ORIGINAL ARTICLE

Cluster Randomized Trial to Evaluate the Effect of a Multimodal Hand Hygiene Improvement Strategy in Primary Care

Carmen Martín-Madrazo, RN, MRes;[1] Sonia Soto-Díaz, MD;[2] Asuncion Cañada-Dorado, RN;[3] Miguel Angel Salinero-Fort, MD;[4] Manuela Medina-Fernández, RN;[5] Enrique Carrillo de Santa Pau, PhD;[6] Paloma Gómez-Campelo, PhD;[7] Juan Carlos Abánades-Herranz, MD[8]

OBJECTIVE. To evaluate the effectiveness of a multimodal intervention in primary care health professionals for improved compliance with hand hygiene practice, based on the World Health Organization's 5 Moments for Health Hygiene.

DESIGN. Cluster randomized trial, parallel 2-group study (intervention and control).

SETTING. Primary healthcare centers in Madrid, Spain.

PARTICIPANTS. Eleven healthcare centers with 198 healthcare workers (general practitioners, nurses, pediatricians, auxiliary nurses, midwives, odontostomatologists, and dental hygienists).

METHODS. The multimodal hand hygiene improvement strategy consisted of training of healthcare workers by teaching sessions, implementation of hydroalcoholic solutions, and installation of reminder posters. The hand hygiene compliance level was evaluated by observation during regular care activities in the office visit setting, at the baseline moment, and 6 months after the intervention, all by a single external observer.

RESULTS. The overall baseline compliance level was 8.1% (95% confidence interval [CI], 6.2–10.1), and the healthcare workers of the intervention group increased their hand hygiene compliance level by 21.6% (95% CI, 13.83–28.48) compared with the control group.

CONCLUSIONS. This study has demonstrated that hand hygiene compliance in primary healthcare workers can be improved with a multimodal hand hygiene improvement strategy.

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Healthcare-associated infections (HAIs) are deemed the most frequent adverse event threatening patients' safety worldwide,[1] representing 1.7 million patients affected in the US and 4.1 million in the European Union and nearly 100,000 and 37,000 associated deaths, respectively.[2,3] In Spain in 2010, the prevalence of hospital-acquired nosocomial infections was 6.70%,[4] data very similar to those for developed countries in terms of frequency, economic cost, and mortality.[5]

Since 1984, when Jarvis[6] summarized how Semmelweis advocated handwashing (washing with plain or antimicrobial soap and water) to reduce puerperal sepsis, many studies have demonstrated the inverse relationship between hand hygiene and nosocomial infections.[7-13] Nowadays, hand hygiene of healthcare workers, including hand disinfection (washing with gel, foam, and liquid solutions; alcohols), remains the single most low-cost procedure and constitutes the most effective and efficient measure to prevent HAIs and the propagation of resistance to antimicrobial agents.[14] With regard to hand hygiene procedures, the use of gloves does not replace the need for hand hygiene, and individuals should still use the conventional precautions and measures to prevent contact transmission.[15]

Hand hygiene is a simple procedure not sufficiently recognized by healthcare workers,[6] and the poor compliance level, up to 40%, has been documented repeatedly.[16-20] This poor compliance is associated with different factors, such as type of healthcare worker (physician), hospital location (intensive care unit), and level of risk for contamination (high-risk procedure).[17]

Although some previous research shows that interventions to improve hand hygiene compliance level have been successful, none has achieved lasting improvement.[6,16,21] To over-

Affiliations: 1. Centro de Salud Monóvar, Gerencia de Atención Primaria de Madrid, Spain; 2. Unidad de Apoyo Técnico a la Investigación, Gerencia de Atención Primaria de Madrid, Spain; 3. Dirección Técnica de Procesos y Calidad, Gerencia Atención Primaria de Madrid, Spain; 4. Fundación Investigación Biomedica, Hospital Carlos III Madrid, Spain; 5. Centro de Salud Miraflores, Gerencia de Atención Primaria de Madrid, Spain; 6. Unidad de Apoyo a la Investigación, Gerencia de Atención Primaria de Madrid, Spain; 7. Unidad de Epidemiología Clínica, Hospital Carlos III Madrid, Spain; 8. Unidad de Docencia e Investigación, Gerencia de Atención Primaria de Madrid, Spain.

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come some of these problems, in 2002 the Centers for Disease Control and Prevention published recommendations on hand hygiene in healthcare settings, which promoted the use of alcohol solutions and the implementation of multimodal and multidisciplinary strategies to improve hand hygiene compliance.[22] In 2004, the World Health Organization (WHO) approved the Alliance for Patient Safety, considering hand hygiene the cornerstone in preventing the dissemination of pathogen agents in the healthcare setting.[15,23] Recommendations were drawn up to reinforce the need for multimodal interventions, including key elements such as education and motivation of health personnel, incorporation of hydroalcoholic preparations, use of indicators of compliance, and commitment of all health managers. Nowadays, the WHO proposes a multimodal strategy for hand hygiene improvement that includes system change (the necessary infrastructure is in place to allow healthcare workers to practice hand hygiene), training/education (regular training on hand hygiene, based on the WHO's My 5 Moments for Hand Hygiene: before touching a patient, before a procedure, after a procedure or body fluid exposure risk, after touching a patient, and after touching a patient's surroundings), evaluation and feedback (monitoring hand hygiene practices and infrastructure along with related perceptions and knowledge among healthcare workers), reminders in the workplace (prompting and reminding healthcare workers about the importance, indications, and procedures of hand hygiene), and institutional safety environment (facilitating raising awareness about patient safety issues and guaranteeing hand hygiene improvement as a high priority).[24]

Hand hygiene is important in primary healthcare centers because this setting is undergoing considerable transformations, with the incorporation of more complex and invasive techniques than previously; in fact, the length of hospital stays has been reduced, and health care is moving to homes. All these factors increase the risk of developing and transmitting infections associated with healthcare outside the hospital.[25] However, in spite of the growing official documentation that supports the advocacy of hand hygiene procedures in primary care,[26] there is not enough scientific evidence of hand hygiene procedures being carried out in this setting.[27]

According to available evidence, multimodal intervention strategies improve hand hygiene and reduce HAIs.[28-30] The latest revision carried out by the Cochrane Collaboration on hand hygiene in 2010, which sought to establish which strategies are most effective in improving hand hygiene compliance, concludes that there is insufficient evidence to justify the election of these interventions and that it is necessary to carry out methodologically solid research.[28]

In this context, our study evaluates the effectiveness of a multimodal hand hygiene improvement strategy in primary healthcare workers, based on 3 sequential points: theoretical-practical workshop, implementation of hydroalcoholic solutions, and utilization of reminder advertisements. This intervention to improve hand hygiene compliance is based on the WHO's 5 Moments for Hand Hygiene.[24]

METHODS

Design

Cluster randomized trial, parallel 2-group study (intervention and control), carried out at primary healthcare centers in Madrid from January 2009 to December 2009.

Participants

The target population consisted of all healthcare workers (747) belonging to 21 primary healthcare centers. They are distributed in 7 healthcare worker categories: general practitioners, nurses, pediatricians, auxiliary nurses, midwives, odontostomatologists, and dental hygienists.

The methodology of the study has been previously described in detail.[31] Briefly, we calculated the power of the study adjusted for clustering effects, and the number of healthcare workers available to participate in this study was estimated a priori to be approximately 100 in each group (5 healthcare centers in each group). With this sample size, we calculated that the effect of the multimodal hand hygiene improvement strategy could be detected with 85% power with $\alpha = 0.05$, assuming a standard deviation of 5 percentage points. Given the unequal number of healthcare workers in the different primary healthcare centers, 1 group was composed of 5 centers and 104 healthcare workers, and the other was composed of 6 centers and 110 healthcare workers.

Randomization and Masking

The selection of the sample was done in 2 stages: first, 11 primary healthcare centers were selected by random sampling; then, in these selected centers, the healthcare workers were chosen by stratified random sampling (healthcare workers category strata). The flow diagram of participants is shown in Figure 1.

We sent a letter to the selected healthcare workers, informing them that a research study was being undertaken in relation to patient safety, which involved the observation of their regular care activities in the consultation office, the content of which could not be revealed to minimize the Hawthorne effect (altered behavior resulting from awareness of being a part of an experimental study).

All healthcare workers who accepted participating in the study had to sign the informed consent. The protocol of the study was approved by the ethics committee of reference (Hospital Ramón y Cajal, Madrid).

Measurement Instruments

Structured observation. Each healthcare worker that participated in the study was evaluated by direct, objective, and nonparticipatory observation of opportunities of hand hygiene, defined as all situations in which hand hygiene is in-

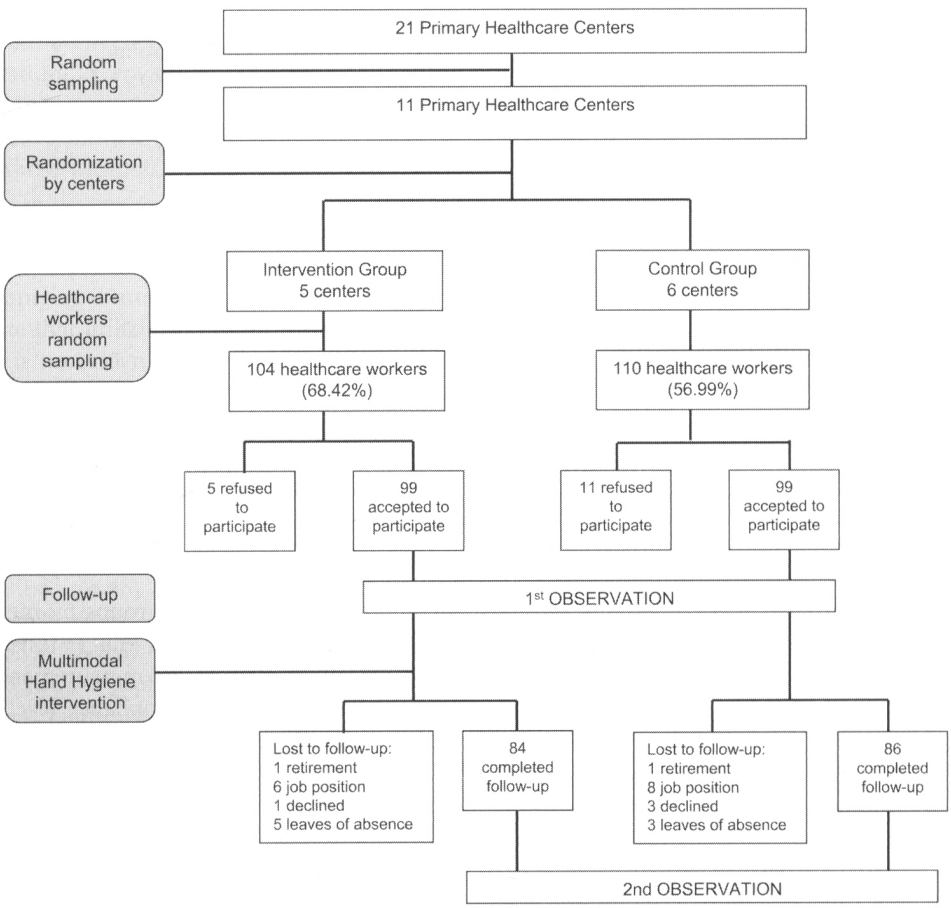

FIGURE 1. Flow diagram of participants in the study. The time of follow-up was 6 months.

dicated according to international guidelines of the WHO.[15,24] The baseline observation was performed in both groups over a period of 3 months. The multimodal hand hygiene improvement strategy was subsequently performed in the intervention group. In both groups, a second observation was conducted 6 months after completion of the multimodal hand hygiene improvement strategy. The healthcare workers were observed during routine patient care visits, with a total of 10 opportunities for hand hygiene observed per each healthcare worker on each observation.

Training of the observer. The observer received 5 hours of training of hand hygiene practices, which basically included the WHO's recommendations. Once trained, and before beginning observations, there was a pilot test of 20 observations at a primary healthcare center to evaluate the level of concordance between the observer and 2 healthcare workers expert on hand hygiene. When the κ index was equal to or higher than 80%, the study began. The degree of concordance between the observer and the 2 healthcare workers expert on hand hygiene during training of the observer and the pilot test was 0.90, according to the κ index (95% confidence interval [CI], 0.76–1.03).

Variables

The variables of healthcare workers studied were sex, healthcare worker category, type of contract, and professional experience (years). For outcomes, the variables baseline hand hygiene compliance level (HHC1) and hand hygiene compliance level at second observation (HHC2) were recorded. The hand hygiene compliance level was operationalized as the number of opportunities for hand hygiene taken divided by 10, which is the total number of opportunities for hand hygiene observed, and it was expressed as a percentage. The variable change was calculated in both groups as HHC2 minus HHC1. Finally, the effect of the multimodal hand hygiene improvement strategy was calculated as change in the intervention group minus change in the control group; a positive value indicated that the change was superior in the intervention group with respect to the control group, and a negative value indicated the opposite.

Intervention

At the centers to which the intervention group belonged, once the first observation had finalized, a combined multimodal

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TABLE 1. Baseline Characteristics of the Study Population

	Intervention group ($n = 99$)	Control group ($n = 99$)	P
Sex			
Male	24 (24.2)	22 (22.2)	.43
Female	75 (75.8)	77 (77.8)	
Healthcare worker category			
Nurse	42 (42.4)	43 (43.4)	.98
General practitioner	35 (35.4)	34 (34.3)	
Pediatrician	12 (12.1)	10 (10.2)	
Other[a]	10 (10.1)	12 (12.1)	
Type of contract			
Permanent	66 (66.7)	68 (68.7)	.91
Temporary	14 (14.1)	12 (12.1)	
Substitute	19 (19.2)	19 (19.2)	
Professional experience, mean (SD), years	19.49 (9.7)	20.93 (9.9)	.31

NOTE. Data are no. (%), unless otherwise indicated.

[a] Odontostomatologists, auxiliary nurses, dental hygienists, and midwives.

hand hygiene improvement strategy was carried out, on the basis of the WHO guidelines for hand hygiene in healthcare,[15] which includes training of healthcare workers by teaching sessions, implementation of hydroalcoholic preparations, and installation of reminder poster.

First, the teaching sessions—4 sessions of 50 minutes each for each health center selected—were provided after the collection of baseline data in the intervention group. The 6 steps of European Norms 1500 hand hygiene technique[32] was demonstrated by presenting a video that showed an on-site presentation by infection control healthcare workers and making recommendations for improvement after individuals passed the visual evaluation. Also, there were practical demonstrations of hand washing. Briefly, the hydroalcoholic preparation was tinted with fluorescent dye. After the hand hygiene procedure, healthcare workers placed their hands in a standardized box under ultraviolet light, and the number of areas that had been cleaned properly was calculated in a semiquantitative fashion. A score of 5 denoted hand hygiene disinfection applied to all fingertips (perfect technique) and a score of 0 denoted no visible disinfection on the fingertips (very poor technique). The 4 sessions were conducted by 2 nurses in a period of 1 month. Second, hydroalcoholic solutions were placed in each consultation office. Finally, reminder posters about the infection control measures (explaining the hand disinfection technique that is specified in the European guidelines[32] and that complies with guidelines issued by the WHO) on the walls were placed at key points (waiting room, emergency room, consultation office). The intervention was performed immediately after the first observation. The second observation was performed 6 months after the first in both groups.

Statistical Analysis

Healthcare worker characteristics and overall hand hygiene compliance level at baseline were compared between the intervention and the control groups by means of a Student t test for independent samples and χ^2 tests.

Within-group changes of measurements from HHC1 to HHC2 of hand hygiene compliance level were tested using paired t tests. The change between both groups was compared using a Student t test, after making sure that the analysis of the results with hierarchical or multilevel models was unnecessary, despite being a randomized study by clusters.

The trial was analyzed by intention to treat, including all randomized participants, with baseline observation carried forward for missing data and in the participants who completed the hand hygiene compliance level at second observation.

A level of $P = .05$ was considered significant in all analysis. The SPSS 17.0 statistical software package was used for the statistical analyses.

RESULTS

Of the 214 randomized healthcare workers, 170 (79.4%) completed the study. In the first observation, 16 declined to participate in the study (7.47%), and at the second observation, there were 28 losses (14.1%): 14 job position changes (50.0%), 8 leaves of absence (28.6%), 4 declines to participate (14.3%), and 2 retirements (7.1%). Following the analysis of the baseline characteristics of these losses, we verified that there were no significant differences (sex, age, healthcare worker category) with the rest of the population that finally completed the study. Figure 1 shows the flow of the participants in the study. Despite the losses, the power observed in the trial was more than 99%.

Our data show no statistically significant differences between groups in sex, healthcare worker category, years of experience, and type of contract (Table 1).

The HHC1 was 8.1% (95% CI, 6.2–10.1) in the overall sample and 7.98% (95% CI, 4.5–10.2) and 8.26% (95% CI, 6.2–11.6) for the intervention and the control group, re-

spectively ($P = .45$). In HHC1, there were no statistically significant differences between groups in the characteristics of the study population, except for the variable professional experience: healthcare workers with more than 20 years of professional experience showed a level of compliance significantly lower than those with less than 20 years of experience ($P = .001$; Table 2).

Because sampling was by clusters (primary healthcare centers), we have performed a preliminary analysis to evaluate the suitability of applying a multilevel model. The results of this analysis indicate that utilizing the multilevel approach is unnecessary: there is no evidence that the variance between the health centers in the variable change of hand hygiene compliance is different from 0 ($P = .36$), and the intraclass correlation coefficient has a value of 0.036.

Table 3 shows the difference between HHC2 and HHC1, change in each group, and effect of the multimodal hand hygiene improvement strategy. The effect of the strategy was 21.16% (95% CI, 13.83–28.48; $P < .001$). Data were greater for pediatricians (46%; 95% CI, 22.15–69.85), temporary contract (37.64%; 95% CI, 8.57–66.71) and healthcare workers with less than 20 years of professional experience (23.46%; 95% CI, 11.81–35.11; Figure 2).

TABLE 2. Baseline Hand Hygiene Compliance Level in the Total Sample ($n = 198$)

	n	Level of compliance, mean (95% CI)	P
Sex			
Male	46	10.0 (5.1–14.9)	.52
Female	152	7.6 (5.4–9.7)	
Healthcare worker category			
Nurse	85	8.5 (3.8–9.5)	.24
General practitioner	69	6.7 (5.4–11.5)	
Pediatrician	22	15.0 (5.4–24.5)	
Other[a]	22	4.5 (0.3–8.8)	
Type of contract			
Permanent	134	6.9 (4.8–9.0)	.19
Temporary	26	11.9 (4.2–19.7)	
Substitute	38	9.7 (4.9–14.5)	
Job experience			
≤20 years	110	10.9 (7.8–14.0)	.001
>20 years	88	4.6 (2.6–6.7)	

NOTE. CI, confidence interval.
[a] Odontostomatologists, auxiliary nurses, dental hygienists, and midwives.

DISCUSSION

Our results show that a multimodal hand hygiene improvement strategy improves the compliance level of hand hygiene in primary healthcare workers by 21.6%, compared with the control group. These data were consistent with those provided by different observational and experimental studies without a control group, which show, with educational interventions, similar degrees of repercussion, with increments of between 18% and 41.4% in hand hygiene compliance.[9,33-35] Recently, Erasmus et al,[36] in a before-and-after study to explore the usability and indications for efficacy of using action plans among nurses in 2 hospital staff in order to improve hand hygiene, found data that the intervention improved hand hygiene compliance by 16.1%, which is very similar to the results reported by our study.

To our knowledge, there are few clinical trials that have compared improving hand hygiene using a double-masked procedure for both the observer, who did not know which group was being observed, and the healthcare workers, who were unaware in which activity they were being observed.

Also, no studies have been conducted in primary care settings,[27] impeding the comparison of our results to similar settings. Furthermore, although direct observation has been established as the gold standard for hand hygiene monitoring,[37] the reports in the literature show high variability to measure adherence to hand hygiene; this makes it difficult to compare the results of effective practices.[38,39]

Our study contributes, in part, to filling the gap that exists in evaluations of an educational multimodal hand hygiene improvement strategy, applying the most recognized design for evaluating the effectiveness of an intervention: a randomized trial with a parallel 2-group methodology (intervention and control). We think that professionals did not know the purposes of observation, because this information was not disclosed to the participating centers. Indeed, our view is reinforced by the fact that the control group slightly improved their level of compliance at the second observation. This circumstance would not have happened if the objective were known.

We believe that our results have greater-level evidence than those published with other designs—such as simple before-and-after designs, which constituted 47% of studies of hand hygiene compliance included in the systematic review of Erasmus et al[20]—because during any given period, multiple changes typically occur within a healthcare system (nosocomial infections, onset of national programs on infection control), and 1 or more of these other changes might have produced the observed improvements. For this reason, it is necessary to use a randomized clinical trial with a control group, as used in our study.

The multifactorial character of the intervention makes it difficult to ascertain which implemented actions are most effective. The hydroalcohols tend to be introduced as part of interventions with several components of hand hygiene compliance and not separately, and it is difficult to evaluate their effects independently. A systematic review carried out by the National Health Service in Scotland to evaluate the clinical effectiveness of hydroalcoholic solutions in improving hand hygiene compliance could find no conclusive evidence that alcohol-based products either have any impact on hand hygiene compliance or reduce levels of HAI, because clinical trials were poorly designed.[40] In our study, the improvement of 3.6% in the control group at 6 months with respect to the

TABLE 3. Effect of Multimodal Intervention on Hand Hygiene Compliance in Both Groups

	Intervention group (n = 84 [SOC], 99 [BOCF])				Control group (n = 86 [SOC], 99 [BOCF])					
Overall compliance level	HHC1	HHC2	Change	P	HHC1	HHC2	Change	P	Effect (95% CI)	P
SOC	7.98	32.74	24.76	.001	8.26	11.86	3.60	.037	21.16 (13.83–28.48)	.001
BOCF	7.37	28.38	21.01	.001	8.89	12.02	3.13	.037	17.88 (11.41–24.35)	.001

NOTE. Data are percentages, unless otherwise indicated. BOCF, baseline observation carried forward; CI, confidence interval; HHC1, baseline hand hygiene compliance level; HHC2, hand hygiene compliance level at second observation; SOC, second observation completed.

baseline moment might be attributed to the introduction of hydroalcoholic solution dispensers at all the healthcare centers in the area, not only in the intervention group, resulting from the 2009 campaign of standard measures indicated in the pandemic influenza A (H1N1) virus.

Our study was carried out with healthcare workers in primary healthcare settings. It was conducted at this community primary care setting because evidence shows that infections have increased very rapidly in recent years in healthy people without risk factors, caused by methicillin-resistant *Staphylococcus aureus*[41] and by multiresistant germs.[42] Hand hygiene has been underestimated since the appearance of antibiotics. However, currently, the European Centre for Disease Prevention and Control and the Conference on Healthcare-Associated Infection,[43] among others, propose hand hygiene as the main measure for the control of the propagation of *Staphylococcus* in hospitals and outside the hospital. The strict observance of hand hygiene applied before and after direct contact with the patient as well as standard precautionary measures are recommended.

HHC1 in our study was 8.1%, extraordinarily low in relation to that published in a hospital setting, which varies from 30% to 50%.[11,14,16] These data, much lower than the values considered suitable, could be explained, in part, because primary healthcare workers have high patient volume and spend between 4 and 5 minutes per patient visit,[44] and an inverse relationship between high intensity of care and low hand hygiene compliance[45] is known; this may have rendered a reduction of the Hawthorne effect, since the healthcare workers did not know the reason for observation. Pittet et al[19] associated this effect with hand hygiene compliance, and it is known that the Hawthorne effect has been quantified in a 14% overestimation of hand hygiene compliance.[46]

The healthcare workers with more than 20 years of experience had worse levels of HHC1. This association between professional experience and hand hygiene compliance is controversial in the literature; some authors have found no relationship between age of healthcare worker or professional experience and hand hygiene compliance,[47-48] whereas other studies have revealed that senior healthcare workers have the lowest compliance compared with junior healthcare workers.[49] Although it can be expected that senior healthcare workers possess the best knowledge and have the relevant professional experience, this does not seem to translate

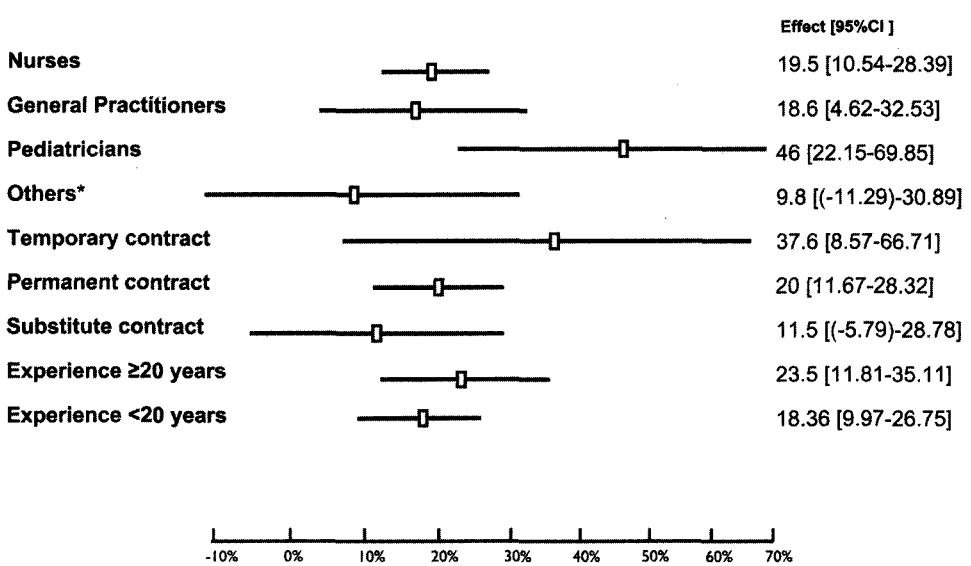

FIGURE 2. Effect of multimodal hand hygiene improvement strategy, stratified by healthcare worker category, type of contract, and years of job experience. Others = odontostomatologists, auxiliary nurses, dental hygienists, and midwives. CI, confidence interval.

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automatically into clinical practice. It is possible that professional burnout—given that job seniority in primary care is associated with high levels of professional burnout—has a negative effect on day-to-day work, in this case on the correct practice of hand hygiene.[50]

Numerous studies have noted that nurses comply the most with hand hygiene practice.[11] However, our data indicate that in HHC1, the pediatricians were those who disinfected their hands with the highest frequency. This may be because these healthcare workers have a higher perception of risk in the propagation of infectious agents through the hands, possibly because pathologies of an infectious origin are the most common reason for a pediatric visit in our care setting.

Our findings should be interpreted in the context of several limitations. First, the potential spillover effect from the intervention group to the control group was minimized by cluster randomization to the groups. If a spillover effect still occurred, it would have tended to reduce the observed effects of the multimodal hand hygiene improvement strategy. Second, the hydroalcoholic solutions were introduced at all healthcare centers of Madrid, coinciding with the pandemic influenza A. This point could undermine the effectiveness of the intervention. Also, the N1H1 pandemic may have influenced the results. Finally, the increase of hand hygiene compliance level before implementation of the multimodal hand hygiene improvement strategy might be partly explained by a phenomenon of regression to mean that would have happened in both groups.

The fundamental contribution of our study has been to demonstrate, with a robust methodology, the utility of a multimodal hand hygiene improvement strategy to improve hand hygiene compliance in primary healthcare settings. However, although the benefit of the intervention was statistically significant, there is still a wide margin for improvement. In this sense, it is necessary to incorporate objectives of care management that include hand hygiene within the primary healthcare management contracts. Also, a program focused on amplifying the role of health professionals as a strategy to further reduce HAIs in the future is necessary.

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Address correspondence to Carmen Martín Madrazo, RN, MRes, Centro de Salud Monóvar, Gerencia de Atención Primaria de Madrid, Spain (cmartinm.gapm04@salud.madrid.org).

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