Concept and design of a cluster-randomized trial

TESTING THE IMPACT OF DISSEMINATING EVIDENCE-BASED RECOMMENDATIONS

in non-communicable diseases in Colombia

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Background

In the last decade Colombia's health care system has moved towards evidence-based healthcare practice (launching over 50 clinical practice guidelines backed by the ministry of health, and a national health technology assessment agency). Despite these advances, it is uncertain to which extent using a systematic strategy to disseminate evidence-based recommendations (EBR) can change practices among patients, caregivers, and health professionals locally.

Study design

Parallel-group, cluster-randomized trial, to test whether a systematic approach to deliver selected EBR using a combination of communication media, may change the frequency of recommended practices on seven non-communicable diseases (acute coronary syndrome, stroke and heart failure, diabetes, hypertension, COPD and asthma), compared to current use of information in health care facilities of Bogotá, Colombia.

Population

Clusters (n=20) of samples of patients with one of the conditions of interest and a subset of their caregivers (4:1 ratio) linked to at least 250 clinicians within each participant institution.

Intervention

A selection of 40 EBRs on the seven conditions of interest, covering different care scenarios (prehospital, post discharge or outpatient care), type of recommendations (in direction and strength), or type of PICO questions posed (diagnosis or treatment), using predetermined quotas.

The EBRs will be delivered through packages of communication media (printed material, SMS, email leading to web-page interactive messages). Using a 3x2 factorial design, the material will be offered in two pre-established levels of frequency, with or without supporting content or with/without person-to-person visits).

In addition to the primary comparisons (including the whole population for comparisons both between study arms and within the active intervention arm), we plan to make a number of additional subgroup (randomized or non-randomized) comparisons.

Outcomes and implications

Our project will report, for the first time in Colombia, the impact of using a systematic approach for dissemination of EBRs, and inform the best possible way to reach patients, caregivers, and health professionals, to have a positive impact on their health practices.

Relevance to diversity: This study will include Colombian patients and caregivers. Relevance to patients and consumers: Significance for patients and caregivers: The goal with this project is to advance in refining locally-validated strategies to improve knowledge management towards different groups of health information users. Our project should also help to identify the more useful contents, formats, communication media and scenarios for uptaking EBR among health professionals, but also patients and their caregivers.

Figure 1. Study desgin

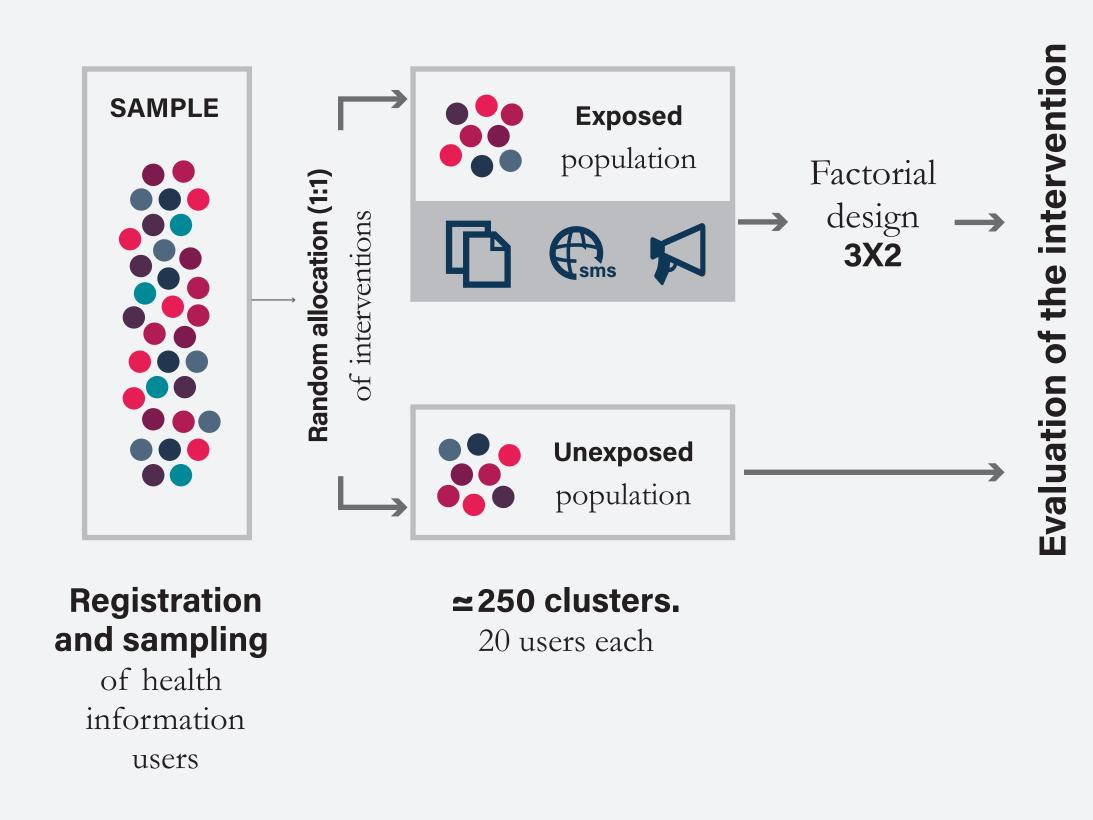
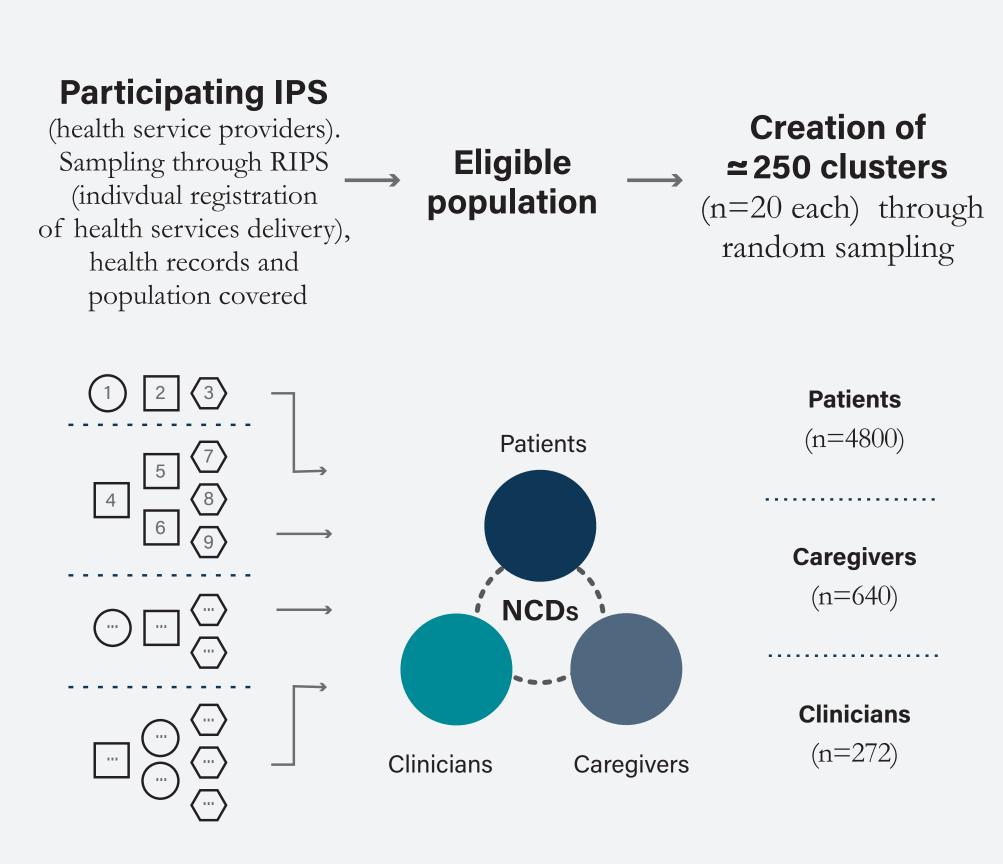


Table 1: Factorial design

	3x2 factorial design		
·	Frequency	Educational content	Visit
Exposed	Higher (50%)	Yes (50%)	Yes (70%)
			No (30%)
		No (50%)	Yes (70%)
			No (30%)
	Lower (50%)	Yes (50%)	Yes (70%)
			No (30%)
		No (50%)	Yes (70%)
			No (30%)

Figure 2: Conformation of the clusters



Operates: Cooperate:













SECRETARÍA DE SALUD



Implements:

Funds: