USO DE LA TECNOLOGÍA APLICADA EN LACTANCIA: ANÁLISIS DE LAS USUARIAS Y EL USO DE UNA mHEALTH



Laia Aguilar Camprubí Desirée Mena Tudela

Abril de 2023



Programa de Doctorado en Ciències de la Infermeria

Escuela de Doctorado de la Universitat Jaume I

USO DE LA TECNOLOGÍA APLICADA EN LACTANCIA: ANÁLISIS DE LAS USUARIAS Y EL USO DE UNA mHEALTH

Memoria presentada por Laia Aguilar Camprubí para optar al grado de doctor/a p	or la
Universitat Jaume I	

Laia Aguilar Camprubí

Desirée Mena Tudela

Castelló de la Plana, abril de 2023

FINANCIACIÓN Y DERECHOS DE AUTOR

Financiación

Relacionado con el objetivo 1: Realizar un análisis descriptivo de una aplicación móvil sobre lactancia materna (LactApp) para estudiar el perfil de usuario, así como las consultas más frecuentes.

Se recibió la siguiente ayuda:

 Universitat Jaume I, Investigadora principal: Desirée Mena Tudela. Fechas de desarrollo: 01/01/2020 31/12/2021. Título: VALIDACIÓN CLÍNICA Y DE PROCESOS DIAGNÓSTICOS DE UNA MHEALTH APP DE APOYO A LA LACTANCIA MATERNA. Código del proyecto:UJI-A2019-06

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Tesis por compendio de las siguientes publicaciones:

- Padró-Arocas, A., Mena-Tudela, D., Baladía, E., Cervera-Gasch, A., González-Chordá, V. M., & Aguilar-Camprubí, L. (2021). Telelactation with a Mobile App: User Profile and Most Common Queries. Breastfeeding medicine: the official journal of the Academy of Breastfeeding Medicine, 16(4), 338–345. https://doi.org/10.1089/bfm.2020.0269
 - Factor de impacto de 2,335 y perteneció al lugar 81 de 184 de la categoría "Pediatrics" del Journal of Citations Reports (JCR) en su año, ocupando el segundo cuartil (Q2) y el segundo tercil (T2)
- Padró-Arocas, A., Quifer-Rada, P., Aguilar-Camprubí, L., Mena-Tudela, D. (2021). Description
 of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers
 seek support at critical breastfeeding points and according to their infant's age. Research in
 nursing & health, 44(1), 173–186. https://doi.org/10.1002/nur.22095.
 - o Factor de impacto de 2,228, perteneciendo al puesto 45 de un total de 126 indexadas en la categoría "Nursing". Por lo tanto, esta revista ocupa un segundo cuartil (Q2) y el segundo tercil (T2) en el listado correspondiente del JCR.
- Quifer-Rada, P., Aguilar-Camprubí, L., Padró-Arocas, A., Gómez-Sebastià, I., & Mena-Tudela, D. (2022).
 Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support. Telemedicine journal and e-health: the official journal of the American Telemedicine Association, 10.1089/tmj.2021.0586. Advance online publication. https://doi.org/10.1089/tmj.2021.0586
 - Según el JCR de 2021, esta revista tiene un factor de impacto de 5.033, perteneciendo al puesto 19 de un total de 109 indexadas en la categoría "Health Care Sciences & Services". Por lo tanto, esta revista ocupa un primer cuartil (Q1) y el primer tercil (T1) en el listado correspondiente del JCR.

"Esta tesis dispone de la aceptación de los coautores de las publicaciones que el doctorando/a presenta como tesis y su renuncia expresa a presentarlas como parte de otra tesis doctoral."

ÍNDICE

6	Agradecimientos	
8	Abreviaturas	
9	Resumen	
12	Abstract	
16	Introducción	
16	La lactancia materna	
28	Herramientas tecnológicas, mHealth y eHealth	
30	Aplicación móvil de apoyo a la lactancia materna: LactApp	
34	La pandemia de SARS-CoV2 y la lactancia	
36	Hipótesis	
37	Objetivos	
38	Metodología y resultados	
39	Objetivo específico 1	
70	Objetivo específico 2	
98	Objetivo específico 3	
125	Discusión y conclusiones	
125	Objetivo general	
127	Objetivo específico 1	
131	Objetivo específico 2	
135	Objetivo específico 3	
142	Conclusiones generales	
143	Futuras líneas de investigación	
145	Bibliografía	
154	Índice de figuras, tablas y gráficos	
156	Anexos	
156	Anexo 1: Autorizaciones de las coautoras para el uso de las publicaciones como parte de la presente tesis doctoral.	
164	Anexo 2: Auditorías de Organisation for the Review of Care and Healt Apps (ORCHA)	

AGRADECIMIENTOS

Esta tesis doctoral es fruto del esfuerzo de muchas personas que me han apoyado de una forma u otra para que la pudiera realizar.

Empiezo agradeciendo el trabajo de mi directora de tesis, la Dra Desirée Mena, que me ha animado a hacer la tesis desde el principio y guiado y apoyado durante todo este tiempo. Tener una referente de la investigación en lactancia y en violencia obstétrica y perspectiva de género como guía del trabajo ha sido un lujo.

Y precisamente junto con ella, quiero agradecer de forma muy encarecida a todas las personas que han realizado las investigaciones que se han plasmado en las publicaciones en las que se basa esta tesis: la Dra Paola Quífer, la Dra Águeda Cervera, el Dr Víctor M. Chordá, el Dr Eduard Baladia, el Dr Ingasi Gómez y Alba Padró. Creo que el trabajo realizado por estos investigadores ha sido excepcional, agrandando el cuerpo de conocimiento en el campo de la atención a la lactancia.

¿He dicho Alba Padró? Sí, lo he dicho. Alba Padró y Maria Berruezo, que en realidad son las principales artífices de esta tesis. Ellas, junto Enric Pallarès, fundaron LactApp, le dieron forma y la lanzaron para que todas las personas que de alguna forma entran en contacto con la lactancia, tengan la información necesaria y el apoyo para poder decidir sobre su cuerpo, su lactancia y su crianza. Y esto es revolucionario. Y además, lo han hecho de forma tan exquisita que todas nos podemos sentir incluídas en ella, amamantemos o no, seamos madres, profesionales o familiares.

Como parte de LactApp además es un placer inmenso estar en su equipo. Un equipo de personas extraordinarias, que están pensando cada día cómo mejorar algo tan importante como es facilitar la toma de decisiones informadas de las madres y familias. ¿Cómo no estar agradecida a todas y cada una de ellas?

Aún así, algunas me han tenido que soportar un poco más intensamente.

Nadjet ha tenido un sitio especial por ayudarme con la redacción de la definición de la inteligencia artificial en LactApp y por leer y aportar mejoras en el trabajo de tesis.

Judit, que fue la primera persona que le leyó la tesis. Es hogar.

Rocío, por sus intentos de contabilizar de nuevo los caminos posibles de la aplicación. Ya lo he entendido. Son infinitos.

Y vuelvo a Alba y a Maria. Ellas en realidad son las responsables de que este trabajo esté hecho. La confianza que depositan en mí cada día me estremece un poco. Mi agradecimiento siempre se queda corto. A nivel profesional, y a nivel personal. Sois familia.

Y sigo con los agradecimientos, esta vez a todas y a cada una de las usuarias de LactApp, sin ellas, esto no sería posible. Tanto las que usan la aplicación como las que son usuarias de las visitas o hacen talleres o cursos o el posgrado universitario. Nos permiten aprender cada día e intentar mejorar nuestra atención y nuestros conocimientos en torno a la lactancia.

Trabajos como este, requieren tener un entorno que te empuje y te recoja en momentos complicados. Mis hijos, Arnau y Mariona, y mi pareja, Jofre, me han sostenido y han tenido una paciencia inmensa. Gracias por teneros siempre.

A mi hermana Anna, gracias por ilusionarte con mis ilusiones, por hacerme sentir tan especial. Y, sobre todo, por querernos tanto, ahora que nos hemos quedado un poco huérfanas, con este vacío inmenso.

Y a hermana Mireia, que ya no se lo podré decir de viva voz, también es artífice de esto. Porque su confianza en mí era ciega, porque me recogía en los momentos difíciles y me daba cobijo, porque hacía brillar a todo el mundo mientras se lo miraba tapada con su capa de invisibilidad. T'estimo, Mi. Sempre et porto a dins.

A todas ellas, gracias.

ABREVIATURAS

AAP American Academy of Pediatrics

CDC Centro para el Control y la Prevención de Enfermedades

ENS Encuesta Nacional de Salud

FISABIO Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana

IA Inteligencia artificial

IHAN Iniciativa para el parto humanizado y atención al nacimiento

INE Instituto Nacional de estadística

JCR Journal of Citations Reports

LM Lactancia Materna

LME Lactancia Materna Exclusiva

MAUQ mHealth App Usability Questionnaire

OMS Organización Mundial de la Salud

ONU Organización de las Naciones Unidas

ORCHA Organisation for the Review of Care and Health Apps

PCA Análisis de Componentes Principales

PLN Procesamiento de Lenguaje Natural

Q1 Primer Cuartil

Q2 Segundo Cuartil

RN Recién Nacido

SMS Short Message Service

SSD Sistema de Soporte de Decisiones

T1 Primer Tercil

T2 Segundo Tercil

TPC Three month percentage change

UNICEF United Nations International Children's Emergency Fund

RESUMEN

Una gran mayoría de madres desean amamantar a sus crías, tomando esta decisión durante el embarazo. Sin embargo, las tasas de lactancia materna reflejan que el deseo de llevar a cabo este tipo de alimentación no se cumple, así como tampoco se alcanzan las tasas recomendadas por las instituciones internacionales y éstas varían significativamente entre los países. La alimentación con lactancia materna ha demostrado ser una intervención muy importante de salud pública, con destacables resultados sobre el gasto sanitario y el medioambiente.

Las aplicaciones móviles, pueden mejorar la información y el apoyo en salud. El uso de tecnologías móviles, o mHealth, puede ser beneficioso para la gestión de la lactancia materna, ayudando en la difusión de información, aprendizaje y apoyo a las madres lactantes.

LactApp es una aplicación móvil que proporciona respuestas personalizadas a través de un cuestionario autoadministrado. La aplicación cuenta con más de 70 árboles de decisión y más de 74.000 posibles caminos para resolver las dudas de las usuarias sobre lactancia materna. Además, LactApp tiene un blog con 1.700 entradas y un canal de consultas de texto atendido por expertas en lactancia, tests de situaciones de lactancia y planes personalizados. La aplicación tiene una versión gratuita y una versión Premium que ofrece formaciones multimedia y píldoras diarias de aprendizaje en lactancia y temas relacionados con la maternidad.

Durante la pandemia de SARS-CoV-2, muchos servicios de salud se cerraron y se centraron en tratar a pacientes con COVID-19, lo que causó una falta de apoyo a la lactancia materna. Además, se ha podido comprobar cómo ciertas prácticas de atención obstétrica tuvieron un impacto negativo en la instauración de la lactancia materna.

El objetivo general de la presente tesis es conocer cómo una mHealth de lactancia (LactApp) da apoyo a sus usuarias. Para poder responderlo, se han definido 4 objetivos específicos. El primero trata de realizar un análisis descriptivo de la aplicación móvil de lactancia materna (LactApp) para estudiar el perfil de la usuaria, así como las consultas más frecuentes. El segundo objetivo específico se centra en analizar las consultas realizadas por las usuarias en función de la edad de sus bebés en LactApp. El tercer objetivo específico pretende evaluar el impacto de la pandemia de SARS-CoV-2 en las consultas de lactancia en LactApp. Finalmente, el cuarto objetivo específico quiere determinar si el

uso de LactApp mejora los porcentajes de lactancia materna a los 15 días, las 6 semanas, los 3 meses y los 6 meses de edad del recién nacido.

En el análisis descriptivo de la aplicación de lactancia materna, se realizó un estudio retrospectivo, comparativo y descriptivo de series temporales sobre los datos registrados por la aplicación móvil LactApp desde el 1 de julio de 2016 hasta el 30 de junio de 2019. Durante este periodo, 115.830 usuarias se registraron en la aplicación, siendo España el país donde más usuarias residían, con un 53,84% de la población. En el mismo periodo, 71.780 bebés fueron registrados. Se iniciaron un total de 1.767.308 sesiones, con una clara tendencia al alza y se visualizaron un total de 11.838.570 pantallas. Se llegó a 2.757.702 respuestas finales a través de consultas automatizadas.

En el análisis de las consultas realizadas por las usuarias en función de la edad de sus bebés, se realizó un estudio observacional, descriptivo y retrospectivo usando los datos recogidos por LactApp del 1 de enero de 2019 al 31 de diciembre de 2019, en el que se incluyó 2.725.925 consultas clasificadas en 48 temas (incluyendo test) de 130.000 usuarias activas. LactApp registró 71.807 nuevas usuarias en sus bases de datos y fueron registrados 44.342 bebés. Los temas más consultados durante el 2019 fueron aquellos relacionados con la "técnica de lactancia" y "sueño del bebé". Además se pudo comprobar que tanto las consultas como los test de LactApp cambiaban según la edad del bebé.

Para responder al tercer objetivo específico, se realizó un estudio observacional, descriptivo y retrospectivo con los datos recogidos por LactApp desde julio de 2018 hasta marzo de 2021, incluyendo 9.151.456 consultas automáticas, clasificadas en 48 temas de 137.327 usuarias.

Entre julio de 2018 hasta marzo de 2021, las usuarias registradas en LactApp crecieron un 133% y las consultas automatizadas totales aumentaron un 116% después del brote de SARS-CoV-2, por lo que hubo 389.984 consultas automatizadas de lactancia mensuales. En la funcionalidad de chat, también aumentaron las consultas en un 28,5% durante el brote de SARS-CoV-2.

El cuarto objetivo específico trata de una investigación que actualmente aún está en fase de análisis de datos. Es un estudio experimental, multicéntrico y prospectivo con grupo experimental y grupo control, que comparará la duración de la lactancia materna exclusiva. Actualmente se están realizando los análisis pertinentes para poder comprobar el impacto de la aplicación en la lactancia de las participantes.

En conclusión, este trabajo de tesis ha podido comprobar que LactApp es una potente herramienta de apoyo a la lactancia, ofreciendo respuestas personalizadas que permiten a las usuarias tomar

decisiones informadas y acompañadas en torno a la lactancia. Es además una herramienta para el apoyo de la práctica clínica de profesionales que atienden a las mujeres en este momento vital. En situaciones de emergencia LactApp tiene la capacidad de seguir siendo útil, adaptándose rápidamente a las necesidades de las usuarias, ya que, las consultas realizadas a LactApp por parte de las usuarias cambiaron durante el tiempo de confinamiento y pandemia. En definitiva, LactApp es una herramienta tecnológica potente y eficaz para la toma de decisiones en la lactancia materna, tanto para madres y familias como para profesionales que las atienden.

ABSTRACT

A large majority of mothers wish to breastfeed their children, making this decision during pregnancy. However, breastfeeding rates reflect that the desire to breastfeed is not fulfilled, that the rates recommended by international institutions are not achieved, and they vary significantly between countries. Breastfeeding has proven to be a very important on public health intervention, with remarkable results on public health spending and the environment.

Mobile applications can improve health information and support. The use of mobile technologies, or mHealth, can be beneficial for breastfeeding management, helping in the dissemination of information, learning and support to breastfeeding mothers.

LactApp is a mobile application that provides personalized answers through a self-administered questionnaire. The app has more than 70 decision trees and more than 74,000 possible paths to solve users' breastfeeding questions. In addition, LactApp has a blog with 1,700 posts and a channel for text queries answered by breastfeeding experts, breastfeeding situation tests and personalized plans. The app has a free version and a premium version that offers multimedia training and daily learning pills on breastfeeding and other topics related to motherhood..

During the SARS-CoV-2 pandemic, many health services were closed and focused on treating patients with COVID-19, causing a lack of support for breastfeeding. In addition, it has been possible to show how certain obstetric care practices had a negative impact on the establishment of breastfeeding.

The general objective of the present thesis is to know how a breastfeeding mHealth app (LactApp) supports its users. In order to address this, four specific objectives have been defined. The first one is to perform a descriptive analysis of the breastfeeding mobile application (LactApp) to study the user's profile, as well as the most frequent queries. The second specific objective focuses on analyzing the queries made by users according to the age of their babies in LactApp. The third specific objective aims to evaluate the impact of the SARS–CoV–2 pandemic on breastfeeding consultations in LactApp. Finally, the fourth specific objective aims to determine whether the use of LactApp improves breastfeeding rates at 15 days, 6 weeks, 3 months, and 6 months of newborn age.

In the descriptive analysis of the breastfeeding app, a retrospective, comparative, descriptive time series study was conducted on data recorded by the LactApp mobile app from July 1, 2016 to June 30, 2019. During this period, 115,830 users were registered in the application, with Spain being the country where most users resided, with 53.84% of the population. In the same period, 71,780 babies were registered. A total of 1,767,308 sessions were initiated, with a clear upward trend, and a total of 1,838,570 screens were viewed. A total of 2,757,702 final responses were reached through automated queries.

In the analysis of queries made by users based on the age of their babies, an observational, descriptive and retrospective study was conducted using data collected by LactApp from January 1, 2019 to December 31, 2019, which included 2,725,925 queries classified into 48 topics (including quiz) from 130,000 active users. LactApp registered 71,807 new users in its databases and 44,342 babies were registered. The most frequently consulted topics in 2019 were those related to "breastfeeding technique" and "baby sleep". In addition, it was found that both the queries and the LactApp tests changed according to the age of the baby.

To answer the third specific objective, an observational, descriptive, retrospective study was conducted with data collected by LactApp from July 2018 to March 2021, including 9,151,456 automatic queries, classified into 48 topics from 137,327 users.

From July 2018 to March 2021, registered LactApp users grew by 133% and total automated queries increased by 116% after the SARS-CoV-2 outbreak, resulting in 389,984 monthly automated breastfeeding queries. In chat functionality, queries also increased by 28.5% during the SARS-CoV-2 outbreak.

The fourth specific objective deals with an investigation that is currently still in the data analysis phase. It is an experimental, multicenter, prospective study with control groups, which will compare the duration of exclusive breastfeeding. The relevant analyses are currently underway to be able to verify the impact of the application on the breastfeeding experience of the participants.

In conclusion, this thesis work has shown that LactApp is a powerful breastfeeding support tool, offering personalized answers that allow users to make informed and accompanied decisions about breastfeeding. It is also a tool to support the clinical practice of professionals who care for women in this vital moment. In emergency situations, LactApp has the capacity to continue to be useful, adapting quickly to the needs of users, since the queries made to LactApp by users changed during

the time of confinement and pandemic. In short, LactApp is a powerful and effective technological tool for decision making in breastfeeding, both for mothers and families as well as for the professionals who care for them.

"El conocimiento del cuerpo es el primer paso para la liberación de la mujer. Solo cuando sabemos cómo funciona nuestro cuerpo, podemos tomar decisiones informadas sobre nuestra salud, sexualidad y reproducción"

Bell Hooks 2004

INTRODUCCIÓN

La lactancia materna

La lactancia materna está definida por la Organización Mundial de la Salud como aquella alimentación en la que el bebé recibe leche materna del pecho, sea de forma directa al pecho, extraída o de nodriza(1). Yourkavitch y Chetwynd proponen como definición de lactancia maternael fenómeno fisiológico de la producción de leche desde la perspectiva del proveedor(2).

Labbok y Starling afirman que debido a la falta de definiciones claras y coherentes utilizadas en las publicaciones científicas sobre lactancia materna la generalización y comparación de los resultados ha sido difícil, y la interpretación de los resultados es a menudo limitada(3).

Una definición alternativa sería que la lactancia materna se entendería como una relación mutualista entre madre (o adulto cuidador) y criatura que tiene como objetivo principal la alimentación del bebé así como ser una experiencia vital de la madre.

La lactancia materna forma parte de la esfera sexual de la mujer y también contribuye a la salud del bebé. Y así está recogido como uno de los derechos de salud sexual y reproductiva(4).

El amamantamiento es un acto bio-socio-cultural para la mujer, aunque instintivo para el recién nacido(5). Se considera un proceso fisiológico. El recién nacido, en condiciones óptimas de salud, está capacitado, con reflejos específicos, para el inicio y mantenimiento de la lactancia; en el caso de la madre, la lactancia precisa de un proceso de aprendizaje. Por ello, el apoyo, el asesoramiento y la educación son estrategias fundamentales para que la madre siga amamantando.

Aunque no se ha encontrado evidencia en mujeres, el comportamiento materno en las hembras de primates superiores podría no ser totalmente instintivo, sino que puede que esté influido por un periodo de aprendizaje. Se conoce que las hembras de chimpancés y gorilas, tienen dificultades para amamantar a sus crías cuando son criadas por humanos, en cautividad, mientras que no se conocen dificultades en la lactancia cuando están en su hábitat salvaje(6).

La lactancia materna puede formar parte de una decisión mucho más amplia que significa tener un hijo o hija. Las decisiones tomadas durante la gestación, el parto y la lactancia tienen una implicación también en la forma cómo estos procesos son vividos por parte de madre, bebé y familia. Hay múltiples factores que pueden influenciar la decisión de amamantar, aun así, el simple hecho de

querer vivir la experiencia, puede ser suficiente para que las madres decidan hacerlo. Simplemente porque los senos están preparados para que las madres puedan alimentar a sus crías. Según Ballesta et al, en España, hasta el 97% de las mujeres gestantes toman la decisión de amamantar al hijo que esperan durante el embarazo(7).

En una investigación liderada por Lööf-Johanson et al, en la que se realiza una serie de preguntas a mujeres de diferentes generaciones que han amamantado se afirma textualmente: "La lactancia materna aparece en todas las categorías como un valor específico y distinto en la vida de las mujeres: La dimensión emocional de la lactancia materna crea una sensación de haber llegado a la vida". El valor vital de la lactancia materna se refiere a las experiencias poderosas y positivas de la lactancia materna y al sentido que proporciona. Está firmemente ligado a la lactancia y no a la experiencia global de tener un hijo y convertirse en madre. La decisión y el instinto, junto con el trabajo que conlleva la lactancia materna, proporcionan un fuerte sentimiento de presencia en la vida. La alegría y el placer que aportaba, proporciona una fuerte autoestima a la mujer. El valor vital de la lactancia materna, incluye la capacidad de la mujer para afrontar todos los problemas prácticos de la lactancia, el cansancio, los conflictos y la decepción, por ejemplo"(8).

Es de destacar que la lactancia aparece en un momento muy vulnerable en la vida de la madre, donde múltiples factores pueden estar influyendo en su evolución. Tener un hijo o hija comporta cambios y adaptaciones profundas en la vida de las personas. Una de las nuevas situaciones será el establecimiento de la lactancia.

Lactancia materna óptima

La lactancia materna es una estrategia clave en la salud de madres y bebés. Es una de las formas más eficaces para garantizar la salud y la supervivencia de los niños(1). Se ha demostrado que la lactancia materna exclusiva, durante los 6 primeros meses de vida, y junto con otros alimentos hasta los dos años o más, aporta beneficios de salud a corto y largo plazo. La Organización Mundial de la Salud (OMS) así como UNICEF avalan también estas recomendaciones.

La Organización Mundial de la Salud define la "lactancia materna exclusiva" (LME) como la alimentación con leche materna únicamente, sin ningún otro líquido, sólidos a excepción de soluciones hidratantes, vitaminas, minerales o medicamentos. Un lactante que recibe agua o zumo

pero no leche artificial se considera "amamantado predominantemente", mientras que un lactante que recibe leche artificial, aunque solo sea para una toma, se considera "amamantado parcialmente", y "nunca amamantado" se refiere a una situación en la que nunca se inició la lactancia(1).

Beneficios en salud de la lactancia materna

La lactancia materna disminuye el riesgo de que los bebés presenten infecciones, maloclusiones orales y, seguramente, también disminuye el riesgo de obesidad y diabetes diabetes tipo II(9).

Victora et al. también al afirman a través de un artículo publicado en la revista The Lancet en 2016 que si se hubieran seguido las recomendaciones de la OMS en todo el mundo se podrían evitar 823.000 muertes de niños menores de 5 años anualmente en países de ingresos bajos y medios y se salvarían 22.216 vidas adicionales al año si se aumentara la duración de la lactancia materna desde los niveles actuales a 12 meses por niño en los países de ingresos altos(9).

La obesidad infantil es una de las enfermedades no transmisibles que más preocupa a los agentes de salud. Se sabe que en los últimos años ha aumentado el número de niños y niñas con obesidad en todo el mundo(10). La obesidad infantil se relaciona con el riesgo de obesidad en la edad adulta y la diabetes tipo II e hipertensión arterial en la adolescencia y en la edad adulta(11–13). La lactancia materna se asocia a una reducción significativa de las probabilidades de obesidad general y de grasa corporal elevada en niños de 9 a 11 años de todo el mundo(14).

La Asociación Americana de Pediatría (AAP), redactó en 2018 un artículo titulado "Defensa de la mejora de la nutrición en los primeros 1000 días para favorecer el desarrollo infantil y la salud de los adultos" en el que fija la lactancia como la alimentación óptima para los bebés, recomendando la lactancia materna exclusiva durante los 6 primeros meses de vida y relacionando el inicio temprano de la alimentación complementaria con índices más altos de obesidad infantil(15).

La lactancia no solamentereduce el riesgo de diabetes debido a la reducción de la obesidad, sino que también se ha demostrado que por sí misma puede reducir la incidencia de diabetes tipo I en población adolescente y la diabetes tipo II en población adulta(16).

La lactancia materna protege contra las infecciones y las enfermedades inmunomediadas, tanto durante el periodo de lactancia como después, es decir, a corto y largo plazo(17). Se ha visto que la lactancia materna proporciona a los neonatos anticuerpos maternos que ofrecen una inmunidad pasiva contra los patógenos en el entorno compartido entre la madre y el bebé. Así, se ha observado

que puede mediar en las respuestas inmunitarias a través de las propiedades bioactivas e inmunomoduladoras que contiene, o a través del impacto del tipo de leche en la microbiota intestinal(18). Además, la leche materna es rica en anticuerpos IgA secretores y principios bioactivos, como puede ser la lactoferrina bactericida(19), células inmunitarias, microbios, mucinas, citocinas, receptores solubles y oligosacáridos(17). Esto, junto con la transferencia de numerosas citoquinas y factores de crecimiento a través de la leche, puede contribuir a una estimulación activa del sistema inmunitario del lactante. En consecuencia, el lactante podría responder mejor tanto a las infecciones como a las vacunas. Esta función mejorada también podría explicar por qué la lactancia materna puede proteger contra enfermedades inmunológicas como la enfermedad celíaca y, posiblemente, la alergia(19).

También existe evidencia de protección contra las infecciones durante la lactancia, por ejemplo, contra la diarrea aguda y prolongada, las infecciones del tracto respiratorio, la otitis media, la infección del tracto urinario, la septicemia neonatal y la enterocolitis necrotizante, así como también contra el desarrollo del asma y las enfermedades alérgicas en las niñas y niños(18,19).

El ejercicio de succión que realiza el bebé durante la lactancia tiene un impacto en el desarrollo de las estructuras mandibulares. Se ha observado que la lactancia materna durante 6 meses o más reduce el riesgo de mordida cruzada posterior y de maloclusión de clase II en dentición primaria y mixta(20). Este hecho tiene una implicación directa ya no solamente en la posición de los dientes, sino también en la forma del paladar, la respiración nasal, que es la más fisiológica, y está relacionada con la disminución de la calidad del sueño y la obstrucción de las vías respiratorias y los trastornos de conducta diurnos en los niños(21).

El cáncer infantil es una de las principales causas de mortalidad entre los niños y adolescentes en el mundo desarrollado y su incidencia aumenta un 0,9% cada año. La leucemia representa alrededor del 30% de todos los cánceres infantiles, pero su etiología sigue siendo mayoritariamente desconocida. En una revisión sistemática con metaanálisis se observó que la lactancia materna superior a los 6 meses, se relaciona con un riesgo de entre un 14% y un 20% menor de leucemia infantil en todos los estudios incluidos (22).

Por otro lado, la mujer que amamanta también obtiene beneficios para su salud, tanto a corto como a largo plazo(16). Ya justo después del parto, disminuye el riesgo de hemorragia posparto(23), siendo

una de las estrategias más fáciles y baratas de llevar a término, junto con contacto precoz piel con piel.

La depresión posparto es un trastorno mental afectivo severo que se calcula que a nivel mundial afecta a un 15% de las mujeres que han tenido un hijo y sube hasta a un 56% en las mujeres latinas residentes en México y Estados Unidos que han tenido un bebé en los últimos 4 meses(24). Se asocia al suicidio que es una de las causas más importantes de muerte materna durante el período perinatal(25). La depresión posparto tiene consecuencias en el apego de la díada madre-bebé así como en el desarrollo del pequeño o pequeña(26). La lactancia materna podría promover procesos hormonales que protegen a las madres contra la depresión posparto al modular la respuesta del cortisol al estrés(27). También puede reducir el riesgo de depresión posparto, al ayudar a la regulación de los patrones de sueño y vigilia de la madre y el niño, mejorar el sentimiento de autoeficacia de la madre y su implicación emocional con el bebé y promover una mejor interacción entre ellos(28). Algunos estudios señalan que la depresión posparto podría estar relacionada con el cese precoz de la lactancia o podría ser la depresión la causa de este destete(28).

El cáncer de mama es el cáncer con más incidencia y el responsable de más muertes a nivel mundial. La lactancia materna se ha comprobado que es un factor protector de este tipo de cáncer(29).

Tanto es así, que se calcula que se evitarían 19.464 muertes anuales por cáncer de mama si la lactancia tuviera las características recomendadas en comparación con un escenario en el que ninguna mujer amamanta. Este punto tiene especial relevancia también en países de altos ingresos, que es donde la incidencia de cáncer de mama es más alta(30).

En las mujeres, la lactancia materna también se asocia a una disminución significativa del riesgo de cáncer de ovario en general y del subtipo seroso de alto grado, el tipo más letal de cáncer de ovario independientemente del embarazo y el riesgo ya empieza a ser significativo con pocos meses de lactancia(31). En varias revisiones bibliográficas se ha podido observar la disminución de la incidencia de la diabetes tipo II materna en mujeres que han amamantado a sus bebés(32–34).

En cuanto a otras afecciones crónicas y las asociaciones protectoras con la lactancia materna, se ha visto una reducción de la hipertensión arterial, de la diabetes, la hiperlipidemia y las enfermedades cardiovasculares en mujeres que han amamantado durante más de 12 meses a lo largo de su vida.

Prevención de muertes e impacto económico de la lactancia materna subóptima

Muchos de estos beneficios, se pudieron ver plasmados en la publicación de la Dra Melissa Bartick(35), en el que cuantificó el exceso de casos de enfermedades pediátricas y maternas, muertes y costes atribuibles a las tasas de lactancia materna subóptimas en Estados Unidos (EE.UU.). Bartick definió la lactancia materna subóptima como aquella que no sigue la siguiente recomendación: 6 meses de lactancia materna exclusiva y, como mínimo, hasta el año junto con otros alimentos.

Sus resultados fueron muy impactantes: si el 90% de las lactancias fueran óptimas en EE.UU. se prevendrían al año 2.619 muertes maternas y 721 muertes infantiles. Este punto fue muy interesante porque es una de las primeras veces que se pone en relieve la salud materna, que especialmente en países con ingresos altos, pocas veces se tenía en cuenta. El equipo investigador de Bartick desgranó los casos prevenidos, tanto maternas como infantiles:

Casos maternos prevenidos

- Cáncer de mama: 5.023 casos

- Diabetes tipo II: 12.320 casos

- Hipertensión: 35.982 casos

- Infarto agudo de miocardio: 8.487 casos

Casos infantiles prevenidos

- Leucemia: 185 casos

- Infecciones de oído: 601.825 casos

- Enfermedad de Crohn y colitis ulcerosa: 271 casos

- Gastroenteritis infecciosas: 2.558.629 casos

- Infecciones respiratorias severas de vías bajas: 20.900 casos

- Obesidad infantil: 45.298 casos

- Enterocolitis necrotizante: 1.355 casos

El impacto de la lactancia materna en la salud tanto materna como infantil, puede cuantificarse también económicamente. Conseguir mejores tasas de lactancia tendría también como consecuencia un ahorro económico de los sistemas de salud. Hay diferentes investigaciones que han estudiado este punto.

En España, Quesada et al. hicieron una estimación del ahorro sanitario que se hubiera tenido si en 2014 la lactancia materna exclusiva fuera la forma de alimentación del 90% de los bebés al alta posparto, en vez del 85% que fue el dato real, y si el 50% de los bebés hubieran sido amamantados de forma exclusiva a los 6 meses de vida, en vez del 15% que era la incidencia en aquel momento (36).

Se fijaron en 4 patologías: otitis media, gastroenteritis, enterocolitis necrotizante e infecciones respiratorias y el coste sanitario que comportan al Sistema Nacional de Salud. Su conclusión es que con el objetivo de la OMS, es decir llegar al 90% de lactancia materna exclusiva al alta y al 50% a los 6 meses, el estado se hubiera ahorrado 197 millones de euros por año, lo que supone un ahorro de 464 € por niño al año como consecuencia de las patologías analizadas(36).

En el Hospital Universitario Marqués de Valdecilla de Santander, durante el 2018, se realizó una investigación para estimar los costes sanitarios asociados al tipo de alimentación de enfermedades infecciosas. Se registró cada enfermedad infecciosa que se produjo en los primeros 12 meses de vida de la cohorte y cada uso del sistema sanitario debida a esas enfermedades infecciosas en el primer año de vida. Esto incluía el número de consultas con pediatras de atención primaria, el número de consultas con pediatras de hospital, el tratamiento farmacológico, las pruebas de laboratorio, el número de visitas a urgencias y el número de ingresos hospitalarios. La conclusión a la que llegan los investigadores es que los costes de atención sanitaria debidos a enfermedades infecciosas durante el primer año de vida de los neonatos alimentados con alimentación artificial fueron significativamente más elevados que los alimentados con lactancia materna(37).

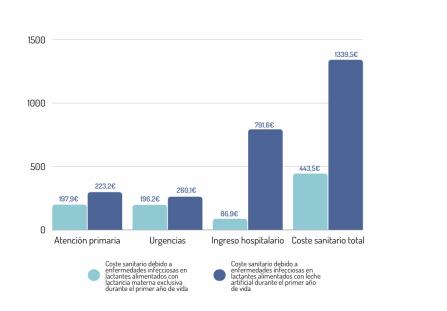


GRÁFICO 1: Costes sanitarios según alimentación del lactante. Fuente: Lechosa-Muñiz et al.(2020)

Santacruz realizó la tesis doctoral sobre la diferencia de costes para el Sistema Nacional de Salud según la alimentación recibida por el bebé. Se centró en los bebés nacidos en el Área de Salud de Toledo. Observó que cuanto más tiempo de lactancia materna exclusiva recibieron los recién nacidos,

menor era el promedio de gasto sanitario ocasionado al Sistema Nacional de Salud, siendo menor durante los primeros 6 meses (Gráfico 2)(38).

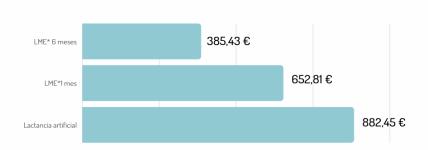


GRÁFICO 2: Promedio de gasto sanitario total ocasionado al Sistema Nacional de Salud.

*LME = Lactancia materna exclusiva

Todos los artículos encontrados han relacionado la lactancia materna con una disminución importante de los costes sanitarios.

En una revisión sistemática llevada a cabo por el equipo de Rollins un aumento del 10% en la lactancia materna exclusiva hasta los 6 meses o en la lactancia materna continuada hasta el año o los 2 años (dependiendo del país y del trastorno) se traduciría en una reducción de los costes de tratamiento de los trastornos infantiles de al menos 2,45 millones de dólares en EE.UU., 29,5 millones de dólares en el Reino Unido, 223,6 millones de dólares en la China urbana y 6 millones de dólares en Brasil(39).

Como se ha comentado en el anterior apartado, Bartick et al ya cuantificaron el coste económico que significaba la lactancia subóptima en EE.UU. De esta manera, en el año 2014, se estableció una cifra de coste 3.000 millones de dólares estadounidenses de costes médicos totales, 1.300 millones de dólares de costes no médicos y 14.200 millones de dólares de costes de muertes prematuras(35). Santacruz, en la tesis doctoral que se ha citado anteriormente, observa que el ahorro económico para el Sistema Sanitario público Español hubiera sido de 51.255.769 € en un año teniendo en cuenta que el 50% de mujeres mantuviese la LME hasta los 6 meses y la tasa de ahorro de costes sería de 157.552 € / 1000 niños atendidos, en base al exceso de utilización de los recursos sanitarios y mayor consumo farmacológico por los RN que no se han alimentado con LME durante 6 meses(38).

Lactancia y medioambiente

Los costes medioambientales también están asociados a la falta de lactancia materna. La leche materna es un "alimento natural y renovable" que es seguro para el medio ambiente y se produce y entrega al consumidor sin contaminar, sin envases innecesarios ni residuos. Los sucedáneos de la leche materna dejan una huella ecológica y necesitan energía para su fabricación, materiales para su envasado, combustible para su distribución en el transporte, y agua, combustible y productos de limpieza para su preparación y uso diario, y se generan numerosos contaminantes a lo largo de esta vía. Se calcula que se necesitan más de 4.000 litros de agua a lo largo del proceso de producción para fabricar tan sólo 1 kg de sucedáneo de leche materna en polvo. En EE.UU., 550 millones de latas, 86.000 toneladas de metal y 364.000 toneladas de papel que son utilizados anualmente para envasar esos productos acaban en los vertederos(39).

Prevalencia de lactancia materna

Como se ha descrito anteriormente, la lactancia materna es la forma idónea de alimentación tanto para madres y bebés según las instituciones internacionales referentes en salud y además las investigaciones indican que las madres desean en su inmensa mayoría alimentar a sus bebés con lactancia materna. Aun así, las tasas de lactancia difieren mucho de los propósitos de ambos, madres y recomendaciones científicas. Una de las limitaciones más importantes en los datos sobre lactancia es que las estadísticas sobre la prevalencia de la lactancia materna o no existen o suelen estar desactualizadas.

Sin embargo, según la OMS, a los 6 meses solo el 38% de los lactantes sigue recibiendo leche materna(40). En España, en la Encuesta Nacional de Salud (ENS) del año 2017 realizada por el Instituto Nacional de Estadística (INE) aporta: a las 6 semanas de vida, el 73,9% de los lactantes son alimentados exclusivamente con leche materna, a los 3 meses el 63,9% y a los 6 meses el 39,0%. A nivel europeo, Theurich MA et al, realizó una revisión de las prevalencias de lactancia materna en 11 países europeos incluyendo España(41). Las prevalencias difieren enormemente entre los países estudiados, teniendo cifras de lactancia materna de entre el 56 y el 98% al alta hospitalaria y de entre el 13 y el 71% a los 6 meses de vida. Esta revisión utiliza, para conocer la prevalencia de lactancia materna en España, los datos del Instituto Nacional de Estadística (INE).

Una investigación sobre la prevalencia de lactancia en Austria describió que la tasa de lactancia materna inicial fue del 97,5% y se redujo al 40,8% después de 12 meses. La tasa de lactancia materna exclusiva a la semana de vida fue del 55,5% y se redujo al 1,9% después de seis meses. La mitad de los lactantes recibieron leche artificial por primera vez en los tres primeros días de vida (mediana). De las madres que destetaron en los primeros 12 meses, la duración media fue de 27 semanas (42).

Diferentes estudios han analizado la prevalencia de lactancia materna en nuestro entorno. En Cataluña los datos del INE de 2017 reflejan que a las 6 semanas posparto la lactancia materna exclusiva es de un 69,57%, a los 3 meses de un 55,88% y a los 6 meses de un 28,89%(43). Oves Suárez, B. et al realizó un estudio de una cohorte representativa de la población de lactantes aragoneses donde se analiza la lactancia materna según el origen de la madre. En él se encuentra una prevalencia de lactancia materna total, que se refiere a la suma de lactancia materna exclusiva y lactancia materna mixta, de entre el 69,5 y el 75,4% en el alta hospitalaria, del 37,2 y el 43% a los cuatro meses de vida del lactante y de entre el 13,9 y el 23,8% a los 6 meses de vida. La prevalencia más alta se asocia a las mujeres inmigrantes(44).

Según el trabajo de Rius JM et al, que estudia los factores asociados del abandono precoz en una región del este de España, la prevalencia de lactancia materna total es la siguiente: al alta hospitalaria: 80%, al mes: 52%, a los 3 meses: 40%, a los 6 meses: 20% y a los 12 meses: 5%(45).

En Guipúzcoa, se estimó la prevalencia de la lactancia materna exclusiva al alta hospitalaria, a los 4 meses y a los 6, siendo, respectivamente, del 84,8%, del 53,7% y del 15,4%(46).

Ramiro González, MD. et al, midió la lactancia materna exclusiva así como la lactancia materna total en la Comunidad de Madrid(47). Se realizó mediante una encuesta telefónica. En el alta hospitalaria, la prevalencia de lactancia materna era del 77,6% frente al 88% de la total. Al mes de vida, del 70,5 frente al 82,8%, a los 3 meses de vida, el 59,8% de las encuestadas daban lactancia materna exclusiva a sus lactantes frente al 73,4% de la suma de todas las lactancias. A los 6 meses, la lactancia materna exclusiva tenía una prevalencia del 25,4%. Todas las formas de lactancia materna sumaban un 49,4%. Al año de vida del lactante, el 20,4% de las madres seguían con lactancia materna y a los 24 meses, el 7,7%. Como se puede observar, los datos aportados son muy dispares, según las zonas estudiadas y la forma de agrupar el tipo de lactancia.

En la región metropolitana norte de Barcelona se realizó otro estudio observacional multicéntrico a binomios madre-hijo desde la semana 35 de gestación hasta los 6 meses de vida entre el 2015 y el

2016 en el que se recogió la prevalencia y la duración de la lactancia. Los resultados indican que la lactancia materna total al alta fue del 94,8% y 63,3% a los 6 meses. En el caso de la LME los datos cambian, siendo un 75,3% al alta y un 16,8% a los 6 meses, muy lejos de las recomendaciones de la OMS(48).

Factores que influyen en la lactancia materna

Se puede constatar que los factores con más impacto en la duración de la lactancia materna son la incorporación al trabajo de la madre y la sensación de hipogalactia o que el recién nacido tenga hambre (46,48).

Centrándonos en los sentimientos que generan a las mujeres el hecho de no amamantar o no conseguir la lactancia deseada, Cortés (2019), muestra que las madres mostraban sentimientos ambivalentes, mientras que la lactancia materna se consideraba una experiencia satisfactoria, también era sacrificada y dolorosa. Hay referencia a la falta de conocimientos, y parece que la inseguridad sobre la alimentación del bebé y el dolor físico suelen ser las razones más importantes para abandonar la LM. También vio que existe una dualidad de sentimientos entre la tranquilidad que proporciona la alimentación artificial, al saber que su hijo está bien alimentado, y el sentimiento de culpa por no haber mantenido la LM. Las mujeres que Cortés entrevistó, consideran que los profesionales no realizaron adecuadamente su labor de promoción de la lactancia materna, refiriendo numerosas ocasiones en las que los propios profesionales sanitarios habían realizado prácticas contrarias a su instauración y mantenimiento (49).

Otro factor importante se explica con el concepto de "autoeficacia", desarrollado por Albert Bandura en la "Teoría social cognitiva" (50). La autoeficacia percibida es la creencia en la propia capacidad para organizar y ejecutar el curso de la acción requerida para llegar a una meta. En la validación de la versión española de una escala de autoeficacia en lactancia materna se define la autoeficacia en lactancia materna como la creencia de la madre sobre su capacidad para afrontar satisfactoriamente la lactancia materna (51).

En este aspecto, se pueden destacar trabajos como los de Hanne Kronborg y colaboradores y de Gael Shipp, que apuntan que los niveles de autoeficacia bajos están directamente relacionados con un cese prematuro de la lactancia materna y sugieren que las intervenciones en lactancia tendrían que incluir elementos para mejorar la autoeficacia (52–54).

Asimismo, que la madre tenga sensación de suficiente leche supone un factor de protección frente al abandono precoz según Rius, JM, et al (45).

Siguiendo esta línea, la ayuda y el asesoramiento del personal profesional especializado, según Esmeralda Santacruz, es crucial para evitar el cese de la lactancia materna exclusiva, especialmente en los primeros días. El apoyo y la ayuda de los profesionales de la salud pueden evitar dificultades y resolver problemas y dudas en la madre, incluida la inseguridad en la cantidad de leche producida y, por tanto, la correcta alimentación de su hijo (55).

Así, pese a que casi todas las mujeres son biológicamente capaces de amamantar, tal y como indica Nigel C. Rollins, las prácticas de lactancia se ven afectadas por una amplia gama de factores históricos, socioeconómicos, culturales e individuales (39). Nigel C. Rollins creó un modelo conceptual, tras realizar una revisión sistemática de los estudios disponibles, para identificar los determinantes de la lactancia materna que operan a múltiples niveles y afectan a las decisiones y comportamientos de lactancia a lo largo del tiempo.

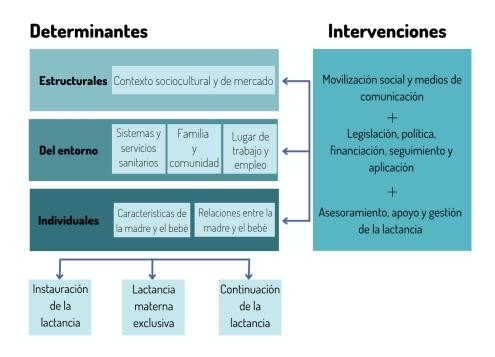


FIGURA 1: Determinantes de la lactancia materna adaptado de Rollins et al

Por este motivo, en la revisión que realizó Bellù, concluyó que la lactancia materna es un objetivo colectivo, no solamente materno. Al estar la lactancia afectada por diferentes factores, las intervenciones para promoverla incluyen aspectos individuales, sociales, económicos y políticos (56).

Por si no fuera suficiente, la LM es además contemplada como un derecho en la "Declaración conjunta de los relatores especiales de la ONU sobre el derecho a la alimentación, el derecho a la salud, en el Grupo de Trabajo sobre la Discriminación contra la Mujer en la Ley y en la Práctica y en el Comité de los Derechos del Niño en apoyo de mayores esfuerzos para promover, apoyar y proteger la lactancia materna". Y se expresa que en la restricción de la autonomía de las mujeres a la hora de tomar decisiones sobre su propia vida y por lo tanto también sobre su lactancia conduce a la violación de los derechos de las mujeres a la salud y atenta contra la dignidad y la integridad corporal de las mujeres (57).

Herramientas tecnológicas, mHealth y eHealth

Las herramientas tecnológicas pueden proporcionar información y apoyo en cualquier momento y en cualquier sitio, siendo accesibles para la mayoría de la población.

Cada vez son más las aplicaciones móviles que ofrecen información o servicios de salud. Algunas publicaciones ya apuntan que las aplicaciones móviles de lactancia pueden mejorar las tasas de lactancia en ciertas poblaciones(58).

Herramientas tecnológicas y lactancia

Las nuevas tecnologías demuestran la efectividad en muchas áreas relacionadas con la salud y específicamente en salud materno-infantil(59–61). El uso de una m-health puede estar en diferentes intervenciones, tanto de apoyo como de difusión y de ayuda a la gestión de la lactancia. Así, la lactancia materna, como proceso fisiológico y como aprendizaje, también puede beneficiarse del uso de esta tecnología y, este punto de aprendizaje cultural es el que hace que, de manera constante, las madres busquen información para amamantar a sus bebés lactantes. Esta búsqueda activa de información se realiza actualmente desde la red (62,63), siendo una constante que las nuevas tecnologías mejoran las tasas de lactancia materna en muchas versiones informáticas como la llamada telefónica(64), mensajes cortos (SMS)(65), técnicas de telelactancia(66) e incluso los foros en línea(67).

Melisa Sayyedi y colaboradores (2021) realizaron un ensayo controlado aleatorio en el que el grupo de intervención usó una aplicación móvil diseñada para ofrecer educación a las madres que amamantaban. En el estudio, la autoeficacia para la lactancia materna de las madres mostró un progreso significativo a favor del grupo de intervención(68).

En una revisión sistemática sobre el apoyo de la lactancia en el lugar de trabajo, se concluye que cuando se ofrece un programa integral de apoyo a la lactancia en el que haya, además de salas de lactancia y flexibilidad para poder extraerse leche, educación sobre lactancia y acceso a información sobre esta vía web, la posibilidad conseguir lactancias más largas es mayor. Además, se concluye que las empresas que adoptan un programa de apoyo a la lactancia ahorran una media de tres dólares por cada dólar que invierten(69).

En el Reino Unido, el uso de las tecnologías móviles en la atención a la salud o enfermedad es algo que está extendido. Los facultativos, pueden prescribir aplicaciones móviles a sus pacientes como una práctica más del abordaje de situaciones de salud. El departamento de Salud Pública del Reino Unido publicó una encuesta realizada a 1000 madres atendidas en sus hospitales en la que se les preguntaba, entre otras cosas, sobre la atención a la lactancia (70). Entre otras, las respuestas fueron:

- 1 de cada 4 (26%) de las que dieron el pecho a su primer hijo hubiera deseado haber sabido que pedir ayuda puede suponer una verdadera diferencia en la lactancia.
- Casi un tercio (31%) de las madres se sienten avergonzadas de pedir ayuda a los profesionales sanitarios especializados en lactancia. A muchas madres les resulta difícil dar el pecho y, a menudo, esto les hace destetar.
- Casi dos tercios (64%) consideraban que el acceso a un apoyo a la lactancia materna 24 horas al día, 7 días a la semana, como una línea telefónica, un sitio web o un chatbot, haría que las nuevas madres:
 - tuvieran más probabilidades de tener una experiencia positiva de la lactancia materna
 - que se decidieran a probar la lactancia materna (59%)
 - amamantaran durante más tiempo (58%)
- 1 de cada 4 (26%) madres consideró que el uso de más herramientas e información online/digital les habría ayudado a estar más preparadas para ser madres

LactApp

LactApp es una aplicación móvil que ofrece respuestas individualizadas de forma automática. Mediante un cuestionario autoadministrado. La usuaria, a partir de más de 70 árboles de decisión y a través de más de 74.000 posibles caminos, llega a una de las 2.637 posibles respuestas finales que tratan de resolver una duda planteada.

Además, la aplicación cuenta con un blog de unas 1.700 entradas, así como la posibilidad de hacer planes personalizados o test del estado de la lactancia u otros. También cuenta con un canal de consultas de texto que son contestadas por expertas en lactancia.

LactApp se puede descargar de forma gratuita en los markets (App Store y Google Play) y cuenta con una versión Premium donde se pueden encontrar formaciones multimedia, píldoras diarias de aprendizajes en lactancia y temas relacionados con la maternidad, así como avisos de las siguientes etapas que se van a encontrar las madres según la edad de sus bebés.

Con este material, además, desde LactApp se está desarrollando una herramienta a partir de las consultas de texto de las madres y de las imágenes que son enviadas a través del canal de consultas aplicando técnicas de inteligencia artificial (explicado más adelante).

En 2021, LactApp se convirtió en la App de lactancia número 1 en España donde el 24% de las nuevas mamás realizan alrededor de 120.000 consultas semanales, que suman más de 1,1 millones de consultas mensuales. Mediante un crecimiento puramente orgánico desde su lanzamiento en 2016, acumula más de 600.000 descargas y ha gestionado más de 19 millones de consultas desde 2018 procedentes de 180 países en castellano, inglés y portugués, sin ningún tipo de inversión de marketing o adquisición de usuarias.

Para poner estos datos en contexto, un estudio sobre aplicaciones telemáticas en el entorno de la salud a nivel mundial arroja que el 80% de las aplicaciones no supera las 50.000 descargas al año(71). El número de usuarias activas al mes, es decir, las usuarias que interactúan con la aplicación, llega hasta las 50.000. El mismo estudio muestra que la aplicación tiene más usuarias activas que el 98% del resto de aplicaciones de salud del mundo.

Dichos datos respaldan que LactApp se encuentra entre el 20% de aplicaciones con más descargas y usuarias activas del mundo y pone de manifiesto el potencial de la aplicación para proporcionar apoyo a las madres en relación a la lactancia y su maternidad. LactApp ha adquirido esta tracción sin gasto

de marketing gracias al aval de los profesionales de la salud y a la alta satisfacción de las usuarias, ya que califican la App con un 94% de Net Promoter Score(72).

LactApp ha sido revisada por la Organisation for the Review of Care and Health Apps (ORCHA) del Reino Unido. ORCHA es una entidad que evalúa las aplicaciones móviles de salud, por ejemplo, para el Departamento de Salud Pública del Reino Unido con una calificación general del 80% y una puntuación de garantía profesional del 74% (Anexo II).

El volumen de información que tiene hace de LactApp sea una herramienta muy usada por las madres, por lo que el estudio del perfil de éstas y su comportamiento dentro de la aplicación puede dar mucha información de las necesidades de las madres lactantes en este momento vital.

Clasificación Automática de las Consultas de las Usuarias mediante Inteligencia Artificial

LactApp se comporta como un Sistema de Soporte de Decisiones (SSD) cuyo objetivo es la resolución de dudas que pueden tener las madres sobre lactancia y maternidad. El eje del SSD es un conjunto de "árboles de decisión" que han sido elaborados manualmente por profesionales de la lactancia y que están respaldados por evidencia científica y actualizados con las últimas recomendaciones de los organismos oficiales de salud. Actualmente existen cinco grupos de árboles que son: "Sobre mí", "Mi bebé", "Maternidad y Crianza", "Mi Embarazo" y "Mi Salud". Cada grupo reúne árboles sobre el tema: por ejemplo, el grupo "Mi Salud" incluye árboles como "Emociones", "Punto Violeta" y "Menstruación y fertilidad".

Cada árbol, o tema, consiste en los siguientes elementos:

- Preguntas: Son los nodos de decisión (que no siempre son preguntas) del árbol y que llevan a diferentes opciones, como por ejemplo "¿En qué momento y en qué lugar del pecho sientes dolor?" o "Sobre la/s persona/s que se quedará/n con el bebé:".
- Opciones: Son las opciones que puede escoger la usuaria en respuesta a la "pregunta" anterior, como por ejemplo "Me duele el pecho cuando el bebé mama" o "No sé cuándo tiene hambre".
- Respuestas finales: Son las hojas del árbol y consisten en textos de uno o varios párrafos con enlaces y referencias opcionales.

En la tabla 1 se resumen los componentes del SSD así como el número de instancias de cada componente. Esta representación da un total de 76.000 diferentes caminos en los que se pueden navegar en la aplicación.

Nodo de decision	Número	Ejemplos
Temas	56	"Vuelta al trabajo "Dificultades en el agarre"
Preguntas	777	"¿Cuál de las siguientes opciones describe mejor tu situación?" "Selecciona la posición que quisieras aprender"
Opciones	3381	"Mi bebé no me mira o evita el contacto" "Quiero destetarle y parar la lactancia"
Respuestas	2578	"Si tengo COVID, ¿mi bebé está en riesgo?" "De 10 a 25 días, mi bebé aún no ha recuperado el peso del nacimiento"

TABLA 1: Elementos del Sistema de Soporte de Decisiones (a fecha de Marzo 2022)

Cada pregunta es una pantalla con sus opciones, cuya selección puede llevar a una respuesta final a otra pregunta, dependiendo del perfil de la usuaria (por ejemplo, si está embarazada o la edad de su bebé). De esta forma la usuaria puede escoger, mediante una serie de preguntas y opciones el mejor camino que la llevará a la respuesta más pertinente para su caso específico.

Además de navegar por los árboles de decisión, la usuaria también puede hacer consultas a expertas en lactancia, iniciando así una conversación. Actualmente hay casi 25.000 turnos de conversación de las usuarias desde el 2016, para un total de 43.860 usuarias.

Debido al gran volumen de consultas vía el canal de consultas (unas 700consultas semanales), se ha desarrollado un modelo de clasificación automática de las consultas. Este modelo, que usa técnicas avanzadas de Inteligencia Artificial (IA) y Procesamiento de Lenguaje Natural (PLN), asigna cada texto a una de las diferentes clases (por eso se le llama *modelo multiclase)*.

Para ello, se usa lo que se llama un *modelo de lenguaje*, que es una representación probabilística del lenguaje, donde dado una secuencia de palabras, el sistema es capaz de predecir la palabra siguiente. A grandes rasgos, esos modelos de lenguaje, además de ser capaces de representar el lenguaje

humano, se pueden utilizar para codificar cualquier tipo de texto y aprender los rasgos característicos de cualquiera clase de interés sobre el conjunto de textos, como por ejemplo el sentimiento (reseña positiva o negativa) de un texto, su tema (artículo sobre deporte o economía), etc. Los modelos de lenguajes están entrenados sobre un conjunto de datos enormes (miles de millones de textos) una sola vez, típicamente por grandes empresas como Google o OpenAI, y se pueden reutilizar y adaptar a cualquier otro dominio con recursos computacionales moderados con una técnica llamada aprendizaje por transferencia (transfer learning). Además, cuentan con una arquitectura muy avanzada llamada transformers, basadas en redes neuronales profundas y técnicas de procesamiento de secuencias que permiten tener en cuenta la dependencia de largo rango entre palabras de un texto. Estos avances han revolucionado el campo del PLN desde el 2017 y han permitido grandes avances en distintas tareas de PLN como análisis de sentimiento, diálogo, clasificación, etc.

Se entrena el clasificador de mensajes de las usuarias a base de uno de esos modelos de lenguaje pre-entrenados en un proceso llamado aprendizaje supervisado que precisa de un conjunto de consultas clasificadas manualmente por parte de una de las expertas de LactApp. Actualmente, la predicción del modelo está destinada a la experta que hace un primer "triaje" manual de los nuevos mensajes enviados por las usuarias en el canal de consultas. Concretamente, el modelo proporciona a la experta las 5 clases más probables en orden descendente, como muestra la Figura 2. Estas clases son temas como "Salud de mi Bebé" o grupos de temas como "Grupo Dolor", o "bonsais" (subárboles). La experta puede validar una de estas propuestas, aumentando así el conjunto de consultas manualmente clasificadas. Además, la experta puede elegir mandar la respuesta automática correspondiente a la clase predicha por el modelo, es decir que se manda a la usuaria el enlace en la app a su correspondiente nodo de decisión en la app, sea la raíz de un árbol o un nodo dentro de ese árbol. Alternativamente, o si la usuaria así lo requiere, la experta puede iniciar una conversación con la usuaria con una conversación convencional por chat.

Actualmente el acierto global del clasificador automático es de 69% con la mejor predicción, 87% con las 3 mejores predicciones y 91% con las 5 mejores predicciones.

```
Buenas tardes! Mi bebé de 1 mes tiene muguet en la boca, me gustaría saber si para
eliminarlo de las tetinas del biberón y chupetes basta con esterilizarlos en agua hirviendo o
debemos tirarlos y comprar nuevos, muchas gracias!
Use /sk [text] to reply
Sponsored Conversations APP 4:32 PM
http://iasmooch.lactapp.es:5000/prediction/6348217bbf245200f9953d24
La IA pensa que es un tree : SALUD DE MI BEBÉ amb puntuació 66.05318785608353 Classify
La IA pensa que es un tree : PRODUCTOS PARA LA LACTANCIA amb puntuació 29.053675876986652 Classify.
La IA pensa que es un group : Grupo Dolor que conté:

    tree: DOLOR EN EL PECHO amb puntuació 2.137705889567349 Classify.

  tree: BULTOS EN EL PECHO amb puntuació 2.137705889567349 Classify
• tree: GUÍA DEL DOLOR AL AMAMANTAR amb puntuació 2.137705889567349 Classify.
  tree: GRIETAS Y HERIDAS amb puntuació 2.137705889567349 Classify.
  bonsai : ¿Tienes algún tipo de herida en el pezón o areola? amb puntuació 2.137705889567349 Classify.
  bonsai : ¿Tienes una zona del pecho enrojecida? amb puntuació 2.137705889567349 Classify
  bonsai : ¿En qué momento y en qué lugar del pecho sientes dolor? amb puntuació 2.137705889567349 Classify.
  bonsai : ¿Tienes algún bulto en el pecho? amb puntuació 2.137705889567349 Classify.
  bonsai : Sobre la corriente que sientes en el pecho: amb puntuació 2.137705889567349 Classify.
  bonsai : ¿Tienes un punto blanco en el pezón que no se va? amb puntuació 2.137705889567349 Classify.
  bonsai : Observa el pezón después de la toma. Tienes...
                                                   amb puntuació 2.137705889567349 /6348217bbf245200f9953d24/bonsai/88b3cec64aafffe84908500f>Classify.
  bonsai : ¿Tienes fiebre? amb puntuació 2.137705889567349 Classify.
La IA pensa que es un group : Grupo Salud que conté:

    tree: PRUEBAS DIAGNÓSTICAS amb puntuació 1.5839753442815747 Classify

· tree: ¿QUÉ HAGO SI...? amb puntuació 1.5839753442815747 Classify.

    tree: ESTOY ENFERMA amb puntuació 1.5839753442815747 Classify
```

FIGURA 2: Ejemplo de 5 grupos de temas proporcionados por la IA a la experta para clasificar una consulta

La pandemia de SARS-CoV-2 y la lactancia

La pandemia por SARS-CoV-2 provocó el cierre de servicios de salud presenciales y el desvío de todos los esfuerzos hacia la atención de enfermos por COVID-19. Y se hizo, en la mayoría de las ocasiones, caso omiso a las recomendaciones de la Organización Mundial de la Salud (OMS) sobre la atención a la lactancia materna en urgencias o catástrofes, que recomiendan protegerla y ofrecer apoyo continuo a las madres(73).

Aún y con estas premisas, los estudios sobre la seguridad de la lactancia en situación de que la madre estuviera infectada costaron mucho que salieran y muchas recomendaciones que se hacían en los centros hospitalarios continuaban siendo contradictorias a las líneas de actuación de la OMS(74,75). En este momento, multitud de literatura científica apoya la seguridad de la lactancia materna directa en caso de que la madre sea positiva en SARS-CoV-2(76–79).

En la revisión que realizó Lubbe y colaboradores (2022), pudieron verificar que los factores que influyeron en el apoyo a la lactancia materna durante la pandemia COVID-19 fueron la separación, la falta de contacto piel con piel, el apoyo insuficiente, el impacto de la pandemia en las tasas y experiencias de lactancia materna, los temores de la pandemia y la necesidad de apoyo adicional. La pandemia influyó mayoritariamente en el apoyo a la lactancia materna de forma negativa, con una

pequeña excepción en la que algunas madres experimentaron el cierre como algo positivo, ya que protegía a la díada madre-lactante de visitas no deseadas(79).

Tales hallazgos también salieron a la luz con la investigación del equipo de Sakalidis (2022), que observaron que las mujeres que dieron a luz durante la pandemia tuvieron un acceso restringido a la atención postnatal(80). Además, la continuación de la lactancia materna puede ser protectora para el lactante, ya que ofrece inmunidad pasiva contra el SRAS-CoV-2, y la vacunación contra el COVID-19 es segura y eficaz para las mujeres embarazadas y lactantes. Una atención a la lactancia innovadora y adaptable, que incluya servicios holísticos de apoyo perinatal, de salud mental y social, tanto digitales como presenciales, ayudaría a las madres a seguir amamantando durante futuros brotes.

Brown y Shenken (2021) realizaron una investigación sobre el impacto de la pandemia en la duración de la lactancia, las experiencias y el apoyo recibido en el Reino Unido. Para ello, realizaron una encuesta en línea a 1.219 madres lactantes de bebés de entre 0 y 12 meses. En su publicación, explican que hubieron dos experiencias muy diferentes: el 41,8% de las madres consideraron que la lactancia estaba protegida debido al confinamiento, pero el 27,0% de las madres tuvieron dificultades para obtener apoyo y tuvieron numerosas barreras derivadas del confinamiento, y algunas dejaron de amamantar sin desearlo. Las madres con menor nivel de estudios, con circunstancias de vida más difíciles y de origen étnico negro y minoritario eran más propensas a encontrar el impacto del bloqueo como un reto y a dejar de amamantar(81).

En España, acaba de publicarse una investigación liderada por la Dra Mena en la que se realizó una encuesta online a través de las redes sociales de la que se obtuvieron 6.270 cuestionarios. En ellos se preguntaban cuestiones sobre datos demográficos, violencia obstétrica sufrida, la percepción de apoyo a la lactancia, ofrecimiento de leche de fórmula, contacto con los grupos de apoyo a la lactancia, cese de la lactancia por vacunarse contra el SARS-CoV-2 y sentimientos de las mujeres. Entre otros hallazgos, se objetivó que a las mujeres que tuvieron bebés entre marzo del 2020 y abril de 2021 se les ofreció menos apoyo para la lactancia materna, más alimentación con fórmula, menos contacto con grupos de apoyo en la zona y más recomendaciones de abandonar la lactancia materna para vacunarse contra el SARS-CoV-2, no estando avaladas estas actuaciones por la literatura científica actual(82).

HIPÓTESIS

La tecnología aplicada al ámbito sanitario, especialmente en áreas donde el apoyo es clave como ocurre con la lactancia materna es fundamental. Además, puede que la necesidad de este apoyo para las mujeres haga que una herramienta mHealth como LactApp sea muy utilizada. Es posible que este tipo de tecnología personalizada y aplicada a la lactancia materna, sea utilizada según el perfil y la edad del bebé y cambie, se modifique o adapte ante cualquier adversidad sanitaria, como con la reciente pandemia por el SARS-CoV-2.

OBJETIVOS

Objetivo general

Conocer cómo una mHealth de lactancia (LactApp) da apoyo a sus usuarias

Objetivo específico 1

Realizar un análisis descriptivo de una aplicación móvil sobre lactancia materna (LactApp) para estudiar el perfil de la usuaria, así como las consultas más frecuentes.

Objetivo específico 2

Analizar las consultas realizadas por las usuarias en función de la edad del bebé en LactApp

Objetivo específico 3

Evaluar el impacto de la pandemia de SARS-CoV-2 en las consultas de lactancia materna en LactApp.

METODOLOGÍA Y RESULTADOS

Objetivo específico 1

Analizar las consultas realizadas por las usuarias en una app de lactancia.

Para este objetivo se realizó un trabajo que se publicó en formato artículo en marzo de 2021 en la revista científica Breastfeeding Medicine. Esta revista tuvo un factor de impacto de 2,335 y perteneció al lugar 81 de 184 de la categoría "Pediatrics" del Journal of Citations Reports (JCR) en su año, ocupando el segundo cuartil (Q2) y el segundo tercil (T2). El trabajo se tituló: Telelactation with a Mobile App: User Profile and Most Common Queries.

Cita bibliográfica: Padró-Arocas, A., Mena-Tudela, D., Baladía, E., Cervera-Gasch, A., González-Chordá, V. M., & Aguilar-Camprubí, L. (2021). Telelactation with a Mobile App: User Profile and Most Common Queries. Breastfeeding medicine: the official journal of the Academy of Breastfeeding Medicine, 16(4), 338–345. https://doi.org/10.1089/bfm.2020.0269

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Metodología

Diseño

Para responder a este objetivo, se ha realizado un estudio retrospectivo, comparativo y descriptivo de series temporales sobre los datos registrados por la aplicación móvil LactApp desde el 1 de julio de 2016 hasta el 30 de junio de 2019.

Ámbito, población y muestra

LactApp, como se ha descrito anteriormente, es una aplicación móvil que funciona a partir de un cuestionario autoadministrado, en que el momento de la investigación, se basaba en más de 50 árboles de decisión construidos por preguntas y respuestas desarrolladas por profesionales expertas en lactancia, apoyadas por literatura científica y recomendaciones oficiales de salud.

En el momento de la investigación, había más de 2.300 respuestas personalizadas a las que se podía llegar a través de más de 76.100 posibles caminos, que variaban según el perfil de la usuaria y de las opciones que ésta iba seleccionando.

Para llegar a una respuesta final del cuestionario, la usuaria debe registrarse previamente en la aplicación con su correo electrónico y navegar por las opciones del cuestionario autoadministrado hasta llegar a la respuesta final.

LactApp también presenta otras funcionalidades de seguimiento de la lactancia: los llamados "trackers" o registros. En el momento de la investigación, había un registro de tomas de lactancia, donde se podía anotar el número y duración de las tomas, el horario, las dificultades relacionadas con la lactancia (dolor, grietas, bultos, cambios de coloración del pezón, grado de sensación del dolor y estado de ánimo). También había un registro de la evolución del peso y de la talla del lactante, así como de sus deposiciones.

Otra funcionalidad que dispone la aplicación son los test y planes personalizados. Los test son 5 cuestionarios tipo test que permiten tener una respuesta rápida en relación a situaciones que se pueden presentar durante la lactancia. Los planes personalizados son cuestionarios con varias posibles respuestas y recomendaciones a las usuarias en función de sus necesidades y preferencias. Finalmente, en la misma aplicación se pueden realizar consultas en vivo a través de un chat atendido por expertas en lactancia. Es a partir de este chat que se entrena la inteligencia artificial a partir de técnicas de machine *learning* y case based reasoning.

Un blog con un amplio contenido también forma parte de los servicios que ofrece la aplicación.

Cuando se realizó este análisis, LactApp disponía de la versión Medical de la app, en la que los profesionales sanitarios, podían disponer de todo el conocimiento de la aplicación perfilando la respuesta a partir de la consulta del profesional. En este momento, LactApp Medical es una aplicación diferenciada de la app para madres, con contenido exclusivo para profesionales de la salud y/o relacionados con la lactancia.

La población del estudio está formada por todas las usuarias de LactApp.

Variables y Recogida de datos

Las variables estudiadas fueron las usuarias registradas en la aplicación y sus bebés, las consultas automatizadas, así como las respuestas finales a las que se ha llegado y los test de la aplicación.

Para la recogida de datos se utilizó la herramienta Google Analytics. La extracción de datos se procedió por trimestres para poder comparar su tendencia. Entre las variables recogidas con Google Analytics se encuentran: número de usuarios, número de sesiones y pantallas, duración de la sesión, usuarios nuevos y usuarios recurrentes, idiomas de acceso, países desde los que se accede, sistema operativo usado y tipos de eventos más consultados: número de consultas y temas, acceso al chat y realización de test. Sobre los eventos se tuvieron en cuenta los Unique Events, definidos por Google Analytics como: *interactions with content by a single user within a single sesion* (Google, 2019).

Consideraciones éticas

Este estudio cumplió con la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales. El registro en LactApp requiere que las usuarias acepten el Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos (Reglamento general de protección de datos).

Análisis de datos

Se realizó un análisis descriptivo para todas las variables, utilizando la frecuencia absoluta y relativa expresada en porcentajes para las variables cualitativas y media y desviación típica para las variables cuantitativas. Se estimó la tendencia temporal de las consultas realizadas en la aplicación realizando auto-regresiones de Prais-Winsten, basadas en el método Durbin-Watson. Este análisis permite obtener la tendencia global de variables cuantitativas relativas a momentos específicos y estudiados

según su distribución en el tiempo. Así, se determinó si la tendencia de uso fue creciente, decreciente o estática mediante el cálculo de la Variación Porcentual Trimestral (TPC, en sus siglas en inglés) y sus intervalos de confianza del 95% (IC95%) (Antunes & Cardoso, 2015). El análisis se realizó usando Hojas de Cálculo de Excel para los cálculos generales y el programa Stata 14.0 para las series temporales (2015).

Resultados

Perfil de las usuarias registradas

Se registraron un total de 115.830 usuarias en la aplicación LactApp en el periodo de estudio (del 01/07/2016 hasta el 30/06/2019). De éstas, el 98,09 % eran usuarias con perfil de madre y el 1,91% (n=2.207) eran usuarias de la versión Medical de la aplicación.



GRÁFICO 3: Perfil de las usuarias de LactApp

De las usuarias con el perfil no profesional, 110,015 (el 96,8%) utilizaban la aplicación en español y 2.457 en inglés (el 2,2%). El sistema operativo móvil más usado era Android, con 62,4% de las usuarias (70.939 usuarias). El 86,4% (n=95.477) de las usuarias eran mujeres y la edad de éstas se concentraba mayoritariamente en la franja de 25 a 44 años.

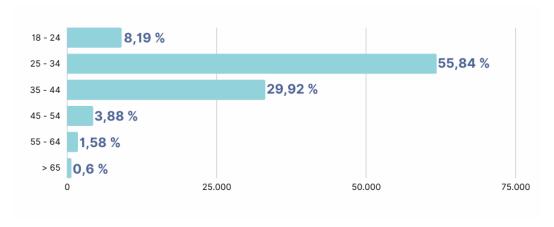


GRÁFICO 4: Fdad de las usuarias

La distribución de países por porcentaje de las usuarias de LactApp fue el siguiente: España (53,84%, n=62.363), México (11,35%, n=13.147), Argentina (5,48%, n=6.347), Estados Unidos (5,30%, n=6.139), Chile (4,48%, n=5.606), Perú (1,57%, n=1.818), Uruguay (1,26%, n=1.460) y Costa Rica (1,1%, n=1274).

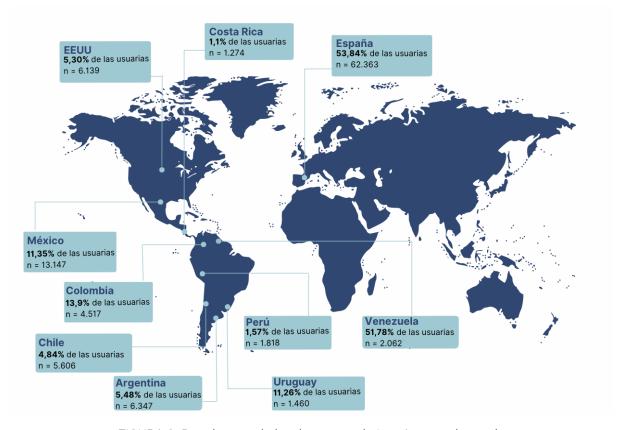


FIGURA 3: Distribución de las descargas de LactApp en el mundo

El idioma más utilizado por las usuarias fue el español, con 89,94% (n=112.092), mientras que en inglés lo utilizaron el 5,22% de las usuarias (n=2.477)

Había 3 perfiles de usuarias no profesionales: 3.274 (2,9%) eran usuarias que estaban embarazadas, 43.417 (38,2%) eran usuarias que habían indicado que no estaban embarazadas en aquel momento y 66.931 (58,9%) usuarias no habían especificado si estaban embarazadas o no.

El 79,1% (n=89,879) de las usuarias, indicaba en su perfil que en ese momento no tenía ningún hijo o hija previos y el 11,2% (n=12.766) que tenía uno. Un 3,3% de las usuarias indicaron que tenían 2 hijos (n=3.784), un 0,5% indicaron tener 3 hijos (n=0,5) y un 0,2% de las usuarias registradas indicaron tener 4 o más hijos (n=90).

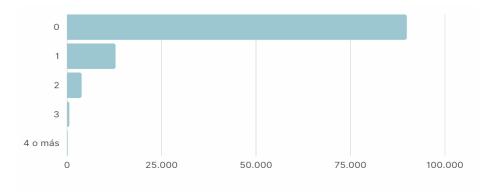


GRÁFICO 5: Número de hijas o hijos previos

Perfil de los bebés

Durante este mismo periodo, 71.780 bebés fueron registrados, de los cuales 35.446 (49,4%) eran niñas y 36.334 (50,6%) niños. La mediana de edad de los bebés registrados fue de 21 meses (con un rango de intercuartil de 14 meses; un máximo de 78 meses y un mínimo de 0 meses). Al nacer, los bebés tenían una mediana de peso de 3.211,3g (±498,17g) y una mediana de talla de 49,61 cm (±2,42 cm). El 6,1% (n=4.388) de los bebés registrados nacieron de partos prematuros, entre la semana 25 y la semana 36 de gestación, con una media de 34,73 semanas de gestación con una desviación estándar de 2,05 semanas.

Perfil de las usuarias de la versión Medical

La edad media de las usuarias de la versión Medical fue de 34,57 años (±6,02 años). Las profesiones más destacadas en la versión Medical fueron: Enfermería, con un 17,3% (n=382), Medicina con un 15,3% (n=337) y Matronería con un 13,4% (n=296).

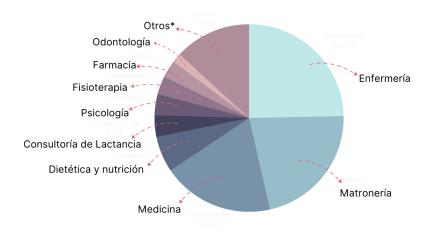


GRÁFICO 6: Perfiles profesionales en versión Medical*

Sesiones, pantallas y tiempo de visualización de LactApp

Durante el periodo de la investigación, se iniciaron un total de 1.767.308 sesiones con una clara tendencia al alza y se visualizaron un total de 11.838.570 pantallas con una tendencia estática durante el periodo de la investigación. El número medio de pantallas visualizadas por sesión fue de 6,7, con una tendencia al decrecimiento significativa y una duración de 6 minutos y 2 segundos por sesión que no decreció durante el periodo estudiado. El porcentaje de usuarias recurrentes en ese período aumentó significativamente y el de nuevas usuarias, decreció.

Se iniciaron 62.173 como mínimo una vez uno de los 5 test durante el periodo de estudio y el 71,13% (n=44.222) lo acabaron completamente. De las usuarias que llegaron a la respuesta final del test, el 15,11% (n=6.680) dieron su opinión con un 93,01% de "Likes".

El test que más fue iniciado fue "¿Mi bebé mama bien?", con un 32,32% (n=20.094), seguido por "Superando el primer mes con éxito", con un 18,34% (n=11.400), "Los primeros 5 días de tu bebé", con un 17,56% (n=10.920), "¿Mi bebé está preparado para comer sólidos?" con un 16,59% (n=10.313) y, finalmente, "¿Sabes si tu bebé tiene el frenillo de la lengua corto?" con el 15,19% (n=9.446).

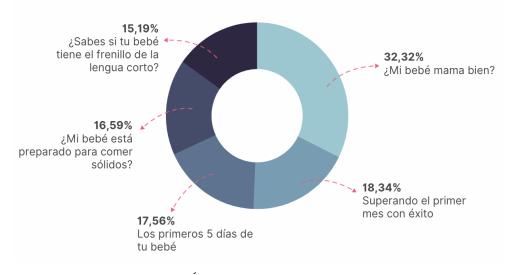


GRÁFICO 7: Test empezados

Al término de la investigación, las usuarias llegaron a 2.757.702 respuestas finales en LactApp a través de las consultas automatizadas.

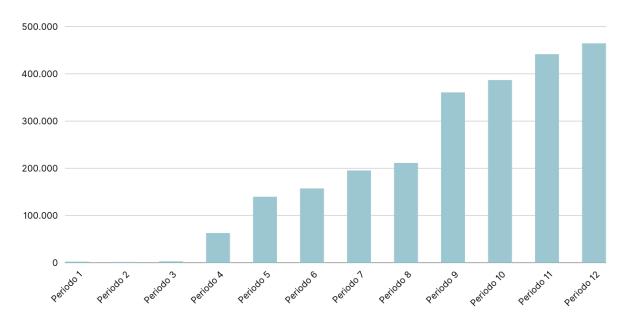


GRÁFICO 8: Consultas automatizadas según el periodo estudiado

Periodo 1: del 1 de julio de 2016; Periodo 3: del 1 de enero de 2016; Periodo 3: del 1 de enero de 2017 al 31 de marzo de 2017; Periodo 4: del 1 de abril de 2017 al 30 de junio de 2017; Periodo 5: del 1 de julio de 2017 al 30 de septiembre de 2017; Periodo 6: del 1 de octubre del 2017 al 31 de diciembre de 2017; Periodo 7: del 1 de enero de 2018 al 31 de marzo de 2018; Periodo 8: del 1 de abril de 2018 al 30 de junio de 2018; Periodo 9: del 1 de julio de 2018 al 30 de septiembre de 2018; Periodo 10: del 1 de octubre de 2018 al 31 de diciembre de 2018; Periodo 11: del 1 de enero de 2019 al 31 de marzo de 2019; Periodo 12: del 1 de abril de 2019 al 30 de junio de 2019.

El 30,17% (n=58.6101) de las respuestas correspondieron a temas como el "sueño del bebé" (n=246.628; el 8,94%), la "extracción y conservación de la leche" (n=245.785; 8,91%), las "crisis de lactancia" (n=169.911; el 6,16%) y la "evolución fisiológica de la lactancia" (n=169,562; el 6,15%).

Dentro del tema "Sueño del bebé" las respuestas finales más consultadas fueron: "Horas de sueño según la edad del bebé" (n=19.048; 7,72%) con un TPC de 252.785, un intervalo de confianza del 95% entre 125.204 y 380.366; "El bebé se despierta cuando lo pongo en la cuna" (n=10.331; 4,19%) con un TPC 209.297 y un intervalo de confianza del 95% entre 144.360 y 274.366; y "Métodos para dormir al bebé" (n= 10.548; 4,28%), con un TPC 122.259 y un intervalo de confianza del 95% entre 46.712 y 197.805, todas ellas con una tendencia creciente.

Dentro del tema de "Extracción y conservación de la leche" las respuestas finales más consultadas fueron: "Tabla rápida de conservación de la leche" (n=17.305; 7,04%) con un TPC de 247,590 y un intervalo de confianza del 95% entre 158.833 y 336.347; "Cómo calentar la leche" (n=11.172; 4,55%) con un TPC de 197.093 y un intervalo de confianza del 95% entre 151.771 y 242.414; "Cómo descongelar

la leche" (n= 9.463; 3,85%) con un TPC de 127.258 y un intervalo de confianza del 95% entre 748.980 y 197.805, todas ellas con una tendencia creciente.

Dentro del tema de "Crisis de lactancia", las respuestas finales más consultadas, fueron: "Crisis de los 15 días" (n=16.992; 10,60%), con un TPC de 457.806 y un intervalo de confianza del 95% entre 336.182 y 579.430; "Crisis de las 7 semanas" (n=18.631; 11,62%) con un TPC de 520.075 y un intervalo de confianza del 95% entre 378.066 y 662.083; "Crisis de los 3 meses" (n=18.193; 11,35%) con un TPC de 450.133 y un intervalo de confianza del 95% entre 305.692 y 594.573, todas ellas con una tendencia creciente.

Y, finalmente, dentro del tema de "Evolución fisiológica de la lactancia", las respuestas finales más consultadas, fueron: "Evolución fisiológica de la lactancia a los 15 días" (n=12.502; 12,34%) con un TPC de 240.687 y un intervalo de confianza del 95% entre 108.204 y 373.170; "Evolución fisiológica de la lactancia en el primer mes" (n=12.177; 12,02%) con un TPC de 220.093 y un intervalo de confianza del 95% entre 74.233 y 365.952; "Evolución fisiológica de la lactancia a los 2 meses" (n=14.032; 13,86%) con un TPC de 258.157 y un intervalo de confianza del 95% entre 84.595 y 431.718, todas ellas con una tendencia creciente.

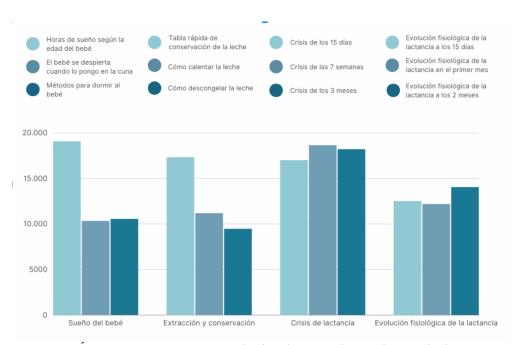


GRÁFICO 9: Temas más consultados durante el periodo estudiado

De estas respuestas el 1,68% (n=46.374) de las usuarias dieron su opinión sobre las respuestas finales. El 89,26% (n=41.392) pulsaron el botón de "like" versus el 10,74% (n=4.982) que pulsaron el botón de "unlike".

La funcionalidad del canal de consultas atendidas por expertas en lactancia se inició en enero del 2018. El total de consultas realizadas fueron de 38.568 desde enero de 2018 a junio de 2019.

Telelactation with a mobile app: user profile and most common queries Abstract

Background: Mobile applications related to health issues are currently expanding. Different uses of new technologies have produced positive results regarding breastfeeding support.

Breastfeeding applications are increasing.

Research aim: We conducted a descriptive analysis of a mobile application for breastfeeding (LactApp) to study the user profile and the most frequent queries.

Methods: This was a retrospective, comparative and descriptive ecological time series study of LactApp from 2016 to 2019. Google Analytics and the app itself were used for data collection. The data were analysed in Excel, and for the time series, Prais-Winsten auto-regressions were applied based on the Durbin-Watson method in Stata.

Results: A total of 115,830 users and 71,780 infants were registered in the application. A total of 1.91% of these users obtained the medical version. The application was used for both queries and tests and for users to interact through chat. A total of 27.69% of the responses were related to "baby's sleep", 8.91% were related to "milk extraction and preservation", 6.16% were related to "breastfeeding crisis", and 3.67% were related to "physiological evolution of breastfeeding", all with an increasing trend.

Conclusion: LactApp is a potent resource for breastfeeding that is widely downloaded and used by a substantial number of individuals. The most recurring topics were baby's sleep, milk extraction and preservation, breastfeeding crisis and physiological evolution of breastfeeding.

Well Established

Mothers who do not breastfeed and infants who are not breastfed are exposed to risks to their health. Despite the efforts of international organizations to improve breastfeeding rates, breastfeeding rates remain low.

Technologies are being developing at a vertiginous rate and can be used to enhance and support both the establishment and maintenance of breastfeeding.

Newly Expressed

While some studies have explored whether a given new technology can help mothers maintain breastfeeding, it is unknown how breastfeeding applications are utilized. Knowing the most recurring topics can help reinforce the critical issues in which there are more questions related to breastfeeding. This support could have a positive effect on the maintenance and duration of breastfeeding and, therefore, on the health of mothers and babies.

Background

The scientific literature states that infants who are not breastfed and mothers who do not breastfeed are exposed to many health risks, both in the short term and long term. The World Health Organization (WHO), the United Nations Children's Fund (UNICEF) and other international organizations recommend initiating breastfeeding (BF) during the first hour of life of the new-born and exclusively BF up to 6 months of age, subsequently introducing adequate complementary foods without stopping BF until the child is at least 2 years old (Kim y colaboradores 2018; Smith y colaboradores, 2018). The rates of BF at the global level do not conform to these recommendations; each year, approximately 823,000 children's lives could be saved if the infants were breastfed (The Lancet, 2016), and only 40% of infants younger than 6 months receive breast milk as exclusive food (World Health Organization, 2017a).

BF is a bio-socio-cultural act for women, although it is instinctive for the new-born. Therefore, support, counselling and education are fundamental strategies for a mother to continue breastfeeding (Sutton, O'Donoghue, Keane, Farragher, & Long, 2016). With the intention of increasing BF rates, transferring the marketing and promotion techniques used by artificial milk companies to promote BF may be beneficial, and making use of new technologies, social media and mobile phones may generate positive results (World Health Organization, 2017b). Interventions such as telephone calls (Patel y colaboradores, 2018), short messages (SMS) (Hmone, Li, Alam, & Dibley, 2017; Unger y colaboradores, 2018), telelactation techniques (Demirci, Kotzias, Bogen, Ray, & Uscher-Pines, 2018; Kapinos, K; Kotzias, V; Bogen, D; Ray, K; Demirci, J; Rigas, MA; Uscher-Pines, 2019) and online forums (White, Giglia, Scott, & Burns, 2018) have shown positive efficacy in establishing and maintaining BF, noting that women increasingly use the Internet to stay updated about BF (Alianmoghaddam, Phibbs, & Benn, 2019; Simpson, Garbett, Comber, & Balaam, 2016).

The development of mobile applications related to health issues has been increasing in recent years (Baskerville, Struik, & Dash, 2018; Ruiz-López y colaboradores, 2019; Simons y colaboradores, 2018). This increase has also occurred with mobile applications (apps) related to BF, with a progressive increase in the launch of apps for BF from 2011 to the present; in 2016 and 2017 there was a striking peak in the launch of these apps (Díaz Cano, Margaix Fontestad, & Esplugues, 2019). The number of app downloads is also high (Balaguer Martínez y colaboradores, 2018; Díaz Cano y colaboradores, 2019), which indicates a new method for mothers to seek support and information related to BF. One of these apps is LactApp, which was developed in Spain and has been in use since 2016. The objective of this study was to perform a descriptive analysis LactApp to study the profile of users as well as the most frequent queries.

Methods

Study Design

A retrospective, comparative and descriptive ecological study of time series data recorded by the LactApp tool from 01.07.2016 to 30.06.2019.

Setting

The LactApp tool is a mobile application dedicated to BF. This tool is accessible 24 hours a day with an Internet connection, providing personalized and convenient support using artificial intelligence. LactApp functions as a self-administered questionnaire based on more than 50 decision trees constructed with questions and answers developed by professional breastfeeding experts, backed by scientific evidence and updated with official health recommendations. The result of the questionnaire provides more than 2,300 personalized responses that can be reached through more than 76,100 possible paths, which vary according to the profile of the user and the options that she selects. This allows data sampling through an ecological momentary assessment (Runyan & Steinke, 2015). To arrive at a final response in the questionnaire, the user must have registered on the application and provided her e-mail address and then navigate through the options of the self-administered questionnaire until reaching a final response.

The main functionality of LactApp is its automated breastfeeding query system. It also provides features related to lactation monitoring, such as a record of breastfeeding sessions, where the user can record the number of and time for daily BF sessions and difficulties related to BF (pain, cracks, lumps, colour changes in the nipple, degree of pain sensation, and mood). The weight, height, and bowel movements of the infant can also be recorded.

Other functionalities that LactApp currently has are breastfeeding tests and personalized plans. The former comprise 5 questionnaires that allow for a quick response in relation to situations that a mother can experience during breastfeeding (The first 5 days with your baby; Successfully completing the first month; Does my baby breastfeed well?; Is my baby ready to eat solids?; Do you know if your baby has a short tongue frenulum?). Personalized plans involve questionnaires that use propositional logic with several variables for proposals and recommendations to users based on their needs and preferences.

In addition to the self-administered questionnaire, it is also possible to consult or comment on BF questions through a live chat feature hosted by an IBCLC (International Board Certified Lactation Consultant) expert on the LactApp team (implemented in the first trimester of 2018). The flow of queries and interactions through chat allows the accumulation of artificial intelligence for the machine learning and case-based reasoning used by the app. LactApp has 50 query topics related to BF, maternity, maternal and infant health and pregnancy, among others, divided into large query areas.

In addition to the app, LactApp also has social channels, such as the LactApp blog, Instagram, Facebook and YouTube, to disseminate information regarding BF and receive comments and inquiries. Finally, this application has a medical version in which health professionals can access all the available content of the application involving a response as a function of a query made by the professional, for example, the age of the infant involved in the consultation. LactApp is available in Spanish and English.

Measurement and Data collection

Google Analytics was used for data collection. This tool does not contain any personal data or confidential information and is presented as aggregated data (Clark, Nicholas, & Jamali, 2014). Data extraction was performed by trimesters to compare data trends. Among the variables

collected with Google Analytics were number of users, number of sessions and screens, duration of the session, new users and recurring users, access languages, countries from which the app was accessed, operating system used and types of events: number of queries and topics, chat access and test performance. Unique events, defined by Google Analytics as interactions with content by a single user within a single session (Google, 2019), were taken into account for the events. In addition, registration in LactApp by the users allows the collection sociodemographic data such as age, gender, number of children, country, academic degree and profession (medical version).

Data analysis

A descriptive analysis was performed for all variables, using the absolute and relative frequencies expressed in percentages for qualitative variables and the mean and standard deviation for quantitative variables. In addition, the temporal trend of the queries performed in the application was estimated by performing Prais-Winsten auto-regressions based on the Durbin-Watson method. This analysis allows obtaining the global trend of the quantitative variables related to specific and studied moments according to their distribution over time. Thus, the usage trend was determined (increasing, decreasing or static) by calculating the 3-month percent change (TPC) and its 95% confidence interval (95% CI) (Antunes & Cardoso, 2015). The analysis was performed using Excel spreadsheets for general calculations and Stata 14.0 software for time series (2015).

Ethical Considerations

This study complied with Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights. Registration in LactApp requires users to accept Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 regarding the protection of individuals with respect to the processing of personal data and the free circulation of these data (General Regulation of Data Protection).

Results

A total of 115,830 users were registered in the LactApp application in the study period (from 01.07.2016 to 30.06.2019). Of these, 1.91% (n = 2,207) obtained the medical version of the application. The mean age of the users of the medical version was 34.57 years (\pm 6.02 years). The most

prominent professions in the medical version were nurse (17.3%, n = 382), physician (15.3%, n = 337) and midwife (13.4%, n = 296). Sociodemographic data are shown in Table 1.

	n	%
Users	113,623	98.09
Language		
Spanish	110,015	96.8
English	2,457	2.2
Operating system		
Android	70,939	62.4
iOS	42,683	37.6
Sex		
Female	95,477	86.4
Male	15,026	13.6
Age		
18-24 años	9050	8.19
25-34 años	61700	55.84
35-44 años	33057	29.92
45-54 años	4287	3.88
55-64 años	1747	1.58
>65 años	662	0.6
Status		
Pregnant	3,274	2.9
No Pregnant	43,417	38.2
Undefined	66,931	58.9
Number of children		
0	89,879	79,1
1	12,766	11.2
2	3,784	3.3
3	544	0.5
≥4	90	0.2

Medical		
Language		
Spanish	2,077	94.1
English	20	0.9
Operating system		
Android	1,088	49.3
iOS	1,119	50.7
Status		
Pregnant	732	33.2
No Pregnant	1,071	48.5
Undefined	404	18.3
Number of children		
0	1,550	73.6
1	358	17
2	155	7.4
3	39	1.9
≥4	5	0.2
-		

Table 1. Sociodemographic profile of LactApp users from July 2016 to June 2019.

In the same period, a total of 71,780 infants were registered. Of these, 49.4% (n = 35,446) were female and 50.6% (n = 36,334) were male. The mean age of the registered infants was 16.84 months (\pm 12.09 months; minimum = 0 and maximum = 78 months). The mean weight of infants at birth was 3,211.3 grams (\pm 498.17 grams), with an average height of 49.61 centimetres (\pm 2.42 centimetres). A total of 4,388 (6.1%) of the infants were premature, born between weeks 25 and 36 of gestation, with a mean of 34.73 weeks (\pm 2.05 weeks).

During the study period, a total of 1,767,308 sessions were initiated, with a significant increasing trend (TPC = 24976.5; 95% CI = 11660.83 to 38292.26), and a total of 11,838,570 screens were viewed, with a static trend (TPC = -16851,55; CI95% = -137923.5-104220). The average number

of screens consulted per session was 6.7, with a significant decreasing trend (TPC = -1978; 95% CI = -3.266 to -0.689) and an average duration of 6 minutes and 2 seconds per session, which did not decrease in a significant way in the period studied (TPC = -0.172; 95% CI = -0.569 to 0.224). The percentage of recurrent users increased significantly in this period (TPC = 1.512; CI95% = 1.032 to 1.992). Table 2 shows these data distributed by trimester.

Perioda	Sessions	Screens	s Screens / Duration		New users ^c	Recurrent
			session	b		users ^c
1	59604	1550279	26.01	07:41	25.6	74.4
2	53106	1235492	23.26	06:48	16.1	83.9
3	51628	935907	18.13	07:17	20.9	79.1
4	52832	484823	9.18	06:20	20.4	79.6
5	58806	490626	8.34	06:03	20	80
6	71809	506894	7.06	05:34	19.2	80.8
7	110171	649790	5.9	05:20	16.1	83.9
8	167860	865688	5.16	05:47	12.2	87.8
9	233858	1083382	4.63	05:43	13.2	86.8
10	289566	1164363	4.02	05:31	7.3	92.7
11	281043	1211740	4.31	06:00	8.2	91.8
12	327415	1333087	4.07	06:10	7	93
TPC ^d	24976.54	-16851.55	-1.978	-0.172	-1.512	1.512
95% CI°	11660.83	-137923.5	-3.266	569	-1.992	1.032
33% UI	38292.26	104220.4	-0.689	0.224	-1.032	1.992
Trend	Growing	Static	Decreasing	Static	Decreasing	Growing

Table 2. Number of Sessions, Screens, Duration of each Visit and Users of LactApp. Study period from July 1, 2016, to June 30, 2019.

The distribution of countries by percentage of overall LactApp users was as follows: Spain (53.84%), Mexico (11.35%); Argentina (5.48%), United States (5.30%), Chile (4.84%), Colombia

(3.9%), Venezuela (1.78%), Peru (1.57%), Uruguay (1.26%) and Costa Rica (1.1%). The most consulted languages were Spanish (89.94%) and English (5.22%).

Table 3 provides unique events among the most relevant events in LactApp by trimester in the study period. In the study period, users started 1 of the 5 existing tests 62,173 times (TPC = 429.203; 95% CI = -8,903 to 867,311; trend = increasing), of which 71.13% (n = 44,222) got to answer completely, with an increasing trend (TPC = 287.183; 95% CI = 22.430 to 551.936). Regarding the opinion of the users who arrived at a final response to the tests, 15.11% (n = 6,680) provided their opinion, with 93.01% (n = 6.215) clicking "Like". The test that was most often initiated was "Does my baby breastfeed well?", with 32.32% (n = 20,094) (TPC = 140.871; 95% CI = -5.184 to 286.927; trend = static), followed by "Successfully completing the first month", with 18.34% (n = 11,400) (TPC = 80.817; Cl95% = 1.542 to 160.092; trend = growing), "The first 5 days with your baby", with 17.56% (n = 10,920) (TPC = 67.956; Cl95% = -9.766 to 145.678; trend = static), "Is my baby ready to eat solids?", with 16.59% (n = 10,313) (TPC = 73.731; 95% CI = 2.550 to 144.912; trend = increasing) and, finally, "Do you know if your baby has a short tongue frenulum?", with 15.19% (n = 9,446) (TPC = 71.174; 95% CI = 3.904 to 138.443; trend = increasing).

	Test ^b		Chat		Queries ^c	
Perioda	n	%	n %		n	%
1	3,231	7.31	-	-	2,112	0.09
2	2,102	4.75	-	-	1,311	0.05
3	1,862	4.21	-	-	2,704	0.11
4	1,578	3.57	-		62,631	2.59
5	2,573	5.82	-		139,374	5.75
6	2,640	5.97	-		156,979	6.48
7	3,168	7.16	1,507 3.91		194,992	8.05
8	5,103	11.54	5,015	12.99	210,944	8.71
9	5,494	12.42	8,470	21.96	360,213	14.87
10	5,301	11.99	7,490	19.42	386,282	15.94
11	5,648	12.77	7,245	18.79	441,044	18.21
12	5,522	12.49	8,841	22.93	463,946	19.15

Total	44,222	100	38,568	100	2,422,532	100
TPC ^d	287.183		1,300.187		46112.14	
95%CI°	22.43		-62.095		37,479.22	
	551.936		2,662.46		54,745.06	
Trend	Grow	ring	Stal	ic	Growir	ng

Table 3. Unique Events among the most relevant LactApp Events. Period July 2016-June 2019.

^a Period: 1: 01/07/2016-30/09/2016; 2: 01/10/2016-31/12/2016; 3: 01/01/2017-31/03/2017; 4: 01/04/2017-30/06/2017; 5: 01/07/2017-30/09/2017; 6: 01/10/2017-31/12/2017; 7: 01/01/2018-31/03/2018; 8: 01/04/2018-30/06/2018; 9: 01/07/2018-30/09/2018; 10: 01/10/2018-31/12/2018; 11: 01/01/2019-31/03/2019; 12: 01/04/2019-30/06/2019

Finally, in the study period, users obtained 2,757,702 (TPC = 33531.9; 95% CI = 16096.64 to 50967.17; Tendency = increasing) final responses in LactApp. Of these responses, 1.68% (n = 46,374) of users opined on the quality of the final responses, with 89.26% (n = 41,392) clicking "Like" and 10.74% (n = 4,982) clicking "Unlike". A total of 27.69% of the responses corresponded to the topics "baby's Sleep" (n = 246,628; 8.94%; TPC = 3630.897; 95% CI = 1987.616 to 5274.178; trend = increasing), "extraction and preservation of milk" (n = 245,785; 8.91%; TPC = 3630.49; 95% CI = 2554.29 to 4706.69; trend = increasing), "breastfeeding crisis" (n = 169,911; 6.16%; TPC = 2845.199; 95% CI = 2005.913 to 3684,485; trend = increasing), and "physiological evolution of breastfeeding" (n = 101.273; 3.67%; TPC = 1823,578; 95% CI = 6621.756 to 2984; trend = increasing) (Table 4). The most consulted final responses are shown in Table 5.

^b Tests answered in full

^c Queries that arrive at a final response

d TPC: Three-month percent change

and 95% CI: 95% confidence interval

Period ^a	Total Queries	Baby's sleep	Extraction and	Breastfee ding crisis	Physiological evolution of
			preservatio		breastfeedin
			n of milk		g
1	119,684	7,275	5,798	859	3,424
2	113,708	6,222	5,466	4,127	3,841
3	107,905	5,467	5,454	4,577	3,209
4	62,631	3,698	5,151	3,878	2,284
5	139,374	9,086	13,092	9,373	4,442
6	156,979	14,387	15,336	9,078	4,022
7	194,992	18,342	20,220	11,394	5,042
8	210,944	24,245	21,910	14,364	7,330
9	360,213	41,979	37,647	24,586	13,114
10	386,282	40,521	36,481	27,358	13,899
11	441,044	33,774	40,686	29,520	16,703
12	463,946	41,632	38,544	30,797	23,963
TPC ^b	3,3531.9	3,630.897	3,630.49	2,845.199	1,823.578
95% CI°	16,096.64	1,987.616	2,554.29	2,005.9133,	6,621.756
30% CI	50,967.17	5,274.178	4,706.69	684.485	2,984.981
Trend	Growing	Growing	Growing	Growing	Growing

Table 4. Most visited topics as unique LactApp Events. Period July 2016-June 2019.

^a Period: 1: 01/07/2016-30/09/2016; 2: 01/10/2016-31/12/2016; 3: 01/01/2017-31/03/2017; 4: 01/04/2017-30/06/2017; 5: 01/07/2017-30/09/2017; 6: 01/10/2017-31/12/2017; 7: 01/01/2018-31/03/2018; 8: 01/04/2018-30/06/2018; 9: 01/07/2018-30/09/2018; 10: 01/10/2018-31/12/2018; 11: 01/01/2019-31/03/2019; 12: 01/04/2019-30/06/2019

^b TPC: Three-month percent change

^c 95% CI: 95% Confidence interval

Final response	n	%	TPC ^a	95%CI ^b	Trend
Hours of sleep for the	19,048	7.72	252.785	125.204	Growing
baby's age				380.366	
7 week crisis	18,631	11.62	520.075	378.066	Growing
				662.083	
3 month crisis	18,193	11.35	450.133	305.692	Growing
				594.573	
Table for rapid milk	17,305	7.04	247.590	158.833	Growing
preservation				336.347	
15 day crisis	16,992	10.60	457.806	336.182	Growing
				579.430	
Physiological evolution of	14,032	13.86	258.157	84.595	Growing
breastfeeding at 2 months				431.718	
Physiological evolution of	12,502	12.34	240.687	108.204	Growing
breastfeeding at 15 days				373.170	
Physiological evolution of	12,177	12.02	220.093	74.233	Growing
breastfeeding in the first				365.952	
month					
How to warm breast milk	11,172	4.55	197.093	151.771	Growing
				242.414	
Methods for getting the	10,548	4.28	122.259	46.712	Growing
baby to sleep				197.805	
The baby wakes up when I	10,331	4.19	209.297	144.360	Growing
put it in the crib				274.233	
How to thaw breast milk	9,463	3.85	127.258	748.980	Growing
				179.617	

Table 5. Most visited final responses as unique LactApp Events. Period July 2016-June 2019.

^a TPC: Three-month percent change

^b 95% CI: 95% confidence interval

Discussion

This study aimed to describe the queries and interactions of users of a mobile application for BF (LactApp) in order to study both the user profile and the most frequent queries. Notably, the large number of users of LactApp as well as the growing number of queries suggests that it is a very relevant way of consulting for maternal support regarding breastfeeding.

According to the mHealth Economics report (Research 2 Guidance, 2017), downloads of health-related applications have been growing exponentially since 2013. Taking into account the figures provided by this report, LactApp obtained more active users than 83% of apps, being among the 20% most downloaded apps and active users in the world. It is important to highlight that almost 2% of these users are health professionals who, perhaps, in search of information or in the form of support in this professional field make use of LactApp, given the lack of training and support that, in general, health professionals receive in Spain (Gómez Fernández-Vegue, M.; Menéndez Orenga, 2019) and at the international level (Chuisano & Anderson, 2019; Gavine y colaboradores, 2017); notably, 30.7% of these professionals belong to nursing staff.

Internet users increasingly obtain more information through smartphones (Ditrendia, 2018); therefore, the use of apps in the field of BF is gaining ground and becoming a pillar in the establishment and subsequent maintenance of BF. (Silva, Pontes, Sousa, & Vasconcelos, 2019). This globalized fact can explain the growing trend in queries in LactApp. The static trend regarding the number of screens visited by the users and the duration of each session, in addition to the decreasing trend of the average number of screens consulted, may be related to the improvements implemented in LactApp throughout the studied time period. Improvements that stand out are those to the interface, revitalisation of queries and reorganization of content.

Regarding the users, an advantage of LactApp is the ability to have personalized information (Swerts, Marlies; Westhof, Ellen; Lemiengre, Joke & Bogaerts, 2019) related to BF 24 hours a day, a fact that both mothers (Robinson, Lauckner, Davis, Hall, & Anderson, 2019) and health professionals (Garner y colaboradores, 2016) point out as an essential issue in the maintenance of BF. This fact can be related to the increasing number of users within the app and with the number of recurring users increasingly growing. It must be taken into account that the decreasing number of new users may be due to the rapid diffusion of LactApp among mothers and health professionals; since the

extreme initial growth, it has not been possible to capture so many new users. Regarding this aspect, users who enter the application stay and use it regularly to address their breastfeeding questions, so they become recurrent users. BF children registered in LactApp have a profile very similar to that of international statistical reports (World Health Organization, 2012), implying that the profiles are real.

The most consulted topics within LactApp are related to critical issues regarding when women stop BF. The critical issues that stand out are related to the "baby's sleep", a topic that different authors note as important in relation to the establishment and maintenance of BF (Bailey, Tawia, & McGuire, 2019). Also noteworthy is the lack of training that health professionals have regarding safe sleeping and its importance, both in the prevention of sudden infant death syndrome and with the maintenance of BF. (Angal, J; Gogoi, M; Zenel, J; Elliott, 2019; Moon, Darnall, Feldman-Winter, Goodstein, & Hauck, 2016; Salm Ward, Kanu, & Anderson, 2018). Another topic to highlight is the "extraction and preservation of milk" (Becker, Smith, & Cooney, 2016) because it is closely related to the duration of maternity leave and the return to work of the mother, agreeing with different authors that the completion of maternal leave and reinsertion of the mother into paid work is an important issue related to stopping BF (Dinour & Szaro, 2017; Navarro-Rosenblatt & Garmendia, 2018; Sun, Chen, Yin, Wu, & Gao, 2017; Tadesse, Alemayehu, Shine, Asresahegn, & Tadesse, 2019). A "breastfeeding crisis" is deeply related to the maternal sensation of lack of milk, which is one of the most prominent causes for stopping BF (Ramiro González y colaboradores, 2017; Vila-Candel, Soriano-Vidal, Murillo-Llorente, Pérez-Bermejo, & Castro-Sánchez, 2018), and there are still gaps in how to offer effective support in these situations (Galipeau, Baillot, Trottier, & Lemire, 2018). Finally, the lack of knowledge, skills and attitudes of mothers regarding BF, i.e., the loss of the culture of BF, is another critical point for stopping BF (Brockway, Benzies, & Hayden, 2017; Zielińska, Sobczak, & Hamułka, 2017). Thus, the "physiological evolution of breastfeeding" is another section in LactApp that mothers consult often. A new study hypothesis is that apart from being informed, LactApp helps women maintain BF at times when they would normally stop this type of feeding in rural (Demirci y colaboradores, 2018) and urban areas, but this hypothesis should be confirmed in future studies.

Limitations

This is an ecological study based on aggregate data so that there is a risk of incurring ecological fallacies in the interpretation of the data as they do not consider possible variables that can influence the results (Borja-Aburto, 2000).

Additionally, data were collected with Google Analytics, and some limitations should be taken into account, such as data sampling when the volume of data traffic is greater than 500,000 sessions. Finally, we must be aware that the launch of LactApp produced very high initial statistics, which may lead to a change in the statistical estimates presented in the coming years.

Conclusions

LactApp is a mobile application with powerful resources for breastfeeding and is currently widely downloaded and in use by a significant number of users. These users periodically consult the application, with the most consulted topics being those related to the baby's sleep, the extraction and preservation of milk, breastfeeding crises and the physiological evolution of BF.

The increasing use of LactApp supports the need for future research on the validation of the application as well as on the degree to which the recommendations offered are correlated with the best available scientific evidence.

Funding Statement: The authors received no financial support for the research, authorship, and/or publication of this article.

Conflicts of Interest: The authors declared the following potential conflicts of interest with respect to the research, authorship and/or publication of this article: AP created and designed the software. EB has personal friendly relationships with the creators of the software under investigation.

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Objetivo específico 2

Realizar un análisis descriptivo de una aplicación móvil sobre lactancia materna (LactApp) para estudiar el perfil de usuaria, así como las consultas más frecuentes.

Este objetivo se trabajó en un artículo titulado "Description of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers seek support at critical breastfeeding points and according to their infant 's age". Este artículo se publicó en noviembre de 2020 en la revista "Research in Nursing and Health". Según el JCR de 2020, esta revista tiene un factor de impacto de 2.228, perteneciendo al puesto 45 de un total de 126 indexadas en la categoría "Nursing". Por lo tanto, esta revista ocupa un segundo cuartil (Q2) y el segundo tercil (T2) en el listado correspondiente del JCR.

Cita bibliográfica: Padró-Arocas, A., Quifer-Rada, P., Aguilar-Camprubí, L., Mena-Tudela, D. (2021). Description of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers seek support at critical breastfeeding points and according to their infant's age. Research in nursing & health, 44(1), 173–186. https://doi.org/10.1002/nur.22095.

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Metodología

Diseño

Se realizó un estudio observacional, descriptivo y retrospectivo usando los datos recogidos por LactApp del 1 de enero de 2019 al 31 de diciembre de 2019, en la que se incluyó 2.725.925 consultas clasificadas como 48 temas (incluyendo test) de 130.000 usuarias activas

Ámbito, población y muestra

En el momento de la investigación, LactApp contaba con 48 árboles de decisión en los que se encontraban temas sobre lactancia, maternidad y salud materno-infantil. Se contaba con más de 2.373 respuestas personalizadas a las que se llegaba a través de más de 76.232 posibles caminos que variaban según el perfil de la madre o del bebé.

Para llegar a una respuesta final, la usuaria se tenía que registrar en la app y proporcionar su dirección de correo electrónico o iniciar la sesión usando la funcionalidad de Facebook o Apple. La población del estudio está formada por todas las usuarias de LactApp.

Variables y recogida de datos

LactApp recoge los datos de las usuarias registradas, como el correo electrónico, la edad, la población, el tipo de usuaria (embarazada o no embarazada), la fecha probable de parto y el número de hijos o hijas. También guarda datos sobre los bebés registrados, como la fecha de nacimiento, el sexo, edad gestacional al nacimiento, condición de prematuridad y el peso y la talla al nacer.

Finalmente, se registran también las respuestas finales de los cuestionarios autoadministrados por la usuaria, la identificación de la usuaria, el sistema operativo del dispositivo móvil y la lengua usada.

Se seleccionó Google Analytics y Firebase para recoger los datos sobre la usabilidad de la app que fueron anonimizados y agregados. También se recogió: el número de usuarias activas (entendida como aquella usuaria que accedió a la app durante el periodo descrito), el número de sesiones y pantallas, la duración de la sesión, las lenguas utilizadas, países de los que se accede a la aplicación y sistema operativo del dispositivo.

También se pudieron monitorizar el número de consultas realizadas, así como las visitas en los tests. La extracción de los datos se realizó de forma mensual entre el 1 de enero de 2019 y el 31 de diciembre de 2019.

Consideraciones éticas

Este estudio siguió la Ley Orgánica 3/2018 de 5 de diciembre de Protección de Datos y Garantía de los Derechos Digitales. El registro en LactApp requiere que las usuarias acepten el Reglamente (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016 relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos (Reglamento General de Protección de Datos).

Análisis de datos

Toda la gestión de los datos brutos y los análisis estadísticos se realizaron mediante R v 3.6.2 en el entorno R studio (v. 1.2.5001). Los datos de todas las respuestas finales alcanzadas por las usuarias se agregaron semanal, mensual y anualmente, y como categorías del tema. Los datos también se agregaron según la edad del bebé en el momento de la consulta, ya que era la variable principal que pretendíamos estudiar. Todas las variables no presentaban una distribución normal (prueba de Shapiro-Wilk, p < 0,05), por lo que se realizaron pruebas estadísticas no paramétricas de Kruskal-Wallis con pruebas post hoc de Dunn para evaluar las diferencias significativas en las visitas de las consultas agregadas como temas según la edad del bebé del usuario. Los valores de p se corrigieron por el número de usuarios en cada categoría de grupo y se ajustaron por la tasa de falsos descubrimientos. También se realizó un Análisis de Componentes Principales (ACP o PCA por sus siglas en inglés) para trazar la diferencia en los usos de las consultas según la edad del bebé de la usuaria.

Resultados

Perfil de usuaria y actividad en la app

LactApp tuvo 130.000 usuarias activas en el año 2019.

Las usuarias fueron monitorizadas diaria, semanal y mensualmente. En 2019, LactApp tuvo una media de 2.400 usuarias activas al día, 10.000 a la semana y 28.000 al mes.

En 2019, LactApp recibió 2.725.925 consultas, que representa una media de 52.421 consultas semanales y 78.087 usuarias que accedieron en la aplicación para consultar temas sobre lactancia, lo

que supuso una media de 32,8 consultas por usuaria y una duración de 6 minutos con 18 segundos por sesión.

Según las bases de datos de Google Analytics y Firebase, el 90% (n=68.977) de las usuarias activas eran mujeres, y su edad estaba comprendida entre los 25 y los 34 años (58% n=51.124).

Si hablamos del número total de usuarias registradas en la app, nos encontramos que el 39,3% de ellas (n=51.124) tienen una edad comprendida entre los 25 y los 34 años

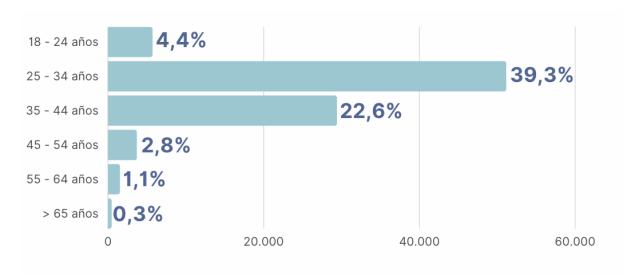


GRÁFICO 10: Edad de las usuarias registradas

Las principales regiones desde las cuales las usuarias accedieron a la app fueron España (79,4%), México (4,5%), Chile (2,8%), Colombia (1,8%) y Estados Unidos (1,1%).

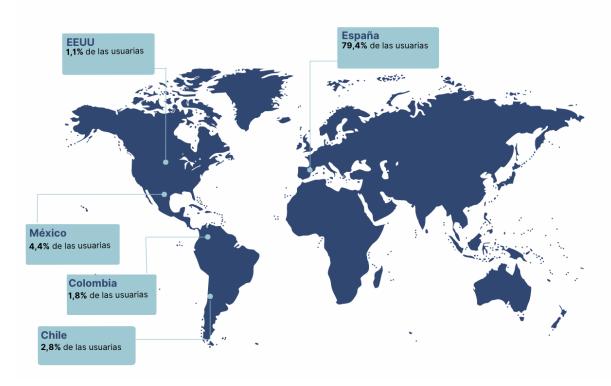


FIGURA 4: Distribución de las descargas de LactApp en el mundo

Durante el periodo de tiempo del estudio, el porcentaje de los idiomas de uso de la aplicación se distribuyeron en el 89,5% (n=116.400) para el español y el 6,4% (n=8.315) para el inglés.

El sistema operativo más usado fue el Android, representando el 64,6% (n=84.000) de las descargas, comparado con iOS, que representó el 35,3% (n=46.000) de ellas.

LactApp registró 71.807 nuevas usuarias en sus bases de datos, pero solo 1.559 (2,17%) de ellas se registraron con sus datos personales. De las usuarias registradas en LactApp en 2019, el 94% (n=1.471) estaban embarazadas y la mayoría (68%, n=1.063) eran primigestas.

Durante este mismo periodo, fueron registrados 44.342 bebés, de los cuales, el 50,7% (n=22.511) eran varones con una media de edad de 3,4 meses (±6,4 meses), una media de peso al nacer de 3.210,8 g (±492,8 g) y con talla al nacimiento con una media de 49,6 cm (±2,48 cm). Finalmente, el 6,12% (n=2.715) de los bebés registrados fueron prematuros, con una media de edad gestacional al nacer de 33,7 semanas (±4,2 semanas).

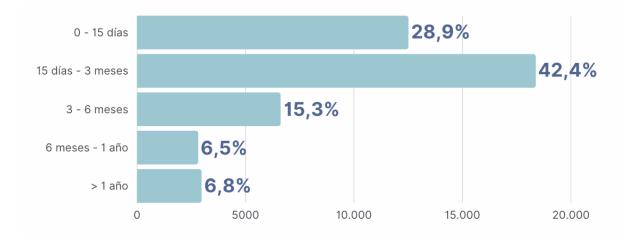


GRÁFICO 11: Edad de los bebés registrados

Usabilidad de LactApp

Consultas más frecuentes

Los temas más consultados durante el 2019 fueron aquellos relacionados con la "técnica de lactancia", con 321.265 consultas (11.8%), "sueño del bebé", con 253.046 consultas (9,3%), la "conservación y manipulación de la leche", con 202.948 consultas (7,4%), los "mitos de la lactancia", con 158.675 consultas (5,8%), las "etapas de la lactancia", con 134.507 consultas (4,9%), la "alimentación complementaria", con 130.732 consultas (4,2%), el "cuidado del bebé" con 125.961 consultas (4,6%), los "productos para la lactancia", con 113.382 consultas (4,2%), la "lactancia mixta" con 94.004 consultas (3,4%) y la "vuelta al trabajo" con 91.071 consultas (3,3%). Estas consultas representaron el 59,6% (n=1.625.591) de todas las consultas que se hicieron, y pueden ser representativas de un punto crítico en la lactancia. El gráfico 11 muestra los temas más consultados durante el periodo de tiempo estudiado.

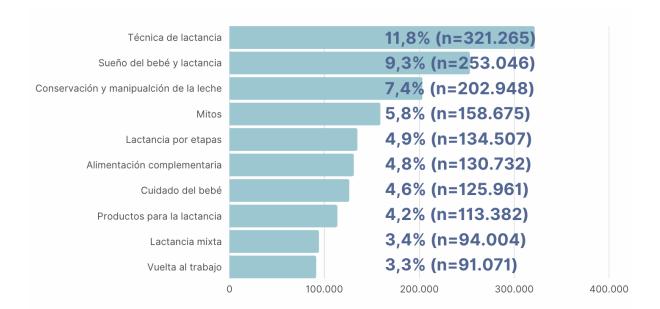


GRÁFICO 12: Frecuencia de los temas más consultados en LactApp

La frecuencia anual de consultas por temas se detalla en el gráfico 12, donde podemos observar que la consulta más realizada fue sobre "técnica de lactancia" (n=321.265, 11,8%), seguida de "sueño del bebé y lactancia" (n=253.046, 9,3%), "manipulación y conservación de la leche" (n=202.948, 7,4%), "mitos de lactancia (n=158.675, 5,8%), "alimentación complementaria (n=130.732, 4,8%), el "cuidado del bebé" (n=125.961, 4,9%) y "productos para la lactancia" (n=113.382, 4,2%), todas ellas con un porcentaje acumulado del 52,8% de todas las consultas realizadas en este periodo.

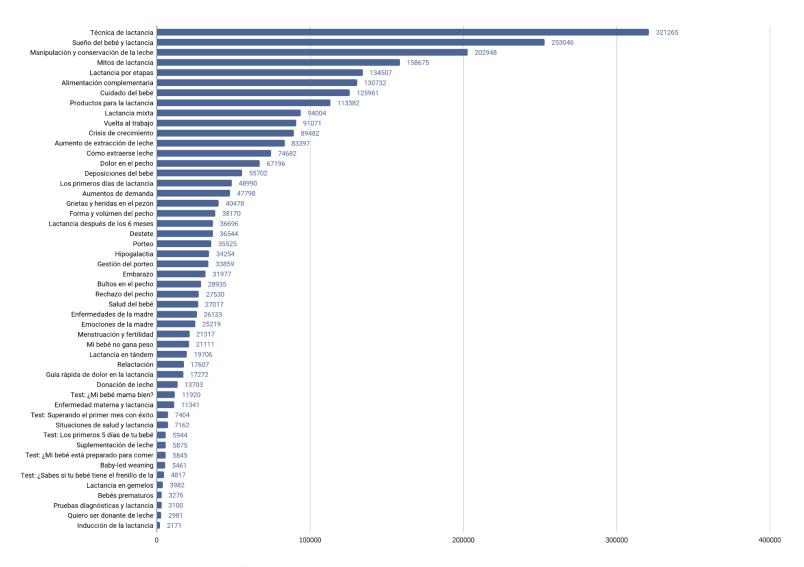


GRÁFICO 13: Frecuencia anual de consultas por temas

Uso de LactApp según la edad del bebé

Se realizó la media de consultas semanales agregadas por temas según la edad del bebé de la usuaria. Las edades del bebé se establecieron en los siguientes periodos: entre 0 y 15 días, con una n=13.220, entre 15 días y 3 meses, con una n de 27.355, entre 3 meses y 6 meses, con una n de 18.471, entre 6 meses y 1 año, con una n de 11.434 y mayores de 1 año, con una n de 8.626.

Durante el establecimiento de la lactancia, las consultas más frecuentes fueron de "técnica de lactancia", con una media de 1.762,1 consultas, seguidas de los primeros días de lactancia, con una media de 803,5 "consultas, sueño del bebé", con una media de 567,1 consultas, "dolor en el pecho", con una media de 459,5 consultas y "productos para la lactancia" con una media de 363,6 consultas. Entre los 15 días y los 3 meses, las consultas más frecuentes fueron las relacionadas con la "técnica de lactancia", con una media de 3.696,7 consultas, el "sueño infantil", con una media de 2.406,4 consultas, la "conservación y manipulación de la leche", con una media de 1.762,4 consultas, los "mitos en la lactancia", con una media de 1.693,5 consultas, y el "cuidado del bebé" con una media de 1.590 consultas.

De los 3 a los 6 meses, las respuestas más consultadas estaban relacionadas con la "conservación y manipulación de la leche materna", con una media de 1.247,2 consultas, la "alimentación complementaria", con una media de 1.129,2 consultas, la "manipulación y conservación de la leche", con una media de 1.247,2 consultas, la "alimentación complementaria", con una media de 1.129,2 consultas, el "sueño infantil", con una media de 978,3 consultas, la "vuelta al trabajo", con una media de 767,1 consultas, y los "mitos de la lactancia", con una media de 553,7 consultas.

De los 6 meses al año, las usuarias consultaron temas relacionados con la "alimentación complementaria", con una media de 1.312,9 consultas, el "sueño del bebé", con una media de 482,8 consultas, la "manipulación y conservación de la leche", con una media de 329,4 consultas, la "lactancia en bebés mayores de 6 meses",con una media de 294,2 consultas, , los "mitos de la lactancia", con una media de 202,3 consultas, seguida de muy de cerca por el "dolor en el pecho" con una media de 202,2 consultas.

Una vez el bebé es mayor de 1 año, las usuarias visitaron las respuestas relacionadas con el "sueño infantil", con una media de 265,8 consultas, las "etapas de lactancia" con una media de 159,7 consultas, el "dolor en el pecho", con una media de 246,1 consultas, la "técnica de lactancia", con una media de 238,9 consultas, el "destete", con una media de 200,9 consultas, seguidas muy de cerca por la

"gestión del destete", con una media de 200,4 consultas y el "tándem en lactancia" con una media de 194,2 consultas.

Las principales consultas semanales agregadas por temas según la edad del bebé se pueden observar en el gráfico 13.

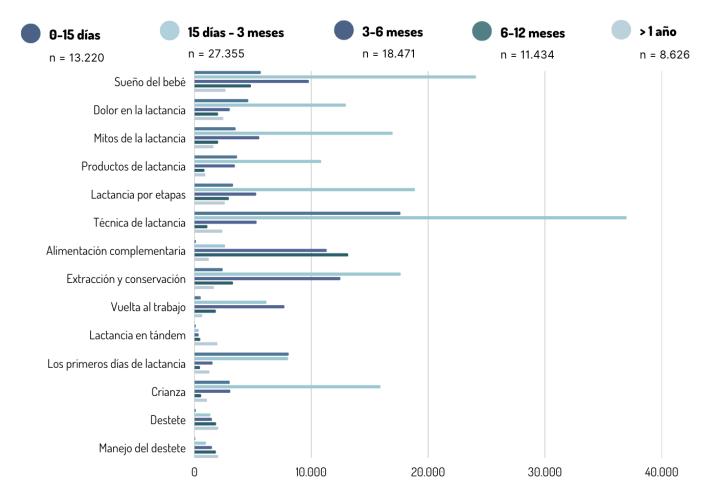


GRÁFICO 14: Principales consultas semanales agregadas por temas según la edad del bebé

Algunos temas fueron muy consultados independientemente de la edad del bebé, como el sueño del bebé o la técnica de lactancia. Para explorar qué temas se asociaban a cada categoría de edad, se realizó un PCA ilustrado en la Figura 5. Se observa que el tema "los primeros días de lactancia materna" se asoció con el grupo de edad de 0 a 15 días, mientras que la "vuelta al trabajo", el "destete", la "gestión del destete", la "alimentación complementaria", el "destete dirigido por el bebé" y la "lactancia materna en lactantes de más de 6 meses" se relacionaron con los grupos de edad de 3 a 6 meses y de 6 meses a 1 año. La "lactancia en tándem" se relacionó con la categoría de edad de más

de 1 año. Por último, el grupo de edad de 15 días a 3 meses, fue el más diverso en temas de consulta y se asoció con varios temas como las "crisis de crecimiento", el "dolor en los pechos", el "rechazo del pecho", la "forma y tamaño de los pechos", la "extracción y conservación de la leche" y el "aumento de la demanda del bebé", entre otros.

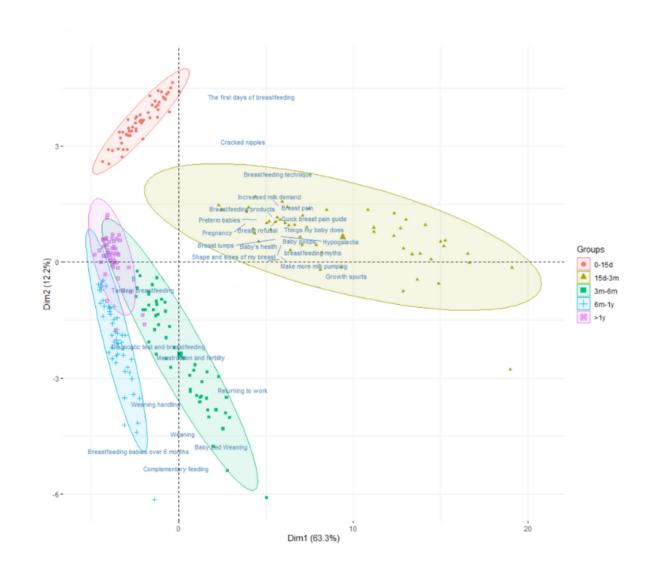


FIGURA 5: Biplot del análisis de componentes principales de las consultas semanales agregadas como temas según la edad del bebé de las usuarias

La Figura 6 muestra el diagrama Boxplots de los 16 temas que más contribuyeron a construir los componentes principales, con lo que fueron las variables más discriminantes entre las categorías de edad de los lactantes.

La frecuencia de visitas semanales de los temas "crisis de crecimiento, "mitos de la lactancia", "cuidados del lactante", "extracción de la leche", "cómo extraerse leche", "hipogalactia", "lactancia mixta", "forma y tamaño del pecho", "cacas del lactante", "etapas de la lactancia", "destete", "vuelta al trabajo" y "grietas en el pezón" aumentó significativamente (p<0,05) en el grupo de edad de entre 15 días y 3 meses en comparación con los demás grupos de edad. Las consultas sobre "alimentación complementaria", "lactancia materna en lactantes de más de 6 meses", "destete dirigido por el bebé" y "destete" aumentaron significativamente (p<0,05) en los grupos de edad de 3 a 6 meses y de 6 meses a 1 año en comparación con los demás grupos de edad. Por último, las consultas sobre "lactancia en tándem", "destete" y "gestión del destete" aumentaron significativamente (p<0,05) en el grupo de más de 1 año en comparación con los demás grupos de edad.

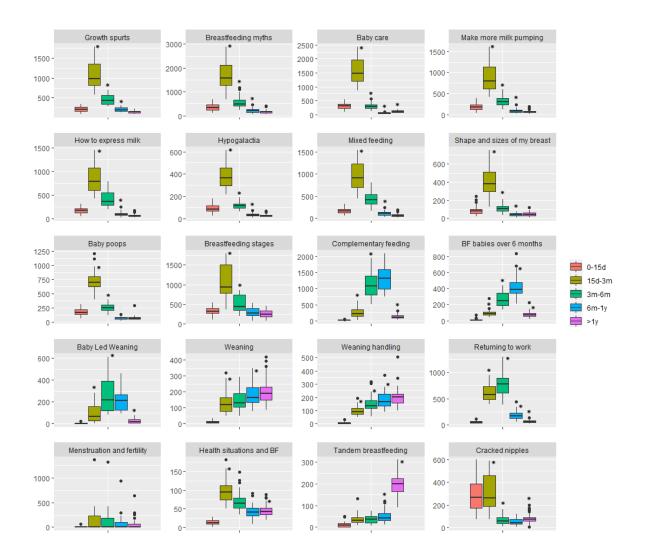


FIGURA 6: Boxplots de los temas que más contribuyen a discriminar los grupos de edad infantil de las usuarias. Diferencias significativas en comparación con el grupo de edad infantil anterior (p<,05 de Dunn post hoc de la prueba de Kruskal-Wallis, p valor corregido por el número de usuarias en cada categoría de grupo y ajustado por la falsa tasa de descubrimiento.

El uso de los test de LactApp también cambió según la edad de los bebés de las usuarias.

En el gráfico 14 se puede observar el uso de los test según edad del bebé.

En la franja de los primeros 15 días, el test más utilizado fue el "Los primeros 5 días de tu bebé", con una media semanal de 59,6 consultas, seguido del test "¿Mi bebé mama bien?", con una media semanal de 27 consultas.

En la etapa de 15 días a 3 meses, el test más realizado fue el de "¿Mi bebé mama bien?" con una media semanal de 142,2 consultas, seguido de "Superando el primer mes con éxito", con 120,1 consultas.

En la etapa de 3 a 6 meses, el test más realizado fue "¿Mi bebé está preparado para comer sólidos?" con una media semanal de 69,3 consultas, seguido por el test "¿Mi bebé mama bien?", con una media semanal de 40,2 consultas.

En la etapa de edad entre 6 meses y un año, el test más realizado fue el de "¿Mi bebé está preparado para comer sólidos?" con una media semanal de 29,2 consultas, seguido del test "¿Sabes si tu bebé tiene el frenillo de la lengua corto?", con una media semanal de 5,7 consultas.

En la última etapa, la que comprende a bebés de más de un año de edad, se observó que el test más consultado fue "Los primeros 5 días de tu bebé", con una media de consultas semanales del 9,7 seguido del test "¿Mi bebé mama bien?", con una media semanal de 9,6 consultas.

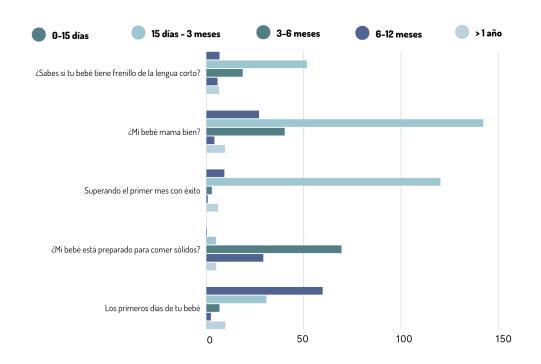


GRÁFICO 15: Tests realizados por las usuarias semanalmente agrupados por edad del bebé

Se realizó un PCA que ilustró que el inicio de la lactancia se relaciona con el test "Los primeros cinco días de tu bebé", mientras que el test "¿Está mi bebé listo para comer sólidos?" está relacionado con bebés de edad de entre 3 a 6 meses. El grupo de entre 15 días y 3 meses, fue más heterogéneo y se relacionaba con el test "¿Sabes si tu bebé tiene frenillo?", "¿Mi bebé mama bien?" y "Superando el primer mes con éxito.

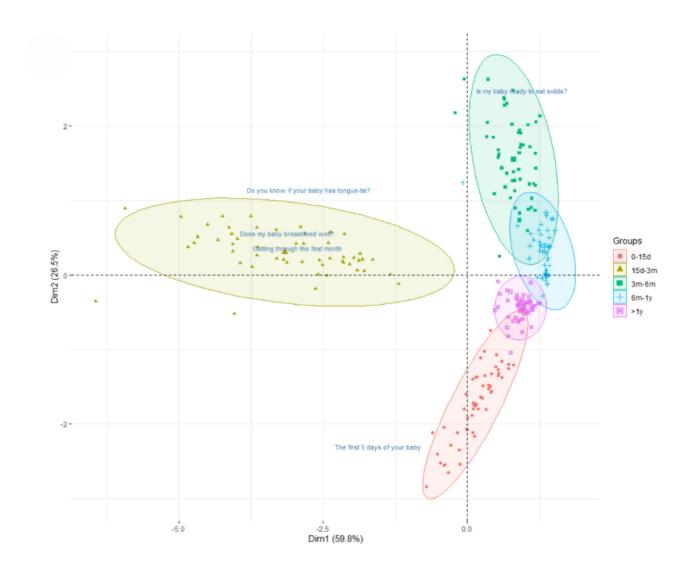


FIGURA 7: Biplot del análisis de componentes principales de las consultas semanales agregadas de los test según la edad del bebé de las usuarias.

SPECIAL ISSUE ON TELEHEALTH AND mHEALTH



Description of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers seek support at critical breastfeeding points and according to their infant's age

Alba Padró-Arocas¹ | Paola Quifer-Rada^{1,2} | Laia Aguilar-Camprubí¹ | Desirée Mena-Tudela³ ©

Correspondence

Desirée Mena-Tudela, Department of Nursing, University Jaume I, Avda. Sos I Baynat s/n 12071, Castellón de la Plana, Spain.

Email: dmena@uji.es

Funding information

Universitat Jaume I, Grant/Award Number: UJI-A2019-06

Abstract

Interventions in mHealth have had positive effects on establishing and maintaining breastfeeding, but we still do not know what content women consult when downloading a breastfeeding mobile application. We conducted an observational, descriptive, and retrospective study using the data recorded by LactApp in 2019. The most frequently consulted topics were those related to breastfeeding technique, infant sleep, human milk management and storage, breastfeeding myths, breastfeeding stages, complementary feeding, infant care, and returning to work. Our study results suggest that LactApp's support seems to develop with mothers' needs according to their infant's development stage. The first breastfeeding days include more physiological answers. Between 15 days and 3 months, mothers look for support in topics like breastfeeding crisis/complications and returning to work. At 3 months to 1 year, answers are related to complementary feeding and weaning. When the user's infant is 1 year of age, mothers seek support for weaning, weaning management, and tandem breastfeeding.

KEYWORDS

breastfeeding application, breastfeeding crisis, breastfeeding support, mHealth

1 | BACKGROUND

We face new challenges in health care today. Technology and health applications are increasingly developing to improve user care. Of these improvements, Electronic Healthcare (eHealth) is expected to improve the quality and safety of medical care, as well as healthcare costs (Roberts et al., 2015). Using eHealth services helps to support self-care, enable health service use, and make care and health professionals more accessible (Lindberg et al., 2013).

The use of smartphones for behavioral changes and to adapt to new habits has been demonstrated (Scott & Mars, 2020). There are countless mobile applications that aim to influence the population's health (mHealth). These applications are designed to address different issues, such as blood pressure monitoring (Wang et al., 2019), stress management (Hwang & Jo, 2019), smoking cessation counseling (Heffner et al., 2019), or weight management (Cueto et al., 2019). For maternal and neonatal care, there are also applications (Sondaal et al., 2016), focusing on child care, pregnancy, and before pregnancy (Zhang et al., 2018). The specific care these applications focus on is aimed at reducing weight gain during pregnancy, increasing fruit and vegetable intake, cessation of smoking, or preventing infection (Bush et al., 2017; Overdijkink et al., 2018). They all seem to bring positive results (Bush et al., 2017; DeNicola et al., 2020; Hussain et al., 2020).

Res Nurs Health. 2021;44:173–186. wileyonlinelibrary.com/journal/nur © 2020 Wiley Periodicals LLC 17

¹Research and Development Department, LactApp Women Health, Barcelona, Spain

²Department of Endocrinology and Nutrition, CIBER of Diabetes and Associated Metabolic Diseases, Biomedical Research Institute Sant Pau, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

³Department of Nursing, University Jaume I, Castellón de la Plana, Spain

The World Health Organization (WHO) recommends exclusive breastfeeding (BF) for the first 6 months, followed by supplementation with other foods up to the age of 2 years or beyond (Kim et al., 2018), but these recommendations are poorly implemented. Some data suggest that only 40% of infants aged under 6 months are exclusively breastfed worldwide (World Health Organization, 2017). For this reason, the WHO proposed a global objective of 50% exclusive breastfeeding in the first 6 months of an infant's life (World Health Organization, 2014). Some studies show that the percentage for exclusive breastfeeding in Spain is 16.8% at 6 months (Cabedo et al., 2019). Interventions in mHealth have shown positive efficacy in also establishing and maintaining BF (Uscher-Pines et al., 2019; White et al., 2018), with a significant increase in the marketing of mobile applications related to BF since 2016 (Díaz Cano et al., 2019). Perhaps one of the strengths of the information provided by mHealth is the personalization and interaction of the information, a point highlighted by women (Halili et al., 2018). However, we are still unaware of what content women actually consult when downloading a BF mobile application. Knowing what content a lactating mother is looking for can help health professionals reinforce specific BF content, and enable them to carry out certain health education interventions that address pre- and postnatal women. Thus, these authors aimed to analyze what content women seek in a BF application.

2 | METHODS

2.1 | LactApp: An mHealth for breastfeeding

LactApp started to operate in Spain in 2014 as a Facebook page that collected mothers' consultations about breastfeeding. This information was classified on an Excel file and that became the core structure of decision trees found in the application (app). LactApp launched its first version of the app in October 2015. Since then, it has been growing in content and improving its navigation over time. This app was founded by two female cofounders.

LactApp is a free mobile app designed for BF support. This app is accessible 24 h a day with an Internet connection and offers personalized support. LactApp works as a self-administered questionnaire based on 48 decision trees that include topics about BF, maternity, and maternal-infant health and was built with questions and answers written by an International Board-Certified Lactation Consultant. It is supported by scientific evidence and up-to-date official health guidelines, such as the Spanish Ministry of Health (Ministerio de Sanidad Servicios Sociales e Igualdad, 2017) or the protocols of the Academy of Breastfeeding Medicine (Eglash & Simon, 2017). The result of the questionnaire provides over 2373 personalized answers reached through more than 76,232 possible paths across the decision trees, which vary according to the user's and her infant's profiles. To reach a final answer, the user must register in the app, and provide his or her e-mail address or sign in using Facebook or Apple sign in.

LactApp's main functionality is its automated BF consultation system. However, it also provides functionalities of BF monitoring,

such as child growth trackers, child's bowel movements, and BF trackers, where users can record the number of daily BF sessions and their duration.

Other features that LactApp offers are BF tests and personalized plans. The tests are five questionnaires that allow a quick answer about specific situations that arise during BF (The first 5 days of your infant; Getting through the first month; Does my infant breastfeed well?; Is my infant ready to eat solids?; Do you know if your infant has a tongue-tie?). Personalized plans involve questionnaires that use a logic of proposals with several variables to provide users with proposals and recommendations according to their needs.

BF questions can be consulted through a live chat function answered by an International Board-Certified Lactation Consultants, midwives, nutritionists, and pediatricians of the LactApp team. Moreover, the flow of queries and interactions through chat collects data for artificial intelligence (AI) and machine learning. LactApp's AI is currently being developed and trained to reply autonomously to consultations.

LactApp is available in English and Spanish. This app can be downloaded on the Android and iOS systems.

2.2 | Study design

We conducted an observational, descriptive, and retrospective study using the data recorded by LactApp in 2019 (January 1, 2019–December 31, 2019), which included 2,725,925 queries classified as 48 topics (including tests) among 130,000 active users.

2.3 | Data collection

LactApp has an SQL-based database that collects data from registered users, such as e-mail, age, home city, user status (pregnant or not pregnant), due date, and number of infants. LactApp also collects data about the registered child to access the answer to a query, such as an infant's birth date, gender, whether he or she was premature or not, and gestation week, and weight and height at birth.

LactApp's database also registers user's query history by registering all final answers of the questionnaires that a user reached, along with date and time of the query, the user identifier, the operating system of the mobile phone used, and the language used. All these data from 2019 were extracted and merged with the users and their child data using SQL to create a suitable data set to perform data analysis.

Google Analytics and Firebase were selected to collect data about the app's usability, and the data from those platforms were anonymized and aggregated (Clark et al., 2014). The following variables were collected with these platforms: Number of active users, number of sessions and screens, duration of the session, languages accessed, countries accessed from, and operating system. We were also able to monitor the performance of events: Number of queries and test visits. Unique events are defined by Google Analytics as interactions with content by a single user within a single session

(Google, 2019). Data extraction was performed monthly between January 1, 2019 and December 31, 2019.

2.4 | Data analysis

All raw data management and statistical analyses were performed by the R v 3.6.2 in the R studio environment (v. 1.2.5001). The data of all final answers reached by users were aggregated weekly, monthly, and yearly, and as categories of the topic. Data were also aggregated by the infant's age at the time of the query because it was the main variable that we intended to study.

All the variables were not normally distributed (Shapiro-Wilk test p < .05), thus nonparametric Kruskal-Wallis statistical tests with Dunn post hoc tests were performed to assess the significant differences in the visits of the gueries aggregated as topics according to the user's infant's age. The p values were corrected by the number of users in each group category and adjusted by the false discovery rate. A principal component analysis (PCA) was also carried out to plot the difference in uses of gueries according to the user's infant's age.

2.5 | Ethical considerations

This study followed Spanish Organic Law 3/2018, of December 5, on Personal Data Protection and Guaranteeing Digital Rights, Registration in LactApp requires users accepting Regulation (EU) 2016/ 679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with regard to the Processing of Personal Data and on the Free Movement of Such Data (General Data Protection Regulation).

3 | RESULTS

3.1 User profile and app activity

LactApp had 130,000 active users in 2019. Active users were those who accessed the app during the last estimated time period, employed to measure the app's relevance. Daily, weekly, and monthly users were normally evaluated. In 2019, LactApp had an average of 2400 active users a day, 10,000 a week, and 28,000 a month.

In 2019, LactApp received 2,725,925 queries, which represents an average of 52,421 weekly queries, and 78,087 users accessed LactApp to answer questions about BF, which accounted for a mean of 32.8 queries per user and a mean 6-min duration with 18 s per session.

According to Google Analytics and Firebase databases, 90% of active users were female aged between 25 and 34 years (58%). The main regions from which users accessed the app were Spain (79.4%), Mexico (4.5%), Chile (2.8%), Colombia (1.8%), and the United States (1.1%).

Table 1 provides sociodemographic data of registered users and their infants in 2019. LactApp registered 71.807 new users in its

TABLE 1 Sociodemographic data of LactApp users in 2019

TABLE 1	Sociodemographic data o	f LactApp users i	n 2019
		n	%
Active users	in 2019	130,000	
Language			
Spanish		116,400	89.5
English		8315	6.4
Operating	system		
Android	system -	84,000	64.6
iOS		46,000	35.3
Gender			
Female		68,977	87
Male		10,341	13
Age (years)			
18-24		5689	4.4
25-34		51,124	39.3
35-44		29,378	22.6
45-54		3675	2.8
55-64		1501	1.1
>65		441	0.3
Registered u	users in 2019	71,807	
Users with	registered data	1559	
Status			
Pregna		1471	94
Not Pi	regnant	88	6
Number of	children		
0		1063	68
1		396	25
2		83 14	5 1
3 ≥4		3	0.2
	nfants in 2019	44,342	0.2
	njants in 2019	44,342	
Gender Female		24.024	40.0
Male		21,831 22,511	49.2 50.7
		22,311	30.7
Age 0-15 day		12,495	20.0
	ys -3 months	18,360	28.9 42.4
3–6 mon		6603	15.3
6 month		2806	6.5
>1 year	,	2960	6.8
Birth weigh	nt (g)		
1000		13	0.03
1000-15	500	224	0.52
1500-20	000	2977	6.9
2500-40	000	37,723	88.2
>4000		1793	4.19
Birth heigh	it (cm)		
≤48		11,388	27.6
			(Continues)

89



TABLE 1 (Continued)

48-52 25,912 6	
	2.9
>52 3909 9	.48
Premature	
Preterm 2715 6	5.1
Full-term 41,627 9	3.9

database, but only 1559 (2.17%) of them optionally recorded their personal data. Of registered users in LactApp in 2019, 94% (n = 1471) were pregnant and most (68%, n = 1063) were primiparous.

During the same period, 44,342 infants were registered, of whom 50.7% (n = 22,511) were male with an average age of 3.4 months (\pm 6.4 months), a mean birth weight of 3210.8 g (\pm 492.8 g), and a birth height of 49.6 cm (\pm 2.48 cm). Finally, 6.12% (n = 2715) of registered infants were premature at a mean gestation of 33.7 weeks (\pm 4.2 weeks).

3.2 | LactApp's usability

3.2.1 | Most frequent queries

Tables 2 and A1 offers the annual frequency of the responses aggregated as topics.

The 10 most frequently consulted topics in 2019 were those related to BF technique, infant sleep, human milk management and storage, BF myths, BF stages, complementary feeding, infant care, BF products, mixed feeding, and returning to work. These queries represented 59.6% (n = 1,625,591) of all the queries made, which could represent the critical BF point.

3.2.2 | Using LactApp's content according to infant's age

Tables 3 and B1 offers the mean weekly queries aggregated as topics according to the user's infant's age. As we can see, the queries visited by users changed according to their infant's age, and a pattern of needs appeared depending on the infant's development stage.

The most frequently made queries at lactation onset were related to the BF technique, followed by the first days of BF, infant sleep, breast pain, and BF products. Between the ages of 15 days and 3 months, the most frequently made queries were related to BF technique, infant sleep, human milk management and storage, BF myths, and infant care. In the age category of 3 to 6 months, the most consulted responses were related to human milk management and storage, complementary feeding, infant sleep, returning to work, and BF myths. In the age group from 6 months to 1 year of age, users consulted queries related to complementary feeding, infant sleep, BF infants over 6 months.

TABLE 2 Annual frequency of the 10 most popular queries according to topics

Торіс	Query frequency	%	Accumulated %
Breastfeeding technique	321,265	11.8	11.8
Infant sleep and breastfeeding	253,046	9.3	21.1
Human milk management and storage	202,948	7.4	28.5
Breastfeeding myths	158,675	5.8	34.3
Breastfeeding stages	134,507	4.9	39.3
Complementary feeding	130,732	4.8	44.1
Infant care	125,961	4.6	48.7
Breastfeeding products	113,382	4.2	52.8
Mixed feeding	94,004	3.4	56.3
Returning to work	91,071	3.3	59.6

human milk management and storage, and BF stages. Once the infant was older than 1 year, users visited responses related to infant sleep, BF stages, breast pain, BF technique, weaning, weaning management, and tandem BF.

Some topics were frequently consulted regardless of the infant's age, such as infant sleep and BF technique. However, some were consulted much more often in accordance with the infant's developmental stage. To explore which topics were associated with each age category, a PCA was performed. Figure 1 shows the PCA biplot, which illustrates that the topic "the first days of BF" was associated with the 0- to 15-days age group, whereas "returning to work," "weaning," "weaning management," "complementary feeding," "baby-led weaning," and "BF infants over 6 months" were related to the 3- to 6-months and the 6-months to 1-year age groups. "Tandem BF" was associated with the over 1-year age category. Finally, the 15-days to 3-months age group was the most diverse group in consulting topics and was associated with various topics like "growth spurts," "breast pain," "breast refusal," "breast shape and size," "pumping milk," and "increased milk demand," among others.

Figure 2 shows the boxplot of the 16 topics that contributed more to construct principal components 1 and 2 which were, thus, the most discriminating variables among the infant age categories. The weekly visiting frequency of the topics "growth spurts," "BF myths," "infant care," "make more milk pumping," "how to express milk," "hypogalactia," "mixed feeding," "breast shape and size," "infant poops," "BF stages," "weaning," "returning to work," and "cracked nipples" significantly increased (p < .05) for the 15-days to 3-months age group compared to the other age groups. "Complementary feeding," "BF infants over 6 months," "baby-led weaning," and "weaning" queries significantly increased (p < .05) for the 3- to 6-months and the 6-months to 1-year age groups compared to the other age groups. Lastly, "tandem BF," "weaning," and "weaning" and "weaning"

TABLE 3 Mean weekly queries aggregated as the most consulted topics according to the user's infant's age

	Infant's age					
Topic	0-15 days (n = 13,220)	15 days-3 months (n = 27,355)	3-6 months (n = 18,471)	6 months-1 year (n = 11,434)	>1 year (n = 8626)	Overall p
Infant sleep and breastfeeding	567.1	2406.4	978.3	482.8	265.8	<.01
Breast pain	459.5	1293.8	301.2	202.2	246.1	<.01
Breastfeeding myths	351.8	1693.5	553.7	202.3	162.7	<.01
Breastfeeding products	363.6	1081.9	344.9	85.2	92.9	<.01
Breastfeeding stages	329.8	1084.4	528.2	294.2	259.7	<.01
Breastfeeding technique	1762.1	3696.7	531.1	110.7	238.9	0.01
Complementary feeding	12.6	261	1129.2	1312.9	122.8	<.01
Human milk management and storage	241.9	1762.4	1247.2	329.4	165.9	<.01
Returning to work	53.8	614	767.1	183	65.7	<.01
Tandem breastfeeding	11.2	36.3	35.3	48.7	194.2	<.01
The first days of breastfeeding	803.5	799	154.5	47.7	127.8	<.01
Infant care	301.5	1590	305.9	57	107.7	<.01
Weaning	11.1	134.6	147.3	183.1	200.9	<.01
Weaning management	7	96.2	147.9	180.4	200.4	<.01

^{*}Nonparametric Kruskal-Wallis test, p values adjusted for the number of users of each age category and corrected by the "false discovery rate."

management" queries significantly rose (p < .05) for the over-1-year age group compared to the other age groups.

3.2.3 | Usage of LactApp's tests according to infant age

Visits to LactApp's tests also changed according to the user's infant's age (see Table 4). As the PCA biplot in Figure 3 illustrates, lactation onset was associated with the test "The first 5 days of your infant," whereas the most frequently visited test was "Is my infant ready to eat solids?" for the 3- to 6-months age group. The 15-days to 3-months age group was more heterogeneous and associated with "Do you know if your infant has a tongue-tie?," "Does my infant breastfed well?," and "Getting through the first month."

4 | DISCUSSION

e-Technologies and mHealth applications can be promising tools for BF support and increasing BF rates (Lau et al., 2016; Lee et al., 2016). The authors of one study reported that the main reasons technologies can help establish or maintain breastfeeding are portability, efficiency, reduced mobility limitations, improved confidence, better social support, or a wide range of information (Lau et al., 2016).

However, none of these studies has examined how lactating mothers seek support when using the mHealth tool. The present study aimed to analyze which content and answers women look for during BF and according to their infant's age.

The sustained LactApp user activity, as shown by the number of active users and visits, proves that LactApp may be a BF support tool, and not just for its content, but also for its features like tests and trackers, live chat with BF experts, and personalized plans. Personalized information and more interaction are characteristics that women demand (Halili et al., 2018). This personalized information is highlighted as essential for BF maintenance by mothers and health professionals (Garner et al., 2016; Robinson et al., 2019). A previous study revealed that LactApp queries increased between July 2016 and June 2019 and the trend of queries has grown according to Prais–Winsten autoregressions based on the Durbin–Watson model (article under peer review).

Different factors can contribute to shorter BF durations, including mother's perception of insufficient milk supply, nipple or breast pain, lack of social support, lack of confidence, physical and social embarrassment, comfort and trust in formula (Morrison et al., 2019; Schindler-Ruwisch et al., 2018), which are associated with difficulty with latch and position, and the presence of infant tonguetie, among other factors (Kent et al., 2015). Furthermore, there are critical moments that encourage the abandonment of breastfeeding such as the feeling of lack of milk in periods of high growth of the infant (Vila-Candel et al., 2019), or the return to work and short

FIGURE 1 Principal component analysis biplot of the weekly queries aggregated as topics according to users' infant's age [Color figure can be viewed at wileyonlinelibrary.com]

Dim1 (63.3%)

maternal leaves (Cabedo et al., 2019; Dinour & Szaro, 2017; Morrison et al., 2019; Navarro-Rosenblatt & Garmendia, 2018; Tsai, 2013). To maintain breastfeeding after returning to work, mothers need to pump and store their milk (Kozhimannil et al., 2016). This factor causes much concern in mothers (Valizadeh et al., 2017), as reflected by the numerous visits that LactApp receives about how to pump milk correctly and more effectively, and how to store milk appropriately. The most frequently queried topics in 2019 were those related to critical stages in which mothers need more support, such as BF technique and myths, infant sleep, infant care and behavior, growth spurts, BF stages, mixed feeding, complementary feeding, pumping milk and its storage and returning to work. There are still gaps in how to provide effective support in these situations (Galipeau et al., 2018). Thus, LactApp's personalized answers could provide lactating mothers support in these situations of high BF abandonment.

The results of this study suggest that LactApp's support seems to develop with mothers' needs according to their infant's developmental stage. The topics that mothers seek differ at lactation onset than when their infant is 1-year old. At BF onset, women consult topics related to the first days of BF, which include the answers to the most frequent concerns, like "should I wake my infant up?" "my infant is not making any bowel movements," "how frequently do infants breastfeed?" "lack of milk supply perception in the first days," "warning signs," or "my infant does not latch on or struggles to latch on." At the beginning of lactation, mothers also make queries about breast pain in relation to sore nipples, mastitis, and other common complications. This coincides with the most common reasons for early cessation of breastfeeding according to the literature (Morrison et al., 2019).

20

When infants are aged between 15 days and 3 months, mothers submit more diverse queries. In this BF stage, mothers look for

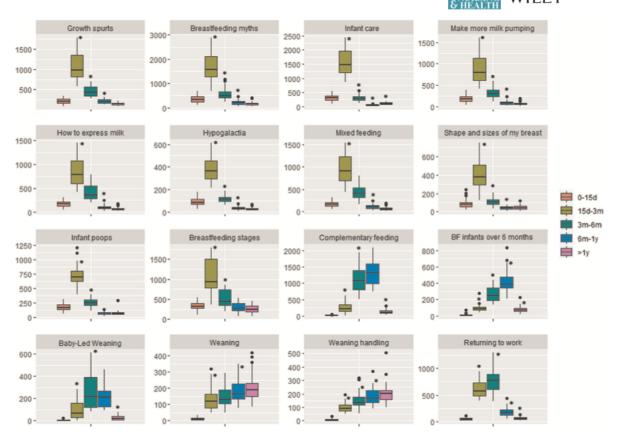


FIGURE 2 Boxplots of the topics that most contribute to discriminate users' infant age groups. *Significant differences compared to the prior infant age group (p < .05 of Dunn post hoc of the Kruskal-Wallis test, p value corrected by the number of users in each group category and adjusted for false discovery rate) [Color figure can be viewed at wileyonlinelibrary.com]

support in diverse topics that can be further grouped according to BF crisis, returning to work, and BF complications. Answers to mothers' queries related to BF crises include "growth spurts," "increased milk demand," "my breast feels empty and soft," my infant gets frustrated on the breast," "my infant is not gaining weight," or the test "Do you know if your infant has tongue-tie?" "Does my infant breastfeed well?" and "Getting through the first month." In Spain, due to short maternal leaves, at this age mothers start preparing to return to

work (Cabedo et al., 2019; Dinour & Szaro, 2017; Morrison et al., 2019; Navarro-Rosenblatt & Garmendia, 2018), and seek more answers about mixed feeding, how to express milk efficiently, and how to manage and store milk.

When infants are aged between 3 and 6 months and 6 months and 1 year, lactating mothers seek similar answers related mostly to complementary feeding and weaning. The topics of BF infants over 6 months old include answers like: "My infant has stopped

TABLE 4 Mean weekly tests performed by users according to the infant's age

TABLE 4 Medit Weekly tests performed by discis decording to the infant's age							
	Infant's age						
Test	0-15 days	15 days-3 months	3-6 months	6 month-1 year	>1 year	Overall p value	
Do you know if your infant has tongue-tie?	6.7	51.5	18.6	5.7	6.5	<.01	
Does my infant breastfeed well?	27	142.2	40.2	4.1	9.6	<.01	
Getting through the first month	9.2	120.1	2.8	0.7	6	<.01	
Is my infant ready to eat solids?	0.3	4.9	69.3	29.2	5	<.01	
The first 5 days of your infant	59.6	30.8	6.7	2.3	9.7	<.01	

^{*}Nonparametric Kruskal-Wallis test, p value was corrected by the number of users of each age category.

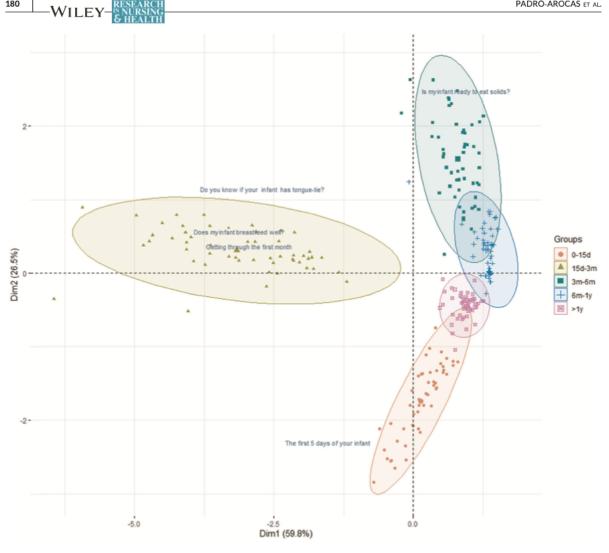


FIGURE 3 Principal component analysis biplot of the weekly queries aggregated as tests according to users' infant's age [Color figure can be viewed at wileyonlinelibrary.com]

eating solids," "my infant bites my breasts," "my infant feeds too much at night," "weaning my infant at night," "I think my infant is too dependent on my breast," "infant demands breast aggressively," "I feel uncomfortable breastfeeding in public," or "I'm getting tired of breastfeeding." Finally, when infants are 1-year old, mothers look for support in weaning, weaning management (Brockway & Venturato, 2016; Yate, 2017), and tandem BF (O'Rourke & Spatz, 2019).

Finally, it is necessary to discuss other findings that have been highlighted. Thirteen percent of LactApp users were men, which demonstrates the importance of the father's role in breastfeeding (deMontigny et al., 2018; Rempel et al., 2017), the father's influence on the duration of breastfeeding (Rempel et al., 2017), and the increasing involvement of fathers in breastfeeding (deMontigny et al., 2018). Another interesting finding related to sociodemographic data

may be the percentage of active users according to age. LactApp has an international vision and the age of maternity can be very varied around the world. Though in South America, women are younger mothers (Yu et al., 2016), in Spain the maternity age is increasing (Instituto Nacional de Estadística, 2019).

With all these findings, we believe that LactApp can influence the maintenance of BF, as does social media (Black et al., 2020) and other applications (Gonzalez-Darias et al., 2020); but this should be tested in future studies. In future studies, we would also like to determine whether there are differences between what mothers consult depending on their culture, their sociodemographic data, or whether their infants were born prematurely or with low birth weight. Through this study, it can be highly interesting to know what kind of support mothers expect and need during breastfeeding. We believe that, for mothers, LactApp can also be a female empowerment tool that allows women to make informed decisions about BF. On the contrary, given the lack of knowledge of healthcare professionals about BF (Colaceci et al., 2020; Quinn & Tanis, 2020) and the insufficient time in health professionals' consultations (Gilmour et al., 2016), LactApp can be prescribed by healthcare providers, like other tools (Agarwal et al., 2019; Dufour et al., 2019).

The main limitation of our study is that the profile set up of users and their infant is optional and not verified, thus models may involve some uncontrolled bias. Moreover, data from Google Analytics and Firebase, employed to characterize users, may also include some uncontrolled bias as women might use the smartphone of their husband, partner, or other family members to consult LactApp. Another limitation to consider is that some users might browse the application without a specific consultation, whereas others might consult for a third person by acting as an intermediator between LactApp and the consulting person. We have also detected users who do not make preestablished queries and go directly to the live chat. These considerations may influence the number of visits received.

In conclusion, the most consulted queries in LactApp made by lactating mothers are those related to critical moments in the abandonment of BF. LactApp is a tool that provides lactating women with BF support and information in those critical stages by offering personalized answers. The use of LactApp's content changes depending on the BF stage and users' infant's age. These findings may be of great interest in determining women's empowerment to make informed decisions about BF and about the effectiveness of LactApp in maintaining BF. Finally, LactApp can be a powerful mHealth tool prescribed by healthcare professionals.

ACKNOWLEDGMENTS

Paola Quifer-Rada is grateful for the Torres y Quevedo aid program from the Ministerio de Ciencia e Innovación. The LactApp team thanks all the women who made LactApp a reality. This study has been funded by Jaume I University (Grant no. UJI-A2019-06).

CONFLICT OF INTERESTS

The authors declared the following potential conflicts of interest in relation to the research, authorship, and/or publication of this article: Alba Padró-Arocas created and designed the software. Laia Aguilar-Camprubí serves as a consultant at LactApp. Nevertheless, none of these potential conflicts affected the study design, data collection, analysis, and interpretation, or the writing of the manuscript by Paola Quifer-Rada and Desirée Mena-Tudela.

ORCID

Desirée Mena-Tudela https://orcid.org/0000-0003-1596-3064

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How to cite this article: Padró-Arocas A, Quifer-Rada P, Aguilar-Camprubí L, Mena-Tudela D. Description of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers seek support at critical breastfeeding points and according to their infant's age. *Res Nurs Health*. 2021;44:173–186. https://doi.org/10.1002/nur.22095

Objetivo específico 3

Evaluar el impacto de la pandemia de SARS-CoV-2 en las consultas de lactancia materna en LactApp.

La pandemia por SARS-CoV-2 que se inició en diciembre de 2019 causó un confinamiento total de la población que se inició masivo en marzo de 2020 en España, tuvo en el uso de la aplicación. Durante el curso del trabajo de esta tesis doctoral, se vio la necesidad de analizar el impacto que la pandemia de SARS-CoV-2 tuvo en el uso de LactApp.

Este objetivo se trabajó en un artículo titulado "Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support". Este artículo se publicó en la revista "Telemedicine & e-Health". Según el JCR de 2021, esta revista tiene un factor de impacto de 5.033, perteneciendo al puesto 19 de un total de 109 indexadas en la categoría "Health Care Sciences & Services". Por lo tanto, esta revista ocupa un primer cuartil (Q1) y el primer tercil (T1) en el listado correspondiente del JCR.

Cita bibliográfica: Quifer-Rada, P., Aguilar-Camprubí, L., Padró-Arocas, A., Gómez-Sebastià, I., & Mena-Tudela, D. (2022). Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support. Telemedicine journal and e-health: the official journal of the American Telemedicine Association, 10.1089/tmj.2021.0586. Advance online publication. https://doi.org/10.1089/tmj.2021.0586

Citas recibidas:

Moise, I.K., Ivanova, N., Wilson, C. et al. Lessons from digital technology-enabled health interventions implemented during the coronavirus pandemic to improve maternal and birth outcomes: a global scoping review. BMC Pregnancy Childbirth 23, 195 (2023). https://doi.org/10.1186/s12884-023-05454-3 Impact Factor: 3,105. Categoría: Obstetrics & Gynecology. Posición: 36/85

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Metodología

Diseño

Para llevar a cabo esta investigación, se realizó un estudio observacional, descriptivo y retrospectivo con los datos recogidos por LactApp desde julio de 2018 hasta marzo de 2021, incluyendo 9.151.456 consultas automáticas, clasificadas en 48 temas de 137.327 usuarias.

Ámbito, población y muestra

Como se ha explicado en los artículos anteriores, LactApp es una aplicación móvil que se ha desarrollado para brindar apoyo e información sobre lactancia materna. Su principal funcionalidad es un sistema automatizado de consultas sobre lactancia materna que trabaja como a cuestionario autoadministrado basado en 48 árboles de decisión que incluyen temas relacionado con la lactancia materna, la maternidad, la salud materno-infantil, construido con preguntas y respuestas respaldada por pruebas científicas y directrices sanitarias oficiales actualizadas. El resultado del cuestionario lleva a más de 2.300 respuestas individualizadas que pueden ser alcanzadas a través de más de 76.100 posibles caminos de los árboles de decisiones, que varían según el perfil de la usuaria y de su bebé. LactApp también cuenta con funcionalidades de contadores (o trackers), como la de la monitorización del crecimiento del bebé, las deposiciones del bebé y otros contadores de lactancia. También ofrece test y planes personalizados y así como la posibilidad de realizar consultas mediante la función de chat, contestado por expertas en lactancia del equipo de LactApp.

Además, LactApp está desarrollando una tecnología de inteligencia artificial (IA) que es capaz de entender las consultas de las usuarias en la funcionalidad de chat y ofrecer una respuesta inmediata y personalizada.

Debido a la necesidad de informar a las usuarias sobre la COVID-19 y la lactancia, LactApp incluyó un nuevo árbol de decisiones con preguntas y respuestas específicas sobre este tema. Esta información estaba basada en organizaciones científicas internacionales, como la Organización Mundial de la Salud (OMS) o el Centro para el Control y Prevención de Enfermedades de EE.UU. (CDC).

La población del estudio está formada por todas las usuarias de LactApp.

Variables y recogida de datos

Como se ha explicado anteriormente, LactApp recoge el e-mail de las usuarias registradas junto con otros datos opcionales como la edad, la ciudad de residencia, si se está embarazada o no, la fecha probable de parto y el número de hijos o hijas.

LactApp también recoge datos sobre el bebé que tiene registrado la madre: su fecha de nacimiento, el sexo, si el bebé es prematuro o no, la edad gestacional en el momento de nacer, y el peso y la talla al nacimiento.

Además, Lactapp también registra todas las respuestas finales que la usuaria llega con la fecha y la hora de la consulta, su identificación, el sistema operativo de su móvil y el lenguaje usado.

Finalmente, Google Firebase se utilizó para registrar el número de usuarias activas y consultas totales visitadas en la aplicación desde 2017 hasta 2021. Los datos de esa plataforma están agregados y anonimizados.

Consideraciones éticas

Este estudio siguió la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales. El registro en LactApp requiere que las usuarias acepten el Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y a la libre circulación de estos datos (Reglamento General de Protección de Datos).

No se ha utilizado información personal de ninguna usuaria y los datos se han tratado de forma totalmente anónima.

Análisis de datos

Los datos y el análisis estadístico fue realizado usando R v3.6.2 en R studio environment (v. 1.2.5001). Los datos de las respuestas finales alcanzadas por las usuarias fueron agregados trimestralmente y anualmente por categorías de temas usando Microsoft Power Bl. El aumento de las consultas automatizadas visitadas fue evaluado trimestralmente y anualmente.

Se usó un análisis de series temporales interrumpidas para estudiar el impacto del brote de SARS-CoV-2 en el número de consultas automatizadas realizadas en LactApp y el número de usuarias activas. usando un modelo de series temporales interrumpidas, pudimos calcular las consultas automatizadas y usuarias que LactApp hubiera recibido si no hubiera ocurrido la pandemia de SARS-CoV-2, el impacto inmediato real en el número de consultas automatizadas y usuarias, y el efecto a

largo plazo de la pandemia en el número de usuarias y consultas automatizadas. El test de Shapiro-Wilk se usó para evaluar la distribución normal de las variables.

Las variables no seguían una distribución normal, con lo que se usó el test no paramétrico de Wilcoxon para comparar los periodos pre-pandémico (de julio de 2018 a febrero de 2020) y pandémico (de marzo de 2020 a marzo de 2021). Para reducir el sesgo debido al incremento del número de usuarias de LactApp durante el periodo de pandemia, las consultas automatizadas fueron corregidas usando el ratio consulta por usuaria. Las consultas fueron posteriormente agregadas por meses; por ello, los principales resultados de la presente investigación están expresados en consultas mensuales por usuaria. Las consultas por chat se clasificaron por temas usando inteligencia artificial y se agregaron por semanas y, por lo tanto, los resultados se expresan en consultas por chat semanales.

Resultados

Las usuarias de Lactapp crecieron un 133% y las consultas automatizadas totales aumentaron un 116% después del brote de SARS-CoV-2, por lo que hubo 389.984 consultas automatizadas de lactancia mensuales.

El análisis de series temporales interrumpidas, muestra que hubo un importante crecimiento de las consultas automatizadas en LactApp y un aumento de usuarias desde 2017 hasta 2021. En el gráfico 15 se observa este aumento.

Aun así, el número de consultas y usuarias predictivo según el crecimiento natural en LactApp está igualmente trazado para mostrar cómo la pandemia impactó en la actividad de LactApp desde marzo de 2020 (el inicio de la pandemia de SARS-CoV-2 en Europa).

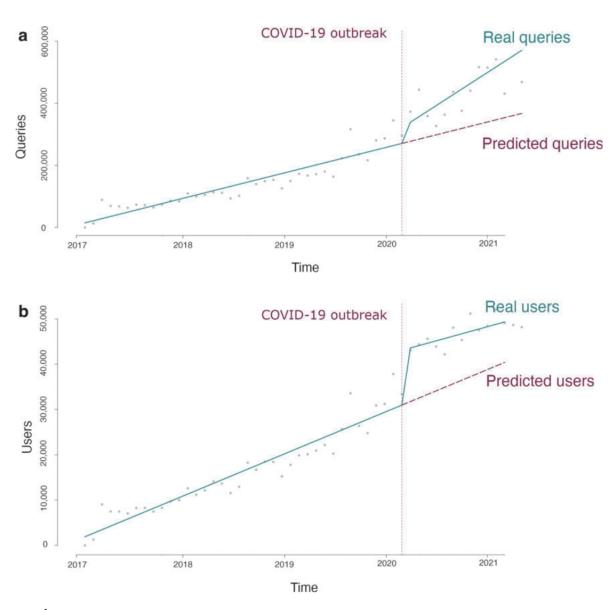


GRÁFICO 16: Análisis de series temporales del número de consultas (a) y usuarias activas (b) de LactApp desde 2017 a 2021. Los valores reales y los predictivos han sido trazados desde el brote de SARS-CoV-2. Los datos fueron extraídos de Google Firebase.

El paso del tiempo aumentó significativamente tanto las consultas automatizadas realizadas en LactApp (6.919 consultas mensuales, p<0,001) como las usuarias activas (785,3 usuarias mensuales, p<0,001). El brote de SARS-CoV-2 y el inicio del confinamiento en Europa aumentó significativamente las usuarias activas en 12.092 usuarias (p<0,001). Después del brote de la pandemia, el paso del tiempo aumentó significativamente en consultas automatizadas realizadas en 10.899 consultas mensuales (p=0.003). Después de la pandemia, las consultas aumentaron positivamente a un ritmo de 3.980 mensuales.

	Número de automa		Número de usuarias		
	Coeficiente	p	Coeficiente	p	
Tiempo	6.919	<0,001	785,3	<0,001	
Brote de SARS-CoV-2	50.562	0,14	12.092	<0,001	
Tiempo des del brote de SARS-CoV- 2	10.899	0,003	-263,2	0,15	
Intercepción	7,699	0,65	117,9	0,21	

TABLA 2: Modelo de series temporales interrumpidas para el número de consultas automatizadas y usuarias activas de LactApp

Como se mostró en las investigaciones anteriores, las consultas más visitadas en LactApp fueron las relacionadas con la "técnica de lactancia" (12,6%), el "sueño del bebé y lactancia" (8,9%), las "crisis de crecimiento" (5,5%), la introducción de "alimentación complementaria" (5%) y la "lactancia por etapas" (4,9%).

Las consultas mensuales por usuaria incrementaron significativamente durante la pandemia de SARS-CoV-2 (en periodo pre-pandémico de 19,25 de media a valores pandémicos de 23,11 de media con una p = 0,02).

Los temas de lactancia que incrementaron significativamente después del brote de SARS-CoV-2 fueron los relacionados con las "crisis de crecimiento" (con un aumento medio significativo del 107%, p<0,001), la "lactancia por etapas" (con un aumento medio significativo del 76,8%, p=0,01), la "técnica de lactancia" (con un aumento medio significativo del 56%, p=0,003), el "dolor en el pecho" y mastitis" (con un aumento medio significativo del 43,3%, p<001), la "enfermedad materna y lactancia" (con un aumento medio significativo del 38,5%, p=0,005), las "dificultades con los bebés que no ganan peso adecuadamente" (con un aumento medio significativo del 31,2%, p=0,04), la "hipogalactia y sensación de producción insuficiente de leche" (con un aumento medio significativo del 26,4%, p<0,001),

el"incremento de demanda" (con un aumento medio significativo del 21%, *p*<0,001) y la "relactación" (con un aumento medio significativo del "plan personalizado de relactación" de 15,3%).

Sin embargo, las consultas por usuaria que no cambiaron significativamente entre el periodo prepandémico y el periodo pandémico fueron las relacionadas con la "lactancia en tándem" (p=0,29), la "lactancia de gemelos" (p=73) o la "lactancia de bebés mayores" (p=0,98), la "extracción de leche" (p=0,3), y la "donación de leche" (p=0,8), el "cuidado del bebé" (p=0,31) y el "sueño del bebé" (p=0,5), la "menstruación y fertilidad" (p=0,1), el "embarazo" (p=0,78), la "vuelta al trabajo" (p=0,7), la "salud materna" (p=0,9), Lasemociones en la lactancia" (p=0,67) y el "destete" (p=062).

	Periodo pre-pandémico (n=68.242 usuarias únicas)		Periodo pandémico (n=88.822 usuarias únicas)		p
	Mediana	IQR	Mediana	IQR	- T
Complicaciones en la lactancia					
Bultos en el pecho	2,9	0,7	3,09	0,5	0,02
Dolor en el pecho y mastitis	3,48	0,4	4,16	0,4	<0,001
Hipogalactia	2,69	0,4	2,9	0,4	<0,001
Grietas y heridas en los pezones	3,19	0,99	3,93	0,6	0,001
Técnica de lactancia					
Rechazo del pecho	2,01	0,3	2,37	0,2	0,001
Lactancia en bebés de más de 6 meses	3,11	0,7	3,05	0,5	0,98
Mitos de lactancia	7,58	1,4	6,77	1,1	0,01
Productos de lactancia	5,54	1,1	5,05	1	0,02
Lactancia por etapas	2,77	0,2	3,04	2,1	0,01
Técnica de lactancia	8,39	4,1	13,15	1,7	0,003
Lactancia en gemelos	2,73	1,5	2,67	1,5	0,73
Aumento de la demanda	1,96	0,3	2,38	0,2	<0,001
Inducción a la lactancia	2,93	2,6	2,42	1,7	0,22
Lactancia mixta	6,22	1,2	6,43	1,2	0,41
Relactación	1,9	0,4	2,13	0,6	0,29
Plan personalizado de relactación	1,8	0,3	2,01	0,3	<0,001
Tamaño y forma de los pechos	3,93	1	3,97	0,8	0,7
Lactancia en tándem	5,17	2,5	5,27	2,3	0,29
Los primeros días de lactancia	2,92	0,5	3,34	0,4	<0,001
Destete	3,22	0,7	3,23	0,5	0,62
Bebé y lactancia					
Crisis de crecimiento	2,38	0,2	2,58	2,1	<0,001
Cuidado del bebé	5,2	0,7	5,27	0,5	0,31
El bebé no gana peso	2,59	0,5	2,7	0,4	0,04
Deposición del bebé	4,24	0,5	4,08	0,7	0,2
Sueño del bebé y lactancia	7,59	1	7,42	0,8	0,5
Salud del bebé	3,1	0,9	2,76	0,5	0,03
Introducción a la alimentación complementaria	9,32	2,4	8,45	1,4	0,01
Bebé prematuro	2,51	1,5	2,7	1	0,06
Extracción de leche					
Conservación y manipulación de la leche	7,76	1,3	9,12	1,23	0,01
Situaciones de salud y lactancia	2,48	1,1	2,33	0,8	0,2
Cómo extraerse leche	3,49	0,5	3,36	0,4	0,3
Donación de leche	5,42	3,5	5,52	3,1	0,81
Salud de la madre					
Menstruación y fertilidad	3,38	0,9	3,62	0,7	0,1
Enfermedad de la madre y lactancia	2,37	0,88	2,08	1	0,05
Enfermedades de la madre	2,07	0,3	1,94	0,4	0,02
Emociones de la madre	3,78	1	3,6	0,8	0,67
Embarazo	4,19	1,2	4,03	0,9	0,78
Vuelta al trabajo	4,35	0,8	4,31	0,8	0,7
Consultas totales	18,23	3,9	20,57	4	0,02

TABLA 3: Consultas automatizadas mensuales agregadas por usuaria según los temas antes y después de la pandemia de SARS-CoV-2

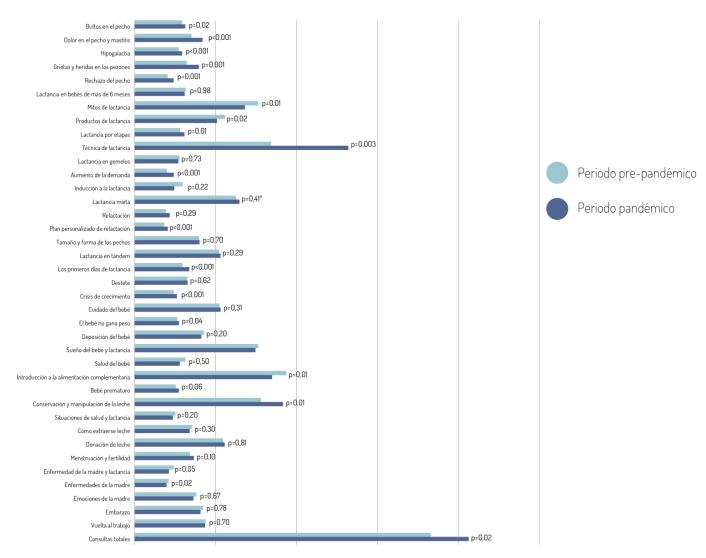


GRÁFICO 17: Consultas automatizadas agregadas de los períodos pre-pandémico y pandémico

Las consultas automatizadas sobre COVID-19 fueron muy visitadas durante el periodo pandémico (una media de 11.304 consultas por mes desde marzo de 2020 a marzo de 2021), y estuvieron en el top 20 de las consultas más frecuentes en 2020, y la sexta más consultada en el primer trimestre de 2021. La consulta más respondida sobre COVID-19 fue sobre la compatibilidad de la vacuna con la lactancia.

Pero no solamente aumentaron las consultas automatizadas. En la funcionalidad de chat, también aumentaron las consultas en un 28,5% durante el brote de SARS-CoV-2. Al estar estas consultas clasificadas por las expertas de LactApp, se pudo analizar también los diferentes temas consultados. El chat de LactApp recibió de forma significativa más consultas sobre mastitis y dolor en el pecho (con un aumento medio significativo del 105,7%, *p*=0,01) y cómo conseguir un agarre correcto al pecho

(con un aumento medio significativo del 88,4%, *p*=0,04). Otros temas como conceptos básicos, el bebé que no gana peso correctamente, la introducción de la alimentación complementaria y crisis de crecimiento, aumentaron más de un 50% durante la pandemia. Aun así, este aumento no fue estadísticamente significativo debido a la alta dispersión de las consultas semanales en el chat.

Impact of COVID-19 pandemic in breastfeeding consultations on LactApp, a mHealth solution for breastfeeding support.

Runnig head: Influence of COVID-19 in an mHealth breastfeeding app

Paola Quifer-Rada, PhD,^{1,2}, Desirée Mena-Tudela, MSN, PhD,³, Laia Aguilar-Camprubí, BN, CNM, ¹, Ignasi Gómez-Sebastià, PhD,^{1,4}, Alba Padró-Arocas, ADN,^{1*}

¹LactApp Women Health, Barcelona, Spain.

²Department of Endocrinology & Nutrition, CIBER of Diabetes and Associated Metabolic Diseases, Biomedical Research Institute Sant Pau, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain.

³Department of Nursing. University Jaume I, Castellón de la Plana, Spain.

⁴Computer Science Department, Universitat Politècnica de Catalunya (UPC), C/Jordi Girona 1-3, E-08034, Barcelona, Spain

Corresponding author: Alba Padró-Arocas, LactApp Women's Health. c/Valencia, 263, 3°1°, 08028 Barcelona, Spain. E-mail: alba@lactapp.es

Keywords: Breastfeeding support, mHealth, COVID-19, pandemic, lockdown

ABSTRACT

Introduction: Breastfeeding is an unquestionable right of mothers and their children; however, it is not a one-woman job. For breastfeeding to succeed, women must have access to appropriate support and guidance. The COVID-19 pandemic and subsequent restriction measures and lockdown to reduce community spread of the disease has negatively impacted breastfeeding support from health services and thus, in mother's breastfeeding experiences.

Objective: The aim of the present study is to evaluate the impact of COVID-19 pandemic on breastfeeding consultations in LactApp (a mobile app for mHealth focused on breastfeeding support, www.lactapp.com) during the COVID-19 pandemic.

Materials and Methods: We conducted an observational, descriptive and retrospective study with LactApp data recorded between July 2018 and March 2021 including 9,151,456 queries classified in 48 topics among 137,327 active users.

Results: Monthly queries per user significantly increased during the COVID-19 pandemic (23.11 queries per user and per month) compared to the pre-pandemic period (19.25 queries per user and per month) (p<0.005). The breastfeeding topics that significantly increased after the COVID-19 outbreak are those related to growth spurts (mean increase of 107%), breastfeeding stages (mean increase of 76.8%), breastfeeding technique (mean increase of 56%), breast pain and mastitis (mean increase of 43.3%), mother's disease and breastfeeding (mean increase of 38.5%), problems with infants not gaining weight correctly (mean increase of 31.2%), hypogalactia (mean increase of 26.4%), increased milk demand (mean increase of 21%), and relactation (mean increase of 15.3%). These findings are important to understand the potential of online tools when face-to-face professional support is unavailable.

Conclusions: Critical issues in breastfeeding establishment were highly consulted and significantly increased in the App during the pandemic. We believe that LactApp was a useful tool for breastfeeding support when women could not obtain appropriate support elsewhere. LactApp might be a powerful tool to identify critical issues of breastfeeding and trends in an automatized way.

Introduction

Breastfeeding is an important part of women's reproductive cycle and its practice benefits both mother and child. It is the natural result of pregnancy and childbirth and causes changes in the maternal organism that favours good physical and emotional health, not only during breastfeeding but in women's future life¹⁻³.

Breastfeeding is an unquestionable right of mothers and their children; however, it is not a one-woman job. Whereas the baby's instinct to nurse is innate, the act of breastfeeding is not always natural, and women need to learn. Women who choose to breastfeed need the support of their families, health professionals and healthcare systems, society, and governments. For breastfeeding to succeed, women must have access to appropriate support and guidance⁴.

The COVID-19 pandemic has brought fear and anxiety among countries and has led to restrictive public health measures to reduce the community spread of the disease^{5,6}. These measures affected women's well-being during pregnancy, birth and postnatal care period⁸. A few recent studies have reported that policies aimed at limiting interpersonal contact to reduce SARS-CoV-2 transmission led to negative postpartum experience, poor postpartum mental health and problems with breastfeeding due to lack of in-person breastfeeding support which caused early cessation of breastfeeding⁷⁻¹⁴.

A few studies have reported that during the pandemic women needed support in technical issues such as difficulties with latch, perception of insufficient milk, breast pain, relactation, and reducing supplemental infant formula milk^{12,14}.

Under this paradigm, women needed to seek breastfeeding support in technological tools like web pages and mobile applications such as LactApp (https://lactapp.com/)^{15,16}. LactApp is an mHealth solution designed for breastfeeding support^{15,16}. LactApp gives mothers customized expert answers to breastfeeding and maternity questions by leveraging Artificial Intelligence (IA) technology. Downloaded by over 500,000 users worldwide, since 2018 the App has answered over 16.6 million consultations automatically so far and is available to download in English and Spanish as a free version for mothers and as free or premium version for healthcare professionals (LactApp Medical). Due to the large number of breastfeeding consultations that LactApp receives, it might be a potential tool to identify difficulties, critical points of breastfeeding and changes in women breastfeeding experiences in a semi-automatized way.

The aim of the present study is to evaluate the impact of COVID-19 pandemic on breastfeeding consultations in LactApp.

Materials and method

LactApp: an mHealth solution for breastfeeding support

LactApp is a free mobile application developed to support breastfeeding. LactApp's performance has been described elsewhere ^{15,16}, but briefly LactApp 's main functionality is an automated breastfeeding consultation system that works as a self-administered questionnaire based on 48 decision trees that include topics related to breastfeeding, maternity, maternal and child health, built with questions and answers and supported by scientific evidence and up-to-date official health guidelines. The result of the questionnaire leads to more than 2,300 personalized answers that can be reached through more than 76,100 possible paths across the decisions trees, which vary according to the user's and her baby's profile. Personalized answers include messaging to seek for professional medical help when needed.

LactApp also provides functionalities of breastfeeding monitoring, such as child growth tracking functions, child's bowel movements and breastfeeding trackers. Other features that LactApp offers are breastfeeding tests and personalized plans and it is also possible to consult questions through a live chat function, hosted by lactation experts from the LactApp team.

Furthermore, we are developing an IA that is able to understand user queries in the live text-based chat and offer an immediate and personalized response, by effectively providing semi-automated (difficult questions are still replied to by experts) and real-time immediate guidance on the different breastfeeding topics that LactApp covers.

Due to the need to inform users about COVID-19 and lactation compatibility, LactApp included a new decision tree with specific questions and answers about this matter. That information is based on information from official organizations such as WHO and Centre for Disease Control and Prevention (CDC).

Study design and data collection

We conducted an observational, descriptive, and retrospective study with LactApp data recorded between July 2018 and March 2021 including 9,151,456 queries classified in 48 topics among 137,327 active users.

LactApp's data collection system has been explained previously¹⁵. Briefly, LactApp collects the e-mail of registered users along with other optional data about age, home city, pregnant or not pregnant, due date, number of children. Also, LactApp collects data about mother's registered child: baby's date of birth, sex, whether it was premature or not, gestational week born at, and weight and height when born.

Moreover, LactApp also registers all final answers that the user reached along with the day and time of the query, user identifier, operating system of the mobile phone used and language used in the query.

Additionaly, Google Firebase was used to register the number of active users and total queries visited in the app from 2017 to 2021. The data from those platforms are anonymized and aggregated¹⁷.

Data analysis

Raw data management and statistical analysis were performed using R v 3.6.2 in R studio environment (v. 1.2.5001). Data of all final answers reached by the users were aggregated quarterly and yearly and by categories of the topic using Microsoft Power BI. The growth of visited queries was evaluated quarterly and yearly.

Interrupted time series analysis was performed to study the impact of the COVID-19 outbreak in number of queries consulted in LactApp and number of active users. Using Interrupted time series model, we were able to calculate the predicted queries and users that LactApp would have received if the COVID-19 pandemic did not occur, the real immediate impact on number of queries and user and the long-term impact of the pandemic in number of users and queries.

Shapiro-Wilk test was used to evaluate the normality distribution of the variables.

Since variables did not follow a normal distribution, non-parametric Wilcoxon test was used to compare between the pre-pandemic (from July 2018 to February 2020) and the pandemic period (from March 2020 to March 2021). In order to reduce bias in the comparison due to the increased number of LactApp users during the pandemic period, queries were corrected using queries per

unique user ratio. Queries were further aggregated by months; thus the main results of the present study are expressed in monthly queries per user. Live chat consultations classified by topics using IA were aggregated by weeks and therefore the results have been expressed in weekly consultations.

Ethical considerations

This study followed the Spanish Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights. Registration in LactApp requires users to accept Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 regarding the protection of individuals with respect to the processing of personal data and the free circulation of these data (General Regulation of Data Protection).

For the present study, no user's personal information has been used and the data was treated completely anonymous.

Results

LactApp's active users increased 133% and total queries increased 116% after the COVID-19 outbreak, resulting in a mean of 389,984 breastfeeding consultations per month.

Figure 1 shows the real growth in queries consulted in LactApp and active user since 2017 to 2020. Since the time point of March 2019 (the begging of the COVID-19 pandemic in Europe) the predicted number of queries and users according to the natural growth over time of LactApp is also plotted to show how the pandemic impacted LactApp's activity.

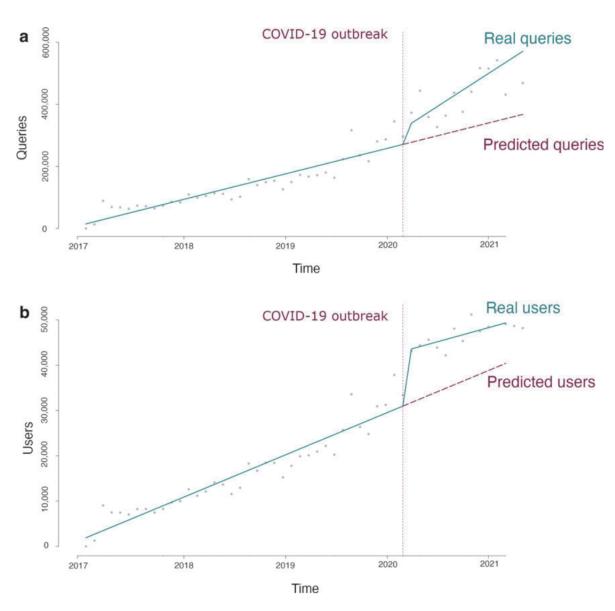


Figure 1. Interrupted time series analysis of the number of queries (a) and active users (b) of LactApp from 2017 to 2020. Real and Predicted values are plotted since COVID-19 outbreak. Data was extracted from Google Firebase¹⁷

Table 1 shows the main results of the Interrupted time series model for total queries and active users. Time significantly increased active users (627.5 users per months, p-value<0-001) and queries consulted in LactApp (4,985 queries per month, p-value<0-001). COVID-19 outbreak did not have any significant immediate effect on either active users and queries consulted in the app (p>0-005), however time since the COVID-19 outbreak significantly increased queries consulted by 948.6 users per month (p-value<0.001) and 10,764 queries per month (p-value<0-001). Thus, after the COVID-19 pandemic, queries and users positively increased of 5778 and 321, respectively, each month.

As reported previously¹⁵, the most consulted queries in LactApp are related to breastfeeding technique (12.6%), infant sleep and breastfeeding (8.9%), growth spurts (5.5%), introducing solid foods (5%) and breastfeeding stages (4.9%).

Monthly queries per user significantly increased during the COVID-19 pandemic (pre-pandemic=mean 19.25, pandemic=mean 23.11, p-value=0.02) as it is shown in Table 1.

	Number of	f queries	Number of users		
	Coefficient	p-value	Coefficient	p-value	
Time	4986	<0.001	627.5	<0.001	
COVID-19 outbreak	-11299	0.53	-402.4	0.83	
Time since COVID-19 outbreak	10764	<0.001	948.6	<0.001	
Intercept	30347	0.01	2966	0.03	

Table 1. Interrupted time series model for LactApp's number of gueries and active users.

The breastfeeding topics that significantly increased after COVID-19 outbreak are those related to growth spurts (mean increase of 107%, p-value<0.001), breastfeeding stages (mean increase of 76.8%, p-value=0.01), breastfeeding technique (mean increase of 56%, p-value=0.003), breast pain and mastitis (mean increase of 43.3%, p-value<0-001), mother's disease and breastfeeding (mean increase of 38.5%, p-value=0.05), problems with infants not gaining weight correctly (mean increase of 31.2%, p-value=0.04), hypogalactia and sensation of insufficient milk production (mean increase of 26.4%, p-value<0.001), increased milk demand (mean increase of 21%, p-value<0.001), and relactation (significant mean increase of relactation personalized plan by 15.3%, p-value<0.001). Whereas monthly queries per user that did not significantly change between the pre-pandemic and pandemic period were related to tandem breastfeeding (p-value=0.29), breastfeeding twins (pvalue=0.73) or breastfeeding older infants (p-value=0.98), breastmilk pumping (p-value=0.3,) and breastmilk donation (p-value=0.8), infant care (p-value=0.31) and infant sleep (p-value=0.5), menstruation and fertility (p-value=0.1), pregnancy (p-value=0.78), returning to work (p-value=0.7), mother's health (p-value=0.9), feelings (p-value=0.67) and weaning (p-value=0.62) (Table 1). Queries about COVID-19 have been highly visited during the pandemic (mean 11,304 queries per month from March 2020 to March 2021) and were in the top 20 most consulted queries in 2020,

and the sixth most consulted in the first quarter of 2021. The most answered question about COVID-19 was about the compatibility of the vaccine with breastfeeding.

One of LactApp 's core functionalities is its automated breastfeeding symptom checker. However, it is also possible to consult breastfeeding questions through an in-app live chat function, answered by breastfeeding experts within the LactApp team. Live chat consultations increased by 28.5% during the outbreak of COVID-19. Furthermore, thanks to Lactapp's expert's effort to classify those queries into the different topics covered, (which is required for training IA) we can assess the impact of such an increase in each of the different topics. Therefore, we can see how LactApp's live chat received significantly more consultations about mastitis and breast pain (mean increase of 105.7%, p-value=0.01) and how to latch onto the breast correctly (mean increase of 88.4, p-value=0.04) (Table 2). Other topics such as breastfeeding basics, infant not gaining weight correctly, introducing solid foods and growth spurts increased by more than 50% during the pandemic, however, this increase was not statistically conclusive due to high dispersion of the weekly consultations in the live chat.

	Pre-pandemic (n= 68242 unique		Pandemic (n= 88822 unique		p-value
	users)		users)		
	Median	IQR	Median	IQR	
Breastfeeding complications					
Breast lumps	2.9	0.7	3.09	0.5	0.02
Breast pain and mastitis	3.48	0.4	4.16	0.4	<0.001
Hypogalactia	2.69	0.4	2.90	0.4	<0.001
Sore nipples	3.19	0.99	3.93	0.60	0.001
Breastfeeding technique					
Breast refusal	2.01	0.3	2.37	0.2	0.001
Breastfeeding infants over 6 months	3.11	0.7	3.05	0.5	0.98
Breastfeeding myths	7.58	1.4	6.77	1.1	0.01
Breastfeeding products	5.54	1.1	5.05	1.0	0.02
Breastfeeding stages	2.77	0.2	3.04	2.1	0.01
Breastfeeding technique	8.39	4.1	13.15	1.7	0.003
Breastfeeding twins	2.73	1.5	2.67	1.5	0.73

Increased milk demand	1.96	0.3	2.38	0.2	<0.001
Induced lactation	2.93	2.6	2.42	1.7	0.22
Mixed feeding	6.22	1.2	6.43	1.2	0.41
Relactation	1.90	0.4	2.13	0.6	0.29
Relactation Personalized Plan	1.80	0.3	2.01	0.3	<0.001
Shape and sizes of my breast	3.93	1.0	3.97	0.8	0.7
Tandem breastfeeding	5.17	2.5	5.27	2.3	0.29
The first days of breastfeeding	2.92	0.5	3.34	0.4	<0.001
Weaning	3.22	0.7	3.23	0.5	0.62
Infant care and breastfeeding					
Growth spurts	2.38	0.2	2.58	2.1	<0.001
Infant care	5.20	0.7	5.27	0.5	0.31
Infant does not gain weight	2.59	0.5	2.6	0.4	0.04
Infant poops	4.24	0.5	4.08	0.7	0.2
Infant sleep and breastfeeding	7.59	1	7.42	0.8	0.5
Infant's health	3.1	0.9	2.76	0.5	0.03
Introduction to solid foods	9.32	2.4	8.45	1.4	0.01
Preterm infants	2.51	1.5	2.70	1.0	0.06
Milk pumping					
Handling and storage of breastmilk	9.76	1.3	9.12	1.23	0.01
Health situation and breastfeeding	2.48	1.1	2.33	0.8	0.2
How to express milk	3.49	0.5	3.36	0.4	0.3
Milk donation	5.42	3.5	5.52	3.1	0.81
Women and breastfeeding					
Menstruation and fertility	3.38	0.9	3.62	0.7	0.1
Mother's disease and breastfeeding	2.37	0.88	2.08	1	0.05
Mother's diseases	2.07	0.3	1.94	0.4	0.02
Mother's feelings	3.78	1.0	3.60	0.8	0.67
Pregnancy	4.19	1.2	4.03	0.9	0.78
Returning to work	4.35	0.8	4.31	0.8	0.7
Total queries	18.23	3.9	20.57	4.0	0.02

Table 2. Monthly breastfeeding queries per user aggregated by topics before and after COVID-19 pandemic. Results are expressed in median along with interquartile range (IQR).

Discussion

The COVID-19 pandemic has unquestionably changed our daily life in every aspect. The general restriction measures affected women's well-being during pregnancy, birth and postnatal care period⁵. In-person support from a lactation specialist were restricted and mothers experienced increased levels of stress and isolation.¹²

Recent studies have reported that exclusive breastfeeding rates might have decreased during COVID-19 pandemic and lockdown in UK, Italy, US and Canada^{7-9,13,14,18,19}. The reasons for breastfeeding cessation were shorter hospitals stays at birth, deficient professional support the first days of life, worries about the safety of breastfeeding and symptomatology of COVID-19. Due to the lack of in-person professional support from pediatricians, midwives, lactation experts and support lactation groups, mothers sought breastfeeding support in technological tools such as telehealth services (either phone-only or videoconferencing), chats and texting support via WhatsApp or HouseParty App, online support groups, and web pages^{8,20,21} and breastfeeding apps²² such as LactApp.

Our main results are in concordance with an online survey of the Australian Breastfeeding
Association reporting that mothers' main concerns during the pandemic were related to insufficient milk or weight gain, painful breasts, relactation and reducing supplemental infant formula milk. And these concerns were aggravated by the lack of health care access due to fear and unavailability¹².

Our results are also in agreement with Brown and Shenker 2021¹⁴ which reported that the most common reasons for women to stop breastfeeding during the pandemic were insufficient professional support and technical issues such as difficulties with latch, perception of insufficient milk, breast pain and exhaustion¹⁴. All these factors were highly consulted in LactApp and significantly more visited during the pandemic compared to the pre-pandemic period. Thus, LactApp could have been a potent tool to breastfeeding support when women had no support from health services. Moreover, since LactApp has been able to detect an increased need for support in this critical topic without asking breastfeeding mothers directly, LactApp might also be a powerful tool to identify trends, difficulties and critical issues of breastfeeding in an automatized way.

Our results reveal a clear change in breastfeeding consultations due to the COVID-19 pandemic. Our lactation experts that are daily in contact with breastfeeding mothers through the live chat function also detected a significant change in breastfeeding consultations. This data is not shown in the present work however this knowledge has help to interpret the main results of this article. Monthly queries per user about breastfeeding technique significantly increase in the pandemic period compared to pre-pandemic by 56%. The most consulted gueries about this topic during the COVID-19 pandemic were about latching, breastfeeding on demand, breastfeeding positions and milk production. Accordingly, another issue that significantly increased during the pandemic were queries related to infants not gaining weight correctly, monthly queries per user about those queries increased by 31%. Based on the information we obtained from breastfeeding women on the live chat, we believe that this fact could be attributed to the lack of breastfeeding support during the pandemic since mothers did not have professional guidance in latching correctly, optimal milk transfer and breastfeeding on demand which could have led to a deficient breastfeeding technique and poor milk transfer to the child. As a result, monthly queries about user perception of insufficient milk supply also significantly increased by 26%. These results are also in concordance with Brown et al. 2020 study which reported that women either expressed milk or gave formula as a supplement during the pandemic due to the lack of support which led to pain or poor latch¹⁴. We also believe that queries related to hypogalactia increased due to the perception of women not having enough milk supply, since they did not receive adequate in-person support to correct latching issues, positioning or even evaluate potential oral complications of the infant such as ankyloglossia. However, further studies are needed to confirm this hypothesis.

Another feature that increased highly in consultations is the personalized relactation plan in the app. Relactation is the process by which a mother reestablishes breastfeeding after reducing milk production or having interrupted it for some time. Based on what breastfeeding women reported to us, mothers needed to search for information about relactation since breastfeeding was not successfully established in the crucial first days because most families were sent home shortly after birth without any further information or guidance. Another reason to search for information about relactation could be that infected mothers with COVID-19 were separated from their children either at birth or in older infants. And front-line midwives, nurses and physicians might have also been

discouraging mothers to breastfeed during the first COVID-19 outbreak leading to an interruption of breastfeeding.

Monthly consultations per user about mastitis and breast pain also significantly increased by 43% in the self-administered questionnaire and by 105.7% in the live chat. As reported by breastfeeding women in the live chat this could be due to the fact, that most of face-to-face appointments were cancelled, many health care staff were unavailable because of the pandemic and women were afraid to go to a medical centre. This resulted in women seeking information about mastitis symptomatology, handling, and its treatment on LactApp. Accordingly, queries about nipple damage care and breast lumps were also significantly increased during the pandemic by 36% and 37%, respectively. These types of consultations are often dealt with in healthcare centers since they cause acute pain and other possible symptoms such as fever. However, as medical centers were unavailable, these consultations might have been transferred to LactApp.

The main limitations of the present study are that LactApp is available worldwide however, most of the users are from Spain (80%) followed by Mexico (4.3%), Argentina (2.3%), Chile (2.1%), United States (2.1%), Colombia (1.4%), Germany (0.7%), Peru (0.7%), United Kingdom (0.7%), and Uruguay (0.5%). Thus, the results of the present study might be biased by the Spanish COVID-19 restriction measures and lockdown as well as Spanish culture, social habits and healthcare system. Moreover, user profile data and their children's data entry are optional and are not verified, thus the models may include some uncontrolled bias. Another limitation that we detected is that final answers are given according to user's and their registered child's data, for example, mother's status (pregnant or not pregnant). If the user does not update her status in her user profile, personalized answers given by the decision tree algorithm might not have been corrected. Since we only registered the final answer but not the whole path, some of the results might also have bias.

In conclusion, COVID-19 restrictions impacted negatively on breastfeeding support and mother's breastfeeding experiences. Critical issues in breastfeeding establishment such as inadequate latching, perception of insufficient milk supply, breast pain and poor infant weight gain worsened during the COVID-19 pandemic, due to lack of in-person professional guidance. These issues were highly consulted and significantly increased in the App during the pandemic. We believe that LactApp was a useful tool for breastfeeding support when women could not obtain appropriate

support elsewhere. And LactApp might be a powerful tool to identify critical issues of breastfeeding and trends in an automatized way. However, this must be studied in detail in future approaches.

Acknowledgments

Paola Quifer-Rada and Ignasi Gomez-Sebastià are grateful for the Torres y Quevedo aid program from the Ministerio de Ciencia e Innovación.

LactApp team thanks all the women who make LactApp a reality.

Author contribution

P.Q.R, D.M.T, L.A.C and A.P.A were responsible for concept and design, methodology and interpretation of data. P.Q.R and I.G.S extracted the data and performed the analysis. P.Q.R drafted the manuscript and created tables and figures. All authors revised and approved the final version of the manuscript.

All authors meet the criteria detailed in Author Instructions

Competing Interests statement:

The authors declared the following potential conflicts of interest with respect to the research, authorship and/or publication of this article: A.P.A created and designed the software. L.A.C serves as a consultant at LactApp. Nevertheless, none of these potential conflicts affected the study design, the collection, analysis and interpretation of data, or the writing of the manuscript produced by P.Q.R. D.M.T and I.G.S.

Funding statement:

This research received no external funding

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DISCUSIÓN Y CONCLUSIONES

Objetivo general

Conocer cómo una mHealth de lactancia (LactApp) da apoyo a sus usuarias

El objetivo general de esta tesis es conocer cómo una mHealth de lactancia (LactApp) da apoyo a sus usuarias. Para poderlo responder se ha realizado un estudio amplio tanto de las usuarias y de sus bebés como de las consultas que éstas realizaban en la aplicación móvil. Además, durante el periodo de estudio, la pandemia de Sars-CoV-2 impactó de forma directa en cómo estas usuarias usaban la aplicación, además de evidenciar un incremento de su uso entre las madres lactantes.

Las tres publicaciones aportan datos relevantes de las necesidades de información y apoyo que precisan las madres durante el periodo de lactancia. Además, tal necesidad de información va a variar según la etapa por la que atraviesa la madre, comprobándose que las consultas varían según la edad del bebé o el estado de la madre.

La lactancia materna está recogida dentro de los derechos de salud sexual y reproductiva de las mujeres (83). LactApp es una herramienta de información y acompañamiento a la lactancia, sin ser su objetivo primario el aumento de las ratios en lactancia. Por este motivo, puede ser usada por todas las mujeres que dan a luz o que hayan tenido un bebé, sea cual sea la forma escogida para alimentar a su bebé. Tanto si se desea amamantar a un bebé como si este no es el deseo de la madre, la gestión de la lactancia es algo que aparecerá durante los primeros días. Además, si se desea amamantar, durante los primeros días es bastante habitual que aparezcan dificultades, como el dolor o la falta de producción de leche, sea real o sea sentida. Cuando la lactancia ya está instaurada, otras situaciones fisiológicas como las crisis de crecimiento o el cambio de producción de leche pueden aparecer y la madre puede necesitar una fuente fiable de información. La vuelta al trabajo, la gestión de la lactancia durante la noche, el inicio de la alimentación complementaria, el destete, el comportamiento normal de bebé, son momentos que pueden acarrear de nuevo dudas. Y cuanto mayor es el bebé, más difícil es encontrar profesionales que tengan formación sobre estas situaciones.

Tener acceso a herramientas tecnológicas con contenido experto en lactancia puede dar información y acompañamiento a las madres que dan el pecho. A la vez, se ve la necesidad del apoyo continuado, en cualquier momento y a cualquier hora a la lactancia materna(59,61,70).

Actualmente el uso de teléfonos inteligentes (smart phones) vestá muy normalizado, sobre todo entre los jóvenes. Esto permite tener al alcance de la mano toda la información disponible en la web, lo que puede resultar ser un arma de doble filo: es difícil encontrar información rigurosa y bien referenciada mientras que, en el caso de la lactancia, abundan los mitos e información errónea. El conocimiento de la fisiología del cuerpo humano y, particularmente, el cuerpo femenino es muy escaso tanto en la población general como a nivel del cuerpo de conocimiento de los profesionales. Es conocido el *gap* que existe de investigaciones científicas sobre el cuerpo de la mujer. Además, en los currículums de las formaciones de grado sanitarias, la lactancia materna no se suele abordar de forma amplia, con lo que las profesionales no suelen tener un conocimiento extenso sobre ella.

LactApp ha demostrado ser una herramienta muy utilizada para las mujeres que amamantan y esto, junto con la validación que pueden dar organizaciones como ORCHA, indica que es muy útil para este momento vital aportar información útil y contrastada.

ORCHA es una organización para la revisión de aplicaciones de atención y salud del Reino Unido. De forma periódica, realiza una auditoría de las 2 aplicaciones de LactApp, la de madres en iOS y Android y la de profesionales, también en iOS y Android. En la última revisión de enero 2023, en la LactApp dirigida a madres, en sistema iOS obtuvo una media del 80,5%, en Android, del 80,75%, de la aplicación dirigida a profesionales, LactApp Medical, en iOS del 74,5% y en Android del 74,25% (ANEXO II).

Las madres utilizan la aplicación de forma distinta según la edad del bebé, con lo que se evidencia la capacidad de la mHealth de poder individualizar según el momento de este periodo.

La pandemia de SARS-CoV-2 colapsó el sistema sanitario, tanto público como privado, y con ello, la atención a la lactancia también se vio afectada(84-86).

En aquel momento, las usuarias de LactApp cambiaron su comportamiento dentro de la app. El crecimiento del número de usuarios fue más grande que en los años anteriores y las consultas más frecuentes también cambiaron de forma clara.

Objetivo específico 1:

Realizar un análisis descriptivo de una aplicación móvil sobre lactancia materna (LactApp) para estudiar el perfil de la usuaria, así como las consultas más frecuentes.

Discusión del objetivo 1

El objetivo de esta publicación era realizar un análisis descriptivo de una aplicación móvil sobre lactancia materna (LactApp) para estudiar el perfil de usuario, así como las consultas más frecuentes.

Cabe destacar que el gran número de usuarias de LactApp, así como el creciente número de consultas, sugiere que se trata de un medio de consulta muy relevante para el apoyo materno en relación con la lactancia materna.

Según el informe de mHealth Economics, las descargas de aplicaciones relacionadas con la salud han crecido exponencialmente desde 2013. Teniendo en cuenta las cifras aportadas por este informe, LactApp obtuvo más usuarias activas que el 83% de las apps, situándose entre el 20% de las apps más descargadas y con más usuarios activos del mundo(87).

Un dato destacable es que el 60,94% de las usuarias de la versión Medical de LactApp eran profesionales sanitarios. Es probable que estas usuarias utilizaran LactApp como fuente de información y apoyo en su práctica clínica de atención a la lactancia, ya que existe una falta de formación en este ámbito de tanto en España (88) como a nivel internacional(89).

Los usuarios de internet cada vez obtienen más información a través de los smart phones (90); por ello, el uso de apps en el ámbito de la lactancia materna está ganando terreno y se está convirtiendo en un pilar en la instauración y posterior mantenimiento de ésta(89). Este hecho global puede explicar la tendencia creciente de consultas en LactApp. La tendencia estática en cuanto al número medio de pantallas consultadas puede estar relacionada con las mejoras implementadas en LactApp a lo largo del tiempo estudiado. Destacan las mejoras en la interfaz, la mejora de la accesibilidad al chat en vivo y la reorganización de los contenidos.

En cuanto a las usuarias, una ventaja de LactApp es la posibilidad de disponer de información personalizada(91) relacionada con la lactancia materna las 24h al día, hecho que tanto las madres(92) como los profesionales sanitarios(93) señalan como una cuestión esencial en el mantenimiento de la

lactancia materna. Este hecho puede relacionarse con el número creciente de usuarias dentro de la app y con una recurrencia cada vez mayor.

Hay que tener en cuenta que la disminución del número de nuevas usuarias puede deberse a la rápida difusión de LactApp entre madres y profesionales sanitarios; desde el gran crecimiento inicial, no se vio, en esta investigación, otro pico de crecimiento igual.

En cuanto a este aspecto, la retención de usuarias es la generalidad y el uso que hacen de la aplicación es recurrente para resolver sus dudas sobre lactancia.

Los bebés lactantes registrados en LactApp tienen un perfil muy similar al de los informes estadísticos internacionales(94), lo que les da veracidad.

En cuanto a los bebés, es importante destacar que LactApp la actualiza automáticamente con el paso de los días para poder adaptar las respuestas que ofrece a las madres en función de la edad de su bebé. Por el contrario, sólo el 2,9% de las usuarias se registran como embarazadas y el 79,1% declaran no haber tenido hijos anteriormente.

Es posible que estos resultados se deban a que no se exige completar estos datos durante el proceso de registro de la app.

El 10% de las usuarias indicaron que no estuvieron satisfechas con la respuesta dada por la aplicación clicando el botón "no me gusta"; se debería considerar si sintieron la necesidad de obtener más información sobre su consulta y probar otras formas de acceder a la función de chat en vivo de la aplicación, por ejemplo.

Los temas más consultados en LactApp fueron los relacionados con las dificultades por las que las mujeres destetan.

De los contenidos más consultados destacan el "sueño del bebé", tema que diferentes autores señalan como clave en relación con el establecimiento y mantenimiento de la lactancia materna(95). También destaca la falta de formación que tienen los profesionales sanitarios en relación con el sueño seguro y su importancia, tanto en la prevención del Síndrome de la muerte súbita del lactante como en el mantenimiento de la lactancia materna(96–98). Otro tema a destacar es la "conservación(99) de la leche" por estar estrechamente relacionada con la duración de la baja maternal y la vuelta al trabajo de la madre, coincidiendo con diferentes autores que la finalización de la baja maternal y la

reinserción al trabajo remunerado plantea una dificultad importante y está relacionada con el cese de la lactancia(100). Una "crisis de lactancia" está profundamente relacionada con la sensación materna de falta de leche, que es una de las causas más destacadas para dejar de amamantar(101), y todavía existen lagunas sobre cómo ofrecer un apoyo eficaz en estas situaciones(102).

Por último, la falta de conocimientos, habilidades y actitudes de las madres respecto a la lactancia, es decir, la pérdida de la cultura de la lactancia, es otro punto crítico para dejar de amamantar(103). Así, la "evolución fisiológica de la lactancia" es otra sección de LactApp que las madres consultan a menudo. Una nueva hipótesis del estudio es que, además de brindar información, LactApp ayuda a las usuarias a mantener la lactancia en momentos en los que normalmente la interrumpirían en zonas rurales(104) y urbanas, aunque esta hipótesis se deberá confirmar en futuros estudios.

Limitaciones

Esta publicación trata de un estudio ecológico basado en datos agregados, por lo que se corre el riesgo de incurrir en falacias ecológicas en la interpretación de los datos al no considerar posibles variables que puedan influir en los resultados.

Además, los datos se recopilaron en Google Analytics, por lo que deben tenerse en cuenta algunas limitaciones, tales como el muestreo de datos cuando el volumen de tráfico de datos es de más de 500sesiones.

La actualización automática de la edad de los bebés, podría afectar a los resultados, aumentando la mediana porque las madres pueden seguir utilizando la app.

Para registrarse en LactApp no es necesario completar todos los datos sociodemográficos.

Por último, se debe ser consciente de que el lanzamiento de LactApp produjo unas estadísticas iniciales muy elevadas, lo que puede dar lugar a un cambio en las estimaciones estadísticas presentadas en los próximos años.

Conclusiones

LactApp es una aplicación móvil con potentes recursos para la lactancia materna y actualmente está ampliamente descargada y en uso por un importante número de usuarias.

Esas usuarias consultan periódicamente la aplicación, siendo los temas más consultados los relacionados con el sueño del bebé, la extracción y conservación de la leche, las crisis de lactancia y la evolución fisiológica de la lactancia.

A pesar de ciertas limitaciones, LactApp puede ser una herramienta para que los profesionales de la salud para conocer dónde las mujeres necesitan más apoyo. Además, puede ser interesante para investigadores y desarrolladores debido a la inteligencia artificial y la usabilidad, y para las organizaciones que promocionan la lactancia materna y están involucradas con iniciativas como la IHAN.

Objetivo específico 2:

Analizar las consultas realizadas por las usuarias en función de la edad del bebé en LactApp

Discusión

Las herramientas tecnológicas y las aplicaciones de salud móvil pueden ser herramientas prometedoras para apoyar la lactancia materna y aumentar sus tasas(105,106).

Sin embargo, ninguno de estos estudios ha examinado cómo buscan apoyo las madres lactantes cuando utilizan una herramienta mHealth. El presente artículo pretendía analizar qué contenidos y respuestas buscan las mujeres durante la lactancia, según la edad del bebé.

La actividad sostenida de las usuarias de LactApp, como demuestra el número de usuarias activas y de visitas, evidencia que esta herramienta tecnológica da apoyo a la lactancia materna, y no sólo por su contenido, sino también por sus funciones como tests, trackers, chat en directo con expertas en lactancia y planes personalizados.

La información personalizada y una mayor interacción son características que las mujeres demandan(107). Esta información personalizada es destacada como esencial para el mantenimiento de la lactancia materna por las madres y los profesionales de la salud(93). Precisamente, uno de los artículos presentados en este trabajo de tesis(108), revela que las consultas a LactApp aumentaron entre julio de 2016 y junio de 2019, y la tendencia de las consultas ha crecido según el modelo de autoregresiones de Prais-Winsten basadas en el modelo de Durbin-Watson.

La menor duración de la lactancia materna tiene causas multifactoriales, incluída la percepción por parte de la madre de una producción insuficiente de leche, dolor en el pezón o en el pecho, falta de apoyo social, falta de confianza, vergüenza física y vergüenza social, comodidad y confianza de la leche artificial(108), que se asocian a la dificultad del agarre y la posición y la presencia de anquiloglosia del lactante, entre otros factores(109).

Además, existen momentos críticos que favorecen el abandono de la lactancia materna como la sensación de falta de leche en periodos de alto crecimiento del lactante(110) o la vuelta al trabajo y bajas maternales cortas(49).

Para mantener la lactancia materna tras la vuelta al trabajo, las madres necesitan extraer y almacenar (111). Este factor causa mucha preocupación a las madres (112), como reflejan las numerosas consultas

que recibe LactApp sobre cómo extraerse leche de forma correcta y más eficaz, y cómo almacenarla adecuadamente.

Los temas más consultados en 2019 fueron los relacionados con temas críticos en las que las madres necesitan más apoyo, como la técnica de lactancia, los mitos de la lactancia materna, el sueño infantil, los cuidados del bebé y el comportamiento del lactante, las crisis de crecimiento, las etapas de la lactancia materna, la lactancia mixta, la alimentación complementaria, la extracción de leche y su almacenamiento y la vuelta al trabajo.

Hay todavía brechas de conocimiento sobre cómo proporcionar un apoyo eficaz en estas situaciones(113). De esta manera, las respuestas personalizadas de LactApp podrían proporcionar a las madres lactantes apoyo en estas situaciones que abocan a un abandono alto.

Los resultados del estudio publicado sugieren que el apoyo de LactApp parece evolucionar con las necesidades de las madres en función de la etapa de desarrollo del bebé. Los temas que buscan las madres difieren al inicio de la lactancia de cuando el bebé tiene un año. Al inicio de la lactancia las usuarias consultan temas relacionadas con los primeros días de lactancia, que incluyen las respuestas a las preocupaciones más frecuentes, como "¿debo despertar a mi bebé?", "mi bebé no hace deposiciones", "¿con qué frecuencia se amamanta a los bebés?", "percepción de la falta de producción de leche en los primeros días", "señales de alarma", "mi bebé no hace caca", "mi bebé no se agarra o le cuesta agarrarse al pecho". Al principio de la lactancia, las usuarias también hacen preguntas sobre el dolor al pecho en relación con las grietas del pezón, la mastitis y otras situaciones habituales. Esto coincide con las razones más comunes para el abandono precoz de la lactancia materna según la bibliografía(114).

Cuando los bebés tienen entre 15 días y 3 meses, las usuarias presentan consultas más diversas. En esta etapa de la lactancia materna, las madres buscan apoyo en diversos temas que pueden agruparse a su vez en crisis de lactancia, vuelta al trabajo y complicaciones de la lactancia materna. Las respuestas a las preguntas de las madres relacionadas con las crisis de lactancia incluyen las "crisis de crecimiento", "aumento de la demanda de leche", "siento el pecho vacío y blando", "mi bebé se frustra al mamar", "mi bebé no aumenta de peso" o los tests "¿Sabes si tu bebé tiene el frenillo de la lengua corto?", "¿Mi bebé mama bien?" y "Superando el primer mes con éxito".

En España, debido a las bajas maternales cortas, a esta edad las madres comienzan a prepararse para volver al trabajo(48,114–116), y buscan más respuestas sobre la lactancia mixta, cómo extraerse leche de forma eficiente y cómo manipular y almacenar la leche.

Cuando los bebés tienen entre 3 y 6 meses y entre 6 meses y 1 año, las usuarias buscan respuestas similares relacionadas sobre todo con la alimentación complementaria y el destete.

En los temas consultados cuando el bebé tiene más de 6 meses se incluyen respuestas como "mi bebé ha dejado de comer sólidos", "mi bebé me muerde el pecho", "mi bebé se mama mucho por la noche", "creo que mi bebé depende demasiado de mi pecho", "el bebé pide el pecho de forma agresiva", "me siento incómoda dando el pecho en público" o "me estoy cansando de dar el pecho". Por último, cuando los bebés tienen 1 año, las madres buscan apoyo para el destete, la gestión del destete(117) y la lactancia materna en tándem(118).

El 13% de los usuarios de LactApp eran hombres, lo que demuestra la importancia del papel del padre en la lactancia(119), la influencia del padre en la duración de la lactancia(120) y la creciente implicación de los padres en la lactancia(119).

Otro hallazgo interesante relacionado con los datos sociodemográficos es el porcentaje de usuarias activas según la edad. LactApp tiene una proyección internacional y la edad materna puede ser muy variada en todo el mundo. En Sudamérica las mujeres son madre más jóvenes(121) y en España la edad de maternidad está aumentando(122).

Con todos estos hallazgos, LactApp puede influir en el mantenimiento de la lactancia materna, al igual que las redes sociales(123) y otras aplicaciones(124), aunque esto se debe comprobar en futuras investigaciones.

Otras líneas de investigación futuras van en torno a si existen diferencias entre lo que consultan las usuarias en función de su cultura, sus datos sociodemográficos o si sus bebés nacieron prematuros o con bajo peso. A través de estas líneas de investigación se puede conocer qué tipo de apoyo esperan y necesitan las madres durante la lactancia.

Con los resultados obtenidos, creemos que para las usuarias, LactApp puede ser una herramienta para tomar decisiones informadas sobre la lactancia materna. Por el contrario, dado el desconocimiento de los profesionales sanitarios sobre la lactancia(124) y el tiempo insuficiente que tienen en las consultas(125), los profesionales pueden ser prescriptores de LactApp al igual que otras herramientas (126.127).

Limitaciones

La principal limitación de la investigación es que la configuración del perfil de las usuarias y de su bebé es opcional y no está verificada, por lo que los modelos pueden incluir algún sesgo no controlado. Además, los datos de Google Analytics y Firebase, empleados para describir las usuarias, también pueden incluir algún sesgo no controlado, ya que éstas pueden usar el smartphone de otra persona. Otra limitación a tener en cuenta es que algunas usuarias podrían navegar por la aplicación sin una consulta específica, mientras que otras podrían consultar por una tercera persona actuando de intermediario entre LactApp y la persona consultante. También hemos detectado usuarias que no realizan consultas preestablecidas y acuden directamente al chat en vivo. Estas consideraciones pueden influir en el número de visitas recibidas.

Conclusiones

Se puede concluir que las consultas más frecuentes en LactApp realizadas por las madres lactantes son las relacionadas con los momentos críticos del abandono de la lactancia. LactApp es una herramienta que proporciona a las mujeres lactantes respuestas personalizadas. El uso de los contenidos de LactApp cambia en función de la etapa de lactancia y de la edad del bebé de las usuarias, con lo que se puede considerar una herramienta eficaz para el acompañamiento en todo el periodo de lactancia ya que cambian las necesidades y las dudas y así lo expresan las usuarias, cambiando sus consultas.

LactApp puede ser una herramienta potente de mHealth prescrita por profesionales sanitarios.

Objetivo específico 3:

Evaluar el impacto de la pandemia de SARS-CoV-2 en las consultas de lactancia materna en LactApp.

Discusión

La pandemia de Sars-CoV-2 cambió incuestionablemente la vida cotidiana en todos los aspectos. La restricción general afectó al bienestar de las mujeres durante el embarazo, el parto y el periodo de cuidados en el posparto(85). El apoyo presencial de una experta en lactancia se restringió y, en consecuencia, las madres experimentaron mayores niveles de estrés y aislamiento(74).

Las investigaciones han demostrado que las tasas de lactancia materna exclusiva podrían haber disminuido durante la pandemia y en el confinamiento por Sars-CoV-2 en el Reino Unido, Italia, Estados Unidos y Canadá (81,84,86,128–130).

Las razones para el cese de la lactancia materna fueron estancias hospitalarias más cortas al nacer, apoyo profesional subóptimo durante los primeros días de vida, preocupaciones sobre la seguridad de la lactancia materna y la sintomatología de COVID-19.

Debido a la falta de apoyo profesional presencial por parte de pediatras, matronas, expertas en lactancia y grupos de apoyo a la lactancia, las madres buscaron otras formas de apoyo para amamantar a sus bebés como las herramientas tecnológicas, servicios de telesalud (vía telefónica o vía videoconferencia), chats y mensajes de texto de apoyo a través de WhatsApp o HouseParty App, grupos de apoyo en línea, páginas web y aplicaciones de lactancia como LactApp(131–134).

El modelo de series temporales interrumpidas mostró que las usuarias activas de LactApp aumentaron en gran medida durante el brote de SARS-CoV-2 y el confinamiento y las consultas mensuales realizadas en LactApp también aumentaron significativamente tras el brote pandémico. Los principales resultados de la investigación llevada a cabo en el artículo "Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support" concuerdan con una encuesta de la Asociación Australiana de Lactancia Materna que informaba de que las principales preocupaciones de las madres durante la pandemia estaban relacionadas con la insuficiencia de leche o el aumento de peso del bebé, el dolor en los pechos, la relactación y la reducción de la leche artificial suplementada. Estas preocupaciones se vieron agravadas por la falta de acceso a la atención sanitaria debido al miedo y a la falta de disponibilidad de los servicios sanitarios y expertas(74).

La pandemia de SARS-CoV-2 afectó negativamente al apoyo a la lactancia y a la experiencia de lactancia que tuvieron las madres. Las dificultades en la instauración de la lactancia materna, como el agarre incorrecto, la percepción de producción insuficiente de leche, el dolor en el pecho y el escaso aumento ponderal del bebé, se incrementaron durante la pandemia de SARS-CoV-2 debido a la falta de atención profesional presencial.

Precisamente estos son los temas que en la aplicación fueron muy consultados y tuvieron un incremento significativo de consultas durante la pandemia. Por este motivo, LactApp fue una herramienta útil de apoyo a la lactancia. Además, como ya se ha comentado anteriormente, LactApp puede ser una herramienta interesante para identificar los problemas principales que se encuentran durante la lactancia así como las tendencias de las consultas.

Los resultados de la investigación llevado a cabo en LactApp también coinciden con los de Brown et al (2021), que informaron de que las razones más comunes por las que las mujeres dejaban de dar el pecho durante la pandemia eran por un apoyo profesional deficiente y cuestiones técnicas como las dificultades en el agarre, la percepción de producción de leche insuficiente, el dolor en los pechos y el agotamiento(81). Precisamente, todos estos temas fueron muy consultados en LactApp y significativamente más visitados durante la pandemia en comparación con el periodo prepandémico. De esta manera, LactApp puede haber sido una potente herramienta de apoyo a la lactancia materna cuando las mujeres no contaban con el recurso de los servicios sanitarios. Además, dado que LactApp fue capaz de detectar una mayor necesidad de apoyo en el ámbito de la lactancia sin hacer una encuesta directa a las madres, se podría considerar que LactApp puede también ser una herramienta para identificar tendencias, dificultades y temas críticos de la lactancia materna de forma automatizada.

Los resultados revelan un cambio claro en las consultas sobre lactancia materna debido a la pandemia de SARS-CoV-2. Las expertas en lactancia de LactApp que estuvieron diariamente en contacto con las madres lactantes a través de la función del chat en directo, también detectaron un cambio significativo en las consultas sobre lactancia materna. Las consultas estaban cargadas de gran angustia por lo que estaban sufriendo las madres que amamantaban a sus bebés. Sobre todo, al inicio del confinamiento en España, la mayoría de las consultas fueron realizadas por sanitarias, que expresaban mucha ansiedad. Además se les había hecho recomendaciones en base a la lactancia.

"Hola, buenas tardes, soy xxx. Parece ser que me he contagiado con el covid 19, soy enfermera y he mantenido contacto estrecho con pacientes infectados. Estoy siguiendo con la lactancia de mi bebé de casi 7 meses extremando las medidas de higiene. Mi duda es, cabría la posibilidad de que se me "cortase" la leche? Me han recomendado comprar fórmula por si pasaba y la verdad es que no se me había ocurrido. Muchas gracias de antemano. Un saludo".

"Buenas tardes, soy sanitaria, estoy aislamiento domiciliario, ahora sin síntomas, me ha de hacer PCR por covid-19. Tengo entendido que con mascarilla, guantes y lavado de manos se puede mantener lactancia materna. En un primer momento me dijeron esto, hoy me lo han prohibido, y con el extractor no me extraigo lo que ella necesita. ¿He estado haciendo mal? Creo que como no saben mucho al respecto por eso son tan estrictos."

"Hola... soy madre lactante con una niña de 15 meses. Soy enfermera de cuidados intensivos y me encuentro trabajando con paciente covid. Actualmente estoy asintomática y he tomado todas las medidas necesarias pero... ¿Debo dejar de darle el pecho? Tenemos esa duda en nuestro servicio ya que no encontramos literatura al respecto. pero tengo miedo a que sea portadora y se la transmita por vía parenteral"

"Hola buenos días era para comentaros mi caso, trabajo en urgencias como enfermera en el hospital xxxx y tengo un bebé de 12 meses con lactancia, mi marido también trabaja en el hospital y hay días que hemos de dejar a la peque en casa de mi madre, el día que de positivo en covid 19 no sé qué hacer si dejar lactancia e irme de casa etc o seguir con la lactancia? Yo creo que es mejor la lactancia pero hay riesgo de contagiar al bebé porque no puedo aislarme en casa, pero hay gente

que dice que al tener 12 meses que le quite la lactancia, que me recomendáis"

"Hola buenas tardes. Soy TCAE en el hospital xxxx. Mi planta habitualmente de cirugía de otorrino, urología y maxilofacial, ahora es una planta habilitada para el covid. Están trabajando sin epis, con mascarillas hechas por ellas mismas en sus casas, un desastre vamos. Estoy de baja por maternidad, que termina en junio. Doy lactancia materna exclusiva, y me horroriza volver al trabajo. o sé si son las hormonas, o qué me pasa, pero tengo ataques de ansiedad... me da miedo contagiarme (soy asmática e hipertensa), o contagiar a mi familia. Tengo una hija de 13 años, otra de 11 y el bebé. Qué puedo hacer?"

"Hola!! Quisiera hacer una consulta, he retirado la lactancia a mi bebé, yaq ues oy enfermera y tengo que incorporarme a trabajar esta semana en planta covid, no podré extraerse en mínimo 12 horas, así que decidí retirarla, lo he hecho durante esta semana de forma gradual, notaba que se me endurecían los pechos y me molestaban los primeros 3 días, me saqué en esas ocasiones y eston poniéndome hielo. Ahora no noto endurecimiento, pero sí que noto molestias en el pecho, es normalque me sigua pasando unos días? Debo seguir extrayendo? ya solo saco unos 10 ml si lo intento. Sigo con el hielo cada 2-3 horas. Muchas gracias!"

Estos datos no se muestran en el presente trabajo, sin embargo, este conocimiento ha ayudado a interpretar los principales resultados de la publicación. Estas consultas serán estudiadas en futuras líneas de investigación cualitativa.

Las consultas mensuales por usuaria sobre la "técnica de lactancia" aumentaron significativamente en un 56% durante el periodo pandémico. Las consultas más realizadas sobre este tema durante la

pandemia de SARS-CoV-2 fueron sobre el agarre, la lactancia a demanda, las posiciones de lactancia y la producción de leche. En consecuencia, otro tema que aumentó significativamente durante la pandemia fueron las consultas relacionadas con bebés que no ganaban peso correctamente, y las consultas mensuales por usuaria sobre estos temas aumentaron un 31%.

Basándonos en la información que se obtuvo de las mujeres lactantes en el chat en directo, creemos que este hecho se podría atribuir a la falta de apoyo a la lactancia materna durante la pandemia, ya que las madres no disponían de orientación profesional sobre un agarre adecuado, una transferencia óptima de leche y la lactancia a demanda, lo que podría haber dado lugar a una técnica de lactancia deficiente y a una mala transferencia de leche al bebé. En consecuencia, las consultas mensuales sobre la percepción de las usuarias de un suministro insuficiente de leche también aumentaron significativamente en un 26%. Estos resultados también concuerdan con el estudio de Brown et al (2021), que informaron que las mujeres se extraían leche o daban leche artificial como suplemento durante la pandemia debido a la falta de apoyo, lo que podía desencadenar en dolor a la madre o un mal agarre(81), posicionamiento o incluso para evaluar posibles complicaciones orales del lactante, como la anquiloglosia. Sin embargo, se necesitan más estudios para confirmar esta hipótesis.

Otra funcionalidad de LactApp que tuvo un incremento en el uso fue el plan personalizado en la app. El plan de relactación fue el que más aumentó. La relactación es el proceso por el que una madre aumenta la producción de leche cuando la producción era insuficiente o se había interrumpido durante un tiempo. De acuerdo con lo que las usuarias contaban en el chat en directo, las madres necesitaban información sobre este tema porque la lactancia no se establecía con éxito en los primeros días de vida del bebé.

Otra razón para buscar información sobre relactación podría ser que las madres infectadas por SARS-CoV-2 fueron separadas de sus bebés al nacer o cuando éstos eran más mayores. Además, las matronas, enfermeras y médicas de primera línea también podrían haber estado disuadiendo a las madres de amamantar durante el primer brote de SARS-CoV-2, lo que llevó a una interrupción de la lactancia materna.

Las consultas mensuales por usuaria sobre mastitis y dolor mamario también aumentaron significativamente en un 43% en las preguntas automatizadas y en un 105,5% en el chat en vivo. Según informaron las mujeres lactantes, en el chat en vivo esto podría deberse al hecho de que la mayoría de las citas presenciales se cancelaron, el personal sanitario no estaba disponible debido a

las nuevas cargas de trabajo derivadas de la pandemia y el miedo que sentían las mujeres de acudir a los centros de salud.

Esta situación llevó a las mujeres a buscar información sobre la sintomatología, el manejo y el tratamiento de la mastitis en LactApp.

En consecuencia, las consultas sobre el cuidado de las grietas en los pezones y los bultos en el pecho también aumentaron significativamente durante la pandemia, en un 36% y en un 37% respectivamente. Este tipo de consultas suelen atenderse en los centros de salud, ya que provocan dolor agudo junto con otros posibles síntomas como fiebre. Sin embargo, como los centros médicos no estaban disponibles, estas consultas podrían haber sido transferidas a LactApp.

Limitaciones

Las principales limitaciones de la investigación son que LactApp estaba disponible en todo el mundo, sin embargo, la mayoría de las usuarias procedían de España (80%), seguidas de las de México (4,3%), Argentina (2,3%), Chile (2,1%), Estados Unidos (2,1%), Colombia (1,4%), Alemania (0,7%), Perú (0,7%), Reino Unido (0,7%) y Uruguay (0,5%). Por lo tanto, los resultados de la investigación podrían estar sesgados por las medidas de restricción y confinamiento SARS-CoV-2 españolas, así como por la cultura, los hábitos sociales y el sistema sanitario español.

Además, los datos de perfil de usuaria y la entrada de datos de los bebés son opcionales y no se verifican, por lo que los modelos pueden incluir algún sesgo no controlado.

Otra limitación que se detectó es que las respuestas finales se dan en función de los datos de la usuaria y de sus bebés registrados, por ejemplo, el estado de la madre (embarazada o no embarazada). Si la usuaria no actualiza su estado en su perfil de usuaria, las respuestas personalizadas dadas por el algoritmo del árbol de decisión podrían no haberse corregido.

Dado que se ha analizado la respuesta final y no el camino completo para llegar a ella, algunos resultados también podrían estar sesgados

Conclusiones

En conclusión, las restricciones por la pandemia de SARS-CoV-2 tuvieron un impacto negativo en el apoyo a la lactancia materna y las experiencias de lactancia de las madres. Los problemas críticos en el establecimiento de la lactancia materna, como el agarre inadecuado, la percepción de una producción insuficiente de leche, el dolor en el pecho y el escaso aumento ponderal del lactante,

empeoraron durante la pandemia de SARS-CoV-2 debido a la falta de orientación profesional presencial.

Precisamente, las consultas de estos temas aumentaron significativamente en la aplicación durante la pandemia. Los resultados de la investigación, apoyan que LactApp fue una herramienta útil de apoyo a la lactancia cuando las mujeres no pudieron encontrar apoyo adecuado en otros lugares. LactApp podría ser una potente herramienta para identificar de forma automática aspectos críticos de la lactancia materna así como sus tendencias. Sin embargo, este punto debe ser estudiado en detalle en futuras investigaciones.

CONCLUSIONES GENERALES

LactApp es una aplicación con una capacidad alta de diseminación entre la población a la que está destinada, ya que en ningún momento se realizó campañas de márquetin o publicidad, sino que el crecimiento del número de usuarias es 100% orgánico. Además, los resultados de la investigación demuestran que el crecimiento en el número de usuarias es continuo, de forma que cada vez es una aplicación móvil más usada. Los temas más consultados son "Técnica de lactancia" y "Sueño del bebé", con lo que se confirma la necesidad que tienen las madres y las familias de información sobre los procesos fisiológicos en torno a la lactancia y al bebé. La gran mayoría de las usuarias son madres, aunque hay un porcentaje nada desdeñable de profesionales sanitarios que usan la aplicación.

Las usuarias de LactApp usan la aplicación en los momentos más críticos de la lactancia, obteniendo respuestas personalizadas en función de la edad de su bebé. A pesar que las consultas más frecuentes están relacionadas con temas vinculadas a técnica de lactancia y sueño del bebé, se observan diferencias según la edad de los bebés. De esta forma las mujeres pueden tomar decisiones en torno a su lactancia de manera informada y acompañada.

En situaciones de emergencia, como fue la pandemia de SARS-CoV-2, LactApp ha demostrado ser una herramienta útil para la atención a la lactancia, adaptándose fácilmente a la situación desbordante de muchas usuarias que no tenían la posibilidad de ser atendidas por un sistema sanitario colapsado.

Por todos los puntos anteriores, LactApp podría ser una herramienta tecnológica potente y eficaz para la toma de decisiones en la lactancia materna y la atención y apoyo en esta etapa de la vida, tanto para madres y familias como para las profesionales que las atienden.

FUTURAS LÍNEAS DE INVESTIGACIÓN

Dado que LactApp ha demostrado tener una gran utilidad en apoyo y acompañamiento en la lactancia, se ve necesaria su validación a través de un estudio clínico experimental, para determinar si el uso de Lactapp mejora los porcentajes de lactancia materna a los 15 días después del parto, a las 6 semanas, a los 3 meses y a los 6 meses de edad del recién nacido.

En este momento, se está llevando a cabo una investigación multicéntrica en los Departamentos de Salud La Ribera, Xàtiva-Ontinyent y Castelló, en la Comunidad Valenciana, y en el Hospital Universitario de Cáceres, con la aprobación de los comités éticos correspondientes.

Se trata de un estudio experimental, multicéntrico, y prospectivo con grupo experimental y grupo control, que comparará la duración de la LME. Será realizado en el Departamento de Salud de la Ribera, Xàtiva-Ontinyent y Castelló durante los años 2021 y 2022. Las mujeres serán asignadas de forma aleatoria a cada una de las ramas de estudio. En el grupo control, se seguirá la práctica clínica habitual desde el tercer trimestre de gestación para el fomento de la LME. En el grupo de intervención, la mujer, además de la práctica clínica habitual utilizará LactApp desde el tercer trimestre hasta los 6 meses postparto. Se realizará el seguimiento del tipo de lactancia al parto, 15 días, 6 semanas, 3 meses y 6 meses postparto, y se recogerán las causas de abandono de la LME en ambos grupos. También se recogerán datos sociodemográficos, así como resultados reportados por la mujer durante el proceso de embarazo, parto y postparto. La propia aplicación reportará datos sobre usabilidad, temas consultados y tiempos de uso. La hipótesis nula que se plantea es que la aplicación móvil LactApp no mejora el mantenimiento de la lactancia materna a los 6 meses postparto en comparación con la práctica clínica habitual.

Actualmente se están realizando los análisis pertinentes para poder comprobar el impacto de la aplicación en la lactancia de las participantes.

Esta investigación lleva por título "Ensayo Clínico Aleatorizado para la evaluación de la efectividad de una aplicación móvil en la mejora de la lactancia materna exclusiva hasta los 6 meses", con referencia UGP-20-100, proyecto de concurrencia competitiva financiado por la Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO), concedido en la - IV

Convocatoria de Ayudas para el fomento de la actividad investigadora para Grupos Emergentes FISABIO 2019-, y siendo el periodo de ejecución desde el 01/01/2021 hasta el 31/12/2022.

Además, también se está realizando una investigación sobre la usabilidad de la aplicación y la satisfacción de sus usuarias. Por eso, recientemente, las investigadoras de LactApp han realizado la validación al español de la escala mHealth App Usability Questionnaire MAUQ adaptada al entorno de esta aplicación. MAUQ es una herramienta validada en inglés para conocer la usabilidad de una m-Health realizando 18 preguntas que se valoran del 1 al 7. La validación de esta herramienta está en proceso de publicación por la revista International Journal of Medical Informatics, que el 27 de marzo de 2023 aceptó su publicación. Según el Journal of Citation Reports (JCR) de 2021, esta revista tiene un factor de impacto de 4.730, perteneciendo al puesto 23 de un total de 109 indexadas en la categoría "Health Care Sciences & Services". Por lo tanto, esta revista ocupa un primer cuartil (Q1) y el primer tercil (T1) en el listado correspondiente del JCR. Al ser LactApp una herramienta tecnológica tan usada, puede aportar muchísima información tanto a las necesidades de las madres lactantes como de las profesionales que las atienden.

El hecho de que su crecimiento haya sido orgánico también indica que brinda información adecuada y que esta es necesaria para la madre, con lo que su estudio puede aportar más conocimiento en cómo abordar las dificultades en la lactancia materna.

Cita bibliográfica: Quifer-Rada P, Aguilar-Camprubí L, Gómez-Sebastià I, Padró-Arocas A, Mena-Tudela D. (2023) Spanish version of the mHealth App Usability Questionnaire (MAUQ) and adaptation to breastfeeding support apps. Int J Med Inform.

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ÍNDICE DE FIGURAS, TABLAS Y GRÁFICOS

Índice de figuras

uicc	- 11501 d 3
Pág	Figura
27	FIGURA 1: Determinantes de la lactancia materna adaptado de Rollins et al
34	FIGURA 2: Ejemplo de 5 grupos de temas proporcionados por la IA a la experta para clasificar una consulta
43	FIGURA 3: Distribución de las descargas de LactApp en el mundo
75	FIGURA 4: Distribución de las descargas de LactApp en el mundo
82	FIGURA 5: Biplot del análisis de componentes principales de las consultas semanales agregadas como temas según la edad del bebé de las usuarias
84	FIGURA 6: Boxplots de los temas que más contribuyen a discriminar los grupos de edad infantil de las usuarias. Diferencias significativas en comparación con el grupo de edad infantil anterior (p<,05 de Dunn post hoc de la prueba de Kruskal-Wallis, p valor corregido por el número de usuarios en cada categoría de grupo y ajustado por la falsa tasa de descubrimiento.
86	FIGURA 7: Biplot del análisis de componentes principales de las consultas semanales agregadas de los test según la edad del bebé de las usuarias.

Índice de tablas

Pág	Tabla
32	TABLA 1: Elementos del Sistema de Soporte de Decisiones (a fecha de Marzo 2022)
104	TABLA 2: Modelo de series temporales interrumpidas para el número de consultas automatizadas y usuarias activas de LactApp
106	TABLA 3: Consultas automatizadas mensuales agregadas por usuaria según los temas antes y después de la pandemia de SARS-CoV-2

Índice de gráficos

pandémico

Pág Gráfico 21 GRÁFICO 1: Costes sanitarios según alimentación del lactante extraídos de la publicación de Lechosa-Muñiz et al. 22 GRAFICO 2: Promedio de gasto sanitario total ocasionado al Sistema Nacional de Salud. 42 GRÁFICO 3: Perfil de las usuarias de LactApp GRÁFICO 4: Edad de las usuarias 42 GRÁFICO 5: Número de hijas o hijos previos 44 GRÁFICO 6: Perfiles profesionales en versión Medical 44 45 GRÁFICO 7: Test empezados GRÁFICO 8: Consultas automatizadas según el periodo estudiado 46 47 GRÁFICO 9: Temas más consultados durante el periodo estudiado 74 GRAFICO 10: Edad de las usuarias registradas 76 GRÁFICO 11: Edad de los bebés registrados 77 GRÁFICO 12: Frecuencia de los temas más consultados en LactApp GRÁFICO 13: Frecuencia anual de consultas por temas 78 80 GRÁFICO 14: Principales consultas semanales agregadas por temas según la edad del bebé 85 GRÁFICO 15: Tests realizados por las usuarias semanalmente agrupados por edad del bebé 103 GRÁFICO 16: Análisis de series temporales del número de consultas (a) y usuarias activas (b) de LactApp desde 2017 a 2021. Los valores reales y los predictivos han sido trazados desde el brote de SARS-CoV-2. Los datos fueron extraídos de Google Firebase. 107 GRÁFICO 17: Consultas automatizadas agregadas de los períodos pre-pandémico y

ANEXOS

Anexo 1

Autorizaciones de las coautoras para el uso de las publicaciones como parte de la presente tesis doctoral.

A. Cervera Gasch como coautor/ coautora doy mi **autorización** a (Nombre del doctorando/ doctoranda) Laia Aguilar Camprubí para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Padró-Arocas, A., Mena-Tudela, D., Baladía, E., Cervera-Gasch, A., González-Chordá, V. M., & Aguilar-Camprubí, L. (2021). Telelactation with a Mobile App: User Profile and Most Common Queries. *Breastfeeding medicine : the official journal of the Academy of Breastfeeding Medicine*, 16(4), 338–345. https://doi.org/10.1089/bfm.2020.0269

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Lugar, fecha y firma



Todo ello, atendiendo al artículo 23 de la Normativa de los Estudios de Doctorado, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobada por el Consejo de Gobierno núm. 19 de 26 de Enero de 2012, modificada por el Consejo de Gobierno núm. 29 de 27 de Noviembre de 2012 y con posterior modificación por el Consejo de Gobierno núm. 37 de 25 de Julio de 2013):

"(...)

Alba Padró Arocas, como coautor/ coautora doy mi **autorización** a (Nombre del doctorando/ doctoranda) Laia Aguilar Camprubí para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Padró-Arocas, A., Quifer-Rada, P., Aguilar-Camprubí, L., & Mena-Tudela, D. (2021). Description of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers seek support at critical breastfeeding points and according to their infant's age. *Research in nursing & health*, 44(1), 173–186. https://doi.org/10.1002/nur.22095Padró-Arocas, A., Quifer-Rada, P., Aguilar-Camprubí, L., & Mena-Tudela, D. (2021). Description of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers seek support at critical breastfeeding points and according to their infant's age. *Research in nursing & health*, 44(1), 173–186. https://doi.org/10.1002/nur.22095
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- Quifer-Rada, P., Aguilar-Camprubí, L., Padró-Arocas, A., Gómez-Sebastià, I., & Mena-Tudela, D. (2022). Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support. *Telemedicine journal and e-health: the official journal of the American Telemedicine Association*, 10.1089/tmj.2021.0586. Advance online publication. https://doi.org/10.1089/tmj.2021.0586

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Lugar, fecha y firma

Barcelona 17 de junio de 2022

Todo ello, atendiendo al artículo 23 de la Normativa de los Estudios de Doctorado, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobada por el Consejo de Gobierno núm. 19 de 26 de Enero de 2012, modificada por el Consejo de Gobierno núm. 29 de 27 de Noviembre de 2012 y con posterior modificación por el Consejo de Gobierno núm. 37 de 25 de Julio de 2013):

"(...)



Desirée Mena Tudela, como coautora doy mi **autorización** a Laia Aguilar Camprubí para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Padró-Arocas, A., Mena-Tudela, D., Baladía, E., Cervera-Gasch, A., González-Chordá, V. M., & Aguilar-Camprubí, L. (2021). Telelactation with a Mobile App: User Profile and Most Common Queries. Breastfeeding medicine: the official journal of the Academy of Breastfeeding Medicine, 16(4), 338–345. https://doi.org/10.1089/bfm.2020.0269
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- Quifer-Rada, P., Aguilar-Camprubí, L., Padró-Arocas, A., Gómez-Sebastià, I., & Mena-Tudela, D. (2022). Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support. Telemedicine journal and e-health: the official journal of the American Telemedicine Association, 10.1089/tmj.2021.0586. Advance online publication. https://doi.org/10.1089/tmj.2021.0586

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

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Lugar, fecha y firma

Todo ello, atendiendo al artículo 23 de la Normativa de los Estudios de Doctorado, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobada por el Consejo de Gobierno núm. 19 de 26 de Enero de 2012, modificada por el Consejo de Gobierno núm. 29 de 27 de Noviembre de 2012 y con posterior modificación por el Consejo de Gobierno núm. 37 de 25 de Julio de 2013):

[&]quot;Aquellas tesis doctorales que opten por la incorporación de artículos (compendio de publicaciones) deben de ajustarse, en la medida de lo posible, a la siguiente estructura: -Introducción/objetivos - Un capítulo por artículo incorporado - Discusión general de los resultados - Conclusiones. -Aceptación de los coautores de que el doctorando presente el trabajo como tesis y renuncia expresa de estos a presentarlo como parte de otra tesis doctoral."

Eduard Baladia como coautor/ coautora doy mi **autorización** a (Nombre del doctorando/doctoranda) Laia Aguilar Camprubí para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Padró-Arocas, A., Mena-Tudela, D., Baladía, E., Cervera-Gasch, A., González-Chordá, V. M., & Aguilar-Camprubí, L. (2021). Telelactation with a Mobile App: User Profile and Most Common Queries. *Breastfeeding medicine: the official journal of the Academy of Breastfeeding Medicine*, 16(4), 338–345. https://doi.org/10.1089/bfm.2020.0269

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

- dul

Lugar, fecha y firma

21/06/2022 Muntanyola

Todo ello, atendiendo al artículo 23 de la Normativa de los Estudios de Doctorado, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobada por el Consejo de Gobierno núm. 19 de 26 de Enero de 2012, modificada por el Consejo de Gobierno núm. 29 de 27 de Noviembre de 2012 y con posterior modificación por el Consejo de Gobierno núm. 37 de 25 de Julio de 2013):

"(...)

Ignasi Gómez Sebastià, como coautor/ coautora doy mi **autorización** a (Nombre del doctorando/doctoranda) Laia Aguilar Camprubí para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Quifer-Rada, P., Aguilar-Camprubí, L., Padró-Arocas, A., Gómez-Sebastià, I., & Mena-Tudela, D. (2022). Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support. *Telemedicine journal and e-health: the official journal of the American Telemedicine Association*, 10.1089/tmj.2021.0586. Advance online publication. https://doi.org/10.1089/tmj.2021.0586

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Lugar, fecha y firma

Barcelona, 17 de Junio de 2022

Firmado digitalmente por GOMEZ SEBASTIA, IGNASI (AUTENTICACIÓN) Nombre de reconocimiento (DN): c=ES, serialNumber=37391435J, sn=GOMEZ, givenName=IGNASI, cn=GOMEZ SEBASTIA, IGNASI (AUTENTICACIÓN)

Fecha: 2022.06.17 11:19:39 +02'00'

Todo ello, atendiendo al artículo 23 de la Normativa de los Estudios de Doctorado, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobada por el Consejo de Gobierno núm. 19 de 26 de Enero de 2012, modificada por el Consejo de Gobierno núm. 29 de 27 de Noviembre de 2012 y con posterior modificación por el Consejo de Gobierno núm. 37 de 25 de Julio de 2013):

Víctor Manuel González Chordá como coautor/ coautora doy mi **autorización** a (Nombre del doctorando/doctoranda) Laia Aguilar Camprubí para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Padró-Arocas, A., Mena-Tudela, D., Baladía, E., Cervera-Gasch, A., González-Chordá, V. M., & Aguilar-Camprubí, L. (2021). Telelactation with a Mobile App: User Profile and Most Common Queries. *Breastfeeding medicine : the official journal of the Academy of Breastfeeding Medicine*, 16(4), 338–345. https://doi.org/10.1089/bfm.2020.0269

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Lugar, fecha y firma

Victor M Gonzalez Chorda Firmado digitalmente por Victor M Gonzalez Chorda Nombre de reconocimiento (DN): cn=Victor M Gonzalez Chorda, o=Universitat Jaume I, o=Universitat Jaume I, o=Universitat Jaume I, o=Departamento de Enfermeria, email=vchorda@uji.es, c=ES Fecha: 2022.06.17 09:47:07 +02'00'

Todo ello, atendiendo al artículo 23 de la Normativa de los Estudios de Doctorado, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobada por el Consejo de Gobierno núm. 19 de 26 de Enero de 2012, modificada por el Consejo de Gobierno núm. 29 de 27 de Noviembre de 2012 y con posterior modificación por el Consejo de Gobierno núm. 37 de 25 de Julio de 2013):

_"(...)

Paola Quifer Rada, como coautor/ coautora doy mi **autorización** a Laia Aguilar Camprubí para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

Relación de publicaciones:

- Padró-Arocas, A., Quifer-Rada, P., Aguilar-Camprubí, L., & Mena-Tudela, D. (2021). Description of an mHealth tool for breastfeeding support: LactApp. Analysis of how lactating mothers seek support at critical breastfeeding points and according to their infant's age. Research in nursing & health, 44(1), 173–186. https://doi.org/10.1002/nur.22095
- Quifer-Rada, P., Aguilar-Camprubí, L., Padró-Arocas, A., Gómez-Sebastià, I., & Mena-Tudela, D. (2022). Impact of COVID-19 Pandemic in Breastfeeding Consultations on LactApp, an m-Health Solution for Breastfeeding Support. *Telemedicine journal and e-health: the official journal of the American Telemedicine Association*, 10.1089/tmj.2021.0586. Advance online publication. https://doi.org/10.1089/tmj.2021.0586

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

Lugar, fecha y firma

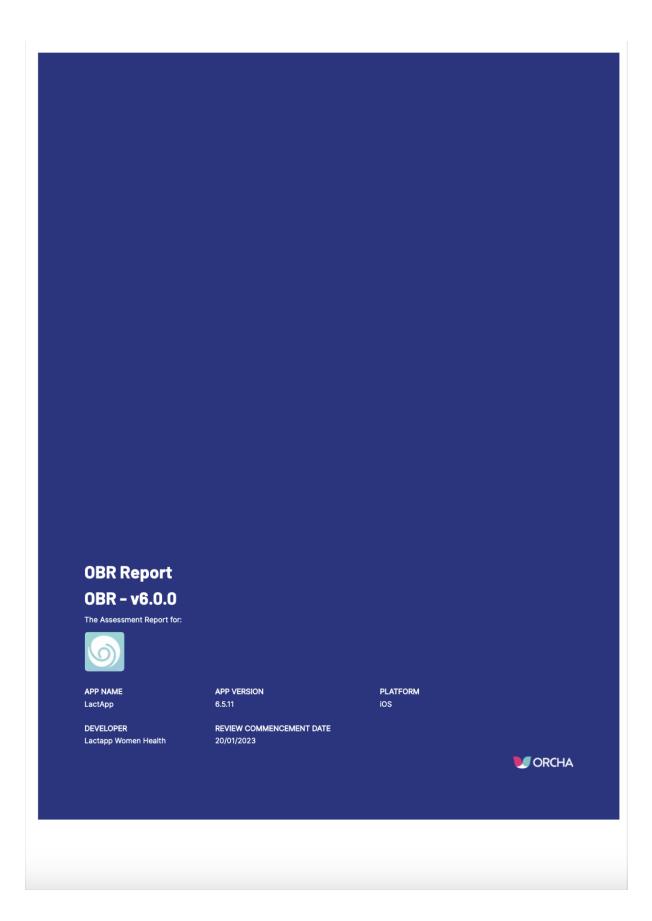
Barcelona, 17 de junio del 2022

Todo ello, atendiendo al artículo 23 de la Normativa de los Estudios de Doctorado, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobada por el Consejo de Gobierno núm. 19 de 26 de Enero de 2012, modificada por el Consejo de Gobierno núm. 29 de 27 de Noviembre de 2012 y con posterior modificación por el Consejo de Gobierno núm. 37 de 25 de Julio de 2013):

"(...)

Anexo 2

Auditorías de Organisation for the Review of Care and Health Apps (ORCHA)





APP NAME LactApp

DEVELOPER Lactapp Women Health APP VERSION 6.5.11 REVIEW COMMENCEMENT DATE 20/01/2023

PLATFORM ios REVIEW TYPE OBR - v6.0.0

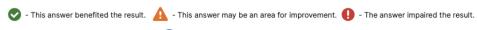
Overview

We have reviewed your app and found the	e following results:		
Review Result:	Data: 81%		Usability & Accessibility:
Professional Assurance:			
Section Fundamentals			
Scene Setters: Passed	Passed		Usability & Accessibility: Passed
Professional Assurance: Passed	Reviewer Comments:		
App Categories: Health Diary		Breast feeding	
Child Development		Pregnancy	
OBR - v6.0.0	Version 6.0 of the ORCHA Ba	seline Review	
Get in Touch	Email: hello@orchahealth.com Website: www.orchahealth.com		
	HH HAVE I GIBLIOGIA I AND		

Scene Setters

Fundamentals:

Passed



1 - The answer only provided information.

Question Code	Question and Answer	Impact
ORC_SS01	Is the app health focused? Yes	•
ORC_D01	Does the app collect data? Yes	6
ORC_DT10	What type of data is collected by the app? Name (Full Name, Nickname or First Name Only), Mobile Number / Device Number / Home Phone Number, Email, Age / DOB, Location Data, General Wellness Data, Physical Description, Marital Status / Family / Lifestyle / Social Circumstance, Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements), Usage Data, Physical and/or Mental Health Data, Gender (self-declared or observed), Other Online Identifiers, other (please specify)	•
ORC_DT14	Are users required to sign up / register to use the service? Yes	6
ORC_DT11	Is data collected through cookles? Yes	6
ORC_DT12	What type of cookles are used? Third Party, Unclear	6
ORC_DT13	Is the Data (cookle and/or none cookle) Collected: Sensitive	6
ORC_DC01	How is none cookie data collected? manual user input, measurement capability in the device (eg. automatic GPS, motion, microphone, camera), other apps, other third party sources, automatically generated by the app	•

DRC_DC02	What other apps is the App connected to?	A
	facebook and apple	
ORC_DS01	Can the user prevent cookle data being collected and still use the App? Yes	•
DRC_DS02	Does the disabiling of cookles impact the use of the App in anyway? Yes	6
RC_DS03	Can/is data shared? (excluding cookies) Yes	6
PRC_DS04	Can data be shared through a direct, manual action by the user? {e.g. by sending data via email or manually choosing to post/share something within the app etc} Yes	6
DRC_DS05	How is the user able to manually share their data? Manually choosing who to share information with in the app	6
PRC_DS06	Is data ONLY shareable through a direct, manual action by the user? (excluding cookies) No	6
DRC_DS07	Can the user control any automatic data sharing, through setting individual sharing preferences in the app? (excluding cookies) No	6
DRC_DS09	Is any data (excluding cookie data) shared automatically as soon as the App is accessed – based only on agreement to relevant T&C's or Privacy Policy? Yes	6
DRC_DS10	Where/With who is data automatically shared - based only on user agreement to the developer's Privacy Policy and/or T&C's? Developer, Third Parties (Google Fit, Facebook)	6
DRC_DS12	What data is automatically shared with the developer? Email, Physical and/or Mental Health Data, Mobile Number / Device Number / Home Phone Number, Name (Full Name, Nickname or First Name Only), General Wellness Data, Gender (self-declared or observed), Usage Data, Location Data, Age / DOB, Marital Status / Family / Lifestyle / Social Circumstance, Other Online Identifiers, other (please specify), Physical Description, Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements)	6
DRC_DS15	What data is automatically shared with third parties? Physical and/or Mental Health Data, Name (Full Name, Nickname or First Name Only), Mobile Number / Device Number / Home Phone Number, Email, other (please specify), Gender (self- declared or observed), Usage Data, Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements), Marital Status / Family / Lifestyle / Social Circumstance, Age / DOB, Other Online Identifiers, Physical Description, Location Data, General Wellness Data	6
ORC_DS17	Does the app allow users to access their own NHS personal health records e.g. patient access?	A

ORC_DS18	Does the App appear to access and/or process NHS Patient Information?	1
ORC_AI01	Does the app contain algorithms? Yes	•
ORC_AI02	How does the app use the algorithm? calculates groph from data input by user for progression of feeding	6
ORC_AI03	Does the app appear to use Al?	6
ORC_I01	Is the app designed to provide information or guidance? Yes	6
ORC_I02	Does the app provide information that is personalised to an end user's specific circumstances? Yes	1
ORC_F08	Does the app provide users with information regarding where they are able to find local or suitable support services? Yes	6
ORC_F03	Does the app provide environmental data not specific to the patient? No	6
ORC_EF07	Does the App provide information, resources or activities to the public, patients or clinicians, either about a specific condition or general health and lifestlye? Yes	6
ORC_PD01	Is the data the app collects automatically assessed for the purposes of evaluating risk or providing diagnostic support? No	6
ORC_DG02	Does the app diagnose a specific condition?	6
ORC_DG04	Does the app provide the option for further assessment or analysis by a healthcare professional?	6
ORC_DG05	Is the app/does the app include a Symptom Checker? Yes	1
ORC_DG06	Does the app indicate likelihood of a match for the listed conditions?	6
ORC_DG07	Can users filter results to display by highest risk / likelihood / severity? No	6
ORC_DG08	Does the app provide treatment recommendations for the listed conditions?	6

ORC_DG09	Does the app only signpost the user to suitable care or recommend seeking further advice? (eg. Go to A&E, book an appointment with your GP, call 111) Y/N Yes	1
ORC_TS01	Does the app contain a clinical calculator?	•
ORC_MD01	Is the app intended to be (or does the developer claim it can be) used for the prevention of disease? No	1
ORC_TS05	Does the app provide treatment of a condition? No	1
ORC_TS07	Does the app guide the treatment of a condition?	1
ORC_TS03	Does the app support healthcare professionals' decisions about treatments?	1
ORC_TS14	Does the app automate the treatment pathway for an individual patient? No	1
ORC_TS15	Is the app intended to be (or does the developer claim it can be) used as a physical intervention to reduce the symptoms or severity of a disease, injury or handicap?	1
ORC_MD07	Is the app intended to (or does the developer claim it can be used to) compensate an injury or handlcap? No	1
ORC_CC01	Does the app predict the fertile window? No	1
ORC_AE20	is the App used in combination with drugs or medication? {e.g. medication reminders} No	1
ORC_MN01	Does the app allow the monitoring of key health information? Specific Condition data	1
ORC_MN02	Does the app involve the recording of relevant data over time for the user to access and review (with no 'intelligent' manipulation of that data by the app)? Yes	1
ORC_MN03	Does the app involve the automated assessment or interpretation of relevant data to deliver alerts, insights, reminders or adjustments regarding the user's health or lifestyle? No	1
ORC_MN04	is the app? a Standard Self Management app?	1
ORC_MN06	Does the app allow others (i.e. not the user) to monitor or view the health data captured?	1

ORC_MN07	Does the app automatically measure and/or record data about a user's specified condition, and transmit the data to a professional, carer or third party organisation, without any input from the user? No	•
ORC_TS11	What type of intervention or treatment does the app provide? Monitoring (basic eg. diary)	€
ORC_F14	Can the app be used for patients to have online consultations conversations, or related Health Care services with a healthcare professional? Yes	•
ORC_OC02	Is this through video consultation?	€
ORC_EF09	Does the App allow healthcare professionals to provide clinical advice, as opposed to the App providing advice itself? Yes	€
ORC_OC01	If the app allows healthcare professionals to provide clinical advice through the app, rather than the app providing the advice itself, how does it do this? through a chat service within the app	•
ORC_CQC01	Does the App deliver any services in England which may require registration with the Care Quality Commission (CQC)?	•
ORC_AS01	Is this an administrative app which does not directly impact patient care?	€
ORC_F13	Does the app allow users to order and request prescriptions?	€
ORC_PC01	Does the App constitute a Pharmacy Service?	€
ORC_D29	Does the app send push notifications? Yes	€
ORC_D30	Does the app send email notifications?	€
ORC_F30	Do any of the features or functions of the app appear to allow it to be used to control a medical device? No	•
ORC_U19	Are there opportunities to link with other users (buddying, forums or group education)? Yes	€
ORC_FC01	Does the app provide an internally hosted forum or online community for their users?	•

ORC_FC02	Does the app link to a third-party service to host a forum or online community for their users? No	1
ORC_EF10	Does the App allow two-way communication between citizens, patients or healthcare professionals? Yes	6
ORC_F06	Does the app provide gamification or goal setting features for the user?	6
ORC_CUS01	Can the app presentation be customised by the user? Yes	1
ORC_CUS02	Does the app respond to preferences in the device? Yes	1
ORC_U29	Is the App totally free? No	1
ORC_BM01	How is the app funded? in app purchases, donations	1
ORC_U27	Does the app contain adverts?	1
ORC_BF01	What are the claimed or implied benefits of the app? Implied increase in access to care	a





APP NAME

LactApp: Breastfeeding expert DEVELOPER LactApp Women Health

APP VERSION 6.5.4 REVIEW COMMENCEMENT DATE 20/01/2023

PLATFORM Android
REVIEW TYPE OBR - v6.0.0

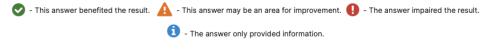
Overview

	nd the following results:	
Score Overview Review Result:	 Data: 81%	Usability & Accessibility:
Professional Assurance:	_	7070
Section Fundamentals		
Scene Setters: Passed	Passed	Usability & Accessibility: Passed
Professional Assurance: Passed	Reviewer Comments: Passed	
App Categories:		
Breast feeding	Child	Development
Pregnancy	Heal	th Diary
OBR - v6.0.0	Version 6.0 of the ORCHA Baseline R	eview
	Email:	

Scene Setters

Fundamentals:

Passed



Question Code	Question and Answer	Impact
ORC_SS01	Is the app health focused? Yes	1
ORC_D01	Does the app collect data? Yes	•
ORC_DT10	What type of data is collected by the app? Name (Full Name, Nickname or First Name Only), Mobile Number / Device Number / Home Phone Number, Email, Age / DOB, Location Data, General Wellness Data, Physical Description, Marital Status / Family / Lifestyle / Social Circumstance, Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements), Usage Data, Physical and/or Mental Health Data, Gender (self-declared or observed), Other Online Identifiers, other (please specify)	•
ORC_DT14	Are users required to sign up / register to use the service? Yes	6
ORC_DT11	Is data collected through cookles? Yes	•
ORC_DT12	What type of cookies are used? Third Party, Unclear	6
ORC_DT13	Is the Data (cookle and/or none cookle) Collected: Sensitive	6
ORC_DC01	How is none cookie data collected? manual user input, measurement capability in the device (eg. automatic GPS, motion, microphone, camera), other apps, other third party sources, automatically generated by the app	6

ORC_DC02	What other apps is the App connected to? Facebook	•
ORC_DS01	Can the user prevent cookle data being collected and still use the App? Yes	•
ORC_DS02	Does the disabling of cookles impact the use of the App in anyway? Yes	•
ORC_DS03	Can/is data shared? (excluding cookles) Yes	1
ORC_DS04	Can data be shared through a direct, manual action by the user? {e.g. by sending data via email or manually choosing to post/share something within the app etc} Yes	•
ORC_DS05	How is the user able to manually share their data? Manually choosing who to share information with in the app	•
ORC_DS06	Is data ONLY shareable through a direct, manual action by the user? (excluding cookies)	•
ORC_DS07	Can the user control any automatic data sharing, through setting individual sharing preferences in the app? (excluding cookles) No	6
ORC_DS09	Is any data (excluding cookie data) shared automatically as soon as the App is accessed – based only on agreement to relevant T&C's or Privacy Policy? Yes	6
ORC_DS10	Where/With who is data automatically shared - based only on user agreement to the developer's Privacy Policy and/or T&C's? Developer, Third Parties (Google Fit, Facebook)	6
ORC_DS12	What data is automatically shared with the developer? Email, Physical and/or Mental Health Data, Mobile Number / Device Number / Home Phone Number, Name (Full Name, Nickname or First Name Only), General Wellness Data, Gender (self-declared or observed), Usage Data, Location Data, Age / DOB, Marital Status / Family / Lifestyle / Social Circumstance, Other Online Identifiers, other (please specify), Physical Description, Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements)	1
ORC_DS15	What data is automatically shared with third parties? Physical and/or Mental Health Data, Name (Full Name, Nickname or First Name Only), Mobile Number / Device Number / Home Phone Number, Email, other (please specify), Gender (self-declared or observed), Usage Data, Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements), Marital Status / Family / Lifestyle / Social Circumstance, Age / DOB, Other Online Identifiers, Physical Description, Location Data, General Wellness Data	6
ORC_DS17	Does the app allow users to access their own NHS personal health records e.g. patient access?	6

ORC_DS18	Does the App appear to access and/or process NHS Patient Information?	1
ORC_AI01	Does the app contain algorithms? Yes	6
ORC_AI02	How does the app use the algorithm? calculates groph from data input by user for progression of feeding	i
ORC_AI03	Does the app appear to use AI?	1
ORC_I01	Is the app designed to provide information or guidance? Yes	1
ORC_I02	Does the app provide information that is personalised to an end user's specific circumstances? Yes	6
ORC_F08	Does the app provide users with information regarding where they are able to find local or suitable support services? Yes	1
ORC_F03	Does the app provide environmental data not specific to the patient?	1
ORC_EF07	Does the App provide information, resources or activities to the public, patients or clinicians, either about a specific condition or general health and lifestlye? Yes	6
ORC_PD01	Is the data the app collects automatically assessed for the purposes of evaluating risk or providing diagnostic support?	6
ORC_DG02	Does the app diagnose a specific condition?	6
ORC_DG04	Does the app provide the option for further assessment or analysis by a healthcare professional? No	6
ORC_DG05	Is the app/does the app include a Symptom Checker? Yes	1
ORC_DG06	Does the app indicate likelihood of a match for the listed conditions?	6
ORC_DG07	Can users filter results to display by highest risk / likelihood / severity?	6
ORC_DG08	Does the app provide treatment recommendations for the listed conditions?	6

ORC_DG09	Does the app only signpost the user to suitable care or recommend seeking further advice? (eg. Go to A&E, book an appointment with your GP, call 111) Y/N Yes	•
ORC_TS01	Does the app contain a clinical calculator?	6
ORC_MD01	Is the app intended to be (or does the developer claim it can be) used for the prevention of disease? No	•
ORC_TS05	Does the app provide treatment of a condition? No	1
ORC_TS07	Does the app guide the treatment of a condition? No	1
ORC_TS03	Does the app support healthcare professionals' decisions about treatments? No	1
ORC_TS14	Does the app automate the treatment pathway for an individual patient? No	•
ORC_TS15	Is the app intended to be (or does the developer claim it can be) used as a physical intervention to reduce the symptoms or severity of a disease, injury or handicap?	•
ORC_MD07	Is the app intended to (or does the developer claim it can be used to) compensate an injury or handlcap? No	6
ORC_CC01	Does the app predict the fertile window?	6
ORC_AE20	Is the App used in combination with drugs or medication? {e.g. medication reminders}	•
ORC_MN01	Does the app allow the monitoring of key health information? Specific Condition data	1
ORC_MN02	Does the app involve the recording of relevant data over time for the user to access and review (with no 'intelligent' manipulation of that data by the app)? Yes	•
ORC_MN03	Does the app involve the automated assessment or interpretation of relevant data to deliver alerts, insights, reminders or adjustments regarding the user's health or lifestyle? No	6
ORC_MN04	Is the app? a Standard Self Management app?	6
ORC_MN06	Does the app allow others (i.e. not the user) to monitor or view the health data captured?	1

ORC_MN07	Does the app automatically measure and/or record data about a user's specified condition, and transmit the data to a professional, carer or third party organisation, without any input from the user? No	6
ORC_TS11	What type of intervention or treatment does the app provide? Monitoring (basic eg. diary)	1
ORC_F14	Can the app be used for patients to have online consultations conversations, or related Health Care services with a healthcare professional? Yes	1
ORC_OC02	Is this through video consultation?	6
ORC_EF09	Does the App allow healthcare professionals to provide clinical advice, as opposed to the App providing advice itself? Yes	1
ORC_OC01	If the app allows healthcare professionals to provide clinical advice through the app, rather than the app providing the advice itself, how does it do this? through the chat function based on what you have asked a question regrading.	1
ORC_CQC01	Does the App deliver any services in England which may require registration with the Care Quality Commission (CQC)?	•
ORC_AS01	Is this an administrative app which does not directly impact patient care?	1
ORC_F13	Does the app allow users to order and request prescriptions?	1
ORC_PC01	Does the App constitute a Pharmacy Service?	•
ORC_D29	Does the app send push notifications? Yes	1
ORC_D30	Does the app send email notifications?	1
ORC_F30	Do any of the features or functions of the app appear to allow it to be used to control a medical device? No	•
ORC_U19	Are there opportunities to link with other users (buddying, forums or group education)? Yes	1
ORC_FC01	Does the app provide an internally hosted forum or online community for their users?	1

ORC_FC02	Does the app link to a third-party service to host a forum or online community for their users?	6
ORC_EF10	Does the App allow two-way communication between citizens, patients or healthcare professionals? Yes	•
ORC_F06	Does the app provide gamification or goal setting features for the user? No	6
ORC_CUS01	Can the app presentation be customised by the user? Yes	6
ORC_CUS02	Does the app respond to preferences in the device? Yes	6
ORC_U29	Is the App totally free?	6
ORC_BM01	How is the app funded? in app purchases, donations	6
ORC_U27	Does the app contain adverts?	6
ORC_BF01	What are the claimed or implied benefits of the app? Implied increase in access to care	6

APP NAME

LactApp: Breastfeeding expert

DEVELOPER LactApp Women Health

 REVIEW TYPEAPP VERSION
 PLATFORM
 REVIEW COMMENCEMENT DATE

 OBR - v6.0.0
 6.5.4
 Android
 20/01/2023

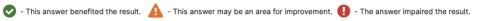
Data

Your Score: 81%

Fundamentals:

Passed





1 - The answer only provided information.

Question Code	Question and Answer	Impact
ORC_D39a	Is there a Privacy Policy clearly available via the App/Web App/Website? Yes	•
ORC_DP03	Is the Privacy Policy made immediately available when the user first opens the app?	A
ORC_DP04	Is the policy made available when the user is signing up to use the services? Yes	•
ORC_DP01	Is it published within the app? No	A
ORC_DP02	Is it available externally via the app? No	A
ORC_DP05	Is it available via the relevant app store? Yes	A
ORC_DP06	What data does the Privacy Policy state the developer collects? Email, Mobile Number / Device Number / Home Phone Number, Gender (self-declared or	
	chail, Mobile Number / Device Number / Home Phone Number, Gender (self-declared or observed), Name (Full Name, Nickname or First Name Only), Physical and/or Mental Health Data, Other Online Identifiers, Location Data, General Wellness Data, Marital Status / Family / Lifestyle / Social Circumstance, Usage Data, Age / DOB, Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements), other (please specify)	6

ORC_DP07	Is the policy accurate, with regards to the data the developer intends to collect? Yes	
ORC_DP08	How does the developer obtain consent for the processing of user data? Unmarked opt in check box, separate from other terms and conditions and/or consent requests	•
ORC_DP14	Does the Privacy Policy Provide the name and contact details of their Data Protection Officer (DPO), or similar individual representative for the company? No	A
ORC_D69	Does the developer fully inform the user of how they will collect data about them? Eg. Directly from the user or through third party sources Yes	•
ORC_D13	Does the developer provide users with details on all the purposes of processing user data? Yes	•
ORC_DP10	What is automatically shared data used for? legal obligations, performance of contract, research, improving developer services, marketing, provision of services	•
ORC_D38	Does the developer appear to intend to share or process the user data collected by the app for any purposes that have not been made clear to the user, or for any purposes they deem necessary? No	•
ORC_D71	Does the developer inform users that they would like to use their data for the purpose of marketing, or providing information on products or services that might be of interest to the user? Yes	6
ORC_DP12	Does the developer obtain informed consent separately, for the purpose of marketing? Yes	•
ORC_D28	Is the user informed of how they can opt out of each of the processing activities?	6
ORC_DP13	If the user can not opt out of all processing activity, does the developer clearly explain which activities the cannot opt out of and why?	0
ORC_D16	Is the user informed that their data will not be shared with other parties, except for the purposes that have been set out in the privacy policy? Yes	•
ORC_DST01	Does the data privacy policy or equivalent provide detail about where the data collected by the app will be stored (i.e. on the app or in an external data warehouse, cloud server etc.)? Yes	•
ORC_DST02	Where is the data stored? All this data will be stored in a secure server at Amazon, outside the app. And all the communication between the server and the app is made over HTTPS so it is TLS encrypted.	6

ORC_DST03	Does the Data Privacy Policy, or equivalent, state whether personal data is stored using recognised secure data storage technologies? Yes	A
ORC_D17	Is all personally identifiable data encrypted in transit between the device and any external host storage? Yes	•
ORC_DM01	Does the policy state its compliance with recognised International Data Management Standards? (ISO, BSI)? None	A
ORC_D19	Is there a policy or statement that contains details of the length of time data will be retained for? Yes	•
ORC_D20	Is there a policy or statement that details the developer's intentions for data destruction? Yes	•
ORC_D21	Is there a policy or statement that sets out a process for managing data confidentiality breaches? Yes	•
ORC_D23	Is there a policy or statement that confirms the App's compliance with GDPR? Yes	•
ORC_D60	Is the user informed of the legal basis for which data is collected from them? i.e. Consent, Performance of Contract, Legal Obligation, Vital Interests, Public Interest or Legitimate Interest. Please Specify. Yes	•
ORC_DPR03	Is the user informed that the developer will only collect minimum data items that are necessary to provide their services, therefore ensuring data minimisation principles are met? Yes	•
ORC_D61	Is there a statement that the policy will be updated if there is a change in the purpose of data collection? This may mean re-obtaining user consent (if consent was the lawful basis). No	•
ORC_DPR01	Are users informed of their rights with regards to their data? Yes	•
ORC_D93	Has the developer made the existence of the data subject's right to request that their personal data is deleted clear? Yes	•
ORC_D25	Has the developer made the existence of the data subject's right to access their personal data clear? Yes	•
ORC_D56	Has the developer made the existence of the data subject's right to rectify their personal data clear? Yes	•

ORC_D81	Has the developer made the existence of the data subject's right to restrict the use of their personal data clear? Yes	•
ORC_D57	Has the developer made the existence of the data subject's right to object to the processing of his/her personal data clear? Yes	•
ORC_D59	Has the developer made the existence of the data subject's right to portability of their personal data clear? No	A
ORC_D58	Has the developer made the existence of the data subject's right to withdraw consent for the use of their personal data clear? Yes	•
ORC_DPR02	Has the developer made clear the existence of the user's right to request that they are not subject to a decision based solely on automated processing, including profiling, which produces legal/significant effects concerning the user? No	A
ORC_D82	Does the developer provide details that the user can contact them on to exercise their rights? Yes	•
ORC_D83	Is the user informed of the time frame in which the developer will respond to any requests to exercise their rights? This time frame should be within two months of receipt of any request. Yes	•
ORC_D99	Are users clearly informed of the use of cookies when first landing on the developers site/app? No	•
ORC_D100	Are user's required to confirm their acceptance of the developer's use of cookies, when initially informed of the use? No	0
ORC_D84	Does the developer provide a full Cookie Policy, separate from the Terms of Service and/or Privacy Policy? Yes	•
ORC_D44	Is the app 'particularly likely' to be used by children, even if they are not the primary market for the app? No	1
ORC_DO01	Are users informed of how they can report, to the developer, any knowledge of a child accessing the app and providing personal data, without parental consent? No	0
ORC_D91	Is the user made aware that by following links to third party websites, the developer's policies no longer apply and that the user should make themselves aware of the third party's policies? Yes	•
ORC_D92	Is the user informed of how they can make further enquiries about the company's privacy policy? Yes	•

ORC_D06	Does the app allow the user to set their preferences for sharing the app data with or from other apps (e.g. Facebook / Instagram/Fitbit etc)? Yes	•
ORC_D002	Is it strictly necessary for anyone to easily access the information that persists on the app? eg. to access health info during an emergency No	6
DRC_DO03	Are users provided options to introduce additional security measures to protect their data on the app? eg. set additional pass codes for access to the app, after accessing the device is unlocked. No	A
DRC_DO04	Does the app use a sign up/sign in verification/authentication model? Yes	•
DRC_DO05	What type of model is being used? Other one-step authentication, Two-step authentication	1

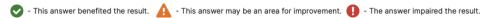
Usability & Accessibility

Your Score:

75%

Fundamentals:

Passed







1 - The answer only provided information.

Question Code	Question and Answer	Impact
ORC_DE01	Is there a statement within the app outlining compliance with any currently recognised app design standards? None	A
ORC_DT01	Is there a statement within the app or store about user feedback during design and/or development? Yes	•
ORC_DT02	Is there a statement either in the app or store about user involvement in testing? Yes	•
ORC_U04	Can the user change the font size within the App or does the app respond to font preferences in the device? Yes	•
ORC_U07	Does the app provide support options for users with poor sight? Yes	•
ORC_U08	Does the app provide support options for users with hearing difficulty? Yes	Ø
ORC_U06	Can the user change the presentation theme? Yes	•

ORC_U32	Does the app include the following functions: Home/Menu button, Back button, Search button	1
ORC_U15	Are any clinical or technical terms used explained clearly to the user? (either within the content of the app or via a glossary) Yes	•
ORC_D31	Does the user have options to manage the notification settings for push/email notifications within the app for convenience/privacy? Yes	•
ORC_D32	Does the app inform the user how to manage notification settings for convenience / privacy (eg to prevent divulging personal information if the device is locked but on show?) No	A
ORC_U23	During review, was there any evidence of bugs?	•
ORC_U24	Is there any statement or evidence of how to report issues to the developers? (e.g. this may be a help button with contact form, instructions or email details) Yes	1
ORC_U33	What kind of support is offered? Email address, eTicket	0
ORC_U25	Is there any statement within the app about the developer's commitment to addressing problems reported to them? (e.g. timescales to respond, commitment to eradicate reported bugs and faults) No	A
ORC_UX01	Does the Developer publish or make available unedited User Feedback Data? No	A
ORC_UX02	Does the Developer publish or otherwise make available any unedited user usage Data? No	A

Professional Assurance

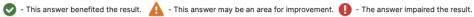
Your Score:

85%

Fundamentals:

Passed







1 - The answer only provided information.

Question Code	Question and Answer	Impact
ORC_MD11	Is the app a medical device? (autofill but there to validate) No	6
ORC_FDA01	Has the app been FDA approved?	6
ORC_FDA02	Has the app been FDA cleared?	6
ORC_ESF05	Is the app ESF Tier 3b?	6
ORC_ESF04	Is the app ESF Tier 3a?	6
ORC_ESF03	Is the app ESF Tier 2b? Yes	6
ORC_ESF02	Is the app ESF Tier 2a?	6
ORC_ESF01	Is the app ESF Tier 1? No	6

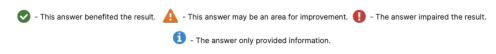
ORC_EE02	What type/s of evidence is available? Survey, Indicated User Acceptance/Benefit	•
ORC_EE14	How many pieces of evidence does the app provide? Two	•
ORC_EE10	What category does the evidence relate to? Pregnancy	6
ORC_EE11	What benefit does the evidence relate to? improvement in access to care	6
ORC_EE03	Provide links to the publicly available evidence/published evidence that the developer has provided. 73% of our users say that LactApp has 'been key' or 'improved' their breastfeeding experience. 97% of them would recommend the app and more than 97% are satisfied with the content we offer.	6
ORC_EE03b	Provide links to the publicly available evidence/published evidence that the developer has provided. In addition, 23% of all new mothers in Spain use LactApp. Data updated in March 2022	6
ORC_PB01	Is there a suitably qualified Professional involved in the Development team of the App? Yes	6
ORC_PB02	Has the app been developed by a recognised or national health body? No	•
ORC_PB03	Is there evidence of an endorsement by a relevant body? Yes	•
ORC_PB04	Are organisations using the App? No	A
ORC_PB05	Is there a statement that it has been positively evaluated or validated by a relevant healthcare professional? No	A
ORC_PB06	Is there evidence within the app that the developer has validated any guidance with relevant reliable information sources or references? Yes	•
ORC_AE13	Is there a statement or any evidence showing that appropriate safeguarding measures are in place around peer-support and other communication functions within the platform? Yes	•
ORC_S01	Does the Developer clearly identify who the app should be used by? Yes	•
ORC_S02	Does the Developer publish their risk management processes? No	A

ORC_S03	Does the Developer make clear risks associated with using the app?	A
ORC_S04	Is there a way for the user to confirm that the data input is accurate?	0
ORC_S05	Does the Developer list a Clinical Safety Officer on/in any relevant sites/content?	A
ORC_ESF06	Has the app met Tier 1 minimum requirements? Yes	A
ORC_ESF07	Has the app met Tier 2a minimum requirements? Yes	A
ORC_ESF08	Has the app met Tier 2b minimum requirements? Yes	•
ORC_ESF09	Has the app met Tier 3a minimum requirements?	A
ORC_ESF10	Has the app met Tier 3b minimum requirements?	A
ORC_ESF11	Does the app have appropriate evidence for the ESF tier? Yes	6

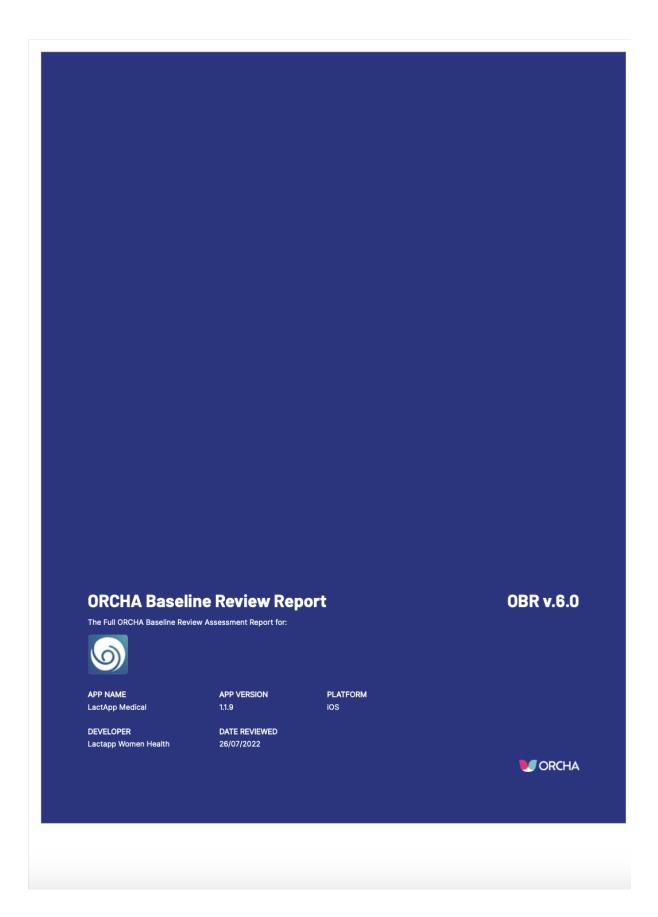
Reviewer **Comments**

Fundamentals:

Passed



Question Code	Question and Answer	Impact
ORC_RC01a	Would you like to provide any additional review notes for the sign off and/or further discussion? No	6
ORC_RC02a	Would you like to provide any additional app review notes to be displayed on the developer report and website?	•





APP NAME
LactApp Medical
DEVELOPER
Lactapp Women Health

APP VERSION
1.1.9

DATE REVIEWED
26/07/2022

PLATFORM IOS

Overview

We have reviewed your app and found the following results:

Baseline Review Score: 74%	Data Score: 79%	Professional Assurance Score: 63%
Usability/ Accessibility Score:	Level:	ORCHA ESF Tier:
App Categories: Breast feeding, Clinical Reference, Maternity, Educational, Information, Clinical tools		
Reviewer Notes	No notes	
Functional Characteristics		functional assessment to generate the functional characteristics assist users/ health care professionals in to them.
	The Functional assessment also d	ynamically changes the lines of enquiry that ORCHA
	possible to the particular app type	v, again to ensure that the assessment is as tailored as b. This allows the review to capture an indication of how the to tailor their searches appropriately to find apps that actuall ed support around.
	possible to the particular app type app functions and allows all users	b. This allows the review to capture an indication of how the to tailor their searches appropriately to find apps that actuall ed support around.
■ Data Capture - The App capture	possible to the particular app type app functions and allows all users do the things that they want or ne	b. This allows the review to capture an indication of how the to tailor their searches appropriately to find apps that actuall ed support around.
Data Capture - The App capture Health Monitoring - The App pr allow users to monitor their consimple recording of relevant data	possible to the particular app type app functions and allows all users do the things that they want or new We have evaluated your app to how the suser data.	b. This allows the review to capture an indication of how the to tailor their searches appropriately to find apps that actuall ed support around. Id the following characteristics: Data Sharing - The App allows you to share information

Further App Characteristics User Data Collection Sensitive We also examine what user data your app collects. From our review we evaluated your app to Medical Device Unlikely to be a medical device We also evaluate if an app is likely to be a medical device. We found that your app is: ORCHA ESF Tier Tier 2a We have adapted the NICE Evidence Standards Framework for evaluation within our review. We utilise our functional assessment to generate the ESF Tier and then evaluate against the required evidence for that tier. Designed For We have also assessed your app against which age group or population it is intended for. The $\,$ ORCHA designed for categories are: Everyone No limit on who can use the app Adult 18 Years Old + Child 5-9 Years Old Teen 13-18 Years Old Pre-Teen 10-12 Years Old Infant 0-4 Years Old Health Care Professional (HCP) App is Designed for clinician or relevant health care professional Patient App can only be used if a patient is linked with a HCP Research Participant For people taking part in research or a clinical trial Career For the use of a carer Health Care Administrator For this use of a health care administrator e.g. scheduling apps We have assessed your app as being designed for: Clinicians

Therefore users will be able to filter by this when searching for relevant apps.

APP NAME DEVELOPER APP VERSION PLATFORM DATE REVIEWED
LactApp Medical Lactapp Women Health 119 ios 26/07/2022

Full Assessment Report

The ORCHA Baseline Review

At ORCHA we seek out the most popular digital health solutions and review them for compliance and best practice. The majority of solutions we review are Apps (defined as a self-contained software program designed to fulfil a particular purpose, as downloaded by a user to a mobile device). We have extended our scope to also now include Web Apps and Progressive Web Apps (web-based software apps that are customised for a mobile platform, but that are run on a server and accessed via a web browser).

Our ORCHA Baseline Review(OBR) examines how apps comply with relevant regulation and follow best practice. We examine three domains through a set of object questions -Data Privacy, Professional Assurance and Usability/Accessibility. How your app performed in our assessment is shown below.

If you disagree with anyof this information please get in touch at with us at reviews@orcha.co.uk and we will be happy to discuss our answers and make edits if needed.

ORCHA Scoring System

The ORCHA score is designed to reward developers for best practice, and highlight poor practice and non-compliance. By following best practice, apps can earn "value points," and poor practice or non-compliance (where necessary) will earn "risk points." The score begins at a baseline of 65% and allows apps to go up or down in score depending on the answers to the questions.

To make the score fair across apps, not every question is asked of every app. For example if the app does not collect any user data, the questions around processing of user data will not be active in the review. We include functional "scene setter" questions at the beginning of the review to capture this.

We also weight the separate sections of the review differently based on the app level. We expect apps with higher levels of clinical functionality, for example one with diagnostic or treatment components to show a higher level of professional assurance than simple relaxation apps. Therefore we weight the section scores across levels.

 Level
 Privacy
 Assurance
 Accessibility

 Level 2
 30%
 40%
 30%

Please find a full explanation of our scoring mechanism in the "further information" section at the end of this report.

Result Statements

The OBR score, categorisation, functional characteristics and some select review points are displayed to users of our ORCHA app libraries. However, a full breakdown of exactly how we evaluated your app can be found below with the question code and "result statement". You will be able to see exactly what we have found and given credit for (denoted with a 'tick') and advice as to how you could improve your score where we could not find the relevant criteria(denoted with an 'exclamation point'). For the results to our 'Scene Setters' section, we have not included a 'tick' or 'exclamation point' as these are all none scoring. Once an app has been updated and a new version released, it will automatically be placed in our queue for a "re - review" and will undergo the assessment again. This will capture any changes made by the developer.

A full list of the OBR questions can be found in our Version 6 OBR documentation on our website(www.orcha.co.uk).

Review Sources

For our review we evaluate the app, the supporting website (if applicable) and the relevant 'app store' entry (for native apps).

Our reviewers will also at the time of the review do a general 'google' search of the relevant product to check for any related information such as references to Clinical Trials or Studies. These are the review sources("Review Sources") and only information that is available publicly through these sources is considered in the review.

Sometimes the evidence we are seeking in the review does exist but has not been made available to end users. We do not believe that this is appropriate for the types of information we assess and will only take into account information that can be freely accessed by end users.

APP NAME

DEVELOPER

APP VERSION PLATFORM

DATE REVIEWED

Scene Setters

The OBR begins with a series of questions to capture an app>s core purpose and functionality. These include the type of data the app collects and the apps primary functions and features. None of our scene setter questions have any scoring implications and are purely to decide on the line of enquiry further in the review.

Data Collection Assessment

We evaluate the app and and the privacy policy to answer our review questions regarding data collection and usage. The answers to these questions have no scoring implications but alter the line of enquiry for the review. For example, if we did not find that the app collects user data, none of the user data compliance questions will be asked.

Question I.D.

ORC_DT10

From our review, we found that the app collects the following user data:

- Mobile Number / Device Number / Home Phone Number
- Full Address/Postcode
- Age / DOB
- Location Data
- General Wellness Data
- Physical Description
- Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements)
- Usage Data
- Card/Payment/Financial Information
- Physical and/or Mental Health Data
- Gender (self-declared or observed)
- Other Online Identifiers

ORC_DT11

The app makes use of cookies to collect user data.

ORC_DT14

Users are required to, or have the option to sign up or register before they can use the app.

ORC_DT12

We found that the following cookies are used:

- Unclear

ORC_DC01

We found that user data is collected in the following ways:

- measurement capability in the device (eg. automatic GPS, motion, microphone, camera)
- other apps
- other third party sources
- from device storage
- automatically generated by the app

Data Sharing

We evaluate the app and and the privacy policy to answer our review questions regarding data sharing.

Question I.D.

ORC_DS01

We found that the app can still be used if the user prevents the use of cookies.

ORC_DS02	We found that disabling cookies impacts the use of the app for the user.
ORC_DS03	We found that data is, or can be shared/ exported from the app (this excludes cookie data)
ORC_DS04	We found that the user can choose to manually share their data from the app.
ORC_DS09	We found that non-cookie data is shared automatically, as soon as the app is downloaded, based only on agreement to relevant T&Cs or Privacy Policy.
ORC_DS10	We found that user data is automatically shared with: - Third Parties (Google Fit, Facebook)
Functional Assessment	We examine the app, app store description and associated website (where appropriate) to carry out the functional assessment.
Algorithm/Al	
Question I.D.	
ORC_AI01	We found that the app utilises algorithms.
Information	
Question I.D.	
ORC_I01	We found that the app provides general information or guidance.
ORC_F08	We found that the app provides signposting to local or online services.
ORC_EF07	We found that the app provides information, resources, or activities to the public, patients or clinicians, either about a specific condition or general health and lifestyle.
Monitoring	
Question I.D.	
ORC_MN02	We found that the app utilises the recording of relevant data over time, for the user to access and review.
Notifications	
Question I.D.	
ORC_D29	We found that the app sends push notifications.
Forums and Contacts	
Question I.D.	

ORC_U19	We found that the app allows users to link with other app users.
ORC_EF10	We found that the app allows two-way communication, between citizens, patients or healthcare professionals.

 APP NAME
 DEVELOPER
 APP VERSION
 PLATFORM
 DATE REVIEWED

 LactApp Medical
 Lactapp Women Health
 11.9
 10S
 26/07/2022

Level

We have assessed your app to be:

Level 2

There are a wide array of different types of health and care Apps available with an equally wide array of functionality and sophistication. ORCHA believe that just because an App offers more complex functionality, it doesn't mean it is automatically better than a functionally simple App. Apps that for example simply provide information and guidance – similar to health 'leaflets' – can be very useful in certain circumstances and this isn't impacted by their relative functional simplicity.

In order to assess and score these Apps in a way that enables a fair comparison of like for like solutions, ORCHA has devised a Level system. These Levels (currently ranging between Level 1 - 4), are indicative of the area of focus an App has (wellbeing, general health or specific conditions) and the level of functional complexity and associated risk. The Levels are an important part of the ORCHA Baseline scoring system which adjusts between each Level to reflect a shifting prioritisation from the usability measures towards the professional assurance review domain (outlined below).

Level 1 Well-being / Utility	These apps are focused on either general well-being with a health focus or are utility apps used in a health context.
Level 2 General Health	These Apps are focused on general health.
Level 3 Condition Management	These Apps can be focused on general health or supporting specific health conditions.
Level 4 Regulated	These Apps can be focused on general health or specific conditions and contain advanced and complex features that are subject to formal regulation.

APP NAME LactApp Medica DEVELOPER

APP VERSION PLATFORM

DATE REVIEWED

Data & Privacy

Your Data Score:

79%

Prior to answering any questions in the Data & Privacy area of the review, the Scene Setters will have captured much of the practical information about the observed data capture and use.

There are no scoring implications of the Scene Setter questions. At this point, the review will have determined if any data is collected and retained, which data types are collected and shared, and how that data is used.

The OBR is particularly interested in whether the app collects personally identifiable data, or sensitive data, as well as cookies and device information data. It is to be noted that the OBR does consider cookies and IP address to be personally identifiable data. If the app does make use of cookies, the OBR will consider information also provided within the cookie policy(if available).

Also within the Scene Setters section, the OBR looks at what user data is shared, who it is shared with, how it is shared(either manually or automatically), and whether the user has control or choice over this. The OBR considers whether the app is able to connect to any third party apps, or external devices. If so, it is then considered whether the app offers the user any choice in connecting to other apps or devices. Data sharing to other apps or devices can be of benefit, providing the user has given explicit consent and has control over the sharing of their data.

The OBR looks into data use, data storage and transit, data standards and management and compliance with the General Data Protection Regulation 2018 (GDPR). The review looks into privacy information which is publicly available to the end user, contained within the privacy policy applicable to the health app. The following questions provide detail of what information is expected to be provided to the user in relation to the use of their data.

Privacy Policy

Initially, the OBR identifies the relevant privacy policy for the app, which is available to users through the app and/or the App Store or Play Store. The more transparent the privacy policy, the better. Ultimately, the privacy policy must clearly state that user data will not be used or shared with other parties, except as described in the privacy policy, or without express consent of the user. Ideally it will identify:

- what data is collected from the user and how
- if the user is informed of the developer's intentions with processing and sharing their data
- if the user's consent is obtained

The privacy policy should accurately reflect the data usage of the app. The reviewers will be able to note if any data is collected outside of what is detailed in the privacy policy. Additionally, the policy should inform users of the developer's intent to use their data for marketing purposes. If user data is shared for any other purposes other than basic use of the app, or legal obligations, then the OBR considers if the user is able to opt out of these activities.

Privacy Policy Results

ORC_DP03

We identified a privacy policy specifically for the app which is available for users via the App/Web App/Website.

ORC_DP03

The privacy policy was not made immediately available to the user upon first opening of the app.

ORC_DP04

We found that the Privacy Policy is made available to the user upon registration.

ORC_DP02

We found that the Privacy Policy is available externally via the app.

Deta Use ORC_D69 We found that the Privacy Policy fully informs the user of how they will collect user data. ORC_D13 We found that the Privacy Policy provides users with details on all purposes of processing their data. ORC_D38 We found that no user data is intended to be shared or processed for any purpose that has not been made cle to the user. ORC_D912 We found that informed consent is obtained separately from the user, for the purpose of marketing. ORC_D93 We could not find a statement explaining to the user how they can opt out of each of the processing activities of, and why. ORC_D94 We found that the privacy policy did not explain to the user which data processing scrivities they cannot opt or of, and why. ORC_D95 We found that the Privacy Policy informs the user that their data will not be shared without user consent. The key areas in this section are surrounding data storage and data transfer. The data privacy policy should inform the user of where their data is storad, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The ORR looks for specific and secure storage techniques, such as encryption or firewalls.During transit, it is preferable that data is protected using SSL encryption. Results ORC_D5T01 We found that the Privacy Policy details where data collected by the app is stored. ORC_D5T03 We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies. ORC_D7T07 We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies. If applicable to the app, the ORR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as 1SO 27001. The privacy policy with any recognised NHS Data Standards such as 1SO 27001. The privacy policy has the Data Standards such as 1SO 27001. The privacy policy has the Data Standards such as 1SO 27001. The privacy policy has the D		
Data Use DRC_DB9	ORC_DP05	☞ We found that the Privacy Policy is available via the relevant app store.
ORC_D89 Si We found that the Privacy Policy fully informs the user of how they will collect user data. ORC_D13 Si We found that the Privacy Policy provides users with details on all purposes of processing their data. ORC_D38 We found that no user data is intended to be shared or processed for any purpose that has not been made cle to the user. ORC_D912 We found that informed consent is obtained separately from the user, for the purpose of marketing. ORC_D93 We could not find a statement explaining to the user how they can opt out of each of the processing activities on the user. ORC_D94 We found that the privacy policy did not explain to the user which data processing activities they cannot opt or f, and why. ORC_D95 We found that the Privacy Policy informs the user that their data will not be shared without user consent. The key areas in this section are surrounding data storage and data transfer. The data privacy policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The OBR looks for specific and secure storage techniques, such as encryption or firewalls. During transit, it is preferable that data is protected using SSL encryption. Results ORC_D\$T03 Si We found that the Privacy Policy details where data collected by the app is stored. ORC_D\$T03 Si We found that the Privacy Policy details that user data is encrypted between the device and any external host storage. Deta Standards and Management If applicable to the app, the OBR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Tookit (DSFP), or any international Data Management Standards such as 150 27001. The privacy policy details that user data is an encrypted between the device and any external host storage.	ORC_DP07	■ We found the Privacy Policy to accurately reflect the developer's intentions for data collection.
ORC_D13	ORC_DP14	• We could not find that the Privacy Policy provides details of a named Data Protection Officer (DPO) for the app.
ORC_D13 We found that the Privacy Policy provides users with details on all purposes of processing their data. ORC_D38 We found that no user data is intended to be shared or processed for any purpose that has not been made cle to the user. ORC_D12 We found that informed consent is obtained separately from the user, for the purpose of marketing. ORC_D28 We could not find a statement explaining to the user how they can opt out of each of the processing activities or, and why. ORC_D19 We found that the privacy policy did not explain to the user which data processing activities they cannot opt or, and why. ORC_D16 We found that the Privacy Policy informs the user that their data will not be shared without user consent. Data Storage and Transit/Transfer The key areas in this section are surrounding data storage and data transfer. The data privacy policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The ORR looks for specific and secure storage techniques, such as encryption or firewalls. During transit, it is preferable that data is protected using SSL encryption. Results ORC_DST01 We found that the Privacy Policy details where data collected by the app is stored. ORC_DST03 We found that the Privacy Policy details that user data is encrypted between the device and any external host storage. Data Standards and Management If applicable to the app, the ORR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy polic should inform users of a data retention period, and a method for data destruction. The ORR als identifies whether the developer has a policy in place to deal with any data security breaches.	Data Use	
ORC_DP12	ORC_D69	■ We found that the Privacy Policy fully informs the user of how they will collect user data.
to the user. ORC_DP12	ORC_D13	■ We found that the Privacy Policy provides users with details on all purposes of processing their data.
ORC_DP13 • We found that the privacy policy did not explain to the user which data processing activities they cannot opt of, and why. ORC_DP16 • We found that the privacy policy informs the user that their data will not be shared without user consent. Data Storage and Transit/Transfer The key areas in this section are surrounding data storage and data transfer. The data privacy policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The ORR looks for specific and secure storage techniques, such as encryption or firewalls. During transit, it is preferable that data is protected using SSL encryption. Results ORC_DST01 • We found that the Privacy Policy details where data collected by the app is stored. ORC_DST03 • We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies. ORC_DT04 • We found that the Privacy Policy details that user data is encrypted between the device and any external host storage. Data Standards and Management If applicable to the app, the ORR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as 180 27001. The privacy policy should inform users of a data retention period, and a method for data destruction. The ORR als identifies whether the developer has a policy in place to deal with any data security breaches.	ORC_D38	• We found that no user data is intended to be shared or processed for any purpose that has not been made clear to the user.
ORC_D13	ORC_DP12	■ We found that informed consent is obtained separately from the user, for the purpose of marketing.
ORC_D16	ORC_D28	We could not find a statement explaining to the user how they can opt out of each of the processing activities.
Data Storage and Transit/Transfer The key areas in this section are surrounding data storage and data transfer. The data privacy policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The OBR looks for specific and secure storage techniques, such as encryption or firewalls. During transit, it is preferable that data is protected using SSL encryption. Results ORC_DST01 We found that the Privacy Policy details where data collected by the app is stored. ORC_DST03 We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies. ORC_DT07 We found that the Privacy Policy details that user data is encrypted between the device and any external host storage. Data Standards and Management If applicable to the app, the OBR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy polic should inform users of a data retention period, and a method for data destruction. The OBR als identifies whether the developer has a policy in place to deal with any data security breaches.	ORC_DP13	
policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The OBR looks for specific and secure storage techniques, such as encryption or firewalls. During transit, it is preferable that data is protected using SSL encryption. Results ORC_DST01 We found that the Privacy Policy details where data collected by the app is stored. ORC_DST03 We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies. ORC_D17 We found that the Privacy Policy details that user data is encrypted between the device and any external host storage. If applicable to the app, the OBR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy polic should inform users of a data retention period, and a method for data destruction. The OBR als identifies whether the developer has a policy in place to deal with any data security breaches.	ORC_D16	■ We found that the Privacy Policy informs the user that their data will not be shared without user consent.
ORC_DST01 We found that the Privacy Policy details where data collected by the app is stored. ORC_DST03 We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies. ORC_D17 We found that the Privacy Policy details that user data is encrypted between the device and any external host storage. Data Standards and Management If applicable to the app, the OBR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy polic should inform users of a data retention period, and a method for data destruction. The OBR als identifies whether the developer has a policy in place to deal with any data security breaches. Results	Data Storage and	policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The OBR looks for specific and secure storage techniques, such as encryption or firewalls. During
technologies. ORC_D17		■ We found that the Privacy Policy details where data collected by the app is stored.
Data Standards and Management If applicable to the app, the OBR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy polic should inform users of a data retention period, and a method for data destruction. The OBR als identifies whether the developer has a policy in place to deal with any data security breaches. Results	ORC_DST03	
with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy polic should inform users of a data retention period, and a method for data destruction. The OBR als identifies whether the developer has a policy in place to deal with any data security breaches. Results	ORC_D17	
	Data Standards a	with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy policy should inform users of a data retention period, and a method for data destruction. The OBR also
ORC_D19	Results	
	ORC_D19	■ We found that the Privacy Policy details the length of time which user data is retained.

ORC_D20

We found that the Privacy Policy details a method of data destruction for user data, following the expiration of the retention period.

ORC_D21

• We could not find a statement informing the user of a process for managing data confidentiality breaches, or informing users that they have the right to complain to their Local Supervisory Authority, or to the Information Commissioner's Office, should they suspect there has been a breach of data confidentiality.

GDPR

This review area focuses on the General Data Protection Regulation (GDPR), which in May 2018 came into force to replace the Data Protection Act 1998. The OBR is concerned that all apps, particularly those developed in the UK and the EU, are fully compliant with the GDPR. This means a clear and explicit statement of compliance, as well as confirming that the user is entitled to the 8 user rights, which are:

- the right to access
- the right to rectification
- the right to erasure
- the right to restrict processing
- the right to object to processing
- the right to data portability
- the right to withdraw consent
- the right to request that they are not subject to a decision based solely on automated processing, including profiling

The developer should also inform the user of how they can exercise these rights, and should commit to responding within a time frame of 2 months or less. Under the GDPR, the policy should outline the legal basis for collection of user data, and ensure that only minimal data is collected from the user. All question relating to GDPR will only be asked for apps that collect and process personal and/or sensitive data.

Results

ORC_D23	☑ We found the app to be compliant with GDPR 2018.
ORC_D60	■ We found that the user is informed of the legal basis for which data is collected from them.
ORC_DPR03	■ We found that the developer intends to ensure that data minimisation principles are met.
ORC_D61	• We could not find a statement outlining that, should the purpose of data collection change, the user will be informed and consent re-obtained (if consent was the lawful basis).
ORC_DPR01	We found that users are clearly informed of their rights with regards to their data, which they are entitled to expect under GDPR.
ORC_D93	■ We found that users are clearly informed of their right to request that their personal data is deleted.
ORC_D25	■ We found that users are clearly informed of their right to access their personal data.
ORC_D56	☑ We found that users are clearly informed of their right to rectify their personal data.
ORC_D81	■ We found that users are clearly informed of their right to restrict the user of their personal data.
ORC_D57	■ We found that users are clearly informed of their right to object to the processing of their personal data.
ORC_D59	

ORC_D58	
ORC_DPR02	• We could not find a statement which clearly informs users of their right to request that they are not subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.
ORC_D82	☑ We found that users are clearly informed of contact details for the developer, relating to how they can exercise their rights.
ORC_D83	☑ We found that users are clearly informed of a suitable time frame in which the developer will respond to any requests to exercise their rights.
Other Data Questions	This section looks into children's data use (if applicable), and if a user can report knowledge of a child accessing the app without parental consent. The transparency of the privacy policy should extend to inform the user that any links to third party websites or apps are not covered by the developer's privacy policy, and users should make themselves aware of such third party policies. The privacy policy should contain contact details, should the user wish to make further enquiries regarding their data. The OBR also awards additional value points if the app provides the user with an additional, optional layer of security to protect their data.
Results	
ORC_D99	We could not find a statement which clearly informs users of the use of cookies when first opening the app, to make individuals aware of automatic data sharing.
ORC_D100	We could not find evidence of users being required to confirm their acceptance of the use of cookies when first opening the app.
ORC_D84	We could not find a full cookies policy relating to the app, separate from the Terms of Service/ Privacy Policy.
ORC_DO01	We could not find a statement in the Privacy Policy detailing how users can report any knowledge of a child accessing the app and providing personal data, without parental consent.
ORC_D91	
ORC_D92	☑ We found that the user is informed of how they can make further enquiries about the company's Privacy Policy.
ORC_D06	The app does allow users to set their own sharing preferences, with or from other apps.
ORC_DO03	We could not find any additional, optional security measures for users to protect their data on the app, for example, set additional pass codes for access to the app, after accessing the device is unlocked
ORC_DO04	☑ We found that the app uses a verification/authentication model for the sign up/sign in process.

APP NAME

DEVELOPER

APP VERSION PLATFORM

DATE REVIEWED

Professional Assurance

Registration Requirements (jurisdiction dependent)

If the app requires registration with a relevant regulatory body, we look for evidence of this. For example, in the UK we examine if the app is registered with the General Pharmaceutical Council(GPhC) and Care Quality Commission(CQC).

Your Professional Assurance Score:

63%

Medical Devices

We first assess if the app is likely to be a medical device under the current guidance from the MDR (https://ec.europa.eu/growth/sectors/medical-devices_en). We then evaluate if the app displays the relevant CE mark.

If a Reviewer identifies that an app is likely to be a medical device under MDR, and the app does not display a CE mark, then the review is assigned to a Senior Reviewer for sign off. If the Senior Reviewer agrees that the app should be displaying a CE mark, the review will not appear on the ORCHA app library. However, the developer will be contacted and we welcome entering a discussion about medical device status.

It should be noted that whilst the V6 assessment has been developed with the forthcoming Medical Devices Regulations in mind, until such time as these Regulations come into force the OBR is calibrated to the existing MDD.

Results

ORC_MD11

 Our functional assessment found that the app is unlikely to qualify as a medical device under The Medical Device Directives, and therefore does not need a CE mark

Professional Backing

We look for evidence of an appropriate professional being involved in the app>s design and development, or if the app has been externally accredited. A relevant professional is deduced in the context of an app.For example, for a simple yoga app we would accept a qualified yoga instructor as a relevant professional, but for a complex clinical solution we would only accept a relevantly qualified clinician.

Results

ORC_PB01

☑ We found that there was a suitably qualified professional involved in the development of the app.

ORC_PB02

• The app does not appear to have been developed by a recognised or national health body.

ORC_PB03

We found evidence of an endorsement of the app by a relevant body.

ORC_PB04

• We could not find information showing that there are organisations using the app.

ORC_PB05	• We could not find information showing that the app has been positively evaluated or validated by a relevant healthcare professional.
ORC_PB06	■ We found that there is evidence that information within the app has been validated, or has been provided alongside reliable sources or references.
Safety/Risk Managem	The review assesses whether the information in the app will be updated frequently in line with up to date health research, and what that frequency may be. We also look for any safeguarding measures in communication functions of the app, if relevant.
Results	
ORC_AE13	❸ We found a statement explaining how users were protected when using peer-support or communication functions within the app.
ORC_S01	
ORC_S02	We could not find the risk management process for the app published for users to see.
ORC_S03	We could not find a statement explaining the risks associated with using the app.
ORC_S04	■ We found that the user is able to confirm their data input is accurate.
ORC_S05	We could not find a named Clinical Safety Officer for the app.

ESF Compliance

Your ORCHA ESF Tier:

Tier 2a

The first part of this section assesses which ESF Tier the app falls under, and is nonscoring. The second part of this section evaluates the available evidence for the app as described in the Evidence of Effectiveness section. Compliance with the ESF is determined by the app showing the appropriate evidence for it's tier.

For further information about the ORCHA adaptation of the NICE ESF, please refer to our website.

The app **did not** meet all the evidence criteria for its tier as per the ORCHA ESF guidelines.

APP NAME

LactApp Medical

DEVELOPER

APP VERSION 1.1.9

PLATFORM

26/07/2022

Usability and Accessibility

This section looks at the overall user experience, including usability and accessibility of the app. This includes catering for specific user needs, and providing adequate user support if necessary. To complete this section, our reviewers use all publicly available information. Usually, this consists of any supporting information on the website. Of course, our Reviewers will download and use the app to get a feel for the whole user experience.

Your Usability & Accessibility Score:

82%

Design and Development

The OBR considers the design and development of the app and whether it follows any recognised app design standards, such as WC3, WCAG 2.0 AA, WCAG 2.1 AA, ISO 9241, Apple HIG, or Android App Quality Guidelines. The review also considers whether there was any user involvement during the development of the app, or if any features were based on user feedback.

Results

ORC_DE01

• There was no evidence that the app is compliant with any recognised app design standards

ORC_DT01

We found a statement that user feedback was collected during design/ development.

Accessibility

Accessibility is important to consider, as the app should be accessible to all users regardless of their specific needs. The OBR considers whether the app is customisable to suit certain needs, such as poor sight or hearing impairments. If the app uses any specialist or medical terms, these should be clearly explained to the user.

Results

ORC_U04

During our review, the user could not change the font size.

ORC_U07

During our review, we found that the app did support users with poor sight.

ORC_U08

During our review, we found that the app did support users with hearing difficulty.

Usability

The Usability of the app includes further customisation options. The review identifies if the app has any functions to aid navigation, such as a home, back, help or search features. If the app utilises push or email notifications, the review identifies whether the user has options to manage these for their own preference or privacy. If the app contains a forum, then the OBR looks for a statement to ensure that forum content is moderated. Finally, if there are any bugs identified during review, this will be flagged.

Results

ORC_U06

f arphi During our review, we found that the user could change the presentation theme.

ORC_U32	▼ The app included the following functions:			
	- Help/About button			
	- Search button			
ORC_U15	☑ We found that specialist terms within the app were explained clearly to the user.			
ORC_D31	We could not find a function to control notification settings within the app for convenience/ privacy.			
ORC_D32	☑ We found that the user was informed how to manage notification settings.			
Support	It is important that users are informed of ways in which they can contact the developer should they have any problems or questions with the app. This is one of the key changes for V6 in the Usability section. The OBR now also asks what type of support is offered to users, and if there is a commitment from the developer to respond to any user queries. We would expect to see the type of support offered is appropriate to the app level - a higher level app would therefore require a more sophisticated offer of user support.			
Results				
ORC_U33	 ♂ The app offered the following support: - eTicket 			
ORC_U25	☑ We found evidence that the app developers are committed to providing a response to user support issues.			
User Experience Data	The final section of this review area covers user experience data, and would require clear and specific examples of publication, or sharing of user data.			
Results				
ORC_UX01	We could not find any publicly available unedited User Feedback Data about the app.			
ORC_UX02	We could not find any publicly available unedited User Usage Data about the app.			

 APP NAME
 DEVELOPER
 APP VERSION
 PLATFORM
 DATE REVIEWED

 LactApp Medical
 Lactapp Women Health
 1.1.9
 iOS
 26/07/2022

Further Information

Review Process and Controls

The OBR is both an assessment framework and an assessment process. The process side of the equation is crucial to ensuring that the overall Review can be undertaken effectively and efficiently. With over 6 years of experience the OBR processes and associated controls have evolved to ensure speed and accuracy can both be achieved.

The OBR is undertaken by one of ORCHA's Professional full time Reviewers who are trained specifically on all aspects of Digital Health assessment and the Standards that underpin this.

The Reviewer undertaking an OBR will download or access the relevant app and explore all of its features. They will then familiarise themselves with the other applicable Review Sources and then commence the assessment.

The OBR assessment is managed through the ORCHA Review Engine which is an online platform that hosts all our ORCHA and Client Reviews. The Review Engine will manage the workflow of the Review and also houses the crucial question and scoring logic that dynamically adjusts the Review in response to the inputs from the Reviewer. This element of the process ensures that the Reviewer answers all required and relevant questions, but is not required to answer irrelevant questions. Upon completion the principle Reviewer will mark the Review as Ready for Sign - Off.

Each Review is signed off by a second Reviewer and for higher Level apps(see above), this sign - off process is always undertaken by a Senior Reviewer. The SignOff process requires the second Reviewer to check specific aspects of the original Review and the scale of these checks is automatically increased the higher the Level of the app.

In addition to the Sign-Off process, spot checks are also undertaken at regular intervals on specific Reviews by the Senior Review Team and the ORCHA Subject Matter Experts.

Additionally, the Review team habitually undertake a Calibration Review exercise which entails all Reviewers assessing a specific app and comparing results to ensure all Reviewers are interpreting evidence in the same way.

When a Sign-Off is completed, the relevant Review enters the Publication Process. This involves a 10 Day cooling off period where the Review is only made available to the relevant app Developer. This is done via an email notification which enables the relevant Developer to access a Pre-View of the Review before it goes 'live' on all relevant ORCHA supported Platforms.

Finally, we have a feedback mechanism on all ORCHA supported platforms for end users (professional and none professional) to alert us to any inaccuracies or errors that they believe maybe present in the Review or more broadly any wider concerns or risks they have identified in using the app. We will respond to and look to resolve all such queries within a 7 day point.

We believe that this combination of process controls, checks and feedback loops minimises the risks of inaccuracies in the Review itself.

OBR Scoring

The ORCHA Score aims to deliver a meritocratic evaluation with all Apps being treated equally and fairly irrespective of their current popularity or the financial position of their Developers. The primary mechanism is a 'tariff' based model which is described below. This has evolved over many iterations of the OBR and through many interactions with Developers, Health and Care Professionals and the wider expert community.

The aim of the scoring is ultimately reward best practice and highlight poor practice and none compliance. The mechanisms used are designed to ensure that wherever possible the score reflects relative performance and properly differentiates between similar apps.

ORCHA's Line of Compliance is 65%. Any score below 65% would indicate that an App has some issues that users should investigate further prior to using this App. Scores below 45% indicate that an App has considerable issues or challenges and in its current form is potentially unhelpful or unsafe.

Whilst a high scoring App is not guaranteed to be effective or safe or a poorly scoring App is not necessarily ineffective or unsafe, it does mean that the relevant Developer has taken more or less care over the Apps compliance with these key Standards than other similar Apps. In the critical area of health and care, we believe that developers should take compliance with Standards extremely seriously. No matter how good the user experience of an App might be, if the App is not safe and robust or its treatment of often sensitive health data is not clear and correct, it should be treated with caution.

ORCHA are not promoting or recommending any particular Apps through this process but are providing impartial information about an Apps compliance with standards and a mechanism for end users to easily identify those Apps that best meet those standards and to check which ones

Value and Risk Points

The data collected during the OBR – which are detailed in the individual review domain sections below – is either classed as 'scoring' or 'none scoring' data. The scoring elements are used to derive a series of 'section scores' which combine to create an overall ORCHA score. Some scoring questions earn positive ('value') points and some earn negative ('risk') points. Each scoring question has either a Risk implication or a Value implication. The quantum of the Risk or Value implication is decided by the relevant tariff:

- Risk area tariffs range from small, medium, high or exceptionally high.
- Value area tariffs range from small, medium or high.
- In addition to the base Tariff, some Risk and Value related questions attract a ratchet that will increase the relevant Tariff based on certain related app characteristics.

The following table sets out the actual numeric value of each Tariff:

For Example:

In the Data Section, the impact of failure to comply with key standards is increased through a Tariff ratchet depending on the nature of the Data captured, i.e. personal data, sensitive data etc. A similar ratchet applies in the Professional Assurance section in relation to an App>s compliance with the NICE Evidence Standards Framework. The ratchet here is driven by the ORCHA App Level and increased the Risk Points associated with failure to comply with this framework as the Level of the App increases.

The Tariff based approach is used consistently through all the sections but there are some specific adjustments to the basic model in the Data and Professional and Clinical Assurance sections.

Fundamentals

In addition to the value and risk scoring mechanism, we also utilise "fundamental" requirements in the professional assurance section. If an app does not adhere to a legal requirement (not just best practice or international standard) we give it a professional assurance score of 0, regardless of what the answers are for the rest of the professional assurance section. We also do not showcase any app which has failed "fundamentals" on any of our app libraries. This only comes into effect when an app is required to adhere to these standards (this is determined by the scene setter questions).

Section Scoring

- The baseline score is set at 65% in all sections. This means that if an App does not attract any Risk Points its risk score will equate to 0 which is the equivalent of 65%. If the same App also achieved no Value Points its Value score would be 0 which also equates to 65%.
- If an app attracts Risk Points the total Risk Points will be converted into a % the total possible Risk Points in a given section and this will be the % of the Risk % (65%) that the score will be reduced.
- If an app attracts Value Points the total Value Points will be converted into a % of the total possible Value Points that that app can achieve and this will be the % of the Value % (35%) that the score will be increased by.
- The total Risk accrued is combined with the total Value earned to achieve an overall Section Score.

For Example:

If the total possible Risk Points in a section is 100 and an app accrues 50 of these, it will attract 50% of the risk i.e. 50% of the 65% equivalent to 32.5% If the total possible Value Points in a section is 100 but the app in question could only ever achieve 80 of these points (due to its characteristics) then this is the total achievable Value Points. If the app actually achieves 40 of these then it will earn 50% of the available Value i.e. 50% of 35% equivalent to 17.25% Combining the Risk and Value we end up with a Section Score of 32.5% + 17.25% = 49.75%

Note:

It is worth noting the distinction between the approach to calculating Risk which is always based on the total available Risk in that section being the numerator and the actual Risk being the denominator. In the Value calculation however the numerator is not automatically the total available Value in a section but the total Value that any given app could achieve.

The rational for this distinction is that in the Risk arena, all the available Risks are theoretically possible for all apps and apps either mitigate or eliminate these risks by design or by relevant compliance action. In the Value arena there are many Value elements that an app simply could not achieve because of the nature of the app and therefore it is right that only the Value Points that are achievable should be factored in.

Get in Touch

Telephone:

+44 (0) 1925 606 542

Email:

reviews@orcha.co.uk

Website

www.orcha.co.uk

Main Office:

Sci-tech Daresbury Vanguard House Keckwick Lane Daresbury WA4 4AB





APP NAME
LactApp Medical
DEVELOPER
LactApp Women Health

APP VERSION 1.0.22 DATE REVIEWED 26/07/2022 PLATFORM Android

Overview

We have reviewed your app and found the following results:

Baseline Review Score:	Data Score:	Professional Assurance Score:
74%	79%	63%
Usability/ Accessibility Score:	Level:	ORCHA ESF Tier:
81%	Level 2	Tier 2a
App Categories: Breast feeding, Clinical Reference, Maternity, Educational, Information, Clinical tools	_	
Reviewer Notes	No notes	
Functional Characteristics	During our review, we carr	y out a functional assessment to generate the functional
	characteristics. These fun- selecting an app which is	ctional characteristics assist users/ health care professionals in
		t also dynamically changes the lines of enquiry that ORCHA e review, again to ensure that the assessment is as tailored as
	possible to the particular a	app type. This allows the review to capture an indication of how the
		Ill users to tailor their searches appropriately to find apps that actually nt or need support around.
	We have evaluated your a	op to hold the following characteristics:
	es user data.	Data Sharing - The App allows you to share information in the App with others or other Apps/Systems
Data Capture - The App capture		
Data Capture - The App capture Health Monitoring - The App pro allow users to monitor their con- simple recording of relevant dat	ditions, this may involve	Information Provision - The App provides general information.

Further App Characteristics User Data Collection We also examine what user data your app collects. From our review we evaluated your app to Sensitive Medical Device We also evaluate if an app is likely to be a medical device. We found that your app is: Unlikely to be a medical device ORCHA ESF Tier We have adapted the NICE Evidence Standards Framework for evaluation within our review. We Tier 2a utilise our functional assessment to generate the ESF Tier and then evaluate against the required evidence for that tier. Designed For We have also assessed your app against which age group or population it is intended for. The ORCHA designed for categories are: Everyone No limit on who can use the app Adult 18 Years Old + Child 5-9 Years Old 13-18 Years Old Teen 10-12 Years Old Pre-Teen Infant 0-4 Years Old Health Care Professional (HCP) App is Designed for clinician or relevant health care professional Patient App can only be used if a patient is linked with a HCP Research Participant For people taking part in research or a clinical trial Career For the use of a carer Health Care Administrator For this use of a health care administrator e.g. scheduling apps We have assessed your app as being designed for: Clinicians

Therefore users will be able to filter by this when searching for relevant apps.

Result Statements

The OBR score, categorisation, functional characteristics and some select review points are displayed to users of our ORCHA app libraries. However, a full breakdown of exactly how we evaluated your app can be found below with the question code and "result statement". You will be able to see exactly what we have found and given credit for (denoted with a 'tick') and advice as to how you could improve your score where we could not find the relevant criteria(denoted with an 'exclamation point'). For the results to our 'Scene Setters' section, we have not included a 'tick' or 'exclamation point' as these are all none scoring. Once an app has been updated and a new version released, it will automatically be placed in our queue for a "re - review" and will undergo the assessment again. This will capture any changes made by the developer.

A full list of the OBR questions can be found in our Version 6 OBR documentation on our website(www.orcha.co.uk).

Review Sources

For our review we evaluate the app, the supporting website (if applicable) and the relevant 'app store' entry (for native apps).

Our reviewers will also at the time of the review do a general 'google' search of the relevant product to check for any related information such as references to Clinical Trials or Studies.

These are the review sources("Review Sources") and only information that is available publicly through these sources is considered in the review.

Sometimes the evidence we are seeking in the review does exist but has not been made available to end users. We do not believe that this is appropriate for the types of information we assess and will only take into account information that can be freely accessed by end users.

APP NAME DEVELOPER APP VERSION PLATFORM DATE REVIEWED

Scene Setters

The OBR begins with a series of questions to capture an appys core purpose and functionality. These include the type of data the app collects and the apps primary functions and features. None of our scene setter questions have any scoring implications and are purely to decide on the line of enquiry further in the review.

Data Collection Assessment

We evaluate the app and and the privacy policy to answer our review questions regarding data collection and usage. The answers to these questions have no scoring implications but alter the line of enquiry for the review. For example, if we did not find that the app collects user data, none of the user data compliance questions will be asked.

Question I.D.

ORC_DT10

From our review, we found that the app collects the following user data:

- Mobile Number / Device Number / Home Phone Number
- Emai
- Full Address/Postcode
- Age / DOB
- Location Data
- General Wellness Data
- Physical Description
- Cookies / Web Beacons etc. (used for tracking an individuals online browsing behaviours/movements)
- Usage Data
- Physical and/or Mental Health Data
- Gender (self-declared or observed)
- Other Online Identifiers

ORC_DT11 The app makes use of cookies to collect user data.

ORC_DT14 Users are required to, or have the option to sign up or register before they can use the app.

ORC_DT12 We found that the following cookies are used:

- Unclear

ORC_DC01

We found that user data is collected in the following ways:

- measurement capability in the device (eg. automatic GPS, motion, microphone, camera)
- other apps
- other third party sources
- from device storage
- automatically generated by the app

Data Sharing

We evaluate the app and and the privacy policy to answer our review questions regarding data sharing.

Question I.D.

ORC_DS01

We found that the app can still be used if the user prevents the use of cookies.

ORC_DS02

We found that disabling cookies impacts the use of the app for the user. $\label{eq:cookies} % \begin{center} \begin{center}$

ORC_DS03	We found that data is, or can be shared/ exported from the app (this excludes cookie data)
ORC_DS04	We found that the user can choose to manually share their data from the app.
ORC_DS09	We found that non-cookie data is shared automatically, as soon as the app is downloaded, based only on agreement to relevant T&Cs or Privacy Policy.
ORC_DS10	We found that user data is automatically shared with: - Third Parties (Google Fit, Facebook)
Functional Assessmen	We examine the app, app store description and associated website (where appropriate) to carry out the functional assessment.
Algorithm/Al Question I.D.	
ORC_AI01	We found that the app utilises algorithms.
Information Question I.D.	
ORC_I01	We found that the app provides general information or guidance.
ORC_F08	We found that the app provides signposting to local or online services.
ORC_EF07	We found that the app provides information, resources, or activities to the public, patients or clinicians, either about a specific condition or general health and lifestyle.
Monitoring Question I.D.	
ORC_MN02	We found that the app utilises the recording of relevant data over time, for the user to access and review.
Notifications Question I.D.	
ORC_D29	We found that the app sends push notifications.
Forums and Contacts Question I.D.	
ORC_U19	We found that the app allows users to link with other app users.
ORC_EF10	We found that the app allows two-way communication, between citizens, patients or healthcare professionals.

APP NAME DEVELOPER LactApp Medical

APP VERSION PLATFORM DATE REVIEWED 1.0.22

26/07/2022

Level

We have assessed your app to be:

Level 2

Level 4 Regulated

There are a wide array of different types of health and care Apps available with an equally wide array of functionality and sophistication. ORCHA believe that just because an App offers more complex functionality, it doesn't mean it is automatically better than a functionally simple App. Apps that for example simply provide information and guidance - similar to health 'leaflets' - canbe very useful in certain circumstances and this isn't impacted by their relative functional simplicity.

In order to assess and score these Apps in a way that enables a fair comparison of like for like solutions, ORCHA has devised a Level system. These Levels (currently ranging between Level 1 -4), are indicative of the area of focus an App has(wellbeing, general health or specific conditions) and the level of functional complexity and associated risk. The Levels are an important part of the ORCHA Baseline scoring system which adjusts between each Level to reflect a shifting prioritisation from the usability measures towards the professional assurance review domain(outlined below).

Level 1 Well-being / Utility These apps are focused on either general well-being with a health focus or are utility apps used in a health context. Level 2 General Health These Apps are focused on general health.

Level 3 Condition Management These Apps can be focused on general health or supporting specific health conditions.

> These Apps can be focused on general health or specific conditions and contain advanced and complex features that are subject to formal regulation.

APP NAME

LactApp Medica

DEVELOPER

APP VERSION PLATFORM DATE REVIEWED

Data & Privacy

Your Data Score: 79%

Prior to answering any guestions in the Data & Privacy area of the review, the Scene Setters will have captured much of the practical information about the observed data capture and use. There are no scoring implications of the Scene Setter questions. At this point, the review will have determined if any data is collected and retained, which data types are collected and shared, and how that data is used.

The OBR is particularly interested in whether the app collects personally identifiable data, or sensitive data, as well as cookies and device information data. It is to be noted that the OBR does consider cookies and IP address to be personally identifiable data if the app does make use of cookies, the OBR will consider information also provided within the cookie policy(if available).

Also within the Scene Setters section, the OBR looks at what user data is shared, who it is shared with, how it is shared(either manually or automatically), and whether the user has control or choice over this. The OBR considers whether the app is able to connect to any third party apps, or external devices. If so, it is then considered whether the app offers the user any choice in connecting to other apps or devices. Data sharing to other apps or devices can be of benefit, providing the user has given explicit consent and has control over the sharing of their data.

The OBR looks into data use, data storage and transit, data standards and management and compliance with the General Data Protection Regulation 2018 (GDPR). The review looks into privacy information which is publicly available to the end user, contained within the privacy policy applicable to the health app. The following questions provide detail of what information is expected to be provided to the user in relation to the use of their data.

Privacy Policy

Initially, the OBR identifies the relevant privacy policy for the app, which is available to users through the app and/or the App Store or Play Store. The more transparent the privacy policy, the better. Ultimately, the privacy policy must clearly state that user data will not be used or shared with other parties, except as described in the privacy policy, or without express consent of the user. Ideally it will identify:

- what data is collected from the user and how
- if the user is informed of the developer's intentions with processing and sharing their data
- if the user's consent is obtained

The privacy policy should accurately reflect the data usage of the app. The reviewers will be able to note if any data is collected outside of what is detailed in the privacy policy. Additionally, the policy should inform users of the developer's intent to use their data for marketing purposes. If user data is shared for any other purposes other than basic use of the app, or legal obligations, then the OBR considers if the user is able to opt out of these activities.

Privacy Policy Results

ORC_D39a	
ORC_DP03	The privacy policy was not made immediately available to the user upon first opening of the app.
ORC_DP04	
ORC_DP02	

ORC_DP05	❸ We found that the Privacy Policy is available via the relevant app store.
ORC_DP07	■ We found the Privacy Policy to accurately reflect the developer's intentions for data collection.
ORC_DP14	• We could not find that the Privacy Policy provides details of a named Data Protection Officer (DPO) for the app.
Data Use	
ORC_D69	■ We found that the Privacy Policy fully informs the user of how they will collect user data.
ORC_D13	■ We found that the Privacy Policy provides users with details on all purposes of processing their data.
ORC_D38	• We found that no user data is intended to be shared or processed for any purpose that has not been made clear to the user.
ORC_DP12	■ We found that informed consent is obtained separately from the user, for the purpose of marketing.
ORC_D28	We could not find a statement explaining to the user how they can opt out of each of the processing activities.
ORC_DP13	• We found that the privacy policy did not explain to the user which data processing activities they cannot opt out of, and why.
ORC_D16	
Data Storage and	Transit/Transfer The key areas in this section are surrounding data storage and data transfer. The data privacy policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The OBR looks for specific and secure storage techniques, such as encryption or firewalls. During transit, it is preferable that data is protected using SSL encryption.
Results ORC_DST01	■ We found that the Privacy Policy details where data collected by the app is stored.
ORC_DST03	We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies.
ORC_D17	■ We found that the Privacy Policy details that user data is encrypted between the device and any external host storage.
Data Standards a	If applicable to the app, the OBR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy policy should inform users of a data retention period, and a method for data destruction. The OBR also identifies whether the developer has a policy in place to deal with any data security breaches.
Results	
ORC_D19	

ORC_D20

 \mathbf{G} We found that the Privacy Policy details a method of data destruction for user data, following the expiration of the retention period.

ORC_D21

• We could not find a statement informing the user of a process for managing data confidentiality breaches, or informing users that they have the right to complain to their Local Supervisory Authority, or to the Information Commissioner's Office, should they suspect there has been a breach of data confidentiality.

GDPR

This review area focuses on the General Data Protection Regulation (GDPR), which in May 2018 came into force to replace the Data Protection Act 1998. The OBR is concerned that all apps, particularly those developed in the UK and the EU, are fully compliant with the GDPR. This means a clear and explicit statement of compliance, as well as confirming that the user is entitled to the 8 user rights, which are:

- the right to access
- the right to rectification
- the right to erasure
- the right to restrict processing
- the right to object to processing
- the right to data portability
- the right to withdraw consent
- the right to request that they are not subject to a decision based solely on automated processing, including profiling

The developer should also inform the user of how they can exercise these rights, and should commit to responding within a time frame of 2 months or less. Under the GDPR, the policy should outline the legal basis for collection of user data, and ensure that only minimal data is collected from the user. All question relating to GDPR will only be asked for apps that collect and process personal and/or sensitive data.

Results

ORC_D23	✓ We found the app to be compliant with GDPR 2018.
ORC_D60	✓ We found that the user is informed of the legal basis for which data is collected from them.
ORC_DPR03	✓ We found that the developer intends to ensure that data minimisation principles are met.
ORC_D61	• We could not find a statement outlining that, should the purpose of data collection change, the user will be informed and consent re-obtained (if consent was the lawful basis).
ORC_DPR01	☑ We found that users are clearly informed of their rights with regards to their data, which they are entitled to expect under GDPR.
ORC_D93	
ORC_D25	
ORC_D56	
ORC_D81	
ORC_D57	
ORC_D59	

ORC_D58	We found that users are clearly informed of their right to withdraw consent for the use of their personal data.
ORC_DPR02	• We could not find a statement which clearly informs users of their right to request that they are not subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.
ORC_D82	☑ We found that users are clearly informed of contact details for the developer, relating to how they can exercise their rights.
ORC_D83	We found that users are clearly informed of a suitable time frame in which the developer will respond to any requests to exercise their rights.
Other Data Questions	This section looks into children's data use (if applicable), and if a user can report knowledge of a child accessing the app without parental consent. The transparency of the privacy policy should extend to inform the user that any links to third party websites or apps are not covered by the developer's privacy policy, and users should make themselves aware of such third party policies. The privacy policy should contain contact details, should the user wish to make further enquiries regarding their data. The OBR also awards additional value points if the app provides the user with an additional, optional layer of security to protect their data.
Results	
ORC_D99	We could not find a statement which clearly informs users of the use of cookies when first opening the app, to make individuals aware of automatic data sharing.
ORC_D100	• We could not find evidence of users being required to confirm their acceptance of the use of cookies when first opening the app.
ORC_D84	We could not find a full cookies policy relating to the app, separate from the Terms of Service/ Privacy Policy.
ORC_DO01	We could not find a statement in the Privacy Policy detailing how users can report any knowledge of a child accessing the app and providing personal data, without parental consent.
ORC_D91	☑ We found that users are made aware that the developer's Privacy Policy no longer applies when following links to any third party websites.
ORC_D92	We found that the user is informed of how they can make further enquiries about the company's Privacy Policy.
ORC_D06	The app does allow users to set their own sharing preferences, with or from other apps.
ORC_DO03	We could not find any additional, optional security measures for users to protect their data on the app, for example, set additional pass codes for access to the app, after accessing the device is unlocked
ORC_DO04	☑ We found that the app uses a verification/authentication model for the sign up/sign in process.

APP NAME

DEVELOPER

APP VERSION PLATFORM

DATE REVIEWED

Professional Assurance

Registration Requirements (jurisdiction dependent)

If the app requires registration with a relevant regulatory body, we look for evidence of this. For example, in the UK we examine if the app is registered with the General Pharmaceutical Council(GPhC) and Care Quality Commission(CQC).

Your Professional Assurance Score:

63%

Medical Devices

We first assess if the app is likely to be a medical device under the current guidance from the MDR (https://ec.europa.eu/growth/sectors/medical-devices_en). We then evaluate if the app displays the relevant CE mark.

If a Reviewer identifies that an app is likely to be a medical device under MDR, and the app does not display a CE mark, then the review is assigned to a Senior Reviewer for sign off. If the Senior Reviewer agrees that the app should be displaying a CE mark, the review will not appear on the ORCHA app library. However, the developer will be contacted and we welcome entering a discussion about medical device status.

It should be noted that whilst the V6 assessment has been developed with the forthcoming Medical Devices Regulations in mind, until such time as these Regulations come into force the OBR is calibrated to the existing MDD.

ORC_MD11

• Our functional assessment found that the app is unlikely to qualify as a medical device under The Medical Device Directives, and therefore does not need a CE mark.

Professional Backing

We look for evidence of an appropriate professional being involved in the app>s design and development, or if the app has been externally accredited. A relevant professional is deduced in the context of an app. For example, for a simple yoga app we would accept a qualified yoga instructor as a relevant professional, but for a complex clinical solution we would only accept a relevantly qualified clinician.

Results

ORC_PB01

f arphi We found that there was a suitably qualified professional involved in the development of the app.

ORC_PB02

• The app does not appear to have been developed by a recognised or national health body.

ORC_PB03

 $oldsymbol{arphi}$ We found evidence of an endorsement of the app by a relevant body.

ORC_PB04

• We could not find information showing that there are organisations using the app.

ORC_PB05	We could not find information showing that the app has been positively evaluated or validated by a relevant
	healthcare professional.
ORC_PB06	We found that there is evidence that information within the app has been validated, or has been provided alongside reliable sources or references.
Safety/Risk Managerr	The review assesses whether the information in the app will be updated frequently in line with up to date health research, and what that frequency may be. We also look for any safeguarding measures in communication functions of the app, if relevant.
Results	
ORC_AE13	❸ We found a statement explaining how users were protected when using peer-support or communication functions within the app.
ORC_S01	■ We found a clear explanation of who should and who should not use the app.
ORC_S02	We could not find the risk management process for the app published for users to see.
ORC_S03	We could not find a statement explaining the risks associated with using the app.
ORC_S04	■ We found that the user is able to confirm their data input is accurate.
ORC_S05	We could not find a named Clinical Safety Officer for the app.

ESF Compliance

Your ORCHA ESF Tier:

Tier 2a

The first part of this section assesses which ESF Tier the app falls under, and is nonscoring. The second part of this section evaluates the available evidence for the app as described in the Evidence of Effectiveness section. Compliance with the ESF is determined by the app showing the appropriate evidence for it's tier.

For further information about the ORCHA adaptation of the NICE ESF, please refer to our website.

The app **did not** meet all the evidence criteria for its tier as per the ORCHA ESF guidelines.

APP NAME

LactApp Medical

DEVELOPER

LactApp Women Health

APP VERSION 1.0.22 PLATFORM

26/07/2022

Usability and Accessibility

This section looks at the overall user experience, including usability and accessibility of the app. This includes catering for specific user needs, and providing adequate user support if necessary. To complete this section, our reviewers use all publicly available information. Usually, this consists of any supporting information on the website. Of course, our Reviewers will download and use the app to get a feel for the whole user experience.

Your Usability & Accessibility Score:

81%

Design and Development

The OBR considers the design and development of the app and whether it follows any recognised app design standards, such as WC3, WCAG 2.0 AA, WCAG 2.1 AA, ISO 9241, Apple HIG, or Android App Quality Guidelines. The review also considers whether there was any user involvement during the development of the app, or if any features were based on user feedback.

Results

ORC_DE01

• There was no evidence that the app is compliant with any recognised app design standards

ORC_DT01

We found a statement that user feedback was collected during design/ development.

Accessibility

Accessibility is important to consider, as the app should be accessible to all users regardless of their specific needs. The OBR considers whether the app is customisable to suit certain needs, such as poor sight or hearing impairments. If the app uses any specialist or medical terms, these should be clearly explained to the user.

Results

ORC_U04

During our review, the user could not change the font size.

ORC_U07

During our review, we found that the app did support users with poor sight.

ORC_U08

During our review, we found that the app did support users with hearing difficulty.

Usability

The Usability of the app includes further customisation options. The review identifies if the app has any functions to aid navigation, such as a home, back, help or search features. If the app utilises push or email notifications, the review identifies whether the user has options to manage these for their own preference or privacy. If the app contains a forum, then the OBR looks for a statement to ensure that forum content is moderated. Finally, if there are any bugs identified during review, this will be flagged.

Results

ORC_U06

f arphi During our review, we found that the user could change the presentation theme.

ORC_U32	✓ The app included the following functions:- Help/About button
	- Search button
ORC_U15	
ORC_D31	We could not find a function to control notification settings within the app for convenience/ privacy.
ORC_D32	We found that the user was not informed how to manage notification settings.
Support	It is important that users are informed of ways in which they can contact the developer should they have any problems or questions with the app. This is one of the key changes for V6 in the Usability section. The OBR now also asks what type of support is offered to users, and if there is a commitment from the developer to respond to any user queries. We would expect to see the type of support offered is appropriate to the app level - a higher level app would therefore require a more sophisticated offer of user support.
Results	
ORC_U33	☑ The app offered the following support:- eTicket
ORC_U25	
User Experience Data	The final section of this review area covers user experience data, and would require clear and specific examples of publication, or sharing of user data.
Results	
ORC_UX01	We could not find any publicly available unedited User Feedback Data about the app.
ORC_UX02	We could not find any publicly available unedited User Usage Data about the app.

 APP NAME
 DEVELOPER
 APP VERSION
 PLATFORM
 DATE REVIEWED

 LactApp Medical
 LactApp Women Health
 10.22
 Android
 26/07/2022

Further Information

Review Process and Controls

The OBR is both an assessment framework and an assessment process. The process side of the equation is crucial to ensuring that the overall Review can be undertaken effectively and efficiently. With over 6 years of experience the OBR processes and associated controls have evolved to ensure speed and accuracy can both be achieved.

The OBR is undertaken by one of ORCHA's Professional full time Reviewers who are trained specifically on all aspects of Digital Health assessment and the Standards that undergin this.

The Reviewer undertaking an OBR will download or access the relevant app and explore all of its features. They will then familiarise themselves with the other applicable Review Sources and then commence the assessment.

The OBR assessment is managed through the ORCHA Review Engine which is an online platform that hosts all our ORCHA and Client Reviews. The Review Engine will manage the workflow of the Review and also houses the crucial question and scoring logic that dynamically adjusts the Review in response to the inputs from the Reviewer. This element of the process ensures that the Reviewer answers all required and relevant questions, but is not required to answer irrelevant questions. Upon completion the principle Reviewer will mark the Review as Ready for Sign - Off.

Each Review is signed off by a second Reviewer and for higher Level apps(see above), this sign - off process is always undertaken by a Senior Reviewer. The SignOff process requires the second Reviewer to check specific aspects of the original Review and the scale of these checks is automatically increased the higher the Level of the app.

In addition to the Sign-Off process, spot checks are also undertaken at regular intervals on specific Reviews by the Senior Review Team and the ORCHA Subject Matter Experts.

Additionally, the Review team habitually undertake a Calibration Review exercise which entails all Reviewers assessing a specific app and comparing results to ensure all Reviewers are interpreting evidence in the same way.

When a Sign-Off is completed, the relevant Review enters the Publication Process. This involves a 10 Day cooling off period where the Review is only made available to the relevant app Developer. This is done via an email notification which enables the relevant Developer to access a Pre-View of the Review before it goes 'live' on all relevant ORCHA supported Platforms.

Finally, we have a feedback mechanism on all ORCHA supported platforms for end users(professional and none professional) to alert us to any inaccuracies or errors that they believe maybe present in the Review or more broadly any wider concerns or risks they have identified in using the app. We will respond to and look to resolve all such queries within a 7 day period.

We believe that this combination of process controls, checks and feedback loops minimises the risks of inaccuracies in the Review itself.

OBR Scoring

The ORCHA Score aims to deliver a meritocratic evaluation with all Apps being treated equally and fairly irrespective of their current popularity or the financial position of their Developers. The primary mechanism is a 'tariff' based model which is described below. This has evolved over many iterations of the OBR and through many interactions with Developers, Health and Care Professionals and the wider expert community.

The aim of the scoring is ultimately reward best practice and highlight poor practice and none compliance. The mechanisms used are designed to ensure that wherever possible the score reflects relative performance and properly differentiates between similar apps.

ORCHA's Line of Compliance is 65%. Any score below 65% would indicate that an App has some issues that users should investigate further prior to using this App. Scores below 45% indicate that an App has considerable issues or challenges and in its current form is potentially unhelpful or unsafe.

Whilst a high scoring App is not guaranteed to be effective or safe or a poorly scoring App is not necessarily ineffective or unsafe, it does mean that the relevant Developer has taken more or less care over the Apps compliance with these key Standards than other similar Apps. In the critical area of health and care, we believe that developers should take compliance with Standards extremely seriously. No matter how good the user experience of an App might be, if the App is not safe and robust or its treatment of often sensitive health data is not clear and correct, it should be treated with caution.

ORCHA are not promoting or recommending any particular Apps through this process but are providing impartial information about an Apps compliance with standards and a mechanism for end users to easily identify those Apps that best meet those standards and to check which ones don't.

Value and Risk Points

The data collected during the OBR – which are detailed in the individual review domain sections below – is either classed as 'scoring' or 'none scoring' data. The scoring elements are used to derive a series of 'section scores' which combine to create an overall ORCHA score. Some scoring questions earn positive ('value') points and some earn negative ('risk') points. Each scoring question has either a Risk implication or a Value implication. The quantum of the Risk or Value implication is decided by the relevant tariff:

- Risk area tariffs range from small, medium, high or exceptionally high.
- Value area tariffs range from small, medium or high.
- In addition to the base Tariff, some Risk and Value related questions attract a ratchet that will increase the relevant Tariff based on certain related app characteristics.

The following table sets out the actual numeric value of each Tariff:

For Example:

In the Data Section, the impact of failure to comply with key standards is increased through a Tariff ratchet depending on the nature of the Data captured, i.e. personal data, sensitive data etc. A similar ratchet applies in the Professional Assurance section in relation to an App's compliance with the NICE Evidence Standards Framework. The ratchet here is driven by the ORCHA App Level and increased the Risk Points associated with failure to comply with this framework as the Level of the App increases.

The Tariff based approach is used consistently through all the sections but there are some specific adjustments to the basic model in the Data and Professional and Clinical Assurance sections.

Fundamentals

In addition to the value and risk scoring mechanism, we also utilise "fundamental" requirements in the professional assurance section. If an app does not adhere to a legal requirement (not just best practice or international standard) we give it a professional assurance score of 0, regardless of what the answers are for the rest of the professional assurance section. We also do not showcase any app which has failed "fundamentals" on any of our app libraries. This only comes into effect when an app is required to adhere to these standards(this is determined by the scene setter questions).

Section Scoring

- The baseline score is set at 65% in all sections. This means that if an App does not attract any Risk Points its risk score will equate to 0 which is the equivalent of 65%. If the same App also achieved no Value Points its Value score would be 0 which also equates to 65%.
- If an app attracts Risk Points the total Risk Points will be converted into a % the total possible Risk Points in a given section and this will be the % of the Risk % (65%) that the score will be reduced.
- If an app attracts Value Points the total Value Points will be converted into a % of the total possible Value Points that that app can achieve and this will be the % of the Value % (35%) that the score will be increased by.
- The total Risk accrued is combined with the total Value earned to achieve an overall Section Score.

For Example:

If the total possible Risk Points in a section is 100 and an app accrues 50 of these, it will attract 50% of the risk i.e. 50% of the 65% equivalent to 32.5% If the total possible Value Points in a section is 100 but the app in question could only ever achieve 80 of these points (due to its characteristics) then this is the total achievable Value Points. If the app actually achieves 40 of these then it will earn 50% of the available Value i.e. 50% of 35% equivalent to 17.25% Combining the Risk and Value we end up with a Section Score of 32.5% + 17.25% = 49.75%

Note:

It is worth noting the distinction between the approach to calculating Risk which is always based on the total available Risk in that section being the numerator and the actual Risk being the denominator. In the Value calculation however the numerator is not automatically the total available Value in a section but the total Value that any given app could achieve.

The rational for this distinction is that in the Risk arena, all the available Risks are theoretically possible for all apps and apps either mitigate or eliminate these risks by design or by relevant compliance action. In the Value arena there are many Value elements that an app simply could not achieve because of the nature of the app and therefore it is right that only the Value Points that are achievable should be factored in.

Get in Touch

Telephone:

+44 (0) 1925 606 542

Email

reviews@orcha.co.uk

Website:

www.orcha.co.uk

Main Office:

Sci-tech Daresbury Vanguard House Keckwick Lane Daresbury WA4 4AB
 APP NAME
 DEVELOPER
 APP VERSION
 PLATFORM
 DATE REVIEWE

 LactApp Medical
 LactApp Women Health
 10.22
 Android
 26/07/202

Full Assessment Report

The ORCHA Baseline Review

At ORCHA we seek out the most popular digital health solutions and review them for compliance and best practice. The majority of solutions we review are Apps (defined as a self-contained software program designed to fulfil a particular purpose, as downloaded by a user to a mobile device). We have extended our scope to also now include Web Apps and Progressive Web Apps (web-based software apps that are customised for a mobile platform, but that are run on a server and accessed via a web browser).

Our ORCHA Baseline Review(OBR) examines how apps comply with relevant regulation and follow best practice. We examine three domains through a set of object questions -Data Privacy, Professional Assurance and Usability/Accessibility. How your app performed in our assessment is shown below.

If you disagree with anyof this information please get in touch at with us at reviews@orcha.co.uk and we will be happy to discuss our answers and make edits if needed.

ORCHA Scoring System

The ORCHA score is designed to reward developers for best practice, and highlight poor practice and non-compliance. By following best practice, apps can earn "value points," and poor practice or non-compliance (where necessary) will earn "risk points." The score begins at a baseline of 65% and allows apps to go up or down in score depending on the answers to the questions.

To make the score fair across apps, not every question is asked of every app. For example if the app does not collect any user data, the questions around processing of user data will not be active in the review. We include functional "scene setter" questions at the beginning of the review to capture this.

We also weight the separate sections of the review differently based on the app level. We expect apps with higher levels of clinical functionality, for example one with diagnostic or treatment components to show a higher level of professional assurance than simple relaxation apps. Therefore we weight the section scores across levels.

 Level
 Privacy
 Assurance
 Accessibility

 Level 2
 30%
 40%
 30%

Please find a full explanation of our scoring mechanism in the "further information" section at the end of this report.