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CIÊNCIA DE DADOS DE SAÚDE

Attitudes and perceptions of clinicians and individuals toward digital mental health apps

Diogo Flor Dias Nogueira Leite

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FACULDADE DE MEDICINA
UNIVERSIDADE DO PORTO

Attitudes and perceptions of clinicians and individuals toward digital mental health apps

By

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Supervised by

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Title

Attitudes and perceptions of clinicians and individuals toward digital mental health apps

Candidate

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Supervisor:

Professor Ricardo João Cruz Correia, Ph.D.

To those who always believed in me, you had more faith than St. Thomas.
To those who never believed in me, thank you for making me prove you wrong.
To my defeats, thank you for teaching me.
To my victories, the best is yet to come.

Biographical Note

Diogo Flor Dias Nogueira Leite was born in Lisbon on July 31, 1990.

He holds a B.Sc. in Economics (2008) and an M.Sc. in Finance (2013) from the NOVA School of Business and Economics (NOVA SBE), New University of Lisbon. He also holds a Master's in International Management (2014) degree from the CEMS Alliance, awarded by the NOVA SBE and the Warsaw School of Economics. Diogo also completed post-graduate courses in Healthcare Management (CLSBE, 2018) and Law and Economics of Health and Medicines (FDUL, 2021).

Diogo has had relevant experiences in the private and public sectors and academia. After several Marketing positions in Henkel and Microsoft between 2014 and 2015, Diogo was invited to serve his country as an Economic Technical Expert in the Cabinet of the Secretary of State of the Presidency of the Council of Ministers (2015-16), an opportunity he feels grateful for until today.

He left this function in September 2016 to pursue his passion for academia and joined what is today NOVA Health and Economics Knowledge Center (NHEM KC). Diogo remains a researcher of NHEM KC to this day. Diogo proudly served under then Vice-Rector Pedro Pita Barros and Rector António Rendas of the New University of Lisbon as a Project Manager for NOVAhealth between February and November 2017 and worked as a Senior Consultant in EY's Advisory practice for Health and Public Sector between December 2017 and April 2018.

After enrolling in a Ph.D. in Economics at the University of Surrey in September 2018, Diogo left that program in October 2018 to join the Cabinet of the Secretary of State for Administrative Modernization as an Economic Technical Expert. Diogo devoted his efforts to this task until August 2019, when he was invited to join the Member of the European Parliament Maria Manuel Leitão Marques team. His responsibilities as an Accredited Parliamentary Assistant on digital and research and innovation policies, along with the breadth of stakeholders he engaged with in the Brussels scene, put Diogo in contact with the power of data and their potential uses in health.

Diogo's first encounter with HEADS – and, funnily enough, with his supervisor-to-be – occurred in January 2020, shortly after the COVID-19 pandemic had started. In September 2020, Diogo returned to Portugal from Belgium and left his position in the

European Parliament to dedicate himself to pursuing HEADS. This was the beginning of a long story that this document concludes.

During his curricular year, which coincided with Portugal's Presidency of the Council of the European Union (PPEU '21), Diogo was invited by the President of INFARMED, I.P. (the national regulatory authority on medicines and medical devices) to be his Executive Assistant. Diogo had an active role in shaping the country's response to the pandemic and supporting the activities of INFARMED under PPEU '21, many of which were at the intersection of digital, health, and economics.

Diogo lived in Porto between January 2022 and January 2023 working as a Research Assistant in "CR-Digital: Digitalizar a investigação clínica no Norte de Portugal" (NORTE-01-0145-FEDER-083448). This project envisaged digitizing clinical research in the North of Portugal by allowing the sharing of data for performing clinical trials between the Academic Clinical Centers of Braga and Porto, and Diogo was his Project Management Officer. Diogo's involvement with MEDCIDS – Department of Community Medicine, Information, and Decision in Health deepened during this period.

Finally, Diogo was invited to serve his country once more in the Cabinet of the Secretary of State for Digitalization and Administrative Modernization of the Portuguese Republic's XXIII Government, Mário Campolargo, where he started to work on February 13, 2023.

Throughout his career so far, Diogo has served on the boards and has been an active member of several non-profit organizations, namely Fundação Cardeal Cerejeira (a charitable foundation dedicated to the elderly), e-MAIS (Portuguese Health Information Systems Association), and APES (Portuguese Association of Health Economics).

Diogo has presented his research at national (National Conference of Health Economics '21 and '23) and international (AIME '21; CHASM '22) conferences and lectured several post-graduate courses on topics related to Health Data Science, Economics, and Finance. His success in delivering high-impact research is proved by his publications and their scientific and mediatic relevance, aiming to impact decisions on investment priorities.

Acknowledgments

Now comes the sweet part... One where one feels tempted to forget all the pain, all the long hours and sleepless nights, the permanent existential restlessness, and the infinite number of hours of self-doubt and “keep on moving” moments devoted to completing such a monumental endeavor as a doctoral thesis is. Whoever dismisses this either did not experience the best and worst of this process or took the easy road. Either way, I feel entitled to start this section by acknowledging that it feels humbling and inspiring to say this: I did it!

Nevertheless, no man is an island, or so the poem goes. And this particular man feels proud to say that he could count on many people to help him through it all. I cannot list them all as they would be extensive so that I will keep to the essentials. Apologies in advance!

Let’s start with the ‘bosses’: **Maria Manuel Leitão Marques**, the first Minister I met and worked with, who dared me to conclude my Ph.D. in 3 years (btw, MM: I did it). I became fascinated with the potential of health data science while working with her, and probably would not have started it otherwise. **Rui Santos Ivo**, President of INFARMED, who became a friend and kept our agreement on splitting my time between my tasks and my Ph.D. coursework, and for whose support I’ll always be grateful. **Mariana Maia Rafeiro**, a friend and a boss who always made it possible for me to chase my passions while serving at the highest level of what it means to be a public official. Our track record speaks volumes about our bond. **Mário Campolargo**, the most talented, devoted, humane member of Government I have served with, thank you for your good humor, for letting me be honest (sometimes bluntly!), and for giving me the tools to be my best self.

There is, of course, a ‘boss’ I did not mention: **Ricardo Cruz Correia**, my supervisor, my friend, and my boss during my year working at FMUP as a Research Assistant. You are an inspiration as a person and as a professional. I could not have done this without you and your kindness, your insights, and your support. If there ever was a person with a solution to every problem, you are that person. In you, I thank everyone at FMUP who helped make this time of my life a little easier: **Alexandra Vieira**, **Rui Guedes**, and Professors **João Almeida Fonseca**, **Guilhermina Rêgo**, **Pedro Pereira Rodrigues**, **Luís Azevedo** and **Bernardo Sousa Pinto**.

To my co-authors, **José Miguel Diniz** and **Manuel Marques da Cruz** – you guys are freaking rockstars! My papers would have been a pale shadow of their final forms if not for your authorship. I feel sorry that our Public Health System does not take advantage of having such gifted, genuine, and hard-working people as you among their ranks; rest assured, I do. I thank you for your dedication, for your friendship, and for putting all you had into what we built over these months. A particular hat-tip to **João Miguel Alves** and **Marta Temporão**, whose friendship and support on this journey were also very important. It would not have been possible without you.

Before moving to a more personal level (and wording, apologies!), I want to thank all those whose paths have crossed mine, who believed in me, and who gave me their hand when I needed to. In Externato S. Miguel Arcanjo, it was professors **Carlos Lopes** and **Cesaltina Sousa**. Physical Ed. and History – my worst and my best. Fortunately, Mr. Lopes didn't quit on the underdog, and Ms. Cesaltina was kind enough to encourage me to seek your best while not getting bothered if someone messed with you. Both made me realize that most human growth is derived from persistence – from running alongside you until you finish the school race and making people cheer for you to challenging you to study harder and be more diligent so you can be better. In Escola Secundária da Portela, to professors **Luísa Magalhães** and **Teresa Ventura**. Professor Luísa taught us immensely, from life sciences to project management – content and method; Professor Teresa was that teacher that takes a shine to you when nobody else has and helps you carry on and grow up. They are dear to my heart and make me believe Portugal's schools can be filled with inspiring, people-shaping teachers. This paragraph would be incomplete without referencing **Dr. Fernando Pêgo**, my long-time psychiatrist. He lifted me and helped me cope with my personal challenges several times, giving me the tools to learn how to fend for myself. If there's an inspiration and a contribution to this field through me, he's largely responsible for it.

To the friends who never forgot me even when I forgot to keep in touch: this one is also for you. I want to thank their patience, kindness, and words of encouragement and for standing by me without needing to ask for it. This one goes out to the 'Pilares' and the 'Fénix' gangs, my very own Musketeers, and the great people of NHEM KC and at e-MAIS. Let me take the chance to thank a dear friend, a mentor, and one of the most intelligent persons I have ever met: **Pedro Pita Barros**. Pedro was one of the first persons I talked to about doing a Ph.D., and through it all – with many hiccups and, lately, quite

a few successes – his guidance has never failed, his insight has never faltered, and he never gave up on me. I am proud to call you a friend; every snappy string of curiosity in this thesis is covered with that secret sauce that always makes our conversation so damn interesting.

Rita Salvador (now also Chameca) deserves her own caption. The friend who never gives up on you, even when you are literally burned out. The neighbor everyone wants to grow next to. Wherever our lives take us, I know there will not be anyone who knows where Diogo came from as well as you, nor the other way around. It has been one of my life's privileges to grow alongside you, and your presence can be seen in this document and your precious contribution to it. Just like us, right to the end.

To **Martinha** – my blood, my sister, my pride and joy. There are not enough lines in this section to tell you what your enduring support and love have done for me. Even if there were a Diogo in an alternate universe to write this thesis, he would not have been a fraction of the man I am because of you. Being a brother to you has been the greatest lesson of my life, and even if the winter winds blow, our pack survives.

To my parents, **Simão** and **Isabel**. I appreciate all you have done for me throughout my life more and more with each passing day. To raise a child is an act of courage; to raise such a complicated one is heroic. I am privileged for having had you as parents and for all you taught me and gave me. You might not have gone to university, but you have more knowledge and wisdom than you can learn in any classroom. All the sacrifices you made find their culmination in this thesis. I will not hesitate for a moment in saying that it is as much yours as it is mine.

To those who have left this world and whom I love tenderly, albeit at a distance: avô **Zé Carlos**, avó **Didi**, and tia **Guida**, who departed too early in the beginning of this Ph.D. Your legacy is well alive in this thesis and in me. Avô Zé Carlos was right when he said no cause is lost until you have given up on it. Avó Didi was right in saying we must do what's right even if others do not correspond – our conscience matters more. And tia Guida was right in teaching me to love all living things from a very early age; I will never go to a zoo and cherish all the wonders that happen there without remembering you.

It will not be strange that I finish my long list of 'thank-you' with a very special person. The person who taught me that loving and being loved is truly life's greatest gift. She has stood by me through hardship and venture with unrelenting loyalty, endless care, and

undying faithfulness. To my fiancée, **Joana Gomes da Costa**, herself a Ph.D.: live for each second without hesitation, and never forget I'm your man. I love you, and I thank you for it all.

Winston Churchill, a longtime inspiration of mine, is reputed to have stated that “success is not final, failure is not fatal; it is the courage to continue that counts”. Sir Winston was proven right once more. After all, the young man living through one of his darkest times, standing in the waiting room of his GP and promising to do something about mental health in Portugal, did deliver. And he is damn proud of it.

Apologies if I was too lengthy, but this was as short as I could possibly keep it. I mean, if there ever was a moment where I could do this, it's this one, right? On the other hand, it truly is great having so many people to be thankful to, even if really summing it up!

So, I say: Thank you for the music – for giving it to me.

Abstract

Mental disorders were globally responsible for 13.04% of all disease prevalence cases and 4.92% of total Disability Adjusted Life-Years. Portugal presents significantly higher disease prevalence (19.27%) and DALY (8.27%) related to mental disorders. The dynamics of the market for healthcare's digital transformation, amplified by the COVID-19 pandemic, have given digital health apps an important role in delivering healthcare and promoting health.

Digital mental health applications present strong dynamics and promise to be a means to increase the convenience, accessibility, and personalization of mental healthcare. The strong demand for these apps resulted in a multitude of approaches, making it difficult to separate the wheat from the chaff. Concerns regarding their technical and clinical quality have driven several countries to put forward regulatory frameworks to assess digital health apps' clinical and technical robustness and clarify their benefits and risks.

In this doctoral thesis, we aim to map the expectations of the demand and supply sides for DMHA to understand how regulatory action might enable responsible and proactive regulation without hampering innovation, and whether digital mental health applications would constitute a valid alternative in the Portuguese political economy.

To do so, we developed and published a peer-reviewed research protocol that created an easily replicable and rigorous instrument to systematically evaluate attitudes and perceptions toward digital mental health applications. This was grounded on a two-study, web-survey-based methodology to assess physicians' and potential users' attitudes and perspectives toward digital mental health applications.

In the first study, we assessed the attitudes and expectations of physicians, defined as psychiatrists and psychologists, toward digital mental health applications in the Portuguese context, as well as perceived benefits, barriers, and actions to support their adoption. 87.2% of the cross-sectional web survey's respondents endorsed the opportunity to prescribe digital mental health apps. Increased health literacy (87%), wider adherence to treatment (86%), and proper disease management (79%) were the most frequently agreed upon benefits of DMHA. 43.6% of respondents planned to prescribe or recommend DMHA, with psychologists being more favorable than psychiatrists.

Professionals still face substantial barriers, such as lack of information on DMHA (96%), the level of initial training effort (72%), and the need for adjustments of clinical processes and records (71%). The measures to promote the adoption of DMHA that gathered the most consensus, in turn, were having more information on the available apps and their suitability for health objectives (94%) and more scientific evidence of the validity of the apps as a health intervention (92%). Established recommendations of apps by specific clinical guidelines or professional societies (91%) would also be essential to foster adoption. Even though the benefits, barriers, and measures to promote the adoption of DMHA are consensual, more evidence is needed, along with the further promotion of mental health professionals' digital literacy.

The second study aimed to ascertain the factors determining DMHA use in the academic community of the University of Porto, considering it a proxy for the Portuguese population. The survey participants had a mean age of 24.3 years, with 68.3% identifying as female and 26.9% as male. Of the 539 respondents, 93.9% identified as White, 2.2% identified as having more than one ethnicity, and 0.6% identified as Asian. Faculty members and administrative staff also answered the survey (7.1% and 2.8% of the sample).

Of the 539 participants, 5.9% reported currently using digital mental health apps. Perceived stress was positively associated with DMHA use. A latent variable comprising self-perceptions of mental health problems and coping strategies in place was also positively related to their use. Privacy concerns regarding one's information being accessible to others were negatively associated with DMHA use. Perceived stigma, need to seek help, and having close relationships did not have a statistically significant direct effect. Financial reasons (37.3%), the perceived helpfulness of these apps (26.9%), uncertainty about the seriousness of one's needs (26.3%), and the waiting time to access mental health resources (24.9%) were the main barriers to DMHA access.

Both supply and demand sides are willing to try digital mental health applications and consider them reasonable alternatives. However, barriers related to financial and digital literacy issues and quality assurance issues remain. This thesis constitutes a relevant contribution to the scientific literature not only on life sciences and their digital potential but also in terms of the industrial characterization of health economics for these subtopics and the mapping of expectations, through attitude and perception elicitation, from both supply and demand sides of mental healthcare.

Resumo

As perturbações mentais foram globalmente responsáveis por 13,04% de todos os casos de prevalência de doenças e 4,92% do total de anos de vida ajustados por incapacidade (DALY). Portugal apresenta prevalências significativamente mais elevadas de doenças (19,27%) e DALY (8,27%) relacionadas com perturbações mentais. A dinâmica do mercado de transformação digital da saúde, amplificada pela pandemia do COVID-19, conferiu às aplicações digitais de saúde um papel importante na prestação de cuidados de saúde e na promoção da saúde.

As aplicações digitais de saúde mental apresentam uma forte dinâmica e prometem ser um meio para aumentar a conveniência, acessibilidade e personalização dos cuidados de saúde mental (DMHA). A grande procura por estas aplicações resultou numa multitude de abordagens, dificultando a proverbial separação do trigo do joio. As preocupações com a qualidade técnica e clínica destas aplicações levaram vários países a apresentar estruturas regulatórias para avaliar a robustez clínica e técnica das aplicações digitais de saúde e esclarecer quais os seus benefícios e riscos.

Nesta tese de doutoramento, pretendemos mapear as expectativas dos lados da procura e da oferta de DMHA para perceber como a atividade regulatória pode permitir uma regulação responsável e proativa sem prejudicar a inovação, bem como se as aplicações digitais de saúde mental constituiriam uma alternativa válida na economia política do mercado português de prestação de cuidados de saúde e promoção da saúde.

Para este efeito, desenvolvemos e publicámos um protocolo de investigação em revista com revisão por pares, criando um instrumento rigoroso e facilmente replicável para avaliar sistematicamente atitudes e perceções em relação a aplicações digitais de saúde mental. Este instrumento baseia-se numa metodologia de dois estudos baseados em inquéritos via *web* para avaliar as atitudes e perspetivas de médicos e potenciais utilizadores relativamente a aplicações digitais de saúde mental.

No primeiro estudo, avaliámos as atitudes e perceções dos profissionais de saúde mental, definidos como psiquiatras e psicólogos, em relação às aplicações digitais de saúde mental no contexto português, bem como os benefícios percebidos, barreiras, e ações para apoiar a sua adoção. 87,2% dos entrevistados do estudo transversal via *web* endossaram a oportunidade de prescrever ou recomendar aplicações digitais de saúde mental. Maior

conhecimento sobre o seu impacto na saúde dos utilizadores (87%), melhor adesão à terapêutica (86%), e gestão adequada da doença (79%) foram os benefícios mais frequentemente acordados das DMHA. 43,6% dos entrevistados planeavam prescrever ou recomendar DMHA, sendo os psicólogos mais favoráveis do que os psiquiatras.

Os profissionais ainda enfrentam barreiras substanciais, como a falta de informação sobre DMHA (96%), o nível de esforço de treino inicial (72%), e a necessidade de ajustamento de processos e registos clínicos (71%). As medidas para promover a adoção do DMHA que obtiveram mais consenso, por sua vez, foram ter mais informações sobre as aplicações disponíveis e sua adequação aos objetivos de saúde (94%), e mais evidência científica sobre a sua validade como intervenção de saúde (92%). A recomendação de aplicações através de diretrizes clínicas específicas ou sociedades profissionais (91%) também seria essencial para promover a adoção. Embora os benefícios, barreiras e medidas para promover a adoção do DMHA sejam consensuais, é necessária mais evidência, juntamente com a promoção da literacia digital dos profissionais de saúde mental.

O segundo estudo teve como objetivo entender os fatores determinantes da utilização de DMHA na comunidade académica da Universidade do Porto, considerando-a uma aproximação da população portuguesa. Os participantes no inquérito tinham uma idade média de 24,3 anos, sendo que 68,3% se identificavam como mulheres e 26,9% como homens. Dos 539 entrevistados, 93,9% identificaram-se como brancos, 2,2% como tendo mais que uma etnia, e 0,6% se identificaram como asiáticos. Docentes e funcionários administrativos também responderam à pesquisa (7,1% e 2,8% da amostra, respetivamente).

Dos 539 participantes, 5,9% relataram usar aplicações digitais de saúde mental. O stresse percebido foi positivamente associado ao uso de DMHA. Uma variável latente que compreende a autoperceção de problemas de saúde mental e a utilização de estratégias para lidar com os mesmos também foi positivamente associada ao seu uso. Preocupações com a privacidade na perspetiva de as suas informações serem acessíveis por outras pessoas tiveram uma associação negativa com o uso de DMHA. O estigma percebido, a necessidade de procurar ajuda, e a existência de relações sociais próximas não tiveram um efeito direto estatisticamente significativo. Motivos financeiros (37,3%), a utilidade percebida dessas aplicações (26,9%), a incerteza sobre a gravidade das próprias

necessidades (26,3%), e o tempo de espera para aceder a recursos de saúde mental (24,9%) foram as principais barreiras ao acesso a aplicações digitais de saúde mental.

Os lados da oferta e da procura estão dispostos a experimentar aplicativos digitais de saúde mental e a considerá-los alternativas terapêuticas razoáveis. No entanto, as barreiras relacionadas com questões de literacia financeira e digital, assim como questões relacionadas com a garantia da sua qualidade, permanecem bloqueios ativos.

Esta tese constitui um contributo relevante para a literatura científica não só sobre as ciências da vida e o seu potencial digital, mas também ao nível da caracterização industrial da economia da saúde para estes subtópicos através do mapeamento de expectativas dos agentes envolvidos na oferta e procura por cuidados de saúde mental por via da determinação das suas atitudes e perceções face às aplicações digitais de saúde mental.

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List of Outputs

This thesis is the culmination of a series of outputs developed during the journey that is taking a Ph.D. Therefore, despite its text being based on specific publications, a more comprehensive array of articles, presentations, and classes were essential to formulate a more robust scholarly perspective of many of the issues at the interplay of digital, data, and health.

They also reflect a need for academia to serve the wider community and engage with different stakeholders. In the author's case, this meant producing scholarly work, aside from that directly related to the thesis topic, comprising COVID-19 and the relationship between disease burden and modifiable risk factors. Both are critical to Portuguese society and provoked discussions far beyond their initial intended reach.

Research Papers and Abstracts Directly Related to the Thesis

- **Physicians' and individuals' attitudes toward Digital Mental Health Tools: Protocol for a web survey study with physician and stakeholder interviews.**

JMIR Iproceedings 9:e39858, 2023. <https://doi.org/10.2196/39858>

Diogo Nogueira-Leite and Ricardo Cruz-Correia

- **Attitudes of Physicians and Individuals Toward Digital Mental Health Tools: Protocol for a Web-Based Survey Research Project**

JMIR Research Protocols. 09/01/2023:41040. <https://doi.org/10.2196/41040>

Diogo Nogueira-Leite and Ricardo Cruz-Correia.

- **Mental Health Professionals' Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Mixed Methods Study**

JMIR Human Factors. 02/06/2023:45949. <https://doi.org/10.2196/45949>

Diogo Nogueira-Leite, José Miguel Diniz, and Ricardo Cruz-Correia.

- Individuals' Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Web-Based Survey

(submitted to BMC Medical Informatics and Decision Making, 2023)

Diogo Nogueira-Leite, Manuel Marques-Cruz, and Ricardo Cruz-Correia.

Other Published Research Papers During the Ph.D. Program

- COVID-19 Contact Tracing as an Indicator for Evaluating a Pandemic Situation: Simulation Study

JMIR Public Health and Surveillance. 06/04/2023:43836. <https://doi.org/10.2196/43836>

Manuel Marques-Cruz; Diogo Nogueira-Leite; João Miguel Alves; Francisco Fernandes; José Miguel Fernandes; Miguel Ângelo Almeida; Patrícia Cunha Correia; Paula Perestrelo; Ricardo Cruz-Correia; Pedro Pita Barros

- A Cautionary Tale on Using Covid-19 Data for Machine Learning
International Conference on Artificial Intelligence in Medicine Conference Proceedings (2021). https://doi.org/10.1007/978-3-030-77211-6_30

Manuel Marques-Cruz; Diogo Nogueira-Leite; João Miguel Alves; Ricardo Cruz-Correia

Conferences: Presentations and Accepted Papers & Posters

- 18th National Conference of Health Economics (CNES), Lisbon and Virtual, 2023
(<https://18cn.es.apes.pt/>)

Date: 12th and 13th October 2023

Participation: Two papers submitted and published in the Conference Proceedings:

- Oral Presentation: “Mental Health Professionals’ Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Mixed Methods Study”, Diogo Nogueira-Leite, José Miguel Diniz, and Ricardo Cruz-Correia, 2023

- Flash Talk: “Individuals’ Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Web-Based Survey”, Diogo Nogueira-Leite, Manuel Marques-Cruz, and Ricardo Cruz-Correia, 2023

- **U. Conn. Center for mHealth and Social Media 6th Annual Conference (CHASM), Virtual, 2022** (<https://mhealth.inchip.uconn.edu/conferences/>)

Date: 19th and 20th May 2022

Participation: live virtual presentation of a video poster on “Protocol for a research project on physicians’ and individuals’ attitudes toward Digital Mental Health Tools” (available at <https://youtu.be/TzN1EjQTkgQ>) and Q&A discussion

Award received: Most Viewed Video.

- **17th National Conference of Health Economics (CNES), Lisbon and Virtual, 2021** (<https://17cnes.apes.pt/>)

Date: 21st and 22nd October 2021

Participation: Two papers submitted and published in the Conference Proceedings:

- “A Cautionary Tale on Using COVID-19 Data for Machine Learning”, Diogo Nogueira-Leite, João Miguel Alves, Manuel Marques-Cruz, and Ricardo Cruz-Correia, 2021
- “Estimating Disease Burden through Modifiable Risk Factors: a Model Simulation”, Diogo Nogueira-Leite, João Miguel Alves, Manuel Marques-Cruz, and Marta Temporão, 2021

- **Artificial Intelligence in Medicine (AIME) Conference, Porto (Virtual), 2021** (<https://aime21.aimedicine.info/>)

Date: 17th June 2021

Participation: live virtual presentation of the Long Paper “A Cautionary Tale on Using COVID-19 Data for Machine Learning”, Diogo Nogueira-Leite, João Miguel Alves, Manuel Marques-Cruz, and Ricardo Cruz-Correia, 2021 and Q&A discussion

Classes & Courses Taught

- **“Health Data and Economics”, 15th Short Postgraduate Course in Medical Confidentiality, Personal Data, and Clinical Process, FDUC** (<http://www.centrodedireitobiomedico.org/curso/segreto-m%C3%A9dico-e-processo-cl%C3%ADnico/14%C2%BA-curso-breve-de-p%C3%B3s-gradua%C3%A7%C3%A3o-em-segreto-m%C3%A9dico-dados>)

Date: 1st June 2023

Participation: Lecturer of a class on “Health Data and Economics”, presenting key initial concepts regarding health data science, digital health, and their underlying economic trade-offs.

- **“Data Management”, III Post-graduate course on Law & Economics of Health and Medicines, FDUL** (<https://www.cidp.pt/curso/ii-curso-de-posgraduacao-em-direito-e-economia-da-saude-e-do-medicamento/160>)

Date: 9th February 2023

Participation: Lecturer of a class on “Data Management”, presenting key initial concepts regarding health data science, digital health, and their underlying economic trade-offs.

- **“Health Data and Economics”, 14th Short Postgraduate Course in Medical Confidentiality, Personal Data, and Clinical Process, FDUC** (<http://www.centrodedireitobiomedico.org/curso/segreto-m%C3%A9dico-e-processo-cl%C3%ADnico/14%C2%BA-curso-breve-de-p%C3%B3s-gradua%C3%A7%C3%A3o-em-segreto-m%C3%A9dico-dados>)

Date: 31st May 2022

Participation: Lecturer of a class on “Health Data and Economics”, presenting key initial concepts regarding health data science, digital health, and their underlying economic trade-offs.

- **“Data Management”, II Post-graduate course on Law & Economics of Health and Medicines, FDUL** (<https://www.cidp.pt/curso/ii-curso-de-posgraduacao-em-direito-e-economia-da-saude-e-do-medicamento/160>)

Date: 26th May 2022

Participation: Lecturer of a class on “Data Management”, presenting key initial concepts regarding health data science, digital health, and their underlying economic trade-offs.

- **Finance and Management Control, PAAS, FMUP**
(<https://paas.med.up.pt/financas-e-controlo-de-gestao/>)

Date: 23rd February – 21st April 2022

Participation: Lecturer in charge of classes regarding specific knowledge and skills in financial management and management control.

- **GATHER – Health Data Collection, HEADS, FMUP**
(<https://heads.med.up.pt/en/1o-ano/>)

Date: 14th February – 28th June 2022

Participation: Aided Professor Ricardo Cruz Correia in planning, preparing, and delivering classes and seminar sessions.

- **“Health Data and Economics”, 13th Short Postgraduate Course in Medical Confidentiality, Personal Data, and Clinical Process, FDUC**
(<https://www.centrodedireitobiomedico.org/curso/segreto-m%C3%A9dico-e-processo-cl%C3%ADnico/13%C2%BA-curso-breve-de-p%C3%B3s-gradua%C3%A7%C3%A3o-em-segreto-m%C3%A9dico-dados>)

Date: 27th March 2021

Participation: Lecturer of a class on “Health Data and Economics”, presenting key initial concepts regarding health data science, digital health, and their underlying economic trade-offs.

Media outreach

During his Ph.D Diogo had several engagements with media outlets that envisaged making science communication in digital health closer to the general public’s interests. This subsection aims at listing them for a better understanding of this dimension of his journey:

- Diogo participated on five live comments for national television on news channel SIC Notícias, all of them related to health policy issues such as obstetric emergency rooms in the Summer of 2022 and the announcement of the Executive Commission of the National Health System.
- Diogo was the guest speaker on Episode 5 of the Science Network Pod(Cast), devoted to Data Science and Health (<https://open.spotify.com/episode/4kRgk640vB63cD9U5YXxyK?si=305a3a50c769438d>).
- Diogo published several op-eds on health data science, health systems and policies, mental health, and health economics in outlets such as Netfarma (pharma's distribution online magazine), the Portuguese Association of Health Economics, or NOVA SBE Role to Play initiative.
- Diogo contributed, alongside distinguished colleagues and scholars, on two public consultation documents as a part of NHEM KC which had high political and mediatic impact: the first on the Portuguese Government's proposal for the Recovery and Resilience Plan to be submitted to the European Commission, and the second on the Portuguese Directorate-General of Health's National Health Plan for 2021-2030.
- Diogo was a guest speaker on digital health in several fora, such as the 2022 BeMedTech Workshop in Brussels (remote), the Congress of 2022 of the Portuguese Orthopedics Society, Encontro Renal 2022, or 11th Conferência Valor APAH.
- Diogo was the main organizer of FMUP/MEDCIDS event "Espaço Europeu de Dados de Saúde: Acesso, Economia e Partilha" and its rapporteur for the workshop's collaborative document submitted to the European Commission's ex-post public consultation on the EHDS.
- Diogo and the research team of the second paper of this thesis (José Miguel Diniz and Ricardo Cruz Correia) were interviewed by SAPO Tek and MeuCapital, two national online media outlets, on that paper's results and implications. This drove significant media interest and resharing of the paper.

Abbreviations

AI: Artificial Intelligence

B2C: Business-to-Consumer

BfArM: German Federal Agency for Medicines and Health Products

CAGR: Compounded Annual Growth Rate

DALY(s): Disability Adjusted Life-Year(s)

DiGA: Digital Health Applications (as referred to in the program's official page by Germany's Ministry of Health)

DMHA: Digital Mental Health Apps

EU: European Union

FDA: Food and Drug Administration

GDPR: General Data Protection Regulation

INFARMED: Regulatory Authority for Medicines and Medical Devices (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.)

KOL: Key Opinion Leader

MDR: Medical Devices Regulation

MH: Mental Health

NHS: National Health Service (Serviço Nacional de Saúde, or SNS, in Portuguese)

SPMS: Shared Services of the Portuguese Ministry of Health (Serviços Partilhados do Ministério da Saúde, in Portuguese)

UI: User Interface

USA: United States of America

UX: User Experience

WHO: World Health Organization

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List of Appendixes

The appendixes to the papers produced during the research work this thesis reflects are quite lengthy in terms of pages. In keeping this thesis as lean as possible, the appendixes to these papers are solely listed here per manuscript for greater clarity and ease of reference.

All appendixes are made available in the .zip file that accompanies this manuscript's file ("MA_Thesis_DNL.zip"), with their division per manuscript holding as listed below:

- **Paper 1:**

- Multimedia Appendix 1 – First study's final questionnaire in Portuguese and English.
- Multimedia Appendix 2 – Second study's final questionnaire in Portuguese and English.
- Multimedia Appendix 3 – Checklist for a future researcher.

- **Paper 2:**

- Multimedia Appendix 1 – Translated adapted survey questionnaire (Portuguese to English).
- Multimedia Appendix 2 – Translated original survey questionnaire (English to Portuguese).
- Multimedia Appendix 3 – Summary of modifications between survey questionnaires.

- **Paper 3:**

- Multimedia Appendix 1 – Translated original survey questionnaire (EN-PT).
- Multimedia Appendix 2 – Translated adapted survey questionnaire (PT-EN).
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- Multimedia Appendix 4 – Comparative characteristics of participants.
- Multimedia Appendix 5 – Characteristics of users (current or past) and never users.
- Multimedia Appendix 6 – Overview of responses to survey items.

1. Outline

Although based on different original studies, this thesis delivers a consolidated message organized into separate chapters.

Chapter 2 provides some background on the global, European, and Portuguese mental health landscape regarding disease prevalence and healthcare access. This chapter also introduces the reader to the linkage between health data science, the growth in data-driven health data applications in recent years, and how digital mental health applications (DMHA) may be used to expand access and improve the quality of mental healthcare. Chapter 2 also introduces the reader to the dynamics of supply and demand for digital health in general and DMHA in specific, and the role of attitudes and perceptions in shaping expectations, which is crucial for any health intervention, product, or service. Finally, it sheds light on the latest regulatory developments in the field of digital health applications and how this impacts the viability of DMHA as a screening/diagnosis/treatment alternative.

Chapter 3 defines the aim and specific research questions of the thesis.

Chapters 4, 5, and 6 reproduce the submitted original papers corresponding to the studies conducted to achieve the thesis's aim and objectives mentioned above.

Chapter 4 exhibits a peer-reviewed and published original research protocol that synthesizes the main evidence published in the literature regarding DMHA and outlines a scientifically rigorous methodology to assess demand and supply expectations' for DMHA through attitude and perception elicitation.

Chapter 5 presents a peer-reviewed and published original mixed-method study employing a web survey and a Key Opinion analysis to identify and evaluate the attitudes and perceptions of physicians concerning digital mental health applications.

Chapter 6 offers an original web-based survey study conducted on the academic community (i.e., students, teachers, and administrative staff) of the University of Porto to ascertain the determinants of DMHA use, submitted to BMC Medical Informatics and Decision-Making on June 20, 2023 and still awaiting editorial feedback.

Chapter 7 presents a succinct discussion of the facts presented in Chapter 2 and informed by the remaining chapters, along with recommendations for the future of digital mental

health applications, namely a SWOT analysis and the possible ways forward for DMHA development and validation.

Chapter 8 is a compilation of all the references used in the introduction and discussion of this thesis. All chapters corresponding to the original papers developed during the Ph.D. degree work contain their specific references for easiness of consultation.

The main achievements of this journey are illustrated in the below timeline.

Year	2022										2023									
Major Milestones	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	
Proposal approval by Director of Doctoral Programme																				
Proposal approval by Ethics Committee of FMUP																				
Protocol - Presentation of abstract at CHASM 2022																				
Protocol - Manuscript writing and submission																				
Paper I – Establishment of partnership with professional orders																				
Paper I – Survey translation and adaptation																				
Paper I – Survey launch and data collection																				
M4 – Paper I – Data cleaning and analysis																				
M5 – Paper I – Manuscript writing and submission																				
Paper II – Survey translation and adaptation																				
Paper II – Survey launch and data collection																				
Paper II – Data analysis																				
Paper II – Manuscript writing and submission																				
Thesis – Manuscript writing and submission for approval																				
Admin. procedures to and performing doctoral thesis defense																				

2. Introduction

Mental health: definitions and dynamics

Defining mental health

The definition of mental health, like that of health itself, is challenging. This topic has been debated over the years. Even though many have tried to create a simple and concise definition, the collective body of evidence still needs to establish a definite concept [1]. The usual proxy for this would-be universal consensus has been the World Health Organization (WHO), whose definition of 2004 for mental health is “(...) a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community” [21].

This definition, adopted by entities such as the American Psychological Association [32], presents the complexity involved, given the number of individuals with different sets of values, beliefs, and backgrounds. It also reflects a given timeframe and general awareness of mental health, mental illness, and the need to take care of mental ill-health or disease. No definition is impervious to societal evolution and the passage of time.

The increased relevance mental health issues have earned due to an increased social awareness of their prevalence and impact on individual and population health has led scholars to call for the revision of this concept [43]. Others have focused on defining mental health through its contrary, i.e., mental illness or mental disorder. Some of the most prominent examples of this line of work have been the American Psychiatric Organization [53] or the works of Dan Stein and other authors [6,7x]. It is interesting to observe that, in most cases, an explicit reference to a need for further validation-oriented approaches and to the need to move the discussion beyond self-harm and disability is present. This reinforces the prior assertion that these definitions are essentially moving targets.

As such, and for this thesis, we will consider the latest definition of the WHO for mental health, presented in its World mental health report: Transforming mental health for all [8x]: “Mental health is an integral part of our general health and well-being and a basic human right. Having good mental health means we are better able to connect, function, cope and thrive. Mental health exists on a complex continuum, with experiences ranging

from an optimal state of well-being to debilitating states of great suffering and emotional pain.”

Global, regional, and national dynamics of mental health

It is interesting to note that the WHO itself considers, still resorting to the latest report by the WHO on mental health [8], that the recommendations made in 2001 regarding mental health would still be applicable in June 2022. The amplification of advocacy, governmental, and clinical efforts, alongside the increased availability of evidence-based tools, has changed the landscape. However, this is acknowledged as slow progress, where “(...) the approach to mental health care remains very much business as usual”.

The consequences of maintaining the current healthcare delivery model, criticized for putting too little emphasis on community-based mental health care and an excessive focus on hospital-based services, are evident in society’s cohesion, economy, and individual well-being. Situations and events such as economic downturns and inequality or the COVID-19 pandemic (whose deleterious impact on mental health is amply divulged [9x]) further exacerbated populational mental health conditions in the last years, either through direct effects on the individual or the disruption of mental health services and consequent widening of the treatment gap.

The Institute for Health Metrics and Evaluations’ Global Burden of Disease [10x] is one of the major longitudinal data sources for those interested in understanding the impact on mortality and disability across the globe. And its appreciation of the global, regional, and national dynamics of mental disorders (the category that groups all mental health issues) are peremptory concerning their relevance when it comes to Humanity’s ailments.

Table 1 presents a breakdown of the impact mental disorders as a category, alongside anxiety and depression, had not only in global health but also on the health status of some geographies of concern for us in this thesis: the United States of America (USA), the European Union (EU), Germany, and Portugal. Data was gathered using the previously mentioned GBD Compare tool.

Table 1. Share of DALY and disease prevalence (in percentage points) per condition and geography. *Data source: Institute for Health Metrics and Evaluation (IHME). GBD Compare Data Visualization. Seattle, WA: IHME, University of Washington, 2020.*

	World		USA		Germany		Portugal	
	DALY	Prevalence	DALY	Prevalence	DALY	Prevalence	DALY	Prevalence
Mental disorders	4.92%	13.04%	6.56%	17.03%	6.43%	15.59%	8.27%	19.27%
Depression	1.84%	3.76%	2.38%	4.92%	2.16%	4.32%	3.16%	5.88%
Anxiety	1.13%	4.05%	1.68%	6.51%	1.95%	7.07%	2.58%	9.08%

Mental disorders are globally responsible for 13.04% of all disease prevalence cases and 4.92% of total disability-adjusted life-years (DALY). It is noteworthy that depressive disorders account for 3.76% of total disease prevalence and 1.84% of global DALY, while anxiety disorders answer for 4.05% of global disease prevalence and 1.13% of global DALY.

The two conditions accounted for more than half of the impact mental health disorders had on global health in 2019, according to the Institute for Health Metrics and Evaluation and its GBD Compare tool. In all considered geographies, the paradigm holds: depression and anxiety account for over half of the burden of disease generated by mental disorders. Furthermore, these conditions are always a relevant public health issue in any of the mentioned contexts due to their high prevalence, thus making the importance of addressing them undisputable.

It is also important to note that these data report to 2019 and consequently do not factor in the consequences of the COVID-19 pandemic and the impact of containment measures on mental health deterioration. Many experts have alerted to this pandemic's deleterious effect, especially for children and adolescents [11,12]. They have issued calls to action to tackle this issue without hesitation [13,14].

Although the data for Portugal shows the magnitude of the existing problem, there is also (very) limited access to psychological and psychiatric care to deal with: waiting times for a psychiatry consultation ranged from 10 to 349 days for a psychiatry consultation in the 91 institutions of the Portuguese National Health Service that reported them in the period between September and November 2022. [15] The timeframe for a psychology consultation in the 12 institutions that reported for the same period ranged from 15 to 148 days.

Considering most depression and anxiety cases, albeit responsible for most of the disease prevalence of mental disorders, are classified as non-priority cases, waiting times can be expected to range from 30 to 349 days, depending on where someone lives or receives care. It is likewise important to emphasize i) the high geographical asymmetries, ii) the concentration of waiting times on higher bounds (e.g., above 100 days of waiting time), and iii) the cruciality of timely intervention in delivering mental healthcare.

In a country burdened by out-of-pocket payments about double the EU average [16,17], the possibility of resorting to private sector providers is minimal, as insurers only cover some associated costs. It is necessary and urgent to find new solutions.

Health data science and the market dynamics of data-driven health data applications

Growth in the data economy – i.e., a global digital ecosystem in which data is gathered, organized, and exchanged by a network of vendors to derive value from the accumulated information [18] – is tremendous. According to the European Commission’s Data Act Factsheet [19], global data volume is expected to quintuple, growing from 33 zettabytes in 2018 to 175 zettabytes in 2025. That means a 530% data volume increase.

The same factsheet mentions that this growth, partially due to the increase in connected devices and data generated and shared through them, could deliver a potential of EUR 120 billion in savings in the EU health sector per year. Moreover, it reports that the estimated value of the data economy will go up to EUR 829 billion in 2025 from EUR 301 billion in 2018. Even though these figures are merely projections – and do not consider essential events such as the COVID-19 pandemic – it is undeniable that health data is one of the most valued assets in data-driven applications.

This bullish perspective for both the data economy and its healthcare component is strengthened by Stanford University’s AI Index Report of 2022 [20]. The number of English-language publications in data-supported AI has grown from 162,444 in 2010 to 334,497 in 2021, and the number of AI patent filings increased 30 times between 2015 and 2021 (equivalent to a 76.9% CAGR), totaling 141,240.

Filings were distributed differently across geographies: 62.14% were filed in East Asia and the Pacific, 17.07% in North America, and only 4.16% in Europe and Central Asia. In monetary terms, private investment soared, more than doubling 2020’s record and

reaching USD 93.5 billion in 2021. Of these USD 93.5 billion, USD 11.29 billion was allocated to the medical and healthcare sector, whose sum of private investment in AI for 2017-2021 totaled USD 28.92 billion.

Peek and Rodrigues outline what the author perceives to be this market's fundamental enabler: the wealth of data that routine operations in modern healthcare systems produce, as well as the great potential to utilize these regular data for health research to derive new knowledge about health, disease, and treatments. [21] The breadth of products, services, and interventions that can be developed across several areas [22] based on health data, interoperable databases, and connected devices promises to increase the volume of generated data by several orders of magnitude. Therefore, the role of health data science is to deliver data science skills to support the research, development, and innovation that can come from health data.

A good way of measuring the market dynamics of a given market is to understand its growth rate across a three- or four-year period, as Stanford's report did. According to specialized consulting firm Future Market Insights [23], the market for digital transformation in healthcare has grown at a compounded annual growth rate (CAGR) of 10.4%. The forecast for the 2021-2031 period presented a CAGR of over 14%.

2022 was a challenging year for digital health, signaling investor caution and risk aversion in the face of an adverse macroeconomic outlook marked by geopolitical tensions, high inflation and interest rates, and the backdrop of the COVID-19 pandemic. Rock Health Advisory reports funding of USD 15.3 billion across 572 deals was reached, compared with 2021's USD 29.3 billion [24]. However, it is also worth noting that, in a very adverse macroeconomic outlook, this value is higher than that raised in 2020 and superior to previous years by a wide margin.

Therefore, solid market dynamics driven by exponentially-increasing amounts of data, growing interest from governments, increasingly robust value propositions from the industry – where investor appetite allied with the push for evidence-based products and services – and from patients and healthcare providers, whose digital tool adoption has increased substantially recently because of the collective responses to the COVID-19 pandemic such as contact tracing apps [25,26].

Digital mental health applications and the role of expectations in shaping supply and demand

The prominent public and individual concern that mental illness constitutes and the significant scientific and investment potential digital health interventions have beg the question: what is the role of digital mental health applications? What explains their growth? And what will shape supply and demand in the coming years?

DMHA: the market-based landscape

Digital health applications present a wide diversity of medical needs and specialties, business models, and means of delivery. According to IQVIA's seminal report on Digital Health Trends 2021 [27], they can range from providing a platform for services such as virtual doctor appointments and chronic-disease management to consumer health apps that help people manage their health through tracking daily steps and accessing exercise and nutrition programs. Its dynamics are impressive: according to IQVIA's report, more than 350,000 health apps are available from various app stores, with 110 downloaded over 10 million times and accounting for almost 50% of all downloads.

Among the usual benefits listed for digital health apps are improved patient care, reduction of healthcare provision cost through increased time and budgetary efficiency, empowering of patients to manage their own conditions, addressing disparities in healthcare due to several access inequities, and making education and refresher training more accessible to health professionals [28-30]. On the other hand, some of the potential risks listed for digital health apps are patient safety [31], data protection and privacy [32-34], lack of diagnosis or treatment accuracy [35], deepening already existing biases through discrimination of different nature [36-39], or creating more health inequities by widening treatment gaps through the digital divide and its determinants [40-43].

At this point, it is interesting to note that health apps are increasingly focused on health-condition management rather than wellness management, with the proportion of the former growing from 28% in 2015 to 47% in 2020 [27]. Mental health-related apps, along with diabetes and cardiovascular disease-related apps, account for almost half of disease-specific apps.

The growth in the volume of digital mental health applications (DMHA) is remarkable. According to Grand View Research's 2022 report [44], the global DMHA market was

valued at USD 5.2 billion in 2022. It is expected to be worth USD 6.2 billion in revenue in 2023 and to grow to USD 17.5 billion in 2030, attaining a CAGR of 15.9% between 2023-2030. has increased by 54.6% between 2019 and 2021, reaching a valuation of USD 1.4 billion in 2021. These numbers gain further credibility as an article from Deloitte, a competing firm, shares the same conclusions [45].

Grand View's report characterizes demand as owing to two primary factors: rising utilization of mental health apps for improving treatment outcomes and lifestyle and increasing awareness of mental health as a significant health condition. Companies are changing their perspective, perceiving DMHA as beneficial and an enhancer of employee well-being and productivity.

Furthermore, the increased number of downloads for DMHA and the upsurge in downloads during the COVID-19 pandemic, already substantiated by both the OECD and IQVIA, are some of the other prominent factors fueling market growth. The COVID-19 pandemic not only led to an increase in downloads of mental health apps but also increased awareness regarding mental health as a grave problem. This, in turn, has demonstrated substantial growth potential in the digital health and mobile health space.

One interesting detail of Grand View's report is the breakdown into application types and regional markets. In keeping with the report, depression and anxiety management had the most significant slice of market revenue, with 29.8%. The remaining categories were meditation and stress management, which shared similar market shares, followed by wellness management. The prevalence and expected growth in the incidence of stress, anxiety, and depressive disorders in the aftermath of the COVID-19 pandemic is signaled as the primary market driver. Concerning regional revenue distribution, North America accounted for 37.4% of the DMHA market, while the Asia Pacific region is expected to be the fastest-growing regional market. High network coverage, internet penetration, and mobile phone usage are critical determinants in both cases.

The role of expectations in shaping supply and demand

The role of expectations has been the object of extensive economic literature as far as economic policy, namely its monetary component, is concerned [46-49]. Even though the literature is very limited on their role in digital markets and how they can shape supply and demand [50-53], there is little doubt that they impact platform and service exchange dynamics, where one could include DMHA.

In summary, the author argues, mainly based on Voss and Grewal [52], that expectations will have a two-fold, sequential role in shaping supply and demand for a product such as DMHA. Expectations will mainly impact the demand side by being i) key in determining adherence to digital products, services, and platforms, and hence demand, and ii) determined by the level of service and the utility individuals perceive these products, services, and platforms to have in the satisfaction of their needs.

Therefore, supply is not expected to generate demand, but demand will have more market power to define supply as it will be very sensitive (in economic literature, elastic) regarding how well supply fits specific needs at the individual level. This is likely to result in highly customizable products and services and an increased focus on product or service adaptability and usability. Moreover, it will dictate more concentration in supply-side operators to sustain high minimum efficient scales [54]. Minimum efficient scales are posited to increase due not to high marginal production costs but rather increased switching costs between platforms and consumer lock-in behavior. A competitive behavior such as this would mimic the developments in the digital economy so far regarding, e.g., cloud platforms [55].

What determines expectations if expectations dictate demand and demand shapes supply and, hence, market structure? Given the high level of required customization, the very low to null marginal switching costs for the individual, and that supply has limited ability to influence individual behavior; it will essentially be the perceived value of the solutions presented to those individuals, i.e., their attitudes and perceptions.

This argument is central to the author's thesis, who has grounded it on the need to understand the attitudes and perceptions of the demand and supply sides of DMHA.

Regulatory approaches and challenges

Digital market regulation and consequences for digital health apps

Regulation plays a crucial role in ensuring the proper functioning of markets for the sake of society as a whole [56]. Digital market regulations have started to emerge in the face of the growing market power of platforms and their increasing gatekeeping role, i.e., point of entry in accessing online products and services. The EU's Digital Markets Act [57] provides the first example of horizontal (i.e., non-specific to a given sector) regulation imposed by a sizeable geoeconomic bloc. The other two references on the global stage,

China and the United States of America (USA), have similarly taken antitrust action on their respective tech sectors [58,59], albeit with different orders of magnitude. Some efforts have been made to map AI-related governance efforts' global and regional interconnections [60].

Digital health apps overall are sure to be impacted by the regulation of digital markets, and there has been no shortage of calls to use regulation to separate the wheat from chaff [61-63] while trying to potentiate the impact of digital health apps to improve health outcomes at lower costs and satisfy historically underserved populations' unmet medical needs. The debate on the challenges involved ranges from the dichotomy between regulation and innovation (and whether this applies) to the degree of scrutiny regulators should take in proportion to the risk each intervention represents (e.g., whether a data breach can severely compromise a person's identity and intimacy).

The identification of digital health apps that are safe and effective while keeping quality standards presents a significant challenge for health systems across the globe, making proper regulation essential to minimize risks and magnify benefits. Apps that tackle high-risk or chronic conditions, or that attempt to perform diagnosis and treatment, are especially relevant in this scenario, given the length of time one is expected to use them or the sensitivity of associated information. DMHA, due to the sensitivity of disclosed information and privacy concerns, constitutes prominent high-risk products that warrant regulation.

Furthermore, regulation constitutes an aprioristic need to produce payment and reimbursement pathways that balance costs and benefits while ensuring access and defining clear use policies aside from market-based ones (e.g., star ratings in app stores). [64]. Even though the literature and current evidence show that there are different stages of the discussion at several levels, one can already detect some commonalities between the so-far created regulatory mechanisms for digital health apps.

The global regulatory landscape of digital health apps

Germany assumed a pioneering role in implementing a regulatory framework aimed at digital health apps and their market access and reimbursement. Its DiGA (Digitale Gesundheitsanwendungen, in German, meaning digital health applications) [65] program was inaugurated in October 2020, and, on January 30, 2023, 41 apps qualified for

statutory insurance reimbursement. Of these, 18, or 44%, were classified as being DiGA for mental disorders by the DiGA Directory [66].

An app is accepted into the DiGA program after the German Federal Agency for Medicines and Health Products (BfArM) evaluates it in terms of general requisites (concerning technical safety and user-friendliness) and of positive clinical effects. If an app has yet to prove the latter, it has twelve months to do so and is included in a provisory listing; if it fails to comply, it is withdrawn. Suppose the app can prove compliance with general requisites and positive clinical effects. In that case, BfArM approves it, and price and reimbursement negotiations follow with the association of statutory insurers (GKV-SV), after which it is included in the DiGA Directory. France is studying a replication of the DiGA approach and is expected to implement it until end-2022 [67,68]. However, there still needs to be public information on the evolution of this reimbursement track.

Belgium ranks second in implementation, and even though the mHealthBelgium [69] initiative was launched in 2018, it officially started conducting appraisal and reimbursement processes in January 2021. Its selection process is based on a 3-level validation pyramid [70] consisting of criteria related to legal and regulatory issues (level 1), safe communication and privacy (level 2), and financing and reimbursement (level 3, subdivided into 3⁻, if it has provisional reimbursement while proving socioeconomic benefits, and 3⁺ if it already has proven those same benefits). On January 30, 2023, 23 apps had level 1 clearance, and 12 apps had level 2 clearance. Moreover, one app received 3⁻ support, and none had been cleared for level 3⁺.

Other European countries have so far opted for softer, more decentralized approaches, with legal obligations and compliance rules based on the General Data Protection Regulation (GDPR) [71] or the Medical Devices Regulation (MDR) [72]. A comprehensive mapping of regulatory approaches across Europe is contained in the Belgian Health Care Knowledge Center's (KCE) recent report on the evaluation of digital medical technologies [73].

On the other hand, Singapore and the USA resort to their medical device regulations. The Food and Drug Administration (FDA) has been particularly active, basing its assessment of apps and digital therapeutics under the software as a medical device framework [74,75]. In September 2022, it updated its “Policy for Device Software Functions and Mobile Medical Applications” [76], its guidance on clinical decision support software

[77], divulged its key findings from the pre-certification pilot program at the federal level [78], and launched its “Digital Health Policy Navigator” for developers [79].

What about Portugal?

Unleashing the eventual potential of digital health to help manage health conditions overall and mental health issues (such as anxiety and depression) in the Portuguese context implies understanding the agents, their incentives, and interconnections. The problem has two main actors: physicians (defined as psychiatrists or psychologists) and patients, which can be portrayed by individuals residing in Portugal.

Doctors are essential since patients usually delegate medical decisions to doctors [80,81]. Therefore, mental health professionals’ attitudes towards digital health apps are a key success factor likely to steer adherence and outcomes [82]. We can expect doctors to be more willing to use digital tools if patients demand them. Consequently, patient buy-in is needed to make this system work, and that will only be possible if digital health developers and companies consider their expectations and concerns [83]. These can range from user interface (UI) and user experience (UX) [84] considerations to confidentiality and privacy issues [85-87].

Portugal has no direct equivalent to prescription apps or the German Ministry of Health’s DiGA program. The Portuguese reimbursement scheme for pharmaceuticals is centrally negotiated and decided by the Regulatory Authority for Medicines and Medical Devices (INFARMED). Medical devices in the EU market are subject to a conformity assessment, being the definition of medical devices already extended, in law, to software and software applications. INFARMED is the authority responsible for notified bodies. It has a coordinating role in verifying conformity assessments and selecting third parties to become notified bodies accountable for conformity assessments in high-risk cases.

In turn, the Shared Services of the Portuguese Ministry of Health (SPMS), primarily responsible for the development of the country’s eHealth strategy, make adhesion to their health app store (MySNS Seleção [88]) conditional on an assessment system that evaluates apps concerning performance, safety, public utility, and information quality and security according to EU Law [89]. Even though these two regulatory players display some level of scrutiny in EU terms, ample room remains for economic, social, and regulatory development, showing a lag vis-à-vis German, Belgian, or French ambitions [90,91].

This research project is an opportunity to assess whether DMHA would be welcomed in Portugal and a healthcare system with its political economy. By comparing Portugal with Germany (from the physicians' point of view) and the USA (from the individual's point of view) in similar settings, we hope to enrich the comparison between health systems with a very significant private sector role and systems where government plays a key function in ensuring access to and funding of health care, particularly concerning mental health and the use of electronic/digital tools.

This constitutes a relevant contribution to the scientific literature not only of life sciences and their digital potential but also in terms of the industrial characterization of health economics for these subtopics and the mapping of expectations, through attitude and perception elicitation, from both supply and demand sides of mental healthcare.

3. Objectives

This thesis aims to understand how physicians and individuals perceive digital mental health applications and, through that, to provide a more precise landscape of the digital health setting in Portugal. This will support academic, policy, and business development regarding DMHA and how their potential use might offer professionals and patients the necessary tools to tackle the increasingly unmanageable burden of mental health disorders.

This aim will be achieved through the answers to the following research questions exposed in the peer-reviewed and published original research protocol (Chapter 4), which are distributed by their respective chapters:

Chapter 5:

- How do physicians perceive digital health applications?
- How digitally literate do physicians perceive themselves and their patients to be?
- How do physicians see their role in digitalizing health care provision?
- What are the most significant benefits, risks, barriers, and opportunities in digital health applications for physicians and their patients, in their opinion?

Chapter 6:

- How do individuals perceive mental health apps? Which factors determine the decision to use mental health apps, and how do individuals feel about it?
- What are individuals' preferences concerning resources and strategies for getting mental healthcare?
- How do individuals rate their mental health, and what impacts it?
- What perceptions do individuals have regarding mental health and its treatment?

4. Attitudes of Physicians and Individuals Toward Digital Mental Health Tools: Protocol for a Web-Based Survey Research Project

Paper 1 of the thesis.

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Attitudes of Physicians and Individuals Toward Digital Mental Health Tools: Protocol for a Web-Based Survey Research Project

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Abstract

Background: Digital transformation is impacting health care delivery. Great market dynamism is bringing opportunities and concerns alike into public discussion. Digital health apps are a vibrant segment where regulation is emerging, with Germany paving the way with its DiGA (Digitale Gesundheitsanwendungen, in German, meaning digital health apps) program. Simultaneously, mental ill-health constitutes a global health concern, and prevalence is expected to worsen due to the COVID-19 pandemic and its containment measures. Portugal and its National Health System may be a useful testbed for digital health interventions.

Objective: The paper outlines the protocol for a research project on the attitudes of physicians and potential users toward digital mental health apps to improve access to care, patient outcomes, and reduce the burden of disease of mental ill-health.

Methods: Web surveys will be conducted to acquire data from the main stakeholders (physicians and the academic community). Data analysis will replicate the statistical analysis performed in the studies from Dahlhausen and Borghouts to derive conclusions regarding the relative acceptance and likelihood of successful implementation of digital mental health apps in Portugal.

Results: The findings of the proposed studies will elicit important information on how physicians and individuals perceive digital mental health app interventions to improve access to care, patient outcomes, and reduce the burden of disease of mental ill-health. Data collection ran between September 26 and November 6, 2022, for the first study and September 20 and October 20, 2022, for the second study. We obtained 160 responses to the first study's survey and 539 answers to the second study's survey. Data analysis is concluded, and both studies' results are expected to be published in 2023.

Conclusion: The results of the studies projected in this research protocol will have implications for researchers and academia, industry, and policy makers concerning the adoption and implementation of digital health mental apps and associated interventions.

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Keywords: Mental health; digital technology; depression; anxiety; government regulation; mobile apps

Introduction

Digital Transformation in Health

Digital transformation and its impact on health [1] is evermore present [2]. Investment inflow into the digital transformation in the health care market registered a 10.4% compounded annual growth rate from 2016 to 2020, with a further 14% compounded annual growth rate expected in 2021-2031, denoting strong market dynamics [3]. According to IQVIA Institute for Human Data Science's Digital Health Trends 2021 report [4], mobile apps in the business-to-consumer market registered at "(...) top app stores worldwide are now over 350,000 in number, with more than 90,000 digital health apps added in 2020—an average of more than 250 apps per day."

The growth of digital tools applied to health has, however, been largely achieved without regulatory scrutiny appropriate to the needs of a digital society and due consideration for the quality, safety, and effectiveness of tools. There is rising concern that mobile apps, for one, do not meet enough clinical or technical validation standards or even register any type of empirical support [5-8]. Further, following a rush of optimism as the COVID-19 pandemic became a global challenge and research organizations tried to leverage technological tools, the evidence showed that, for instance, artificial intelligence-based mechanisms often failed to deliver on their promise [9], thus making the discussion more relevant. If COVID-19 brought concerns about the tools used for digital health delivery, it is also true that it provided a very significant impulse to their adoption, laying the ground for their widespread use in a post pandemic world [10], including in fields such as digital mental health (MH) [11].

Physicians and prospective patients alike have several concerns regarding digital health, and there are myriad challenges and risks ahead. These include lack of digital literacy, barriers to health care access that stem from the digital divide, and worries about losing touch with a familiar model such as face-to-face consultation [12-16]. Further questions arise around legal and ethical questions around topics such as confidentiality, privacy, patient autonomy, or the trustworthiness and accountability of care delivery [17-20].

The scope of our research protocol encompasses 2 different concepts that need clarification: digital health and, more particularly, digital mental health apps (DMHAs). This clarification is important as none of these constructs has a stabilized definition due

both to the evolving nature of their underlying fields and to the heterogeneity of stakeholders that work with them, ranging from academia to governmental institutions and industry.

For this research protocol and its papers, digital health will be defined as technologies that connect and empower people and populations to manage their health and wellness by augmenting workforce capacity while leveraging digital tools and technologies to shape care delivery [21]. It uses information and communication technologies to facilitate the understanding of health problems and challenges faced by people receiving medical treatment and social prescribing in more personalized and precise ways [22-25].

Within digital health, we will be focusing on DMHAs—a type of digital MH [26] tool that uses the format of a mobile app to aid MH assessment, support, prevention, and treatment [27,28].

The rise of digital health applications – regulatory concerns

Digital health apps promise to empower users and provide a unique opportunity for access to health (eg, by expanding remote care) while increasing the volume and variety of information available to physicians. More than 350,000 health apps are available from various app stores, with 110 downloaded over 10 million times and accounting for almost 50% of all downloads [4]. According to the same source, COVID-19 increased app use, and MH, cardiovascular, and diabetes condition management apps accounted for nearly 50% of disease-focused apps. However, considering the difficulty in assessing the impact of digital health apps [29] on health, policy makers have recently taken measures to reduce the uncertainty surrounding digital health apps by introducing standardized processes for evaluation akin to medicines or medical devices [30].

The identification of digital health apps that are safe and effective presents a significant challenge for health systems across the globe, making proper regulation essential to minimize risks and magnify benefits. Apps that tackle high-risk or chronic conditions, or that attempt to perform diagnosis or treatment, are especially relevant in this scenario given the time one is expected to use them or the sensitivity of associated information. Regulation constitutes an aprioristic need to produce payment and reimbursement pathways that balance costs and benefits while ensuring access and defining clear use policies aside from those that are market based (eg, star ratings in app stores) [31].

When it comes to implementing a regulatory framework aimed at digital health apps and their market access and reimbursement, Germany assumed a pioneering role. Its DiGA (Digitale Gesundheitsanwendungen, in German, meaning digital health apps) [32] program was inaugurated in October 2020, and, on December 20, 2022, 34 apps had qualified for statutory insurance reimbursement (of these, 14, or 41%, were classified as being DiGA for mental disorders) [33]. An app is accepted into the DiGA program after the German Federal Agency for Medicines and Health Products evaluates it in terms of general requisites (concerning technical safety and user-friendliness) and positive clinical effects. If an app has not yet proven the latter, it has 12 months to do so and is included in a provisory listing; if it fails to comply, it is withdrawn. If the app can prove both compliances with general requisites and positive clinical effects, German Federal Agency for Medicines and Health Products approves it, and price and reimbursement negotiations follow with the association of statutory insurers (GKV-SV), after which it is included in the DiGA Directory [33]. France is studying a replication of the DiGA approach and is expected to implement it until the end of 2022 [34].

Belgium ranks second in implementation—even though the mHealthBelgium [35] initiative was launched in 2018, it officially started conducting appraisal and reimbursement processes in January 2021. Its selection process is based on a 3-level validation pyramid [36] consisting of criteria related to legal and regulatory issues (level 1), safe communication and privacy (level 2), and financing and reimbursement (level 3, subdivided into 3–, if it has provisional reimbursement while proving socioeconomic benefits, and 3+, if it already has proven those same benefits). On June 2, 2022, 23 apps had level 1 clearance, and 12 apps had level 2 clearance. Moreover, 1 app received 3– clearance, and none had been cleared for level 3+.

Other European countries have so far opted for softer, more decentralized approaches, with legal obligations and compliance rules based on the General Data Protection Regulation [37] or the Medical Devices Regulation [38]. Singapore and the United States, on the other hand, resort to their own medical devices regulations, with the Food and Drug Administration issuing guidance in 2021 [39] regarding a pilot project at the federal level and, thus far, assessing software as a medical device [40].

Mental health, anxiety and depression, and pandemics: a troublesome cocktail

Mental disorders are globally responsible for 4.92% of total disability-adjusted life years (DALYs) and 13.04% of all disease prevalence cases. Depressive disorders are accountable for 1.84% of global DALYs and 3.76% of total disease prevalence, while anxiety answers for 1.13% of global DALYs and 4.05% of disease prevalence in the globe [41]. The 2 conditions accounted for more than half of the impact MH disorders had on global health in 2019 according to the GBD Compare tool developed by the Institute for Health Metrics and Evaluation.

Table 1 presents a breakdown of the impact mental disorders as a category, alongside anxiety and depression, had not only in global health but also on the health status of some geographies of concern for us in this protocol—the United States, the European Union, and Germany—in 2019, measured in DALY and disease prevalence cases. Data were gathered using the previously mentioned GBD Compare tool [41].

Table 1. Share of DALY and disease prevalence (in percentage points) per condition and geography. *Data source: Institute for Health Metrics and Evaluation (IHME). GBD Compare Data Visualization. Seattle, WA: IHME, University of Washington, 2020.*

	World		USA		EU		Germany	
	DALY	Prevalence	DALY	Prevalence	DALY	Prevalence	DALY	Prevalence
Mental disorders	4.92%	13.04%	6.56%	17.03%	6.65%	15.34%	6.43%	15.59%
Depression	1.84%	3.76%	2.38%	4.92%	2.42%	4.6%	2.16%	4.32%
Anxiety	1.13%	4.05%	1.68%	6.51%	1.69%	5.82%	1.95%	7.07%

In all geographies considered in the paradigm, depression and anxiety account for over half of the burden of disease generated by mental disorders. Furthermore, these conditions are always a relevant public health issue in any of the mentioned contexts due to their prevalence, thus making the importance of addressing them undisputable.

These data are with regard to 2019, and consequently do not factor in the consequences of the COVID-19 pandemic and its containment measures in MH deterioration. Many experts have alerted to the deleterious impact [42-44] of this pandemic, especially for children and adolescents [45], and have issued calls to action on the need to tackle this issue heads on [46,47]. It has been suggested that digital MH tools could help manage the burden of the disease brought about by mental disorders, in particular anxiety and

depression [48]. Rapid and affordable mechanisms of population screening and follow-up are necessary in a post pandemic world; otherwise, the burden of the disease will be unbearable for any health system [49-51].

Portugal and its mental health landscape

The Portuguese National Health Service (NHS) is a publicly owned, tax-financed health system that aims at ensuring wide, universal, and mostly free-of-charge care [52]. Regarding total health care activity in Portugal in 2019 (the most recent and pandemic-free full-year available), the NHS delivered 59.8% of 21.1 million outpatient consultations, 76.5% of 8.2 million emergency room episodes, and performed 66.2% of 1.21 million surgeries. The NHS was also responsible for 82.1% of 180.3 million uses of complementary means of medical diagnosis and therapy, as well as for 71.5% of 1.1 million hospitalizations and 84.7% of 86.4 thousand births [53]. The Portuguese NHS was therefore accountable for 79.5% of the health care delivered in Portugal. Regarding funding, the government financed 63.8% of total health care expenditure, with out-of-pocket family spending representing 30.5% and private insurance companies accounting for 3.8% of the total [54].

The data point to an eminently public health system both in funding and activity, with significant household financial strain and a modest contribution of private insurers. It also means that most of the Portuguese population relies on the care provided by the publicly financed and managed NHS. This is a significant difference from health systems such as those of Germany [55] or the United States [56], where health and care are largely privately owned, financed, and managed. In these countries, the government only intervenes in specific cases, mostly related to income deprivation or market failures. Such differences entail different economic, managerial, and organizational incentives, reflecting different cultures and preferences [57].

Several studies draw attention to a lack of MH and care resources within the scope of the Portuguese NHS, chief among them is the first (and so far, sole) national epidemiological questionnaire on MH [58]. This constitutes an alarming background considering the Portuguese population's particularly worrisome MH status: 51.4% of the population is expected to have a MH issue at some point in their lives. This datum reports to 2013; the Order of Portuguese Psychologists reported, in its factsheet on depression dated December 2021, that depression alone affected 10% of the population [59].

Evidence on the quasiepidemic nature of MH issues grows; the prevalence of MH disorders in 2019 was estimated at 8.27% of DALYs and 19.27% of disease cases. The statistics for anxiety and depressive disorders were, respectively, expected to be 2.58% and 3.16% of total DALYs and prevalence valued at 9.08% and 5.88% [60].

These data add to the public health relevance of these conditions, and several experts point out that, due to socioeconomic constraints ranging from stigma to lack of accessibility or affordability, these figures might be altogether underestimated [61-64]. At the same time, the World Health Organization expects the COVID-19 pandemic to have a detrimental effect on these statistics, further exacerbating the issue [65]. Children and adolescents at risk due to both family context and the COVID-19 pandemic [66-68] constitute further cause for worry.

Primary care services and digital health tools for self-management have been singled out as an opportunity to tackle this and other issues concerning health and care [69-72], namely chronic illness and quality of life, rising health costs, or significant burden of disease [73,74]. Portugal has registered a very significant uptake of telemedicine consultations [75] in its NHS, and the pandemic has arguably played a role in catalyzing this change. In context, the country ranks 16th (ie, slightly below average) in the European Commission's 2021 Digital Economy and Society Index [76], which assesses the digital maturity of each Member State.

Unleashing the eventual potential of digital health to help manage health conditions overall and MH issues (such as anxiety and depression) in the Portuguese context implies understanding the agents, their incentives, and interconnections. The problem at its core has 2 main primary actors: physicians (defined as psychiatrists or psychologists) and patients.

Doctors are important since patients usually delegate medical decisions to doctors [77,78]; therefore, MH professionals' attitudes toward digital health apps are a key success factor likely to steer not only adherence but also outcomes as well [79]. By the same token, we can expect doctors to be more willing to use digital tools if patients demand them. Consequently, patient buy-in is needed to make this system work, and that will only be possible if digital health developers and companies consider their expectations and concerns [80]. These can range from user interface and user experience [81] considerations to confidentiality and privacy issues [82-84].

Portugal has no direct equivalent to prescription apps or the German Ministry of Health's DiGA program. The Portuguese reimbursement scheme for pharmaceuticals is centrally negotiated and decided by the Regulatory Authority for Medicines and Medical Devices (INFARMED). Medical devices in the European Union market are subject to a conformity assessment [38], being the definition of medical devices already extended, in law, to software and software apps. INFARMED is the authority responsible for notified bodies and has a coordinating role in verifying conformity assessments and selecting third parties to become notified bodies responsible for conformity assessments in high-risk cases.

In turn, the Shared Services of the Portuguese Ministry of Health (SPMS), largely responsible for the development of the country's eHealth strategy, make adherence to their health app store (MySNS Seleção [85]) conditional on an assessment system that evaluates apps concerning performance, safety, public utility, and information quality and security according to European Union Law [86]. Even though these 2 regulatory players display some level of scrutiny in European Union terms, ample room remains for economic, social, and regulatory development, showing a lag vis-à-vis German, Belgian, or French ambitions [87].

This research project is an opportunity to assess whether DMHA would be welcomed in Portugal and in a health care system with its political economy. By comparing Portugal with Germany (from the physicians' point of view) and the United States (from the individual's point of view) in similar settings, we hope to enrich the comparison between health systems with a very significant private sector role and systems where government plays a key function in ensuring access to and funding of health care, particularly concerning MH and the use of electronic or digital tools.

This constitutes a relevant contribution to the scientific literature not only of life sciences and their digital potential but also in terms of the industrial characterization of health economics for these subtopics and the mapping of expectations and perceptions from both supply and demand sides of MH and care.

Aim and objectives

The research project we refer to is composed of 2 papers, both aimed at publication in the context of a doctoral research project being pursued by the first author of this paper under the supervision of its second author.

In this research project, we aim to understand how physicians and individuals might perceive digital MH tools. These constitute, respectively, the supply and demand sides of this market. Furthermore, we seek to provide a more precise landscape of the digital health setting in Portugal and provide grounds for academic, policy, and business development. Finally, we speculate on the potential use of digital health interventions for quantifying and providing tools to tackle the increasingly unmanageable burden of mild to moderate anxiety disorder and depression.

We will try to answer the following research questions: (1) How do physicians perceive digital health apps? (2) How digitally literate do physicians perceive themselves and their patients to be? (3) How do physicians see their own role in digitalizing health care provision? (4) What are the largest benefits, risks, barriers, and opportunities in digital health apps? (5) How do individuals perceive MH apps? Which factors determine the decision of using MH apps, and how do individuals feel about doing it? (6) What are individuals' preferences concerning resources and strategies for getting MH care? (7) How do individuals rate their MH and what impacts it? and (8) What perceptions do individuals have regarding MH and its treatment?

Methods

First paper (physicians)

The first paper will replicate the study performed by Dahlhausen et al [88] with adaptations. It will seek to understand the attitudes of physicians (both psychiatrists and psychologists) toward DMHA. The paper will allow us to characterize the implications of the supply side (ie, physicians who constitute the labor for the provision of MH services) for the adoption of DMHA in Portugal.

The study will be based on a cross-sectional, web-based survey. We will not include the qualitative part of Dahlhausen study as it was destined to complement the literature's findings to develop a survey. Instead, we will take the final survey questionnaire made available on Dahlhausen's study as given.

We will first translate it to Portuguese using a licensed translator and deliver it to physicians (both psychologists and psychiatrists, 5 each) for input. Physicians' feedback

will be focused on how to calibrate it to (1) reflect important questions to ask regarding the usage of digital health tools by doctors and (2) adapt to a Portuguese MH care context.

The feedback obtained from physicians will be incorporated to produce a final web-based survey questionnaire for this study. This survey will be deployed via Inqueritos@UP (the University of Porto’s internal survey manager, powered by LimeSurvey) as widely as possible and with the support of the Portuguese Order of Psychologists and the Psychiatry Specialty College of the Portuguese Order of Medical Doctors.

The survey will adhere to and be reported following the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) guidelines. For the certified translation of the Dahlhausen et al [88] questionnaire to Portuguese, as well as our final survey questionnaire in both Portuguese and English (the latter produced by a certified native Portuguese speaker translator from Portuguese to English), refer to Multimedia Appendix 1. Figure 1 summarizes the study’s stages.

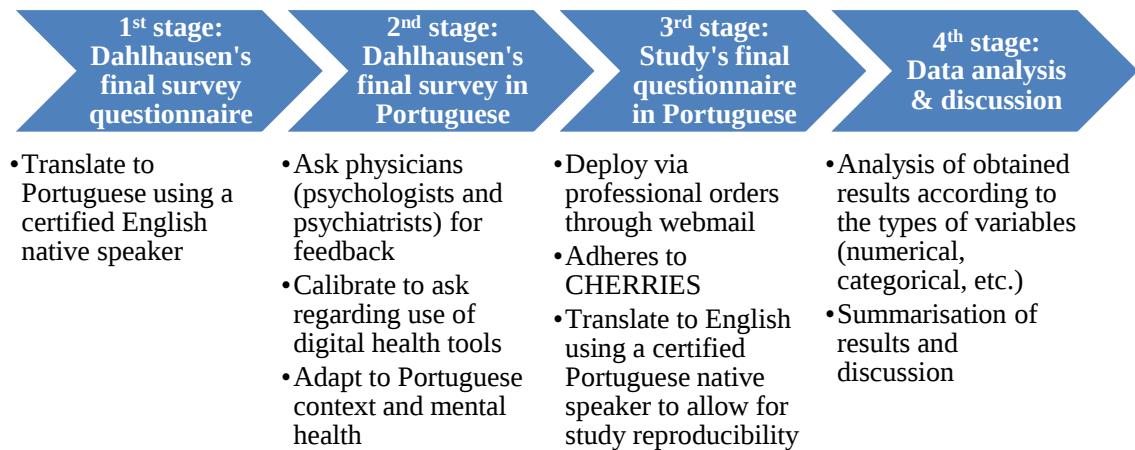


Figure 1. First study workflow.

There is no public information concerning the number of psychologists registered with the Order of Portuguese Psychologists. Registered psychiatrists (summing the stand-alone specialty with the subspecialty of children and adolescents) are a total of 1528. All will be invited to participate in this web-based survey via their respective professional orders.

To preserve privacy, respondents will not be asked to provide any identifiable information for completion of the survey. Additionally, invited participants will not be tracked for having started or completed the survey, increasing privacy but limiting the possibility of

reminders. To establish a basis for comparison with a reimbursable apps system, we will ask physicians who answer the survey to bear in mind a scenario where these apps fulfill regulatory requirements and address safety, quality, and efficacy concerns. This establishes an equivalency between the definition of DiGA apps as outlined in the “Introduction” section and the definition of DMHA used in our study.

To maximize response, the only inclusion criterion will be that of being registered and of good standing (ie, not responsible for any infractions) with the physician’s respective professional order. No exclusion criteria will be introduced. There will be no financial incentives for filling the survey.

Gathered data will be assessed according to the same model as in the Dahlhausen et al [88] paper to allow for maximum comparability between results. This entails the breakdown between the sociodemographic characteristics of the sample and the answers to the questions in the survey concerning the 4 main topics at hand: perceived benefits, potential barriers to, measures to support adherence to, and prescription intentions for DMHA. All variables that allow for it will be characterized by descriptive statistical analysis. Estimates of association for the variables that correspond to the Dahlhausen et al [88] “Perceived Benefits From and Attitudes Toward DiGA” and “Prescription Intentions” subsections will also be computed.

Only data excluded due to different health system organizations and their consequences for citizens or physicians (eg, statutory health insurance in Germany vs little to no point-of-care payments in Portugal) or to reasonable suggestion during the foreseen feedback period will be treated differently, being subjected to either descriptive statistical analysis or association estimation according to the nature of the variable at hand.

Second paper (individuals)

The second study produced in the context of this doctoral research project will replicate the paper by Borghouts et al [89]. The paper’s aim is to ascertain which factors determine public acceptance and usage of MH apps. The definition of MH apps in Borghouts study encompasses generic apps that can fall, for example, into the category of wellness, and our survey instrument will not impose any restrictions, thereby considering DMHA as an equivalent of MH apps in a broad sense.

The described study will simultaneously allow us to illustrate the demand side (ie, people who may potentially request MH services and care) for the adoption of MH apps in Portugal. Even though it is limited to an academic community, it is expected that it will have a reasonable mix of population characteristics. Limitations, both ex-ante and ex-post data collection, will be documented in the paper.

The study will start with a cross-sectional, web-based survey delivered through the University of Porto's dynamic email function. The web-based survey will be based on the survey questionnaire made available in Borghouts paper. This questionnaire will be translated into Portuguese using a licensed translator. Afterward, it will be circulated between an equal number of students and teachers (estimated to be 5 each) affiliated with the Faculty of Medicine of the University of Porto for input. Received input will concentrate on how to adjust it to (1) include important questions to ask regarding the usage of digital health tools with a focus on MH and (2) adapt to a Portuguese MH context.

Obtained feedback will be incorporated to produce a final web-based survey questionnaire for this study. This survey will be deployed via Inqueritos@UP (the University of Porto's internal survey manager, powered by LimeSurvey) as widely as possible and with the support of the University of Porto's services.

The survey will abide by and be reported following CHERRIES guidelines. For the certified translation of the Borghouts et al [89] questionnaire from English to Portuguese, as well as our final survey questionnaire in both Portuguese and English (the latter produced by a certified native Portuguese speaker translator from Portuguese to English), refer to Multimedia Appendix 2. Figure 2 summarizes the study's stages.

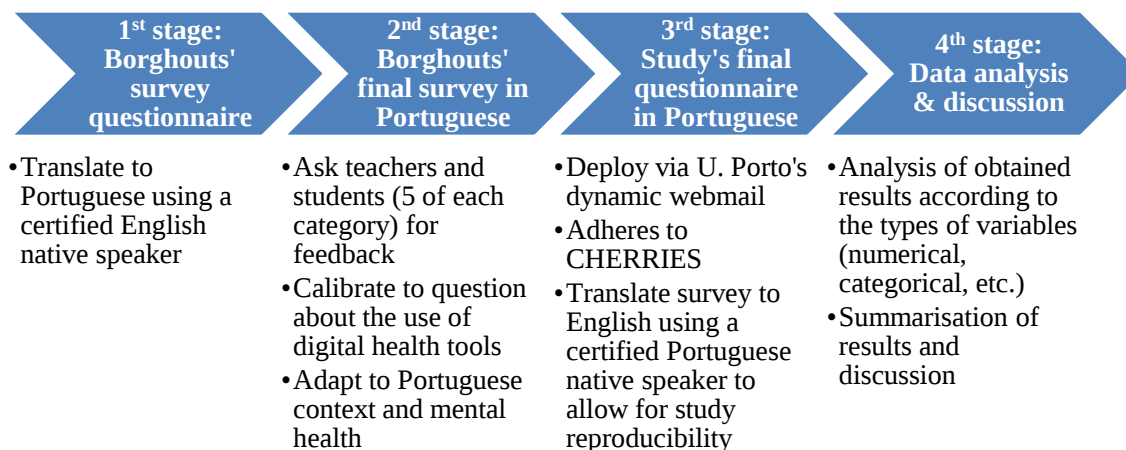


Figure 2. Second study workflow.

It is estimated that the dynamic email function of the University of Porto will allow us to reach approximately 36,700 members of the University's community and invite them to take part in this anonymous web-based survey. We will also ask the University of Porto's website management team to divulge the survey, providing a link to access it and following all privacy-related issues.

To preserve privacy, respondents will not be asked to provide any identifiable information. Additionally, invited participants will not be tracked for having started or completed the survey, increasing privacy but limiting the possibility of reminders.

High comparability with the Borghouts et al [89] study is expected due to the nature of the questions in the Borghouts et al [89] survey instrument and their relevance in a Portuguese population, leading us to believe that few questions will be dropped or significantly altered. Gathered data will be assessed according to the same pattern as that offered in the Borghouts et al [89] paper to allow for maximum comparability between results. This means that, aside from a sociodemographic depiction of the sample, we will measure the same constructs as the Borghouts et al [89] paper: barriers to MH resources, important aspects of MH apps, activities people wish for in MH apps, the presence of MH issues, past use of professional MH services, perceived stress, perceived need to seek help, MH concerns, perceived stigma, the impact of other people's expectations, and privacy concerns. Factor analysis and multicollinearity checking will be performed to limit the analysis to relevant constructs. Direct effect and full mediation models will be built.

All variables will be characterized by descriptive statistical analysis except when not possible. Only data that are excluded due to reasonable suggestion during pretest interviews will be treated differently, being subjected to either descriptive statistical analysis or association estimation according to the nature of the variable at hand.

To maximize response, the only inclusion criterion will be active registration with the University of Porto, defined as the ability to receive the email containing the invitation to answer the questionnaire. No exclusion criteria will be introduced. There will be no financial incentives for filling out the survey.

Ethical considerations

Ethical considerations and safeguards for the two manuscripts to be produced and their supporting documents include the following and incorporate advice received from the Data Protection Officer of the University of Porto:

- To preserve participants' privacy, they will not be asked to provide any personally identifiable information. In addition, participants will not be tracked for having started or completed the survey, increasing privacy but limiting the possibility of reminders.
- **Informed consent and consenting capacity:** all potential participants (physicians and academic community members) will be given online written information on the study and its objectives and will be asked to provide consent (click-to-agree) that they are happy to participate and that nonparticipation will not compromise their current roles. Participation in the study will be voluntary, and no inducements or incentives will be offered.
- **Confidentiality:** Any data/personal details that could potentially reveal the identity of individuals will be removed. Only anonymized, deidentified information will leave the place of origin. A database with responses will be maintained on a password-protected database. All research data will be stored on a password-protected desktop computer at the host organization. Study participants will be invited, through a link provided on the last page of the survey, to provide their name and electronic address to allow the research team to facilitate their receiving a synopsis of the study findings on publication. This list will be kept separately on a password-protected database and a password-protected desktop computer at the host organization. All data will be stored securely at the host institution and destroyed three years after the Ph.D. defense date.

- **General Data Protection Regulation:** GDPR compliance will be adhered to in terms of the following:
 - Data privacy rights – participants will have the right to request information about their data throughout the research process.
 - Transfer of data – participants will be informed about the circumstances under which their data may be transferred and safety measures that will be taken to protect the data (e.g., data are encoded).
 - Retention of data – participants will be informed how long their data will be stored.

By using Inqueritos@UP, survey data will be stored at the University of Porto's servers, and thus not shared with external entities, constituting another layer of privacy protection.

The Ethics Committee of the Faculty of Medicine of the University of Porto has pronounced itself favorable to the research project on June 30, 2022.

Ethics Approval

The research protocol was approved by the Doctoral Program in Health Data Science Director and the Ethics Committee of the Faculty of Medicine of the University of Porto (Rapport 52/CEFMUP/2022 of June 30, 2022). Data collection ran from September 26 and November 6, 2022, for the first study, and between September 20 and October 20, 2022, for the second study.

Results

The findings of the proposed studies will elicit important information on how physicians and potential users perceive and respond to the usage of DMHAs to improve access to care and patient outcomes, along with the reduction of the burden of disease.

Discussion

Principal Findings

This will be the first research project known to the authors with the specific aim of assessing whether DMHA would be welcomed in Portugal and in a health care system with its political economy. It will do so by mapping the expectations of agents that determine the demand and supply sides for DMHA.

As such, the research project will provide valuable inputs on what would be the key success factors for any market- or government-based actors who decide to enter the market by collecting key information to advise health policy and service development in Portugal and in international settings by providing a key benchmarking tool by comparing Portugal with Germany (from the physicians' point of view) and Portugal with the United States (from the individual's point of view) in similar contexts.

It is also the first research project establishing a comparison between health systems with a very significant private sector component and systems where government plays a key role in ensuring access to and funding health and care, particularly concerning MH and the use of digital tools. Finally, in characterizing the market's industrial organization by mapping the expectations of demand and supply sides, it adds to the literature on digital health economics.

Strengths and Limitations

Potential limitations of the research project include bias associated with the method chosen to select the sample in the second paper, as it considers that the academic community replicates the country's population distribution. Bias may impact external validity as this community may not necessarily replicate the Portuguese population's digital literacy or access to information and communication technology tools, and therefore the implicit digital divide.

In addition, the sample's average age may be younger than the country's average due to the teacher-student ratio and the respective average ages of these groups. Lack of generalizability may also derive from participant self-selection; those more interested in research or in using digital health tools will more likely fill the survey. Question-order, interviewer, and acquiescence biases may have a minor influence on conducted surveys. Notwithstanding these limitations, our research project is expected to provide important information on physicians' and individuals' attitudes toward digital MH tools.

To counter the previously identified limitations and enhance the comparability of results, the authors have produced a "Checklist for a future researcher" (Multimedia Appendix 3). Its aim is to facilitate further research both in Portugal and abroad by listing the main points requiring adaptation to reproduce this protocol in different settings.

Conclusions

The results of the studies projected in this research protocol will have implications for researchers and academia, industry, and policy makers concerning the adoption and implementation of digital health mental apps and associated interventions. Rapid and accessible screening, diagnostic, and treatment care strategies are needed to provide post-pandemic access to MH care, and this project will inform key factors in designing and implementing successful digital health interventions based on DMHA both in Portugal and abroad.

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Data Availability

The data sets generated during and analyzed during the current study are not publicly available but are available from the corresponding author upon reasonable request.

Conflicts of Interest

This study was conducted as part of the doctoral research project at the Health Data Science Ph.D. Program, Faculty of Medicine of the University of Porto, Portugal. All authors participated in these projects while employed by the Faculty of Medicine of the University of Porto. Both are working on a project co-funded by the European Union concerning the digitalization of clinical trials in the North of Portugal (CR – Digital: Digitize clinical research in the North of Portugal” (NORTE-01-0145-FEDER-083448).

This research protocol was executed during the authors’ time. The European-funded project or the Faculty of Medicine of the University of Porto were at no point involved in the research besides required administrative approvals. There was also no funding, pay, or other commercial interest provided by the Faculty of Medicine of the University of Porto aside from the costs related to the publication of this article.

Multimedia Appendix 1

First study's final questionnaire in Portuguese and English.

Multimedia Appendix 2

Second study's final questionnaire in Portuguese and English.

Multimedia Appendix 3

Checklist for a future researcher.

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5. Mental Health Professionals' Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Mixed Methods Study

Paper 2 of the thesis.

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Mental Health Professionals' Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Mixed Methods Study

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Abstract

Background: Digital health apps are among the most visible facets of the ongoing digital transition in health care, with mental health–focused apps as one of the main therapeutic areas. However, concerns regarding their scientific robustness drove regulators to establish evaluation procedures, with Germany’s Digitale Gesundheitsanwendungen program pioneering in app prescription with costs covered by statutory health insurance. Portugal gathers a set of conditions and requirements that position it as an excellent test bed for digital health apps. Its daunting mental health landscape reinforces the potential interest in new interventions. To understand if they would be acceptable, we need to understand the supply side’s attitudes and perceptions toward them, that is, those of psychiatrists and psychologists.

Objective: This study aims to understand the attitudes and expectations of psychiatrists and psychologists toward digital mental health apps (DMHAs) in the Portuguese context, as well as perceived benefits, barriers, and actions to support their adoption.

Methods: We conducted a 2-stage sequential mixed methods study. Stage 1 consisted of a cross-sectional web survey adapted to the Portuguese context that was delivered to mental health professionals and psychologists. Stage 2 complemented the insights of the web survey results with a key opinion leader analysis.

Results: A total of 160 complete survey responses were recorded, most of which were from psychologists. This is the most extensive study on mental health professionals’ attitudes and perceptions of DMHAs in Portugal. A total of 87.2% (136/156) of the respondents supported the opportunity to prescribe DMHAs. Increased health literacy (139/160, 86.9%), wider adherence to treatment (137/160, 85.6%), and proper disease management (127/160, 79.4%) were the most frequently agreed upon benefits of DMHAs. However, only less than half (68/156, 43.6%) of the respondents planned to prescribe or recommend DMHAs, with psychologists being more favorable than psychiatrists. Professionals faced substantial barriers, such as a lack of information on DMHAs (154/160, 96.3%), the level of initial training effort (115/160, 71.9%), and the need for adjustments of clinical processes and records (113/160, 70.6%). Professionals reported that having more information on the available apps and their suitability for health objectives (151/160, 94.4%), more scientific evidence of the validity of the apps as a

health intervention (147/160, 91.9%), and established recommendations of apps by specific clinical guidelines or professional societies (145/160, 90.6%) would be essential to foster adoption.

Conclusions: More information about DMHAs regarding their clinical validity and how they work is necessary so that such an intervention can be adopted in Portugal. Recommendations from professional and scientific societies, as well as from governmental bodies, are strongly encouraged. Although the benefits of and the barriers to using these apps are consensual, more evidence, along with further promotion of mental health professionals' digital literacy, is needed.

Introduction

Digital Health Apps

Digital health apps substantiate, perhaps more tangibly than most solutions developed so far, the opportunities the digital age may bring for human health [1-3]. Chief among them is the potential to make health care simultaneously more accessible and personalized. The magnitude of the business-to-consumer market speaks for itself; according to IQVIA's Digital Health Trends 2021 report [4], >350,000 health apps are available in various app stores, with 110 apps downloaded >10 million times and accounting for approximately 50% of all downloads.

The same report [4] highlights that the COVID-19 pandemic gave a solid impulse to app use, with mental health, cardiovascular disease, and diabetes management–related apps accounting for approximately 50% of disease-focused offering in app stores. The number of downloads and the variety of apps allowed many to conclude that there is an apparent demand at the consumer level. Simultaneously, patients' perspectives on app use in settings where prescriptions are available [5,6] reflect that patient acceptance still has a long way to go, although some evidence on how to enhance it is already available.

Regulatory Approaches

The realization that most tools in the field needed to be more mature to match formulated expectations prompted specialists to increasingly voice concerns that most apps need to meet more clinical and technical validation standards, often lacking any empirical support for their adoption [7-11]. A growing consensus is that regulation is needed, especially for apps that diagnose, treat, or manage high-risk conditions [12,13]. Governments and regulators have started to define policy frameworks to determine the benefits of digital solutions [14-18], trying to understand ways to reduce uncertainty around digital health app use and kick-start discussions on their potential payment or reimbursement.

Germany took the lead by implementing a regulatory framework specific to digital health apps and their market access and reimbursement. Its Digitale Gesundheitsanwendungen (DiGA) program [19] was inaugurated in October 2020, and on January 23, 2023, a total of 40 apps qualified for statutory insurance reimbursements. Of these 40 apps, 18 (45%) were classified as DiGA for mental disorders [20]. France is studying a replication of the

DiGA approach and has a preliminary reimbursement process through its assessments of mediatechnical and medical benefits [21,22].

Belgium ranks second in implementation; although mHealthBelgium [23] was launched in 2018, it officially started conducting appraisal and reimbursement processes in January 2021, with its selection process based on a 3-level validation pyramid [24]. Most European countries have so far opted for softer, more decentralized approaches, with legal obligations and compliance rules based on the General Data Protection Regulation [25] or the Medical Devices Regulation [26]. By contrast, Singapore and the United States resort to their medical device regulations. The Food and Drug Administration has been particularly active, basing its assessment of apps and digital therapeutics on the Software as a Medical Device framework [27,28]. In September 2022, it updated its *Policy for Device Software Functions and Mobile Medical Applications* [29] and its guidance on clinical decision support software [30], divulged its key findings from the precertification pilot program at the federal level [31], and launched its *Digital Health Policy Navigator* for developers [32].

Promise of Digital Mental Health Apps to Aid Care Delivery

Mental disorders are one of the areas where the penetration of digital health apps is most prevalent [4,20]. Reasons for their apparent popularity range from the stigma of seeking treatment and individual privacy needs to the convenience of doing it from everywhere and the diversity of treatments available (eg, meditation, cognitive behavioral therapy, group therapy, teleconsultation, etc) [33-38]. These disorders are also one of the disease areas in desperate need for increased and enhanced access. This need already existed before the COVID-19 pandemic, and many have pointed to the deleterious impact of the pandemic on mental health as one of its considerable long-term consequences [39-41]. The burden of disease it entails, both before and after the COVID-19 pandemic, and the way it impacts many other health conditions make it a priority for action [42-44].

Portugal is often cited as a country where mental disorders, particularly anxiety and depression, are above average; the prevalence of mental health disorders in 2019 was estimated at 8.27% of disability-adjusted life years and 19.27% of disease cases. The statistics for anxiety and depressive disorders were expected to be 2.58% and 3.16% of the total disability-adjusted life years and 9.08% and 5.88% of the disease prevalence,

respectively [45]. A summary of its comparison with the global, European Union (EU), and German landscape is presented in Table 1.

Table 1. Share of disability-adjusted life years (DALY) and disease prevalence (in percentage points) per condition and geography. *Data source: Institute for Health Metrics and Evaluation (IHME). GBD Compare Data Visualization. Seattle, WA: IHME, University of Washington, 2020.*

	Portugal		Germany		EU ^a		World	
	DALY (%)	Prevalence (%)	DALY (%)	Prevalence (%)	DALY (%)	Prevalence (%)	DALY (%)	Prevalence (%)
Mental disorders	8.27	19.27	6.43	15.59	6.65	15.34	4.92	13.04
Depression	3.16	5.88	2.16	4.32	2.42	4.6	1.84	3.76
Anxiety	2.58	9.08	1.95	7.07	1.69	5.82	1.13	4.05

^a EU: European Union.

Conversely, there is limited access to psychological and psychiatric care, with waiting times ranging from 13 to 237 days for a psychiatry consultation in the Portuguese National Health Service from July to September 2022 [46]. The time frame for a psychology consultation in the 11 institutions that reported it for the same period ranged from 15 to 134 days. Considering most depression and anxiety cases, albeit responsible for most of the disease prevalence of mental disorders, are classified as nonpriority cases, waiting times can be expected to range from 44 to 237 days.

In a country burdened by out-of-pocket payments about double the EU average [47,48], the possibility of resorting to private sector providers is minimal, as insurers cover only some associated costs. It is necessary and urgent to find new solutions. The combination of disease prevalence and lack of access to care, along with a relatively digitized health system and average indicators of digital literacy, makes Portugal an excellent test bed to understand whether digital mental health apps (DMHAs) can, or cannot, help people receive the care they need.

One of the key promises of digital health apps is increased access. However, no innovative intervention in health—be it a drug, medical device, or any other—achieves critical mass without the endorsement of health professionals [49-51]. Therefore, it becomes essential to understand, from the perspective of mental health professionals

(here defined as psychologists and psychiatrists), their level of comfort with digital health apps, their main challenges in adopting them, and what can enable and enhance their use.

To our knowledge, only one study has been performed on the Portuguese landscape of web-based interventions for psychologists [52]. No studies were found concerning the attitudes of psychiatrists in Portugal or combining the attitudes and perspectives of Portuguese psychiatrists and psychologists toward DMHA as a specific web-based intervention. Our study aimed not only at bridging these gaps but also at contributing importantly to do so (1) after the COVID-19 pandemic and its catalyzing effect on telehealth adoption [53]; (2) after major prescription and reimbursement processes were enacted in the EU space; and (3) by mapping the supply side of web-based mental health care, given the mediating effect of mental health professionals [50]. Our study contributes substantially to researchers, academia, industry, and policy makers by providing necessary information on how to leverage the DMHA as a tool to increase access to mental health care and improve patient outcomes while reducing the burden of disease associated with mental health disorders.

Objective

This paper aimed to understand mental health professionals' attitudes (defined as psychologists and psychiatrists in this study) toward DMHAs in the Portuguese context. Mental health professionals will be questioned regarding perceived benefits, barriers to adoption, and potential ways of supporting the adoption of DMHAs. These apps were the focus of this study. The authors aimed to achieve this by directly inquiring mental health professionals regarding their specific clinical practices, perceived needs, and expectations.

Methods

Study Design

The research team used a mixed methods methodology. Stage 1 consisted of a cross-sectional web-based survey adapted to the Portuguese context and delivered to mental health professionals and psychologists. It used a web-based quantitative data-focused survey, adapted to the Portuguese context, which served as a primary data source. Stage 2 used the answers collected from the survey to help conduct a qualitative key opinion leader (KOL) analysis.

As per the research protocol [54], the methods initially intended for this study had to be adapted because of the survey's low response rate. Both the web-based survey and the structure of the KOL analysis followed the same constructs studied by Dahlhausen et al [55] to maximize comparability with that study and the German landscape, albeit focused on mental health.

Notably, this study did not include a literature review of technology adoption, relevant case studies, or subsequent interviews with mental health professionals and psychologists on their views and perceptions toward DMHAs. This was deemed appropriate, as such processes had the objective of building up the questionnaire, and we intended to apply a translated version of the survey to the Portuguese context. Following the original publication, we conducted a web-based survey on a pretest group of health care professionals.

In Portugal, psychiatrists and psychologists are expected to prescribe or otherwise interact with DMHAs and act upon the patients' mental health. To maximize the targeting of these professionals, we restricted our approach to these 2 groups of health care workers. Moreover, to complement our interpretation of the survey results and help us understand the meaning and generalizability to the national context, we conducted a KOL analysis with a select set of professionals belonging to 1 of the 2 surveyed groups, with roles in clinical practice, academia, industry, or a combination of these.

Furthermore, given that no prescription processes are established in Portugal for DMHAs, it is not possible to rigorously define who would be authorized to recommend or prescribe DMHAs. Therefore, we asked clinicians to answer questions that report to recommendation or prescription according to their own cases, as psychiatrists are allowed to prescribe medication in Portugal, whereas psychologists are not. Our results should be interpreted accordingly.

Moreover, in our survey, we did not ask about health insurance coverage status, as it proves more relevant, in the Portuguese context, to understand whether they work for the National Health Service, in private practice, or both. As previously stated, we targeted only psychiatrists and psychologists for this survey, with the latter comprising most of the respondents (127/158, 80.4% of the answers). Although no data regarding the number of psychologists are available at the time of this study's conclusion, it is our perception

and that of the KOLs that the largest share of mental health professionals would be attributable to this group of practitioners.

In addition, we chose to represent survey data differently, intending to highlight the distribution of the categorical (Likert scale) answers and define their centrality without recurring to arithmetic operations.

Web-Based Survey Design

The first part of the study comprised a cross-sectional, web-based survey. We used the final survey questionnaire available in the Multimedia Appendix 1 in the study by Dahlhausen et al [55] as given and translated it to Portuguese using a licensed translator (Multimedia Appendix 2).

This translation was delivered to 10 mental health professionals—5 from each professional group, psychologists and psychiatrists—to gather their input. Mental health professionals' feedback was focused on calibrating the survey to (1) reflect essential questions to ask regarding the use of digital health tools by mental health professionals and (2) adapt to a Portuguese mental health care context. This allowed us to focus solely on mental health and DMHAs. The survey used by Dahlhausen et al [55] depicted, although implicitly and more pragmatically, the theoretical constructs of the Unified Theory of Acceptance and Use of Technology [56]. Given that our adaptation process did not affect this, we considered our questionnaire, by the same token, to adapt to the same theory and its constructs. The obtained feedback was incorporated to produce a final survey questionnaire for this study, available in English in Multimedia Appendix 1. Therefore, several changes were made, including modifying and adding questions, per the survey reviewers' suggestions. Although these limit the direct comparability between studies, they reflect the different needs and issues of the 2 countries. Both translations—the questionnaire by Dahlhausen et al [55] to Portuguese for adaptation and the final adapted survey questionnaire in Portuguese to English—were performed by SPS Traduções, a specialized translation firm.

Before broad diffusion, the survey questionnaire was pretested by 5 different colleagues to determine the completion time and identify shortcomings. As a result, an introductory page on digital health apps and developments in their regulatory landscape was included to provide initial baseline information before the start of the survey. The completion time was estimated to be between 4 and 7 minutes. To establish a basis for comparison with a

reimbursable app system, mental health professionals were asked to consider a scenario in which these apps fulfilled regulatory requirements and addressed safety, quality, and efficacy concerns. Accordingly, mental health professionals' responses are to be interpreted under this assumption and not necessarily to these apps' current form as available in Portugal. Nonetheless, it could be argued that because both Portugal and Germany belong to the EU and its internal market, an app developer would want to maximize comparability between apps, tweaking them for populational specificities.

Several web-based channels and methods were used to distribute the questionnaire to health care professionals. The survey's link was circulated in the newsletter of the Portuguese Order of Psychologists and through the social media of several members of the Psychiatry Specialty College of the Portuguese Order of Medical Doctors. The professionals who engaged in the questionnaire's adaptation were invited to perform snowball recruiting by sharing the survey link through their social media accounts and with professional contacts and forums where they were involved.

In addition, Knok healthcare [57], a fully integrated telemedicine platform company, offered to disseminate the questionnaire on its social media accounts to its relevant audience of health care professionals. This free initiative is part of Knok's mission to deliver social impact by divulging the potential benefits of telemedicine. Finally, the Portuguese Society of Psychiatry and Mental Health agreed to disseminate the survey via social media on Twitter.

The platform used was Inqueritos@UP, the University of Porto's internal survey manager by LimeSurvey. The survey adhered to and was reported following the Checklist for Reporting Results of Internet E-Survey (CHERRIES) guidelines. The period for answer collection ran from September 26, 2022, to November 6, 2022, the same 6-week period applied in the study by Dahlhausen et al [55].

The study's Data Protection and Privacy Policy, made available in the *Ethics Approval, Informed Consent, and Participation* section, comprises all relevant information on these aspects. To maximize responses, the only inclusion criterion was to be registered with the mental health professional's respective professional order. No exclusion criteria were introduced, and no financial incentives were offered. Figure 1 summarizes the survey's adaptation and communication workflow.

The gathered data were analyzed according to the methods used in the study by Dahlhausen et al [55] to allow for maximum comparability between the results. Descriptive statistical analyses were performed for all variables, whenever possible. Estimates of association for the variables corresponding to “Results” subsections in the study by Dahlhausen et al [55] were also computed.

Only data excluded because of different health system organizations and their consequences for mental health professionals (eg, statutory health insurance in Germany vs little to no point-of-care payments in Portugal) or of reasonable suggestion during the feedback period were treated differently and according to the nature of each variable.

The correspondence map between the initial questionnaire (ie, by Dahlhausen et al [55]) and the final survey questionnaire is presented in the table in Multimedia Appendix 3 [54].

Furthermore, data were analyzed to find associations among variables, especially between health care professionals’ demographic and professional characteristics, attitudes toward DMHAs, and the likelihood of prescription. These were conducted on RStudio (version 2022.07.1 build 554; RStudio Inc) using chi-square tests or, when conditions for using chi-square tests were not met, Fisher exact tests with Monte Carlo approximation and 2000 replicates [58,59]. R packages used for data processing, analysis, and graphical representations were *tidyverse*, *data.table*, *png*, *gt*, *gtExtras*, *gtsummary*, *Hmisc*, *likert*, *grid*, *forcats*, *scales*, *reshape2*, and *rcompanion*.

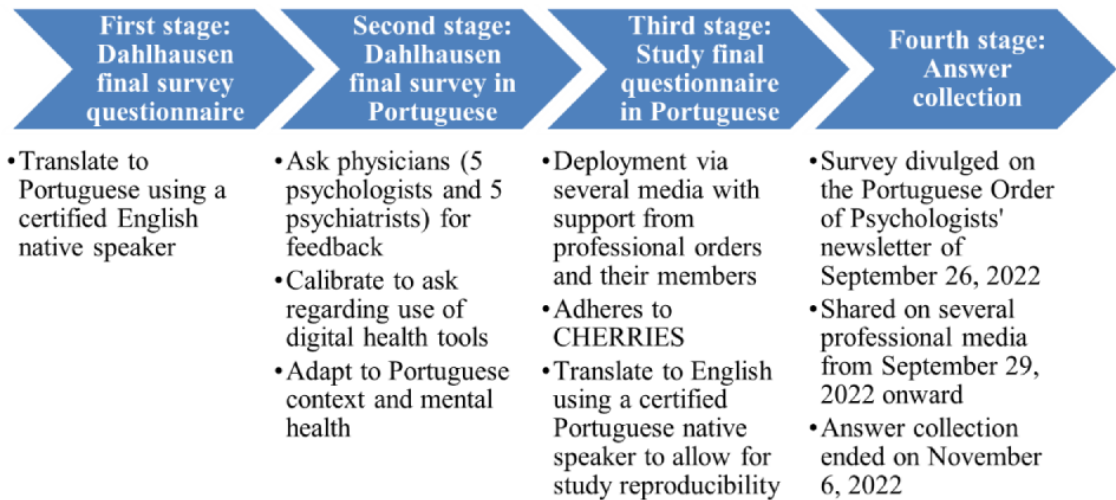


Figure 1. Survey adaptation and communication workflow. CHERRIES: Checklist for Reporting Results of Internet E-Survey.

KOL Analysis

The KOL analysis [60] served two purposes: (1) to compile what the prominent opinion voices in psychiatry and psychology in Portugal and across academia, clinical practice, and industry understand to be the main benefits, adoption barriers, and measures that can support the adoption of DMHAs and (2) to gather their input on the conducted survey's results to understand whether they agree with their perception of most Portuguese psychiatrists' and psychologists' views on DMHAs.

The KOL analysis followed a 2-step approach. The first step consisted of semistructured individual web-based interviews, followed by a second round of confirmation of the gathered consensus. The method used for the KOL analysis could be defined as a compromise between the Nominal Group Technique and the Delphi Technique [61].

In the first part of this interview, each KOL was asked what were, in their opinion, the top 3 benefits, barriers to adoption, and measures that could support the adoption of DMHAs in the Portuguese context. In the second part of the interview, the interviewers showed KOLs the results of the conducted web survey and asked them to comment on the results. The requested comments were focused on whether these results agreed with their perception of most Portuguese psychiatrists and psychologists, asking them to justify their opinions and statements.

The second stage of the KOL analysis consisted of circulating the main elements gathered during performed interviews and asking for their comments in free text, namely, whether they agreed with the established consensus and whether something important was missing. This analysis was divided into benefits, barriers to adoption, and support measures to ensure methodological consistency.

A total of 25 KOLs were identified and selected to participate in this research (practicing psychiatrists or psychologists, researchers, and managers with a psychiatry or psychology background working in digital health companies). Invitations to participate were made via email through the identification of publicly available professional email addresses. Snowball recruiting was used to find more participants; every contacted KOL was asked to suggest other KOLs that could be reached for this study. KOLs were given a 7-day period to answer whether they wanted to participate and, if so, to point to 3 dates and times for the interview. Those who did not respond to the initial invitation received a

follow-up email after 3 days to increase the response rate. Interviews ran from November 25 to December 23, 2022, lasting between 35 and 70 minutes.

Overall, 4 of the KOLs were psychiatrists and 2 were psychologists. This is an important feature to remember, as the number of psychiatrists who answered the survey was much smaller than that of the psychologists. This allowed us to expand the interpretation power of the answers provided by psychiatrists. Notably, every KOL contributes regularly to the public discourse on mental health and the use of technology to tackle problems around mental ill health, for example, in written media. Moreover, half of the KOLs (3/6, 50%) have already developed DMHAs or more comprehensive digital health tools, and 5 (83%) out of 6 KOLs work in academia and private or public sector.

Ethics Approval, Informed Consent, and Participation

The Ethics Committee of the Faculty of Medicine of the University of Porto pronounced itself favorable to the research project on June 30, 2022 (Opinion 52/CEFMUP/2022).

Ethical considerations and safeguards for the study and its supporting documents (including the web-based survey) were encoded in the study's Data Protection and Privacy Policy, which received approval from the Data Protection Officer of the University of Porto and is transcribed as follows:

- To preserve participants' privacy, they will not be asked to provide any personally identifiable information. In addition, participants will not be tracked for having started or completed the survey, increasing privacy but limiting the possibility of reminders.
- *Informed consent and consenting capacity*: all potential participants (mental health professionals and academic community members) will be given web-based written information on the study and its objectives and will be asked to provide consent (click to agree) that they are willing to participate, do so freely and voluntarily. Nonparticipation will not compromise their current roles. Participation in the study will be voluntary, and no inducements or incentives to participate will be offered.
- *Confidentiality*: Any data or personal details that could potentially reveal the identity of individuals will be removed. Only anonymized, deidentified information will leave the place of origin. A database with responses will be maintained on a password-protected database. All research data will be stored on a password-

protected desktop computer at the host organization. Study participants will be invited, through a link provided on the last page of the survey, to provide their name and electronic address to allow the research team to facilitate their receipt of a synopsis of the study findings on publication. This list will be kept separately on a password-protected database and a password-protected desktop computer at the host organization. All data will be stored securely at the host institution and destroyed 3 years after the PhD defense date. It is estimated that the PhD will be defended between October 2023 and December 2023.

- General Data Protection Regulation compliance will be adhered to in terms of the following:
 - Data privacy rights: participants will have the right to request information about their data throughout the research process.
 - Transfer of data: participants will be informed about the circumstances under which their data may be transferred and safety measures that will be taken to protect the data (eg, data are encoded).
 - Retention of data: Participants will be informed of the duration for which their data will be stored.

Using Inquéritos@UP, survey data were stored at the university's servers and thus not shared with external entities, constituting another layer of privacy protection. Furthermore, the survey's first page briefly explained the required data and the rationale behind it.

Results

Web-Based Survey

Demographics

A total of 160 health care professionals completed the questionnaire, with only some nonresponses to specific questions. Although the overall survey response rate could not be determined, given its means of distribution and the adopted privacy-ensuring settings, 400 people opened the survey. This translates into a completion rate of 40%, making this study the most extensive on mental health care professionals' attitudes and expectations toward DMHAs in Portugal.

Table 2 shows the characteristics of those who completed the questionnaire and their work. The most common age group was the 36-45 years segment (59/160, 36.9%), closely followed by the 26-35 years segment (56/160, 35%), being skewed toward a younger population. Of the 160 participants, 134 (83.7%) participants were female, likely presenting a higher representation in the sample than in the national presentation (52.8% of all psychiatrists in Portugal were female, with no publicly available data for psychologists) [62]. Most respondents (136/160, 85%) served populations with >20,000 residents, representing a primarily urban setting.

Many practitioners worked in >1 type of practice, most commonly at clinics (57/160, 35.6%) and hospitals (56/160, 35%), with only 10.6% (17/160) working at the primary care level. A considerable portion of professionals were involved with private consultation services, either individually (35/160, 21.9%) or in a group (39/160, 24.4%). However, in the study by Dahlhausen et al [55], most clinicians were split between single or joint practice environments. Among those who answered about the number of mental health professionals and psychologists they worked with, most (64/119, 53.8%) reported having ≥ 5 such professionals in their workplace, with 26.9% (32/119) of participants reporting >10 professionals in their workplace. Of these 160 participants, 127 (79.4%) were psychologists and 25 (15.6%) were medical psychiatrists. The distribution of answers was relatively homogeneous with regard to the number of mental health professionals in the workplace. In the replicated paper, approximately half of the respondents (613/1268, 48.3%) reported having only 1 practitioner.

Table 2. Demographic and professional characteristics of the sample (N=160).

Characteristics	Values, n (%)
Age (years)	
<26	4 (2.5)
26-35	56 (35)
36-45	59 (36.9)
46-55	31 (19.4)
56-65	6 (3.8)
>65	4 (2.5)
Sex	
Female	134 (83.8)
Male	26 (16.2)
Size of population covered (inhabitants)	
<5000	5 (3.5)
5001-20,000	0 (0)
20,001-100,000	36 (25.5)

	100,001-500,000	52 (36.9)
	>500,000	48 (34)
	Unknown	19 (11.9)
Workplace		
	Hospital	56 (35)
	Primary care	17 (10.6)
	Clinic	57 (35.6)
	Individual private consultation	35 (21.9)
	Collective private consultation	39 (24.4)
Number of doctors and psychologists in workplace		
	1	19 (16)
	2	15 (12.6)
	3	13 (10.9)
	4	8 (6.7)
	5	10 (8.4)
	6	6 (5)
	7	5 (4.2)
	8	4 (3.4)
	9	4 (3.4)
	10	3 (2.5)
	>10	32 (26.9)
	Unknown	41 (25.6)
Profession		
	Psychologist	127 (79.4)
	Psychiatrist	25 (15.6)
	Other	6 (3.8)
	Unknown	2 (1.3)

Perceived Potential Benefits From DMHAs and Attitudes Toward DMHAs

Figure 2, as it happens to the following figures (ie, Figures 3-5), provides a visual representation of the Likert scale responses, ordered according to the color-coded legend. For each question (eg, increased health literacy), an overall share is represented for negative (“Totally Disagree” or “Disagree”), neutral (“Don’t Know” or “Neither Agree nor Disagree”), or positive (“Agree” or “Totally Agree”) answers. Their percentage is displayed on the left, central, and right positions of the stacked bars, respectively. As far as central tendency measures are concerned, we selected the median value of each group of answers besides the corresponding bar. The neutral response group was set as the center of the axis to facilitate comparisons between answers, with distribution graphs representing the distribution of the provided answers.

Potential benefits to the patient from DMHAs, namely, improved ability to make informed choices, proper disease management, improved treatment adherence, improved access to health care, and increased health literacy were perceived very positively by responding health professionals. This was demonstrated by the overall positive perceptions toward using DMHA services; in no case did the general agreement have <65% of the responses. A higher general agreement proportion of the answers (including “Agree” and “Totally Agree”) was found concerning the gains in health literacy (139/160, 86.8%) and treatment adherence (137/160, 85.6%).

With regard to general disagreement ratios (including “Disagree” and “Totally Disagree”), the most unfavorable perceptions (24/160, 15%) were demonstrated toward the capacitation of informed choices by the patients. This question (32/160, 20%) and another regarding improved access to health care (29/160, 18.1%) represented the highest proportions of neutral answers (including “Don’t Know” and “Neither Agree nor Disagree”).

In parallel, the same evaluation process was used to assess the practitioners’ attitudes and perceived potential benefits of these apps for health care professionals. The domains covered were satisfaction of higher DMHA-based demand from new patients, improved patient satisfaction, time savings owing to efficiency gains, better quality of care for patients, greater treatment success, and additional treatment options.

Overall, the distribution of the answers represented a reasonably positive impression of practitioner-specific potential benefits, although with a slightly inferior portion of general agreement answers owing to conditioning by higher neutral and general disagreement responses.

The highest general agreement proportion of the answers was attributed to better time management owing to efficiency gains (112/160, 70%), closely followed by the benefit of having an additional treatment option (106/160, 66.3%). The lowest general agreement ratio was regarding the expectation of greater treatment success (62/160, 38.8%), which also demonstrated the highest neutral and second highest general disagreement shares.

For the general disagreement ratios, the highest proportion was described concerning the possibility of improving the quality of patient assistance (27/160, 16.9%), closely followed by the previously mentioned improved treatment success. The share of neutral

answers ranged from 21.3% (34/160; regarding better time management owing to efficiency gains) to 46.3% (74/160; regarding improved treatment success).

Our adapted survey did not assess the perceptions on additional new patients, or additional income for this group of benefits, having added others regarding the satisfaction of higher DMHA-based demand and the DMHA as an additional treatment option at the suggestion of our survey reviewers.

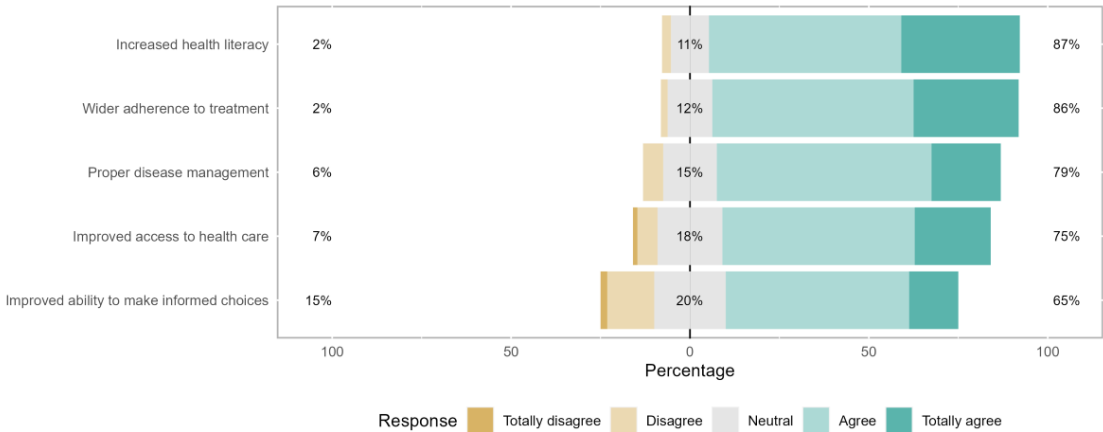


Figure 2. Perceptions of potential benefits for patients.

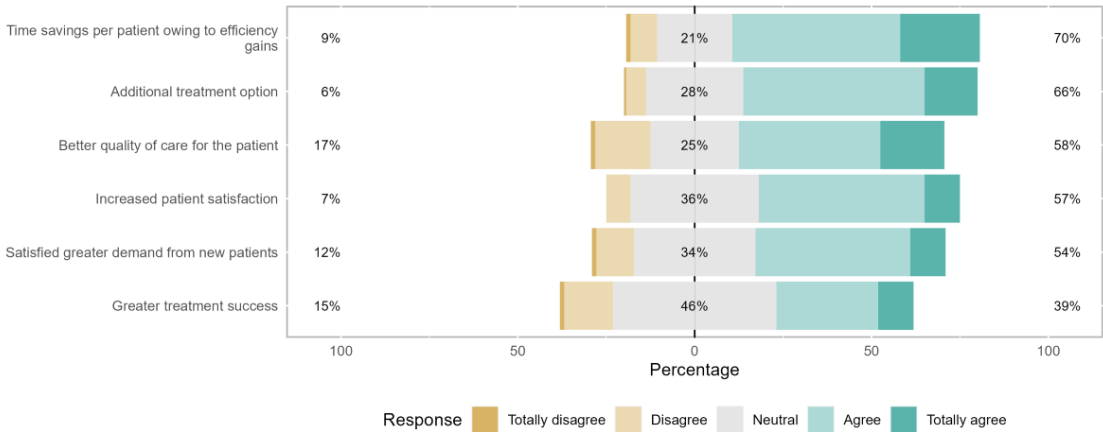


Figure 3. Perceptions of potential benefits for health care professionals.

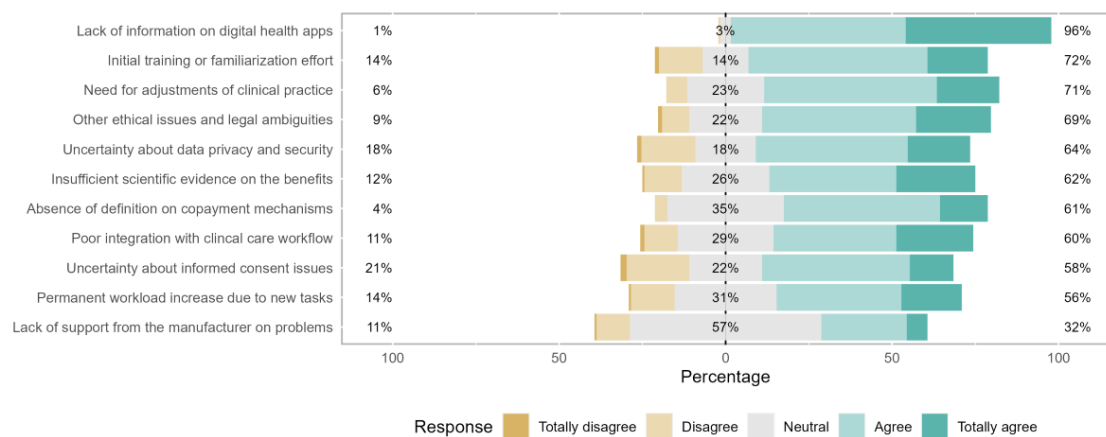


Figure 4. Perceived barriers to prescription.

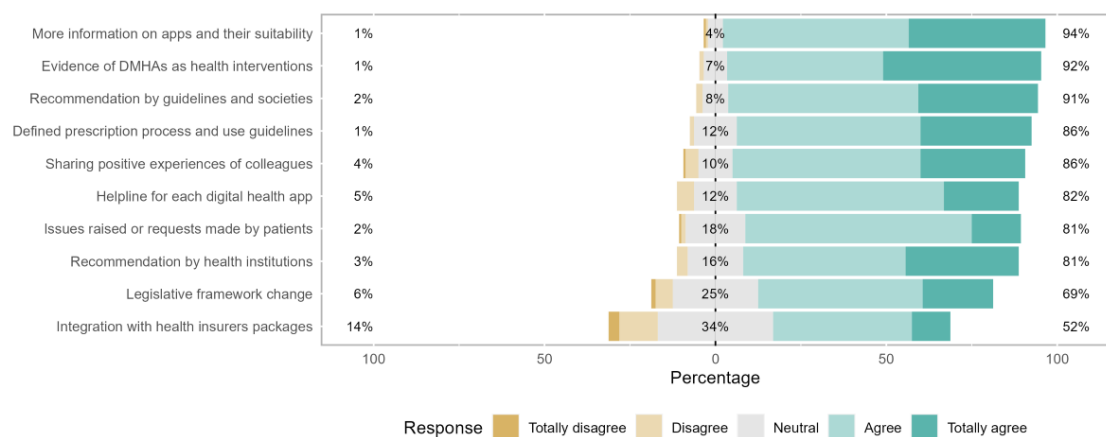


Figure 5. Measures to support adoption. DMHA: digital mental health app.

Prescription Intentions of DMHAs

Of the 160 participants, 68 health care professionals (n=62, 91% psychologists; n=6, 9% psychiatrists) declared to have an increased likelihood (“Likely” or “Very Likely”) to prescribe DMHAs in the coming 12 months, representing 42.5% of all the answers.

There were some differences in the prescription intentions between the 2 professional groups analyzed. For this variable, psychologists revealed a 48% share of increased likelihood answers, whereas psychiatrists only had 22% of their responses corresponding to these.

Concerning professionals’ attitudes, 136 mental health care professionals (n=114, 84% psychologists; n=22, 16% psychiatrists) declared to have a generally positive (“Positive” or “Very Positive”) attitude toward the possibility of mental health professionals and psychologists being able to prescribe, recommend, or use clinically and technically

validated DMHAs, representing 85% of all the answers. A much smaller difference was found in comparison with their intentions to prescribe. Psychologists and psychiatrists responded with 88% and 81%, respectively, generally positive attitude answers.

It is important to note while describing prescription intentions that practically no respondents to the survey have prescribed DMHAs to their patients. Simultaneously, there is no legally established prescription and reimbursement process in Portugal, as described in the *Introduction* section. This leads us to conclude that what we observe in this sample are the aprioristic perceptions and attitudes toward DMHAs.

Respondents who reported more positive attitudes toward DMHAs ($\chi^2_1=3.9$; $P=.048$; Cramer $V=0.19$) and those who worked in a clinic (Fisher exact $P=.03$) reported a higher intention of prescription. Male respondents also reported a higher likelihood of assuming more positive attitudes toward DMHAs (Fisher exact $P=.046$). The demographic or work-related characteristics of other health care professionals were not significantly associated with either DMHA attitudes or prescription intentions.

We found a statistically significant association between the digital affinity score and prescription intention (Fisher exact $P=.01$). This was not the case for the association between the digital affinity and the mental health professionals' attitudes (Fisher exact $P=.67$). Our results lead us to believe that Portuguese professionals expect to prescribe DMHAs shortly (the next 12 months); however, they are not currently very optimistic about these tools. This may suggest that they are open to changing their views.

Perceived Barriers to DMHA Prescription

Overall, 11 potential obstacles to DMHA prescription were listed. For most cases, except for lack of support from the manufacturer for technical issues, the answers demonstrated an agreement or total agreement with the characterization of the following as barriers to the prescription of these solutions.

With the highest share of agreement (154/160, 96.3%), the lack of information about digital apps gathered the most support from the respondents, including the highest percentage of "Totally Agree" answers. In addition, important issues such as the initial effort for health professionals (115/160, 71.9%), the need to adjust and adapt clinical records and practices (113/160, 70.6%), and ethical and legal questions (110/160, 68.8%) were very commonly identified as obstacles.

Respondents were found to disagree more frequently with the idea that uncertainty around informed consent (33/160, 20.6%) and data privacy and safety (28/160, 17.5%) would be substantial obstacles to DMHA adoption. At the same time, the most neutral answers (“Don’t Know” or “Neither Agree nor Disagree”) were registered regarding the lack of support from the manufacturer for technical issues (92/160, 57.5%), considerably superior to the next highest value (absence of copayment mechanisms; 56/160, 35%).

Measures to Support Adoption of DMHAs

In total, 10 different measures were presented to increase the adoption of DMHAs. For all cases, respondents expressed a favorable agreement with the utility of their adoption, ranging from 52% to 94% of the answers.

The highest share of agreement was reached concerning the need for more information about available DMHAs (151/160, 94.4%). Closely behind, most professionals considered that the existence of scientific evidence about the validity of the apps (147/160, 91.9%), the recommendation by professional and scientific societies (145/160, 90.6%), and the definition of the prescription process (138/160, 86.3%) along with the sharing and reporting of positive experiences by peers (137/160, 85.6%) were relevant measures to foster adoption.

The highest levels of disagreement were registered for the need to integrate DMHAs in health insurance plans (23/160, 14.4%), followed by changes to the legal framework (10/160, 6.3%) and manufacturer helplines for health care professionals (8/160, 5%). The most relevant share of neutral answers was registered regarding the integration of DMHAs in health insurance plans (54/160, 33.8%), which also reported the lowest level of agreement (83/160, 51.9%).

KOL Analysis

Overview

Of the 25 contacted KOLs, 11 (44%) replied to our invitation to participate in the interviews, 7 (64%) of whom gave positive replies. One KOL did not show up for the scheduled interview, and the remaining 6 were interviewed during the period mentioned in the *Methods* section. The interviews started with an overview of the study by the coauthors. They proceeded to ask the KOLs what were, in their opinion, the 3 main benefits of, barriers to, and measures to support the adoption of DMHAs in the Portuguese

context in descending order. An initial briefing was shared with the invitation to participate.

Perceived Potential Benefits From DMHAs and Attitudes Toward DMHAs

The 3 main benefits identified by the interviewed KOLs and that gathered consensus were the following:

- Improved access and accessibility to health care at the personal and population levels, including geographically more remote areas and preventive services.
- Improved efficiency in providing care, both from the point of view of direct cost (payment per treatment) and allocation of available human resources.
- Proximity to the user (including personalization of care, real-time monitoring, consideration of the user as an active participant, a more relevant number of potential users, and a potential for collecting real-world data for research).

Perceived Barriers to DMHA Prescription

The 3 main perceived barriers to DMHA adoption identified by interviewed KOLs and that gathered consensus were the following:

- Lack of knowledge and literacy of professionals at the digital skills level about existing DMHAs and related evidence-based information.
- Absence of training programs on DMHAs, especially those that positively position them and do not constitute them as a threat to professionals (especially as a risk of being replaced).
- The health system is not designed to consider digital tools (including their use, technical standards for information technology and information security, reimbursement, and stabilization of ethical and data protection concepts).

Measures to Support Adoption of DMHAs

The 3 main measures to support DMHA adoption identified by interviewed KOLs and that gathered consensus were the following:

- Creation of appropriate regulation, especially for clinical practice and reimbursement, and adequate health policies to boost the digital component safely.
- Promotion of literacy on mental health and training in digital apps (especially the younger generations), building awareness, and competency in digital tools in a constructive and collaborative perspective.
- Production of directives by the Ministry of Health and Professional Orders, such as an executive document with a selection of apps that could be useful and easy to implement while demonstrating good screening test characteristics.

Input Gathered From the KOLs

The second part of the interview consisted of the presentation of the results of the survey (as displayed in the previous subsections of the *Results* section for the web-based survey, ie, *Demographics, Perceived Potential Benefits From DMHAs and Attitudes Toward DMHAs, Prescription Intentions of DMHAs, Perceived Barriers to DMHA Prescription, Measures to Support Adoption of DMHAs*) to the KOLs and asking them whether they believed the obtained results to be aligned with their perception of most Portuguese psychiatrists and psychologists, justifying why.

Concerning the benefits of DMHAs, KOLs were aligned with the identified benefits for both users and professionals, as well as with the answer distribution of the sample. No KOL dissented from this view. KOLs expressed a perception of bias in the sample, reflecting a higher proportion of promoters of digital tools than the global average of mental health professionals. The answer to the hypothesis “improved ability to make informed choices” was the point that raised the most questions, and it is interesting to understand the rationale behind it. Greater adherence to treatment, access, disease management, and health literacy were in line with expectations. Response data were more balanced when evaluating the benefits for health professionals than for patients, where positive expectations seem to exist *a priori*.

Concerning the perceived barriers to the adoption of DMHAs, KOLs were generally aligned with identified benefits and the distribution of the answers in the survey, with only 1 KOL stating that they did not think these were representative of their peers’ opinions. KOLs considered that respondents had a favorable perception of digital apps, with a lack of technical support from the manufacturer and the need to adjust work

processes surprising them. The first item was a surprise owing to the low degree of disagreement; the second item surprised them because it entailed that the adaptation process would necessarily be painful. In the KOLs' opinion, professionals need help formulating the problems that concern them the most and whether or not it is a problem. They attributed these issues to a lack of experience with DMHAs. Furthermore, KOLs stated that they expected that a higher percentage would agree with the lack of reimbursement owing to being included in insurers' commercial packages as a relevant barrier.

Finally, regarding the measures to support the adoption of DMHAs, the KOLs aligned with the adoption support measures identified in the survey and the distribution of responses. The action "integration of applications in health insurance" generated the most comments. KOLs considered that it could reflect ≥ 1 of the following 3 issues: *a priori* concerns about data privacy (including data sharing with third parties), low payment fees to professionals, or matters related to stigma.

In addition, KOLs pointed out several peculiarities of the Portuguese context that they believed were important for any stakeholder (government, business, academia, or others) who wishes to develop a likely successful DMHA to address mental health professionals' needs. These were as follows:

- Health system financing and the incentives it produces must be considered, as health systems with budgeting practices based on production estimates instead of outcomes will experience severe difficulties in monetizing DMHAs and validating them as productive or cost-effective investments.
- Even if they are not inferior to other interventions, DMHAs may allocate resources more effectively and deliver savings by shifting individuals with lower mental health care needs to DMHAs and allowing mental health professionals to focus more of their time and attention on more complex cases.
- Professionals' resistance to novelty and workflow change, as well as negativity bias and feelings of being replaced by apps, must be addressed to ensure a successful embracement of DMHAs. KOLs considered this to be particularly true for psychiatrists, supported by the number of people who answered that they had the expectation of increased initial effort for health professionals (72% of the survey's

respondents), need to adjust and adapt clinical records (71%), and additional workload (56%).

- DMHAs must be adapted for use in a clinical setting, namely for severe mental issues (such as schizophrenia), where DMHAs are currently unfit to deal with acute severe episodes. Furthermore, DMHAs must be balanced to prevent a user's perception of pseudoautonomy that leads to the early abandonment of therapeutic interventions. Further research and development are required in these areas.
- Stigma plays a key role. This is not exclusive to one type of actor and ranges from the perceptions that professionals have of users and patients to insurance companies' pricing policies and offers. Information sharing with third parties other than professionals and users must be selective and scrutinized to prevent distrust in these tools and to avoid discrimination toward people who use them.
- Any DMHA must bear in mind cybersecurity risks and their impact on the user. Mental health issues are usually intimate matters, and that places a higher emphasis on information security.
- Research and development on DMHAs must be ongoing, both from a clinical and a technical standpoint. Evidence generation, treatment, and analysis are expected to be performed on a rolling basis owing to their digital nature.

Discussion

Principal Findings

Perceived Benefits, Barriers, and Measures to Foster Adoption

Regarding the perceived benefits of DMHAs for patients, our findings were generally aligned with those of the study by Dahlhausen et al [55] despite notable differences. Portuguese respondents were less optimistic about improved access to care and more positive about enhanced adherence to treatment. The time-saving potential benefit generated the most positive responses, whereas it was the worst regarding the perceptions of shared questions in the study by Dahlhausen et al [55]. The same is true for patient satisfaction, which was almost evenly split in the study by Dahlhausen et al [55]. Conversely, Portuguese professionals had some of the least positive perceptions concerning treatment success and quality of patient assistance. In contrast, German

professionals ranked some of their most positive scores for this variable. Overall, participants demonstrated a very high agreement with the listed potential benefits.

The respondents were less enthusiastic about the perceived benefits of DMHAs for professionals, namely, regarding the expectation of improved treatment success and the possibility of improving the quality of patient care. They did recognize the benefits of better time management owing to efficiency gains and the benefit of having additional treatment options.

We found a wider gap between the practitioners' attitudes toward DMHAs and their intentions to prescribe them in comparison with German professionals. This may be because of the effects of social desirability bias on provided answers [63-66] and the consequent positive aprioristic expectations. Their role might be expanded in the provided answers given the absence of a regulatory track for prescription and payment and general knowledge about DMHAs.

Concerning the barriers to DMHA adoption, our respondents agreed more with the importance of the lack of information about digital apps and the initial effort for health professionals, as well as the need to adjust and adapt clinical records and practices, alongside ethical and legal questions. They demonstrated general neutrality toward the importance of the lack of support from the manufacturer for technical issues and reimbursement schemes, and KOLs have attributed this neutrality to a lack of knowledge about these tools or concerns with patient data privacy.

By contrast, these mental health professionals agreed that more information about DMHAs, increased scientific evidence about their validity, recommendations by professional and scientific societies, and the definition of a prescription process along with the sharing and reporting of positive experiences by peers were all relevant measures to foster adoption.

To leverage DMHA adoption, both Portuguese and German professionals recognized the importance of the first 2 points and concurred on classifying direct exchange with developers as one of the least important issues. They disagreed, however, on the necessity of integrating apps into health insurers' commercial packages.

Attitudes and Prescription or Recommendation Intentions

In the German study, health care professionals with higher digital affinity were considerably more positive toward attitudes and prescription intentions; however, the strength of the associations was weak. While DiGA is already at work, DMHAs do not currently have a clear path for partaking in Portugal's clinical process and care provision.

Although a direct comparison between the professional groups of this study and the ones in the replicated paper is not immediate, the strictest association occurs in practitioners in psychiatric specialties ("child and adolescent psychiatry and psychotherapy" and "psychiatry and psychotherapy"), corresponding to the Portuguese psychiatrists, and the remaining specialties ("psychological psychotherapy" and "psychosomatic medicine and psychotherapy"), corresponding to psychologists in the Portuguese case.

The first group's differences between attitude and intention toward recommendation or prescription ranged from 38.5% to 45.9%, whereas the second group's differences ranged from 35.2% to 36.6%. In our study, for psychiatrists, we found a difference of 59% between the reported positive attitudes toward DMHAs and their intention to prescribe them (between 81% and 22%, respectively). For psychologists, the same difference was 40% (between 88% and 48%, respectively).

Although Portuguese psychologists' answers are more favorable than their German counterparts, the differences between attitudes and intentions have a similar magnitude. However, more Portuguese psychiatrists presented positive attitudes, while slightly fewer reported prescription intentions, thus yielding a larger difference than the one found in German psychiatrists.

KOL Analysis

First, it is important to highlight that in a country with no payment or reimbursement tracks or clinical or technical validation standards specific to digital health apps, these findings are based on the individual KOL's experience and perception of the national landscape.

Second, the interviewed KOLs mainly considered that the survey's results, despite the sample size and a possible bias in favor of digital tools, were representative of the study's intended population. This increased our confidence in the obtained results and, consequently, in the conclusions they can draw toward DMHA promotion.

Third, the fact that KOLs were unanimous regarding several issues—such as access to care, patient centricity, or (need for) mental health professionals’ digital literacy draws attention to the fact that the Portuguese health system needs profound transformation. Alerts have been abundant since Europe’s health systems suffered from the COVID-19 pandemic and its clinical backlog [67], which have come on top of long-lasting struggles such as workforce skills, motivation, and retention [68,69]; speed of digital transformation [70]; or the need to foster innovation [71]. The reference to these topics in unison between knowledgeable people, in a blinded and independent fashion, strengthens these arguments and reinforces the need to act on a broader digital health strategy that encompasses digital health applications.

Relationship With the Wider Portuguese Health System

The reported results from the survey and the KOL analysis revealed a general immaturity in implementing DMHAs (digital medical products, services, and interventions in general) in Portugal.

The survey shows an explicit generalized agreement with the perceptions listed concerning potential benefits, barriers, or measures to foster adoption. These results seem polarized to one of the extremes, as disagreement answers were never >21% for the specific questions.

Moreover, the topics generating the most neutral answers require some practical implementation of these tools—specifically, on the improvement of patient satisfaction, treatment success, and capability to make informed choices; on the lack of support from the manufacturer for technical issues; and on reimbursement of medical prescription, as well as integration of DMHAs in health insurance coverage. We hypothesize that this neutrality confirms a lack of practical experience with these tools. Otherwise, professionals would have more positive or negative perceptions because of their experience and less ambiguity or one-way polarization.

Our theory is compatible with other findings from the survey; although Portuguese professionals are at least as positive in their attitudes toward DMHAs as German professionals, the former group has only a smaller share of those who do intend to prescribe them, thus generating a wider gap between attitudes and prescription intentions for Portuguese mental health professionals than that found for German counterparts in the study by Dahlhausen et al [55]. If their intentions to prescribe are inferior to their German

counterparts, then it is expected that they will do so less often, aggravating the know-difference in the practical knowledge of using these tools. They also differ regarding the perceived importance of required workflow adjustments as a limitation to adoption.

This theory is also compatible with the Portuguese health system paradigm concerning mental health as described by the KOLs, who repeatedly reported the professionals' resistance to change and novelty, as well as the intrinsic fear of being replaced by DMHAs, as barriers to DMHA adoption. This barrier should be taken seriously so as not to create a negative reinforcement loop that further restrains professionals from adopting and applying such tools.

This is all the truer as the Portuguese National Health Plan [72] ranks “access to mental healthcare” as the sixth most important health determinant for the country's needs but fails to set any of its 37 health objectives to address this issue and its consequences. A specific National Program for Mental Health, responsible for producing a National Plan for Mental Health, existed from 2008 [73] until 2020. The National Coordination for Mental Health Policies replaced it at the beginning of 2022 [74]. Although the former has considerably failed to enact mental health care reform [75] and had no mention of DMHAs, the new Coordination is yet to publish its plan and objectives.

Strengths and Limitations

Portugal faces important challenges despite being a relatively small country (approximately 10.5 million inhabitants), namely, a rapidly growing aging population [76], declining birth rates [77], and an overburdened health system [46]. These challenges are similar to those encountered in many high-income countries. Therefore, Portugal might serve as a test bed to validate digital solutions that ease the workload on health care providers and increase patient autonomy. Our study contributes to this understanding as it is, to the best of the authors' knowledge, the first work of its kind on the Portuguese landscape concerning DMHAs.

The study elicits preferences and issues that are clearly important to understand the demand side, as it is visible, for example, through the high degree of agreement in survey answers and KOL responses. Furthermore, the mixed methods methodology allows us to combine the perspective of those closest to potential users with a helicopter view with in-depth knowledge, making the derived conclusions more robust.

All biases inherent to sampling and KOL selection are potential limitations of this study, with the social desirability of the provided answers and the role of expectation in the survey's answer process (ie, the belief respondents might have that they are expected to answer more favorably about technology than they would otherwise do), as well as self-selection, being among the most relevant. Their impact on provided answers is mitigated by the fact that in a postpandemic reality, telehealth (albeit limited to teleconsultation volume) [53] has proven its benefits to a large extent and certainly more than at the time Dahlhausen et al [55] conducted their study.

The sample number may constitute a further limitation, as 160 answers only partially characterize a population of 1528 psychiatrists and an undetermined number of psychologists. However, the level of agreement between the elements gathered in the survey and the KOLs' assessment, both before and after seeing the survey results, leads us to believe that the underlying uncertainty in the provided answers might not be as considerable as expected. Furthermore, the proportion between psychologists and psychiatrists in our study and the study by Dahlhausen et al [55] is approximately the same (6 to 1, respectively). This is a relevant sample characteristic that favors the comparison between the results of both studies.

Finally, the comparability between studies is limited by their different scopes and stages of regulatory development: the study by Dahlhausen et al [55] was produced when DiGA was starting to roll out and for all digital health applications (ie, not exclusive to mental health); as of the conclusion of this study, Portugal does not have a payment or reimbursement system in place for digital health apps in general, or DMHAs specifically. Even then, the similarity of methods, presentation of results, and the produced discussion allow, in our view, for a proper comparison.

Future Work

From a general perspective of digital health apps, it would be useful to fully replicate this study to understand which points are common to all apps and which are solely applicable to DMHAs. Deloitte's report for Health Cluster Portugal [78] is the only known work on the Portuguese domestic market. However, its high-level nature reveals how immature the market is in terms of digital health apps. More research is needed to understand their market dynamics, namely, when it comes to the expectations of supply and demand sides. To further improve the interpretation of results and have a clearer sense of the actual

differences between Portuguese mental health professionals and their German counterparts, it would be helpful to implement this or similar surveys on the overall Portuguese population. By evaluating the differences between mental health professionals and the people they serve, one could distinguish between context and specific differences attributable to training or skillset.

Moreover, as this is a portrait of the landscape as far as DMHA are concerned and one of the main difficulties that we felt was survey engagement (despite extensive dissemination efforts), it would be essential to perform this extended work with further engagement from professional orders, professional societies, and market-based stakeholders (eg, developers of apps such as 29kFJN [79]). Outreach to international stakeholders such as BfArM, mobile health Belgium, and market operators with products that have already secured regulatory approval by them would be beneficial.

Given that this necessarily entails regulation, it would be interesting to expand further on the regulatory science angle and the opportunity for either regulatory tracks at the EU level (following calls for European Health Union and increasing competencies of the EU in health care [80]) or regulatory replication to ensure a fair, competitive, and innovative digital health market in the EU. This is in the interests of regulators, companies, and citizens.

Finally, it is widely agreed that digital interventions have appreciable potential to deliver more and better health care. However, if these—or any other health interventions—are to succeed, they need rigorous planning by diagnosing the status, defining targets and priorities, establishing objectives and desirable results, and outlining the best evidence-based strategies and plans to achieve them [81]. Monitoring and evaluating the attained results and deriving learned lessons are also necessary. In the authors' view, this road map for DMHAs would potentially be the most relevant future work that could be done.

Conclusions

Portuguese mental health professionals' perceptions of digital health apps present clear aprioristic expectations regarding the benefits of DMHAs for users, especially concerning improved therapeutic adherence and health literacy. Although professionals generally recognize the benefits for patients, they are less optimistic about the expected advantages for themselves and their peers. Although the usefulness of DMHAs for professionals

needs to be clarified, benefits such as efficiency gains and having an additional treatment option are among the most valued benefits from the onset.

Chief among the main perceived barriers are the need for more information about digital health apps, preconceptions of initial use efforts for health professionals, and the need to adjust and adapt clinical records. The main enablers of DMHA use identified include more information about these apps, both regarding how they work and scientific evidence about the validity of such apps, as well as recommendations by professional and scientific societies. Governmental or regulatory guidelines are strongly recommended.

Portuguese mental health professionals, compared with German mental health professionals, were similar in most of the reported answers. Some notable differences were fewer positive perceptions concerning treatment success and quality of patient assistance, a wider gap between attitudes and prescription intentions for Portuguese mental health professionals, and the need for considerable workflow adjustments as limitations for adoption.

Concerning how digitally literate mental health professionals perceive themselves and their patients to be, the scores of digital literacy–related issues in terms of barriers and measures to support adoption in the survey, along with the conclusion by the KOLs that this is one of the main issues faced by mental health professionals in Portugal, lead us to posit that mental health professionals perceive themselves to have high degrees of digital illiteracy. They also perceived a strong need for patients to be educated should DMHAs or other digital tools be implemented to deliver mental health care.

Mental health professionals believe that their role in digitalizing health care provision consists mainly of promoting literacy among peers, namely, to and by younger age groups, thus forming communities able to capacitate a growing number of professionals. Their participation in professional and scientific societies is another avenue for further engagement. Finally, mental health professionals believe that the Portuguese government sector should play a crucial role in shaping the health system and enabling the proper organizational and financial means and incentives to catalyze transformation.

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Data Availability

The data sets generated or analyzed during this study are not publicly available but are available from the corresponding author upon reasonable request.

Conflicts of Interest

This study was conducted as part of the doctoral research project at the Health Data Science PhD Program, Faculty of Medicine of the University of Porto, Portugal. Two authors participated in this project while employed by the Faculty of Medicine of the University of Porto. Diogo Nogueira-Leite and Ricardo Cruz-Correia were working on a project cofunded by the European Union concerning the digitalization of clinical trials in the north of Portugal (CR—Digital: Digitize clinical research in the North of Portugal NORTE-01-0145-FEDER-083448).

All work concerning this study was conducted during the authors' personal time. The European-funded project or the Faculty of Medicine of the University of Porto were at no point involved in the research, aside from the required administrative approvals. There was also no funding, pay, or other commercial interest provided by the Faculty of Medicine of the University of Porto, aside from the costs related to the publication of this paper.

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Survey

DiGA: Digitale Gesundheitsanwendungen

DMHA: digital mental health app

EU: European Union

KOL: key opinion leader

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6. Individuals' Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Web-Based Survey

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Individuals' Attitudes Toward Digital Mental Health Apps and Implications for Adoption in Portugal: Web-Based Survey

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Abstract

Background:

The literature is consensual regarding the academic community exhibiting higher levels of mental disorder prevalence than the general population. The potential of digital mental health apps for improving access to resources to cope with these issues is ample. However, studies have yet to be performed in Portugal on individuals' attitudes and perceptions toward digital mental health applications or their preferences and decision drivers on obtaining mental health care, self-assessment, or treatment.

Objective:

This study aims to understand the determinants of digital mental health applications use in the Portuguese academic community of Porto, along with potential adoption barriers and enablers.

Methods:

A cross-sectional, web-based survey was delivered via dynamic email to the University of Porto's academic community. Data collection occurred between September 20 and October 20, 2022. We used structural equation modeling to build three models, replicating a peer-reviewed and published study and producing a newly full mediation model shaped by the collected data. We tested the relationships between use of digital mental health apps and perceived stress, perceived need to seek help for mental health, perceived stigma, past use of mental health services, privacy concerns, and social influence.

Results:

Of the 539 participants, 169 (31.4%) reported having used digital mental health apps. Perceived stress and a latent variable, comprising perceptions of mental health problems and coping strategies, were positively associated with mental health app use, while privacy concerns regarding one's information being accessible to others were negatively associated. Perceived stigma, need to seek help, and close relationships did not have a statistically significant direct effect.

Conclusions:

These findings can inform product and policy development of new, better-targeted digital mental health app interventions, with implications for researchers and academia, industry, and policymakers. Our study concludes that, to maximize adherence to these apps, they should have low to no financial charges, demonstrate evidence of their helpfulness and focus on the timely delivery of care. We also conclude that to foster digital mental health app use, there is a need to improve mental health literacy, namely regarding self-awareness of one's conditions, acceptable stress levels, and overall behavior towards mental health.

Trial Registration:

RR2-10.2196/41040

Keywords: mobile health; mHealth; digital health; apps; technology acceptance; adoption; mental health; mental health services; community mental health services

Introduction

Background

The lack of mental health, or a high prevalence of mental disorders, is associated with lower levels of quality of life [1,2], life satisfaction [3,4], and physical health [5], thus constituting a limiting factor to most aspects of human activity and autonomy [6].

Portugal presents worrisome mental health indicators in terms of disease cases and disability-adjusted life years (DALY): mental health disorders in 2019 were estimated at 19.27% of disease cases and 8.27% of DALY. The statistics for anxiety and depressive disorders were, respectively, expected to be 2.58% and 3.16% of total DALY and 9.08% and 5.88% of disease prevalence [7]. A summary of the comparison with the global and European Union (EU) landscape is available in Table 1.

Table 1. Share of DALY and disease prevalence (in percentage points) per condition and geography. *Data source: Institute for Health Metrics and Evaluation (IHME). GBD Compare Data Visualization. Seattle, WA: IHME, University of Washington, 2020.*

	World		EU		Portugal	
	DALY	Prevalence	DALY	Prevalence	DALY	Prevalence
Mental disorders	4.92%	13.04%	6.65%	15.34%	8.27%	19.27%
Depression	1.84%	3.76%	2.42%	4.6%	3.16%	5.88%
Anxiety	1.13%	4.05%	1.69%	5.82%	2.58%	9.08%

The data for Portugal shows the magnitude of the existing problem, and the difficulties in accessing psychological and psychiatric care are evident. Waiting times for a psychiatry consultation ranged from 10 to 349 days for a psychiatry consultation in the 91 institutions of the Portuguese National Health Service that reported them from September to November 2022. [8] The timeframe for a psychology consultation in the 12 institutions that reported it for the same period ranged from 15 to 148 days.

Considering most depression and anxiety cases, albeit responsible for most of the disease prevalence of mental disorders, are classified as non-priority cases, waiting times can be expected to range from 30 to 349 days, depending on where someone lives or receives care. It is likewise important to emphasize i) the geographical asymmetries, ii) the

concentration of waiting times on higher bounds (e.g., above 100 days of waiting time), and iii) the criticality of timely delivery of mental healthcare.

The limited access is further strangled by a share of out-of-pocket payments at about double the EU average [9,10], making access to private sector providers a privilege for the few who can pay it.

The momentum of mental health is visible in two other contexts: digital health applications (apps), where there is ample penetration of apps for mental health purposes, and academic communities, where mental diseases are more prevalent and several experts have alerted to the situation at hand [11-13]. Various studies have been conducted to understand digital interventions' impact in academic settings [14-19].

Digital Health Applications

Digital health apps promise to make healthcare more accessible and personalized by delivering healthcare in constrained contexts, namely remote locations, lack of workforce resources, or insufficient transport infrastructure [20-23]. According to IQVIA's Digital Health Trends 2021 [24], over 350,000 health apps are available in various app stores, 110 of which with over 10 million downloads.

The same report highlights that mental health, cardiovascular, and diabetes condition management apps account for nearly 50% of disease-focused applications in app stores. The number of downloads and variety of apps allowed many to conclude that there is apparent demand at the consumer level.

The scarcity of clinical and technical validation, and to a great extent of robust scientific evidence, is among the most significant perils digital health apps present [25]. Even though mental health is one of the disease areas where apps have proliferated, they can be misleading, as many of the tools currently being used for mental health fit into mindfulness or wellness categories, not being necessarily apps specifically designed to support patients in detecting or controlling specific diseases (e.g., anxiety or depression).

The diversity and volume of digital health apps in the mental health field add to the argument that this is one of the disease areas urgently needing widespread access due to its burden of disease and impact on health and health-related quality of life. And if no new intervention in health gains traction without individuals adhering to it, the volume

and variety of mental health apps and related downloads is an argument that there is a market for it, and individuals are at least willing to test this approach.

Mental Health Determinants and the Academic Community

Mental health problems affect young individuals disproportionately. OECD's Health at a Glance 2022 for Europe [26] estimated that the COVID-19 pandemic significantly impacted young people's mental health (defined as those whose ages ranged between 15-29 years old), with the rate of depressive symptoms more than doubling in several countries. Furthermore, around half of them faced unmet needs for mental health care both in 2021 and 2022, a rate about double that of all adults.

The report further emphasizes that young people with pre-existing and severe mental health issues reported worsening of their symptoms during the pandemic, that mental distress remains high into 2022, and that the pandemic highlighted linkages between income, inequality, and mental health. All these problems must be taken into a context where most mental healthcare facilities were already stretched, and severe disruptions in mental healthcare delivery were registered.

The academic community has been infamous regarding the mental health status of students, teachers, and administrative staff [27-30]. Taking into consideration Portugal's worrisome mental health indicators, the pandemic's detrimental effect on these indicators, and the alerts about the mental health problems in the country's academic communities [29-33], one could argue that the academic community of one of the country's largest universities is a good place to understand whether digital mental health apps (DMHA) could be a relevant resource to increase access to mental health resources for the wider population.

We anticipate this to hold as this community is expected to (i) reflect the urgent need for mental health resources and (ii) mimic the behavior of the section of the population most likely to adopt it (due to familiarity with smartphone usage, age, and literacy, among other factors). Despite recognizing that these characteristics are not fully replicable to the Portuguese population due to age structure, gender, and literacy levels, we expect our study's results to help tailor specific interventions from academia, industry, and government in the academic context, as well as to pave the way for further research at the population level.

We anticipate that specific determinants of mental health in college students will be important for the analysis done in our study for DMHA use. Namely, we hypothesize that students having good social relationships with close ones and feeling comfortable about sharing their concerns with them [34-36], namely family and partners, is an essential affective association that may condition DMHA utilization. We also consider that the individual's perception of their need to seek care due to having a diagnosed mental health problem or having a specific problem [35-38] is an important aspect to identify, and that may help explain their attitude and behavior toward DMHA in a more technologically enabled population [39].

Moreover, we hypothesize that another important factor in ascertaining these expectations and perceptions might be whether, in an era of ever-increasing connectivity and access to information, some already have certain coping or mental health-enhancing strategies in place [40-42]. Art therapy, comprising painting, drawing, coloring, and photography, can be effectively used in coping leisure strategies to aid in managing mental health.

While several articles have been published regarding the use of DMHA, most such efforts have been trials of the effectiveness of already developed DMHA [16,19,43-46]. Borghouts et al. [47] have applied a questionnaire to college students regarding the potential use of DMHA and associated perceived barriers. In that sense, applying the same questionnaire, with due adaptations, to a Portuguese academic community would build on the relevant perceptions already identified and insights on the mental health status of this population while allowing for a direct comparison with a different college population.

To the authors' knowledge, no studies have been performed in Portugal on individuals' perceptions of DMHA, their preferences and decision drivers on obtaining mental health care, mental health self-assessment, or their perceptions of mental health and its treatment. Our study aims at bridging these gaps by mapping the expectations of the demand side of digital mental health apps. Our work may further provide necessary information for researchers, academia, industry, and policymakers on how to leverage DHMA as a tool to increase access to mental health care while ultimately contributing to reducing the burden of disease associated with mental health disorders.

Objective

This paper aims to understand individuals' attitudes toward DMHA in the Portuguese context. Participants were questioned regarding perceived benefits, barriers to adoption, and potential ways of supporting the adoption of DHMA.

Methods

Study Design

The study is based on the structure outlined in a previously published research protocol [48]. It replicates the paper by Borghouts et al. [47] with adaptations to determine the factors that impact the acceptance and use of DHMA in Portugal, using the academic community of Porto as a proxy. It is an attempt to provide a clearer, if limited, landscape of what policymakers and product developers should expect regarding the demand characteristics for these tools.

Given that the sample is obtained from one academic community of a specific university in the north of Portugal, among other issues that arise from convenience sampling (such as potential biases regarding gender representativeness), the generalizability of results to the overall Portuguese population is expected to be limited. Nevertheless, we expect our findings to be, at least, generalizable to university populations in Portugal. Furthermore, we expect this to be the best possible proxy to the more digitally literate segments of the general population (and, thus, those more likely to try DMHA), given the overall levels of digital literacy, education, and age of the academic community's population [39].

We first applied a questionnaire resulting from an adaptation of Borghouts' implemented questionnaire to the Portuguese context. The questionnaire was delivered through the University of Porto's dynamic e-mail function to maximize our reach potential to the entire academic community of the University. We then described the sociodemographic characteristics of the sample. We established a comparison with the replicated study by highlighting the differences in the methodology used and the results obtained. Our team then outlined the structural models we developed and their specificities.

Questionnaire

We took the final survey questionnaire available on Borghouts [47] and translated it to Portuguese through a licensed translator (Additional File 1). This translation was delivered to selected members of the academic community – five students and five teachers – for review. These members were asked to focus their feedback on how to calibrate the questionnaire to 1) reflect important questions to ask regarding the use of digital health tools by individuals and 2) a Portuguese mental health care context, particularly that for the screening of anxiety and depression.

Obtained feedback was incorporated to produce a final online survey questionnaire for this study (available in English in Additional File 2), except for the used pre-validated scales, where no major changes were made.

The final version was divided into 6 parts, namely demographic information, smartphone use, mental health apps use and perceptions, use of healthcare resources, stress, well-being and mental health experiences and mental health perceptions. Prevalidated scales used on Borghouts et al. were included in our study in their translated versions and were measured as follows:

- Perceived stress was measured with the 7-item version of the College Student Stress Scale (scored 1-5 in each item);
- Perceived need to seek help because of problems with mental health in the past 12 months was measured by dichotomous response item;
- 2 dichotomous (yes or no) response items were used to identify past use of professional mental health services, such as a counselor, for mental health concerns in the past 12 months, where an answer “yes” to any of the two questions meant past use of health resources;
- Perceived stigma was measured using 9 statements from the Perceived Stigma subscale of the Depression Stigma Scale (scored 0-4 in each item);
- Social influence was measured using three statements (e.g., “People who are important to me think I should use mental health apps”);
- Privacy concerns were measured using 6 statements (scored 1-5 each) originally adapted by Borghouts et al. to refer to mental health apps specifically. These statements were further divided into two privacy constructs, with three questions each

The survey questionnaire was pretested by five different colleagues to determine completion time and identify shortcomings. Completion time was estimated to be between twelve and twenty minutes. No shortcomings were identified.

The survey’s link was circulated via dynamic email by the University of Porto’s Communication Department. This tool allowed us to reach the complete total of the academic community – students, teachers, and administrative staff. The first communication email was sent out on September 20, and a reminder followed on October 6. The period for answer collection ran from September 20 to October 20, 2022. A total number of 33,668 email addresses received both emails. The platform used was Inqueritos@UP, the University of Porto’s internal survey manager by LimeSurvey, and the survey adheres to and is reported following the Checklist for Reporting Results of Internet E-Survey (CHERRIES) guidelines.

To maximize response, the only inclusion criterion was to have an active registration with the University of Porto domain, defined as the ability to receive the survey invitation email. No exclusion criteria were introduced, and no financial incentives were offered. Figure 1 summarizes the survey’s adaptation and communication workflow.

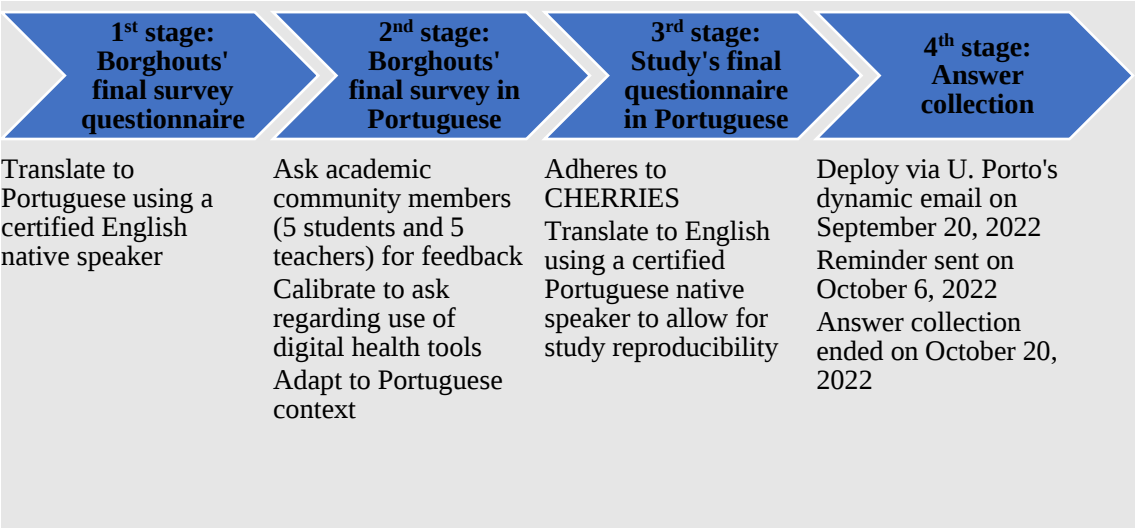


Figure 1. Survey adaptation and communication workflow.

Gathered data were analyzed according to the methods used by Borghouts et al. to allow for maximum comparability between results. We mapped the summary of modifications between the initial questionnaire (i.e., Borghouts’) and the final survey questionnaire used, and made it available in Additional File 3.

Participants

A total of 968 participants started the survey, and 539 completed it, resulting in a response rate of 1.7% and a 55.7% completion rate. The survey participants had a mean age of 24.3 years (SD 11.1); 68.3% identified as female and 26.9% as male. Of the 539 respondents, 506 (93.9%) identified as White, 12 (2.2%) identified as having more than one ethnicity, and 3 (0.6%) identified as Asian.

Most reported being unemployed (72.5%), living with their families (59.9%), and being single (63.3%). Some faculty members (7.1% of the sample) and administrative staff (2.8% of the sample) answered the survey. This sample thus meets the goal of encompassing the academic community beyond the traditional scope of students only. Of the 539 participants, 77 (14.3%) had an annual household income of less than EUR €10,000. Most participants (77.7%) had health insurance, but only 27.1% of those with insurance were sure that their plan provided coverage for mental health services. Further demographic characteristics are shown in Additional File 4.

Differences between participants who had used or were currently using DMHA (users) and participants who never used a DMHA (never-users) were also assessed (Additional File 5). DMHA users were significantly older (mean 25.6 vs 20.9 years old, $p < .001$), with a higher proportion of females (74.0% vs 65.7%) and other genders (10.7% vs 2.2%) ($p < .001$). Significant differences were also found in enrollment status ($p = .003$), with full-time enrollment of 91.1% vs 79.7% and faculty members of 1.2% vs 8.1%; marital status ($p = .003$), with married participants of 4.2% vs 16.0%; children whom they were responsible for (96.4% vs 82.4%, $p < .001$); household income ($p = .023$), with 32.4% vs 16.5% reporting an annual household income of less than EUR €10,000 and 40.0% vs 49.2% reporting between €10,000 and €27,500; and presence of a disability (11.4% vs 5.7%, $p = .022$). Employment status, race, living arrangements, homelessness, and health coverage were not significantly different between users and never-users.

Our study sample had a significantly higher number of females, full-time students, white people, and unemployed than Borghouts et al.'s sample. It also had a significantly lower number of homeless people and health insurance compared with Borghouts et al. A statistically significant difference was also found in maternal status and living situation. The age and existence of children and dependents or disabilities were not significantly different.

Comparison with the replicated study

The survey followed the same structure as Borghouts et al. concerning Barriers to Mental Health Resources, Mental Health Problems, Mental Health App Use, Past Use of Professional Mental Health Services, Perceived Stress, Perceived Need to Seek Help, Mental Health Concerns, Perceived Stigma, Social Influence, and Privacy Concerns. More detail can be found in the primary survey instrument in Borghouts et al. Our final questionnaire in English is available in this study's Additional File 2, and a summary of modifications is available in Additional File 3.

To reflect the hypotheses, we laid out in the introduction, we focused our study on the following items:

- Deriving from a multiple-answer question (Q31), we created a new variable where the existence of a support network was defined as usually talking to a family member or partner when feeling sad, anxious, preoccupied, or stressed.
- From question Q23a, we grouped participants into a new single variable defining participants reporting depression, eating disorders, obsessions, and compulsions interfering with daily activities or bipolar disorder as determinants of the perceived need to seek help given their prevalence in the academic community. These specific mental health problems were chosen because they had a weak correlation (defined as a correlation coefficient between .10 and .30) with each other.
- From question Q32, one other variable ("Coping Strategies") was created that included individuals that reported spending time with pets (a strategy added to our questionnaire), social media, painting, drawing, coloring, and photography, or writing as leisure strategies used to aid in managing mental health.

Structural models

Three models were developed: two replicating Borghouts et al. and a third model representative of the data obtained from our questionnaire.

For the replicated models, we used the same variable definitions, namely two privacy constructs and social influence as latent variables, since the items included were adapted from validated scales but have not been tested in prior work as a single scale beyond the work of Borghouts et al. Gender, age, perceived stress, past use of professional mental

health services, perceived need to seek help, and perceived stigma were included as observed variables.

Our model was based on the direct effects model of Borghouts et al., including the variables with statistically significant relations with the use of mental health apps. On top of said model, we included coping strategies as an observed variable, and a latent variable (Perceived Mental Health Problem) derived from three observed variables, namely the grouped variable from Q23a, a self-reported mental health problem (Q41), and perceived need to seek help. We also expected to find a high correlation between coping strategies and perceived mental health problem and combined them into a single latent variable. The correlation matrices for these two latent variables are presented in Tables 2 and 3.

Table 2. Correlation matrix for Perceived Mental Health Problem

		Q23a	Q41	Perceived need
	Q23a	1.000		
	Q41	0.558	1.000	
	Perceived need	0.415	0.475	1.000

Table 3. Correlation matrix for latent variable.

		Coping strategies	Perceived problem
	Coping strategies	1.000	
	Perceived problem	0.523	1.000

The correlation matrix of the variables is displayed in Table 4. The correlation values further show that there were no strong correlations between the variables, except for perceived need and latent variable (unsurprising when considering that perceived need also contributed to the latent variable).

Table 4. Correlation matrix of model variables.

		Perceived	Perceived	Close	Perceived	Privacy	Latent

		need	stigma	relationship	stress	construct 1	variable
	Perceived need	1.000					
	Perceived stigma	0.226	1.000				
	Close relationships	-0.079	0.028	1.000			
	Perceived stress	0.000	0.000	0.000	1.000		
	Privacy construct 1	-0.012	-0.009	0.003	0.000	1.000	
	Latent variable	0.546	0.414	-0.144	0.000	-0.023	1.000

Analysis

The model's dependent variable was the participants' mental health app use as a dichotomous (yes or no) variable. For the replicated models, the independent variables were perceived stress, perceived need to seek help (shortened in the *Results* section as perceived need), past use of professional mental health services (abbreviated in the *Results* section as past use of services), perceived stigma, social influence, and privacy concerns represented by two different constructs (numbered 1 and 2, respectively). Age and gender were added as covariables. Table 5 shows the names and descriptions of all variables included in our models.

Table 5. Name and description of model variables.

	Name	Borghouts	Description
	User	User	Participants' mental health app use
	Perceived Stress	Perceived Stress	7-item version of the College Student Stress Scale originally included in Borghouts et al. and translated in our questionnaire.

	Perceived Need	Perceived Need	A dichotomous response item originally included in Borghouts et al. and translated in our questionnaire.
	Past Use of Services	Past Use of Services	2 dichotomous response items originally included in Borghouts et al. and translated in our questionnaire.
	Perceived Stigma	Perceived Stigma	9 statements from the Perceived Stigma subscale of the Depression Stigma Scale originally included in Borghouts et al. and translated in our questionnaire.
	Social Influence	Social Influence	3 statements originally included in Borghouts et al. and translated in our questionnaire.
	Privacy Construct (1 and 2)	Privacy Construct (1 and 2)	6 statements (3 for each construct) originally included in Borghouts et al. and translated in our questionnaire.
	Age	Age	
	Gender	Gender	In our study, we included “other” gender.
	Coping Strategies	-	Individuals that reported spending time with pets, social media, painting, drawing, coloring, photography, or writing to aid in managing mental health.
	Perceived Problem	-	Perceived Mental Health Problem: latent variable defined by the self-reporting of depression, eating disorders, obsessions, and compulsions interfering with daily activities or bipolar disorder, a mental health problem and Perceived Need.
	Latent Variable	-	Latent variable resulting from Perceived Problem and Coping Strategies.
	Close relationships	-	Multiple choice question, regarding each person’s support network. Considered to have a support network of close

			relationships if either family or partners were included as people to whom they talk when feeling sad, anxious, worried or stressed.
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In our extended model, a latent variable, including coping strategies and perceived mental health problem, was added to the model as an independent variable.

Structural equation modeling (SEM) tested the relationships between measured variables. The measurement models' fit was evaluated with the comparative fit index (CFI), the models' chi-square, the RMSEA, and the SRMR [49]. Maximum likelihood was used as an estimator for the structural equation models.

We compared the fit of our extended model with the full mediation and direct effect models based on the replicated study. Our extended model did not consider mediating effects of any variable. However, perceived need was included as a direct variable and inside perceived problem.

In our extended model, a latent variable was added as an independent variable, including non-clinical strategies and perception of mental health problems.

Full maximum likelihood was used to impute missing data on scales. Participants with missing data on dichotomous model variables (i.e., perceived need and past use of services) were excluded from the model. The software environment R (R Foundation for Statistical Computing) was used for statistical analysis, and the R package lavaan was used for the structural equation models and bootstrapping [50].

Results

Technological and mental health resources and concerns

Of the 539 participants in our study, 265 (49.2%) reported that they had experienced a mental or psychological illness, significantly higher than Borghouts' 189 (37.8%). Regarding specific mental health issues, 347 (64.4%) of respondents reported anxiety concerns, and 309 (57.3%) participants reported stress-related problems. These issues, also among Borghouts' top two mental health concerns, differed significantly in their

study, with 207 (41.4%) and 219 (43.8%) participants reporting anxiety and stress, respectively.

The stigma score in our sample is higher and less dispersed than that of Borghouts' sample: 23.9 (SD 5.4) compared with 22.4, respectively, suggesting higher perceived stigma. Moreover, 169 (31.4%) respondents to our survey currently use or have used a mental health app, compared with Borghouts' 106 (21.2%). A full overview of the responses to the questionnaire can be found in Additional File 6.

Barriers to Mental Health Resources (non-app)

Some mental health resources, such as counseling and mindfulness or stress management workshops, are provided by the University of Porto and its Faculty of Medicine. During the process of survey adaptation described in the "Questionnaire" sub-section of "Methods", several answer options for the barriers to accessing mental health resources were changed, limiting the comparability between both studies. The frequency of each perceived barrier to mental health resources from our sample can be found in Additional File 6.

The main barrier to mental healthcare is financial, with 201 persons (37.3%) feeling that constraint. The extent to which these resources might be helpful, along with self-doubts concerning the seriousness of one's needs, gathered 145 (26.9%) and 142 (26.3%) of provided answers. It should be noted that 24.9% of the sample considered the waiting time to access mental healthcare resources too long, resulting in a barrier to the mental health resources offered by the University of Porto. Furthermore, the fact that stress is accepted as usual at college (22.6%) and believing the problem will improve by itself (19.3%) are belief-related issues that could prove challenging to shape. Finally, it is interesting that a significant minority does not have the time to access these resources (16.1%) or that it does not access them due to privacy concerns (16%).

Important Aspects of Mental Health Apps, and Activities People Would Like to Do With Mental Health Apps

In our survey respondents' opinion (Additional File 6), the most critical aspect of using mental health apps was the app being free of charge (83.3%). This was also the most

important aspect of Borghouts' survey, registering a similar magnitude (85.8%). The assurance that personal information will be kept private and that parts of the app can be accessed online came in second and third, respectively, with 437 (81.1%) and 288 (53.4%) responses. Borghouts' study, on the other hand, registered the same second-ranked option but differed on the third most-voted option (people on the app having similar mental health experiences to theirs): 45.6% of Borghouts' sample believed this to be important, in contrast with 29.7% in our sample.

Regarding the most common activities participants would like to do on apps (Additional File 6), our survey's respondents stated that working through negative emotions and thoughts would be the primary use (70.1%), similar to Borghouts' survey (65.8%). The ranking order was also the same for the second and third most reported items. Identifying or recognizing symptoms was the second most reported answer option in both surveys, with our sample registering 63.5% and Borghouts 58%. Tracking symptoms was the third most reported option, with 54.9% in our survey and 47.8% in Borghouts'.

Models based on Borghouts et al.

We proceeded to elaborate on the direct and fully mediated effects models based on Borghouts et al.'s work.

The standardized path coefficients of the direct effect model are shown in Figure 2. The model fit indices were $\chi^2_{57}=173.118$, SRMR=0.067, and RMSEA=0.064. The adjusted R^2 value of the model was 0.205.

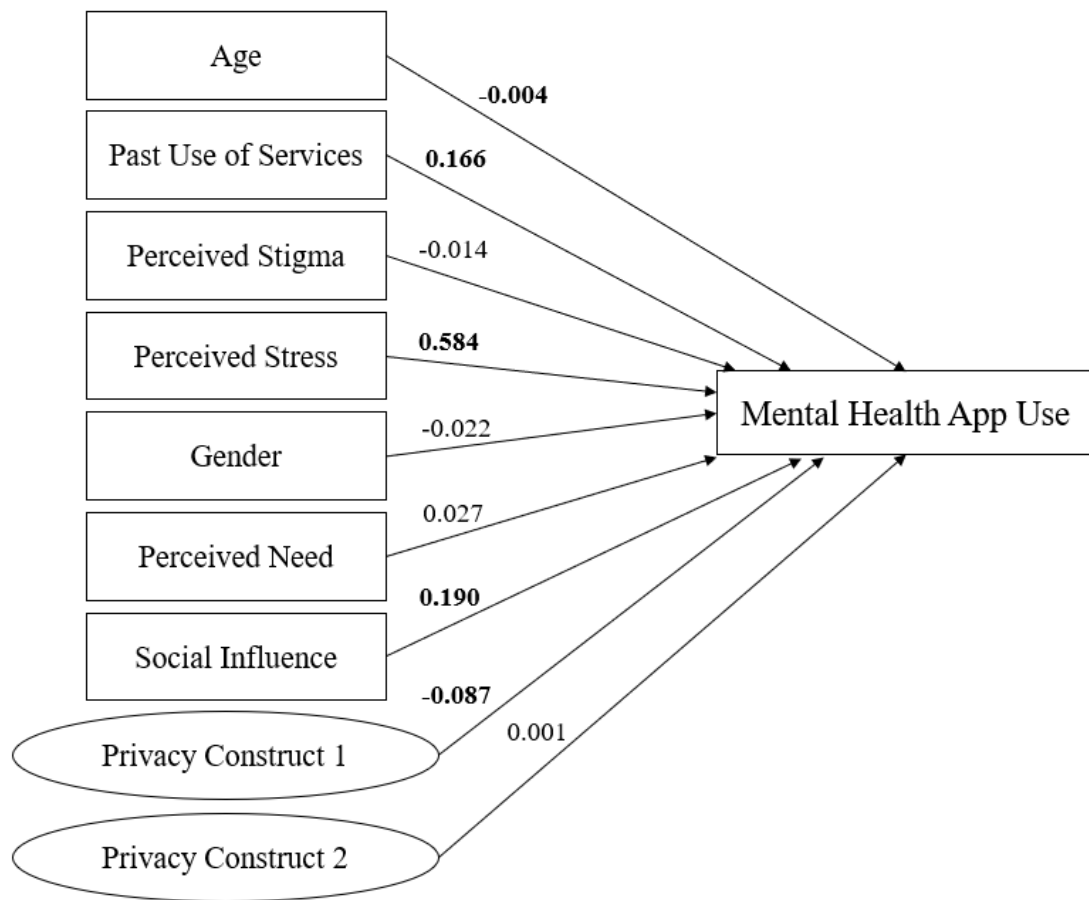


Figure 2. Direct effect model showing the path coefficients and levels of significance for relationships among variables. Coefficients in bold are statistically significant at $P < .05$; $n=499$.

The standardized path coefficients of the full mediation model are shown in Figure 3. The model fit indices showed an appropriate model: $\chi^2_{60}=264.901$, SRMR=0.045, and RMSEA=0.051. The adjusted R^2 value of the model was 0.202.

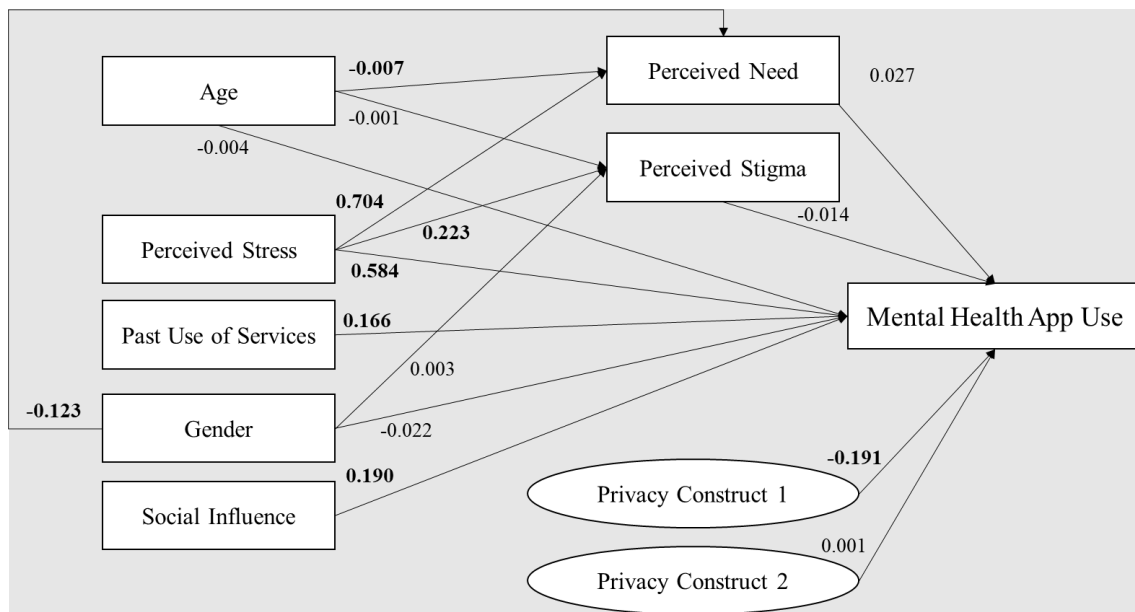


Figure 3. Full mediation model showing the path coefficients and levels of significance for relationships among variables. Coefficients in bold are statistically significant at $P < .05$; $n = 499$.

Model fit and R-squared obtained for the direct effect model were comparable to those from Borghouts et al., but the same cannot be said of the full mediation model: our R-squared was considerably lower (0.202, vs. Borghouts' 0.326), despite other fit indices being relatively similar.

Model with additional MH determinants

Based on the previously detailed hypotheses regarding MH determinants, we developed a model to represent our data in this study. This research effort endeavored to build on Borghouts et al.'s work and elicit more information to more precisely depict the Portuguese context portrayed by this survey.

The standardized path coefficients of the full mediation model are shown in Figure 4. The model fit indices showed an acceptable model fit: $\chi^2_{69} = 218.123$, SRMR=0.088, and RMSEA=0.065. The adjusted R^2 value of the model was significantly higher than the results obtained via the mediated effects model of Borghouts et al.'s work (R^2 : 0.419).

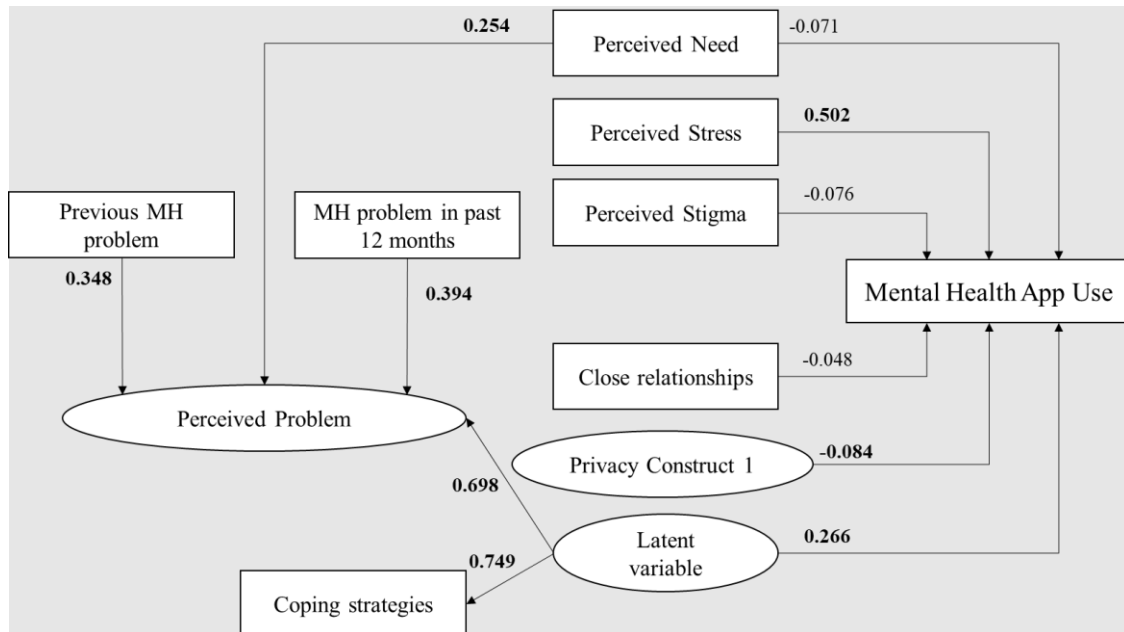


Figure 4. Extended mediation model showing path coefficients and levels of significance for relationships among variables. Coefficients in bold are statistically significant at $P < .05$; $n = 499$.

Table 6 compares the fit indices of our direct effect and full mediation models based on Borghouts et al. with those of our extended model, as shown in Figure 4.

Our model showed that using mental health apps was significantly associated with perceived stress and Privacy Construct 1. DMHA use was also associated with a latent variable incorporating coping strategies and perceived mental health problems.

Table 6. Fit indices of the direct effects model and full mediation model.

Statistic	Direct effects model (based on [47])	Full mediation model (based on [47])	Extended model
Chi-square (df)	173.118 (57)	264.901 (60)	218.123 (69)
SRMRa	0.067	0.045	0.088
RMSEAb	0.064	0.051	0.065

	Statistic	Direct effects model (based on [47])	Full mediation model (based on [47])	Extended model
	R ²	0.205	0.202	0.419

- a. SRMR: standardized root mean square residual.
- b. RMSEA: root mean square error of approximation.

Discussion

Principal Findings

This paper aimed to identify factors associated with mental health app use in the academic community of the University of Porto as a proxy for the Portuguese population and compare our results with Borghouts et al. Our results revealed that participants' use of DMHA was associated with four factors: perceived stress and privacy concerns directly, and perception of mental health problem and having coping strategies in place through a latent variable comprising both.

The data's descriptive analytics were like Borghouts' except for the race breakdown (namely, the percentage the white population represented and, consequently, the lack of ethnic diversity found in Borghouts et al.). We also did not find statistical significance for perceived need for social influence, whereas Borghouts et al. did.

Our structural model also attained an R^2 of 0.419, which is almost 20% above the result achieved from the mediated effect model applied to our sample, and 10% above the same result obtained by Borghouts et al. in their sample. Based on our initial hypotheses, we were able to develop a model that can expand Borghouts' work and provide a better explanation for the factors that contribute to DMHA use for our sample. It is noteworthy, however, that our full mediation model replicating Borghouts' underperformed it in terms of R-squared.

Perceived Stress

Stress was the second most common mental health concern among participants (approximately 57% of participants experienced stress), just behind anxiety (64% of the sample vs. 41% in Borghouts). Our study's results, like Borghouts', indicate that the perceived stress level predicted mental health app use. Consequently, the more stress people in the academic community reported, the more likely they used DMHA. We found this variable statistically significant and directly linked to DMHA use.

In contrast, Borghouts found it statistically significant only through a mediating effect of perceived need to seek help and not as a standalone variable. We posit, as Borghouts did, that this may represent a linkage between one's use of DMHA and a potential benefit in stress reduction, which is supported by prior evidence [51,52]. However, a causal link is still absent, and further research with that specific intent would be precious. This is reinforced by the widespread lack of robust scientific evidence of efficacy in most DMHA [16,53].

Latent variable

In our expanded model, the latent variable, which mediates the perception of a mental health problem and having coping strategies related to DMHA use, was demonstrated to be statistically significant and positively associated with DMHA use. This variable captures very diverse information. Its result means that a higher perception of having a mental health problem, a prior diagnosis of mental illness (either throughout one's life or in the past 12 months), having used DMHA in the past, or having leisure coping strategies in place makes one more likely to use DMHA.

We hypothesized this variable based on a set of assumptions. Firstly, the available scientific evidence points to previous mental illness as a predictor of mental illness onset [54,55]. This might lead one to seek help, as can an increased perception of having a mental health problem, e.g., trying the most downloaded DMHA or obtaining a diagnosis through a symptom checker. Secondly, past use of DMHA, especially if the experience was positive, may reinforce behavior or make someone more familiar with this intervention and thus more prone to do it again. Borghouts et al. found a positive and

statistically significant relation between past use of services and DMHA use in their full mediation model, as we did while replicating it.

Finally, we assumed that having leisure coping strategies in place might reflect higher self-awareness concerning mental health and methods to enhance it. Thus, people with higher use of leisure coping strategies might be more inclined to use DMHA to maintain their mental health. Our results seem to point to our hypotheses being valid, but they did not have the same degree of association standalone. Still, the result of aggregating them in a latent variable warrants a further detailed study of these variables and their interconnections.

Privacy

In our expanded model, the first privacy construct, i.e., related to one's information being visible to others, demonstrated to be statistically significant and negatively associated with DMHA use, just as in Borghouts' study. This result means that if someone is concerned about their information being visible to others that person would be less likely to use a DMHA. Curiously, the magnitude of the relationship is almost four times higher compared to Borghouts et al., albeit privacy concerns rank quite low in terms of stated barriers to DMHA use.

When specifically asked about privacy, respondents maximized its importance, while in confrontation with other barriers (e.g., financial burden), privacy assumed a relatively smaller weight. Although the literature and various anecdotal cases demonstrate how privacy policies and practices in DMHA are important [18] but often frail [16,56], this result might illustrate the relative premium people place on keeping their personal information private, as well as how much of an obstacle it is to DMHA use. Moreover, we registered a non-significant relation for the second privacy construct (personal information being subsequently used), just as in Borghouts' study.

These results allow us to fundament the need to have a deeper understanding of what privacy means to people and how they perceive it to be preserved, as beliefs with no technical background may result in a future loss of trust in DMHA or other digital interventions. It also begs the need for more studies on digital literacy and how it relates to privacy perceptions and attitudes.

Other Important Findings

Self-reported mental illness registered significant differences between our sample and Borghouts' sample: 49% of our sample said they had a mental illness compared with Borghouts' 38%. Regarding their prevalence, we found that our sample had the most common mental illness, anxiety (64%), followed by stress (57%). In Borghouts' sample, the rates for the same diseases were 41% and 44%, respectively. This very significant difference may be explained by having different populations under study. Given the pandemic's impact on young people and digital health tool utilization [26], it cannot be excluded that this difference may be partially explained by the cross-sections performed during and after the pandemic's most critical stage.

Another of the most significant differences we found between our sample and Borghouts et al.'s was the self-reported perceived need to seek help: 13% said they perceived that need against Borghouts 44%. Furthermore, concerning the use of professional services in the past 12 months, 43% of our sample reported having used such services, while Borghouts' rate for the same variable was 23%. DMHA use was relatively similar except for the segment of past users of DMHA: 25% of our sample reported having used them in the past, contrasting with Borghouts' 14%. All these issues could be fitted in the access to care category.

We hypothesize they may be due to differing capabilities in accessing mental healthcare and its consequences in lowering the perceived need to seek help – assuming the quicker one gets help, the lower the perceived need to seek help. Moreover, we hypothesize they may be due to two factors: the pandemic impact on access to digital healthcare and the sources of financial protection in illness.

Regarding the first factor, the difference in the past use of DMHA may be partially attributable to having tried DMHA as a means of coping with the pandemic, which is corroborated by the existing evidence on download numbers [24]. On the other hand, the significant difference in the percentage of people with health insurance between samples – 65% of our sample had it, compared with Borghouts' 80% – is likely owed to different health system organizations. In Portugal, the National Health Service, funded by general taxation, is the central piece of the system, mainly providing free access at point-of-care and thus having low financial barriers to seeking healthcare. In this context, health insurance is often used as an ancillary means to speed up healthcare access by contracting

with privately-owned healthcare providers. In the United States of America, given the centrality of health insurance in the system (either publicly or privately funded), there might be more significant financial barriers to seeking care, including mental health.

Implications

Previous work has shown that despite interest in mental health apps among students, the use of these apps can be limited [57-59]. Building on the earlier work whose methodology we replicated, our findings allowed us to uncover various factors associated with DMHA use in the academic community and, more particularly, its students. We hope this work helps build more robust development and implementation efforts of digital mental health interventions, particularly app-based ones, on campuses or similar contexts.

First, it must be highlighted that no doubts remain concerning the importance of the academic community having the necessary mental health resources to tackle its very significant needs. The prevalence of mental illness and the identified mental illnesses are perfectly in line with the alerts regarding the COVID-19 pandemic's impact on mental health [29]. There must be decisive action and involvement of all stakeholders in designing these interventions to answer the community's needs better.

Secondly, we have discovered a strong association between privacy and DMHA use. This trait's prevalence and relative weight make it critical to keep in mind when developing and implementing successful DMHA-based interventions. It is also important to foster digital literacy regarding privacy best practices to generate trust in digital tools, particularly those applied to mental healthcare.

Thirdly, the fact that the latent variable, while containing such diverse information, presents a considerable value leads us to believe that it is essential to look closely at the factors mediated through it. All of them are associated with prior mental illness and past use of services. This suggests that interventions should be tailored to efficiently triage between those who have already experienced mental health issues and those who have not, as well as constituting a pleasant and easy-to-use entry point to provide practical, evidence-based mental health-promoting resources.

Fourthly, one needs to carefully ponder the importance of social determinants of mental health [60] to properly engage the academic community, specifically its students, with

DMHA use. Even though social influence was not statistically significant, mental illness is complex and involves issues such as poverty, low incomes, emotional strain, and poor housing conditions. Due to the pandemic and insufficient responses, many of these issues have increased in Portuguese society in recent years [33, 61]. Any digital intervention, app-based or not, must consider social determinants and adequately adjust its user interface and experience if it wishes to be successful.

Finally, all the above may have important implications for connected areas of knowledge and care delivery, namely public health, medical work, and social work and counselling: all these roles can be made more effective if they take the above implications into consideration. By tailoring these apps to better suit the perceptions and overcome identified barriers to their use may, for example, enable the deployment of public health interventions such as screening for common mental disorders in a scalable and adaptable manner. By the same token, the impact of properly designed and delivered DMHA on medical work may improve and enlarge access to diagnosis, treatment, and follow-up, as well as emergency, real-time consultations. At last, social work and counseling may be deployed in a more personalized manner and at a lower cost per episode, allowing for a better allocation of resources to high-priority cases without disregarding the long tail of low-priority, but high disease burden, cases.

Limitations and Future Work

This study has several limitations. First, the sample came from one academic community of a specific university in the north of Portugal. This means that the generalizability of the results is limited. Nevertheless, we expect our findings to be generalizable to university populations.

Another of our sample's significant limitations is gender representativeness: while 68.3% of our sample were female respondents and 26.9% were male respondents, with the remaining gender self-identifications amounting to 4.8%, 54% of the students in the University of Porto are female [62], with no further gender breakdown. This element also limits the generalizability of obtained results. Two other issues that should be borne in mind are the difficulty recruiting students and the wider academic community [63] and the ethical impact of DMHA. Some work has been done in this field [64], but much remains to be done.

A nationwide survey that addresses the challenges mentioned above would be a welcome addition to the body of evidence surrounding the issue of DMHA-based interventions, enabling a more accurate mapping of attitudes and expectations from academic communities. However, it should also be recognized that full institutional support is necessary to succeed.

Additionally, we focused on presenting and discussing a specific model that expanded a prior one to test the effects of six factors on mental health app use. Despite allowing for a significant degree of novelty and a different perspective owing to a different population, we did not consider other factors that may impact DMHA utilization, such as user interface and engagement concerns [65]. These issues deserve further exploration, especially concerning how important engagement is to lower dropout rates of digital health mental apps [66].

Societal issues such as shame, fear, and stigma also merit further research. Even though we replicated Borghouts' approach to stigma assessment for methodological replication purposes, that does not necessarily mean this theoretical construct (Depression Stigma Scale by Griffiths et al. [67]) was the most suitable one. Given that stigma showed no statistically significant association with DMHA use in all designed models, replicating these analyses with other validated stigma assessment tools (e.g., the Stigma Scale [68] or the Portuguese Version of the Stigma Scale [69]) on a nationwide survey might bring about further insights on the impact of societal issues on DMHA use.

Lastly, the response rate was 1.7%. Despite this not being a typical response rate for web-based surveys among student populations [46], that is due to the number of potential respondents being so high compared with similar studies (ca. 4,000 students). Nonetheless, the potential for response bias and self-selection remains, and there may be differences between non-responders and responders.

Conclusions

This study focused on the academic community of the University of Porto and found four factors associated with DMHA use. Our results revealed that participants' use of DMHA was directly associated with perceived stress and privacy concerns and a latent variable comprising both perceptions of mental health problems and coping strategies in place. All

these issues and their implications must be factored into the decision to promote a DMHA-based approach to providing mental health resources to the academic community, and have implications for researchers and academia, industry, and policymakers concerning the adoption and implementation of digital mental health apps and associated interventions.

Regarding access barriers and their importance, developers should consider delivering these apps with low to no financial charges, offering evidence of their helpfulness, and focusing on timely care delivery. To increase DMHA use, there is a need to shape mindsets through mental health literacy, namely concerning discernment in terms of the seriousness of one's conditions, acceptable stress levels, and overall behavior toward mental health. The results can inform the appropriate development and implementation of DMHA that meet the needs of the academic community.

List of Abbreviations

DALY: Disability-Adjusted Life Years

DMHA: Digital Mental Health Applications/Apps

EU: European Union

OECD: Organisation for Economic Co-operation and Development

Declarations

Ethics Approval and Consent to Participate

The Ethics Committee of the Faculty of Medicine of the University of Porto pronounced itself favorable to the research project on June 30, 2022 (Opinion 52/CEFMUP/2022).

Ethical considerations and safeguards for the study and its supporting documents (including the online survey) comprise the following, having received approval from the Data Protection Officer of the University of Porto:

- To preserve participants' privacy, they will not be asked to provide any personally identifiable information. In addition, participants will not be tracked for having started or completed the survey, increasing privacy but limiting the possibility of reminders.
- **Informed consent and consenting capacity:** all potential participants (physicians and academic community members) will be given online written information on the

study and its objectives and will be asked to provide consent (click-to-agree) that they are happy to participate, and that nonparticipation will not compromise their current roles. Participation in the study will be voluntary, and no inducements or incentives will be offered.

- **Confidentiality:** Any data/personal details that could potentially reveal the identity of individuals will be removed. Only anonymized, deidentified information will leave the place of origin. A database with responses will be maintained on a password-protected database. All research data will be stored on a password-protected desktop computer at the host organization. Study participants will be invited, through a link provided on the last page of the survey, to provide their name and electronic address to allow the research team to facilitate their receiving a synopsis of the study findings on publication. This list will be kept separately on a password-protected database and a password-protected desktop computer at the host organization. All data will be stored securely at the host institution and destroyed three years after the Ph.D. defense date, expected in September-October 2023.
- **General Data Protection Regulation:** GDPR compliance will be adhered to in terms of the following:
 - Data privacy rights – participants will have the right to request information about their data throughout the research process.
 - Transfer of data – participants will be informed about the circumstances under which their data may be transferred and safety measures that will be taken to protect the data (e.g., data are encoded).
 - Retention of data – participants will be informed how long their data will be stored.

Inquéritos@UP stores survey data at U. Porto's servers and thus is not shared with external entities, constituting another layer of privacy protection. Further, the survey's first page briefly explained the required data and the rationale for asking for it.

Consent for Publication

Informed consent and consent for publication was obtained via click-to-agree, as previously mentioned in the Ethics Approval and Consent to Participate section.

Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

This study was conducted as part of a doctoral research project at the Health Data Science Ph.D. Program, Faculty of Medicine of the University of Porto, Portugal. Two of the authors (DNL and RCC) participated in this research project while employed by the Faculty of Medicine of the University of Porto. Both worked on a project co-funded by the European Union concerning the digitalization of clinical trials in the North of Portugal (CR – Digital: Digitize clinical research in the North of Portugal” (NORTE-01-0145-FEDER-083448). MMC works in the Public Health Unit of Marão e Douro Norte and is also a doctoral researcher at the Health Data Science Ph.D. Program.

This research article was executed during the authors’ time. The European-funded project or the Faculty of Medicine of the University of Porto were at no point involved in the research besides required administrative approvals. There was also no funding, pay, or other commercial interest provided by the Faculty of Medicine of the University of Porto aside from the costs related to the publication of this article.

None of the authors has competing interests to declare.

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Authors’ contributions

DNL outlined the research protocol on which the article is based, conducted the literature review for the article’s background, and derived the main findings and implications of this study. MMC designed and implemented the analysis, interpretation, and structural equation model architecture. Both DNL and MMC were major contributors in writing the manuscript. RCC provided a high-level perspective on the manuscript’s focus areas and provided scientific guidance and academic supervision, as well as thorough sequential review. All authors read and approved the final manuscript.

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Additional Files

Additional File 1

Translated original survey questionnaire (EN-PT).

Additional File 2

Translated adapted survey questionnaire (PT-EN).

Additional File 3

Summary of modifications between questionnaires.

Additional File 4

Comparative characteristics of participants.

Additional File 5

Characteristics of users (current or past) and never users.

Additional File 6

Overview of responses to survey items.

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7. Discussion and Conclusion

Summary of findings

Our research is, to the best of our knowledge, the first attempt at assessing whether DMHA would be welcomed in Portugal and a healthcare system with its political economy. By comparing Portugal with Germany (from the physicians' point of view) and the USA (from the individual's point of view) in similar settings, we hope to enrich the comparison between health systems with a very significant private sector role (USA and Germany) and systems where government plays a key function in ensuring access to and funding of health care (Portugal), particularly regarding digital mental health provision based on mobile applications.

Our peer-reviewed and published research protocol created a methodological instrument that provides not only an updated literature review of the intersection between mental health, data science, and digital developments but also an actionable tool that can easily be replicated to systematically evaluate attitudes and perceptions of DMHA from both demand and supply for DMHA in each country.

Our second paper, concerning physicians' (psychiatrists and psychologists) attitudes and perceptions toward DMHA, demonstrated that 87.2% of the 160 respondents to our cross-sectional web survey supported the opportunity to prescribe digital mental health apps. Increased health literacy (87%), wider adherence to treatment (86%), and proper disease management (79%) were the most frequently agreed upon benefits of DMHA. However, only 43.6% of respondents planned to prescribe or recommend DMHA, with psychologists being more favorable than psychiatrists.

Professionals still face substantial barriers, such as a lack of information on DMHA (96%), the level of initial training effort (72%), and the need for adjustments of clinical processes and records (71%). Regarding measures to promote the adoption of DMHA, having more information on the available apps and their suitability for health objectives (94%) and more scientific evidence of the validity of the apps as a health intervention (92%). Established recommendations of apps by specific clinical guidelines or professional societies (91%) would also be essential to foster adoption. Even though the benefits, barriers, and measures to promote the adoption of DMHA are consensual, more

evidence is needed, along with the further promotion of mental health professionals' digital literacy.

Our third article on the factors that determine DMHA use in the academic community of the University of Porto using it as a proxy for the Portuguese population. Even though this assumption might seem farfetched at first, it is important to bear in mind that young people are generally those with the highest exposure to digital technologies and, as such, are both particularly exposed to potential harms resulting from their use and uniquely equipped to shape positive health futures through codesign of digital health solutions, participatory research, and decision making [92]. Given the prevalence of and the high contact with young people in academia, there is hardly a better scenario to derive a proxy of the model population.

Using the University of Porto's dynamic email, we could reach 36,668 addresses. Nine hundred sixty-eight participants started the survey, resulting in a response rate of 1.7% (539/36,668) and a 55.7% completion rate. The survey participants had a mean age of 24.3 years, with 68.3% identifying as female and 26.9% as male. Of the 539 respondents, 93.9% identified as White, 2.2% identified as having more than one ethnicity, and 0.6% identified as Asian. Some faculty members (7.1% of the sample) and administrative staff (2.8% of the sample) answered the survey. This sample thus meets the goal of encompassing the academic community beyond the traditional scope of students only.

Of the 539 participants, 5.9% reported currently using digital mental health apps. Perceived stress was positively associated with DMHA use. A latent variable comprising self-perceptions of mental health problems and coping strategies in place was also positively related to their use. Privacy concerns regarding one's information being accessible to others were negatively associated with DMHA use. Perceived stigma, need to seek help, and having close relationships did not have a statistically significant direct effect. Financial reasons (37.3%), the perceived helpfulness of these apps (26.9%), uncertainty about the seriousness of one's needs (26.3%), and the waiting time to access mental health resources (24.9%) were the main barriers to DMHA access.

This constitutes a relevant contribution to the scientific literature not only of life sciences and their digital potential but also in terms of the industrial characterization of health economics for these subtopics and the mapping of expectations, through attitude and perception elicitation, from both supply and demand sides of mental healthcare. The

developers of decisions concerning DMHA-based interventions in the academic community should consider delivering these apps with low to no financial charges, offering evidence of their helpfulness and with a focus on the timely delivery of care. To further DMHA use, there is a need to shape mindsets through mental health literacy, namely regarding self-awareness of one's conditions, acceptable stress levels, and overall behavior toward mental health. These findings can inform product and policy development of new, better-targeted DMHA-based interventions that enable the academic community to take a more targeted, evidence-based approach to the mental health needs of its members.

Our research is, to the best of our knowledge, the first attempt at assessing whether DMHA would be welcomed in Portugal and a healthcare system with its political economy. By comparing Portugal with Germany (from the physicians' point of view) and the USA (from the individual's point of view) in similar settings, we hope to enrich the comparison between health systems with a very significant private sector role (USA and Germany) and systems where government plays a key function in ensuring access to and funding of health care (Portugal), particularly regarding digital mental health provision.

We see high similarity between German and Portuguese psychiatrists and psychologists in the selected study for replication in the latter context. Some differences were found, however, between the American sample of Borghouts et al. and ours. Self-reported mental illness (49% vs. 38% in Borghouts' sample), mental illness prevalence (anxiety (64% vs. 41%) and stress (57% vs. 44%)), self-reported perceived need to seek help (13% in our sample vs. Borghouts' 44%), use of professional services in the past 12 months (43% vs. 23%), and in past users of DMHA (25% of our sample reported having used them in the past, contrasting with Borghouts' 14%). Finally, 65% of our sample had health insurance compared with Borghouts' 80%.

We hypothesize that observed differences in both cases are owed to two main factors. The first is that all our studies were performed in the aftermath of the COVID-19 pandemic. Thus, interviewed populations had higher familiarity with – or opportunity to test – digital health tools.

The second factor is the different health system organizations and the incentives they elicit regarding healthcare access, financing, and coverage. In Portugal, the National Health Service, funded by general taxation, is the central piece of the system, mainly

providing free access at point-of-care and thus having low financial barriers to seeking healthcare. In this context, health insurance is often used as an ancillary means to speed up healthcare access by contracting with privately-owned healthcare providers.

In the United States of America, given the centrality of health insurance in the system (either publicly or privately funded) and several economic strata of the population being unable to buy better health insurance, there might be more significant financial barriers to seeking care, including mental health. On the other hand, even though the health system is fully insurance-based in the German system, there is better coverage and access, with financial barriers being inducers of medical activity rather than constraints for individuals seeking care. A follow-up hypothesis is that this might be due to differing levels of intervention regarding regulatory action and institutional political economy.

This further emphasizes the importance of regulatory action. John Torous recently called for a “(...) new generation of digital mental health tools to support more accessible, effective, and equitable care” [93]. Regulators that work with stakeholders to promote better evidence collection, analysis, and continuous review will not only be making their jobs easier to do; they will be catalyzing the creative possibilities that will endow every citizen with the tools to use (or choose not to!), engage with, and demand more of what they need from mental healthcare. Digital mental health applications are still maturing, and this thesis aims to feed into the exponentially growing body of knowledge that supports their analysis.

SWOT analysis for the Portuguese context

Given that our work consists of an intersection of digital, health, and economics, as well as its strong practical focus and the specialization of the candidate (Health Interventions, Policies, and Services), we believe that a proper way to conclude our discussion would be to use a mechanism often applied in strategic management: a SWOT analysis [94].

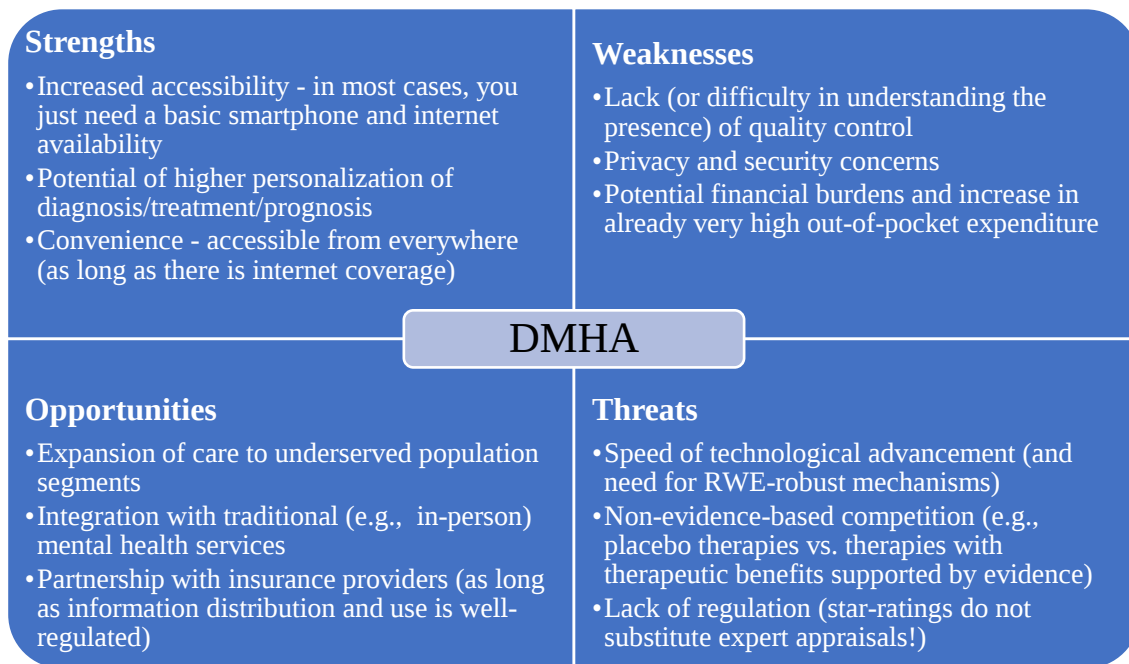


Figure 1. SWOT analysis of the Portuguese landscape.

Conclusion

Now that we have started the “How?” discussion, it is also essential to kick off the “Why?” debate.

Are we treating the symptom or the root cause of the problem? What are the actual mechanisms behind mental illnesses from a biochemical standpoint? Where do we draw the line between what is chemistry and what is human? Do the mental health concerns we observe result from how our society is structured? And, if so, what do we need to reform it and reduce human suffering structurally? How can we achieve that without doing no harm?

There are more questions than answers, and even our answers could be more perfect and dated; they have errors. That will likely always be the case. The march of human and scientific progress carries on, and error is the measure of our room for improvement. It stands enormous. We need a large-scale shift in perspective, both in terms of ideas and minds. And we need everyone if we want to, as a society, to have good mental health and the mechanisms for, better than treating mental illness, prevent it.

At the very least, we will have improved our probability of living a well-lived life.

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