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Promoting healthier lifestyles and preventing chronic diseases in underserved urban communities across Europe

Submission date
12/06/2025

Recruitment status
Recruiting

Registration date
04/08/2025

Overall study status
Ongoing

Last Edited
04/08/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to develop pilot interventions in three European countries (Croatia, the Netherlands and Spain) to promote behaviour change towards healthier lifestyles and to support citizens in making optimal use of the urban environment they live in while reducing risk behaviours related to chronic diseases, including type 2 diabetes and cardiovascular diseases. In comparison with 'usual activities of citizens', the HORUS concept is expected to achieve more favourable outcomes for low-income populations, migrants and ethnic minorities. This study aims to examine the effectiveness and implementation of HORUS in three large-scale pilots in Europe, including Rijeka (Croatia), Rotterdam (the Netherlands), and Valencia (Spain).

Who can participate?
Adults aged 18 years and older living in the participating areas

What does the study involve?
Each pilot site will design an intervention pathway based on the HORUS concept for the target population. The intervention will be supported by a mobile application (i.e., the Wakamola app) designed for citizen engagement. With informed consent, health or social care professionals will have access to a monitoring dashboard to track participant progress over time.
Data will be collected in pilot sites at inclusion (at the start of the HORUS intervention) and after 9 months to assess the benefits of the HORUS concept versus continuation of usual activities. Information on indicators of lifestyle behaviour, motivation, self-efficacy, health outcomes, use of the urban environment, and sense of belonging will be collected. In addition, the acceptability, appropriateness, feasibility, adoption, penetration, implementation costs, and sustainability of HORUS will be measured.

What are the possible benefits and risks of participating?
By participating in this study, individuals contribute to the development and evaluation of community-based prevention programs aimed at promoting healthier lifestyles and reducing the risk of chronic diseases such as type 2 diabetes and cardiovascular conditions. Participants in the intervention group may benefit from personalized support, including motivational interviewing,

tailored health plans, and digital tools, to improve their nutrition, physical activity, and overall well-being. The intervention is designed with a particular focus on addressing the needs of low-income individuals, migrants, and ethnic minorities, and aims to support better use of local urban environments for health promotion.
As this is a non-invasive study, no significant risks for participants are foreseen.

Where is the study run from?
Universitat de Valencia (Spain)

When is the study starting and how long is it expected to run for?
July 2025 to June 2026

Who is the main contact?
The European HORUS study:
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The Netherlands: Esmée Bally, PhD; e.bally@erasmusmc.nl
Croatia: Vanja Vasiljev, PhD; vanjav@medri.uniri.hr
Spain: Susana Rovira Llopis, PhD; susana.rovira@fisabio.es

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Horizon Europe Grant Agreement number 101136516

Study information

Scientific Title
Health Outcomes from Raised Urban Settings (HORUS): a preventive community-based program to promote healthier lifestyles and prevent NCDs among socially disadvantaged populations in three European countries

Acronym
HORUS

Study objectives
Citizens in the intervention group (i.e. individuals receiving HORUS) will have more favourable results with regard to indicators of healthy lifestyle behaviour compared with citizens participating in the comparison group (i.e. individuals continuing their usual activities). Furthermore, we will explore whether citizens in the intervention group make better use of the urban built environment for their health.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 30/04/2025, Comité Ético de Investigación con Medicamentos del Hospital Universitario Doctor Peset de Valencia (C/ San Lázaro s/n. Edificio CIPS 1ª Planta, Valencia, 46017, Spain; +34 (0)963131660; ceic_peset@gva.es), ref: 129/23

2. approved 26/03/2024, Ethics Committee for Biomedical Research of the Faculty of Medicine of the University of Rijeka (Braće Branchetta 20, Rijeka, 51000, Croatia; +385 (0)51 651157 / +385 (0)51554901; mamaja.jancic@uniri.hr), ref: ref: 007-08/24-01/21; registry number: 2170-1-42-04-36/1-24-6

3. submitted 28/05/2025, Medische Ethische Commissie (MEC), Erasmus University Medical Center Rotterdam (Dr. Molewaterplein 40, Rotterdam, 3015 GD, Netherlands; +31 (0)10-70 34428, +31 (0)10-70 33625; metc@erasmusmc.nl), ref: N/A

Study design
Multicenter mixed-methods pre-post controlled study design

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of non-communicable diseases in citizens with low income, migrants and ethnic minorities

Interventions
In Spain, participants will be randomly assigned in a 1:1 ratio to either the intervention group or the control group. Randomization will be performed using computer-generated random numbers to ensure allocation concealment and reduce selection bias. A randomization sequence will be generated using SPSS, which will automatically allocate each eligible participant to one of the two groups after enrollment.

In the intervention condition, the HORUS concept will be implemented, while participants in the control group will continue with their usual activities. Each pilot site has the flexibility to adapt the general implementation framework of the HORUS concept to its specific local context.

The intervention starts with a structured assessment using self-reported questionnaires to evaluate lifestyle behaviors, motivation, self-efficacy, health outcomes, use of the urban environment, and sense of belonging. This assessment aims to identify individual needs and inform personalized support strategies.

Following the assessment, participants will engage in motivational interviewing to enhance intrinsic motivation for adopting healthier lifestyle behaviors. Based on the outcomes of both the assessment and motivational interview, a personalized intervention plan will be developed collaboratively by the participant and a health or social care professional. This co-produced plan will be reviewed periodically and adjusted as needed to support participants' evolving health and wellbeing needs. The plan will emphasize at least promotion of healthy nutrition and physical activity.

The intervention is supported by the HORUS technical solution, which facilitates implementation of the nutrition and physical activity components. Specific activities within each pilot site will be selected based on local relevance and available resources. The intervention will be supported by a mobile application (i.e., the Wakamola app) designed for citizen engagement. With informed consent, health or social care professionals will have access to a monitoring dashboard to track participant progress over time.

Data will be collected at baseline (T0) and after 9 months (T1), using self-reported questionnaires.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome measure of lifestyle is measured using the following variables of diet, physical activity, alcohol consumption and smoking:
1. Diet is measured using the Rapid Prime Diet Score Screener (rPDQS) at baseline and after 9 months
2. Physical activity is measured using the International Physical Activity Questionnaire (IPAQ-SF) at baseline and after 9 months
3. Alcohol consumption is measured using the Alcohol Use Disorders Identification Test (AUDIT-C) at baseline and after 9 months
4. Smoking status is measured with 4 items, including the use of vapes at baseline and after 9 months.

Key secondary outcome(s))
1. Self-efficacy is measured using the Nutrition Self-Efficacy Scale, Physical Exercise Self Efficacy Scale, and Alcohol Resistance Self Efficacy Scale at baseline and after 9 months.
2. Body Mass Index (BMI) is measured by asking length and weight of the participant at baseline and after 9 months
3. Chronic conditions are measured using the Cumulative Illness Rating Scale (CIRS) at baseline and after 9 months
4. Lifestyle advice is measured by core items of the WHO STEPwise approach to noncommunicable disease risk factor surveillance (WHO STEPS) at baseline and after 9 months
5. Health-Related Quality of Life is measured by the Patient Reported Outcomes Measurement Information System 10-Question Short Form (PROMIS-10) at baseline and after 9 months
6. Neighbourhood belonging is measured by 15 items in the Neighbourhood Cohesion Scale at baseline and after 9 months

Implementation outcomes will be continuously measured with administrative data, questionnaire data and qualitative data in terms of acceptability, appropriateness, feasibility, adoption, penetration, implementation costs, and sustainability following the taxonomy of Proctor et al. (2011).

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Adults 18 years and older
2. Inhabitants of selected neighbourhoods within one of the pilot sites (Rijeka, Rotterdam and Valencia)
3. Able to give informed consent
4. Comprehension of the local language
5. Belong to one (or more) of the following groups:
5.1. General population from the selected vulnerable neighbourhood
5.2. Socially disadvantaged populations including low-income populations, migrants and ethnic minorities
5.3. Individuals who are at risk for NCDs or already have type 2 diabetes and/or CVD

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals under the age of 18 years
2. Individuals living outside selected neighbourhoods
3. Individuals with severe or terminal illnesses unrelated to NCDs that could affect their ability to participate in the study
4. Participants with conditions requiring intensive medical care or beyond the intervention capabilities of the project
5. Individuals who do not fulfil the socioeconomic or ethnic criteria specified in the inclusion criteria
6. Individuals who do not consent or who are unwilling to participate in the data collection and study activities

Date of first enrolment
01/07/2025

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
Croatia

Netherlands

Spain

Study participating centre
University of Rijeka, Faculty of Medicine
Braće Branchetta 20/1
Rijeka
Croatia
51000

Study participating centre
Erasmus University Medical Center
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Study participating centre
Fundacion Fisabio
Calle Micer Masco 31
Valencia
Spain
46010

Sponsor information

Organisation
Universitat de València

ROR
https://ror.org/043nxc105

Organisation
Erasmus MC

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Government

Funder Name
European Health and Digital Executive Agency

Alternative Name(s)
Health and Digital Executive Agency, HaDEA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes