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Study Identification

Unique Protocol ID: IRB00010617

Brief Title: Pandemic-adapted Caries Care Multicentre Single-group Interventional Study

Official Title: CariesCare International Adapted for the Pandemic in Children: Multicentre Single-group Interventional Study

Secondary IDs:

Study Status

Record Verification: November 2023

Overall Status: Completed

Study Start: November 15, 2020 [Actual]

Primary Completion: December 30, 2021 [Actual]

Study Completion: December 30, 2021 [Actual]

Sponsor/Collaborators

Sponsor: Universidad El Bosque, Bogotá

Responsible Party: Principal Investigator

Investigator: Stefania Martignon [smartignon]

Official Title: Principal Investigator

Affiliation: Universidad El Bosque, Bogotá

Collaborators: King's College London

University of Leeds

University of Sheffield

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: IRB00010617

Board Name: Institutional Ethics Committee

Board Affiliation: Universidad El Bosque

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Study Description

Brief Summary: The current understanding of dental caries has not been completely transferred into the clinical practice to control caries lesion progression (severity / activity) and the individual risk of caries. This situation led to the development of the CariesCare International CCI Caries Management System (2018), derived from ICCMS™- International Caries Classification and Management System (2012) and the ICDAS - International Caries Detection and Assessment System (2002) in a consensus among more than 45 cariologists, epidemiologists, public health professionals, researchers and clinicians from all over the world. The consensus aimed to guide dentists and dental teams in clinical practice, facilitating the control of the caries process and the maintenance of oral health in their patients.

The general lack of implementation of an updated management of dental caries is evident in Colombia, in the survey of 1094 clinicians, teachers and students, failures were reported to adopt related behaviours, motivation barriers (remuneration), opportunity (in terms of relevance, physical/infrastructure resources, time) and training. As an additional barrier, the Colombian Chapter of the Alliance for a Cavity-Free Future (ACFF), evidences the absence of a facilitating Oral Health Record (OHR), this situation lead to establish a new Alliance between the Ministry of Health and Social Protection (MSPS) and the AFLC to develop an inter-institutional consensus at the national level, of a clinical history for diagnosis and management of lesions and caries risk. Finally, 55 institutions participated in this consensus, and we have just finished a pilot test of the forms to submit a proposal for national standardization from the MSPS.

The aim of this multicentre case series is to assess after 3, 6 and 12 months in children oral health outcomes, caregivers' satisfaction and in dentists' process outcomes, after the implementation of the CCI system adapted for the COVID-19 era –non-aerosol generating procedures. Oral health outcomes will be evaluated in terms of:

- Effectiveness of CCI to control bacterial plaque, caries progression and caries risk, and to achieve behavioural change in oral health in children.
- Acceptance of CCI caries management adapted for COVID-19 through Treatment Evaluation Inventory in dentists, and in children/parents through satisfaction questionnaire.
- Costs of CCI adapted for caries management, in economic terms, number and appointment time.

Detailed Description: This study has been planned to be developed in 21 centres: 5 Colombian, 14 international dental schools, 1 Colombian health care provider and a demonstrative centre of the ACFF. Each center will implement the CCI management adapted for COVID-19 era in a total of 20 3 to 5- and 6 to 8-year-old children. Children's caries care can be delivered at dental schools' clinics and private practice. Follow-up assessments will be conducted at 3, 6 and 12 months.

Conditions

Conditions: Dental Caries in Children

Keywords: Dental caries
 Children
 COVID-19
 Dental care
 Conservative care
 Aerosols
 Remote consultation
 Outcome assessment
 Multicenter study

Study Design

Study Type: Observational
 Observational Study Model: Case-Only
 Time Perspective: Prospective
 Biospecimen Retention: None Retained
 Biospecimen Description:
 Enrollment: 409 [Actual]
 Number of Groups/Cohorts: 1

Groups and Interventions

Groups/Cohorts	Interventions
Adapted-CCI single-intervention group in children <p>The single-group intervention will be the adapted-CCI 4D-cycle caries care, with non-AGP and reduced in-office appointments' time. A trained examiner per centre will conduct examinations at baseline, at 5-5.5 months (three months after basic management), 8.5 and 12 months, assessing the child's CCI caries risk and oral-health behaviour, visually staging and assessing caries-lesions severity and activity without air-drying (ICDAS-merged Epi); fillings/sealants; missing/dental-sepsis teeth, and tooth symptoms, synthetizing together with parent and external-trained dental practitioner (DP) the patient- and tooth-surface level diagnoses and personalised care plan. DP will deliver the adapted-CCI caries care. Parents' and dentists' process acceptability will be assessed via Treatment-Evaluation-Inventory questionnaires, and costs in terms of number of appointments and activities. Twenty-one centres in 13 countries will participate.</p>	Procedure/Surgery: Modified CariesCare International management Interventions of this single-group study correspond to the 4D, to be implemented by the external DP, when possible with remote care and only with non-AGP: 1D-DETERMINE risk assessing the protective and risk factors (social/medical/behavioural and clinical), using remote tools. Additionally, the description of tooth brushing behaviours and consumption of free sugars is included. 2D-DETECT & ASSESS: Caries staging and activity: ICDAS-merged visual criteria Caries OUT (without using compressed air, and avoiding radiographs). Clinical risk factors are assessed as well. 3D-DECIDE a personalized care plan: individually designed for caries management home and clinical approaches. 4D-DO: Appropriate Tooth-preserving & Patient-level caries: Management plan at the Patient and at the Lesion level and the implementation of the Change Behaviour Tool (CBT) designed for this protocol. The follow-up

Groups/Cohorts	Interventions
	data will include a T1, T2 and T3 assessment.

Outcome Measures

Primary Outcome Measure:

1. Difference in T0-to-T1y mean number of tooth surfaces with caries and T1y percentage of tooth surfaces with control of caries progression at one-year follow-up.

With the implementation of the CCI 4D-cycle adapted for the COVID-19 pandemic characterized by the patient-centred risk-based caries management systems, the primary outcomes consist of: At the tooth surface level in avoidance of individuals and average number of surfaces with caries progression. At the individual level consist in avoidance of caries risk level increase/no control, plaque control, and avoidance of extraction, pain, failure of the restoration. Figures will be described using mean and standard deviation (SD) for quantitative variables and percentages for qualitative variables.

[Time Frame: up to 12 months]

Secondary Outcome Measure:

2. Proportion of subjects with control of caries progression at one-year follow-up.

Figures will be described using mean and standard deviation (SD) for quantitative variables and percentages for qualitative variables.

[Time Frame: up to 12 months]

3. Proportion of subjects with 1-year avoidance of: being designated as High-caries risk, having Inadequate/Very-inadequate oral-health behavior; with control of: extractions, toothache, and of failure of fillings/sealants.

Figures will be described using mean and standard deviation (SD) for quantitative variables and percentages for qualitative variables.

[Time Frame: up to 12 months]

4. Proportion of parents and dentists with reported high-acceptability levels of the dental care process.

Figures will be described using mean and standard deviation (SD) for quantitative variables and percentages for qualitative variables.

[Time Frame: up to 12 months]

Eligibility

Study Population: Participants will be enrolled from the University Dental clinics, dental health providers and dental private practice across 21 multi-centre sites. The parents/caregivers of patients, aged 3 to 5 years and 6 to 8 years will be invited by the dentist to participate in the study and that their children are eligible to be considered for recruitment.

Sampling Method: Non-Probability Sample

Minimum Age: 3 Years

Maximum Age: 8 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- Children 3 to 5 and 6 to 8 years of age.

Exclusion Criteria:

- Family plans to move during the study time
- Oral-health related systemic conditions or physical/mental disabilities
- Presence of orthodontic/orthopaedic appliances
- Presence of MIH in first permanent molars with indication of extraction
- Children attending for a dental emergency/urgency

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IPDSharing

Plan to Share IPD: Yes

All IPD

Supporting Information:

Study Protocol

Time Frame:

CariesCare International adapted for the pandemic in children: Caries OUT
multicentre single-group interventional study protocol

Access Criteria:

URL:

References

Citations: **[Study Results]** Martignon S, Cortes A, Douglas GVA, Newton JT, Pitts NB, Avila V, Usuga-Vacca M, Gamboa LF, Deery C, Abreu-Placeres N, Bonifacio C, Braga MM, Carletto-Korber F, Castro P, P Cerezo M, Chavarria N, Cifuentes OL, Echeverri B, Jacome-Lievano S, Kuzmina I, Lara JS, Manton D, Martinez-Mier EA, Melo P, Muller-Bolla M, Ochoa E, Osorio JR, Ramos K, Sanabria AF, Sanjuan J, San-Martin M, Squassi A, Velasco AK, Villena R, Zandona AF, Beltran EO. CariesCare International adapted for the pandemic in children: Caries OUT multicentre single-group interventional study protocol. *BMC Oral Health.* 2021 Jul 1;21(1):329. doi: 10.1186/s12903-021-01674-1. PubMed 34210281

Links:

Available IPD/Information: