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DESENVOLVIMENTO E AVALIAÇÃO DE UM APLICATIVO MÓVEL PARA MONITORAMENTO DE PACIENTES FISSURADOS

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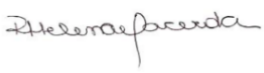

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DESENVOLVIMENTO E AVALIAÇÃO DE UM APLICATIVO MÓVEL PARA MONITORAMENTO DE PACIENTES FISSURADOS

DEVELOPMENT AND EVALUATION OF A MOBILE APPLICATION FOR MONITORING CLEFT PATIENTS

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia, da Universidade Federal da Paraíba (UFPB), como parte dos requisitos para obtenção do título de Mestre em Odontologia – Área de Concentração Ciências Odontológicas.

Orientador: Prof. Dr. Paulo Rogério Ferreti Bonan

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João Pessoa

2024

DEDICATÓRIA

A mainha e painho, que sob o sol escaldante me permitiram chegar até aqui, na sombra.

RESUMO

A pandemia de COVID-19 desencadeou mudanças significativas na abordagem dos processos de saúde e doença, levando à adoção de novas estratégias de atendimento, como a Teleodontologia. Mesmo após o término da pandemia, a Teleodontologia permaneceu como recurso útil para superar outros desafios no cuidado à saúde. Por meio do telemonitoramento e da teleorientação, pacientes podem ser acompanhados remotamente, utilizando Tecnologias da Informação e Comunicação (TICs), o que tem contribuído para melhorar a qualidade e a eficiência dos serviços de saúde. O uso crescente de smartphones no Brasil torna os aplicativos móveis uma opção viável para essa modalidade. Dito isso, este estudo teve dois planos de trabalho. O primeiro envolveu a elaboração de um protocolo e de uma revisão de escopo, cujo objetivo foi mapear os recursos e tecnologias digitais disponíveis para o monitoramento de pacientes com FL±P por meio da análise de estudos primários. Esse processo visou responder à seguinte pergunta: "Quais recursos e tecnologias digitais estão sendo aplicados no monitoramento de pacientes com FL±P e qual o impacto dessa abordagem na qualidade de vida desses pacientes?". O protocolo final foi registrado na Open Science Framework (DOI: 10.17605/OSF.IO/Y6AG8). Foram incluídos quatro estudos publicados entre 2017 e 2023, predominantemente dos Estados Unidos, que utilizaram telemedicina para consultas remotas, jogos digitais para terapia da fala e jogos de realidade virtual para apoio psicossocial. Quanto ao segundo plano de trabalho, este envolveu o desenvolvimento e avaliação de um aplicativo móvel com o intuito de viabilizar o monitoramento e orientação remota dos bebês com FL±P e seus cuidadores, durante o tratamento com a MNA. O aplicativo foi desenvolvido seguindo a metodologia de Design Centrado no Usuário (DCU) e avaliado com base em parâmetros de usabilidade e satisfação do usuário. No total, 20 cuidadores participaram deste estudo, juntamente com seus respectivos bebês. Entre os 20 cuidadores, a maioria era do sexo feminino (n = 18; 90%), com idade média de 29,3 anos e com vínculo materno (n = 18; 90%). Em relação à renda, 40% (n = 8) tinham uma renda familiar entre 1 e 2 salários-mínimos, enquanto 35% (n = 7) tinham completado o ensino superior e 30% (n = 6) tinham concluído o ensino médio. A maioria dos participantes residia no estado de São Paulo (n = 13; 65%), todos tinham acesso à internet, e utilizavam principalmente o sistema operacional Android (n = 16; 80%). A distância média de seus municípios até os centros de tratamento era de 55,72 quilômetros. Dos bebês registrados no aplicativo, 70% (n = 14) eram do sexo masculino, com idade média de aproximadamente 23 dias no início do tratamento com MNA, predominantemente apresentando fissura labiopalatina unilateral (14; 70%). Em termos de usabilidade, o aplicativo desenvolvido alcançou uma pontuação de 83.63 na Escala de Usabilidade de Sistemas (SUS), indicando um nível satisfatório. No que diz respeito à satisfação, a maioria dos participantes relatou estar satisfeita com a ferramenta. Em conclusão, a revisão de escopo revela que há uma escassez de recursos e tecnologias digitais para o monitoramento remoto de pacientes com FL±P, indicando a necessidade de mais pesquisas e desenvolvimento. O TeleCleft se destaca como uma solução promissora, oferecendo monitoramento remoto durante o tratamento ortopédico pré-cirúrgico com a MNA. O aplicativo desenvolvido com a metodologia do Design Centrado no Usuário (DCU) mostrou-se eficaz, com alta pontuação na SUS e alta satisfação dos cuidadores. Esses resultados destacam a importância de abordar as necessidades dos usuários ao projetar soluções tecnológicas e destacam o potencial da Teleodontologia para melhorar o cuidado com pacientes e cuidadores.

Palavras-chaves: Teleodontologia. Telemonitoramento. Aplicativos Móveis. Fissura Labial. Fissura Palatina.

ABSTRACT

The COVID-19 pandemic triggered significant changes in the approach to health and disease processes, leading to the adoption of new care strategies, such as Teleorthodontics. Even after the end of the pandemic, Teleorthodontics remained a useful resource for overcoming other challenges in healthcare. Through telemonitoring and teleorientation, patients can be remotely monitored, using Information and Communication Technologies (ICTs), which has contributed to improving the quality and efficiency of healthcare services. The increasing use of smartphones in Brazil makes mobile applications a viable option for this type of care. In this context, the proposal to develop a mobile application dedicated to the telemonitoring and guidance of pediatric patients with cleft lip and/or palate (CL±P) during pre-surgical orthopedic treatment with nasoalveolar molding (NAM) arises. This study also aims to identify, through a scoping review, the technologies available for monitoring patients with CL±P. For this purpose, the first work plan consisted of developing a protocol and scoping review to map the digital resources and technologies available for monitoring patients with CL±P through the analysis of primary studies. This process aims to answer the following question: "What digital resources and technologies are being applied in monitoring patients with CL±P and what is the impact of this approach on the quality of life of these patients?". The final protocol was registered in the Open Science Framework (DOI: 10.17605/OSF.IO/Y6AG8). Currently, the review is in the article selection phase, following the previously outlined search strategy. As for the second work plan, it involved the development and evaluation of a mobile application aimed at enabling the remote monitoring and guidance of babies with CL±P and their caregivers during treatment with NAM. The application was developed following the User-Centered Design (UCD) methodology and evaluated based on usability and user satisfaction parameters. In total, 20 caregivers participated in this study, along with their respective babies. Among the 20 caregivers, the majority were female (n = 18; 90%), with an average age of 29.3 years and maternal bond (n = 18; 90%). Regarding income, 40% (n = 8) had a family income between 1 and 2 minimum wages, while 35% (n = 7) had completed higher education and 30% (n = 6) had completed high school. The majority of participants resided in the state of São Paulo (n = 13; 65%), all had internet access, and mainly used the Android operating system (n = 16; 80%). The average distance from their municipalities to the treatment centers was 55.72 kilometers. Of the babies registered in the application, 70% (n = 14) were male, with an average age of approximately 23 days at the beginning of NAM treatment, predominantly presenting unilateral cleft lip and palate (14; 70%). In terms of usability, the developed application achieved a score of 83.63 on the System Usability Scale (SUS), indicating a satisfactory level. Regarding satisfaction, the majority of participants reported being satisfied with the tool.

Keywords: Teledentistry. Telemonitoring. Mobile Applications. Cleft Lip. Cleft Palate.

SUMÁRIO

1. INTRODUÇÃO

A pandemia do COVID-19 trouxe significativas mudanças na forma de vivenciar os processos de saúde e doença, tanto para o indivíduo quanto para o profissional de saúde. Prontamente, em réplica à crise sanitária instaurada, foram idealizadas novas estratégias de atendimento em saúde com o intuito de oportunizar a continuidade do cuidado aos pacientes. Na Odontologia, foi a partir da Resolução 226/2020 do Conselho Federal de Odontologia (CFO), que houve a regulamentação do exercício profissional à distância, pautada, sobretudo, nos preceitos da Teleodontologia (CFO, 2020; Brasil, 2022).

Apesar do fim da pandemia, a Teleodontologia permaneceu como um recurso útil para a solucionar outros entraves do atendimento em saúde. O telemonitoramento, por exemplo, pode viabilizar o acompanhamento periódico, à distância, de pacientes que já estão em tratamento odontológico. Além do telemonitoramento, há também a modalidade de teleorientação, que permite instruir e esclarecer os pacientes acerca das demandas do seu tratamento e de suas condições de saúde. As Tecnologias da Informação e Comunicação (TICs) são o alicerce para o desenvolvimento dessas atividades, já que o conjunto de tecnologias permite o acesso à informação mediado pela telecomunicação (Alverson, 2020; Brasil, 2022).

Como resultado do avanço contínuo das TICs na esfera da saúde, os serviços proporcionados por meio desses recursos têm ganhado destaque crescente. A aplicação de tecnologias na atenção à saúde não apenas contribui para a melhoria da qualidade da assistência, mas também promove a otimização na prestação de serviços. As TICs englobam uma ampla gama de recursos e aplicações na área da saúde, incluindo o uso de aplicativos móveis para práticas remotas, que abrangem desde o monitoramento até o diagnóstico. Atualmente, com a expansão crescente do acesso a smartphones, a incorporação de aplicativos tornou-se inerente ao cotidiano social (Rocha et al., 2016; Santos, 2017; Allen, 2021).

De acordo com o estudo conduzido pela Fundação Getúlio Vargas no Brasil (FGV), existem cerca de 234 milhões de smartphones em uso, isto é, mais de 1 smartphone por habitante. Outra pesquisa sobre o mercado de conteúdo móveis revela que 98% dos brasileiros já instalaram, em algum momento, um aplicativo de qualquer natureza. Logo, percebeu-se a receptividade, por parte da população, ao uso de aplicativos (Meirelles, 2022; Paiva; 2022). Com base nessa premissa, surge a proposta de telemonitoramento de pacientes pediátricos portadores de fissura labial e/ou palatina (FL±P) durante o tratamento ortopédico pré-cirúrgico, juntamente com a orientação de seus responsáveis, por meio de um aplicativo dedicado.

No preparo pré-cirúrgico para corrigir fissuras em pacientes pediátricos, podem ser empregadas técnicas, como a modelagem nasoalveolar (MNA), com o objetivo de reduzir a largura da fissura e melhorar a simetria nasal em pacientes com FL±P (Buthiani et al., 2020). Contudo, a utilização dos modeladores pode ocasionar complicações, como lesões nos tecidos moles, tais como irritações e ulcerações, meganostril e aumentar o risco de infecções fúngicas em caso de higiene inadequada. Além disso, o cuidador do bebê desempenha um papel crucial no tratamento, sendo responsável pela manutenção, higiene e ativação do dispositivo. A execução inadequada desses procedimentos pode impactar a saúde do bebê e o resultado da modelagem (Levy-Bercowski, 2009).

Para prevenir complicações, é imprescindível monitorar regularmente o paciente durante o uso do modelador e orientar adequadamente seu cuidador sobre o dispositivo. No entanto, as visitas periódicas ao consultório odontológico podem acarretar despesas que, poucas vezes, os cuidadores conseguem arcar. Além da parte financeira, o tempo despendido para as consultas pode se tornar um desafio durante o tratamento. Esse cenário é ainda pior, quando se trata de famílias que residem em locais distantes dos centros de tratamento. Diante dessas considerações, este estudo teve por objetivo desenvolver e avaliar um aplicativo móvel para telemonitoramento e teleorientação, centrado no binômio paciente/cuidador.

Adicionalmente, busca-se mapear, por meio de uma revisão de escopo, quais os recursos e tecnologias digitais disponíveis para o monitoramento de pacientes com FL±P. Para execução dos objetivos propostos, foram elaborados dois planos de trabalhos. Para o primeiro plano de trabalho, foi elaborado um protocolo e de uma revisão de escopo, cujo objetivo é mapear os recursos e tecnologias digitais disponíveis para o monitoramento de pacientes com FL±P por meio da análise de estudos primários. Esse processo visa responder à seguinte pergunta: “Quais recursos e tecnologias digitais estão sendo aplicados no monitoramento de pacientes com FL±P e qual o impacto dessa abordagem na qualidade de vida desses pacientes?”. Quanto ao segundo plano de trabalho, este envolveu o desenvolvimento e avaliação do aplicativo de telemonitoramento, com a finalidade de produzir uma ferramenta viável para o monitoramento e orientação remota de pacientes com FL±P.

2. REVISÃO DA LITERATURA

2.1. Considerações gerais sobre fissuras labiopalatinas

As fissuras orofaciais são as malformações mais comuns em todo o mundo, com uma taxa de recorrência de aproximadamente 1 em cada 700 bebês nascidos vivos (Dixon et al., 2011). Podem ocorrer isoladamente nos lábios ou no palato, ou afetar ambos os sítios, caracterizando a fissura labiopalatina (FLP) (Babai; Irving, 2023). A formação da FL±P ocorre já nas primeiras semanas de vida intrauterina do feto, mais especificamente a partir da 4ª semana, quando uma falha embriológica resulta no insucesso da união dos processos frontonasais com os processos maxilares (Mossey et al., 2009; Ambrosio et al., 2023). Embora os fatores etiológicos envolvidos nesse processo sejam incertos, além dos fatores genéticos, os fatores ambientais aos quais a mãe pode ser exposta durante a geração podem contribuir para o aparecimento do defeito (Lu et al., 2019).

Alguns estudos apontam que o consumo de substâncias nocivas, como álcool e tabaco, durante o período gestacional pode representar fatores de risco para o aparecimento de fissuras (Angulo-Castro et al., 2017; Xu et al., 2018; Silva et al., 2018). Além disso, fatores adicionais, como a consanguinidade dos pais e um histórico familiar de fissuras, podem estar associados a um maior risco de desenvolvimento de fissuras (Jamilian et al., 2017). A falta de suplementação materna adequada, principalmente no primeiro trimestre de gestação, com a deficiência de ácido fólico, pode aumentar a probabilidade de ocorrência de FL±P (Rusdy et al. 2022). No que diz respeito ao diagnóstico, este pode ser feito ainda durante a fase intrauterina com o auxílio de exames de imagem, como ultrassonografias e ressonâncias magnéticas (Baeza-Pagador et al., 2024).

Em relação à classificação, de acordo com Spina et al. (1972), as fissuras são categorizadas conforme sua localização em relação ao forame incisivo. Esse sistema de classificação menciona quatro classes de malformações: pré-forame, transforame, pós-forame e raras da face. As fissuras ainda são subclassificadas como unilaterais ou bilaterais e completas ou incompletas. Uma fissura transforame unilateral completa, por exemplo, afetando apenas um lado, estendendo-se desde os lábios e rebordo alveolar até o palato, além da região nasolabial. O nível de comprometimento das estruturas craniofaciais pela fissura orienta o tratamento da condição, uma vez que a abordagem terapêutica varia de acordo com o tipo e gravidade da fissura (Moreira; Bernaola-Paredes, 2020). O tratamento de FL±P requer a colaboração de vários profissionais e começa desde a infância do bebê (Akbulut, 2020).

Um dos tratamentos iniciados logo após o nascimento é o tratamento ortopédico que precede a primeira cirurgia corretiva. Esta abordagem envolve o uso de um dispositivo chamado modelador nasoalveolar (MNA), que tem por objetivo facilitar o reparo cirúrgico, reduzindo o tamanho da fissura e remodelando a morfologia nasal (Buthiani et al., 2020). O MNA visa a redução da gravidade da fissura, o realinhamento dos segmentos ósseos maxilares, a melhoria da simetria nasal e a preparação adequada dos tecidos para intervenções cirúrgicas posteriores (Saad et al., 2020). Ao promover o desenvolvimento das estruturas faciais durante o crescimento craniofacial da criança, a MNA desempenha um importante papel na obtenção de resultados estéticos e funcionais satisfatórios, além de reduzir o número de intervenções cirúrgicas ao longo do tratamento (Alkhames et al., 2023).

No entanto, apesar dos benefícios, de acordo com a revisão sistemática conduzida por Padovano et al. (2022), ainda não há evidências suficientes para determinar o impacto do uso do MNA no desenvolvimento da arcada dentária dos pacientes. Em contrapartida, outros estudos, como a também revisão sistemática elaborada por Dunworth et al. (2024), constataram que os riscos para o crescimento facial e o desenvolvimento dentário são baixos. Para além disso, o uso do MNA não é isento de complicações, visto que a utilização inadequada do dispositivo pode desencadear o aparecimento de lesões nos tecidos moles, como ulcerações e irritações na pele (Alvear et al., 2021). Para o ajuste do dispositivo, é importante um acompanhamento com consultas semanais, o que pode encarecer o tratamento (Wlodarczyk et al., 2021).

2.2. Teleodontologia

Para oferecer o monitoramento remoto, reduzindo a necessidade de consultas presenciais e, consequentemente, os custos associados a deslocamentos, a Teleodontologia surge como uma alternativa viável. Autorizada e regulamentada pela Resolução 226/2020 do CFO (CFO, 2020), a Teleodontologia, embora tenha ganhado destaque neste período, tem suas raízes muito antes da pandemia de 2020. Em 1994, a Teleodontologia foi concebida como parte do projeto Total Dental Access (TDA) pelo Departamento de Defesa dos Estados Unidos. Este projeto permitia que cirurgiões-dentistas das Forças Armadas consultassem especialistas para trocar informações sobre o caso de um paciente, difundindo a cobertura de saúde bucal para as tropas americanas (Rocca et al., 1999). Poucos anos depois, em 1997, Cook definiu pela primeira vez a Teleodontologia como o uso de tecnologias de videoconferência para fornecer atendimento remoto a pacientes (Cook et al., 2001).

Desde então, a Teleodontologia tem ganhado cada vez mais destaque, especialmente durante o período da pandemia, onde foi observado um aumento considerável no número de estudos publicados na área (Valeri et al., 2023). Ao permitir a prestação de cuidados odontológicos à distância, essa modalidade se torna essencial para atender às necessidades de pacientes que residem em áreas remotas ou com dificuldades de locomoção (Behera, 2020). Além disso, a teleorientação e o telemonitoramento, modalidades de Teleodontologia já previstas na Resolução 226/2020 (CFO, 2020), possibilitam uma assistência mais abrangente e personalizada, garantindo que os pacientes recebam orientações, orientações adequadas e acompanhamento necessário ao longo do tratamento. Do ponto de vista do paciente, a Teleodontologia também oferece benefícios significativos, uma vez que pode reduzir os custos associados ao tratamento odontológico (Arora et al., 2019; Özveren et al., 2023).

Conforme apontado por Arora et al. (2019), tanto os pacientes quanto os profissionais já expressam uma atitude positiva sobre a Teleodontologia. De acordo com o estudo conduzido, dos 336 cirurgiões-dentistas que participaram, 86.9% alegaram que estariam dispostos a utilizar a Teleodontologia para o acompanhamento de seus pacientes. Além disso, 21,1% dos profissionais acreditam que essa modalidade poderia se tornar o novo padrão de saúde bucal. Já do ponto de vista do paciente, dos 477 que participaram, 74.5% afirmaram que a comunicação com o profissional poderia ser facilitada através de um aplicativo de Teleodontologia, enquanto 76.3% acreditam que os custos seriam reduzidos. De forma similar, a revisão sistemática conduzida por Fernández et al. (2021) sugere que a Teleodontologia, sobretudo a mediada por mensagens e aplicativos (*mHealth*), é uma ferramenta promissora para promoção e prevenção em saúde bucal.

2.3. Metodologias de desenvolvimento de aplicativos móveis

A abreviação popularmente conhecida como *app* remete à expressão inglesa *application*, que em termos simples, refere-se a um programa de *software* projetado para ser executado, principalmente, em dispositivos móveis, como smartphones e tablets (Pressman; Maxin, 2021). O uso de *apps* móveis pela população tem crescido exponencialmente, principalmente no âmbito da saúde. Aqui entra o conceito de *mHealth*, que envolve intervenções de saúde móvel, como o uso de aplicações (Vaghefi, 2019). Nesse sentido, é interessante compreender os processos que podem ser utilizados no desenvolvimento de *apps*. Assim como na pesquisa científica, várias metodologias podem ser empregadas para

desenvolver *apps*, sendo uma delas o Design Centrado no Usuário (DCU) (Lowdermilk, 2013; Norman, 2013).

O DCU foi um conceito elencado pelo professor Donald Arthur Norman, reconhecido como o pai da User Experience (UX). Essa abordagem coloca o usuário no centro do processo de desenvolvimento, levando em consideração suas necessidades, capacidades e preferências. O objetivo é criar produtos e serviços que sejam intuitivos, eficientes e agradáveis de usar, alinhados com as expectativas e demandas do usuário final (Norman, 2013). De acordo com Norman (2013), o processo de DCU é pautado em um ciclo iterativo organizado em quatros etapas, nomeadamente: 1) Observação; 2) Idealização; 3) Prototipagem e 4) Testagem.O DCU, ao ser aplicado em intervenções de *mHealth*, pode viabilizar uma compreensão mais assertiva das necessidades, preferências e preocupações dos usuários em relação às aplicações.

Essa estratégia, por sua vez, pode aumentar a adesão e a efetividade dos *apps* que serão desenvolvidos (Griffin et al., 2019; Bonet-Olivencia et al., 2024). Isso foi evidenciado no estudo conduzido por Griffin et al. (2019), no qual o DCU foi utilizado para desenvolver um *app* móvel para triagem do câncer colorretal. Os usuários foram envolvidos no processo de desenvolvimento, fornecendo opiniões que contribuíram para personalizar o aplicativo às necessidades do usuário final, resultando na maximização de sua adesão (Griffin et al., 2019). Para além do DCU, outras metodologias também podem ser utilizadas no desenvolvimento de *apps* na área da saúde, como o Design Instrucional Contextualizado (DIC) ou ainda o Ciclo de Vida de Desenvolvimento de Sistemas (CVDS) (Barra et al., 2018).

O primeiro deles, o DIC, é uma metodologia frequentemente utilizada no desenvolvimento de tecnologias destinadas ao ensino das ciências da saúde, como *apps* educacionais. Suas etapas incluem análise, design, desenvolvimento, implementação e avaliação, visando criar ferramentas que considerem o contexto específico dos usuários (Silveira et al., 2023). Já o CVDS segue uma abordagem semelhante, contemplando desde a análise até a implementação da tecnologia, dividindo-se em três categorias principais: ciclo de vida clássico, ciclo de vida em espiral e ciclo de vida de prototipagem (Barra et al., 2018). Em síntese, ao idealizar o desenvolvimento de um aplicativo voltado para *mHealth*, deve-se considerar e aplicar metodologias existentes de acordo com o escopo específico do aplicativo a ser desenvolvido. Para o aplicativo desenvolvido neste trabalho, foi escolhido o DCU devido à sua ampla aplicação em projetos na área da saúde e aos benefícios que oferece em termos de adesão e efetividade.

3. ARTIGO I

O manuscrito a seguir foi submetido e aceito para publicação no periódico "BMJ Open".

Protocol

Digital resources in the monitoring of patients with cleft lip and palate: Protocol for a scoping review

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Abstract

Introduction: Cleft lip and/or palate (CL+/-P) is a congenital malformation affecting the lip and palate, requiring long-term treatment due to potential associated complications. For this reason, it is important for the patient to be continuously monitored and followed for health promotion and prevention, as well as improving the quality of life. The aim of this scoping review protocol is, therefore, to identify and map the available evidence regarding the application of digital resources and technologies in monitoring and following up patients with CL+/-P. **Methods and Analysis:** This scoping review protocol follows the guidelines recommended by the Joanna Briggs Institute Manual, employing the PCC acronym (Patient/Concept/Context). Searches will be conducted, in May 2024, from PubMed, Wos, Scopus, Latin American and Caribbean Health Sciences Literature (LILACS), ScienceDirect, as well as gray literature indexed in ProQuest Open Access Dissertations & Theses and Google Scholar. The study will consider all types of published studies, including gray literature, in English, Portuguese, and Spanish languages, and will encompass studies regardless of publication date. Exclusions will apply to studies that do not address the use of digital resources and technologies in CL+/-P monitoring and follow-up. The study considers all types of published studies, with no language restrictions, and includes gray literature, excluding those

that don't address the use of digital resources and technologies in CL+/-P monitoring and follow-up. **Ethics and Dissemination:** As this is a scoping review, no Ethics Committee submission is required. After completion, the plan is to publish results in scientific journals on craniofacial malformations. **Study Registration:** Open Science Framework (OSF), DOI:10.17605/OSF.IO/Y6AG8.

Keywords: Digital Technology; Cleft Lip; Cleft Palate; Scoping Review.

Strengths and limitations of this study

- The scoping review will provide a comprehensive overview of digital resources for healthcare professionals to monitor patients with cleft lip and/or palate (CL+/-P).
- This scoping analysis will adhere to the guidelines of the Joanna Briggs Institute and employ the Scoping Review extension for Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-ScR), adopting a rigorous methodology.
- This scoping review will depend on the information available at the time of analysis; if precise, complete, or updated information is lacking, the review may be constrained in its scope and accuracy.

Introduction

Cleft lip and/or palate (CL+/-P) is characterized as a congenital malformation that simultaneously affects the lip and palate. Although the exact cause of the condition is unknown, there is consensus around the interaction between genetic and environmental factors as triggers of this anomaly [1]. As a congenital malformation, the diagnosis of CL+/-P can be made during the prenatal monitoring phase, through imaging exams such as ultrasound and magnetic resonance imaging. The latter, in particular, is recognized for its accuracy in the fetal diagnosis of CL+/-P [2].

On a global scale, the prevalence of cleft lip is 0.3 per 1,000 live births, cleft palate is 0.33 per live birth, and labiopalatal cleft is 0.45 per 1,000 live births [3]. Regarding treatment, the patient with this condition faces a long journey guided by a multidisciplinary team that ideally should start working during the prenatal phase [4]. In this lengthy journey, it is crucial for the team to maintain continuous monitoring and follow-up with the patient since other issues may arise as a result of the condition, such as a higher incidence of dental caries and dental anomalies [5]. Beyond dental issues, patients may experience challenges related to speech and swallowing alterations, hearing issues, nutritional deficiencies, and psychosocial problems [6].

With that in mind, it is important to map out which tools are available and can be used by the multidisciplinary team for monitoring and following up these patients. However, no literature addressing this perspective was found in the databases or record platforms. In this context, the aim of this study is to introduce a scoping review protocol in the scientific literature concerning the evidence related to digital resources and technologies, such as mobile applications or telemedicine platforms, aimed at monitoring and following up this segment of the population. This approach seeks to ensure a comprehensive analysis of the various tools used, regardless of the specific characteristics of the patients under monitoring.

Methods and Analysis

The current work is a scoping review protocol. To conduct the proposed review, we will utilize the methodological framework recommended by the Joanna Briggs Institute (JBI) Manual [7], outlining five stages for scoping reviews. Additionally, for the final study reporting, we will adhere to the PRISMA-ScR checklist for scoping review [8].

Question of the review

For the formulation of the research question, we have adopted the PCC acronym (Population, Concept, and Context), as recommended by the JBI guidelines. Thus, the following elements have been established as generators of interest for the study: *Population* (P): Patients with CL+/-P; *Concept* (C): monitoring; *Context* (C): digital resources and technologies applied to monitoring and follow-up for the improvement in the quality of life of cleft patients.
Based on this search strategy, the established research question is:

- What digital resources and technologies are being applied in the monitoring of patients with cleft lip and/or palate, and what is the impact of this approach on the quality of life of these patients?

Study Selection

To select studies, eligibility criteria aligned with the PCC acronym, as described in Table 1, will be used. Studies in English, Portuguese, and Spanish languages, regardless of the publication date, will be included.

Table 1. Eligibility criteria for studies, according to the PCC strategy used**.**

Eligibility criteria	
Population	*Inclusion*: Studies involving patients with CL+/-P, without any distinction of gender, ethnicity, or age group.
	Exclusion: Studies involving only patients with clefts that are not cleft lip and palate (non-labiopalatal).
Concept	*Inclusion*: Studies involving aspects related to the monitoring and follow-up of patients with CL+/-P.
	Exclusion: Studies that deal with monitoring and follow-up not directly related to patients with CL+/-P.
Context	*Inclusion*: Studies that address the application of digital resources and technologies in monitoring and follow-up of patients with CL+/-P.
	Exclusion: Studies that do not investigate the application of digital resources and technologies in the monitoring and follow-up of patients with CL+/-P.
Sources and Types of Studies	*Inclusion*: Published studies of any methodological design, with no language restrictions, and considering gray literature.
	Exclusion: Studies that do not address the use of digital resources and technologies in monitoring and follow-up of CL+/-P.

Search Strategy

For the review process, the search strategy will be developed in three stages: I) initial search; II) database-specific adaptations; and III) manual search, taking into account the specificities of each database. The first stage involves searching in the PubMed and Web of Science (WoS) databases using Medical Subject Headings (MeSH) descriptors to identify articles on the topic and refine the search strategy. In the second stage, considering the specific characteristics of each database, adjustments will be made to meet the objectives of each one. Finally, in the third stage, a manual search will be conducted in the reference lists of the selected articles to ensure that all relevant articles on the topic are included. Searches will be conducted in the following databases: PubMed, WoS, Scopus, Latin American and Caribbean Health Sciences Literature (LILACS), ScienceDirect, as well as in gray literature indexed in ProQuest Open Access Dissertations & Theses and Google Scholar. It is worth noting that the entire process of developing the search strategy will be supervised by a librarian to ensure its

compliance with the guidelines outlined in the JBI manual. A description of the initial search strategy is available as supplementary material for this protocol.

Data Extraction

Searches will be conducted in May 2024, on a single day, across all databases. The selected studies for the review will be exported to the reference management software EndNote Basic® (Clarivate Analytics, USA) to remove duplicates. Subsequently, the studies will be exported to the Rayyan-Intelligent Systematic Review® software (Qatar Computing Research Institute), where two blind and independent reviewers will assess and read the title and abstract. If the study aligns with the review, the full material will be read, and inclusion or exclusion of the work will be determined. In cases of disagreement, a third reviewer will be consulted for the final decision.

Analysis and presentation of data

At the end of the study selection, the data will be extracted and tabulated in an electronic spreadsheet using Google Sheets, where they will be organized and analyzed. The information to be collected is described in Table 2. Subsequently, the data will be analyzed, and the results will be presented through a descriptive narrative method. Finally, the results will be compared with relevant scientific literature.

Table 2. Information to be collected from selected studies.

Information	
Title	Study Title
Authors	Authors who participated
Publication Type	Type of publication (article, dissertation, or thesis)
Publication Year	Publication year of the study
Country	Country where the study was conducted
Objective	Study objective
Study Type	Methodological design of the study
Resources and Technologies	Digital resources and technologies applied to the monitoring and follow-up of patients with CL+/-P.

Study registration

This protocol has been registered on the Open Science Framework (OSF) - Registration (https://osf.io/) with the DOI: 10.17605/OSF.IO/Y6AG8.

Patient and Public Involvement

None.

Ethics and dissemination

As this is a scoping review, the research will not be submitted to the Research Ethics Committee. Regarding dissemination, upon completing the scoping review, the intention is to publish the results in scientific journals addressing the theme of craniofacial malformations.

Abbreviations

CL+/-P: Cleft lip and/or palate

JBI: Joanna Briggs Institute

LILACS: Latin American and Caribbean Literature in Health Sciences

MeSH: Medical Subject Headings

OSF: Open Science Framework

PCC: Population, Concept, Context

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

WoS: Web of Science

Declarations

Consent for publication

Not applicable.

Competing interests

The authors declare no conflict of interest.

Availability of data and materials

Not applicable.

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Authors' contributions

The conception of this scoping review protocol was proposed by the authors LIMC and EGOA, who were also responsible for drafting the manuscript, together with BESS. HDDM contributed to review and editing. RHWL and PRFB supervised and managed the project. All authors reviewed and approved the manuscript.

Authors' information

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4. ARTIGO II

O manuscrito a seguir será submetido para publicação no periódico "Digital Dentistry Journal".

Digital resources in the monitoring of patients with cleft lip and palate: a scoping review

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Abstract

Background: E-health, including telehealth, enhances healthcare by reducing costs and improving patient access. It is particularly beneficial for managing cleft lip and/or palate (CL±P) by facilitating remote monitoring and comprehensive care. This study investigates the digital resources and technologies used in monitoring CL±P patients and their impact on quality of life. **Methods:** A scoping review was conducted in May 2024, using databases such as PubMed, WoS, Scopus, Latin American and Caribbean Health Sciences Literature, ScienceDirect, and grey literature indexed in ProQuest Open Access Dissertations & Theses and Google Scholar. Two independent reviewers, blinded to each other's selection decisions, screened the titles and abstracts to determine which met the inclusion criteria. **Results:** Four studies published between 2017 and 2023 were included in the sample, predominantly from the United States. The digital resources and technologies utilized included telehealth for remote consultations, digital games for speech therapy, and virtual reality games for psychosocial support. **Conclusion:** Few studies focus on developing and applying digital technologies for monitoring CL±P patients. More research is needed to validate these tools and identify best practices. The current tools show promise in improving care and support for CL±P patients.

Keywords: Digital Technology; Cleft Lip; Cleft Palate; Scoping Review.

Introduction

The use of information and communication technologies in healthcare, known as e-health, has become increasingly popular.[1] This mode of care can involve the use of software and mobile devices, as well as the implementation of telehealth services, providing new possibilities for remote monitoring and treatment.[2] This approach can reduce costs for healthcare systems while enhancing the care experience for patients.[3] This is because e-health helps expand access to specialized services and reduces the time and costs associated with patients traveling to in-person appointments.[4]

The potential of e-health, especially telehealth, also extends to providing care for patients with cleft lip and/or palate (CL±P). This not only facilitates equitable access to treatment in developing countries but also promotes a more effective and comprehensive approach to managing this condition.[5] With a multifactorial etiology, clefts can affect the lip, palate, or both, occurring in approximately 1 in every 700 live births.[6-7] Patients with CLP face a lengthy treatment journey that begins in early childhood. Necessary appointments during treatment can incur direct costs ranging from US$4 to US$1,220, representing a significant financial burden for families.[8]

The treatment of CL±P is multidisciplinary and involves collaboration among physicians, dentists, nutritionists, speech therapists, and psychologists for a comprehensive patient-centered approach.[9] Due to the need for multiple appointments throughout treatment[8], implementing remote monitoring strategies can be beneficial in certain situations. This type of monitoring utilizes digital transmission of information to healthcare professionals, enhancing communication and enabling prompt and accurate adjustments to the care plan.[10] Therefore, understanding which technologies can be applied for effective patient monitoring during CLP treatment is essential.

Based on this premise, the main objective of this study was to conduct a scoping review. The aim was to investigate the current landscape of digital resources and technologies used in monitoring patients with CL±P. Specifically, the study sought to address the central research question: "What digital resources and technologies are being applied in the monitoring of patients with CL±P, and what is the impact of this approach on their quality of life?" This exploration is necessary to understand how technological advancements can potentially enhance healthcare delivery and outcomes for individuals undergoing treatment for CL±P.

Methods

To conduct the proposed scoping review, we used the methodological framework recommended by the Joanna Briggs Institute Manual[11], which outlined five stages for scoping reviews. Additionally, for the final study reporting, we adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[12] checklist for scoping reviews. The protocol by Carvalho et al.[13] was also employed in this process. The protocol used is registered with the Open Science Framework (DOI: 10.17605/OSF.IO/Y6AG8).

Research question

For the formulation of the research question, we have adopted the PCC acronym (Population, Concept and Context), as recommended by the JBI guidelines. Thus, the following elements have been established as generators of interest for the study: Population (P): Patients with CL±P; Concept (C): monitoring; Context (C): digital resources and technologies applied to monitoring and follow-up for the improvement in the quality of life of cleft patients. The established research question is:

- What digital resources and technologies are being applied in the monitoring of patients with CL±P, and what is the impact of this approach on the quality of life of these patients?

Selection criteria

- To select studies, eligibility criteria aligned with the PCC acronym, as described in Table 1, were used. Studies in English, Portuguese, and Spanish, regardless of the publication date, were included.

Table 1. Eligibility criteria for studies, according to the PCC strategy used**.**

Eligibility criteria	
Population	*Inclusion*: Studies involving patients with CL±P, without any distinction of gender, ethnicity, or age group.
	Exclusion: Studies involving only patients with clefts that are not cleft lip and palate (non-labiopalatal).
	Inclusion: Studies involving aspects related to the monitoring and follow-up of patients with CL±P.

Concept	*Exclusion*: Studies that deal with monitoring and follow-up not directly related to patients with CL±P.
Context	*Inclusion*: Studies that address the application of digital resources and technologies in monitoring and follow-up of patients with CL±P.
	Exclusion: Studies that do not investigate the application of digital resources and technologies in the monitoring and follow-up of patients with CL±P.
Sources and Types of Studies	*Inclusion*: Published studies of any methodological design, with no language restrictions, and considering gray literature.
	Exclusion: Studies that do not address the use of digital resources and technologies in monitoring and follow-up of CL±P.

Procedure

The searches were conducted in the following databases: PubMed, WoS, Scopus, Latin American and Caribbean Health Sciences Literature, ScienceDirect, as well as in grey literature indexed in ProQuest Open Access Dissertations & Theses and Google Scholar, in May 2024. For the search process, a pre-developed strategy was employed with the assistance of a librarian, as recommended by the JBI manual. The initial search returned a total of 5,444 citations. After removing duplicates, 1,032 citations remained and were imported into the Rayyan (Rayyan-Intelligent Systematic Review - Qatar Computing Research Institute) manager for title and abstract screening. Two independent reviewers, blinded to each other's selection decisions, screened the titles and abstracts to determine which met the inclusion criteria. When this screening was insufficient, the full-text articles were retrieved for a more detailed assessment to determine if they met the selection criteria. After the initial selection, 26 articles were chosen for full-text reading. Of these, 22 were conference abstracts and were therefore excluded. In the end, only 4 studies were included in the sample (Figure 1).

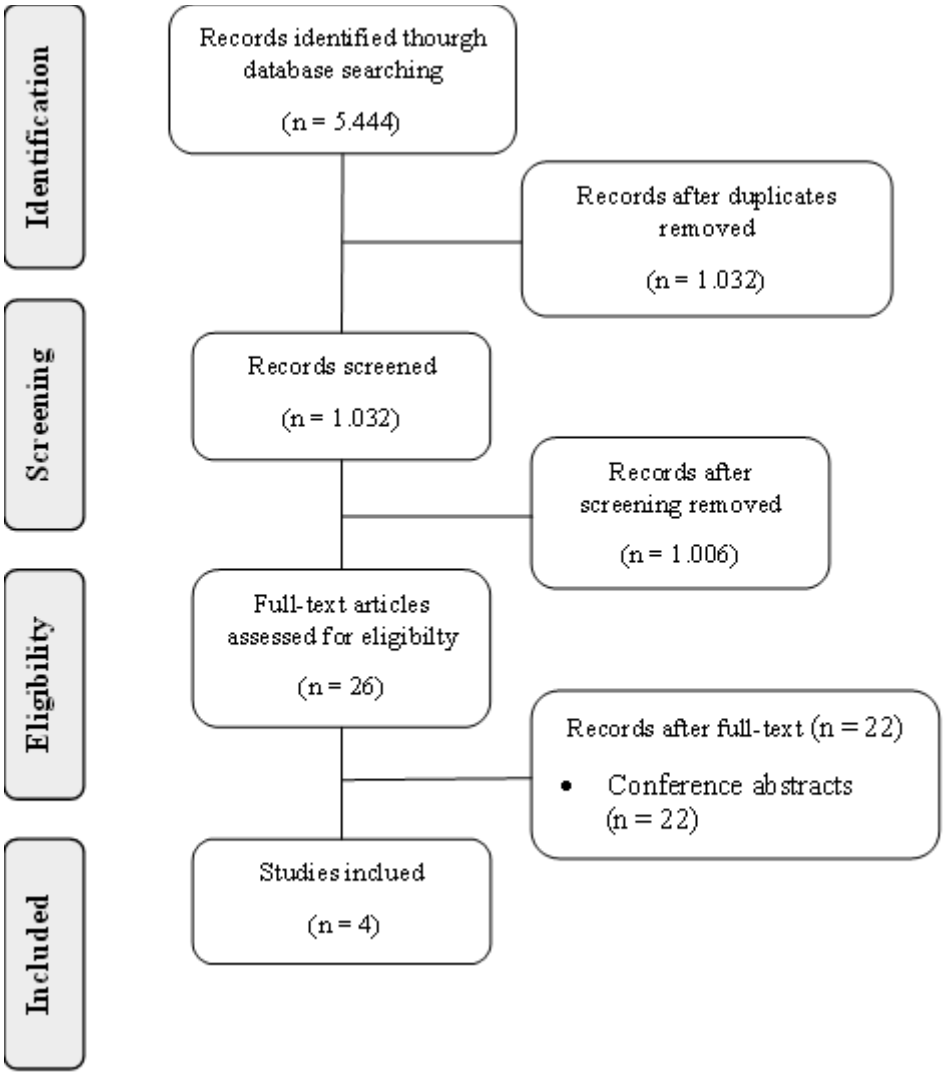

Figure 1. PRISMA flowchart of the articles included in this review.

Data extraction

For data extraction, we used an electronic spreadsheet on Google Sheets. We gathered information such as the study title, involved authors, type of publication (article, dissertation, or thesis), year of publication, country where the study was conducted, research objective, study type (methodological design), and digital resources and technologies applied to monitoring and supporting patients with CL±P.

Results

In total, 4 articles were included in the final sample of this scoping review; the collected information is described in Table 2.

Table 2. Summary table of included studies.

Title	Authors	Country	Objective	Resource
Development and evaluation of software tools for speech therapy	Rubin (2017)[14]	USA	Develop and evaluate software tools specifically for speech therapy, aiming to improve articulation and speech clarity in CL±P patients.	Virtual game
Evolution of a virtual multidisciplinary cleft and craniofacial team clinic during the COVID-19 pandemic: children's hospital Colorado experience	Andrews et al. (2021)[15]	USA	Describe the experience of developing a multidisciplinary telehealth program for the care of cleft and craniofacial patients during the COVID-19 pandemic at Children's Hospital Colorado.	Telehealth via Zoom conference
Utilizing teledentistry to manage cleft lip and palate patients in an outpatient setting	Viswanathan et al. (2022)[16]	UK	Evaluate the effectiveness of the service provided by pediatric dental consultants at the South Thames Cleft Service at Evelina Children's Hospital during the COVID-19 pandemic through virtual clinics.	Telehealth via mobile phone
Designing and evaluating a serious virtual reality game for the psychosocial support of preadolescents with orofacial cleft lip and/or palate	Thang (2023)[17]	USA	Design and evaluate a serious virtual reality game to provide psychosocial support for preadolescents with CL±P.	Virtual reality game

Studies primarily focus on the United States, with only one conducted in the United Kingdom. Two studies were articles, while the other two were postgraduate academic works, including a thesis and a dissertation. In terms of publication timeline, the first study was published in 2017, followed by subsequent years of 2021, 2022, and 2023 for the remaining studies.

The study conducted by Rubin[14] in the United States developed a software tool for speech therapy in patients with phonetic pathologies, such as those present in patients with CL±P. This experimental study included 10 children, aged 2 to 7 years, with CL±P. Additionally, 5 adults with mild to moderate intellectual disabilities also participated. The results showed that the use of specialized software can improve the articulation and communication of patients, providing an effective alternative to in-person speech therapy. In the game, players were encouraged to use their voices to say specific phrases and would progress through levels based on their phonetic improvement. Healthcare professionals could access the system to view the phrases, scores, and daily time spent by patients. Additionally, professionals could customize the game for each patient by enabling or disabling consonants, which would adjust the corresponding games and dictionaries in the system. This allowed for remote monitoring of patients' progress, providing effective teletherapy.

The experience report presented by Andrews et al.[15] in the United States, specifically at Children's Hospital Colorado, described the adaptation of a virtual multidisciplinary clinic for the treatment of cleft and craniofacial conditions during the COVID-19 pandemic. The clinical team organized consultations to ensure continuity of care, allowing up to 10 patients to be seen in a day, with the participation of various professionals through Zoom videoconferencing. Utilizing telehealth, specifically telemedicine via Zoom, the study highlighted the effectiveness of the virtual clinic in maintaining continuity of care and reducing the need for in-person visits, thereby improving treatment accessibility. In this format, parents were tasked with sending standardized photographic records of clinical and radiological images, which were then recorded in an electronic medical record, allowing professionals to monitor the health status of these children with CL±P.

One interesting aspect is that, thanks to the potential of telehealth, they were able to maintain clinical discussion meetings among team professionals where photographs sent by parents and available in the electronic medical record were analyzed. With this information already in hand, remote consultations with parents and children were conducted. The main benefits of the virtual format included ease of access for families living far away, reduced wait times between professionals, and the ability to review patient records and images in real-time. However, challenges such as lack of personal interaction, connectivity issues, and the need for interpreters were identified.[15] Continuing with the perspective of telehealth, but now in the United Kingdom at Evelina Children's Hospital, the study conducted by Viswanathan et al.[16] evaluated the use of telehealth to manage CL±P patients in an outpatient setting.

The idea was to implement a triage system using the RAG (Red, Amber, Green) scale, which helped classify the urgency of required care. Initially, 215 patients were contacted by phone, with a response rate of 97% (208 patients). Patients were scheduled for a "telephone clinic" and received text message reminders about their appointments. This approach allowed healthcare professionals to conduct assessments and offer support without the need for in-person visits, remotely monitoring these patients. During the consultations, 88% (n = 189) of the patients did not require urgent in-person consultations, while 9% (n = 20) required elective treatment necessitating an in-person visit, and only 3% (n = 6) needed urgent care. It was observed that virtual consultations were effective in providing advice and reassurance to patients, especially those requiring ongoing care, such as those with associated syndromes.[16]

The article also highlights the challenges faced, such as the difficulty of contacting some patients and the lack of personal interaction, which is important for building a relationship with families. Despite these limitations, the "telephone clinics" proved to be an effective solution during the pandemic, allowing care to continue safely. The conclusion emphasizes the importance of maintaining this model as a complement to in-person visits in the future. [15] On the other hand, the study by Thang et al.[17] designed and evaluated a virtual reality game aimed at providing psychosocial support for adolescents and pre-adolescents with CL±P. With a psychological focus, the game was designed for children aged 11 to 15, a critical period of psychosocial development. The game's development was based on thematic analysis of interviews with pre-adolescent and adolescent patients with cleft lip and palate, as well as interviews with experienced psychologists in the field. [17]

The game's storyline revolves around a superhero and their pet, the "Super Pet Pal," who guides the patient on a journey to help others using skills that the patient already possesses and can further develop. The game features a mirror tool that allows patients to view their skills and progress, fostering self-recognition and self-esteem. In summary, the game combines an engaging narrative with multiplayer features to create an educational and interactive experience. It helps patients with CL±P develop social and emotional skills while interacting in real time with psychologists and other players. Additionally, psychologists can monitor the psychological conditions of patients during gameplay, as they play simultaneously with up to two patients and can intervene in the game when necessary. The experimental study demonstrated that virtual reality games can enhance patients' psychosocial well-being by helping them address the emotional challenges associated with their condition. [17]

Regarding the impact on quality of life, the studies included in the review address this issue indirectly, highlighting the positive impact of digital technologies and telehealth on the treatment and monitoring of patients with CL±P. The implementation of virtual multidisciplinary clinics, as described by Andrews et al. [15], ensured the continuity of care during the COVID-19 pandemic, reducing the need for frequent travel and facilitating access to specialized treatment, which can decrease stress and anxiety for families. Rubin's[14] study on the use of a virtual game for speech therapy showed that digital tools can improve patients' phonetic articulation and communication, providing essential treatment for their social integration. Additionally, the virtual reality game developed by Thang[17] can provide psychosocial support, helping to improve the emotional well-being of adolescents and pre-adolescents with CL±P. Finally, the teledentistry studied by Viswanathan et al.[16] enabled effective triage and continuous support, enhancing the provision of care and offering peace of mind to patients and their families. Thus, although the studies do not directly address quality of life, it is evident that digital resources and technologies have the potential to improve various aspects of these patients' lives, from access to care to emotional and social support.

Discussion

The results of this scoping review highlight the application of digital resources and technologies in the management of patients with CL±P. Although the number of included studies is limited, the existing evidence demonstrates the potential of these approaches to improve the quality and access to care for these patients. Scientific literature already confirms that the telehealth modality can be as effective as, and in some cases even superior to, traditional in-person care without compromising the quality of service provided.[18] However, according to Stozen and Sratman[19], some challenges in implementing this modality include the lack or instability of internet connection, especially in remote and rural areas. This limitation was also observed in studies by Andrews et al.[15] and Viswanathan et al.[16]., where connectivity instability emerged as an obstacle to telehealth. These findings collectively suggest that the effective implementation of telehealth practices depends on adequate internet infrastructure and mobile network coverage.

Another issue highlighted in both Viswanath's[16] and Andrews'[15] studies is the need for interpreters for teleconsultations when patients speak a different language than the professionals. This issue of linguistic disparity was also observed by Gallegos-Rejas et al.[20] in his cross-sectional study in Australia, where the population with limited English proficiency is

about 66% less likely to use telehealth services than those proficient in English. Given this, to ensure that patients are properly understood, even with the presence of interpreters, it is necessary for professionals to be prepared to handle different linguistic and cultural contexts. Additionally, they must be able to communicate effectively with interpreters during consultations to ensure clear and precise communication with the patient. According to Guizado de Nathan, Shaw and Doolen[21], this preparation for virtual communication should begin during undergraduate education so that professionals know how to manage interpreter-mediated consultations.

Regarding the software, while Rubin's[14] game focuses on enhancing phonetic articulation through a playful and interactive approach, the game developed by Thang[17] aims to provide psychosocial support, helping patients cope with the emotional and social challenges associated with CL±P. Both authors affirm the potential of virtual games to complement and enrich traditional treatments, offering benefits that extend beyond conventional approaches. Kim et al.'s[22] study supports the use of games in speech therapy. With 13 children treated for 8 weeks using Smart Speech, improvements in voice and articulation parameters were observed, suggesting that the game may be an effective therapeutic alternative. Additionally, the systematic review conducted by Zayeni, Raynaud and Revet[23] highlighted that games and video games can be valuable therapeutic resources in child and adolescent psychotherapy and psychiatry. In summary, the digital resources and technologies available for monitoring patients with CL±P are still limited and require more thorough investigation. The limitations of this study include the small number of reviewed articles, the diversity of methods used, and the lack of solid information on the long-term effectiveness of these technologies.

Conclusion

It can be concluded that there are still few studies focused on the development and application of digital technologies for monitoring this specific population. The field of telemonitoring for patients with CL±P is still in its early stages and presents a vast area to be explored. The development of new technologies and further research are necessary to validate the effectiveness of these tools and to identify best practices for their implementation. Therefore, while the tools presented here are promising, there is a clear need for more studies to explore and expand the use of digital resources and technologies in monitoring and caring for patients with CL±P, with the aim of further improving the care provided to this population.

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5. ARTIGO III

O manuscrito a seguir foi submetido e aceito para publicação no periódico "The Cleft Palate Craniofacial Journal".

Original Research

TeleCleft: Development and evaluation of a mobile application for monitoring cleft patients

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Running Title: TeleCleft: Mobile App for Cleft Patient Monitoring.

TeleCleft: Development and evaluation of a mobile application for monitoring cleft patients

Abstract

Objective: Development and evaluation of a mobile application for remote monitoring and guidance of pediatric patients diagnosed with cleft lip and/or palate (CL±P) and their caregivers.

Design: This is a pilot cross-sectional, applied, and quantitative study.

Setting: The study was conducted in two tertiary care treatment centers in Brazil.

Participants: The participants included 20 caregivers and infants undergoing treatment with nasoalveolar molding (NAM) for CL±P.

Interventions: The intervention involved using the TeleCleft mobile application for remote monitoring and guidance of caregivers and infants during NAM treatment.

Main Outcome Measure(s): The main outcome measures included usability and satisfaction of users with the *TeleCleft* application.

Results: The results showed high usability and satisfaction ratings among users of the TeleCleft application. Most participants found remote monitoring to be effective and expressed positive opinions about its convenience and usefulness.

Conclusion: *TeleCleft* could be a viable tool for remote monitoring and guidance, reducing the need for patients and caregivers to travel to treatment centers, which could potentially alleviate the burden of care faced by families during the journey of CL±P treatment.

Keywords: cleft lip and palate, mobile applications, nasoalveolar molding.

Introduction

Cleft lip and/or palate (CL±P) is a congenital craniofacial anomaly that can affect the lips and/or palate, affecting approximately 1:700 live births globally.[1] Despite its frequency, the etiopathogenesis of the condition is uncertain, as multiple factors, both genetic and environmental, may converge in the development of the cleft.[2] Regarding diagnosis, CL±P can be identified even in the intrauterine phase through imaging exams such as ultrasounds and magnetic resonance imaging.[3] As for the consequences for the baby, CL±P can have impacts beyond appearance, causing psychosocial impairments such as social isolation starting from childhood.[4]

The treatment of CL±P can be complex and begins with the diagnosis of the baby. When this diagnosis occurs early, one of the intervention options is the use of orthopedics as part of pre-surgical therapy.[5] In this context, specific techniques can be employed, such as presurgical nasoalveolar molding (NAM), aiming to bring the edges of the cleft closer together, reducing the gap between them, to facilitating the union of these segments during corrective surgeries.[6] Furthermore, by reducing the severity of the deformity, this approach not only contributes to more aesthetically pleasing surgical outcomes and reduces the need for additional surgical interventions, but also alleviates the burden of care for patients with CL±P.[7]

Despite the numerous benefits of NAM, it is important to be aware of the potential complications that can arise in both soft and hard tissues. In the case of soft tissues, it is common to experience irritations, ulcerations and bleeding in the gums, face or nasal region.[8] Additionally, there is a risk of opportunistic infections, such as candidiasis.[9] On the other hand, in hard tissues, complications may include premature eruption of dental elements and misalignment of alveolar segments. Other complications to consider are related to care, such as improper use and intolerance to the device.[8]

To avoid potential complications and ensure proper management of NAM, more frequent visits to treatment centers may be necessary.[10] However, increased visits to centers may result in additional costs for families, potentially affecting treatment adherence, and increasing the burden of care for cleft lip and palate. Additionally, it is important to provide support to caregivers during the pre-surgical period, as initiating treatment for the baby with the nasal molding device is associated with a significant emotional burden, including anxiety stemming from the discovery of the cleft lip and palate and the responsibility of caring for a child with this condition.[11,12] Thus, the purpose of this pilot study was to develop a monitoring application for patients undergoing NAM treatment, capable of remotely guiding their

caregivers. In addition to app development, the goal was also to assess user usability and satisfaction with this tool.

Methods

This is a pilot cross-sectional, applied, and quantitative study focused on the development and evaluation of a mobile application for remote monitoring and guidance of pediatric patients diagnosed with CL±P and their caregivers. This study was approved by the local Research Ethics Committee (5.996.381). The sample selection for the study was conducted using an accessible sample approach, consisting of infants with CL±P and their caregivers attending two treatment centers. Inclusion criteria comprised patients diagnosed with CL±P who were initiating or already undergoing NAM treatment. Regarding restrictions, individuals without internet access and without a smartphone with a camera compatible with Android or iOS operating systems were excluded from the sample. In total, 20 caregivers, including their babies, agreed to participate in the study.

Application Development

The application was developed following the principles of User-Centered Design (UCD), a creation method conceived by Professor Donald Arthur Norman, recognized as the father of User Experience (UX). The method advocates for the needs and capabilities of the user, following four fundamental steps integrated into a continuous and iterative flow for development, namely: I) Observation; II) Idealization; III) Prototyping, and IV) Testing (Norman, 2013).

I) Observation

The initial phase, observation, entails identifying the problem that needs to be addressed.[13] Improper use of the nasoalveolar appliance can lead to complications, therefore, patients using NAM should be periodically monitored, requiring frequent visits to healthcare centers. However, these visits can increase the burden of care for the caregivers without sufficient resources to cover transportation costs, especially when they reside in remote areas. Linked to this is the need for closer support for caregivers, as they play a fundamental role in the success of the treatment.[8] In this context, two issues have been identified: 1) The need for

regular monitoring of NAM in infants and 2) The need for guidance and support for caregivers. Furthermore, the main concern has become: How can we ensure that patients and their families are periodically assisted without incurring costs and unnecessary visits to healthcare centers?

II) Idealization

Given the problem identified in the previous stage, it was necessary to devise a solution. This solution was grounded in the application of teledentistry, regulated by Resolution 226/2020 of the Federal Council of Dentistry, which authorizes remote monitoring and guidance modalities in Brazil.[14] Based on this context, the proposal to develop a dedicated mobile application for monitoring and guidance emerged. For monitoring, the approach would include weekly photographic records of the baby's face (frontal and subnasal) and data collection through a descriptive questionnaire. The images captured and the responses submitted by the application would be made available to service professionals, who would assume responsibility for evaluating and monitoring the use of the device.

The professionals would have access to a restricted tab where they would receive photos and information provided by the caregivers. After analyzing the photographic records and responses, they would assess the position of the molding hook to ensure correct placement. They would also check the pressure of the elastic splint to determine its adequacy. Additionally, they would review the duration of device usage and whether it was removed at any time. Any difficulties reported by caregivers during the week, as well as the presence of complications such as soft tissue lesions, would also be evaluated. Following this assessment, the professionals would provide feedback on the treatment progress via the application. They could suggest improvements, including sending photos of the baby to demonstrate the correct position of the device, which would help caregivers achieve the ideal placement. As for guidance, this would be conducted through proprietary videos embedded in the application, addressing relevant issues related to the use of the NAM in CL±P.

III) Prototyping

According to Norman (2013)[13], the prototyping stage involves creating an initial mockup of the envisioned solution, essentially a sketch of what the final product could become. For this purpose, a preliminary layout of the application was designed using Balsamiq® (Balsamiq Studios, LLC) (Figure 1).

Figure 1. Preliminary application layout.

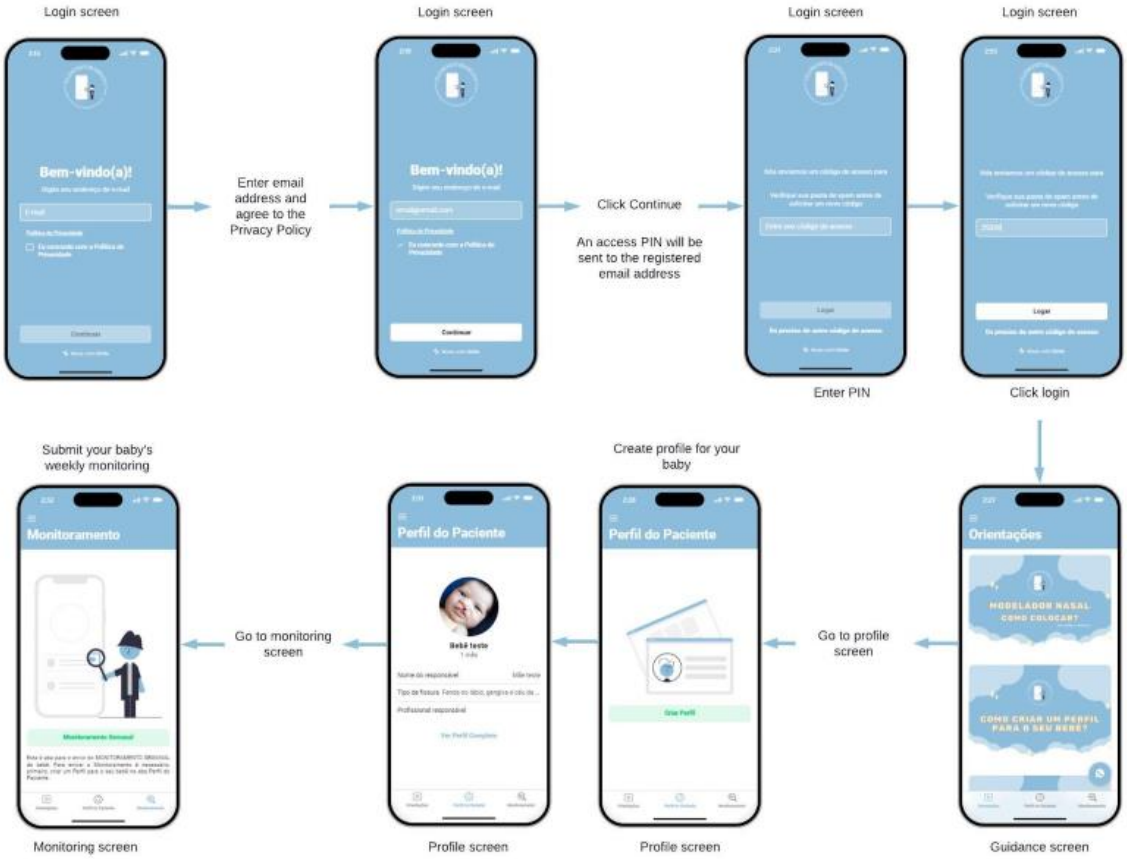
The proposal was for the application to have interchangeable tabs for profile options, guidance, and monitoring. In the guidance tab, videos on the use of NAM in CL±P would be available, while in the monitoring tab, users could submit photographic records and completed questionnaires. In the application, it would also be feasible for the responsible professionals to access the submitted monitorings through a restricted access tab and provide feedback, which the patients would receive via the application. In addition to the initial mockup, the user flow in the application was also defined (Figure 2). The user flow begins with the registration of the caregiver in the application, followed by the creation of a profile for the patient, where the following initial information is recorded: patient's name, date of birth, type of cleft, date of arrival at the service, date of starting NAM, age at starting NAM (in months and days), initial weight, and caregiver's name. After the mockup creation and defining the user flow, the next step was to materialize the proposed idea, for which the Glide™ platform was used.

IV) Testing

For testing, immediately after completing the prototype (Figure 2), scenarios of the application's usage were staged at the Digital Dentistry Laboratory to assess and correct any potential application errors. Two members of the laboratory assumed different roles, with one acting as a caregiver and the other as a professional, to simulate tool usage. The caregiver was responsible for registering her baby and submitting monitoring, while the professional provided feedback in response to this interaction. These processes, both registration and submission,

were repeated several times, resulting in the identification of some errors, which were promptly addressed.

Figure 2. Application prototype with user flow.



Application Evaluation

To assess the application, an online questionnaire was used, divided into three sections. Each section addressed a specific topic: the first collected user profile data, the second focused on usability, and the third addressed user satisfaction. The questionnaire was structured on JotForms, and the link was sent to the 20 participating caregivers via WhatsApp, inviting them to respond.

I) User Profile

To deepen the understanding of the application users' profiles, information was collected through a questionnaire covering various aspects. The caregivers, who were the users, provided

data such as gender, age, bond with the baby, family income, education level, city of residence, internet access, and device operating system. As for the babies, information regarding gender, age, and type of cleft was collected.

II) Usability and Satisfaction

For this purpose, the System Usability Scale (SUS) was employed, proposed in 1986 by John Brooke, which assesses the usability of technology systems. SUS is considered one of the primary instruments for evaluating usability in healthcare applications, considering the ease and speed of questionnaire administration, prompting its widespread adoption by the scientific community.[15,16] This scale is structured as a 10-item questionnaire, where the user rates each point on a scale ranging from 1 (totally disagree) to 5 (totally agree). Following the evaluation, scores are calculated, yielding a single value ranging from 0 to 100, with scores below 68 considered unsatisfactory.[15,16] The interpretation of the scores assigned on the SUS scale was also assessed using the Curved Grading Scale (CGS) approach, which classifies usability as follows: A+ (84.1–100), A (80.8–84.0), A- (78.9–80.7), B+ (77.2–78.8), B (74.1–77.1), B- (72.6–74.0), C+ (71.1–72.5), C (65.0–71.0), C- (62.7–64.9), D (51.7–62.6) and F (0.0–51.6).[17] Furthermore, user satisfaction was also evaluated, as it is a fundamental quality indicator in the assessment process of a healthcare service.[18] Specifically, an optional field in the satisfaction section was left open for users to express their opinions about the application.

Data Analysis

The data collected through the questionnaires were exported from JotForms, and subsequently, only the quantitative data were imported into the statistical analysis software Jamovi® (version 2.3.28). In Jamovi, a descriptive statistical analysis was conducted, calculating relative and percentage frequencies of the obtained data. For the analysis of qualitative data related to the field of suggestions and/or complaints, an approach to the thematic analysis technique proposed by Bardin (2016)[19] was used.

Results

After all development phases, the final version of the application, named *TeleCleft*, was made available to caregivers for use. A total of 20 users, and consequently, 20 babies, participated in this study.

User Profile

Among the 20 caregivers, 18 (90%) were female, with an average age of 29.3 years. The majority of caregivers assumed the role of mother (n = 18; 90%) to the babies. Regarding income, 8 (40%) had a family income between 1 and 2 minimum wages, while 7 (35%) had completed college and 6 (30%) had completed high school. The majority of participants resided in the state of São Paulo (n = 13; 65%), and all had internet access, mostly using the Android operating system (n = 16; 80%). The average distance from the users' municipality of residence to the cities where the treatment centers were located was 55,72 kilometers. Among the registered babies, 14 (70%) were male, with an approximate average age of 23 days at the start of NAM treatment, predominantly presenting unilateral cleft lip and palate (14; 70%) (Table 1).

Table 1. User profile.

Variable	n (%)
Caregiver's Gender	
Male	2 (10)
Female	18 (90)
Baby's Gender	
Male	14 (70)
Female	6 (30)
Caregiver's Age	
< 30 years old	13 (75)
≥ 30 years old	7 (35)
Baby's Age	
< 1 month	15 (75)
≥ 1 month	5 (25)
Family Income	
No income	1 (10)
Less than 1 minimum wage	5 (25)
1 to 2 minimum wages	8 (40)
More than 2 minimum wages	5 (25)
Family Bond	
Mother	18 (90)
Father	2 (10)
Education Level	
Incomplete elementary education	1 (5)
Complete elementary education	0 (0)
Incomplete high school education	3 (15)
Complete high school education	7 (35)

Incomplete higher education	3 (15)
Complete higher education	6 (30)
State of Residence	
Paraíba	7 (35)
São Paulo	13 (65)
Internet Acess	
Yes	20 (100)
No	0 (0)
Operational System	
Android	16 (80)
iOS	4 (20)

Note: The minimum wage at the time of data collection was just over $200 USD.

Usability and Satisfaction Assessment

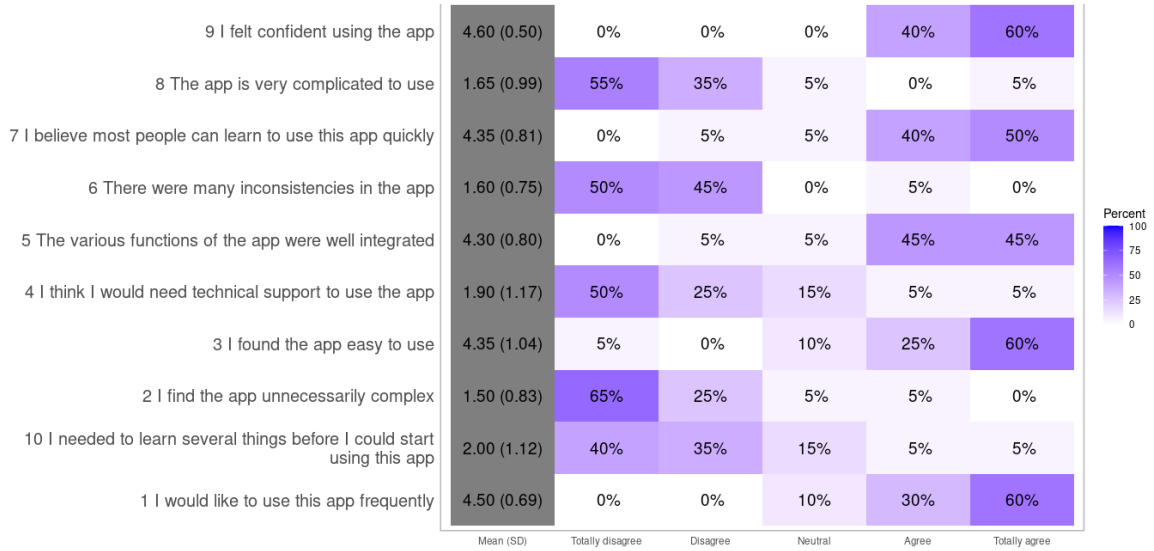
Regarding overall usability, according to the SUS scale[15], users rated the application with an average of 83.63, and based on the CGS approach[17], it was classified as "A", indicating a satisfactory level of usability (Table 2).

Table 2. Distribution of users according to the System Usability Scale.

Attribute	N	Mean	Standard Deviation	Minimum	Maximum	CGS
Satisfied	18	86.9	10.2	72.5	100	A+
Dissatisfied	2	53.8	12.4	45	65.5	D

In Figure 3, each item comprising the SUS[15] is presented, demonstrating alternation between positive aspects (odd-numbered items) and negative aspects (even-numbered items). It was observed that regarding the positive aspects, the majority of users expressed agreement.

Figure 3. Usability according to SUS criteria[15].



Regarding satisfaction, 16 (80%) users reported being satisfied with the application, while only 2 (10%) mentioned experiencing some difficulty in its use. The level of difficulty in using the application was low, with 9 (45%) users rating it as "easy" and 7 (35%) as "very easy." Concerning utility, all caregivers claimed that the tool was indeed useful during the treatment with NAM. Approximately 90% managed to submit their monitoring data easily, and all considered that the instructional videos provided were sufficient to clarify their doubts. Moreover, 65% of users reported a reduction in the number of face-to-face appointments and, consequently, in financial costs. Similarly, 65% of users believe that remote monitoring can be equivalent to an in-person appointment. Finally, the average likelihood of caregivers recommending the tool, on a scale from 0 to 10, was 9.65.

Another aspect evaluated was users' opinions about the application. In an optional open space, users were able to share their opinions, both positive and suggestions. Among the 20 participants, 10 provided some type of opinion. Among the opinions, 7 were positive and 3 were suggestions and/or complaints about the tool. Regarding positive reviews, users 1, 2, 16, and 20 highlighted the ease, usefulness and suitability, confirming the potential of the application for what it proposes. User 18, on the other hand, reports the usefulness of the tool in reducing trips to the treatment center, in addition to expressing the desire for the application to be used continuously, even after the completion of NAM. This indicates an expectation of continuity of support and care offered through the tool (Table 4).

Regarding suggestions, user 14 suggested that data could be edited after registration, which is indeed a pertinent idea and has been implemented in the application. Another suggestion, this time from user 19, was to improve the clarity of the monitoring process in the

application. He suggests that the necessary information to fill out the weekly monitoring should already be available when entering the corresponding screen, avoiding the need to press another button. This suggestion can enhance usability by making the process more intuitive and efficient. From another perspective, user 16 brings up a limitation in the application's functionality, specifically related to compatibility with different mobile systems. This suggests an area for improvement to ensure that all users can access the application's features, regardless of the device they are using (Table 3).

Table 3. Users' opinions about the application.

Positive evaluations	*Easy and useful application.* ***User 1***
	Everything's okay for me. ***User 2***
	The application was very helpful in answering questions and monitoring my child's treatment. I just thank you for the care and affection. ***User 8***
	The app is great. ***User 9***
	I have nothing to complain about the app, very useful. Congratulations to everyone involved! ***User 16***
	I have no complaints, just gratitude to the entire team that developed the application, because as I live 150 km away from the care center, it was very useful for me, reducing the trips to the center. I wish it could also be used after surgeries in some way. ***User 18***
	Excellent. ***User 20***
Suggestions	*It would be great to be able to edit the registration data after accessing it.* ***User 14***
	The application doesn't open the option to send photos on all cellphone systems. ***User 16***

	I think the monitoring part could be clearer. Without needing to press the button to enter the weekly monitoring, when you enter the tab, all the information to fill out is already there. ***User 19***

Discussion

This pilot study describes the development of the *TeleCleft* mobile application, designed to remotely monitor and guide caregivers and infants undergoing NAM treatment. In addition to tool development, the study focused on evaluating user usability and satisfaction. The *TeleCleft* was conceptualized using UCD, as advocated by Norman (2013).[13] Under this user-centered perspective, the overall usability of the application was considered high, with an average score of 83.63 and an "A" rating on the CGS scale. These results suggest that the developed application may apply to the proposed context, as the concept of usability is directly related to the ease with which users interact with the system, without encountering significant difficulties.[20]

Additionally, it is important to measure the usability parameters of a system, as according to the International Organization for Standardization (ISO - 9126)[21] standard. This is an indispensable requirement to ensure the quality of software, and *TeleCleft* meets this requirement. The overall satisfaction of users with the application was also positive, as reported by 80% of users. Another positive aspect is that, on a scale of 0 to 10, the average rating of the application was 9.65. In other words, the likelihood of a user recommending TeleCleft to another person is high. This is in line with the probability theory of recommendation proposed by Reichheld (2003)[22], which introduces the Net Promoter Score (NPS), which, based on a single question, evaluates whether the user would recommend the service to another person.

Despite achieving successful usability and satisfaction scores, some users provided feedback regarding potential improvements to be made in the application. One suggestion mentioned the possibility of editing information after registering the baby, which was considered relevant and suitable for implementation in the application. Another user noted that the monitoring process could be clearer, a suggestion that may be considered for future enhancements. Additionally, another feedback pointed out that the application did not offer the option to select photos on all devices, which could be a technical limitation or a flaw in the

implementation of the tool. These results suggest improvements and corrections that will be addressed and implemented in *TeleCleft*.

In terms of monitoring, the majority of users reported that remote monitoring through the application can be equivalent to an in-person consultation. This positive perception of remote interface has been observed in other studies as well. For example, in a study conducted by Dalessandri (2021)[23], the perception of orthodontists and patients regarding orthodontic telemonitoring using Dental Monitoring™ software was analyzed, revealing that 97.5% of patients positively evaluated this approach. Similarly, in the study conducted by Homsi (2023)[24], it was observed that participants showed good acceptance of orthodontic telemonitoring, conducted during the COVID-19 pandemic. Taken together, these findings suggest that telemonitoring is a modality accepted by users and can be utilized.

Another aspect noticed by users was the reduction in the number of in-person visits and, consequently, in the financial expenses associated with traveling to treatment centers. This reduction not only pertains to travel costs but may also impact the burden of care for caregivers. The term "burden of care" relates to how much the patient and their family sacrifice in terms of time and quality of life during treatment.[25] In the case of CL±P treatment, especially during NAM, the burden of care can be significant, particularly in physical terms, considering the number of appointments, distance traveled, and associated costs.[12] With the reduction in the number of appointments and visits to centers, as reported by users of the application, it is conceivable that this burden of care is diminished when using *TeleCleft*.

Finally, this study has some limitations, such as the small sample size, which may affect the generalization of the results. Additionally, the study may have been susceptible to selection bias, as participants were selected from only two treatment centers in Brazil. These limitations should be taken into account when interpreting the results and applying the conclusions of this study in other contexts. In future scenarios, it is estimated to expand the sample size, incorporate the suggested improvements, and extend the implementation of *TeleCleft* to other treatment centers. This will allow us to obtain a more comprehensive understanding of the usability of the application in other settings, as well as to confirm the results.

Conclusion

TeleCleft could be a viable tool for remote monitoring and guidance, reducing the need for patients and caregivers to travel to treatment centers, which could potentially alleviate the burden of care faced by families during the journey of CL±P treatment. Furthermore, they showed a positive perception of remote monitoring. Despite suggestions for improvement, the application has already proven to be effective and useful, indicating its potential to optimize care for patients and families during NAM treatment.

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6. CONSIDERAÇÕES FINAIS

A revisão de escopo desenvolvida evidencia que os recursos e tecnologias digitais aplicados ao monitoramento remoto de pacientes com FL±P são escassos, destacando a necessidade de mais pesquisas de desenvolvimento e avaliação desses recursos. Nesse contexto, o *TeleCleft* surge como uma solução promissora. Através do telemonitoramento e da teleorientação, viabilizados pelo *TeleCleft*, foi possível oferecer um acompanhamento mais próximo e personalizado durante o tratamento ortopédico pré-cirúrgico com a MNA. O desenvolvimento do aplicativo, guiado pela metodologia do DCU, demonstrou ser eficaz na criação de uma ferramenta acessível e amigável, como evidenciado pela alta pontuação obtida na SUS e pela satisfação relatada pelos cuidadores que utilizaram o *app*. Esses resultados destacam a importância de considerar as necessidades e experiências dos usuários ao projetar soluções tecnológicas para a área da saúde. Em resumo, este estudo não somente evidencia o potencial da Teleodontologia, mas também destaca a importância de abordagens tecnológicas inovadoras para melhorar o cuidado à saúde dos pacientes com FL±P e seus cuidadores.

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APÊNDICE I - Termo de Consentimento Livre e Esclarecido (TCLE).

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO (TCLE)

Este é um convite para o (a) Sr. (a) e seu (sua) filho(a) participarem da pesquisa "DESENVOLVIMENTO E AVALIAÇÃO DE APLICATIVO MÓVEL PARA TELEMONITORAMENTO DE PACIENTES FISSURADOS", sob responsabilidade da Cirurgiã-dentista (CD) Livian Isabel de Medeiros Carvalho. Esta pesquisa busca desenvolver e avaliar um aplicativo para monitoramento e orientação, à distância, dos pacientes fissurados que irão iniciar o tratamento com o modelador nasal e seus respectivos responsáveis legais.

A pesquisa tem como objetivo desenvolver e avaliar um aplicativo voltado para o telemonitoramento e teleorientação dos pacientes pediátricos com fissura lábio palatina que irão iniciar o tratamento com o modelador nasal, bem como seus responsáveis legais. O aplicativo será desenvolvido para smartphones (celulares) compatíveis com o sistema operacional Android. No aplicativo estarão disponíveis vídeos de orientação para o responsável sobre o uso do modelador nasal na fissura lábio palatina, além de tarefas para o monitoramento do bebê. As tarefas de monitoramento deverão ser feitas semanalmente e incluem: 1) registros fotográficos do rosto do bebê (frontal e subnasal) e 2) resolução de questionário. A partir do envio das tarefas, os consultores do aplicativo irão enviar um feedback a respeito do uso do modelador.

Para avaliação do aplicativo, será aplicado um questionário online sobre a usabilidade, a sua satisfação e o seu grau de dificuldade em utilizar o aplicativo. Tendo em vista que esta pesquisa é pautada no desenvolvimento e avaliação de um aplicativo em ambiente virtual, os riscos inerentes à participação no estudo não implicará grandes transtornos. Porém, este tipo de pesquisa poderá trazer alguns riscos, a saber: exposição de dados e informações confidenciais em meio digital, no entanto, todas as medidas preventivas de segurança virtual serão adotadas para evitar esse transtorno. Além disso, você estará assegurado pela Lei Geral de Proteção de Dados (LGPD), que rege sobre o tratamento de dados pessoais em meio digital. Vale destacar que suas identidades serão resguardadas e mantidas em sigilo.

Os benefícios da pesquisa serão diretos e indiretos, visto que, os participantes serão favorecidos pela possibilidade de serem monitorados e orientados, à distância, pelo aplicativo. Dessa forma, minimizando o número de consultas presenciais e, por consequência, os gastos envolvidos no deslocamento. Do mesmo modo, as informações prestadas por você poderão promover melhorias significativas para o aplicativo desenvolvido. Durante todo o período da pesquisa você poderá tirar dúvidas ligando para Livian Isabel de Medeiros Carvalho, no Curso

de Pós-graduação em Odontologia da Universidade Federal da Paraíba (UFPB), no endereço Campus I Loteamento Cidade Universitária, João Pessoa - PB, CEP: 58051-900, pelo telefone (83) 99305-8986 ou e- mail: isabel.livian@hotmail.com.

A participação é voluntária, o que significa que você poderá desistir a qualquer momento, retirando seu consentimento, sem que isso lhe traga nenhum prejuízo ou penalidade. Todas as informações obtidas serão sigilosas e seus nomes não serão identificados em nenhum momento. Os dados serão guardados em local seguro e a divulgação dos resultados em congressos ou publicações científicas será feita de forma a não identificar os voluntários. Os dados coletados serão arquivados pelo pesquisador responsável por essa pesquisa em local seguro e por um período de 5 anos. Se você tiver algum gasto que seja devido à sua participação na pesquisa, você será ressarcido, caso solicite. Em qualquer momento, se você sofrer algum dano comprovadamente decorrente desta pesquisa, você terá direito a indenização.

Toda e qualquer dúvida a respeito dos aspectos éticos da pesquisa poderá ser questionada ao Comitê de Ética em Pesquisa do Hospital Universitário Lauro Wanderley (HULW), no endereço Rua Tabelião Estanislau Eloy, 585 - Castelo Branco, João Pessoa - PB, CEP: 58050-585, no 2º andar do HULW, pelo telefone (83) 3206-0754 ou pelo e- mail: cep.hulw@ebserh.gov.br. Este documento será disponibilizado em duas vias e você ficará com uma cópia deste Termo e a outra com os responsáveis pela pesquisa.

CONSENTIMENTO LIVRE E ESCLARECIDO

Após ter sido esclarecido sobre os objetivos, importância e o modo como os dados serão coletados nesta pesquisa, além de conhecer os riscos, desconfortos e benefícios e ter ficado ciente de todos os direitos:

Eu_____, portador do RG Nº_____, concordo em participar voluntariamente da pesquisa "DESENVOLVIMENTO E AVALIAÇÃO DE APLICATIVO MÓVEL PARA TELEMONITORAMENTO DE PACIENTES FISSURADOS" e autorizo a divulgação das informações que serão fornecidas em congressos e/ou publicações científicas desde que nenhuma informação possa me identificar. Concordo também, voluntariamente, com a participação do meu filho(o) ou filha(a)_____, nessa pesquisa.

João Pessoa - Paraíba, ___/___/_____

Assinatura Participante

Assinatura do Pesquisador

APÊNDICE II - Questionário para avaliação de usabilidade e satisfação do *TeleCleft*.

Dados Sociodemográficos

Centro de Tratamento

( ) Hospital Municipal Menino Jesus

( ) Serviço de Fissurados do Hospital Universitário Lauro Wanderley

Cidade de Residência:_____

Idade: _____ Sexo: ( ) Feminino ( ) Masculino

Vínculo: ( ) Mãe ( ) Pai ( ) Avós ( ) Outros

Sexo do bebê: ( ) Feminino ( ) Masculino

Idade do bebê: ( ) Feminino ( ) Masculino

Parte I – Usabilidade (System Usability Scale - SUS)

1. Eu gostaria de usar esse aplicativo frequentemente

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

2. Eu acho o aplicativo é desnecessariamente complexo

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

3. Eu achei o aplicativo fácil de usar

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

4. Eu acho que precisaria de ajuda de um suporte técnico para usar o aplicativo

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

5. As várias funções do aplicativo estavam bem integradas?

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

6. Havia muitas inconsistências no aplicativo

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

7. Acredito que a maioria das pessoas possa aprender a usar esse aplicativo rapidamente

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

8. O aplicativo é muito complicado de usar

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

9. Me senti confiante em utilizar o aplicativo

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

10. Precisei aprender várias coisas antes que eu pudesse começar a usar esse aplicativo

( ) Discordo totalmente ( ) Discordo ( ) Neutro ( ) Concordo ( ) Concordo totalmente

Parte II – Satisfação do Usuário

No geral, o quanto você está satisfeito com o aplicativo?

( ) Muito insatisfeito ( ) Insatisfeito ( ) Neutro ( ) Satisfeito ( ) Muito satisfeito

Você sentiu dificuldade em utilizar o aplicativo?

( ) Sim ( ) Não ( ) Parcialmente

Qual foi o seu grau de dificuldade em utilizar o aplicativo?

( ) Muito difícil ( ) Difícil ( ) Moderado ( ) Fácil ( ) Muito fácil.

Você considera que a utilização do aplicativo foi útil durante o tratamento com o modelador?

( ) Sim ( ) Não ( ) Talvez

Você conseguiu realizar os registros de monitoramento (questionário + fotos) com facilidade?

( ) Sim ( ) Não ( ) Parcialmente

Os vídeos de orientação disponibilizados no aplicativo foram suficientes para esclarecer suas dúvidas?

( ) Sim ( ) Não ( ) Parcialmente

Você acredita que graças ao uso do aplicativo, o número de consultas presenciais e, por consequência, os gastos de deslocamento até o serviço, foram reduzidos?

( ) Sim ( ) Não ( ) Parcialmente

Você acredita que o monitoramento e a orientação, à distância, pelo aplicativo sejam equivalentes à uma consulta presencial?

( ) Sim ( ) Não ( ) Parcialmente

Em uma escala de 0 a 10, qual a probabilidade de você recomendar o aplicativo?

( ) 0 ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( ) 6 ( ) 7 ( ) 8 ( ) 9 ( ) 10

Você tem alguma sugestão e/ou reclamação para relatar sobre o aplicativo?

_____

_____

_____

APÊNDICE III - Política de Privacidade do *TeleCleft*.

Política de Privacidade

Esta política é válida a partir de Mar 2023.

O aplicativo *TeleCleft* é um produto desenvolvido pelo Laboratório de Odontologia Digital - UFPB, que é a controladora de seus dados pessoais. Nós adotamos esta Política de Privacidade, que determina como processamos as informações coletadas pelo aplicativo *TeleCleft* e também explica por que razões nós precisamos coletar dados pessoais sobre você e o seu bebê. Portanto, você deve ler esta Política de Privacidade antes de usar o aplicativo *TeleCleft*. Nós cuidamos dos seus dados pessoais e assumimos a responsabilidade de garantir a confidencialidade e segurança de suas informações pessoais e do seu bebê.

Dados coletados

O público em geral poderá acessar as funcionalidades do aplicativo. No entanto, algumas funções, como o envio do monitoramento, irão depender do cadastro de um perfil para o bebê. Quando você acessa o aplicativo *TeleCleft*, nós automaticamente coletamos certas informações sobre seu dispositivo, incluindo informações sobre seu navegador, endereço IP, fuso horário e alguns dos cookies instalados no seu dispositivo. Nós nos referimos a essas informações coletadas automaticamente como "Informações sobre o dispositivo". Nós podemos coletar dados pessoais que você fornecer (incluindo, mas não limitado a: nome, sobrenome, endereço etc.) durante o processo de registro.

Isto posto, nós iremos coletar:

1. Dados de Perfil: foto de perfil do bebê, e-mail, contato, nome completo do responsável, nome completo do bebê, estado, cidade, data de nascimento do bebê, data de início do tratamento, data da primeira consulta, peso inicial, tipo de fissura, síndrome, diagnóstico da síndrome, profissional responsável e serviço responsável.

1.1. Dados de Participação no Projeto de Pesquisa - Termo de Consentimento Livre e Esclarecido (TCLE): nome completo do responsável, nome completo do bebê, data de nascimento do bebê, concordância com o TCLE, RG do responsável e assinatura do responsável.

2. Dados de Monitoramento: e-mail, contato, nome completo do bebê, data de envio do monitoramento, registros fotográficos do bebê e respostas fornecidas ao formulário.

Compartilhamento de Dados com terceiros

Nossa maior prioridade é a segurança dos dados pessoais dos usuários e, portanto, o processamento e compartilhamento de dados é realizado apenas para fins de manutenção do aplicativo e avaliação do tratamento do seu bebê. É válido destacar que os dados, fornecidos durante o envio do Monitoramento Semanal, serão compartilhados com os profissionais responsáveis que irão analisar a evolução do tratamento com o modelador nasal do bebê. Do mesmo modo, os profissionais poderão ter acesso às informações coletadas durante o cadastro de perfil do bebê. Destaca-se que, apenas profissionais e administradores do aplicativo, devidamente cadastrados, poderão ter acesso aos dados coletados pelo aplicativo.

Links para outros sites e/ou aplicativos

Nosso aplicativo pode conter links para outros sites e/ou aplicativos que não são controlados por nós e/ou não são de nossa propriedade. Por favor, esteja ciente de que nós não somos responsáveis pelas políticas de privacidade de tais sites e organizações terciárias. Nós incentivamos você a estar ciente de quando sair do nosso aplicativo, e também incentivamos você a ler a política de privacidade de cada um dos sites e/ou aplicativos que podem coletar suas informações pessoais.

Segurança de Dados

Buscamos adotar as medidas técnicas e organizacionais previstas pelas Leis de Proteção de Dados (LGPD) Lei nº 13.709/2018 adequadas para proteção dos Dados Pessoais no nosso aplicativo. Infelizmente, nenhuma transmissão ou sistema de armazenamento de dados tem a garantia de serem 100% seguros. Caso tenha motivos para acreditar que sua interação conosco tenha deixado de ser segura (por exemplo, caso acredite que a segurança de qualquer uma de suas contas foi comprometida), favor nos notificar imediatamente.

Direitos

Se você reside no Brasil, estes são os direitos garantidos quanto aos seus dados pessoais conforme a Lei Geral de Proteção de Dados (LGPD) Lei nº 13.709/2018. Você pode, a qualquer momento, requerer: (i) confirmação de que seus Dados Pessoais estão sendo tratados; (ii) acesso aos seus Dados Pessoais; (iii) correções a dados incompletos, inexatos ou desatualizados; (iv) anonimização, bloqueio ou eliminação de dados desnecessários, excessivos ou tratados em desconformidade com o disposto em lei; (v) portabilidade de Dados Pessoais a outro prestador de serviços, contanto que isso não afete nossos segredos industriais e comerciais; (vi) eliminação de Dados Pessoais tratados com seu consentimento, na medida do permitido em lei;

(vii) informações sobre as entidades às quais seus Dados Pessoais tenham sido compartilhados; (viii) informações sobre a possibilidade de não fornecer o consentimento e sobre as consequências da negativa; e (ix) revogação do consentimento. Os seus pedidos serão tratados com especial cuidado de forma a que possamos assegurar a eficácia dos seus direitos. Poderá lhe ser pedido que faça prova da sua identidade de modo a assegurar que a partilha dos Dados Pessoais é apenas feita com o seu titular.

Você deverá ter em mente que, em certos casos (por exemplo, devido a requisitos legais), o seu pedido poderá não ser imediatamente satisfeito, além de que nós poderemos não conseguir atendê-lo por conta de cumprimento de obrigações legais.

Atualizações da Política de Privacidade

Se modificarmos nossa Política de Privacidade, publicaremos o novo texto no aplicativo, com a data de revisão atualizada. Podemos alterar esta Política de Privacidade a qualquer momento. Caso haja alteração significativa nos termos desta Política de Privacidade, podemos informá-lo por meio das informações de contato que tivermos em nosso banco de dados ou por meio de notificação em nosso aplicativo.

Recordamos que nós temos como compromisso não tratar os seus Dados Pessoais de forma incompatível com os objetivos descritos acima, exceto se de outra forma requerido por lei ou ordem judicial.Sua utilização do aplicativo após as alterações significa que aceitou as Políticas de Privacidade revisadas. Caso, após a leitura da versão revisada, você não esteja de acordo com seus termos, favor encerrar o acesso ao aplicativo. Participação no Projeto de Pesquisa Para acessar todas as funcionalidades do aplicativo, os usuários são convidados a participar do Projeto de Pesquisa intitulado "Desenvolvimento e avaliação de aplicativo móvel para Telemonitoramento de pacientes fissurados", que deu origem ao aplicativo *TeleCleft*. Sua participação e, por consequência, a participação do seu bebê são voluntárias e poderão ser revogadas a qualquer momento. Para participar da pesquisa, você deverá consentir mediante assinatura do Termo de Consentimento Livre e Esclarecido (TCLE), disponibilizado no próprio aplicativo, durante a criação do Perfil do seu bebê. Caso aceite participar da pesquisa, você receberá uma cópia do TCLE assinado por e-mail. Além disso, também é disponibilizado, no aplicativo, um modelo não preenchido do TCLE, para maiores esclarecimentos. Se porventura, você quiser visualizar previamente as condições descritas no TCLE acesse o link: https://drive.google.com/file/d/1g2bIed89wWUSC8-Ur8NKoEEBUs37Ieg0/view?usp=sharing

Declaração legal

Nós vamos divulgar qualquer informação que coletamos, usarmos ou recebermos caso tal divulgação seja solicitada ou permitida por lei, de forma a cumprir intimações ou processos judiciais similares, e quando considerarmos em boa fé que a divulgação é necessária para a proteção de nossos direitos, para a proteção da segurança de outros, para investigações de fraude ou para responder a uma solicitação do governo.

Informações de contato

Se você quiser entrar em contato conosco para saber mais sobre esta Política de Privacidade, ou quiser acessar quaisquer informações relativas aos seus direitos individuais e às suas informações fornecidas, você poderá enviar um e-mail para o endereço lab.odontodigital.ufpb@gmail.com.

APÊNDICE IV - QR Code para acesso aos vídeos instrutivos disponibilizados no *TeleCleft*.

APÊNDICE V - Folder informativo.

Como acessar o APP?

1 Escaneie o **QR CODE**

Ou acesse: https://telemonitoramento-uf-rio6.glideapp.io

2 Insira seu e-mail

Lembre-se de inserir um e-mail válido que você tenha acesso.

2 Consentimento

Para acessar o APP , você deverá consentir com o Termo de Consentimento Livre e Esclarecido.

3 Insira o PIN de acesso

Você receberá o PIN de acesso, pelo e-mail cadastrado, para acessar o APP.

Cadastro concluído!

4 Crie um Perfil

Crie um Perfil para o seu bebê.

5 Envie o Monitoramento

Preencha o Formulário de Monitoramento e envie as fotos do seu bebê.

Você receberá o Feedback sobre o tratamento do seu bebê pelo seu e-mail e no APP.