**KARINA HAIBARA DE NATAL**

# Using information and communication technologies (ICT) to solve the repressed demand for primary dental care in the Brazilian Unified Health System due to the COVID-19 pandemic

São Paulo

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**Corrected Version**

Thesis presented to the School of Dentistry, University of Sao Paulo, by the Graduate Program in Dental Sciences to obtain the degree of PhD in Sciences.

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*"Eu escolho honrar cada pessoa que já cruzou o meu caminho: pelos aprendizados, transformações e pelo impulso para que me torne cada vez mais quem eu escolhi ser nesta vida. "- Isabella Mezzadri*

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*“Fazer o que se ama, não é sobre amar o que se faz todos os dias, mas sim, sobre trabalhar com algo que você acredita.*

*Não é sobre ser recompensado financeiramente, mas sim sobre as pessoas que você toca e o mundo que transforma.*

*Não é sobre saber tudo e ter todas as respostas, mas sim, ser um eterno aprendiz de si mesmo”*

*Gabriela Stapff*

## ABSTRACT

Haibara KN. Using information and communication technologies (ICT) to solve the repressed demand for primary dental care in the Brazilian Unified System due to the COVID-19 pandemic [thesis]. São Paulo: Universidade de São Paulo, Faculdade de Odontologia; 2022. Corrected Version.

In March 2020, a pandemic caused by SARS-CoV-2 virus was declared by the World Health Organization (WHO). To deal with it, social distancing was recommended as one of the few effective ways of distancing the disease. Since dental activities are one of the most critical in relation to contamination, health systems suspended elective procedures in dentistry, with maintenance only of emergencies and emergencies in several countries. Faced with this scenario, thousands of children, even inserted without dental care from one moment to the next, creating a repressed demand and being considered in the planning of Public Health Policies. Teledentistry has proven to be effective in both the cost and dissemination of access, being a means of democratization and equity. In this sense, this thesis sought to show the impact of the use of information and communication technologies (ICT) on the resolution of the pent-up demand for primary dental care to children in the Unified Health System (SUS), due to the COVID-19 pandemic, proposing the use of telemonitoring, teleorientation and telescreening to resolve and address the demands caused by this outage in primary care. For this, the thesis was divided into two chapters, the first being the protocol of a controlled and randomized study nested to a type of study before and after with economic analyses. In order to identify the pent-up demand for the outage of dental care and the benefits, difficulties, as well as the perception of users, in the implementation of new strategies of non-face-to-face care based on technology; perform different forms of economic evaluation to measure whether the gains achieved with the compensate for the teleservice compensate for the additional costs possibly associated with it; and explore how the introduction of these technologies could benefit the SUS in the trans and post-pandemic periods, as well as result in possible differences when explored in different Brazilian scenarios. It is expected that with the results of this project we can modify the work process of oral health teams in the state of São Paulo, because being a state that induces policies

and their experiences serve as an example for other stated and even countries, we can generate knowledge with public resources and disseminate them at scale for good practices to all users of the SUS, prospecting and expanding contributions to different realities related to SUS within Brazil. In chapter 2, we bring the results of the study before and after mentioned in the study protocol of chapter 1 to measure the positive, negative and demand resolution stemming from the implementation of telemonitoring, teleorientation and telescreening in primary care for children, having as cell unit the mobile dental unit of the School of Dentistry of the University of São Paulo installed in the municipality of Barueri, acquired with FAPESP research aid (Process 2012\ 50716-0). The teleservices were performed by the digital platform Video For Health – VH4 by researchers trained so that the service was performed in a standardized way. In total, 328 patients were assisted by teleservice, 22% needed welcoming (95% CI: 0.17 to 0.27), 44% individualized orientations (95% CI: 0.39 to 0.50), 15% had specific complaints that could be resolved by teleservice (95% CI: 0.14 to 0.22) and 15% had complaints that required face-to-face care to be resolved (95% CI: 0.11 to 0.19). We were able to resolve 57% of the demands in a partial way (when the patient had more than one demand to be resolved) and 54% in a total way. The overall rate of resolution of the demands was 0.58 ($\sigma$ = 0.51). The total direct cost of the call was 164 reais and the total indirect cost of 15 reais. The highest cost observed was with the development of the digital platform. The implementation of new health technologies should be carefully analyzed and evaluated to ensure even more sustainability to the system. This thesis brings contributions in this sense and important findings for the formulation of strategies in the resumption of oral health in a pandemic and post-pandemic scenario. We conclude that the use of Information and Communication Technologies in primary dental care for children can help in the resolution of some demands that do not necessarily require a face-to-face consultation and that the costs of using this technology can be suppressed by other health gains.

Keywords: Child. Teledentistry. Telemonitoring. Teleorientation. COVID-19.

# RESUMO

Haibara KN. Utilizando tecnologias de informação e comunicação (TIC) para solucionar a demanda reprimida de atenção básica odontológica no Sistema Único de Saúde (SUS) em função da pandemia de COVID-19. [tese]. São Paulo: Universidade de São Paulo, Faculdade de Odontologia; 2022. Corrected Version.

Em março de 2020, foi decretado estado de pandemia causado por vírus SARS-CoV-2 pela Organização Mundial da Saúde (OMS). Para lidar com a mesma, o distanciamento social foi recomendado como uma das poucas maneiras efetivas de trasmissão da doença. Sendo as atividades odontológicas uma das mais críticas em relação á contaminação, os sistemas de saúde suspenderam os procedimentos eletivos em odontologia, com manutenção apenas de urgências e emergências em diversos países. Diante desse cenário, milhares de crianças, mesmo inseridas dentro de um programa de atenção primária, ficaram sem atendimento odontológico de um momento para o outro, criando uma demanda reprimida a ser considerada no planejamento de Políticas Públicas de Saúde. A teleodontologia tem se mostrado eficaz tanto no custo quanto na disseminação do acesso, sendo um meio de democratização e equidade. Nesse sentido, essa tese procurou mostrar o impacto do uso de tecnologias de informação e comunicação (TIC) na resolução da demanda reprimida por atenção odontológica primária a crianças no SUS, em função da pandemia COVID-19, propondo o uso do telemonitoramento, teleorientação e teletriagem para resolução e direcionamento das demandas causadas por essa paralisação na atenção primária. Para isso, a tese foi dividida em dois capítulos, sendo o primeiro o protocolo de um estudo controlado e randomizado aninhado a um estudo tipo antes e depois com análises econômicas. Com o objetivo de identificar a demanda reprimida pela paralisação do atendimento odontológico e os benefícios, dificuldades, bem como a percepção dos usuários, na implementação de novas estratégias de atendimento não presencial baseada em tecnologia; realizar diferentes formas de avaliação econômica para mensurar se os ganhos conseguidos com a implementação do teleatendimento compensam os custos adicionais possivelmente associados à mesma; e explorar como a introdução dessas tecnologias poderiam beneficiar o SUS no período trans e pós-pandêmico, bem

como resultar em possíveis diferenças quando explorados em diferentes cenários brasileiros. Espera-se que com os resultados deste projeto possamos modificar o processo de trabalho das equipes de saúde bucal no Estado de São Paulo, pois sendo um estado que induz políticas e suas experiências servem de exemplo para outros estados e até mesmo países, possamos gerar conhecimento com recursos públicos e disseminá-las em escala para boas práticas a todos os usuários do SUS, prospectando e expandindo as contribuições para diferentes realidades ligadas ao SUS dentro do Brasil. No capítulo 2, trazemos os resultados do estudo antes e depois mencionado no protocolo de estudo do capítulo 1, para mensurar os efeitos positivos, negativos e a resolutividade de demanda oriundos pela implementação do telemonitoramento, teleorientação e teletriagem na atenção primária para crianças, tendo como unidade-célula a unidade móvel odontológica da Faculdade de Odontologia da Universidade de São Paulo instalada no munícipio de Barueri, adquirida com auxílio á pesquisa FAPESP (Processo 2012\50716-0). Os teleatendimentos foram realizados pela plataforma digital Video For Health – VH4 por pesquisadores treinados para que o atendimento fosse realizado de forma padronizada. No total, 328 pacientes foram assistidos por teleatendimento, sendo que 22% necessitaram de acolhimento (95% CI: 0.17 a 0.27), 44% de orientações individualizadas (95% CI: 0.39 a 0.50), 15% tinham queixas específicas que foram passíveis de serem resolvidas pelo teleatendimento (95% CI: 0.14 a 0.22) e 15% tinham queixas que necessitavam de um atendimento presencial para serem solucionadas (95% CI: 0.11 a 0.19). Nós conseguimos resolver 57% das demandas de uma forma parcial (quando paciente tinha mais de uma demanda a ser resolvida) e 54% de uma forma total. A taxa global de resolução das demandas foi de 0.58 ($\sigma$ = 0.51). O custo direto total do teleatendimento foi de 164 reais e o custo indireto total de 15 reais. O maior custo observado foi com o desenvolvimento da plataforma digital. A implementação de novas tecnologias em saúde deve ser cuidadosamente analisada e avaliada para garantir ainda mais sustentabilidade ao sistema. Esta tese traz contribuições nesse sentido e achados importantes para formulação de estratégias na retomada da saúde bucal em um cenário pandêmico e pós pandêmico. Concluímos que uso de Tecnologias de Informação e Comunicação na atenção primária odontológica para crianças pode auxiliar na resolução de algumas demandas que não necessariamente requerem uma consulta presencial e que os custos do uso dessa tecnologia podem ser suprimidos por outros ganhos em saúde.

Palavras-chave: Crianças. Teleodontologia. Telemonitoramento. Teleorientação. COVID-19.

## LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| BIA | Budget Impact Analysis |
| CA | Content Analysis |
| CI | Informatics Center |
| CONSORT | Consolidated Standards of Reporting Trials |
| COVID-19 | Corona Virus Disease |
| EVPI | Expect Value of Perfect Information |
| FB | Fabiana Bracco |
| FAPESP | São Paulo State Research Foundation |
| FOUSP | University of Sao Paulo School of Dentistry |
| GMM | Gabriela Manco Machado |
| JDYV | Jhandira Daibelis Yampa Vargas |
| KHN | Karina Haibara De Natal |
| LAVID | Research and Extensions Center |
| MEFV | Maria Eduarda Franco Viganó |
| MMB | Mariana Minatel Braga |
| ICF | Informed Consent Form |
| ICT | Information and Communication Technologies |
| RNP | National Network of Teaching and Research |
| RT | Resolution Rate |
| SPIRIT | Standard Protocol Items: Recommendations for Interventional Trials |
| SUS | Brazilian Unified Health System |
| TGOM | Thais Gomes de Oliveira Machado |
| UHS | Unified Health System |
| UFPB | Federal University of Paraiba |
| UNIFESP | Federal University of the State of São Paulo |
| V4H | Video for Health Platform |
| VOI | Value of the Information |
| WHO | Word Health Organization |

**CONTENTS**

## 1. INTRODUCTION

On March 11th 2020, the World Health Organization (WHO) declared a pandemic state for the outbreak of coronavirus disease (COVID-19) (1). Since then, the organization has been recommended some public health measures, including social distancing. In this sense, several restrictions were implemented, cancellation of public events, interruption of presential educational activities and consequently, many health programs were paralyzed, including clinical care in dental practice.

Furthermore, the dental health professional had been suddenly exposed to a higher risk of infection since the SARS-CoV-2 virus can also be transmitted by saliva and droplets in the air and aerosols, which are often produced in dental practice (2). Therefore, the American Dental Association (ADA) recommended postponing elective procedures in Dentistry to prevent the spread of the COVID-19 virus and avoid contamination of health professionals (3).

With the abrupt interruption of dental care, thousands of children were left without treatment, even if inserted into a primary health care program. In Brazil, since the first case of COVID-19, a 66% reduction in pediatric dental treatments performed in the Brazilian Unified Health System (Sistema Único de Saúde – SUS) was observed, and such reduction increased to 89% in the period of exponential contagion (4). This scenario generated a repressed demand to be considered in the planning of Public Health Policies. The main goal to be achieved should be not to overload services in the future and not negatively impact those improvements observed in the availability of dental services in the last decade (5).

In this sense, the use of Information and Communication Technologies (ICT) in the health area could contribute to such type of achievement related to the momentaneous repressed demand for dental care. Teledentistry has been pointed out as a facilitator of extension to oral health for facilitating access to specialized care without the patient having to leave their own home or work environment (6). Recent systematic reviews have shown the benefits that

Teledentistry can bring to public health services. Among the benefits, we can enumerate: reduction in waiting times, the sought for early treatments, limitation of unnecessary exams/referrals and reduction in inequalities in health care as providing poor communities with better access to these services (6,7). In Brazil, the Telessaúde Brasil Redes national program is an example of the ICT benefit regarding solvability/costs and establishment of specific protocols for teleconsultation (8).

On the other hand, most studies found on Teledentistry are conducted in developed countries (United States America and European countries) (9) In developing countries, contrariwise, there is a lack of resources, infrastructure, and conservatism of decision-makers in using suck kind such ICT resources (9). Thus, studies that show how ICT can be used in health systems in developing countries to solve demands that do not require face-to-face care are still necessary. They may bring essential answers about how this strategy could reduce waiting lists, extend health care for populations, and resume primary health care activities after the COVID pandemic breakout.

In this sense, this thesis is composed of two chapters, a study protocol and a before-and-after clinical study that proposes the use of a package of ICT (telemonitoring, teleorientation and telescreening) for the resolution and direction of the repressed demand for primary dental care to children in the SUS due to the COVID-19 pandemic. The purpose was to use this strategy at a SUS-simulated scenario, measure its impact under different perspectives and extrapolate such scenario to the Brazilian reality, as detailed in the protocol (Chapter 1). Then, Chapter 2 brings the effect of implementing the mentioned intervention in real life, including its capacity to solve specific demands, perception of users', barriers and strengths identified by the users, and the preliminary economic impact of such implementation. Findings presented in this thesis may elicit essential aspects of the ICT adoption in primary dental care and make significant contributions to the possible use of these technologies in future contexts and scenarios, even after effective pandemic control/end.

## 2. PROPOSITION

The general objective of this thesis to show the impact of the use of ICT on the resolution of the pent-up demand for primary dental care to children in the SUS, due to the COVID-19 pandemic. To reach this objective, in Chapter I, we describe a protocol from a randomized controlled study nested to a before and after study including economic assessments. And in Chapter II, we presented the first results of the study before and after with economic assessments planned in protocol study of Chapter I.

As a part, the following specific objectives have been defined:

1. To propose research strategies to demonstrate the impact of implementing ICT in primary dental care for children and extrapolating findings to a real-world context to guide further research, practice and policies.

2. Carry out economic assessment of the cost-effectiveness type to measure whether the gains achieved from the implementation of teleservice (telescreening, teleorientation and telemonitoring) compensate for the additional, costs possibly associated with it, or whether they are associated with a long-term resource economy.

3. Explore how the introduction of these technologies could benefit the SUS in the trans and post-pandemic period, contribute to the correction of possible inequities in health care and other social aspects.

## 3. CHAPTER I: TRIAL PROTOCOL

**Using information and communication technologies (ICT) to solve the repressed demand for primary dental care in the Brazilian Unified Health System due to the COVID-19 pandemic: a randomized controlled study protocol nested with a before-and-after study including economic analysis.**

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**Abstract**

Background: With the COVID-19 pandemic, thousands of children had their dental care interrupted or postponed, generating a pent-up demand for primary care. To minimize the impact of this outage, information and communication technologies (ICT) could be an alternative. The aim of this study is to elucidate the impact of implementing the ICTs in primary dental care for children on resolving the pent-up demand for primary dental care to children in the SUS due to the COVID-19 pandemic.

Methods: Different research strategies are being proposed to demonstrate such effect and extrapolating findings to a real-world context to guide further research, practice and policies: two clinical trials (one randomized controlled by the waiting list study (RCT) and a before-and-after study), one simulation study to prospect trial results to a broader population and three economic evaluations using different effects. Children enrolled in a reference dental unit will be invited to participate in the before-and-after study for trials. The first 368 families will be randomized for the RCT to the intervention vs waiting list. All participants will receive the intervention, but the waiting list group will be assessed before the intervention is available for them. The intervention comprises standardized non-face-to-face primary dental care using the V4H platform. The problem-solving and the family's perception will be the primary outcomes set for the before-and-after study and RCT, respectively. They will be measured 2 weeks after randomization. Based on trial findings, we will develop theoretical models to estimate how the intervention could benefit the population included in the national health system service (SUS). Three economic evaluations will be carried out considering different trial effects (cost-effectiveness analyses). A societal perspective and the pandemic time horizon will be considered. Possible social impact (inequalities) will also be explored.

Discussion: This ongoing trial may be an essential contribution to clarify positive and negative aspects related to the use of technologies for non-face-to-face dental care for children. Trial products may bring relevant contributions to the pandemic context and the post-pandemic period. Potential benefits may be feasible to implement and preserve in the health system even in the post-pandemic period.

Trial registration: Clinicaltrials.gov registration NCT04798599 (registered March 2021).

Keywords: Child. Teledentistry. Telemonitoring. Teleorientation. Coronavirus infections.

## Background

A drastic repressed demand for primary dental care has been created since the beginning of the COVID-19 pandemic (1-3). Due to the health professionals' higher risk of contamination (4) associated with aerosol generation (5,6) dentists have been orientated to postpone elective treatments in different locations (7). A reduction of almost 90% in primary dental care for children was noted in the National Health System (Unified Health System – SUS) compared to the beginning of the pandemic time (8). This scenario, therefore, contributed to thousands of children lacking primary care, both for their non-operative and operative needs, representing essential pent-up demand for Public Health and should urgently guide policies to deal with this context.

The use of technologies could be a meaningful strategy for minimizing such impact on the health systems. Teledentistry has been demonstrated to be equivalent (or even valid) to face-to-face sessions for different purposes related to primary care, as screening, consultations, orientations and referrals (9,10). The use of technology in dental health care has been demonstrated to result in health equity services, reduction in waiting time, and costs with treatment (9). Its benefit has been noted, especially in school-based programs and patients with limited access to care. The pandemic has created an unexpected and unusual difficulty to access that could be overcome by using this kind of technology.

We hypothesized that using the Teledentistry resources in primary dental care for children might aid to solve some demands that do not necessarily require a face-to-face appointment. Indeed, a teleconsultation could reduce the waiting time for seeing a professional and comfort the patients/parents, solve patients'/parents' doubts, orient about habits and conducts, and refer to other services when necessary. In addition, the pandemic could be a window of opportunity to introduce regular oral health care (11), and the potential for implementation should also be explored.

On the other hand, some barriers have also been associated with this promising alternative, such as infrastructure, patients' motivation/compliance, stakeholders' resistance, and legal and security issues (9,12). They are more frequent in developing countries, in which there is a lack of robust evidence about the use of this technological strategy. Indeed, very few assessment studies about ICTs have been performed in developing countries (9). Understanding what possible adaptations to the intervention are needed to overcome these barriers is crucial to its effective implementation because the core components of the intervention must be retained for effectiveness (13).

Broad implementation of any intervention in diverse practice systems demands understanding the perspectives of different stakeholders who will affect and be affected by

such intervention (14). When planning health actions, users' judgment/satisfaction with health services are also imposing indicators to consider (15). Besides, the allocation of resources is another relevant aspect for planning actions within health services. It is worth knowing whether the proposed strategy represents an efficient allocation of resources to substitute what has been currently done (or in such case, what is not being done). Thus, economic evaluations can be used as additional tools for making political and economic decisions (16-18).

The present trial aims to elucidate the impact of implementing the ICTs in primary dental care for children on resolving the pent-up demand for primary dental care to children in the SUS due to the COVID-19 pandemic. In this sense, different research strategies are being proposed to demonstrate such effect and extrapolating findings to a real-world context to guide further research, practice and policies. Trial products may bring relevant contributions to the pandemic context and the post-pandemic period.

The following specific objectives are defined:

1. To identify the repressed demand for the outage of dental care and the benefits and difficulties, as well as the perception of users, in the implementation of new strategies of non-face-to-face care based on technology (teleservice), using a primary care cell unit for children and prospecting, through models, this situation for the scenario of the Unified Health System (SUS).

2. Perform different forms of economic evaluation to measure whether the gains achieved with the implementation of teleservice (telescreening, teleorientation and telemonitoring) compensate for the additional costs possibly associated with it, or whether they are associated with a long-term resource savings, considering the implementation sized for the Brazilian public health system.

3. Explore how the introduction of these technologies could benefit the SUS in the trans and post-pandemic period, contribute to the correction of possible inequities in the health care and other social aspects, as well as result in possible differences when different Brazilian scenarios are explored.

**Methods**

This manuscript was written following the Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) (19) for clinical studies (Supplemental File 1) and potential items to be included in Health Economics Analysis Plans (HEAPs) for Trial-

Based Economic Evaluations (20) for economic evaluation (Additional File 2). The primary trial was registered on Clinicaltrials.gov (TeleDent-COVID19 - registration NCT04798599) in 2020.

*Study Setting*

A mobile dental unit was chosen as the reference unit to collect outcomes related to implementing technologies for primary dental care for children. This unit is in the Greater São Paulo and has been providing dental care for children since 2014 (FAPESP-2012/50716-0). Since then, approximately 10,500 operative and non-operative dental appointments have been accomplished.

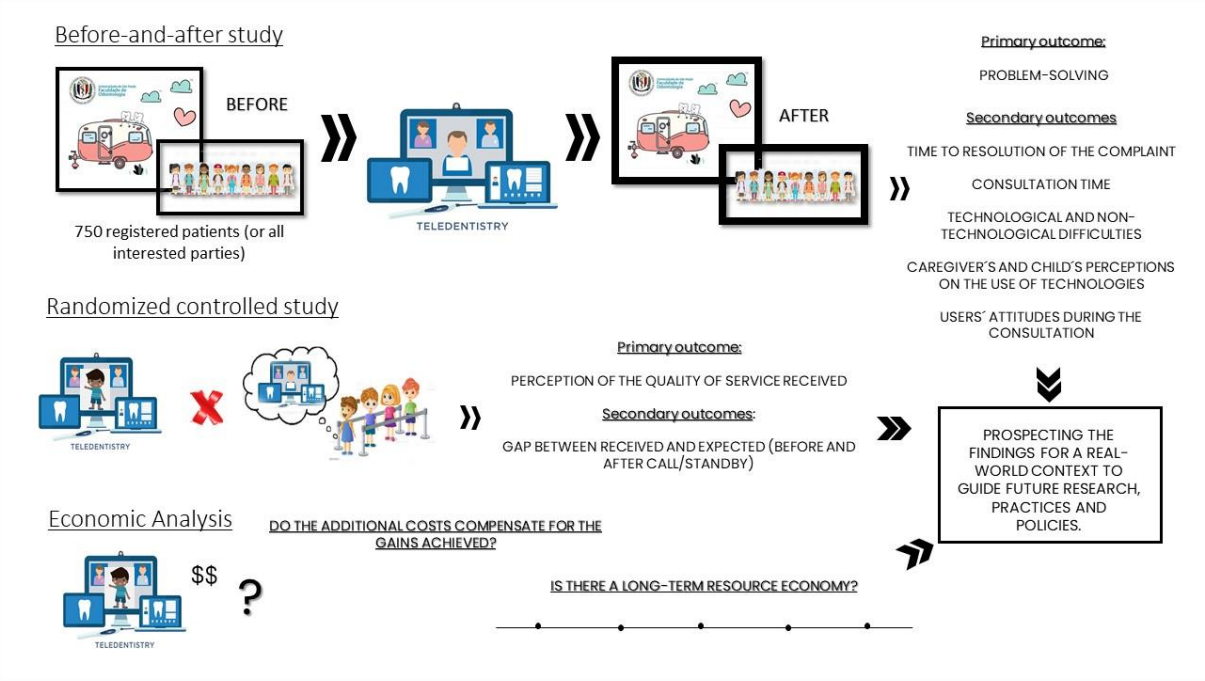
Currently, 750 children are enrolled for being cared for in this unit. They have participated in some previous clinical trials whose Recruitment was done at the unit. In the pre-pandemic period, nearly 40 children were regularly seen per week. Dental care was part of research protocols developed in the unit and fulfilled patients' needs. Emergency care was also part of the routine. On average, eight emergency visits were performed per month. Toothache and prolonged tooth retention were the main reasons for them. Due to the current pandemic scenario, face-to-face care was suspended, causing our team to seek new alternatives for welcoming these patients. Then, an intervention for non-face-to-face caring using technologies was designed to overcome such situations and the Teletrailer program was launched (Figure 1).

Figure 1. Teletrailer program logo – program for non-face-to-face primary dental care for children, the intervention tested in TeleDent-COVID-19.

*Trial design and participant timeline*

A randomized controlled trial (RCT) was designed to be nested in a before-and-after study to cover different outcomes explored when implementing the ICTs in primary dental care for children (Figure 2). A health system-simulated scenario was set using a mobile dental unit as a cell unit for primary data collection.

Figure 2. The architecture of studies proposed to demonstrate the effect of implementing the non-face-to-face primary dental care for children using technological resources and extrapolating these findings to a real-world context to guide further research, practice and policies.

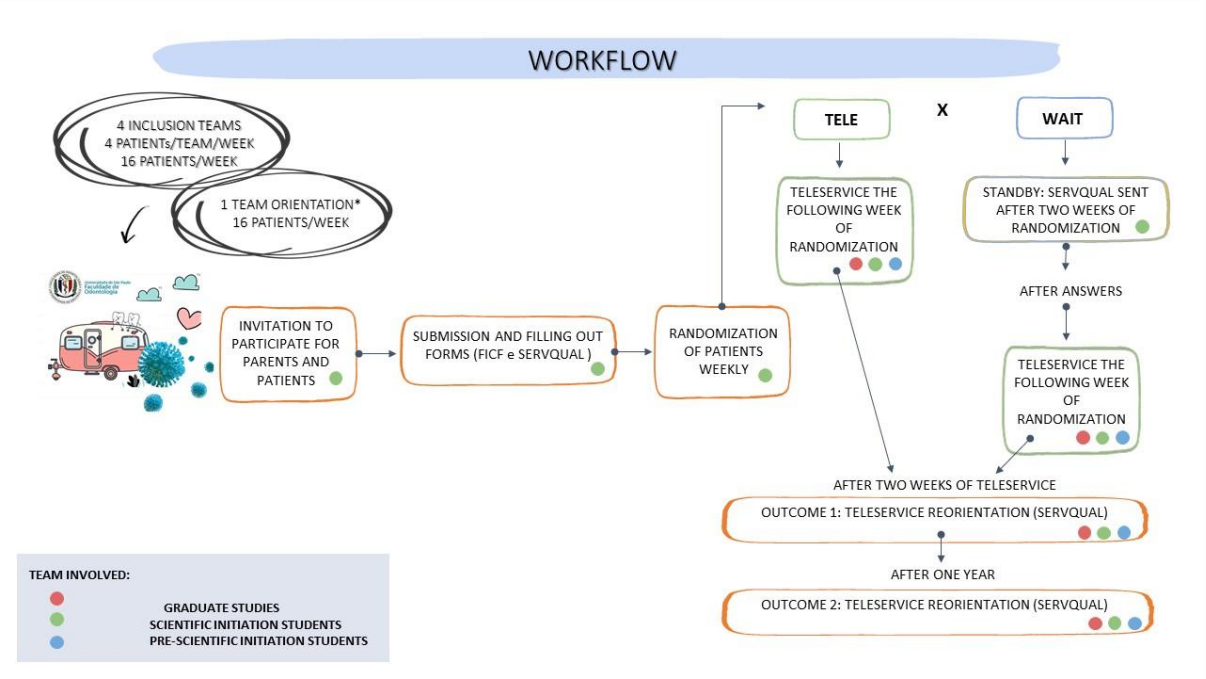



The primary outcome was set in the RCT. Such a study was controlled by participants' waiting list and measures users' /parents' perceptions about the health care offered and permitted using the participants waiting for dental care as reference (Figure 2). The before-and-after study collected data related to the natural implementation of ICT in the Teletrailer program.

The situation before the non-face-to-face intervention was considered the control to the before-and-after study. To measure it, besides the consultation, researchers will establish telephone contact with all registered patients and collect information about pain during the trans pandemic period, search for dental care in other public or private units and other possible complaints that occurred during this period. Besides, information reported during the teleconsultation will be considered as that. Thus, we will have an overview of the impact of the outage of care in the unit after social distancing. Outcomes are related to pen-up

demand solving, as well as the strengths and barriers of the program implementation. They were collected in the "after" moment, two weeks after implementing the intervention. Other outcomes in this study design were collected after one year from intervention as detailed further (Figures 2 and 3).

Figure 3. Schematic diagrams representing (a) the workflow for conciliating the studies (b) the time schedule of enrolment, interventions, assessments, and visits for participants.



| | STUDY PERIOD | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Enrolment | Allocation | Post-allocation | | | | | Close-out |
| TIMEPOINT | -t1 & t0 | 0 | t1 –t10 | | | t12 | t13-t17 | t18 |
| | | | | 1 week after | 2 weeks after | | | |
| Sample invitation and inclusion | | | | | | | | |
| Informed Consent | | | | | | | | |
| Telephone contact with patients | | | | | | | | |
| Allocation | | | | | | | | |
| Interventions (teleservice) Group intervention | | | | | | | | |
| Interventions (teleservice) Group Control | | | | | | | | |
| Revaluation 1 (Demand resolution) | | | | | | | | |
| Perception pf caregivers regarding primary care and dental care | | | | | | | | |
| Revaluation 2 | | | | | | | | |
| Increment in caries experience since the interruption of dental care | | | | | | | | |
| Increment or changes in the needs for dental treatment | | | | | | | | |
| Need for reorientation about oral hygiene | | | | | | | | |
| Baseline Variables | | | | | | | | |
| Independent variables | | | | | | | | |
| Demand needs | | | | | | | | |
| Economic Analysis | | | | | | | | |
| Prospecting results of a Public Health System | | | | | | | | |

Included children will continue to be followed every six months, following the systematic proposal when implementing technology-mediated interventions until the return of face-to-face activities is possible and the entire structure of the dental unit is prepared for dental care. The systematic recording of new complaints and complications will be maintained both during the consultation and in spontaneous contacts of the participants.

Apart from these clinical studies, simulation models will be used to prospect the ideally found in the cell unit to a SUS-simulated scenario, predicting the actual implementation on regular health units in SUS. Economic and social impact (including inequalities exploration) will also be explored in secondary analyses exploring data collected in the mentioned primary studies (Figure 2). The following sessions will be described considering each of the research strategies mentioned, as illustrated in Figure 2. The individual items related to the study design were described separately for each one. For the clinical studies, some sessions were merged to a broader comprehensive.

*The before-and-after study*

*Main Purpose*

Measuring the natural impact on pent-up demand solving and other effects resulting from telecare implementation in primary care for children.

*Participants: eligibility criteria*

All children enrolled for dental care in the unit were eligible for this trial. Their parents/caregivers will be contacted and invited to be part of the non-face-to-face program. After several attempts, children who cannot be contacted will be excluded from the sample. Children or guardians who do not agree to participate in the research were be computed as an outcome, as described further. In this case, teleconsultation may be performed if they desire, but without other data collection for research purposes.

*Interventions*

The intervention is the non-face-to-face strategy used in the Teletrailer Program, based on teledentistry resources to minimize the interruption of primary dental care (prevention and curative) during the pandemic. The consultation was guided by a standardized protocol (Figure 4) and performed by a team of dentists (graduate students), also responsible for previous face-to-face care at the unit. The session was divided into three parts (Figure 4).

i. Recognition of the child's and family's condition during the pandemic (updates on medical history, current oral health condition, sought dental care in other units, need for referral, change in hygiene and diet habits).

ii. Situational recognition on habits related to oral health (diet, hygiene and other oral-related habits), followed by individualized orientations about them.

iii. Personalized management of patients' and families' needs according to their reports and complaints, looking to solve their specific demand. The management strategy will follow a pre-defined and standardized structure based on the best evidence available in the subject. Standard strategies should be used depending on which patients' report (Figure 5).

Figure 4 - Standard Operational Procedures (SOP) that were used to guide the non-face-to-face consultation in the Teletrailer program.

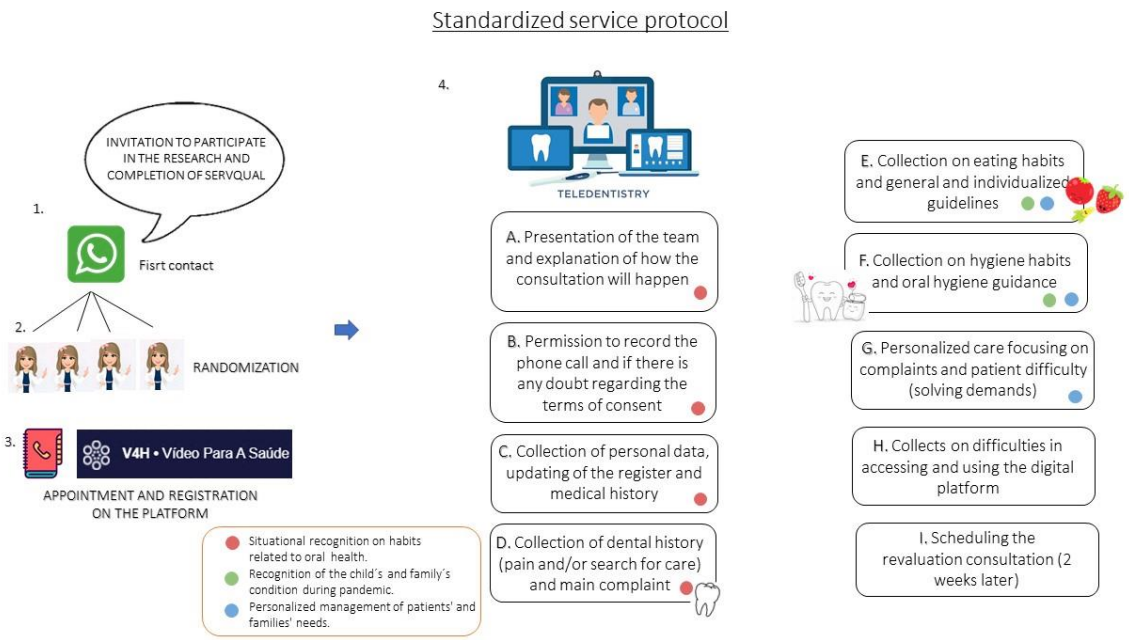


Figure 5. Clinical decision-making to meet the patients' and families' reported demands related to oral care.

| Hypothetical situations | Targeting | Expectation of resolution | Measure of resolution (outcome) and time |
|---|---|---|---|
| Need for reception, but no specific complaints | Reception, conversation, opening pf another communication channel | Immediate | Complaints addressed – 2 weeks after |
| Need for guidance, but no specific complaints | Reception, conversation, opening of another channel of communication and individualized guidance based on evidence | Immediate – short term | **A.** Complaints addressed – 2 weeks after<br><br>**B.** Targeted evaluation of habits – 2 weeks after<br><br>**C**. Survey of facilitators and barriers (checklist and qualitative research). |
| Need to resolve specific complaints that can be made not in person | Reception, conversation, opening of another communication channel, individualized guidance based on evidence and/or resolution of the table pointed by means of instructions, prescription of medicines or therapies | Immediate – short term | **A.** Complaints addressed – 2 weeks after<br><br>**B.** Survey of facilitators and barriers (checklist and qualitative research). |
| Need to resolve specific complaints not likely to be made not in person | Reception, conversation, opening of another communication channel, individualized guidance based on evidence, referral to emergency service, through prior contact of the professional responsible for care | Immediate – short term | **A.** Complaints addressed – 2 weeks after<br><br>**B**. Survey of facilitators and barriers (checklist and qualitative research). |

An electronic form was created to guide consultation and permit data collection. The data collected by the form was stored under the supervision of the principal investigator (MMB), in cloud storage and on a USB stick.

The teleservice will be carried out through a digital platform (Video for Health – V4H). This platform is innovative, 100% Brazilian, created by the Research and Extension Center

(Lavid) of the Informatics Center in Federal University of Paraiba (UFPB) in partnership with the Federal University of São Paulo (Unifesp) and financially supported by the National Network of Teaching and Research (RNP). The Teledentistry Center of Dental School, University of São Paulo contributed to adapting platform functionalities to the context of the SUS and the private sector in Brazil. The platform offers confidentiality in data traffic between participants, preservation for the time it is necessary to recover recorded videos, secure recording (with encryption) and registration in blockchain or trust protocol and a distributed registration technology to guarantee security in using it.

The operators were trained to use the V4H platform resources by expert researchers in teleservice and V4H development and support staff. Besides, they will receive the necessary technical support from the V4H team during the study. They are also calibrated on following Standard Operational Procedures to guide the consultation in a standardized way. Families enrolled in the Teletrailer program will receive information and support to use the platform from the Teletrailer team.

*Outcomes*

As the primary outcome for this before-and-after study, we consider problem-solving, considering the participant as the measurement unit. We will consider all the complaints pointed out by patients and their families during the baseline consultation. To measure that, a 2-weeks-later interview using the same platform (V4H) will address aspects relevant to understanding if the patients' and families' demands are solved during this time. A checklist to identify possible barriers and facilitators related to each type of complaint will be employed on these interviews. The time to resolution of the complaint will be computed as a secondary outcome.

Children will also be asked to toothbrush and floss during this assessment consultation. An external assessor will check the problem-solving related to the demand for oral hygiene orientations. The guidelines for orientation will be used as the reference standard to check if the demand was solved. If the child fulfils all oriented aspects, the demand is fully solved. If at least one assessment criterion is fulfilled, it is considered a partially solved demand. Cases of non-compliance with intervention sessions or those families that give up the consultations were also considered to understand the studied service's implementation.

Other outcomes will be assessed as secondary ones. The teleservice platform will measure consultation time. Technological and non-technological difficulties during the consultation (absences or delays, non-compliance, difficulties in using the platform, accessing the internet or even the computer or mobile phone) will be registered by an external assessor

in a specific file at the end of the online session. The caregivers' and child's perceptions on the use of technologies in primary dental care will be collected by specific questionnaire (21) in the two-week-later assessment.

The users' attitudes during the consultation will be evaluated. An assessor, who participates as a spectator in the videocall, will use a specific scale, PANAS (22). The scale records necessary actions to classify this outcome. Besides, a semi-structured interview using guided questions will also be performed. It intends to identify participants' and parents' perceptions and potential barriers and facilitators for receiving the non-face-to-face dental during the pandemic. Afterwards, an external examiner will assess the video recordings using the same scale and perform qualitative analysis. This external examiner will be not included in the consultation and is unaware of previous evaluations.

For this qualitative phase, individual interviews will be recorded and transcribed. For this, individual interviews will be recorded and transcribed. The software Maxqda® will be used for categorizing the recorded speeches and, later, a content analysis (CA) will be performed (23). For this analysis, categories are created following the common themes that emerge from the transcribed text. The analysis technique consists of three major steps: (1) pre-analysis; (2) the exploitation of the material; (3) the treatment of results and interpretation. Thus, we hope to identify qualitative differences between the groups that received technology-mediated care during the pandemic period or not, which cannot be captured through quantitative methods.

Finally, long-term outcomes will also be collected. Increment in caries experience since the interruption of dental and increment (or changes) in the needs for dental treatment will be assessed one year after the intervention. Presential clinical examination will be performed focused using dmft and DMFT and dental treatment need (including untreated caries, need for restoration repair, need of gingival or periodontal treatment, need for extractions for any reason) at this time point. An examiner unaware of baseline conditions will assess these indices and needs. These outcomes will be compared to those previously recorded in participants' records, resulting in the difference between the indices between these moments.

*Sample size and Recruitment*

As we have a demand study, all children enrolled for dental treatment at the dental unit will be potentially recruited for this before-and-after study and no sample size is required. The child will be our unit of analysis for that. As previously described, refusals and non-compliance with non-face-to-face consultations will also be registered as outcomes. At least

five attempts to contact participants who accept to participate will be used. In these attempts, we will consider different manners of communication, including phone calls, text and Whatsapp messages, email messages (when possible).

*Randomized controlled trial (controlled by waiting list)*

*Main Purpose*

We outlined a randomized patient-controlled study on the waiting list for care to assess the impact of teleservice implementation under the patients' and their families' perspectives, permitting comparison with a reference, in this case, those patients who are not participating in the Teletrailer program yet.

*Participants: eligibility criteria*

Children eligible for the previous study are also eligible for this one and followed the randomization step. Similarly, those who cannot be contacted after several attempts will be excluded from the sample. Children or guardians who do not agree to participate in the research were excluded from this randomizable sample.

*Interventions*

The family (including all children enrolled at the unit from the same family) will be randomized using stratified randomization by one researcher to one of the groups (intervention vs waiting list). The stratification will be performed considering the dentist will provide the non-face-to-face consultation and the week for inclusion. In this way, balanced randomization was obtained per professional each week.

Randomization order will be generated by the website sealedenvelope.com. The list was stored under the supervision of the person responsible for randomization (TGOM) and the principal investigator (MMB), in cloud storage and on a USB stick. The dentist who will provide the dental care will be unaware of randomization. They will receive the list with families/patients they are supposed to care for each week sent via email by the person in charge of randomization.

The two groups will differ according to the time of application of the intervention and outcome assessment. The non-face-to-face intervention group will receive the intervention immediately after randomization (t0). Then, after two weeks, the outcome will be measured as described further (t2). The waiting list group (control) will not receive the intervention as randomized and then assessed after the same period to permit controlling the answers (t2). Once this is done, the children on the waiting list will receive the intervention regularly (t3) and

become part of the previously detailed list of before-and-after study participants. However, for the present RCT, only data without intervention will be considered (t2). The intervention will be provided as described in the before-and-after study *Interventions* section. Both groups will have been contacted by a research team member to explain the study and will have answered a baseline questionnaire previous to randomization (t-2). At this time, all will know the teleservice will be available, but they will not know when that will happen.

*Outcomes*

We set the family's perception of dental care quality as a primary outcome. We will consider the caregiver's perspective (those who participate in the non-face-to-face consultation) measured two weeks after the intervention (teleservice test group) or two weeks after waiting for care (control group) (Figures 2 and 3). The SERVQUAL questionnaire will be used (24) (Additional File 3). SERVQUAL is a summary instrument of multiple scales, with a high level of reliability and validity already used in Portuguese (24). It can be used to understand users' expectations and perceptions concerning a wide range of services. In the present study, it is supposed the participants evaluate the degree to which they perceived the proposed service.

The questionnaire consists of 22 items, divided into 5 dimensions related to the service (tangible aspects – appearance of physical facilities, equipment, personnel and communication materials; reliability – ability to perform the promised service safely and correctly; responsiveness – willingness to help clients and provide prompt service; assurance – knowledge and courtesy of employees and their ability to inspire trust and empathy – personalized attention given to customers) (25). A total of 100 points is allocated among the five dimensions.

As secondary outcomes, we define the gap between users' perception and expectations, each partial assessment for five different domains included in the SERVQUAL questionnaire, and finally, the overall participants' perception of the service.

A model previously proposed was used to detect the gap between users' perceptions and expectations (26). For that, the SERVQUAL questionnaire was applied in two different moments (before and after receiving care). Then, the difference between the scores that customers attribute to the different pairs of statements. After consent to participate in this study, the baseline questionnaire will be sent to participants when contacted to participate in the study. This baseline assessment (t-2) should be done two weeks before the allocation (t0). We will calculate the mean score attributed in the primary SERVQUAL assessment (t2) in each dimension to evaluate individual dimensions separately. Finally, one extra item was

included besides the mentioned questionnaire (t2): "How do you feel about these service attributes that are already provided?". It was scored on a 5-point Likert-type scale of "very bad (1)" to "very good (5)." to identify overall participants' perceptions.

*Sample size and Recruitment*

The sample calculation was made using the application sample-size.net and considered the primary outcome for the RCT as a reference. As more than one dimension is considered in evaluating the primary outcome, we consider an average between them. A hypothetical user's difference between the perceived and the expected users' quality appraisal related to a regular health service clinic (27) was used to estimate a minimum difference for this trial, aiming at a more conservative calculation. The minimum difference expected was set, then, as 0,17 (effect size) and a standard deviation of 0,53 assumed (based on the worst case scenario in the referred study) (27). A minimum sample of 306 users or family representatives in the RCT was estimated. Extra 20% was added to compensate for possible losses, resulting in a final sample of 368 families recruited. Thus, the first 368 families from the unit's care list will be included (randomized). To reach the required number of children, all participants registered at the mobile dental care unit will be invited to participate in this study by telephone contact or message by conversation application, as detailed in the before-and-after study.

*Independent variables collection*

For both clinical trials described, available data will be collected from a data repository (medical records) administered by the researchers. Variables as time since the last consultation, oral health conditions associated (previous needs, caries experience, treatment adhesion/retention, oral-related habits, socioeconomic factors) may be used as independent variables. In addition, other independent variables will be collected parallel to intervention (teleconsultation), as changes in habits during the pandemic, level of education, age and occupation of the caregiver users involved in teleservice and previous experiences in health assisted by technologies.

*Statistical methods*

We will adopt the intention to treat analysis for both clinical trials, and all recruited participants will be considered when expressing our findings. Imputations of the outcomes will be considered whenever missing data is detected. In these cases, using conditional imputation methods will be used.

- <u>Before-and-after study</u>

Firstly, we will calculate the problem-solving rate achieved with non-face-to-face care. Besides, a subgroup analysis will consider different demands identified. We will also calculate the average time of resolution of the demands (difference between the moment of the appearance of the complaint or demand and the moment of its resolution) and the reduction of the waiting time (time-lapse from when the care is provided and the regular face-to-face activities re-opening).

Regarding children's and caregivers' perception, we will calculate the usability rate (ease of use by caregiver users), satisfaction with the tools, behavior towards proposed strategies, and difficulties encountered, dividing them into difficulties with technologies and not related to technologies.

Regression models will demonstrate the association of demand solving and the independent variables mentioned above. The same statistical approach will be used to outcomes related to the children's and caregivers' perception (usability, satisfaction, and behaviour to the technologies with the resolution of cases) and the time to resolution of complaints will be considered a dependent variable of conditional risk models. The events will be attention needs and the time counted from the last face-to-face contact. In these models, we will explore as independent variables the other variables also mentioned above, as well as aspects related to the difficulties reported by users.

The qualitative content analysis of the non-face-to-face consultations mediated by technology will be descriptive. It will look for possible explanations to different caregivers' perceptions and identify barriers and facilitators associated with the type of care offered.

- The RCT (waiting list controlled)

This study will first compare the satisfaction with the health care received using the SERVQUAL score between the groups (with and without technology-mediated care). We will use an appropriate statistical test depending on the distribution of scores. The scores assigned for the perception of each dimension will also be compared. Appropriate regression analyses may also be performed to verify other variables' influence, besides the group (test vs control) on users' perception of the received care.

We will also compare the gaps (difference between expected and perceived between groups. Comparisons between the perceived and expected in each one of the groups will also be performed. Once again, distributions will be checked to choose the appropriate statistical approach to be used.

*Simulation study - prospecting the findings for the reality of the national health system*

After collecting the effects of implementing the technology-assisted primary care strategy, we will simulate a situation adapted to the scenario of interest (the national public health system), the SUS (Figure 2). This strategy has been used to provide subsidies (measurements) related to changes safely and efficiently before they are implemented on a large scale (28).

We will use simulations considering the characteristics of the basic health units that provide primary dental care for children. We will create a specific model considering the distribution of variables in the sample for outcomes collected in trials but prospecting for a wider population eligible for primary care in SUS. We will use some index variables, e.g. caries experience, that we have collected in the trials and can also be found in official national data. The relationship between such variables and the studied outcomes will be investigated in our sample and will guide the model building.

Finally, using a bootstrapping technique, we will simulate data equivalent to SUS reality, considering appropriate variables as reference for that, as mentioned. We will collect updated official data on the impact of the pandemic on the Brazilian public health system and data on oral health conditions in the age group obtained through the last oral health survey (SB Brasil 2010) (29). We will assume the essential characteristics of these units, which will also be considered in this simulation model. Some scenarios will be set to represent different contexts from different Brazilian regions.

From this simulation study, we hope to find the mean values and their 95% confidence intervals related to the problem-solving rate, reduction of waiting for time and user satisfaction related to the implementation of technology-mediated health care in the primary care of children assisted by the SUS.

*Economic and social impact evaluations on the implementation of teleservice in primary dental care for children*

Some economic evaluations were outlined to answer the efficiency of resource allocation when implementing teleassistance activities to solve the pent-up demand caused by the pandemic. To comprehend a broader overview of the economic impact of this implementation process, we will consider the different effects explored in the trials, both child- and parent-centred.

(a) Perspective and Time Horizon: We will adopt a societal perspective for the analyses. The time horizon will be set as the trans-pandemic time, considering as limits the beginning of social distancing in Brazil and as an end, the date of return to normality of activities officially determined for it according to official government recommendations. Eventually, subgroup analyses will be considered for different Brazilian regions with different profiles regarding the duration of the pandemic. Alternatively, we may also model data using another time horizon, in which we consider the achievement of an ideal vaccination rate in Brazil (or in specific regions).

(b) Type of Evaluation/Effects: Three different trial-based economic evaluations will then be performed using cost-effectiveness approaches. A different effect will be used for each one (Figure 6). Mainly, data will be extracted from trials described elsewhere in this protocol. Modelling strategies will be used to simulate more prolonged effects than those measured in the trials.

Figure 6. Economic evaluations (cost-effectiveness type), respective effects, questions to be answered and possible subgroup analyses foreseen.

| Economic Assessment | Effect | Test Group | Control Group | Economic Question |
|---|---|---|---|---|
| I. | Resolution Rate (RT) | TR observed or estimated | TR = 0* | Are teleorientation and telemonitoring efficient options for allocating resources compared to the non-implementation of these strategies when thinking of resolving the complaints and demands of pediatric dental patients whose demand for care has been suppressed due to the pandemic? How much does it cost to solve the demand for suppressed care due to the pandemic? |
| II. | Complaint resolution time (TRQ) | TRQ observed or estimated | TRQ post pandemic ** | How much it costs for teleorientation and telemonitoring to reduce in one day the resolution of complaints in the pandemic period? |
| III. | Satisfaction of users with the attention received | SERVQUAL test group score | SERVQUAL test group score | Are telemonitoring and teleorientation efficient options for allocating resources compared to the non-implementation of these strategies when thinking about leaving the family nuclei of pediatric dental patients? |

* Assuming the interruption of face-to-face care and the absence of non-face-to-face alternatives implemented.
** Time of the pandemic – from the beginning of social distancing to the return to normally of face-to-face activities.

(c) Costs: The costs will be considered as described below for each assessment. The unit of analysis will be the research participant (patient/child) to which primary care was being directed and the strategy of micro-costing. Resources used will be valued as described in the Figure 7. The direct costs will be those related to the provision and installation of services. In contrast, indirect costs will consider the patient's cost for the use of dental services or costs derived from care) that must be computed in a broader character (Figure 5). All costs will be valued in Brazilian Real and converted into dollars.

Direct costs will be computed considering the time of use of the teleservice. This time will be recorded on the platform and by the service professional to double-check. For the calculation for the professional cost: the salaries of professionals will be based on the official national data will be used. With this, it will be multiplied by the time spent. Sensitivity analyses will be performed using data from different regions and/or different available services/positions.

The costs for the installation and maintenance of the teledentistry system take into account the program's implementation and its continuous operation. This type of cost will consider the time spent by the team for developing the system and the cost of maintaining and using the platform. An hourly value for using the technology will be calculated based on system capacity and usage flow data per month (30) and thus the value of the time obtained. A similar strategy will be made considering the expenses related to training and training of the team to implement the strategy (31).

To value the cost of using the technology by the patient/family, the average prices for 1Mbps of internet and Kwh of energy in Brazil, taking into account the time spent in each consultation. The value for patient´s and caregiver´s time and caregiver will be valued using arbitrary reference values (for example, the minimum wage and/or average salary of the population) and the time spent during care.

To value the treatments received outside the dental unit, the average value per procedure was obtained from a data repository of costs related to care provided at the same unit when performing another clinical study (NCT02473107). If a child needs to perform a restoration during the period, a value is estimated for that based on that repository.

In the case of unresolved complaints or patients who miss the expected follow-up until the end of the pandemic, the costs of possible complications will be valued based on the expected outcomes using models.

In the case of patients who will not receive the intervention, the costs of the intervention will not be considered since face-to-face care at the time of the pandemic is suspended (Figure 5).

Figure 7. Cost components to be valued for the economic evaluations.

| Cost Types | | Form of stocking | Intervention Group | Control Group |
|---|---|---|---|---|
| Direct Cost | Professional Coat | Hour/ Professional Value | Estimated by direct measurement | Not considered** |
| | Cost of installation and operation of the service – and professional | Hour/ Usage Value | Estimated by direct measurement | Not considered** |
| Indirect Cost | Cost of derived treatments, use of services, complications | Value per treatment/ Repository | Estimated by repository data*and modeling | Estimated by repository data |
| | Cost of the patient to use the service (out-of-pocket costs) | Hourly/ Usage values | Estimated by direct measurement | Not considered** |
| | Cost of patient time and caretaker | Hourly/ Usage values | Estimated by direct measurement | Not considered** |
| | Cost with lost productivity loss of day of service | Hourly/ Usage values | ** | Estimated by repository data |

* Data collected in the care unit and used as a repository to estimate values of dental procedures received by children due to their complaints, complications of these possible complaint and/or urgent treatments received during the period of interruption of face-to-face care.
** Not considered due to the interruption of face-to-face care, which this group aims to simulate.

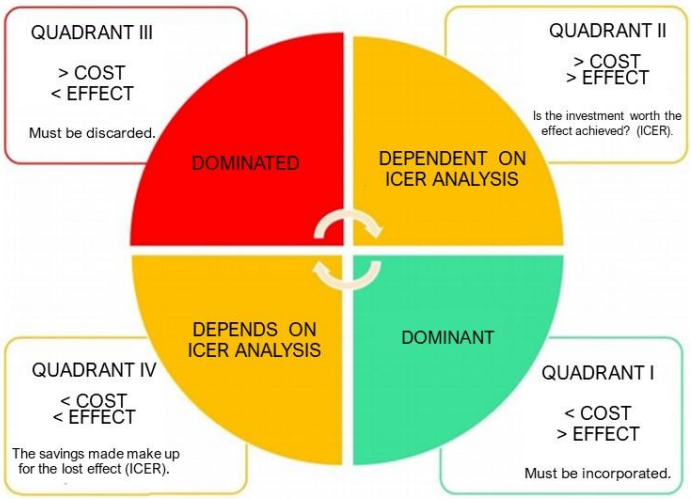
(e) Analysis Plan: The cost-effectiveness strategy will be used for economic analyses. Incremental values will be calculated both for costs and effects. Therefore, the difference between the new strategy and the one you want to replace will be calculated. ($\Delta E=E_{with\_tele} - E_{without\_tele}$ and $\Delta C=C_{with\_tele} - C_{without\_tele}$). The confidence intervals will be estimated, for each parameter, using the bootstrap technique and considering the sample values referring to costs, effects, incremental costs and incremental cost ratio incremental effectiveness.

The decision-making will depend on the interpretation that will be made of the values collected in the cost-effectiveness plane. Depending on the quadrant in which these simulation results are placed, it may be called dominant or dominated, so an incremental-effectiveness cost ratio calculation may be required for the decision to be made. If the results are in the Northeast or Southwest quadrant (Figure 8), the incremental cost-effectiveness ratio will help to decide whether or not the intervention will be cost-effective, that is, whether the extra

expenditure attributed to the strategy is really worth the effect achieved by it, or even, whether what will be saved with the new strategy is worth the loss that has in its effect.

Acceptability curves will be plotted considering different ceiling ratios. This strategy will be used for each tested effect to check the strategy's cost-effectiveness in different economic evaluations.

Figure 8. Diagram for interpretation of costs and effects in the cost-effectiveness plan.




(f) Sensitivity analyses: The economic evaluations will initially be evaluated considering a SUS-simulated scenario in which non-face-to-face care is implemented. The confidence limits of the parameters used (effects and costs) will be considered for performing deterministic sensitivity analyses.

We will adopt a Bayesian strategy to probabilistic sensitivity analyses to explore the uncertainties of health effects and costs (32-34). For this, following the sample distribution, we will create simulations for both effects and costs, using XLSTAT 2021 (Addinsoft, Paris, France) and the effects and incremental costs. Also, the distributions of these parameters will be considered when the probabilistic analyses are performed.

Next, we will also perform other sensitivity analyses, considering the values prospected for the national health system, considering its magnitude and peculiarities. If necessary, subgroup analyses may be adopted to address specific Brazilian regions.

Finally, we will also analyze the expected value of perfect information (EVPI) and budget impact analysis (BIA). The first analysis (EVPI) allows us to know the value attributed to lousy decision-making due to the uncertainties presented in the data when the strategy is incorporated. It also allows us to estimate the value of the information (VOI), allowing the manager to have tangible arguments to decide whether there is interest in searching for evidence for the subject (35). On the other hand, the BIA is an elemental analysis for planning and dimensioning the expenses inherent to incorporating a new strategy in the health system (36).

Still considering the above scenarios (dental reference unit and SUS), we will use the economic modelling strategy to consider some aspects not directly measurable in the evaluations described above but relevant from the point of view of decision-making. For this purpose, in the model, we will consider the costs and effects (including risks and benefits) inherent to the face-to-face resolution of some complaints and demands that could be resolved in the clinical studies described above.

To construct and validate these models, a group of experts, including experts in economic assessments, in evidence-based practice, service representatives and managers/decision-makers will be involved. The values related to the probability of occurrence of the different effects considered, as well as the costs derived from each of the situations or states included in the decision tree, will be obtained from the clinical studies conducted in the format of face-to-face care and official data sources or pertinent bibliography. If necessary, data compilation will be done in meta-analysis format for a more robust estimate. Once this is done, the same analytical strategies previously scored will be employed.

Suppose a potential positive effect of the technology applied to primary dental care for children is detected. Then, models to understand how these tools could be used in the post-pandemic period to optimize the care and demand of this type of care within the SUS. For this, new decision trees will be proposed considering for each type of relevant demand (welcoming, guidance, resolution of some complaints without face-to-face need), possibilities of evolution, leading to inherent effects and costs. Then, another economic evaluation considering the economic impact of maintaining these technological tools within the context of primary care in the SUS in the post-pandemic period may be carried out. Such models may consider values related to the family's need for going to a dental unit for being cared for, caregivers' productivity losses because they accompany children in some visits, increase of dentist's productivity, possible losses due to difficulties in access and technological domain, among

other possible points raised in clinical studies and also by the experts involved in the construction of the theoretical framework and validation of the models.

For the proposed frameworks, Markov models will be used, constructed and rotated in the appropriate software TreeAge. Annual cycles will be established and, a priori, a 10-year time horizon will be considered. The base case and health states will also be defined, given what was observed in previous studies. In these models, we will try to contemplate quantitative aspects (size of the population of children in the age group covered by the system) and qualitative (regional specificities) characteristics of the SUS. Exploratory analyses will be made considering possible variations in time horizons.

To verify if the insertion of technologies in primary dental care will impact social inequalities, we will analyze how some parameters associated with access may influence studied outcomes. Participants will be divided into groups considering socioeconomic factors, such as income, maternal education, agglomerate. Further, we will test if there are differences, for example, regarding the difficulties of access to technologies for care and guidance in primary care between these groups. We will collect pertinent data from the clinical studies and consider the mathematically simulated data for prospecting the reality to the national health system.

We will use managed entry agreement schemes to deal with the risk of heterogeneity of findings in economic analyses (37) adapted to the Brazilian reality. At this stage, we will consider the models and decision tress built to check the efficiency of resource allocation when implementing technologies in the management of relevant situations in the face of the COVID-19 pandemic and possible subsequent implementation in the SUS. The risks of uncertainty will be quantified using an instrument proposed for this purpose (38), and its actual impact can be evidenced for the health system managers, for example. That will also be a way to compare the different strategies in different environments (settings) to be incorporated within the national public health system.

## Discussion

Given the scenario of COVID-19, in which social distancing is necessary, the professionals had to review their conduct to minimize the chances of contagion with the virus. Thus, Teledentistry has been gaining prominence, as it is an innovative method of providing health services that allow contact guidance without the need for face-to-face care (39).

On the other hand, because it is an innovative type of care, many issues are being raised around the telehealth. While teleservice support is argued to improve equitable access to health care, it may also cause disparities in access due to digital difficulty (40,41). It is a fact that this type of care presents some challenges, not only related to digital complications, access, connection but also of performing a preliminary physical examination, difficulty in visualization, difficulty in diagnosis. But even so, telehealth can contribute substantially to finding a balance between face-to-face encounters and remote follow-up of patients, especially in pandemic moments (42). These findings demonstrate the need for evidences who actually support the use of such strategies in primary dental care.

In Brazil, we have not found many studies related to the implementation of Teledentistry, especially with children. This series of studies on the implementation of non-face-to-face care may bring essential contributions to understanding how such technologic inclusion in dental practice could result. For that, both different study designs and different outcomes are being explored in this protocol. As we designed here, small-scale studies can more closely approximate the clinical or community context of an RCT and may be helpful to test some aspects of intervention feasibility (14). Looking at "how does strategy may work" for performing care for children when a face-to-face consultation is not feasible is our big deal in this protocol. As "how it works" may be answered in different ways (14), we opted for exploring aspects that matter to the dentist and the patient/family and society in general.

For deciding to include this type of technology (or not) in the health system, or even in any dental practice, we need information related to acceptability, demand, costs, implementation power, efficacy. All these areas may be addressed for feasibility studies (14). It is expected that with the results of this project, we can contribute scientifically to all these issues, and permanently modify the work process of oral health teams in Brazil, and maybe, in other parts of the world.

The teleservice is not a new tool in health care. However, the COVID-19 pandemic created an opportunity window that makes this approach more visible and probably desirable. We believe after this pandemic and returning of regular clinical appointments, some positive lessons may become perennial. Thus, it is also crucial to understand how all these efforts performed during this atypical period may contribute to the real-life after the pandemic ends.

Another important mission in this protocol is bringing out robust findings that may induce policies and show experiences serve as examples even for other countries. We reinforce the responsibility and mission to generate knowledge with public resources and disseminate them at scale so that good practices can be carried out to ensure benefits to all

SUS users, prospecting and expanding contributions, possibly, to different realities related to the SUS within Brazil or even, throughout the world.

*Competing interests*

The authors declare that they have no competing interests.

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*Authors' contributions*

MMB, FCAC, MCSN conceived the study idea. MMB, FCAC, MCSN, DPR, FMM, JCPI, GLSF, EHGL, YWC and CIS designed the study. MMB, KHN, TGM, FB, LIL, MEFV, GMM, JDYV and FCAC are responsible for implementation of the clinical trial and data collection. MMB, FCAC, MCSN are the trial coordinators. MMB and FCAC are the principal investigators. KHN, TGM, FB, LIL, MEFV, GMM, JDYV are the dentists who perform the teleservices. MMB, KHN and TGM are accountable for organizing and monitoring the treatments. All authors wrote and revised the manuscript.

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- Collaborative study group:

  Thais Gomes de Oliveira Machado, Maria Eduarda Franco Viganó, Jhandira Daibelis, Gabriela do Manco Machado, Fabiana Bracco, Lucas Gabriel Santini Rodrigues, Gabriele de Oliveira, Isabella Petroline leite, Luiz Ivan Lemos Silva, João Victor Rezende Pompeu, Letícia Furtado Ramalho.

- V4H group (https://v4h.cloud/):

  Guido Lemos, Marco Gutierrez, Cicero I. Da Silva, Giuliano Maia, Denio Mariz, Rosangela Gundim, André do Prado, Lucas Aversari, Igor Gadelha, Clístenes Onassis, Erick Dias, Leoberto Soares, Fernando Máximo and Matheus Queiroz.

*Dissemination policy*

All the findings of this trial will be reported in peer-reviewed journals, patient newsletters and a website.

*Trial status*

The trial is recruiting participants at this moment. The recruitment has been in progress from December 2020 until now. The end of the recruitment is planned for June 2022.

*List of abbreviations*

*BIA*- Budget Impact Analysis

*CA*- Content Analysis

*CI*- Informatics Center

*EVPI*- Expect Value of Perfect Information

*FAPESP*- São Paulo State Research Foundation

*FOUSP*- University of São Paulo School of Dentistry

*LAVID*- Research and Extensions Center

*ICT*- Information and communication technologies

*RNP*- National Network of Teaching and Research

*SPIRIT*- Standard Protocol Items: Recommendations for Interventional Trials

*SUS*- Unified Health System

*V4H*- Video for Health

*VOI*- Value of the Information

## References

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**Supplemental File 1.** SPIRIT checklist.

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Pag | Description |
|---|---|---|
| **Administrative information** | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions,and, if applicable, trial acronym |
| Trial registration | 7 | Trial identifier and registry name. If not yet registered, name ofintended registry |
| | 7/30 | All items from the World Health Organization Trial Registration DataSet |
| Protocol version | 7 | Date and version identifier |
| Funding | 8/31 | Sources and types of financial, material, and other support |
| Roles and responsibilities | 31/32 | Names, affiliations, and roles of protocol contributors |
| | 3 | Name and contact information for the trial sponsor |
| | 32 | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report;and the decision to submit the report for publication, including whetherthey will have ultimate authority over any of these activities |

| | | |
|---|---|---|
| | - | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing thetrial, if applicable (see Item 21a for data monitoring committee) |

## Introduction

| | | |
|---|---|---|
| Background and rationale | 5-7 | Description of research question and justification for undertaking thetrial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention |
| | 6 | Explanation for choice of comparators |
| Objectives | 7 | Specific objectives or hypotheses |

## Methods: Participants, interventions, and outcomes

| | | |
|---|---|---|
| Study setting | 8/10 | Description of study settings (eg, community clinic, academic hospital)and list of countries where data will be collected. Reference to where list of study sites can be obtained |
| Eligibility criteria | 10/14 | Inclusion and exclusion criteria for participants. If applicable, eligibilitycriteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) |
| Interventions | 10-12/ 15-16 | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered |
| | 10 | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms,participant request, or improving/worsening disease) |
| | 14 | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) |
| | - | Relevant concomitant care and interventions that are permitted or prohibited during the trial |
| Outcomes | 12-14/ 16-17 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy andharm outcomes is strongly recommended |
| Participant timeline | 8-10/ 15-16 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) |
| Sample size | 14/ 17-18 | Estimated number of participants needed to achieve study objectivesand how it was determined, including clinical and statistical assumptions supporting any sample size calculations |
| Recruitment | 14 | Strategies for achieving adequate participant enrolment to reach target sample size |

## Methods: Assignment of interventions (for controlled trials)

Allocation:

| | | |
|---|---|---|
| Sequence generation | 15 | Method of generating the allocation sequence (eg, computer- generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any plannedrestriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions |

| | | |
|---|---|---|
| Allocation concealment mechanism | 15-16 | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions areassigned |
| Implementation | 15-16 | Who will generate the allocation sequence, who will enrol participants,and who will assign participants to interventions |
| Blinding (masking) | 15 | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), andhow |
| | | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial |

**Methods: Data collection, management, and analysis**

| | | |
|---|---|---|
| Data collection methods | 10-11/13/16-17 | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg,duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol |
| | 14 | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants whodiscontinue or deviate from intervention protocols |
| Data management | 11/15 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol |
| Statistical methods | 18-20 | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can befound, if not in the protocol |
| | 20 | Methods for any additional analyses (eg, subgroup and adjusted analyses) |
| | 18 | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) |

**Methods: Monitoring**

| | | |
|---|---|---|
| Data monitoring | 31 | Composition of data monitoring committee (DMC); summary of its roleand reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed |

| | | |
|---|---|---|
| | 31 | Description of any interim analyses and stopping guidelines, includingwho will have access to these interim results and make the final decision to terminate the trial |
| Harms | - | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct |
| Auditing | 31 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and thesponsor |

## Ethics and dissemination

| | | |
|---|---|---|
| Research ethics approval | 31 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval |
| Protocol amendments | 31/33 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals,regulators) |
| Consent or assent | 31 | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) |
| | - | Additional consent provisions for collection and use of participant dataand biological specimens in ancillary studies, if applicable |
| Confidentiality | 11/15/31 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial |
| Declaration of interests | 31 | Financial and other competing interests for principal investigators forthe overall trial and each study site |
| Access to data | 31 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators |
| Ancillary and post-trial care | - | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation |
| Dissemination policy | 33 | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions |
| | - | Authorship eligibility guidelines and any intended use of professional writers |
| | - | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code |

## Appendices

| | | |
|---|---|---|
| Informed consent materials | Supplemental file 5 | Model consent form and other related documentation given to participants and authorised surrogates |
| Biological specimens | - | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. 

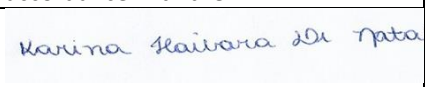
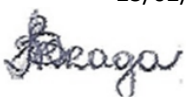
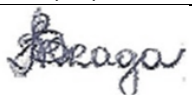
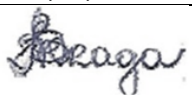
**Supplemental File 2.** Checklist for Health Economics Analysis Plans (HEAPs) for Trial-Based Economic Evaluations (20)

## Health Economics Analysis Plan (HEAP) template v1.0

The full list of essential and optional items is given below, with expanded item descriptions and practical examples of how the item might appear in a HEAP. Please note that the examples are drawn from a number of different studies.[†]

## Essential items

| | | Description | Example |
|---|---|---|---|
| **Section 1: Administrative information** | | | |
| 1.1 | Title | Title that matches protocol and which includes the phrase 'Health Economics Analysis Plan' | Using information and communication technologies (ICTs) to solve the repressed demand for primary dental care in the Brazilian Unified Health System due to the COVID-19 pandemic: a randomized controlled study protocol nested with before-and-after study including economic analysis. |
| 1.2 | Trial registration number | Trial registration number and name of registry that uniquely identifies the clinical trial on a publicly accessible registry (and other relevant trial study numbers) | Registration NCT04798599 |
| 1.3 | Source of funding | Name of funders for trial and economic evaluation and funder(s)' reference number(s) | FAPESP-2012/50716-0 and Coordination for the Improvement of Higher Education Personnel (CAPES) (2017-2022). |
| 1.4 | Purpose of HEAP | Brief statement of the purpose of the HEAP | The present trial aims to elucidate the impact of implementing the ICTs in primary dental care for children on resolving the pent-up demand for primary dental care to children in the SUS due to the COVID-19 pandemic. |
| 1.5 | Trial protocol version | Trial protocol version number associated with this HEAP | This document has been written based on information contained in the trial protocol version 1, dated 23 February 2022. |
| 1.6 | Trial Statistical Analysis Plan (SAP) version | SAP version number associated with this HEAP | SAP Version: 1.0, Date: 23 February 2022 |
| 1.7 | Trial HEAP version | Sequential number and date of this version | HEAP Version: 1.0, Date: 23 February 2022. |

| | | | |
|---|---|---|---|
| 1.8 | HEAP revisions | Date, justification for revision and summary of changes to the HEAP. Specify the individual making any revisions/changes to the HEAP. | This manuscript was written following the Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) for clinical studies (Supplemental File 1) and potential items to be included in Health Economics Analysis Plans (HEAPs) for Trial-Based Economic Evaluations for economic evaluation (Supplemental File 2). |
| 1.9 | Roles and responsibilities | Names, affiliations and roles of individuals who have significantly contributed to the HEAP | This study protocol was prepared by Karina Haibara De Natal and approved by, Prof/Dr Mariana Minatel Braga. The trial health economist(s) Mariana Minatel Braga are responsible for conducting and reporting the economic evaluation in accordance with the HEAP. |
| 1.10 a | Signature(s) of person(s) writing HEAP | Signature(s) of the person(s) writing the HEAP (and date) |  <br>23/02/2022<br>  <br>23/02/2022 |
| 1.10 b | Signature of senior health economist | Signature of senior health economist who is guarantor of the economic evaluation (and date) |  <br>23/02/2022 |
| 1.10 c | Signature of Chief Investigator | Signature of the Chief Investigator for the trial (and date) |  <br>23/02/2022 |
| **Section 2: Trial introduction & background** | | | |

| | | | |
|---|---|---|---|
| 2.1 | Trial background and rationale | Synopsis of trial background and rationale including a brief description of research question and brief justification for undertaking the trial | With the COVID-19 pandemic, thousands of children had their dental care interrupted or postponed, generating a pent-up demand for primary care. To minimize the impact of this interruption of face-to-face care, information and communication technologies can be an alternative and even likely to be envisioned within the Unified Health System (SUS). In this sense, this study sought to show the impact of the use of information and communication technologies (ICT) in the resolution of the repressed demand for primary dental care to children in the SUS, due to the COVID-19 pandemic proposing the use of telemonitoring, teleorientation and telescreening to solve meet the demands arising from this interruption in primary elective care. |
| 2.2 | Aim(s) of the trial | Clearly and briefly state the main aim(s) of the trial | This proposal has a general objective to show the impact of the use of information and communication technologies (ICT) on the resolution of the pent-up demand for primary dental care for children in the SUS, due to the COVID-19 pandemic. |

| | | | |
|---|---|---|---|
| 2.3 | Objectives and/or research hypotheses of the trial | Describe specific trial objectives (primary and secondary) or trial hypotheses | 1. To identify the repressed demand for the interruption of dental care and the benefits and difficulties, as well the perception of users, in the implementation of new strategies of non-face-to-face care based on technology (teleservice), using a cellular unit of primary care for the child and prospect, through models, this situation for the scenario of the Unified Health System.<br>2. Perform different forms of economic evaluation to measure whether the gains achieved with the implementation of the teleservice compensate for the additional costs possibly associated with it, or if the teleservice modalities are associated with the long-term resource savings, considering the scaled implementation for the Brazilian public health system.<br>3. Explore how the introduction of these technologies could benefit the Unified Health System in the trans and post-pandemic period, contribute to the correction of possible inequities in health care and other social aspects, as well as result in possible differences when exploring the different Brazilian scenarios.<br>. |

| | | | |
|---|---|---|---|
| 2.4 | Trial population | Describe the trial inclusion and exclusion criteria | All children enrolled for dental care in the unit were eligible for this trial. Their parents/caregivers will be contacted and invited to be part of the non-face-to-face program. After several attempts, children who cannot be contacted will be excluded from the sample. Children or guardians who do not agree to participate in the research were be computed as an outcome, as described further. In this case, teleconsultation may be performed if they desire, but without other data collection for research purposes. |
| 2.5 | Intervention(s) and comparator(s) | Describe the intervention(s) and comparator(s) | Intervention: The teleservice will be carried out through a digital platform (Video for Health -V4H). The service will consist of 3 parts: a) recognition of the condition identified in the pandemic period, b) realization of diet guidance, hygiene and other necessary habits, c) targeting the needs presented. The guidelines, although individualized for each child´s needs, will follow a pre-defined and standardized structure and based on the best evidence available on the subject. In the control group, children waiting for the intervention (under implementation in the unit due to the pandemic) will be evaluated for outcomes. |
| 2.6 | Trial design | Briefly describe the trial design including type of trial such as cluster, crossover, etc. Can also include details of power calculation, sample size (including any separate calculations for economic endpoints), randomisation and blinding. | Randomized, patient-controlled waiting list study nested with a before-after study to be conducted in a cellular unit, simulating a basic dental health unit. Next, a modeling study was conceived, prospecting the situation found for the reality and full demand of the Unified Health System. Expected sample of 368 families. Triple masking (participant, service professional and result evaluator). Simples randomization. |
| 2.7 | Trial start and end dates | Trial recruitment start and end dates and the follow-up period | Recruitment started in December 2020 and is due to finish in June 2021. The follow-up period will run for 12 months until December 2021. |
| **Section 3: Economic approach/overview** | | | |

| | | | |
|---|---|---|---|
| 3.1 | Aim(s) of economic evaluation | Describe the aim(s) of the economic evaluation | Are teleorientation and telemonitoring efficient options for allocating resources compared to the non-implementation of these strategies when thinking of resolving the complaints and demands of pediatric dental patients whose demand for care has been suppressed due to the pandemic? How much does it cost to solve the demand for suppressed care due to the pandemic? How much it costs for teleorientation and telemonitoring to reduce in one day the resolution of complaints in the pandemic period? Are telemonitoring and teleorientation efficient options for allocating resources compared to the non-implementation of these strategies when thinking about leaving the family nuclei of pediatric dental patients? |
| 3.2 | Objective(s) of economic evaluation | Describe the objectives (primary and secondary) of the economic evaluation | Perform different forms of economic evaluation to measure whether the gains achieved with the implementation of teleservice compensate for the additional costs possibly associated with it, or whether they are associated with a long-term resource savings, considering the implementation sized for the Brazilian public health system. Explore how the introduction of these technologies could benefit the SUS in the trans and post-pandemic period, contribute to the correction of possible inequities in the health care and other social aspects, as well as result in possible differences when different Brazilian scenarios are explored. |
| 3.3 | Overview of economic analysis | Briefly outline and justify the type of economic evaluation to be undertaken, identifying the primary economic analysis and outlining the analysis plan and the methods that will be used | Three economic evaluations will then be performed, using cost-effectiveness analyses. These assessments will be based on a clinical study and will include, for prospecting for longer effects, associated economic modelling strategies. The unit of analysis will be the research participant (patient) to which primary care was being directed and the strategy of micro-costing. |

| | | | |
|---|---|---|---|
| 3.4 | Jurisdiction(s) | Specify the jurisdiction(s) in which the analysis will be conducted including details of the country(s) and health system(s) | The trial is conducted in Brazil which has one the largest public health systems (SUS). |
| 3.5 | Perspective(s) | State the perspective(s) from which the economic analysis is being conducted, such as societal perspective and/or healthcare payer perspective | We will consider as perspective the society. |
| 3.6 | Time horizon(s) | State the time horizon(s) over which costs and consequences are being evaluated | As a time horizon, the trans-pandemic time, considering as limit the beginning of social distancing in the state and, as an end, the date of return to normality of activities officially determined for it, according to the São Paulo Plan (green phase). |

| Section 4: Economic data collection & management | | | |
|---|---|---|---|
| 4.1 | Statistical software | Specify the statistical software that will be used to carry out the health economic analysis | XLSTAT 2021 (Addinsoft, Paris, France) |
| 4.2 | Identification of resources | Justify and describe items of resource use that will be measured as part of the trial | Provision and installation of services considering the time of use of the teleservice: professional cost, cost of installation and operation of the service.<br>Patient´s cost for the use of dental service: cost of derived treatments, use of services, complications; cost of the patient to the service; cost of patient time and caretaker; cost with lost productivity loss of day of service. |
| 4.3 | Measurement of resource-use data | Describe the resource-use data collection method(s) (including external routine datasets) and the time points at which they will be used. | Resource-use data will be collected util 12 months post randomisation and to value the treatments received outside the dental unit, the average value per procedure was obtained from a data repository of cost related to care provided at the same unit when performing another clinical study (NCT02473107). |
| 4.4 | Valuation of resource-use data | For each resource item measured, describe how the unit cost will be derived and from which specific price year. Outline how adjustments will be made for sources from different price years and which inflation index will be used. | Table 7. |
| 4.5 | Identification of outcome(s) | Specify and justify the outcome(s) that will be measured | Resolution Rate (How much does it cost to solve the demand for supressed care due to the pandemic?)Ç Complaint Resolution Time (How much it costs for teleorientation and telemonitoring to reduce in one day the resolution of complaints in the pandemic period?); Satisfaction of users with the attention received (Are teleorientation and telemonitoring efficient options for allocating resources compared to the non-implementation of these strategies?). |

| | | | |
|---|---|---|---|
| 4.6 | Measurement of outcome(s) | Describe the outcome data collection method(s) and the time points at which they will be used | The data will be collected during a year in which the teleservices will be made, a data repository held in the same unit-cell will be used to value calls offered in the non-face-to-face form. And they will be used after 12 months of study to perform the analyses. |
| 4.7 | Valuation of outcome(s) | For each outcome measured, describe how it will be valued and the source of these valuations | The cost-effectiveness strategy will be used for economic analyses. Incremental values will be calculated both for costs and effects. Therefore, the difference between the new strategy and the one you want to replace will be calculated. The confidence intervals will be estimated, for each parameter, using the bootstrap technique and considering the sample values referring to costs, effects, incremental costs, and incremental cost ratio incremental effectiveness. |
| **Section 5: Economic data analysis** | | | |
| 5.1 | Analysis population | Outline the analysis population that will be used in the economic base-case analysis (such as intention to treat, per protocol) | The full analysis set will include all randomised participants, which is in accordance with the "intention to treat" (ITT) principle. |
| 5.2 | Timing of analyses | Describe the timing of all planned analyses (e.g. interim and final analyses) | The time horizon will be set as the trans-pandemic time, considering as limits the beginning of social distancing in Brazil and as an end, the date of return to normality of activities officially determined for it according to official government recommendations. Alternatively, we may also model data using another time horizon, in which we consider the achievement of an ideal vaccination rate in Brazil (or in specific regions). The primary analyses will be performed after one year of study and data collection and the other analyses when the study is finalized according to the time horizon described above. |
| 5.3 | Discount rates for costs and benefits | Detail the source of, and justification for, discount rates used for costs and benefits | - |
| 5.4 | Cost-effectiveness threshold(s) | Detail the cost-effectiveness threshold(s) to be used in analysis/interpretation | Figure 6. |

| | | | |
|---|---|---|---|
| 5.5 | Statistical decision rule(s) | Describe how inference will be drawn (e.g. significance level, confidence intervals or mean net benefit) | The cost-effectiveness strategy will be used for economic analyses. Incremental values will be calculated both for costs and effects. Therefore, the difference between the new strategy and the one you want to replace will be calculated. ($\Delta E=E_{with\_tele} - E_{without\_tele}$ and $\Delta C=C_{with\_tele} - C_{without\_tele.}$ The confidence intervals will be estimated, for each parameter, using the bootstrap technique and considering the sample values referring to costs, effects, incremental costs and incremental cost ratio incremental effectiveness. |
| 5.6 | Analysis of resource use | Describe how differences in the use of resources/services between randomised groups will be compared | Participants will be divided into groups considering socioeconomic factors, such as income, maternal education, agglomerate. Further, we will test if there are differences, for example, regarding the difficulties of access to technologies for care and guidance in primary care between these groups. We will collect pertinent data from the clinical studies and consider the mathematically simulated data for prospecting the reality to the national health system. |

| | | | |
|---|---|---|---|
| 5.7 | Analysis of costs | Describe analyses of the cost data, specifying any covariates for statistical adjustment, assumptions, and alternative methods | The economic evaluations will initially be evaluated considering a SUS-simulated scenario in which non-face-to-face care is implemented. The confidence limits of the parameters used (effects and costs) will be considered for performing deterministic sensitivity analyses.<br><br>We will adopt a Bayesian strategy to probabilistic sensitivity analyses to explore the uncertainties of health effects and costs (37–39). Next, we will also perform other sensitivity analyses, considering the values prospected for the national health system, considering its magnitude and peculiarities. If necessary, subgroup analyses may be adopted to address specific Brazilian regions. |
| 5.8 | Analysis of outcomes | For each outcome used in the economic analysis, describe how the outcome will be analysed, specifying any covariates for statistical adjustment, assumptions, and alternative methods | Page 62-66. |
| 5.9 | Data cleaning for analysis | Outline how data will be cleaned before analysis | - |
| 5.10 | Missing data | Specify the procedure for dealing with missing data | Analysis Intention to treat (ITT) |
| 5.11 | Analysis of cost-effectiveness | Describe the methods that will be used to summarise cost-effectiveness. | |
| 5.12 | Sampling uncertainty | Describe how uncertainty around the costs and effectiveness estimates and summary cost-effectiveness measures will be explored | The risks of uncertainty will be quantified using an instrument proposed for this purpose, and its actual impact can be evidenced for the health system managers, for example. That will also be a way to compare the different strategies in different environments (settings) to be incorporated within the national public health system. |
| 5.13 | Subgroup analyses or analysis of heterogeneity | Describe any analyses of subgroups or heterogeneity in cost-effectiveness and the analysis methods used | Subgroup analyses will be considered for different Brazilian regions with different profiles regarding the duration of the pandemic. |

| | | | |
|---|---|---|---|
| 5.14 | Sensitivity analyses | Describe any sensitivity analyses and their form | The economic evaluations will initially be evaluated considering a SUS-simulated scenario in which non-face-to-face care is implemented. The confidence limits of the parameters used (effects and costs) will be considered for performing deterministic sensitivity analyses.<br>We will adopt a Bayesian strategy to probabilistic sensitivity analyses to explore the uncertainties of health effects and costs. we will also perform other sensitivity analyses, considering the values prospected for the national health system, considering its magnitude and peculiarities.<br>Finally, we will also analyse the expected value of perfect information (EVPI) and budget impact analysis (BIA). |
| **Section 6: Modelling** | | | |
| 6.1 | Extrapolation or decision analytic modelling | Outline whether decision analytic modelling or any other extrapolation will be used to estimate cost-effectiveness results beyond the period of the trial or to introduce an additional comparator or other evidence. | We will simulate a situation adapted to the scenario of interest (the national public health system), the SUS. We will use simulations considering the characteristics of the basic health units that provide primary dental care for children. We also using a bootstrapping technique, we will simulate data equivalent to SUS reality |
| 6.2 | Model type | Describe the modelling approach that will be used and duration of extrapolation | We will create a specific model considering the distribution of variables in the sample for outcomes collected in trials but prospecting for a wider population eligible for primary care in SUS. We will use some index variables, e.g. caries experience, that we have collected in the trials and can also be found in official national data. |
| 6.3 | Model structure | Detail the model structure (where possible, include diagram of model states and transitions between them) | Figure 8. |

| | | | |
|---|---|---|---|
| 6.4 | Treatment effect beyond the end of the trial | Describe the duration and size of treatment effect in the period beyond the end of the trial | The time horizon will be set as the trans-pandemic time, considering as limits the beginning of social distancing in Brazil and as an end, the date of return to normality of activities officially determined for it according to official government recommendations. |
| 6.5 | Other key assumptions | List the key structural assumptions of the model | - |
| 6.6 | Methods for identifying and estimating parameters | For each model parameter, describe the methods and data sources that will be used to estimate the parameter (e.g. from the RCT, systematic review, meta-analysis, other published data or expert opinion) | Page 71. |
| 6.7 | Model uncertainty | Describe the methods that will be used to assess parameter uncertainty in the results. Describe sensitivity analyses for the impact of other types of uncertainty on results. | Page 63- 66. |

## **Supplemental File 3**. SERVQUAL questionnaire (English version)

SERVQUAL questionnaire applied in this protocol

SERVQUAL QUESTIONNAIRE APPLIED **BEFORE** CARE

*This questionnaire will be applied in Portuguese

Patient name:

Name of the person responsible:

Degree of kinship: ( ) mother ( ) father ( ) grandparents ( ) cousin ( ) brother ( ) other

- What grade would you give for the care your child receives?

Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What grade would you give to the facility, staff and materials offered for your child´s oral treatment?Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What grade would you give for the waiting time between one appointment and the other?Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What grade would you give for the duration of each query?

Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What grade would you give for the behavior of dentists in the care?

Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What note would you give to the team´s willingness in response and take your questions?Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

What grade would you give to the knowledge offered by the team and to answer your questions?

Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What note would you give for the personalized attention offered to your child?Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What grade would you give for service hours?

Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- What grade would you give to supply your child´s needs?

Being 1 the worst grade and 7 the best grade: ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

SERVQUAL QUESTIONNAIRE APPLIED **AFTER** ATTENDANCE

Patient name:

Name of the person responsible:

Degree of kinship: ( ) mother ( ) father ( ) grandparents ( ) cousin ( ) brother ( ) other

- From 1 to 7, what note would you give for the waiting time between one query and the other?( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, would you give that note for the personalized attention your child receives?( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, on the supply of your child´s needs, what grade would you give?( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, in relation to the duration of each query, what grade would you give?( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, in relation to the behavior of dentists in the visits, what grade would you give?( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, regarding the installation, the staff and materials offered for your child´s oral treatment,what grade would you give?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, in relation to the team´s willingness to answer your questions, what grade would yougive?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, in relation to the hours of attendance, what grade would you give?( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

- From 1 to 7, in relation to the knowledge offered by the team to answer your questions, what gradewould you give?

( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7

# 4. CHAPTER II:

## Is non-face-to-face primary dental care mediated by technologies feasible to be implemented for children? – a before and after study assessing demand resolution and costs

## 4.1 ABSTRACT

During the COVID-19 pandemic, healthcare using technology has been extremely advocated throughout the world. Although several advantages of such strategies are known, some deals in implementation may be faced, especially in developing countries. This is a pioneering demand study assessing the impact of implementing non-face-to-face consultation for primary care in children, measuring the problem-solving rates and also valuing the cost of such implementation. A before-and-after study was designed to answer such questions. A dental unit in greater São Paulo, Brazil, was used to represent the national public health system. The teleservice was performed through the Video For Health – V4H platform by dentists (reseachers) using a standardized protocol both to recognize and address those demands identified among participants. Problem-solving assessment was done two weeks after receiving the intervention. For that, a structured interview was performed with participants' caregivers (after) and compared to those data obtained previous to intervention (before) in a baseline telephone contact and during the teleconsultation. Intention to treat analyses were performed. The resolution rates were calculated and its association with independent variables tested in multiple regression models. We performed a descriptive analysis of usability and difficulties reported related to the implementation of such intervention. We also estimate costs related to this implementation using a societal perspective and a short time horizon (2 weeks). 328 patients received the teleservice and the most solved was the welcoming (proximally 90% solved). Even demands require face-to-face resolution could be mostly solved (60%). 77% of patients who needed welcoming had their demands resolved, followed by 48% of patients who needed individualized guidance, 32% of patients who had complaints that were able to be resolved by ICT and 33%

of patients who had complaints that needed face-to-face care to be resolved. Most patients had no difficulty in using the platform and felt benefited from it (73.4%). We could observe that many needs reported by patients can be solved through ICT, as many are not dental emergencies that require face-to-face care. Thus, ICT can help solve the pent-up demand caused by the outage of care due to the COVID-19 pandemic. Although many patients are not yet so open to testing new health technologies, those who propose to use them are satisfied with the care. One limitation of this study is that it shows the point of view of a specific population, so more studies should be conducted in other regions and populations to better evaluated the results. As for the costs involved in the use of this technology, the highest cost is the development of the digital platform and the total cost of the service was 200 reais. We could observe that many needs reported by patients can be solved through ICT, as many are not dental emergencies that require face-to-face care. Thus, the non-face-to-face consultation used in primary dental care for children is feasible to solve most pent-up demand caused by the paralyzing of child dental care caused by the COVID-19 pandemic at an acceptable cost.

## 4.2 BACKGROUND

The unified health system (SUS) is one of the best public health systems in the world, benefiting the Brazilian population with procedures that involve everything from prevention to more complex procedures. With the establishment of the COVID-19 pandemic in March 2020, health systems had to reinvent themselves and find innovative ways to provide health care for the population.

Studies have already proven the strong and negative impact on the provision of primary health care treatments and services, including dentistry (1,2). Dental care had a significant decrease in private and public clinics, with the largest drop in preventive procedures (reduction ≤ 99%), between April and August 2020 (1). Ustun et al. evaluated the impact of the pandemic on dental care in children and observed a 81.6% drop in total non-emergency dental visits in pediatric clinics (2). This sudden stoppage of the supply of services, created a pent-up demand of patients who were

without dental care, even if inserted in some health program. This fact can result in an overloaded post pandemic system and an increase in the waiting list for some type of dental treatment.

In this sense, although the World Health Organization already recommend telehealth as a strategy to improve the quality of services, especially in universal systems, such as the SUS, Information and Communication Technologies has been gaining prominence. After all, they open doors for the provision of health services such as telemonitoring, teleorientation, telescreening and teleconsulting, facilitating access to health care beyond physical distance (3,4).

In Brazil, the Federal Council of Dentistry regulated the exercise of remote dentistry the permission to perform teleorientation and telemonitoring during the pandemic (Resolution 226, year 2020). But despite the legalization and the growing progress that ICT has been gaining, there is still a shortage of studies involving this type of technology especially in underdeveloped countries (5).

For public health, it is important that the implementation of new interventions (any program, service, policy or product) is based on critical and robust evidence that is related to health behavior, is relevant to the target population and has the potential to achieve its objective in that population (6). Thus, it is necessary to understand who the population is, what their needs, demands, complaints and how open to a new intervention they are. So, if, on the one hand, the use of ICT can be great ally in the resolution of pent-up demand and increase access to health, especially in a pandemic moment, it is important to understand whether it will be adequate, satisfactory and problem-solving to patients and professionals in the area.

Another important point for planning new interventions is the allocation of resources: whether the proposed strategy represents and efficient allocation of resources in place of what is usually done. Thus, economic evaluation is an important ally in political and economic decision-making. In teledentistry, there is still a lack of evidence about the real economic benefits it can offer (7).

Thus, the aim of this pioneering before-and-after study is to assess the impact of implementing non-face-to-face consultation for primary care in children, measuring the problem-solving rates and also valuing the cost of such implementation.

## 4.3 MATERIAL AND METHODS

This chapter was written in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guideline (Attachment A) and Consolidated Health Economic Evaluation Reporting Standards (CHEERS) (Attachment B).

### 4.3.1 Ethical aspects

This study was recorded in Clinicaltrials.gov (record NCT04798599) and previously approved by the Research Ethics Committee of FOUSP, São Paulo, Brazil (registration 39012720.5.0000.0075) in November 2020 (Attachment C)

The patients included in this study met the eligibility criteria and were only included after their parents and legal guardians signed the free and informed consent form (Attachment D) and the child consented to their participation in the study (Attachment E).

Medical records and dental questionnaires were applied virtually to the patients. The data were stored in cloud files under confidentiality and access only by the responsible researchers (MMB and KHN). After the end of data collection, the files were transferred to a USB stick (erased from the clouds) and stored in the file room of the Department of Pediatric Dentistry of FOUSP.

### 4.3.2 Participants – Eligibility Criteria

All children aged 3 to 13-years-old registered in the dental school unit of FOUSP, and who have already undergone follow-up for 6 to 60 months in the unit, were contacted and invited to participate in this study. The caregivers of the children who accepted the invitation filled out, online, via Google Forms, the Informed Consent Form (ICF) and the literate children filled out the Consent Form. If they did

not agree to participate in the research, but wanted to perform the service, they received the intervention in the same way, but the data were not collected and computed for research purposes.

### 4.3.3 Scenario

A mobile dental unit of FOUSP installed in the Carlos Osmarinho de Lima Educational Complex, located in the municipality of Barueri, since 2014, acquired from FAPESP research assistance (Process 2012/50716-0) was chosen as a cell unit to collect outcomes related to the impact of implementing the use of technologies for telescreening, telemonitoring, and teleorientation for children undergoing dental care in primary care and whose consultation were interrupted due to the COVID-19 pandemic.

In the pre-pandemic period, the visits occurred five times a week (Monday to Friday), eight hours per day, totaling 40 hours per week and, on average, 40 children were seen weekly. Each day a graduate student was responsible for the attendances and had the support of two undergraduate students. The appointment was based on the patient´s need described in the treatment plan prepared by an external examiner, which was based on the evaluation performed in the follow-up consultation (which took place every 3, 6 or 12 months). In cases of urgency, the caregiver who contacted a team member was instructed to take the child immediately to undergo an evaluation in the unit. There were on average eight emergency visits performed in the month, with pain and prolonged tooth retention being the main reasons. Due to the current scenario, face-to-face care had to be suspended indefinitely, leading our team to seek new alternatives for welcoming these patients.

The dental care unit was chosen because it is a reference for primary care in childhood, in the and because it has a complete repository of data on the population assisted, such as health, socioeconomic, contextual, and dental treatment conditions previously performed. Furthermore, it allows a full control of the interventions implemented, providing, first, a faithful measure of what the intervention itself could provide.

### 4.3.4 Intervention

Five graduate students who were responsible for face-to-face care at the unit were trained to use teledentistry resources by expert researchers in the area, so that intervention could be performed in a standardized manner. The teleservice was performed through a digital platform (Video for Health – V4H) and was guided by a standardized protocol (Figure 4 – Chapter I) and divided in three parts described in Chapter I. In figure 5 of the previous Chapter, it is standard strategies should be used depending on which patient´s report.

The impact of the pandemic on the community served by the mobile unit was the control situation (called “before”). For this, the researchers established telephone contact with all registered patients and collected information about pain during the trans pandemic period, search for dental care in other public or private units and other possible complaints that occurred during this period. This information gave us an overview of what impact the unit´s outage had due to the isolation caused by the COVID-19 pandemic.

### 4.3.5 Outcomes – effect

As a primary outcome, we consider the problem-solving capacity, assigning the number of demands (or “complaints”) resolved. For different types of demand, different solutions were considered (Table 1). Measurements were performed as detailed in Figure 5 (Chapter 1), two weeks after the intervention being implemented. For that, a second consultation was scheduled, and a structured interview was used to guide data collection about demand solving (Attachment F). Researchers not involved in the first care (TGOM and FB) were in charge of these assessments.

Basically, for exclusive welcoming, we considered the satisfaction in receiving health care using the non-face-to-face appointment was considered as solved demand. For orientation, we considered aspects relevant to the practice and which had been explained, orientated in the intervention session. For checking for resolution of specific complaints, we directed some questions to understand patients’

complaints. In case of they had been scheduled or addressed to be treated in other units, a specific question about that was made. To measure the resolution of the emergency, we made a new call with the patients and their guardians, using the same platform described above. Cases in which the resolution of the identified problem had not been resolved and/or the existence of a recurring complaint or new complaint were also recorded. The Table 1 details the assessment of problem solving regarding different type of demands.

Table 1. Problem solving depending on the type of demand.

| Demand | Expected solution | Measurement | Assessor | Time-frame |
|---|---|---|---|---|
| Welcoming | Child' satisfaction to be cared in non-face-to-face program | Structured question during the follow-up visiting directed to child under care "Did you like to participate in the non-face-to-face consultation?" | Self-reported | 2 weeks after intervention |
| Oral hygiene orientation | Children performance in toothbrushing | Checklist to be filled during the assessment containg aspects orientated and important in oral hygiene– child was supposed | External examiner | 2 weeks after intervention |

| | | | | |
|---|---|---|---|---|
| | | to comply with all them. | | |
| Complaints possible to be solved virtually | Parents' answer about recent complaints or need and comparison to the previous one | Structured questions during the follow-up visiting directed to child under care | Self-reported | 2 weeks after intervention and in intermediate phone calls or text messages, if it was the case |
| Complaints only possible to be solved in person | Parents' answer about recent complaints or need and comparison to the previous one | Structured questions during the follow-up visiting directed to child under care | Self-reported | 2 weeks after intervention and in intermediate phone calls or text messages, if it was the case |

Besides looking for the solution to possible participants' needs, the structured form also contained a checklist to identify possible barriers and facilitators related to each type of complaint. Complications that occurred were considered as a secondary outcome (technological or not – for example: forgetfulness of the consultation, non-compliance with the schedule, difficulty in using the platform, difficulty in accessing the Internet, technical difficulty in using the computer or mobile phone – noted by the professional responsible for the service immediately after the end of access). All these outcomes were also assessed two weeks after the intervention implemented.

### 4.3.6. Independent Variables

As independent variables, we collected some data from the research participants as time in the virtual platform, waiting time until the patient enters the teleservice, the number of absences in face-to-face and virtual care, and time when the patient is under follow-up in the dental unit. Some data related to the patient´s oral health was also collected, such as the need for previous care, toothache, dental caries experience, oral hygiene habits and dietary habits.

Gender, ethnicity, formal education of mother, who accompanied the patient on the call, household income, difficulties with the platform, medical history, primary complaint, and changes in behaviour during the pandemic were also collected during teleservices.

### 4.3.7 Analysis – effects

Data analyses were performed using the statistical software in Stata® 13.1 statistical software. The statistical unit considered was the child.

The analyses were carried out using an intention-to-treat approach in the resolution of demands and protocol analyses to describe the sample and its needs. We calculated the rate of general resolution achieved with non-face-to-face visits, considering the sum of the different demands identified. Overall resolution rates and their individual components per demand were calculated. Regression models were used to verify the association of case resolution with the independent variables mentioned above.

We also performed a descriptive analysis identifying the usability rate (ease of use of the digital platform by caregiver users) and difficulties reported when using these technologies, dividing them into difficulties related to technology and not related to technology.

### 4.3.8 Outcomes – cost

We performed a partial economic evaluation to show a preliminary economic impact of implementing this intervention in clinical practice. Details about this evaluation will be given below.

-*Perspective and Time Horizon*: We considered a societal perspective and a 2-week time horizon for this preliminary assessment.

-*Type of Evaluation\Effects*: A cost analysis was performed to value the resources related to the intervention implementation.

-Costs: The unit of analysis was the child who received the intervention for primary dental care was directed. The micro-costing strategy was used. We assumed the valuation of direct and indirect costs. Direct costs are related to the installation and provision of services, while indirect costs are related to the patient´s out of pockets costs for using dental services.

To valuation time-dependent resources, we considered the time of consultation and the time the professional waited for the family to be cared for. Costs with the development and maintenance of the system used were collected with the system administrators. Other costs related to the use of the internet and computers/smartphones were estimated based on an assumption of modalities more used in Brazil. The value of child's and caregivers' time was also based on an assumption to Brazilian scenario. Figure 1 details each valued component and is considered in the economic evaluation. All costs will be value in Reais.

When the child did not comply with the consultation, an assumption of professional waiting time was computed and valued anyway. This assumption was set as 10 min and based on the average waiting time for patients who complied with the consultations.

Figure 1 – Cost components to be valued and considered in economic evaluation.

| Nature of cost | | Cost items | Estimation of resource quantities | Time-frame for resource measurement | Valuation method | Data Analysis |
|---|---|---|---|---|---|---|
| Direct costs | Cost of intervention | **Accommodation** | Time (min) of usage measured per online consultation | One year of online follow-up at Video For Health Platform | Building: Cost per m² of the area used by a dental unit*, rental cost + municipalities taxes of São Paulo, Brazil (https://www.prefeitura.sp.gov.br/cidade/secretarias/fazenda/servicos/iptu/index.php?p=2456)<br>Electricity costs: 2.3 kw/h, monthly use of 160 hours (8 hours per day and 20 days per month). (https://www.eneldistribuicaosp.com.br/para-sua-casa/tarifa-de-energia-eletrica)<br>* Area assumed: 13.5 m² (based on a mobile dental unit area). | The COST PER ONLINE CONSULTATION will be calculated. Then, costs related to all included children will be summed up and the COST PER TREATED ONLINE consultation will be obtained. |
| | | **Computer Equipment, platform development and internet resources** | Time (min) of usage measured per online consultation | | Monthly use of 160 hours/ Life span of software conditions (2 years) and computer equipment (4 years).<br>To platform development was considered a total coast, provided by the development team of: US$ 137.000,00 https://www.bcb.gov.br/conversao<br>Internet resources considering a basic internet package taken of three different commercial internet sites<br>https://www.claro.com.br/internet/banda-larga<br>https://internet.vivo.com.br/vivo-fibra/banda-larga/oferta<br>https://timlive.tim.com.br/ | |
| | | **Staff (dentists and auxiliaries)** | Time (min) of active work measured per online consultation | | Monthly wage, determined by the Brazilian Federal Law (3999/61), considering 20 working hours/week.<br>https://www.planalto.gov.br/ccivil_03/leis/1950-1969/l3999.htm | |
| | | **Dental Materials** | Was just used materials for oral health orientation | | Mean cost of each item in three different Brazilian dental stores assumed as reference.<br>http://www.dentalcremer.com.br<br>https://www.suryadental.com.br/<br>https://www.dentalgutierre.com.br/ | |
| Indirect costs | Commute costs | **Computer Equipment, platform development and internet resources** | Time (min) of usage measured per online consultation | One year of online follow-up at Video For Health Platform | Monthly use of 160 hours/ Life span of software conditions (2 years) and computer equipment (4 years).<br>Internet resources considering a basic internet package taken of three different commercial internet sites<br>https://www.claro.com.br/internet/banda-larga<br>https://internet.vivo.com.br/vivo-fibra/banda-larga/oferta<br>https://timlive.tim.com.br/ | |
| | | **Patient's time (waiting + treatment time)** | Time (min) spent per child**<br>**Waiting time: 10 minutes (assumed)<br>Treatment: sum of time spent in appoitments | | Minimum wage rate for São Paulo, Brazil, according to the state Law 19.953 (https://www.al.sp.gov.br/repositorio/legislacao/lei/2019/lei-16953-18.03.2019.html)<br>Assumptions: the mean number of working days in the same period, 8 working hours per day | COST PER ONLINE CONSULTATION will be calculated and will be fully considered for each online follow up. |
| | | Accompanying person's **time** | Time (h) spent per child**<br>** Waiting time: 10 minutes (assumed)<br>Treatment: sum of time spent in appoitments | | Average monthly income for Brazilian population will be estimated using the mean Brazilian income from 2018-2022 (https://www.ibge.gov.br/).<br>Assumptions: the mean number of working days in the same period, 8 working hours per day. | |
| | Missed consultations | **Number of missed consultations** | 10 minutes (assumed) per missed consultation | | Monthly use of 160 hours/ Life span of software conditions (2 years) and computer equipment (4 years).<br>To platform development was considered a total coast, provided by the development team of: US$ 137.000,00<br>https://www.bcb.gov.br/conversao | |

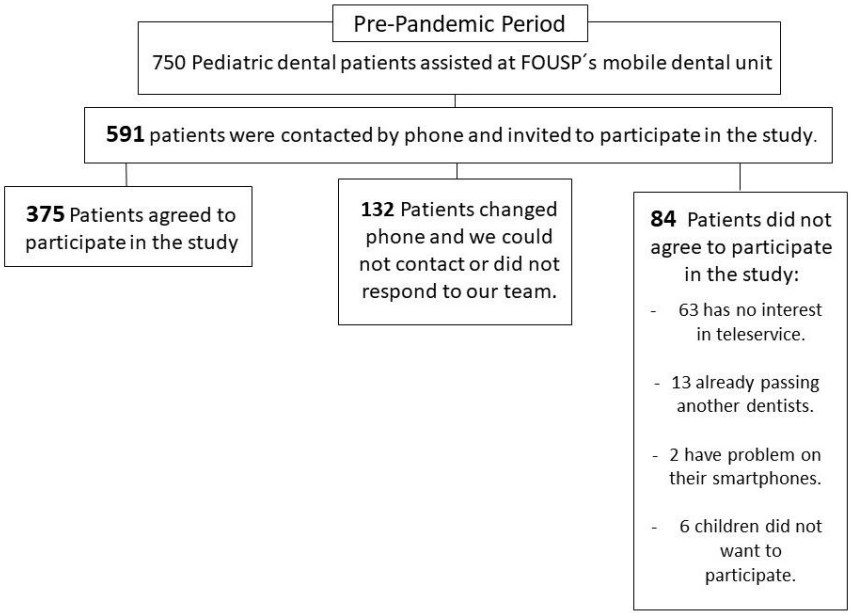
The proposed intervention calculated the mean cost, and its 95% confidence interval was corrected by bootstrapping. Partial means for each component cost was also calculated to permit investigating the proportional use of resources derived from the intervention.

## 4.4 RESULTS

### 4.4.1 Participant Flow

From the period between May 2020 and October 2021, our team contacted Whatsapp, calls and/or social networks with all patients registered in the mobile dental unit of FOUSP (Figure 2). 159 patients had changed their phone or social network, so we were unable to contact them. Thus, 591 patients were invited to participate in our study and perform teleservices. However, 132 patients no longer responded to our contact attempts and 84 did not agree to participate in our study. Among the reasons for not participating in the research were: 75% had no interest in teleservice, 15.4% were under not willing to perform the teleservice, 7.1% of the children did not agree to participate and 2.3% were having problems in their smartphone and did not want to try to overcome this barrier to perform the teleservice. Thus, we totaled our sample with 375 patients who agreed to participate in our research and performed teleservice.

Figure 2 – Flowchart showing the scenario of inclusion of patients in the care unit was chosen because it is a reference for primary care un childhood, in the municipality of Barueri.




Source: By the author

Table 2 – Baseline characteristics of research participants

| Variables | N | n(%) | 95% CI |
|---|---|---|---|
| **Linked to the family** | | | |
| ***Sex*** | | | |
| Female | 375 | 203 (57) | [0.50 to 0.64] |
| Male | | 172 (42) | [0.35 to 0.49] |
| ***Ethnicity*** | | | |
| White | 369 | 212 (59.4) | [0.52 to 0.66] |
| Black | | 151 (38.6) | [0.31 to 0.45] |
| Oriental | | 6 (0.19) | [0.07 to 0.5] |
| ***Responsible person who accompanied in the teleservice*** | | | |
| Mother | 328 | 268 (79.2) | [0.72 to 0.84] |
| Father | | 36 (12.0) | [0.08 to 0.17] |
| Others | | 24 (8.69) | [0.05 to 0.13] |
| ***Mother´s schooling*** | 355 | | |
| Illiterate | | 2 (0) | |
| Incomplete fundamental | | 43 (9.66) | [0.06 to 0.14] |
| Complete fundamental | | 17 (4.34) | [0.02 to 0.08] |
| Incomplete high school | | 23 (6.28) | [0.03 to 0.10] |
| Complete high school | | 186 (54.5) | [0.47 to 0.61] |
| Incomplete higher | | 46 (13.0) | [0.09 to 0.18] |
| Graduated | | 38 (12.0) | [0.08 to 0.17] |
| ***Distribution of visits by dentist*** | 328 | 82 (25.6) | [0.19 to 0.32] |
| Dentist 1 (KN) | | 90 (25.1) | [0.18 to 0.32] |
| Dentist 2 (MEFV) | | 80 (25.6) | [0.19 to 0.33] |
| Dentist 3 (GMM) | | 76 (23.6) | [0.17 to 0.30] |
| Dentist 4 (JDYV) | | | |
| ***Taking any medicine*** | 328 | | |
| Yes | | 35 (11) | [0.07 to 0.16] |
| No | | 293 (88) | [0.83 to 0.92] |

| | | | |
|---|---|---|---|
| ***Fistula appear*** | | | |
| Yes | 328 | 30 (8.6) | [0.5 to 0.13] |
| No | | 298 (91.3) | [0.86 to 0.94] |
| ***Restoration fall*** | | | |
| Yes | 328 | 44 (15.4) | [0.11 to 0.21] |
| No | | 284 (84.5) | [0.78 to 0.88] |
| ***Visited the dentist in social isolation*** | | | |
| *Yes* | 328 | 77 (24.1) | [0.18 to 0.30] |
| *No* | | 251 (75.8) | [0.69 to 0.81] |
| ***Toothache*** | | | |
| Yes | 328 | 98 (32.8) | [0.27 to 0.39] |
| No | | 230 (67.1) | [0.60 to 0.72] |
| ***Change in diet because of pandemic*** | | | |
| No | 327 | 129 (35.2) | [0.28 to 0.42] |
| Eating in greater quantity | | 79 (27.5) | [0.21 to 0.34] |
| Eating in smaller amounts | | 13 (2.89) | [0.01 to 0.06] |
| Eating more ultra-processed | | 49 (13) | [0.09 to 0.18] |
| Eating healthier | | 56 (21.2) | [0.15 to 0.27] |
| ***Change of hygiene habit*** | | | |
| Yes | 319 | 153 (45.8) | [0.38 to 0.53] |
| No | | 166 (54.1) | [0.46 to 0.61] |

N: Absolute number of patients included in the study included in the study

n(%): Number and percentage of patient in relation to the variable

95% IC: 95% confidence interval

Source: By the author

### 4.4.2 Needs of patients in teleservice

192 patients reported having no complaints at the time (58.54%), 30 patients reported having pain or some type of urgency (9.15%), 25 patients reported having

some type of necessary dental treatment (7.62%) and 80 patients reported having complaints but were likely to wait (24.39%).

In relation to the needs detected in the teleservice, 22% of the patients only needed assistance, but had no specific complaints (95% CI: 0.17 to 0.27), 44% needed guidance but without specific complaints (95% CI: 0.39 to 0.5), 17% needed to resolve specific complaints that could be made non-in-person (95% CI: 0.14 to 0.22) and 15% of patients needed to resolve specific complaints that could not be made not-in-person (95% CI: 0.11 to 0.19).

Among patients who reported not having any type of complaint, it was detected in 28.27% (n=54) the need for welcoming, in 60.73% (n=116) the need orientation, in 7.85% (n=15) complaints that could be resolved in a non-face-to-face manner and in 3.14% (n=6) complaints that cannot be performed by teleservice, requiring face-to-face care. Most of the children who reported pain were identified as a demand not solvable virtually (7.85%, n=22).

Table 3 shows the relationship between those needs identified by the dentists during the non-face-to-face appointment and the decision-making adopted as an attempt to solve or minimize the problem identified.

Table 3 – Conducts performed to solve the demands observed by the telemonitoring of patients.

| | **NEEDS** | | | |
|---|---|---|---|---|
| | **%** **95%CI** | | | |
| *CONDUCT* | **WELCOMING** | **ORIENTATIONS** | **NON-FACE-TO-FACE ACTIONS** | **FACE-TO-FACE ACTIONS** |
| *WELCOMING* | 95.8 (0.80 -0.95) | 94.4 (0.89 – 0.97) | * | 81.6 (0.65 – 0.91) |
| *CONVERSATION* | 95.8 (0.80 – 0.95) | 99.3 (0.95 – 0.99) | * | 91.8 (0.79 – 0.97) |

| | | | | |
|---|---|---|---|---|
| *OPENING ANOTHER COMMUNICATION CHANNEL* | 75 (0.62 – 0.84) | 86.2 (0.79 – 0.90) | * | 89.7 (0.77 – 0.95) |
| *INDIVIDUALIZED ORIENTATION* | * | 97.4 (0.92 – 0.98) | * | 97.9 (0.86 – 0.99) |
| *RESOLUTION INSTRUCTIONS* | * | * | 87.7 (0.76 – 0.94) | * |
| *PRESCRIPTION OF MEDICINES* | * | * | 24.5 ( 0.14 – 0.38) | * |
| *REFERRAL* | * | * | * | 59.1 (0.44 – 0.72) |
| *Average number of interventions required* | 2.6 | 3.7 | 5.1 | 4.2 |

n (%) = Percentage of conducts performed in relation to the needs observed in the patient

95% CI = 95% confidence interval

Source: By the author

### 4.4.3 Resolution of demands

Regarding the resolution of the patients´ demands, of the 375 patients treated, 335 patients had one demand to be solved. 200 of theses demands have been resolved. 20 patients presented 2 demands to be solved and 5 patients had both demands resolved and 10 patients had a demand solved. And 20 patients did not present specific complaints. Approximately 50-60% of resolution was achieved considering both the partial (at least one demand solved) or total (all demands solved) resolution. Table 4 shows the number of resolution per demand type.

Table 4 – Demand-type resolution

| *BY DEMAND TYPE* | **RESOLUTIVITY** | **ADJUSTED RESOLUTION (those who have not been served*)** | **REASON EFFECT (with no need vs with need)** |
|---|---|---|---|
| *WELCOMING* | 0.93 | 0.56 | 1.24 |
| *ORIENTATION* | 0.64 | 0.48 | 1.1 |
| *NON-FACE-TO-FACE ACTIONS* | 0.86 | 0.48 | ** |
| *FACE-TO-FACE ACTIONS* | 0.63 | 0.33 | 19.31 |

**For this calculation, it considered the unmet as a demand*

*** Effect on the group without need =0*

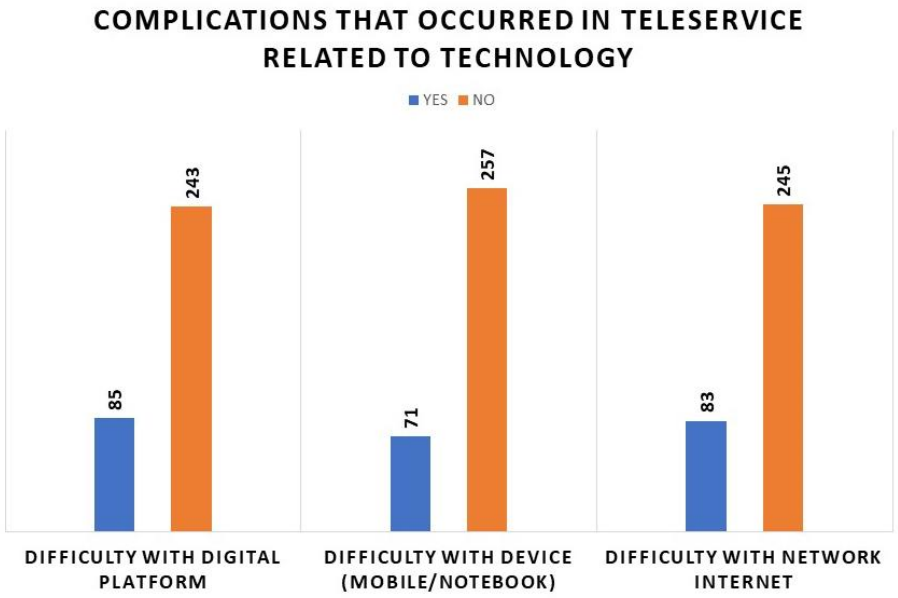
There was a significant relationship between the mother´s schooling and the resolution of the demands (OR=2.64; 95%CI: 1.67 to 4.18). Mothers who had more than 8 years of formal education had a higher resolution of their demands than mothers who had less than 8 years of formal education. Indeed, almost all mothers with more than 8 years of study presented at least one demand and 70% of these mothers have their demands solved after the teleconsultation, while mothers who had less time of study presented lower frequency of demands (77%) but also a lower resolution rate (48%). In a subgroup analyses per type of demand, the same was observed for all types of demand, except for demand for guidance in oral health-related habits.

### 4.4.4 Complications in teleservice

The complications that occurred during the teleservice were divided into technological and non-technological complications. Among those classified as technological are difficulties with the V4H platform, difficulties with sound or camera during teleservice (device) and difficulties with the internet network. The complications classified as technological are non-compliance with the scheduled time for teleservice (delay) and no-show service.

Regarding the difficulties related to technology, 42% (95%CI: 34.8 to 49.5, n= 131) of the patients' caregivers reported that they had some type of difficulty related to technology in the teleservice. Only 30% had some difficulty with the digital platform, 20% reported a problem with the device (mobile phone/notebook) and 25% with the internet network. Graph 1 represents the number of patients (absolute number) who claimed to have technology-related intercurrence.

Graph 1 – Complications that occurred in teleservice related to technology.



The waiting time until the patient entered the teleservice was on average 6.4 minutes (95% CI: 5.2 to 7.5). And the duration dos teleantedimentos fora em média de 45.3 minutes (95% CI: 43.4 to 47.3).

### 4.4.5 User perception

Table 5 shows the answers obtained about the perception of caregivers regarding the use of V4H platform technology to perform teleservice. Most users were satisfied to using the plataform as manner of providing non-face-to-face dental care and believe they were benefited for that. More than 80% reported the strategy saved time and avoided the need for transportation to the dental.unit (Table 5).

Table 5 – Questions related to perception of caregivers in the 2 weeks after the teleservice.

| Questions related to perception | N | n(%) | 95% CI |
|---|---|---|---|
| **Linked to the family** | | | |
| ***Did you enjoy being served online?*** | | | |
| Yes | | 244 (82.6) | [0.76 to 0.87] |
| No | 300 | 20 (5.31) | [0.02 to 0.09] |
| More or less | | 36 (12) | [0.08 to 0.17] |
| ***Do you think it was easy to use the V4H Platform?*** | | | |
| Yes | 277 | 266 (95.1) | [0.90 to 0.97] |
| No | | 11 (4.83) | [0.02 to 0.09] |
| ***Has the teleservice saved your time in any way?*** | 283 | 256 (90.4) | [0.86 to 0.93] |
| Yes | | 25 (8.83) | [0.05 to 0.13] |
| | | 2 (0.7) | [0.001 to 0.02] |

| | | | |
|---|---|---|---|
| No | | | |
| Perhaps | | | |
| | | | |
| ***If so, how?*** | | | |
| Did not crowd\ exposed to COVID19 virus | 241 | 13 (5.31) | [0.02 to 0.09] |
| Need for transportation | | 212 (87.9) | [0.82 to 0.91] |
| Faster\practice query | | 13 (5.79) | [0.03 to 0.10] |
| Don´t you know | | 3 (0.96) | [0.01 to 0.06] |

### 4.4.6 Economic Analysis

On average, the societal cost for providing a non-face-to-face consultation focused on primary dental care for children was less than R$ 200 per child to be seen (Table 6). This cost is mainly comprised of direct costs, especially considering the amortization of the development costs that such type of technological intervention carried on. Non considering the resources spent for developing a new platform that may be the reality once implemented the service, the mean cost per child would descrease to R$110 (95% CI: R$104 to R$117).

Table 6 – Direct and indirect costs related to teleservice

| **Direct Costs** | **Mean** | **95% CI** |
|---|---|---|
| Service | 35.2 | [33.2 to 37.2] |
| Waiting time | 5.84 | [4.79 to 6.90] |
| V4H Development | 88.66 | [83.30 to 94.02] |
| Variables | 0.97 | [0.91 to 1.03] |
| Structure | 0.22 | [0.20 to 0.23] |
| Accommodation | 2.25 | [2.11 to 2.38] |
| Material | 0.0090 | [0.009 to 0.10] |
| Maintenance | 31.7 | [29.84 to 33.68] |
| TOTAL | 164.99 | [155.04 to 174.94] |
| Overall total with fouls | 199.00 | [187.32 to 210.68] |
| **Indirect Costs** | **Mean** | **95% CI** |
| Patient time | 4.30 | [4.04 to 4.56] |
| Responsible time | 9.65 | [9.07 to 10.23] |
| Depreciation | 0.15 | [0.14 to 0.16] |
| Internet | 0.97 | [0.91 to 1.03] |
| Lack | 18.92 | [15.96 to 21.88] |
| TOTAL | 15.08 | [14.17 to 15.99] |

The costs of patients not seen by teleservice (who did not agree to participate in the study or who gave up during the process) were also computed and impacted on cost of the intervention for the society. The mean costs excluding these cases reaches R$180 (95%CI: R$169 to R$191). The same is valid for the patients' no-show. On average, the no-show is valued as R$15.30 (95%CI: R$ 19.44 to 22.70). If we consider the total number of absences that we obtained during the study, the cost

of all of them for the patients treated was on average 225.32 (95% CI: 214.87 to 235. 78).

## 4.5 DISCUSSION

By June 2020, the pandemic had already caused more than 7 million cases worldwide, according WHO (8). Because the virus causing the syndrome (SARS-CoV-2) can be transmitted orally, contact and inhalation of droplets of microorganisms via aerosols (9), dental professionals found themselves in a situation of high risk of contagion. Thus, there was a significant reduction in the supply of dental treatments from one hour to another, increasing waiting lists to health systems, further polarising huge inequalities already present in oral health, and overloading the SUS in the future. Thus, strategies that minimize this pent-up demand are necessary currently.

Given this scenario, ICT have gained an important role because they have a proposal to expand access and strengthen the health care network, allowing the realization of strategies such as telescreening, telemonitoring and teleorientation, which can help in solving the repressed demand for primary dental care. For public health, more than verifying the effectiveness of interventions, it is to identify the feasibility of proposals in a non-ideal world. To what extent can the new idea be successfully delivered to participants from a defined but not fully controlled context? How much demand will there really be to use this intervention? (6) The purpose of this study was to apply ICT in a primary care for children in a preestablished dental unit children and understand how these interventions would work for this target population at a pandemic time.

For this we were able to perform the teleservice with 328 patients who are seen in the mobile dental unit FOUSP. Of these, only 23% patients had sought face-to-face dental care during social isolation. In total, only 15% of the patients had specific complaints that could not be performed virtually, demanding face-to-face care. Often a condition that can be seen as urgent by the patient can be controlled only with individualized evidence-based guidance. Of the patients who reported pain

in our study, only 11% had an emergency condition in which it was necessary to seek face-to-face dental care at that time. Previous studies report data that the most common reason for visits to the dental emergency room was not a matter of urgency (10,11). In this sense, ICT can help in the screening of cases in which they actually require face-to-face care, reduce the occupation of emergency visits and minimize the risk of exposure by COVID or other diseases in the future (12). And even with the fact that in some cases it was necessary to referral to other services, about 60% of these demands were resolved.

Preventive dental services also help in this sense, performing the control and monitoring of conditions that could progress to more serious situations, demanding a more complex care, without time and money from families and the health system. In our study, the most of patients reported no specific complaints, but some needed to be received. Some situations (or even behaviours) are not always detected by patients, emphasizing the importance of preventive care, based essentially in orientation to health-related contents which is not always sought by patients who end up focusing on a more emergency and curative care. As for example, welcoming in a humanized care everyone receives welcoming, either in the form of empathy or listening, but perhaps professionals do not operate this type of effect and do not see it as a demand, this explains the fact that the professionals involved in this study have not recorded this type of demand to all patients, because somehow everyone needs and wants to be welcomed in a service.

Patients who claimed to need individualized guidance performed better in the reorientation consultation (10% more), and patients who claimed to have needs that could be resolved by teledentistry had 19% more of their demands resolve than patients who claimed to have no need that could be resolved from a distance. This makes us think that patients who come more open to a new type of care may also have better results in their use. A resistance in learning and the use of new technologies in health can happen and it is necessary to encourage, support and strategies that can mitigate this barrier.

Another aspect that should be addressed is related education. Mothers with a higher level of education presented more demands to be resolved than mothers with lower level of education, but also greater resolution in their demands. Previous studies have shown that a lower level of education and literacy of caregivers can negatively affect the oral health of infants and children (13,14). Perhaps mothers with

a higher level of education have a greater awareness and concern about the oral health of their children, therefore end up bringing more demands to be solved, but also have greater ease in solving them. In this sense, ICT can be advantageous, because caregivers often cannot accompany their children in face-to-face consultations, by work demands and\or other commitments. ICT can facilitate the presence of caregivers in teleservice since the time of detachment until the care is not necessary and they can participate in the care even if they are not in the same place as the children. Thus, caregivers can also receive guidance on how to conduct the oral health of their children, the family and their own.

Regarding the Internet, which is cited as a barrier to the implementation of telehealth (15), only 26% reported some kind of problem with this during teleservice. None of these difficulties was an impediment to not performing the teleservice, but our study was conducted in an urban area, where access to broadband is facilitated. Public policies should be planned so that internet access is guaranteed even in more remote areas, so that this is not a barrier to the implementation of telehealth. It is also very important that there is training of the health team for teledentistry. In our study we had a trained team for the use of the platform, and a whatsapp group was created with the creators of V4H. Thus, dentists were supported all the time if unforeseen events occurred in access or during care. But these findings reflect a team of researchers committed to applying intervention, experimenting with new technologies and where there are no conflicts of interest, a scenario we may not find in a real world.

Physical dislocated is a well-discussed point in other studies, including systematic reviews, because in this sense teledentistry can reduce social inequalities in health care, providing needy communities with better access. As many communities do not have the clinical infrastructure to attract health professionals, reducing this remoteness in a technological way would reduce burdens for patients who need to make long journeys to get a specialized health professional, and could even cause this population to seek treatments earlier (3, 16-18).

To implement a new technology in health it is necessary more than to observe the costs only in numerical terms. The additional cost of new technology should also consider the needs, preferences and health gains of patients. All stakeholders in the implementation of the new technology should contribute to decision-making (19). An implementation of new health technologies should be carefully analyzed and

evaluated to ensure the sustainability of the system even more in a restricted budget resource environment (20). Santoro Neto et al. analyzed the values behind a decision to incorporate a new health technology according to some professionals directly or indirectly involved in activities related to the process of incorporating health technologies in Brazil. Respondents tended to prefer to allocate resources for new technologies focused on predicting (triage and early treatment) than for emerging cases with late diagnosis (21). The effects derived from the implementation of non-face-to-face primary dental care for children exactly fulfill this goal, promoting health and controlling diseases, justifying the cost of implementing this strategy in clinical practice. Thinking about teledentistry, would its costs not be lowered with some gains such as disease prevention, expansion in access to health and control of conditions that could move to more serious conditions demanding higher cost of procedures and treatments? Further complete economic evaluations, considering the health system as the scenario are important to answer this question.

On the other hand, we can observe that the greatest value is associated with me development of the digital platform. The use of a platform already established in the market could bring an economy in this part, requiring investment only in its maintenance. On the other hand, digital platforms have a lifetime, losing some functionalities that need to be updated over time, so they are points to be considered because we way be talking about an economy that is not advantageous.

Another point to be highlighted is the costs of absences, each absence can cost around 20.00 per patient, which could cost in a public health system. In our study there were many absences and renunciation of patients, this was a point observed by Da Costa et al. as an important obstacles to be overcome for the implementation of teledentistry in the public system (16). New technologies to be implemented may suffer resistance from the population for its conservatism and culture, so it is increasingly necessary to sensitive the population in relation to the service, using strategies that show it the benefits of this new implementation. Because if the population does not adhere to the idea, barriers are created for the use of these new technologies that can even influence its efficiency.

This study brings important findings for the formulation of strategies in the resumption of oral health and so that activities in primary health care are not completely paralyzed in a pandemic and post-pandemic scenario. Few studies have analyzed pediatric dental care during the pandemic, especially in relation to the real

needs that can be found in patients at this time and in the future, and how these demands can be resolved. Comprehensive, humanized and resolutive care may be possible through teledentistry, especially if combined with face-to-face care.

## 4.6 CONCLUSION

We conclude the non-face-to-face consultation used in primary dental care for children is feasible to solve most pent-up demand caused by the paralyzing of child dental care caused by the COVID-19 pandemic at an acceptable cost.

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# 5 FINAL CONSIDERATIONS

In view of the pandemic of COVID-19 and the advance of information and communication technologies, we proposed with this study to show how these technologies can help us overcome the impossibility of face-to-face meetings and the resolution of the repressed demand acquired by the paralyzing of dental care (3). Increasingly we need research that will turn to studies of specific groups, to understand their demands, needs and how we can use teledentistry together with face-to-face care to solve patient´s complaints and increasingly spread access to health. Another problem to be questioned at this moment is the offer of dental services still based on an emergency and curative care (62), lacking the role of preventive care that is very important at this moment, so that gains in public health in the past are not lost (5). A combination of face-to-face and distance health care using ICT may be the most viable and desirable model for care in the future.

There were still no studies analyzing the problem-solving capacity of ICT in the pent-up demand of children´s dentists, so the findings of this study are important to understand the current and future needs that the paralyzing of child dental care can demand and how ICT can help in the screening and resolution of these demands, relieving the burden that public systems have been suffering. Further studies that reflect on the real feasibility of ideas surrounding the implementation of teledentistry are needed to understand how it can work in different specialties, contexts and societies (49). The valuation of resources used is another relevant aspect, which we bring in this study, for the planning of a certain practice within health services.

Despite our findings more research should be conducted to establish a better evidence base around ICT so that it becomes increasingly clear to health professionals and authorities its benefits and barriers, and that its adoption rate is increasing even in post-pandemic moment. Local health authorities should also review their resolutions and establish clear protocols for the expansion of the performance of health professionals beyond the pandemic period, especially in preventive activities.

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**Declarations:**

*Competing interests*

The authors declare that they have no competing interests.

*Funding*

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**ATTACHMENT A -** The Consolidated Standards of Reporting Trials (CONSORT) guideline

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a randomised trial in the title | 87 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | - |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 88/89 |
| | 2b | Specific objectives or hypotheses | 89/90 |
| **Methods** | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 90/91 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | 90 |
| Participants | 4a | Eligibility criteria for participants | 90 |
| | 4b | Settings and locations where the data were collected | 91 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 91/92<br>92/93 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 93<br>93 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | 90 |
| Sample size | 7a | How sample size was determined | - |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | |
| Randomisation: | | | - |
| Sequence generation | 8a | Method used to generate the random allocation sequence | - |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | - |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | - |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | - |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those | - |

**ATTACHMENT B –** Consolidated Health Economic Evaluation Reporting Standards – CHEERS Checklist



**CHEERS Checklist**
**Items to include when reporting economic evaluations of health interventions**

The **ISPOR CHEERS Task Force Report**, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force,* provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

| Section/item | Item No | Recommendation | Reported on page No/ line No |
|---|---|---|---|
| **Title and abstract** | | | |
| Title | 1 | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. **PAGE 87** | |
| Abstract | 2 | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. **PAGE 87/88** | |
| **Introduction** | | | |
| Background and objectives | 3 | Provide an explicit statement of the broader context for the study.<br>Present the study question and its relevance for health policy or practice decisions. **PAGE 89/90** | |
| **Methods** | | | |
| Target population and subgroups | 4 | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | **90/91** |
| Setting and location | 5 | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. **PAGE 90/91** | |
| Study perspective | 6 | Describe the perspective of the study and relate this to the costs being evaluated. **PAGE 94** | |
| Comparators | 7 | Describe the interventions or strategies being compared and state why they were chosen**. PAGE 94** | |
| Time horizon | 8 | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. **PAGE 94** | |
| Discount rate | 9 | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. **PAGE 94-96** | |
| Choice of health outcomes | 10 | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. **96** | |
| Measurement of effectiveness | 11a | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | |

| | | | |
|---|---|---|---|
| | 11b | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | |
| Measurement and valuation of preference based outcomes | 12 | If applicable, describe the population and methods used to elicit preferences for outcomes. | |
| Estimating resources and costs | 13a | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. **PAGE 94/95** | |
| | 13b | *Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | |
| Currency, price date, and conversion | 14 | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. **PAGE 94/95** | |
| Choice of model | 15 | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. **PAGE 96** | |
| Assumptions | 16 | Describe all structural or other assumptions underpinning the decision-analytical model. | |
| Analytical methods | 17 | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. **PAGE 96** | |
| **Results** | | | |
| Study parameters | 18 | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | |
| Incremental costs and outcomes | 19 | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | **104-105** |
| Characterising uncertainty | 20a | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact | |

| | | | |
|---|---|---|---|
| | | of methodological assumptions (such as discount rate, study perspective). | |
| | 20b | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | |
| Characterising heterogeneity | 21 | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. **PAGE 104-105** | |
| **Discussion** | | | |
| Study findings, limitations, generalisability, and current knowledge | 22 | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. **PAGE 111** | |
| **Other** | | | |
| Source of funding | 23 | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | 119 |
| Conflicts of interest | 24 | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | |

For consistency, the CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

The **ISPOR CHEERS Task Force Report** provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* link or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

The citation for the CHEERS Task Force Report is:
Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS)—Explanation and elaboration: A report of the ISPOR health economic evaluations publication guidelines good reporting practices task force. Value Health 2013;16:231-50.

**ATTACHMENT C –** Approval of the Research Ethics Committee

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## PARECER CONSUBSTANCIADO DO CEP

**DADOS DA EMENDA**

**Título da Pesquisa:** Utilizando tecnologias de informação e comunicação (TICs) para solucionar a demanda reprimida de atenção básica odontológica no SUS em função da pandemia COVID-19

**Pesquisador:** Mariana Minatel Braga
**Área Temática:**
**Versão:** 3
**CAAE:** 39012720.5.0000.0075
**Instituição Proponente:** Faculdade de Odontologia da Universidade de São Paulo
**Patrocinador Principal:** Financiamento Próprio

**DADOS DO PARECER**

**Número do Parecer:** 4.432.357

**Apresentação do Projeto:**
Por ocasião da pandemia de COVID-19, associada à necessidade de instituição do distanciamento social e suspensão de atividades presenciais, milhares de crianças tiveram seus atendimentos odontológicos interrompidos ou postergados, gerando uma demanda reprimida por atenção primária. Visando minimizar o impacto dessa paralisação dos atendimentos presenciais, a tecnologias de informação e comunicação (TIC) poderiam ser uma alternativa e, inclusive, passíveis de vislumbradas dentro do Sistema Único de Saúde. Nesse sentido, esse estudo busca mostrar o impacto do uso de TIC na resolução da demanda reprimida por atenção odontológica primária a crianças no SUS, em função da pandemia COVID-19, propondo o uso de telemonitoramento, teleorientação e teletriagem para resolução e direcionamento de demandas oriundas dessa paralisação na atenção primária eletiva. O impacto do uso dessas estratégias será medido em termos de resolutividade, redução dos tempos de espera dos pacientes para resolução das queixas e percepção dos cuidadores sob o cuidado recebido. Para isso dois estudos clínicos foram delineados e uma avaliação econômica associada a eles planejada. Modelos matemáticos serão utilizados para a transposição desses resultados para a realidade do SUS, tendo em vista a Secretaria do Estado de Saúde de SP e diferentes cenários brasileiros. Baseado nos resultados encontrados, será desenvolvido modelos teóricos para estimar como isso beneficiaria a população dentro desse contexto e como isso poderia beneficiar

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os usuários do SUS. Por fim, objetiva-se estudar a possibilidade de implementação dessas tecnologias citadas no cotidiano do SUS, mesmo após pandemia, e checar a possibilidade de incorporação e custeio das mesmas, bem como explorar possível impacto social e relação com possíveis iniquidades em saúde.

**Objetivo da Pesquisa:**

Identificar a demanda reprimida pela paralisação do atendimento odontológico e os benefícios e dificuldades, bem como a percepção dos usuários, na implementação de novas estratégias de atendimento não presencial baseada em tecnologia (teleatendimento), utilizando uma unidade-célula de atenção primária a crianças e prospectar, por meio de modelos, essa situação para o cenário do Sistema Único de Saúde (SUS). Para o estudo randomizado, Como desfecho primário, consideramos a avaliação da qualidade do cuidado odontológico mensurar pelo questionário SERVQUAL, uma semana do atendimento teleassistido (no caso do grupo intervenção) ou uma semana de espera (no caso do grupo controle). Objetivo Secundário:

1.Realizar diferentes formas de avaliação econômica para mensurar se os ganhos conseguidos com a implementação do teleatendimento(teletriagem, teleorientação e telemonitoramento) compensam os custos adicionais possivelmente associados à mesma, ou ainda, se estão

associados a uma economia de recursos a longo prazo, levando-se em conta a implementação dimensionada para sistema de saúde público brasileiro.2. Explorar como a introdução dessas tecnologias poderiam beneficiar o SUS no período trans e pós-pandêmico, contribuir com a correçãode possíveis iniquidades na atenção em saúde e outros aspectos sociais, bem como resultar em possíveis diferenças quando explorados diferentes cenários brasileiros.

**Avaliação dos Riscos e Benefícios:**

Riscos

Os riscos em participar dessa pesquisa são mínimos, pois a identidade dos participantes (crianças e responsáveis) não será revelada em nenhum momento a qualquer pessoa de fora da pesquisa. Todos os dados gravados pela plataforma V4H não serão divulgados a pessoas que não sejam os pesquisadores e mesmo quando usados pelos pesquisadores, a identidade será resguardada e não vinculada individualmente aos dados coletados.A Plataforma utilizada para os atendimentos também apresenta uma sistemática de confiabilidade na guarda dos dados e criptografia, não

oferecendo riscos de exposição dos dados dos participantes Qualquer coisa que você não se sinta à vontade para responder, pode ser deixado em branco. As respostas não influenciarão em nada no atendimento da criança. As gravações serão usadas apenas para coletar os dados da pesquisa. Os participantes também não terão riscos caso não decidam participar da pesquisa. Independente disso, os tele atendimentos ocorrerão normalmente, assim como o atendimento presencial, quando retornar. Além disso, os participantes podem desistir da participação a qualquer momento e seus dados não serão considerados. Todos esses aspectos estão esclarecidos no TCLE e TALE.

Benefícios:

Os benefícios, informados, no TCLE e TALE, podem auxiliar a entender melhor essa ferramenta tecnológica que pode ajudar muitas pessoas a receberem essa atenção mesmo num momento de distanciamento social como estamos vivendo. Os resultados dessa pesquisa, sejam bons ou ruins, serão mostrados publicamente, sem revelar a identidade dos seus participantes, para que isso seja (ou não) usado da melhor maneira possível.

**Comentários e Considerações sobre a Pesquisa:**

Trata-se de um estudo Nacional, Unicêntrico, estudo randomizado, controlado pelos pacientes da lista de espera, aninhado a um estudo tipo antes-depois a ser realizado em uma unidade-célula, mimetizando uma unidade básica de saúde. Na sequência, se idealizou a realização de um estudo por modelagem prospectando a situação encontrada para a realidade e demanda integral do Sistema Único de Saúde. Financiamento próprio, será realizado no Brasil, com 750 participantes. Previso de início 11/2020 e término 06/2022.

**Considerações sobre os Termos de apresentação obrigatória:**

Todos os documentos exigidos pela Resolução CNS 466/12 foram anexados corretamente (Projeto Detalhado, Folha de Rosto, TCLE e TALE, Declaraço da Coordenadora do Trailer e questionários que sero aplicados.

**Conclusões ou Pendências e Lista de Inadequações:**

Trata-se de uma emenda ao projeto aprovado pelo CEP, CAAE 39012720.5.0000.0075, onde os pesquisadores solicitam alteraço do período das consultas de reorientações para aplicação dos questionários de desfecho para duas semanas após o primeiro tele atendimento, e não mais uma semana apenas. (aprovado).

**Considerações Finais a critério do CEP:**

Ressalta-se que cabe ao pesquisador responsável encaminhar os relatórios parciais e final da pesquisa, por meio da Plataforma Brasil, via notificação do tipo "relatório" para que sejam devidamente apreciados no CEP, conforme Norma Operacional CNS nº 001/13, item XI.2.d..

Qualquer alteração no projeto original deve ser apresentada "EMENDA",por meio da Plataforma Brasil, de forma objetiva e com justificativas para nova apreciação (Norma Operacional 001/2013 – letra H).

**Este parecer foi elaborado baseado nos documentos abaixo relacionados:**

| Tipo Documento | Arquivo | Postagem | Autor | Situação |
|---|---|---|---|---|
| Informações Básicas do Projeto | PB_INFORMAÇÕES_BÁSICAS_1658207_E1.pdf | 25/11/2020 11:21:13 | | Aceito |
| Outros | Teletrailer_Logistica_CEP.docx | 25/11/2020 11:13:57 | Mariana Minatel Braga | Aceito |
| Projeto Detalhado / Brochura Investigador | protocolo_cep_ppsus_revisado.docx | 25/11/2020 11:11:04 | Mariana Minatel Braga | Aceito |
| Outros | Desfecho.pdf | 29/10/2020 11:31:41 | Mariana Minatel Braga | Aceito |
| Outros | SERVQUAL.pdf | 29/10/2020 11:30:52 | Mariana Minatel Braga | Aceito |
| Outros | Controle_Consultas_Teletrailer.pdf | 29/10/2020 11:29:50 | Mariana Minatel Braga | Aceito |
| Outros | Ficha_consultas_teleTrailer_2020.pdf | 29/10/2020 11:29:36 | Mariana Minatel Braga | Aceito |
| Declaração de Instituição e Infraestrutura | carta_trailer_coordenador.pdf | 05/10/2020 12:48:50 | Mariana Minatel Braga | Aceito |
| TCLE / Termos de Assentimento / Justificativa de Ausência | assentimento_teletrailer_googleForms.pdf | 05/10/2020 12:40:35 | Mariana Minatel Braga | Aceito |

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Continuação do Parecer: 4.432.357

| | | | | |
|---|---|---|---|---|
| TCLE / Termos de Assentimento / Justificativa de Ausência | tcle_teletrailer_googleforms.pdf | 05/10/2020 12:40:24 | Mariana Minatel Braga | Aceito |
| Folha de Rosto | folhaDeRosto_final.pdf | 05/10/2020 12:26:38 | Mariana Minatel Braga | Aceito |

**Situação do Parecer:**
Aprovado

**Necessita Apreciação da CONEP:**
Não

SAO PAULO, 01 de Dezembro de 2020

**Assinado por:**
**Alyne Simões Gonçalves**
**(Coordenador(a))**

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**ATTACHMENT D** – Informed Consent Form (ICF)

**TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO**

Você e seu filho estão sendo convidados a participar da pesquisa intitulada "Utilizando tecnologias de informação e comunicação (TICs) para solucionar a demanda reprimida de atenção básica odontológica no SUS em função da pandemia COVID-19". Ela é coordenada pela Profa. Dra. Mariana Minatel Braga e realizada por sua equipe da Faculdade de Odontologia da Universidade de São Paulo. Abaixo você tem 2 opções para entender mais sobre essa pesquisa. Você pode ASSISTIR o vídeo (aparece 1o) ou LER o texto mais abaixo (basta descer a tela). Eles têm as mesmas informações. Pode escolher a que você gostar mais ou for mais fácil para você.

Convite para participação em pesquisa _ Assista o vídeo a seguir ou, se preferir, leia o texto mais abaixo.

Convite para participação em pesquisa

Se você está sendo convidado para participar dessa pesquisa é porque seu filho(a) é paciente cadastrado e em acompanhamento no Trailer Odontológico da FOUSP. Nesse momento de pandemia, nossa equipe está buscando a aproximação dos pacientes utilizando os teleatendimentos para acompanhamentos dos nossos pacientes. Essa pesquisa tem por objetivo avaliar o efeito disso e como as crianças e os pais enxergam esse atendimento, feito dessa maneira. Os teleatendimentos serão feitos por meio de um site ou aplicativo chamado V4H, que fica com todos os dados gravados de uma forma segura. Sempre pediremos a permissão para a gravação da sessão, para termos uma documentação depois.

Para avaliar isso, nós enviaremos para todos os pacientes um questionário, via GoogleForms, sobre sua impressão sobre os serviços prestados na unidade de atendimento (o trailer). Esse questionário pode ser preenchido a qualquer momento (basta clicar no link) e você vai demorar cerca de 15 minutos para isso. Esse questionário será enviado em 2 ou 3 momentos, dependendo de um sorteio que faremos para ordenar os atendimentos. Pode ser que você receba o questionário para preencher uma ou duas vezes antes do atendimento, ou, apenas uma. Todos responsáveis receberão, além desses, um último questionário após o teleatendimento e também terão a oportunidade de fazer uma reunião online junto com seus filhos (de mais ou menos 15 minutos) para contar das suas impressões e darem sua opinião sobre o atendimento. Caso não possam ou prefiram de outra maneira, isso poderá ser feito por whatsapp ou telefone. Nós também avaliaremos as gravações para coletar alguns dados sobre a interação dos pacientes e responsáveis com os profissionais durante a consulta, olhando com todos se comportaram, falaram, fizeram gestos.

Quando finalizado o distanciamento social, por conta da pandemia, os pacientes retornarão ao atendimento odontológico na unidade (trailer), e os dados dos exames bucais de seus filhos, que seriam realizados de toda forma para realização do acompanhamento e tratamento, também serão coletados para essa pesquisa.

Os riscos em participar dessa pesquisa são mínimos, pois a identidade de vocês não será revelada em nenhum momento a qualquer pessoa de fora da pesquisa. Todos os dados gravados não serão divulgados a pessoas que não sejam os pesquisadores e mesmo quando usados pelos pesquisadores, veremos o que for preciso, mas a sua identidade e de seu filho não será revelada a ninguém. Qualquer coisa que você não se sinta à vontade para responder, pode ser deixado em branco. As respostas não influenciarão em nada no atendimento da criança. As gravações serão usadas apenas para coletar os dados da pesquisa. Mesmo que você decida não participar da pesquisa, os teleatendimentos ocorrerão normalmente, se você quiser participar deles e a criança também poderá ser atendida no trailer, quando o atendimento presencial retornar. Além disso, você pode desistir da sua participação a qualquer momento e seus dados não serão considerados. Por outro lado, participando dessa pesquisa você pode ajudar a entender melhor essa ferramenta tecnológica que pode ajudar muitas pessoas a receberem essa atenção mesmo num momento de distanciamento social como estamos

vivendo. Os resultados dessa pesquisa, sejam bons ou ruins, serão mostrados publicamente, sem revelar a identidade dos seus participantes, para que isso seja (ou não) usado da melhor maneira possível.

Se você aceitar participar do estudo, as mesmas informações serão passadas, numa linguagem adequada, para seu filho, se ele já tiver em idade escolar (6 anos) e ele poderá também decidir participar ou não dessa pesquisa. Se eventuais danos ou prejuízos em virtude da realização dessa pesquisa ocorrerem, os pesquisadores se responsabilizarão por indenizá-los.

Havendo qualquer problema ou dúvida durante a realização da pesquisa, professora Mariana Minatel Braga, responsável pela pesquisa, pode ser encontrada pelo telefone 11-992014818 ou no Departamento de Odontopediatria, pelo telefone 11-39017835. Eventuais dúvidas poderão ser esclarecidas também pessoalmente, com essa professora, quandoa pandemia acabar, , na própria sede da Faculdade de Odontologia da Universidade de São Paulo – FOUSP- sito à Av. Lineu Prestes 2227, 05508-000, São Paulo.

Esta pesquisa foi aprovada pelo Comitê de Ética da Faculdade de Odontologia da Universidade de São Paulo (FOUSP) – Parecer: XXXXXXXX,. Esse Comitê cuida da segurança das pessoas que participam de pesquisas, como você. Dúvidas sobre a ética da pesquisa entre em contato com o Comitê de Ética em Pesquisa da FOUSP, (Av. Lineu Prestes, 2227 | 05508-000 | São Paulo/SP | e-mail cepfo@usp.br).

Ao aceitar participar da pesquisa, após essas informações, você receberá em seu e-mail (informado acima) uma via desse termo com a nossa assinatura. Isso pode ser pelo email ou whatsapp (como você nos disser abaixo). Se não aceitar, automaticamente não receberá os questionários mencionados acima. Basta que você selecione a opção abaixo. É importante que você guarde em seus arquivos uma via desse documento (impresso ou em pdf). Se preferir, podemos enviar uma cópia impressa pelo correio.

Após receber as informações acima, você e seu filho aceitam participar, de forma voluntária e espontânea, dessa pesquisa:

( ) sim ( ) não

Nome completo do responsável: _____

RG do responsável: _____

Nome completo da criança: _____

Você autoriza a utilização dos dados coletados para essa pesquisa também para outras pesquisas futuras, se todas as condições de sigilo forem mantidas?

( ) sim, autorizo e não preciso ser consultado novamente, caso isso ocorra.

( ) sim, autorizo, mas gostaria de ser consultado novamente, caso isso ocorra.

( ) não autorizo.

De que maneira você prefere que enviemos uma via desse termo para você?

( ) arquivo por whatsapp ( ) arquivo por email ( ) impressa por correios

E-mail: _____

Endereço: _____

**ATTACHMENT E** - Informed Assent Form (IAF)

## TERMO DE ASSENTIMENTO LIVRE E ESCLARECIDO

Este é um convite para você e seu pai ou mãe participarem de uma pesquisa. O nome dela é "Utilizando tecnologias de informação e comunicação (TICs) para solucionar a demanda reprimida de atenção básica odontológica no SUS em função da pandemia COVID-19". Quem cuida dessa pesquisa é a Profa. Dra. Mariana Minatel Braga juto com sua equipe que é Faculdade de Odontologia da USP. Abaixo você tem 2 opções para entender mais sobre essa pesquisa. Você pode ASSISTIR o vídeo (aparece 1o) ou LER o texto mais abaixo (basta descer a tela). Eles têm as mesmas informações. Pode escolher a que você gostar mais ou for mais fácil para você.

Convite para participação em pesquisa - Assista o vídeo a seguir ou, se preferir, leia o texto mais abaixo.

Convite para participação em pesquisa

Você é um paciente que faz tratamento no Trailer Odontológico da FOUSP e, agora, por causa da pandemia não estamos podendo atender você. Por isso, começamos os atendimentos pela internet/computador para ficar mais perto de você. Nessa pesquisa que estamos convidando você vamos ver se pacientes como você, e também seus pais, gostam desse tipo de atendimento e como ele pode ajudar as pessoas que não podem ir até o consultório. Esses atendimentos serão feitos por um site ou aplicativo chamado V4H. Nesse lugar, tudo fica gravado e é bastante seguro. Não se preocupe que ninguém, sem ser da pesquisa, poderá ver. Em todas as consultas, também pediremos se você e seus pais deixam gravar o que formos falar.

Se você quiser participar, nós vamos mandar algumas perguntas para seus pais sobre o que ele achou do atendimento e sobre as coisas que fazemos no trailer. Também queremos fazer um encontro online com vocês para que você e seu pai ou sua mãe possam nos contar como se sentiram na consulta, o que acharam bom e ruim. Isso vai demorar uns 15 minutos. Caso não possam ou não queiram, nós também podemos falar por whatsapp ou telefone. Depois, nós também veremos os vídeos gravados para ver como o dentista e vocês conversaram, olharam, se movimentaram durante a consulta.

Quando a pandemia acabar, você voltará a ser atendido ao vivo no consultório do trailer e continuará a olhar e cuidar dos seus dentes lá, como antes. Nós vamos ver como estarão seus dentes pelas fichas que os dentistas do trailer usarão, quando isso acontecer.

Se você participar dessa pesquisa, não devem ocorrer problemas (riscos) para você, porque ninguém saberá nada sobre você. Nós vamos olhar os vídeos gravados e veremos o que for preciso, mas eles não poderão ser passados a outras pessoas, só as pessoas que estão fazendo a pesquisa. Se você não tiver vontade de responder alguma coisa, é só não responder. Mesmo sem responder ou se não quiser participar da pesquisa, você será atendido no trailer e cuidaremos dos seus dentes sem problemas. Não se preocupe. Você também pode não querer mais participar da pesquisa a qualquer hora. É só falar pra gente.

Se você participar, você vai ajudar a saber se essa consulta pelo computador/internet pode ajudar outras crianças que não podem ir num consultório de dentista por algum motivo como a pandemia, por exemplo. Tudo o que descobrirmos nessa pesquisa, de bom e de ruim, será mostrado a todas as pessoas, sem mostrar você ou seu nome. Isso poderá ajudar pessoas no mundo todo que quiserem usar esse tipo de consulta.

Para participar da pesquisa, seu pai ou sua mãe precisam autorizar. Se, por acaso, algum mal ocorrer pra você e seus pais pela pesquisa, as pessoas que fazem a pesquisa farão o que precisar para ajudá-los.

Qualquer problema ou dúvida que você tenha sobre algo que está sendo feito, você pode falar com a professora Mariana Minatel Braga, que cuida dessa pesquisa. Você pode ligar para ela no telefone 11-992014818 ou n 11-39017835. Você também pode procurá-la, quando a pandemia acabar, na própria sede da

Faculdade de Odontologia da Universidade de São Paulo – FOUSP, Av. Lineu Prestes 2227, 05508-000, São Paulo.

Um lugar que controla as pesquisas, para que ninguém faça mal a você, nos deixou fazer essa pesquisa porque ela é segura para você. Esse lugar se chama Comitê de Ética da Faculdade de Odontologia da Universidade de São Paulo (FOUSP) – Parecer: XXXXXXXX. . Se você ativer dúvidas se essa pesquisa pode prejudicar os participantes de algum jeito, você pode também procurar o Comitê de Ética em Pesquisa da FOUSP, (Av. Lineu Prestes, 2227 | 05508-000 | São Paulo/SP | e-mail cepfo@usp.br).

Se você e seus pais quiserem participar da pesquisa, vocês receberão um documento igual a essa por email, Whatsapp pu carta. Guardem sempre esse documento.

Depois de ler tudo que explicamos, você quer participar da pesquisa? Clique abaixo SIM ou NÃO.

( ) SIM ( ) NÃO

Se você respondeu sim, você deixa que nós também possamos usar o que tivermos dessa pesquisa, sobre você, de novo, em outras pesquisas, se te falarmos que ninguém saberá quem é vocês?

( ) Sim, mas quero que me perguntem antes.

( ) Sim, e não precisam me perguntar de novo se quero.

( ) Não.

Nome da criança: _____

## **ATTACHMENT F** - Form (developed on Google Forms) completed in return queries

## 2 weeks after call

### QUESTIONÁRIO DE DESFECHO E REORIENTAÇÃO

Via Google Formulários

Nome do paciente:

_____

Em qual pesquisa o paciente pertence na Unidade Móvel Odontológica:

( ) Bebês ( ) Cardec 2 ( ) Cardec 6 ( ) Moderadas ( ) Molar ( ) Restaurados

Número do paciente na pesquisa: _____

Data da consulta de desfecho: _____

Nome do responsável:

_____

Grau de parentesco: ( ) Mãe ( ) Pai ( ) Avós ( ) Outros

Faltou: ( ) sim ( ) não

Tempo de espera até o paciente entrar na plataforma: _____

Aceitou ter filmado e fotografado: ( ) sim ( ) não

PERGUNTAS PARA A CRIANÇA

Você gostou de ser atendido pela internet? ( ) sim ( ) não ( ) mais ou menos

Você conseguiu entender a explicação que a dentista fez no atendimento? ( ) sim ( ) não ( ) mais ou menos

Você conseguiu fazer os movimentos ensinados facilmente? ( ) sim ( ) não ( ) mais ou menos

Como você se sentiu ao ser tratado (a) na internet?

( ) 1  ( ) 2  ( ) 3  ( ) 4  ( ) 5 

Ao pedir que a criança reproduza os movimentos ensinados no atendimento, quais movimentos ela realizou corretamente?

( ) vai e vém ( ) circular ( ) varredura ( ) lingua

Está realizando de forma correta? ( ) sim ( ) não

A escova está adequada? ( ) sim ( ) não

Se não, por que? ( ) Tamanho da cabeça da escova ( ) Cerdas desorganizadas ( ) Tamanho do cabo

A criança utiliza pasta de dente com flúor? ( ) sim ( ) não

Qual marca da pasta? _____

Qual a quantidade de pasta? ( ) Grão de arroz ( ) Ervilha ( ) Escova toda

A criança escova todos os dias? ( ) sim ( ) não

Quantas vezes por dia? ( ) 1 ( ) 2 ( ) 3 ( ) 4 ou mais

O responsável está realizando a escovação? ( ) sim ( ) não

Está passando o fio? ( ) sim ( ) não Está passando da forma correta? ( ) sim ( ) não

A gengiva sangra ao escovar ou passar o fio dental? ( ) sim, ao escovar ( ) sim, ao passar o fio dental

( ) sim, ao escovar e passar o fio dental ( ) não sangra

PERGUNTAS AO RESPONSÁVEL

No último atendimento, o paciente foi encaminhado? ( ) sim ( ) não

Se sim, por qual motivo?

_____

Conseguiu atendimento necessário? ( ) sim ( ) não

Se sim, o atendimento odontológico foi realizado em qual ambiente? ( ) Setor Público ( ) Setor Privado

O que foi realizado: ( ) Restauração ( ) Prevenção ( ) Exodontia ( ) Endodontia ( ) Ortodontia ( ) Aplicação de flúor ( ) Outros _____

Qual era a queixa principal antes de ser encaminhada?

_____

Foi receitado algum medicamento? ( ) sim ( ) não Se sim, qual?

_____

A queixa principal foi resolvida? ( ) sim ( ) não

Se não, o que a criança está sentindo?

_____

Satisfação do atendimento recebido no local:

| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sendo zero a pior nota | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | Sendo dez a melhor nota |

A criança passou por algum tratamento médico atualmente? ( ) sim ( ) não

Se sim, qual? _____

PERGUNTAS SOBRE O TELEATENDIMENTO

Teve alguma dificuldade em acessar a plataforma? ( ) sim ( ) não ( ) talvez

Se sim, qual? _____

Você acha que a plataforma foi fácil de usar? ( ) sim ( ) não

O teleatendimento economizou seu tempo de alguma forma? ( ) sim ( ) não ( ) talvez

Se sim, de que forma? _____

A comunicação do dentista com vocês no teleatendimento foi feita de maneira clara?

( ) sim ( ) não ( ) talvez

Você acha que o teleatendimento atendeu às necessidades do seu filho (a) ?

( ) sim ( ) não ( ) talvez

Você acha que o teleatendimento prestado teve o mesmo efeito de uma consulta presencial?

( ) sim ( ) não ( ) talvez

Por qual motivo? _____

Mesmo com o fim da pandemia, você consideraria futuras consultas de maneira virtual?

( ) sim ( ) não ( ) talvez