




# 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

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Colorectal cancer (CRC) screening has been recommended for adults ages 50–75 years old. Screening rates remain low in Argentina with rates below 20%. A quality improvement intervention may increase the CRC screening with faecal immunochemical test in the primary care setting.

### WHAT THIS STUDY ADDS

⇒ 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.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings of this study highlight the importance of providers involvement in redesigning process of care. The effect size founded is a very good example of insufficient care and potential benefits that are of enough impact to justify the continuous establishment of improvement teams at the primary care level along health systems in Latin America.

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.<sup>1</sup> In Argentina, 81% of deaths are from CNCD, 35% are caused by cardiovascular diseases and 21% by cancer.<sup>2</sup>

Colorectal cancer (CRC) is the second most frequent cancer in Argentina,<sup>3</sup> and approximately 20 people die each day due to this cause.<sup>4,5</sup> For more than 20 years, research has shown that CRC screening reduces cancer incidence and mortality.<sup>6–8</sup> CRC screening has been recommended for adults ages 50–75 years old since 2008.<sup>9</sup> Nonetheless, screening rates remain low in Argentina with



rates below 20%, mainly among underserved groups and people covered exclusively by the public sector.<sup>10</sup>

The National Program for Prevention and Early Detection of CRC (Programa Nacional de Prevención y Detección del Cáncer Colorrectal—PNCCR—in Spanish) created by the National Cancer Institute aims to reduce the incidence and mortality of this condition.<sup>11</sup> Among the different available choices for screening, the performance of the faecal immunochemical test (FIT) proved to be cost-effective in Argentina,<sup>12</sup> 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.<sup>11 12</sup>

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.<sup>13 14</sup>

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.<sup>2 15</sup> In addition, Argentina presents higher CRC mortality than expected according to the incidence of this cancer in the country.<sup>2</sup> 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.<sup>10</sup> 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.<sup>10</sup> 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.*<sup>16</sup>

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.

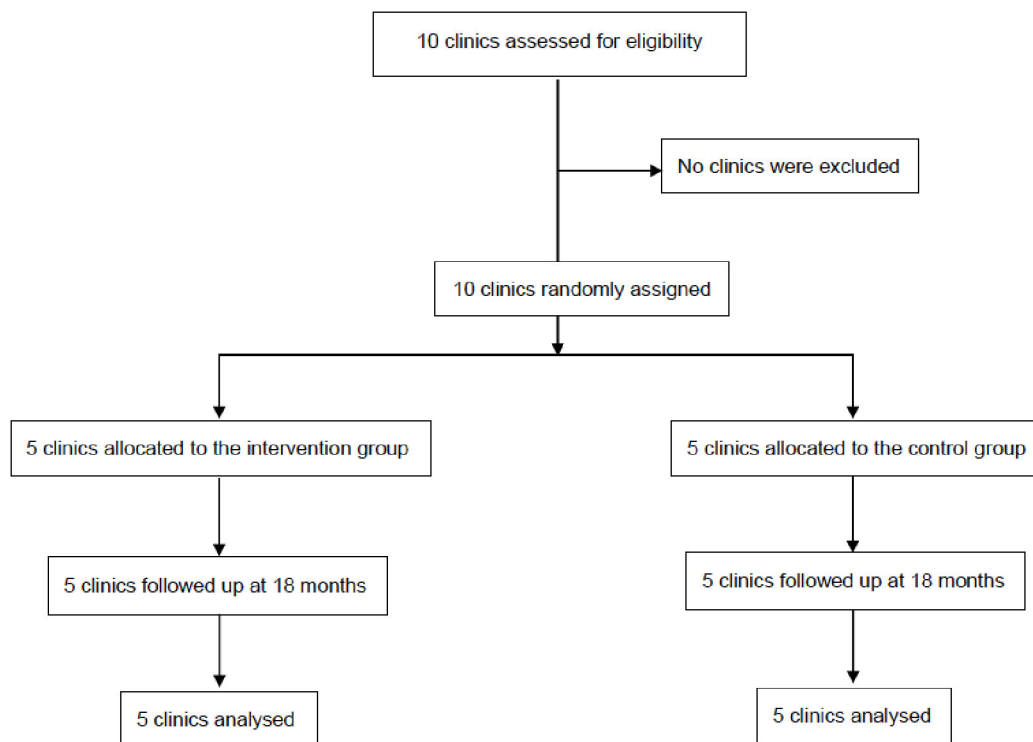
To measure the primary and secondary outcomes, specially trained personnel visited all the PHCs included in the study and registered the tests delivered and their results in laboratory lists and medical records.

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.<sup>17 18</sup> 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



**Figure 1** Trial design.

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.<sup>17</sup> A prioritisation process based on the nominal group technique was conducted to identify the initial actions to be carried out.<sup>19</sup>

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

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 intracluster 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

**Table 1** Study population characteristics

Characteristic	Control arm (n=750)	Intervention arm (n=750)
Male, n (%)	484 (66.8)	470 (62.8)
Age in years, mean (SD)	60.6 (6.8)	60.0 (6.7)
Primary education or less, n (%)	640 (86.7)	620 (82.9)
Lives alone, n (%)	289 (39.2)	302 (40.4)
Smoking, n (%)	135 (18.3)	142 (19.1)
Alcohol consumption, n (%)	8 (1.6)	18 (3.0)
BMI, n (%)		
Normal	100 (17.2)	81 (15.1)
Overweight	224 (38.6)	199 (37.0)
Obesity	257 (44.2)	258 (48.0)
Low consumption of fruits and vegetables, n (%)	705 (98.9)	590 (97.8)
Low level of physical activity, n (%)	295 (62.0)	340 (71.3)
Health condition, n (%)		
Excellent-Very Good-Good	555 (74.5)	507 (68.7)
Income, n (%)		
ARS 1 to ARS 8000	191 (25.5)	302 (40.3)
ARS 8001 to ARS 15000	138 (18.4)	223 (29.7)
ARS 15001 or more	75 (10.0)	28 (3.7)
Do not know/Do not answer	346 (46.1)	197 (26.3)
Employment, n (%)		
Unemployed	465 (62.5)	512 (69.4)
PHC close to home, n (%)	398 (53.9)	359 (48.0)
Consult at the PHC in the last year	549 (85.5)	554 (74.1)
Consult with a physician in the last year	617 (83.6)	595 (79.8)
PHCs close to home: distance to home <1 km. BMI, body mass index; PHC, primary healthcare centre.		

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

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

Primary drivers proposed to teams	Secondary drivers proposed to teams	Ideas for change: Commitments from the teams
Identification of the target population in the PHCs area of responsibility	Active recruitment in the community	<ul style="list-style-type: none"> <li>▶ Incorporate active screening into the health rounds of community health workers.</li> <li>▶ Expand the reference area for the rounds to the farthest sectors.</li> </ul>
	Opportunistic recruitment at PHCs	<ul style="list-style-type: none"> <li>▶ Identify target population from the list of scheduled shifts.</li> <li>▶ Identify target population during spontaneous demand consultations.</li> <li>▶ Stand to offer the test in the PHCs waiting room.</li> </ul>
	Registration of the target population	<ul style="list-style-type: none"> <li>▶ The change idea discussed for this driver was the creation of a registry, but it was not proposed by the teams.</li> </ul>
Awareness rising about CRC screening for the population	Educational campaigns	<ul style="list-style-type: none"> <li>▶ Disseminate information using local media, for example, posters in the neighbourhood and distribution of information material/brochures house to house.</li> <li>▶ Give informative talks at retirement centres.</li> <li>▶ Set up an information booth, hand out brochures and show videos on prevention and early diagnosis of CRC in the PHCs waiting room.</li> </ul>
	Disposition of professionals as educators	<ul style="list-style-type: none"> <li>▶ Organise informative talks for PHCs professionals.</li> <li>▶ Incorporate the subject into conferences or meetings to discuss cases among professionals.</li> </ul>
Interaction between multiple stakeholders of the health system	Teamwork	<ul style="list-style-type: none"> <li>▶ Distribute tasks and assign responsibilities by work shift.</li> <li>▶ Hold team meetings.</li> <li>▶ Internally audit the screening process.</li> </ul>
	Algorithm standardisation	<ul style="list-style-type: none"> <li>▶ Develop a screening protocol.</li> <li>▶ Prepare a flow chart of procedures for the PHCs.</li> </ul>
	Reduction of communication barriers among the different stakeholders	<ul style="list-style-type: none"> <li>▶ Multidisciplinary team meetings.</li> </ul>
	Training	<ul style="list-style-type: none"> <li>▶ Provide practical training for the use of the kit and reading the test.</li> <li>▶ Implement periodic retraining for stable and rotating staff.</li> </ul>
Access and service	FITs supply	<ul style="list-style-type: none"> <li>▶ Review the stock of pharmacy kits periodically and plan the orders.</li> <li>▶ Carry out practical demonstrations to improve sampling and adherence to the study.</li> </ul>
	Case tracking circuits	<ul style="list-style-type: none"> <li>▶ Create WhatsApp groups with reminder messages for return kits and results.</li> <li>▶ Identify effective channels of communication with the second level for performing colonoscopy in cases of positive tests.</li> <li>▶ Implement test-retrieval lists.</li> </ul>

CRC, colorectal cancer; FIT, faecal immunochemical test; PHC, primary healthcare 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.

### 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 recognise 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

	Control arm % (95% CI)	Intervention arm % (95% CI)	P value	OR (95% CI)
Proportion of participants with effective screening	54.2 (44.1 to 64.0)	75.0 (67.3 to 81.5)	0.0010	2.5 (1.4 to 4.4)

Data source: SITAM and registries at the health 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

SITAM was raised, although no strategies were identified to improve it. However, we could interpret that there were some changes in the workflow given the numerical difference.

Among the strengths of the study, we highlight: (i) the controlled and randomised design that ensured internal validity and allowed us to obtain conclusive results about the effectiveness of the intervention; (ii) the broad selection criteria for health centres that will allow the extrapolation of the results to a wider range of primary care centres in Argentina (external validity) and (iii) the development of the intervention in the daily context of health centres, which contributes to the feasibility of scaling up and sustainability of the proposed strategies.

The main limitation of the study was that the learning curve of the improvement cycles methodology in the different work groups was variable and required more time than initially estimated. Therefore, components, such as the quantification of intermediate results as a tool decision-making, were not fully implemented until late in the follow-up period. We believe that an initial training stage in quantitative tools could have improved this learning.

## 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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