older adults across four European countries. Secondary objectives include assessing the feasibility of collecting data on obesity-related risk factors, including diet, PA, anthropometry, smoking status, sleep patterns, microbiota composition, oxidative stress and inflammatory status.

METHODS AND ANALYSIS

Study design

The pilot studies will be prospective, single-arm trials, with a 3-month intervention period in 2025/2026. However, future adaptation may incorporate a waitlist control group or historical comparison to enhance causal inference.

Each study will include either 30 or 60 older adults, depending on the country, and a total of 240 participants (table 1). These studies will be conducted in Bulgaria (Sofia and Varna), Germany (Bremen), Luxembourg (Strassen) and Spain (Barcelona, Zaragoza and Palma de Mallorca); all trials are registered under NCT07011368. The study designs will be similar across countries, with slight modifications to account for local contexts. The sponsors (responsible institutions) of the studies will be the local coordinators in each country, and the studies are funded by the European Union's Horizon Europe

Table 1 Recruitment strategies for countries participating in the HealthyW8 older adults' trials, as well as for coordinating entities

Country and entity	Number of participants targeted for enrolment	Number of participants required for study conclusion	Recruitment strategies	Coordinating entity	Medical principal investigator *
Bulgaria, RCNE	30	20	Using the network of the Regional Cluster North-East (RCNE), word of mouth	RCNE	No
Bulgaria, Virtech	30	20	Cascade enrolment—via proxy institutions: schools and networks	Virtech	No
Germany, BIPS	30	15	Word of mouth, flyer, press release, Instagram	Bremer Institute for Prevention Research (BIPS)	No
Luxembourg, LIH	30	20	Word of mouth, newspaper advertisement, flyers, physician involvement and social media	Clinical and Epidemiological Investigation Center (CIEC)	Yes
Spain, CITA	60†	25	Word of mouth, newspaper advertisement, flyers and physician involvement	Agro-Food Technological Center of Aragon (CITA)	No
Spain, CREDA	30	20	Using the network of the Regional Senior Classrooms as university extension programmes tailored to individuals aged 65 and above‡	Center for Research in Agro-Food Economy and Development (CREDA)	No
Spain, IDISBA	30	20	Word of mouth, newspaper advertisement, flyers, physicians and other healthcare professionals.	Balearic Islands Ethics Committee (CEIm-IB)	Yes

*Medical principal investigator refers to the presence of a physician responsible for the safety of the study participants.
†A larger number of persons will be included in the control group.
‡Recruitment was conducted through the established network of Aulas Senior, university extension programmes where older adults regularly participate in educational and cultural activities on UPC (Universidad Politécnica de Cataluña) campuses.
IDISBA, Health Research Institute of the Balearic Islands; LIH, Luxembourg Institute of Health.

Research and Innovation Programme (grant agreement no. 101080645). All participating partners have received ethical approval and follow the data protection regulations applicable in their country.

Recruitment

Recruitment at some sites started in early 2025. However, the initiation of recruitment differed across pilot studies due to variations in the timing of ethical approvals. If the recruitment window is insufficient to meet the target enrolment or if the dropout rate is high, the period may be extended until the targeted number of participants is reached. The different recruitment methods are described in table 1. Interested candidates can register by phone, email or regular mail. Study staff will contact the registered candidates to provide a brief overview of the project, schedule an appointment for an information session and send a copy of the 'participants' information sheet'. This will allow candidates to review the study details and experimental procedures before signing the informed consent. The Luxembourg Institute of Health's (LIH) informed consent was added in online supplemental material (Ethical Information Notice). Participants will receive a copy of their signed informed consent and the study protocol.

Participants, inclusion and exclusion criteria

Participants must meet the following inclusion criteria: older adults (≥65 years), being male or female, residing in the locations where trials will be conducted, having overweight (BMI 25.0–29.9 kg/m^2), willingness to participate in the study, and owning a smartphone and basic abilities to use mobile applications. In contrast, exclusion criteria will include chronic diseases such as cancer and Parkinson's disease as well as other conditions requiring specific treatments or significantly altering normal physiology (eg, metabolism). Also, individuals with cognitive diseases, such as Alzheimer's, or those unable to live independently, will be excluded, as they may struggle to handle the HLRS tools and applications. Individuals on a specific diet (eg, a vegan or low-carbohydrate diet) will not be eligible for the study due to potential incompatibility with the study's dietary recommendations. Populations with compromised ability to provide voluntary informed consent, including prisoners and individuals with severe mental disabilities, will likewise be excluded. Besides, to ensure the feasibility of the intervention tasks, participants with significant mobility impairments or conditions that preclude participation in moderate PA (eg, severe arthritis, recent fractures) will be excluded.

However, individuals being treated for type 2 diabetes, high blood pressure or elevated blood lipids (triglycerides, cholesterol) will be included. This is to ensure realistic recruitment feasibility, as a significant proportion of older adults experience these complications and are treated for them.

Withdrawal/discontinuation of participants

Participants may withdraw from the study at any time without providing a reason or facing negative consequences. Additional reasons for withdrawing may include:

a. Ineligibility: participants who no longer meet the inclusion criteria or develop health conditions (eg, acute illness).
b. Adverse events: events compromising participants' health, as determined by the (medical) principal investigator (PI); we will continue to monitor for any adverse events and participants will be able to report such events at all times during the study.
c. Non-compliance: consistent failure to adhere to study protocols or procedures.
d. Lost to follow-up: inability to contact participants or repeated failure to attend scheduled visits.
e. Medical PI or (if not required in trial) PI decision: withdrawal based on safety concerns, protocol violations or other considerations decided by the (medical) PI. In addition, a medical professional or institutional medical services will be consulted to address any adverse effect or medical emergency. These decisions will be taken after evaluating baseline or mid-point data.

Data from participants who withdraw or discontinue the study will be included in the analysis, as their reasons for discontinuation may provide valuable insights into whether the cause was related to the HLRS or other factors.

If the dropout or discontinuation rate exceeds 10%, additional participants will be recruited to ensure that at least 15–25 participants complete the study, depending on the country.

Patient and public involvement

The HLRS functionalities were developed through participatory design workshops to ensure interventions aligned with older adults' needs and socioeconomic context. The workshops were conducted at each institution, with a pilot study involving the general population, including older adults, and experts in the field of public health.[42]

Intervention with the HLRS

The intervention period will last at least 6 weeks and up to 3 months. However, not all participants will begin the intervention simultaneously, which will extend the total study duration to up to 9 months to allow participants to complete the intervention phase (table 2). The intervention has been collaboratively developed within the HealthyW8 consortium, alongside international healthcare professionals, to address the specific needs of older adults. The intervention includes the use of the HLRS, a comprehensive eHealth solution developed by the HealthyW8 consortium. The HLRS currently includes the following components: the Nutrida-app, GameBus and a Calendar function, a screenshot of the HLRS applications is provided in online supplemental figure 1.

- The nutrida application: it provides weekly meal plans tailored to the user's preferences, allowing

Table 2 Devices and apps used for the intervention studies, tools involved and endpoints assessed

Country	Length of intervention (months)	Maximum length of run-in time	Nutrida-App and GameBus	Calendar function app	Accelerometer device	Smartwatch device	Biological samples
Bulgaria, RCNE	3	6	Yes	Yes	Yes	Garmin	No*
Bulgaria, Virtech	3	5	Yes	Yes	Yes	Garmin	No
Germany, BIPS	3	6	Yes	No	No	Samsung	No
Luxembourg, LIH	3	6	Yes	Yes	Yes	Garmin	Yes
Spain, CITA	3	6	Yes	No	No	Garmin	No
Spain, CREDA	3	3	Yes	Yes	Yes	Garmin	No
Spain, IDISBA	3	3	Yes	Yes	Yes	Garmin	Yes

All studies administered questionnaires to assess user satisfaction and lifestyle behaviours.
*Certain institutions lack facilities for biological sample collection, and budget limitations restrict access to accelerometers for physical activity assessment.
BIPS, Bremer Institute for Prevention Research; CITA, Agro-Food Technological Center of Aragon; CREDA, Center for Research in Agro-Food Economy and Development; IDISBA, Health Research Institute of the Balearic Islands; LIH, Luxembourg Institute of Health; RCNE, Regional Cluster North-East.

participants to choose dietary options based on factors such as dietary preferences, allergies and cooking skills. Participants will have access to typical recipes from the country, using local ingredients, translated into their own language(s). This meal recommender system is based on the previous Active Assisted Living (AAL) project, LIFANA[53] and has been further developed into the Nutrida app, owned by NIUM (Esch-sur-Alzette, Luxembourg). The development involved a collaboration between the Luxembourg Institute of Science and Technology (LIST) and the European Federation of the Association of Dieticians, which integrated country-specific recipes into the app.

- GameBus is a gamified web platform designed to promote healthy lifestyle behaviours, such as PA (eg, walking and step counting), diet (eg, increasing consumption of fruits and vegetables and increasing water intake) and social participation (eg, engaging in cultural activities). Gamification refers to the use of motivational techniques that employ game-like elements (eg, earning points, unlocking levels or competing on leaderboards) to motivate users to engage in target behaviours through enjoyable experiences.[54] For example, users can earn points for walking 5000 steps in a day or for logging their fruit intake. The platform is highly configurable, allowing organisers from each pilot study to create tailored 'campaigns', a structured set of tasks, challenges and game-like elements based on the target population's needs and interests (such as nutrition, PA, sleeping and mental health). In this project, each participating country has developed its own campaign setup based on insights and data collected from cocreation workshops with older adults (described in the Patient and public involvement section). The app was developed by the Technical University of Eindhoven, a HealthyW8 consortium partner.[54 55] GameBus serves as a prototype health data management platform that facilitates engagement through mHealth platforms. It offers a closed-source Java/Spring-based REST API, an open-source web app frontend (built with Ionic) and a restricted smartwatch frontend.
- A calendar web application: developed by EU HealthyW8 partner VirTech (Sofia, Bulgaria) that allows a study leader to schedule local events and inform participants about events (social and sport events) they may be participating in. Data will be stored on servers provided by VirTech in Bulgaria.

Regarding the wearable device, participants will use either the Samsung Galaxy Active 2 smartwatches (galaxy-watch-active2); or the Garmin Vivosmart 5 (Garmin vivosmart 5|Fitness Activity Tracker) to assess their 24-hour movement behaviour, total step count, calories burned and heart rate and variability as well as derived stress levels. Both devices comply with General Data Protection Regulation (GDPR) requirements[56] and ensure data protection. The final device selection will depend on specific study requirements, as both options collect similar data.

At the baseline visit, participants will receive a smartwatch (Garmin or Samsung), a user account for the various apps and a study-specific password, which will allow them to access GameBus, the Nutrida app and the Calendar (the same user account will be used for all). Participants will install (download) the Nutrida app on their smartphones from the Google Play Store or Apple App Store (available only in countries participating in the HealthyW8 project). Then, they will have to create a shortcut to the GameBus website on their phones to access it. The Calendar can be accessed through GameBus (participants will see a link that opens the Calendar website). If necessary, participants will receive assistance from a staff member to install all the apps.

Participants with a Garmin smartwatch will install the HealthyW8 Watch app (from Google Play Store), which collects data from the Garmin smartwatches (such as step counts, calories burnt, heart rate and stress score) via Bluetooth and transfers it to GameBus servers at TU/e. Participants with the Samsung watch connect directly to GameBus. GameBus enables participants to earn points or complete tasks by achieving a specific number of steps per day with smartwatches. GameBus and Nutrida are also linked, allowing participants to create meal plans and earn points for this task on GameBus.

Also, the Calendar app is part of the HLRS and will likewise be linked to GameBus, enabling the earning of points for joining local proposed cultural events or organised trainings by, eg, sporting clubs. Participants will also have optional access to the Open Stakeholders Platform of the HealthyW8 project, a website that provides free online supplemental information on healthy living[57] and serves as a data and information-sharing hub for stakeholders involved in obesity prevention.

Older adults will receive a workshop or individualised guidance from study personnel during the baseline visit to explain the installation of all applications on their smartphones and to provide brief instructions on how to log in and begin using the apps. In addition, participants will receive user manuals and videos to support app use after the baseline visit. If any questions or technical issues arise during the study, participants will be able to contact the study personnel by phone, WhatsApp or email.

CREDA will offer ongoing monitoring via on-demand WhatsApp check-ins by trained staff when inactivity or technical issues are detected, and brief in-person check-ins every 2 weeks during regular Senior Classroom sessions to troubleshoot HLRS/devices and identify any adverse events early.

Assessments

The pilot studies can include four phases (table 3): enrolment (day-x), baseline (day 0), mid-point (day 45 for a 3-month intervention) and final visits (day 90 for a 3-month intervention), as illustrated in figure 1. Germany and Spain (Zaragoza) will conduct enrolment, baseline and final measurements, while Bulgaria (Sofia and Varna), Luxembourg and Spain (Mallorca) will include all four phases, including the mid-term visits.

The study phases are described as follows:

a. Enrolment visit (day-x): participants will receive written and oral information about the study's objectives, risks and benefits before signing the informed consent and data notice form. Participant eligibility will be evaluated based on anthropometric measurements (additionally in Luxembourg: urine spot test (eg, Kosmetex Urine Test Strips)) combined with a general health and lifestyle questionnaire. Participants who meet the inclusion and exclusion criteria will receive further information about the study's procedures.
b. Baseline visit (day 0). During this visit, participants will complete several questionnaires (outlined in Table 4, with the assistance of study staff (especially in those assessing diet). Trained personnel will collect anthropometric data, and a nurse will obtain biological samples (blood, urine, saliva and stool). Stool samples may be provided during the visit or shipped later. Additionally, countries (except for BIPS and CITA) will provide an accelerometer (ActiGraph GT3X+, Pensacola, Florida, USA) to be used during the first week of the intervention. Participants will also receive instructions on using the developed HLRS.
c. Intermediate follow-up (day 45): this will involve a brief phone interview or an in-person meeting, depending

Table 3 Study design—commonalities and differences

Country, entity	Enrolment visit with urine test	PA measure before baseline	Baseline assessment	Mid-term visit (phone or in-person)	PA before the final meeting	Final meeting at the end of the study
Bulgaria, RCNE	No	Yes	Yes	Yes	Yes	Yes
Bulgaria, Virtech	No	Yes	Yes	Yes	Yes	Yes
Germany, BIPS	No	Yes (IPAQ questionnaire)	Yes	Weekly/biweekly meetings	Yes (IPAQ)	Yes
Luxembourg, LIH	Yes	No, it will be provided at baseline	Yes	Yes	Yes	Yes
Spain, CITA	No	No	Yes	Weekly/biweekly meetings	No	Yes
Spain, CREDA	No	Yes	Yes	Yes	Yes	Yes
Spain, IDISBA	No	Yes	Yes	Yes	Yes	Yes

Regular weekly or biweekly meetings to monitor the Healthy Lifestyle Recommender System (apps and wearables) usage and manage challenges and participant difficulties.
BIPS, Bremer Institute for Prevention Research; CITA, Agro-Food Technological Center of Aragon; CREDA, Center for Research in Agro-Food Economy and Development; IDISBA, Health Research Institute of the Balearic Islands; IPAQ, International Physical Activity Questionnaire; LIH, Luxembourg Institute of Health; PA, physical activity; RCNE, Regional Cluster North-East.

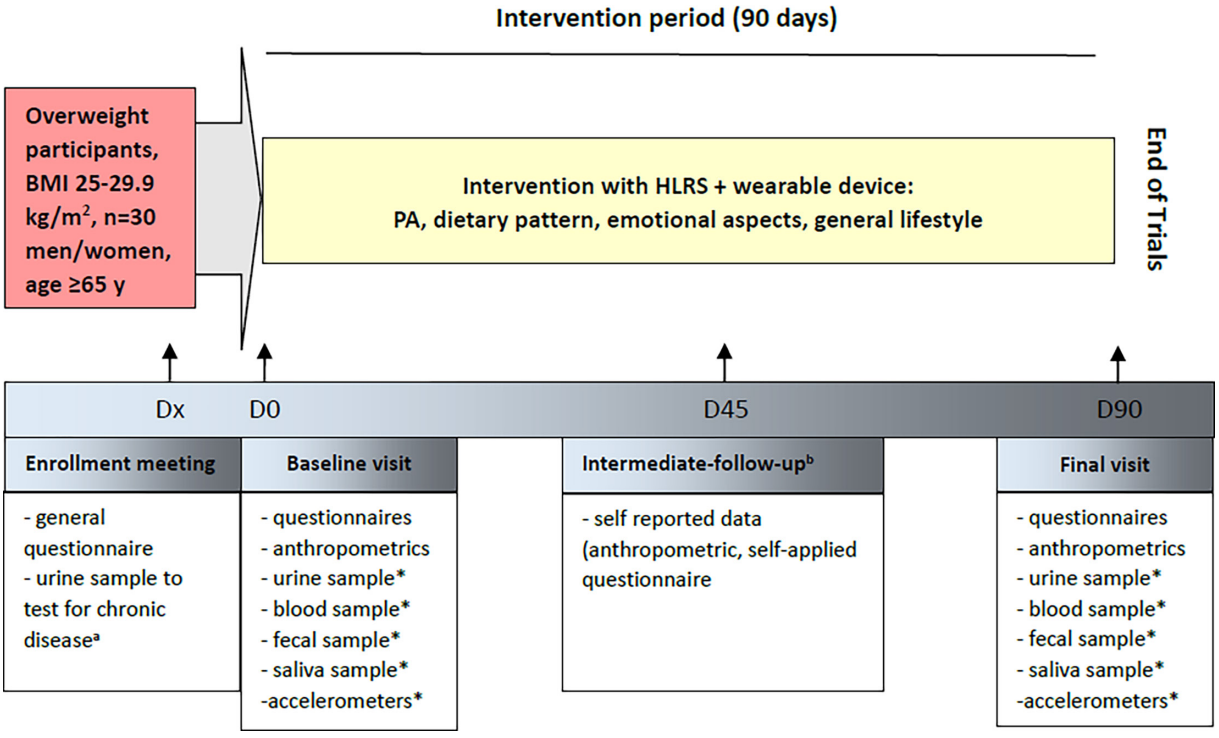

Figure 1 Overview of the trial design and data and sample collection—example for Luxembourg. [a]University of the Balearic Islands (IDISBA) will not collect this sample. [b]BIPS and CITA will have intermediate meetings with participants on a 1 or 2 week basis to improve adherence to the HLRS and to reduce the possibility of any malfunctions of the HLRS. *Not collected by all partners. BMI, body mass index; BIPS, Bremer Institute for Prevention Research; CITA, Agro-Food Technological Center of Aragon; HLRS, Healthy Lifestyle Recommender System; IDISBA, Health Research Institute of the Balearic Islands; PA, physical activity.

on the participant's preference, to complete specific questionnaires.

d. Final visit (day 90): the same measurements and questionnaires from the baseline visit will be repeated.

Outcomes

Primary outcomes are feasibility, usage patterns (adherence) and user satisfaction. Feasibility will be interpreted with respect to drop-outs, ability to collect all targeted data from questionnaires, anthropometric data and also biological samples. Adherence will be assessed through adherence metrics, such as the frequency of use (measured as time per day and week) or number of logins. Satisfaction with the overall design and user-friendliness will be assessed by the User Experience Questionnaire (UEQ+, 26 items) and the usability test (Short Questionnaire for gathering feedback on the HealthyW8 intervention strategies and tools functionalities), which will be included at mid-term or final visit to evaluate the likelihood of sustained HLRS use. This will help assess the potential for long-term adoption beyond the study period.

Secondary outcomes target the examination of obesity-related changes during the 3-month intervention, as detailed in table 4. The collected data will provide insights into the feasibility of collecting and implementing these measures in planned long-term studies to assess healthier lifestyle patterns. Furthermore, the study will examine whether the overall design is suitable for the participants, with the aim of fostering improvements in their lifestyles.

Data collection

Questionnaires

Validated questionnaires adapted to the specific characteristics and needs of older adults are used to ensure the reliability and relevance of the data collected. Standardised, widely accepted protocols are used for data collection, intervention delivery and outcome assessment, promoting consistency and reducing variability. For dietary data, the developed and standardised food frequency questionnaire with 129 items will be compared and validated against a 3-day, 24-hour recall method to ensure accuracy.

Biomarker analysis from plasma, urine and stool

Accredited laboratories in each country will conduct most of the clinical analyses. Additional analyses, including assessment of markers of oxidative stress and inflammation, will be conducted using commercial ELISA kits according to the manufacturer's recommendations. Stool samples collected during the pilot studies will be sent to the LIH for 16S rRNA sequencing to analyse the microbiome composition. DNA will be extracted from faecal samples using DNA extraction kits. For each participant, the V4 region of the 16S rRNA genes will be amplified

Table 4 Measures included in the 3-month pilot studies

Marker class	Marker	Bulgaria, RCNE	Bulgaria, Virtech	Germany, BIPS	Luxembourg, LIH	Spain, CITA	Spain, CREDA	Spain, IDISBA
Anthropometrics	Height, weight, BMI	Yes	Yes	No	Yes	Yes	Yes	Yes
	Waist and hip circumference and ratio	No	No	No	Yes	No	Yes	Yes
	%body fat	No	No	No	Yes	No	Yes	Yes
	Visceral fat	No	No	No	Yes	No	Yes	Yes
	Thigh circumference	No	No	No	Yes	No	Yes	Yes
Clinical	Pulse/heart rate variability	No	No	No	Yes	No	Yes	Yes
	Blood pressure (systolic and diastolic)	No	No	No	Yes	No	Yes	Yes
PA	Accelerometer	Yes	Yes	No	Yes	No	Yes	Yes
	IPAQ	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fitness	Hand grip strength, step-up test	No	No	No	Yes	No	No	No
Dietary patterns	FFQ	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	24 hours recall	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Mediterranean eating patterns (MEDAS-14)*	No	No	No	Yes	Yes	No	No
General questionnaires	Baseline questionnaires	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Quality of life (WHOQOL-Bref (26 items))*	Yes	Yes	Yes	Yes	No	Yes	Yes
	Depression (PHQ-9 (9 items))*	Yes	No	Yes	Yes	No	Yes	Yes
	Mood/emotion (PANAS)*	No	No	No	Yes	No	No	No
	Psychological hardiness (DRS-15)*	No	No	No	Yes	No	No	No
	Sleeping patterns (eg, Pittsburgh Sleep Quality Index)*	No	No	No	Yes	No	Yes	Yes
	Intrinsic motivation (IMI (7 items))*	Yes	Yes	No	Yes	Yes	Yes	Yes
	Smoking (Fagerstrom (6 items))*	No	No	Yes	Yes	No	No	No
	Alcohol intake (Audit (10 items))*	No	No	Yes	Yes	No	No	No
	Personality traits (BFI-10 scale (10 items))*	Yes	Yes	No	Yes	Yes	Yes	Yes
Biomarkers, inflammation	Cytokines (adiponectin, TNF-α, IL6, IL1-β, CRP†	No	No	No	Yes	No	No	Yes
Biomarkers, oxidative stress	F2- isoprostanes, malondialdehyde, DNA/RNA breakdown products, antioxidant activity (FRAP, ABTS, MDA)	No	No	No	Yes	No	No	Yes
Biomarkers of nutrient intakes	Vitamin E, blood cell counts†, carotenoids‡, microalbuminuria†, vitamin D, albumin†, prealbumin†,	No	No	No	Yes	No	No	Yes

Continued

Table 4 Continued

Marker class	Marker	Bulgaria, RCNE	Bulgaria, Virtech	Germany, BIPS	Luxembourg, LIH	Spain, CITA	Spain, CREDA	Spain, IDISBA
Glucose metabolism	HbA1c and fasting blood glucose, insulin, HOMA-IR	No	No	No	Yes	No	No	Yes
Lipid profile	Total cholesterol, HDL-C, LDL-C, triglycerides	No	No	No	Yes	No	No	Yes
Urinary markers	Uric acid†, urinary creatinine†, urinary sodium†,	No	No	No	Yes	No	No	Yes
Saliva	Cortisol	No	No	No	No	No	No	Yes
Stool	16S rRNA	No	No	No	Yes	No	No	No
HLRS	Nutrida-app: personalised meal recommender plan (based on age, gender, PA, dietary restrictions, culinary/ cultural personal preferences and local dishes, budget…)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	GameBus: promotes a healthy lifestyle through games and tasks linked to Nutrida and smartwatches.	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Smartwatch: to register step count, pulse and sleep quality	Yes	Yes	Yes	Yes	No	Yes	Yes
	Calendar function to schedule social events for the participants	Yes	Yes	Yes	Yes	No	No	No
	UEQ+ (26 items)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Open Stakeholder Platform	Health-video clips, recipes, lifestyle recommendations	No	No	Yes	Yes	No	Yes	Yes

*Self-applied questionnaires.
†Measured by a commercial accredited laboratory (ie, Laboratoires Réunis at Luxembourg).
‡Assessed by a partner in the US (North Carolina State University, Department of Molecular and Structural Biochemistry).
ABTS, 2,2′-Azino-bis(3-ethylbenzothiazoline-6-sulfonic acid); BFI-10, Big Five Inventory (10 items); BMI, body mass index; CRP, C-reactive Protein; DRS-15, Dispositional Resilience Scale (15-item); FFQ, food frequency questionnaire; FRAP, Ferric Reducing Antioxidant Power; HbA1c, Glycated Hemoglobin; HDL-C, High-Density Lipoprotein Cholesterol; HLRS, Healthy Lifestyle Recommender System; HOMA-IR, Homeostatic Model Assessment of Insulin Resistance; IDISBA, Health Research Institute of the Balearic Islands; IL, Interleukin; LDL-C, Low-Density Lipoprotein Cholesterol; LIH, Luxembourg Institute of Health; MDA, Malondialdehyde; MEDAS-14, Mediterranean Diet Adherence Screener (14-item); PA, physical activity; PANAS, Positive and Negative Affect Schedule; PHQ-9, Patient Health Questionnaire (9-items); TNF, Tumor Necrosis Factor; UEQ, User Experience Questionnaire; WHOQOL-Bref, World Health Organization Quality of Life – Brief Version.

by PCR using designed primers. Also, total miRNAs will be extracted from blood to assess the feasibility of using these in future long-term trials as potential markers of weight and metabolic changes.

All analyses will be performed by trained technicians to ensure precision and reliability. Samples will be stored locally, and no secondary usage is envisioned.

Case report forms

An electronic Case Report Form (eCRF) has been designed and developed using REDCap (Research Electronic Data Capture, Vanderbilt University, USA) to collect study data and ensure data quality, integrity and security. The eCRF will allow data to be stored across partners in a central database located at the LIH. All eCRF items will be completed by designated, trained staff on site. eCRFs will be reviewed and electronically locked by the medical Principal Investigators (PIs) or delegates. All eCRF data will be pseudonymised (identification numbers only), and the correspondence tables will be maintained by staff enrolling participants on site, physically separated from the eCRF clinical data in REDCap.

The eCRF clinical data will be electronically completed by each partner's site, and questionnaires/surveys will be entered by participants in the REDCap system, either remotely or together with trained personnel. All REDCap data (from eCRF, questionnaires and biological sample analyses) will be stored on secure LIH servers, and LIH's Department of Medical Informatics will manage access to the data. In the event of an adverse event, only the staff on site enrolling patients will be able to access participants' data in non-pseudonymised form, in addition to the (medical) PI. In case of a preference for traditional paper-based surveys, data may be collected from participants and later transferred to the RedCap system.

Sample size

An accurate sample size estimation for feasibility studies, especially when rather qualitative outcomes are measured as in this study, may not be feasible; instead, a recent guidance document[58] has suggested that sample 'size should be based on practical considerations including participant flow, budgetary constraints and the number of participants needed to evaluate feasibility goals reasonably', also emphasising that 30 or less could be a meaningful goal for qualitative work. In the present study, we target a sample size of 30, with an anticipated maximum dropout rate of 33%. Approximately equal numbers of men and women will be recruited to enable the generalisability of results across genders.

Assuring adherence to the intervention

The mHealth solution, that is, the HLRS, was developed with nudging and gamification elements to foster adherence. These adherence-promoting features include personalised reminders, adaptive goal setting, real-time feedback, motivational prompts and gamification elements such as scoreboards, among others. These mechanisms are designed to reinforce engagement and support sustained behaviour change. Participants will be contacted by email or telephone when a participant has not initiated use of the app, in order to address potential technical issues or to provide login credentials if necessary. Participants will also receive, if they wish, at the end of the studies, a brief review interpretation of their health condition. Participants will also be able to continue the HLRS (with a new account) and may keep the smartwatch.

Strategies for achieving adequate participant enrolment

Each country coordinator has ample experience conducting human trials and will advertise locally through their networks, including websites, flyers and advertisements at physicians' offices. Should the recruitment rate remain low despite all efforts, BMI will be extended to normal weight (18.50–24.99 kg/m^2), and the age category will be extended to include anyone 55 years of age or older. Such changes, as any other major changes to the study design, may be subjected to ethical review, depending on the local ethical review board's rules.

Data analysis

Missing data and dropouts

Missing data will not be imputed in these studies. Participants who drop out will be excluded from analyses beyond their last available data point. To preserve the study's sample size, participants who leave will be replaced until at least 20 persons have finalised the study. This will ensure adequate exposure to the intervention and to test operational procedures, not to estimate intervention effects.

All dropouts and replacements will be fully documented, including timing and reasons for withdrawal. Feasibility outcomes (eg, recruitment and retention) will be reported based on the original enrolled cohort, with replacement participants analysed separately. Participants who withdraw will remain classified as dropouts for all feasibility outcomes, ensuring retention and adherence reflect true acceptability. Replacement will occur only when a dropout happens early before completing key study visits or minimum intervention exposure and only to secure enough completers for secondary outcomes. Replacement cases will not be included in feasibility indicators. This approach preserves feasibility validity while maintaining adequate sample size for secondary analyses.

Methods for minimising bias

Explicit inclusion and exclusion criteria are established to ensure minimising the risk of including participants who could introduce bias. Strategies to minimise attrition include maintaining regular contact with participants via phone and addressing barriers to participation to preserve the integrity of the study sample. For example, at LIH, study nurses will contact participants by email or telephone when it is identified that a participant has not initiated use of the app, to solve any potential technical issues or including password credentials.

Data monitoring and quality assurance procedures are implemented to ensure the accuracy and reliability of the collected data. While the study lacks a control group, efforts are made to reduce bias by thoughtful study design and transparent reporting.

Analyses

Descriptive statistics will summarise baseline characteristics and provide an overview of the initial distributions of variables. Normality of continuous data will be assessed using Q-Q plots and the Kolmogorov-Smirnov test. If the data are not normally distributed, non-parametric analysis (Friedman tests followed by t-tests) will be performed, with log-transformations as needed.

For the primary outcomes, we will compare feasibility, adherence and user satisfaction as explained in the chapter 'outcomes' over time or during the time of data collection (baseline, mid and endpoint). To this end, linear mixed models will be set up, with adherence and user satisfaction related as dependent variables and participant and time as independent fixed factors. Potentially, other relevant variables, such as BMI, age and gender, will be included in further refined models. In addition, a more qualitative questionnaire developed by the consortium will be completed after 6 weeks of use to assess usability features. P values below 0.05 (two-sided) will be considered statistically significant. All analyses will be performed using IBM SPSS (Statistical Package for the Social Sciences) Statistics, V.29.0 (IBM, Armonk, New York) and R (V.4.4.1) for mixed effects models. For theory-driven path analyses, we will use partial least squares structural equation modelling (PLS SEM) to examine hypothesised relationships among psychosocial constructs and adherence/usability outcomes; this will be implemented with SmartPLS 4 or equivalent PLS SEM software (eg, seminr/ plspm in R). Primary analyses will also be conducted on a pooled individual participant dataset, with country/site included as a factor (fixed effect) and participant as a random effect in linear or generalised linear mixed effects models to account for clustering and to quantify heterogeneity (site×time interactions). Each site will generate local descriptive summaries and perform predefined Quality Control checks; pooled modelling and PLS SEM will be run centrally.

Secondary analyses

Secondary outcomes include anthropometric measurements, multiple biomarkers, questionnaires to assess lifestyle quality, dietary patterns, emotional well-being and PA, in part assessed by wearable devices (a smartwatch and an accelerometer) to track 24-hour activity patterns. These analyses will include regression models and are expected to produce estimates that will be used to set up ensuing larger-scale trials in the near future. Advanced statistical techniques such as propensity score matching or instrumental variable analysis may be employed to address confounding and potential biases.

Exploratory analyses

To ensure a comprehensive analysis of transcriptomics (miRNA) and faecal 16S rRNA data in the context of the obesity intervention, the data will first undergo preprocessing to handle missing values and outliers and undergo normalisation to ensure data quality and comparability. Subsequently, exploratory data analysis techniques are employed to gain insights into the data's characteristics and to identify patterns and relationships. Statistical tests are then applied to each dataset: in transcriptomics, differential expression analysis techniques such as DESeq2 or edgeR can identify dysregulated microRNAs associated with obesity, and in faecal 16S rRNA, alpha or beta diversity indices and statistical tests such as t-tests or analysis of variance (ANOVA) can quantify and compare diversity levels. Multiple testing correction methods are employed to control false positives.

ETHICS AND DISSEMINATION

Statements of compliance

The research teams are responsible for ensuring that the study will be conducted in compliance with the presented protocol, good clinical practices, the internal quality management system and the ethical principles outlined in the Declaration of Helsinki. The study will adhere to the local health authority's regulatory and legal requirements. Authorisation from the relevant local ethics committees has been obtained for the pilot studies. For Bulgaria, the approval (registration number: 07032025) for the pilot in Sofia was obtained from the Ethics Committee at the Sofia Knowledge City Cluster, and for Varna (registration number: 19.09.2025 r) was from the Ethics Committee of the Regional Cluster North-East. Germany had the ethics vote from the University of Bremen Ethics Committee (registration number: Aktenzeichen 2024–22), The National Research Ethics Committee for Luxembourg (registration number: 202411/04). Finally, in Spain, two institutions received approval from the Balearic Islands Ethics Committee (CEIm-IB) (IDISBA: IB 5752/25 PI and CREDA: 2025/01), and in Aragon, the Ethics Committee for Research Involving Human Beings (CEISH) of CITA (registration number: CEISH_2024_9) is responsible for experiments without clinical studies involving biomarkers. All studies are subjected to audits by the local authorities and could be either announced or unannounced.

Risks and benefits

At the end of the study, participants who complete their participation can continue using the HLRS features on their mobile phones at their own risk. There are potential risks associated with the HLRS, such as the possibility of hacking the participant's account, which could compromise the confidentiality of health and personal data. However, this risk is considered low, and precautions are in place to minimise it.

The risks associated with this study protocol for older adults are considered minimal. Only peripheral blood

draws may cause mild discomfort or bruising, as no other invasive procedures will be performed. Any participant experiencing significant adverse or unexpected medical issues (eg, severe allergic reaction or high fever) will be withdrawn from the study. Similarly, participants showing emotional or psychological problems requiring professional intervention will be advised to seek treatment and will be withdrawn from the study if necessary.

All adverse events must be reported immediately to the PI of each team within 24 hours of occurrence, who will include these events in the annual report submitted to the local ethics committees. All project partners will secure an insurance policy in accordance with local regulations to provide coverage for any injuries or damage that may occur during the clinical study.

Data handling and storage

Data protection

All analyses will be conducted on pseudonymised data by the EU Consortium HealthyW8. All project partners will jointly own the shared data (acting as joint controllers). Participants' data will be protected according to regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (GDPR) and of the Act of 1 August 2018 on the organisation of the National Data Protection Commission and the general data protection framework, particularly articles 63 to 65 of said Act. An extra insurance will be set up for each participant during the study duration covering unforeseen events such as accidents. Participants have the right to inspect, correct errors or restrict processing of their data as well as the right to data portability according to the conditions foreseen in articles 15 to 21 of the GDPR. Participants may request that their samples and collected data at the LIH be destroyed at any time up to 10 years after the end of the study by contacting the medical PIs, sponsors or their delegates, who will notify the researcher of the request, and all unused samples will be destroyed.

Data and sample storage

All partners take appropriate security measures, based on the sensitivity of the information concerned, to protect the participants' data from the risk of unauthorised access, loss, fraudulent use, disclosure, modification and destruction.

The verification of the eCRF data will be done by directly inspecting source documents. Standard procedures will be used in all steps of the data collection to ensure standardisation, data quality and data integrity.

Data from the Samsung smartwatches and GameBus will be stored on the GameBus server provided by the University of Eindhoven, the Netherlands, our consortium partner in charge of the GameBus application, on local and safe servers. Data from Nutrida will be stored on a server provided by our consortium partner NIUM in the EU (Amazon servers). Data from the calendar application will be stored in a database on a server provided by LIST in Luxembourg. Regarding data from Garmin smartwatches, it will be stored directly on the device. Biological samples will be stored at local premises in appropriately cooled storage conditions. Data originating from sample analysis will be stored in secure folders in the LIH cloud, requiring a two-stage permission procedure. Data will be stored in accordance with applicable legal provisions and in a manner that allows participants to be identified for a pre-specified period, eg, 10 years, following the last visit of the last participant included in the study. After this period, the table linking participants' identities to the other data will be deleted, which means that data collected for the purpose of the study will be anonymised. Then, partners will continue to process the data for research purposes for a period of 5 years following their anonymisation.

PUBLICATION AND DISSEMINATION

The EU consortium HealthyW8 will implement a comprehensive open science policy throughout the research cycle, ensuring transparency, inclusivity and accessibility. By involving diverse end-users and stakeholders and employing participatory approaches, HealthyW8 aims to enhance bias control and goal-oriented knowledge generation. Open science practices will be applied across study design, data collection and analysis, with a commitment to Gold Open Access for publications and research data, which will be anonymised if required. Outputs will be archived in OpenAIRE-compliant repositories, such as Zenodo, to support reproducibility. Additional practices include open peer review, preprint sharing and regular ORCID updates. The consortium also aims to make health and nutrition resources openly accessible, including recipe content under a Creative Commons licence and will integrate open-source tools to encourage the adoption of open standards.

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