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#### **Editorial**

# Building interventions in primary health care for long-term effectiveness in health promotion and disease prevention. A focus on complex and multi-risk interventions



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#### Introduction

Chronic diseases represent a major social, personal, and economic burden in today's society and an important challenge for health care systems. Cardiovascular diseases and cancer are the leading causes of morbidity and mortality throughout the world. Lifetime prevalence of mental disorders is between 12.0% and 47.4%, depending on the country (Kessler et al., 2009). By 2030, major depression is projected to rank second on a list of 15 major diseases in terms of burden, due to its high prevalence, high impact on daily functioning, frequent recurrences, and early-age onset (Mathers and Loncar, 2006). The mortality rate for patients with mental health problems ranges up to twice as high as in the general population (Grigoletti et al., 2009).

Most of these diseases and their potential complications are preventable through the use of health promotion and disease prevention strategies. The World Health Organization (WHO) estimates that approximately 80% of cardiovascular diseases and 30% of all cancers could be avoided with the adoption of health-promoting behaviors: a major portion of these diseases are closely related to smoking, unhealthy diet, sedentary lifestyle, and excessive use of alcohol (World Health Organization, 2014). Furthermore, a reciprocal relationship exists between these diseases and mental health (Sturgeon, 2006). For example, cardiac diseases are more frequent in patients with depression, and almost half of the people with heart disease have experienced an episode of major depression.

Therefore, policies designed to encourage health-promoting behaviors, the prevention of specific diseases, and better adherence to screening programs and recommended drug therapies are a key element of current health care systems. Their objective is to reduce the risk of disease and disability, support active and healthy aging, and decrease the need for more expensive health care services.

Primary health care as an ideal setting for health promotion and disease prevention interventions

Primary health care (PHC) provides the most accessible and most frequently used health care services, offering integrated and continuous care that is patient-centered (Green et al., 2001; Starfield et al., 2005), and therefore presents an ideal setting for individual, group and community interventions to encourage health promotion and disease prevention. Major organizations, such as the Canadian Task Force on Periodic Health Examination, US Preventive Services Task Force, WHO or Preventive Activities and Health Promotion Program (PAPPS) in Spain, recommend integrating this type of interventions into the daily practice of health professionals in this care setting.

However, due to workload issues, lack of time or lack of knowledge and skills make it difficult to incorporate such interventions into daily practice (Brotons et al., 2005; Rubio-Valera et al., 2014). On the other hand, most PHC patients report more than one behavior that is unhealthy or have more than one risk factor for disease (Galán et al., 2006). There is controversy about whether to intervene simultaneously in more than one of these aspects. Advocates suggest that a multibehavior or multirisk intervention could be more effective and more efficient (Prochaska et al., 2010). Nonetheless, although health professionals are aware of the importance of providing patient-centered counseling, in actual practice the most frequently used strategy is counseling directed at just one health-promoting behavior or risk factor (Lambe and Collins, 2010). This discrepancy between patient reality and clinical practice is likely because the evidence for the effectiveness of the multirisk or multibehavior approach remains scarce; the great majority of studies to date have focused on determining the effect of interventions on a single risk factor or behavior (Butler et al., 2013; Goldstein et al., 2004).

Successful implementation of health promotion and disease prevention interventions requires that they be designed with an awareness of the barriers that exist in the setting where they will be carried out, the skills of the professionals responsible for the intervention, and the characteristics, health status, needs, values and preferences of patients. Rigorous evaluation of this type of interventions will contribute knowledge about their effectiveness in actual practice as well as about the mechanisms that affect success. In this sense, the methodology for designing and evaluating complex interventions offers a unique opportunity to improve public health.

Design and evaluation of complex interventions: an emerging methodology

Interventions designed to encourage the adoption of healthpromoting behaviors involve a broad spectrum of complexity due to S2 Editorial

various factors: the number and difficulty of the behaviors required of participants, the coexistence of diverse components that may interact or act independently, the participation of multiple disciplines, and the need for flexibility in adapting to changing contexts (Craig et al., 2008). It is essential to gain a deep understanding of the context, which also influences the effectiveness of the intervention.

Complex interventions are increasingly represented in the scientific literature. The range of topics studied is very broad and may focus on health promotion or specific health problems such as cancer, diabetes and mental health, or on social interventions, theory, or methodology (Datta and Petticrew, 2013). The importance of this line of research has also attracted attention among those engaged in synthesizing available evidence, who have recognized the value of focusing systematic reviews on mixed methods and complex interventions to better respond to the needs of health care managers, health professionals, and the general public (Hannes et al., 2013).

Evaluating a complex intervention requires not only assessing its effectiveness in achieving its outcome measures but also how, when, why, and under what circumstances it was carried out (Datta and Petticrew, 2013); therefore, a mixed (quantitative and qualitative) methodology is needed to ensure proper evaluation. In addition, the theoretical foundation of the intervention is indispensable because the evaluation must include an understanding of how the intervention could have produced the desired behaviors. Similarly, the study of complex interventions generates knowledge about aspects related to their implementation, such as patient acceptance or their feasibility in actual clinical practice, among others (Lancaster and Campbell, 2010; Proctor et al., 2011). Therefore, experimental studies that include complex interventions represent a turning point from the traditional methods (Hawe et al., 2004; Tarquinio et al., 2015) and they are classified as implementation research, a field in which it is important to evaluate and understand the actual context of daily practice rather than attempt to control its influence on outcomes (Peters et al., 2013).

The main directives for the design, implementation, and evaluation of this type of interventions were developed by the Medical Research Council (MRC) and published as the MRC Framework (Campbell et al., 2007; Craig et al., 2008). This mixed-method approach has five sequential phases: i) definition of the theoretical foundation, ii) construction of a model, iii) development of a pilot study, iv) completion of the definitive trial, and v) long-term implementation. The MRC Framework promotes research participation by the general public and practicing professionals, which increases the intervention's acceptance and feasibility in addition to facilitating participant recruitment and follow-up. This approach also improves the validity and reliability of the assessment tools and ensures the cultural and social relevance of the intervention. These design strengths can also help to increase the sustainability of the intervention, transfer research findings to actual practice, and increase the long-term impact of the health outcomes (Smith et al., 2012; Tapp and Dulin, 2010).

#### About this supplement

According to the MRC Framework, the first phase in the design and evaluation of a complex intervention is the "pre-clinical" or "theoretical" phase. During this phase, the available theories and evidence are evaluated with the goal of establishing a foundation upon which to build an intervention with the capacity to produce the desired outcomes (Campbell et al., 2007; Craig et al., 2008). The 10 systematic reviews presented in this supplement are the result of the pre-clinical phase of our research. Our objective is to carry out and evaluate a complex, multi-risk intervention designed for PHC patients aged 45 to 75 years, with the goal of developing health-promoting behaviors that improve the patients' quality of life and avoid the most frequent chronic diseases and their potential complications. This first phase of our research identified three areas of relevant literature: mental health (4 reviews), healthy

lifestyle (4 reviews), and two key elements in health promotion, theoretical models and community interventions (2 reviews).

#### Mental health

Three of the selected reviews focus on the effectiveness in the adult population of interventions by PHC professionals to promote mental health (Fernández et al., 2015-in this issue), prevent the onset of anxiety (García-Campayo et al., 2015-in this issue), and prevent the relapse and recurrence of depression (Gili et al., 2015-in this issue). All three show similar results: few studies and lack of evidence of effectiveness. A fourth review (Bellón et al., 2015-in this issue) addresses the effectiveness of psycho-educational interventions to prevent the onset of depression in all types of populations and settings. The researchers found that such interventions are effective, although most have small or medium effect sizes and some questions remain unanswered, mainly long-term effectiveness and superiority of the different interventions. There is some evidence about the effectiveness of primary prevention and promotion of mental health in settings such as schools and workplaces. However, despite support for integrating mental health promotion and primary prevention into PHC services, there is a lack of implementation and/or evaluation of these initiatives. In the case of interventions for preventing relapse or recurrence of depression, another constraint is added: most studies examining relapse – and especially recurrence – were performed in secondary care or in primary and secondary care together. With respect to anxiety, different interventions have been shown to reduce the incidence and effects (van't Veer-Tazelaar et al., 2011; Zalta, 2011); nonetheless, no studies were implemented by PHC professionals. All these findings emphasize the need to develop programs and studies designed for mental health promotion and the prevention of these health problems that are so frequent in the adult population, to apply a highly rigorous methodology, and to carry them out in one of the main - and the most accessible and frequently accessed - health promotion and disease prevention settings: PHC.

#### Healthy lifestyle

Three of the reviews focus on identifying the effectiveness of interventions designed to promote healthy behaviors related to physical activity, diet, and alcohol use (Álvarez-Bueno et al., 2015; Maderuelo-Fernandez et al., 2015; Sanchez et al., 2015-in this issue). The healthful benefits of regular physical activity are well known, and the majority of the systematic reviews and meta-analyses clearly show a positive effect of counseling interventions. However, a majority of the population in developed countries does not follow physical activity recommendations (Tucker et al., 2011). The potential protective effect against numerous diseases of the Mediterranean diet and the consumption of fruits and vegetables is also well known (Bamia et al., 2013; Estruch et al., 2013). Nonetheless, the effectiveness of interventions to increase adherence to the Mediterranean diet has not been well studied (Pignone et al., 2003) and there is a need to design studies that test counseling interventions that are compatible with the characteristics of the PHC practice. Due to the heterogeneity of brief interventions to decrease alcohol consumption conducted in PHC settings and of the conclusions about effectiveness that can be drawn from the studies, it is difficult for health professionals to apply these strategies (Bertholet et al., 2005).

Another review evaluated the effectiveness of multifactorial interventions in preventing cardiovascular diseases (Álvarez-Bueno et al., 2015-in this issue). Some cardiovascular disease (CVD) risk factors are well established: smoking, obesity, high cholesterol, and high blood pressure. A logical, efficient way to modify such risk factors to prevent CVD is by promoting healthy lifestyles. Lifestyle recommendations are also directed towards primary prevention of both CVD and stroke, with a wide array of population-based strategies. Some systematic reviews have assessed the effectiveness of a primary prevention strategy simultaneously targeting multiple cardiovascular risk factors in the

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