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Evaluating the implementation of community engagement guidelines (EVALUA GPS project): a study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-062383
Article Type:	Protocol
Date Submitted by the Author:	03-Mar-2022
Complete List of Authors:	<p>Cassetti, Viola; Independent Researcher, López-Ruiz, María Victoria; Andalusian Health Service District Cordoba; Instituto Maimonides de Investigacion Biomedica de Cordoba Dominguez, Marta ; Aragonese Health Service; Health Research Institute Aragón GALLEGO ROYO, ALBA; Aragonese Health Service; Health Research Institute Aragón García, Ana; University of Valencia; CIBERER Gea-Caballero, Vicente; La Fe University and Polytechnic Hospital, NURSING; Health Research Institute La Fe, GREIACC Nuñez, Catalina; Health Promotion Service. General Directorate of Public Health. Paredes-Carbonell, Joan Josep; Primary Care Management. Health department La Ribera PÉRULA DE TORRES, LUIS ÁNGEL; Instituto Maimonides de Investigacion Biomedica de Cordoba, ; Teaching Unit of Family and Community Medicine. Health District of Cordoba and Guadalquivir. , Pola-Garcia, Marina; aragon health service; Health Research Institute Aragón EvaluAGPS Research Group, EvaluAGPS Research Group; Independent Research Group Benedé. Azagra, Carmen Belen; Aragonese Health Service; Health Research Institute Aragón</p>
Keywords:	PUBLIC HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, SOCIAL MEDICINE

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Manuscripts

TITLE:

Evaluating the implementation of community engagement guidelines (EVALUA GPS project): a study protocol

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Abstract

Introduction

The EVALUA GPS project aims to evaluate the impact of the implementation of the NICE guideline “Community engagement: improving health and wellbeing and reducing health inequalities” adapted to the Spanish context.

Methods and analysis

EVALUA GPS project will be carried out through three phases:

I: A tool will be designed to evaluate the impact of implementing the recommendations of the adapted NICE guideline. The tool will be developed through an analysis of the literature on implementation of public health guidelines and an expert’s panel consensus using an adapted Delphi method.

II: the developed tool will be implemented in a selection of community-based interventions through a quasi-experimental pre-post study. Twelve interventions will be receiving the implementation tool and an implementation workshop developed ad hoc. Four interventions will receive the implementation tool only.

III: an online web tool will be developed to support the implementation of the adapted NICE guidelines recommendations in other contexts and programmes.

Data collection and analysis: Data will be collected through surveys and interviews aimed at exploring changes in interventions. Quantitative data will be analysed through descriptive statistics and qualitative data through thematic analysis to identify implementation scenarios, changes in community engagement approaches, barriers and facilitators to the implementation of the recommendations and strategies to overcome them. The data collected in the implementation phase will be further synthesised in order to develop the online tool and improve the transferability of the results.

Ethics and dissemination

The proposed research has been approved by the Clinical Research Ethics Committee of Aragon (CEICA). Results will be presented at national and international conferences and published in peer-reviewed open access journals. A short animated video summarising the project will be produced. In addition, the interactive online tool (phase III) will include examples of the application fieldwork.

Article Summary

Strengths and limitations of this study

- The mixed methods (quantitative and qualitative) approach adopted in this research could support both researchers and participants to increase their knowledge and practice about community engagement in health programmes
- Research on public health guidelines implementation and evaluation is limited, and evidence is needed
- This study may contribute to reducing the gap between research, policy and practice
- Engaging a variety of stakeholders from different backgrounds strengthen the research project and the potential transferability of the study results
- Researching community engagement during the covid-19 pandemic is challenging but this project can support community interventions in these difficult times

Keywords: community engagement; implementation research; community health; public health guidelines

Word count: 2745

Introduction

Engaging people and communities is central to the improvement of their health and well-being and to the reduction of health inequalities [1]. According to the World Health Organization [2], community engagement in health is essential to protect and improve populations' health. Through community engagement, local people increase their decision-making capacities and trust among themselves, allowing them to influence the social determinants of health that affect them, to improve their health and that of their community [3,4]. Nonetheless, despite increasing evidence on its importance [5,6], there is still a need to improve knowledge and practice about community engagement in health [7].

The NICE Guidance NG44, published in 2016 [1], reviewed the evidence on the effect of community engagement on the health and wellbeing of communities and on reduction of health inequalities, and provided recommendations for incorporating community engagement into health policies and interventions. During 2017 and 2018 a collaborative project was carried out by a group of health-related professionals in Spain to adapt the NICE guideline NG44 to the Spanish context, the AdaptA GPS project [8]. The project resulted in the first public health guideline included in GuíaSalud, the clinical guidelines catalogue of the Spanish Ministry of Health [8]. At present, there is no evaluation of the implementation of the guidelines in the GuíaSalud catalogue: once developed, there is no evaluation of their impact on practice or health.

The research project EvaluA GPS (from its Spanish acronym: Evaluating the Application of Health Promotion Guidelines) aims to evaluate the impact of the

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3 implementation of the Spanish adapted NICE guideline NG44, through the following
4 specific objectives:
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7 Objective 1.1: To develop an implementation and evaluation tool based on the
8 recommendations of NICE guideline NG44, in order to identify changes which can
9 improve community engagement in interventions where the recommendations are
10 applied.
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13 Objective 1.2: To evaluate the impact of implementing the recommendations of NICE
14 guideline NG44 in a selection of community health interventions.
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17 Objective 1.3: To identify different implementation approaches according to different
18 contexts.
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20 21 **Methods and analysis**

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23 EVALUA GPS Project will be developed through three main phases, as illustrated in
24 Figure 1. Phase I will centre on developing a tool to evaluate the impact of the
25 recommendations. The tool will be developed through an analysis of the literature on
26 implementation of public health guidelines and an expert's panel consensus using an
27 adapted Delphi method. In phase II, the developed tool will be implemented in a
28 selection of community-based health interventions through a quasi-experimental
29 study, with pre-post surveys on community engagement approaches and interviews
30 with key stakeholders to explore changes in the interventions. Phase III will then
31 synthesise the information from the implementation phase, to develop an online tool
32 to support the implementation of the adapted guidelines recommendations in different
33 scenarios.
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38 39 **Phase I: evaluation tool development**

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41 To develop the first version of the evaluation tool (Evalguia 0.1), the EvaluA GPS team
42 will carry out an integrative review of the literature on public health guidelines
43 implementation. This first version (Evalguia 0.1) will then be reviewed by a panel of
44 experts in community health interventions through an adapted Delphi method.
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47 48 ***Phase I, part one: integrative review***

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50 An integrative review will be conducted to identify the available literature on the
51 implementation of public health guidelines and to inform the development of the first
52 version of the Evalguia tool (0.1). A systematic search strategy will be developed,
53 which will include a combination of key terms and synonyms related to
54 "implementation", "guidelines" and "analysis" or "evaluation". To avoid errors, excess
55 of superfluous information and/or loss of relevant information, peer review of the
56 search strategy will be performed at different stages [9]. The literature search will be
57 conducted using the databases PubMed, CINAHL, Web of Science and Scopus.
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3 Following the aim of the EvaluA GPS project, only studies analysing and/or evaluating
4 the implementation of public health guidelines will be included: (1) studies evaluating
5 the implementation of public health guidelines (2) studies analysing the
6 implementation of public health guidelines (3) studies showing both processes
7 (analysing and evaluating the implementation of public health guidelines). Three
8 researchers will identify the papers to be included in the review through screening titles
9 and abstracts and data will be extracted on: topic and context, implementation
10 process, barriers and facilitators, and evaluation methods used. A thematic synthesis
11 approach will be applied to synthesise the extracted information in a narrative way
12 [10]. The review will follow the ENTREQ statement to structure and report the review
13 process [11]. The analysis of the literature on guidelines implementation will then
14 inform the development of the first version of the Evalguia tool (Evalguia 0.1).
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21 ***Phase I, part two: experts panel through adapted Delphi method***

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24 The Evalguia 0.1 will then be tested through a panel of experts [Cassetti V, Lopez-
25 Ruiz MV, Pola García M, *et al.* An integrative review of the implementation of public
26 health guidelines. (unpublished. *Manuscript submitted for review*)]. This will be
27 organised through an adapted Delphi method [12], through two rounds of review of the
28 developed Evalguia 0.1 tool. This will enhance the quality of the Evalguia tool, which
29 will be evidence and practice-based.
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33 To identify experts in community health interventions, each researcher of the EvaluA
34 GPS team will be asked to suggest at least one potential participant, who will be
35 independent to the project. Participants will be experts in community-based actions, in
36 community health evaluation and/or be active members of a community health
37 intervention. Once the list has been compiled, an online invitation will be sent by email
38 to these experts, who, after expressing their interest in participating, will be sent an
39 informed consent form, which they will have to sign and return.
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43 The first version of the tool (Evalguia 0.1) will then be sent to all participating experts
44 who have signed the informed consent form. They will be asked to review it with a
45 focus on content, language and design. After receiving comments from the first round
46 of review, the research team will compile and discuss the proposed changes. The tool
47 will then be modified accordingly and Evalguia version 0.2 will be developed.
48 Participants who have not submitted the revision will be excluded from the following
49 round. Evalguia 0.2 will then be sent again to the participating experts, requesting their
50 final revision after the proposed changes.
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54 Finally, after receiving the second round of reviews, the research team will discuss the
55 proposed changes and modify the tool accordingly. This final version, Evalguia version
56 0.3, will therefore be considered as the final version of the tool to be implemented in
57 Phase II.
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Phase II: implementation

This phase aims to pilot-test the developed implementation and evaluation tool in a selection of community-based interventions, using a quasi-experimental pre-post study. To select the interventions, researchers from the EvaluA GPS team will identify a total of twenty local initiatives in four different Spanish regions, with the following inclusion and exclusion criteria:

1. Inclusion criteria:

- a. the intervention should aim to improve community health or follow at least one of the five lines of actions of the Ottawa Charter for Health Promotion (“1-building healthy public policy, 2-creating supportive environments, 3-strengthening community action, 4-developing personal skills, and 5-reorienting health care services toward promotion of health”) [13];
- b. the community should participate in at least two phases of the intervention (health needs assessment, design, implementation, evaluation);
- c. the level of community engagement can be defined according to the levels used in the development of the adapted guidelines (informing, consulting, co-creating decisions and actions, multiple and shared leadership, community control) [8];
- d. the intervention should have been ongoing for at least one year

2. Exclusion criteria:

- a. The intervention aims to promote individual health only, lacking a community health approach;
- b. The level of community engagement is limited to informing or consulting the community.

Intervention

All the 20 participating health interventions will receive the implementation tool (*Evalguia*), which includes textual explanations on how the tool should be implemented. A selection of sixteen interventions, named here as the workshop interventions will also receive an implementation workshop developed *ad hoc* by the research team based on previous experience in the field of community-based actions and on the results from Phase I, while the remaining four, named here as control interventions, will only receive the implementation tool. This will allow to evaluate whether the implementation tool alone improves community engagement in the

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3 participating interventions, and to identify potential facilitators for the implementation,
4 such as receiving support through a tailored implementation workshop.
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7 The implementation workshop will be organised with key stakeholders such as
8 intervention managers, front-line workers and community members involved in the
9 intervention. This will preferably be carried out in two sessions, preferably in two
10 different days or with a lunch break in between. It will be recommended to have a
11 maximum of 15 people attending, to facilitate the process and the group activities. In
12 the first session, after a general presentation of the project and the participants, we
13 will define key terms included in the guidelines, such as community engagement,
14 health assets, intersectoral work, vulnerable groups and empowerment, to ensure all
15 participants will have a shared understanding of these concepts. Then the Evalguía
16 tool will be implemented, followed by a group reflection on the results. In a second
17 session, an action plan aimed at improving community engagement following the
18 adapted guidelines recommendations will be elaborated. It is foreseen that the
19 workshop will be held in person, although as a consequence of the COVID-19
20 pandemic these may have to be held online.
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26 **Data collection**

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28 The implementation process will be structured in 4 stages, over a period of 15-18
29 months. In each stage, data will be collected through audio recording of interviews
30 with key stakeholders, observation notes, and photos of the products which may be
31 developed during the working sessions (diagrams, action plans). A written informed
32 consent will be asked to each participating stakeholder.
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36 In stage 1 (months 1-2), an unstructured interview will be held with the intervention
37 managers (duration 60-90 minutes) to better understand the intervention, its origins,
38 its aims and objectives and how it is being implemented and carried out daily.
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41 In stage 2 (months 4-6), the Evalguia tool will be implemented, 16 interventions will be
42 supported through the implementation workshop, while the 4 control interventions will
43 only receive the implementation tool. Prior to the implementation of the Evalguia tool,
44 all the participating interventions (n=20) will answer an initial questionnaire (Q1), which
45 will explore their perspective on the community engagement approach currently being
46 used in their intervention. Workshop interventions (n=16) will also answer a final
47 questionnaire (Q2) after the workshop, exploring their perception of the tool (15
48 minutes) and of the workshop itself. The control interventions will answer a
49 questionnaire (Q2 bis) exploring their perceptions on the tool only.
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54 In stage 3 (7-9 months after the Evalguia implementation), participants of all 20
55 interventions will be asked to answer again to answer to the first questionnaire on
56 community engagement (Q1), and a second unstructured interview (60 minutes) will
57 be carried out with the intervention managers to explore their perspectives on potential
58 changes in the intervention over the past months.
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3 In stage 4 (12 to 14 months after the Evalguia implementation), data collection will be
4 completed. Stakeholders will again answer the questionnaire on community
5 engagement, and a final interview with all the intervention managers will be conducted
6 (60 minutes). Finally, an evaluation session will be organised with all the stakeholders
7 from the 20 participating interventions to discuss the final changes to Evalguia and to
8 respond to a final questionnaire on the Evalguía tool (15 minutes).
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14 **Phase III: online tool development**

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16 The data collected through the implementation phase will then support the
17 development of an interactive online tool. The tool will be structured according to
18 different potential scenarios for implementation and will include examples from the
19 field as evidence of good practice to improve community engagement. The online tool
20 will be tested with representatives of the interventions involved in the study, to ensure
21 its language and design are user-friendly and accessible for a lay public.
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27 **Analysis**

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29 The data collected through the fieldwork in Phase II will be analysed to identify
30 changes in community engagement approaches and other possible changes resulting
31 from the implementation of the recommendations and/or of the workshops (such as
32 organisational changes and changes in relationships). Data from the questionnaires
33 will be analysed using descriptive statistics, to compare changes pre and post
34 intervention in both the workshop interventions and the control interventions. Data
35 from interviews and workshops will be analysed using a thematic analysis approach
36 [14]. The analysis will focus on synthesising similarities identified in the workshop and
37 control interventions to identify different implementation scenarios where community
38 engagement can be enhanced and allow the transferability of results to different
39 contexts. Moreover, the analysis will identify (a) barriers and facilitators in the
40 implementation of the recommendations and (b) strategies to overcome these barriers
41 and promote facilitators, to support implementation in other contexts.
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47 The quantitative data will contribute to respond to the main objective of the study by
48 providing an assessment of changes in community engagement which could be
49 attributed to the implementation of the guideline recommendations, allowing also to
50 evaluate the impact of the workshops. The qualitative data will set the basis to develop
51 the online tool to support the implementation of the adapted guidelines
52 recommendations in other interventions and contexts, thus enhancing the
53 transferability and applicability of the study results.
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57 To conclude, EvaluA GPS aims to enhance translational research, and through
58 implementation and evaluation it aims to contribute to reducing the gap between
59 research, policy and practice [15]. Moreover, it is hoped that generating more practice-
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3 based evidence in community engagement in health in Spain will strengthen and
4 enhance good practices in community health interventions, contributing to promote the
5 health of people and communities and reduce health inequalities.
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10 **Patient and Public Involvement Statement**

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12 EVALUA GPS Project is based on the findings of the previous research project,
13 AdaptA GPS [8], in which community members from eleven local interventions across
14 Spain were involved to test the adapted NICE NG44 guidance. EvaluA GPS was
15 designed based on their feedback on the need to simplify the language used in the
16 recommendations and provide more practical examples on how to implement the
17 community engagement recommendations. Community members are also key
18 stakeholders in the EvaluA GPS project, as they will be involved in the implementation
19 phase, through recruiting participants for the workshops; additionally, in the case of
20 the four control interventions, community members will also be responsible for the
21 implementation of the Evalguia tool.
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26 **Ethics and dissemination**

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28 All participants will receive an information sheet detailing all the phases of the research
29 project and will be informed of the objectives and characteristics of the study, as well
30 as their voluntary participation and the possibility of leaving the study at any time
31 during the research process. The workshop interventions will be informed that they will
32 receive a workshop to implement the Evalguia, while the control interventions will be
33 informed that they will receive the Evalguia and will have to implement it on their own.
34 If they agree to participate in the study, they will be asked to sign an informed consent
35 form. Data confidentiality will be guaranteed in accordance with Spanish Organic Law
36 3/2018 on the protection of personal data and guarantee of digital rights, being
37 analysed anonymously and described in aggregate form to avoid identification at an
38 individual level. The research project has been approved by the Clinical Research
39 Ethics Committee of Aragón (CEICA), PI20/116.
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45 As for dissemination, study results will be presented at national and international
46 conferences, as well as published in open access peer-reviewed journals. Moreover,
47 the research team will develop a short animated video summarising the project [16]
48 which will support presenting the research to lay people. In addition to that, the
49 interactive web tool will be designed with lay and inclusive language, and will include
50 evidence of good practices in community engagement gathered from the participating
51 interventions.
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57 **Author contributions:** VC, MVLR, CBBA, JPC, AMG, LAPdT and CN developed the
58 study proposal and protocol. VC, MVLR, MPG, AGR, MD, CN and VG wrote the initial
59 draft of the paper which has then been iteratively revised and reviewed by all authors.
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3 All the authors approved the final version to be published. All the authors agree on
4 being accountable for all aspects of the work in ensuring that questions related to the
5 accuracy or integrity of any part of the work are appropriately investigated and
6 resolved.
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10
11 **Funding:** This work was supported by the Carlos III Institutes of the Spanish Ministry
12 of Health [grants number: PI19/01079; PI19/01525; PI19/00773 for the years 2020-
13 2022]
14
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17 **Competing interests:** None declared
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20
21 **Acknowledgements: (EvaluAGPS Research Group):** Aldecoa Landesa, Susana;
22 Aliaga Train, Pilar; Aviñó Juan-Ulpiano, Dory; Baraza Cano, Pilar; Barona Vilar,
23 Carmen; Botello Diaz, Blanca del Rocío; Bueno, Manuel; Couso Viana, Sabela;
24 Dominguez, Marta; Egea Ronda, Ana; Enriquez, Natalia; Gallego Dieguez, Javier;
25 GallegoRoyo, Alba; Gea Caballero, Vicente; Hernán García, Mariano; Hernández
26 Gómez, Mercedes Adelaida; Iriarte, María Teresa; Lou Alcaine, María Luz; Martínez
27 Pecharromán, María del Mar; Morin, Victoria; Nuñez Jiménez, Catalina; Peyman-
28 Fard, Nima; Pla Consegra, Margarita; Romaguera Lliso, Amparo; Ruiz Azarola,
29 Ainhoa; Sainz Ruiz, Pablo. EvaluAGPS Research Group is a multidisciplinary
30 research group formed for the EvaluA GPS project. EvaluA GPS is a research
31 coordinated by three institutions: IIS (Instituto de Investigación Sanitaria de Aragón);
32 FISABIO (Fundación para el Fomento de la Investigación Sanitaria y Biomédica,
33 Comunitat Valenciana) and IMIBIC-FIBICO (Maimonides Institute for Biomedical
34 Research of Cordoba, Andalucía) and with the participation of the IAPP network, the
35 PACAP program and the Community Health Alliance.
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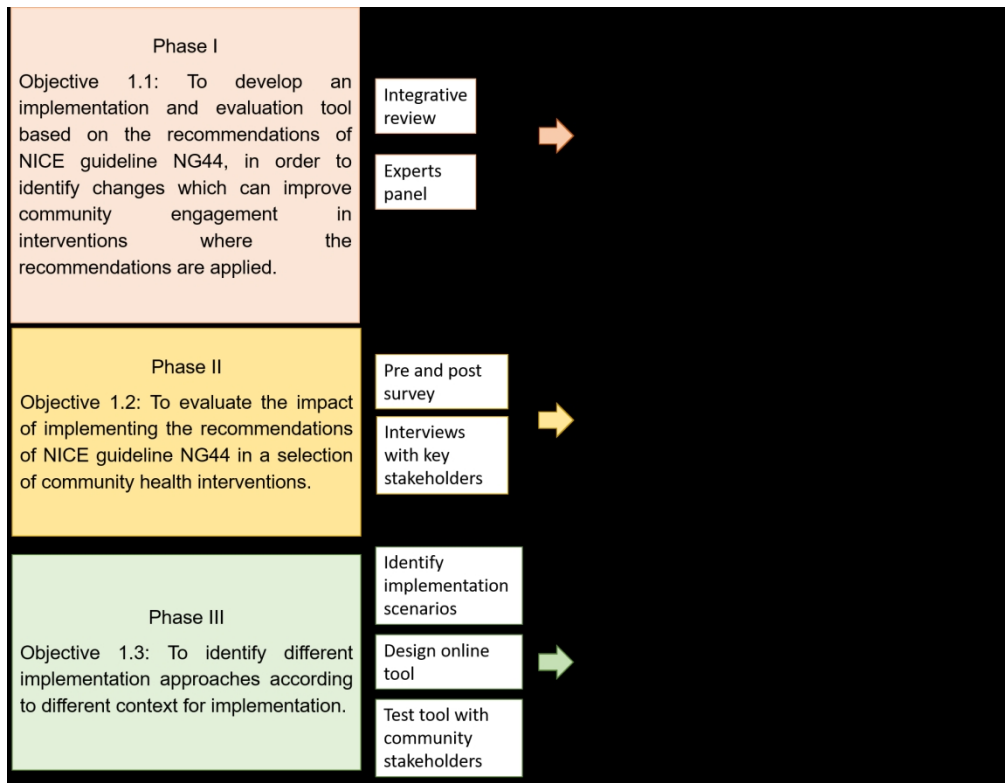


Figure 1. The three phases of the EvaluA GPS project

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BMJ Open

Evaluating the implementation of community engagement guidelines (EVALUA GPS project): a study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-062383.R1
Article Type:	Protocol
Date Submitted by the Author:	31-Jul-2022
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Primary Subject Heading:	Public health
Secondary Subject Heading:	Evidence based practice, Qualitative research, Health policy
Keywords:	PUBLIC HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, SOCIAL MEDICINE

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Manuscripts

TITLE:

Evaluating the implementation of community engagement guidelines (EVALUA GPS project): a study protocol

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Abstract

Introduction

The EVALUA GPS project aims to evaluate the impact of the implementation of the NICE guideline “Community engagement: improving health and wellbeing and reducing health inequalities” adapted to the Spanish context.

Methods and analysis

Phase I: A tool will be designed to evaluate the impact of implementing the recommendations of the adapted NICE guideline. The tool will be developed through a review of the literature on implementation of public health guidelines between 2000 and 2021 and an expert’s panel consensus using an adapted Delphi method.

Phase II: The developed tool will be implemented in a selection of community-based initiatives through a quasi-experimental pre-post study. Sixteen initiatives will be receiving the implementation tool and an implementation workshop developed ad hoc. Four initiatives will receive the implementation tool only.

Phase III: A final online web tool, based on all previously collected information, will be developed to support the implementation of the adapted NICE guidelines recommendations in other contexts and programmes.

Data collection and analysis: Data will be collected through surveys and semi-structured interviews aimed at exploring changes in the community-based initiatives and collecting experiences in the use of the tool. Quantitative data will be analysed through descriptive statistics and qualitative data through thematic analysis to identify implementation scenarios, changes in community engagement approaches in the community-based initiatives, barriers and facilitators to the implementation of the recommendations and strategies to overcome them. The data collected in the implementation phase (Phase II) will be further synthesised in order to develop the online tool.

Ethics and dissemination

The proposed research has been approved by the Clinical Research Ethics Committee of Aragon (CEICA). Results will be presented at national and international conferences and published in peer-reviewed open access journals. The interactive online tool (Phase III) will include examples of its application from the fieldwork.

Article Summary

Strengths and limitations of this study

- The mixed methods (quantitative and qualitative) approach adopted in this research could support both researchers and participants to increase their knowledge and practice about community engagement in health programmes
- Research on public health guidelines implementation and evaluation is limited, and evidence is needed to help bridge the gap between research, policy and practice.
- Engaging a variety of stakeholders from different backgrounds the phases of the project strengthen the research project and the potential transferability of the study results.
- One of the limitations can be defined in the lack of engagement of community members in the design of the research project, due to the requirements in the funds application scheme.
- Researching community engagement during the COVID-19 pandemic is challenging but this project can support community initiatives in these difficult times

Keywords: community engagement; implementation research; community health; public health guidelines

Word count: 3474

Introduction

Engaging people and communities is central to the improvement of their health and well-being and to the reduction of health inequalities [1]. According to the World Health Organization [2], community engagement in health is essential to protect and improve populations' health. Through community engagement, local people increase their decision-making capacities and trust among themselves, allowing them to influence the social determinants of health that affect them, to improve their health and that of their community [3,4]. Nonetheless, despite increasing evidence on its importance [5,6], there is still a need to improve knowledge and practice about community engagement in health [7].

In 2016, the National Institute for Health Care and Excellence (NICE), a UK institute dedicated to the development of evidence-based guidelines, related to both clinical and public health topics, reviewed the evidence on the effect of community engagement on the health and wellbeing of communities and on reduction of health inequalities, and provided recommendations for incorporating community engagement into health policies and interventions in the published NICE Guidance NG44 [1]. During 2017 and 2018 a collaborative project was carried out by a group of health-related professionals in Spain to adapt the NICE guideline NG44 to the Spanish context, the AdaptA GPS project [8]. The project resulted in the first public health guideline included in GuíaSalud, the clinical guidelines catalogue of the Spanish Ministry of Health [8]. At present, there is no evaluation of the implementation of the guidelines in the

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3 GuíaSalud catalogue: once developed, there is no evaluation of their impact on
4 practice or health.
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7 The research project EvaluA GPS (from its Spanish acronym: Evaluating the
8 Application of Health Promotion Guidelines) aims to evaluate the impact of the
9 implementation of the Spanish adapted NICE guideline NG44, through the following
10 specific objectives:
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12
13 Objective 1: To develop an implementation and evaluation tool based on the
14 recommendations of NICE guideline NG44, in order to identify changes which can
15 improve community engagement in community-based health initiatives carried out
16 in different contexts.
17

18
19 Objective 2: To evaluate the impact of implementing the recommendations of NICE
20 guideline NG44 on community engagement in a selection of community-based
21 initiatives
22

23
24 Objective 3: To identify different implementation approaches according to different
25 contexts.
26
27

28 **Methods and analysis**

29
30 EVALUA GPS Project will be developed through three main phases, as illustrated in
31 Figure 1. Phase I will centre on developing a tool to evaluate the impact of the
32 recommendations (Objective 1). The tool will be developed through a review of the
33 literature on implementation of public health guidelines (Phase I, part one) and an
34 expert's panel consensus using an adapted Delphi method (Phase I, part two). In
35 Phase II, the developed tool will be implemented in a selection of community-based
36 initiatives through a quasi-experimental study, with pre-post surveys on community
37 engagement approaches and interviews with key stakeholders to explore changes in
38 the initiatives (Objective 2). Phase III will then synthesise the information from the
39 implementation phase, to develop an online tool to support the implementation of the
40 adapted guidelines recommendations in different scenarios (Objective 1).
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45 ***Phase I: evaluation tool development***

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47 To develop the first version of the evaluation tool (Evalguia 0.1), the EvaluA GPS
48 research team carried out an integrative review of the literature on public health
49 guidelines implementation [9]. An integrative review uses a systematic approach to
50 search relevant articles about the topic of interest, and provides a critical analysis of
51 the findings, often including a thematic synthesis approach, as it has been done in this
52 case [10]. This first version (Evalguia 0.1) was then reviewed by a panel of
53 experts in community-based health interventions through an adapted Delphi method.
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58 ***Phase I, part one: integrative review***

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3 An integrative review was conducted to identify the available literature on the
4 implementation of public health guidelines and to inform the development of the first
5 version of the Evalguia tool (0.1) [9]. A systematic search strategy combining key
6 terms and synonyms related to "implementation", "guidelines" and "analysis" or
7 "evaluation" was conducted using the databases PubMed, CINAHL, Web of Science
8 and Scopus.
9

10
11
12 Following the aim of the EvaluA GPS project, only studies analysing and/or evaluating
13 the implementation of public health guidelines were included. Three researchers
14 identified the papers to be included in the review through screening titles and
15 abstracts and data has been analysed using a thematic synthesis approach [11
16]. The review followed the ENTREQ (Enhancing transparency in reporting the
17 synthesis of qualitative research) statement to structure and report the review process
18 [12]. The analysis of the literature on guidelines implementation then informed
19 the development of the first version of the Evalguia tool (Evalguia 0.1).
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23 24 25 ***Phase I, part two: experts panel through adapted Delphi method***

26
27
28 The Evalguia 0.1 was then tested through a panel of experts [12]. This was
29 organised through an adapted Delphi method [13], through two rounds of review of the
30 developed Evalguia 0.1 tool, to It is defined as 'adapted' Delphi as each expert
31 will provide individual feedback to the tool, but the analysis and modification will be
32 carried out by the EvaluA GPS research team, with an aim to include all comments
33 provided.
34
35

36
37 To identify experts in community health interventions, each researcher of the EvaluA
38 GPS team (composed of a total of 35 researchers) will be asked to suggest at least
39 one potential participant, who will be independent to the project. A maximum of
40 60 experts will be identified prior to the first round of invitation, considering both
41 geographical variability (experts from different regions of Spain) and roles (academic,
42 practitioners, community workers, local organisations' members) as selection criteria.
43 Once the list has been compiled, an online invitation will be sent by email to these
44 experts, who, after expressing their interest in participating, will be sent an informed
45 consent form, which they will have to sign and return.
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49
50 The first version of the tool (Evalguia 0.1) will then be sent to all participating experts
51 who have signed the informed consent form in a word document format. They will be
52 asked to review it with a focus on content, language and design. After receiving
53 comments from the first round of review, the research team will compile and discuss
54 the proposed changes, and will finally select the changes to be made. The tool will
55 then be modified accordingly and Evalguia version 0.2 will be developed. Participants
56 who have not submitted the revision will be excluded from the following round.
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3 Evalguia 0.2 will then be sent again to the participating experts, requesting their final
4 revision after the proposed changes.
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7 Finally, after receiving the second round of reviews, the research team will discuss the
8 proposed changes and modify the tool accordingly. This final version, Evalguia version
9 0.3, will therefore be considered as the final version of the tool to be implemented in
10 Phase II.
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14 **Phase II: implementation**

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17 This phase aims to pilot-test the developed implementation and evaluation tool in a
18 selection of community-based initiatives , using a quasi-experimental pre-post study
19 (Objective 2). To select the initiatives , researchers from the Evalua GPS team will
20 suggest ongoing community-based initiatives, with an aim to identify a total of sixteen
21 local initiatives in four different Spanish regions to act as ‘interventions’. Four
22 additional initiatives will be selected to act as ‘control’ in only one of the regions (NAME
23 OF THE REGION anonymised for review). The initiatives will not be randomly
24 assigned to the intervention or to the control group, but deliberately selected for each
25 group. All community-based initiatives will be selected with the following inclusion and
26 exclusion criteria:
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30 1. Inclusion criteria:

- 31
32 a. the initiative should aim to improve community health or follow at least
33 one of the five lines of actions of the Ottawa Charter for Health Promotion
34 (“1-building healthy public policy, 2-creating supportive environments, 3-
35 strengthening community action, 4-developing personal skills, and 5-
36 reorienting health care services toward promotion of health”) [14];
37
38 b. the community should participate in at least two phases of the initiative
39 (health needs assessment, design, implementation, evaluation);
40
41 c. the level of community engagement can be defined according to one of
42 the next five participation levels: informing, consulting, co-creating
43 decisions and actions, multiple and shared leadership and/or,
44 community control, as described on NICE Guidance NG44 [1].
45
46 d. the initiative should have been ongoing for at least one year.
47
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49 2. Exclusion criteria:

- 50
51 a. The initiative aims to promote individual health only, lacking a
52 community-based health approach;
53
54 b. The level of community engagement is limited to informing or consulting
55 the community.
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60 **Intervention**

All the 20 selected community-based initiatives (16 interventions, 4 control) will receive the implementation tool (*Evalguia 0.3*), in the form of a written document, which will include written explanations on how the tool should be implemented. The selected sixteen intervention initiatives will also receive an implementation workshop developed *ad hoc* by the research team based on previous experience in the field of community-based actions and on the results from Phase I, while the remaining four control initiatives will only receive the implementation tool. This will allow to evaluate whether the implementation tool alone (without supplementary support from the workshop) improves community engagement in the selected initiatives, and to identify potential facilitators for the implementation.

In each intervention initiative, the workshop will be delivered to key stakeholders such as managers, front-line workers and community members involved in the projects. The workshop will preferably be carried out in two sessions, preferably on two different days or with a lunch break in between. It will be recommended to have a maximum of 15 people attending, to facilitate the process and the group activities. In the first session, after a general presentation of the project and the participants, we will define key terms included in the guidelines, such as community engagement, health assets, intersectoral work, vulnerable groups and empowerment, to ensure all participants will have a shared understanding of these concepts. Then the *Evalguia* tool will be presented and implemented, followed by a group reflection on the results. In a second session, an action plan aimed at improving community engagement in the project following the adapted guidelines recommendations will be elaborated. It is foreseen that the workshop will be held in person, although as a consequence of the COVID-19 pandemic these may have to be held online.

Data collection

In Phase II the implementation process will be structured in 4 stages, over a period of 15-18 months (Figure 2). In each stage, data will be collected through audio recording of semi-structured interviews with key stakeholders, observation notes, and photos of the products which may be developed during the working sessions (e.g. diagrams or action plans). Audio recording of interviews will be transcribed, and all data will be imported to Nvivo v12 software for qualitative analysis. Written consent will be obtained from each stakeholder prior to data collection commencing.

In stage 1 (months 1-2), a semi-structured interview (SI1) will be held with the initiative's managers (duration 60-90 minutes) to better understand the community-based initiative, its origins, its aims and objectives and how it is being implemented and carried out daily.

In stage 2 (months 4-6), the *Evalguia* tool will be applied, 16 intervention initiatives will be supported through the implementation workshop, while the 4 'control' initiatives will only receive the tool. Prior to the use of the *Evalguia* tool, all the participating initiatives (n=20) will answer an initial closed-answer questionnaire (Q1.1) which

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3 will explore their perspective on the community engagement approach currently being
4 used in their initiatives . The initial questionnaire will include questions about who
5 is currently involved in the community-based initiatives and who are the main decision-
6 makers at each project stage (health assessment, design, implementation and
7 evaluation). This information will provide a baseline as to what extent community
8 members are engaged in the different stages of the selected community-based
9 initiatives, and it will allow comparison before and after the implementation of the
10 Evalguia tool to check its impact on community engagement in the initiative. At the
11 end of the implementation session, to evaluate the Evalguia tool and the workshop,
12 participants from the intervention initiatives (n=16) will answer a final
13 closed-answer questionnaire (Q2.1) , exploring their opinion of the tool (15
14 minutes) and of the workshop itself. Participants in the control initiatives will
15 answer a questionnaire (Q2.1 bis) exploring their opinions on the tool only.

16
17
18 In stage 3 (7-9 months after the Evalguia application), participants of all 20 initiatives
19 will be asked to answer a short questionnaire on perceived changes in community
20 engagement in their initiatives (Q1.2), and a second semi-structured interview (60
21 minutes) (SI2) will be carried out with the managers (one from each project) to
22 explore their perspectives on potential changes in their initiative over the past
23 months.

24
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26 In stage 4 (12 to 14 months after the Evalguia application), data collection will be
27 completed. All initiatives (n=20) will implement again the Evalguia tool in their own
28 project, to check whether there have been changes in community engagement
29 approaches. Stakeholders who participated in the Evalguia application will then
30 answer a questionnaire on perceived changes in community engagement in their
31 initiatives (Q1.3), and a final questionnaire on the Evalguía tool (Q2.2 and Q2.2 bis
32 for participants from the intervention and control initiative respectively) (15 minutes).
33 A final semi-structured interview (SI3) with the managers will be conducted
34 (60 minutes) to discuss perceived changes in their initiatives. To conclude , an online
35 evaluation session will be organised with all the participants from the 20
36 initiatives to discuss the final changes to Evalguia .

47 ***Phase III: online tool development***

48
49 The data collected through the implementation phase will then support the
50 development of an interactive online tool. The tool will be structured according to
51 different potential scenarios for implementation and will include examples from the
52 field as evidence of good practice to improve community engagement. The online tool
53 will be tested through a final online evaluation session with the stakeholders who
54 participated in the application of Evalguia , to ensure its language and design are
55 user-friendly and accessible for a lay public.
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Analysis

The data collected through the fieldwork in Phase II will be analysed to identify changes in community engagement approaches and other possible changes resulting from the implementation of the recommendations and/or of the workshops (such as organisational changes and changes in relationships). Data from the questionnaires will be analysed using descriptive statistics using SPSS, to compare changes pre and post intervention in both the interventions and the control initiatives. Data from interviews and workshops will be transcribed and analysed using a thematic analysis approach [15]. The analysis will focus on synthesising similarities identified in the intervention and control initiatives to identify different implementation scenarios where community engagement can be enhanced and allow the transferability of results to different contexts. Moreover, the analysis will identify (a) barriers and facilitators in the implementation of the recommendations and (b) strategies to overcome these barriers and promote facilitators, to support implementation in other contexts. Qualitative analysis will be conducted by two researchers separately, using NVivo Software v12, and codes and themes will then be checked and compared to define a common structure for the findings. These findings will then be presented to the coordinating team composed of 9 researchers, to reach consensus on the analysis.

Both quantitative and qualitative data will contribute to answering the objectives of the study. Triangulation of both types of data will strengthen the results of the study, as quantitative data will provide an assessment of changes in community engagement which could be attributed to the implementation of the guideline recommendations, allowing also to evaluate the impact of the workshops. These changes will be checked against codes and themes identified in the qualitative analysis. The qualitative analysis about contextual factors and barriers and facilitators to the implementation, together with quantitative data about the Evalguia tool will then set the basis to develop the online tool to support the implementation of the adapted guidelines recommendations in other initiatives and contexts, thus enhancing the transferability and applicability of the study results.

The EvaluA GPS research described here may enhance translational research, as it intends to enforce the application of evidence-based recommendations for community-based health initiatives, hence contributing to reducing the gap between research, policy and practice [16]. One of the goals of translational research is the translation of new approaches into a form amenable to widespread adoption and implementation [17]. At EvaluA GPS we aim to develop implementation scenarios to facilitate project design and evaluation. Moreover, it is hoped that generating more practice-based evidence in community engagement in health in Spain will strengthen and enhance good practices in community health initiatives, contributing to promote the health of people and communities and reduce health inequalities.

Patient and Public Involvement Statement

EVALUA GPS Project is based on the findings of the previous research project, AdaptA GPS [8], in which community members from eleven local community-based initiatives across Spain were involved to test the adapted NICE NG44 guidance. EvaluA GPS was designed based on their feedback on the need to simplify the language used in the recommendations and provide more practical examples on how to implement the community engagement recommendations. Community members are also key stakeholders in the EvaluA GPS project, as they will be involved in all stages of the project. In the initial phase, local organisations' members will be invited to participate in the review of the Evalguia tool through the adapted Delphi method. Following this, in the implementation phase, community members will be engaged as recruiters for the workshops, to ensure that community members will be consulted about the Evalguia tool; additionally, in the case of the four control initiatives, community members will also be responsible for the implementation of the Evalguia tool, as these initiatives will not receive the workshop. Additionally, community members from the 20 health initiatives will be invited to the final online evaluation session to consult them about how to improve the Evalguia tool in its online version.

Ethics and dissemination

All participants will receive an information sheet detailing all the phases of the research project and will be informed of the objectives and characteristics of the study, as well as their voluntary participation and the possibility of leaving the study at any time during the research process. The intervention initiatives will be informed that they will receive a workshop to implement the Evalguia, while the control initiatives will be informed that they will receive the Evalguia and will have to implement it on their own. If they agree to participate in the study, participants will be asked to sign an informed consent form. Data confidentiality will be guaranteed in accordance with Spanish Organic Law 3/2018 on the protection of personal data and guarantee of digital rights, being analysed anonymously and described in aggregate form to avoid identification at an individual level. The research project has been approved by the Clinical Research Ethics Committee of Aragón (CEICA), PI20/116.

As for dissemination, study results will be presented at national and international conferences, as well as published in open access peer-reviewed journals. Moreover, the research team will develop a short animated video summarising the project [18] which will support presenting the research to lay people. In addition to that, the interactive web tool will be designed with lay and inclusive language, and will include evidence of good practices in community engagement gathered from the participating initiatives.

Author contributions: VC, MVLR, CBBA, JPC, AMG, LAPdT and CN developed the study proposal and protocol. VC, MVLR, MPG, AGR, MD, CN, and VG wrote the initial

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3 draft of the paper which has then been iteratively revised and reviewed by all authors
4 (included EvaluAGPS Research Group). All the authors approved the final version to
5 be published. All the authors agree on being accountable for all aspects of the work in
6 ensuring that questions related to the accuracy or integrity of any part of the work are
7 appropriately investigated and resolved.
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12 **Funding:** This work was supported by the research projects PI19/01079, PI19/01525
13 and PI19/00773 integrated into the Plan Estatal de I+D+I 2013-2016 and co-financed
14 by the ISCIII-Subdirección General de Evaluación y Fomento de la Investigación and
15 the Fondo Europeo de Desarrollo Regional (FEDER).
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19
20 **Competing interests:** None declared
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23 **Acknowledgements: (EvaluAGPS Research Group):** Aldecoa Landesa, Susana;
24 Aliaga Train, Pilar; Aviñó Juan-Ulpiano, Dory; Baraza Cano, Pilar; Barona Vilar,
25 Carmen; Botello Díaz, Blanca del Rocío; Bueno, Manuel; Couso Viana, Sabela;
26 Dominguez, Marta; Egea Ronda, Ana; Enriquez, Natalia; Gallego Dieguez, Javier;
27 Gallego Royo, Alba; Gea Caballero, Vicente; Hernán García, Mariano; Hernández
28 Gómez, Mercedes Adelaida; Iriarte, María Teresa; Lou Alcaine, María Luz; Martínez
29 Pecharromán, María del Mar; Morin, Victoria; Nuñez Jiménez, Catalina; Peyman-
30 Fard, Nima; Pla Consegra, Margarita; Romaguera Lliso, Amparo; Ruiz Azarola,
31 Ainhoa; Sainz Ruiz, Pablo. EvaluAGPS Research Group is a multidisciplinary
32 research group formed for the EvaluA GPS project. EvaluA GPS is a research
33 coordinated by three institutions: IIS (Instituto de Investigación Sanitaria de Aragón);
34 FISABIO (Fundación para el Fomento de la Investigación Sanitaria y Biomédica,
35 Comunitat Valenciana) and IMIBIC-FIBICO (Maimonides Institute for Biomedical
36 Research of Cordoba, Andalucía) and with the participation of the IAPP network, the
37 PACAP program, PAPPS program and the Community Health Alliance.
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4 Figure Legend

5 Figure 1: The three phases of EvaluA GPS project. Source: self made.

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7 Figure 2: Data collection phase II. Source: self made.
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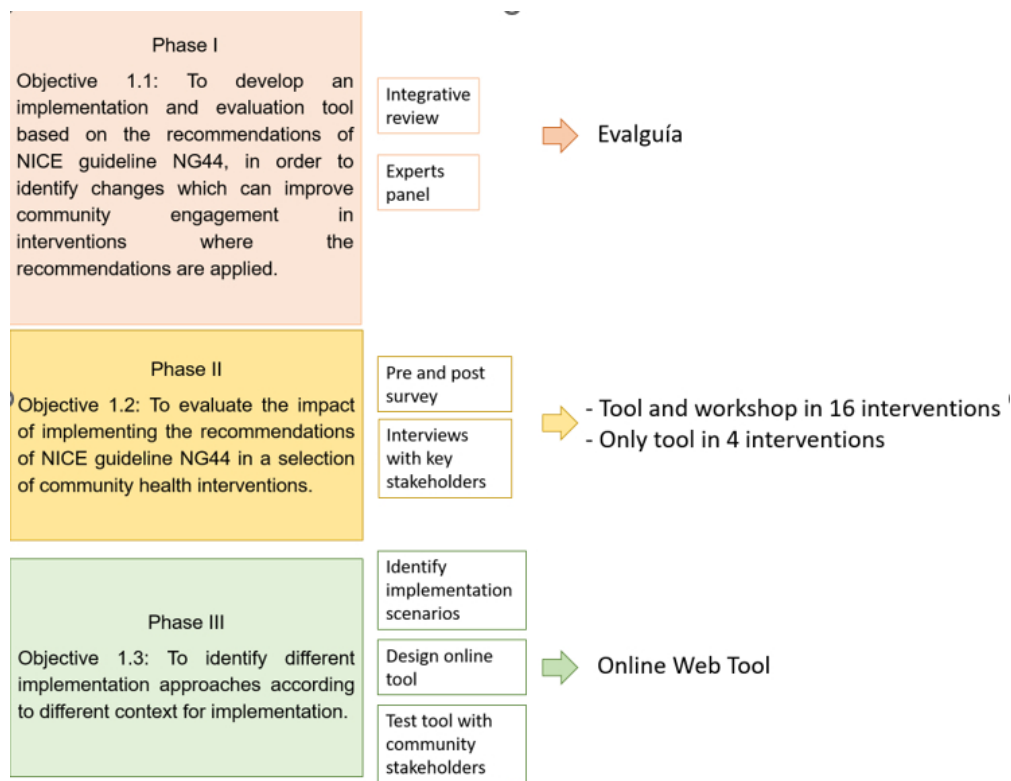


Figure 1: The three phases of the EvaluA GPS project

401x311mm (47 x 47 DPI)

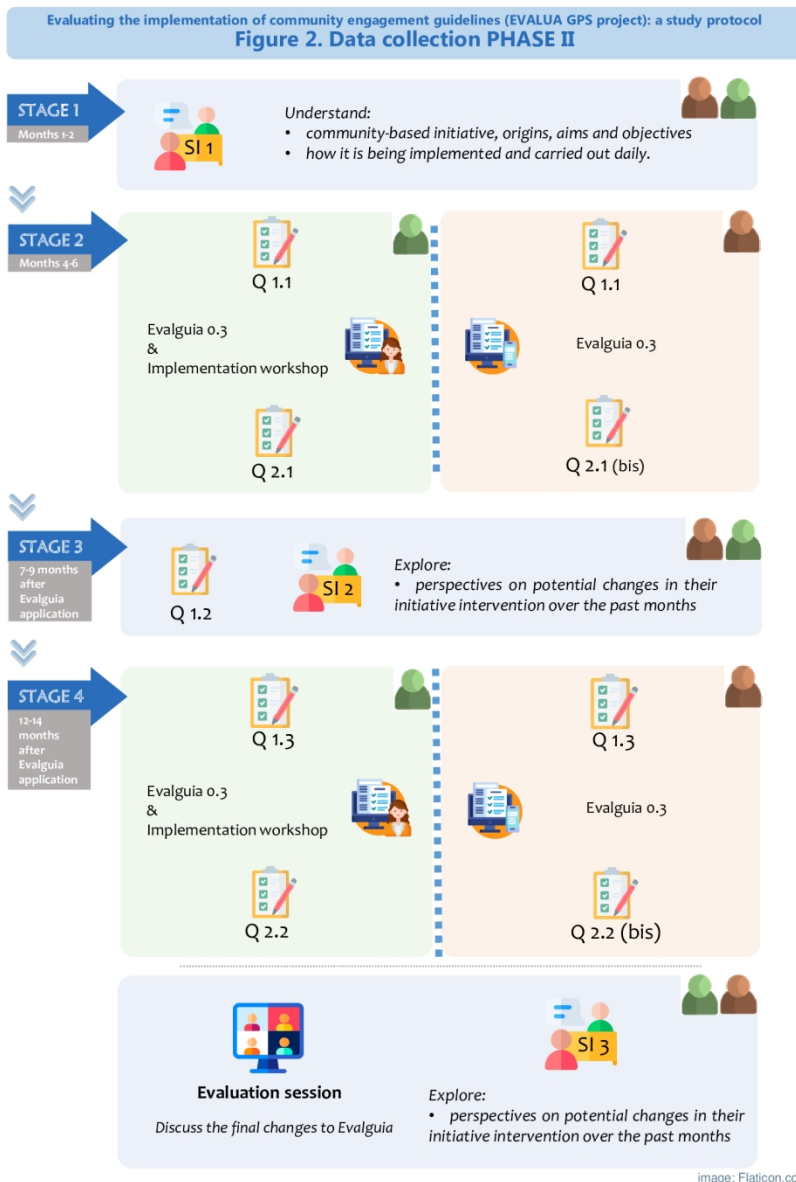


Figure 2. Data collection PHASE II. Source: self made.

190x275mm (200 x 200 DPI)

BMJ Open

Evaluating the implementation of community engagement guidelines (EVALUA GPS project): a study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-062383.R2
Article Type:	Protocol
Date Submitted by the Author:	10-Nov-2022
Complete List of Authors:	<p>Cassetti, Viola; Independent Researcher, López-Ruiz, María Victoria; Government of Andalusia Andalusian Health Service; Instituto Maimonides de Investigacion Biomedica de Cordoba Domínguez, Marta ; Servicio Aragonés de Salud; Health Research Institute Aragón</p> <p>GALLEGO ROYO, ALBA; Servicio Aragonés de Salud; Health Research Institute Aragón</p> <p>García, Ana; University of Valencia; CIBERER</p> <p>Gea-Caballero, Vicente; La Fe University and Polytechnic Hospital, NURSING; Health Research Institute La Fe, GREIACC</p> <p>Nuñez, Catalina; Health Promotion Service. General Directorate of Public Health.</p> <p>Paredes-Carbonell, Joan Josep; Primary Care Management. Health department La Ribera</p> <p>PÉRULA DE TORRES, LUIS ÁNGEL; Instituto Maimonides de Investigacion Biomedica de Cordoba, ; Teaching Unit of Family and Community Medicine. Health District of Cordoba and Guadalquivir. ,</p> <p>Pola-Garcia, Marina; Servicio Aragonés de Salud; Health Research Institute Aragón</p> <p>EvaluAGPS Research Group, EvaluAGPS Research Group; Independent Research Group</p> <p>Benedé. Azagra, Carmen Belen; Servicio Aragonés de Salud; Health Research Institute Aragón</p>
Primary Subject Heading:	Public health
Secondary Subject Heading:	Evidence based practice, Qualitative research, Health policy
Keywords:	PUBLIC HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, SOCIAL MEDICINE

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Manuscripts

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Abstract

Introduction

The EVALUA GPS project aims to evaluate the impact of the implementation of the NICE guideline “Community engagement: improving health and wellbeing and reducing health inequalities” adapted to the Spanish context.

Methods and analysis

Phase I: A tool will be designed to evaluate the impact of implementing the recommendations of the adapted NICE guideline. The tool will be developed through a review of the literature on implementation of public health guidelines between 2000 and 2021 and an expert’s panel consensus .

Phase II: The developed tool will be implemented in sixteen community-based programmes, acting as intervention sites, and four controls through a quasi-experimental pre-post study.

Phase III: A final online web tool, based on all previously collected information, will be developed to support the implementation of the adapted NICE guidelines recommendations in other contexts and programmes.

Data collection and analysis: Data will be collected through surveys and semi-structured interviews. Quantitative and qualitative data will be analysed to identify implementation scenarios, changes in community engagement approaches and barriers and facilitators to the implementation of the recommendations. All this information will be further synthesised to develop the online tool.

Ethics and dissemination

The proposed research has been approved by the Clinical Research Ethics Committee of Aragon (CEICA). Results will be presented at national and international conferences and published in peer-reviewed open access journals. The interactive online tool (Phase III) will include examples of its application from the fieldwork.

Article Summary

Strengths and limitations of this study

- The mixed methods (quantitative and qualitative) approach adopted in this research could support both researchers and participants to increase their knowledge and practice about community engagement in health programmes
- Research on public health guidelines implementation and evaluation is limited, and evidence is needed to help bridge the gap between research, policy and practice.

- Engaging a variety of stakeholders from different backgrounds the phases of the project strengthen the research project and the potential transferability of the study results.
- One of the limitations can be defined in the lack of engagement of community members in the design of the research project, due to the requirements in the funds application scheme.
- Researching community engagement during the COVID-19 pandemic is challenging but this project can support community programmes in these difficult times

Keywords: community engagement; implementation research; community health; public health guidelines

Word count: 3396

Introduction

Engaging people and communities is central to the improvement of their health and well-being and to the reduction of health inequalities [1]. According to the World Health Organization [2], community engagement in health is essential to protect and improve populations' health. Through community engagement, local people increase their decision-making capacities and trust among themselves, allowing them to influence the social determinants of health that affect them, to improve their health and that of their community [3,4]. Nonetheless, despite increasing evidence on its importance [5,6], there is still a need to improve knowledge and practice about community engagement in health [7].

In 2016, the National Institute for Health Care and Excellence (NICE), a UK institute dedicated to the development of evidence-based guidelines, related to both clinical and public health topics, reviewed the evidence on the effect of community engagement on the health and wellbeing of communities and on reduction of health inequalities, and provided recommendations for incorporating community engagement into health policies and interventions in the published NICE Guidance NG44 [1]. During 2017 and 2018 a collaborative project was carried out by a group of health-related professionals in Spain to adapt the NICE guideline NG44 to the Spanish context, the AdaptA GPS project [8]. The project resulted in the first public health guideline included in GuíaSalud, the clinical guidelines catalogue of the Spanish Ministry of Health [8]. At present, there is no evaluation of the implementation of the guidelines in the GuíaSalud catalogue: once developed, there is no evaluation of their impact on practice or health.

The project EvaluA GPS (from its Spanish acronym: Evaluating the Application of Health Promotion Guidelines) aims to evaluate the impact of the implementation of the Spanish adapted NICE guideline NG44, through the following specific objectives:

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3 Objective 1: To develop an implementation and evaluation tool based on the
4 recommendations of NICE guideline NG44, in order to identify changes which can
5 improve community engagement in community-based health programmes carried
6 out in different contexts.
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9 Objective 2: To evaluate the impact of implementing the recommendations of NICE
10 guideline NG44 on community engagement in a selection of community-based
11 programmes.
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14 Objective 3: To identify different implementation approaches according to different
15 contexts.
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17 This paper presents the research protocol for the project EvaluA GPS.
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20 21 **Methods and analysis**

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23 EVALUA GPS Project will be developed through three main phases, as illustrated in
24 Figure 1. Phase I will centre on developing a tool to evaluate the impact of the
25 recommendations (Objective 1). In Phase II, the developed tool will be implemented
26 in a selection of community-based programmes to explore changes in community
27 engagement (Objective 2). Phase III will then synthesise the information from the
28 implementation phase, to develop an online tool to support the implementation of the
29 adapted guidelines recommendations in different scenarios (Objective 3).
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32 33 ***Phase I: Development of the implementation and evaluation tool (Evalguía)***

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35 The implementation and evaluation tool will be developed using evidence from an
36 integrative review of the literature on public health guidelines implementation [9] and
37 an experts panel using an adapted Delphi method [10].
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40 To develop the first version of the evaluation tool (Evalguia 0.1), an integrative review
41 was conducted to identify the available literature on the implementation of public health
42 guidelines [9]. Integrative reviews use a systematic approach to search relevant
43 articles about the topic of interest, and provide a critical analysis of the findings, often
44 including a thematic synthesis approach, as it has been done in this case [11]. A
45 systematic search strategy combining key terms and synonyms related to
46 "implementation", "guidelines" and "analysis" or "evaluation" was conducted using the
47 databases PubMed, CINAHL, Web of Science and Scopus.
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51 Only studies analysing and/or evaluating the implementation of public health
52 guidelines were included. Three researchers identified the papers to be included in the
53 review through screening titles and abstracts and data was analysed using a thematic
54 synthesis approach [12]. The review followed the ENTREQ (Enhancing transparency
55 in reporting the synthesis of qualitative research) statement to structure and report the
56 review process [13]. The findings from the integrative review informed the
57 development of the first version of the Evalguia tool (Evalguia 0.1).
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3 The Evalguia 0.1 will be tested through a panel of experts. This will be organised
4 through an adapted Delphi method [10], through two rounds of review of the tool. It is
5 defined as 'adapted' Delphi as each expert will provide individual feedback to the tool,
6 but the analysis and consensus on the modification to be made to the tool will be
7 carried out by the EvaluA GPS research team, with an aim to include all comments
8 provided by the experts.
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12 To identify experts in community health interventions, each researcher of the EvaluA
13 GPS team (composed of a total of 35 researchers) will be asked to suggest at least
14 one potential participant, who will be independent to the project. A maximum of 60
15 experts will be identified prior to the first round of invitation, considering both
16 geographical variability (experts from different regions of Spain) and roles (academic,
17 practitioners, community workers, local organisations' members) as selection criteria.
18 No exclusion criteria will be considered. Once the list has been compiled, an online
19 invitation will be sent by email to these experts, who, after expressing their interest in
20 participating, will be sent an informed consent form, which they will have to sign and
21 return.
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26 All participating experts will then receive the Evalguía 0.1 in a word document online
27 so that they can provide their feedback and suggestions directly in the word document.
28 They will be asked to review it with a focus on content, language and design. After
29 receiving comments from the first round of review, the research team will compile and
30 discuss the proposed changes, and will finally select the changes to be made. The
31 tool will then be modified accordingly and Evalguia version 0.2 will be developed.
32 Participants who have not submitted the revision will be excluded from the following
33 round. Evalguia 0.2 will then be sent again to the participating experts, requesting their
34 final revision after the proposed changes.
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39 Finally, after receiving the second round of reviews, the research team will discuss the
40 proposed changes and modify the tool accordingly, trying to include them all where
41 possible. This final version, Evalguia version 0.3, will therefore be considered as the
42 final version of the tool to be implemented in Phase II.
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47 ***Phase II: implementation***

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49 This phase aims to pilot-test the developed implementation and evaluation tool in a
50 selection of community-based programmes, using a quasi-experimental pre-post
51 study (Objective 2). To select the programmes, researchers from the EvaluA GPS
52 team will suggest ongoing community-based programmes, with an aim to identify a
53 total of sixteen local programmes in four different Spanish regions to act as
54 'interventions sites'. Four additional programmes will be selected to act as 'control
55 sites' in only one of the regions (Aragon). The programmes will not be randomly
56 assigned to become intervention or control sites, but deliberately selected for each
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group. All programmes will be selected with the following inclusion and exclusion criteria:

1. Inclusion criteria:

- a. the community-based programme should aim to improve community health or follow at least one of the five lines of actions of the Ottawa Charter for Health Promotion (“1-building healthy public policy, 2-creating supportive environments, 3-strengthening community action, 4-developing personal skills, and 5-reorienting health care services toward promotion of health”) [14];
- b. the community should participate in at least two phases of the programme (health needs assessment, design, implementation, evaluation);
- c. the level of community engagement can be defined according to one of the next five participation levels: informing, consulting, co-creating decisions and actions, multiple and shared leadership and/or community control, as described in the NICE Guidance NG44 [1].
- d. the programme should have been ongoing for at least one year.

2. Exclusion criteria:

- a. The programme aims to promote individual health only, lacking a community-based health approach;
- b. The level of community engagement is limited to informing or consulting the community.

Intervention

All the 20 selected community-based programmes (Intervention sites n=16, and control sites n=4) will receive the implementation tool (*Evalguia 0.3*), in the form of a written document, which will include written instructions on how the tool should be implemented. The selected sixteen intervention sites will also receive an implementation workshop developed *ad hoc* by the research team based on previous experience in the field of community-based actions and on the results from Phase I, while the remaining four control sites will only receive the implementation tool which they will have to self-administer following the written instructions. This will allow to evaluate whether the implementation tool alone (without supplementary support from the workshop) improves community engagement in the selected community-based programmes, and to identify potential facilitators for the implementation.

In each intervention site, the workshop will be delivered to key stakeholders such as managers, front-line workers and community members involved in the projects. The research team will recommend that the workshop will be carried out in two sessions, and where possible on two different days or with a lunch break in between. However,

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3 the research team will need to adapt to the availability of the participating stakeholders.
4 It will be recommended to have a maximum of 15 people attending, to facilitate the
5 process and the group activities. In the first workshop session, after a general
6 presentation of the project and the participants, we will define key terms included in
7 the guidelines, such as community engagement, health assets, intersectoral work,
8 vulnerable groups and empowerment, to ensure all participants will have a shared
9 understanding of these concepts. Then the Evalguía tool will be presented and
10 implemented, followed by a group discussion on the results. This will allow
11 participating stakeholders to reflect how community engagement is being currently
12 carried out in their programmes, and to identify areas for improvement. In a second
13 session, an action plan aimed at improving community engagement in the project
14 following the adapted guidelines recommendations will be elaborated. It is foreseen
15 that the workshop will be held in person, although as a consequence of the COVID-19
16 pandemic these may have to be held online.
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22 **Data collection**

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24 Data collection during the implementation process (Phase II) will be structured in 4
25 stages, over a period of 15-18 months (Figure 2).
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28 In stage 1 (months 1-2), a semi-structured interview (S11) will be held with the
29 programme's managers (duration 60-90 minutes) to better understand the community-
30 based programme, its origins, its aims and objectives and how it is being implemented
31 and carried out daily.
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34 In stage 2 (months 4-6), the Evalguia tool will be applied, 16 'intervention sites'
35 will be supported through the implementation workshop, while the 4 'control sites'
36 will only receive the tool. Prior to the application of the Evalguia tool, all the
37 participating programmes (n=20) will answer an initial closed-answer questionnaire
38 (Q1.1) which will explore their perspective on the community engagement approach
39 currently being used in their programmes. The initial questionnaire will include
40 questions about who is currently involved in the community-based programmes and
41 who are the main decision-makers at each project stage (health assessment, design,
42 implementation and evaluation). This information will provide a baseline as to what
43 extent community members are engaged in the different stages of the selected
44 community-based programmes, and it will allow comparison before and after the
45 implementation of the Evalguia tool, to check its impact on community engagement in
46 the programme. At the end of the implementation session, to evaluate the Evalguia
47 tool and the workshop, participants from the intervention programmes (n=16) will
48 answer a closed-answer questionnaire (Q2.1), exploring their opinion of the tool (15
49 minutes) and of the workshop itself. Participants in the control programmes will answer
50 a questionnaire (Q2.1 bis) exploring their opinions on the tool only.
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58 In stage 3 (7-9 months after the Evalguia application), participants of all 20
59 programmes will be asked to answer a short questionnaire on perceived changed in
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3 community engagement in their programmes (Q1.2), and a second semi-structured
4 interview (60 minutes) (SI2) will be carried out with programme managers to explore
5 their perspectives on potential changes in their programme over the past months.
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8 In stage 4 (12 to 14 months after the Evalguia application), all community-based
9 programmes (n=20) will implement again the Evalguia tool in their own project (16
10 intervention sites will be supported by a EvaluA GPS team member, while the four
11 control site will self-administer the tool), to check whether there have been changes in
12 community engagement approaches. Stakeholders who participated in the Evalguia
13 application will then answer a questionnaire on perceived changes in community
14 engagement in their programmes (Q1.3), and a final questionnaire on the Evalguia
15 tool (Q2.2 and Q2.2 bis for participants from the intervention and control programme
16 respectively). A final semi-structured interview (SI3) with the managers will be
17 conducted (60 minutes) to discuss perceived changes in their programmes. To
18 conclude, an online evaluation session will be organised with all the participants
19 from the 20 programmes to discuss the final changes to Evalguia.
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25 Written consent will be obtained from each stakeholder prior to data collection.
26 Interviews will be audio-recorded and transcribed, and the intervention workshop as
27 well as the application session in the control group will be audio-recorded. Then,
28 transcripts, audio recordings and the action plans will be imported to Nvivo v12
29 software to support the qualitative analysis.
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34 Analysis

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36 The data collected through the fieldwork in Phase II will be analysed to identify
37 changes in community engagement approaches and other possible changes resulting
38 from the implementation of the recommendations and/or of the workshops (such as
39 organisational changes and changes in relationships). Data from the questionnaires
40 will be analysed using descriptive statistics using SPSS, to compare changes pre and
41 post intervention in both the interventions and the control programme. Data from
42 interviews and workshops will be analysed using a thematic analysis approach [15].
43 The analysis will focus on synthesising similarities identified in the intervention and
44 control programmes to identify different implementation scenarios where community
45 engagement can be enhanced and allow the transferability of results to different
46 contexts. Moreover, the analysis will identify (a) barriers and facilitators in the
47 implementation of the recommendations and (b) strategies to overcome these barriers
48 and promote facilitators, to support implementation in other contexts. Qualitative
49 analysis will be conducted by two researchers separately, using NVivo Software v12
50 to aid the analytical process. Codes and themes will be then compared and
51 synthesised together.
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58 Both quantitative and qualitative data will contribute to answering the objectives of the
59 study. Triangulation of both types of data will strengthen the results of the study, as
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3 quantitative data will provide an assessment of changes in community engagement
4 which could be attributed to the implementation of the guideline recommendations,
5 allowing also to evaluate the impact of the workshops. These changes will be checked
6 against codes and themes identified in the qualitative analysis. The qualitative analysis
7 about contextual factors and barriers and facilitators to the implementation, together
8 with quantitative data about the Evalguia tool will then set the basis to develop an
9 online tool (Phase III) to support the implementation of the adapted guidelines
10 recommendations in other programmes and contexts, thus enhancing the
11 transferability and applicability of the study results.
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18 ***Phase III: online tool development***

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20 The data collected through the implementation phase will then support the
21 development of an interactive online tool. The tool will be structured according to
22 different potential scenarios for implementation and will include examples from the
23 field as evidence of good practice to improve community engagement. Importantly, the
24 interactive web tool will be designed with lay and inclusive language. The online tool
25 will be tested through a final online evaluation session with the stakeholders who
26 participated in the application of Evalguia, to ensure its language and design are user-
27 friendly and accessible for a lay audience.
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34 **Patient and Public Involvement Statement**

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36 EVALUA GPS Project is based on the findings of the previous research project,
37 AdaptA GPS [8], in which community members from eleven local community-based
38 programmes across Spain were involved to test the adapted NICE NG44 guidance.
39 EvaluA GPS was designed based on their feedback on the need to simplify the
40 language used in the recommendations and provide more practical examples on how
41 to implement the community engagement recommendations. Community members
42 are also key stakeholders in the EvaluA GPS project, as they will be involved in all
43 stages of the project. In the initial phase, local organisations' members will be invited
44 to participate in the review of the Evalguia tool through the adapted Delphi method.
45 Following this, in the implementation phase, community members will be recruited to
46 participate in the workshops (intervention). In addition, community members will be
47 invited to the final online evaluation session to consult them on how to improve the
48 Evalguia tool in its online version.
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56 **Ethics and dissemination**

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58 All participants will receive an information sheet detailing all the phases of the research
59 project and will be informed of the objectives and characteristics of the study, as well
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3 as their voluntary participation and the possibility of leaving the study at any time
4 during the research process. The intervention programmes will be informed that they
5 will receive a workshop to implement the EvaluA, while the control programmes will
6 be informed that they will receive the EvaluA and will have to implement it on their
7 own. If they agree to participate in the study, participants will be asked to sign an
8 informed consent form. Data confidentiality will be guaranteed in accordance with
9 Spanish Organic Law 3/2018 on the protection of personal data and guarantee of
10 digital rights, being analysed anonymously and described in aggregate form to avoid
11 identification at an individual level. The research project has been approved by the
12 Clinical Research Ethics Committee of Aragón (CEICA), PI20/116.
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17 As for dissemination, study results will be presented at national and international
18 conferences, as well as published in open access peer-reviewed journals. Moreover,
19 the research team will develop a short animated video summarising the project [16]
20 which will support presenting the research to lay people.
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23 One of the goals of translational research is the translation of new approaches into a
24 form amenable to widespread adoption and implementation [17]. The EvaluA GPS
25 research described here may enhance translational research, as it intends to facilitate
26 the application of evidence-based recommendations for community-based health
27 programmes, hence contributing to reducing the gap between research, policy and
28 practice [18]. At EvaluA GPS we aim to develop implementation scenarios to facilitate
29 project design and evaluation. Moreover, it is hoped that generating more practice-
30 based evidence in community engagement in health in Spain will strengthen and
31 enhance good practices in community health programmes, contributing to promote the
32 health of people and communities and reduce health inequalities.
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36

37 **Author contributions:** VC, MVLR, CBBA, JPC, AMG, LAPdT and CN developed the
38 study proposal and protocol. VC, MVLR, MPG, AGR, MD, CN, and VG wrote the initial
39 draft of the paper which has then been iteratively revised and reviewed by all authors
40 (included EvaluAGPS Research Group). All the authors approved the final version to
41 be published. All the authors agree on being accountable for all aspects of the work in
42 ensuring that questions related to the accuracy or integrity of any part of the work are
43 appropriately investigated and resolved.
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49 **Funding:** This work was supported by the research projects PI19/01079, PI19/01525
50 and PI19/00773 co-financed by the Health Institute Carlos III- [Ministerio de](#)
51 [Economía y Competitividad](#) and the [European Regional Development Fund](#)
52 (FEDER).
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57 **Competing interests:** None declared
58
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Acknowledgements: (EvaluAGPS Research Group): Aldecoa Landesa, Susana; Aliaga Train, Pilar; Aviñó Juan-Ulpiano, Dory; Baraza Cano, Pilar; Barona Vilar, Carmen; Botello Díaz, Blanca del Rocío; Bueno, Manuel; Couso Viana, Sabela; Dominguez, Marta; Egea Ronda, Ana; Enriquez, Natalia; Gallego Dieguez, Javier; Gallego Royo, Alba; Gea Caballero, Vicente; Hernán García, Mariano; Hernández Gómez, Mercedes Adelaida; Iriarte, María Teresa; Lou Alcaine, María Luz; Martínez Pecharromán, María del Mar; Morin, Victoria; Nuñez Jiménez, Catalina; Peyman-Fard, Nima; Pla Consegra, Margarita; Romaguera Lliso, Amparo; Ruiz Azarola, Ainhoa; Sainz Ruiz, Pablo. EvaluAGPS Research Group is a multidisciplinary research group formed for the EvaluA GPS project. EvaluA GPS is a research coordinated by three institutions: IIS (Instituto de Investigación Sanitaria de Aragón); FISABIO (Fundación para el Fomento de la Investigación Sanitaria y Biomédica, Comunitat Valenciana) and IMIBIC-FIBICO (Maimonides Institute for Biomedical Research of Cordoba, Andalucía) and with the participation of the IAPP network, the PACAP program, PAPPS program and the Community Health Alliance.

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4 Figure Legend

5 Figure 1: The three phases of EvaluA GPS project. Own elaboration.

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7 Figure 2: Data collection phase II. Own elaboration
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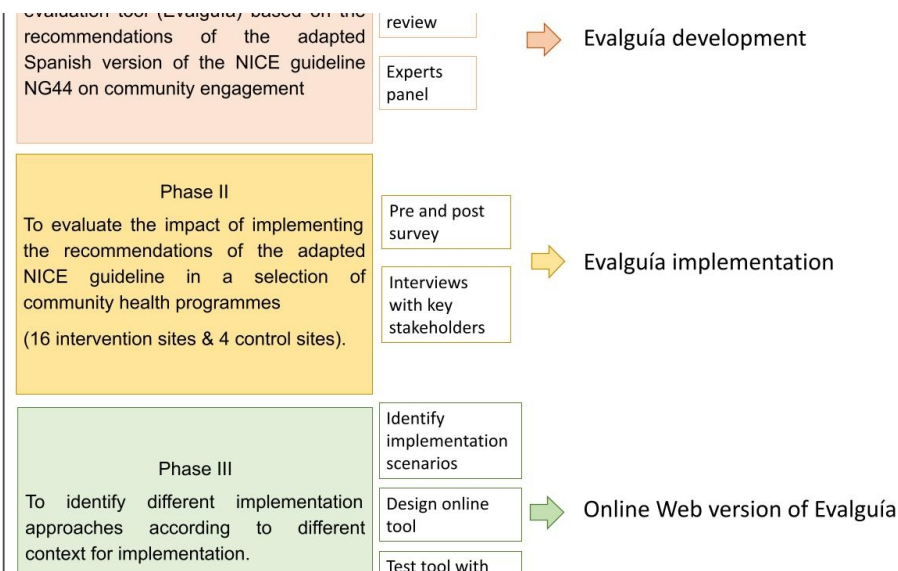


Figure 1: The three phases of EvaluA GPS

451x254mm (72 x 72 DPI)

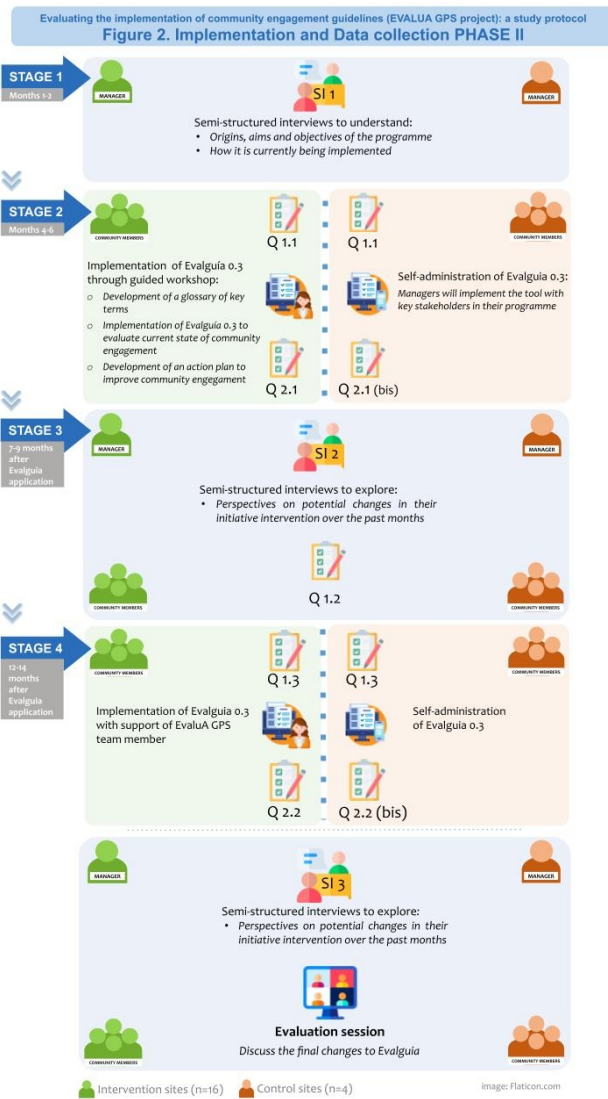


Figure 2. Implementation and Data collection PHASE II

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BMJ Open

Evaluating the implementation of community engagement guidelines (EVALUA GPS project): a study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-062383.R3
Article Type:	Protocol
Date Submitted by the Author:	27-Dec-2022
Complete List of Authors:	<p>Cassetti, Viola; Independent Researcher, López-Ruiz, María Victoria; Government of Andalusia Andalusian Health Service; Instituto Maimonides de Investigacion Biomedica de Cordoba Domínguez, Marta ; Servicio Aragonés de Salud; Health Research Institute Aragón</p> <p>GALLEGO ROYO, ALBA; Servicio Aragonés de Salud; Health Research Institute Aragón</p> <p>García, Ana; University of Valencia; CIBERER</p> <p>Gea-Caballero, Vicente; La Fe University and Polytechnic Hospital, NURSING; Health Research Institute La Fe, GREIACC</p> <p>Nuñez, Catalina; Health Promotion Service. General Directorate of Public Health.</p> <p>Paredes-Carbonell, Joan Josep; Primary Care Management. Health department La Ribera</p> <p>PÉRULA DE TORRES, LUIS ÁNGEL; Instituto Maimonides de Investigacion Biomedica de Cordoba, ; Teaching Unit of Family and Community Medicine. Health District of Cordoba and Guadalquivir. ,</p> <p>Pola-Garcia, Marina; Servicio Aragonés de Salud; Health Research Institute Aragón</p> <p>EvaluAGPS Research Group, EvaluAGPS Research Group; Independent Research Group</p> <p>Benedé. Azagra, Carmen Belen; Servicio Aragonés de Salud; Health Research Institute Aragón</p>
Primary Subject Heading:	Public health
Secondary Subject Heading:	Evidence based practice, Qualitative research, Health policy
Keywords:	PUBLIC HEALTH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, SOCIAL MEDICINE

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Manuscripts

TITLE:

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Abstract

Introduction

The EVALUA GPS project aims to evaluate the impact of the implementation of the NICE guideline “Community engagement: improving health and wellbeing and reducing health inequalities” adapted to the Spanish context.

Methods and analysis

Phase I: A tool will be designed to evaluate the impact of implementing the recommendations of the adapted NICE guideline. The tool will be developed through a review of the literature on implementation of public health guidelines between 2000 and 2021 and an expert’s panel consensus.

Phase II: The developed tool will be implemented in sixteen community-based programmes, acting as intervention sites, and four controls through a quasi-experimental pre-post study.

Phase III: A final online web tool, based on all previously collected information, will be developed to support the implementation of the adapted NICE guidelines recommendations in other contexts and programmes.

Data collection and analysis: Data will be collected through surveys and semi-structured interviews. Quantitative and qualitative data will be analysed to identify implementation scenarios, changes in community engagement approaches, and barriers and facilitators to the implementation of the recommendations. All this information will be further synthesised to develop the online tool.

Ethics and dissemination

The proposed research has been approved by the Clinical Research Ethics Committee of Aragon (CEICA). Results will be presented at national and international conferences and published in peer-reviewed open access journals. The interactive online tool (Phase III) will include examples of its application from the fieldwork.

Article Summary

Strengths and limitations of this study

- The mixed methods (quantitative and qualitative) approach adopted in this research could support both researchers and participants to increase their knowledge and practice about community engagement in health programmes
- Research on public health guidelines implementation and evaluation is limited, and evidence is needed to help bridge the gap between research, policy and practice.

- Engaging a variety of stakeholders from different backgrounds throughout the phases of the project strengthens the research project and the potential transferability of the study results.
- Researching community engagement during the COVID-19 pandemic is challenging but this project can support community programmes in these difficult times

Keywords: community engagement; implementation research; community health; public health guidelines

Word count: 3081

Introduction

Engaging people and communities is central to the improvement of their health and well-being and to the reduction of health inequalities [1]. According to the World Health Organization [2], community engagement in health is essential to protect and improve populations' health. Through community engagement, local people increase their decision-making capacities and trust among themselves, allowing them to influence the social determinants of health that affect them, to improve their health and that of their community [3,4]. Nonetheless, despite increasing evidence on its importance [5,6], there is still a need to improve knowledge and practice about community engagement in health [7].

In 2016, the National Institute for Health Care and Excellence (NICE), a UK institute dedicated to the development of evidence-based guidelines, related to both clinical and public health topics, reviewed the evidence on the effect of community engagement on the health and wellbeing of communities and on reduction of health inequalities, and provided recommendations for incorporating community engagement into health policies and interventions in the published NICE Guidance NG44 [1]. During 2017 and 2018 a collaborative project was carried out by a group of health-related professionals in Spain to adapt the NICE guideline NG44 to the Spanish context, the AdaptA GPS project [8]. The project resulted in the first public health guideline included in GuíaSalud, the clinical guidelines catalogue of the Spanish Ministry of Health [8]. At present, there is no evaluation of the implementation of the guidelines in the GuíaSalud catalogue: once developed, there is no evaluation of their impact on practice or health.

The project EvaluA GPS (from its Spanish acronym: Evaluating the Application of Health Promotion Guidelines) aims to evaluate the impact of the implementation of the Spanish adapted NICE guideline NG44, through the following specific objectives:

Objective 1: To develop an implementation and evaluation tool based on the recommendations of NICE guideline NG44, in order to identify changes which can

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3 improve community engagement in community-based health programmes carried out
4 in different contexts.
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6 Objective 2: To evaluate the impact of implementing the recommendations of NICE
7 guideline NG44 on community engagement in a selection of community-based
8 programmes.
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11 Objective 3: To identify different implementation approaches according to different
12 contexts.
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15 This paper presents the research protocol for the project EvaluA GPS.
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18 **Methods and analysis**

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20 EVALUA GPS Project will be developed through three main phases, as illustrated in
21 Figure 1. Phase I will centre on developing a tool to evaluate the impact of the
22 recommendations (Objective 1). In Phase II, the developed tool will be implemented
23 in a selection of community-based programmes to explore changes in community
24 engagement (Objective 2). Phase III will then synthesise the information from the
25 implementation phase, to develop an online tool to support the implementation of the
26 adapted guidelines recommendations in different scenarios (Objective 3).
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30 ***Phase I: Development of the implementation and evaluation tool (Evalguía)***

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32 The implementation and evaluation tool will be developed using evidence from an
33 integrative review of the literature on public health guidelines implementation [9] and
34 an expert panel using an adapted Delphi method [10].
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39 To develop the first version of the evaluation tool (Evalguia 0.1), an integrative review
40 was conducted to identify the available literature on the implementation of public health
41 guidelines [9]. Integrative reviews use a systematic approach to search relevant
42 articles about the topic of interest, and provide a critical analysis of the findings, often
43 including a thematic synthesis approach, as it has been done in this case [11]. A
44 systematic search strategy combining key terms and synonyms related to
45 "implementation", "guidelines" and "analysis" or "evaluation" was conducted using the
46 databases PubMed, CINAHL, Web of Science and Scopus.
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50 Only studies analysing and/or evaluating the implementation of public health
51 guidelines were included. Three researchers identified the papers to be included in the
52 review through screening titles and abstracts and data was analysed using a thematic
53 synthesis approach [12]. The review followed the ENTREQ (Enhancing transparency
54 in reporting the synthesis of qualitative research) statement to structure and report the
55 review process [13]. The findings from the integrative review informed the
56 development of the first version of the Evalguia tool (Evalguia 0.1).
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3 The Evalguia 0.1 will be tested through a panel of experts. This will be organised
4 through an adapted Delphi method [10], through two rounds of review of the tool. It is
5 defined as 'adapted' Delphi as each expert will provide individual feedback about the
6 tool, but the analysis and consensus on the modifications to be made to the tool will
7 be carried out by the EvaluA GPS research team, with an aim to include all comments
8 provided by the experts.
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12 To identify experts in community health interventions, each researcher of the EvaluA
13 GPS team (composed of a total of 35 researchers) will be asked to suggest at least
14 one potential participant, who will be independent to the project. A maximum of 60
15 experts will be identified prior to the first round of invitation, considering both
16 geographical variability (experts from different regions of Spain) and roles (academic,
17 practitioners, community workers, local organisations' members) as selection criteria.
18 No exclusion criteria will be considered. Once the list has been compiled, an online
19 invitation will be sent by email to these experts, who, after expressing their interest in
20 participating, will be sent an informed consent form, which they will have to sign and
21 return.
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26 All participating experts will then receive the Evalguía 0.1 in a word document online,
27 so that they can provide their feedback and suggestions directly in the word document.
28 They will be asked to review it with a focus on content, language and design. After
29 receiving comments from the first round of review, the research team will compile and
30 discuss the proposed changes, and will finally select the changes to be made. The
31 tool will then be modified accordingly and Evalguia version 0.2 will be developed.
32 Participants who have not submitted the revision will be excluded from the following
33 round. Evalguia 0.2 will then be sent again to the participating experts, requesting their
34 final revision after the proposed changes.
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39 Finally, after receiving the second round of reviews, the research team will discuss the
40 proposed changes and modify the tool accordingly, trying to include them all where
41 possible. This final version, Evalguia version 0.3, will therefore be considered as the
42 final version of the tool to be implemented in Phase II.
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47 ***Phase II: implementation***

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49 This phase aims to pilot-test the developed implementation and evaluation tool in a
50 selection of community-based programmes, using a quasi-experimental pre-post
51 study (Objective 2). To select the programmes, researchers from the EvaluA GPS
52 team will suggest ongoing community-based programmes, with an aim to identify a
53 total of sixteen local programmes in four different Spanish regions to act as
54 'interventions sites'. Four additional programmes will be selected to act as 'control
55 sites' in only one of the regions (Aragon). The programmes will not be randomly
56 assigned to become intervention or control sites, but deliberately selected for each
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group. All programmes will be selected with the following inclusion and exclusion criteria:

1. Inclusion criteria:

- a. the community-based programme should aim to improve community health or follow at least one of the five lines of actions of the Ottawa Charter for Health Promotion (“1-building healthy public policy, 2-creating supportive environments, 3-strengthening community action, 4-developing personal skills, and 5-reorienting health care services toward promotion of health”) [14];
- b. the community should participate in at least two phases of the programme (health needs assessment, design, implementation, evaluation);
- c. the level of community engagement can be defined according to one of the next five participation levels: informing, consulting, co-creating decisions and actions, multiple and shared leadership and/or community control, as described in the NICE Guidance NG44 [1].
- d. the programme should have been ongoing for at least one year.

2. Exclusion criteria:

- a. The programme aims to promote individual health only, lacking a community-based health approach;
- b. The level of community engagement is limited to informing or consulting the community.

Intervention

All the 20 selected community-based programmes (Intervention sites, n=16, and control sites, n=4) will receive the implementation tool (*Evalguia 0.3*), in the form of a written document, which will include written instructions on how the tool should be implemented. The selected sixteen intervention sites will also receive an implementation workshop developed *ad hoc* by the research team based on previous experience in the field of community-based actions and on the results from Phase I, while the remaining four control sites will only receive the implementation tool which they will have to self-administer following the written instructions. This will allow to evaluate whether the implementation tool alone (without supplementary support from the workshop) improves community engagement in the selected community-based programmes, and to identify potential facilitators for the implementation.

In each intervention site, the workshop will be delivered to key stakeholders such as managers, front-line workers and community members involved in the projects. The research team will recommend that the workshop will be carried out in two sessions, and where possible on two different days or with a lunch break in between. However,

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3 the research team will need to adapt to the availability of the participating stakeholders.
4 It will be recommended to have a maximum of 15 people attending, to facilitate the
5 process and the group activities. In the first workshop session, after a general
6 presentation of the project and the participants, we will define key terms included in
7 the guidelines, such as community engagement, health assets, intersectoral work,
8 vulnerable groups and empowerment, to ensure all participants will have a shared
9 understanding of these concepts. Then the Evalguía tool will be presented and
10 implemented, followed by a group discussion on the results. This will allow
11 participating stakeholders to reflect how community engagement is being currently
12 carried out in their programmes, and to identify areas for improvement. In a second
13 session, an action plan aimed at improving community engagement in the project
14 following the adapted guidelines recommendations will be elaborated. It is foreseen
15 that the workshop will be held in person, although as a consequence of the COVID-19
16 pandemic these may have to be held online.
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22 **Data collection**

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24 Data collection during the implementation process (Phase II) will be structured in 4
25 stages, over a period of 15-18 months (Figure 2).
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28 In stage 1 (months 1-2), a semi-structured interview (S11) will be held with the
29 programme's managers (duration 60-90 minutes) to better understand the community-
30 based programme, its origins, its aims and objectives and how it is being implemented
31 and carried out daily.
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34 In stage 2 (months 4-6), the Evalguia tool will be applied, 16 'intervention sites' will be
35 supported through the implementation workshop, while the 4 'control sites' will only
36 receive the tool. Prior to the application of the Evalguia tool, all the participating
37 programmes (n=20) will answer an initial closed-answer questionnaire (Q1.1) which
38 will explore their perspective on the community engagement approach currently being
39 used in their programmes. The initial questionnaire will include questions about who
40 is currently involved in the community-based programmes and who are the main
41 decision-makers at each project stage (health assessment, design, implementation
42 and evaluation). This information will provide a baseline as to what extent community
43 members are engaged in the different stages of the selected community-based
44 programmes, and it will allow comparison before and after the implementation of the
45 Evalguia tool, to check its impact on community engagement in the programme. At the
46 end of the implementation session, to evaluate the Evalguia tool and the workshop,
47 participants from the intervention programmes (n=16) will answer a closed-answer
48 questionnaire (Q2.1), exploring their opinion of the tool (15 minutes) and of the
49 workshop itself. Participants in the control programmes will answer a questionnaire
50 (Q2.1 bis) exploring their opinions on the tool only.
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58 In stage 3 (7-9 months after the Evalguia application), participants of all 20
59 programmes will be asked to answer a short questionnaire on perceived changed in
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3 community engagement in their programmes (Q1.2), and a second semi-structured
4 interview (60 minutes) (SI2) will be carried out with programme managers to explore
5 their perspectives on potential changes in their programme over the past months.
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8 In stage 4 (12 to 14 months after the Evalguia application), all community-based
9 programmes (n=20) will implement again the Evalguia tool in their own project (16
10 intervention sites will be supported by a EvaluA GPS team member, while the four
11 control site will self-administer the tool), to check whether there have been changes in
12 community engagement approaches. Stakeholders who participated in the Evalguia
13 application will then answer a questionnaire on perceived changes in community
14 engagement in their programmes (Q1.3), and a final questionnaire on the Evalguia
15 tool (Q2.2 and Q2.2 bis for participants from the intervention and control programme
16 respectively). A final semi-structured interview (SI3) with the managers will be
17 conducted (60 minutes) to discuss perceived changes in their programmes. To
18 conclude, an online evaluation session will be organised with all the participants from
19 the 20 programmes to discuss the final changes to Evalguia.
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24 Written consent will be obtained from each stakeholder prior to data collection.
25 Interviews will be audio-recorded and transcribed, and the intervention workshop as
26 well as the application session in the control group will be audio-recorded. Then,
27 transcripts, audio recordings and the action plans will be imported to Nvivo v12
28 software to support the qualitative analysis.
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34 Analysis

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36 The data collected through the fieldwork in Phase II will be analysed to identify
37 changes in community engagement approaches and other possible changes resulting
38 from the implementation of the recommendations and/or of the workshops (such as
39 organisational changes and changes in relationships). Data from the questionnaires
40 will be analysed using descriptive statistics using SPSS, to compare changes pre and
41 post intervention in both the interventions and the control programme. Data from
42 interviews and workshops will be analysed using a thematic analysis approach [15].
43 The analysis will focus on synthesising similarities identified in the intervention and
44 control programmes to identify different implementation scenarios where community
45 engagement can be enhanced and allow the transferability of results to different
46 contexts. Moreover, the analysis will identify (a) barriers and facilitators in the
47 implementation of the recommendations and (b) strategies to overcome these barriers
48 and promote facilitators, to support implementation in other contexts. Qualitative
49 analysis will be conducted by two researchers separately, using NVivo Software v12
50 to aid the analytical process. Codes and themes will be then compared and
51 synthesised together.
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58 Both quantitative and qualitative data will contribute to answering the objectives of the
59 study. Triangulation will strengthen the results of the study [16], as quantitative data
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3 will provide an assessment of changes in community engagement which could be
4 attributed to the implementation of the guideline recommendations, allowing also to
5 evaluate the impact of the workshops. These changes will be checked against codes
6 and themes identified in the qualitative analysis. The qualitative analysis about
7 contextual factors and barriers and facilitators to the implementation, together with
8 quantitative data about the Evalguia tool will then set the basis to develop an online
9 tool (Phase III) to support the implementation of the adapted guidelines
10 recommendations in other programmes and contexts, thus enhancing the
11 transferability and applicability of the study results.
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16 The data collected through the implementation phase will then support the
17 development of an interactive online tool. The tool will be structured according to
18 different potential scenarios for implementation and will include examples from the
19 field as evidence of good practice to improve community engagement. Importantly, the
20 interactive web tool will be designed with lay and inclusive language. The online tool
21 will be tested through a final online evaluation session with the stakeholders who
22 participated in the application of Evalguia, to ensure its language and design are user-
23 friendly and accessible for a lay audience.
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30 **Patient and Public Involvement Statement**

31 EVALUA GPS Project is based on the findings of the previous research project,
32 AdaptA GPS [8], in which community members from eleven local community-based
33 programmes across Spain were involved to test the adapted NICE NG44 guidance.
34 The Evalua GPS protocol has been developed following their feedback on the need
35 to simplify the language used in the recommendations and provide more practical
36 examples on how to implement the community engagement recommendations.
37 Community members are also key stakeholders in the Evalua GPS project, as they
38 will be involved in all stages of the project. In the initial phase, local organisations'
39 members will be invited to participate in the review of the Evalguia tool through the
40 adapted Delphi method. Following this, in the implementation phase, community
41 members will be recruited to participate in the workshops (intervention). In addition,
42 community members will be invited to the final online evaluation session to consult
43 them on how to improve the Evalguia tool in its online version.
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50 **Ethics and dissemination**

51 All participants will receive an information sheet detailing all the phases of the research
52 project and will be informed of the objectives and characteristics of the study, as well
53 as their voluntary participation and the possibility of leaving the study at any time
54 during the research process. The intervention programmes will be informed that they
55 will receive a workshop to implement the Evalguia, while the control programmes will
56 be informed that they will receive the Evalguia and will have to implement it on their
57 own. If they agree to participate in the study, participants will be asked to sign an
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3 informed consent form. Data confidentiality will be guaranteed in accordance with
4 Spanish Organic Law 3/2018 on the protection of personal data and guarantee of
5 digital rights, being analysed anonymously and described in aggregate form to avoid
6 identification at an individual level. The research project has been approved by the
7 Clinical Research Ethics Committee of Aragón (CEICA), PI20/116.
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10 The dissemination strategies include that study results will be presented at national
11 and international conferences, as well as published in open access peer-reviewed
12 journals. Moreover, the research team will develop a short animated video
13 summarising the project [17] which will support presenting the research to lay people.
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16 One of the goals of translational research is the translation of new approaches into a
17 form amenable to widespread adoption and implementation [18]. The EvaluA GPS
18 research described here may enhance translational research, as it intends to facilitate
19 the application of evidence-based recommendations for community-based health
20 programmes, hence contributing to reducing the gap between research, policy and
21 practice [19]. At EvaluA GPS we aim to develop implementation scenarios to facilitate
22 project design and evaluation. Moreover, it is hoped that generating more practice-
23 based evidence in community engagement in health in Spain will strengthen and
24 enhance good practices in community health programmes, contributing to promote the
25 health of people and communities and reduce health inequalities.
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33 **Author contributions:** VC, MVLR, CBBA, JPC, AMG, LAPdT and CN developed the
34 study proposal and protocol. VC, MVLR, MPG, AGR, MD, CN, and VG wrote the initial
35 draft of the paper which has then been iteratively revised and reviewed by all authors
36 (included EvaluAGPS Research Group). All the authors approved the final version to
37 be published. All the authors agree on being accountable for all aspects of the work in
38 ensuring that questions related to the accuracy or integrity of any part of the work are
39 appropriately investigated and resolved.
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45 **Funding:** This work was supported by the research projects PI19/01079, PI19/01525
46 and PI19/00773 co-financed by the ISCIII-Ministerio de Economía y Competitividad
47 and the Fondo Europeo de Desarrollo Regional (FEDER).
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51 **Competing interests:** None declared
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54 **Acknowledgements:** (*EvaluAGPS Research Group*): Aldecoa Landesa, Susana;
55 Aliaga Train, Pilar; Aviñó Juan-Ulpiano, Dory; Baraza Cano, Pilar; Barona Vilar,
56 Carmen; Botello Diaz, Blanca del Rocío; Bueno, Manuel; Couso Viana, Sabela;
57 Dominguez, Marta; Egea Ronda, Ana; Enriquez, Natalia; Gallego Dieguez, Javier;
58 Gallego Royo, Alba; Gea Caballero, Vicente; Hernán García, Mariano; Hernández
59 Gómez, Mercedes Adelaida; Iriarte, María Teresa; Lou Alcaine, María Luz; Martínez
60

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3 Pecharromán, María del Mar; Morin, Victoria; Nuñez Jiménez, Catalina; Peyman-
4 Fard, Nima; Pla Consegra, Margarita; Romaguera Lliso, Amparo; Ruiz Azarola,
5 Ainhoa; Sainz Ruiz, Pablo. EvaluAGPS Research Group is a multidisciplinary
6 research group formed for the EvaluA GPS project. EvaluA GPS is a research
7 coordinated by three institutions: IIS (Instituto de Investigación Sanitaria de Aragón);
8 FISABIO (Fundación para el Fomento de la Investigación Sanitaria y Biomédica,
9 Comunitat Valenciana) and IMIBIC-FIBICO (Maimonides Institute for Biomedical
10 Research of Cordoba, Andalucía) and with the participation of the IAPP network, the
11 PACAP program, PAPPS program and the Community Health Alliance.
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22 health inequalities. 2016. <https://www.nice.org.uk/guidance/ng44>
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Figure Legend

Figure 1: The three phases of EvaluA GPS project. Own elaboration

Figure 2: Data collection phase II. Own elaboration

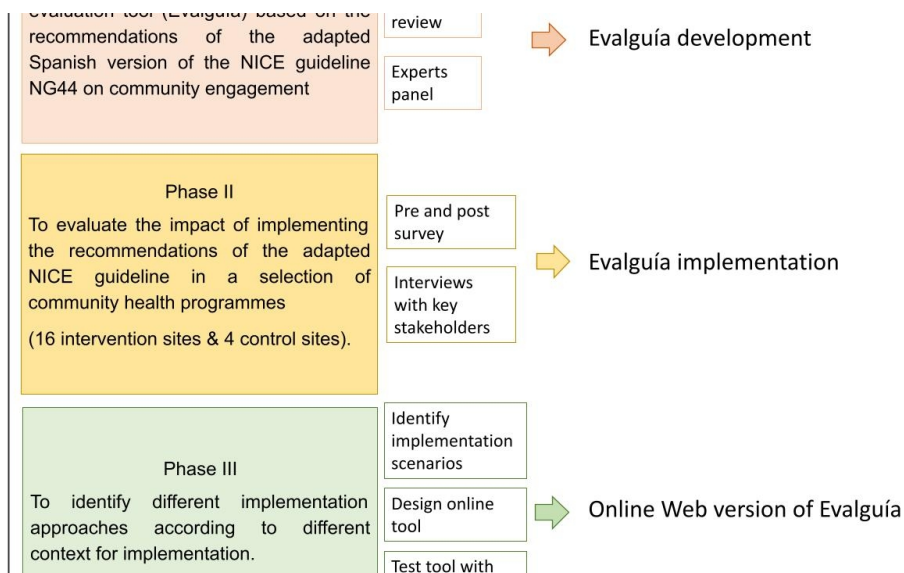


Figure 1: The three phases of EvaluA GPS

451x254mm (72 x 72 DPI)

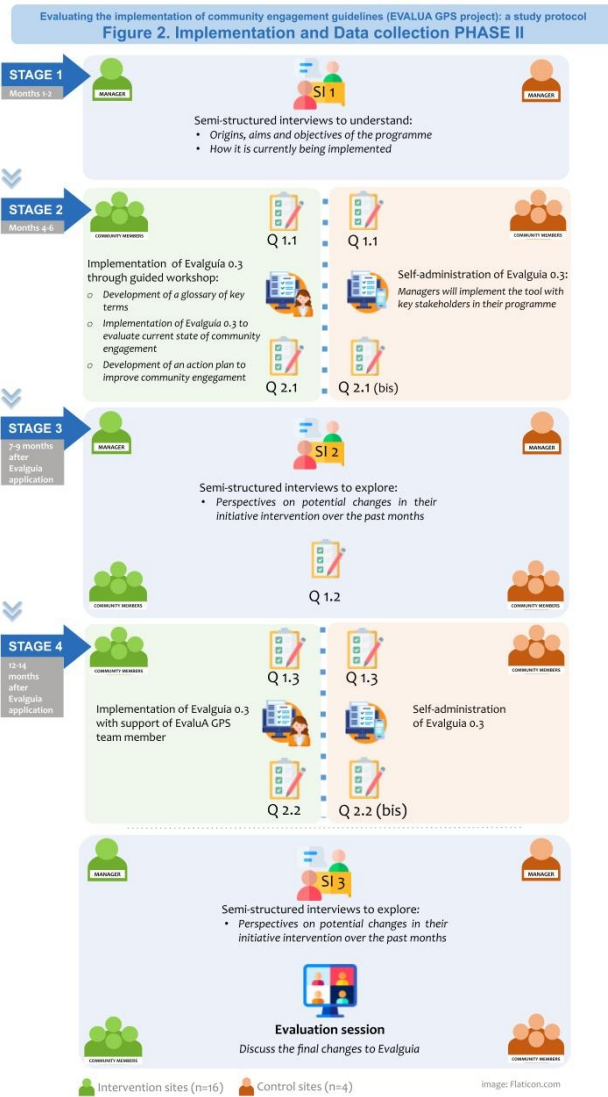


Figure 2. Implementation and Data collection PHASE II

253x482mm (72 x 72 DPI)