Barriers to and Facilitators of Implementing DEPENAS Biopsychosocial Intervention in Primary Care: A Study Protocol

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Abstract

Background: Our team has developed a biopsychosocial intervention called DEPENAS that has shown to be effective in primary health care in improving health and quality of life of patients with medically unexplained symptoms. We also found that general practitioners participating in the clinical trial do not use the intervention systematically because of barriers related to psychological determinants among professionals themselves. Based on the Theoretical Domains Framework (TDF) of Susan Michie, our study aims (1) to identify psychological determinants among professionals who are perceived to be facilitators of or barriers to the systematic and generalized use of the intervention in the consultation room and (2) to design an implementation strategy that considers these determinants and helps us to address them with a series of predesigned and validated techniques. Method: A qualitative exploratory study has been designed based on semistructured individual interviews conducted following a script based on the 14 TDF domains and analyzed in a deductive way. Participants will be doctors and nurses previously trained in the intervention that was put into practice under real-world conditions, from different health centers. Results of the analysis of the interviews will be used as the basis for designing the implementation strategy. Discussion: The implementation of the DEPENAS intervention in primary care to achieve its sustained and widespread use among primary care professionals involves changes in the model of patient care and the model of the health system, toward models that are more in tune with the needs of modern society. Investigating psychological determinants in professionals and addressing them with validated techniques, as part of the strategy for implementing a given intervention, is a novel approach that has the potential to help change the way in which we tackle change in healthcare organizations.

Keywords
implementation, biopsychosocial model, medically unexplained symptoms, Theoretical Domains Framework, qualitative research

Background

Rationale of the Study

More than 20 years ago, it was reported that doctors were failing to detect and consider the psychosocial needs/demands of patients, this resulting in patients failing to obtain a satisfactory response despite repeatedly attending medical appointments (Baez et al., 1998; Neal, Dowell, Heywood, & Morley, 1996). Far from being resolved, this situation has worsened and become a real problem, not only for doctors and patients but also for the organization of services. This is because psychosocial problems and related suffering including physical pain should not be considered a priori mental illnesses;
nevertheless, individuals with this type of problem are too often referred to mental health centers, overwhelming them with people who do not have mental health problems, and categorizing as “ill” people who do not meet criteria for mental illness. These patients and those with functional syndromes, for whom the biomedical model does not provide an adequate response, generate around 30% of primary care visits (Báez et al., 1998), leading to frustration both for doctors and patients.

Our team has developed a biopsychosocial intervention to be used by general practitioners with their somatizing patients called DEPENAS, from the Spanish for the detection of psychological suffering (Detección del sufrimiento psicológico), contextualized explanation of symptoms (Explicación contextualizada de los síntomas), intervention planning (Planificación de la intervención), psychosocial examination (Exploración psicosocial), standardization (Normalización), action (Acción), and follow-up (Seguimiento; Aiarzaguena, 2003; Aiarzaguena & Ariño J 1999). In a randomized clinical trial, we demonstrated that this intervention improves the quality of life of somatizing patients (Aiarzaguena et al., 2007).

Unfortunately, biopsychosocial interventions with proven efficacy to manage patients with functional syndromes are not in sustained and widespread use among primary care professionals. In our case, we confirmed this reality in a subsequent study to assess the opinion of doctors who participated in the aforementioned clinical trial, finding that they were not going to carry on using the DEPENAS intervention in their routine clinical practice because it led to difficult doctor–patient interactions (Aiarzaguena et al., 2009). In order to explore these difficult interactions, we conducted a qualitative study analyzing real video recordings of doctors carrying out the intervention with their patients (Aiarzaguena et al., 2013). We found that a high percentage of the difficult interactions were related to (1) doctors not accepting patient resistance, (2) doctors giving premature advice, and (3) interactions in which patients felt that they were judged by the doctors. These results led us to prioritize achieving a safe and welcoming environment for the patient in the intervention in which the main tasks of the health professional were to determine and understand the perspective and point of view of their patients and to help them to be self-aware and understand themselves better, avoiding giving premature advice and making value judgments.

After designing a methodological guide with an emphasis on the need to change attitudes among health professionals, in 2017, we piloted the training for doctors and nurses in the DEPENAS intervention, using the aforementioned guide and practical training. Few health professionals were willing to enroll on these courses and those who did reported concerns: concerns about opening Pandora’s box in dealing with these patients, concerns about losing their identity as a professional, and a lack of confidence in their own abilities to carry out this type of intervention, among others. This led us to think that, as well as difficulties professionals encounter with delivering the intervention itself, there are underlying issues related to their self-attributed role as doctors or nurses, their training, and their beliefs that may hamper the implementation but have not emerged to date due to the lack of an enabling theoretical framework.

**Method**

**Explanation and Justification of Method**

In summary, as there was no implementation of the DEPENAS intervention achieving its sustained and widespread use among primary care professionals, we decided to undertake this qualitative exploratory study based on implementation research strategies. Implementation research can be defined as the scientific study of methods to promote the systematic adoption of the results from clinical research in routine practice and, as such, may be able to help us address our problem (Eccles et al., 2009). This type of research shows that the interventions most likely to be adopted into practice are those that have developed an appropriate implementation strategy, taking into account all stakeholders in a collaborative action research process and providing a structure and support for effective change (Grol & Grimshaw, 2003; Leykum, Pugh, Lanham, Harmon, & McDaniel, 2009; “Optimizing practice through research:” n.d.; Waterman, Tillen, Dickson, & De Koning, 2001).

Experts in this type of research always recommend basing the work on a theoretical framework to guide the entire process (Improved Clinical Effectiveness Through Behavioural Research Group, 2006; “What can management theories offer evidence-based practice?” n.d.).

The Theoretical Domains Framework (TDF) was specifically developed to identify determinants of professional behavior change (Michie et al., 2005), and hence, we considered that it might be useful in our case. This framework includes 11 key determinants from 35 different theoretical models of behavior, and the original version covers knowledge, skills, beliefs about consequences, beliefs about abilities, social influences, emotions, motivation/goals, professional role or identity, memory and decision processes, environmental context and resources, and action planning. A later version also covers optimism and reinforcement and separates motivation (intention) from objectives (Cane, O’Connor, & Michie, 2012). In addition, a set of behavior change techniques has been mapped onto the framework, and these may be used to address the determinants identified in the professionals (Michie, Johnston, Francis, Hardeman, & Eccles, 2008; Michie et al., 2013).

Our study provides information concerning how to develop an implementation strategy for the biopsychosocial intervention DEPENAS to achieve its sustained and widespread use among primary care professionals. Based on this theoretical framework, our study aims (1) to identify psychological determinants in professionals who are perceived to be facilitators of or barriers to the systematic and generalized use of the DEPENAS intervention in the consultation room and (2) to design an implementation strategy that considers these determinants and helps us to address them with a series of predefined and validated techniques.
Study Design

A qualitative exploratory study has been designed based on semistructured individual interviews following a script based on the 14 TDF domains. The participants are to be male and female doctors and nurses assigned to one of several primary care centers in Bizkaia, who have been trained in the DEPENAS intervention, tried using it, and completed it with at least one patient.

The initial objective is to interview between 15 and 30 individuals. The reason for this wide range in the sample size is that, this being a qualitative exploratory study, the number of interviews needed depends on when theme saturation is reached. The reason for this is that, as the study progresses, the research team will gain a deeper understanding of the intervention's impact and how it is perceived by those involved.

Ethics Discussion

The decision to approach patient consultations in a way that takes into account psychosocial factors is down to the doctor. It is evident that this type of initiative from a doctor entails potential risks as well as potential benefits. The most important potential risk is that we mistakenly attribute a patient’s symptoms to the psychological factors when they are really organic and provide psychological interventions that will be insufficient. We consider that dichotomous diagnostic strategies seeking to classify patients’ symptoms as either organic or functional should be abandoned; rather, we defend the view that both of them should be addressed concurrently, and hence, it will always be necessary to do diagnostic tests at the same time as the psychosocial intervention is being provided (Aiarzaguena, Grandes, Salazar, Gaminde, & Sanchez, 2008). This requirement is emphasized in the training of doctors in the intervention.

Further, in cases when the contribution of psychological factors to the symptoms of the patient is evident, we, the clinical professionals, are the ones who have the initiative to propose the psychosocial intervention. This also has ethical implications, and specifically, we need to have strong evidence of the effectiveness of interventions that we will offer to patients. Notably, we have already demonstrated that the DEPENAS intervention improves the quality of life of somatizing patients in a randomized clinical trial (Aiarzaguena et al., 2007).

Given all this and bearing in mind the possibility of comorbid diagnoses and the availability of an effective intervention, it can be considered acceptable, from an ethical point of view, to take an approach that includes both the emotional and social life of patients seeking to help them by improving their symptoms and their quality of life. What we now need is research in implementation to investigate the feasibility of these interventions if they are used in a sustained and widespread way in primary care consultations, their times, and their costs, among other factors. This study has been approved by the clinical research ethics committee of the Basque Country (Code: PI2016045).

Data Collection

We have developed a semistructured interview script with questions based on the domains of the TDF of Michie et al. (Cane et al., 2012; Michie et al., “Psychological Theory” Group, 2005; Michie et al., 2008, 2013) but also referring to the intervention under study and factors that may represent facilitators of or barriers to implementing the intervention (Table 1). In this way, the interviewer will encourage discussion of additional topics not covered by this theoretical framework. The questions that make up the script were drafted by the research team, composed of a primary care doctor, a sociologist, and a psychologist, in line with the definitions, for each of the domains of the American Psychological Association’s Dictionary of Psychology (APA Dictionary of Psychology, n.d.).

We expect that the duration of the interview, on average, should not exceed 1 hour but since there will be open questions, it is likely to vary among participants. We have selected this technique because we will discuss personal psychological issues with the interviewees, and this type of interview facilitates the emergence of topics more easily than other techniques (such as discussion groups or a more structured type of interview) as well as easing the data analysis.

Sampling/Recruitment

Recruitment will be carried out through a letter sent to the head of primary care units offering training in the DEPENAS biopsychosocial intervention, for doctors and nurses, together with the possibility of participating in the study of barriers and facilitators encountered when implementing the intervention in their daily practice.

Data Handling/Analysis

The individual semistructured interviews will be carried out by a member of the research team with extensive experience in qualitative research and will be audio-recorded and subsequently transcribed. The researcher will not take notes during the interview but will immediately after it, regarding nonverbal contextual information about the interview.

Each of the transcripts will be checked for accuracy by the interviewer. The transcripts will be anonymized in such a way that people outside the research team will not be able to identify the interviewees; nevertheless, to keep it clear who makes comments in the interview, the speaker will be identified using letters (“e” and “E,” from the Spanish for interviewer and interviewee). The coding process, carried out by two members of the research team independently, and a third in case of disagreement, will be deductive with the selected theoretical domains as an organizational framework. Specifically, we
will analyze the degree of importance of each of the domains in the discourse (e.g., how often they appear, the use of examples to illustrate their importance, and associated assessments) and whether they represent a barrier, a facilitator, or a prerequisite. If the codes validate the TDF domains, they will be used as the basis for designing the components of our implementation strategy.

ATLAS.ti qualitative analysis software will be used for data management and analysis. In addition, this software facilitates the visualization of data and exploration of relationships between the different constructs of a theoretical framework.

The design of the implementation strategy will require the members of the research team to take collective decisions on the basis of mutual agreements. To this end, we will use various consensus techniques to help us to achieve these types of agreements and decisions in an organized and systematic manner.

The agreements will be set out in a document that will serve as the basis for the guide to the implementation, considering the behavior change techniques linked to the TDF (Michie et al., 2008, 2013; “The behaviour change wheel” n.d.).

**Limitations of the Study**

One of the biases of the study, inherent to qualitative research in general and the need for participants to have had experience with the intervention in particular, is that it is likely that our interviewees are more open to change, and hence, their views and attitudes toward change may be more favorable than those of the average clinician. Given this, in the recruitment phase, the research team will strive to obtain a heterogeneous sample that should enable us to identify different points of view.

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**Table 1. Interview Questions.**

| Domain                        | Question                                                                                                                                                                                                 |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Knowledge                     | Do you know the protocol for the DEPENAS intervention? Have you used it? Do you think that you know the intervention well? Are you clear about your role in the framework of the DEPENAS intervention? How important do you think it is to have knowledge of the intervention to be able to deliver it (very, somewhat, and not at all)? |
| Skills                        | Have you delivered the intervention following the protocol? Have you received training in using the intervention? Do you know how to deliver it? How important do you think it is to have practice when it comes to delivering the DEPENAS intervention? Do you think that the necessary skills can be acquired by practice? |
| Social/professional role and identity | Do you consider dealing with the psychological needs of patients with functional syndromes to be part of your role? Do you think that delivering the DEPENAS intervention is an effective use of your time? How important do you think it is for the intervention to be in line with your role as a professional? |
| Beliefs about capabilities     | Do you think that you have the abilities or skills required to treat this type of patient using the DEPENAS intervention? How important do you feel the skills of the professional are when it comes to using the intervention? |
| Optimism                      | In your work as a doctor/nurse, are you usually optimistic at times of uncertainty? How important do you consider optimism when it comes to implementing the DEPENAS intervention? |
| Beliefs about consequences     | Do you think that patients appreciate an approach like that of the DEPENAS intervention? Do you believe that the intervention will improve the quality of life of the patients targeted? How important do you think these issues are to the success of the implementation? |
| Reinforcement                 | Do you think that it is worth treating these patients following the guide? How important is it to receive institutional and peer support for implementing DEPENAS in primary care? |
| Intentions                    | After the training, how committed were you to delivering the intervention to your patients? How important is it that there is prior commitment when it comes to implementing the intervention? |
| Goals                         | What do you hope to achieve by using the DEPENAS intervention with some of your patients? Do you think that the result expected by the professional might be important in the implementation of the intervention? |
| Memory, attention, and decision processes | Is it easy to remember to treat these patients following the DEPENAS protocol? And what about deciding whether or not to treat a patient using this approach? How important do you think these issues are to the success of the implementation? |
| Environmental context and resources | Does your working environment facilitate the use of an intervention of this nature? What resources are available to you? Are there any incentives? Has any system been set up for addressing barriers you encounter? How important do you think the context is when it comes to routinely delivering the DEPENAS intervention? |
| Social influences             | Are your colleagues supportive when it comes to using the intervention? Do you feel able to consult them if you have concerns? Do your colleagues use it? Do they think that it is good? How important do you think these issues are to the success of the implementation? |
| Emotion                       | How does delivering the DEPENAS intervention to patients make you feel? Do you think that the feelings it generates in the clinician are an important issue in the implementation? |
| Behavioral regulation         | When you use the DEPENAS intervention, do you have a plan of action with your patient? Do you manage to follow the plan? In your routine practice, do you often have to prioritize other activities over treating this type of patient with the DEPENAS intervention? How important do you think these issues are to the success of the implementation? |
Discussion

According to Michie, improving the implementation of evidence-based practice depends on successful behavior change interventions. A necessary step prior to such interventions is the identification of the specific factors to be changed, namely, those that are obstacles to health professionals adopting evidence-based practice, in our case, delivering the DEPENAS intervention. This step goes beyond analysis of the barriers to the adoption of commonly used interventions, since it also explores barriers to specific clinical behaviors that are necessary for approaching patients through the DEPENAS intervention.

The use of the TDF is expected to help us to identify the factors to be changed in an organized way, and this theoretical framework has the advantages of its empirical validity and that it fits well with the behavior change wheel (APA Dictionary of Psychology, n.d.), a guide to classifying behavior change techniques and designing interventions. Specifically, it is hoped that the behavior change wheel will help us choose techniques appropriate to each of the factors identified and hence design a suitable implementation strategy for the DEPENAS intervention, as described for other types of interventions in other settings (Alexander, Brijnath, & Mazza, 2014; Gould et al., 2017; Murphy et al., 2014).

In May 2012, the 65th World Health Assembly adopted resolution WHA65.4 on the global burden of mental disorders and the need for a comprehensive, coordinated response from health and social sectors at the country level. According to the World Health Organization, mental well-being is a key element in the definition of health, which is defined as “A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.” Good mental health enables individuals to realize their potential, cope with normal stresses of life, work productively, and contribute to their community (Murphy et al., 2014). The application of strategies to promote mental well-being and prevent mental illness, integrated in primary care, is therefore an essential part of our work as clinicians, and in relation to this, the use of interventions such as DEPENAS may help us do this in an effective and structured way.

Authors’ Note

The study was approved by the Clinical Research Ethics Committee of the Basque Country. Written informed consent was approved by this Committee and given by all participants of the study (Code: PI2016045).

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