Quality improvement intervention to increase colorectal cancer screening at the primary care setting: a cluster-randomised controlled trial

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ABSTRACT

Background Approximately 81% of deaths in Argentina are from chronic non-communicable diseases and 21% caused by cancer. Colorectal cancer (CRC) is the second most frequent cancer in Argentina. Even though CRC screening has been recommended for adults from 50 to 75 years old by using a faecal immunochemical test (FIT) annually, screening rates remain below 20% in the country.

Methods We conducted an 18-month, two-arm, pragmatic cluster-randomised controlled trial evaluating the effect of a quality improvement intervention, based on the Plan-Do-Study-Act cycles, considering barriers and catalysts to articulate theory and practice, to increase CRC screening rates using FITs at primary care level. The study involved ten public primary health centres in Mendoza province, Argentina. The primary outcome measure was the rate of effective CRC screening. Secondary outcomes were the rate of participants with a positive FIT, tests with invalid results and the rate of participants referred for colonoscopy.

Results Screening was effective in 75% of the participants in the intervention arm vs 54.2% in the control arm, OR 2.5 (95% CI 1.4 to 4.4, p=0.001). These results remained unchanged after adjusting for individual demographic and socioeconomic characteristics.

Regarding secondary outcomes, the overall prevalence of positive tests was 17.7% (21.1% in the control arm and 14.7% in the intervention arm, p=0.3648). The overall proportion of participants with inadequate test results was 5.2% (4.9% in the control arm vs 5.5% in the intervention arm, p=0.8516). All the participants with positive tests were referred for colonoscopy in both groups.

Conclusions An intervention based on quality improvement strategies proved to be highly successful in increasing effective CRC screening in Argentina’s primary care setting within the public healthcare system.

Trial registration number NCT04293315.

BACKGROUND

Every year 40 million people die from chronic non-communicable diseases (CNCDs), equivalent to 70% of all deaths worldwide. Among these conditions, the leading causes of death are diabetes, cardiovascular disease, chronic obstructive pulmonary disease and cancer. CNCDs are the leading cause of death in most low-income and middle-income countries.1 In Argentina, 81% of deaths are from CNCD, 35% are caused by cardiovascular diseases and 21% by cancer.2 Colorectal cancer (CRC) is the second most frequent cancer in Argentina,3 and approximately 20 people die each day due to this cause.15 For more than 20 years, research has shown that CRC screening reduces cancer incidence and mortality.6-8 CRC screening has been recommended for adults ages 50–75 years old since 2008.9 Nonetheless, screening rates remain low in Argentina with...
rates below 20%, mainly among underserved groups and people covered exclusively by the public sector.\textsuperscript{10} The National Program for Prevention and Early Detection of CRC (Programa Nacional de Prevención y Detec-ción del Cáncer Colorrectal—PNCCR—in Spanish) created by the National Cancer Institute aims to reduce the incidence and mortality of this condition.\textsuperscript{11} Among the different available choices for screening, the performance of the faecal immunochemical test (FIT) proved to be cost-effective in Argentina,\textsuperscript{12} which is why the PNCCR recommends performing FITs annually to the general population between 50 and 75 years without symptoms or family history of CRC. A colonoscopy is recommended in cases with a positive FIT result.\textsuperscript{11,12}

Healthcare system in Argentina is composed of three sectors: a public sector, a social security sector and a private sector. The public sector is financed by the Ministry of Health and its main beneficiaries are persons without health insurance, usually from lower socioeconomic groups. The social security sector is grounded in the principle of social insurance, which requires all employers and employees to make payments to a trust fund. This sector provides services for a variety of institutions, which vary greatly depending on their employee base and the medical insurance coverage provided. The private sector provides service to individuals of high socioeconomic status who may have different types of pre-paid health insurance packages. At least 38% of Argentina’s population is covered only by the public health system care (exclusive public health coverage) and the social insurance sector provides health coverage to 45%–50% of the population.\textsuperscript{13,14}

FIT kits are distributed free of charge in Argentina’s public sector health centres. However, screening rates are far below what is considered optimal, particularly in the most vulnerable groups.\textsuperscript{2,15} In addition, Argentina presents higher CRC mortality than expected according to the incidence of this cancer in the country.\textsuperscript{2} Public policies that increase the population’s access to early detection could amend these unfortunate rates.

Multiple barriers that lead to less than 20% of the population with exclusive public health coverage having undergone a FIT in their lifetime.\textsuperscript{10} Among the most important obstacles are: low awareness in the population, low availability of the test, low adherence from primary care providers to screening recommendations, lack of human resources properly trained and difficulties in articulation between the primary and secondary levels of care.\textsuperscript{10} The main strategies proposed in the literature to address these barriers are summarised in the Framework for Improved Quality of CRC Screening and Outcomes developed by Gupta et al.\textsuperscript{16}

We conducted a cluster-randomised controlled trial to evaluate the effect of a quality improvement intervention to increase the CRC screening with FIT in the primary care setting.

METHODS
An 18-month, two-arm, pragmatic cluster-randomised controlled trial was conducted, with primary healthcare centres (PHCs) as the randomisation unit. The study included 10 public PHCs in Mendoza province, Argentina. Five PHCs were randomly allocated to receive a quality improvement intervention to increase the rate of effective CRC screening. The other five PHCs allocated to the control arm did not receive intervention and continued with usual care (figure 1). Data were collected during the 18-month intervention period. FITs were provided to control and intervention PHCs by the National Program for CRC Prevention.

Eligibility criteria for clusters were: (a) being part of the Redes Program—National Ministry of Health -, (b) being part of the National Program of CRC Prevention, (c) located in an urban area, (c) having at least 800 visits of adult patients per month, (d) having community health workers as part of the staff, (e) having primary care physicians in the staff and (f) having a catchment area without overlap with other PHCs.

Eligibility criteria for patients were (a) 50–75 years old, (b) no current symptoms or history of CRC or colorectal polyps, (c) exclusive public health coverage and (d) living on the catchment area of selected PHCs.

The primary outcome was the rate of effective CRC screening, defined as the proportion of tests delivered to individuals, with a valid FIT result within 90 days after the sample was collected. Secondary outcomes were (a) rate of participants with a positive FIT, (b) rate of participants with invalid results in FIT and (c) rate of participants referred for colonoscopy.

To measure the primary and secondary outcomes, specially trained personnel visited all the PHCs included in the study and registered the tests delivered and their results in laboratory lists and medical records.

Additionally, a formative phase using in-depth interviews and focus groups was conducted in the intervention group at the end of the study to assess the perceptions of healthcare workers about Plan-Do-Study-Act (PDSA) cycles, barriers and catalysts for the implementation and lessons learnt.

Intervention
The intervention applied the model for Quality Improvement Collaboratives from the Institute for Healthcare Improvement.\textsuperscript{17,18} We developed an intervention based on the improvement model: the PDSA and the application in 2-month cycles, considering barriers and catalysts to articulate theory and practice for the teams.

The research team developed an implementation framework based on the collaborative model to apply in 2-month cycles. This model was drawn on a process of key-informant interviews to identify barriers and facilitating factors that would help teams to articulate theory and practice. For example, for effective CRC screening, the simplicity of the test and the fact that it did not require specialised personnel to read the results were considered.
facilitators at the primary level of care. Likewise, the lack of awareness about the importance of taking the test, both by the population and by many health professionals, as well as the difficulty to record the activities carried out in the health centre were identified as key barriers to achieving an effective screening.

The multidisciplinary team at each intervention PHC consisted of 3 to 5 health providers (physicians and nurses) and administrative staff. The intervention combined the participation of these multidisciplinary teams for the codesign of the intervention, measurement, periodic feedback and innovation. A summary of the key actions to improve the CRC screening and its evidence base was available to teams.

Each team was trained in an initial face-to-face workshop on improvement projects, implementation of changes or improvements cycles, generalisation of changes when they are effective, and measurement, and reporting data. Each team established objectives that would increase the counter-reference and specific activities to achieve them. A driver diagram was developed to identify initiatives to improve CRC screening.17 A prioritisation process based on the nominal group technique was conducted to identify the initial actions to be carried out.19

After the initial workshop, learning sessions were conducted bimonthly. Each session constituted the analysis of the phases of the improvement cycle (PDSA) by discussing results, lessons learnt, the applicability of interventions and modifications to the work plan. Each of the improvement opportunities was recorded and committed to a standardised improvement opportunity model. These sessions were alternated with ‘action periods’ (time between learning sessions), when teams tested and executed changes in their PHCs, collected data to measure the impact of the changes; and shared them in monthly videoconferences with the other teams. Each team had to report the development of improvement opportunities with a standardised report developed for this purpose. In the PHCs assigned to the control group, no interventions were performed.

**Data management**

To measure the primary and secondary outcomes, specially trained personnel visited all the PHCs included in the study and recorded the number of FITs delivered and their results in two sources: laboratory lists and medical records. Additionally, records from the national screening system (Sistema de Información para el Tamizaje, in Spanish, SITAM) during the study period was independently performed by personnel from the National Cancer Institute. SITAM is an online information system of the National Ministry of Health that allows registration of people who undergo procedures for the prevention, detection, diagnosis and treatment of CRC, breast or cervical cancer, in PHCs and hospitals of the public sector. The National Program for Prevention and Early Detection of CRC promotes the registration in SITAM of all practices related to CRC screening and diagnosis at the first and second levels of care. SITAM facilitates individualised monitoring of patients in the different stages of the patient’s care process. However, since its creation, there has been a high level of under-reporting due to time and human resources shortage in

![Figure 1](https://example.com/image.png)
primary care centres, limited data registration culture and competing activities at the clinic.

Follow-up visits (audits) were carried out in all the participating PHCs (both arms), and periodic communication was maintained between the Coordinating Centre and the PHCs by telephone, email and WhatsApp.

Randomisation, data monitoring and statistical analysis was conducted at the Department of Data Management of the Institute of Clinical Effectiveness and Health Policy (IECS).

**Statistical analysis and sample size calculation**

A sample size of 1500 participants (750 per arm) was calculated to detect a minimum absolute difference of 15% in the primary outcome between both arms, assuming an intraclass correlation coefficient of 0.03 or less, an alpha level of statistical significance of 0.05 and power of the study of 80%. Descriptive measures were used to characterise the study population, and hypothesis tests were applied to compare the baseline characteristics of both groups (T-test for continuous variables and $\chi^2$ test for categorical variables).

We used a multivariable model to evaluate the effect of the intervention, adjusting for potential confounders, considering age, sex and those variables in which a significant imbalance was found in the characteristics of the study population (see table 2). Model parameters were estimated using the generalised estimation equations method, which considers the effect of clustering. ORs are presented with their 95% CI. The PROC GENMOD procedure of the SAS 9.3 statistical package was used.

**Patient and public involvement**

Patients or members of the public were not involved in the design, conduct, reporting or dissemination plans of this research. Local healthcare authorities were consulted and involved during its design and implementation.

**RESULTS**

Ten clinics were randomly allocated to either the intervention (n=5) or control (n=5) arm (figure 1).

Between June 2018 and October 2019, 1500 participants were included. Table 1 presents the main characteristics of the participants in both arms.

Eight rapid improvement cycles were carried out, with bimonthly frequency within a collaborative model, following the guidelines previously described. We estimate a time commitment of 3–4 hours every 2 months for team meetings. Additionally, each team reported 1–2 hours monthly for monitoring purposes.

Table 2 summarises the causal relationship (Driver Diagram) proposed by the teams between the proposed improvements, the system factors sought to be modified (primary and secondary drivers) and the team’s goal (increase effective CRC screening). For example, the first factor (primary driver) considered was the identification of the target population in the PHCs area. The PHCs did not have a nominalised population that included the age of the people to identify those who should receive screening. From this primary driver, three factors (secondary drivers) were identified as relevant to the primary driver: (1) active recruitment visits in the community had not been carried out; (2) lack of opportunistic recruitment of those who attended the PHCs for other reasons and who constituted a missed opportunity for screening and (3) the enumeration and generation of a formal registry that would provide a tool to control the scope of the screening had not been implemented. Finally, proposals for change were codesigned to modify the first two and, thus, improve identification of the target population and effective screening. The same logic was applied to the other factors of the system.

Primary outcome: Screening was effective in 75% of the participants in the Intervention Arm vs 54.2% in the Control Arm (p=0.001). The OR for effective screening was 2.5 (95% CI 1.4 to 4.4). This association remained significant imbalance was found in the characteristics of both groups (T-test for continuous variables and $\chi^2$ test for categorical variables).

**Table 1** Study population characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control arm (n=750)</th>
<th>Intervention arm (n=750)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>484 (66.8)</td>
<td>470 (62.8)</td>
</tr>
<tr>
<td>Age in years, mean (SD)</td>
<td>60.6 (6.8)</td>
<td>60.0 (6.7)</td>
</tr>
<tr>
<td>Primary education or less, n (%)</td>
<td>640 (86.7)</td>
<td>620 (82.9)</td>
</tr>
<tr>
<td>Lives alone, n (%)</td>
<td>289 (39.2)</td>
<td>302 (40.4)</td>
</tr>
<tr>
<td>Smoking, n (%)</td>
<td>135 (18.3)</td>
<td>142 (19.1)</td>
</tr>
<tr>
<td>Alcohol consumption, n (%)</td>
<td>8 (1.6)</td>
<td>18 (3.0)</td>
</tr>
<tr>
<td>BMI, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>100 (17.2)</td>
<td>81 (15.1)</td>
</tr>
<tr>
<td>Overweight</td>
<td>224 (38.6)</td>
<td>199 (37.0)</td>
</tr>
<tr>
<td>Obesity</td>
<td>257 (44.2)</td>
<td>258 (48.0)</td>
</tr>
<tr>
<td>Low consumption of fruits and vegetables, n (%)</td>
<td>705 (98.9)</td>
<td>590 (97.8)</td>
</tr>
<tr>
<td>Low level of physical activity, n (%)</td>
<td>295 (62.0)</td>
<td>340 (71.3)</td>
</tr>
<tr>
<td>Health condition, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent-Very Good-Good</td>
<td>555 (74.5)</td>
<td>507 (68.7)</td>
</tr>
<tr>
<td>Income, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARS 1 to ARS 8000</td>
<td>191 (25.5)</td>
<td>302 (40.3)</td>
</tr>
<tr>
<td>ARS 8001 to ARS 15000</td>
<td>138 (18.4)</td>
<td>223 (29.7)</td>
</tr>
<tr>
<td>ARS 15001 or more</td>
<td>75 (10.0)</td>
<td>28 (3.7)</td>
</tr>
<tr>
<td>Do not know/Do not answer</td>
<td>346 (46.1)</td>
<td>197 (26.3)</td>
</tr>
<tr>
<td>Employment, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>465 (62.5)</td>
<td>512 (69.4)</td>
</tr>
<tr>
<td>PHC close to home, n (%)</td>
<td>398 (53.9)</td>
<td>359 (48.0)</td>
</tr>
<tr>
<td>Consult at the PHC in the last year</td>
<td>549 (85.5)</td>
<td>554 (74.1)</td>
</tr>
<tr>
<td>Consult with a physician in the last year</td>
<td>617 (83.6)</td>
<td>595 (79.8)</td>
</tr>
<tr>
<td>PHCs close to home: distance to home &lt;1 km</td>
<td></td>
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BMI, body mass index; PHC, primary healthcare centre.
Qualitative findings
The face-to-face sessions in each improvement cycle represented a space for dialogue with healthcare teams belonging to different PHCs. This dialogue allowed teams to compare everyday conditions in varied contexts and recognize similarities and differences that helped them rethink their environment, assess their resources and identify shortcomings.

All team members valued the intervention codesign strategy that gave them a more significant role and

Table 3 Proportion of participants with effective screening

<table>
<thead>
<tr>
<th></th>
<th>Control arm % (95% CI)</th>
<th>Intervention arm % (95% CI)</th>
<th>P value</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of participants with effective screening</td>
<td>54.2 (44.1 to 64.0)</td>
<td>75.0 (67.3 to 81.5)</td>
<td>0.0010</td>
<td>2.5 (1.4 to 4.4)</td>
</tr>
</tbody>
</table>

Data source: SITAM and registries at the health centre.

unchanged after adjusting for demographic and socio-economic characteristics, including gender, education and employment status (table 3).

Secondary outcomes: the overall prevalence of positive tests was 17.7% (21.1% in the Control Arm and 14.7% in the Intervention Arm, p=0.3648). The overall proportion of participants with inadequate test results was 5.2% (4.9% in the Control Arm vs 5.5% in the Intervention Arm, p=0.8516). All the participants with positive tests were referred for colonoscopy in both groups.

Table 2 Driver diagram and list of improvement interventions implemented by the PHCs

<table>
<thead>
<tr>
<th>Primary drivers proposed to teams</th>
<th>Secondary drivers proposed to teams</th>
<th>Ideas for change: Commitments from the teams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of the target population in the PHCs area of responsibility</td>
<td>Active recruitment in the community</td>
<td>▶ Incorporate active screening into the health rounds of community health workers.</td>
</tr>
<tr>
<td></td>
<td>Opportunistic recruitment at PHCs</td>
<td>▶ Identify target population from the list of scheduled shifts.</td>
</tr>
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<td></td>
<td>Registration of the target population</td>
<td>▶ Identify target population during spontaneous demand consultations.</td>
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<tr>
<td></td>
<td></td>
<td>▶ Stand to offer the test in the PHCs waiting room.</td>
</tr>
<tr>
<td>Awareness rising about CRC screening for the population</td>
<td>Educational campaigns</td>
<td>▶ Disseminate information using local media, for example, posters in the neighbourhood and distribution of information material/brochures house to house.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Give informative talks at retirement centres.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Set up an information booth, hand out brochures and show videos on prevention and early diagnosis of CRC in the PHCs waiting room.</td>
</tr>
<tr>
<td>Disposition of professionals as educators</td>
<td></td>
<td>▶ Organise informative talks for PHCs professionals.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Incorporate the subject into conferences or meetings to discuss cases among professionals.</td>
</tr>
<tr>
<td>Interaction between multiple stakeholders of the health system</td>
<td>Teamwork</td>
<td>▶ Distribute tasks and assign responsibilities by work shift.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Hold team meetings.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Internally audit the screening process.</td>
</tr>
<tr>
<td>Algorithm standardisation</td>
<td></td>
<td>▶ Develop a screening protocol.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Prepare a flow chart of procedures for the PHCs.</td>
</tr>
<tr>
<td>Reduction of communication barriers among the different stakeholders</td>
<td></td>
<td>▶ Multidisciplinary team meetings.</td>
</tr>
<tr>
<td>Training</td>
<td></td>
<td>▶ Provide practical training for the use of the kit and reading the test.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Implement periodic retraining for stable and rotating staff.</td>
</tr>
<tr>
<td>Access and service</td>
<td>FITs supply</td>
<td>▶ Review the stock of pharmacy kits periodically and plan the orders.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Carry out practical demonstrations to improve sampling and adherence to the study.</td>
</tr>
<tr>
<td>Case tracking circuits</td>
<td></td>
<td>▶ Create WhatsApp groups with reminder messages for return kits and results.</td>
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<tr>
<td></td>
<td></td>
<td>▶ Identify effective channels of communication with the second level for performing colonoscopy in cases of positive tests.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Implement test-retrieval lists.</td>
</tr>
</tbody>
</table>

CRC, colorectal cancer; FIT, faecal immunochemical test; PHC, primary healthcare centre.
generated a deeper commitment to the implementation of the solutions that they had proposed. The discussion space also represented the possibility of having protected time to think about strategies beyond day-to-day problems. The dialogue between peers was enriching, both within each team and between different teams. Some people stated that, in the first sessions, they felt reluctant to share experiences, especially those that had not been successful.

Most of the team members emphasised that, in the first sessions, they focused more on complaints and claims. However, as they incorporated the proposed methodology, they began to redirect their attention to the search for solutions. It was challenging for them to incorporate objective measurements of the results obtained with each strategy. Until very late in the cycles, they prioritised subjective evaluation, which seemed sufficient to make decisions. As cycles progressed, all team members recognised the importance of quantitative measurement of results but found it difficult to incorporate them into their practice. Despite the motivation generated by the learning sessions, some participants reported great difficulty in incorporating the innovations into daily practice. Mostly due to work overload, lack of personnel and activities that competed with the planning of the screening (eg, vaccination campaigns, health checks for school certificates, specific campaigns designed by other national or provincial programmes).

**DISCUSSION**

The study results show that an initiative based on rapid cycles of improvement at the primary care setting, combined with the collaborative model, increased effective screening for CRC, measured through the proportion of people with a FIT valid result available within 90 days of the delivery of the test. The effective screening rate in the Intervention Arm was 75% compared with 54% in the Control Arm. These results are highly relevant to the scope of the CCR screening strategy in the community and the efficiency in the use of resources in the public sector and inform the ongoing national programme of CCR prevention.

In the Control Arm, about half of the tests distributed were not returned, and the result is unknown. This lack of completion represents a loss of material resources, and more importantly, the risk of underdiagnosing early lesions in the population that had access to the screening opportunity. For instance, if the proportion of positive test results remains constant, we can estimate that, in the Control Arm, approximately 78 people out of 750 (more than 10%) could be positive and do not know it because the test was not read, and the result is not available. In the group that implemented the improvement cycles, this number would be significantly reduced to 35 people over 750 (less than 5%).

To interpret these results, we also considered the potential influence that individual’s characteristics could have had in both groups, since some of these characteristics turned out to be significantly different. Attributes associated with greater barriers to effective screening include low income, unemployment, greater distance from home to PHCs and underuse of health services in the last year. However, after randomisation, these attributes were more prevalent in the Intervention Arm, which might have contributed to some degree of underestimation of the potential benefit of the intervention. On the other hand, educational level was comparatively lower in the Control Arm; however, this difference loses relevance given that globally more than 80% of all the participants in both groups had an elementary or lower educational level. Of note, in spite of some unbalance between arms in the proportion of people who did not report their income, all participants belonged to vulnerable populations in the lowest deciles of income since they were receiving care from the public healthcare sector exclusively.

As for the strategies proposed by the PHCs, during the development of the improvement cycles, the teams identified problems for the adequate implementation of screening in the target population and proposed solutions adapted to each context. Activities were planned to tackle barriers that had so far hampered the effectiveness of CRC screening. Difficulties arose both from the point of view of healthcare providers to deliver the kit, and from people in the community to return to the PHCs once the sample had been taken to read the result. The improvement proposals codified by the local teams were of different kinds. However, most of the proposals were oriented towards better work organisation in PHCs and proactive screening strategies. Many of the PHCs chose to work on aspects related to work groups, teamwork and workflow, which reflects part of the implementation challenges faced by healthcare personnel. Likewise, active recruitment in the community, screening in the health centre and tracking down unread tests were central axes in most clinics.

Regarding the dynamics of the cycles, face-to-face and distance meetings among PHCs motivated the monitoring of activities by the teams, sharing strategies and lessons learnt and elaborating on common difficulties and the particularities of each context.

At the primary care level, health personnel received the rapid improvement cycles methodology positively. The improvement cycles process may have served to stimulate PHCs staff to collaborate with the common goal of optimising the implementation of the PNCCR in a shared practice. The staff involved in the process found the intervention useful to identify and solve their problems. However, the staff also identified the need for further training on tools to monitor the results.

Finally, the level of underreporting in the national screening system (SITAM) was not statistically different between the groups (38.8% in the Control Arm vs 26.2% in the Intervention Arm, p 0.138). What could partly explain the results is that during the execution of the improvement cycles, the importance of registering in
CONCLUSION

In conclusion, the intervention proved to be highly successful in increasing effective CRC screening in the public domain of primary healthcare in a province of Argentina. This study contributes concrete tools to the improvement of the quality of CRC detection at the first level of care in the public health sector.

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Patient consent for publication Not applicable.

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RESEARCH PROTOCOL

Study title: Evaluation of the effectiveness of a collaborative strategy to increase colorectal cancer screening in the public health care sector in Argentina.

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Abstract

This study is a pragmatic cluster randomized clinical trial that combines a participatory and dynamic methodology based on improvement cycles. The objective is to evaluate the effectiveness of a multicomponent strategy to improve screening and early detection of Colorectal Cancer (CRC) in at-risk population of Primary Care Centers (CAPS) of the public health system in Argentina. Ten CAPS will be selected: 5 will be randomly assigned to receive an intervention to increase CRC screening rates (improvement cycles) and 5 to the control arm (usual strategies). The study will be conducted in the reference area of selected CAPS included in the National Program for Prevention and Early Detection for CRC (PNCCR) of the province of Mendoza. It will include people from the community with usual risk for CRC and those with increased risk due to selected factors. A total of 119 participants per CAPS will be included, in total, 1190 participants.

In the intervention arm, at least 3 learning sessions will be carried out with the members of the care system to identify opportunities for improvement aimed at designing and implementing an innovative intervention based on best practices. Each of the sessions will constitute an analysis of the improvement cycle, following the following steps: 1) Selection of participants; 2) Development of work model based on literature review and initial qualitative phase; 3) Initial session with effectors for training in continuous improvement, agreeing on objectives, interventions and data collection; 4) Learning sessions to discuss results, applicability of interventions and modifications to the work plan; 5) Closing session to evaluate preliminary results and discuss continuity of interventions beyond the project.

The primary outcomes to be measured are percentage of the population at risk that completes screening; and percentage of the population classified as being at usual or increased risk due to risk factors.

The expected outcome is to develop a multicomponent intervention that will increase CRC screening rates in the public sector setting.
INTRODUCTION

Chronic non-communicable diseases

In 2013, the World Health Organization promoted the “Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020”, which aimed to reduce premature mortality caused by cancer, cardiovascular diseases, diabetes and chronic respiratory diseases by 25% until 2025 (1).

Among the main chronic non-communicable diseases, cancer is the second leading cause of death in the world, with almost nine million deaths recorded in 2015 (2). In 2012 there were fourteen million new cases and the incidence is estimated to increase by 70% in the next 20 years (3). Nearly 70% of cancer deaths occur in low- and middle-income countries. Strategies to prevent cancer should be aimed at changing unhealthy habits such as smoking, diet, physical exercise, exposure to ultraviolet rays and alcohol. Smoking is the main risk factor causing about 22% of cancer deaths (4). On the other hand, early detection and screening can improve the prognosis of cancer patients. However, detection of cancer at an advanced stage and lack of diagnosis and treatment are common problems. In 2015, only 35% of low-income countries reported that public healthcare had pathology services to serve the general population.

Screening and early diagnosis

Cancer mortality can be reduced if cases are detected and treated early. Early detection activities have two components: screening and early diagnosis. There is a need to raise awareness and ensure access to health care, build capacity for timely diagnosis and referral, and improve access to appropriate treatment (5).

Within early detection, screening has been shown to be an effective strategy for the prevention of some types of cancer. The objective of screening is to identify abnormalities indicative of a cancerous or precancerous lesion before they produce symptoms. Screening is defined as the identification of unrecognized disease in apparently healthy individuals by means of studies, examinations or other procedures that can be applied rapidly (6). Screening programs can be very effective for certain types of cancer if appropriate tests are selected and used, other measures are applied in parallel in the context of screening, and the quality of the interventions is assured. In general, screening programs are much more complex public health interventions than early diagnosis. A screening program should include all components of the process that begins with the invitation of the target population and continues with access to effective treatment for patients who are diagnosed with the disease.
It is important, therefore, to increase the rate of cancer screening for which this intervention has been shown to be effective (cervical, breast, colorectal).

**Context**

Colorectal cancer (CRC) is the second most frequent cancer in our country (2). During 2015, a total of 7603 deaths were registered in Argentina, causing 12% of all deaths due to malignant tumors (7,8). However, CRC is one of the most feasible cancers to prevent and cure since it has a precursor lesion, the detection and resection of which makes it possible to effectively decrease the incidence. Screening for CRC is an effective strategy for reducing mortality by around 20% (9). The National Cancer Institute (INC) created the National Program for the Prevention and Early Detection of CRC (PNCCR) in 2013 with the aim of reducing the incidence and mortality rate. The performance of the Fecal Occult Blood Fecal Immunochemical Test (FIT) was shown to be cost-effective in Argentina (10), so the PNCCR recommends performing FIT annually, to the population between 50 and 75 years of age. In cases with a positive result, colonoscopy is recommended to visualize the interior of the intestine and remove the lesions found (11). However, due to multiple barriers at different levels, less than 20% of the population with exclusive public health coverage have undergone a FIT in their lifetime. The development of pilot projects in some regions of Argentina (Misiones, Tucumán, and Mendoza) made it possible to identify the main barriers that determine the low screening percentages in the population. Among the most important are low awareness among the population, low levels of coverage, need for greater political support, adherence of the first level of care, lack and deficit of training of human resources, problems of articulation between the different levels (12).

The design and implementation of new strategies to solve known problems are relevant to achieve the goal of reducing CRC incidence and mortality in Argentina. Strategies that contemplate different approaches, in addition to traditional methods, and that are feasible to implement are necessary to increase screening coverage.

**RATIONALE**

It is known that early detection of certain types of cancer significantly increases the probability of successful treatment and reduces mortality from these causes. The use of screening tools and early detection of selected tumors such as CRC are lower than expected in the public health care system in our country. Although the government funds the centralized provision of supplies for early detection activities, this does not necessarily extend the coverage of services in the public sector.
Theoretical Framework

Based on the evidence and analytical frameworks developed by the Guide to Community Preventive Services (13,14) we develop below a comprehensive analytical framework that takes into account strategies, interventions, outcomes and indicators for evaluation.

Strategies to increase the tracking rate can be categorized into:

- Strategies to increase community demand
- Strategies to increase community access to tracking.
- Targeted strategies for the health care provider to increase tracking.

Strategies for Increasing Community Demand

- Group Education
- Individual Education
- Reminders to the population
- Public incentives
- Mass media
- Small media outlets

Strategies to Increase Community Access to Tracking

- Reducing structural barriers: conducting tracking in different settings (community outreach) or eliminating or simplifying processes (structured diary or patient navigators, transportation to tracking site)
- Reduce out-of-pocket costs

Tracking Promotion Strategies in Healthcare Providers

- Performance evaluation and provider feedback
- Provider incentives
- Provider training
OBJECTIVE

To evaluate the effectiveness of a multicomponent strategy to improve screening and early detection of CRC by primary care centers in the public sector in our country.

STUDY DESIGN

A pragmatic clinical trial randomized by clusters will be carried out. The unit of randomization will be the health centers, 10 in total, 5 will be randomly assigned to receive an intervention aimed at increasing CRC screening rates (improvement cycles) and 5 to the control arm (usual care). A total of 119 participants will be included in each CAPS, in total, 1190 participants.

Selection of Health Centers

Eligibility criteria for Health Centers

Ten Health Centers in the province of Mendoza will be included which will be selected according to the inclusion criteria detailed below.

The research team will invite the selected health centers to participate in the study after an evaluation visit to determine their eligibility.

Inclusion Criteria

- PHCs belonging to the REDES Program and the PNCCR.
- PHCs located in an urban area according to 2010 census data.
- PHCs with ≥ 800 adult outpatient consultations per month.
- PHCs with health agents/health promoters and/or nurses available for active recruitment of persons at risk for CRC in the community.
- PHCs with primary care or general practitioners treating adult patients.
- PHCs with good connectivity and/or wifi for adequate data management and communication with the coordinating center.
- PHCs with well-differentiated programmatic areas that do not overlap with each other

Subject Selection

Study Population

Participant eligibility criteria

Inclusion criteria
• Subjects with only public health coverage
• Age between 50 and 75 years.
• Residence in the area of influence of the study health centers.
• Subjects who have an indication for CRC screening with FIT and have not undergone the test in the last year.

Namely:
- Both sexes, between 50 and 75 years of age.
- No personal or family history.
- No symptoms that can be related to colonic pathology (bleeding or changes in the usual way of evacuating the bowel, frequent abdominal or rectal pain, anemia or weight loss).

Exclusion criteria
• Persons who are immobilized.
• Persons who do not give informed consent.
• Persons planning to move in the next 3 months.

Enrolment of subjects

The 10 selected health centers that meet the inclusion criteria will be randomly assigned to the intervention or control group. Randomization will be performed centrally at the IECS data management unit. Five health centers will be randomly assigned to the intervention arm that provides for improvement cycles and five health centers to the control arm that will continue with usual care. Each health center will recruit 119 people eligible for the study.

Recruitment will take place both in the PHCs (waiting room, consultations, etc.) and in the community. For this purpose, health personnel (nurses, health workers, etc.) will have to actively search in the community. In this study, health personnel will visit households and those subjects who meet the eligibility criteria of the study will be invited to participate.

STUDY PROCEDURES

Screening

Trained and certified health personnel will search for eligible population in the PHCs and will visit the homes of the reference population of the corresponding health center. Responding subjects will be asked questions for a socio-demographic characterization and risk factors for CRC will be surveyed.
following the usual procedures of the PNCCR. Subsequently, the eligibility criteria for the study will be determined. Those subjects who meet the required criteria will be invited to participate in the study. Subjects who do not meet the required criteria will be given risk feedback and thanked for their time.

*Initial evaluation*
Participants who agree to participate will be explained what the study consists of and the informed consent form will be read to them. Those who indicate that they understand the study and are willing to participate in the whole process will be asked to sign an informed consent form and will be given a copy.

Subsequently, a brief questionnaire will be completed to collect personal data and clinical history (baseline data collection). They will also be given feedback regarding their increased risk for CRC, they will be given a FIT kit and will be informed about opening hours and consultations at the PHCs for evaluation and follow-up with a health professional.

**INTERVENTION**

This intervention model is based on the Institute for Healthcare Improvement’s breakthrough collaboratives, which combine the participation of providers with co-design of the intervention, periodic measurement and feedback, and innovation throughout the intervention period. Each of the sessions will constitute the analysis of the rapid improvement cycle. This model has been used in numerous improvement processes with varying success according to the selected objectives, scope and appropriate selection of participants (15,16).

**Theoretical Rationale:**
Quality improvement collaboratives are improvement methods that involve groups of providers coming together, whether from one organization or belonging to multiple organizations, to learn from and motivate each other to improve healthcare quality with common goal and common methods (17).

The approach is designed to help organizations make 'innovative breakthroughs' to close the gap between current practice and existing best practice by facilitating a structure in which healthcare organizations can learn from each other and from other experts (17). It therefore proposes an organized, multi-faceted approach that involves teams from different healthcare organizations coming together to learn, apply and share improvement methods, ideas and data on the performance of a service for a specific healthcare topic (18).
Based on the theory of change, healthcare teams learn faster and are more effective in implementing, disseminating improvement ideas and evaluating their own progress when they collaborate and benchmark with other teams (17,19,20).

**Previous activities:**

**Literature review:** to identify evidence-based best practices and interventions to increase CRC screening, a literature review will be conducted and summarize key interventions and supporting evidence.

**Recruitment of experts/coordinator:** discipline experts in both content and program delivery topics will be identified, as well as individual health providers who have already demonstrated innovative advancement in their own practice. The expert(s) will assist the study coordination in creating specific content for the collaborative project, including deciding on goals where appropriate, measurement strategies, and a list of evidence-based changes. An improvement consultant from the coordinating team teaches and mentors improvement methodology and how to apply it in the local setting (21).

**Description of the Intervention**

**Pre-randomization activities**

Presentation of the study to the participating health centers (both intervention and control): a 2-hour seminar will be developed centrally or virtually through the Webex or Zoom platform with representatives of all participating CAPS (physicians, nurses and/or health agents) as the first activity. This activity is considered necessary to introduce the study and to ensure that all providers from participating health centers have the same opportunity to learn about the relevance of the problem and current recommendations.

**Activities with health centers branch intervention**

The intervention combines the participation of the selected improvement teams in the health centers for the co-design of the intervention, measurement and periodic feedback and innovation throughout the intervention time. Each of the sessions will constitute the analysis of the phases of the improvement cycle (PDSA). This model has been used in numerous improvement processes with varying success according to the selected objectives, scope and appropriate selection of participants (15,16.)

**The following phases are proposed:**
1. **Formation of multidisciplinary work teams:** each health center in the intervention branch should form a multidisciplinary work team comprising 3-5 health providers (physicians, nurses and/or health workers) and health center staff (administrative staff) to learn from the collaborative process, implement small-scale changes and help generalize the changes when they are effective.

2. **Development of working model based on literature review and formative phase:** the study coordinating team will develop an implementation model based on the improvement model and considering barriers and facilitators that may be present to help improvement teams articulate the theory into objective outcomes.

3. **Initial workshop with providers for training in continuous improvement, agreeing on objectives, interventions and data collection:** the multidisciplinary teams will participate in an initial two-day face-to-face workshop conducted by the researchers and the study coordinating team, who will act as tutors. The main objective is for them to learn 1) collaborative projects; 2) implementation of changes or improvements; 3) generalization of changes when effective; 4) data measurement and reporting.

4. **Learning sessions:** to discuss results, applicability of interventions and modifications to the work plan. At least 3 face-to-face learning sessions of 1 day will be developed where all the multidisciplinary teams from each participating center (in one place) and experts will meet to exchange ideas. In the first learning session the experts present their vision of an ideal service in the topic under discussion, as well as suggestions for specific changes called "Change Packages". In the second and third learning sessions team members learn even more from each other by reporting their progress and successes, barriers encountered, and lessons learned in general sessions, working groups and presentations as well as in informal dialogue and exchanges. Formal academic knowledge is reinforced by the practical voices of expert team members. In between the learning sessions, so-called "Action Periods" take place. During these, teams test and implement changes in their health centers and collect data to measure the impact of the changes. The teams prepare and share monthly progress reports virtually (via Webex or Zoom platform) for all teams participating in the collaborative project.

5. **Closing session to evaluate preliminary results and discuss continuity of interventions beyond the project.** A closing session will be held towards the end of the study to present
the preliminary results of the intervention and discuss the factors that will ensure the persistence of the changes developed and adopted by the services.

**ACTIVITIES AT THE CONTROL GROUP HEALTH CENTERS**

To the participants belonging to the health centers assigned to the control group, the health personnel will give them a briefing on their risk for CRC, will give them FITS kit and will inform them about the possibilities of screening, evaluation and follow-up with a health professional from that health center.

**DATA COLLECTION AND FOLLOW-UP**

**Baseline data collection**

**Screening form**

The health personnel will complete the screening form for all subjects who agree to participate in the study. The data to be recorded are:

- Participant's name and surname
- ID NUMBER
- Date of visit
- Gender
- Age
- Date of birth
- Met eligibility criteria: YES/NO
- Provided informed consent: YES/NO

**Baseline assessment**

The following information will be collected in the baseline assessment questionnaire:

- Contact data: telephone and address
- Sociodemographic data: gender, age
- Socioeconomic data: employment status (employed, unemployed, retired), number of working hours per week, educational level, household income.
- Behavioral risk factors: weight and height per self-reported physical inactivity, diet, smoking, alcohol consumption.
Non-modifiable risk factors: personal history of CRC or polyps, personal history of inflammatory bowel disease, family history of CRC or polyps, hereditary syndromes, type 2 diabetes.

Distance from home to health center measured in blocks or km.

**Follow-up**

The follow-up of the FITs performed by the participants during the duration of the study will be carried out. This information will be obtained from the data recorded in the clinical history, in the kit delivery forms of the centers and records of the Screening Information System (SITAM) of the INC, in those PHCs where it is available.

**Table 1. Data collection**

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<tr>
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<td>Screening Form</td>
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<tr>
<td>Baseline questionnaire</td>
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<td>Follow-up questionnaire</td>
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**RESULTS OF THE STUDY**

The primary outcomes of the study are as follows:

1) Percentage of at-risk population completing screening.

2) Percentage of population classified as being at usual or increased risk due to risk factors in the reference population of the selected health centers.

**POWER AND SAMPLE SIZE**

For the initial calculation of the sample size we considered the following parameters: 1- baseline proportion of screening for Colorectal Cancer of 5%; 2- absolute minimum delta of 10% (proportion of screening in the intervention group higher than 15%); 3- intraclass correlation coefficient (ICC) 0.02; 4- two-tailed alpha level 0.05; 5- study power of 80%; and 6- potential data losses up to 10%. Ten health centers (clusters) will be included, 5 centers in the intervention arm and 5 centers in the control arm. The total sample size of the study will be 1,190 participants (595 participants per cluster), that is, 119 participants per health center. To calculate the sample size, the formula
developed by Donner, A. and Klar, N. 2000 was used. Design and Analysis of Cluster Randomization Trials in Health Research. Arnold. London and was applied in the Power Analysis and Sample Size software (PASS 2008, NCSS, Kaysville, UT) (23).

Data analysis plan

Statistical analysis will be performed on an intention-to-treat basis, in which primary outcomes will be compared between participants based on randomization of health centers to interventions or control regardless of their actual adherence to the intervention. Baseline patient characteristics will be compared between the intervention and control groups using one-way ANOVA or Chi 2 test depending on the type of data. For the primary outcome, a multiple logistic regression model will be constructed to assess the effect of the intervention. The parameters of the model will be estimated using the generalized estimating equations (GEE) method, which takes into account the grouping of patients within health centers (clusters). Odds ratio values will be calculated with a 95% confidence interval.

ETHICAL ASPECTS

Risks and discomfort

There are no foreseeable risks as the intervention in this study does not evaluate any drugs, devices, or procedures that are invasive. There is a risk of increased anxiety for those whose risk for CRC is habitual or increased. We anticipate that this will be mitigated by providing the participant with information on how to access a consultation with a trained health professional for a medical evaluation at health centers.

Potential Benefits

Current strategies to identify individuals at risk for CRC and screen with SOMFi are not achieving the expected results. We anticipate that implementing these strategies based on improvement cycles will significantly increase the proportion of people who perform the test, which could lead to improved outcomes associated with the prognosis of early-detected CRC.

Data Confidentiality

Mechanisms will be implemented to ensure the integrity of the study data, which comprise the Data Protection Plan described below.
All study staff will be trained to promote objective and standardized data collection and recording of participant information. Evaluation instruments will be edited immediately after completion for readability, consistency, and compilation. Data will be imported into a password-protected database, backed up via a secure external connection.

All paper files will be locked in filing cabinets and electronic documents will be protected with security passwords. In addition, both paper and electronic records will be uniquely identified with the participant’s identification number. Information linking the participant to the participant’s ID number will be retained in locked file cabinets.

To protect the confidentiality of the participants, the following steps will be followed:

- De-identification: Once the participant enters the study, he/she will be assigned an identification number. This number will be used to identify the case in all physical and electronic documents and will be part of the study data. Participants’ personal data will be kept in separate databases.

- All research data will be kept under lock and key in a file cabinet and will be available only to research staff directly involved in this project. Data will be identified only by study numbers (individual's identification number).

- Health care providers at the health centers will be the only persons with access to the data for the purpose of managing appointments and follow-up health information visits.

The principal investigator and the coordinating center for this project at IECS will have the ultimate responsibility for data safekeeping, for ensuring that the data protection procedures proposed here are properly applied, and for training field staff in data safekeeping techniques, as well as for supervising all personnel who handle files, studies, forms, and other information that identifies participants. Each person involved in data collection or data handling will sign a confidentiality agreement. Study data will be treated as strictly confidential.

All data identifying study participants will be destroyed with a paper shredder one month after the close of the project at each site. Consent forms will be retained after project closure.

**DATA QUALITY ASSURANCE AND QUALITY CONTROL**

**Development of the procedure’s manual**

The procedures manual will describe the instructions for conducting the baseline assessment of participants. It will describe the activities for each branch of the study and their implementation in the field, along with other operational aspects of the study.
TRAINING AND CERTIFICATION

In order to participate in the study, all personnel will be required to attend a training session prior to the start of field work. The training sessions will include all aspects of the protocol and procedural manual on enrollment, follow-up, intervention protocol and measurement procedures. Those who have acquired the expected competencies will be certified to perform the study procedures. Staff will be retrained if necessary.

Quality monitoring and reporting
Periodic monitoring of compliance with study procedures, including data management, will be conducted by the central coordinating team.

Site audit visits
Audit visits will be made to the health centers to monitor the progress of the fieldwork, identify problems, and carry out retraining if necessary.

STUDY ORGANIZATION

Study Management
In this project, the IECS will be responsible for carrying out the study, as well as the management activities (Dr. Irazola and Garcia Elorrio, principal investigators), in collaboration with the participating districts, which will provide logistical support for the study.

Study Data Coordinating Center
The data unit will work closely with each health center in patient recruitment, assessments, intervention implementation, data collection and quality control. The Data Coordinating Center will be located at the IECS.

Field Coordinating Center
IECS investigators will be responsible for overseeing the implementation of the intervention program, as well as participant follow-up.
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