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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

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Competing interests: The authors declare no conflicts of interest.

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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

ABSTRACT

Objective: To evaluate the implementation and development of a complex intervention on health promotion and changes in health-promoting behaviours in primary health care according to health-care attendees and health professionals.

Design: Descriptive qualitative evaluation research conducted with 94 informants. Data collection techniques consisted of 14 semi-structured individual interviews, 9 discussion groups, 1 triangular group and 6 documents. Three analysts carried out a thematic content analysis with the support of Atlas.ti software. This evaluation was modelled on Proctor and colleagues’ concept of outcomes for implementation research.

Setting: 7 primary care centres from 7 Spanish regions: Andalusia, Aragon, Balearic Islands, Basque Country, Castilla-La Mancha, Castilla-Leon and Catalonia.

Participants: The study population were health-care attendees (theoretical sampling) and health professionals (opportunistic sampling) who had participated in the exploratory trial of the EIRA intervention (2015).

Results: Health-care attendees and professionals had a positive perception of the study. Health-care attendees even reported that they would recommend participation to family and friends. Health professionals became aware of the significance of the motivational interview, especially for health promotion, and emphasized social prescribing of physical activity. They also put forward recommendations to improve recruitment, screening and retention of participants. Health-care attendees modified behaviours and health professionals modified working practices. To achieve sustainability, health professionals believe that it is crucial to adapt agendas and involve all the staff.

Conclusions: The discourses of all stakeholders on the intervention must be taken into consideration for the successful, setting-specific implementation of adequate, acceptable, equitable and sustainable strategies aimed at health promotion and well-being.

Keywords: Complex interventions; Implementation Research; Evaluation; Health Promotion; Health Behaviour; Primary Health Care; Qualitative Research.

Abbreviations

CRF: Case Report Form

DG: Discussion Groups

DT: Documentary Technique

MRC: Medical Research Council

PCC: Primary Care Centre

PHC: Primary Health Care

SI: Semi-structured Interview

SMS: Short Message Service

TG: Triangular Group

Strengths and limitations of the study

- The sampling method of the qualitative evaluation might only have captured the experiences and views of the professionals and attendees more involved and positive with regard to the intervention and to health promotion.
- The rigour procedures applied (methodological adequacy, triangulation of techniques and analysis and reflexivity of the interdisciplinary research team) ensured the validity and reliability of the findings.
- The richness and complementarity of the information generated by health-care attendees and health professionals from seven distinct regions will contribute to the adaptation of the intervention to the various settings to ultimately achieve feasible, sustainable integration in everyday primary care practice.

Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

BACKGROUND

Primary Health Care (PHC), the most accessible and most frequently used health service, provides comprehensive, long-term person-focused care [1]. It is considered the ideal setting to implement individual, group and community health promotion interventions. However, these implementations face barriers and challenges set up by the system, the professionals and the public [2,3].

Since it is very common for the same person to accumulate interrelated unhealthy behaviours, complex interventions are increasingly used in studies of behavioural change. In addition, first-hand knowledge of the setting where health promotion takes place is crucial when evaluating its effect. Complexity results from the number of interacting components, namely the amount and difficulty of behaviours required by those delivering or receiving the intervention, the number of groups or organizational levels targeted, the number and variability of outcomes and the degree of flexibility of the intervention [4,5]. The main directives for the design, implementation and evaluation of complex interventions were developed by the Medical Research Council (MRC)[4,6,7] using a mixed-method approach with five sequential phases: i) definition of the theoretical foundation (preclinical phase), ii) construction of a model (phase I), iii) development of a pilot study (phase II), iv) completion of the definitive trial (phase III), and v) long-term implementation (phase IV).

The EIRA project started in Spain in 2012 with the objective to modify unhealthy behaviours in primary care patients following the MRC framework for complex interventions [6,7]. To date, the first 3 phases have been completed [3,8–11]. Specifically, the objective of the EIRA Project was to design, conduct and evaluate a complex, multi-risk intervention to enhance adherence to the Mediterranean diet, increase insufficient physical activity and reduce smoking, cardiovascular risk factors and risk of depression in people aged 45 to 75 years that contact primary health care services with at least two of these behaviours or risk factors. Participants receive individual recommendations on their behaviour and risk factors and they are offered to attend group sessions and social prescription of health promoting community assets. The person-centered approach uses the motivational interview and the attendee becomes an active agent in her own life. Participants allocated to the control group receive the usual care (Figure 1).

A key question in evaluating a complex intervention is actual effectiveness. However, the process itself is also important: what happens, how, when and why. The process evaluation in trials explores the implementation of an intervention, assesses its quality and fidelity, clarifies causal mechanisms and

identifies contextual factors associated with variation in outcomes [4,12]. Qualitative methodology has a unique role in understanding the implementation process of an intervention [13]. Interestingly, qualitative research can be used concurrently with a pilot trial, for instance to optimise recruitment and informed consent strategies, to identify acceptability of the intervention, to provide insights into processes of change and to help interpret findings [14].

This qualitative evaluation presents the results of the second phase (development of an exploratory trial) of the EIRA Project. The objective was to evaluate (1) the process of implementation and development of a complex intervention on health promotion in primary care according to health-care attendees and health professionals and (2) changes in health-promoting behaviours.

METHODS

Design

Descriptive qualitative research based on the experiences of participants was used to evaluate the exploratory trial of the EIRA complex intervention.

Setting and study population

Seven primary care centres (PCC) included in the intervention group of the EIRA Project from 7 Spanish regions (1 PCC per region) participated: Andalusia, Aragon, Balearic Islands, Basque Country, Castilla-La Mancha, Castilla-Leon and Catalonia. The control group of the exploratory trial did not participate in the qualitative evaluation.

The study population were: a) PHC professionals from participating PCC (including family physicians, primary care nurses, social workers and administrative staff) and assistant researchers (in charge of performing baseline and 6-month measurements and questionnaires); and b) health-care attendees aged 45 to 75 years who participated and completed the EIRA study.

Sample design and participant selection strategy

PHC professionals from participating PCC and assistant researchers were selected by means of opportunistic sampling [15]. The site investigator of each PCC contacted all professionals who participated in the EIRA study to book group interviews 2-3 months after the beginning of recruitment (February 2015 in 3 centres) and at the end of the intervention (summer of 2015 in the 7 centres of the intervention group). For health-care attendees we applied theoretical sampling based on a prior definition of participants' characteristics to obtain optimal variety and discursive wealth [15]. Fifteen informant profiles emerged from the discursive variants sex, age, educational level and type of intervention (the approach to the first component of the intervention was decided by the participant); two of these profiles were randomly allocated to each centre; one centre had 3 profiles. At the end of the intervention (summer 2015), the site investigator contacted the health-care attendees to explain the objectives of the qualitative evaluation and invited them to participate.

Data collection and generation techniques

Conversational techniques were used for PHC professionals: 3 discussion groups in February 2015 and 6 discussion groups at the end of the intervention, in the summer of 2015; 1 triangular group [16]; and 1 individual interview with a community agent. In addition, we collected the written reports of 6 professionals who could not attend the discussion groups because of scheduling conflict (2 documentary techniques in

February and 4 in summer). Table 1 details the main characteristics of the 81 PHC professionals who participated in the study.

Semi-structured individual interviews were used to collect information from health-care attendees. We initially planned a semi-structured individual interview for each of the 15 profiles of informant; however, 2 semi-structured individual interviews could not take place because the participants could not be contacted after the end of the study. We finally held 13 interviews with health-care attendees. Table 2 shows the characteristics of these 13 participants.

Semi-structured individual interviews, discussions groups and triangular group followed a topic guide with open-end questions, with some adaptations according to type of informant and study period (Table 3). The topic guides were based on a review of the literature and the objectives of the study. After obtaining informed consent from the participants, all interviews were audio or audio and video recorded. The discussion groups took place in the PCC with one moderator and one observer, and lasted between 90 and 120 minutes. Semi-structured individual interviews took place in a setting accessible for the health-care attendees and lasted between 15 and 60 minutes. The field work was carried out by interviewers of each region. Informative richness for a deeper understanding of the development and implementation of the intervention was achieved.

Data analysis

All interviews and discussion groups were transcribed verbatim and de-identified by trained personnel [17]. A thematic content analysis was carried out [18,19] with the support of Atlas.ti software. The data were analysed as follows by 3 researchers (NCA, MPV and EPR, a nurse, a pharmacist and a physician, respectively): 1) formulation of preanalytical intuitions after successive readings of the transcriptions and the notes from documentary techniques; 2) creation of an initial analytical plan and text codification; 3) creation of categories by grouping the codes according to the analogy criterion based on Proctor and colleagues' model of outcomes for implementation research [20] and new elements from the discourses; 4) analysis of each category and relationship with the others.; and 5) elaboration of the new text with the main results. These results were presented and discussed in a meeting with all research members of the EIRA project (January 2016).

Rigour and quality criteria

To guarantee quality and rigour we adhered to the following recommendations [21–23]: description of the intervention, the context, the participants and the research process; methodological adequacy; working with

different actors; triangulation of techniques and analysis; and reflexivity of the interdisciplinary research team. Sufficient data were collected to meaningfully answer the research question.

Ethical considerations

This study followed the tenets of the Declaration of Helsinki and was approved by the Research Ethics Committee of the IDIAP Jordi Gol (2013; P12/073). All participants signed the informed consent form. Anonymity, confidentiality and data protection were guaranteed.

Patient and public involvement

Study participants were not involved in the development of the research question or the outcome measures nor the design of the study. The results will be presented to study participants and citizens through informative activities and the media.

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RESULTS

The results are classified in 5 categories: acceptability, appropriateness and feasibility, sustainability, penetration (changes implemented) and suggestions for improvement. Table 4 shows the definitions of these categories complemented with illustrative quotations from the discussions. .

Acceptability

In general, health-care attendees and health professionals were happy about their participation and their final evaluation was positive. Health-care attendees were thankful to the professionals for their support and they explained that they felt more confident making decisions about the process of change. All health-care attendees interviewed would recommend participating in the study to family and friends, and in fact some had already done it. They affirmed that participation requires being ready to pay attention, to listen and to reflect.

Health professionals believed in health promotion and while they did not consider the contents of the intervention innovative, they thought that it changes working practices, notably the systematization of recommendations and the boost of social prescription. However, they remained critical and underscored that the project was too ambitious, too long, somehow unclear and unorganized, which led to confusion during implementation. They specifically highlighted difficulties in the approach to risk of depression. Moreover, in some primary care teams tension emerged between professionals that participated and their non-participating colleagues.

Appropriateness and feasibility

The results have been categorised according to the phases of the study:

Although some professionals considered that the training conducted prior intervention was appropriate and provided new concepts, they maintained that it was insufficient for the actual implementation of the intervention, specifically concerning the motivational interview and the approach to risk of depression. There was no practical training in the use of online Case Report Forms (CRF) and in one of the centres the training was provided too early. Some theoretical aspects could not be translated into practice due to lack of time or skills.

With regard to coordination, the professionals found the meetings with the research team useful. However, it was sometimes unclear how to proceed, how to give appointments and refer health-care attendees for follow up or who was responsible for reviewing the study tests. In addition, some procedures were changed after the start of the study. Reiteration of questions and lost to follow up were generated by the complexity of circuits and the lack of communication between professionals.

Most professionals agreed that **recruitment** involved a higher workload than anticipated and that it took place in a short timeframe. They explained that it was difficult to explain the study and to encourage health-care attendees to participate, and they believed that many enrolled because they felt obliged to their professionals. Health-care attendees explained that they participated because they thought it was interesting, they had time and they felt obliged to their doctors.

Professionals pointed at a selection bias caused by the recruitment of frequent attenders, patients generally better controlled and more motivated. No random systematic sampling was applied and any reason for consultation was accepted. Few admission staff chose to take part and their involvement was often hurried and uncoordinated, which increased the workload of the other professionals who participated.

First visit with the health professional (prioritization of behaviours to modify and intervention plan): Most health-care attendees evaluated positively their involvement in decision making and many explained that they participated in the prioritization of behaviours and risks that needed changing. Patients asserted that trust in the health professional facilitates change. Health professionals evaluated positively the patients' assessment of their own risk behaviours followed by the decision about which behaviours to modify. Professionals also indicated that the prioritization algorithm was useful.

Individual intervention: Health-care attendees believed that the advice was useful and applicable and they felt that health professionals really cared and listened to them. They emphasized that in comparison to usual visits health professionals had more time to attend them without rush and to do a holistic valuation. The health-care attendees that received health promotion recommendations in regular practice mixed them up with the intervention advice of the study. They also mixed up the clinical intervention with the collection of information for the clinical trial. They thought that the follow up period should be extended and include more people. The professionals were positive about the person-centred approach and have become more aware of the significance of the motivational interview and of health promotion.

Group intervention: Group activities focused on physical activity and nutrition. Health-care attendees explained that sharing experiences was positive, they made friends and organized walking groups. Some professionals reported that these activities are difficult to implement due to lack of time. For others, these activities do not fall within their duties (they considered them additional activities or simply going for a stroll with health-care attendees).

Community intervention: Although few centres used activities already popular in the neighbourhood, social

prescription was very positively evaluated both by health-care attendees and professionals. The town councils organized most physical activities prescribed. For professionals, social prescription was a new concept, and they emphasized that adherence is unknown since attendance was not registered.

Health education leaflets: Health-care attenders favoured personal contact over patient information leaflets. However, the few comments received on leaflets are all positive, especially those about diet or mental health. Health care professionals considered that the leaflets were a useful tool, particularly regarding diet, and even patients who did not participate in the study received them. They also believed that health-care attendees appreciate written information.

SMS and health education webpage: Few health-care attendees agreed to receive SMS, but those that accepted explained that SMS were helpful and encouraging. Professionals considered SMS useful reminders. The webpage was hardly accessed, for which health-care attendees and professionals provided various reasons: nobody recommended it, they did not have access to the internet or to a computer, they were not motivated, and they did not like to sit in front of a screen.

The professionals believed that the study **online CRF** was too complicated, too slow and that it was difficult to register personalised agreements. Also, since the programme was separate from the electronic health records, they had to work with both programmes simultaneously. In addition, poor internet connection slowed the work of some professionals.

Health professionals indicated that **follow up** data such as adherence rates were somewhat unclear and would be interested in learning about the final results. They believed that retention of participants might be determined by difficulties in attending the intervention visits, loss of interest and the perception that no added value is attached to these interventions.

Evaluation of the intervention (baseline and final) – role of the Assistant researchers: Generally, health-care attendees evaluated positively the questionnaires and tests carried out by the assistant researchers (blood tests, evaluation of vascular health, etc.) because they felt listened to and had more time to talk. The professionals believed that health-care attendees felt well cared for because they spent sufficient time with the interviews. The assistant researchers indicated that they had to administer too many questionnaires. They also pointed at the following issues: insufficient information, lack of their own working space, irregular access to the CRF and lack of authorisation to consult the medical history of health-care attendees.

Sustainability

Some professionals considered that it is important to extend this intervention to other PCC but underscored the need for the support of institutions, for extended consultation length and the involvement of all professionals. In addition, risk of depression remains a controversial component of the intervention. Some professionals would exclude it altogether, while others believed that it needs a different approach.

Penetration: Changes implemented by health-care attendees and professionals after the intervention

Health-care attendees reported increased motivation and knowledge of healthy behaviours and feeling more positive toward change. Those working with physical activity and nutrition explained that they implemented changes and felt very happy about it: they walked more, got less tired and felt fitter, ate healthier (smaller amounts, more vegetables, fruit and nuts and use of olive oil) and some stated that they drank less alcohol. They also stated that they smoked less cigarettes. Professionals agreed that health care attendees made an effort to meet their objectives, to implement changes and to start healthier habits.

The barriers for change according to health-care attendees were: family responsibilities (care of the sick, care of grandchildren, house chores, etc.), life-work imbalance, weather conditions and lack of willpower. The professionals agreed with these barriers and added financial issues and unawareness of the need to change. Facilitators of change according to health-care attendees were: group activities and trust in health professionals. For health professionals, the health-care attendees should decide which behaviours to modify because their commitment implies autonomy and empowerment and facilitates change.

The **professionals** reflected on how to approach health promotion in primary care: with a holistic view of the patient, providing evidence-based advice, being more purposeful, using motivational interview, involving the family and prioritizing social prescription. Participation in the intervention facilitated a deeper knowledge of health-care attendees and extended consultation length. Professionals believed that they assess and register activities better.

Suggestions for improvement

Table 5 shows the discourses and suggestions for improvement of participants.

DISCUSSION

Overall, health professionals and health-care attendees shared a positive perception of their participation in the study. Indeed, health-care attendees would even recommend it to family and friends. Health professionals realised the significance of the motivational interview, in particular with regard to health promotion. They also underscored the potential of social prescribing in relation to physical activity. In addition, health professionals put forward suggestions to improve recruitment, screening and retention of participants. Health-care attendees modified behaviours and health professionals revised working practices. According to health professionals, the continuity of this programme is contingent upon adapting agendas and involving all staff.

We regard the positive attitude of health-care attendees and health professionals toward this health promotion multibehavioural intervention as an endorsement of the definitive trial of the EIRA project. However, we acknowledge that the current version of this intervention cannot yet be integrated in primary care practice until fundamental organisational changes that ensure feasibility and sustainability in real world conditions take place. Even though the intervention was adapted and implemented following the recommendations of health-care attendees and health professionals obtained in prior phases of the EIRA project [3,8–11], further adjustments are required. For instance, in the EIRA project we concluded that for health promotion it is essential to involve most primary care professionals, including administrative staff, to avoid tension and to challenge the notion that health promotion is voluntary or based on personal preference. It is also important to reduce the work overload (objectively high), to simplify recruitment and screening questionnaires and to modify the approach to emotional discomfort and risk of depression. On the other hand, it is crucial to participate in the dissemination of social prescription and to continue the research in implementation strategies focusing on equity and on improving overall results. It has also been observed that primary care professionals require more resources, time, skills and motivation to reach out and work with the community in health promotion [24].

Health-care attendees were happy with the study because they felt that professionals gave them enough time and listened to their needs and preferences. They also felt supported during the process of change and were able to initiate sustainable healthy behaviours. We might thus conclude that the intervention encouraged a holistic, person-centred approach underscoring the key role of the primary care professional and of the motivational interview as a useful strategy to promote behavioural change [25]. The motivational interview requires training and extended consultation times [26], and although health professionals received basic training (4 hours at the beginning of the study), most agree that further training is required.

Although some health professionals underscored the pivotal role of primary health care to manage risk of depression, many worried about lack of skills, attitudes, tools and experience, in agreement with others authors [27]. In addition, some health-care attendees had a positive opinion about the opportunity to know their depression risk [28]. To some extent, the recommendations to manage emotional discomfort in primary care take all these views into account [29]. The real objective of the first approach is to ascertain the nature of the emotional discomfort by means of active listening, probing and empathy to understand the meaning, adaptability and problem solving skills of each person to avoid chronification and medicalization.

This project encourages participation in community activities, particularly physical activity, even though many participants did not follow these recommendations. In agreement with the results of the systematic review by March et al., which shows that in primary care preventive interventions the community might be more effective than the individual approach [30], health professionals underscored a more systematic use of social prescription in regular practice, which indicates an interest in implementing a more biopsychosocial model [11]. This qualitative assessment suggests that despite early resistance, professionals and health-care attendees became eventually aware of the importance of the community components of health promotion interventions. In addition, the feasibility of community recommendations is suggested as a selection criteria of PCC with capability to develop complex health promotion interventions based on networks that identify, promote and evaluate local health assets [31]. In contrast, despite the growing holistic, psychological and collective conception of health [10], the persistence of the biomedical paradigm is shown by the positive evaluation of medical tests by health-care attendees.

Most professionals and health-care attendees found SMS, a low cost method that preserves privacy, useful for people with mobile phones. Even though some gaps still exist regarding the effectiveness of SMS in health promotion interventions, they can be used to provide positive feedback in order to effect and maintain behavioural change, particularly with regard to quitting smoking and physical activity [32–34]. In contrast, the webpage was not considered useful for participants, in agreement with other studies which stress the relevance of the patient-health professional relationship [34,35].

Limitations and strengths

In the EIRA project, health-care attendees and health professionals provided information and were consulted about the development and evaluation of the intervention. However, the real shift in research practice would be actual public involvement in research design [36].

Despite the use of theoretical sampling for health-care attendees, the voice of participants with higher education qualifications (only 6% in the pilot trial) was insufficient. Also, the recruitment characteristics of

health care attendees and professionals might have biased the results towards a positive view of the intervention and of health promotion. On the other hand, the detailed description of less successful aspects, the polarization of professionals regarding the benefits of the study and the suggestions for improvement point at a diversity of standpoints. We believe that it is nonetheless fundamental to add the perspective of less motivated professionals and of participants that dropped out or that simply decided not join the study.

One strength of the study is the use of the MRC approach for the design, implementation, and evaluation of complex interventions [4,6,7]. The following phase of the intervention (definitive trial) will more specifically adapt to the people and setting and will be more sustainable thanks to the richness and complementarity of the information generated by health-care attendees and professionals from these seven regions. The evaluation process was also analysed by quantitative methods (paper under construction), but considering the limited sample of the pilot trial and the low response rate to questionnaires, qualitative evaluation has proven crucial to understand how health-care attendees and professionals perceive the intervention. Moreover, the rigour procedures applied ensured the validity and reliability of the findings.

Conclusions

The discourses of all stakeholders with regard to the intervention must be taken into consideration for a successful, setting-specific implementation of the most adequate, acceptable, equitable and sustainable strategies for health promotion and well-being.

CONTRIBUTORS: MPV, AB and EPR designed the study and wrote the protocol. EPR, MPV, AB, BM, MPF, SM, HP and CR participated in data collection and generation techniques. MPV, NCA and EPR conducted the analysis. All authors contributed to the interpretation of results. MPV, AB and EPR wrote the first draft of the manuscript. All authors read, contributed and approved the final version of the manuscript.

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Table 1: Description of participating health-care professionals according to study period and region

| Date | Region | Technique* | Participants | Age | Sex | Occupation |
|-----------------------------------|--------------------|------------|--------------|--|---------------------|---|
| February 2015 | Balearic Islands | 1 DG | 13 | 6 age 30-49 years 7 age 50-65 years | 9 Female 4 Male | 1 Administrative staff 5 Nurses 5 Physicians 2 Psychologists, one assistant researcher |
| | Castilla-La Mancha | 1 DG | 6 | 1 under 30 years 1 age 30-49 years 4 age 50-65 years | 5 Female 1 Male | 6 Nurses |
| | | 2 DT | 2 | Missing information | 2 Female | 2 Assistant researchers (nurses) |
| | Catalonia | 1 DG | 8 | 7 age 30-49 years 1 age 50-65 years | 7 Female 1 Male | 6 Nurses 2 Physicians |
| Summer 2015 – end of intervention | Andalusia | 1 DG | 5 | 1 age 30-49 years 4 age 50-65 years | 1 Female 4 Male | 5 Physicians |
| | Aragon | 1 DG | 4 | 2 age 30-49 years 2 age 50-65 years | 3 Female 1 Male | 3 Nurses 1 Physician |
| | Balearic Islands | 1 DG | 9 | 4 age 30-49 years 5 age 50-65 years | 7 Female 2 Male | 1 Administrative staff 1 Assistant researcher (psychologist) 3 Nurses 4 Physicians |
| | | 1 DT | 1 | 1 age 30-49 years | 1 Female | 1 Assistant researcher (psychologist) |
| | Basque Country | 1 DG | 11 | 2 under 30 years 3 age 30-49 years 6 age 50-65 years | 10 Female 1 Male | 1 Administrative staff 1 Assistant researcher 4 Nurses 5 Physicians |
| | | 1 SI | 1 | 1 age 30-49 years | 1 Female | 1 Community agent |
| | Castilla-León | 1 DG | 9 | 2 under 30 years 1 age 30-49 years 6 age 50-65 years | 8 Female 1 Male | 6 Nurses 3 Physicians |
| | Castilla-La Mancha | 1 TG | 3 | 1 age 30-49 years 2 age 50-65 years | 3 Female | 3 Nurses |
| | Catalonia | 1 DG | 6 | 6 age 30-49 years | 5 Female 1 Male | 4 Nurses 2 Physicians |
| | | 3 DT | 3 | 3 age 30-49 years | 2 Female 1 Male | 1 Assistant researcher (psychologist) 2 Nurses |

*Technique: Discussion Groups (DG); Semi-structured Interview (SI); Triangular Group (TG) and Documentary Technique (DT).
Most people taking part in the various techniques in February 2015 took also part at the end of the intervention (Summer 2015).
The data is aggregated for confidentiality reasons. Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 2: Description of participant health-care attendees by region (Summer 2015, end of the intervention)

| Region | Risks at the start of the study (intervention on risk: yes/no) | Sex | Educational level | Age |
|--------------------|--|--------|---------------------|-----|
| Andalusia | Diet (yes); Cardiovascular risk (yes) | Male | Primary education | 70 |
| | Physical activity (yes); Diet (yes); Depression risk (no) | Female | Primary education | 58 |
| Aragon | Physical activity (yes); Diet (yes) | Male | Primary education | 51 |
| | Diet (yes); Physical activity (no); Cardiovascular risk (no) | Male | Secondary education | 64 |
| Basque Country | Physical activity (yes); Depression risk (yes) | Female | Primary education | 75 |
| | Physical activity (yes); Cardiovascular risk (yes) | Female | Secondary education | 62 |
| Castilla-León | Depression risk (yes); Diet (yes); Physical activity (yes) | Female | Secondary education | 69 |
| | Physical activity (yes); Smoking (yes); Cardiovascular risk (yes) | Female | Primary education | 58 |
| Castilla-La Mancha | Physical activity (yes); Diet (yes); Smoking (yes) | Female | Primary education | 49 |
| | Depression risk (yes); Diet (yes); Smoking (yes) | Female | Primary education | 52 |
| Catalonia | Diet (No); Physical activity (No); Smoking (yes) | Female | No education | 47 |
| | Physical activity (yes); Diet (yes); cardiovascular risk (yes); Smoking (No) | Male | Primary education | 59 |
| | Physical activity (yes); Diet (yes); Depression risk (yes) | Female | Secondary education | 55 |

No semi-structured interviews with health-care attendees took place in the Balearic Islands.

Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 3: Topic guide for the data generation techniques based on type of informant and study period

| |
|--|
| Primary health care professionals and assistant researchers (February 2015) |
| We will start talking about recruitment: in your experience, what do you suggest to enhance recruitment? |
| Based on your experience, how can we improve the suggested screening strategy? |
| What is your experience with the algorithm of prioritisation and what do you suggest to improve it? |
| What is your overall assessment of the proposed intervention? |
| What do you suggest to improve the feasibility of each component of the intervention (diet, physical activity, smoking, cardiovascular risk and depression risk)? |
| What are your views and experiences on the resources and materials of the intervention? (Web for professionals, Web for patients, patient information leaflets, SMS, other ICTs) |
| How does the target population accept each aspect of the study? (how do they feel, ask and talk about their difficulties with regard to behavioural change) |
| How could we boost participation in the study? (consent at recruitment, follow up ...) |
| What do you suggest to improve the coordination of the project? |
| Finally, how do you perceive your participation in this project? |
| Primary health care professionals and assistant researchers (Summer 2015) |
| What is your overall assessment of the intervention? |
| Has your participation in this study been useful to modify any aspect of clinical practice? Do you think that it has been useful for patients? |
| What are your suggestions to improve the feasibility of each component of the intervention? |
| Concerning each component of the intervention: Would you keep them in the definitive trial? Would you keep them at each level of intervention? How does the population accept them? (How do they feel, ask and talk about their difficulties with regard to behavioural change?) |
| What are your views on the relevance and usefulness of the resources and materials of the intervention? (Web for professionals, Web for patients, patient information leaflets, SMS, other ICTs) |
| How could we improve the coordination of the project? |
| How do you assess the feasibility of expanding this project to other primary care centres? |
| How do you evaluate your participation in this project? |
| Finally, do you have any comment on recruitment, screening strategy and prioritisation algorithm? |
| Health-care attendees (Summer 2015) |
| Could you please explain your overall experience with the EIRA study? |
| Which activities have you carried out during your participation in the study? (If none, ask about group interventions and social prescription) |
| Do you think that you have participated in decision making about your own health? How was your experience? |
| Has this study contributed to adopt healthier behaviours? Has any aspect of your life changed since you entered the study? Do you think that it is feasible to integrate the recommendations and activities suggested by primary care professionals into your daily life? |
| Have you found useful the resources related to the EIRA project such as the webpage, SMS, etc.? |
| What could we improve? |
| Would you recommend participation in a similar study to your family and friends? |
| How do you evaluate your participation in the EIRA project? |

Table 4: Verbatim Quotations of Participants

| Acceptability | |
|--|---|
| Perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory. | |
| Actually, I'd say that many health-care attendees, not 100%, or even 50%, rather 30 to 40%, are very happy. Not just happy, but very very happy... We are talking about individual interviews, aren't we? With health-care attendee and health professional. (Female physician, Basque Country) | |
| Feeling more confident about it yes, because probably I was not confident at all, see? I was talking about that. I have integrated it now, because I felt a bit insecure, and now, well, now I know I'm doing the right thing. (Woman, 52*, health-care attendee, Castilla-La Mancha) | |
| I think it's fine. The questions I'm asked, the blood tests with results that I know very well and that other issue. (Man, 70, health-care attendee, Andalusia) | |
| Generally speaking I'm happy with the intervention, I believe that with the EIRA project I have acquired tools to evaluate my daily work. They have been useful to us professionals because it has helped to structure, plan and prioritize our intervention. Motivation and decision-making with the patient have really contributed to achieve the objectives. (Female nurse, 40, Catalonia) | |
| I have found it truly interesting, but also very long and difficult to implement with our current work overload. (Female physician, 42, Catalonia) | |
| Appropriateness and feasibility | |
| Appropriateness is the perceived fit, relevance or compatibility of the innovation or evidence based practice for a given practice setting, provider or consumer; and/or perceived fit of the innovation to address a particular issue. | |
| Feasibility is the extent to which a new treatment or innovation can be successfully used within a given agency or setting. | |
| Experience of professionals | I think that the training on motivational interviewing has been interesting. (Female physician, 42, Catalonia) |
| | I would say no, we did not learn anything new. If it was meant to provide the same baseline for everybody, well, then fine. But we did not see it as what we actually had to deliver for the project, I mean, we saw it as something that they tell you and then you have to face the real thing. (Female nurse, 61, Castilla-La Mancha) |
| | Well, whenever we receive specific training we benefit, we become aware of many things that we don't do... we become more aware, we realise that we overlook some issues, in this sense it has been useful, sure. (Female physician, 42, Balearic Islands) |
| Coordination | Let's see, I really believe that this was planned top-down, and as a research project, well, it has been carried out in a hurry like all research projects, so the truth is we need more time for reflection. (Female nurse, 62, Aragon) |
| | I think that in our health centre all this work has mainly focused on the nurses ...we have not been as involved... I think that we should have coordinated better, I think that's a fair point. (Male physician, Basque Country) |
| Recruitment | The recruitment bit was the worst, seeing the patients between consultations, explaining about consent, that took a long time, and sometimes they did not even participate. (Female nurse, 39, Catalonia) |
| | The recruitment should be different, another model, because the participants are regular attendees, and they manage, they more or less manage their health. (Female nurse, 61, Castilla-La Mancha) |
| Baseline visit of allocated health professional | And what did you decide to work on? Mainly, the diet to lower cholesterol. And I have succeeded. (Man, 59, health-care attendee, Catalonia) |
| | Some have started with one and then become involved and used to it ...this here started walking and exercising and he finally has come for quitting smoking, he is a multiplier. I really think that this approach is very useful, to make them commit, when we talked about contract. The contract is crucial, when they realise that they have to sign the commitment form. (Male physician, 61, Andalusia) |
| | I thought it was fantastic, very good, wonderful, having a tool (i.e., prioritization algorithm) like that to assist you. (Female nurse, 26, Castilla-León) |
| Individual intervention | ... but the test of arteries and all that, they were really delighted with this. And also the people got confused, like with depression, mainly in patients with diabetes or that have been advised on diet and lifestyles for ages, they also mixed this with the study. (Female professional, 39, assistant researcher, Balearic Islands) |
| | I think it has been too short, basically a short question. Just a couple of interviews and that's it. (Man, 51, health-care attendee, Aragon) |

| | |
|---|---|
| Group intervention | For sharing and all that. It's wonderful. I think that in these matters the people benefit from the group. (Woman, 75, health-care attendee, Basque Country) ... the conflict of some doctors that have not quite grasped why the nurse went for a walk and protested "now I don't have a nurse, I want her to stay here", and these apparent trifles that if all perhaps ... just having patients from 5 GPs out of 11 has not worked out very well, maybe...the whole health centre should have participated... (Male physician, 42, Balearic Islands) |
| Community intervention | And in relation to community activities, like other times, it's always the same, it's difficult to get them started, it was hard to get them going, but it is eventually rewarding because they already ask when they will be happening again. (Female physician, Basque Country) Yes, but now it has stopped because it's unpredictable, it depends on the policies of the council, so now we have it and later we don't, and now they even have changed coordinator so my expectations... (Male nurse, 40, Catalonia) And the community assets should be better exploited. Here in our neighbourhood there are things available that we don't know about and then maybe talking I learn that a neighbourhood association organises fitness sessions. And the Council, they also have initiatives, the City Council has a programme with a doctor, let's say in charge of the programme, they have done it for a while and sometimes they have wanted to come, they even came here. (Male physician, 62, Castilla-León) |
| Patient information leaflets | That on depression too, what is anxiety, how to manage sleeplessness, patients have found it very interesting. (Female physician, 43, Andalusia) The information is very good, that on sleeplessness is outstanding. (Male physician, 61, Andalusia) |
| SMS and Webpage to support advice provided | Yes, yes, yes. Because it's a reminder that... that is good, and it's there. I don't delete it, it's there and sometimes I say, come on, I'll go and have a look. Yes, it's a reminder that's available. For me it's quite...good. (Woman, 52, health-care attendee, Castilla-La Mancha) Well, I very well, because I read that and really integrated that information. Sometimes I even laughed. (Woman, 47, health-care attendee, Catalonia) Just being as thoughtful as to send an encouraging message, it's great because sometimes it reaches you just when you most need it. (Woman, 55, health-care attendee, Catalonia) Even with the mobile phone and messages, the mobile phone, "my mobile is only to phone and to receive calls, no messages". Well, it's more difficult than anticipated. (Female nurse, 45, Aragon) Text messaging is really good, it's a very good idea and I think it has been used a great deal... the platform was meant for an age group of health care attendees with not very advanced IT skills. I really believe that our health care attendees, very few will have used this platform because they are not used to, they don't know how to use it and therefore, the platform has probably not been very useful, what do you think? I mean, you receive the message and you see it, and it seems that the mobile is easier to manage, while internet access... If you don't have internet access at home where are you going to read it? (Female nurse, 31, Castilla-La Mancha) |
| Data Collection Notebook (DCN) | You cannot register the commitment with the patient in the DCN, it's not even practical. It is not adapted to the commitment you make with the patient and that suggested is so cumbersome that it's impossible to see it through, that of physical exercise planned the, the objectives attainable in a week, during the week, during every day of the week (Physician, Balearic Islands) |
| Follow up | Many have refused to undertake the final evaluation because they had the baseline evaluation and did not implement the intervention or maybe, perhaps at the time they had problems to come to the health centre or had something else going on and they already disconnected, you and the patient, from the study and the evaluation and follow up never took place; and others that dropped out because they are not interested, they say not now because it's complicated, I have problems etc., I don't want to do it or... (Female professional, 39, assistant researcher, Balearic Islands) |
| Evaluation of intervention (baseline and final). Role of assistant researchers | ...it is essential to remain within the centre (laughs) because otherwise we left things undone and the possibility to be face to face, talking with them about things that I'm missing, that need completing...the coordination with them has worked well. (Female professional, 39, assistant researcher, Balearic Islands) I'm also having trouble with the internet connection because I don't have my own password and I don't have my own physical workspace, which results in work overload. (Female professional, assistant researcher, Castilla-La Mancha) |
| Sustainability | |
| The extent to which a newly implemented treatment is maintained or institutionalized within ongoing, stable operations of a service setting. | |
| Yes, I really think so, I think that with time it's doable. (Female nurse, Castilla-León) | |
| If you specifically mean this project, I think that I would consider depression separately. (Female physician, 55, Aragon) | |
| I liked it, well it's my opinion, it's one of these things that, I enjoyed doing and I would like to continue because there are aspects that, I don't know, that I find very positive. (Female nurse, Balearic Islands) | |

| | |
|--|--|
| We have talked about this in the Community Health Meeting that has just taken place and it seems that it mainly hinges on political will ... to include purposefully the activities in the portfolio of services, some proposals suggested to include community health in the portfolio of services, because otherwise it's always some kind of favour and that the... and therefore I believe that the top management should really rally behind it, to be able to expand, I think. (Female nurse, 62 , Aragon) | |
| The project can be extended to other centres, but it's crucial to adapt the schedule of the professionals that are in charge of these interventions, which might cause conflict with other professionals or additional burden for participants. Best to carry out the project with the whole team. (Female nurse, Catalonia) | |
| Penetration: changes implemented by health-care attendees and professionals after the intervention | |
| Integration of a practice within a service setting and its subsystems. | |
| Health-care attendees | <p>...every now and then it's good to get it out even if it's by answering questions I used to think about the questions that he asked, which since my life is so hectic I had not even considered. (Woman, 55, health-care attendee, Catalonia)</p> <p>I feel very well, very well. More fit and all that. Well, at first to climb to the eight floor was so very challenging. I feel better. All in all, it has worked for me. (Woman, 62, health-care attendee, Basque Country)</p> <p>...it has helped, before I used to smoke anything I could find and now I smoke 5 or 6 or 7 more or less. But before I used to smoke much more. (Woman, 47, health-care attendee, Catalonia)</p> <p>Yes, let's see, before I didn't have nuts and now I know that they are good for me. So now I feel good when I eat them, because I eat them now. Fruit? Well, I didn't have that much and... and now I eat more. (Woman, 52, health-care attendee, Castilla-La Mancha)</p> <p>Do you think that all this has been helpful? I think so, more so because I lacked willpower, and taking all literally and it has been like a push, a push. (Man, 59, health-care attendee , Catalonia)</p> <p>Yes, it has helped... it also helped a lot mentally, for my own reflection. I needed it badly, because I felt very unhappy, unemployed, I carried a lot of luggage. My family far away, I was suffering... I still have lots to do, it was very very very useful. (Woman, 47, health care attendee, Catalonia)</p> <p>I even spoke to my children after that (...) and I told them: If you are going to give me something give it to me while I'm alive, love, affection... don't do, you don't have to do anything for me. (Woman, 55, health-care attendee, Catalonia)</p> <p>About walking, I've tried, it has been a very complicated period because I've had very difficult family issues ... but I've tried to walk a bit more (Woman, 58, health-care attendee, Castilla-León)</p> |
| Health professionals | <p>...to be more aware maybe toward the patient. I think it has been useful, perhaps not for everybody, I don't know, the feeling is that, we act sensibly and that yes, that we have to encourage it more, but I don't know how. (Female physician, 42, Balearic Islands)</p> |

These quotations were translated by a professional scientific bilingual translator. Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 5: Suggestions for improving the intervention according to participating health care attendees and professionals

| | Health-care attendees | Primary health care professionals and assistant researchers | Quotations |
|-------------------------------|--|---|---|
| Training | | More practical training, in particular regarding the online Case Report Form. More training on motivational interview and on the approach to risk of depression. | I think that the concepts were explained, they talked about nutrition, this and that... but not with the platform and we needed to do it in front of the platform. More practical workshop, practice it before starting and for all of us to do the same. (Female nurse, 61, Castilla-La Mancha) |
| Organisation and coordination | | Improve the flow of information and communication within institutions and work groups. Specify the responsibilities of each professional (what, how, when, where). Create a shared agenda. Involve all staff in the PCC. Guarantee connectivity and computers in working order. Shift current agenda to commit more time to health promotion. Actively involve community and institutions. | Regarding the project coordination for doctors and nurses, maybe the area of community prescription with other organisations and entities. (Male physician, 62, Castilla-León) It is important that we get involved and that the authorities get on board to disseminate the healthy lifestyles, what we have now with food in the supermarkets, to label fat and sugars much more clearly, in short, we need to send the message that nutrition is crucial. This will determine if we are more or less sick in the future, and the same goes for depression. I mean, if we do not take it seriously now we will end up with wonderful medicines to patch up all these diseases but... (Female physician, 43, Andalusia) |
| Recruitment | | Extended period avoiding peak times. Extend consultation length. Involve all staff in the PCC. | And the recruitment has been hard, because when we have got 60, it means that we have seen 120. Or even more than that. And of course, and this within the daily schedule is hard. In fact, it's not even feasible. You can only do this for a short while. (Female nurse, 61, Castilla-La Mancha) |
| Individual intervention | Continuity of follow up. Increase frequency of visits to be able to talk. More specific advice. | Availability of referral specialists for each type of behaviour (each professional should manage the behaviours where she feels more competent). Promote the motivational interview. Social assessment of participant. Consider the results perceived by the people. Continuity of follow up. Promote the role of nursing in the follow up. | Well...I'd say that...it's working fine with these improvements I've just mentioned ...extend length of consultation...give direct advice... (Man, 51, health-care attendee, Aragon) I would add some manner of social assessment, some evaluation of social interaction... of going out, if she socialises... For instance, I would include more questions on prevention of social isolation... (Female nurse, 62, Aragon) |
| Group intervention | Enhance group activities. | Enhance group activities. | Actually... the... the topic... I think it is well presented... maybe what I missed was... well... what I mean with a meeting... not with a big group... perhaps six or eight people... for each person to be able to talk about what they want to talk... what they do... (Man, 64, health-care attendee, Aragon) |
| Community intervention | | Reaching out to the community. | I really believe that we need to change, we need to completely rethink nursing, because it should become more community oriented, we should reach out more. It is already happening in other countries like Great Britain and others, where the nurse spends more time in the community than inside the consultation room of the surgery, that's why I reckon that they'll need to rethink, I don't know, it's just my opinion (Female physician, Balearic Islands) |
| Patient information leaflets | | Review patient information leaflets on physical activity and depression | ... with stretching exercises, with... an idea of the type of exercise recommended for them, I think. Some more guidance, because I'm not an expert on this, I know very little about it, really, as a professional, and as a patient it's even worse. (Female nurse, Basque Country) |
| SMS | Pay attention to time when sending SMS. | | Yes, about that... once I got an SMS at 12.30 at night, at 12.30 at night it does not make any sense, I'm on standby for my father and the phone might ring (Man, 59 years, health-care attendee, Catalonia) |

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|---|--|---|---|
| Webpage | | More dynamic, user-friendly and practical. | And after the ICT tool, I would like to see a warning like a summary with a very clear idea of what you have to do next, you know “book an appointment in a month” or “no”, you know? (Female physician, 45, Balearic Islands) |
| Online Case Report Form | | Easier and more practical. Possibility during follow up to register priority changes in the behaviours or risks to be modified. Systematic recording of drop outs and causes. | Yet again, this platform does not allow you to register the commitment of the patient and it is not practical. It does not reflect the agreement that you reach with the patient and the one suggested is so cumbersome that it is impossible to fulfil... (Male physician, Balearic Islands) |
| Evaluation of the intervention (Assistant researchers) | Explain results of questionnaires and tests during the visit. | Structured support for the assistant researchers. Move the 3-month blood test to 6 months. | That the assistant researchers were here on a permanent basis. For the whole duration of the study. Not just come one day and we'll see. Here during our same working hours (Female nurse, 31, Castilla-La Mancha) |
| Project dissemination | Use of various strategies to disseminate to the community the different phases of the project and the results. | Use of various strategies to disseminate to the community the different phases of the project and the results. | I'd say that mainly, for instance mmm... How can I put it? Go some day to places like a marketplace, you know, to talk to people (Woman, 47, health-care attendee, Catalonia) ... to promote it, so that people know it exists, and of its purpose when they see it, listen what is this in that case I'd like, I mean, for people to see that this study is happening, experimental or pilot or whatever you call it, but that they can access that programme, that screening. (Female nurse, 60 years, Castilla-La Mancha) |

These quotations were translated by a professional scientific bilingual translator. Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Figure 1: Second phase (development of an exploratory trial) of the EIRA Project, which follows the UK Medical Research Council framework for complex interventions

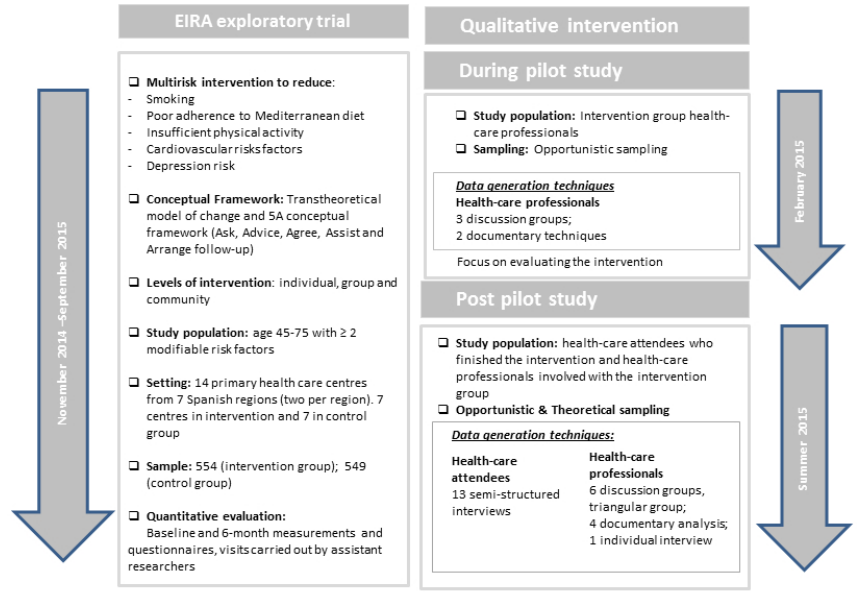


Figure 1: Second phase (development of an exploratory trial) of the EIRA Project, which follows the UK Medical Research Council framework for complex interventions

81x60mm (300 x 300 DPI)

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No Item | Guide questions/description | Reported on Page |
|--|--|---|
| Domain 1: Research team and reflexivity | | |
| <i>Personal Characteristics</i> | | |
| 1. Interviewer/ facilitator | Which author/s conducted the interview or focus group? | Contributors, page 17 |
| 2. Credentials | What were the researcher's credentials? E.g. PhD, MD | Mariona Pons-Vigués (PhD), Anna Berenguera (PhD), Núria Coma-Auli (Nurs.), Sebastià March (Sociol.), Haizea Pombo (PhD), Barbara Masluk (Psych.), Montserrat Pulido-Fuentes (PhD), Carmela Rodriguez (Nurs.), Juan Ángel Bellón (PhD, MD), Enriqueta Pujol-Ribera (MD). |
| 3. Occupation | What was their occupation at the time of the study? | Affiliations, page 1 |
| 4. Gender | Was the researcher male or female? | 8 female + 2 male |
| 5. Experience and training | What experience or training did the researcher have? | Contributors, page 17 |
| <i>Relationship with participants</i> | | |
| 6. Relationship established | Was a relationship established prior to study commencement? | The interviewer of one of the primary health centre could know the professionals |
| 7. Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. personal goals, reasons for doing the research | Sample design and participant selection strategy, page 8 |
| 8. Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic | Sample design and participant selection strategy, page 8 |
| Domain 2: study design | | |
| <i>Theoretical framework</i> | | |
| 9. Methodological orientation and Theory | What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis | Methods, page 8 |
| <i>Participant selection</i> | | |
| 10. Sampling | How were participants selected? e.g. purposive, convenience, consecutive, snowball | Sample design and participant selection strategy, page 8 |
| 11. Method of approach | How were participants approached? e.g. face-to-face, telephone, mail, email | Sample design and participant selection strategy, page 8 |
| 12. Sample size | How many participants were in the study? | Data collection and generation techniques, page 8 Tables 1 and 2 |
| 13. Non-participation | How many people refused to participate or dropped out? Reasons? | Sample design and participant selection strategy, page 8 |
| <i>Setting</i> | | |
| 14. Setting of data collection | Where was the data collected? E.g. home, clinic, workplace | Sample design and participant selection strategy, page 8 |
| 15. Presence of non-participants | Was anyone else present besides the participants and researchers? | Data collection and generation techniques |
| 16. Description of sample | What are the important characteristics of the sample? e.g. demographic data, date | Tables 1 and 2 |
| <i>Data collection</i> | | |
| 17. Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Data collection and generation techniques, page 8 Table 3 |
| 18. Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. Audio/ visual recording | Did the research use audio or visual recording to collect the data? | Data collection and generation techniques, page 8 |

| | | |
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| 20. Field notes | Were field notes made during and/or after the interview or focus group? | Data analysis, page 9 |
| 21. Duration | What was the duration of the interviews or focus group? | Data collection and generation techniques, page 9 |
| 22. Data saturation | Was data saturation discussed? | Data collection and generation techniques, page 9 Rigour and quality criteria, page 9 |
| 23. Transcripts returned | Were transcripts returned to participants for comment and/or correction? | No |
| Domain 3: analysis and findings | | |
| <i>Data analysis</i> | | |
| 24. Number of data coders | How many data coders coded the data? | Data analysis, page 9 |
| 25. Description of the coding tree | Did authors provide a description of the coding tree? | Data analysis, page 9 Results, page 11 Tables 4 and 5 |
| 26. Derivation of themes | Were themes identified in advance or derived from the data? | Data analysis, page 9 |
| 27. Software | What software, if applicable, was used to manage the data? | Data analysis, page 9 |
| 28. Participant checking | Did participants provide feedback on the findings? | No |
| <i>Reporting</i> | | |
| 29. Quotations presented | Were participant quotations presented to illustrate the themes /findings? Was each quotation identified? e.g. participant number | Tables 4 and 5 |
| 30. Data and findings consistent | Was there consistency between the data presented and the findings? | Table 4 and 5 |
| 31. Clarity of major themes | Were major themes clearly presented in the findings? | Results, page 11 Tables 4 and 5 |
| 32. Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Results, page 11 Tables 4 and 5 |

BMJ Open

Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

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| Primary Subject Heading: | General practice / Family practice |
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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

Authors

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Competing interests: The authors declare no conflicts of interest.

Ethics approval: The study was approved by the Research Ethics Committee of the IDIAP Jordi Gol (2013; P12/073). The authors guarantee the accuracy, transparency and honesty of the data and information contained in the study.

Patient consent: Obtained.

Data sharing statement: No additional data are available.

Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

ABSTRACT

Objective: To evaluate the implementation and development of a complex intervention on health promotion and changes in health-promoting behaviours in primary health care according to health-care attendees and health professionals.

Design: Descriptive qualitative evaluation research conducted with 94 informants. Data collection techniques consisted of 14 semi-structured individual interviews, 9 discussion groups, 1 triangular group and 6 documents. Three analysts carried out a thematic content analysis with the support of Atlas.ti software. This evaluation was modelled on Proctor and colleagues' concept of outcomes for implementation research.

Setting: 7 primary care centres from 7 Spanish regions: Andalusia, Aragon, Balearic Islands, Basque Country, Castilla-La Mancha, Castilla-Leon and Catalonia.

Participants: The study population were health-care attendees (theoretical sampling) and health professionals (opportunistic sampling) who had participated in the exploratory trial of the EIRA intervention (2015).

Results: Health-care attendees and professionals had a positive perception of the study. Health-care attendees even reported that they would recommend participation to family and friends. Health professionals became aware of the significance of the motivational interview, especially for health promotion, and emphasized social prescribing of physical activity. They also put forward recommendations to improve recruitment, screening and retention of participants. Health-care attendees modified behaviours and health professionals modified working practices. To achieve sustainability, health professionals believe that it is crucial to adapt agendas and involve all the staff.

Conclusions: The discourses of all stakeholders on the intervention must be taken into consideration for the successful, setting-specific implementation of adequate, acceptable, equitable and sustainable strategies aimed at health promotion and well-being.

Keywords: Complex interventions; Implementation Research; Evaluation; Health Promotion; Health Behaviour; Primary Health Care; Qualitative Research.

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Abbreviations

CRF: Case Report Form

DG: Discussion Groups

DT: Documentary Technique

MRC: Medical Research Council

PCC: Primary Care Centre

PHC: Primary Health Care

SI: Semi-structured Interview

SMS: Short Message Service

TG: Triangular Group

Strengths and limitations of the study

- The sampling method of the qualitative evaluation might only have captured the experiences and views of the professionals and attendees more involved and positive with regard to the intervention and to health promotion.
- The rigour procedures applied (methodological adequacy, triangulation of techniques and analysis and reflexivity of the interdisciplinary research team) ensured the validity and reliability of the findings.
- The richness and complementarity of the information generated by health-care attendees and health professionals from seven distinct regions will contribute to the adaptation of the intervention to the various settings to ultimately achieve feasible, sustainable integration in everyday primary care practice.

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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

BACKGROUND

Primary Health Care (PHC), the most accessible and most frequently used health service, provides comprehensive, long-term person-focused care [1]. It is considered the ideal setting to implement individual, group and community health promotion interventions. However, these implementations face barriers and challenges set up by the system, the professionals and the public [2,3].

Since it is very common for the same person to accumulate interrelated unhealthy behaviours, complex interventions are increasingly used in studies of behavioural change. In addition, first-hand knowledge of the setting where health promotion takes place is crucial when evaluating its effect. Complexity results from the number of interacting components, namely the amount and difficulty of behaviours required by those delivering or receiving the intervention, the number of groups or organizational levels targeted, the number and variability of outcomes and the degree of flexibility of the intervention [4,5]. The main directives for the design, implementation and evaluation of complex interventions were developed by the Medical Research Council (MRC)[4,6,7] using a mixed-method approach with five sequential phases: i) definition of the theoretical foundation (preclinical phase), ii) construction of a model (phase I), iii) development of a pilot study (phase II), iv) completion of the definitive trial (phase III), and v) long-term implementation (phase IV).

The EIRA project started in Spain in 2012 with the objective to modify unhealthy behaviours in primary care patients following the MRC framework for complex interventions [6,7]. To date, the first 3 phases have been completed [2,3,8–10]. Specifically, the objective of the EIRA Project was to design, conduct and evaluate a complex, multi-risk intervention to enhance adherence to the Mediterranean diet, increase insufficient physical activity and reduce smoking, cardiovascular risk factors and risk of depression in people aged 45 to 75 years that contact primary health care services with at least two of these behaviours or risk factors. Participants receive individual recommendations on their behaviour and risk factors and they are offered to attend group sessions and social prescription of health promoting community assets. The person-centered approach uses the motivational interview and the attendee becomes an active agent in her own life. Participants allocated to the control group receive the usual care (Figure 1).

A key question in evaluating a complex intervention is actual effectiveness. However, the process itself is also important: what happens, how, when and why. The process evaluation in trials explores the implementation of an intervention, assesses its quality and fidelity, clarifies causal mechanisms and

identifies contextual factors associated with variation in outcomes [4,11]. Qualitative methodology has a unique role in understanding the implementation process of an intervention [12]: Interestingly, qualitative research can be used concurrently with a pilot trial, for instance to optimise recruitment and informed consent strategies, to identify acceptability of the intervention, to provide insights into processes of change and to help interpret findings [13]. Accordingly, the qualitative evaluation of the intervention implementation process is able to identify determinants of clinical practice such as barriers and facilitators that influence the adoption of organizational and professional change [14]. This qualitative evaluation facilitates understanding of how and why the different components of the intervention are successfully or unsuccessfully implemented; it also contributes to identify predictive factors of success and generates useful knowledge for advancing the implementation of scientific evidence [15]. In addition, the qualitative methodological perspective might transcend the main limitations of the quantitative approach that prevails in clinical trials, and provides essential information on the evaluation of interventions, since it involves the different stakeholders, which actively convey their experiences, opinions, needs and suggestions for improvement.

This qualitative evaluation presents the results of the second phase (development of an exploratory trial) of the EIRA Project. The objective was to evaluate (1) the process of implementation and development of a complex intervention on health promotion in primary care according to health-care attendees and health professionals and (2) changes in health-promoting behaviours.

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METHODS

Design

Descriptive qualitative research based on the experiences of participants was used to evaluate the exploratory trial of the EIRA complex intervention.

Setting and study population

Seven primary care centres (PCC) included in the intervention group of the EIRA Project from 7 Spanish regions (1 PCC per region) participated: Andalusia, Aragon, Balearic Islands, Basque Country, Castilla-La Mancha, Castilla-Leon and Catalonia. The control group of the exploratory trial did not participate in the qualitative evaluation.

The study population were: a) PHC professionals from participating PCC (including family physicians, primary care nurses, social workers and administrative staff) and assistant researchers (in charge of performing baseline and 6-month measurements and questionnaires); and b) health-care attendees aged 45 to 75 years who participated and completed the EIRA study.

Sample design and participant selection strategy

PHC professionals from participating PCC and assistant researchers were selected by means of opportunistic sampling [16]. The site investigator of each PCC contacted all professionals who participated in the EIRA study to book group interviews 2-3 months after the beginning of recruitment (February 2015 in 3 centres) and at the end of the intervention (summer of 2015 in the 7 centres of the intervention group). The decision of PHC professionals to participate in the group interviews was voluntary. For health-care attendees we applied theoretical sampling based on a prior definition of participants' characteristics to obtain optimal variety and discursive wealth [16]. Fifteen informant profiles emerged from the discursive variants sex, age, educational level and type of intervention (the approach to the first component of the intervention was decided by the participant). Next, two of these profiles were randomly allocated to each PCC included in the intervention group of the EIRA Project; one PCC had 3 profiles. At the end of the intervention (summer 2015), the site investigator of each PCC contacted by phone the health-care attendees participating in the EIRA project who met the specific informant profile for the PCC to explain the objectives of the qualitative evaluation and invited them to participate in an interview. The voluntary aspect of participation was also emphasized to health-care attendees.

Data collection and generation techniques

Conversational techniques were used for PHC professionals: 3 discussion groups in February 2015 and 6 discussion groups at the end of the intervention, in the summer of 2015; 1 triangular group (a meeting of 3 people to discuss together a topic or issue with the aim of ascertaining the range and intensity of their views) [17]; and 1 individual interview with a community agent. In addition, we collected the written reports of 6 professionals who could not attend the discussion groups because of scheduling conflict (2 documentary techniques in February and 4 in summer). Table 1 details the main characteristics of the 81 PHC professionals who participated in the study.

Semi-structured individual interviews were used to collect information from health-care attendees. We initially planned a semi-structured individual interview for each of the 15 profiles of informant; however, 2 semi-structured individual interviews could not take place because the participants could not be contacted after the end of the study. We finally held 13 interviews with health-care attendees. Table 2 shows the characteristics of these 13 participants.

In total, data collection techniques consisted of 14 semi-structured individual interviews, 9 discussion groups, 1 triangular group and 6 documents. Semi-structured individual interviews, discussions groups and triangular group followed a topic guide with open-end questions, with some adaptations according to type of informant and study period (Table 3). The topic guides were based on a review of the literature and the objectives of the study. After obtaining informed consent from the participants, all interviews were audio or audio and video recorded. The discussion groups took place in the PCC with one moderator and one observer, and lasted between 90 and 120 minutes. Semi-structured individual interviews took place in a setting accessible for the health-care attendees and lasted between 15 and 60 minutes. The field work was carried out in each region by qualified interviewers with experience in qualitative research. Informative richness for a deeper understanding of the development and implementation of the intervention was achieved.

Data analysis

All interviews and discussion groups were transcribed verbatim and de-identified by trained personnel [18]. A thematic content analysis was carried out [19,20] with the support of Atlas.ti software. The data were analysed as follows by 3 researchers (NCA, MPV and EPR, a nurse, a pharmacist and a physician, respectively): 1) formulation of preanalytical intuitions after successive readings of the transcriptions and the notes from documentary techniques; 2) creation of an initial analytical plan and text codification; 3) creation of categories by grouping the codes according to the analogy criterion based on Proctor and colleagues' model of outcomes for implementation research [21] and new elements from the discourses; 4) analysis of

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each category and relationship with the others.; and 5) elaboration of the new text with the main results. These results were presented and discussed in a meeting with all research members of the EIRA project (January 2016).

Rigour and quality criteria

To guarantee quality and rigour we adhered to the following recommendations [22, 23]: description of the intervention, the context, the participants and the research process; methodological adequacy; working with different actors; triangulation of techniques (comparison of data obtained by means of different information collection techniques) and analysis (contrasting and comparing the data analyses performed by different analysts to strengthen the credibility and confirmability of the study results); and reflexivity of the interdisciplinary research team. Sufficient data were collected to meaningfully answer the research question.

Ethical considerations

This study followed the tenets of the Declaration of Helsinki and was approved by the Research Ethics Committee of the IDIAP Jordi Gol (2013; P12/073). All participants signed the informed consent form. Anonymity, confidentiality and data protection were guaranteed.

Patient and public involvement

Study participants were not involved in the development of the research question or the outcome measures nor the design of the study. The results will be presented to study participants and citizens through informative activities and the media.

RESULTS

The results are classified in 5 categories: acceptability, appropriateness and feasibility, sustainability, penetration (changes implemented) and suggestions for improvement. Table 4 shows the definitions of these categories complemented with illustrative quotations from the discussions. .

Acceptability

In general, health-care attendees and health professionals reported satisfaction with their participation and their final evaluation was positive. Health-care attendees described being thankful to the professionals for their support and they explained that they felt more confident making decisions about the process of change. All health-care attendees interviewed would recommend participating in the study to family and friends, and in fact some had already done it. They affirmed that participation requires being ready to pay attention, to listen and to reflect.

Health professionals believed in health promotion and while they did not consider the contents of the intervention innovative, they indicated that it changes working practices, notably the systematization of recommendations and the boost of social prescription. However, they remained critical and underscored that the project was too ambitious, too long, somehow unclear and unorganized, which led to confusion during implementation. They specifically highlighted difficulties in the approach to risk of depression. Moreover, in some primary care teams tension emerged between professionals that participated and their non-participating colleagues.

Appropriateness and feasibility

The results have been categorised according to the phases of the study:

Although some professionals considered that the training conducted prior intervention was appropriate and provided new concepts, they maintained that it was insufficient for the actual implementation of the intervention, specifically concerning the motivational interview and the approach to risk of depression. There was no practical training in the use of online Case Report Forms (CRF) and in one of the centres the training was provided too early. Some theoretical aspects could not be translated into practice due to lack of time or skills.

With regard to coordination, the professionals found the meetings with the research team useful. However, it was sometimes unclear how to proceed, how to give appointments and refer health-care attendees for follow up or who was responsible for reviewing the study tests. In addition, some procedures were changed after the start of the study. Reiteration of questions and lost to follow up were generated by the complexity of circuits and the lack of communication between professionals.

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Most professionals agreed that **recruitment** involved a higher workload than anticipated and that it took place in a short timeframe. They explained that it was difficult to explain the study and to encourage health-care attendees to participate, and they believed that many enrolled because they felt obliged to their professionals. Health-care attendees explained that they participated because they thought it was interesting, they had time and they felt obliged to their regular health professionals.

Professionals pointed at a selection bias caused by the recruitment of frequent attenders, patients generally better controlled and more motivated. No random systematic sampling was applied and any reason for consultation was accepted. Several professionals from the selected PCC declined participation. In particular, few admission staff chose to take part and their involvement was often hurried and uncoordinated, which increased the workload of the professionals involved in the study.

First visit with the health professional (prioritization of behaviours to modify and intervention plan): Most health -care attendees evaluated positively their involvement in decision making and many explained that they participated in the prioritization of behaviours and risks that needed changing. Patients asserted that trust in the health professional facilitates change. Health professionals evaluated positively the patients' assessment of their own risk behaviours followed by the decision about which behaviours to modify. Professionals also indicated that the prioritization algorithm was useful.

Individual intervention: Health-care attendees believed that the advice was useful and applicable and they felt that health professionals really cared and listened to them. They emphasized that in comparison to usual visits health professionals had more time to attend them without rush and to do a holistic valuation. The health-care attendees that received health promotion recommendations in regular practice mixed them up with the intervention advice of the study. They also mixed up the clinical intervention with the collection of information for the clinical trial. They thought that the follow up period should be extended and include more people. The professionals were positive about the person-centred approach and have become more aware of the significance of the motivational interview and of health promotion.

Group intervention: Group activities focused on physical activity and nutrition. Health-care attendees explained that sharing experiences was positive, they established new relationships and organized walking groups. Some professionals reported that these activities are difficult to implement due to lack of time. For others, these activities do not fall within their duties (they considered them additional activities or simply going for a stroll with health-care attendees).

Community intervention: Although few centres used activities already popular in the neighbourhood, social prescription was very positively evaluated both by health-care attendees and professionals. Most physical activities prescribed were organized by the town councils. For professionals, social prescription was a novel concept, and they emphasized that adherence is unknown since attendance was not registered.

Health education leaflets: Health-care attenders favoured personal contact over patient information leaflets. However, the few comments received on leaflets are all positive, especially those about diet or mental health. Health care professionals considered that the leaflets were a useful tool, particularly regarding diet, and even patients who did not participate in the study received them. They also believed that health-care attendees appreciate written information.

SMS and health education webpage: Few health-care attendees agreed to receive SMS, but those that accepted explained that SMS were helpful and encouraging. Professionals considered SMS useful reminders. The webpage was hardly accessed, for which health-care attendees and professionals provided various reasons: lack of recommendation, no access to computers/ Internet, lack of motivation, and feeling uncomfortable sitting in front of a screen.

The professionals believed that the study **online CRF** was too complicated, too slow and that it was difficult to register personalised agreements. Also, since the programme was separate from the electronic health records, they had to work with both programmes simultaneously. In addition, poor internet connection slowed the work of some professionals.

Health professionals indicated that **follow up** data such as adherence rates were somewhat unclear and would be interested in learning about the final results. They believed that retention of participants might be determined by difficulties in attending the intervention visits, loss of interest and the perception that no added value is attached to these interventions.

Evaluation of the intervention (baseline and final) – role of the Assistant researchers: Generally, health-care attendees evaluated positively the questionnaires and tests carried out by the assistant researchers (blood tests, evaluation of vascular health, etc.) because they felt listened to and had more time to talk. The professionals believed that health-care attendees felt well cared for because they spent sufficient time with the interviews. The assistant researchers indicated that they had to administer too many questionnaires. They also pointed at the following issues: insufficient information, lack of their own working space, irregular access to the CRF and lack of authorisation to consult the medical history of health-care attendees.

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Sustainability

Some professionals considered that it is important to extend this intervention to other PCC but underscored the need for the support of institutions, for extended consultation length and the involvement of all professionals. In addition, risk of depression remains a controversial component of the intervention. Some professionals would exclude it altogether, while others believed that it needs a different approach.

Penetration: Changes implemented by health-care attendees and professionals after the intervention

Health-care attendees reported increased motivation and knowledge of healthy behaviours and feeling more positive toward change. Those working with physical activity and nutrition explained that they implemented changes and described high levels of satisfaction: they walked more, got less tired and felt fitter, ate healthier (smaller amounts, more vegetables, fruit and nuts and use of olive oil) and some stated that they drank less alcohol. They also stated that they smoked less cigarettes. Professionals agreed that health care attendees made an effort to meet their objectives, to implement changes and to start healthier habits.

The barriers for change according to health-care attendees were: family responsibilities (care of the sick, care of grandchildren, house chores, etc.), life-work imbalance, weather conditions and lack of willpower. The professionals agreed with these barriers and added financial issues and unawareness of the need to change. Facilitators of change according to health-care attendees were: group activities and trust in health professionals. For health professionals, the health-care attendees should decide which behaviours to modify because their commitment implies autonomy and empowerment and facilitates change.

The professionals reflected on how to approach health promotion in primary care: with a holistic view of health care attendees, providing evidence-based advice, being more purposeful, using motivational interview, involving the family and prioritizing social prescription. Participation in the intervention facilitated a deeper knowledge of health-care attendees and extended consultation length. Professionals reported improvement in the assessment and register of activities in the electronic health records.

Suggestions for improvement

Table 5 shows the discourses and suggestions for improvement of participants.

DISCUSSION

Overall, health professionals and health-care attendees shared a positive perception of their participation in the study. Indeed, health-care attendees would even recommend it to family and friends. Health professionals realised the significance of the motivational interview, in particular with regard to health promotion. They also underscored the potential of social prescribing in relation to physical activity. In addition, health professionals put forward suggestions to improve recruitment, screening and retention of participants. Health-care attendees modified behaviours and health professionals revised working practices. According to health professionals, the continuity of this programme is contingent upon adapting agendas and involving all staff.

We regard the positive attitude of health-care attendees and health professionals toward this health promotion multibehavioural intervention as an endorsement of the definitive trial of the EIRA project. However, we acknowledge that the current version of this intervention cannot yet be integrated in primary care practice until fundamental organisational changes that ensure feasibility and sustainability in real world conditions take place. Even though the intervention was adapted and implemented following the recommendations of health-care attendees and health professionals obtained in prior phases of the EIRA project [2,3, 8–10], further adjustments are required. For instance, in the EIRA project we concluded that for health promotion it is essential to involve most primary care professionals, including administrative staff, to avoid tension and to challenge the notion that health promotion is voluntary or based on personal preference. It is also important to reduce the work overload (objectively high), to simplify recruitment and screening questionnaires and to modify the approach to emotional discomfort and risk of depression. On the other hand, it is crucial to participate in the dissemination of social prescription and to continue the research in implementation strategies focusing on equity and on improving overall results. It has also been observed that primary care professionals require more resources, time, skills and motivation to reach out and work with the community in health promotion [24].

Health-care attendees reported high levels of satisfaction with the study because they felt that professionals gave them enough time and listened to their needs and preferences. They also felt supported during the process of change and were able to initiate sustainable healthy behaviours. We might thus conclude that the intervention encouraged a holistic, person-centred approach underscoring the key role of the primary care professional and of the motivational interview as a useful strategy to promote behavioural change [25]. The motivational interview requires training and extended consultation times [26], and although health professionals received basic training (4 hours at the beginning of the study), most agree that further training is required.

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Although some health professionals underscored the pivotal role of primary health care to manage risk of depression, many worried about lack of skills, attitudes, tools and experience, in agreement with others authors [27]. In addition, some health-care attendees had a positive opinion about the opportunity to know their depression risk [28]. To some extent, the recommendations to manage emotional discomfort in primary care take all these views into account [29]. The real objective of the first approach is to ascertain the nature of the emotional discomfort by means of active listening, probing and empathy to understand the meaning, adaptability and problem solving skills of each person to avoid chronification and medicalization.

This project encourages participation in community activities, particularly physical activity, even though many participants did not follow these recommendations. In agreement with the results of the systematic review by March et al., which shows that in primary care preventive interventions the community might be more effective than the individual approach [30], health professionals underscored a more systematic use of social prescription in regular practice, which indicates an interest in implementing a more biopsychosocial model [31]. This qualitative assessment suggests that despite early resistance, professionals and health-care attendees became eventually aware of the importance of the community components of health promotion interventions. In addition, the feasibility of community recommendations is suggested as a selection criteria of PCC with capability to develop complex health promotion interventions based on networks that identify, promote and evaluate local health assets [32]. In contrast, despite the growing holistic, psychological and collective conception of health [9], the persistence of the biomedical paradigm is shown by the positive evaluation of medical tests by health-care attendees.

Most professionals and health-care attendees considered SMS, a low cost method that preserves privacy, useful for people with mobile phones. This outcome is consistent with other studies which suggest that SMS are effective in health promotion interventions, particularly regarding quitting smoking and physical activity, where SMS can be used to provide positive feedback in order to effect and maintain behavioural change[33–35]. In contrast, the webpage was not considered useful for participants, in agreement with other studies which stress the relevance of the patient-health professional relationship [35,36].

Limitations and strengths

In the EIRA project, health-care attendees and health professionals provided information and were consulted about the development and evaluation of the intervention. However, further steps toward deeper changes in research practice should involve more effective participation in decision making [37].

Despite the use of theoretical sampling for health-care attendees, the voice of participants with higher education qualifications (only 6% in the pilot trial) was insufficient. Also, the voluntary character of participation of health care attendees and professionals in this qualitative evaluation might imply that only the experiences and opinions of people with a positive view of the intervention and of health promotion were collected. On the other hand, the detailed description of less successful aspects, the polarization of professionals regarding the benefits of the study and the suggestions for improvement point at a diversity of standpoints. We believe that it is nonetheless fundamental to add the perspective of less motivated professionals and of participants that dropped out or that simply decided not join the study. Although participants of this qualitative study and of the EIRA Project comprise people from various geographical origins, the contribution of particularly vulnerable individuals (female carers, immigrants and people with precarious employment) remains inadequate. This subpopulation probably lack sufficient time and need more attention regarding health promoting behaviour. More research is needed to further understanding of vulnerable patients.

One strength of the study is the use of the MRC approach for the design, implementation, and evaluation of complex interventions [4,6,7]. The following phase of the intervention (definitive trial) will more specifically adapt to the people and setting and will be more sustainable thanks to the richness and complementarity of the information generated by health-care attendees and professionals from these seven regions. The evaluation process was also analysed by quantitative methods (paper under construction), but considering the limited sample of the pilot trial and the low response rate to questionnaires, qualitative evaluation has proven crucial to understand how health-care attendees and professionals perceive the intervention. Moreover, the rigour procedures applied ensured the validity and reliability of the findings. Although the authors of the current evaluation are also members of the EIRA research team, positive and negative information on the intervention was rigorously collected to deepen understanding on the components that need improvement (see Table 5).

Conclusions

The discourses of all stakeholders with regard to the intervention must be taken into consideration for a successful, setting-specific implementation of the most adequate, acceptable, equitable and sustainable strategies for health promotion and well-being.

CONTRIBUTORS: MPV, AB and EPR designed the study and wrote the protocol. EPR, MPV, AB, BM, MPF, SM, HP, CR and JAB participated in data collection and generation techniques. MPV, NCA and EPR conducted the

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analysis. All authors contributed to the interpretation of results. MPV, AB and EPR wrote the first draft of the manuscript. All authors read, contributed and approved the final version of the manuscript.

For peer review only

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Table 1: Description of participating health-care professionals according to study period and region

| Date | Region | Technique* | Participants | Age | Sex | Occupation |
|-----------------------------------|--------------------|------------|--------------|--|---------------------|---|
| February 2015 | Balearic Islands | 1 DG | 13 | 6 age 30-49 years 7 age 50-65 years | 9 Female 4 Male | 1 Administrative staff 5 Nurses 5 Physicians 2 Psychologists, one assistant researcher |
| | Castilla-La Mancha | 1 DG | 6 | 1 under 30 years 1 age 30-49 years 4 age 50-65 years | 5 Female 1 Male | 6 Nurses |
| | | 2 DT | 2 | Missing information | 2 Female | 2 Assistant researchers (nurses) |
| | Catalonia | 1 DG | 8 | 7 age 30-49 years 1 age 50-65 years | 7 Female 1 Male | 6 Nurses 2 Physicians |
| Summer 2015 – end of intervention | Andalusia | 1 DG | 5 | 1 age 30-49 years 4 age 50-65 years | 1 Female 4 Male | 5 Physicians |
| | Aragon | 1 DG | 4 | 2 age 30-49 years 2 age 50-65 years | 3 Female 1 Male | 3 Nurses 1 Physician |
| | Balearic Islands | 1 DG | 9 | 4 age 30-49 years 5 age 50-65 years | 7 Female 2 Male | 1 Administrative staff 1 Assistant researcher (psychologist) 3 Nurses 4 Physicians |
| | | 1 DT | 1 | 1 age 30-49 years | 1 Female | 1 Assistant researcher (psychologist) |
| | Basque Country | 1 DG | 11 | 2 under 30 years 3 age 30-49 years 6 age 50-65 years | 10 Female 1 Male | 1 Administrative staff 1 Assistant researcher 4 Nurses 5 Physicians |
| | | 1 SI | 1 | 1 age 30-49 years | 1 Female | 1 Community agent |
| | Castilla-León | 1 DG | 9 | 2 under 30 years 1 age 30-49 years 6 age 50-65 years | 8 Female 1 Male | 6 Nurses 3 Physicians |
| | Castilla-La Mancha | 1 TG | 3 | 1 age 30-49 years 2 age 50-65 years | 3 Female | 3 Nurses |
| | Catalonia | 1 DG | 6 | 6 age 30-49 years | 5 Female 1 Male | 4 Nurses 2 Physicians |
| | | 3 DT | 3 | 3 age 30-49 years | 2 Female 1 Male | 1 Assistant researcher (psychologist) 2 Nurses |

*Technique: Discussion Groups (DG); Semi-structured Interview (SI); Triangular Group (TG) and Documentary Technique (DT).
Most people taking part in the various techniques in February 2015 took also part at the end of the intervention (Summer 2015).
The data is aggregated for confidentiality reasons. Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 2: Description of participant health-care attendees by region (Summer 2015, end of the intervention)

| Region | Risks at the start of the study (intervention on risk: yes/no) | Sex | Educational level | Age |
|--------------------|--|--------|---------------------|-----|
| Andalusia | Diet (yes); Cardiovascular risk (yes) | Male | Primary education | 70 |
| | Physical activity (yes); Diet (yes); Depression risk (no) | Female | Primary education | 58 |
| Aragon | Physical activity (yes); Diet (yes) | Male | Primary education | 51 |
| | Diet (yes); Physical activity (no); Cardiovascular risk (no) | Male | Secondary education | 64 |
| Basque Country | Physical activity (yes); Depression risk (yes) | Female | Primary education | 75 |
| | Physical activity (yes); Cardiovascular risk (yes) | Female | Secondary education | 62 |
| Castilla-León | Depression risk (yes); Diet (yes); Physical activity (yes) | Female | Secondary education | 69 |
| | Physical activity (yes); Smoking (yes); Cardiovascular risk (yes) | Female | Primary education | 58 |
| Castilla-La Mancha | Physical activity (yes); Diet (yes); Smoking (yes) | Female | Primary education | 49 |
| | Depression risk (yes); Diet (yes); Smoking (yes) | Female | Primary education | 52 |
| Catalonia | Diet (No); Physical activity (No); Smoking (yes) | Female | No education | 47 |
| | Physical activity (yes); Diet (yes); cardiovascular risk (yes); Smoking (No) | Male | Primary education | 59 |
| | Physical activity (yes); Diet (yes); Depression risk (yes) | Female | Secondary education | 55 |

No semi-structured interviews with health-care attendees took place in the Balearic Islands.

Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 3: Topic guide for the data generation techniques based on type of informant and study period

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| Primary health care professionals and assistant researchers (February 2015) |
| We will start talking about recruitment: in your experience, what do you suggest to enhance recruitment? |
| Based on your experience, how can we improve the suggested screening strategy? |
| What is your experience with the algorithm of prioritisation and what do you suggest to improve it? |
| What is your overall assessment of the proposed intervention? |
| What do you suggest to improve the feasibility of each component of the intervention (diet, physical activity, smoking, cardiovascular risk and depression risk)? |
| What are your views and experiences on the resources and materials of the intervention? (Web for professionals, Web for patients, patient information leaflets, SMS, other ICTs) |
| How does the target population accept each aspect of the study? (how do they feel, ask and talk about their difficulties with regard to behavioural change) |
| How could we boost participation in the study? (consent at recruitment, follow up ...) |
| What do you suggest to improve the coordination of the project? |
| Finally, how do you perceive your participation in this project? |
| Primary health care professionals and assistant researchers (Summer 2015) |
| What is your overall assessment of the intervention? |
| Has your participation in this study been useful to modify any aspect of clinical practice? Do you think that it has been useful for patients? |
| What are your suggestions to improve the feasibility of each component of the intervention? |
| Concerning each component of the intervention: Would you keep them in the definitive trial? Would you keep them at each level of intervention? How does the population accept them? (How do they feel, ask and talk about their difficulties with regard to behavioural change?) |
| What are your views on the relevance and usefulness of the resources and materials of the intervention? (Web for professionals, Web for patients, patient information leaflets, SMS, other ICTs) |
| How could we improve the coordination of the project? |
| How do you assess the feasibility of expanding this project to other primary care centres? |
| How do you evaluate your participation in this project? |
| Finally, do you have any comment on recruitment, screening strategy and prioritisation algorithm? |
| Health-care attendees (Summer 2015) |
| Could you please explain your overall experience with the EIRA study? |
| Which activities have you carried out during your participation in the study? (If none, ask about group interventions and social prescription) |
| Do you think that you have participated in decision making about your own health? How was your experience? |
| Has this study contributed to adopt healthier behaviours? Has any aspect of your life changed since you entered the study? Do you think that it is feasible to integrate the recommendations and activities suggested by primary care professionals into your daily life? |
| Have you found useful the resources related to the EIRA project such as the webpage, SMS, etc.? |
| What could we improve? |
| Would you recommend participation in a similar study to your family and friends? |
| How do you evaluate your participation in the EIRA project? |

Table 4: Verbatim Quotations of Participants

| Acceptability | |
|--|--|
| Perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory. | |
| Actually, I'd say that many health-care attendees, not 100%, or even 50%, rather 30 to 40%, are very happy. Not just happy, but very very happy... We're talking about individual interviews, aren't we? With health-care attendee and health professional. (Female physician, Basque Country) | |
| Feeling more confident about it yes, because probably I was not confident at all, see? I was talking about that. I have integrated it now, because I felt a bit insecure, and now, well, now I know I'm doing the right thing. (Woman, 52*, health-care attendee, Castilla-La Mancha) | |
| I think it's fine. The questions I'm asked, the blood tests with results that I know very well and that other issue. (Man, 70, health-care attendee, Andalusia) | |
| Generally speaking I'm happy with the intervention, I believe that with the EIRA project I have acquired tools to evaluate my daily work. They have been useful to us professionals because it has helped to structure, plan and prioritize our intervention. Motivation and decision-making with the patient have really contributed to achieve the objectives. (Female nurse, 40, Andalusia) | |
| I have found it truly interesting, but also very long and difficult to implement with our current work overload. (Female physician, 42, Catalonia) | |
| Appropriateness and feasibility | |
| Appropriateness is the perceived fit, relevance or compatibility of the innovation or evidence based practice for a given practice setting, provider or consumer; and/or perceived fit of the innovation to address a particular issue. | |
| Feasibility is the extent to which a new treatment or innovation can be successfully used within a given agency or setting. | |
| Experience of professionals | <p>I think that the training on motivational interviewing has been interesting. (Female physician, 42, Catalonia)</p> <p>I would say no, we did not learn anything new. If it was meant to provide the same baseline for everybody, well, then fine. But we did not see it as what we actually had to deliver for the project, I mean, we saw it as something that they tell you and then you have to face the real thing. (Female nurse, 61, Castilla-La Mancha)</p> <p>Well, whenever we receive specific training we benefit, we become aware of many things that we don't do... we become more aware, we realise that we overlook some issues, in this sense it has been useful, sure. (Female physician, 42, Balearic Islands)</p> |
| Coordination | <p>Let's see, I really believe that this was planned top-down, and as a research project, well, it has been carried out in a hurry like all research projects, so the truth is we need more time for reflection. (Female nurse, 62, Aragon)</p> <p>I think that in our health centre all this work has mainly focused on the nurses ...we have not been as involved... I think that we should have coordinated better, I think that's a fair point. (Male physician, Basque Country)</p> |
| Recruitment | <p>The recruitment bit was the worst, seeing the patients between consultations, explaining about consent, that took a long time, and sometimes they did not even participate. (Female nurse, 39, Catalonia)</p> <p>The recruitment should be different, another model, because the participants are regular attendees, and they manage, they more or less manage their health. (Female nurse, 61, Castilla-La Mancha)</p> |
| Baseline visit of allocated health professional | <p>And what did you decide to work on? Mainly, the diet to lower cholesterol. And I have succeeded. (Man, 59, health-care attendee, Catalonia)</p> <p>Some have started with one and then become involved and used to it ...this here started walking and exercising and he finally has come for quitting smoking, he is a multiplier. I really think that this approach is very useful, to make them commit, when we talked about contract. The contract is crucial, when they realise that they have to sign the commitment form. (Male physician, 61, Andalusia)</p> <p>I thought it was fantastic, very good, wonderful, having a tool (i.e., prioritization algorithm) like that to assist you. (Female nurse, 26, Castilla-León)</p> |
| Individual intervention | <p>... but the test of arteries and all that, they were really delighted with this. And also the people got confused, like with depression, mainly in patients with diabetes or that have been advised on diet and lifestyles for ages, they also mixed this with the study. (Female professional, 39, assistant researcher, Balearic Islands)</p> <p>I think it has been too short, basically a short question. Just a couple of interviews and that's it. (Man, 51, health-care attendee, Aragon)</p> |

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| Group intervention | For sharing and all that. It's wonderful. I think that in these matters the people benefit from the group. (Woman, 75, health-care attendee, Basque Country) ... the conflict of some doctors that have not quite grasped why the nurse went for a walk and protested "now I don't have a nurse, I want her to stay here", and these apparent trifles that if all perhaps ... just having patients from 5 GPs out of 11 has not worked out very well, maybe...the whole health centre should have participated... (Male physician, 42, Balearic Islands) |
| Community intervention | And in relation to community activities, like other times, it's always the same, it's difficult to get them started, it was hard to get them going, but it is eventually rewarding because they already ask when they will be happening again. (Female physician, Basque Country) Yes, but now it has stopped because it's unpredictable, it depends on the policies of the council, so now we have it and later we don't and now they even have changed coordinator so my expectations... (Male nurse, 40, Catalonia) And the community assets should be better exploited. Here in our neighbourhood there are things available that we don't know how to use and then maybe talking I learn that a neighbourhood association organises fitness sessions. And the Council, they also have initiatives, the City Council has a programme with a doctor, they say in charge of the programme, they have done it for a while and sometimes they have wanted to come, they even came here. (Male physician, 62, Castilla-León) |
| Patient information leaflets | That on depression too, what is anxiety, how to manage sleeplessness, patients have found it very interesting. (Female physician, Andalusia) The information is very good, that on sleeplessness is outstanding. (Male physician, 61 , Andalusia) |
| SMS and Webpage to support advice provided | Yes, yes, yes. Because it's a reminder that... that is good, and it's there. I don't delete it, it's there and sometimes I say, come on I'll have a look. Yes, it's a reminder that's available. For me it's quite...good. (Woman, 52, health-care attendee, Castilla-La Mancha) Well, I very well, because I read that and really integrated that information. Sometimes I even laughed. (Woman, 47, health-care attendee, Catalonia) Just being as thoughtful as to send an encouraging message, it's great because sometimes it reaches you just when you most need it. (Woman, 55, health-care attendee, Catalonia) Even with the mobile phone and messages, the mobile phone, "my mobile is only to phone and to receive calls, no messages". Well, it's more difficult than anticipated. (Female nurse, 45, Aragon) Text messaging is really good, it's a very good idea and I think it has been used a great deal... the platform was meant for an age group of health care attendees with not very advanced IT skills. I really believe that our health care attendees, very few will have used this platform because they are not used to, they don't know how to use it and therefore, the platform has probably not been very useful, what do you think? I mean, you receive the message and you see it, and it seems that the mobile is easier to manage, while internet access... If you don't have internet access at home where are you going to read it? (Female nurse, 31, Castilla-La Mancha) |
| Data Collection Notebook (DCN) | You cannot register the commitment with the patient in the DCN, it's not even practical. It is not adapted to the commitment you make with the patient and that suggested is so cumbersome that it's impossible to see it through, that of physical exercise planned the, the objectives attainable in a week, during the week during every day of the week (Physician, Balearic Islands) |
| Follow up | Many have refused to undertake the final evaluation because they had the baseline evaluation and did not implement the intervention or maybe, perhaps at the time they had problems to come to the health centre or had something else going on and they already disconnected, you and the patient, from the study and the evaluation and follow up never took place; and others that dropped out because they are not interested, they say not now because it's complicated, I have problems etc., I don't want to do it ... (Female professional, 39, assistant researcher, Balearic Islands) |
| Evaluation of intervention (baseline and final). Role of assistant researchers | ...it is essential to remain within the centre (laughs) because otherwise we left things undone and the possibility to be face to face, taking with them about things that I'm missing, that need completing...the coordination with them has worked well. (Female professional, 39, assistant researcher, Balearic Islands) I'm also having trouble with the internet connection because I don't have my own password and I don't have my own physical workspace, which results in work overload. (Female professional, assistant researcher, Castilla-La Mancha) |
| Sustainability | |
| The extent to which a newly implemented treatment is maintained or institutionalized within ongoing, stable operations of a service setting. | |
| Yes, I really think so, I think that with time it's doable. (Female nurse, Castilla-León) | |
| If you specifically mean this project, I think that I would consider depression separately. (Female physician, 55, Aragon) | |
| I liked it, well it's my opinion, it's one of these things that, I enjoyed doing and I would like to continue because there are aspects that, I don't know, that I find very positive. (Female nurse, Balearic Islands) | |

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| <p>We have talked about this in the Community Health Meeting that has just taken place and it seems that it mainly hinges on political will ... to include proposals suggested to include community health in the portfolio of services, because otherwise it's always some kind of favour and that the... and the reform... believe that the top management should really rally behind it, to be able to expand, I think. (Female nurse, 62 , Aragon)</p> <p>The project can be extended to other centres, but it's crucial to adapt the schedule of the professionals that are in charge of these interventions, which might cause conflict with other professionals or additional burden for participants. Best to carry out the project with the whole team. (Female nurse, Catalonia)</p> | |
| <p>Penetration: changes implemented by health-care attendees and professionals after the intervention</p> <p>Integration of a practice within a service setting and its subsystems.</p> | |
| Health-care attendees | <p>...every now and then it's good to get it out even if it's by answering questions I used to think about the questions that he asked me, which since my life is so hectic I had not even considered. (Woman, 55, health-care attendee, Catalonia)</p> <p>I feel very well, very well. More fit and all that. Well, at first to climb to the eight floor was so very challenging. I feel better. All in all, it has worked for me. (Woman, 62, health-care attendee, Basque Country)</p> <p>...it has helped, before I used to smoke anything I could find and now I smoke 5 or 6 or 7 more or less. But before I used to smoke much more. (Woman, 47, health-care attendee, Catalonia)</p> <p>Yes, let's see, before I didn't have nuts and now I know that they are good for me. So now I feel good when I eat them, because I eat them now. Fruit? Well, I didn't have that much and... and now I eat more. (Woman, 52, health-care attendee, Castilla-La Mancha)</p> <p>Do you think that all this has been helpful? I think so, more so because I lacked willpower, and taking all literally and it has been like a push, a push. (Man, 59, health-care attendee , Catalonia)</p> <p>Yes, it has helped... it also helped a lot mentally, for my own reflection. I needed it badly, because I felt very unhappy, unemployed, I carried a lot of luggage. My family far away, I was suffering... I still have lots to do, it was very very very useful. (Woman, 47, health care attendee, Catalonia)</p> <p>I even spoke to my children after that (...) and I told them: If you are going to give me something give it to me while I'm alive, love, affection... don't do, you don't have to do anything for me. (Woman, 55, health-care attendee, Catalonia)</p> <p>About walking, I've tried, it has been a very complicated period because I've had very difficult family issues ... but I've tried to walk a bit more (Woman, 58, health-care attendee, Castilla-León)</p> |
| Health professionals | <p>...to be more aware maybe toward the patient. I think it has been useful, perhaps not for everybody, I don't know, the feeling is that we act sensibly and that yes, that we have to encourage it more, but I don't know how. (Female physician, 42, Balearic Islands)</p> |

These quotations were translated by a professional scientific bilingual translator. Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 5: Suggestions for improving the intervention according to participating health care attendees and professionals

| | Health-care attendees | Primary health care professionals and assistant researchers | Quotations |
|-------------------------------|--|---|--|
| Training | | More practical training, in particular regarding the online Case Report Form. More training on motivational interview and on the approach to risk of depression. | I think that the concepts were explained, they talked about nutrition, this and that... but not with the platform and we needed to do it in front of the platform. More practical workshop practice it before starting and for all of us to do the same. (Female nurse, 61, Castilla-La Mancha) |
| Organisation and coordination | | Improve the flow of information and communication within institutions and work groups. Specify the responsibilities of each professional (what, how, when, where). Create a shared agenda. Involve all staff in the PCC. Guarantee connectivity and computers in working order. Shift current agenda to commit more time to health promotion. Actively involve community and institutions. | Regarding the project coordination for doctors and nurses, maybe the area of community prescription with other organisations and entities. (Male physician, 62, Castilla-León) It is important that we be involved and that the authorities get on board to disseminate the healthy lifestyles, what we have now with food in the supermarkets, to label and sugars much more clearly, in short, we need to send the message that nutrition is crucial. This will determine if we are more or less sick in the future, and the same goes for depression. I mean, if we do not take it seriously now we will end up with wonderful medicines to patch up all these diseases but... (Female physician, 43, Andalusia) |
| Recruitment | | Extended period avoiding peak times. Extend consultation length. Involve all staff in the PCC. | And the recruitment has been hard, because when we have got 60, it means that we have seen 120. Or even more than that. And of course, and this within the daily schedule is hard. In fact, it is not even feasible. You can only do this for a short while. (Female nurse, 61, Castilla-La Mancha) |
| Individual intervention | Continuity of follow up. Increase frequency of visits to be able to talk. More specific advice. | Availability of referral specialists for each type of behaviour (each professional should manage the behaviours where she feels more competent). Promote the motivational interview. Social assessment of participant. Consider the results perceived by the people. Continuity of follow up. Promote the role of nursing in the follow up. | Well...I'd say that...it's working fine with these improvements I've just mentioned ...extend length of consultation...give direct advice... (Man, 51, health-care attendee, Aragon) I would add some manner of social assessment, some evaluation of social interaction... of going out if she socialises... For instance, I would include more questions on prevention on social isolation... (Female nurse, 62, Aragon) |
| Group intervention | Enhance group activities. | Enhance group activities. | Actually... the... the topic I think it is well presented... maybe what I missed was... well... what I mean with a meeting... not with a big group... perhaps six or eight people... for each person to be able to talk about what they want to talk... what they do... (Man, 64, health-care attendee, Aragon) |
| Community intervention | | Reaching out to the community. | I really believe that we need to change, we need to completely rethink nursing, because it should become more community oriented, we should reach out more. It is already happening in other countries like Great Britain and others, where the nurse spends more time in the community than inside the consultation room of the surgery, that's why I reckon that they'll need to rethink, I don't know, it's just my opinion (Female physician, Balearic Islands) |
| Patient information leaflets | | Review patient information leaflets on physical activity and depression | ... with stretching exercises, with... an idea of the type of exercise recommended for them, I think. Some more guidance, because I'm not an expert on this, I know very little about it, really, as a professional, and as a patient it's even worse. (Female nurse, Basque Country) |
| SMS | Pay attention to time when sending SMS. | | Yes, about that... once I get an SMS at 12.30 at night, at 12.30 at night it does not make any sense, I'm on standby for my father and the phone might ring (Man, 59 years, health-care attendee, Catalonia) |

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| Webpage | | More dynamic, user-friendly and practical. | And after the ICT tool, I would like to see a warning like a summary with a very clear idea of what you have to do next, you know “book an appointment in a month” or “no”, you know? (Female physician, 45, Balearic Islands) |
| Online Case Report Form | | Easier and more practical. Possibility during follow up to register priority changes in the behaviours or risks to be modified. Systematic recording of drop outs and causes. | Yet again, this platform does not allow you to register the commitment of the patient and it is not practical. It does not reflect the agreement that you reach with the patient and the one suggested is so cumbersome that it is impossible to fulfil... (Male physician, Balearic Islands) |
| Evaluation of the intervention (Assistant researchers) | Explain results of questionnaires and tests during the visit. | Structured support for the assistant researchers. Move the 3-month blood test to 6 months. | That the assistant researchers were here on a permanent basis. For the whole duration of the study, they must come one day and we'll see. Here during our same working hours (Female nurse, 31, Castilla-La Mancha) |
| Project dissemination | Use of various strategies to disseminate to the community the different phases of the project and the results. | Use of various strategies to disseminate to the community the different phases of the project and the results. | I'd say that mainly, ... to promote it, so that people know it exists, and of its purpose when they see it, listen what is this in that case I'd like, I mean, for people to see that this study is happening, experimental or pilot or whatever you call it, but that they can access that programme, the screening. (Female nurse, 60 years, Castilla-La Mancha) |

These quotations were translated by a professional scientific bilingual translator. Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Figure 1: Second phase (development of an exploratory trial) of the EIRA Project, which follows the UK Medical Research Council framework for complex interventions

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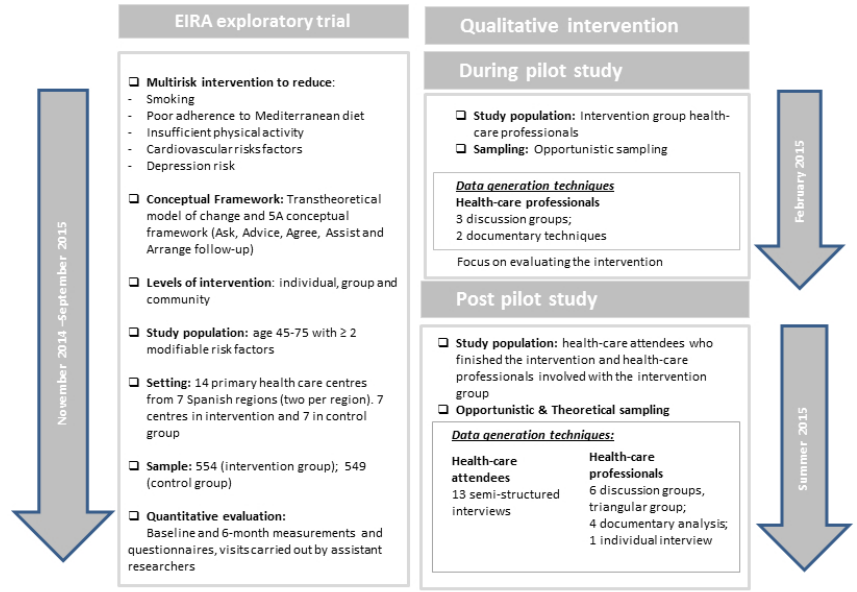


Figure 1: Second phase (development of an exploratory trial) of the EIRA Project, which follows the UK Medical Research Council framework for complex interventions

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No Item | Guide questions/description | Reported on Page |
|--|--|---|
| Domain 1: Research team and reflexivity | | |
| <i>Personal Characteristics</i> | | |
| 1. Interviewer/ facilitator | Which author/s conducted the interview or focus group? | Contributors, page 17 |
| 2. Credentials | What were the researcher's credentials? E.g. PhD, MD | Mariona Pons-Vigués (PhD), Anna Berenguera (PhD), Núria Coma-Auli (Nurs.), Sebastià March (Sociol.), Haizea Pombo (PhD), Barbara Masluk (Psych.), Montserrat Pulido-Fuentes (PhD), Carmela Rodriguez (Nurs.), Juan Ángel Bellón (PhD, MD), Enriqueta Pujol-Ribera (MD). |
| 3. Occupation | What was their occupation at the time of the study? | Affiliations, page 1 |
| 4. Gender | Was the researcher male or female? | 8 female + 2 male |
| 5. Experience and training | What experience or training did the researcher have? | Contributors, page 17 |
| <i>Relationship with participants</i> | | |
| 6. Relationship established | Was a relationship established prior to study commencement? | The interviewer of one of the primary health centre could know the professionals |
| 7. Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. personal goals, reasons for doing the research | Sample design and participant selection strategy, page 8 |
| 8. Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic | Sample design and participant selection strategy, page 8 |
| Domain 2: study design | | |
| <i>Theoretical framework</i> | | |
| 9. Methodological orientation and Theory | What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis | Methods, page 8 |
| <i>Participant selection</i> | | |
| 10. Sampling | How were participants selected? e.g. purposive, convenience, consecutive, snowball | Sample design and participant selection strategy, page 8 |
| 11. Method of approach | How were participants approached? e.g. face-to-face, telephone, mail, email | Sample design and participant selection strategy, page 8 |
| 12. Sample size | How many participants were in the study? | Data collection and generation techniques, page 8 Tables 1 and 2 |
| 13. Non-participation | How many people refused to participate or dropped out? Reasons? | Sample design and participant selection strategy, page 8 |
| <i>Setting</i> | | |
| 14. Setting of data collection | Where was the data collected? E.g. home, clinic, workplace | Sample design and participant selection strategy, page 8 |
| 15. Presence of non-participants | Was anyone else present besides the participants and researchers? | Data collection and generation techniques |
| 16. Description of sample | What are the important characteristics of the sample? e.g. demographic data, date | Tables 1 and 2 |
| <i>Data collection</i> | | |
| 17. Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Data collection and generation techniques, page 8 Table 3 |
| 18. Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. Audio/ visual recording | Did the research use audio or visual recording to collect the data? | Data collection and generation techniques, page 8 |

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| 20. Field notes | Were field notes made during and/or after the interview or focus group? | Data analysis, page 9 |
| 21. Duration | What was the duration of the interviews or focus group? | Data collection and generation techniques, page 9 |
| 22. Data saturation | Was data saturation discussed? | Data collection and generation techniques, page 9 Rigour and quality criteria, page 9 |
| 23. Transcripts returned | Were transcripts returned to participants for comment and/or correction? | No |
| Domain 3: analysis and findings | | |
| <i>Data analysis</i> | | |
| 24. Number of data coders | How many data coders coded the data? | Data analysis, page 9 |
| 25. Description of the coding tree | Did authors provide a description of the coding tree? | Data analysis, page 9 Results, page 11 Tables 4 and 5 |
| 26. Derivation of themes | Were themes identified in advance or derived from the data? | Data analysis, page 9 |
| 27. Software | What software, if applicable, was used to manage the data? | Data analysis, page 9 |
| 28. Participant checking | Did participants provide feedback on the findings? | No |
| <i>Reporting</i> | | |
| 29. Quotations presented | Were participant quotations presented to illustrate the themes /findings? Was each quotation identified? e.g. participant number | Tables 4 and 5 |
| 30. Data and findings consistent | Was there consistency between the data presented and the findings? | Table 4 and 5 |
| 31. Clarity of major themes | Were major themes clearly presented in the findings? | Results, page 11 Tables 4 and 5 |
| 32. Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Results, page 11 Tables 4 and 5 |

BMJ Open

Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

ABSTRACT

Objective: To evaluate the implementation and development of a complex intervention on health promotion and changes in health-promoting behaviours in primary health care according to health-care attendees and health professionals.

Design: Descriptive qualitative evaluation research conducted with 94 informants. Data collection techniques consisted of 14 semi-structured individual interviews, 9 discussion groups, 1 triangular group and 6 documents. Three analysts carried out a thematic content analysis with the support of Atlas.ti software. This evaluation was modelled on Proctor and colleagues' concept of outcomes for implementation research.

Setting: 7 primary care centres from 7 Spanish regions: Andalusia, Aragon, Balearic Islands, Basque Country, Castilla-La Mancha, Castilla-Leon and Catalonia.

Participants: The study population were health-care attendees (theoretical sampling) and health professionals (opportunistic sampling) who had participated in the exploratory trial of the EIRA intervention (2015).

Results: Health-care attendees and professionals had a positive perception of the study. Health-care attendees even reported that they would recommend participation to family and friends. Health professionals became aware of the significance of the motivational interview, especially for health promotion, and emphasized social prescribing of physical activity. They also put forward recommendations to improve recruitment, screening and retention of participants. Health-care attendees modified behaviours and health professionals modified working practices. To achieve sustainability, health professionals believe that it is crucial to adapt agendas and involve all the staff.

Conclusions: The discourses of all stakeholders on the intervention must be taken into consideration for the successful, setting-specific implementation of adequate, acceptable, equitable and sustainable strategies aimed at health promotion and well-being.

Keywords: Complex interventions; Implementation Research; Evaluation; Health Promotion; Health Behaviour; Primary Health Care; Qualitative Research.

Strengths and limitations of the study

- The sampling method of the qualitative evaluation might only have captured the experiences and views of the professionals and attendees more involved and positive with regard to the intervention and to health promotion.
- The rigour procedures applied (methodological adequacy, triangulation of techniques and analysis and reflexivity of the interdisciplinary research team) ensured the validity and reliability of the findings.
- The richness and complementarity of the information generated by health-care attendees and health professionals from seven distinct regions will contribute to the adaptation of the intervention to the various settings to ultimately achieve feasible, sustainable integration in everyday primary care practice.

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Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)

BACKGROUND

Primary Health Care (PHC), the most accessible and most frequently used health service, provides comprehensive, long-term person-focused care [1]. It is considered the ideal setting to implement individual, group and community health promotion interventions. However, these implementations face barriers and challenges set up by the system, the professionals and the public [2,3].

Since it is very common for the same person to accumulate interrelated unhealthy behaviours, complex interventions are increasingly used in studies of behavioural change. In addition, first-hand knowledge of the setting where health promotion takes place is crucial when evaluating its effect. Complexity results from the number of interacting components, namely the amount and difficulty of behaviours required by those delivering or receiving the intervention, the number of groups or organizational levels targeted, the number and variability of outcomes and the degree of flexibility of the intervention [4,5]. The main directives for the design, implementation and evaluation of complex interventions were developed by the Medical Research Council (MRC)[4,6,7] using a mixed-method approach with five sequential phases: i) definition of the theoretical foundation (preclinical phase), ii) construction of a model (phase I), iii) development of a pilot study (phase II), iv) completion of the definitive trial (phase III), and v) long-term implementation (phase IV).

The EIRA project started in Spain in 2012 with the objective to modify unhealthy behaviours in primary care patients following the MRC framework for complex interventions [6,7]. To date, the first 3 phases have been completed [2,3,8–10]. Specifically, the objective of the EIRA Project was to design, conduct and evaluate a complex, multi-risk intervention to enhance adherence to the Mediterranean diet, increase insufficient physical activity and reduce smoking, cardiovascular risk factors and risk of depression in people aged 45 to 75 years that contact primary health care services with at least two of these behaviours or risk factors. Participants receive individual recommendations on their behaviour and risk factors and they are offered to attend group sessions and social prescription of health promoting community assets. The person-centered approach uses the motivational interview and the attendee becomes an active agent in her own life. Participants allocated to the control group receive the usual care (Figure 1).

A key question in evaluating a complex intervention is actual effectiveness. However, the process itself is also important: what happens, how, when and why. The process evaluation in trials explores the implementation of an intervention, assesses its quality and fidelity, clarifies causal mechanisms and

identifies contextual factors associated with variation in outcomes [4,11]. Qualitative methodology has a unique role in understanding the implementation process of an intervention [12]: Interestingly, qualitative research can be used concurrently with a pilot trial, for instance to optimise recruitment and informed consent strategies, to identify acceptability of the intervention, to provide insights into processes of change and to help interpret findings [13]. Accordingly, the qualitative evaluation of the intervention implementation process is able to identify determinants of clinical practice such as barriers and facilitators that influence the adoption of organizational and professional change [14]. This qualitative evaluation facilitates understanding of how and why the different components of the intervention are successfully or unsuccessfully implemented; it also contributes to identify predictive factors of success and generates useful knowledge for advancing the implementation of scientific evidence [15]. In addition, the qualitative methodological perspective might transcend the main limitations of the quantitative approach that prevails in clinical trials, and provides essential information on the evaluation of interventions, since it involves the different stakeholders, which actively convey their experiences, opinions, needs and suggestions for improvement.

This qualitative evaluation presents the results of the second phase (development of an exploratory trial) of the EIRA Project. The objective was to evaluate (1) the process of implementation and development of a complex intervention on health promotion in primary care according to health-care attendees and health professionals and (2) changes in health-promoting behaviours.

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METHODS

Design

Descriptive qualitative research based on the experiences of participants was used to evaluate the exploratory trial of the EIRA complex intervention.

Setting and study population

Seven primary care centres (PCC) included in the intervention group of the EIRA Project from 7 Spanish regions (1 PCC per region) participated: Andalusia, Aragon, Balearic Islands, Basque Country, Castilla-La Mancha, Castilla-Leon and Catalonia. The control group of the exploratory trial did not participate in the qualitative evaluation.

The study population were: a) PHC professionals from participating PCC (including family physicians, primary care nurses, social workers and administrative staff) and assistant researchers (in charge of performing baseline and 6-month measurements and questionnaires); and b) health-care attendees aged 45 to 75 years who participated and completed the EIRA study.

Sample design and participant selection strategy

PHC professionals from participating PCC and assistant researchers were selected by means of opportunistic sampling [16]. The site investigator of each PCC contacted all professionals who participated in the EIRA study to book group interviews 2-3 months after the beginning of recruitment (February 2015 in 3 centres) and at the end of the intervention (summer of 2015 in the 7 centres of the intervention group). The decision of PHC professionals to participate in the group interviews was voluntary. For health-care attendees we applied theoretical sampling based on a prior definition of participants' characteristics to obtain optimal variety and discursive wealth [16]. Fifteen informant profiles emerged from the discursive variants sex, age, educational level and type of intervention (the approach to the first component of the intervention was decided by the participant). Next, two of these profiles were randomly allocated to each PCC included in the intervention group of the EIRA Project; one PCC had 3 profiles. At the end of the intervention (summer 2015), the site investigator of each PCC contacted by phone the health-care attendees participating in the EIRA project who met the specific informant profile for the PCC to explain the objectives of the qualitative evaluation and invited them to participate in an interview. The voluntary aspect of participation was also emphasized to health-care attendees.

Data collection and generation techniques

Conversational techniques were used for PHC professionals: 3 discussion groups in February 2015 and 6 discussion groups at the end of the intervention, in the summer of 2015; 1 triangular group (a meeting of 3 people to discuss together a topic or issue with the aim of ascertaining the range and intensity of their views) [17]; and 1 individual interview with a community agent. In addition, we collected the written reports of 6 professionals who could not attend the discussion groups because of scheduling conflict (2 documentary techniques in February and 4 in summer). Table 1 details the main characteristics of the 81 PHC professionals who participated in the study.

Semi-structured individual interviews were used to collect information from health-care attendees. We initially planned a semi-structured individual interview for each of the 15 profiles of informant; however, 2 semi-structured individual interviews could not take place because the participants could not be contacted after the end of the study. We finally held 13 interviews with health-care attendees. Table 2 shows the characteristics of these 13 participants.

In total, data collection techniques consisted of 14 semi-structured individual interviews, 9 discussion groups, 1 triangular group and 6 documents. Semi-structured individual interviews, discussions groups and triangular group followed a topic guide with open-end questions, with some adaptations according to type of informant and study period (Table 3). The topic guides were based on a review of the literature and the objectives of the study. After obtaining informed consent from the participants, all interviews were audio or audio and video recorded. The discussion groups took place in the PCC with one moderator and one observer, and lasted between 90 and 120 minutes. Semi-structured individual interviews took place in a setting accessible for the health-care attendees and lasted between 15 and 60 minutes. The field work was carried out in each region by qualified interviewers with experience in qualitative research. Informative richness for a deeper understanding of the development and implementation of the intervention was achieved.

Data analysis

All interviews and discussion groups were transcribed verbatim and de-identified by trained personnel [18]. A thematic content analysis was carried out [19,20] with the support of Atlas.ti software. The data were analysed as follows by 3 researchers (NCA, MPV and EPR, a nurse, a pharmacist and a physician, respectively): 1) formulation of preanalytical intuitions after successive readings of the transcriptions and the notes from documentary techniques; 2) creation of an initial analytical plan and text codification; 3) creation of categories by grouping the codes according to the analogy criterion based on Proctor and colleagues' model of outcomes for implementation research [21] and new elements from the discourses; 4) analysis of

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each category and relationship with the others.; and 5) elaboration of the new text with the main results. These results were presented and discussed in a meeting with all research members of the EIRA project (January 2016).

Rigour and quality criteria

To guarantee quality and rigour we adhered to the following recommendations [22, 23]: description of the intervention, the context, the participants and the research process; methodological adequacy; working with different actors; triangulation of techniques (comparison of data obtained by means of different information collection techniques) and analysis (contrasting and comparing the data analyses performed by different analysts to strengthen the credibility and confirmability of the study results); and reflexivity of the interdisciplinary research team. Sufficient data were collected to meaningfully answer the research question. The authors guarantee the accuracy, transparency and honesty of the data and information contained in the study.

Ethical considerations

This study followed the tenets of the Declaration of Helsinki and was approved by the Research Ethics Committee of the IDIAP Jordi Gol (2013; P12/073). All participants signed the informed consent form. Anonymity, confidentiality and data protection were guaranteed.

Patient and public involvement

Study participants were not involved in the development of the research question or the outcome measures nor the design of the study. The results will be presented to study participants and citizens through informative activities and the media.

RESULTS

The results are classified in 5 categories: acceptability, appropriateness and feasibility, sustainability, penetration (changes implemented) and suggestions for improvement. Table 4 shows the definitions of these categories complemented with illustrative quotations from the discussions. .

Acceptability

In general, health-care attendees and health professionals reported satisfaction with their participation and their final evaluation was positive. Health-care attendees described being thankful to the professionals for their support and they explained that they felt more confident making decisions about the process of change. All health-care attendees interviewed would recommend participating in the study to family and friends, and in fact some had already done it. They affirmed that participation requires being ready to pay attention, to listen and to reflect.

Health professionals believed in health promotion and while they did not consider the contents of the intervention innovative, they indicated that it changes working practices, notably the systematization of recommendations and the boost of social prescription. However, they remained critical and underscored that the project was too ambitious, too long, somehow unclear and unorganized, which led to confusion during implementation. They specifically highlighted difficulties in the approach to risk of depression. Moreover, in some primary care teams tension emerged between professionals that participated and their non-participating colleagues.

Appropriateness and feasibility

The results have been categorised according to the phases of the study:

Although some professionals considered that the training conducted prior intervention was appropriate and provided new concepts, they maintained that it was insufficient for the actual implementation of the intervention, specifically concerning the motivational interview and the approach to risk of depression. There was no practical training in the use of online Case Report Forms (CRF) and in one of the centres the training was provided too early. Some theoretical aspects could not be translated into practice due to lack of time or skills.

With regard to coordination, the professionals found the meetings with the research team useful. However, it was sometimes unclear how to proceed, how to give appointments and refer health-care attendees for follow up or who was responsible for reviewing the study tests. In addition, some procedures were changed after the start of the study. Reiteration of questions and lost to follow up were generated by the complexity of circuits and the lack of communication between professionals.

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Most professionals agreed that **recruitment** involved a higher workload than anticipated and that it took place in a short timeframe. They explained that it was difficult to explain the study and to encourage health-care attendees to participate, and they believed that many enrolled because they felt obliged to their professionals. Health-care attendees explained that they participated because they thought it was interesting, they had time and they felt obliged to their regular health professionals.

Professionals pointed at a selection bias caused by the recruitment of frequent attenders, patients generally better controlled and more motivated. No random systematic sampling was applied and any reason for consultation was accepted. Several professionals from the selected PCC declined participation. In particular, few admission staff chose to take part and their involvement was often hurried and uncoordinated, which increased the workload of the professionals involved in the study.

First visit with the health professional (prioritization of behaviours to modify and intervention plan): Most health -care attendees evaluated positively their involvement in decision making and many explained that they participated in the prioritization of behaviours and risks that needed changing. Patients asserted that trust in the health professional facilitates change. Health professionals evaluated positively the patients' assessment of their own risk behaviours followed by the decision about which behaviours to modify. Professionals also indicated that the prioritization algorithm was useful.

Individual intervention: Health-care attendees believed that the advice was useful and applicable and they felt that health professionals really cared and listened to them. They emphasized that in comparison to usual visits health professionals had more time to attend them without rush and to do a holistic valuation. The health-care attendees that received health promotion recommendations in regular practice mixed them up with the intervention advice of the study. They also mixed up the clinical intervention with the collection of information for the clinical trial. They thought that the follow up period should be extended and include more people. The professionals were positive about the person-centred approach and have become more aware of the significance of the motivational interview and of health promotion.

Group intervention: Group activities focused on physical activity and nutrition. Health-care attendees explained that sharing experiences was positive, they established new relationships and organized walking groups. Some professionals reported that these activities are difficult to implement due to lack of time. For others, these activities do not fall within their duties (they considered them additional activities or simply going for a stroll with health-care attendees).

Community intervention: Although few centres used activities already popular in the neighbourhood, social prescription was very positively evaluated both by health-care attendees and professionals. Most physical activities prescribed were organized by the town councils. For professionals, social prescription was a novel concept, and they emphasized that adherence is unknown since attendance was not registered.

Health education leaflets: Health-care attenders favoured personal contact over patient information leaflets. However, the few comments received on leaflets are all positive, especially those about diet or mental health. Health care professionals considered that the leaflets were a useful tool, particularly regarding diet, and even patients who did not participate in the study received them. They also believed that health-care attendees appreciate written information.

SMS and health education webpage: Few health-care attendees agreed to receive SMS, but those that accepted explained that SMS were helpful and encouraging. Professionals considered SMS useful reminders. The webpage was hardly accessed, for which health-care attendees and professionals provided various reasons: lack of recommendation, no access to computers/ Internet, lack of motivation, and feeling uncomfortable sitting in front of a screen.

The professionals believed that the study **online CRF** was too complicated, too slow and that it was difficult to register personalised agreements. Also, since the programme was separate from the electronic health records, they had to work with both programmes simultaneously. In addition, poor internet connection slowed the work of some professionals.

Health professionals indicated that **follow up** data such as adherence rates were somewhat unclear and would be interested in learning about the final results. They believed that retention of participants might be determined by difficulties in attending the intervention visits, loss of interest and the perception that no added value is attached to these interventions.

Evaluation of the intervention (baseline and final) – role of the Assistant researchers: Generally, health-care attendees evaluated positively the questionnaires and tests carried out by the assistant researchers (blood tests, evaluation of vascular health, etc.) because they felt listened to and had more time to talk. The professionals believed that health-care attendees felt well cared for because they spent sufficient time with the interviews. The assistant researchers indicated that they had to administer too many questionnaires. They also pointed at the following issues: insufficient information, lack of their own working space, irregular access to the CRF and lack of authorisation to consult the medical history of health-care attendees.

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Sustainability

Some professionals considered that it is important to extend this intervention to other PCC but underscored the need for the support of institutions, for extended consultation length and the involvement of all professionals. In addition, risk of depression remains a controversial component of the intervention. Some professionals would exclude it altogether, while others believed that it needs a different approach.

Penetration: Changes implemented by health-care attendees and professionals after the intervention

Health-care attendees reported increased motivation and knowledge of healthy behaviours and feeling more positive toward change. Those working with physical activity and nutrition explained that they implemented changes and described high levels of satisfaction: they walked more, got less tired and felt fitter, ate healthier (smaller amounts, more vegetables, fruit and nuts and use of olive oil) and some stated that they drank less alcohol. They also stated that they smoked less cigarettes. Professionals agreed that health care attendees made an effort to meet their objectives, to implement changes and to start healthier habits.

The barriers for change according to health-care attendees were: family responsibilities (care of the sick, care of grandchildren, house chores, etc.), life-work imbalance, weather conditions and lack of willpower. The professionals agreed with these barriers and added financial issues and unawareness of the need to change. Facilitators of change according to health-care attendees were: group activities and trust in health professionals. For health professionals, the health-care attendees should decide which behaviours to modify because their commitment implies autonomy and empowerment and facilitates change.

The professionals reflected on how to approach health promotion in primary care: with a holistic view of health care attendees, providing evidence-based advice, being more purposeful, using motivational interview, involving the family and prioritizing social prescription. Participation in the intervention facilitated a deeper knowledge of health-care attendees and extended consultation length. Professionals reported improvement in the assessment and register of activities in the electronic health records.

Suggestions for improvement

Table 5 shows the discourses and suggestions for improvement of participants.

DISCUSSION

Overall, health professionals and health-care attendees shared a positive perception of their participation in the study. Indeed, health-care attendees would even recommend it to family and friends. Health professionals realised the significance of the motivational interview, in particular with regard to health promotion. They also underscored the potential of social prescribing in relation to physical activity. In addition, health professionals put forward suggestions to improve recruitment, screening and retention of participants. Health-care attendees modified behaviours and health professionals revised working practices. According to health professionals, the continuity of this programme is contingent upon adapting agendas and involving all staff.

We regard the positive attitude of health-care attendees and health professionals toward this health promotion multibehavioural intervention as an endorsement of the definitive trial of the EIRA project. However, we acknowledge that the current version of this intervention cannot yet be integrated in primary care practice until fundamental organisational changes that ensure feasibility and sustainability in real world conditions take place. Even though the intervention was adapted and implemented following the recommendations of health-care attendees and health professionals obtained in prior phases of the EIRA project [2,3, 8–10], further adjustments are required. For instance, in the EIRA project we concluded that for health promotion it is essential to involve most primary care professionals, including administrative staff, to avoid tension and to challenge the notion that health promotion is voluntary or based on personal preference. It is also important to reduce the work overload (objectively high), to simplify recruitment and screening questionnaires and to modify the approach to emotional discomfort and risk of depression. On the other hand, it is crucial to participate in the dissemination of social prescription and to continue the research in implementation strategies focusing on equity and on improving overall results. It has also been observed that primary care professionals require more resources, time, skills and motivation to reach out and work with the community in health promotion [24].

Health-care attendees reported high levels of satisfaction with the study because they felt that professionals gave them enough time and listened to their needs and preferences. They also felt supported during the process of change and were able to initiate sustainable healthy behaviours. We might thus conclude that the intervention encouraged a holistic, person-centred approach underscoring the key role of the primary care professional and of the motivational interview as a useful strategy to promote behavioural change [25]. The motivational interview requires training and extended consultation times [26], and although health professionals received basic training (4 hours at the beginning of the study), most agree that further training is required.

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Although some health professionals underscored the pivotal role of primary health care to manage risk of depression, many worried about lack of skills, attitudes, tools and experience, in agreement with others authors [27]. In addition, some health-care attendees had a positive opinion about the opportunity to know their depression risk [28]. To some extent, the recommendations to manage emotional discomfort in primary care take all these views into account [29]. The real objective of the first approach is to ascertain the nature of the emotional discomfort by means of active listening, probing and empathy to understand the meaning, adaptability and problem solving skills of each person to avoid chronification and medicalization.

This project encourages participation in community activities, particularly physical activity, even though many participants did not follow these recommendations. In agreement with the results of the systematic review by March et al., which shows that in primary care preventive interventions the community might be more effective than the individual approach [30], health professionals underscored a more systematic use of social prescription in regular practice, which indicates an interest in implementing a more biopsychosocial model [31]. This qualitative assessment suggests that despite early resistance, professionals and health-care attendees became eventually aware of the importance of the community components of health promotion interventions. In addition, the feasibility of community recommendations is suggested as a selection criteria of PCC with capability to develop complex health promotion interventions based on networks that identify, promote and evaluate local health assets [32]. In contrast, despite the growing holistic, psychological and collective conception of health [9], the persistence of the biomedical paradigm is shown by the positive evaluation of medical tests by health-care attendees.

Most professionals and health-care attendees considered SMS, a low cost method that preserves privacy, useful for people with mobile phones. This outcome is consistent with other studies which suggest that SMS are effective in health promotion interventions, particularly regarding quitting smoking and physical activity, where SMS can be used to provide positive feedback in order to effect and maintain behavioural change[33–35]. In contrast, the webpage was not considered useful for participants, in agreement with other studies which stress the relevance of the patient-health professional relationship [35,36].

Limitations and strengths

In the EIRA project, health-care attendees and health professionals provided information and were consulted about the development and evaluation of the intervention. However, further steps toward deeper changes in research practice should involve more effective participation in decision making [37].

Despite the use of theoretical sampling for health-care attendees, the voice of participants with higher education qualifications (only 6% in the pilot trial) was insufficient. Also, the voluntary character of participation of health care attendees and professionals in this qualitative evaluation might imply that only the experiences and opinions of people with a positive view of the intervention and of health promotion were collected. On the other hand, the detailed description of less successful aspects, the polarization of professionals regarding the benefits of the study and the suggestions for improvement point at a diversity of standpoints. We believe that it is nonetheless fundamental to add the perspective of less motivated professionals and of participants that dropped out or that simply decided not join the study. Although participants of this qualitative study and of the EIRA Project comprise people from various geographical origins, the contribution of particularly vulnerable individuals (female carers, immigrants and people with precarious employment) remains inadequate. This subpopulation probably lack sufficient time and need more attention regarding health promoting behaviour. More research is needed to further understanding of vulnerable patients.

One strength of the study is the use of the MRC approach for the design, implementation, and evaluation of complex interventions [4,6,7]. The following phase of the intervention (definitive trial) will more specifically adapt to the people and setting and will be more sustainable thanks to the richness and complementarity of the information generated by health-care attendees and professionals from these seven regions. The evaluation process was also analysed by quantitative methods (paper under construction), but considering the limited sample of the pilot trial and the low response rate to questionnaires, qualitative evaluation has proven crucial to understand how health-care attendees and professionals perceive the intervention. Moreover, the rigour procedures applied ensured the validity and reliability of the findings. Although the authors of the current evaluation are also members of the EIRA research team, positive and negative information on the intervention was rigorously collected to deepen understanding on the components that need improvement (see Table 5).

Conclusions

The discourses of all stakeholders with regard to the intervention must be taken into consideration for a successful, setting-specific implementation of the most adequate, acceptable, equitable and sustainable strategies for health promotion and well-being.

CONTRIBUTORS: MPV, AB and EPR designed the study and wrote the protocol. EPR, MPV, AB, BM, MPF, SM, HP, CR and JAB participated in data collection and generation techniques. MPV, NCA and EPR conducted the

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analysis. All authors contributed to the interpretation of results. MPV, AB and EPR wrote the first draft of the manuscript. All authors read, contributed and approved the final version of the manuscript.

For peer review only

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For peer review only

Table 1: Description of participating health-care professionals according to study period and region

| Date | Region | Technique* | Participants | Age | Sex | Occupation |
|-----------------------------------|--------------------|------------|--------------|--|---------------------|---|
| February 2015 | Balearic Islands | 1 DG | 13 | 6 age 30-49 years 7 age 50-65 years | 9 Female 4 Male | 1 Administrative staff 5 Nurses 5 Physicians 2 Psychologists, one assistant researcher |
| | Castilla-La Mancha | 1 DG | 6 | 1 under 30 years 1 age 30-49 years 4 age 50-65 years | 5 Female 1 Male | 6 Nurses |
| | | 2 DT | 2 | Missing information | 2 Female | 2 Assistant researchers (nurses) |
| | Catalonia | 1 DG | 8 | 7 age 30-49 years 1 age 50-65 years | 7 Female 1 Male | 6 Nurses 2 Physicians |
| Summer 2015 – end of intervention | Andalusia | 1 DG | 5 | 1 age 30-49 years 4 age 50-65 years | 1 Female 4 Male | 5 Physicians |
| | Aragon | 1 DG | 4 | 2 age 30-49 years 2 age 50-65 years | 3 Female 1 Male | 3 Nurses 1 Physician |
| | Balearic Islands | 1 DG | 9 | 4 age 30-49 years 5 age 50-65 years | 7 Female 2 Male | 1 Administrative staff 1 Assistant researcher (psychologist) 3 Nurses 4 Physicians |
| | | 1 DT | 1 | 1 age 30-49 years | 1 Female | 1 Assistant researcher (psychologist) |
| | Basque Country | 1 DG | 11 | 2 under 30 years 3 age 30-49 years 6 age 50-65 years | 10 Female 1 Male | 1 Administrative staff 1 Assistant researcher 4 Nurses 5 Physicians |
| | | 1 SI | 1 | 1 age 30-49 years | 1 Female | 1 Community agent |
| | Castilla-León | 1 DG | 9 | 2 under 30 years 1 age 30-49 years 6 age 50-65 years | 8 Female 1 Male | 6 Nurses 3 Physicians |
| | Castilla-La Mancha | 1 TG | 3 | 1 age 30-49 years 2 age 50-65 years | 3 Female | 3 Nurses |
| | Catalonia | 1 DG | 6 | 6 age 30-49 years | 5 Female 1 Male | 4 Nurses 2 Physicians |
| | | 3 DT | 3 | 3 age 30-49 years | 2 Female 1 Male | 1 Assistant researcher (psychologist) 2 Nurses |

*Technique: Discussion Groups (DG); Semi-structured Interview (SI); Triangular Group (TG) and Documentary Technique (DT).
Most people taking part in the various techniques in February 2015 took also part at the end of the intervention (Summer 2015).
The data is aggregated for confidentiality reasons. Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 2: Description of participant health-care attendees by region (Summer 2015, end of the intervention)

| Region | Risks at the start of the study (intervention on risk: yes/no) | Sex | Educational level | Age |
|--------------------|--|--------|---------------------|-----|
| Andalusia | Diet (yes); Cardiovascular risk (yes) | Male | Primary education | 70 |
| | Physical activity (yes); Diet (yes); Depression risk (no) | Female | Primary education | 58 |
| Aragon | Physical activity (yes); Diet (yes) | Male | Primary education | 51 |
| | Diet (yes); Physical activity (no); Cardiovascular risk (no) | Male | Secondary education | 64 |
| Basque Country | Physical activity (yes); Depression risk (yes) | Female | Primary education | 75 |
| | Physical activity (yes); Cardiovascular risk (yes) | Female | Secondary education | 62 |
| Castilla-León | Depression risk (yes); Diet (yes); Physical activity (yes) | Female | Secondary education | 69 |
| | Physical activity (yes); Smoking (yes); Cardiovascular risk (yes) | Female | Primary education | 58 |
| Castilla-La Mancha | Physical activity (yes); Diet (yes); Smoking (yes) | Female | Primary education | 49 |
| | Depression risk (yes); Diet (yes); Smoking (yes) | Female | Primary education | 52 |
| Catalonia | Diet (No); Physical activity (No); Smoking (yes) | Female | No education | 47 |
| | Physical activity (yes); Diet (yes); cardiovascular risk (yes); Smoking (No) | Male | Primary education | 59 |
| | Physical activity (yes); Diet (yes); Depression risk (yes) | Female | Secondary education | 55 |

No semi-structured interviews with health-care attendees took place in the Balearic Islands.

Anonymity, confidentiality and data protection were guaranteed. It is impossible to identify participants; for example, Catalonia is a Mediterranean region with more than 7 million of inhabitants.

Table 3: Topic guide for the data generation techniques based on type of informant and study period

| |
|--|
| Primary health care professionals and assistant researchers (February 2015) |
| We will start talking about recruitment: in your experience, what do you suggest to enhance recruitment? |
| Based on your experience, how can we improve the suggested screening strategy? |
| What is your experience with the algorithm of prioritisation and what do you suggest to improve it? |
| What is your overall assessment of the proposed intervention? |
| What do you suggest to improve the feasibility of each component of the intervention (diet, physical activity, smoking, cardiovascular risk and depression risk)? |
| What are your views and experiences on the resources and materials of the intervention? (Web for professionals, Web for patients, patient information leaflets, SMS, other ICTs) |
| How does the target population accept each aspect of the study? (how do they feel, ask and talk about their difficulties with regard to behavioural change) |
| How could we boost participation in the study? (consent at recruitment, follow up ...) |
| What do you suggest to improve the coordination of the project? |
| Finally, how do you perceive your participation in this project? |
| Primary health care professionals and assistant researchers (Summer 2015) |
| What is your overall assessment of the intervention? |
| Has your participation in this study been useful to modify any aspect of clinical practice? Do you think that it has been useful for patients? |
| What are your suggestions to improve the feasibility of each component of the intervention? |
| Concerning each component of the intervention: Would you keep them in the definitive trial? Would you keep them at each level of intervention? How does the population accept them? (How do they feel, ask and talk about their difficulties with regard to behavioural change?) |
| What are your views on the relevance and usefulness of the resources and materials of the intervention? (Web for professionals, Web for patients, patient information leaflets, SMS, other ICTs) |
| How could we improve the coordination of the project? |
| How do you assess the feasibility of expanding this project to other primary care centres? |
| How do you evaluate your participation in this project? |
| Finally, do you have any comment on recruitment, screening strategy and prioritisation algorithm? |
| Health-care attendees (Summer 2015) |
| Could you please explain your overall experience with the EIRA study? |
| Which activities have you carried out during your participation in the study? (If none, ask about group interventions and social prescription) |
| Do you think that you have participated in decision making about your own health? How was your experience? |
| Has this study contributed to adopt healthier behaviours? Has any aspect of your life changed since you entered the study? Do you think that it is feasible to integrate the recommendations and activities suggested by primary care professionals into your daily life? |
| Have you found useful the resources related to the EIRA project such as the webpage, SMS, etc.? |
| What could we improve? |
| Would you recommend participation in a similar study to your family and friends? |
| How do you evaluate your participation in the EIRA project? |

Table 4: Verbatim Quotations of Participants

| Acceptability | |
|--|--|
| Perception among implementation stakeholders that a given treatment, service, practice or innovation is agreeable, palatable or satisfactory. | |
| Actually, I'd say that many health-care attendees, not 100%, or even 50%, rather 30 to 40%, are very happy. Not just happy, but very very happy... We're talking about individual interviews, aren't we? With health-care attendee and health professional. (Female physician, Basque Country) | |
| Feeling more confident about it yes, because probably I was not confident at all, see? I was talking about that. I have integrated it now, because I felt a bit insecure, and now, well, now I know I'm doing the right thing. (Woman, 52*, health-care attendee, Castilla-La Mancha) | |
| I think it's fine. The questions I'm asked, the blood tests with results that I know very well and that other issue. (Man, 70, health-care attendee, Andalusia) | |
| Generally speaking I'm happy with the intervention, I believe that with the EIRA project I have acquired tools to evaluate my daily work. They have been useful to us professionals because it has helped to structure, plan and prioritize our intervention. Motivation and decision-making with the patient have really contributed to achieve the objectives. (Female nurse, 40, Andalusia) | |
| I have found it truly interesting, but also very long and difficult to implement with our current work overload. (Female physician, 42, Catalonia) | |
| Appropriateness and feasibility | |
| Appropriateness is the perceived fit, relevance or compatibility of the innovation or evidence based practice for a given practice setting, provider or consumer; and/or perceived fit of the innovation to address a particular issue. | |
| Feasibility is the extent to which a new treatment or innovation can be successfully used within a given agency or setting. | |
| Experience of professionals | <p>I think that the training on motivational interviewing has been interesting. (Female physician, 42, Catalonia)</p> <p>I would say no, we did not learn anything new. If it was meant to provide the same baseline for everybody, well, then fine. But we did not see it as what we actually had to deliver for the project, I mean, we saw it as something that they tell you and then you have to face the real thing. (Female nurse, 61, Castilla-La Mancha)</p> <p>Well, whenever we receive specific training we benefit, we become aware of many things that we don't do... we become more aware, we realise that we overlook some issues, in this sense it has been useful, sure. (Female physician, 42, Balearic Islands)</p> |
| Coordination | <p>Let's see, I really believe that this was planned top-down, and as a research project, well, it has been carried out in a hurry like all research projects, so the truth is we need more time for reflection. (Female nurse, 62, Aragon)</p> <p>I think that in our health centre all this work has mainly focused on the nurses ...we have not been as involved... I think that we should have coordinated better, I think that's a fair point. (Male physician, Basque Country)</p> |
| Recruitment | <p>The recruitment bit was the worst, seeing the patients between consultations, explaining about consent, that took a long time, and sometimes they did not even participate. (Female nurse, 39, Catalonia)</p> <p>The recruitment should be different, another model, because the participants are regular attendees, and they manage, they more or less manage their health. (Female nurse, 61, Castilla-La Mancha)</p> |
| Baseline visit of allocated health professional | <p>And what did you decide to work on? Mainly, the diet to lower cholesterol. And I have succeeded. (Man, 59, health-care attendee, Catalonia)</p> <p>Some have started with one and then become involved and used to it ...this here started walking and exercising and he finally has come for quitting smoking, he is a multiplier. I really think that this approach is very useful, to make them commit, when we talked about contract. The contract is crucial, when they realise that they have to sign the commitment form. (Male physician, 61, Andalusia)</p> <p>I thought it was fantastic, very good, wonderful, having a tool (i.e., prioritization algorithm) like that to assist you. (Female nurse, 26, Castilla-León)</p> |
| Individual intervention | <p>... but the test of arteries and all that, they were really delighted with this. And also the people got confused, like with depression, mainly in patients with diabetes or that have been advised on diet and lifestyles for ages, they also mixed this with the study. (Female professional, 39, assistant researcher, Balearic Islands)</p> <p>I think it has been too short, basically a short question. Just a couple of interviews and that's it. (Man, 51, health-care attendee, Aragon)</p> |

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|---|---|
| Group intervention | For sharing and all that. It's wonderful. I think that in these matters the people benefit from the group. (Woman, 75, health-care attendee, Basque Country) ... the conflict of some doctors that have not quite grasped why the nurse went for a walk and protested "now I don't have a nurse, I want her to stay here", and these apparent trifles that if all perhaps ... just having patients from 5 GPs out of 11 has not worked out very well, maybe...the whole health centre should have participated... (Male physician, 42, Balearic Islands) |
| Community intervention | And in relation to community activities, like other times, it's always the same, it's difficult to get them started, it was hard to get them going, but it is eventually rewarding because they already ask when they will be happening again. (Female physician, Basque Country) Yes, but now it has stopped because it's unpredictable, it depends on the policies of the council, so now we have it and later we don't and now they even have changed coordinator so my expectations... (Male nurse, 40, Catalonia) And the community assets should be better exploited. Here in our neighbourhood there are things available that we don't know how to use and then maybe talking I learn that a neighbourhood association organises fitness sessions. And the Council, they also have initiatives, the City Council has a programme with a doctor, they say in charge of the programme, they have done it for a while and sometimes they have wanted to come, they even came here. (Male physician, 62, Castilla-León) |
| Patient information leaflets | That on depression too, what is anxiety, how to manage sleeplessness, patients have found it very interesting. (Female physician, Andalusia) The information is very good, that on sleeplessness is outstanding. (Male physician, 61 , Andalusia) |
| SMS and Webpage to support advice provided | Yes, yes, yes. Because it's a reminder that... that is good, and it's there. I don't delete it, it's there and sometimes I say, come on I'll have a look. Yes, it's a reminder that's available. For me it's quite...good. (Woman, 52, health-care attendee, Castilla-La Mancha) Well, I very well, because I read that and really integrated that information. Sometimes I even laughed. (Woman, 47, health-care attendee, Catalonia) Just being as thoughtful as to send an encouraging message, it's great because sometimes it reaches you just when you most need it. (Woman, 55, health-care attendee, Catalonia) Even with the mobile phone and messages, the mobile phone, "my mobile is only to phone and to receive calls, no messages". Well, it's more difficult than anticipated. (Female nurse, 45, Aragon) Text messaging is really good, it's a very good idea and I think it has been used a great deal... the platform was meant for an age group of health care attendees with not very advanced IT skills. I really believe that our health care attendees, very few will have used this platform because they are not used to, they don't know how to use it and therefore, the platform has probably not been very useful, what do you think? I mean, you receive the message and you see it, and it seems that the mobile is easier to manage, while internet access... If you don't have internet access at home where are you going to read it? (Female nurse, 31, Castilla-La Mancha) |
| Data Collection Notebook (DCN) | You cannot register the commitment with the patient in the DCN, it's not even practical. It is not adapted to the commitment you make with the patient and that suggested is so cumbersome that it's impossible to see it through, that of physical exercise planned the, the objectives attainable in a week, during the week during every day of the week (Physician, Balearic Islands) |
| Follow up | Many have refused to undertake the final evaluation because they had the baseline evaluation and did not implement the intervention or maybe, perhaps at the time they had problems to come to the health centre or had something else going on and they already disconnected, you and the patient, from the study and the evaluation and follow up never took place; and others that dropped out because they are not interested, they say not now because it's complicated, I have problems etc., I don't want to do it ... (Female professional, 39, assistant researcher, Balearic Islands) |
| Evaluation of intervention (baseline and final). Role of assistant researchers | ...it is essential to remain within the centre (laughs) because otherwise we left things undone and the possibility to be face to face, taking with them about things that I'm missing, that need completing...the coordination with them has worked well. (Female professional, 39, assistant researcher, Balearic Islands) I'm also having trouble with the internet connection because I don't have my own password and I don't have my own physical workspace, which results in work overload. (Female professional, assistant researcher, Castilla-La Mancha) |
| Sustainability | |
| The extent to which a newly implemented treatment is maintained or institutionalized within ongoing, stable operations of a service setting. | |
| Yes, I really think so, I think that with time it's doable. (Female nurse, Castilla-León) | |
| If you specifically mean this project, I think that I would consider depression separately. (Female physician, 55, Aragon) | |
| I liked it, well it's my opinion, it's one of these things that, I enjoyed doing and I would like to continue because there are aspects that, I don't know, that I find very positive. (Female nurse, Balearic Islands) | |

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| <p>We have talked about this in the Community Health Meeting that has just taken place and it seems that it mainly hinges on political will ... to include proposals suggested to include community health in the portfolio of services, because otherwise it's always some kind of favour and that the... and the reform... believe that the top management should really rally behind it, to be able to expand, I think. (Female nurse, 62 , Aragon)</p> <p>The project can be extended to other centres, but it's crucial to adapt the schedule of the professionals that are in charge of these interventions, which might cause conflict with other professionals or additional burden for participants. Best to carry out the project with the whole team. (Female nurse, Catalonia)</p> | |
| <p>Penetration: changes implemented by health-care attendees and professionals after the intervention</p> <p>Integration of a practice within a service setting and its subsystems.</p> | |
| Health-care attendees | <p>...every now and then it's good to get it out even if it's by answering questions I used to think about the questions that he asked me, which since my life is so hectic I had not even considered. (Woman, 55, health-care attendee, Catalonia)</p> <p>I feel very well, very well. More fit and all that. Well, at first to climb to the eight floor was so very challenging. I feel better. All this has worked for me. (Woman, 62, health-care attendee, Basque Country)</p> <p>...it has helped, before I used to smoke anything I could find and now I smoke 5 or 6 or 7 more or less. But before I used to smoke much more. (Woman, 47, health-care attendee, Catalonia)</p> <p>Yes, let's see, before I didn't have nuts and now I know that they are good for me. So now I feel good when I eat them, because I eat them now. Fruit? Well, I didn't have that much and... and now I eat more. (Woman, 52, health-care attendee, Castilla-La Mancha)</p> <p>Do you think that all this has been helpful? I think so, more so because I lacked willpower, and taking all literally and it has been like a push, a push. (Man, 59, health-care attendee , Catalonia)</p> <p>Yes, it has helped... it also helped a lot mentally, for my own reflection. I needed it badly, because I felt very unhappy, unemployed, I carried a lot of luggage. My family far away, I was suffering... I still have lots to do, it was very very very useful. (Woman, 47, health care attendee, Catalonia)</p> <p>I even spoke to my children after that (...) and I told them: If you are going to give me something give it to me while I'm alive, love, affection... don't do, you don't have to do anything for me. (Woman, 55, health-care attendee, Catalonia)</p> <p>About walking, I've tried, it has been a very complicated period because I've had very difficult family issues ... but I've tried to walk a bit more (Woman, 58, health-care attendee, Castilla-León)</p> |
| Health professionals | <p>...to be more aware maybe toward the patient. I think it has been useful, perhaps not for everybody, I don't know, the feeling is that we act sensibly and that yes, that we have to encourage it more, but I don't know how. (Female physician, 42, Balearic Islands)</p> |

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Table 5: Suggestions for improving the intervention according to participating health care attendees and professionals

| | Health-care attendees | Primary health care professionals and assistant researchers | Quotations |
|-------------------------------|--|---|--|
| Training | | More practical training, in particular regarding the online Case Report Form. More training on motivational interview and on the approach to risk of depression. | I think that the concepts were explained, they talked about nutrition, this and that... but not with the platform and we needed to do it in front of the platform. More practical workshop, practice it before starting and for all of us to do the same. (Female nurse, 61, Castilla-La Mancha) |
| Organisation and coordination | | Improve the flow of information and communication within institutions and work groups. Specify the responsibilities of each professional (what, how, when, where). Create a shared agenda. Involve all staff in the PCC. Guarantee connectivity and computers in working order. Shift current agenda to commit more time to health promotion. Actively involve community and institutions. | Regarding the project coordination for doctors and nurses, maybe the area of community prescription with other organisations and entities. (Male physician, 62, Castilla-León) It is important that we be involved and that the authorities get on board to disseminate the healthy lifestyles, what we have now with food in the supermarkets, to label and sugars much more clearly, in short, we need to send the message that nutrition is crucial. This will determine if we are more or less sick in the future, and the same goes for depression. I mean, if we do not take it seriously now we will end up with wonderful medicines to patch up all these diseases but... (Female physician, 43, Andalusia) |
| Recruitment | | Extended period avoiding peak times. Extend consultation length. Involve all staff in the PCC. | And the recruitment has been hard, because when we have got 60, it means that we have seen 120. Or even more than that. And of course, and this within the daily schedule is hard. In fact, it is not even feasible. You can only do this for a short while. (Female nurse, 61, Castilla-La Mancha) |
| Individual intervention | Continuity of follow up. Increase frequency of visits to be able to talk. More specific advice. | Availability of referral specialists for each type of behaviour (each professional should manage the behaviours where she feels more competent). Promote the motivational interview. Social assessment of participant. Consider the results perceived by the people. Continuity of follow up. Promote the role of nursing in the follow up. | Well...I'd say that...it's working fine with these improvements I've just mentioned ...extend length of consultation...give direct advice... (Man, 51, health-care attendee, Aragon) I would add some notion of social assessment, some evaluation of social interaction... of going out if she socialises... For instance, I would include more questions on prevention on social isolation... (Female nurse, 62, Aragon) |
| Group intervention | Enhance group activities. | Enhance group activities. | Actually... the... the topic I think it is well presented... maybe what I missed was... well... what I mean with a meeting... not with a big group... perhaps six or eight people... for each person to be able to talk about what they want to talk... what they do... (Man, 64, health-care attendee, Aragon) |
| Community intervention | | Reaching out to the community. | I really believe that we need to change, we need to completely rethink nursing, because it should become more community oriented, we should reach out more. It is already happening in other countries like Great Britain and others, where the nurse spends more time in the community than inside the consultation room of the surgery, that's why I reckon that they'll need to rethink, I don't know, it's just my opinion (Female physician, Balearic Islands) |
| Patient information leaflets | | Review patient information leaflets on physical activity and depression | ... with stretching exercises, with... an idea of the type of exercise recommended for them, I think. Some more guidance, because I'm not an expert on this, I know very little about it, really, as a professional, and as a patient it's even worse. (Female nurse, Basque Country) |
| SMS | Pay attention to time when sending SMS. | | Yes, about that... once I get an SMS at 12.30 at night, at 12.30 at night it does not make any sense, I'm on standby for my father and the phone might ring (Man, 59 years, health-care attendee, Catalonia) |

| | | | |
|---|--|---|--|
| Webpage | | More dynamic, user-friendly and practical. | And after the ICT tool, I would like to see a warning like a summary with a very clear idea of what you have to do next, you know “book an appointment in a month” or “no”, you know? (Female physician, 45, Balearic Islands) |
| Online Case Report Form | | Easier and more practical. Possibility during follow up to register priority changes in the behaviours or risks to be modified. Systematic recording of drop outs and causes. | Yet again, this platform does not allow you to register the commitment of the patient and it is not practical. It does not reflect the agreement that you reach with the patient and the one suggested is so cumbersome that it is impossible to fulfil... (Male physician, Balearic Islands) |
| Evaluation of the intervention (Assistant researchers) | Explain results of questionnaires and tests during the visit. | Structured support for the assistant researchers. Move the 3-month blood test to 6 months. | That the assistant researchers were here on a permanent basis. For the whole duration of the study, they must come one day and we'll see. Here during our same working hours (Female nurse, 31, Castilla-La Mancha) |
| Project dissemination | Use of various strategies to disseminate to the community the different phases of the project and the results. | Use of various strategies to disseminate to the community the different phases of the project and the results. | I'd say that mainly, ... to promote it, so that people know it exists, and of its purpose when they see it, listen what is this in that case I'd like, I mean, for people to see that this study is happening, experimental or pilot or whatever you call it, but that they can access that programme, the screening. (Female nurse, 60 years, Castilla-La Mancha) |

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Figure 1: Second phase (development of an exploratory trial) of the EIRA Project, which follows the UK Medical Research Council framework for complex interventions

Figure 1: Second phase (development of an exploratory trial) of the EIRA Project, which follows the UK Medical Research Council framework for complex interventions

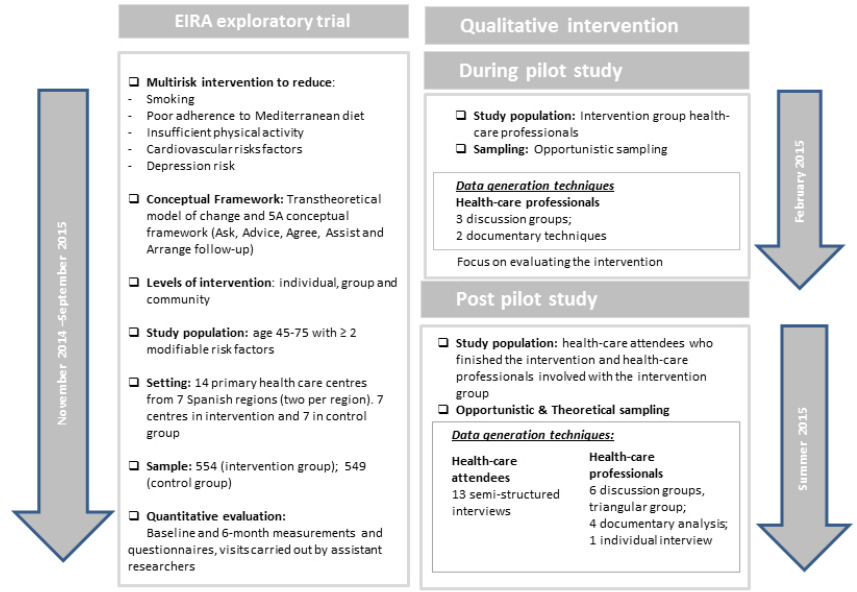


Figure 1: Second phase (development of an exploratory trial) of the EIRA Project, which follows the UK Medical Research Council framework for complex interventions

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

| No Item | Guide questions/description | Reported on Page |
|--|--|---|
| Domain 1: Research team and reflexivity | | |
| <i>Personal Characteristics</i> | | |
| 1. Interviewer/ facilitator | Which author/s conducted the interview or focus group? | Contributors, page 17 |
| 2. Credentials | What were the researcher's credentials? E.g. PhD, MD | Mariona Pons-Vigués (PhD), Anna Berenguera (PhD), Núria Coma-Auli (Nurs.), Sebastià March (Sociol.), Haizea Pombo (PhD), Barbara Masluk (Psych.), Montserrat Pulido-Fuentes (PhD), Carmela Rodriguez (Nurs.), Juan Ángel Bellón (PhD, MD), Enriqueta Pujol-Ribera (MD). |
| 3. Occupation | What was their occupation at the time of the study? | Affiliations, page 1 |
| 4. Gender | Was the researcher male or female? | 8 female + 2 male |
| 5. Experience and training | What experience or training did the researcher have? | Contributors, page 17 |
| <i>Relationship with participants</i> | | |
| 6. Relationship established | Was a relationship established prior to study commencement? | The interviewer of one of the primary health centre could know the professionals |
| 7. Participant knowledge of the interviewer | What did the participants know about the researcher? e.g. personal goals, reasons for doing the research | Sample design and participant selection strategy, page 8 |
| 8. Interviewer characteristics | What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic | Sample design and participant selection strategy, page 8 |
| Domain 2: study design | | |
| <i>Theoretical framework</i> | | |
| 9. Methodological orientation and Theory | What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis | Methods, page 8 |
| <i>Participant selection</i> | | |
| 10. Sampling | How were participants selected? e.g. purposive, convenience, consecutive, snowball | Sample design and participant selection strategy, page 8 |
| 11. Method of approach | How were participants approached? e.g. face-to-face, telephone, mail, email | Sample design and participant selection strategy, page 8 |
| 12. Sample size | How many participants were in the study? | Data collection and generation techniques, page 8 Tables 1 and 2 |
| 13. Non-participation | How many people refused to participate or dropped out? Reasons? | Sample design and participant selection strategy, page 8 |
| <i>Setting</i> | | |
| 14. Setting of data collection | Where was the data collected? E.g. home, clinic, workplace | Sample design and participant selection strategy, page 8 |
| 15. Presence of non-participants | Was anyone else present besides the participants and researchers? | Data collection and generation techniques |
| 16. Description of sample | What are the important characteristics of the sample? e.g. demographic data, date | Tables 1 and 2 |
| <i>Data collection</i> | | |
| 17. Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Data collection and generation techniques, page 8 Table 3 |
| 18. Repeat interviews | Were repeat interviews carried out? If yes, how many? | No |
| 19. Audio/ visual recording | Did the research use audio or visual recording to collect the data? | Data collection and generation techniques, page 8 |

| | | |
|--|--|--|
| 20. Field notes | Were field notes made during and/or after the interview or focus group? | Data analysis, page 9 |
| 21. Duration | What was the duration of the interviews or focus group? | Data collection and generation techniques, page 9 |
| 22. Data saturation | Was data saturation discussed? | Data collection and generation techniques, page 9 Rigour and quality criteria, page 9 |
| 23. Transcripts returned | Were transcripts returned to participants for comment and/or correction? | No |
| Domain 3: analysis and findings | | |
| <i>Data analysis</i> | | |
| 24. Number of data coders | How many data coders coded the data? | Data analysis, page 9 |
| 25. Description of the coding tree | Did authors provide a description of the coding tree? | Data analysis, page 9 Results, page 11 Tables 4 and 5 |
| 26. Derivation of themes | Were themes identified in advance or derived from the data? | Data analysis, page 9 |
| 27. Software | What software, if applicable, was used to manage the data? | Data analysis, page 9 |
| 28. Participant checking | Did participants provide feedback on the findings? | No |
| <i>Reporting</i> | | |
| 29. Quotations presented | Were participant quotations presented to illustrate the themes /findings? Was each quotation identified? e.g. participant number | Tables 4 and 5 |
| 30. Data and findings consistent | Was there consistency between the data presented and the findings? | Table 4 and 5 |
| 31. Clarity of major themes | Were major themes clearly presented in the findings? | Results, page 11 Tables 4 and 5 |
| 32. Clarity of minor themes | Is there a description of diverse cases or discussion of minor themes? | Results, page 11 Tables 4 and 5 |