WELLBASED

D. 4.1 WELLBASED Pilot sites evaluation framework

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Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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List of acronyms

- H2020 – Horizon 2020
- WP – Work Package
- EC – European Commission
- EPOV – Energy Poverty Observatory
- EHR – Electronic Health Records
- ER – Emergency Room
- GDPR – General Data Protection Regulation
- HRQoL – Health Related Quality of Life
- ISRCTN - International Standard Randomised Controlled Trial Number

Executive summary

Nearly 11% of the European population lives in energy poverty. They struggle to afford their basic energy needs. They often live in poorly maintained building stocks and cannot adequately keep their home warm in winter and cool in summer. Energy poverty is a multidimensional problem caused by rising energy prices, low incomes and poor energy efficiency of housing. A number of researchers studied the effects of energy poverty on health and wellbeing of European citizens. They found that people living in energy poverty maintain poorer health and wellbeing than non-energy poor citizens. To tackle this problem, Valencia (Spain), Heerlen (Netherlands), Leeds (UK), Edirne (Turkey), Obuda (Hungary) and Jelgava (Latvia) will design, implement and evaluate six pilot programs. Their goal is to improve health, wellbeing and equality for people affected by energy poverty.

The study aims to recruit 1750 participants across the different pilot cities. Vulnerable adults over the age of 18 who live in energy poverty conditions at one of the pilot sites are invited to participate in the study at a communal centre, at a public space or when visited at home. Participants are allocated to one of two groups. The first group participates in the WELLBASED program and receives interventions such as energy audits, training on energy efficiency and housing improvements. In addition, they are asked to install environmental monitoring sensors that measure temperature, humidity, and air quality in their house, provide information regarding vital signs, and complete a questionnaire at baseline and six, twelve and eighteen months after the start of the study. Twenty participants of each site are asked to participate in two interviews, at the beginning and towards the end of the study. During the interviews, people's experiences of challenges associated with energy poverty and health and with the WELLBASED program are discussed. The second group completes the questionnaire at the same intervals. The study lasts for eighteen months in total. Program activities are monitored to capture reach, adoption, implementation, and maintenance.

Analysis, conclusions, and recommendations drawn from the different sources of data collected during the study are rooted in both the realist approach and the social ecological model. This enables insights into the impacts of interventions on different people, as well as the comparison of interventions across countries. The study's findings should help to propose EU-wide solutions to policymakers and city practitioners, in order to adopt urban programmes aimed at reducing energy poverty at EU level. The study is expected to commence in August 2022.

1. Introduction to the project

Energy poverty is a major urban and societal challenge with direct impact on health that affects around 54 million Europeans (10.7% of the EU population).(1) High-energy prices, low incomes and badly insulated, damp and unhealthy homes are leading to higher energy poverty rates. Electricity prices have gone up significantly in most countries in the past decade, which combined with the recent economic and financial crisis and the poor energy performance of Europe's building stock, has led to increased concerns over energy poverty in Europe.(1) Yet, most EU countries still do not identify or quantify vulnerable energy consumers, and do not adequately target energy poverty measures.

Energy poverty happens when a household finds it difficult or impossible to afford its basic energy needs. It mostly affects low-income households – commonly people who are retired, unemployed or poorly paid, single parents, dependent on social benefits. Their economic disadvantage is often matched with poor energy efficiency in their homes (poor insulation, outdated heating systems, expensive or polluting fuel). In addition, energy-poor households are often socially isolated and lack support from others. They tend to be subjected to degradation of dwellings, excessive debt and also to physical and mental health risks. Evidence from some European countries has shown that energy poverty has an important effect on health and wellbeing.(2-7)[i] Energy poverty is becoming a main challenge of the European welfare systems and beyond, exacerbated by the inequalities derived from living conditions and social determinants, with a direct and negative impact on health and wellbeing, mainly in urban contexts. Health problems attributable to energy poverty include respiratory diseases, heart attacks, stroke, and mental disorders (stress, anxiety, depression), as well as acute health issues, such as hypothermia, injuries or influenza.

Energy poverty is most likely to occur in urban areas with high unemployment and poverty along with poor quality buildings or poor built environment. Interestingly, urban development policies can sometimes leave the poorest parts of the population behind, and this leads to an increase in social and spatial segregation. A problem that must be addressed regards the use of the cheapest fuels. Energy-poor households tend to look for the cheapest available heating fuels (e.g., poor-quality wood - wet, sometimes treated with chemicals) or coal. Burning these fuels will result in high levels of air pollution, especially in terms of particle matter. And when fuel, be it wood or coal, is burned in old and inefficient boilers, it will lead to even more pollution. This means that energy-poor households can not only affect their own health, but also the health of entire urban settlements.(8) The main needs of every household are sufficient warmth for health and enough energy to live comfortably.(9) This is why it is hard to talk about contributing to energy efficiency in cities: it is often necessary to increase energy use in energy-poor dwellings in order to reach temperatures that ensure a minimum level of well-being. However, in many cases improving well-being can be successfully combined with improving the energy efficiency of homes. For example, by changing the heating source and system or by insulating the building, homes become more energy-efficient and more comfortable to live in. Yet, most households facing energy poverty cannot afford energy efficiency measures. Thus, the complex nature of this recently identified phenomenon requires a comprehensive analysis of the problem and its solution from a multidimensional approach, which should involve environmental, political, social, regulatory and psychological issues, thus involving other Social Determinants of Health and health

inequalities.(10, 11) Indeed, the growing energy poverty phenomenon and the corresponding inequality may strongly limit the social and economic development of cities. It may also generate costs amongst others through the potentially lost productivity, the increased probability of poor health and lower educational outcomes. The concentration of energy poverty in certain urban areas, in other words the spatial segregation, may create an additional barrier for healthy and equity living in cities. Local urban authorities can play an important role in tackling energy poverty by introducing or strengthening local policies aligned with the regional and more comprehensive national programmes and regulation. Thus, in this context, urban policies and initiatives might respond very efficiently to energy poverty and its effects on the citizens wellbeing and health, by providing evidence-based interventions covering different angles of the challenges, including complementary actions covering individual (behavioural), community (empowerment) and also social-political actions (regulations, urban planning) that include health in all policies multidimensional approach(12), which should involve environmental, political, social, regulatory and psychological issues, thus involving other Social Determinants of Health and health inequalities.(10, 11)

1.2 Objectives of the WELLBASED project

In this context, the overarching objective of WELLBASED is to propose the design, implementation, and evaluation of a novel, comprehensive urban programme to significantly reduce energy poverty and its effects on the citizens health and wellbeing. The programme is implemented and evaluated in six different pilot cities (Valencia-Spain, Heerlen-Netherlands, Leeds-UK, Edirne-Turkey, Obuda-Hungary, and Jelgava-Latvia). The design of the urban programme is built on evidence-based approaches, representing not only different urban realities but also a diverse range of welfare and healthcare models. The projects' objective is supported by the combined efforts of multiple stakeholders (national, municipal, civil society, and involvement of vulnerable groups), coupled with diverse multidisciplinary expertise from the health, housing, energy, social and environmental sectors. The project's multidisciplinary consortium has been built to guarantee the full coverage of the scientific, clinical, social and environmental competencies, and to gather the viewpoint of different communities and actors necessary to develop, test and evaluate the interventions related to WELLBASED in order to maximize its chances of success.

2. Introduction to the deliverable

Work package (WP) 4 concerns the evaluation of the WELLBASED urban programme. The main objective of WP4 is to perform the evaluation of the 12-month WELLBASED interventions deployed in the six pilot sites. The evaluation study measures health and wellbeing effects, energy poverty indicators and energy efficiency, environmental data from the households, feedback and impressions from participants, and cost-effectiveness. In collaboration with the other work packages implementation of the intervention activities is monitored. The evaluation study collects proper evidence for the WELLBASED urban programme to inform and reshape policy, driving the adaptive implementation of energy poverty alleviation efforts across Europe.

This Deliverable 4.1 describes the framework for the WELLBASED evaluation study. During the project, learnings from the evaluation study can be applied to improve WELLBASED. The evaluation study supports future implementation. There is a continuous interaction with the other work packages in order to perform the WELLBASED study and to disseminate its findings.

2.1 Deliverable objective and scope

This deliverable presents the evaluation framework of the WELLBASED project. The evaluation framework will be aligned with the participants' recruitment in pilot sites and will define the data collection from the implementation set up to the follow up, in order to guarantee scientific standards to achieve project results. The WELLBASED evaluation study combines quantitative and qualitative data collection, gathered from several sources (e.g., IT devices, questionnaires, interviews). Analysis, conclusions, and recommendations are rooted in both the realist approach and the social ecological model. In this deliverable the framework of the study design, methodology, data collection, methods and instruments, analyses and data management are presented.

2.2 Relation to other WPs and deliverables

The evaluation study provides input for scientific output, practical implementation, and policy recommendations. By collecting and integrating data from a variety of resources a comprehensive overview of impact can be generated. There is continuous collaboration with the other work packages and partners. This deliverable is strongly linked to the following WPs and deliverables, presented in Table 1.

Table 1. Deliverable 4.1 in relation to other WPs and deliverables.

WP	Deliverable	Description
WP2	D2.2	General framework of the urban programme (Leader: LNV)
	D2.3	Seven adapted urban programmes (Leader: LNV)

WP3	Task 3.1	Pilot preparation activities (Leader: ASIDEES)
	Task 3.2	Pilots' implementation and monitoring in the six adapted urban programmes (Leader: TNO)
WP5	Task 5.2	Upscaling and replication (Leader: DEM)
	Task 5.5	Policy Recommendations for the scaling up and transferability of evidence-based urban policies to reduce energy poverty (Leader: LNV)
WP6	Task 6.1	Dissemination, communication, city engagement and exploitation (Leader: ENC)
	Task 6.3	Scientific and academic dissemination (Leader: EMC)
	Task 6.4	Exploitation, innovation and business models development (Leader: KVC)
WP7	Task 7.1	Study protocol (Leader: INCLIVA)
	D7.2	Ethical management plan (Leader: INCLIVA)
	Task 7.3	Ethical protocols (Leader: INCLIVA)
	D7.4	Data management plan (Leader: INCLIVA)
WP8	D8.1	H - Requirement No. 2 (Leader: LNV)
	D8.2	POPD - Requirement No. 4 (Leader: LNV)

3. Methodology

3.1 Study design

Six pilot sites participate in the WELLBASED evaluation study. In each pilot site there will be two groups of individuals (or two study groups): individuals who receive the WELLBASED intervention (intervention group) and individuals who do not receive any intervention (control group). The evaluation study will run parallel to the implementation of the WELLBASED program. All participants must provide consent to participate in the evaluation study and data collection. Data collection includes both quantitative methods (e.g., questionnaires) and qualitative methods (e.g., interviews).

Interpretation of the analysis, conclusions and recommendations is based on the social ecological model, in combination with the realist evaluation approach. This enables comparisons across different interventions and countries, as well as generation of specific policy and practice recommendations. The breadth of the data, and the use of these frameworks allows a detailed picture of the outcomes of the pilots, as well as insights into how they work, for different types of people, in different circumstances.

3.2 Participants and recruitment

The target group for the study is adults ≥18 years old in vulnerable situations, living in energy poverty conditions that belong to one of the pilot sites (see 3.2.1). Each pilot site defines the specific target group for their intervention. Table 2 presents the target groups and recruitment sites of pilot sites (for more details see also in D2.3 Seven Urban Programmes).

The selection of individuals is done by, for example, the social services department (or the department in charge of social policies and vulnerable groups in each city), or an NGO dealing with vulnerable groups on the basis of these indicators and/or based on their own decision/judgement (as they have the broadest knowledge of the most vulnerable groups that need assistance and might benefit for the intervention). For example, when a person is assisted by the social services or by other organization (e.g. Red Cross/Caritas) and this organization is paying (directly or indirectly) for their electricity bills, this person is considered in a situation of energy poverty and a suitable candidate for the WELLBASED intervention as a measure of social protection. Pilots will plan their own strategies to identify potential study participants, as explained at D3.1 Pilot Implementation Plans.

Table 2. Pilot site and target group

Pilot sites	Total population	Recruitment target group	Recruitment sites and sample sizes
VALENCIA (SPAIN)	791,413	Low income households within the area of Algirós, Camins al Grau and Poblats Maritims, with high representation of vulnerable groups including older people living alone, Roma, unemployed, etc.	128 houses located in the neighbourhood around the Energy Office (Algirós, Camins al Grau and Poblats Maritims) which include 177 inhabitants per each research group.
HEERLEN (THE NETHERLANDS)	87,087	Social housing tenants with low incomes, high energy bills, low energy measures and bad housing conditions.	Two districts in the northern part of the city (Heerlerheide and Hoensbroek) with 156 inhabitants per each research group.
EDIRNE (TURKEY)	406,855	Low-income households in four neighbourhoods, where vulnerable groups, including older adults and the Roma, are highly represented.	50 houses located in one of the four neighourhoods: Menzil Ahir, Çavuşbey, Yeni İmaret and Yıldırım Hacı Sarraf which include 125 inhabitants per each research group.
JELGAVA (LATVIA)	55,972	The most vulnerable households, described by low income levels, long-term unemployment (>1 year), disabled people, poor housing quality, single-parent families, pensioners (especially suffering loneliness), and provided by the municipality.	Residents from the entire city that are considered to live in energy poverty conditions. 146 inhabitants per each research group.
LEEDS (UK)	789,194	Social housing tenants, managed by the City Council, with poor housing quality, classified as energy efficiency band D or below. Target group has different vulnerabilities: low income, older people, disabled people, single parents and recent migrants.	Tower blocks (40 apartments) located in a multi-ethnic neighbourhood which includes about 125 tenants of mixed ages and compositions per each research group.
OBUDA (HUNGARY)	130,560	Vulnerable inhabitants characterised by low incomes, victims of domestic violence and/or drug abuse, households with disabled and/or chronically ill members, unemployed members, and single mothers.	16-storeyed pre-fabricated housing estates with 40-50 households in Óbuda-Békásmegyer, the 3rd district of Budapest, including 146 inhabitants per each research group.

A person responsible for the household is requested to complete a questionnaire, collect health data, and participate in focus-group interviews. In some cases, several persons per household participate. Data are collected at individual level and at household level. All invited households receive project information and

an informed consent form. Adults who provide informed consent are enrolled in the study. For details on ethical protocols, management and procedures documents are available (D7.1, D7.2, D7.3). All pilot sites apply for Medical Ethical approval for the study from a local Ethics Committee before the evaluation study starts. Data collection is planned to start in August 2022.

3.2.1 Selection criteria

The following criteria guide recruitment and inclusion of participants in the evaluation study.

 1. Adults 18 y.o. or older in vulnerable situations. This includes unemployed individuals, low income, single parents, parents with dependent children, seniors (+65) with dependency conditions, seniors (+ 65) living alone, people with disabilities attended by social services, belonging to a minority, migrant situation, etc. The vulnerability could be understood as a lack of resilience or capacity of an individual or society to emergencies, hazards and disasters; thus, in general, adverse events. As Smith et al (2014) explained, vulnerability encompasses susceptibility to hazard, lack of capacity to cope and adapt, and also lack of resilience, responding to environmental determinants (e.g., weather, climate, adverse exposition to environmental hazards, etc.), structural determinants (e.g., country development, type of healthcare and social care systems, integration, policies and governance, etc.), community determinants (e.g., infrastructures, availability of health and social care, culture-s, socio-demographic factors, etc.) and individual factors (e.g., age, sex or constitution). Other definitions interpret vulnerability as a persistent condition between social inclusion and social exclusion or marginalisation.

2. Living in energy poverty conditions. Since energy poverty is a multi-dimensional concept, it cannot be easily captured by a single indicator. The EC suggests measuring energy poverty by using a suite of indicators, which should be viewed and used in combination since each indicator captures a slightly different aspect of the phenomenon. The primary indicators suggested by EPOV (the EU Observatory on Energy Poverty) are the following:

    i.   arrears on utility bills (Arrears on utility bills - Products Eurostat News - Eurostat (europa.eu));
    ii.   low absolute energy expenditure (M/2);
    iii. high share of energy expenditure in income (2M);
    iv.   inability to keep home adequately warm.

3.Belonging to the recruitment sites identified by the pilot partners for the study. Participants live in one of the designated pilot areas.

Exclusion criteria are:

- Individuals that have already been beneficiaries of a previous similar intervention.
- Individuals with limitations preventing to adequately participate in the intervention actions proposed in the pilots (e.g., intellectual disabilities, unable to attend to workshops, training, meetings; very poor health conditions, severe language limitations preventing the minimum communication).
- Individuals living in households illegally connected to the electricity grid.

The household respondent is chosen according to the following priorities: Priority (1): the person responsible for the accommodation Priority (2): a household member aged 18 and over who is the best placed to provide the information. We aim for a balanced sample based on gender.

For the qualitative evaluation, interviews are held with 20 people in each pilot city, who are interviewed on two occasions (at the beginning of the intervention in months 3-6, and after the intervention in months 15-18). Participants are recruited from the larger sample of respondents, who are asked in the baseline questionnaire if they are willing to be involved in the qualitative part of the study. From these volunteers, we use the baseline questionnaire results to construct a sample which reflects the diversity of the main groups identified. Specific attention is paid to ensuring a gender-balanced sample, and to including people who report a range of health and energy poverty experiences. Note that in the qualitative research tradition the objective is to follow theoretical interests rather than attempting to achieve a representative sample. This allows pilots to focus on particular types of diversity if they need to. Investigating such diversity allows the qualitative interviews to explain unexpected regularities in the quantitative data.

Participants sign informed consent to participate in the WELLBASED evaluation study. Those that participate in part B are provided with an additional information leaflet and sign an additional consent form. This is described in the informed consent and information leaflets.

3.2.2 Power considerations

In order to have adequate power to detect meaningful impact on health, wellbeing and energy poverty indicators we aim to include a total of 1750 participants in the pilot sites in the six countries combined (for numbers per pilot site see table 2). A total of n=875 is included in the intervention group and n=875 in the control group in each of the six pilot sites, with a minimum of 125 participants per arm per pilot site. A 20% loss to follow-up is expected (e.g. due to mortality, rehousing or impossibility to participate, as reflected in for this type of long-term pilots).(15) This means at 18-month follow-up the sample consists of n=700 in the intervention group; n=700 in the control group (total n= 1400).

Partners assume equal standard deviations in the intervention and the control group, alpha of 0.05 and power of 0.80. Thus, given six pilot sites with each an intervention group and control group, applying a correction factor to account for the clustered design, assuming an average cluster size of 117 citizens (1400/12) and an intra-class correlation coefficient of 0.02. For this expected overall sample size and assumptions, with regards to the continuous outcome measures (in particular, HRQoL) a difference of 0.28 SD (standard deviation) between the intervention and the control group can be detected at follow-up. This means that both at the European level, and in addition in each pilot separately, small differences regarding the outcomes in the intervention group compared to the control group can be shown.

3.3 Intervention condition and control condition

Intervention condition

In the intervention condition the WELLBASED program is applied. The definition of the WELLBASED urban programme follows the theoretical basis of the social ecological model.(13) A general framework of the urban programme is established and adapted to each pilot site. Key elements focus on individual lifestyle factors (e.g., energy efficiency measures), social and community networks (e.g., community strengthening), living and working conditions (e.g., home improvements) and general socioeconomic, cultural, and environmental conditions (e.g., access to energy). The general framework of the urban program is adapted to each pilot city. Focus groups are implemented in each pilot site with stakeholders and final users to co-create the interventions, to ensure that they are carried out according to the real needs of beneficiaries at local level and taking into account their insights.

Further details on the intervention design according to the social ecological model and the adaptation of the framework in each pilot site can be found in D2.2 General framework of the urban health programme and D2.3 Seven adapted urban programmes.

Control condition

In the control condition the usual activities of participants continue, there are no intervention actions undertaken.

3.4 Procedures

The study protocol is registered as a clinical trial under ISRTCN registry number ISRCTN14905838 (ISRCTN Registry). The data of registration is 15/02/2022. Before implementation, pilots apply for medical ethical approval (see task 7.3 WP7, leader: INCLIVA). In addition, pilots perform some preparatory actions (task 3.1 Pilot preparation, leader ASIDEES) including assignment of a pilot site coordinator, signing of an "Urban Local Alliance Agreement" and training towards their social and health care workers and technology partners.

3.5 Data collection

There are multiple types of data collected, using complementary resources and methods, to assess impact on health and wellbeing (table 3 and 4), energy poverty and efficiency (table 3), costs (table 6), lived experience (table 7) and to monitor implementation (table 8).

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Data collection in both study groups (intervention and control)

For all participants socio-demographic background information is collected, including sex, education, income, occupation, ethnicity, dwelling type. City-level data that cover air pollution, air quality, weather, climate, and green spaces, are obtained from publicly available data sources. Data collection instruments are based on the survey from the European Statistics on Income and Living conditions survey (EU-SILC).

In both study groups the following data collection methods are used:

- Self-report questionnaire: Individual level data in both research groups are collected through self-reported questionnaires by the participating adult. The questionnaires can be completed on paper or digitally through a secured mobile or web-based application. The participants either complete the questionnaire by themselves or the research assistant asks the questions to the participant and fills in the form. The baseline questionnaire is developed by WP4 in collaboration with partners. The instruments of the questionnaire for which no validated translations are available are translated (forward and backward translations). Before the start of the study, the questionnaires are pilot-tested to ensure its user-friendliness in terms of appropriateness, comprehensibility and length.
- Electronic Health Record (EHR): Data regarding visits to the emergency room and relevant care use outcomes are obtained via the self-report questionnaire or EHR if available.
- Energy usage by providers: Household spending on energy and energy consumption is obtained in both groups via energy providers, smart energy meters, or by self-report.

Data collection in the intervention group only

In the intervention group, additional data are collected through a variety of methods, taking into account workload on the pilot sites, expenses on the equipment and personnel, and geographical distribution of the intervention group participants:

- Health monitoring: Possible combinations of health-monitoring data collection are (1) manually collected data, by dedicated staff e.g., nurses, (2) automatically collected data, using smart devices or (3) a combination of the two. Peak flow, SpO_2, blood pressure and heart rate are measured every 30 days through the use of health monitoring devices such as wearables or manually. Peak flow and SpO_2 are measured in a resting position and after a six minutes' walk. Blood pressure and heart rate are measured three times in a resting position with a three-minutes interval. In addition, sleep quality is measured with the Pittsburgh Sleep Quality Index with a three-month interval.
- Household data: Home sensors collect household data about temperature, humidity and air quality to assess energy-poverty conditions that may impact health. Data is collected near real-time. The plan is to use technology such as sensors that are equipped with NFC (Near Field Communication) for easy configuration and built on the LoRaWAN, for example.
- Lived experience: qualitative interviews are implemented in each pilot site with subjects of the intervention to evaluate the impacts of the intervention and to help explain specific outcomes. General guidelines are provided for the set-up of these interviews, as well as training and support in implementing this part of the research. Partners implement interviews in their pilot sites and

collect the qualitative data from the pilots' participants following the lived experience methodology. Pilot site partners also contribute to qualitative analysis, which is led by University of Leeds.

- Monitoring of implementation: in collaboration with task 3.2. data is collected on the implementation of activities in the intervention sites using registry data, observational data, pilot site visit data.

3.5.1 Outcomes

Health, wellbeing and energy poverty

The effects of the WELLBASED programme with regard indicators of health, wellbeing, energy poverty indicators and energy-efficiency are evaluated. In table 3 and 4 below details are provided on the outcomes collected.

Table 3. Overview of health, well-being and energy-poverty data collected by <u>self-reported questionnaires</u> in the intervention and control group participants

Variable	Instrument/indicator	Timing
Health and wellbeing		
Self-perceived health	SF-12	Baseline, 6 month-, 12 month-, 18 month follow-up
Health related quality of life (HrQoL)	SF-12	Baseline, 6 month-, 12 month-, 18 month follow-up
Mental health and well-being (anxiety, depression, stress)	BSI-18	Baseline, 6 month-, 12 month-, 18 month follow-up
Chronic conditions and physical health	ICHOM Overall Adult Health set and via EHR (if available)	Baseline, 6 month-, 12 month-, 18 month follow-up
Frailty	SELFY-MPI-SF in older adults	Baseline, 6 month-, 12 month-, 18 month follow-up
Loneliness	UCLA 3-item Loneliness Scale	Baseline, 6 month-, 12 month-, 18 month follow-up
Control over Life and social support	Adult Social Care Outcomes Toolkit	Baseline, 6 month-, 12 month-, 18 month follow-up
Energy poverty		

Energy poverty assessment/ energy efficiency	European Statistics on Income and Living conditions survey (EU-SILC) Incl. income spent on energy	Baseline, 6 month-, 12 month-, 18 month follow-up
Subjective comfort in households	European Statistics on Income and Living conditions survey (EU-SILC)	Baseline, 6 month-, 12 month-, 18 month follow-up
Energy behaviours	Incl. motivation to adopt efficiency measures, coping strategies. Self-reported	Baseline, 6 month-, 12 month-, 18 month follow-up
Energy consumption	Self-report and via energy provider (if available)	Questionnaire at baseline, 6 month-, 12 month-, 18 month follow-up.

In the _intervention group only_ the following _health monitoring_ will take place (table 4).

Table 4. Overview of health data collected by health monitoring in intervention group participants

Variable	Instrument/indicator	Timing
Peak flow	Wearable/manually	Monthly (every 30 days)
Sp0$_2$	Wearable/manually	Monthly (every 30 days)
Blood pressure and heart rate	Wearable/manually	Monthly (every 30 days)
Sleep quality	Pittsburgh Sleep Quality Index	Every three months

Household conditions

The following data presented in table 5 are collected in the _intervention group only_ to evaluate impact on household conditions that relate to health, wellbeing and energy poverty.

Table 5. Overview of _household condition data_ to be collected in the intervention group participants homes

Variable	Instrument/indicator	Timing
Household temperature	Sensor	Near real-time monitoring

Household humidity	Sensor	Near real-time monitoring
Household air quality	Sensor	Near real-time monitoring

Costs

Using available information on health care usage and HRQoL outcomes, data to estimate cost-effectiveness are collected. They are presented in table 6 below.

Table 6. Overview of data collected with regard to cost-effectiveness

Variable	Instrument/indicator	Timing
Health care use and health care costs	● E.g. These include resource consumption and unit costs for: tests, drugs, personnel time (technical, physicians, nurses), equipment, consumables, general costs at the hospital, primary care and specialized consultations, emergency assistance, hospital days in ward, intermediate care unit or intensive care unit, research visits and travel time for site visits and work lost work hours. ● No. of visits to doctors/physicians. No. of visits to the emergency room. No. times staying in a hospital. No. of nights spent in hospital. ● SMRC	Questionnaire at baseline, month 6, month 12, month 18 follow-up in combination with local costs and EHR if available.
Energy consumption	Self-report on questionnaire and information from the energy provider if available.	Questionnaire at baseline, month 6, month 12, month 18 follow-up.

Quality of life to calculate quality-adjusted-life-years (QALYs)	EQ-5D-5L	Questionnaire at baseline, month 6, month 12, month 18 follow-up.

Lived experience

During qualitative interviews households' feedback, impressions, comments on their experience and health impacts are gathered, as well as their understandings of why things worked well and badly. These insights provide explanatory findings for the project in general, also allow pilots to modify their activities after the baseline stage to better target those that are excluded, therefore providing key results using the realist evaluation approach. In the qualitative study the following information is collected (table 7).

Table 7. Information to be collected in the <u>interviews</u> with <u>intervention group participants</u>

Variable	Instrument	Timing
Interviews discuss people's experiences of coping without energy; the trade-offs people make; how interventions impact on people's lives; how people experience different challenges associated with energy poverty and health.	Qualitative interviews	3-6 months, 15-18 month follow-up

Implementation of activities

To evaluate the implementation of the WELLBASED programme, the RE-AIM framework is adopted.(14) Indicators such as reach (number and proportion of individuals willing to participate), adoption (number of intervention agents willing to initiate the intervention), implementation (percent of program delivery, adaptation and costs) and maintenance (long-term adaptation of the intervention) are assessed. Both qualitative and quantitative methods are applied to collect the relevant indicators in collaboration with WP3, task 3.2. This is summarised in table 8 below.

Table 8. Overview of monitoring of implementation of activities

Variable	Instrument/indicator	Timing
Reach	e.g. registry of participants to activities, response to questionnaire and activities in pilot sites	Throughout implementation, pilot-site specific, using pilot site visits, observational data.
Adoption	e.g. number of trained professionals to perform activities	Throughout implementation, pilot-site specific, using pilot site visits, observational data.
Implementation	e.g. number of activities implemented as planned, costs	Throughout implementation, pilot-site specific, using pilot site visits, observational data.
Maintenance	e.g. number of activities planned after project end	Throughout implementation, pilot-site specific, using pilot site visits, observational data.

3.6 Data management

To perform the evaluation, data collected is combined from resources and pilot sites. Analyses are performed by Erasmus MC in collaboration with WP4 partners. Details on the data management in described in Deliverable 7.4. A dedicated data platform is developed for data collection and data analyses.

3.6.1 Data analysis

Impact on health, wellbeing and energy-poverty

Participant socio-demographic characteristics and health outcomes will be evaluated at baseline between the intervention and control group in the total study population and in each pilot site separately by means of chi-square tests for categorical variables and one-way ANOVA for continuous variables. These analyses provide insight in the comparability of the participants in both conditions and whether statistical correction for certain characteristics in the analyses is needed.

Main effects at follow-up are evaluated for the total study population, as per "intention to treat", using a multilevel modelling approach. Clustering effects at study site-level are taken into account. Multilevel linear regression analyses are conducted for continuous outcome variables with group (intervention or control) as independent variable. Multilevel logistic regressions are performed for dichotomous outcome variables. We correct effect estimates of multilevel analyses for covariates, based on literature (Metzelthin et al., 2013);

age, sex, living situation, education level and the baseline status of the outcome variable. We assess interactions between intervention condition and study site, gender, age and education level in the association between intervention condition and all outcomes (Franse et al., 2017). Also, season and city level conditions may be corrected for if deemed necessary. We consider a P-value of 0.05 or lower to be statistically significant. The main intervention effects, for example health-related quality of life, are evaluated using comparable analyses stratified per pilot site. Interactions between intervention condition and study site, gender, age and education level are also assessed.

Data from additional resources (i.e., health monitoring, household conditions) is analysed to study intervention impact in the intervention group only quantitatively. This depends on valid data, number of participants and available follow-up data

A per protocol analysis is performed, evaluating the impact on specific participant groups. To do so, we also combine information from the monitoring of implementation of activities. For example, participants who received a higher dose of the intervention compared to the control group participants. To estimate dose we may use the number of activities performed in a pilot site. If available, follow-up monitoring, is used to develop a variable that assesses dose delivered (e.g. exposure to different socio-ecological model level activities). Specific per protocol analyses may be defined during the project in collaboration with pilot sites and partners.

Machine learning analyses implemented by INCLIVA enable the generation of complex multidimensional models to predict and estimate the effects on health and wellbeing of different interventions and policies at urban level linked with energy poverty.

Cost-effectiveness

For economic assessment, a preliminary cost-effectiveness method is used. This is the most appropriate method in a community-based trial with a health promotion objective, as the assessment of health care use in the study largely depends on participant-reported outcomes. With regard to cost-effectiveness an integrated complementary approach is used to analyse outcomes. Firstly, the data analysis estimates the impact of the interventions in the different pilots in terms of energy efficiency and energy savings and costs (coordinated by ASIDEES). Secondly, the economic impact of the improvement of the health conditions is calculated for the different pilots (led by EMC). Finally, a cost-effectiveness estimation from the data obtained in the pilots is carried out, using MAFEIP methodology (performed by KVC), to estimate the impact of the intervention compared to current care through a) collecting the evidence of the effectiveness of the interventions; b) health economics modelling based on Markow model. In addition, all relevant costs and consequences for the interventions (utility gains, e.g. QoL) and their comparators are collected and associated to the interventions. Particularly, on the cost side, data on direct and indirect healthcare costs are considered.

Lived experience

The qualitative data collection from the interviews (i.e. lived experience) are analysed using NVivo with an emphasis on explaining why different households experience the intervention differently, including why

different health and energy poverty outcomes were recorded. Analysis takes place across data from the six different pilot cities, in both a case-based and integrated manner. Some findings are unique to cities, others are generalizable across the whole sample.

Implementation of activities

In collaboration with WP3 monitoring of implementation of activities takes places and relevant data is collected. This includes qualitative data, registration data, and pilot site visit data. Data are combined to gain insight in the implementation of activities. Scores are presented as means (standard deviations) and range, or percentages. Quantitative data also provide insight in the dose delivered, which is also used in the summative evaluation (see above).

Descriptive statistics are used to present quantitative insight in the reach, adoption and feasibility of the WELLBASED program, the attention/retention rates and the specific activities. For example, participation rate by evaluating the number of people being offered an activity, the number of people taking part in the first meeting, and the number of people attending all meetings. Usability and acceptability are also evaluated as part of the qualitative assessments described above.

3.6.2. Data management

In order to collect the data from the pilot sites, a specific WELLBASED platform is created. The platform consists of a database constructed ad hoc for the project with defined fields for each variable and a manual to describe the characteristics, particularities and specific descriptors to insert data that could not be automatically nurtured. Data from the installed environmental sensor(s) are sent to a data cloud. For analysis purposes, data from the WELLBASED platform and data from the clouds belonging to the devices are merged in a separate, suitable data platform. Thus, data are collected in a systematised, integrated and harmonised way, and it is deployed pseudo anonymised at a regular basis, adequately stored and protected in a specific server by INCLIVA through secure channels. Standards for security are established. Once data have been analysed, the resulting data (anonymised and aggregated) may then transferred to and/or shared in other medical repositories or open-data platforms.

Data management is further described in D7.4. All data are stored and analysed for research purposes using pseudo-anonymised coding and following the guidelines set in the GDPR and by national laws.

3.6.3 Data integration

Analysis, conclusions and recommendations drawn from this breadth of data are rooted in both the realist approach and the social ecological model. This enables insights into the impacts of particular interventions on different people, as well as the comparison of interventions across nations. This is done by cross-linking data from different sources and different methodologies.

3.7 Dissemination

Work Package 4 closely collaborates with the other WP's and partners in order to integrate learnings from the evaluation study in the WELLBASED implementation and to support future implementation. The communication and dissemination strategy and the exploitation, innovation and business models are developed in WP6. As part of the communication strategy, scientific project results are disseminated through publications in scientific peer-reviewed journals and conferences. In addition, social media and the website (WELLBASED – Public Health and Energy Poverty) provide a platform to further disseminate key findings of our project to all stakeholders. The publication of results, and the application of the FAIR principles (Findable, Accessible, Interoperable and Reusable) to the data set obtained in any case guarantee the anonymisation and non-identifiability of the research subjects.

An External Advisory Board is created consisting of a group of experts and representatives of stakeholders with complementary profiles and consolidated expertise. The Advisory Board provides critical suggestions and comments throughout the project and is consulted on regular basis with regard to the evaluation study.

4. Findings and conclusions

In this deliverable an overview of the evaluation framework in the WELLBASED project is provided. The evaluation study feeds the WELLBASED project and works interactively with the other partners throughout the project in order to integrate learnings and support future implementation of the program. This document describes the methodology, data collection, and analyses methods that are applied. A combination of methods, resources and analyses is used to perform the evaluation study. The evaluation study enables to build an evidence base about the effects of energy poverty in health through the complex interactions between chronic diseases, socio-economic and socio-cultural diversity and the impact of the physical environment in respiratory diseases, cardiovascular diseases and mental disorders, to mention some.

One of the advantages of a realist evaluation approach is that policy and practice recommendations are precise and nuanced according to the findings. It also allows to compare findings across nations, to recognise any regularities of outcomes across nations, and to understand patterns in the way that people's context impacts on their ability to benefit from interventions. This is a key way in which findings from the six pilot cities will be useful for stakeholders in a broader urban context in the European Union: unpicking why things work or fail for particular people in particular contexts allows policy-makers and practitioners to find parallels from our findings in their own urban contexts.

The study set-up also has some limitations. In particular, participation of vulnerable people living in energy poverty may be challenging. The recruitment strategy seeks to involve societal partners that hold a trusting relationship with the target group. This has been shown to be an effective strategy in engaging hard-to-reach populations in health research.(15, 16) Furthermore, using the questionnaire we aim to capture the most important confounding variables to control for differences between participants in the intervention and control condition; however it remains possible that study results are subject to confounding.

In summary, the results of the evaluation study provide evidence on the benefits of a comprehensive urban programme to tackle energy poverty and its effects on health and wellbeing across Europe. Hence, this study can contribute to EU-wide replicable solutions for policymakers and city practitioners to alleviate energy poverty and improve health and wellbeing of vulnerable people.

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