

Effectiveness of the ICCMS caries management system for children: a 3-year multicentre randomised controlled trial

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ABSTRACT

Objective: This 3-year multicentre randomised controlled trial compared, in 6-7-year-old Colombian children, the effectiveness of the ICCMS (International Caries Classification and Management System) with a conventional caries-management system (CCMS) in terms of individual caries-risk, caries lesions, and secondarily, oral-health-related knowledge/attitudes/practices, and number of appointments.

Material and methods: With ethical approval, 240 6–7-year olds from six Colombian clinics were recruited. Trained examiners conducted the following baseline/follow-up assessments: Caries risk (Cariogram-ICCMS); caries severity/activity staging (ICDAS-merged combined radiographic/visual); seal-ants/fillings/missing teeth, and oral-health-related knowledge, attitudes and practices. Children received their randomly allocated (ICCMS/CCMS) care from dental practitioners. Outcomes: caries-risk control (children); caries-progression control (tooth surfaces); oral-health-related knowledge/attitudes/practices improvement (parents/children), and appointments' number (children). Descriptive and non-parametric/parametric bivariate analyses were performed.

Results: Three-year-follow-up: $n = 187$ (77.9%; ICCMS: $n = 92$; CCMS: $n = 95$) disclosed a baseline-to-3-year overall high-caries-risk children decrease (ICCMS: 60.9–0%, $p < .001$; CCMS: 54.7–5.3%, $p < .001$) ($p > .05$). ICCMS versus CCMS showed: fewer tooth-surface caries progression (6.2% vs 7.1%, $p = .010$) and fewer active-caries lesions (49.8% vs. 59.1%, $p < .05$); higher proportion of children with ≥ 2 /day fluoride-toothpaste tooth-brushing practice ($p < .05$); similar mean number of appointments (10.9 ± 5.9 vs. 10.0 ± 3.8 , $p = .15$).

Conclusion: Both caries-management systems showed similar effectiveness in caries-risk control, with ICCMS more effectively controlling tooth-surface caries progression and improving toothbrushing practices.

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Background

Historically, conventional management of dental caries has focussed on restoration of cavitated caries lesions (tooth decay) combined with population-level preventive measures [1]. This Conventional caries management system (CCMS) is standard care within Colombian dental services [2]. However, current evidence suggests focussing on long-term health, specifically on the preservation of tooth structure, maintaining sound teeth as sound, and controlling caries progression from initial caries stages [1]. Caries management programmes focussing on non-operative approaches have been able to demonstrate better effectiveness in controlling caries progression in schoolchildren [3] and adults [4] than

conventional approaches, and in avoiding dental pain/infection in young children [5]. Consequently, Colombian dental schools agreed in 2013 on a consensus for undergraduates' cariology teaching curriculum with a more preventive/minimally interventive focus [6].

The International Caries Classification and Management System (ICCMSTM) (2012) built upon the International Caries the Detection and Assessment System (ICDAS). ICCMS constitutes a best-practice approach that focuses on health outcomes and is a patient-centred, risk-based, preventively orientated, minimally interventive caries management system [7–9]. Figure 1 shows the ICCMS caries-care four-element cycle, which includes an individual- and a tooth-surface-level examination and respective synthesis/diagnosis and caries-care, as follows: 1D. Determine:

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 Supplemental data for this article can be accessed [here](#).

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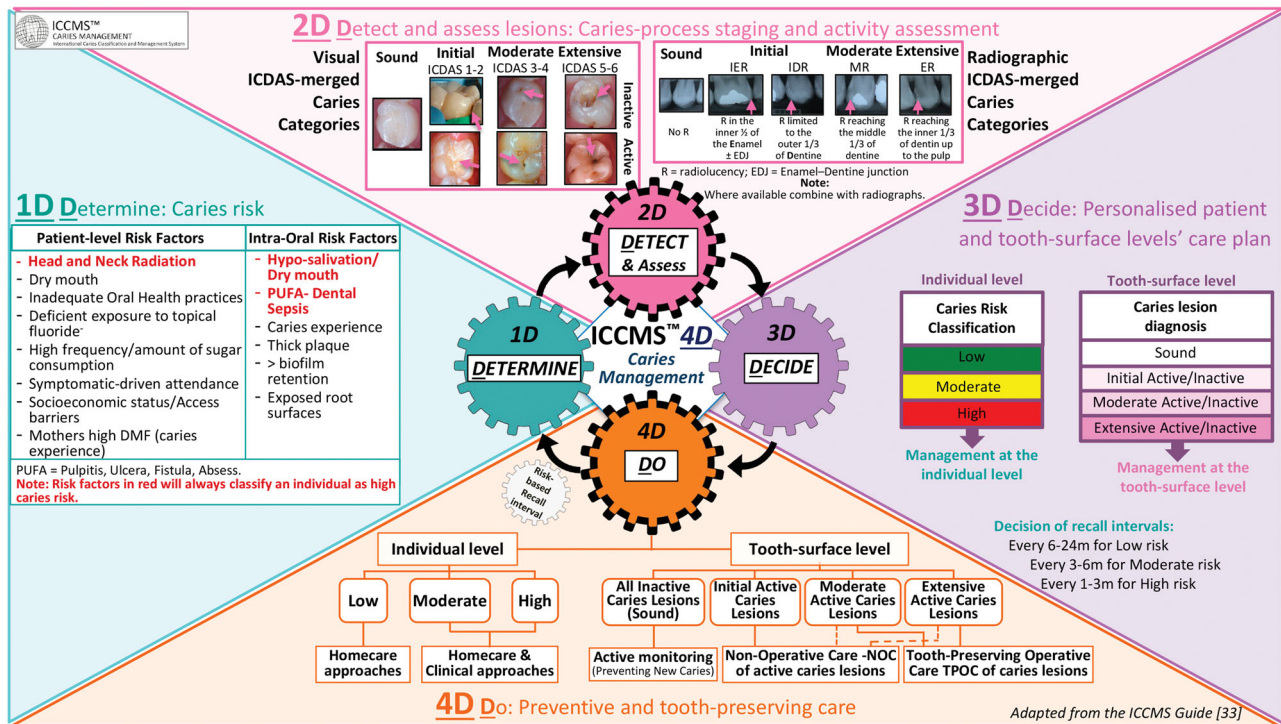


Figure 1. ICCMS™ 4D Caries Management cycle.

caries risk assessment; 2D. Detect and assess: caries-process staging combining visual with radiographic criteria (when available) and activity assessment with the ICDAS-merged system (Initial, Moderate and Extensive Active/Inactive caries lesions); 3D. Decide: personalised patient and tooth-surface levels care plan, and 4D. Do: individual-level risk-adjusted preventive care; tooth-surface level care of active caries lesions: non-operative care of initial caries lesions and moderate caries lesions (when radiographically located up to the outer external dentine third), and tooth-preserving operative care of extensive caries lesions (dentine cavitated), and in cases of moderate caries lesions (when radiographically located deeper than the outer dentine third) [7–9].

Since its launch, research using ICCMS has reported its use in multiple settings: for epidemiology and public health purposes [10–14]; evaluating its use among dental practitioners [15], students [16], and the former two plus educators [17]. A recent randomised clinical trial (2021) [18] comparing caries incidence in young adults after one year of either ICCMS or CAMBRA caries risk management found no significant differences ($p > .05$). To date, however, no research has looked at wider outcomes from the use of the ICCMS system. This multicentre randomised controlled trial (RCT) aimed to assess multiple outcomes over 3 years, in 6–7-year-old Colombian children to compare the effectiveness of ICCMS vs. CCMS. These included, primarily, assessing the progression control in caries risk and caries lesions, and secondarily, oral-health-related knowledge, attitudes and practices, and the number of appointments for patients in each group.

Materials and methods

This multicentre two-arm parallel-RCT was registered on the Clinical Trials website (ClinicalTrials.gov number: NCT04676230;

date: 03/05/2014), was conducted with ethical approval from the Ethics Committee at Universidad El Bosque (UEB 008-2014) and followed the CONSORT guideline. Both the trial protocol and Ethical approval are provided in Supplemental Appendix 1 (in their original language).

The sample size was calculated using the 'Tamaño de Muestra' Program® (version 1.1), taking into account the study conducted by Griffin et al. [19], considering a type-I error of 0.05; a type II error of 0.80. The findings from four previous studies in which initial (non-cavitated) caries lesions received non-operative care sealants vs. no treatment, indicated a caries progression proportion of 0.41 in the control group and of 0.09 in the test group [19]. Thus, a sample size of 108 participants was required, plus a 20% increase to take into consideration dropout over three years, resulting in a sample size of 130 6–7-year-old children (65 in each arm). It was decided that each dental school clinic (centre) should enrol 40 participants (20 per arm) to keep the trial manageable.

All ACFO (Colombian Dental School Association) dental schools ($n = 25$) were invited to participate through an online letter. Nine centres in six corresponding cities (Bogotá: $n = 3$; Barranquilla: $n = 1$; Bucaramanga: $n = 1$; Cali: $n = 1$; Cartagena: $n = 2$, and Manizales: $n = 1$) agreed to participate and went on to participate in training. Each centre had a coordinator, who also acted as baseline examiner, and one to two dental practitioners whose role was to treat the children following their randomly allocated management approach.

Training of each centres' personnel

Baseline examiners/Centre coordination

Baseline examiners were asked to study the ICCMS Guide for Practitioners and Educators in preparation for further training

Table 1. ICDAS-merged radiographic and visual combined caries severity and activity stages.

ICDAS-merged Visual caries and activity stages	ICDAS-merged Radiographic caries stages					
	Sound	IER	Initial		Moderate	Extensive
			IDR	ER		
Sound	No R	R in inner 1/2 of the enamel ± EDJ	R limited to the outer 1/3 of dentine	R reaching the middle 1/3 of dentine	R in the inner 1/3 of dentine up to the pulp	
ICDAS 0	No evidence of visible caries	Initial A/I	Initial A/I	Moderate A/I	Extensive A/I	
ICDAS 1–2	Changes in enamel seen as caries opacity or visible discolouration.	Initial A/I	Initial A/I	Moderate A/I	Extensive A/I	
ICDAS 3–4	Localised enamel breakdown/Underlying dentinal shadow obvious visible dentine cavity in opaque/discoloured enamel	Moderate A/I	Moderate A/I	Moderate A/I	Extensive A/I	
ICDAS 5–6		Extensive A/I	Extensive A/I	Extensive A/I	Extensive A/I	

IER: Initial enamel radiolucency; IDR: initial dentine radiolucency; MR: moderate radiolucency; ER: extensive radiolucency; EDJ: enamel-dentine junction; A: active; I: inactive.

[8,20]. They were clinically trained and calibrated in the visually assessed ICDAS caries severity criteria (Sound: ICDAS 0 and caries lesions: ICDAS 1–6) by an ICDAS expert (SM); this helped to assure inter-/intra-examiner reproducibility [20,21]. The 3-day training and calibration included theoretical, pre-clinical and clinical sessions and discussions followed by the clinical assessment and re-assessment of over 100 preregistered tooth surfaces in 10 patients from which weighted Kappa were calculated. Afterwards, these baseline examiners participated in further one-day training to cover the remaining outcomes. This included assessment of ICDAS caries activity criteria [8,20], using the ICDAS-merged caries criteria for radiographs [8,20] and how to determine ICDAS-merged radiographic-visual combined severity and activity caries stages (Table 1). This training day also covered the ICCMS-Cariogram assessment of individuals' caries risk assessment [8,20,22] and using a questionnaire to assess parents' knowledge, attitudes and practices in relation to children's oral health [23]. For the study coordination part of their role, they were trained in the study protocol, emphasising the ICCMS group interventions (described in Figure 2) and the completion of the clinical record form and the excel database. Their roles also included training and monitoring the dental practitioners in their centre.

Dental practitioners

The dentists in the trial were also asked to study the ICCMS Guide for Practitioners and Educators in preparation for their training [8,20]. Together with their centre coordinator, they attended a one-day training conducted centrally, either in Bogotá, Cali or Cartagena. The training focussed on the two caries management strategies which they would be using in the trial. Emphasis was given to differentiating between the ICCMS system [8,20] – whose concepts were introduced to Colombian dental schools in 2013 [6], and the standard of care in Colombian dental services - the CCMS system [2]. ICCMS was thoroughly discussed, considering the child-level caries risk assessment and caries lesion diagnosis (1D, 2D), decision making (3D) and delivery of care plan (4D). Dental practitioners were asked to adhere to the detailed protocol for each patient's randomly assigned trial arm, these thorough written descriptions of activities for each system, which were discussed to ensure clarity of understanding. The training also included the completion of the clinical record form and the excel database. They received further local training and monitoring by their centre coordinator.

After these training events, three dental schools retired from the project. One closed down (Fundación Universitaria San Martín, Barranquilla) and two, due to their inability to achieve the agreed recruitment timeline (Universidad Santo Tomás, Bucaramanga; Pontificia Universidad Javeriana, Bogotá).

The study took place between March 2014 and November 2017, at six centres, corresponding to dental school clinics: two located in the Northwest on the Caribbean coast (Universidad de Cartagena, Cartagena and Corporación Universitaria Rafael Núñez, Cartagena); one in the West coffee-

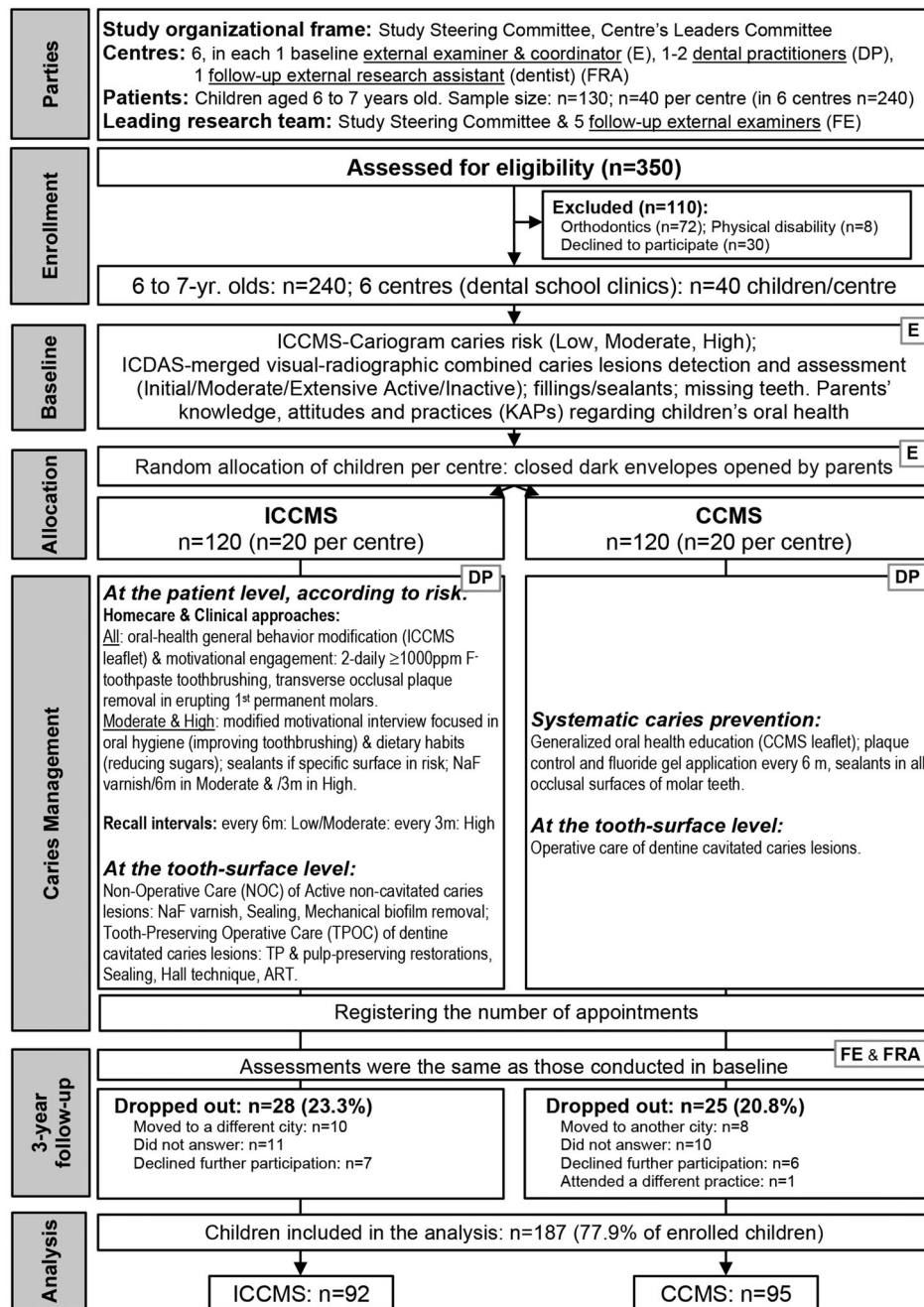


Figure 2. Study flowchart.

growing region (Universidad Autónoma de Manizales, Manizales); one in the South West coffee-growing region (Universidad del Valle, Cali), and two in the centre and capital city of Bogotá (Universidad Colegio Odontológico Colombiano and Universidad El Bosque). The study flowchart is depicted in Figure 2. Children between 6 and 7 years of age attending the participating centres were invited to participate (from March to November 2014) by the local researchers. They were sequentially recruited until the sample size quota of 40 eligible children per centre was reached. Inclusion criteria were children to be receiving dental care only at the centre for the following three years, absence of systemic diseases or motor/

cognitive/physical disabilities, and not undergoing orthodontic treatment. Those who met the eligibility criteria and consented to take part were enrolled from April to November 2014 (Figure 2), assent was obtained from each child. All assessments and care of the 240 enrolled children were performed in each trial centre.

Baseline assessments

Before random assignment of children to their intervention group, baseline child-level caries risk assessment and caries lesion assessment were recorded by the baseline examiner

(Figure 2). The child-level caries risk assessment was done by interviewing the parent and clinically assessing the child. The ICCMS/Cariogram caries risk factors [8,20,23] assessed were: related diseases (reported hyposalivation); diet content (\geq two daily fermentable carbohydrate food/beverage) and frequency (>5 food/beverages daily intakes); fluoride programme (community fluoridation programme, periodic professional fluoride application); dental biofilm index (Silness and Løe modified) [24]; saliva secretion (no clinical signs of hyposalivation); clinical judgement (corresponding here to symptomatic attendance to the dentist); presence of \geq one cavitated (Extensive) caries lesion or a number of teeth with caries experience (dmft plus DMFT: decayed –d/D Moderate and Extensive caries lesions; due-to-caries missing –m/M and filled –f/F teeth in primary and permanent teeth) which was higher than the national average for their age, with the national figures summing up the dmft and the DMFT corresponding to 2 for the 6-year olds, and 4 for the 7-year olds [25]. The visual caries lesions' detection, severity staging and activity assessment was conducted on cleaned teeth (after supervised toothbrushing) using the ICDAS-merged visual-only caries severity criteria: Sound (ICDAS 0), Initial caries (ICDAS 1–2), Moderate caries (ICDAS 3–4), Extensive caries (ICDAS 5–6), and the caries lesion's Active/Inactive status assessment based on the severity of caries (non-cavitated vs. cavitated), the colour (whitish/yellowish vs. whitish/brownish/black) and opacity (loss of lustre vs. shiny), the tactile sensation (rough vs. smooth and in cavitated lesions soft vs. hard), and if located in a plaque stagnation area [8] (Table 1). Missing teeth (m/M) and filled surfaces (f/F) were registered, as well as pits and fissure sealants. The radiographic assessment of caries lesions was conducted using bite-wing radiographs according to the ICDAS-merged caries radiographic criteria: Sound (No radiolucency), Initial caries (Initial Enamel/Dentine Radiolucency), Moderate caries (Moderate Radiolucency), Extensive caries (Extensive Radiolucency). Combined ICDAS-merged caries scores were derived by comparing visual-only plus radiographic ICDAS scores following ICCMS guidance selecting the most severe one, classifying each lesion into Initial, Moderate or Extensive Active/Inactive [8] (Table 1).

Parents' knowledge, attitudes and practices in relation to children's oral health were assessed with a questionnaire based on a validated instrument [23]. This included six items: (1) Knowledge about the feasibility of preventing dental caries; (2) Attitude about the parent's responsibility for the child presenting with caries, and four items related to practices: (3) Symptomatic dental attendance; (4) Brushing the child's teeth twice-a-day with fluoridated toothpaste, (5) Parents actively participating in the child's toothbrushing, and (6) Number of daily sugary food/beverage intakes.

The individual caries risk was calculated using the Cariogram[®] software, classifying the patient into low, moderate or high caries risk [22]. The final clinical severity of caries lesions used the combined radiographic and visual score, as well as its activity/progression status as Active/Inactive [8,20].

The dmfs and DMFS indices were obtained to present epidemiological data, including the Initial ICDAS-merged caries

lesions within the d/D component (ICDAS-dmfs and ICDAS-DMFS) [10,26].

Random allocation

The random allocation of individuals to their trial arm was conducted using the Stata[®] 10.0 statistical software (Stata Corp LP, College Station, TX, USA), stratifying by location with a 1:1 allocation with randomly permuted blocks of random sizes of 2, 4, and 6. Researchers were blind both to the ordering of blocks as to their respective size. This random allocation sequence process was prepared and supervised independently by one of the authors (LFG). Each centre enrolled a total of 40 participants (20 per arm). The baseline assessments were conducted by the examiner prior to the assignment of children to either management system to guarantee examiner's blindness to intervention. The children's assignment to the intervention was afterwards led by the same examiner with sequential closed dark randomisation envelopes and under the presence of an external assistant. The closed-dark envelopes were opened by each child's parent, together with the dental practitioner.

Caries care

At each dental school clinic, all enrolled children received the intended treatment, according to the child's assignment to either ICCMS or CCMS system. The examiner and the dental practitioner planned together the child's respective care plan according to the trial protocol for their randomly allocated trial arm (Figure 2). The ICCMS caries management system [8] corresponded to child-level caries management approaches, with homecare alone for low caries risk, and combined with clinical approaches for moderate and high caries risk. Motivational interviews were used in the dental office to improve inadequate oral hygiene and dietary habits. These use empathic interactions to develop patient's motivation to improve behaviours [27]. ICCMS also included caries lesion care according to their severity and activity status, with either active monitoring (AM), non-operative care (NOC) or tooth-preserving operative care (TOPC), as described in Figure 1 and with detail in Figure 2, including the recall intervals [8,20]. The CCMS caries management system followed the current conventional standard of care, including at the child-level care, systematic caries prevention for all children with generalised oral health education, periodical fluoride gel application and oral biofilm control, and fissure and sealants on all occlusal surfaces; at the tooth-surface level, operative care of cavitated dentine caries lesions (ICDAS Extensive) [2] (Figure 2).

The dental practitioners, who delivered both caries care systems, conducted the randomly assigned care on each patient, recording in the oral health record the date and procedure/s conducted at each appointment. Neither the participants/parents nor the dental practitioners were blinded to the intervention.

Table 2. Baseline demographic and clinical characteristics of children enrolled in the study.

	ICCMS (n = 120)		CCMS (n = 120)	
	n	%	n	%
Age				
6 years	64	53.3	55	45.8
7 years	56	46.7	65	54.2
Sex				
Female	58	48.3	54	45.0
Male	62	51.7	66	55.0
Socioeconomic level				
Low	29	24.2	30	25.0
Middle	84	70.0	84	70.0
High	7	5.8	6	5.0
Caries risk				
Low	8	6.7	9	7.5
Moderate	36	30.0	45	37.5
High	76	63.3	66	55.0
		%		%
Prevalence of caries experience (dmf/DMF)				
Primary teeth (dmf)		70.0		65.0
Permanent teeth (DMF)		23.3		20.0
Primary and permanent teeth combined (dmf/DMF)		75.0		70.0
Prevalence of ICDAS caries experience (ICDAS-dmfs/DMFS)				
Primary teeth (ICDAS-dmfs)		90.0		82.5
Permanent teeth (ICDAS-DMF)		58.3		55.0
Primary and permanent teeth combined (ICDAS-dmfs/DMF)		95.8		90.8
	Mean	SD	Mean	SD
Number of surfaces with caries experience (dmfs/DMFS)				
Primary teeth (dmfs)	5.4	6.8	4.3	5.9
Permanent teeth (DMFS)	0.4	0.9	0.4	1.0
Primary and permanent teeth combined (dmfs + DMFS)	5.8	6.9	4.7	6.0
Number of surfaces with ICDAS caries experience (ICDAS-dmfs/DMFS)				
Primary teeth (ICDAS-dmfs)	9.6	8.6	8.5	7.9
Permanent teeth (ICDAS-DMFS)	2.0	2.7	1.9	2.5
Primary and permanent teeth combined (ICDAS-dmfs + DMFS)	11.6	9.9	10.4	9.1

dmfs and DMFS: caries experience index at the surface (s/S) level for primary teeth and permanent teeth, respectively; decayed (d/D), missing (m/D), filled (f/F); ICDAS-dmfs/DMFS: dmfs/DMFS caries experience indices including Initial and Moderate caries lesions.

Three-year follow-up

Three-year follow-up assessments were conducted in all centres. Assessments were the same as those conducted at the baseline. A local trained research assistant (dentist)-blinded to the intervention- assessed child-level caries risk and knowledge, attitudes and practices. Five new examiners (follow-up examiners) from the leading research team (also blinded to the intervention) conducted the ICDAS visual and ICDAS radiographic assessment of caries, calculating the radiographic-visual combined severity and activity caries stages (ICDAS-merged codes). For this study, the 'follow-up examiners' were re-calibrated in the ICDAS visual caries criteria prior to undertaking assessments (2016) [20]. In addition, these examiners had previous experience in conducting ICDAS visual caries criteria training and calibration courses – being themselves calibrated before [20,21]. They were also trained in the other assessments [20–23].

Child's caries risk and tooth-surface progression control

In this study, the child's caries-risk progression control was defined in terms of a change from a baseline high/moderate

caries risk to a 3-year lower caries risk, or a 3-year maintenance of a baseline low caries risk. Caries progression at the tooth-surface level was defined in terms of a change from a sound or sealed surface to a caries lesion, a filling or a missing tooth; from an existing caries lesion to a more severe caries score and/or an active status; from a filling to a caries lesion or a missing tooth. At the tooth-surface level progression control corresponds lack of progression.

Outcomes

The outcomes of this study were: the proportion of children whose caries risk status progression was controlled; the proportion of tooth surfaces with control of caries progression; the proportion of participants with improved oral-health-related knowledge, attitudes and practices, and the number of dental appointments over the three years.

Statistical analysis. Weighted kappa was used to express the levels of inter-/intra-reproducibility of baseline and follow-up examiners. Minimum required weighted kappa values were 0.7.

Descriptive statistics were used with proportions to express the demographic characteristics, the prevalence of caries experience (ICDAS-dmfs/DMFS), and the variables child-level caries risk (low/moderate/high), lack of progression of caries (lesion severity and activity), and parents' knowledge, attitudes and practices regarding children's oral health. The caries experience (dmfs, DMFS, dmfs + DMFS, and ICDAS-dmfs, ICDAS-DMFS, ICDAS-dmfs + ICDAS-DMFS) and the number of dental appointments were calculated with mean number and standard deviation.

In this study, an intention-to-treat analysis was conducted [28]. *T*-test, paired *t*-test, *U*-Mann Whitney test, *pr*test and Chi-square test were used to determine differences among the variables between trial arms and between baseline and 3-year follow-up, as well as for baseline demographic and clinical characteristics.

The *T*-test or *U*-Mann Whitney test were used to compare, between the two systems, the baseline mean number of surfaces with caries experience (ICDAS-dmfs + ICDAS-DMFS) of those children who left the study during the follow-up period with that of those who remained in the study for the 3-year period.

All analyses were performed using Stata® 10.0 statistical software (StataSE Corp LP, College Station, TX, USA).

For the caries progression analysis, baseline tooth surfaces of unerupted first permanent molar teeth were considered as sound; on the other hand, 3-year follow-up exfoliated primary teeth were considered as their surfaces' after-basic management given score.

Results

A total of 240 children from six centres were recruited, randomly allocated to ICCMS ($n = 120$) or CCMS ($n = 120$) and all received the intervention. Children's mean age at baseline was of 6.5 ± 0.5 years. Table 2 shows children's baseline

demographic and clinical characteristics. No statistically significant differences were found between groups ($p > .05$).

No adverse events related to caries management were reported in any of the groups and there were no exclusions of participants after the initiation of the study.

At the 3-year follow-up, the sample corresponded to 187 children (77.9%) (ICCMS: $n = 92$; CCMS: $n = 95$; 90 girls and 97 boys) ($p > .05$). Few of the children recruited were entirely free of any caries experience at baseline (ICDAS-dmfs + ICDAS-DMFS) with 91.9% having caries, fillings or missing teeth due to caries and this was 99.4% after three years. The overall mean number of surfaces with ICDAS caries experience was high, both in the primary teeth at baseline (7.7 ± 8.3 ; ds-Initial: 3.4 ± 3.4 ; ds-Moderate: 0.8 ± 1.3 ; ds-Extensive: 1.8 ± 3.1 ; ms: 1.0 ± 3.1 ; fs: 0.7 ± 1.8) and after three years (9.1 ± 7.9 ; ds-Initial: 4.4 ± 4.2 ; ds-Moderate: 0.3 ± 0.6 ; ds-Extensive: 0.6 ± 1.2 ; ms: 1.8 ± 4.8 ; fs: 2.0 ± 3.0), as in the permanent teeth at baseline (1.5 ± 2.0 ; DS-Initial: 1.2 ± 1.7 ; DS-Moderate: 0.2 ± 0.6 ; DS-Extensive: 0.1 ± 0.4 ; FS: 0.0 ± 0.2) and after three years (4.6 ± 3.7 ; DS-Initial: 3.7 ± 3.3 ; DS-Moderate: 0.4 ± 0.7 ; DS-Extensive: 0.1 ± 0.3 ; FS: 0.4 ± 0.9).

Dropouts

The 3-year dropout corresponded to 53 children (22.1%), with a similar number in each trial arm (ICCMS: $n = 28$, 23.3%; CCMS: $n = 25$, 20.9%) ($p > .05$). The baseline mean number of tooth surfaces with ICDAS caries experience in both the primary and permanent teeth (ICDAS-dmfs + ICDAS-DMFS) of children who remained in the study did not show significant differences from that of children who dropped out during the 3-year follow-up (ICCMS: 9.5 ± 9.1 vs. 9.0 ± 8.4 , respectively; $p = .81$; CCMS: 8.9 ± 8.7 vs. 8.0 ± 7.2 , respectively; $p = .65$).

Examiners reproducibility

The inter-/intra-examiner reproducibility weighted Kappa values for the ICDAS visual caries criteria were ≥ 0.7 for all baseline and follow-up examiners (Table 3).

Children with control of caries risk progression

Figure 3 shows control of child-level caries-risk progression in both groups without significant differences between groups ($p > .05$). There was a statistically significant baseline to 3-year decrease in the proportion of High-caries-risk children (ICCMS: 60.9–0%, $p < .001$; CCMS: 54.7–5.3%, $p < .001$) and an increase in the proportion of Moderate-caries-risk children in both groups ($p < .001$). With respect to Low-caries risk, there was a statistically significant increase of children in this classification only in the ICCMS group (6.5–17.4%, $p = .019$).

Tooth surfaces with control of caries progression

Out of the total of tooth surfaces assessed at the 3-year follow-up, which could be sound, carious, sealed, filled or missing

due to caries ($n = 20,196$; ICCMS: $n = 9936$; CCMS: $n = 10,260$), the baseline to 3-year follow-up behaviour showed caries progression in 6.7% ($n = 1346$) [95% CI, 6.3–7.0] of tooth surfaces, being significantly lower for ICCMS (6.2%) ($n = 617$); [95% CI, 5.7–6.7] than for CCMS (7.1%) ($n = 729$) [95% CI, 6.6–7.7] ($p = .010$).

Figure 4 shows the proportion of caries lesions according to their activity status per trial arm at baseline (ICCMS: $n = 703$; CCMS: $n = 679$) and after 3 years (ICCMS: $n = 870$; CCMS: $n = 899$). It depicts that at baseline most caries lesions were Active Extensive/Moderate/Initial in both trial arms (ICCMS: 90.8%; CCMS: 90.3%) ($p > .05$). At 3 years most caries lesions in ICCMS were Inactive Extensive/Moderate/Initial (50.2%) conversely to CCMS in which most caries lesions were Active (59.1%). There was a 3-year significant decrease in the proportion of active caries lesions within each system. In ICCMS this value corresponded to 41% [95% CI, 37–44] ($p = .019$) and in CCMS to 31.2% [95% CI, 28–34] ($p = .002$) with a significantly lower proportion of active caries lesions in ICCMS compared to CCMS ($p = .002$), as well as of active initial caries lesions ($p = .001$).

Parents knowledge, attitudes and practices regarding children's oral health

The parents' knowledge, attitudes and practices survey about their children's oral health (Table 4), found a significant increase at the 3-year follow-up in the ICCMS group in relation to limiting sugars (two daily portions of sweetened beverages/foods); parents participating in the child's toothbrushing, and children having their teeth brushed with fluoride toothpaste twice-a-day ($p < .05$). The latter, with a significant 3-year difference between systems ($p = .02$). Both groups showed a significant increase regarding non-symptomatic dental attendance as the reason for the last appointment ($p < .05$).

Number of appointments

Both caries-care systems showed a similar mean number of dental appointments. In ICCMS this was of 10.9 ± 5.9 [95% CI, 9.7–12.1] and in CCMS of 10.0 ± 3.8 [95% CI, 9.2–10.8] ($p = .15$).

Discussion

This multicentre RCT in schoolchildren compared the caries-controlling effectiveness of the ICCMS system with conventional caries management (CCMS). ICCMS acts through patient-centred risk-preventive care to control the caries risk, arrest early caries lesions with non-operative care, and uses minimally-invasive techniques when caries removal is necessary, with patient's recall and review [8]. In comparison, CCMS applies systematic general preventative measures which are not individualised to the patient and usually involve operative care of cavitated caries lesions [2]. The ICCMS system was more effective than the CCMS in

Table 3. ICDAS visual caries criteria inter- and intra-examiner agreements of baseline (E) and follow-up (FE) examiners (weighted kappa).

Reproducibility		Baseline examiners (E) from each centre						Follow-up examiners (FE) from leading research team					
		E1	E2	E3	E4	E5	E6	FE 1	FE 2	FE 3	FE 4	FE 5	FE 6
Inter-examiner	Weighted kappa values	0.71	0.75	0.71	0.72	0.70	0.71	0.70	0.80	0.78	0.83	0.77	0.79
Intra-examiner		0.79	0.92	0.80	0.85	0.87	0.79	0.85	0.94	0.91	0.95	0.88	0.92

Distribution of subjects according to their caries risk classification

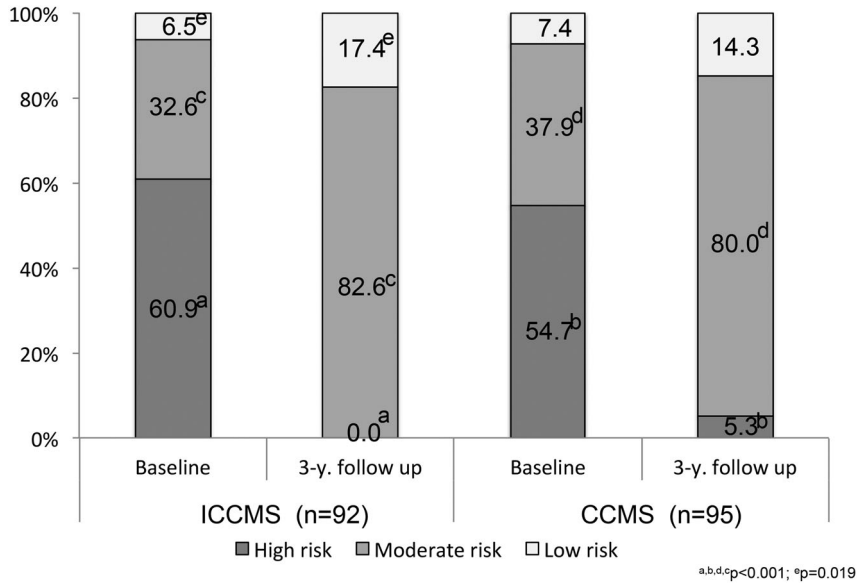


Figure 3. Distribution of baseline and 3-year children according to its caries risk classification.

Distribution of caries lesions according to activity status and severity

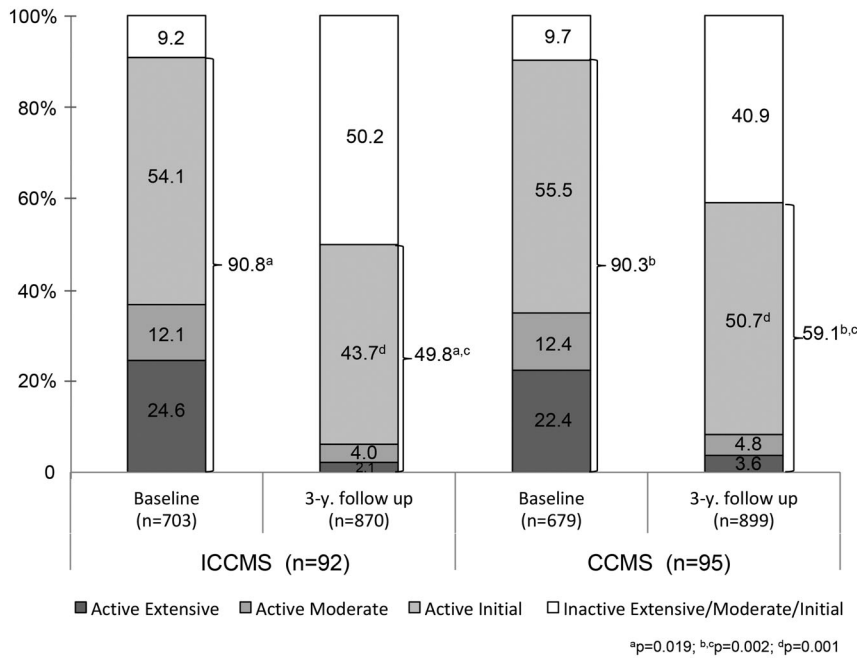


Figure 4. Distribution of baseline and 3-year caries lesions according to activity status and severity stage.

controlling caries progression at the tooth-surface level, without significant differences between systems at the individual level.

The better caries lesion control in the ICCMS group corresponded, first, to a lower proportion of tooth surfaces progressing either to a caries lesion, or to a more severe or an

Table 4. Parents' knowledge, attitudes and practices regarding children's oral health.

KAPs	Question	Answer option	ICCMS (n = 92)				CCMS (n = 95)			
			Baseline		3-y follow-up		Baseline		3-y follow-up	
			n	%	n	%	n	%	n	%
K	In your opinion, is it possible to control and prevent tooth decay?	Yes	91	98.9	91	98.9	92	96.8	94	98.9
		No	1	1.1	1	1.1	3	3.2	1	1.1
A	Do parents have a higher responsibility than the dentist/ teacher for the child having tooth decay?	Yes	69	75.9	76	82.6	69	72.6	77	81.1
		No	22	23.9	16	17.4	26	27.4	18	18.9
P	Were dental symptoms the reason for the last patient's appointment?	Yes	36	39.1	0	0.0	26	27.4	0	0.0
		No	56	60.9 ^a	92	100 ^a	69	72.6 ^a	95	100 ^a
P	How many times a day are the child's teeth being brushed with fluoride toothpaste?	≥2	80	87.0 ^a	91	98.9 ^{ab}	82	86.3	88	92.6 ^b
		<2	12	13.0	1	1.1	14	14.7	7	7.4
P	Do the parents participate in the child's oral hygiene?	Yes	29	31.5 ^{ac}	61	66.3 ^a	39	41.1 ^c	64	67.4
		No	63	68.5	31	33.7	56	58.9	31	32.6
P	How many portions of sugary beverages/foods does the child have per day?	≤ 2	31	33.7 ^a	57	62.0 ^a	31	32.6	49	51.6
		> 2	61	66.3	35	38.0	64	67.4	46	48.4

KAPs: knowledge, attitudes and practices; K: knowledge; A: attitude; P: practice.

^aStatistically significant differences between baseline and 3-year follow-up ($p < .05$).

^bStatistically significant difference between groups at the 3-year follow-up ($p < .05$).

^cStatistically significant difference between groups at baseline ($p < .05$).

active caries lesion; second, to a significantly higher proportion of inactive caries lesions. This could be explained by the emphasis that ICCMS gives to tooth-preserving caries prevention and control [1], or minimal invasive caries management, which goes far beyond the conventional surgical management of caries lesions -only considering those at a cavitated status [29], as in the CCMS [2]. In ICCMS, the diagnosis of caries lesions involves staging the lesion into a continuum of severity categories based upon the histological extent of the lesion within the tooth [7,9,20] and according to the progression status into an active (likely going through mineral loss) or inactive caries lesion [30–32], followed by synthesising its diagnosis and deciding upon appropriate care with preventively-oriented nonsurgical options whenever indicated (non-operative care) and including tooth-preserving management when operative care is needed (tooth-preserving operative care) [7–9,20,33]. In addition, after three years the significant increase in the ICCMS trial arm parents' appropriate practices regarding their children's oral health, related to dietary and toothbrushing habits, highlights the relevance that ICCMS gives to these evidence-based practices and to the personalised preventive care [1,33–36]. This is probably related to the motivational interview element within ICCMS and could also partly explain the significantly higher proportion of inactive caries lesions in that group [27]. In CCMS, participants only received a general oral-health leaflet.

The decrease in caries-risk in both trial arms and the lack of a significant difference between them could be explained, first, by the sample's overall high caries experience burden at baseline in the primary-teeth when the children were 6–7 years old. The prevalence of caries (cavity)-free children ($d_3mf = 0$) of 35.9%, is below the 2000 WHO goal of 50% in 5-year olds, and similar to more recent corresponding national figures in 5-year olds (37.9%) [37]. The caries burden is also clear from the baseline mean number of surfaces with caries experience, with a dmfs of 4.3 ± 6.7 , in which the d component accounted for 2.6 ± 4.4 , and when including Initial and Moderate caries lesions correspondent figures became even higher (ICDAS-dmfs: 7.7 ± 8.3 ; ICDAS-d: 5.9 ± 7.8). Second, both caries-care systems prioritise primary

prevention and long-term health-maintenance: ICCMS, through a patient-centred risk-based care philosophy [20], and the CCMS by managing all children with preventive measures systematically [8].

Other RCTs investigating caries management philosophies similar to ICCMS have also reported clinical effectiveness. Vermaire et al. [3], investigating 6-year-old Dutch children, reported a 3-year study, where there was a lower caries experience increment (DMFS) in the test group compared to the control group (standard of care: twice-a-year fluoride varnish application; pits and fissure sealants on erupting occlusal surfaces of first permanent molar teeth). Curtis et al. [4], in Australian adults managed in private practices, found after two years a significantly lower DMFS increment in the test vs. the control group ('standard': conventional operative care, including of enamel caries lesions detected radiographically). In our study, the dmfs + DMFS (conventional at the d_3/D_3 threshold) increment after three years was higher than in the above studies [3,4], both for the ICCMS (0.8 ± 0.2) and for CCMS (0.8 ± 0.6). We did not use this indicator, due to the high mean number of untreated cavitated caries lesions (as well as non-cavitated) at baseline, and to express caries lesions' progression considering their severity and their activity status [1,30–33]. Innes et al. [5], in 3–7 year-old children in the United Kingdom, with at least one primary molar with dental caries lesion, found no significant difference after three years in the number of episodes of dental pain and/or infection between sealing in carious tooth tissue restoratively versus conventional operative care or only individual-level care, with the first option being more cost-effective.

The ICCMS caries care philosophy (both at the child and at the tooth-surface level) has also been included in the recent ORCA-IADR terminology consensus [38], as well as in recent evidence on best practices and effectiveness of caries management [39–46].

For this study, the ICCMS protocol was adjusted locally as fluoride mouthrinse/solution, atraumatic restorative treatment (ART), and the Hall technique were not used. These adaptations have been referred as 'Glocal' in the ICCMS derived for the dental practice 'CariesCare International'

Guide [33], as a watchword for successful local implementation. The CCMS protocol in this trial corresponded to the standard of care as described in the National Health System guidelines [2].

One limitation of this study could be that the same dental practitioners conducted both caries care systems and this could have led to not following it thoroughly. To ensure that the dentists treated participants strictly as indicated in the study protocol, monthly meetings and review of oral health records (uploaded to the system) were conducted. In this study adherence to each trial protocol seemed to be good. For example, in relation to the use of sealants, in the ICCMS group, where you don't seal sound surfaces unless these are at local risk of caries and other measures don't seem to work, only 1.7% of occlusal sound surfaces were sealed, 0.8% corresponding to high-caries risk participants and only the remaining proportion applied to other caries risk status children against the protocol. In contrast, sealants on initial caries lesions on buccal surfaces don't follow the protocol in the CCMS group. These were present only in 2.2% of buccal surfaces with initial caries lesions, suggesting a very low conduct outside of the protocol.

Regarding the dropout, while we calculated a possible 20%, this ended up being of 22.3%; however, in our study, the final sample was higher than the calculated sample size ($n=187$ vs. $n=130$, respectively) as we worked with six centres, each with 40 enrolled children at baseline. Children in this study were representative of children attending dental care in the National Health System in terms of their caries status.

The fact that around 27% of children presented at the 3-year follow-up ≥ 1 Extensive Active caries lesions is rather disappointing. The starting point seems to be an influencing factor and would be probably related to national caries burden indicators [37], as the studies in The Netherlands in children [3] and in Australia in adults [4] show better oral health indicators at both assessment times, while the one in the United Kingdom in children [5] show worse ones.

The results of this study question that if CCMS is being delivered across the country adequately following the national guidelines, the children's national caries burden should be lower than what it currently shows [37]. We speculate this, based on the fact that while in national figures for similar age group 36% of parents reported symptomatic attendance as the reason for last appointment [37]. We found in our study no report of symptomatic attendance at 3-year follow-up. In addition, Cortes et al. [10], in a two-year caries-progression pattern epidemiological study in Bogotá using the ICDAS-merged visual combined with radiographic scores, also found in the 6-year-old cohort a high caries increment (after two years) in the mean number of ICDAS-dmfs/DMFS (10.5 ± 9.6 vs. 13.3 ± 16.9) compared to our study in the CCMS group after three years (8.9 ± 8.7 vs. 13.4 ± 9.9), but with a higher increment in the proportion of ms/MS in the Bogotá study (1.9–31.6% after two years) vs. our study (11.2–14.1% after three years).

If implemented widely, ICCMS would involve in the short term probably a higher number of appointments (related to

the personalised risk management), even though this study did not show significant differences in this aspect between systems, probably due to the high baseline burden of caries. Additionally, while in the CCMS group, there was a higher proportion of sealants applied (26.4%) compared to the ICCMS group (17.1%) ($p < .05$). However, the CCMS sealing protocol adhered to the national standard of care [2] involving sealing sound surfaces of all molar teeth (primary and permanent). This systematic approach does not adhere to the current best practices and scientific evidence [2,33,47,48] which instead recommends only sealing occlusal surfaces of erupting first permanent molar teeth considered at risk of caries, and sealing active initial (and when it applies also moderate) caries lesions.

Finally, ICCMS is in accordance with the state of the art of caries management [38–46]. There is a growing shift in academia towards a similar approach to ICCMS in the dental caries teaching curricula for undergraduates (e.g. the European leading consensus; the cariology consensus achieved in Colombia, the USA, and the Caribbean countries) [6,49–52], together with the adoption of similar caries management behaviours in dental practice [17]. The CariesCare International caries management guide derived from ICCMS as a friendly version for the practice [33,53] and successful ongoing global public health strategies such as the Alliance for a Cavity Free Future [54] are examples of this shift. In Colombia, the recent public health policy (2016) to implement a patient-centred risk-based strategy that is under adoption also shows this trend [55].

After 3 years, both caries-care systems demonstrated control of caries-risk progression within a similar number of appointments, however, the ICCMS group benefitted from better results in terms of caries lesion control and improvements in oral-health practices.

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