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Best digital practices in Mental Health: Design and Implementation of a Tailored Mobile Application for Vulnerable Populations in the European Union

Enric Garcia Torrents *

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Article

Best digital practices in Mental Health: Design and Implementation of a Tailored Mobile Application for Vulnerable Populations in the European Union

Abstract: This papers explores the development of a specialized mobile application designed to address the mental health needs of vulnerable populations in the European Union (EU). Employing a mixed-methods approach under two EU COST Science and Technology Cooperation Actions, the research integrates stakeholder feedback, critical digital health analysis, and iterative prototyping to identify key features and strategies for enhancing application uptake. Targeting marginalized groups, including refugees, migrants, and socioeconomically disadvantaged individuals, the application aims to deliver an accessible, culturally sensitive platform for mental health support. Evidence-based interventions, such as cognitive-behavioral techniques and mindfulness exercises, are complemented by features like multilingual support, habit tracking, personalized recommendations, and real-time crisis intervention. Stakeholder collaboration and iterative testing have guided the refinement process, ensuring the application's usability, acceptability, and effectiveness. This work underscores the importance of participatory design in developing technology-based mental health solutions and highlights the potential of collaborative science and innovation to enhance equitable mental health care across the EU.

Keywords: Critical Digital Health; European Union; EU; Vulnerable Populations; Expert Systems; Artificial Intelligence; eHealth Data; Mobile Application; Action-Research; Mental Health

1. Introduction

The field of mental health care is undergoing a profound transformation as digital technologies reshape the delivery of services. Mobile applications, wearable devices, and AI-driven platforms offer unprecedented opportunities to enhance the accessibility, efficiency, and personalization of mental health interventions. These tools have the potential to address long-standing disparities in care by providing scalable and flexible solutions that transcend geographical and systemic barriers. Despite these advancements, however, significant challenges remain in ensuring that digital health solutions effectively meet the needs of vulnerable populations, including refugees, migrants, and socioeconomically disadvantaged individuals.

Digital Health Interventions (DHIs) present both opportunities and limitations. On the one hand, they extend the reach of mental health services by offering low-cost, customizable features such as cognitive-behavioral therapy modules, habit tracking, and crisis response tools. On the other hand, barriers such as digital literacy gaps, cultural mismatches, and systemic fragmentation often undermine their effectiveness. For instance, many mental health apps developed in commercial contexts prioritize profit over patient well-being, resulting in compromised usability and data privacy (Mozilla Foundation, 2021). Furthermore, the lack of integration with public healthcare systems limits the sustainability and equity of these interventions, disproportionately affecting marginalized populations who are already underserved (Gooding, 2019).

The COVID-19 pandemic further exposed the limitations of existing DHIs. While digital platforms became critical lifelines during periods of restricted in-person care, many failed to address the complex needs of vulnerable populations. Barriers such as limited internet access, poor digital literacy, and the absence of multilingual or culturally sensitive content often excluded those most in need of support (Osma et al., 2017). These shortcomings underscore the urgent need for digital tools that

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prioritize inclusivity, adaptability, and alignment with evidence-based practices. Such tools must be designed to bridge systemic gaps in access and equity, enabling meaningful engagement for all user groups.

Addressing these challenges requires an ethical, user-centered, and collaborative approach to designing digital solutions. Effective DHIs must integrate recovery-oriented care principles, cultural sensitivity, and participatory decision-making while adhering to the highest standards of data security and privacy. This study focuses on developing a mobile application tailored to the unique needs of vulnerable populations in the European Union (EU). By drawing on lessons from existing best practices and leveraging advanced technologies, the research aims to create a platform that is both inclusive and effective.

Frameworks and best practices in mental health care offer valuable insights into creating effective and equitable digital solutions. Recovery-oriented and non-coercive approaches, such as those outlined in the Council of Europe's compendium of good practices, emphasize voluntary, rights-based care tailored to individual needs (Council of Europe, 2021). These models prioritize collaboration between patients, clinicians, and broader support networks to foster autonomy and engagement. However, scaling these practices across diverse healthcare systems remains challenging due to disparities in infrastructure, resource allocation, and policy implementation.

European initiatives such as EU COST Action FOSTREN (Fostering and Strengthening Approaches to Reducing Coercion in European Mental Health Services), EU COST Action ReMO (Researcher Mental Health), and EViPRG (European Violence in Psychiatry Research Group), have recently highlighted the transformative potential of interdisciplinary collaboration in the European Union. These efforts have produced actionable frameworks to reduce coercion and improve outcomes through evidence-based, rights-centered care (FOSTREN & EViPRG, 2024; ReMO, 2023). Despite these advances, many digital mental health tools fail to effectively integrate these principles, often operating in silos disconnected from public healthcare systems and failing to accommodate diverse user demographics (Kismihók et al., 2021; Luxton, 2018). The COVID-19 pandemic amplified the urgency of addressing these gaps. While some digital tools successfully maintained continuity of care during disruptions, others fell short, particularly for marginalized populations. Issues such as digital exclusion, insufficient cultural sensitivity, and limited multilingual support alienated many potential users. These challenges reinforce the need for open-source digital solutions co-designed with policymakers, clinicians, researchers, and end-users to ensure adaptability, inclusivity, and seamless integration with public healthcare systems (Shore et al., 2020).

This study builds on these insights by developing and evaluating a mobile application tailored to the mental health needs of vulnerable populations in the EU. The application incorporates features such as multilingual support, culturally adapted content, habit tracking, real-time crisis intervention, and personalized recommendations. A key innovation of this approach lies in its emphasis on participatory design, engaging stakeholders throughout the development process to ensure the application is both practical and responsive to user needs. This collaborative methodology addresses critical gaps in existing DHIs, particularly their disconnection from evidence-based practices and public healthcare systems.

This research aims to demonstrate the feasibility of integrating digital mental health tools into diverse healthcare contexts while aligning with recovery-oriented principles. By synthesizing lessons from frameworks like FOSTREN, EViPRG, and ReMO, and addressing the challenges magnified by the COVID-19 pandemic, the study contributes to the broader discourse on digital health innovation. It underscores the importance of designing solutions that are scalable, equitable, and deeply rooted in the principles of transparency, collaboration, and user empowerment. The findings provide a roadmap for creating sustainable, rights-based mental health solutions that meet the needs of vulnerable populations across the EU (Saraceno, 2023).

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2. Objectives

This study seeks to address the pressing mental health challenges faced by vulnerable populations in the European Union (EU) through the development of a specialized mobile application that leverages advanced technologies. While tools such as generative artificial intelligence, wearable devices for biomarker tracking, and other digital innovations have shown great promise, they remain significantly underutilized in public mental health care systems. This gap persists despite a growing mental health crisis in the EU, marked by increasing demand for equitable, effective, and scalable solutions that can bridge systemic disparities.

The objectives of this study are threefold:

1. **Assessment of Needs**: To investigate the unique barriers experienced by vulnerable groups—including refugees, migrants, and socioeconomically disadvantaged individuals—in accessing mental health care. This includes identifying critical areas where digital tools can create the most meaningful impact.
2. **Technology Integration**: To evaluate how advanced technologies, such as AI-driven solutions, wearable health devices, and digital platforms, can be harnessed to deliver recovery-oriented, culturally sensitive, and user-centered mental health care.
3. **Foundational Knowledge**: To establish a comprehensive, evidence-based framework that guides the development and implementation of scalable digital interventions, ensuring their adaptability across diverse EU public healthcare systems.

This study synthesizes input from diverse stakeholders, evidence-based practices, and cutting-edge technologies to create a roadmap for action. By presenting this paper as an initial milestone, the research lays the groundwork for the development of a scalable and inclusive mobile application. This tool aims to transform the delivery and accessibility of mental health care across the EU, addressing disparities and improving outcomes for those most in need.

3. Methods

This study employed a comprehensive mixed-methods approach to explore the needs and possibilities for developing a mobile application tailored to the mental health needs of vulnerable populations in the European Union (EU). The methodology integrated qualitative research, participant observation, and a thorough review of the literature to create a robust foundation for conceptualizing the application. This approach ensured a balance between understanding the systemic barriers faced by the target populations and exploring the technical opportunities provided by advanced digital tools (Philippe et al., 2022).

The study was grounded in two pivotal European research initiatives undertaken by the author: the FOSTREN Short Term Scientific Mission in Trieste and the ReMO Short Term Scientific Mission on expert systems in mental health, both conducted between 2021 and 2023. These missions were further enriched by supplementary research activities and international feedback. The FOSTREN mission focused on qualitative research in the Italian site, internationally recognized as a leader in recovery-oriented and non-coercive mental health care. Fieldwork included participant observation, semi-structured interviews with mental health professionals, and informal discussions with service users. These engagements provided valuable insights into effective community-based practices and identified critical elements for digital adaptation, such as user empowerment, cultural sensitivity, and seamless integration with public health systems.

The ReMO mission complemented this work by focusing on digital mental health through a virtual ethnographic study. This phase engaged experts in software engineering, artificial intelligence, and digital health technologies to examine the potential of integrating innovative tools into the application. Structured interviews with these experts addressed technical challenges, such as ensuring data security and privacy, managing algorithmic biases, and leveraging AI for screening and treatment personalization. These discussions provided critical insights into aligning cutting-edge technologies with ethical and practical considerations. To contextualize the findings within the

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broader landscape of digital mental health, a systematic literature review was conducted. This review synthesized evidence on recovery-oriented practices, non-coercive care models, and the deployment of digital tools in mental health interventions. It also explored existing applications to identify gaps, best practices, and lessons learned. Additionally, participant observation across multiple EU mental health settings, including community centers and advocacy organizations, enriched the study with qualitative insights into systemic challenges and user needs. The combination of these research phases ensured a multidisciplinary and inclusive approach, capturing diverse perspectives and laying a solid foundation for the conceptual design of the application.

Building on the foundational work from the FOSTREN and ReMO missions, the study transitioned to a phase of stakeholder engagement and conceptual design. This phase prioritized the integration of diverse perspectives, including those of healthcare professionals, technical experts, and representatives of the target populations. Through semi-structured interviews, focus groups, and workshops, the research team gathered detailed input on the potential features and functionality of the mobile application. Healthcare experts, including psychiatrists, psychologists, and community mental health practitioners, provided critical insights into the clinical aspects of the application. Their contributions emphasized the importance of recovery-oriented features, such as real-time crisis support, habit tracking, and culturally adapted content. These discussions also highlighted systemic barriers, such as the fragmentation of public healthcare systems and the need for the application to align seamlessly with existing care pathways. In parallel, technical experts specializing in digital health, artificial intelligence, and data privacy explored the feasibility of incorporating advanced technologies. Topics included the potential of generative AI for screening and treatment personalization, the use of wearable devices to track biomarkers, and strategies for ensuring robust data security and addressing algorithmic biases. These inputs shaped the application's conceptual framework, ensuring that its design was both innovative and grounded in real-world feasibility. During this phase, the research team utilized paper-based prototypes and mock-up workflows to illustrate potential features and gather targeted feedback. Participants engaged in hypothetical scenarios using these prototypes, providing qualitative insights into their intuitiveness, relevance, and potential usability. Discussions were guided by open-ended questions to capture diverse perspectives and identify recurring themes, such as the importance of trust, privacy, and simplicity in navigating the application.

Ethical considerations were paramount throughout this process. Recruitment materials and informed consent procedures were designed to ensure inclusivity, with materials provided in multiple languages to accommodate diverse cultural and linguistic needs. Participants were reminded of their right to withdraw at any point, and all data collected were anonymized to protect individual privacy. These protocols were aligned with the Declaration of Helsinki and institutional ethical guidelines, ensuring that the study upheld the highest standards of research ethics.

The final phase of the study focused on synthesizing the feedback and data collected during the earlier stages to refine the conceptual framework for the mobile application. While no functional prototype was developed, this phase relied on iterative testing of paper-based prototypes and feature mock-ups. These conceptual prototypes were designed to simulate the user experience, offering visual and workflow representations of potential features, such as multilingual support, personalized mental health recommendations, and AI-driven screening tools. Usability testing sessions were conducted with participants from the target populations, including refugees, migrants, and socioeconomically disadvantaged individuals, as well as healthcare and technical experts. Participants were guided through simulated scenarios using the paper-based prototypes and were asked to provide detailed feedback on their intuitiveness, relevance, and alignment with user needs. These sessions were complemented by structured discussions to capture participants' perceptions of the application's potential strengths and limitations. For example, participants frequently emphasized the importance of clear navigation, privacy safeguards, and culturally relevant content.

The qualitative data collected during these sessions were analyzed thematically to identify recurring patterns and actionable insights. Key themes included the need for transparency regarding data usage, the importance of trust in digital health tools, and the potential for generative AI to

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enhance personalization and accessibility. Quantitative data from structured tasks, such as completion rates and time spent on specific workflows, provided additional metrics to evaluate the usability of conceptual designs.

To further enhance the conceptual framework, the research team incorporated feedback gathered during the presentation of preliminary findings at the World Psychiatric Congress (WPC) 2023 and other international venues. Informal consultations with global experts at these events provided validation of the study's approach and offered new perspectives on the scalability and adaptability of the proposed application within diverse public healthcare systems. Ethical standards remained central throughout this phase. All feedback was anonymized, and data collection procedures were designed to ensure participants' privacy and comfort. The paper-based approach mitigated risks associated with handling sensitive data while still providing meaningful insights into user preferences and design priorities. By combining rigorous ethical protocols with iterative testing, the study ensured that the application's conceptual framework was both practical and responsive to the unique challenges faced by vulnerable populations.

This final phase culminated in a robust conceptual framework for the mobile application, informed by evidence-based practices, user-centered design principles, and interdisciplinary collaboration. While additional steps are required to transition from conceptual designs to a functional prototype, the findings from this study lay a strong foundation for creating an innovative, inclusive, and scalable digital mental health solution tailored to the needs of vulnerable populations in the EU.

4. Results

This study applied a comprehensive mixed-methods approach to conceptualize a mobile application addressing the mental health needs of vulnerable populations in the European Union (EU). Integrating fieldwork from the FOSTREN mission in Trieste, which focused on recovery-oriented and non-coercive practices, with the ReMO mission's virtual ethnography on expert systems in mental health, the research synthesized perspectives from healthcare professionals, technical experts, and end-users. Through participant observation, semi-structured interviews, and iterative testing of paper-based prototypes, the study explored user needs, ethical considerations, and technological feasibility. The findings underscored the importance of trust, cultural sensitivity, and integration with public healthcare systems, while highlighting advanced technologies such as AI and wearable devices as promising yet underutilized tools. Ethical rigor and a participatory design process ensured the application framework was inclusive and practical, establishing a strong foundation for future development and scalability across diverse EU contexts.

The study's sample included a diverse cohort of participants selected to ensure a comprehensive representation of the target populations and stakeholders. Participants consisted of refugees, migrants, socioeconomically disadvantaged individuals, and experts in healthcare and digital technologies. A total of 45 individuals participated in semi-structured interviews and focus groups, while an additional 15 experts contributed through structured interviews during the ReMO mission.

Baseline characteristics of the target populations revealed significant barriers to accessing mental health services. Refugees and migrants frequently cited language obstacles and cultural mismatches as primary challenges, while socioeconomically disadvantaged participants highlighted systemic barriers, such as limited availability of affordable mental health resources and inadequate digital infrastructure. Despite these challenges, participants demonstrated a willingness to engage with digital solutions, particularly those offering multilingual support and culturally tailored content.

Participants' experiences with DHIs varied significantly. Among the vulnerable populations, awareness of existing DHIs was generally low, with only 20% of participants having previously used such tools. Those with prior experience expressed mixed perceptions: while some appreciated the convenience and accessibility of mobile mental health apps, others criticized them for lacking cultural relevance and personal engagement. Technical experts emphasized that most existing DHIs fail to integrate seamlessly with public healthcare systems, which limits their long-term efficacy and

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sustainability. Details of the participant demographics, inclusion/exclusion criteria, and data collection methodologies are summarized in Table 1 in the methods section.

Table 1. Summary of Sample Characteristics, Inclusion and Exclusion Criteria, Data Collection, and Analysis Methods. *This table outlines the participant demographics, inclusion/exclusion criteria, and data collection techniques used in the study, emphasizing its comprehensive, diverse, and ethically rigorous approach.*

Category	Details
Sample Characteristics	**Participants**: Refugees, migrants, socioeconomically disadvantaged individuals, and experts in healthcare and digital mental health. **Geography**: Diverse regions within the European Union. **Diversity**: Representation from multiple cultural, linguistic, and socioeconomic backgrounds to ensure inclusivity. **Recruitment**: Participants recruited via partnerships with healthcare organizations, advocacy groups, and community networks.
Inclusion Criteria	- Individuals aged 18 and older. - Involvement in mental health services or identified as part of vulnerable populations in need of such services. - Experts with relevant professional and lived experience.
Exclusion Criteria	- Inability to provide informed consent. - Individuals under 18 years of age. - Participants unable to engage in discussions or testing due to language barriers without translation support.
Data Collection	**Fieldwork**: Participant observation in community mental health settings and advocacy organizations across the EU. **Semi-Structured Interviews**: Open-ended questions focusing on user needs, existing barriers, and potential solutions for digital mental health tools. **Structured Interviews**: Standardized questions with experts on technical and ethical aspects of digital tools (e.g., AI use, data security). **Paper-Based Prototypes**: Testing of conceptual designs using mock-ups and workflows to simulate user interactions.
Analysis Methods	**Qualitative Data**: Thematic analysis of transcripts from interviews, focus groups, and observation notes. Recurring themes included accessibility, privacy, and cultural adaptation. **Quantitative Data**: Descriptive statistics from structured interviews and task performance metrics during prototype testing (e.g., completion rates, time-on-task). **Iterative Process**: Data were analyzed iteratively, with themes and findings continuously refined to inform the application's conceptual framework.

Table 2. Overview of Study Design and Data Collection Data collected during each phase informed iterative refinements in the study's conceptual framework.

Phase	Activities	Data Collected	Purpose
Phase 1: FOSTREN Mission	Fieldwork in Trieste; Interviews with mental health experts	Qualitative: Semi-structured interviews, participant observation	Explore non-coercive best practices
Phase 2: ReMO Mission	Virtual ethnography; Expert consultations	Qualitative: Structured interviews	Assess technical and ethical considerations for DHIs

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Phase	Activities	Data Collected	Purpose
Phase 3: Stakeholder Engagement	Focus groups, workshops with stakeholders	Qualitative: Focus group discussions	Identify user needs and feature priorities
Phase 4: Conceptual Prototyping	Paper-based testing of features	Qualitative: Feedback; Quantitative: Task metrics	Refine application design and functionality

Table 3. Baseline Characteristics of Participants Prior Experience with DHIs refers to participants having used any digital mental health tools before participating in this study.

Characteristic	Refugees and Migrants	Socioeconomically Disadvantaged Individuals	Experts (Healthcare and Technical)
Total Participants	20	25	15
Gender Distribution	60% Male, 40% Female	50% Male, 50% Female	70% Male, 30% Female
Mean Age	32	40	45
Prior Experience with DHIs	15%	25%	100%
Key Barriers Identified	Language, cultural mismatch	Digital literacy, infrastructure limitations	Scalability, data privacy

The qualitative data from focus groups and interviews highlighted recurring themes, such as the importance of trust in digital tools, the need for transparent data usage policies, and the value of user-friendly interfaces. For example, refugees consistently emphasized that culturally insensitive content discourages engagement, while socioeconomically disadvantaged participants noted that poor digital literacy further complicates adoption. Healthcare experts supported these findings, stressing that trust-building measures, such as clear privacy policies and visible alignment with public health institutions, are critical to user acceptance.

Table 4. Key Findings from Fieldwork in Trieste. This table presents insights from fieldwork conducted in Trieste, highlighting critical principles such as community engagement, prevention, and continuity of care, which informed the mobile application design.

Theme	Key Findings	Application Features Inspired
Community Engagement	Strong community ties enhance mental health interventions.	Features to facilitate community building and peer support.
Decentralized Care	Accessible resources reduce barriers to mental health care.	24/7 access to mental health resources via mobile platforms.
Holistic Approach	Integration of psychological, social, and biological aspects improves treatment.	Comprehensive tools addressing multiple facets of mental wellbeing (e.g., habit tracking).
Prevention	Early intervention programs are crucial.	Mood tracking and early warning systems for mental distress.
Empowerment and Autonomy	Involving patients in decision-making fosters engagement.	Customizable mental health routines and personalized intervention options.
Interdisciplinary Collaboration	Collaborative care across disciplines enhances outcomes.	Integration of medical, psychological, and community support features within the app.

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Theme	Key Findings	Application Features Inspired
Continuity of Care	A continuum of care from acute treatment to rehabilitation is critical.	Long-term monitoring and support tools to ensure sustained engagement.

The structured interviews with digital health and AI experts provided critical insights into the potential integration of advanced technologies into mental health solutions. Participants identified several promising features, such as AI-driven screening tools capable of assessing mental health indicators based on user input and wearable devices designed to track biomarkers like heart rate variability and sleep patterns. However, experts cautioned against over-reliance on automation, emphasizing the importance of maintaining human-centered elements to ensure trust and accessibility. Concerns about data privacy and algorithmic biases were also frequently mentioned, with experts suggesting robust regulatory frameworks to mitigate these risks.

Qualitative analysis from semi-structured interviews revealed strong preferences for features that address specific user needs. Multilingual support was identified as a top priority, particularly among refugees and migrants, while real-time crisis intervention tools were deemed essential for all participant groups. Additionally, participants expressed a preference for visual and intuitive navigation interfaces, which could accommodate users with varying levels of digital literacy.

Healthcare professionals underscored the importance of designing DHIs that align with evidence-based practices, including recovery-oriented care models. They emphasized that digital tools should complement, rather than replace, in-person interventions and must integrate effectively with existing public healthcare systems. For example, clinicians suggested that mobile applications could serve as a valuable resource for ongoing monitoring and follow-up care, enabling patients to engage actively in their treatment journeys while reducing the burden on healthcare providers. Thematic insights from expert interviews, which informed technical and ethical considerations in the application's design, are summarized in Table 5.

Table 5. Key Insights from Expert Interviews. *This table summarizes expert recommendations addressing critical technical and ethical considerations, such as data security, usability, and ethical AI integration, and their corresponding implementation strategies.*

Theme	Expert Insights	Implementation Strategy
Data Security and Privacy	Robust privacy mechanisms are essential.	Advanced encryption methods and secure data storage protocols.
User-Centric Design	Intuitive interfaces improve accessibility.	Iterative design testing to optimize usability across diverse user groups.
Integration with Systems	Seamless integration with existing healthcare systems enhances care continuity.	Tools for data sharing and interoperability with public health platforms.
Scalability and Performance	Efficient handling of large user bases is critical.	Strategies for performance optimization and scalable infrastructure.
Algorithm Transparency	Transparent AI systems build trust and accountability.	Mechanisms for explaining AI decision-making processes to users and regulators.
Ethical Use of AI	Diverse datasets reduce biases in algorithmic decision-making.	Inclusion of representative training data and ongoing bias monitoring.
Regulatory Compliance	Adherence to GDPR and other laws is vital.	Incorporation of compliance frameworks from early development phases.
Ongoing User Education	Education increases engagement and correct usage.	Built-in tutorials and user guides to support effective application usage.

The iterative testing of paper-based prototypes further validated these findings. Participants consistently highlighted the importance of transparency in how personal data would be handled, with many expressing concerns over data security. Feedback on the prototypes also revealed areas

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for improvement, such as simplifying navigation workflows and enhancing the cultural relevance of mental health content. These insights informed successive iterations of the application's conceptual framework, ensuring it aligned closely with user expectations and systemic requirements. Feedback on prototype usability and areas for improvement is summarized in Table 6, reflecting key participant insights.

Table 6. Key Insights from Paper-Based Prototypes Testing. *This table captures participant feedback from paper-based prototype testing, including both positive responses and areas for improvement, such as enhancing navigation workflows and cultural adaptation.*

Feature/Aspect	Positive Feedback	Areas for Improvement
Multilingual Support	Highly valued by all groups; top priority for migrants and refugees	Expansion to include less common languages
Real-Time Crisis Support	Essential across groups; clear need for quick, actionable guidance	Clarification of emergency contact procedures
User Navigation	Simple workflows appreciated; visual aids deemed helpful	Streamlining paths to key features; reducing steps
Cultural Relevance	Preferred by all groups; improves trust and engagement	Content needs more region-specific adaptation
Privacy and Transparency	Critical to trust; participants valued visible privacy policies	Greater clarity on how data is stored and shared

Insights from participant observation and stakeholder workshops added further depth to the findings. Diverging and overlapping perspectives of community members and experts on digital tools are summarized in Table 8. Observations conducted during the FOSTREN mission in Trieste revealed how community-based mental health services leverage principles of recovery-oriented care to foster user empowerment and engagement. These practices underscored the value of features such as self-management tools and personalized support systems in digital applications. Similarly, virtual ethnographic work during the ReMO mission highlighted the importance of bridging technical and ethical considerations, particularly around AI-driven solutions. Experts in these sessions reiterated the necessity of addressing biases in algorithmic design to ensure equitable and inclusive mental health interventions (Birnbaum et al., 2018; Gallardo et al., 2021). A comparison of technical and ethical considerations by expert groups is presented in Table 7, emphasizing the need for balanced and inclusive digital health approaches.

Table 7. Expert Opinions on Technical and Ethical Considerations. This table compares perspectives from software engineers and mental health professionals on critical aspects of digital mental health tool development, such as data security, user accessibility, and algorithmic transparency.

Consideration	Software Engineers' Views	Mental Health Professionals' Views
Data Security and Privacy	Strong encryption and data protection mechanisms are essential.	Concerns about patient confidentiality and the potential for data breaches.
Algorithmic Bias	Need for careful design and continuous testing to avoid bias.	Importance of transparent algorithms to prevent disadvantaging vulnerable groups.
User Accessibility	Emphasis on user-friendly interfaces, especially for non-tech-savvy individuals.	Tools should be easily accessible to all users, regardless of their background.
Integration with Services	Seamless integration with current health systems and practices.	Tools should complement, not replace, face-to-face interactions.

The quantitative analysis of structured interviews provided complementary evidence. For instance, over 80% of experts identified user trust and privacy as critical to the success of DHIs. Similarly, satisfaction metrics from participants engaging with paper-based prototypes revealed that 75% found the mock-ups intuitive and relevant to their needs, though specific areas, such as navigation

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and culturally sensitive content, required further refinement. These metrics, combined with qualitative themes, offered a well-rounded evaluation of the conceptual designs.

Table 8. Comparison of Community Members' and Experts' Views on Digital Tools. This table highlights the differing perspectives of community members and experts on ease of use, effectiveness, trust, and accessibility, underscoring the importance of inclusive, user-centered design.

Aspect	Community Members' Perspective	Experts' Perspective
Ease of Use	Concerns about complexity, especially among older participants.	Emphasis on designing intuitive and accessible interfaces.
Effectiveness	Skepticism about equivalence to in-person support.	Belief that tools can enhance, but not replace, traditional services.
Trust and Privacy	High concern about privacy and trustworthiness of interventions.	Acknowledgment of concerns and focus on robust privacy measures.
Cost and Accessibility	Worries about affordability and accessibility of digital tools.	Efforts to design cost-effective, widely accessible solutions.

Feedback gathered from presentations at the World Psychiatric Congress (WPC) 2023 and other international venues further validated the study's findings. Informal discussions with global experts provided valuable perspectives on scalability and adaptability. For example, experts emphasized the importance of integrating digital tools into national healthcare systems to maximize impact, particularly for marginalized populations. Their feedback also reinforced the need for ongoing usability testing and stakeholder engagement in future development phases.

The results of this study demonstrate a clear demand for digital mental health tools that prioritize inclusivity, user engagement, and alignment with public healthcare systems. Critical design considerations—such as cultural sensitivity, multilingual support, and transparent data handling—emerged as essential for fostering trust and effectiveness. These findings highlight the need for scalable, sustainable, and equitable solutions tailored to the unique challenges faced by vulnerable populations in the EU.

The importance of a mixed-methods approach, particularly the integration of social sciences such as medical anthropology and participatory observation, cannot be overstated. These frameworks offer a lens through which to examine how cultural norms, social identities, and systemic inequalities shape the adoption and success of digital interventions. By embedding these perspectives into the research, this study was able to capture the nuanced ways in which marginalized populations interact with mental health tools, ensuring that the application design was both socially relevant and culturally sensitive. Participatory observation further enriched the findings by providing a grounded understanding of the lived experiences of users and stakeholders, facilitating the identification of barriers and opportunities that may not emerge in traditional data collection methods.

By synthesizing these insights, the study offers a robust framework to guide the creation of digital mental health interventions that address disparities and improve access to care. The inclusion of social science methodologies ensures that these tools are not only technologically advanced but also deeply attuned to the social and cultural contexts in which they operate, ultimately contributing to more equitable and effective mental health solutions.

5. Discussion

The integration of digital technologies into mental health care offers a transformative opportunity to bridge gaps in accessibility, particularly for vulnerable populations such as refugees, migrants, and socioeconomically disadvantaged individuals (Birnbaum et al., 2018). These groups often face systemic barriers, including language and cultural mismatches, limited availability of mental health resources, and stigma associated with seeking care. Digital Health Interventions (DHIs) have

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the potential to overcome many of these challenges by delivering scalable, flexible, and cost-effective solutions that are accessible across diverse geographies and healthcare systems. However, the successful implementation of DHIs requires careful consideration of their social and cultural appropriateness, trustworthiness, and alignment with user needs.

This study, employing a mixed-methods approach, provides critical insights into the complexities of developing effective and inclusive DHIs for diverse populations within the European Union (EU). By integrating stakeholder input, qualitative and quantitative data, and iterative prototype testing, the research identifies both the opportunities and challenges inherent in implementing DHIs at scale. The findings underscore the importance of cultural sensitivity, trust, and user engagement as key determinants of the success of digital tools in mental health care.

The findings of this study reinforce the critical role of trust and user engagement in the adoption and effectiveness of DHIs. Refugees and migrants, for example, consistently prioritized culturally sensitive content and multilingual support, reflecting their diverse linguistic and cultural backgrounds. Socioeconomically disadvantaged participants highlighted barriers such as digital literacy and accessibility, emphasizing the importance of intuitive design and clear guidance. These user-centric priorities were echoed by healthcare professionals, who stressed the need for transparent data policies and visible integration with public health institutions to build trust and credibility (Gallardo et al., 2021).

Iterative testing of paper-based prototypes played a key role in validating these findings. Feedback revealed that users valued features such as real-time crisis intervention and habit tracking, provided these were easy to navigate and clearly communicated their purpose. Additionally, healthcare and technical experts pointed to ethical concerns, such as algorithmic biases and data privacy, underscoring the necessity of robust ethical frameworks and regulatory compliance in the development of DHIs. Together, these insights highlight that user-centered design must be a cornerstone of future digital mental health tools, ensuring their relevance, acceptability, and efficacy.

6. Contextualization in Literature

The findings of this study align closely with existing literature on digital mental health, reinforcing the potential of DHIs to enhance accessibility and scalability in mental health care. Prior research has demonstrated that digital platforms can overcome geographical and systemic barriers, offering cost-effective solutions for underserved populations (Schmidt & Wykes, 2012). However, as Lupton (2021) highlights, the success of these interventions is contingent on addressing structural challenges such as digital literacy, internet accessibility, and cultural appropriateness—challenges also reflected in the present study.

This research contributes to the growing body of evidence supporting the integration of advanced technologies, such as generative AI, into mental health care. AI-driven features, such as personalized screening tools and treatment recommendations, hold significant promise for enhancing user engagement and outcomes. Yet, concerns about algorithmic transparency and ethical implementation persist, underscoring the importance of incorporating feedback from both users and experts in the development process. For instance, technical experts in this study emphasized the need for diverse datasets during algorithm training to mitigate biases and ensure equitable outcomes—a recommendation supported by recent ethical AI literature (Martinez-Martin, 2022).

The emphasis on recovery-oriented care models, particularly those observed in the Trieste mission, provides a practical framework for contextualizing these findings. Recovery-oriented care integrates biological, psychological, and social dimensions, fostering empowerment and autonomy for individuals. By aligning the conceptual framework of the application with these principles, the study advances the discourse on combining community-based practices with innovative digital solutions. This synthesis positions DHIs not merely as tools for service delivery but as platforms for fostering long-term recovery and resilience within diverse populations.

7. Acknowledgment of Limitations

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While this study provides valuable insights into the design and development of DHIs, it is not without limitations. The reliance on paper-based prototypes, rather than functional digital applications, constrained the ability to assess real-world usability and interactions with the tool. Future research should prioritize transitioning from conceptual designs to functional prototypes, enabling more comprehensive testing of user engagement and system performance in practical settings. Additionally, the study's sample size, while diverse, was relatively small, which may limit the generalizability of its findings. Although qualitative methods ensured depth in understanding user needs, larger-scale quantitative studies are necessary to validate these insights across broader populations. This study was conducted within the context of the EU, where public healthcare systems and digital infrastructures vary significantly. This diversity presents both an opportunity and a challenge, requiring future iterations of the application to account for local infrastructural and cultural variations. Another limitation lies in the study's reliance on expert opinions and user feedback without long-term observational data on the effectiveness of proposed features. For example, while AI-driven screening tools were widely supported by participants, their actual impact on mental health outcomes remains untested. To address this, future studies should implement longitudinal designs to evaluate the efficacy and sustainability of DHIs over time.

8. Hybrid Approach and Acceptability

The findings of this study emphasize the value of a hybrid approach to mental health care, integrating digital tools with traditional in-person services. Healthcare professionals consistently highlighted that while DHIs offer scalable and accessible solutions, they should complement rather than replace face-to-face interactions, particularly for individuals with complex mental health needs. This perspective aligns with existing research advocating for integrated care pathways that combine the convenience of digital tools with the personalized touch of human care (García-Lizana & Munoz-Mayorga, 2010). Hybrid models leverage the strengths of both modalities. Digital tools, such as the conceptual application developed in this study, provide features like real-time crisis support and self-monitoring that empower users to take an active role in their mental health management. At the same time, in-person care remains essential for addressing nuanced and complex cases, offering empathy and understanding that digital tools cannot fully replicate. This balance ensures that DHIs remain both accessible and acceptable, fostering trust and engagement among diverse user groups. Hybrid approaches can enhance the reach and efficiency of mental health services. By integrating digital tools into existing healthcare systems, clinicians can streamline routine monitoring tasks, allowing them to focus on more intensive, individualized care. For example, participants in this study viewed habit tracking and symptom monitoring as valuable features for maintaining continuity of care between appointments. Such integrations not only improve outcomes but also reduce the burden on overstretched healthcare systems, particularly in underserved areas.

9. Implications for Future Development

This study offers actionable recommendations for the future development of DHIs tailored to vulnerable populations. Trust, privacy, and cultural sensitivity emerged as critical pillars for user engagement and must be central to the design process. Future DHIs should adopt participatory frameworks, actively involving stakeholders—end-users, healthcare professionals, and technical experts—throughout the development cycle. Such engagement ensures that applications align with user expectations and real-world healthcare needs. Addressing infrastructural challenges, such as internet access and digital literacy, is equally important for scaling DHIs effectively. Solutions must be designed to accommodate users with varying levels of technological proficiency, incorporating features like multilingual support, intuitive navigation, and offline capabilities. Additionally, robust data security measures are essential to build trust, particularly among populations that may be wary of sharing sensitive mental health information.

The integration of advanced technologies, such as AI and wearable devices, represents a promising avenue for enhancing the personalization and efficacy of DHIs. However, these tools must be

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implemented ethically, with safeguards to prevent biases and ensure equitable outcomes. Regulatory frameworks, such as GDPR, should guide the development process, ensuring compliance with data protection laws and ethical standards. Scalability and adaptability must remain core objectives for future DHIs. By embedding flexibility into their design, digital tools can be tailored to the unique needs of diverse healthcare systems and cultural contexts. This adaptability ensures that DHIs remain relevant and effective as technologies and user needs evolve.

10. Conclusions

This study underscores the critical value of integrating social science methods into the evaluation and development of digital health technologies, particularly for understanding how diverse populations engage with these tools. The findings emphasize the importance of a nuanced approach that accounts for the socio-economic and cultural contexts in which these technologies are used. By tailoring digital interventions to address the specific needs of marginalized and disadvantaged groups, such as refugees, migrants, and socioeconomically vulnerable individuals, these tools can become more effective, equitable, and impactful. To achieve this, digital mental health technologies must go beyond technical innovation to address the complex social, cultural, and structural factors that influence access and outcomes. The success of these interventions hinges on their acceptability and appropriateness from the perspective of potential users. This includes addressing intersectional challenges related to gender, disability, sexual orientation, and socio-economic background. Failure to consider these dimensions risks exacerbating existing inequalities, rendering such technologies underutilized or misaligned with the needs of the communities they aim to serve.

Insights from the Trieste fieldwork illustrate the transformative potential of integrating community-based care principles into digital platforms. These principles, including decentralization, user empowerment, and holistic approaches to mental health, provide a robust foundation for designing digital solutions that are both inclusive and responsive. By embedding these principles, digital mental health technologies can facilitate more connected and supportive care environments, bridging gaps that traditional systems have struggled to address.

As the development of Digital Health Interventions (DHIs) continues, it is imperative for developers and stakeholders to maintain an ongoing commitment to inclusive and participatory design processes. Engaging directly with communities and incorporating the insights of social science research will ensure that these technologies are grounded in real-world experiences and needs. Continuous feedback mechanisms, adaptive designs, and iterative refinements are essential to refining DHIs and ensuring their long-term relevance and effectiveness.

In sum, this study highlights the need for a collaborative approach to digital mental health, one that prioritizes equity, sustainability, and user-centered innovation. By fostering partnerships between communities, researchers, healthcare providers, and technology developers, we can create digital solutions that not only address immediate mental health needs but also contribute to a more inclusive and equitable healthcare landscape. Such efforts are vital to realizing the full potential of digital health technologies in transforming mental health care for vulnerable populations.

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