



D. 4.6 Report on status of posting result

Amy van Grieken
Erasmus University Medical Center (EMC)

WP4 – Evaluation & Data Analysis

Date 27-02-2025



Funded by the Horizon 2020
Framework Programme of the
European Union



WELLBASED has been funded by the European Union's Horizon 2020 Programme under the Grant Agreement GA GA 945097. The contents of this publication are the sole responsibility of the authors from WP4 and do not necessarily reflect the opinion of the European Union.

WP No.: 4

Deliverable No. 4.6

Authors: Amy van Grieken

Level of Dissemination: Public

Version: 2

Version No.	Person in charge	Partner (acronym)	Date	Specifications
1	Amy van Grieken	EMC	November 2024	Draft of Deliverable
1.2	Noemi Garcia Caroline van Ooij	VIC TNO	November 2024	Internal review
1.3	Amy van Grieken	EMC	November 2024	Final version
1.4	Noemi Garcia	VIC	November 2024	Final review
2.0	Amy van Grieken Antonio Fernández	EMC INCLIVA	February 2025	Updated version
2.0	Noemi Garcia	VIC	28 Feb. 2024	Final review

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 This deliverable contains original unpublished work except where clearly indicated otherwise.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.



Table of contents

List of acronyms	3
List of Tables	3
Executive summary	4
1. Introduction to the deliverable	5
1.1 Deliverable objective and scope	5
1.2 Relation to other WPs and deliverables	5
2. Status of posting on results	5
3. Conclusion	6
Annex 1	7

List of acronyms

- WP4 – Work Package on Evaluation & data analysis
- ISRCTN - International Standard Randomised Controlled Trial Number

List of Tables

Table 1. Deliverable 4.6 in relation to other WPs and deliverables	5
--	---



Executive summary

This Deliverable 4.6 (D4.6) presents the status of posting on results in the study registry and the timeline for posting of final results after project end. The WELLBASED study has been registered in the International Standard Randomised Controlled Trial Number (ISRCTN) registry on 21/2/2022 under the number 14905838. The registration can be found here: <https://www.isrctn.com/ISRCTN14905838>. The provided anticipated date for publishing results is set at 1/8/2025.

According to the agreed project processes, an anonymised version of the WELLBASED dataset will be made available to the scientific community on the ZENODO platform. However, due to the complexity of the processes required to perform the anonymisation, this publication has not been achieved at the time of completion of this deliverable. Access to this anonymised dataset hosted on the ZENODO platform will be published in the final technical report.



1. Introduction to the deliverable

1.1 Deliverable objective and scope

This Deliverable presents status of posting on results in the study registry and the timeline for posting of final results after project end.

1.2 Relation to other WPs and deliverables

In general, this deliverable is strongly linked to WP4's tasks related to data analysis. Specifically to D4.1 Pilot sites evaluation framework, D4.2 'Intermediate analysis report' as well as D4.3 'Final pilot sites analysis report' in M45, D4.4 'Data platform with data gathered' and D4.5 'Report from the focus groups on evaluation' (M45). The WELLBASED project will end in M48 (March 2025).

This Deliverable relates also to several sections of D7.4 (Data Management Plan). All WPs, tasks and deliverables this deliverable relates to are presented in Table 1.

Table 1. Deliverable 4.6 in relation to other WPs and deliverables

WP	Deliverable	Description
WP4	Task D4.1	Pilot sites evaluation framework (Leader: EMC)
	Task 4.2	WELLBASED platform creation and data gathering (Leader: INCLIVA)
	Task 4.3	Data analysis: evaluation of the effects on health & wellbeing (Leader: EMC)
	Task 4.4	Data analysis: cost-effectiveness assessment (Leader: EMC)
	Task 4.5	Qualitative data collection and realist evaluation (Leader: UNIVLEEDS)
WP7	Task 7.2	Ethics management (Leader: INCLIVA)
	Task 7.4	Data management (Leader: INCLIVA)

2. Status of posting on results

The WELLBASED study has been registered in the International Standard Randomised Controlled Trial Number (ISRCTN) registry on 21/2/2022 under the number 14905838. The registration can be found here:



<https://www.isrctn.com/ISRCTN14905838>. The provided anticipated date for publishing results is set at 1/8/2025. See Annex I for a copy of the registry information on the WELLBASED study.

As mentioned above, an anonymised version of the WELLBASED dataset will be published and made available to the scientific community on the ZENODO platform in accordance with the procedures agreed in the project. However, due to the complexity of the processes required to perform the anonymisation, this publication has not been achieved at the time of completion of this deliverable. Details on the access to this anonymised dataset hosted on the ZENODO platform will be published in the final technical report.

3. Conclusion

The WELLBASED study has been registered at the ISRCTN at start of the evaluation study. During the evaluation study period relevant information has been updated. The foreseen publication of results is set at 1/8/2025. Anonymised data will be available on the ZENODO platform, after full completion of the risk analysis.



Annex 1

ISRCTN14905838 <https://doi.org/10.1186/ISRCTN14905838>

WELLBASED: Improving health, wellbeing and equality by evidenced-based urban policies for tackling energy poverty

Submission 15/02/2022	dateRecruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/04/2024	Condition category Not Applicable	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

Background and aim

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. People living in energy poverty maintain poorer health and wellbeing than non-energy poor citizens. In the WELLBASED project, six pilot sites (Valencia (Spain), Heerlen (Netherlands), Leeds (UK), Edirne (Turkey), Obuda (Hungary), and Jelgava (Latvia)) will implement and evaluate the WELLBASED urban program. The program is based on the socio-ecological model and adopted to each pilot site, the aim is to support people living in energy poverty and improve health and wellbeing. The study aims to recruit 1750 participants across the different pilot cities. The study's findings should help to propose EU-wide solutions to policy-makers and city practitioners with regard to energy poverty and its impact on health.

Who can participate?

Vulnerable adults aged 18 or older who live in energy poverty conditions at one of the pilot sites.

What does the study involve?

Participants are invited to participate in the study at a communal center, a public space or when visited at home. Participants are allocated to one of two groups. The intervention group participates in the



WELLBASED Urban Program. The other group is the control group. The WELLBASED Urban Program is a comprehensive urban programme based on the four layers of the social-ecological model. It includes actions related to the individual citizen (e.g. energy audits, energy-behavior), the social and community networks (e.g. training of professionals), the living and working conditions (e.g. building improvements) and the socio-economic, cultural and environmental dimension (e.g. policy recommendations) to improve citizens' health and wellbeing. Actions are implemented for a period of 12 months. At baseline, 6 months, 12 months and 18 months participants in both groups complete self-report questionnaires assessing sociodemographic characteristics, energy poverty and health and well-being outcomes. In the intervention group, peak flow, blood pressure, SpO₂, and heart rate are monitored monthly, and sleep quality every three months. Sensors installed inside homes of the participants measure CO₂, humidity, and temperature. In addition, in the intervention group 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.

What are the possible benefits and risks of participating?

Participants in the intervention group will receive the benefits of the WELLBASED urban program and contribute to better health and wellbeing for people living in energy poverty. As this is a non-invasive study, no significant risks for participants are foreseen.

Where is the study run from?

Erasmus University Medical Center (the Netherlands).

The WELLBASED project coordinator is Las Naves (Spain).

When is the study starting and how long is it expected to run for? November 2021 to September 2024

Who is funding the study?

European Union's Horizon 2020 research and innovation programme under grant agreement No 945097.

Who is the main contact?

Dr. Amy van Grieken, a.vangrieken@erasmusmc.nl

Merel Stevens (researcher), m.stevens@erasmusmc.nl

Noemi Garcia (project coördinator), noemi.garcia@lasnaves.com

Study website

<https://wellbased.eu/>

Contact information

Type(s)



Scientific

Contact name

Dr Amy van Grieken

ORCID ID

<http://orcid.org/0000-0001-6767-9159>

Contact details

Molenwaterplein 40

Rotterdam

Netherlands

3015 GD

+31107043498

a.vangrieken@erasmusmc.nl

Type(s)

Public

Contact name

Mrs Merel Stevens

Contact details

Wytemaweg 80

Rotterdam

Netherlands

3000 CA

-

m.stevens@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number



ClinicalTrial

s.gov

number Nil

known

Secondary identifying

numbers 945097

Study information

Scientific Title

A comprehensive urban programme to reduce energy poverty and its effects on health and wellbeing of citizens in six European cities unable to afford their basic energy needs

Acronym

WELLBASED

Study hypothesis

The hypothesis of this study is that vulnerable people living in energy poverty who participate in the WELLBASED programme have more favourable results with regard to indicators of health, wellbeing and quality of life in comparison to the participants in the control condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 03/11/2021, Ethics committee for research with medicines of the university clinical hospital of Valencia (Avenida Blasco Ibáñez 17, 46010 Valencia, Spain; +34 96 197 39 76; ceic_hcv@gva.es), ref: 2021/316
2. Approved 04/07/2022, Ethics committee University of Leeds - AREA (Faculties of Business, Environment and Social Sciences, Leeds, UK; no telephone provided; ResearchEthics@leeds.ac.uk), ref: AREA 21-070
3. Approved 19/04/2022, Central Medical Ethics committee (Brīvības iela 72 k-1, LV 1011, Rīga, Latvia; +371 67876000; vm@vm.gov.lv), ref: Nr. 01-29.1.2/2267
4. Approved 21/03/2022, Medical Ethical Committee of Erasmus Medical Center (P.O. Box 2040, 3000 CA Rotterdam, Room Ae-337, the Netherlands), ref: MEC-2022-0150
5. Approved 06/04/2022, Trakya University Edirne Clinical Studies Ethical Committee (Turkey; no telephone provided; no email address provided), ref: 07/01
6. Approved 11/07/2022, Committee Name Egészségügyi Tudományos Tanács Tudományos és Kutatásetikai Bizottsága, ETT TUKEB (Scientific and Research Ethics Committee of the Medical



Research Council, Ministry of Health, Medical Research Council Arany János u. 6-8 Budapest, H-1051 Hungary; +36 13119651; szolanka.jozsefne@eum.hu), ref. 332/2022

Study design

Multisite pre-post controlled study design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet. lucas.espuig@uv.es

Condition

Energy poverty

Interventions

In the intervention group the WELLBASED Urban Programme is implemented. In the control group no intervention activities are implemented.

The WELLBASED Urban Program is a comprehensive urban programme based on the four layers of the social ecological model. It includes actions related to the individual citizen (e.g. energy audits, energy-behavior), the social and community networks (e.g. training of professionals), the living and working conditions (e.g. building improvements) and the socio-economic, cultural and environmental dimension (e.g. policy recommendations) to improve citizens' health and wellbeing. Actions are implemented for a period of 12 months.

Data using self-report questionnaires will be collected at baseline (start of the implementation of the intervention in the intervention group), 6 months, 12 months and 18 months in both intervention and control group. Additional data is collected in the intervention group using mixed methods research.



Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 28/03/2023:

Health-related quality of life (HR-QoL) score measured using the EQ5D-5L scores at baseline, 6, 12, and 18 months

Previous primary outcome measure:

Health-related quality of life (HR-QoL) score measured using the Short-Form Health Survey 12 (SF-12) scores at baseline, 6, 12, and 18 months

Secondary outcome measures

Current secondary outcome measures as of 28/03/2023:

Measured at baseline, 6, 12 and 18 months:

1. Mental health measured using the Depression Anxiety Stress Scales 18 (DASS-18)
2. Self-perceived health measured using the EQ5D-5L
3. Frailty measured in older adults using the Brief Self-Administered Multidimensional Prognostic Index Short Form (Brief SELFY-MPI-SF)
4. Subjective comfort in households measured using the European Statistics on Income and Living conditions survey (EU-SILC)
5. Comorbidities measured using the ICHOM Overall Adult Health set
6. Lifestyle behaviour: BMI, and smoking status measured using the ICHOM Overall Adult Health set
7. Lifestyle behaviour: Physical activity measured using One item of the Internal Physical Activity Questionnaire (IPAQ)
8. Health care use measured using the Modified SMRC Health Care Utilization questionnaire⁹. Energy poverty indicators measured using the European Statistics on Income and Living conditions survey (EU-SILC)
10. Attitudes measured using a self-reported scale
11. Energy consumption adopted from smart energy meters or self-report in the questionnaire
12. Household income spent on energy reported by the participant

In the intervention group, additional outcomes are collected:

13. Health monitoring: Peak flow, SpO₂, heart rate and blood pressure will be measured every month
14. Sleep quality index measured using the Pittsburgh Sleep Quality Index every 3 months¹⁵. Household conditions temperature, humidity and CO₂ measured in real-time using home sensors
16. Impressions, comments, experience and subjective perceptions captured in a focus group and individual interviews



Previous secondary outcome measures:

Measured at baseline, 6, 12 and 18 months

1. Satisfaction with life measured using the Satisfaction with Life (SWL) scale (
2. Mental health measured using the Depression Anxiety Stress Scales 18 (DASS-18)
3. Self-perceived health measured using the Short Form Health Survey 12 (SF-12)
4. Frailty measured in older adults using the Self-Administered Multidimensional Prognostic

Index Short Form (SELFY-MPI-SF)

5. Subjective comfort in households measured using the European Statistics on Income and Living conditions survey (EU-SILC)
6. Comorbidities measured using the ICHOM Overall Adult Health set
7. Lifestyle behaviour: BMI, alcohol consumption, smoking status measured using the ICHOM Overall Adult Health set
8. Lifestyle behaviour: Physical activity measured using One item of the Internal Physical Activity Questionnaire (IPAQ)
9. Loneliness measured using the UCLA 3-item Loneliness Scale
10. Control over life and social support measured using the Adult Social Care Outcomes Toolkit
11. Health care use measured using the Modified SMRC Health Care Utilization questionnaire
12. Energy poverty indicators measured using the European Statistics on Income and Living conditions survey (EU-SILC)
13. Attitudes measured using a self-reported scale.
14. Energy consumption adopted from energy providers or smart energy meters.
15. Household income spent on energy reported by the participant.

In the intervention group, additional outcomes are collected:

16. Health-monitoring: Peak flow, SpO₂, and blood pressure will be measured every month.
17. Sleep quality index measured using the Pittsburgh Sleep Quality Index every 3 months.
18. Household conditions temperature, humidity and air quality measured real-time using home sensors.
19. Impressions, comments, experience and subjective perceptions captured in focus group and individual interviews.

Overall study start date

03/11/2021

Overall study end date

01/09/2024

Eligibility

Participant inclusion criteria

1. Aged ≥ 18 years old



2. In a vulnerable situation (unemployed, 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.),
3. Living in energy poverty conditions
4. Belonging to the recruitment sites identified by the pilot partners for the study

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1750

Total final enrolment

1340

Participant exclusion criteria

1. Cannot adequately participate in the intervention actions proposed in the pilot (e.g. intellectual disabilities, severe language limitations)
- or 2. Illegally connected to the electricity grid.

Recruitment start

date 01/09/2022

Recruitment end

date 30/06/2023

Locations

Countries of recruitment

England

Hungary



Latvia

Netherlands

Spain

Türkiye

United Kingdom

Study participating centre

Municipality of Heerlen

Geleenstraat 25

Heerlen

Netherlands

6400 AA

Study participating centre

Municipality of Edirne

Babademirtaş Mh., Mimar Sinan Cd. No:1, 22000 Edirne Merkez/Edirne, Turkey Edirne

Türkiye

22000

Study participating centre

València Clima i Energia

Carrer de Joan Verdeguer, 16

València

Spain

46024

Study participating centre

INCLIVA



C. de Menéndez y Pelayo, 4, 46010 Valencia, Spain

Valencia

Spain

46010

Study participating centre

Leeds City Council

Civic Hall

Calverley Street

Leeds

United Kingdom

LS11UR

Study participating centre

Óbuda-Békásmegyer Municipality

Óbuda-Békásmegyer

Budapest

Hungary

-

Study participating centre

Jelgava Municipality Operative Information Center

11 Liela Str., Jelgava, LV-3001

Jelgava

Latvia

LV-3001



Sponsor information

Organisation

European Commission

Sponsor details

Rue de la Loi 200

Brussels

Belgium

1040

+32 2 299 56 32

cordis@publications.europa.eu

Sponsor

type

Government

ent

Website

http://ec.europa.eu/index_en.htmhttps://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

ROR

<https://ror.org/00k4n6c32>

Funder(s)

Funder type

Government

Funder Name

European Union's Horizon 2020 research and innovation programme under grant agreement No 945097.



Results and Publications

Publication and dissemination plan

Scientific dissemination will include papers and proceedings submitted to international conferences or high-impact peer-reviewed journals. Dissemination aimed at local authorities, social workers, health professionals, energy providers and the civil society (associations and NGOs) will be done through the project website (<https://wellbased.eu>), professional magazines, congresses, fairs and (capacity building) workshops organised within the project. Networks and alliances on health and/or poverty, vulnerability or climate change will be strengthened to reinforce the impact of the dissemination activities.

Intention to publish date

01/08/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type facing?	Details	Date created	Date added	Peer reviewed?	Patient-
Protocol article		19/08/2022	22/08/2022	Yes	No