

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

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Registration date 04/08/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/08/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 pilot sites:

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

Study website

<https://horus-urbanhealth.eu/>

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Longitudinal study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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.

Secondary outcome measures

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).

Overall study start date

01/12/2023

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

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

900 in total: 150 participants in the intervention group and 150 participants in the control group in each pilot site.

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

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46010

Sponsor information

Organisation

Universitat de València

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Sponsor type

University/education

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<https://www.uv.es/uvweb/college/en/university-valencia-1285845048380.html>

ROR

<https://ror.org/043nxc105>

Organisation

Erasmus MC

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Sponsor type

University/education

Website

<https://www.erasmusmc.nl>

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

Publication and dissemination plan

Publications in high-impact peer-reviewed journals.

Intention to publish date

01/06/2027

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