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BMJ Open

Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project), study protocol.

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-074252
Article Type:	Protocol
Date Submitted by the Author:	31-Mar-2023
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Keywords:	PUBLIC HEALTH, MENTAL HEALTH, Health Equity, EPIDEMIOLOGIC STUDIES, Quality of Life

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2 3 4 5	1	Title
6 7 8	2	Urban Environment and Health: a cross-sectional multiregional project
9 10 11	3	based on Population Health Surveys in Spain (DAS-EP project), study
12 13 14	4	protocol.
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170 Abstract

Introduction: The European Environment Agency estimates that 75% of the European population lives in cities. Despite the many advantages of city life, the risks and challenges to health arising from urbanization need to be addressed to tackle the growing burden of disease and health inequalities in the cities. This study, *Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain* (DAS-EP project), aims to investigate the complex association between the urban environmental exposures (UrbEE) and health.

Methods and analysis: DAS-EP is a Spanish multiregional cross-sectional project that combines Population Health Surveys (PHS) and Geographical Information System (GIS) allowing to collect rich individual level data from 17,000 adult citizens participating in the PHS conducted in the autonomous communities of the Basque Country, Andalusia, and the Valencian Community, and the city of Barcelona in years 2021-2023. This study focuses on the population living in cities or metropolitan areas with more than 100,000 inhabitants. UrbEE are described by objective estimates at participants' home addresses by GIS and subjective indicators present in PHS. The health outcomes included in the PHS and selected for this study are self-perceived health (general and mental), prevalence of chronic mental disorders, health-related quality of life, consumption of medication for common mental disorders, and sleep quality. We aim to further understand the direct and indirect effect between UrbEE and health as well as to estimate the impact at the population level taking respondents' socio-demographic and socio-economic characteristics, and lifestyle into account.

191 Ethics and dissemination:

192 The study was approved by the regional Research Ethics Committee of the Basque Country 193 (CEIm-E; PI2022138), Andalusia (CEIM GRANADA; 2078-N-22), Barcelona (CEIC-PSMar; 194 2022/10667), and Valencian Community (CEIC DGSP/CSISP; 20221125/04). The results will be

> communicated to the general population, health professionals and institutions through conferences, reports, and scientific articles.

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Strengths and limitations of this study

- The linkage of four independent population health surveys (PHS) will provide a large volume of information and a large sample size of the study.
- The method is novel for the inclusion of objective & subjective UrbEE as well as the • combination of PHS from different study areas and GIS estimates.
- Despite the cross-sectional nature of the study, the results will ultimately help identify • urban indicators, increasing the capacity to detect and intervene in community health,
 - improving the routine surveillance and monitoring of the cities' health information
- systems.

206 1. Introduction

According to World Health Organization, modifiable environmental factors are responsible for 23% and 22% of global mortality and morbidity respectively (1). As reported by the European Environment Agency, in 2021, 75% of the European population lived in urban areas including cities but also smaller urban settlements and suburban areas, developed for residential, industrial or recreational purposes (2). The conditions and quality of the local urban environment influences people's health by determining their level of urban environmental exposures (UrbEE) (3,4). The UrbEE include the totality of the surrounding natural (e.g., green and blue spaces), built (e.g., walkability, urbanisation level, traffic,) and social (e.g., security, public services) environments within which people live, move, and interact, as well as environmental stressors like air pollution and noise. Increasing evidence shows that UrbEE such as lack of greenness, air pollution and noise can impact population's mental and physical health and quality of life (5–9). The health implications of the environmental exposures become even more important in the contemporary demographic setting, given that they are perhaps starker in urban areas (10–14). Moreover, in many regions, environmental exposures are not evenly distributed across socioeconomic status and socio-economically vulnerable populations are also affected by poorer environmental quality (10,11). In fact, this double jeopardy may make individuals from poorer socioeconomic backgrounds more significantly affected by environmental exposures (3,15).

The UrbEE, including environmental stressors, traffic-infrastructure, natural spaces, and the built environment, have all been studied in relation health. Widespread evidence in the literature shows that air pollution, noise and lack of green space are related to a range of chronic physical diseases (16–21). Recently, it has been suggested that air pollution is associated with a range of mental disorders and poorer sleep quality (16,22–25). Other recent studies observed that environmental noise has negative effects on mental health, well-being,

and sleep quality (25–28), while evidence on its impact on prescriptions and consumption of medication for common mental disorders has yet to be scientifically confirmed (29). Otherwise, current scientific evidence indicates that residential greenness is positively associated with mental health and quality of life (28,30,31), and lower consumption of anxiolytics, antidepressants, and sleeping pills (25,32). Blue spaces (aquatic environments such as rivers, lake, and the coast) are expected to have similar health effects to those described here, however, evidence on this subject is limited (32,33). As for the built environment, walkability or accessibility have also been related to reduced obesity and better cardiovascular health (34), improved mental health (35,36) and well-being (37). To date, the main mechanisms proposed to explain these associations are the mitigation of exposure to environmental pollutants, the promotion of physical activity, and the strengthening of social cohesion (30,31,34,38–40). However, these mechanisms are probably synergistic (41). The correlations between several UrbEE and their relationship with behavioural exposures like physical activity, and social cohesion makes the assessment of these associations and pathways highly challenging (42–46). Hence, noise and air pollution could act both as exposures, mediators, or potential confounders. Overall, results of previous studies are quite mixed and the associations as well as the underlying mechanisms between UrbEE and mental health outcomes need more robust scientific evidence (8,45,47–49).

This knowledge gap can be partly explained by the heterogeneity and limitations of exposure and outcome metrics used in the studies (20,49,50). Moreover, there is a lack of studies addressing the impact of UrbEE on health integrating objective and perceived accounts of such exposures (51). Therefore, it is evident that more research is needed to determine which UrbEE are associated with health, the potential mechanisms involved, and the role of social aspects in those associations. Beyond this, researchers are increasingly called to provide information that can guide the selection of the best and most feasible interventions to improve public health in cities. In this respect, experts in the field have claimed the vital role

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that the health impact assessment tool plays in integrating the evidence in the decision-making process (52,53).

Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project) is a 3-year project (2023-2025) aimed at further investigating the associations and underlying mechanisms, including direct and indirect effects, between UrbEE and health with a health equity perspective. Five main objectives have been established for this project:

- 1. To estimate, describe and compare the objective and subjective levels of UrbEE in the study areas.
 - 2. To describe urban environmental inequalities according to socio-demographic and socio-economic variables as well as the study area.
- 3. To estimate the association between UrbEE and self-perceived general and mental health, health-related quality of life, chronic mental disorders, consumption of medication for common mental disorders and sleep quality (Figure 1).
- 4. To estimate the population impact of UrbEE on the health outcomes under evaluation and conduct a health impact assessment.
- 5. To assess the mediating role of physical activity, social cohesion, and environmental stressors on the association between UrbEE and the health outcomes under evaluation (Figure 1).



Figure 1. Conceptual framework designed within the scope of this project, including potential direct and indirect effects of urban environmental exposures (UrbEE) on the health outcomes under study. * Potential mediators on the association between UrbEE and the health outcomes under evaluation.

276 2. Methods and analysis

277 2.1. Study design

 This is a cross-sectional study based on adult population data from Population Health Surveys (PHS) that live in urban areas with more than 100,000 inhabitants in the autonomous communities of the Basque Country and Andalusia, the Valencian Community, and the city of Barcelona in Spain. The study integrates observational data collected within the four independent PHS in 2021-2023 with Geographic Information System (GIS) estimations of individual UrbEE. It entails the following research activities: 1) preparation, integration, and calibration of PHS data from each study area, 2) harmonising the variables that have been collected differently in the four study areas, 3) georeferencing survey respondents' home

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addresses, 4) characterizing each home address in terms of UrbEE by GIS, 5) linking UrbEE estimates with PHS data, and 6) pooling of datasets from the four study areas (Figure 2). Using the final pooled database, we will analyse the association between UrbEE and health in a cross-sectional manner, taking into account sociodemographic, socioeconomic and lifestyle factors. Figure 1 shows the conceptual framework designed within the scope of this project. DAS-EP received Ethics Approval from the regional ethics committee competent at each study area (see more Supplementary file section 5). This project has received funding from the Instituto de Salud Carlos III (ISCIII) under the Strategic Action in Health with the Health Research Fund (FIS) in the call 2022 (file No. PI22/01051 and No. PI22/00512). The project runs from 2023 to 2025.

2.2. Study population



Figure 2. Summary of data management plan and the institutions involved during the development of the final database (DB) to be used by the research group in the analyses.

The target population is the inhabitants of the autonomous communities of the Basque Country and Andalusia, Valencian Community, and the city of Barcelona. The sampling frames are made up of people over 15 or 16 years of age of the respective study areas. The study population includes the PHS' participants living in urban areas with more than 100,000 inhabitants in the autonomous communities of the Basque Country and Andalusia, the Valencian Community, and the city of Barcelona (Figure S1, S2). The cities and metropolitan areas participating in this study are: the city of Vitoria-Gasteiz, and the metropolitan areas of Bilbao and Donostia-San Sebastián in the Basque Country; the cities of Almeria, Cadiz, Cordoba, Huelva, Jaen, and the metropolitan areas of Granada, Malaga, and Seville in Andalusia; the cities of Castellon, Valencia, Elche and Alicante in Valencian Community; and the city of Barcelona (Table S1).

The PHS included in this project are official statistical operations that are incorporated in the Statistical Plans of each study area. These activities are conducted by every regional or local public administrations with competence in health and are a fundamental tool to monitor the status and evolution of relevant health conditions in the population, their main determinants, and the use of health services (54-57). Accordingly, these regional and local cross-sectional epidemiological surveys are carried out by the Basque Department of Health in the Basque Country (54), Andalusian School of Public Health (EASP) in Andalusia (55), Barcelona Public Health Agency (ASPB) in Barcelona (56), and Foundation for the Promotion of Health and Biomedical Research in the Valencian Region (DGSP) in Valencian Community (57). They have been organised every 4-5 years since 1986 (Basque Country), 1999 (Andalusia), 1983 (Barcelona) and 1991 (Valencian Community). The sample design and the selection of the sample is carried out independently by the statistical institutes (EUSTAT in the Basque Country, Institute of Statistics and Cartography of Andalusia or IECA in Andalusia, and municipal statistical office of the Barcelona city council in Barcelona) or health population information systems (Valencian Community). The latest version of these surveys are included in this

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project. After the surveys are completed, it is estimated to obtain a total sample of 16,953 individuals, with a number of 7,846 participants in the Basque Country, 3,085 in Andalusia, 3,134 in Valencian Community and 4,000 in the city of Barcelona. A more detailed information is provided in Table S1. 2.3. Data collection 2.3.1. GIS estimates of urban environmental exposures (UrbEE) Objective measures of UrbEE are estimated by a company specialised in GIS based on the geographic coordinates of the participants' home addresses. A significant number of these variables will be expressed in buffers around each participant's residence or at the building level. All environmental exposures will be assessed preceding, and as close as possible to the time the PHS are being conducted (2021-2023) in order to avoid temporal mismatch (58). The objective UrbEE under study in this project include exposures originated from surrounding natural spaces, built environment, traffic-infrastructure, and environmental stressors. Detailed information on the UrbEE estimated within the scope of this project can be found in the Supplementary file (Table S2). Surrounding natural spaces Green spaces. Five green space exposure metrics will be calculated in buffers of 100, 300 and 500m around each geocode: 1) percentage of green space; 2) mean Normalised Difference Vegetation Index (NDVI) (59,60); 3) percentage of tree cover; 4) Euclidean distance to the nearest green space larger than 5,000m² (61), and 5) presence of a major green area (greater than 5,000 m²). Blue spaces. Any blue environment, including lake, river, or coastline will be considered as

346 surface; 2) percentage of water surface; and 3) Euclidean distance to nearest water surface

 blue space. Three blue space exposure variables will be estimated: 1) presence of water

347 greater than 5,000m². The first two refer 100, 300 and 500m buffers around each geocode
348 (62).

349 Built environment

<u>Building density.</u> The building density around each home address in 100, 300 and 500m
 buffers will be estimated, accounting not only for the perimeter of the buildings but also
 for their height (63).

Walkability. An overall walkability index in 100, 300 and 500m buffers around the
 participants' home addresses will be calculated. This index will be calculated through the
 sum of the following subindices: 1) population density (referring to the census tract of the
 address), 2) destination density, 3) street density, 4) street connectivity, 5) land use, 6)
 facility richness, and 7) average slope (64,65).

358 Traffic infrastructure

359 - <u>Major road (Yes vs. No).</u> Presence of a major road (with >3 million vehicle passages per
 360 year) in 100, 300 and 500m buffers around the participants' home addresses (63).

361 - <u>Distance to major road</u>. Distance to the nearest major road (with >3 million vehicle
 362 passages per year) from the participants home addresses (63).

363 Environmental stressors

<u>Air pollution.</u> Spatiotemporal daily models at household-level for particulate matter (PM₁₀
 and PM_{2.5}) and nitrogen dioxide (NO₂) will be constructed for all study areas using
 multistage mixed models. These models are known as spatiotemporal land-use random forest model (66) and combine ground-level and satellite measurements, land use and
 meteorology. A precise daily estimate of the exposures will be obtained for all study
 subjects (period 2006 to 2023). Using the daily estimates, annual average for the last five

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370 years and the five-year average of NO₂, PM₁₀ and PM_{2.5} exposure levels will be calculated
 371 at PHS respondents' home address as indicators for long-term air quality.

372 The Strategic Noise Maps derived under the EU Directive Environmental noise. 373 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge 374 will be used. All potential sources of environmental noise at street level will be examined, 375 including road traffic, rail, industrial, airports and total noise (67,68). Major roads, major 376 railways, and major airports will be included in cities where this information is available 377 and not included in the agglomeration layer. Agglomerations corresponding to the closest 378 street to the dwelling, and major roads and airports corresponding to the closest isoline 379 will be used. In all cases, the Euclidean distance to each source will also be calculated. The 380 daytime (L_d) , evening (L_e) , night-time (L_n) , and total (L_{den}) noise indices will be assigned.

381 2.3.2. Information collected through Population Health Surveys

382 Information from four independent PHS that represent four study areas is included in the 383 study. The surveys are carried out between 2021-2023, being Barcelona city the earliest in 384 completing the collection (2021 February - 2022 March), followed by the Valencian 385 Community (2022 April – 2022 December), Andalusia (2022 April – 2023 April), and the Basque 386 Country (2022 October - 2023 June) (Table S1). During each survey, detailed information is 387 collected though face-to-face interviews and self-administered questionnaires. The PHS collect 388 information on different health aspects, morbidity and use of health services. It also gathers 389 information on health determinants of health such as socio-economic status, working 390 conditions, social cohesion, health-related behaviours and perception on residential 391 environment. Most of these variables are measured with validated screening tools. The 392 selection of relevant variables to be included in this project was based on a literature review 393 and the most appropriate variables to meet the objectives of the study were selected from 394 among the variables collected by the PHS. All the study areas collected the main variables of BMJ Open

3 4	395	the study (i.e., mental health, health-related quality of life, physical activity, social cohesion,
5 6	396	and sleep), however, in some cases, the measuring instruments differ across the study areas.
7 8	397	Detailed information about the variables and the measuring instruments used in each study
9 10 11	398	area can be found in Table S3.
12 13	399	Health outcomes
14 15 16	400	Several health outcome variables are included in this study.
17 18	401	- Self-perceived general health. Self-assessment of health was measured as an ordinal
19 20 21	402	response, with five categories (1, Excellent; 2, Very good; 3, Good; 4, Fair; 5, Poor).
21 22 23	403	- Self-perceived mental health. This variable was collected with the Mental Health
24 25	404	Inventory (69), the SF-12 (Short-Form Health Survey 12) scale (70) or the General Health
26 27	405	Questionnaire (GHQ-12) (71).
28 29 20	406	- <u>Health-related quality of life.</u> This variable was measured with the Euroqol-5D-5L-EAV scale
30 31 32	407	(72) or the SF-12 (Short-Form Health Survey 12) scale (70).
33 34	408	- <u>Sleep duration and quality.</u> The duration of sleep, indicated as the total number of hours
35 36	409	per day spent on sleep including napping was calculated. The quality of sleep was collected
37 38	410	using the SATED scale (Satisfaction Alertness Timing Efficiency and Duration Scale) (73) or
39 40 41	411	discrete items.
42 43	412	- Prevalence of chronic mental health problems. Self-reported diagnosis of anxiety,
44 45	413	depression and sleeping disorders was collected through the PHS. These dichotomised
46 47	414	indicators were based on the physician diagnosis or self-diagnosis for depression, anxiety
48 49 50	415	and sleeping problems at any time throughout the life.
50 51 52	416	- <u>Consumption of medication for common mental disorders.</u> Information on consumption of
53 54	417	medication for common mental disorders, such as, anxiolytics, antidepressants and
55 56 57	418	hypnotics was reported on bi-daily or bi-weekly basis depending on the study area.
58 59 60	419	Covariates

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420 A set of individual level variables will be used as control variables in the statistical analyses.

<u>Anthropometric variables.</u> The surveys collect information on sex, age, weight, and height
 of individuals. A Body Mass Index (BMI) (kg/m²) will be calculated using information given
 by the participants about their height and weight at the moment of filling the
 questionnaire.

Socio-demographic and socio-economic variables. To describe respondents' individual level socioeconomic status (SES), seven variables will be selected: country of birth,
 household size, level of education, employment and occupational status, reported
 household income, and economic difficulty of the household. Further, neighbourhood level SES will be calculated based on the deprivation index by census tract in 2021 from the
 MEDEA project (forthcoming paper).

431 - <u>Lifestyle factors.</u> These will include consumption habits such as alcohol consumption,
 432 passive smoking at home and tobacco use.

433 - <u>Physical health.</u> A chronicity index will be calculated based on presence of one or more
 434 non-psychological chronic conditions (e.g., diabetes, heart disease, cancer, etc.).

435 The following social and behavioural variables will be treated as potential mediators.

436 - Social cohesion and loneliness. Social cohesion is measured with the Duke-UNC-11 scale

437 (74) or the OSLO-3 tool (75). While perceived loneliness is collected with a single item.

Physical activity. The International Physical Activity Questionnaire (IPAQ) (76) to measure
 the physical activity performed by the participants. Days per week and time spent in
 vigorous physical activity, in moderate physical activity, and walking more than 10
 minutes, and time spent sitting on a normal day will be available.

442 Perception of the neighbourhood

Perceived accounts of UrbEE are collected through PHS employing 3-point or 5-point
Likert format questions depending on the study area. These include: 1) perception of noise

outside the dwelling, 2) perception of shortage of green areas in the residential environment,
3) perception of air pollution in the residential environment, and 4) perception of insecurity in
the neighbourhood.

448 2.4. Data analysis

Initially, all databases will be cleaned. The variables will be harmonised, when needed, following the Maelstrom Research Guidelines for rigorous harmonisation of retrospective data (77). Nonetheless, because most variables have already been collected consistently in the respective Population Health Surveys, few variables will require harmonisation (see Supplementary file Section 3). Among the few variables requiring harmonisation, most will be re-categorised. For more information, see Supplementary file Section 4. Subsequently, both exploratory and descriptive analysis will be applied using numerical and graphical techniques (78). Before proceeding to inference, sample weights for each survey will be adjusted through calibration (79), so that we may compensate for non-response and coverage biases as well as to improve accuracy. This calibration will be carried out separately for each study area, so that region-level estimates are obtained first, and then harmonized to obtain estimates at population level.

The relationships between the various UrbEE and health outcomes will be analysed according to the multilevel, or hierarchical structure (80) that the data will possess, as census tracts are nested within cities, and cities are nested within autonomous communities. Generalised linear mixed models (GLMMs) will be applied to investigate the relationship between urban environment and health. The sets of adjustment covariates used in these models will be chosen by applying robust causal inference techniques based on directed acyclic graphs (DAGs) (81), both for the estimation of direct effects and hypothetical indirect effects mediated by air pollution, environmental noise, physical activity, and social cohesion. This will imply the prior design of a DAG describing the relationships between UrbEE, health

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outcomes and other potentially implicated variables (82; 83). The testable implications derived
from this DAG will be checked following the procedure described by Ankan and colleagues
(84), thereby updating the DAG if needed (85,86). The length of time living in the same
home/place will be taken into account by excluding individuals living at the same place of
residence for less than one and less than five years in separate models.

475 In case of demonstrating a significant relationship between a given exposure and a certain 476 outcome, we also intend to identify the specific exposures that cause most disease in the 477 populations of interest via the population attributable fraction (PAF) (87). To estimate the PAF 478 we will require previous estimations of relative risk (RR) and either the prevalence of exposure 479 in the population or the prevalence of exposure among the cases of disease. All these previous 480 estimates will be available. The possible existence of spatial clusters in the UrbEE distribution 481 will also be studied using the standard spatial scan statistic method (88) and calculating the 482 posteriori probabilities for the smoothed standardised ratios to be greater than unity, in the 483 general framework of Bayesian hierarchical standardised ratio smoothing models.

484 The analyses will be implemented using the latest version of the R software packages
485 *dagitty* (89), *DClusterm* (90,91), *R INLA* (92), *Sampling* (93) and others.

486 2.5. Data Management Plan

The data management plan can be found in the Supplementary file Section 4. The source and type of data that will be collected within the scope of this project is described in this plan, together with the accessibility and ownership of data. Data storage and processing, as well as the procedure to guarantee the specific ethical and legal requirements, are likewise explained.

491 **2.6. Patient and Public Involvement**

492 Patients and the public will not be involved in the design, or conduct, or reporting, or493 dissemination plans of our research.

494 3. Discussion

The present study is a clear commitment to the generation of urban environmental indicators potentially explanatory of self-perceived health (physical and mental), chronic mental disorders, health-related quality of life, consumption of medication for common mental disorders and sleep quality with a health equity perspective. This project responds to the national Spanish Strategic Plan for Health and the Environment (PESMA) 2022-2026 (94), to the local implementation of the Strategy for Health Promotion and Prevention in the National Health System (NHS) (95) as well as to the main objective of the Spanish Urban Agenda 2019 (96) that cities should have a global vision that takes into account the physical, mental, and social well-being of their inhabitants. Likewise, it is aligned with three of the Sustainable Development Goals (SDG) of the World Health Organization (SDG.3 - Good Health and Well-being, SDG.10 - Reduced Inequalities, and SDG.11 - Sustainable Cities and Communities) (97,98).

When it comes to health-promoting urban and transport design, there is a lack of standardized, quantitative indicators to guide the integration of health components right from the outset (53,100). In this context, the DAS-EP project not only aims to obtain individual UrbEE estimates but also to assess their association with and impact on various health outcomes. By means of PHS, the health effects to be studied in this study are derived from an unbiased population, which allows to obtain an approximate estimate of the impact at population level. Moreover, it is important to identify the precise routes that connect urban environment to health because they can guide the most efficient interventions, allowing us to design healthy(er) cities (52,101). In this sense, the DAS-EP project investigates various components of the urban environment and health at individual level. Besides using complementary indicators that describe both the physical and the social urban environment (e.g., neighbourhood insecurity), combines objective and perceived indicators to deepen the

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characterization of the urban environment. By combining these data, it is possible to develop a
more precise understanding of the effects of urban environment on health, while describing
the complexity of the relationship influenced by neighbourhood environmental and individual
characteristics (99,102,103).

The main limitation of this study is its cross-sectional nature. Due to the chronic character of the health conditions included in the study (e.g., depression, insomnia) and the possible long-term effects of UrbEE, a longitudinal design would be more informative and appropriate. Although PHS have a cross-sectional approach, the question "since when have you been living at your current address" enables to account for the extent of exposures. Drawing on this mobility data, sensitivity analysis of the models will be fitted reducing the risk of exposure misclassification. Another limitation is that the samples from the study areas of the Basque Country, Andalusia, and Valencian community, although representative of the study population (considering the inclusion criteria) may not be representative of the autonomous communities from which they come as we are not considering the non-urban municipalities (<100,000 inhabitants). Despite the weight calibration will be conducted to reduce coverage and representativeness biases, the reweighting procedure will not guarantee the elimination of other response biases that may affect data collection from PHS (as acquiescence, social desirability, etc.) that could affect the validity of the results (104,105). Further, the project is subject to residual confounding which in turn implies confounders that could not be controlled and, importantly, measurement errors in the confounders that have been included. In this regard, the estimation UrbEE by GIS is affected by the problem of uncertainty of the temporal and geographical context (106). Finally, the heterogeneity across study areas in terms of geographic scale (autonomous communities vs. city) may be a source of information bias. In this vein, the majority but not all the scales and variables are included in the different PHS are identical. These minor differences in data collection across PHS may lead to additional information biases hindering the comparability of the data. To minimize this

problem, special attention will be paid to the selection and harmonization of the variables to
be included in order to ensure the consistency of data before making the comparisons across
study areas.

As for the strengths of this project, pooling linked surveys across study areas will make it possible to compare the results in different populations, providing a comprehensive dataset that is larger than most existing cohort studies, and that have an unique national and population perspective. The results will be novel in terms of their thematic (objective & subjective UrbEE) and methodological approach (combination of PHS from different study areas and GIS estimates), as well as in terms of the large volume of information that will be handled and the large sample size of the study. Beyond that, the standardization of the procedure here described will generate useful information to assist in the planning of national health surveillance programs, research studies and, more importantly, interventions to strengthen population's health.

In short, the results and products (i.e., databases, computer codes) of this project will greatly contribute to estimate the proportion of the population exposed to different UrbEE, identify health disparities while considering UrbEE, estimate how these exposures relate to and affect various health variables, and conduct a health impact assessment of UrbEE. We will have taken a further step towards understanding and improving the urban environment and being able to establish corrective measures in the urban development plans of the cities.

Declarations

565 Ethics and dissemination

The study was approved by the regional Research Ethics Committee of the **Basque Country**, ETHICS COMMITTEE FOR RESEARCH INVOLVING MEDICINAL PRODUCTS IN THE BASQUE COUNTRY (CEIm-E) (protocol code PI2022138, dated 9th November 2022); Andalusia, BIOMEDICAL RESEARCH ETHICS COMMITTEE OF THE PROVINCE OF GRANADA (CEI/CEIM GRANADA) (protocol code 2078-N-22, dated 27th December 2022); Barcelona, PARC DE SALUT MAR CLINICAL RESEARCH ETHICS COMMITTE (CEIm) (protocol code 2022/10667, dated 2nd December 2022); Valencian Community, ETHICS COMMITTEE FOR CLINICAL RESEARCH OF THE DIRECTORATE GENERAL OF PUBLIC HEALTH AND CENTER FOR ADVANCED RESEARCH IN PUBLIC HEALTH (CEIC DGSP / CSISP) (protocol code 20221125/04, dated 25th November 2022). The results will be communicated to the general population, health professionals and institutions through conferences, reports, and scientific articles.

577 Competing interests

578 The authors declare that they have no competing interests.

579 Funding statement

This project was supported by the Instituto de Salud Carlos III (ISCIII) under the Strategic Action in Health with the Health Research Fund (FIS) in the call 2022 (file No. PI22/01051 and No. PI22/00512). Data collection is funded by the various agencies responsible for the included health surveys. In addition to the FIS funding, the group has its own financial means for other expenses including publication and dissemination of results, travel expenses and conference registrations related to the study.

59 586 Authors' contributions

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595 All authors have read and agreed to the published version of the manuscript.

596 Acknowledgements

597 We thank all institutions [Basque Department of Health in the Basque Country, Andalusian

598 School of Public Health (EASP) in Andalusia, Barcelona Public Health Agency (ASPB) in

599 Barcelona, and Foundation for the Promotion of Health and Biomedical Research in the

600 Valencian Region (DGSP) in Valencian Community] developing the Population Health Surveys

601 that are used in this project.

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1	Supplementary file
2	File name: Supplementary file_DAS-EP
3	File format: Word document (.docx)
4	Title of data: Supplementary data of Urban Environment and Health: a cross-sectional
5	multiregional project based on Population Health Surveys in Spain (DAS-EP project), study
6	protocol.
7	Table of contents
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23 Section 1. GENERAL CHARACTERISTICS OF THE STUDY AREAS



Figure S1. Study areas of the project, being the cities and metropolitan areas (M.A) with more than 100,000 inhabitants from the autonomous communities of the Basque Country and Andalusia, Valencian Community, and the city of Barcelona. Figure edited from Daniel Dalet / d-maps.com.



Figure S2. Population density of Spanish provinces in 2022. Figure edited from Instituto Geográfico Nacional, *La población en España 2022*. Accessed through: <u>https://www.ign.es/pobesp/pe1.htm</u>

36 Section 2. GENERAL CHARACTERISTICS OF THE POPULATION HEALTH SURVEYS

Table S1. Characteristics of the study areas and the population health surveys comprised in the project.

Study area	Cities and areas of influence	Population health survey	Re	sponsible body	Sample size	Data collection period
A.C. Basque Country	Vitoria-Gasteiz Donostia-San Sebastián (M.A) Bilbao (M.A)	Encuesta de Salud de la Comunidad Autónoma País Vasco (ESCAV)	✓	Basque Department of Health	7,846	2022 October – 2023 June
A.C. Andalusia	Almería Cádiz Córdoba Huelva Jaén Granada (M.A) Malaga (M.A) Sevilla (M.A)	Encuesta Andaluza de Salud (EAS)		Andalusian School of Public Health (EASP)	3,085	2022 April – 2023 April
Barcelona city	Barcelona	Encuesta de Salud de Barcelona (ESB)	✓	Barcelona Public Health Agency (ASPB)	4,000	2021 February – 2022 March
Valencian Community	Castellon Valencia Elche Alicante	Encuesta Salud Comunidad Valenciana (ESCV)	~	Foundation for the Promotion of Health and Biomedical Research in the Valencian Region (DGSP)	3,134	2022 April – 2022 December

41 Section 3. OVERVIEW OF THE VARIABLES OF THE STUDY PER STUDY AREA

 Table S2. Objective urban environmental exposures obtained through GIS estimations.

GIS Variables	Study areas: A.C. s	of the Basque Country and Andalusia, Valencian Community & the city of Barcelona
OBJECTIVE URBAN ENVIRONMENTAL	Scale	Variable
EXPOSURES		
a) Surrounding natural spaces		
Green Spaces		
	100, 300, 500m	
Green space percentage	buffers	Percentage of green space.
NDVI	100, 300, 500m	Annual mean Normalised Difference Vegetation Index (NDVI) of the year when the
	buffers	surveys were conducted and the mean NDVI of the last 5 years previous to the
		surveys.
	100, 300, 500m	
Tree percentage	buffers	Percentage of tree cover based on Growing stock volume (GSV) data.
Distance to green space		Euclidean distance to the nearest major green space (green surface over 5,000m ²).
Green spaces Yes (vs. No)	100, 300, 500m	Dichotomous variable of presence of major green spaces (green surface over
	buffers	5,000m ²) from local topographical or Europe-wide maps (Urban atlas).
Blue spaces		
	100, 300, 500m	
Blue spaces Yes (vs. No)	buffers	Dichotomous variable of presence of water surfaces. Based on Urban Atlas.
	100, 300, 500m	
Blue space percentage	buffers	Percentage of water surface. Based on Urban Atlas.
Distance to blue space		Euclidean distance to the nearest water surface over 5,000m ² . Based on Urban

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		Atlas.
b) Built environment		
Building density	100, 300, 500m buffers	The building density around each household will be calculated accounting for the perimeter and height of the buildings from local cadastre data or Europe-wide mathematication (Urban Atlas).
Population density	100, 300, 500m buffers	The number of inhabitants (per km ²) surrounding the home addresses.
Street connectivity	100, 300, 500m buffers	Using data from OpenStreetMap® .
Accessibility (bus lines)	100, 300, 500m buffers	Access to public transport bus lines from local topographical maps or OpenStreetMap®.
Accessibility (bus stops)	100, 300, 500m buffers	Access to public transport bus stops from local topographical maps or OpenStreetMap®.
Facility richness	100, 300, 500m buffers	Using local topographical maps or OpenStreetMap®.
Facility density	100, 300, 500m buffers	Using local topographical maps or OpenStreetMap®.
Land use	100, 300, 500m buffers	Mixed land use will be estimated by Shannon's Eveness Index based on Urban data.
Walkability index	100, 300, 500m buffers	Index constructed from seven indicators: population density, street connectivity, facility richness, land use, destination density, street density, and average slope
c) Traffic infrastructure		
Maior road Yes (vs. No)	100, 300, 500m buffers	Dichotomous variable of presence of a major road (OpenStreetMap®).

Inverse distance		Inverse distance to the nearest major road (OpenStreetMap®).
GIS Variables	Study areas: A.C. s of	f the Basque Country and Andalusia, Valencian Community & the city of Barcelona
OBJECTIVE URBAN ENVIRONMENTAL	Scale	Variable
d) Environmental stressors Air pollution		
PM _{2.5}	Street level (at residential address)	PM _{2.5} exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.
PM ₁₀	Street level (at residential address)	PM ₁₀ exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.
NO ₂	Street level (at residential address)	NO ₂ exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.
Noise		
Day (L _d)	Street level (at residential address)	Exposition to environmental noise at street level during the day indicated as: a) the annual average for the last five years, and b) the five-year average for the last five years based on Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.
Evening (L _e)	Street level (at residential address)	Exposition to environmental noise at street level during the evening indicated as: a) the annual average for the last five years, and b) the five-year average for the last five years based on Strategic Noise Maps derived under the EU Directive
		7
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			2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.
	Night (L _n)	Street level (at	Exposition to environmental noise at street level during the night indicated as: a) the
		residential address)	annual average for the last five years, and b) the five-year average for the last five
			years based on Strategic Noise Maps derived under the EU Directive 2002/49/EC
			from the Ministry for the Ecological Transition and the Demographic Challenge.
	Total (L _{den})	Street level (at	Total exposition to environmental noise at street level indicated as: a) the annual
		residential address)	average for the last five years, and b) the five-year average for the last five years
			based on Strategic Noise Maps derived under the EU Directive 2002/49/EC from the
		40	Ministry for the Ecological Transition and the Demographic Challenge.
	Abbreviations: A.C., Autonomous community;	NDVI, Normalised Differe	ence Vegetation Index; GSV, Growing stock volume; PM _{2.5} , Fine particulate matter with
	a diameter of 2.5 μ m or less; PM ₁₀ , Fine particu	ulate matter with a diamet	ter of 10 μ m or less; NO ₂ , Nitrogen dioxide
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Table S3. Variables collected through Population Health Surveys.

Population Health Survey		Study areas		
Variables	A.C. Basque Country	A.C. Andalusia	Barcelona city	Valencian Community
OUTCOMES				
a) Self-perceived health				
General Health	Ordinal 1-5	Ordinal 1-5	Ordinal 1-5	Ordinal 1-5
Mental Health	Ordinal 1-5 [Mental Health Inventory /5 items]	Ordinal 1-6 [SF-12 / 3 items]	Ordinal 1-4 [GHQ-12/ 12 items]	Ordinal 1-4 [GHQ-12 / 12 items]
b) Quality of life				
Health-related quality of life	Ordinal 1-5 [EuroQoL / 5 items]	Ordinal 1-6/1-5 [SF-12 / 5 items]	Ordinal 1-5 [EuroQoL / 5 items]	Ordinal 1-5 [EuroQoL / 5 items]
c) Sleep				
		Continuous - Total	Continuous - Total	Continuous - Total
Sleep duration	Continuous - Total hours/day	hours/day	hours/day	hours/day
		yes/no & Ordinal 1-4 [4		Ordinal 1-5 [SATED / 5
Quality of sleep	Ordinal 1-5 [SATED / 5 items]	items]	Ordinal 1-10	items]
d) Consumption of medica	tion for common mental disorders ¹			
Antidepressants	yes/no – reference 2 days	yes/no – reference 2 weeks	yes/no - reference 2 days	yes/no - reference 2 weeks
Hypnotics	yes/no - reference 2 days	yes/no - reference 2 weeks	yes/no - reference 2 days	yes/no – reference 2 weeks
Anxiolytics	yes/no - reference 2 days	yes/no - reference 2 weeks	yes/no - reference 2 days	yes/no - reference 2 weeks
e) Chronic mental health p	roblems ²			
Anxiety	yes/no - reference ever	yes/no – reference present	yes/no - reference ever	yes/no – reference ever
Depression	yes/no - reference ever	yes/no - reference present	yes/no - reference ever	yes/no - reference ever

Insomnia	yes/no - reference ever	-	-	yes/no - reference ever
Other	yes/no - reference ever	-	yes/no - reference ever	yes/no - reference ever
COVARIATES				
a) Anthropometric variables				
Age	Discrete	Discrete	Discrete	Discrete
Weight	Continuous	Continuous	Continuous	Continuous
Height	Continuous	Continuous	Continuous	Continuous
BMI	Continuous	Continuous	Continuous	Continuous
Biologic sex	Categorical - 3 conditions	Categorical - 2 conditions	Categorical - 2 conditions	Categorical - 2 conditions
Gender identity	Categorical - 3 conditions	Q	Categorical - 3 conditions	-
b) Socioeconomic variables				
Education level	Categorical - 9 conditions	Categorical - 13 conditions	Categorical - 11 conditions	Categorical - 9 conditions
Occupational status	Categorical [CNO11]	Categorical [CNO11]	Categorical [CNO11]	Categorical [CNO11]
Household size	Discrete	Discrete	Discrete	Discrete
Population Health Survey		Study areas	,	
Variables	A.C. Basque Country	A.C. Andalusia	Barcelona city	Valencian Community
Household income	Categorical - 11 conditions	-	$n_{\rm h}$	Categorical - 8 conditions
Economic difficulty	Categorical - 6 conditions	Categorical - 6 conditions	Categorical - 6 conditions	Categorical - 6 conditions
Employment status	yes/no	yes/no	yes/no	yes/no
Country of birth	Categorical & Open	Categorical & Open	Categorical & Open	Categorical & Open
Marital status	Categorical - 6 conditions	Categorical - 5 conditions	Categorical - 5 conditions	Categorical - 5 conditions
c) Lifestyle factors				
Alcohol consumption	Categorical - 8 conditions	Categorical - 10 conditions	Categorical - 4 conditions	Categorical - 8 conditions
Passive smoking at home	Likert 1-5	yes/no	Discrete (Nº smokers)	yes/no

Daily tobacco				
consumption	yes/no	Categorical - 4 conditions	Categorical - 3 conditions	Categorical - 4 conditior
e) Physical Health				
Non-mental chronic health				
problems	Categorical - 38 conditions	Categorical - 25 conditions	Categorical - 25 conditions	Categorical - 21 condition
d)Mobility				
Years at household	Discrete	-	Discrete	Discrete
MEDIATORS				
a) Physical activity				
Physical activity	Discrete - IPAQ	Discrete - IPAQ	Discrete - IPAQ	Discrete - IPAQ
- Vigorous	MET-min/week	MET-min/week	MET-min/week	MET-min/week
- Moderate	MET-min/week	MET-min/week	MET-min/week	MET-min/week
- Walking	MET-min/week	MET-min/week	MET-min/week	MET-min/week
	Time epopt (hours + minutes)	Time spent (hours +	Time spent (hours +	Time spent (hours +
- Sitting	Time spent (nours + minutes)	minutes)	minutes)	minutes)
b) Social cohesion				
	Ordinal 1 5 [Duka / 11 itama]	Ordinal 1-5 [Duke / 11	Ordinal 1-5/1-4 [OSLO/ 3	Ordinal 1-5 [Duke / 1
Social support	Ordinar 1-5 [Duke / 11 items]	items]	items]	items]
Loneliness	Ordinal 1-4	Ordinal 1-4	Ordinal 1-4	Ordinal 1-4
SUBJECTIVE URBAN ENVIR	CONMENTAL EXPOSURES			
a) Perception of the neighbou	rhood			
Noise outside dwelling	Likert 1-3	Likert 1-3	Likert 1-5	Likert 1-3
Neighbourhood air	Likort 1.2	Likort 1.2		Likort 1.2
pollution	LIKEIT 1-3	LIKEIT 1-3	-	LIKEIT 1-3

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Shortage of green spaces	Likert 1-3	Likert 1-3	-	Likert 1-3
Insecurity	Likert 1-3	Likert 1-3	Likert 1-5	Likert 1-3
¹ The subjects are provided with a	list of medications and are aske	d if they have consumed any of th	em in the last 2 days or 2 wee	eks depending on the
area.				
² The subjects are provided with a	list of chronic health problems a	nd are asked if they currently suff	er or have ever suffered (depe	ending on the study a
from any of them.				

46 Section 4. DATA MANAGEMENT PLAN

47 A) RESEARCH ACTIVITIES

48 <u>Step 1. Population Health Surveys' (PHS) data curation and calibration</u>

The selected individuals were contacted by a phone call, SMS, or letter to arrange an appointment for a face-to face interview for the purpose of the survey. The database produced with the interviews will be pseudonymised from that with the personal data for the contact by assigning a unique code for each participant and remains under the custody of the responsible body in each study area; the Basque Department of Health in the Basque Country, Escuela Andaluza de Salud Pública (EASP) in Andalusia, Agència de Salud Pública de Barcelona (ASPB) in Barcelona, and Conselleria de Salut Universal i Salut Pública (DGSP) in Valencian Community.

56 Step 2. Harmonisation

57 Initially, the databases of each study area will be cleaned, and the variables that require it 58 will be harmonised. The vast majority of the variables to be used in the project have been 59 collected identically in the Population Health Surveys of the study areas included. The variables 60 to be harmonized are listed below and the measures used in each study area can be found in 61 Table S2.

The variables that need harmonisation can be distinguished between simple or complex variables, depending on the level of difficulty and the manipulation of data that require the harmonisation of the respective variable:

Simple variables: Chronic mental health problems, Educational level, Occupation
 status, Household income, Loneliness, Noise outside dwelling, and Insecurity.

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 - Complex variables: mental health, health-related quality of life, sleep quality, consumption of medication for common mental disorders, alcohol consumption, passive smoking at home, tobacco consumption, physical health, and social support.

The Maelstrom Research Guidelines for the rigorous harmonisation of retrospective data (77) will be applied. Among the variables that need harmonisation, the majority can be easily re-categorised (simple variables). For instance, in the case of scales with different score ranges (e.g., Likert scale levels), standardised scores will be calculated, or other procedures will be followed to ensure comparability. The procedure to follow with variables measured with different scales will be more complex (complex variables). For these, the content of each variable will be studied to detect the common content (e.g., items) in each of the study areas. Once detected, aggregate scores will be calculated for the common items, and these scores will be used for statistical analyses. The remaining non-harmonizable variables will be assessed for their potential for performing separate statistical analysis for each study area.

80 Step 3. Georeferentiation

The responsible bodies, in collaboration with regional Statistical Institutes or Population Registers, will link the health survey data to the geographical coordinates of each respondent's home address. The geographical coordinates will also be pseudonymised and sent this way to the research group specialised in Geographic Information System (GIS) estimations that will calculate UrbEE. In order to further ensure the protection of the personal data of the survey participants and enhance their anonymity, fictional coordinates will be created in a number five times the number of participants selected for the study in each study area and sent to the research group specialised in GIS estimations together with the real coordinates.

90 Step 4. GIS estimation of Urban Environmental Exposures (UrbEE)

A company specialised in GIS estimations will calculate the objective urban environmental exposures (UrbEE) of all the geocodes, including the participants' coordinates and the fictional coordinates by GIS.

94 Step 5. Selection and linkage of data

After the estimations are finalised, the responsible bodies of the surveys in each study area will re-select the geocodes of the participants and add the new urban environmental variables to the database with the PHS data. The researchers will be provided with the resultant database of each study area composed by the PHS data and the UrbEE (without geocodes and personal data of the participants). This guarantees that the data supplied are protected by statistical secrecy, not misused and treated anonymously and globally at all times.

102 Step 6. Pooling

Finally, the final databases of all the study areas will be pooled, creating the finalpooled database to be used in the planned analyses.

105 B) DATA STORAGE AND PROCESSING

Data will be kept at all times on servers located in the responsible centre of this project. This way, data will be stored on the University of the Basque Country UPV/EHU's own servers, complying with the greater security and privacy requirements of the LOPD as the data is not sent to external servers. The entire process of recording, dumping and storage of the data will be anonymised, with the data collected being exclusively linked to a sample unit code. Access to the anonymised microdata will be limited to technicians from the responsible centres of each study area through profiles with regulated permissions that allow for supervising and controlling access to the information. Supervision of the data management will be assigned to

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the principal investigators with expert advice, and to the data protection officer of the centreresponsible for the project.

116 C) ETHICAL CONSIDERATIONS AND ACCOUNTABILY

The study was approved by the regional Research Ethics Committee of the **Basque Country**, ETHICS COMMITTEE FOR RESEARCH INVOLVING MEDICINAL PRODUCTS IN THE BASQUE COUNTRY (CEIm-E) (protocol code PI2022138, dated 9th November 2022); Andalusia, BIOMEDICAL RESEARCH ETHICS COMMITTEE OF THE PROVINCE OF GRANADA (CEI/CEIM GRANADA) (protocol code 2078-N-22, dated 27th December 2022); Barcelona, PARC DE SALUT MAR CLINICAL RESEARCH ETHICS COMMITTE (CEIm) (protocol code 2022/10667, dated 2nd December 2022); Valencian Community, ETHICS COMMITTEE FOR CLINICAL RESEARCH OF THE DIRECTORATE GENERAL OF PUBLIC HEALTH AND CENTER FOR ADVANCED RESEARCH IN PUBLIC HEALTH (CEIC DGSP / CSISP) (protocol code 20221125/04, dated 25th November 2022).

This study is based on secondary data obtained from four independent Population Health Surveys (PHS) from Spain. Since the present study does not involve the activity of data collection, to obtain the informed consent from the subjects is not applicable for this study. However, the PHS included this project are official statistical operations included in the respective Statistical Plans of each study area. This ensures that the data provided is protected by statistical confidentiality, it is not misused, its treatment is anonymous and global at all times, and that indirect identification is impossible. Data are collected and processed in accordance with the provisions of the General Data Protection Regulation (GDPR) and in accordance with the provisions of Article 5 of the Organic Law 3/2018 of 5 December on the Protection of Personal Data and the guarantee of digital rights (Regulation (EU) 2016/679), they will be treated confidentially, with access to them being granted to personnel who strictly need to process them in the framework of the study.

Furthermore, the transfer of data occurs between organisations within the Public Health System of each region and the regional or local government itself. This is done in the context of a research project conducted exclusively in the public sphere and with the legitimacy of the use of administrative records as research infrastructures in accordance with the General Health Act, the Biomedical Research Act and the General Law on Public Health. The results of the study will provide information at a sufficiently aggregated territorial level to prevent indirect identification. Furthermore, the project's results will be beneficial to the general population in a holistic way, thanks to its socioeconomic and environmental context, and its evolution over several years from the onset of the COVID-19 pandemic. Therefore, the risk to the privacy of the study population is minimal compared to the potential benefits the results will bring.

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Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project), study protocol.

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-074252.R1
Article Type:	Protocol
Date Submitted by the Author:	03-Jan-2024
Complete List of Authors:	Bereziartua, Ainhoa; University of the Basque Country (UPV/EHU), Department of Preventive Medicine and Public Health; IIS Biodonostia, Group of Environmental Epidemiology and Child Development Cabrera-León, Andrés; Andalusian School of Public Health; CIBERESP Subiza-Pérez, Mikel; University of the Basque Country, Department of Clinical and Health Psychology and Research Methods; Bradford Royal Infirmary García-Baquero, Gonzalo; IIS Biodonostia, Group of Environmental Epidemiology and Child; University of Salamanca Delís Gomez, Salvador; Hospital Universitario Araba Ballester, Ferran; University of Valencia, Faculty of Nursing and Chiropody; Foundation for the Promotion of the Research in Healthcare and Biomedicine, Epidemiology and Environmental Health Joint Research Unit Estarlich, Marisa; Universitat de Valencia, Faculty of Nursing and Chiropody; Foundation for the Promotion of the Research in Healthcare and Biomedicine, Epidemiology and Environmental Health Joint Research Unit Estarlich, Marisa; Universitat de Valencia, Faculty of Nursing and Chiropody; Foundation for the Promotion of the Research in Healthcare and Biomedicine, Epidemiology and Environmental Health Joint Research Unit Merelles, Antonio; Universitat de Valencia, Faculty of Nursing and Chiropody; Foundation for the Promotion of the Research in Healthcare and Biomedicine, Epidemiology and Environmental Health Joint Research Unit Esplugues, Ana; Universitat de Valencia, Faculty of Nursing and Chiropody; Foundation for the Promotion of the Research in Healthcare and Biomedicine, Epidemiology and Environmental Health Joint Research Unit Irles, Maria Angeles; General Directorate of Public Health Barona, Carmen; General Directorate of Public Health Barona, Carmen; General Directorate of Public Health; Foundation for the Promotion of the Research in Healthcare and Biomedicine, Research group "Local Action on Health and Equity (ALES)" Font-Ribera, Laia; Agencia de Salut Publica de Barcelona; Institut d'Investigacio Biomedica Sant Pau Bartoll, X; Agenc

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Primary Subject Heading :	Mental health
Secondary Subject Heading:	Epidemiology
Keywords:	PUBLIC HEALTH, MENTAL HEALTH, Health Equity, EPIDEMIOLOGIC STUDIES, Quality of Life

SCHOLARONE[™] Manuscripts

Title

Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project); study protocol.

Word count: 4,872 (excluding Abstract and Declarations)

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Abstract

Introduction: The European Environment Agency estimates that 75% of the European population lives in cities. Despite the many advantages of city life, the risks and challenges to health arising from urbanization need to be addressed in order to tackle the growing burden of disease and health inequalities in cities. This study, *Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain* (DAS-EP project), aims to investigate the complex association between the urban environmental exposures (UrbEEs) and health.

Methods and analysis: DAS-EP is a Spanish multiregional cross-sectional project that combines Population Health Surveys (PHS) and Geographical Information System (GIS) allowing to collect rich individual level data from 17,000 adult citizens participating in the PHS conducted in the autonomous regions of the Basque Country, Andalusia, and the Valencian Community, and the city of Barcelona in years 2021 to 2023. This study focuses on the population living in cities or metropolitan areas with more than 100,000 inhabitants. UrbEEs are described by objective estimates at participants' home addresses by GIS, and subjective indicators present in PHS. The health outcomes included in the PHS and selected for this study are self-perceived health (general and mental), prevalence of chronic mental disorders, health-related quality of life, consumption of medication for common mental disorders, and sleep quality. We aim to further understand the direct and indirect effect between UrbEEs and health, as well as to estimate the impact at the population level taking respondents' socio-demographic and socioeconomic characteristics, and lifestyle into consideration.

Ethics and dissemination:

The study was approved by the regional Research Ethics Committee of the Basque Country (CEIm-E; PI2022138), Andalusia (CEIM GRANADA; 2078-N-22), Barcelona (CEIC-PSMar; 2022/10667), and Valencian Community (CEIC DGSP/CSISP; 20221125/04). The results will be

communicated to the general population, health professionals and institutions through conferences, reports, and scientific articles.

Strengths and limitations of this study

- The linkage of four independent population health surveys (PHS) will provide the study with a large volume of information and sample size.
- The method is novel for the inclusion of objective & subjective UrbEEs as well as the combination of PHS from different study areas and GIS estimates.
- Despite the cross-sectional nature of the study, the results will ultimately help identify urban indicators, increasing the capacity to detect and intervene in community health outcomes, improving the routine surveillance and monitoring of the cities' health information systems.

1 1. Introduction

According to the World Health Organization, modifiable environmental factors are responsible for 23% and 22% of the global mortality and morbidity respectively [1]. As reported by the European Environment Agency, in 2021 75% of the European population lived in urban areas including cities but also smaller urban settlements and suburban areas, developed for residential, industrial or recreational purposes [2]. The local urban environment influences people's health by determining their level of urban environmental exposures (UrbEEss) [3,4]. The UrbEEss include the totality of the surrounding natural (e.g., green and blue spaces), built (e.g., walkability, urbanisation level, traffic,) and social (e.g., security, public services) environments within which people live, move, and interact, as well as environmental stressors like air pollution and noise. Increasing evidence shows that UrbEEss such as lack of greenness, air pollution and noise can impact population's mental and physical health and quality of life [5–9]. The health implications of environmental exposures become even more relevant in the contemporary demographic setting, given that they are perhaps starker in urban areas [10–14]. Moreover, in many regions, environmental exposures are not evenly distributed across socioeconomic status and thus, socio-economically vulnerable populations are also affected by poorer environmental quality [10,11]. In fact, this double jeopardy may result in individuals from poorer socioeconomic backgrounds more significantly affected by environmental exposures [4,15]. A comprehensive approach is crucial for understanding the interplay of various environmental determinantswith health and well-being within urban settings. A holistic multi-exposure framework should be adopted, as outlined by Hammersen et al. [16], that extends beyond traditional considerations and incorporates critical urban contextual issues such as substandard housing, crowding, economic inequality, and the evolving challenges posed by climate change, as well as individual psychosocial factors [17,18]).

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26 UrbEEs, including environmental stressors, traffic-infrastructure, natural spaces, and 27 built environment, have all been studied in relation to health. Widespread evidence in the 28 literature shows that air pollution, noise, and lack of green space are related to a range of 29 chronic physical diseases [19-24]. Recently, it has been suggested that air pollution is 30 associated with a range of mental disorders and poorer sleep quality [21,25–28]. Other recent 31 studies observed that environmental noise has negative effects on mental health, well-being, 32 and sleep quality [27,29–31], while evidence on its impact on prescriptions and consumption 33 of medication for common mental disorders has yet to be scientifically confirmed [32]. 34 Otherwise, current scientific evidence indicates that residential greenness is positively 35 associated with mental health and quality of life [31,33,34], and lower consumption of 36 anxiolytics, antidepressants, and sleeping pills [27,35]. Blue spaces (aquatic environments such 37 as rivers, lakes, and the coast) are expected to have similar health effects to those described here, however, evidence on this subject is limited [35,36]. As for the built environment, 38 39 walkability or accessibility have also been related to reduced obesity and better cardiovascular 40 health [37], improved mental health [38,39] and well-being [40]. To date, the main 41 mechanisms proposed to explain these associations are the mitigation of exposure to 42 environmental pollutants, the promotion of physical activity, and the strengthening of social 43 cohesion [33,34,37,41–43]. Moreover, these mechanisms are probably synergistic [44]. The 44 correlations between several UrbEEs and their relationship with behavioural exposures, such 45 as physical activity and social cohesion, makes the assessment of these associations and pathways highly challenging [45-49]. Hence, noise and air pollution could act both as 46 47 exposures, mediators, or potential confounders. Overall, results of previous studies are quite 48 mixed and the associations as well as the underlying mechanisms between UrbEEs and mental 49 health outcomes need more robust scientific evidence [5,47,50–52].

50 This knowledge gap can be partly explained by the heterogeneity and limitations of 51 exposure and outcome metrics used in the studies [19,52,53]. Moreover, there is a lack of

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studies addressing the impact of UrbEEs on health integrating objective and perceived accounts of such exposures [54]. Therefore, it is evident that more research is needed to determine which UrbEEs are associated with health, the potential mechanisms involved, and the role of social aspects in those associations. Beyond this, researchers are increasingly called to provide information that can guide the selection of the best and most feasible interventions to improve public health in cities. In this respect, experts in the field have claimed the vital role that health impact assessment tools play when integrating the evidence in the decision-making process [55,56].

Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project) is a 3-year project (2023-2025) aimed at further investigating the associations and underlying mechanisms, including direct and indirect effects, between UrbEEs and health with a health equity perspective. Five main objectives have been established for this project:

1. To estimate, describe, and compare the objective and subjective levels of UrbEEs in the study areas.

- 2. To describe urban environmental inequalities according to socio-demographic and socio-economic variables, as well as the study area.
- 3. To estimate the association of UrbEEs with self-perceived general and mental health, health-related quality of life, chronic mental disorders, consumption of medication for common mental disorders, and sleep quality (Figure 1)¹.
 - 4. To estimate the impact of UrbEEs on the health outcomes under evaluation, at the population level, and to conduct a health impact assessment.

¹ For a summary of current prevalence of common mental disorders in Spain, please see section 3.A in the Supplementary file.

 To assess the mediating role of physical activity, social cohesion, and environmental stressors on the association between UrbEEs and the health outcomes under evaluation (Figure 1).

The general hypothesis of this research project is that the urban environment directly or indirectly affects mental health and quality of life. In line with the first objective of the project, we expect significant differences in levels of exposure to urban environmental variables among the cities under study. Regarding the second objective, we expect participants with lower socio-economic status, lower educational levels, and less remunerated occupations to live in residential environments of poorer environmental quality. We expect them to live in areas with less availability of green and blue spaces, lower walkability scores, and higher levels of noise and air pollution. Finally, we expect the various environmental exposures reported in this study to be significantly associated with the various health and mental health variables studied in the project. Notably, we anticipate that air pollution and noise may have negative effects on mental health, while exposure to natural (green and blue), and more walkable spaces will show protective effects against bad mental health. Furthermore, in line with recent literature, we expect that part of these potential effects on mental health might be produced through increased physical activity and social cohesion.

91 2. Methods and analysis

92 2.1. Study design

This is a cross-sectional study based on information from Population Health Surveys (PHS) carried out in adult population living in urban areas, with more than 100,000 inhabitants, in the autonomous regions of the Basque Country, Andalusia, the Valencian Community, and the city of Barcelona in Spain. The study integrates observational data collected within the four independent PHS in 2021-2023 with Geographic Information System (GIS) estimations of individual UrbEEs. It entails the following research activities: 1) preparing, integrating, and

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calibrating PHS data from each study area, 2) harmonising the variables that have been collected differently in the four study areas, 3) georeferencing survey respondents' home addresses, 4) characterizing each home address in terms of UrbEEs by GIS, 5) linking UrbEEs estimates with PHS data, and 6) pooling of datasets from the four study areas (Figure 2). Using the final pooled database, we will analyse the association between UrbEEs and health in a cross-sectional manner, considering sociodemographic, socioeconomic and lifestyle factors. Figure 1 shows the conceptual framework designed within the scope of this project. DAS-EP received Ethics Approval from the relevant regional ethics committees (see more Supplementary file section 5). This project has received funding from the Instituto de Salud Carlos III (ISCIII) under the Strategic Action in Health with the Health Research Fund (FIS) in the call 2022 (file No. PI22/01051 and No. PI22/00512). The project runs from 2023 to 2025.

2.2. Study population

The target population are inhabitants of the autonomous communities of the Basque Country, Andalusia, the Valencian Community, and the city of Barcelona. The sampling frames are made up of people over 15 or 16 years of age of the respective study areas. The study population includes the PHS' participants living in urban areas with more than 100,000 inhabitants in the regions mentioned before (Figure S1, S2). The cities and metropolitan areas participating in this study are: the city of Vitoria-Gasteiz, and the metropolitan areas of Bilbao and Donostia-San Sebastián in the Basque Country; the cities of Almeria, Cadiz, Cordoba, Huelva, Jaen, and the metropolitan areas of Granada, Malaga, and Seville in Andalusia; the cities of Castellon, Valencia, Elche and Alicante in the Valencian Community; and the city of Barcelona (Table S1).

55121The PHS included in this project are official statistical operations that are incorporated in5657122the Statistical Plans of each study area. These activities are conducted by every regional or5859123local public administration with jurisdiction in health and are a fundamental tool to monitor

> the status and evolution of relevant health conditions in the population, their main determinants, and the use of health services [57–60]. Accordingly, these regional and local cross-sectional epidemiological surveys are carried out by the Basque Department of Health in the Basque Country [57], Andalusian School of Public Health (EASP) in Andalusia [58], Barcelona Public Health Agency (ASPB) in Barcelona [59], and Foundation for the Promotion of Health and Biomedical Research in the Valencian Region (DGSP) in Valencian Community [60]. They have been organised every 4-5 years since 1986 (Basque Country), 1999 (Andalusia), 1983 (Barcelona) and 1991 (Valencian Community). The sample design and the selection of the sample is carried out independently in each region by the statistical institute (The Basque Institute for Statistics in the Basque Country, Institute of Statistics and Cartography of Andalusia in Andalusia, and municipal statistical office of the Barcelona city council in Barcelona) or health population information system (Valencian Community). Data from the latest version of these surveys is included in this project. After the surveys are completed, we expect a total estimated sample of 16,953 individuals, of which 7,846 participants will be from the Basque Country, 3,085 from Andalusia, 3,134 from the Valencian Community, and 4,000 from the city of Barcelona. More detailed information is provided in Table S1.

140 2.3. Data collection

141 2.3.1. GIS estimates of urban environmental exposures (UrbEEs)

Objective measures of UrbEEs are estimated by a company specialised in GIS based on the geographic coordinates of the participants' home addresses. A significant number of these variables will be expressed in buffers around each participant's residence or at the building level. All environmental exposures will be assessed preceding to, and as close as possible to the time the PHS are being conducted (2021-2023) to avoid temporal mismatch [61]. The objective UrbEEs of interest in this project include exposures originated from surrounding natural spaces, built environment, traffic-infrastructure, and environmental stressors. Detailed

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information on the UrbEEs estimated within the scope of this project can be found in theSupplementary file (Table S2).

151 Surrounding natural spaces

<u>Green spaces.</u> Five green space exposure metrics will be calculated in buffers of 100, 300
 and 500 m around each geocode: 1) percentage of green space; 2) mean Normalised
 Difference Vegetation Index (NDVI) [62,63]; 3) percentage of tree cover; 4) Euclidean
 distance to the nearest green space larger than 5,000 m² [64], and 5) presence of a major
 green area (greater than 5,000 m²).

Blue spaces. Any blue environments, including lakes, rivers, or coastline will be considered
 as blue space. Three blue space exposure variables will be estimated: 1) presence of water
 surface; 2) percentage of water surface; and 3) Euclidean distance to nearest water surface
 greater than 5,000m². The first two refer 100, 300 and 500 m buffers around each geocode
 [65].

162 Built environment

Building density. The building density around each home address in 100, 300 and 500 m
buffers will be estimated, considering not only the perimeter of the buildings but also
their height [66].

Walkability. An overall walkability index in 100, 300 and 500 m buffers around the
 participants' home addresses will be calculated. This index will include of the following
 subindices: 1) population density (at the census tract level), 2) street density, 3) street
 connectivity, 4) land use Shannon Evenness Index, 5) facility richness, 6) facility density, 7)
 average slope, and 8) transport density [67,68].

171 Traffic infrastructure

172 - <u>Major road (Yes vs. No).</u> Presence of a major road (with >3 million vehicle passages per

year) in 100, 300 and 500 m buffers around the participants' home addresses [66].

<u>Distance to major road</u>. Distance to the nearest major road (with >3 million vehicle
 passages per year) from the participants home addresses [66].

176 Environmental stressors

Air pollution. Spatiotemporal daily models at household-level for particulate matter (PM₁₀ and $PM_{2.5}$) and nitrogen dioxide (NO₂) will be constructed for all study areas using multistage mixed models. These models are known as spatiotemporal land-use random-forest model [69] and combine ground-level and satellite measurements, land use and meteorology. A precise daily estimate of the exposures will be obtained for all study subjects (period 2006 to 2023). Using the daily estimates, annual average for the last five years and the five-year average of NO₂, PM₁₀ and PM_{2.5} exposure levels will be calculated at PHS respondents' home address as indicators for long-term air quality.

Environmental noise. The Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge will be used. All potential sources of environmental noise at street level will be examined, including road traffic, rail, industrial, airports and total noise [70,71]. Major roads, major railways, and major airports will be included in cities where this information is available and not included in the agglomeration layer. Agglomerations corresponding to the closest street to the dwelling, and major roads and airports corresponding to the closest isoline will be used. In all cases, the Euclidean distance to each source will also be calculated. The daytime (L_d), evening (L_e), night-time (L_n), and total (L_{den}) noise indices will be assigned.

194 2.3.2. Contextual socioeconomic variables

195 Neighbourhood-level socioeconomic status (SES) will be considered via three variables, 196 namely, mean income, income distribution P80/P20, and the MEDEA deprivation index

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(composed by percentage of the population with manual labour, percentage of the population
with casual labour, percentage of the population unemployed, percentage of the population
with insufficient education, percentage of the population of young people with insufficient
education) [72]. All these metrics will be obtained from the publicly available data developed
by the Spanish National Institute for Statistics (INE) and expressed at the census tract level
(Table S3).

203 2.3.3 Individual socio-demographic and socio-economic variables

To describe respondents' individual-level SES, eight variables will be selected: country of birth, marital status, household size, level of education, employment and occupational status, reported household income, and economic difficulty of the household (Table S4)

207 2.3.4 Information collected through Population Health Surveys

Information from four independent PHS that represent four study areas is included in the study. The surveys are carried out between 2021-2023, being Barcelona city the earliest in completing the collection (2021 February – 2022 March), followed by the Valencian Community (2022 April – 2022 December), Andalusia (2022 April – 2023 April), and the Basque Country (2022 October – 2023 June) (Table S1). During each survey, detailed information is collected though face-to-face interviews and self-administered questionnaires. The PHS collect information on different health aspects, morbidity, and use of health services. It also gathers information on social determinants of health such as socio-economic status, working conditions, social cohesion, health-related behaviours and perception on residential environment. Most of these variables are measured with validated screening tools. The selection of relevant variables to be included in this project was based on a literature review and the most appropriate variables to meet the objectives of the study were selected from among the variables collected by the PHS. All the study areas collected the main variables of the study (i.e., mental health, health-related quality of life, physical activity, social cohesion,

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and sleep), however, in some cases, the measuring instruments differ across the study areas. Detailed information about the variables and the measuring instruments used in each study area can be found in Table S4. Health outcomes Several health outcome variables are included in this study. Perceived general health. Self-assessment of health was measured as an ordinal response, with five categories (1, Excellent; 2, Very good; 3, Good; 4, Fair; 5, Poor). Perceived mental health. This variable was collected with the Mental Health Inventory [73], the SF-12 (Short-Form Health Survey 12) scale [74] or the General Health Questionnaire (GHQ-12) [75]. Health-related quality of life. This variable was measured with the Euroqol-5D-5L-EAV scale -[76] or the SF-12 (Short-Form Health Survey 12) scale [74]. Sleep duration and quality. The duration of sleep, indicated as the total number of hours per day spent on sleep including napping was calculated. The quality of sleep was collected using the SATED scale (Satisfaction Alertness Timing Efficiency and Duration Scale) [77] or discrete items. Prevalence of chronic mental health problems. Participants had to indicate whether they had been diagnosed with depression, anxiety, and sleeping disorders at any time throughout the life. We then built a dichotomized (yes/no) variable for each condition. Consumption of medication for common mental disorders. Information on consumption of medication for common mental disorders, such as, anxiolytics, antidepressants and hypnotics was reported on bi-daily or bi-weekly basis depending on the study area. Covariates A set of individual level variables will be used as control variables in the statistical analyses.

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Anthropometric variables. The surveys collect information on sex, age, weight, and height
 of individuals. A Body Mass Index (BMI) (kg/m²) will be calculated using information given
 by the participants about their height and weight at the moment of filling the
 questionnaire.

2 250 - Individual socio-demographic and socio-economic variables. To describe respondents'
 3 251 individual-level SES, eight variables will be selected: country of birth, marital status,
 4 251 household size, level of education, employment and occupational status, reported
 8 253 household income, and economic difficulty of the household.

254 - <u>Lifestyle factors.</u> These will include consumption habits such as alcohol consumption,
 255 passive smoking at home, and tobacco use.

256 - <u>Physical health.</u> A chronicity index will be calculated based on presence of one or more

257 non-psychological chronic conditions (e.g., diabetes, heart disease, cancer, etc.).

258 The following social and behavioural variables will be treated as potential mediators.

259 <u>Social cohesion and loneliness</u>. Social cohesion is measured with the Duke-UNC-11 scale [78]

260 or the OSLO-3 tool [79]. Perceived loneliness is collected with a single item for participants to

261 report about the frequency in which they feel loneliness. The variable is displayed in a 1 to 4

262 (1= always; 2= often; 3= sometimes; 4= never) response scale.

Physical activity. The International Physical Activity Questionnaire (IPAQ) [80] to measure
 the physical activity performed by the participants. Days per week and time spent in
 vigorous physical activity, in moderate physical activity, and walking more than 10
 minutes, and time spent sitting on a normal day will be available.

267 Perception of the neighbourhood

268 Perceived accounts of UrbEEs are collected through PHS employing 3-point or 5-point269 Likert format questions depending on the study area. These include: 1) perception of noise
outside the dwelling, 2) perception of shortage of green areas in the residential environment,
3) perception of air pollution in the residential environment, and 4) perception of insecurity in
the neighbourhood.

273 2.4. Data analysis

Initially, all databases will be cleaned. The variables will be harmonised, when needed, following the Maelstrom Research Guidelines for rigorous harmonisation of retrospective data [81]. Nonetheless, because most variables have already been collected consistently in the respective Population Health Surveys, few variables will require harmonisation (see Supplementary file Section 3). Among the few variables requiring harmonisation, most will be re-categorised. For more information, see Supplementary file Section 4. Subsequently, both exploratory and descriptive analysis will be applied using numerical and graphical techniques [82]. Before proceeding to inference, sample weights for each survey will be adjusted through calibration [83], so that we may compensate for non-response and coverage biases and improve accuracy. This calibration will be carried out separately for each study area, so that region-level estimates are obtained first, and then harmonized to obtain estimates at population level.

The relationships between the various UrbEEs and health outcomes will be analysed according to the multilevel, or hierarchical structure [84] that the data possesses, as census tracts are nested within cities, and cities are nested within autonomous regions. Generalised linear mixed models (GLMMs) will be applied to investigate the relationship between urban environment and health. The sets of adjustment covariates used in these models will be chosen by applying robust causal inference techniques based on directed acyclic graphs (DAGs) [85], both for the estimation of direct effects and hypothetical indirect effects mediated by air pollution, environmental noise, physical activity, and social cohesion. This will imply the prior design of a DAG describing the relationships among UrbEEs, health outcomes and other

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potentially implicated variables [86,87]. The testable implications derived from this DAG will be checked following the procedure described by Ankan and colleagues [88], thereby updating the DAG if needed [89,90]. These graphical models will guide the inclusion of relevant socio-demographic and socioeconomic variables, allowing us to account for potential confounding factors and illuminate causal relationships. The length of time living in the same home/place will be considered by excluding individuals living at the same place of residence for less than one and less than five years in separate models. Equity will be addressed performing subgroup analysis to investigate potential vulnerable groups such as lower-income populations, the elderly, women, and marginalized communities.

In case of demonstrating a significant relationship between a given exposure and a certain outcome, we also intend to identify the specific exposures that cause most disease in the populations of interest via the population attributable fraction (PAF) [91]. To estimate the PAF we will require previous estimations of relative risk (RR) and either the prevalence of exposure in the population or the prevalence of exposure among the cases of disease. All these previous estimates will be available. The possible existence of spatial clusters in the UrbEEs distribution will also be studied using the standard spatial scan statistic method [92] and calculating the posteriori probabilities for the smoothed standardised ratios to be greater than unity, in the general framework of Bayesian hierarchical standardised ratio smoothing models.

313 The analyses will be implemented using the latest version of the R software packages *dagitty* [85], *DClusterm* [93,94], *R INLA* [95], *Sampling* [96] and others.

315 2.5. Data Management Plan

The data management plan can be found in the Supplementary file Section 4. The source and type of data that will be collected within the scope of this project is described in this plan, together with the accessibility and ownership of data. Data storage and processing, as well as the procedure to guarantee the specific ethical and legal requirements, are likewise explained.

2.6. Patient and Public Involvement

Patients and the public will not be involved in the design, or conduct, or reporting, ordissemination plans of our research.

323 3. Discussion

The present study is a clear commitment to the generation of urban environmental indicators potentially explanatory of self-perceived health (physical and mental), chronic mental disorders, health-related quality of life, consumption of medication for common mental disorders and sleep quality with a health equity perspective. This project responds to the national Spanish Strategic Plan for Health and the Environment (PESMA) 2022-2026 [97], to the local implementation of the Strategy for Health Promotion and Prevention in the National Health System [98] as well as to the main objective of the Spanish Urban Agenda 2019 [99] that cities should have a global vision that takes into consideration the physical, mental, and social well-being of their inhabitants. Likewise, it is aligned with three of the Sustainable Development Goals (SDG) of the World Health Organization (SDG.3 - Good Health and Well-being, SDG.10 – Reduced Inequalities, and SDG.11 – Sustainable Cities and Communities) (97,98).

When it comes to health-promoting urban and transport design, there is a lack of standardized, quantitative indicators to guide the integration of health components right from the outset [57,100]. In this context, the DAS-EP project not only aims to obtain individual UrbEEs estimates but also to assess their association with, and impact on various health outcomes. By means of PHS, the health effects to be studied in this project are derived from an unbiased population, which allows to obtain an approximate estimate of the impact at population level. Moreover, it is important to identify the precise routes that connect urban environment to health because they can guide the most efficient interventions, allowing us to design healthy(er) cities [55,101]. In this sense, the DAS-EP project investigates various

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components of the urban environment and health at individual level. Besides using complementary indicators that describe both the physical and the social urban environment (e.g., neighbourhood insecurity), combines objective and perceived indicators to deepen the characterization of the urban environment. By combining these data, it is possible to develop a more precise understanding of the effects of urban environment on health, while describing the complexity of the relationship influenced by neighbourhood environmental and individual characteristics [102–104].

The main limitation of this study is its cross-sectional nature. Due to the chronic character of the health conditions included in the study (e.g., depression, insomnia) and the possible long-term effects of UrbEEs, a longitudinal design would be more informative and appropriate. Although PHS have a cross-sectional approach, the question "since when have you been living at your current address" enables to account for the extent of exposures. Drawing on this mobility data, sensitivity analysis of the models will be fitted reducing the risk of exposure misclassification. Another limitation is that the samples from the study areas of the Basque Country, Andalusia, and Valencian community, although representative of the study population (considering the inclusion criteria) may not be representative of the autonomous communities from which they come as we are not considering the non-urban municipalities (<100,000 inhabitants). Despite the weight calibration to be conducted to reduce coverage and representativeness biases, the reweighing procedure will not guarantee the elimination of other response biases that may affect data collection from PHS (as acquiescence, social desirability, etc.) which could affect the validity of the results [105,106]. Furthermore, the project is subject to residual confounding, which in turn implies confounders that could not be controlled and, importantly, measurement errors in the confounders that have been included. In this regard, the estimation UrbEEs by GIS is affected by the problem of uncertainty of the temporal and geographical context [107].

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The use of buffer zones may not be appropriate to evaluate contextual effects on health because they fail to analyze the spatial-temporal distribution of residents' activities and their relationship with built environment factors. Using activity space measures would be preferable to comprehensively assess of environmental exposures by capturing the complexity of individual movements [108–110]. The reliance on publicly available data applicable to all study areas together with scalability challenges were major barriers to estimate street-level (or microscale) variables like bicycle and pedestrian infrastructure [111-113]. Moreover, future studies should not only include more variables reflecting the social capital (e.g., perceived sense of community) but also analyse the health implications of other relevant urban exposures like substandard housing, crowding, and indoor air pollution. Finally, the heterogeneity across study areas in terms of geographic scale (autonomous communities vs. city) may be a source of information bias. In this vein, the majority -but not all- of the scales and variables included in the different PHS are identical. These minor differences in data collection across PHS may lead to additional information biases hindering the comparability of the data. To minimize this problem, special attention will be paid to the selection and harmonization of the variables to be included to ensure the consistency of data before making the comparisons across study areas.

As for the strengths of this project, pooling linked surveys across study areas will make it possible to compare the results in different populations, providing a comprehensive dataset that is larger than most existing cohort studies, and that have an unique national and population perspective. The results will be novel in terms of their thematic (objective & subjective UrbEEs) and methodological approach (combination of PHS from different study areas and GIS estimates), as well as in terms of the large volume of information that will be handled and the large sample size of the study. Beyond that, the standardization of the procedure described herein will generate useful information to assist in the planning of

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national health surveillance programs, research studies and, more importantly, interventionsto strengthen population's health.

In short, the results and products (i.e., databases, computer codes) of this project will greatly contribute to estimate the proportion of the population exposed to different UrbEEs, identify health disparities while considering UrbEEs, estimate how these exposures relate to and affect various health variables, and conduct a health impact assessment of UrbEEs. We will have taken a further step towards understanding and improving the urban environment and being able to establish corrective measures in the urban development plans of the cities.

Declarations

Ethics and dissemination

The study was approved by the regional Research Ethics Committee of the **Basque Country**, ETHICS COMMITTEE FOR RESEARCH INVOLVING MEDICINAL PRODUCTS IN THE BASQUE COUNTRY *(CEIm-E)* (protocol code PI2022138, dated 9th November 2022); **Andalusia**, BIOMEDICAL RESEARCH ETHICS COMMITTEE OF THE PROVINCE OF GRANADA (CEI/CEIM GRANADA) (protocol code 2078-N-22, dated 27th December 2022); **Barcelona**, PARC DE SALUT MAR CLINICAL RESEARCH ETHICS COMMITTE (CEIm) (protocol code 2022/10667, dated 2nd December 2022); **Valencian Community**, ETHICS COMMITTEE FOR CLINICAL RESEARCH OF THE DIRECTORATE GENERAL OF PUBLIC HEALTH AND CENTER FOR ADVANCED RESEARCH IN PUBLIC HEALTH (CEIC DGSP / CSISP) (protocol code 20221125/04, dated 25th November 2022). The results will be communicated to the general population, health professionals and institutions through conferences, reports, and scientific articles.

Competing interests

The authors declare that they have no competing interests.

Funding statement

This project was supported by the Instituto de Salud Carlos III (ISCIII) under the Strategic Action in Health with the Health Research Fund (FIS) in the call 2022 (file No. PI22/01051 and No. PI22/00512). Data collection is funded by the various agencies responsible for the included health surveys. In addition to the FIS funding, the group has its own financial means for other expenses including publication and dissemination of results, travel expenses and conference registrations related to the study.

Authors' contributions

Conceptualisation, A.L., A.CL., M.S-P
Methodology, A.L., A.CL., M.S-P
Writing, original draft preparation, A.B., A.L., M.S-P., A.C-L
Writing, review and editing, A.B., A.L., M.S-P., A.C-L., S.C.G., G.G-B., S.D.G., F.B., M.E., A.M.,
A.E., M.A.I., C.B., R.M., L.F-R., X.B., K.P., L.O., A-C.B., A.D., L.G., H.G.C., M.L.N., R.C., M.M.R.,
M.S
Project administration, A.L., A.C-L., A.B., M.S-P
Funding acquisition, A.L., A.C-L., M.S-P
All authors have read and agreed to the published version of the manuscript.
Acknowledgements
We thank all institutions [Basque Department of Health in the Basque Country, Andalusian
School of Public Health (EASP) in Andalusia, Barcelona Public Health Agency (ASPB) in
Barcelona, and Foundation for the Promotion of Health and Biomedical Research in the
Valencian Region (DGSP) in Valencian Community] developing the Population Health Surveys
that are used in this project.
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Legends

Figure 1. Conceptual framework designed within the scope of this project, including potential direct and indirect effects of urban environmental exposures (UrbEEs) on the health outcomes under study. * Potential mediators on the association between UrbEEs and the health outcomes under evaluation.

Figure 2. Summary of data management plan and the institutions involved during the development of the final database (DB) to be used by the research group in the analyses.





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Title of data: Supplementary data of Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project), study protocol.

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Section 1. GENERAL CHARACTERISTICS OF THE STUDY AREAS

Figure S1. Study areas of the project, being the cities and metropolitan areas (M.A) with more than 100,000 inhabitants from the autonomous communities of the Basque Country and Andalusia, Valencian Community, and the city of Barcelona. Figure edited from Daniel Dalet / d-maps.com.



Figure S2. Population density of Spanish provinces in 2022. Figure edited from Instituto Geográfico Nacional, *La población en España 2022*. Accessed through: <u>https://www.ign.es/pobesp/pe1.htm</u>

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Section 2. GENERAL CHARACTERISTICS OF THE POPULATION HEALTH SURVEYS

 Table S1. Characteristics of the study areas and the population health surveys comprised in the project.

Study area	Cities and areas of influence	Population health survey	Re	sponsible body	Sample size	Data collection period
A.C. Basque Country	Vitoria-Gasteiz	Encuesta de Salud de	\checkmark	Basque Department of	7,846	2022 October –
	Donostia-San Sebastián (M.A)	la Comunidad		Health		2023 June
	Bilbao (M.A)	Autónoma País Vasco (ESCAV)				
A.C. Andalusia	Almería	Encuesta Andaluza de	\checkmark	Andalusian School of	3,085	2022 April –
	Cádiz	Salud (EAS)		Public Health (EASP)		2023 April
	Córdoba					
	Huelva					
	Jaén					
	Granada (M.A)					
	Malaga (M.A)					
	Sevilla (M.A)			CI.		
Barcelona city	Barcelona	Encuesta de Salud de	\checkmark	Barcelona Public Health	4,000	2021 February –
		Barcelona (ESB)		Agency (ASPB)		2022 March
Valencian	Castellon	Encuesta Salud	✓	Foundation for the	3,134	2022 April –
Community	Valencia	Comunidad		Promotion of Health and		2022 December
	Elche	Valenciana (ESCV)		Biomedical Research in		
	Alicante			the Valencian Region ——— (DGSP)		

Abbreviations: A.C., Autonomous community; M.A, Metropolitan Area.

Section 3. OVERVIEW OF THE VARIABLES OF THE STUDY PER STUDY AREA

 Table S2. Objective urban environmental exposures obtained through GIS estimations.

GIS Variables	Study areas: A.C. s of the Basque Country and Andalusia, Valencian Community & the city of Barcelona		
OBJECTIVE URBAN ENVIRONMENTAL EXPOSURES	Scale	Variable	
a) Surrounding natural spaces Green Spaces			
Green space percentage	100, 300, 500m buffers	Percentage of green space.	
NDVI	100, 300, 500m buffers	Annual mean Normalised Difference Vegetation Index (NDVI) of the year when the surveys were conducted and the mean NDVI of the last 5 years previous to the surveys.	
Tree percentage	100, 300, 500m buffers	Percentage of tree cover based on Growing stock volume (GSV) data.	
Distance to green space		Euclidean distance to the nearest major green space (green surface over 5,000m ²).	
Green spaces Yes (vs. No)	100, 300, 500m buffers	Dichotomous variable of presence of major green spaces (green surface over 5,000m ²) from local topographical or Europe-wide maps (Urban atlas).	
Blue spaces			
Blue spaces Yes (vs. No)	100, 300, 500m buffers	Dichotomous variable of presence of water surfaces. Based on Urban Atlas.	
Blue space percentage	100, 300, 500m buffers	Percentage of water surface. Based on Urban Atlas.	
Distance to blue space		Euclidean distance to the nearest water surface over 5,000m ² . Based on Urban Atlas.	
b) Built environment			
Building density	100, 300, 500m buffers	The building density around each household will be calculated accounting for the perimeter and height of the buildings from local cadastre data or Europe-wide maps (Urban Atlas).	
Population density	100, 300, 500m buffers	The number of inhabitants (per km ²) surrounding the home addresses.	
Street connectivity	100, 300, 500m buffers	Using data from OpenStreetMap [®] .	
Accessibility (bus lines)	100, 300, 500m buffers	Access to public transport bus lines from local topographical maps or OpenStreetMap®.	
Accessibility (bus stops)	100, 300, 500m buffers	Access to public transport bus stops from local topographical maps or OpenStreetMap®.	
Facility richness	100, 300, 500m buffers	Using local topographical maps or OpenStreetMap [®] .	
Facility density	100, 300, 500m buffers	Using local topographical maps or OpenStreetMap [®] .	
Land use	100, 300, 500m buffers	Mixed land use will be estimated by Shannon's Eveness Index based on Urban Atlas data.	
Walkability index	100, 300, 500m buffers	Index constructed from seven indicators: population density, street connectivity, street density, facility richness, facility density, land use, transport density, and average slope.	
c) Traffic infrastructure			
Major road Yes (vs. No)	100, 300, 500m buffers	Dichotomous variable of presence of a major road (OpenStreetMap®).	
Inverse distance		Inverse distance to the nearest major road (OpenStreetMap®).	

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GIS Variables	Study areas: A.C. s of the Basque Country and Andalusia, Valencian Community & the city of Barcelona			
OBJECTIVE URBAN ENVIRONMENTAL EXPOSURES d) Environmental stressors Air pollution	Scale	Variable		
PM _{2.5}	Street level (at residential address)	PM _{2.5} exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.		
PM10	Street level (at residential address)	PM ₁₀ exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.		
NO ₂	Street level (at residential address)	NO ₂ exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.		
Noise				
Day (L _d)	Street level (at residential address)	Exposition to environmental noise at street level during the day indicated as: a) the annuate average for the last five years, and b) the five-year average for the last five years based of Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.		
Evening (L _e)	Street level (at residential address)	Exposition to environmental noise at street level during the evening indicated as: a) the annual average for the last five years, and b) the five-year average for the last five years base on Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.		
Night (Ln)	Street level (at residential address)	Exposition to environmental noise at street level during the night indicated as: a) the annuate average for the last five years, and b) the five-year average for the last five years based of Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.		
Total (L _{den})	Street level (at residential address)	Total exposition to environmental noise at street level indicated as: a) the annual average f the last five years, and b) the five-year average for the last five years based on Strategic Noi Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecologic Transition and the Demographic Challenge.		

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 Table S3. Area-level socioeconomic (SES) variables obtained through GIS estimations.

	A 1	
AREA-LEVEL SES VARIABLES	Scale	Variable
a) Mean income		
Average household net income	Census tract	Average household net income. Income data collection is based on standardised annual requests to the differ collaborating tax organisations. Data from 2021. Data source INE ¹ .
Average household gross income	Census tract	Average household gross income. As components of gross income, five exhaustive categories are considered: way
Average net income per person	Census tract	Net income per person is obtained, for each household, by dividing the net household income by the number of memb of said household. Data from 2021. Data source INE ¹ .
Average gross income person	Census tract	Gross income per person is obtained, for each household, by dividing the gross household income by the numbe members of said household. Data from 2021. Data source INE ¹ .
Average income per consumption unit	Census tract	Equivalised income is a measure of household income that takes account of the differences in a household's size composition, and thus is equivalised or made equivalent for all household sizes and compositions. The equivalesed income is calculated by dividing the household's total net income by its equivalent size, which is calculated using the modified O equivalence scale. This scale attributes a weight to all members of the household: 1.0 to the first adult; 0.5 to the sec and each subsequent person aged 14 and over; 0.3 to each child aged under 14. Data from 2021. Data source INE ¹ .
b) Income distribution P80/P20	Census tract	Ratio between the 80th percentile and the 20th percentile of the income distribution per unit of consumption. Data for 2021. Data source INE^{1} .
c) Gini index	Census tract	The Gini index measures the degree of inequality in the distribution of income/wealth, used to estimate how far a count wealth or income distribution deviates from an equal distribution ² . A Gini coefficient of 0 reflects perfect equality, wh all income or wealth values are the same, while a Gini coefficient of 1 (or 100%) reflects maximal inequality among value a situation where a single individual has all the income while all others have none. Data from 2021. Data source INE ¹ .
d) MEDEA deprivation index	Census tract	A deprivation index developed to study the social inequalities in health in Spain. The index is composed by percentag the population with manual labour, percentage of the population with casual labour, percentage of the population unemployed, percentage of the population with insufficient education, percentage of the population of young people v insufficient education ³ . Data from 2021.

¹ INEbase. Atlas de Distribución de Renta de los Hogares (ADRH). INE. Retrieved 19 December 2023, from <u>https://www.ine.es/metodologia/metodologia_adrh.pdf</u> ² Gini, Corrado (1936). "On the Measure of Concentration with Special Reference to Income and Statistics", Colorado College Publication, General Series No. 208, 73–79. ³ Domínguez-Berjón, M. F., Borrell, C., Cano-Serral, G., Esnaola, S., Nolasco, A., Pasarín, M. I., Ramis, R., Saurina, C., & Escolar-Pujolar, A. (2008). Construcción de un índice de privación a partir de datos censales en grandes ciudades españolas: (Proyecto MEDEA). *Gaceta Sanitaria*, 22(3), 179–187.

Table S4. Variables collected through Population Health Surveys.

Population Health Survey	Study areas					
Variables	A.C. Basque Country	A.C. Andalusia	Barcelona city	Valencian Community		
OUTCOMES						
a) Perceived health						
General Health	Ordinal 1-5	Ordinal 1-5	Ordinal 1-5	Ordinal 1-5		
Mental Health	Ordinal 1-5 [MHI/5 items]	Ordinal 1-6 [SF-12/3 items]	Ordinal 1-4 [GHQ-12/12 items]	Ordinal 1-4 [GHQ-12 /12 items]		
b) Quality of life						
Health-related quality of life	Ordinal 1-5 [EuroQoL / 5 items]	Ordinal 1-6/1-5 [SF-12 / 5 items]	Ordinal 1-5 [EuroQoL / 5 items]	Ordinal 1-5 [EuroQoL / 5 items]		
c) Sleep						
Sleep duration	Continuous - Total hours/day	Continuous - Total hours/day	Continuous - Total hours/day	Continuous - Total hours/day		
Quality of sleep	Ordinal 1-5 [SATED / 5 items]	Ordinal 1-4 [4 items]	Ordinal 1-10	Ordinal 1-5 [SATED / 5 items]		
d) Consumption of medication f	or common mental disorders ¹					
Antidepressants	yes/no – reference 2 days	yes/no – reference 2 weeks	yes/no - reference 2 days	yes/no - reference 2 weeks		
Hypnotics	yes/no - reference 2 days	yes/no - reference 2 weeks	yes/no - reference 2 days	yes/no – reference 2 weeks		
Anxiolytics	yes/no - reference 2 days	yes/no - reference 2 weeks	yes/no - reference 2 days	yes/no - reference 2 weeks		
e) Chronic mental health proble	rms ²					
Anxiety	yes/no - reference ever	yes/no – reference present	yes/no - reference ever	yes/no – reference ever		
Depression	yes/no - reference ever	yes/no - reference present	yes/no - reference ever	yes/no - reference ever		
Insomnia	yes/no - reference ever	-	-	yes/no - reference ever		
Other	yes/no - reference ever	-	yes/no - reference ever	yes/no - reference ever		
COVARIATES						
a) Anthropometric variables						
Age	Discrete	Discrete	Discrete	Discrete		
Weight	Continuous	Continuous	Continuous	Continuous		
Height	Continuous	Continuous	Continuous	Continuous		
BMI	Continuous	Continuous	Continuous	Continuous		
Biologic sex	Categorical - 3 conditions	Categorical - 2 conditions	Categorical - 2 conditions	Categorical - 2 conditions		
Gender identity	Categorical - 3 conditions	-	Categorical - 3 conditions	-		
b) Individual socioeconomic var	iables		C			
Education level	Categorical - 9 conditions	Categorical - 13 conditions	Categorical - 11 conditions	Categorical - 9 conditions		
Occupational status	Categorical [CNO11]	Categorical [CNO11]	Categorical [CNO11]	Categorical [CNO11]		
Household size	Discrete	Discrete	Discrete	Discrete		

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Population Health Survey	Study areas				
Variables	A.C. Basque Country	A.C. Andalusia	Barcelona city	Valencian Com	
Household income	Categorical - 11 conditions	-	-	Categorical - 8 cc	
Economic difficulty	Categorical - 6 conditions	Categorical - 6 conditions	Categorical - 6 conditions	Categorical - 6 co	
Employment status	yes/no	yes/no	yes/no	yes/no	
Country of birth	Categorical & Open	Categorical & Open	Categorical & Open	Categorical &	
Marital status	Categorical - 6 conditions	Categorical - 5 conditions	Categorical - 5 conditions	Categorical - 5 cc	
c) Lifestyle factors					
Alcohol consumption	Categorical - 8 conditions	Categorical - 10 conditions	Categorical - 4 conditions	Categorical - 8 cc	
Passive smoking at home	Likert 1-5	yes/no	Discrete (№ smokers)	yes/no	
Daily tobacco consumption	yes/no	Categorical - 4 conditions	Categorical - 3 conditions	Categorical - 4 co	
e) Physical Health					
Chronic health problems	Categorical - 38 conditions	 Categorical - 25 conditions 	Categorical - 25 conditions	Categorical - 21 c	
d) Mobility					
Years at household	Discrete		Discrete	Discrete	
MEDIATORS					
a) Physical activity					
Physical activity	Discrete - IPAQ	Discrete - IPAQ	Discrete - IPAQ	Discrete - IF	
- Vigorous	MET-min/week	MET-min/week	MET-min/week	MET-min/w	
- Moderate	MET-min/week	MET-min/week	MET-min/week	MET-min/w	
- Walking	MET-min/week	MET-min/week	MET-min/week	MET-min/w	
- Sitting	Time spent (hours + minutes)	Time spent (hours + minutes)	Time spent (hours + minutes)	Time spent (hours	
b) Social cohesion					
Social support	Ordinal 1-5 [Duke / 11 items]	Ordinal 1-5 [Duke / 11 items]	Ordinal 1-5/1-4 [OSLO/ 3 items]	Ordinal 1-5 [Duke /	
Loneliness	Ordinal 1-4	Ordinal 1-4	Ordinal 1-4	Ordinal 1-	
SUBJECTIVE URBAN ENVIRONM	ENTAL EXPOSURES				
a) Perception of the neighbourh	nood				
Noise outside dwelling	Likert 1-3	Likert 1-3	Likert 1-5	Likert 1-3	
Neighbourhood air pollution	Likert 1-3	Likert 1-3	-	Likert 1-3	
Shortage of green spaces	Likert 1-3	Likert 1-3	-	Likert 1-3	
Insecurity	Likert 1-3	Likert 1-3	Likert 1-5	Likert 1-3	

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A) Prevalence of common mental disorders in Spain.

A recent report published by the Spanish National Health System (2020), based on a representative sample of users of said system, found that the overall prevalence of mental health problems in Spain is 27.4%. The most common general mental health issues were anxiety, depression, and sleep disorders, with a prevalence of 6.7%, 4.1%, and 5.4%, respectively. Higher prevalence of these disorders was observed in the female population, those born in Spain and with increasing age. The same report notes that in the case of anxiety and depression, a clear social gradient is observed, with both disorders being 3.4 and 2.5 times more prevalent in the population with lower income levels. In the case medication prescriptions, anxiolytics, antidepressants, and hypnotics were prescribed at rates of 34% for women and 17% for males over 40. The 2020 European Health Survey revealed no discernible territorial differences in the prevalence of chronic mental health conditions among individuals aged 15 and older in Spain. However perceived health status showed slight regional disparities, with Valencia reporting the highest percentage of "bad or very bad" health at 9.4%, followed by Andalucía (7.4%), the Basque Country (7%), and Catalonia (4.9%). However, given that the results presented in this report pertain to a timeframe predating the onset of the COVID-19 pandemic, it is anticipated that the prevalence of these conditions has risen universally among all age groups and regions (Henares Montiel et al., 2020). This increase can be attributed to escalated stress and healthrelated concerns stemming from the pandemic, exacerbated by associated constraints like lockdown measures and the resultant impact on mental health care services during the pandemic (Balluerka et al., 2020).

Balluerka, N., Gómez, J., Hidalgo, M., Gorostiaga, A., Espada, P., Padilla, J., & Santed, M. (2020). LAS CONSECUENCIAS PSICOLÓGICAS DE LA COVID-19 Y EL CONFINAMIENTO INFORME DE INVESTIGACIÓN

Henares Montiel J, Ruiz-Pérez I, Sordo L. Salud mental en España y diferencias por sexo y por comunidades autónomas. *Gaceta Sanitaria*. 2020;34:114–9.

INEbase / Society /Health /European Survey of Health in Spain. INE. Retrieved December 2023. https://www.ine.es/dyngs/INEbase/en/operacion.htm?c=Estadistica_C&cid=1254736176784& idp=1254735573175

Sistema Nacional de Salud. (2020). Base de Datos Clínicos de Atención Primaria-BDCAP. https://cpage.mpr.gob.es/

Section 4. DATA MANAGEMENT PLAN

A) RESEARCH ACTIVITIES

Step 1. Population Health Surveys' (PHS) data curation and calibration

The selected individuals were contacted by a phone call, SMS, or letter to arrange an appointment for a face-to face interview for the purpose of the survey. The database produced with the interviews will be pseudonymised from that with the personal data for the contact by assigning a unique code for each participant and remains under the custody of the responsible body in each study area; the Basque Department of Health in the Basque Country, Escuela Andaluza de Salud Pública (EASP) in Andalusia, Agència de Salud Pública de Barcelona (ASPB) in Barcelona, and Conselleria de Salut Universal i Salut Pública (DGSP) in Valencian Community.

Step 2. Harmonisation

Initially, the databases of each study area will be cleaned, and the variables that require it will be harmonised. The vast majority of the variables to be used in the project have been collected identically in the Population Health Surveys of the study areas included. The variables to be harmonized are listed below and the measures used in each study area can be found in Table S2.

The variables that need harmonisation can be distinguished between simple or complex variables, depending on the level of difficulty and the manipulation of data that require the harmonisation of the respective variable:

Simple variables: Chronic mental health problems, Educational level, Occupation status,
 Household income, Loneliness, Noise outside dwelling, and Insecurity.

- Complex variables: mental health, health-related quality of life, sleep quality, consumption of medication for common mental disorders, alcohol consumption, passive smoking at home, tobacco consumption, physical health, and social support.

The Maelstrom Research Guidelines for the rigorous harmonisation of retrospective data (77) will be applied. Among the variables that need harmonisation, the majority can be easily recategorised (simple variables). For instance, in the case of scales with different score ranges (e.g., Likert scale levels), standardised scores will be calculated, or other procedures will be followed to ensure comparability. The procedure to follow with variables measured with different scales will be more complex (complex variables). For these, the content of each variable will be studied to detect the common content (e.g., items) in each of the study areas. Once detected, aggregate scores will be calculated for the common items, and these scores will be used for statistical analyses. The remaining non-harmonizable variables will be assessed for their potential for performing separate statistical analysis for each study area.

Step 3. Georeferentiation

The responsible bodies, in collaboration with regional Statistical Institutes or Population Registers, will link the health survey data to the geographical coordinates of each respondent's home address. The geographical coordinates will also be pseudonymised and sent this way to the research group specialised in Geographic Information System (GIS) estimations that will calculate UrbEE. In order to further ensure the protection of the personal data of the survey participants and enhance their anonymity, fictional coordinates will be created in a number five times the number of participants selected for the study in each study area and sent to the research group specialised in GIS estimations together with the real coordinates.

Step 4. GIS estimation of Urban Environmental Exposures (UrbEE)

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A company specialised in GIS estimations will calculate the objective urban environmental exposures (UrbEE) of all the geocodes, including the participants' coordinates and the fictional coordinates by GIS.

Step 5. Selection and linkage of data

After the estimations are finalised, the responsible bodies of the surveys in each study area will re-select the geocodes of the participants and add the new urban environmental variables to the database with the PHS data. The researchers will be provided with the resultant database of each study area composed by the PHS data and the UrbEE (without geocodes and personal data of the participants). This guarantees that the data supplied are protected by statistical secrecy, not misused and treated anonymously and globally at all times.

Step 6. Pooling

Finally, the final databases of all the study areas will be pooled, creating the final pooled database to be used in the planned analyses.

B) DATA STORAGE AND PROCESSING

Data will be kept at all times on servers located in the responsible centre of this project. This way, data will be stored on the University of the Basque Country UPV/EHU's own servers, complying with the greater security and privacy requirements of the LOPD as the data is not sent to external servers. The entire process of recording, dumping and storage of the data will be anonymised, with the data collected being exclusively linked to a sample unit code. Access to the anonymised microdata will be limited to technicians from the responsible centres of each study area through profiles with regulated permissions that allow for supervising and controlling access to the information. Supervision of the data management will be assigned to the principal

investigators with expert advice, and to the data protection officer of the centre responsible for the project.

C) ETHICAL CONSIDERATIONS AND ACCOUNTABILY

The study was approved by the regional Research Ethics Committee of the **Basque Country**, ETHICS COMMITTEE FOR RESEARCH INVOLVING MEDICINAL PRODUCTS IN THE BASQUE COUNTRY (CEIm-E) (protocol code PI2022138, dated 9th November 2022); **Andalusia**, BIOMEDICAL RESEARCH ETHICS COMMITTEE OF THE PROVINCE OF GRANADA (CEI/CEIM GRANADA) (protocol code 2078-N-22, dated 27th December 2022); **Barcelona**, PARC DE SALUT MAR CLINICAL RESEARCH ETHICS COMMITTE (CEIm) (protocol code 2022/10667, dated 2nd December 2022); **Valencian Community**, ETHICS COMMITTEE FOR CLINICAL RESEARCH OF THE DIRECTORATE GENERAL OF PUBLIC HEALTH AND CENTER FOR ADVANCED RESEARCH IN PUBLIC HEALTH (CEIC DGSP / CSISP) (protocol code 20221125/04, dated 25th November 2022).

This study is based on secondary data obtained from four independent Population Health Surveys (PHS) from Spain. Since the present study does not involve the activity of data collection, to obtain the informed consent from the subjects is not applicable for this study. However, the PHS included this project are official statistical operations included in the respective Statistical Plans of each study area. This ensures that the data provided is protected by statistical confidentiality, it is not misused, its treatment is anonymous and global at all times, and that indirect identification is impossible. Data are collected and processed in accordance with the provisions of the General Data Protection Regulation (GDPR) and in accordance with the provisions of Article 5 of the Organic Law 3/2018 of 5 December on the Protection of Personal Data and the guarantee of digital rights (Regulation (EU) 2016/679), they will be treated confidentially, with access to them being granted to personnel who strictly need to process them in the framework of the study.

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Furthermore, the transfer of data occurs between organisations within the Public Health System of each region and the regional or local government itself. This is done in the context of a research project conducted exclusively in the public sphere and with the legitimacy of the use of administrative records as research infrastructures in accordance with the General Health Act, the Biomedical Research Act and the General Law on Public Health. The results of the study will provide information at a sufficiently aggregated territorial level to prevent indirect identification. Furthermore, the project's results will be beneficial to the general population in a holistic way, thanks to its socioeconomic and environmental context, and its evolution over several years from the onset of the COVID-19 pandemic. Therefore, the risk to the privacy of the study population is minimal compared to the potential benefits the results will bring.

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Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project), study protocol.

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-074252.R2
Article Type:	Protocol
Date Submitted by the Author:	23-Feb-2024
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Primary Subject Heading :	Mental health
Secondary Subject Heading:	Epidemiology
Keywords:	PUBLIC HEALTH, MENTAL HEALTH, Health Equity, EPIDEMIOLOGIC STUDIES, Quality of Life

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Title

Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project); study protocol.

Word count: 4,872 (excluding Abstract and Declarations)

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Abstract

Introduction: The European Environment Agency estimates that 75% of the European population lives in cities. Despite the many advantages of city life, the risks and challenges to health arising from urbanization need to be addressed in order to tackle the growing burden of disease and health inequalities in cities. This study, *Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain* (DAS-EP project), aims to investigate the complex association between the urban environmental exposures (UrbEEs) and health.

Methods and analysis: DAS-EP is a Spanish multiregional cross-sectional project that combines Population Health Surveys (PHS) and Geographical Information System (GIS) allowing to collect rich individual level data from 17,000 adult citizens participating in the PHS conducted in the autonomous regions of the Basque Country, Andalusia, and the Valencian Community, and the city of Barcelona in years 2021 to 2023. This study focuses on the population living in cities or metropolitan areas with more than 100,000 inhabitants. UrbEEs are described by objective estimates at participants' home addresses by GIS, and subjective indicators present in PHS. The health outcomes included in the PHS and selected for this study are self-perceived health (general and mental), prevalence of chronic mental disorders, health-related quality of life, consumption of medication for common mental disorders, and sleep quality. We aim to further understand the direct and indirect effect between UrbEEs and health, as well as to estimate the impact at the population level taking respondents' socio-demographic and socio-economic characteristics, and lifestyle into consideration.

Ethics and dissemination:

The study was approved by the regional Research Ethics Committee of the Basque Country (CEIm-E; PI2022138), Andalusia (CEIM GRANADA; 2078-N-22), Barcelona (CEIC-PSMar; 2022/10667), and Valencian Community (CEIC DGSP/CSISP; 20221125/04). The results will be

communicated to the general population, health professionals and institutions through conferences, reports, and scientific articles.

Strengths and limitations of this study

- Multicentric project in Spain with a cross-sectional approach
- Large volume of data from a large sample of participants
- Linkage of four independent population health surveys and environmental exposures
- Inclusion of objective & subjective urban environmental exposures
- Health equity perspective

1 1. Introduction

According to the World Health Organization, modifiable environmental factors are responsible for 23% and 22% of the global mortality and morbidity respectively [1]. As reported by the European Environment Agency, in 2021 75% of the European population lived in urban areas including cities but also smaller urban settlements and suburban areas, developed for residential, industrial or recreational purposes [2]. The local urban environment influences people's health by determining their level of urban environmental exposures (UrbEEss) [3,4]. The UrbEEss include the totality of the surrounding natural (e.g., green and blue spaces), built (e.g., walkability, urbanisation level, traffic,) and social (e.g., security, public services) environments within which people live, move, and interact, as well as environmental stressors like air pollution and noise. Increasing evidence shows that UrbEEss such as lack of greenness, air pollution and noise can impact population's mental and physical health and quality of life [5– 9]. The health implications of environmental exposures become even more relevant in the contemporary demographic setting, given that they are perhaps starker in urban areas [10–14]. Moreover, in many regions, environmental exposures are not evenly distributed across socioeconomic status and thus, socio-economically vulnerable populations are also affected by poorer environmental quality [10,11]. In fact, this double jeopardy may result in individuals from poorer socioeconomic backgrounds more significantly affected by environmental exposures [4,15]. A comprehensive approach is crucial for understanding the interplay of various environmental determinantswith health and well-being within urban settings. A holistic multi-exposure framework should be adopted, as outlined by Hammersen et al. [16], that extends beyond traditional considerations and incorporates critical urban contextual issues such as substandard housing, crowding, economic inequality, and the evolving challenges posed by climate change, as well as individual psychosocial factors [17,18]).

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25 UrbEEs, including environmental stressors, traffic-infrastructure, natural spaces, and 26 built environment, have all been studied in relation to health. Widespread evidence in the 27 literature shows that air pollution, noise, and lack of green space are related to a range of chronic 28 physical diseases [19–24]. Recently, it has been suggested that air pollution is associated with a 29 range of mental disorders and poorer sleep quality [21,25–28]. Other recent studies observed 30 that environmental noise has negative effects on mental health, well-being, and sleep quality 31 [27,29–31], while evidence on its impact on prescriptions and consumption of medication for 32 common mental disorders has yet to be scientifically confirmed [32]. Otherwise, current 33 scientific evidence indicates that residential greenness is positively associated with mental 34 health and quality of life [31,33,34], and lower consumption of anxiolytics, antidepressants, and 35 sleeping pills [27,35]. Blue spaces (aquatic environments such as rivers, lakes, and the coast) are 36 expected to have similar health effects to those described here, however, evidence on this 37 subject is limited [35,36]. As for the built environment, walkability or accessibility have also been 38 related to reduced obesity and better cardiovascular health [37], improved mental health 39 [38,39] and well-being [40]. To date, the main mechanisms proposed to explain these 40 associations are the mitigation of exposure to environmental pollutants, the promotion of 41 physical activity, and the strengthening of social cohesion [33,34,37,41–43]. Moreover, these 42 mechanisms are probably synergistic [44]. The correlations between several UrbEEs and their 43 relationship with behavioural exposures, such as physical activity and social cohesion, makes the 44 assessment of these associations and pathways highly challenging [45–49]. Hence, noise and air 45 pollution could act both as exposures, mediators, or potential confounders. Overall, results of 46 previous studies are quite mixed and the associations as well as the underlying mechanisms 47 between UrbEEs and mental health outcomes need more robust scientific evidence [5,47,50-48 52].

49 This knowledge gap can be partly explained by the heterogeneity and limitations of 50 exposure and outcome metrics used in the studies [19,52,53]. Moreover, there is a lack of

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studies addressing the impact of UrbEEs on health integrating objective and perceived accounts of such exposures [54]. Therefore, it is evident that more research is needed to determine which UrbEEs are associated with health, the potential mechanisms involved, and the role of social aspects in those associations. Beyond this, researchers are increasingly called to provide information that can guide the selection of the best and most feasible interventions to improve public health in cities. In this respect, experts in the field have claimed the vital role that health impact assessment tools play when integrating the evidence in the decision-making process [55,56].

59 Urban Environment and Health: a cross-sectional multiregional project based on 60 Population Health Surveys in Spain (DAS-EP project) is a 3-year project (2023-2025) aimed at 61 further investigating the associations and underlying mechanisms, including direct and indirect 62 effects, between UrbEEs and health with a health equity perspective. Five main objectives have 63 been established for this project:

To estimate, describe, and compare the objective and subjective levels of UrbEEs in the
 study areas.

- To describe urban environmental inequalities according to socio-demographic and socio-economic variables, as well as the study area.
- To estimate the association of UrbEEs with self-perceived general and mental health,
 health-related quality of life, chronic mental disorders, consumption of medication for
 common mental disorders, and sleep quality (Figure 1)¹.
- 71 4. To estimate the impact of UrbEEs on the health outcomes under evaluation, at the
 72 population level, and to conduct a health impact assessment.

¹ For a summary of current prevalence of common mental disorders in Spain, please see section 0 in the Supplementary file.

To assess the mediating role of physical activity, social cohesion, and environmental
stressors on the association between UrbEEs and the health outcomes under evaluation
(Figure 1).

The general hypothesis of this research project is that the urban environment directly or indirectly affects mental health and quality of life. In line with the first objective of the project, we expect significant differences in levels of exposure to urban environmental variables among the cities under study. Regarding the second objective, we expect participants with lower socio-economic status, lower educational levels, and less remunerated occupations to live in residential environments of poorer environmental quality. We expect them to live in areas with less availability of green and blue spaces, lower walkability scores, and higher levels of noise and air pollution. Finally, we expect the various environmental exposures reported in this study to be significantly associated with the various health and mental health variables studied in the project. Notably, we anticipate that air pollution and noise may have negative effects on mental health, while exposure to natural (green and blue), and more walkable spaces will show protective effects against bad mental health. Furthermore, in line with recent literature, we expect that part of these potential effects on mental health might be produced through increased physical activity and social cohesion.

90 2. Methods and analysis

91 2.1. Study design

92 This is a cross-sectional study based on information from Population Health Surveys 93 (PHS) carried out in adult population living in urban areas, with more than 100,000 inhabitants, 94 in the autonomous regions of the Basque Country, Andalusia, the Valencian Community, and 95 the city of Barcelona in Spain. The study integrates observational data collected within the four 96 independent PHS in 2021-2023 with Geographic Information System (GIS) estimations of 97 individual UrbEEs. It entails the following research activities: 1) preparing, integrating, and

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calibrating PHS data from each study area, 2) harmonising the variables that have been collected differently in the four study areas, 3) georeferencing survey respondents' home addresses, 4) characterizing each home address in terms of UrbEEs by GIS, 5) linking UrbEEs estimates with PHS data, and 6) pooling of datasets from the four study areas (Figure 2). Using the final pooled database, we will analyse the association between UrbEEs and health in a cross-sectional manner, considering sociodemographic, socioeconomic and lifestyle factors. Figure 1 shows the conceptual framework designed within the scope of this project. DAS-EP received Ethics Approval from the relevant regional ethics committees (see more Supplementary file section 1). This project has received funding from the Instituto de Salud Carlos III (ISCIII) under the Strategic Action in Health with the Health Research Fund (FIS) in the call 2022 (file No. PI22/01051 and No. PI22/00512). The project runs from December 2023 to December 2025.

2.2. Study population

The target population are inhabitants of the autonomous communities of the Basque Country, Andalusia, the Valencian Community, and the city of Barcelona. The sampling frames are made up of people over 15 or 16 years of age of the respective study areas. The study population includes the PHS' participants living in urban areas with more than 100,000 inhabitants in the regions mentioned before (Figure S1, S2). The cities and metropolitan areas participating in this study are: the city of Vitoria-Gasteiz, and the metropolitan areas of Bilbao and Donostia-San Sebastián in the Basque Country; the cities of Almeria, Cadiz, Cordoba, Huelva, Jaen, and the metropolitan areas of Granada, Malaga, and Seville in Andalusia; the cities of Castellon, Valencia, Elche and Alicante in the Valencian Community; and the city of Barcelona (Table S1).

119The PHS included in this project are official statistical operations that are incorporated in53120the Statistical Plans of each study area. These activities are conducted by every regional or local56120public administration with jurisdiction in health and are a fundamental tool to monitor the status58122and evolution of relevant health conditions in the population, their main determinants, and the

use of health services [57–60]. Accordingly, these regional and local cross-sectional epidemiological surveys are carried out by the Basque Department of Health in the Basque Country [57], Andalusian School of Public Health (EASP) in Andalusia [58], Barcelona Public Health Agency (ASPB) in Barcelona [59], and Foundation for the Promotion of Health and Biomedical Research in the Valencian Region (DGSP) in Valencian Community [60]. They have been organised every 4-5 years since 1986 (Basque Country), 1999 (Andalusia), 1983 (Barcelona) and 1991 (Valencian Community). The sample design and the selection of the sample is carried out independently in each region by the statistical institute (The Basque Institute for Statistics in the Basque Country, Institute of Statistics and Cartography of Andalusia in Andalusia, and municipal statistical office of the Barcelona city council in Barcelona) or health population information system (Valencian Community). Data from the latest version of these surveys is included in this project. After the surveys are completed, we expect a total estimated sample of 16,953 individuals, of which 7,846 participants will be from the Basque Country, 3,085 from Andalusia, 3,134 from the Valencian Community, and 4,000 from the city of Barcelona. More detailed information is provided in Table S1.

138 2.3. Data collection

139 2.3.1. GIS estimates of urban environmental exposures (UrbEEs)

Objective measures of UrbEEs are estimated by a company specialised in GIS based on the geographic coordinates of the participants' home addresses. A significant number of these variables will be expressed in buffers around each participant's residence or at the building level. All environmental exposures will be assessed preceding to, and as close as possible to the time the PHS are being conducted (2021-2023) to avoid temporal mismatch [61]. The objective UrbEEs of interest in this project include exposures originated from surrounding natural spaces, built environment, traffic-infrastructure, and environmental stressors. Detailed information on

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4	147	the UrbEEs estimated within the scope of this project can be found in the Supplementary file		
5 6 7	148	(Table S2).		
8 9 10	149	Surrounding natural spaces		
10 11 12	150	- Green spaces. Five green space exposure metrics will be calculated in buffers of 100, 300		
13 14	151	and 500 m around each geocode: 1) percentage of green space; 2) mean Normalised		
15 16 17	152	Difference Vegetation Index (NDVI) [62,63]; 3) percentage of tree cover; 4) Euclidean		
18 19	153	distance to the nearest green space larger than 5,000 m^2 [64], and 5) presence of a major		
20 21	154	green area (greater than 5,000 m ²).		
22 23	155	- <u>Blue spaces.</u> Any blue environments, including lakes, rivers, or coastline will be considered		
24 25 26	156	as blue space. Three blue space exposure variables will be estimated: 1) presence of water		
20 27 28	157	surface; 2) percentage of water surface; and 3) Euclidean distance to nearest water surface		
29 30	158	greater than 5,000m ² . The first two refer 100, 300 and 500 m buffers around each geocode		
31 32 33	159	[65].		
34 35 36	160	Built environment		
37 38	161	- Building density. The building density around each home address in 100, 300 and 500 m		
39 40	162	buffers will be estimated, considering not only the perimeter of the buildings but also their		
41 42 43	163	height [66].		
44 45	164	- Walkability. An overall walkability index in 100, 300 and 500 m buffers around the		
46 47	165	participants' home addresses will be calculated. This index will include of the following		
48 49	166	subindices: 1) population density (at the census tract level), 2) street density, 3) street		
50 51 52	167	connectivity, 4) land use Shannon Evenness Index, 5) facility richness, 6) facility density, 7)		
53 54 55	168	average slope, and 8) transport density [67,68].		

170 - <u>Major road (Yes vs. No).</u> Presence of a major road (with >3 million vehicle passages per year)

in 100, 300 and 500 m buffers around the participants' home addresses [66].

172 - Distance to major road. Distance to the nearest major road (with >3 million vehicle passages

173 per year) from the participants home addresses [66].

174 Environmental stressors

Air pollution. Spatiotemporal daily models at household-level for particulate matter (PM₁₀ and $PM_{2.5}$) and nitrogen dioxide (NO₂) will be constructed for all study areas using multistage mixed models. These models are known as spatiotemporal land-use random-forest model [69] and combine ground-level and satellite measurements, land use and meteorology. A precise daily estimate of the exposures will be obtained for all study subjects (period 2006 to 2023). Using the daily estimates, annual average for the last five years and the five-year average of NO₂, PM₁₀ and PM_{2.5} exposure levels will be calculated at PHS respondents' home address as indicators for long-term air quality.

Environmental noise. The Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge will be used. All potential sources of environmental noise at street level will be examined, including road traffic, rail, industrial, airports and total noise [70,71]. Major roads, major railways, and major airports will be included in cities where this information is available and not included in the agglomeration layer. Agglomerations corresponding to the closest street to the dwelling, and major roads and airports corresponding to the closest isoline will be used. In all cases, the Euclidean distance to each source will also be calculated. The daytime (L_d) , evening (L_e) , night-time (L_n) , and total (L_{den}) noise indices will be assigned.

192 2.3.2. Contextual socioeconomic variables

193 Neighbourhood-level socioeconomic status (SES) will be considered via three variables, namely,
 194 mean income, income distribution P80/P20, and the MEDEA deprivation index (composed by

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195 percentage of the population with manual labour, percentage of the population with casual 196 labour, percentage of the population unemployed, percentage of the population with 197 insufficient education, percentage of the population of young people with insufficient 198 education) [72]. All these metrics will be obtained from the publicly available data developed by 199 the Spanish National Institute for Statistics (INE) and expressed at the census tract level (Table 200 S3).

201 2.3.3 Individual socio-demographic and socio-economic variables

To describe respondents' individual-level SES, eight variables will be selected: country of birth,
marital status, household size, level of education, employment and occupational status,
reported household income, and economic difficulty of the household (Table S4)

205 2.3.4 Information collected through Population Health Surveys

Information from four independent PHS that represent four study areas is included in the study. The surveys are carried out between 2021-2023, being Barcelona city the earliest in completing the collection (2021 February – 2022 March), followed by the Valencian Community (2022 April - 2022 December), Andalusia (2022 April - 2023 April), and the Basque Country (2022 October - 2023 June) (Table S1). During each survey, detailed information is collected though face-to-face interviews and self-administered questionnaires. The PHS collect information on different health aspects, morbidity, and use of health services. It also gathers information on social determinants of health such as socio-economic status, working conditions, social cohesion, health-related behaviours and perception on residential environment. Most of these variables are measured with validated screening tools. The selection of relevant variables to be included in this project was based on a literature review and the most appropriate variables to meet the objectives of the study were selected from among the variables collected by the PHS. All the study areas collected the main variables of the study (i.e., mental health, health-related quality of life, physical activity, social cohesion, and sleep), however, in some cases, the measuring

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220 instruments differ across the study areas. Detailed information about the variables and the

221 measuring instruments used in each study area can be found in Table S4.

222 Health outcomes

- 223 Several health outcome variables are included in this study.
- 224 Perceived general health. Self-assessment of health was measured as an ordinal response,

with five categories (1, Excellent; 2, Very good; 3, Good; 4, Fair; 5, Poor).

226 - <u>Perceived mental health.</u> This variable was collected with the Mental Health Inventory [73],

227 the SF-12 (Short-Form Health Survey 12) scale [74] or the General Health Questionnaire

- ² 228 (GHQ-12) [75].
- 229 <u>Health-related quality of life.</u> This variable was measured with the Euroqol-5D-5L-EAV scale
 6
 7 230 [76] or the SF-12 (Short-Form Health Survey 12) scale [74].

Sleep duration and quality. The duration of sleep, indicated as the total number of hours per
 day spent on sleep including napping was calculated. The quality of sleep was collected using

the SATED scale (Satisfaction Alertness Timing Efficiency and Duration Scale) [77] or discrete
items.

- 235 <u>Prevalence of chronic mental health problems.</u> Participants had to indicate whether they
 236 had been diagnosed with depression, anxiety, and sleeping disorders at any time throughout
 237 the life. We then built a dichotomized (yes/no) variable for each condition.
- 238 Consumption of medication for common mental disorders. Information on consumption of
 239 medication for common mental disorders, such as, anxiolytics, antidepressants and
 240 hypnotics was reported on bi-daily or bi-weekly basis depending on the study area.

241 Covariates

A set of individual level variables will be used as control variables in the statistical analyses.

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4	243	- <u>Anthropometric variables.</u> The surveys collect information on sex, age, weight, and height
5 6	244	of individuals. A Body Mass Index (BMI) (kg/m ²) will be calculated using information given
7 8	245	by the participants about their height and weight at the moment of filling the questionnaire.
9 10 11	246	- Individual socio-demographic and socio-economic variables. To describe respondents'
12 13	247	individual-level SES, eight variables will be selected: country of birth, marital status,
14 15	248	household size, level of education, employment and occupational status, reported
16 17	249	household income, and economic difficulty of the household.
18 19	250	- Lifestyle factors. These will include consumption habits such as alcohol consumption,
20 21 22	251	passive smoking at home, and tobacco use.
23 24	252	- <u>Physical health.</u> A chronicity index will be calculated based on presence of one or more non-
25 26	253	psychological chronic conditions (e.g., diabetes, heart disease, cancer, etc.).
27 28 29	254	The following social and behavioural variables will be treated as potential mediators.
30 31 22	255	Social cohesion and loneliness. Social cohesion is measured with the Duke-UNC-11 scale [78] or
32 33 34	256	the OSLO-3 tool [79]. Perceived loneliness is collected with a single item for participants to
35 36	257	report about the frequency in which they feel loneliness. The variable is displayed in a 1 to 4 (1=
37 38 39	258	always; 2= often; 3= sometimes; 4= never) response scale.
40 41	259	- <u>Physical activity.</u> The International Physical Activity Questionnaire (IPAQ) [80] to measure
42 43	260	the physical activity performed by the participants. Days per week and time spent in
44 45 46	261	vigorous physical activity, in moderate physical activity, and walking more than 10 minutes,
47 48 49	262	and time spent sitting on a normal day will be available.
50 51 52	263	Perception of the neighbourhood
53 54 55	264	Perceived accounts of UrbEEs are collected through PHS employing 3-point or 5-point Likert
56 57	265	format questions depending on the study area. These include: 1) perception of noise outside the
58 59 60	266	dwelling, 2) perception of shortage of green areas in the residential environment, 3) perception

267 of air pollution in the residential environment, and 4) perception of insecurity in the268 neighbourhood.

269 2.4. Data analysis

 Initially, all databases will be cleaned. The variables will be harmonised, when needed, following the Maelstrom Research Guidelines for rigorous harmonisation of retrospective data [81]. Nonetheless, because most variables have already been collected consistently in the respective Population Health Surveys, few variables will require harmonisation (Table S4). Among the few variables requiring harmonisation, most will be re-categorised. For more information, see Supplementary file section 5. Subsequently, both exploratory and descriptive analysis will be applied using numerical and graphical techniques [82]. Before proceeding to inference, sample weights for each survey will be adjusted through calibration [83], so that we may compensate for non-response and coverage biases and improve accuracy. This calibration will be carried out separately for each study area, so that region-level estimates are obtained first, and then harmonized to obtain estimates at population level.

The relationships between the various UrbEEs and health outcomes will be analysed according to the multilevel, or hierarchical structure [84] that the data possesses, as census tracts are nested within cities, and cities are nested within autonomous regions. Generalised linear mixed models (GLMMs) will be applied to investigate the relationship between urban environment and health. The sets of adjustment covariates used in these models will be chosen by applying robust causal inference techniques based on directed acyclic graphs (DAGs) [85], both for the estimation of direct effects and hypothetical indirect effects mediated by air pollution, environmental noise, physical activity, and social cohesion. This will imply the prior design of a DAG describing the relationships among UrbEEs, health outcomes and other potentially implicated variables [86,87]. The testable implications derived from this DAG will be checked following the procedure described by Ankan and colleagues [88], thereby updating the

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DAG if needed [89,90]. These graphical models will guide the inclusion of relevant sociodemographic and socioeconomic variables, allowing us to account for potential confounding factors and illuminate causal relationships. The length of time living in the same home/place will be considered by excluding individuals living at the same place of residence for less than one and less than five years in separate models. Equity will be addressed performing subgroup analysis to investigate potential vulnerable groups such as lower-income populations, the elderly, women, and marginalized communities.

In case of demonstrating a significant relationship between a given exposure and a certain outcome, we also intend to identify the specific exposures that cause most disease in the populations of interest via the population attributable fraction (PAF) [91]. To estimate the PAF we will require previous estimations of relative risk (RR) and either the prevalence of exposure in the population or the prevalence of exposure among the cases of disease. All these previous estimates will be available. The possible existence of spatial clusters in the UrbEEs distribution will also be studied using the standard spatial scan statistic method [92] and calculating the posteriori probabilities for the smoothed standardised ratios to be greater than unity, in the general framework of Bayesian hierarchical standardised ratio smoothing models.

308 The analyses will be implemented using the latest version of the R software packages *dagitty* [85], *DClusterm* [93,94], *R INLA* [95], *Sampling* [96] and others.

310 2.5. Data Management Plan

The data management plan can be found in the Supplementary file section 5. The source and type of data that will be collected within the scope of this project is described in this plan, together with the accessibility and ownership of data. Data storage and processing, as well as the procedure to guarantee the specific ethical and legal requirements, are likewise explained.

315 2.6. Patient and Public Involvement

Patients and the public will not be involved in the design, or conduct, or reporting, or dissemination plans of our research.

Discussion 3.

The present study is a clear commitment to the generation of urban environmental indicators potentially explanatory of self-perceived health (physical and mental), chronic mental disorders, health-related quality of life, consumption of medication for common mental disorders and sleep quality with a health equity perspective. This project responds to the national Spanish Strategic Plan for Health and the Environment (PESMA) 2022-2026 [97], to the local implementation of the Strategy for Health Promotion and Prevention in the National Health System [98] as well as to the main objective of the Spanish Urban Agenda 2019 [99] that cities should have a global vision that takes into consideration the physical, mental, and social well-being of their inhabitants. Likewise, it is aligned with three of the Sustainable Development Goals (SDG) of the World Health Organization (SDG.3 - Good Health and Well-being, SDG.10 -Reduced Inequalities, and SDG.11 – Sustainable Cities and Communities) (97,98).

When it comes to health-promoting urban and transport design, there is a lack of standardized, quantitative indicators to guide the integration of health components right from the outset [57,100]. In this context, the DAS-EP project not only aims to obtain individual UrbEEs estimates but also to assess their association with, and impact on various health outcomes. By means of PHS, the health effects to be studied in this project are derived from an unbiased population, which allows to obtain an approximate estimate of the impact at population level. Moreover, it is important to identify the precise routes that connect urban environment to health because they can guide the most efficient interventions, allowing us to design healthy(er) cities [55,101]. In this sense, the DAS-EP project investigates various components of the urban environment and health at individual level. Besides using complementary indicators that describe both the physical and the social urban environment (e.g., neighbourhood insecurity),

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341 combines objective and perceived indicators to deepen the characterization of the urban
342 environment. By combining these data, it is possible to develop a more precise understanding
343 of the effects of urban environment on health, while describing the complexity of the
344 relationship influenced by neighbourhood environmental and individual characteristics [102–
345 104].

The main limitation of this study is its cross-sectional nature. Due to the chronic character of the health conditions included in the study (e.g., depression, insomnia) and the possible long-term effects of UrbEEs, a longitudinal design would be more informative and appropriate. Although PHS have a cross-sectional approach, the question "since when have you been living at your current address" enables to account for the extent of exposures. Drawing on this mobility data, sensitivity analysis of the models will be fitted reducing the risk of exposure misclassification. Another limitation is that the samples from the study areas of the Basque Country, Andalusia, and Valencian community, although representative of the study population (considering the inclusion criteria) may not be representative of the autonomous communities from which they come as we are not considering the non-urban municipalities (<100,000 inhabitants). Despite the weight calibration to be conducted to reduce coverage and representativeness biases, the reweighing procedure will not guarantee the elimination of other response biases that may affect data collection from PHS (as acquiescence, social desirability, etc.) which could affect the validity of the results [105,106]. Furthermore, the project is subject to residual confounding, which in turn implies confounders that could not be controlled and, importantly, measurement errors in the confounders that have been included. In this regard, the estimation UrbEEs by GIS is affected by the problem of uncertainty of the temporal and geographical context [107].

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54363The use of buffer zones may not be appropriate to evaluate contextual effects on health because55
56364they fail to analyze the spatial-temporal distribution of residents' activities and their relationship57
58365with built environment factors. Using activity space measures would be preferable to59
60366comprehensively assess of environmental exposures by capturing the complexity of individual

> movements [108–110]. The reliance on publicly available data applicable to all study areas together with scalability challenges were major barriers to estimate street-level (or microscale) variables like bicycle and pedestrian infrastructure [111–113]. Moreover, future studies should not only include more variables reflecting the social capital (e.g., perceived sense of community) but also analyse the health implications of other relevant urban exposures like substandard housing, crowding, and indoor air pollution. Finally, the heterogeneity across study areas in terms of geographic scale (autonomous communities vs. city) may be a source of information bias. In this vein, the majority -but not all- of the scales and variables included in the different PHS are identical. These minor differences in data collection across PHS may lead to additional information biases hindering the comparability of the data. To minimize this problem, special attention will be paid to the selection and harmonization of the variables to be included to ensure the consistency of data before making the comparisons across study areas.

As for the strengths of this project, pooling linked surveys across study areas will make it possible to compare the results in different populations, providing a comprehensive dataset that is larger than most existing cohort studies, and that have an unique national and population perspective. The results will be novel in terms of their thematic (objective & subjective UrbEEs) and methodological approach (combination of PHS from different study areas and GIS estimates), as well as in terms of the large volume of information that will be handled and the large sample size of the study. Beyond that, the standardization of the procedure described herein will generate useful information to assist in the planning of national health surveillance programs, research studies and, more importantly, interventions to strengthen population's health.

In short, the results and products (i.e., databases, computer codes) of this project will
 greatly contribute to estimate the proportion of the population exposed to different UrbEEs,
 identify health disparities while considering UrbEEs, estimate how these exposures relate to and

1 2		
3 4	392	affect various health variables, and conduct a health impact assessment of UrbEEs. We will have
5 6	393	taken a further step towards understanding and improving the urban environment and being
4 5 6 7 8 9 10 11 23 14 5 6 7 8 9 10 11 23 14 5 6 7 8 9 0 11 22 23 24 25 26 27 8 9 30 31 23 34 5 36 37 38 9 40 41 23 45 6 7 8 9 50 51 23 45 56 7 8 9 50 51 23 54 55 67 8 9 50 51 23 54 55 67 8 9 50 51 23 54 55 56 75 8 9 50 51 23 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 50 51 52 53 54 55 56 75 8 9 56 57 8 9 56 57 8 9 56 57 8 9 56 57 8 9 50 57 55 55 55 55 55 55 55 55 55 55 55 55	393	taken a further step towards understanding and improving the urban environment and being able to establish corrective measures in the urban development plans of the cities.
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Declarations

Ethics and dissemination

The study was approved by the regional Research Ethics Committee of the **Basque Country**, ETHICS COMMITTEE FOR RESEARCH INVOLVING MEDICINAL PRODUCTS IN THE BASQUE COUNTRY *(CEIm-E)* (protocol code PI2022138, dated 9th November 2022); **Andalusia**, BIOMEDICAL RESEARCH ETHICS COMMITTEE OF THE PROVINCE OF GRANADA (CEI/CEIM GRANADA) (protocol code 2078-N-22, dated 27th December 2022); **Barcelona**, PARC DE SALUT MAR CLINICAL RESEARCH ETHICS COMMITTE (CEIm) (protocol code 2022/10667, dated 2nd December 2022); **Valencian Community**, ETHICS COMMITTEE FOR CLINICAL RESEARCH OF THE DIRECTORATE GENERAL OF PUBLIC HEALTH AND CENTER FOR ADVANCED RESEARCH IN PUBLIC HEALTH (CEIC DGSP / CSISP) (protocol code 20221125/04, dated 25th November 2022). The results will be communicated to the general population, health professionals and institutions through conferences, reports, and scientific articles.

Competing interests

The authors declare that they have no competing interests.

Funding statement

This study has been funded by Instituto de Salud Carlos III (ISCIII) through the projects "PI22/01051" "PI22/00512 and co-funded by the European Union. Data collection is funded by the various agencies responsible for the included health surveys. In addition to this funding, the group has its own financial means for other expenses including publication and dissemination of results, travel expenses and conference registrations related to the study.

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Authors'	contributions
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Methodology, A.L., A.C.-L., M.S-P

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All authors have read and agreed to the published version of the manuscript.

Acknowledgements

We thank all institutions [Basque Department of Health in the Basque Country, Andalusian

School of Public Health (EASP) in Andalusia, Barcelona Public Health Agency (ASPB) in Barcelona,

and Foundation for the Promotion of Health and Biomedical Research in the Valencian Region

(DGSP) in Valencian Community] developing the Population Health Surveys that are used in this

project.

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Legends

Figure 1. Conceptual framework designed within the scope of this project, including potential direct and indirect effects of urban environmental exposures (UrbEEs) on the health outcomes under study. * Potential mediators on the association between UrbEEs and the health outcomes under evaluation.

Figure 2. Summary of data management plan and the institutions involved during the development of the final database (DB) to be used by the research group in the analyses.





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Title of data: Supplementary data of Urban Environment and Health: a cross-sectional multiregional project based on Population Health Surveys in Spain (DAS-EP project), study protocol.

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Section 1. GENERAL CHARACTERISTICS OF THE STUDY AREAS

Figure S1. Study areas of the project, being the cities and metropolitan areas (M.A) with more than 100,000 inhabitants from the autonomous communities of the Basque Country and Andalusia, Valencian Community, and the city of Barcelona. Figure edited from Daniel Dalet / d-maps.com.



Figure S2. Population density of Spanish provinces in 2022. Figure edited from Instituto Geográfico Nacional, *La población en España 2022*. Accessed through: <u>https://www.ign.es/pobesp/pe1.htm</u>

Section 2. GENERAL CHARACTERISTICS OF THE POPULATION HEALTH SURVEYS

 Table S1. Characteristics of the study areas and the population health surveys comprised in the project.

Study area	Cities and areas of influence	Population health survey	Re	sponsible body	Sample size	Data collection period
A.C. Basque Country	Vitoria-Gasteiz	Encuesta de Salud de	\checkmark	Basque Department of	7,846	2022 October –
	Donostia-San Sebastián (M.A)	la Comunidad		Health		2023 June
	Bilbao (M.A)	Autónoma País Vasco (ESCAV)				
A.C. Andalusia	Almería 🔨 🔨	Encuesta Andaluza de	✓	Andalusian School of	3,085	2022 April –
	Cádiz	Salud (EAS)		Public Health (EASP)		2023 April
	Córdoba					
	Huelva					
	Jaén					
	Granada (M.A)					
	Malaga (M.A)					
	Sevilla (M.A)			C/		
Barcelona city	Barcelona	Encuesta de Salud de	\checkmark	Barcelona Public Health	4,000	2021 February –
		Barcelona (ESB)		Agency (ASPB)		2022 March
Valencian	Castellon	Encuesta Salud	\checkmark	Foundation for the	3,134	2022 April –
Community	Valencia	Comunidad		Promotion of Health and		2022 December
	Elche	Valenciana (ESCV)		Biomedical Research in		
	Alicante			the Valencian Region 🥂 (DGSP)		

Abbreviations: A.C., Autonomous community; M.A, Metropolitan Area.

Section 3. OVERVIEW OF THE VARIABLES OF THE STUDY PER STUDY AREA

 Table S2. Objective urban environmental exposures obtained through GIS estimations.

GIS Variables	Study areas: A.C. s of the Basque Country and Andalusia, Valencian Community & the city of Barcelona		
OBJECTIVE URBAN ENVIRONMENTAL EXPOSURES	Scale	Variable	
a) Surrounding natural spaces Green Spaces			
Green space percentage	100, 300, 500m buffers	Percentage of green space.	
NDVI	100, 300, 500m buffers	Annual mean Normalised Difference Vegetation Index (NDVI) of the year when the surveys were conducted and the mean NDVI of the last 5 years previous to the surveys.	
Tree percentage	100, 300, 500m buffers	Percentage of tree cover based on Growing stock volume (GSV) data.	
Distance to green space		Euclidean distance to the nearest major green space (green surface over 5,000m ²).	
Green spaces Yes (vs. No)	100, 300, 500m buffers	Dichotomous variable of presence of major green spaces (green surface over 5,000m ²) from local topographical or Europe-wide maps (Urban atlas).	
Blue spaces			
Blue spaces Yes (vs. No)	100, 300, 500m buffers	Dichotomous variable of presence of water surfaces. Based on Urban Atlas.	
Blue space percentage	100, 300, 500m buffers	Percentage of water surface. Based on Urban Atlas.	
Distance to blue space		Euclidean distance to the nearest water surface over 5,000m ² . Based on Urban Atlas.	
b) Built environment			
Building density	100, 300, 500m buffers	The building density around each household will be calculated accounting for the perimeter and height of the buildings from local cadastre data or Europe-wide maps (Urban Atlas).	
Population density	100, 300, 500m buffers	The number of inhabitants (per km ²) surrounding the home addresses.	
Street connectivity	100, 300, 500m buffers	Using data from OpenStreetMap [®] .	
Accessibility (bus lines)	100, 300, 500m buffers	Access to public transport bus lines from local topographical maps or OpenStreetMap®.	
Accessibility (bus stops)	100, 300, 500m buffers	Access to public transport bus stops from local topographical maps or OpenStreetMap®.	
Facility richness	100, 300, 500m buffers	Using local topographical maps or OpenStreetMap [®] .	
Facility density	100, 300, 500m buffers	Using local topographical maps or OpenStreetMap [®] .	
Land use	100, 300, 500m buffers	Mixed land use will be estimated by Shannon's Eveness Index based on Urban Atlas data.	
Walkability index	100, 300, 500m buffers	Index constructed from seven indicators: population density, street connectivity, street density, facility richness, facility density, land use, transport density, and average slope.	
c) Traffic infrastructure			
Major road Yes (vs. No)	100, 300, 500m buffers	Dichotomous variable of presence of a major road (OpenStreetMap®).	
Inverse distance		Inverse distance to the nearest major road (OpenStreetMap®).	

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GIS Variables	Study areas: A.C. s of the Basque Country and Andalusia, Valencian Community & the city of Barcelona				
OBJECTIVE URBAN ENVIRONMENTAL EXPOSURES d) Environmental stressors Air pollution	Scale	Variable			
PM _{2.5}	Street level (at residential address)	PM _{2.5} exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.			
PM10	Street level (at residential address)	PM ₁₀ exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.			
NO ₂	Street level (at residential address)	NO ₂ exposure indicators include: a) the annual average for the last five years, and b) the five-year average for the last five years based on spatiotemporal land-use random-forest models.			
Noise					
Day (L _d)	Street level (at residential address)	Exposition to environmental noise at street level during the day indicated as: a) the annual average for the last five years, and b) the five-year average for the last five years based of Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.			
Evening (L _e)	Street level (at residential address)	Exposition to environmental noise at street level during the evening indicated as: a) the annual average for the last five years, and b) the five-year average for the last five years base on Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.			
Night (Ln)	Street level (at residential address)	Exposition to environmental noise at street level during the night indicated as: a) the annual average for the last five years, and b) the five-year average for the last five years based of Strategic Noise Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecological Transition and the Demographic Challenge.			
Total (L _{den})	Street level (at residential address)	Total exposition to environmental noise at street level indicated as: a) the annual average f the last five years, and b) the five-year average for the last five years based on Strategic Noi Maps derived under the EU Directive 2002/49/EC from the Ministry for the Ecologic Transition and the Demographic Challenge.			

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 Table S3. Area-level socioeconomic (SES) variables obtained through GIS estimations.

	A 1				
AREA-LEVEL SES VARIABLES	Scale	Variable			
a) Mean income					
Average household net Census tract income		Average household net income. Income data collection is based on standardised annual requests to the differ collaborating tax organisations. Data from 2021. Data source INE ¹ .			
Average household gross Census tract		Average household gross income. As components of gross income, five exhaustive categories are considered: way			
Average net income per Census tract person		Net income per person is obtained, for each household, by dividing the net household income by the number of memb of said household. Data from 2021. Data source INE ¹ .			
Average gross income person Census tract		Gross income per person is obtained, for each household, by dividing the gross household income by the numbe members of said household. Data from 2021. Data source INE ¹ .			
Average income per Census tract consumption unit		Equivalised income is a measure of household income that takes account of the differences in a household's size composition, and thus is equivalised or made equivalent for all household sizes and compositions. The equivalesed income is calculated by dividing the household's total net income by its equivalent size, which is calculated using the modified O equivalence scale. This scale attributes a weight to all members of the household: 1.0 to the first adult; 0.5 to the sec and each subsequent person aged 14 and over; 0.3 to each child aged under 14. Data from 2021. Data source INE ¹ .			
b) Income distribution P80/P20	Census tract	Ratio between the 80th percentile and the 20th percentile of the income distribution per unit of consumption. Data for 2021. Data source INE^{1} .			
c) Gini index	Census tract	The Gini index measures the degree of inequality in the distribution of income/wealth, used to estimate how far a count wealth or income distribution deviates from an equal distribution ² . A Gini coefficient of 0 reflects perfect equality, wh all income or wealth values are the same, while a Gini coefficient of 1 (or 100%) reflects maximal inequality among value a situation where a single individual has all the income while all others have none. Data from 2021. Data source INE ¹ .			
d) MEDEA deprivation index	Census tract	A deprivation index developed to study the social inequalities in health in Spain. The index is composed by percentag the population with manual labour, percentage of the population with casual labour, percentage of the population unemployed, percentage of the population with insufficient education, percentage of the population of young people v insufficient education ³ . Data from 2021.			

¹ INEbase. Atlas de Distribución de Renta de los Hogares (ADRH). INE. Retrieved 19 December 2023, from <u>https://www.ine.es/metodologia/metodologia_adrh.pdf</u> ² Gini, Corrado (1936). "On the Measure of Concentration with Special Reference to Income and Statistics", Colorado College Publication, General Series No. 208, 73–79. ³ Domínguez-Berjón, M. F., Borrell, C., Cano-Serral, G., Esnaola, S., Nolasco, A., Pasarín, M. I., Ramis, R., Saurina, C., & Escolar-Pujolar, A. (2008). Construcción de un índice de privación a partir de datos censales en grandes ciudades españolas: (Proyecto MEDEA). *Gaceta Sanitaria*, 22(3), 179–187.
Table S4. Variables collected through Population Health Surveys.

Population Health Survey	Study areas				
Variables	A.C. Basque Country	A.C. Andalusia	Barcelona city	Valencian Community	
OUTCOMES					
a) Perceived health					
General Health	Ordinal 1-5	Ordinal 1-5	Ordinal 1-5	Ordinal 1-5	
Mental Health	Ordinal 1-5 [MHI/5 items]	Ordinal 1-6 [SF-12/3 items]	Ordinal 1-4 [GHQ-12/12 items]	Ordinal 1-4 [GHQ-12/12 items]	
b) Quality of life					
Health-related quality of life	Ordinal 1-5 [EuroQoL / 5 items]	Ordinal 1-6/1-5 [SF-12 / 5 items]	Ordinal 1-5 [EuroQoL / 5 items]	Ordinal 1-5 [EuroQoL / 5 items]	
c) Sleep					
Sleep duration	Continuous - Total hours/day	Continuous - Total hours/day	Continuous - Total hours/day	Continuous - Total hours/day	
Quality of sleep	Ordinal 1-5 [SATED / 5 items]	Ordinal 1-4 [4 items]	Ordinal 1-10	Ordinal 1-5 [SATED / 5 items]	
d) Consumption of medication f	or common mental disorders ¹				
Antidepressants	yes/no – reference 2 days	yes/no – reference 2 weeks	yes/no - reference 2 days	yes/no - reference 2 weeks	
Hypnotics	yes/no - reference 2 days	yes/no - reference 2 weeks	yes/no - reference 2 days	yes/no – reference 2 weeks	
Anxiolytics	yes/no - reference 2 days	yes/no - reference 2 weeks	yes/no - reference 2 days	yes/no - reference 2 weeks	
e) Chronic mental health proble	rms ²				
Anxiety	yes/no - reference ever	yes/no – reference present	yes/no - reference ever	yes/no – reference ever	
Depression	yes/no - reference ever	yes/no - reference present	yes/no - reference ever	yes/no - reference ever	
Insomnia	yes/no - reference ever	-	-	yes/no - reference ever	
Other	yes/no - reference ever	-	yes/no - reference ever	yes/no - reference ever	
COVARIATES					
a) Anthropometric variables					
Age	Discrete	Discrete	Discrete	Discrete	
Weight	Continuous	Continuous	Continuous	Continuous	
Height	Continuous	Continuous	Continuous	Continuous	
BMI	Continuous	Continuous	Continuous	Continuous	
Biologic sex	Categorical - 3 conditions	Categorical - 2 conditions	Categorical - 2 conditions	Categorical - 2 conditions	
Gender identity	Categorical - 3 conditions	-	Categorical - 3 conditions	-	
b) Individual socioeconomic var	iables				
Education level	Categorical - 9 conditions	Categorical - 13 conditions	Categorical - 11 conditions	Categorical - 9 conditions	
Occupational status	Categorical [CNO11]	Categorical [CNO11]	Categorical [CNO11]	Categorical [CNO11]	
Household size	Discrete	Discrete	Discrete	Discrete	

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Population Health Survey	Study areas				
Variables	A.C. Basque Country	A.C. Andalusia	Barcelona city	Valencian Com	
Household income	Categorical - 11 conditions	-	-	Categorical - 8 co	
Economic difficulty	Categorical - 6 conditions	Categorical - 6 conditions	Categorical - 6 conditions	Categorical - 6 co	
Employment status	yes/no	yes/no	yes/no	yes/no	
Country of birth	Categorical & Open	Categorical & Open	Categorical & Open	Categorical &	
Marital status	Categorical - 6 conditions	Categorical - 5 conditions	Categorical - 5 conditions	Categorical - 5 co	
c) Lifestyle factors					
Alcohol consumption	Categorical - 8 conditions	Categorical - 10 conditions	Categorical - 4 conditions	Categorical - 8 co	
Passive smoking at home	Likert 1-5	yes/no	Discrete (№ smokers)	yes/no	
Daily tobacco consumption	yes/no	Categorical - 4 conditions	Categorical - 3 conditions	Categorical - 4 co	
e) Physical Health				-	
Chronic health problems	Categorical - 38 conditions	Categorical - 25 conditions	Categorical - 25 conditions	Categorical - 21 c	
d) Mobility			-	-	
Years at household	Discrete		Discrete	Discrete	
MEDIATORS					
a) Physical activity					
Physical activity	Discrete - IPAQ	Discrete - IPAQ	Discrete - IPAQ	Discrete - IF	
- Vigorous	MET-min/week	MET-min/week	MET-min/week	MET-min/w	
- Moderate	MET-min/week	MET-min/week	MET-min/week	MET-min/w	
- Walking	MET-min/week	MET-min/week	MET-min/week	MET-min/w	
- Sitting	Time spent (hours + minutes)	Time spent (hours + minutes)	Time spent (hours + minutes)	Time spent (hours	
b) Social cohesion			Uh .		
Social support	Ordinal 1-5 [Duke / 11 items]	Ordinal 1-5 [Duke / 11 items]	Ordinal 1-5/1-4 [OSLO/ 3 items]	Ordinal 1-5 [Duke,	
Loneliness	Ordinal 1-4	Ordinal 1-4	Ordinal 1-4	Ordinal 1-	
SUBJECTIVE URBAN ENVIRONM	IENTAL EXPOSURES				
a) Perception of the neighbourh	nood				
Noise outside dwelling	Likert 1-3	Likert 1-3	Likert 1-5	Likert 1-3	
Neighbourhood air pollution	Likert 1-3	Likert 1-3	-	Likert 1-	
Shortage of green spaces	Likert 1-3	Likert 1-3	-	Likert 1-3	
Insecurity	Likert 1-3	Likert 1-3	Likert 1-5	Likert 1-	

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A) Prevalence of common mental disorders in Spain.

A recent report published by the Spanish National Health System (2020), based on a representative sample of users of said system, found that the overall prevalence of mental health problems in Spain is 27.4%. The most common general mental health issues were anxiety, depression, and sleep disorders, with a prevalence of 6.7%, 4.1%, and 5.4%, respectively. Higher prevalence of these disorders was observed in the female population, those born in Spain and with increasing age. The same report notes that in the case of anxiety and depression, a clear social gradient is observed, with both disorders being 3.4 and 2.5 times more prevalent in the population with lower income levels. In the case medication prescriptions, anxiolytics, antidepressants, and hypnotics were prescribed at rates of 34% for women and 17% for males over 40. The 2020 European Health Survey revealed no discernible territorial differences in the prevalence of chronic mental health conditions among individuals aged 15 and older in Spain. However perceived health status showed slight regional disparities, with Valencia reporting the highest percentage of "bad or very bad" health at 9.4%, followed by Andalucía (7.4%), the Basque Country (7%), and Catalonia (4.9%). However, given that the results presented in this report pertain to a timeframe predating the onset of the COVID-19 pandemic, it is anticipated that the prevalence of these conditions has risen universally among all age groups and regions (Henares Montiel et al., 2020). This increase can be attributed to escalated stress and healthrelated concerns stemming from the pandemic, exacerbated by associated constraints like lockdown measures and the resultant impact on mental health care services during the pandemic (Balluerka et al., 2020).

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Henares Montiel J, Ruiz-Pérez I, Sordo L. Salud mental en España y diferencias por sexo y por comunidades autónomas. *Gaceta Sanitaria*. 2020;34:114–9.

INEbase / Society /Health /European Survey of Health in Spain. INE. Retrieved December 2023. https://www.ine.es/dyngs/INEbase/en/operacion.htm?c=Estadistica_C&cid=1254736176784& idp=1254735573175

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Section 4. DATA MANAGEMENT PLAN

A) RESEARCH ACTIVITIES

Step 1. Population Health Surveys' (PHS) data curation and calibration

The selected individuals were contacted by a phone call, SMS, or letter to arrange an appointment for a face-to face interview for the purpose of the survey. The database produced with the interviews will be pseudonymised from that with the personal data for the contact by assigning a unique code for each participant and remains under the custody of the responsible body in each study area; the Basque Department of Health in the Basque Country, Escuela Andaluza de Salud Pública (EASP) in Andalusia, Agència de Salud Pública de Barcelona (ASPB) in Barcelona, and Conselleria de Salut Universal i Salut Pública (DGSP) in Valencian Community.

Step 2. Harmonisation

Initially, the databases of each study area will be cleaned, and the variables that require it will be harmonised. The vast majority of the variables to be used in the project have been collected identically in the Population Health Surveys of the study areas included. The variables to be harmonized are listed below and the measures used in each study area can be found in Table S2.

The variables that need harmonisation can be distinguished between simple or complex variables, depending on the level of difficulty and the manipulation of data that require the harmonisation of the respective variable:

Simple variables: Chronic mental health problems, Educational level, Occupation status,
 Household income, Loneliness, Noise outside dwelling, and Insecurity.

- Complex variables: mental health, health-related quality of life, sleep quality, consumption of medication for common mental disorders, alcohol consumption, passive smoking at home, tobacco consumption, physical health, and social support.

The Maelstrom Research Guidelines for the rigorous harmonisation of retrospective data (77) will be applied. Among the variables that need harmonisation, the majority can be easily recategorised (simple variables). For instance, in the case of scales with different score ranges (e.g., Likert scale levels), standardised scores will be calculated, or other procedures will be followed to ensure comparability. The procedure to follow with variables measured with different scales will be more complex (complex variables). For these, the content of each variable will be studied to detect the common content (e.g., items) in each of the study areas. Once detected, aggregate scores will be calculated for the common items, and these scores will be used for statistical analyses. The remaining non-harmonizable variables will be assessed for their potential for performing separate statistical analysis for each study area.

Step 3. Georeferentiation

The responsible bodies, in collaboration with regional Statistical Institutes or Population Registers, will link the health survey data to the geographical coordinates of each respondent's home address. The geographical coordinates will also be pseudonymised and sent this way to the research group specialised in Geographic Information System (GIS) estimations that will calculate UrbEE. In order to further ensure the protection of the personal data of the survey participants and enhance their anonymity, fictional coordinates will be created in a number five times the number of participants selected for the study in each study area and sent to the research group specialised in GIS estimations together with the real coordinates.

Step 4. GIS estimation of Urban Environmental Exposures (UrbEE)

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A company specialised in GIS estimations will calculate the objective urban environmental exposures (UrbEE) of all the geocodes, including the participants' coordinates and the fictional coordinates by GIS.

Step 5. Selection and linkage of data

After the estimations are finalised, the responsible bodies of the surveys in each study area will re-select the geocodes of the participants and add the new urban environmental variables to the database with the PHS data. The researchers will be provided with the resultant database of each study area composed by the PHS data and the UrbEE (without geocodes and personal data of the participants). This guarantees that the data supplied are protected by statistical secrecy, not misused and treated anonymously and globally at all times.

Step 6. Pooling

Finally, the final databases of all the study areas will be pooled, creating the final pooled database to be used in the planned analyses.

B) DATA STORAGE AND PROCESSING

Data will be kept at all times on servers located in the responsible centre of this project. This way, data will be stored on the University of the Basque Country UPV/EHU's own servers, complying with the greater security and privacy requirements of the LOPD as the data is not sent to external servers. The entire process of recording, dumping and storage of the data will be anonymised, with the data collected being exclusively linked to a sample unit code. Access to the anonymised microdata will be limited to technicians from the responsible centres of each study area through profiles with regulated permissions that allow for supervising and controlling access to the information. Supervision of the data management will be assigned to the principal

investigators with expert advice, and to the data protection officer of the centre responsible for the project.

C) ETHICAL CONSIDERATIONS AND ACCOUNTABILY

The study was approved by the regional Research Ethics Committee of the **Basque Country**, ETHICS COMMITTEE FOR RESEARCH INVOLVING MEDICINAL PRODUCTS IN THE BASQUE COUNTRY (CEIm-E) (protocol code PI2022138, dated 9th November 2022); **Andalusia**, BIOMEDICAL RESEARCH ETHICS COMMITTEE OF THE PROVINCE OF GRANADA (CEI/CEIM GRANADA) (protocol code 2078-N-22, dated 27th December 2022); **Barcelona**, PARC DE SALUT MAR CLINICAL RESEARCH ETHICS COMMITTE (CEIm) (protocol code 2022/10667, dated 2nd December 2022); **Valencian Community**, ETHICS COMMITTEE FOR CLINICAL RESEARCH OF THE DIRECTORATE GENERAL OF PUBLIC HEALTH AND CENTER FOR ADVANCED RESEARCH IN PUBLIC HEALTH (CEIC DGSP / CSISP) (protocol code 20221125/04, dated 25th November 2022).

This study is based on secondary data obtained from four independent Population Health Surveys (PHS) from Spain. Since the present study does not involve the activity of data collection, to obtain the informed consent from the subjects is not applicable for this study. However, the PHS included this project are official statistical operations included in the respective Statistical Plans of each study area. This ensures that the data provided is protected by statistical confidentiality, it is not misused, its treatment is anonymous and global at all times, and that indirect identification is impossible. Data are collected and processed in accordance with the provisions of the General Data Protection Regulation (GDPR) and in accordance with the provisions of Article 5 of the Organic Law 3/2018 of 5 December on the Protection of Personal Data and the guarantee of digital rights (Regulation (EU) 2016/679), they will be treated confidentially, with access to them being granted to personnel who strictly need to process them in the framework of the study.

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Furthermore, the transfer of data occurs between organisations within the Public Health System of each region and the regional or local government itself. This is done in the context of a research project conducted exclusively in the public sphere and with the legitimacy of the use of administrative records as research infrastructures in accordance with the General Health Act, the Biomedical Research Act and the General Law on Public Health. The results of the study will provide information at a sufficiently aggregated territorial level to prevent indirect identification. Furthermore, the project's results will be beneficial to the general population in a holistic way, thanks to its socioeconomic and environmental context, and its evolution over several years from the onset of the COVID-19 pandemic. Therefore, the risk to the privacy of the study population is minimal compared to the potential benefits the results will bring.