

Study protocol of the Connected for Wellness mobile app for addressing mental health disparities through schools and primary care clinics.

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Abstract

Background: Minoritized youth face greater odds of unmet mental health needs compared to their white peers and are disproportionately affected by the social determinants of health (SDoH). These inequities worsened in the wake of the COVID-19 pandemic. Digital interventions offer a promising solution to deliver quality mental health information, support, and resources, address stigma, and to help link youth and their families to mental health and SDoH-related services for improved wellness.

Objective: This paper outlines an innovative protocol to implement and evaluate a mobile app called Connected for Wellness. Co-developed with youth and caregivers through community participatory informatics and utilizing machine learning, the app personalizes evidence-based emotion regulation skill tools and implements brief wellness assessments and digital linkages to supportive resources. We hypothesize that Connected for Wellness will enhance youth and caregiver self-care practices, help-seeking behaviors and engagement across the care continuum.

Methods: Using a stepped-wedge design, our study involves youth aged 13-22 years and their caregivers from 10 high schools and 10 primary care clinics across two West Coast counties, primarily serving Latino, Black and Asian youth. The primary study outcome is change in youth engagement in mental health care following site-level app implementation of the Connected for Wellness app as a universal public health intervention.

Results: This study was funded in August 2023 by the National Institute of Mental Health in response to the National Institutes of Health Common Fund Transformative Research to Address Health Disparities and Advance Health Equity initiative. The clinical trial phase will begin in early 2025 and is expected to conclude by June 2027.

Conclusions: With their unrivaled ability to reach youth, school-based services and primary care clinics serve as ideal hubs for implementation of a mobile app that facilitates mental health engagement and prevention interventions. A successful study outcome would be implementing Connected for Wellness in these settings, providing an effective, acceptable and engaging mobile app and improving access to and engagement with mental health screening, referral and care through schools and primary care settings. Clinical Trial: NCT06122688

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Original Manuscript

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Abstract

Background: Minoritized youth face greater odds of unmet mental health needs compared to their white peers and are disproportionately affected by the social determinants of health (SDoH). These inequities worsened in the wake of the COVID-19 pandemic. Digital interventions offer a promising solution to deliver quality mental health information, support, and resources, address stigma, and to help link youth and their families to mental health and SDoH-related services for improved wellness.

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We hypothesize that *Connected for Wellness* will enhance youth and caregiver self-care practices, help-seeking behaviors and engagement across the care continuum. **Methods:** Using a stepped-wedge design, our study involves youth aged 13-22 years and their caregivers from 10 high schools and 10 primary care clinics across two West Coast counties, primarily serving Latino, Black and Asian youth. The primary study outcome is change in youth engagement in mental health care following site-level app implementation of the *Connected for Wellness* app as a universal public health intervention.

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engagement with mental health screening, referral and care through schools and primary care settings. (Word Count 332)

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Introduction

Could a mobile mental health app designed for youth and caregivers help address mental health services barriers? For decades, research has documented the ongoing and persistent inequities in mental health care access for racially/ethnically minoritized populations [1-3]. Innovative aspects of the clinical trial protocol reported here include using a mobile app co-developed with youth and families through participatory informatics to drive technological innovation, considering youth and

caregiver priorities for customizable features, and in-app resources.

Our previous work supports the hypothesis that mobile apps and other digital health interventions are effective for delivering mental health and prevention services, provided they meet the needs and preferences of end-users [4]. These interventions can be successfully implemented within child, adolescent, and family-serving systems of care. Unlike clinicians' time, technology offers a non-consumable strategy (i.e., available asynchronous content vs. scheduled therapist time) for improving mental health access [5]. The United States (U.S.) has witnessed an increasing need for youth mental health services, especially for stress-related challenges [6, 7], with minoritized populations disproportionately affected [8]. National data reveals that after controlling for socio-demographics, severity of symptoms, income, and health insurance, Black and Latino youth with similar needs as white youth were almost half as likely to receive mental health services [3].

Barriers to care exist across multiple levels, including cultural, community, family, and systemic factors. For instance, Latino caregivers may perceive children's behavioral challenges as issues to address within the family, struggle with the lack of linguistically and culturally appropriate services, or experience stigma and perceptions of mental health needs that differ from providers in mental health care [9]. Furthermore, racialized healthcare disparities are worse when combined with socioeconomic inequities for groups disproportionately affected by poverty and systemic discrimination. These systematic factors contribute to reduced utilization of mental health services, even in high-risk populations, underscoring the need for focused interventions that can both help mental health symptoms and risks, and promote and facilitate engagement in services [10].

Mobile app interventions, integrated into trusted community settings like schools and primary care clinics, offer scalable solutions to improve access and equity in youth mental health care. To be effective and acceptable, apps need to include features and content that are designed to be engaging for and address the needs of diverse groups [11]. Despite the proliferation of digital health interventions for youth across a range of delivery methods (e.g., websites, apps, games, robots and

virtual reality) [12], few are co-designed with the intended users in mind, and even less for minoritized youth [13]. Furthermore, the methods used for youth and caregiver collaboration in the design process vary widely [14]. This is unfortunate as studies demonstrate high levels of youth acceptability for interface with mobile health app interventions [15]. These tools can be important non-consumable and scalable approaches for delivering mental health prevention and wellness tools [16]. When mobile mental health apps are used to expand access to mental health education and prevention resources, youth may be more likely to initiate and engage in help-seeking behaviors, and families may report greater satisfaction with care and perceive services as more appropriate once they engage [17].

Accessibility to mobile apps is another important consideration [18, 19]. Use of cross-platform frameworks such as React Native (<https://reactnative.dev/>) can ensure that an app is easily available to a wide community of users while retaining a single codebase for agile development. Mobile apps can also be integrated effectively with school-based and primary care services. Schools and primary care clinics are critical providers of healthcare and mental health services[20], especially for under-resourced populations [21]. Pediatric primary care is widely recognized as an important setting for identifying and managing youth mental health needs given most youth make at least one medical visit annually [22]. Additionally, access to mental health supports has often been expanded through educational settings [23], including the adoption of whole-school, multi-tiered systems of support that provide school-wide preventive interventions and mental health services through school-based health clinics and programs [24].

Overview of the *Connected for Wellness Mobile App*

In an effort to address the barriers to care for under-resourced minoritized youth, a codesigned mobile application called, Connected for Wellness, was created with adolescents and their caregivers. The development of the Connected for Wellness mobile app, and its predecessor Connectd for Schools [25], is grounded in participatory informatics approaches. *Participatory*

informatics [26] is an approach to technology co-development that combines best practices from Community Partnered Participatory Research [27] and end user-centered participation in technology design [28]. This approach addresses community health priorities by including intended users as equitable partners throughout the design process. The co-development of the Connected for Wellness mobile app with youth and caregivers was led by the scientific team that includes diverse, multi-lingual research staff, child and adolescent psychiatrists, psychologists, technology development experts, and student researchers. The content includes engaging videos created by and representing diverse youth and caregivers in English and Spanish (Details on the co-development process and protocols are reported elsewhere). In its final form, *Connected for Wellness* has four key components: (1) mental health and wellness education, (2) self-assessment tools, (3) emotion regulation and coping strategies, and (4) site-specific and community resources. The home page features a “Get Help Now” button that directly connects the user to 911, for those who need immediate assistance. The community resources, searchable by zipcode, also feature helplines for specific needs such as domestic violence and the LGBTQ community. Given our priority to ensure the app is widely accessible, we also developed an accessible pdf document, which provides all app content in an accessible format for anyone who is using a screen reader or prefers reading along.

The app includes optional notifications, inspirational messages, and interactive components to promote ongoing engagement. In addition, the co-design process led to the development of an app designed to prioritize user confidentiality and safety. The app allows for anonymous use, does not include two-way communication, and avoids open-text response fields, minimizing the risk of exposing sensitive personal information and ensuring users can engage with the content privately and safely. We collaborated with both English- and Spanish-speaking communities to develop *Connected for Wellness* content in both languages. Table 1 outlines the app’s features and pathways and an image of the app’s user interface.

To enhance customization and interactivity for both youth and caregivers, the *Connected for*

Wellness mobile app uses collaborative filtering techniques [25] to intelligently recommend wellness skills and supportive resources to study participants. One approach, a content-based ("item-item") method, automatically suggests skills based on previously viewed skills and the metadata associated with them. For example, the app clusters content related to similar topics — such as sleep health or emotion regulation — by analyzing descriptions, titles, and other metadata, allowing it to recommend new wellness skills that are semantically similar to those the user has already explored.

Additionally, the app employs a peer-based ("user-user") approach, which identifies users with similar engagement patterns and recommends resources that those similar users have found helpful but the current user has not yet accessed. A second layer of intelligence involves user classification, where youth responses to in-app wellness screeners trigger tailored protocols and personalized content recommendations based on their identified needs. Specifically, *Connected for Wellness* includes the World Health Organization-Five Well-Being Index (WHO-5) [29], a short questionnaire that measures a person's well-being over the past two weeks and is suitable for children aged 9 and up. Users can access this questionnaire on their own and will be reminded to complete it monthly through a notification. Higher scores on the WHO-5 indicate better mental well-being, while lower scores indicate potential risk of mental health concerns. After responding to the wellbeing questions, users receive a wellbeing "score" categorized as low, moderate, or high. Based on their score, they are provided with personalized wellbeing activities and suggestions, which can be saved in the app's "Toolbox" section for easy access later. For example, a user who scores low on the WHO-5 Well-Being Index will receive recommendations for professional help-seeking, along with evidence-based strategies to support wellbeing, such as behavioral activation and emotion regulation techniques. Figure 1 illustrates how the WHO-5 normed scoring system guides the Toolbox recommendations and help-seeking suggestions provided to users based on their check-in results, i.e., scores on the WHO-5: Green for high wellbeing, Yellow for moderate wellbeing, and Orange for low wellbeing.

As outlined in the protocol, the primary objective of this study is to evaluate the effectiveness of the *Connected for Wellness* mobile app in enhancing youth engagement in mental health services when implemented in schools and primary care settings. The study aims to leverage the app's ability to deliver evidence-based, culturally and contextually relevant information to address key barriers to mental health care, including stigma, limited accessibility, and the need for youth autonomy and confidentiality.

Additionally, the study will explore how the app—co-designed with input from both youth and caregivers—enhances engagement with mental health support services and fosters help-seeking behaviors among youth and their families. Our main hypothesis is that the *Connected for Wellness* app will improve cascade-of-care outcomes compared to usual care. Specifically, we expect that youth at sites implementing the intervention will seek help more often, be screened more frequently, and be more likely to attend at least three mental health sessions if identified as needing services. If effective, the app has the potential to be a scalable tool for supporting youth mental health in community-based settings, such as schools and primary care clinics, and advancing public health approaches to connecting youth with care.

Methods

This study protocol was developed in response to the National Institutes of Health Common Fund's Transformative Research to Address Health Disparities and Advance Health Equity initiative and was funded in August 2023 by the National Institute of Mental Health and will be completed by June 2027. Here we present the protocol for implementation of the mobile app using a stepped-wedge design in 10 schools and 10 clinics.

Stepped-wedge Design

We use a stepped-wedge design, a type of cluster randomized trial that involves clusters (such as groups of clinics or schools) randomly assigned to different time points (i.e., waves) to begin

receiving the intervention. The rationale for the stepped-wedge design includes its effectiveness in testing healthcare delivery models and related outcomes for systems of care, particularly when randomization at the individual level is not feasible [31]. A stepped wedge design is also ideal when an intervention must be rolled out gradually due to logistical, financial, or ethical constraints, ensuring all groups eventually receive the intervention. It is particularly useful for evaluating complex, systemic, or behavioral interventions, when simultaneous initiation of the intervention is not feasible. Because the goal is to offer the intervention to all youth and caregivers at participating study sites, two clusters — consisting of five schools and five primary care clinics per wave — are randomly assigned to two different implementation waves. All clusters begin in the control condition, with the *Connected for Wellness* (CFW) mobile app intervention introduced to schools and clinics at predetermined time points. By the end of the trial, all clusters will have received the intervention, allowing for a stepped implementation across the sites. Stepped-wedge designs are becoming increasingly popular for testing health care delivery models [32] and are an innovative approach for evaluating the public health impact of mobile apps delivered as universal or tier 1 interventions in youth and family serving systems of care [33]. **Setting and Participants**

The study will include 13–22-year-old youth (to include the range of possible ages in high school) and will be implemented across 10 public high schools and 10 community-based primary care clinics in two regions in the western U.S. serving mostly Latino, Black, Asian, and immigrant students who live in under-resourced communities (80-90% minority majority populations). Caregivers will also be invited to use a version of the app for support of their child and their own wellbeing, however the study does not monitor caregiver outcomes. Study sites will include urban and rural regions of the Western US. The investigators will collaborate with one large school district and a network of primary care clinics that are part of a Federally Qualified Health Center system. The schools and primary care clinics have existing peer support leaders and/or family navigators, who will integrate the *Connected for Wellness* app into their usual care in supporting students and caregivers in

accessing mental health services and resources, encouraging help-seeking, and using the in-app wellness skills.

Existing peer-to-peer and navigator models

The high schools partnering in this study have an existing peer-to-peer model, in which high school students are trained in a *community health framework*, to deliver health and mental health education on topics relevant to their adolescent peers. This model targets health disparities by promoting wellness and reducing barriers to care within a culturally appropriate and community-centered approach [34, 35]. Trained students lead school-wide campaigns to promote awareness and education, with support from adult allies. Additionally, each school has wellness navigators, who will play a key role in integrating the mobile app into both school-wide educational efforts and individual support provided to students and caregivers. Primary care clinics participating in the study also have bilingual case managers and family navigators who will promote app use. These providers will be partnering with youth and families to help them access mental health information, develop wellness skills, and navigate linkages and referrals to care and community resources through the app.

Participant recruitment, consent and monitoring

For the study sites, 10 schools and 10 primary care clinics have been recruited to use the Connected for Wellness App site-wide, entering the study in two randomized cohorts. All youth and caregivers at each intervention site will be offered the mobile app. Each site will have a site ID code to access the app. All youth 13-22 years old at the site will be invited to participate in the study by using the mobile app. We will use an information kick-off event, other mental health and promotional events, website link, and videos that provide information about the study. Navigators, site champions and peer ambassadors will also promote the app and help with downloads for participants requesting help (e.g., caregivers who are less comfortable with technology). After all youth and/or caregivers download the app, they will choose their preferred language (English or

Spanish) and what role they are (student, caregiver).

As approved by the Institutional Review Board for this study, participants will then complete the in-app consent process, which presents study information in both video and text formats, along with comprehension questions to ensure participants understand the consent. Only those who answer the questions correctly and indicate their willingness to proceed will gain access to the app. To maximize anonymity — a priority identified during the co-development phase — users do not enter any personally identifying information (such as name, email, date of birth, or password). Investigators will regularly review anonymous app data and maintain an aggregated dashboard by site, tracking the number of Spanish- and English-speaking youth and caregivers, as well as gender, race/ethnicity, and other demographic characteristics of app users. The dashboard will also capture app use patterns. Using insights from enrollment and app usage data, the research team will work closely with school and primary care clinic study champions to actively promote study participation and engagement across sites.

Primary Outcomes: Cascade of Care Framework

The primary study outcomes are based on the cascade of care framework that focuses on population-level health needs and tracks individuals across relevant stages of a healthcare continuum [36, 37]. Originally developed by the Juvenile Justice Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS [38, 39]), the steps in the cascade of care are identification of a behavioral health need, referral to behavioral health care, initiation of services, and engagement in services (more than three visits). The cascade of care was adapted for youth in foster care [40]; this version was adapted for the current study. Data on each step of the cascade of care will be obtained from de-identified electronic medical records and administrative data at the individual youth level from each of the study sites. This approach which utilizes established databases will enable comparison of cascade of care outcomes post-implementation to data that was being collected during

pre-implementation years. As detailed in the analytic plan below, individual-level data will be aggregated to the site level to test the hypothesis that implementation of the *Connected for Wellness* mobile app intervention is associated with improvements in youth progression through the cascade of care, compared to the (pre-intervention) control condition. Improvements in the cascade of care is a public health defined outcome, as findings can reveal gaps in care, and evaluate the mobile app intervention effectiveness. At a population level, in schools or primary care, examining the cascade can inform how well an intervention improves youth access, engagement, and outcomes for a specific population, and whether the intervention effectively addresses their unique needs and disparities. Table 2 shows the operational definitions for the cascade of care outcome variables.

Data Analysis

Analyses will be conducted using the SAS statistical software, version 9.4. [41]. Preliminary analyses will include examination of descriptive statistics, distributions, and internal consistency reliability of scaled measures. The primary hypotheses are that the *Connected for Wellness* mobile app will improve all cascade outcomes relative to the usual care control condition. Specifically, we hypothesize that the mobile app will affect site level increases in the progression through the defined cascade of care, e.g., youth at sites with the *Connected for Wellness* mobile app intervention will engage in more help seeking, be screened more frequently, and once screened and identified as needing mental health services, youth will be more likely to attend at least three sessions as compared to the control conditions (prior to implementation of the mobile app intervention).

These hypotheses will be tested within a generalized linear mixed model (GLMM) framework implemented using SAS PROC GLIMMIX. These models accommodate variously distributed dependent variables, including dichotomous outcomes, such as those reflecting the cascade of care outcomes and account for correlations among measurements of the same participants and nesting of youth within sites. Models will employ a binomial distribution and a logit link function. All tests will be two-tailed with a significance level of $p = .05$. For dichotomous outcomes,

we will use a binomial distribution with a logit link function. The models will include county and intervention (vs. control) as fixed effects, with site and youth as random effects. Study month will be treated as a continuous variable. The primary focus will be on the intervention effect, and we will also examine intervention $\times$ time interactions. For time-to-event outcomes (e.g., days to service initiation), we will use Poisson models with a log link function. If overdispersion is detected, we will use a negative binomial model. The relative risk ratio for intervention will indicate whether the app reduces time to service matching and initiation. Finally, we will conduct follow-up analyses to explore differences based on sociodemographic factors.

DISCUSSION

Innovative aspects of our clinical trial include the use of a mobile app co-developed through participatory informatics, integrating youth and caregiver priorities into its design to ensure it addresses their specific needs. The app incorporates machine learning-driven, customizable features that offer personalized mental health resources, focusing not only on mental health but also on addressing social determinants of health, such as housing and education. By promoting local resources and providing tailored, real-time suggestions, the app helps bridge gaps in both mental health care and social services, ensuring that youth and caregivers can access the support they need in their everyday environments.

The growing body of evidence around mobile apps for mental health highlights their potential to improve access to care, engagement, and outcomes, particularly for underserved populations. While mobile health app technologies are increasingly recognized as scalable and accessible tools, their effectiveness is often dependent on personalization and relevance to the user's context. This is especially critical for minoritized youth, a group that has been underserved in many mental health interventions, and who face social, structural and cultural barriers to care. Few studies have focused on participatory, co-design approaches tailored for youth and caregivers, which is where our study stands apart. By integrating machine learning, the app can dynamically adjust to the needs of each

user, positioning it as an innovative solution in the field of mobile health.

Minoritized and low-income populations, who often face barriers to accessing traditional healthcare [2], demonstrate high levels of cell phone and mobile internet use [42]. This provides a unique opportunity for mobile apps to address healthcare disparities. Research has shown that emergency departments increasingly serve as safety nets for underserved populations, especially for low-acuity conditions that could be managed in primary care settings. Mobile app tools designed to connect individuals with timely medical advice could reduce ED utilization, improving overall healthcare access [43]. While the potential exists, understanding the feasibility of underserved populations to engage with mobile apps to improve mental health care is essential [44]. A recent review of 36 trials conducted among youth found that while mobile apps show promise in addressing issues like depression, anxiety, and substance use, the evidence remains uncertain or limited [45]. Most of the studies included in that review were small in scale, focused primarily on efficacy for youth already identified as at risk for depressive symptoms, and highlighted the need for larger trials to assess effectiveness and explore subgroup differences. Our study aims to address these gaps in the scientific literature by testing a comprehensive, participatory, and machine learning-driven mobile app designed to improve wellness practices as a form of prevention, while also improving service use outcomes for youth. The study places a strong emphasis on population health, embedding the intervention within school and primary care clinic settings.

Limitations

The stepped wedge design offers several advantages, including the ability to evaluate the intervention's effectiveness while ensuring that all students in a high school or primary care clinic have the opportunity to access the wellness and prevention components of the app, along with peer and family supports. It also allows for the assessment of temporal trends and the potential for learning or adaptation over time. However, this design also has limitations. The sequential implementation of the intervention may introduce biases, such as those arising from differences in

timing or external events affecting specific sites. Although the mobile app helps ensure fidelity by providing a standardized intervention across sites, the design still requires careful planning to manage logistical complexities and ensure consistency in implementation across diverse settings. Finally, variability in site readiness or capacity to implement the intervention, highlighting the need for robust support and monitoring of the study sites, including implementation influencing variables (e.g., study site size, pre-study mental health services capacity, existing peer-to-peer program) throughout the study.

Conclusions

If successful, this study will demonstrate how mobile apps can serve as universal mental health and prevention tools, complementing existing behavioral health resources and community strategies such as peer support and family navigation programs. The mobile app-supported public health approach offers an equitable, scalable solution that has the potential reach and effectiveness to significantly improve public health outcomes and could reduce mental health care stigma among traditionally underserved communities.

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Conflicts of Interest

None to report.

References

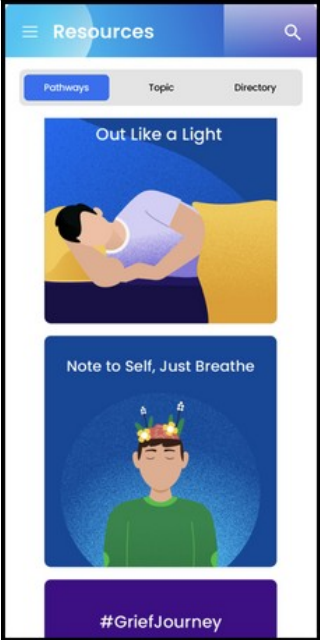
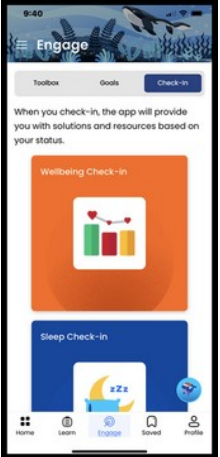
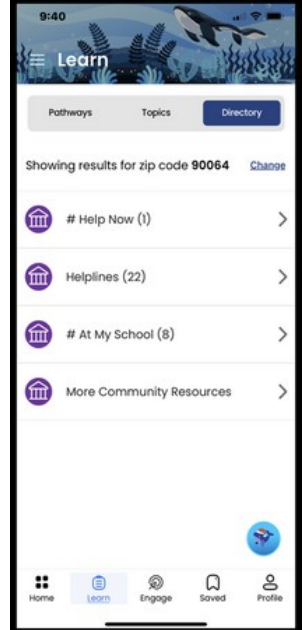
1. Cook, B.L., et al., *Trends in Racial-Ethnic Disparities in Access to Mental Health Care, 2004-2012*. Psychiatr Serv, 2017. **68**(1): p. 9-16.
2. Hoffmann, J.A., et al., *Disparities in Pediatric Mental and Behavioral Health Conditions*. Pediatrics, 2022. **150**(4).
3. Marrast, L., D.U. Himmelstein, and S. Woolhandler, *Racial and Ethnic Disparities in Mental Health Care for Children and Young Adults: A National Study*. Int J Health Serv, 2016. **46**(4): p. 810-24.
4. Satre, D.D., et al., *Opportunities to Integrate Mobile App-Based Interventions Into Mental Health and Substance Use Disorder Treatment Services in the Wake of COVID-19*. Am J Health Promot, 2021. **35**(8): p. 1178-1183.
5. Muñoz, R.F., *Harnessing Psychology and Technology to Contribute to Making Health Care a Universal Human Right*. Cognitive and Behavioral Practice, 2022. **29**(1): p. 4-14.
6. Loades, M.E., et al., *Rapid Systematic Review: The Impact of Social Isolation and Loneliness on the Mental Health of Children and Adolescents in the Context of COVID-19*. J Am Acad Child Adolesc Psychiatry, 2020. **59**(11): p. 1218-1239.e3.
7. Office of the Surgeon, G., *Publications and Reports of the Surgeon General, in Protecting Youth Mental Health: The U.S. Surgeon General's Advisory*. 2021, US Department of Health and Human Services: Washington (DC).
8. Liu, S.R., et al., *Experiences of COVID-19-related racism and impact on depression trajectories among racially/ethnically minoritized adolescents*. Journal of Adolescent Health, 2023. **72**(6): p. 885-891.
9. Kapke, T.L. and A.C. Gerdes, *Latino family participation in youth mental health services: Treatment retention, engagement, and response*. Clin Child Fam Psychol Rev, 2016. **19**(4): p. 329-351.
10. Lee, C., S.L. Ayers, and J.J. Kronenfeld, *The association between perceived provider discrimination, healthcare utilization and health status in racial and ethnic minorities*. Ethn Dis, 2009. **19**(3): p. 330-7.
11. Litke, S.G., et al., *Mobile technologies for supporting mental health in youths: Scoping review of effectiveness, limitations, and inclusivity*. JMIR Ment Health, 2023. **10**: p. e46949.
12. Liverpool, S., et al., *Engaging children and young people in digital mental health interventions: Systematic review of modes of delivery, facilitators, and barriers*. J Med Internet Res, 2020. **22**(6): p. e16317.
13. Bear, H.A., et al., *The acceptability, engagement, and feasibility of mental health apps for marginalized and underserved young people: Systematic review and qualitative study*. J Med Internet Res, 2024. **26**: p. e48964.
14. Bevan Jones, R., et al., *Practitioner review: Co-design of digital mental health technologies with children and young people*. Journal of Child Psychology and Psychiatry, 2020. **61**(8): p. 928-940.
15. Høgstad, H., et al., *Exploring Adolescents' Attitudes Toward Mental Health Apps: Concurrent Mixed Methods Study*. JMIR Form Res, 2024. **8**: p. e50222.
16. Lattie, E.G., et al., *Digital Mental Health Interventions for Depression, Anxiety, and Enhancement of Psychological Well-Being Among College Students: Systematic Review*. J Med Internet Res, 2019. **21**(7): p. e12869.
17. Hickie, I.B., et al., *Project Synergy: co-designing technology-enabled solutions for Australian mental health services reform*. Med J Aust, 2019. **211** Suppl 7: p. S3-s39.
18. Ouellet-Morin, I., M.P. Robitaille, and R.P. Juster, *Applications mobiles pour soutenir la santé mentale des jeunes : opportunités et défis [Mobile Applications to Promote Youth Mental Health: Opportunities and Challenges]*. Sante mentale au Quebec, 2021. **46**(1): p. 17-34.

19. Friis-Healy, E.A., G.A. Nagy, and S.H. Kollins, *It Is time to REACT: Opportunities for digital mental health apps to reduce mental health disparities in racially and ethnically minoritized groups*. JMIR Ment Health, 2021. **8**(1): p. e25456.
20. Burns, B.J., et al., *Children's mental health service use across service sectors*. Health Aff (Millwood), 1995. **14**(3): p. 147-59.
21. Farmer, E.M., et al., *Pathways into and through mental health services for children and adolescents*. Psychiatr Serv, 2003. **54**(1): p. 60-6.
22. Campo, J.V., et al., *Pediatric Behavioral Health in Primary Care: A Collaborative Approach*. Journal of the American Psychiatric Nurses Association, 2005. **11**(5): p. 276-282.
23. Ryst, E. and S.V. Joshi, *Collaboration with schools and school-based health centers*. Child Adolesc Psychiatr Clin N Am, 2021. **30**(4): p. 751-765.
24. Kataoka, S.H., et al., *Applying a Trauma Informed School Systems Approach: Examples from School Community-Academic Partnerships*. Ethn Dis, 2018. **28**(Suppl 2): p. 417-426.
25. Barish, G., et al., *Sensing school community needs: A co-designed, personalized mental health app for high school students, parents, and staff*, in *Adjunct Proceedings of the 2022 ACM International Joint Conference on Pervasive and Ubiquitous Computing and the 2022 ACM International Symposium on Wearable Computers*. 2023, Association for Computing Machinery: Cambridge, United Kingdom. p. 478–482.
26. Arevian, A.C., et al., *Participatory technology development to enhance community resilience*. Ethn Dis, 2018. **28**(Suppl 2): p. 493-502.
27. Chung, B., et al., *Using a community partnered participatory research approach to implement a randomized controlled trial: planning community partners in care*. J Health Care Poor Underserved, 2010. **21**(3): p. 780-95.
28. Lyon, A.R. and K. Koerner, *User-Centered Design for Psychosocial Intervention Development and Implementation*. Clin Psychol (New York), 2016. **23**(2): p. 180-200.
29. Topp, C.W., et al., *The WHO-5 Well-Being Index: a systematic review of the literature*. Psychother Psychosom, 2015. **84**(3): p. 167-76.
30. Heagerty, P.J., *PCORI Final Research Reports, in Developing Statistical Methods to Improve Stepped-Wedge Cluster Randomized Trials*. 2021, Patient-Centered Outcomes Research Institute (PCORI) Copyright © 2022. University of Washington. All Rights Reserved.: Washington (DC).
31. Hussey, M.A. and J.P. Hughes, *Design and analysis of stepped wedge cluster randomized trials*. Contemp Clin Trials, 2007. **28**(2): p. 182-91.
32. Dorsey, S., et al., *Advancing successful implementation of task-shifted mental health care in low-resource settings (BASIC): protocol for a stepped wedge cluster randomized trial*. BMC Psychiatry, 2020. **20**(1): p. 10.
33. Di Simplicio, M., et al., *Imaginator: A proof-of-concept feasibility trial of a brief imagery-based psychological intervention for young people who self-harm*. Suicide Life Threat Behav, 2020. **50**(3): p. 724-740.
34. Covert, H., et al., *Core competencies and a workforce framework for community health workers: A model for advancing the profession*. Am J Public Health, 2019. **109**(2): p. 320-327.
35. Brady, K.J.S., et al., *Barriers and facilitators to integrating behavioral health services and pediatric primary care*. Clinical Practice in Pediatric Psychology, 2020: p. No Pagination Specified-No Pagination Specified.
36. Iroh, P.A., H. Mayo, and A.E. Nijhawan, *The HIV care cascade before, during, and after incarceration: A systematic review and data Synthesis*. Am J Public Health, 2015. **105**(7): p. e5-16.
37. Mugavero, M.J., et al., *The state of engagement in HIV care in the United States: from cascade to continuum to control*. Clin Infect Dis, 2013. **57**(8): p. 1164-71.

38. Belenko, S., et al., *The Juvenile Justice Behavioral Health Services Cascade: A new framework for measuring unmet substance use treatment services needs among adolescent offenders*. J Subst Abuse Treat, 2017. **74**: p. 80-91.
39. Knight, D.K., et al., *Juvenile Justice-Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS): a cluster randomized trial targeting system-wide improvement in substance use services*. Implement Sci, 2016. **11**: p. 57.
40. Tolou-Shams, M., et al., *A family-based mental health navigator intervention for youth in the child welfare system: Protocol for a randomized controlled trial*. JMIR Res Protoc, 2023. **12**: p. e49999.
41. SAS Institute Inc., *SAS/STAT® 15.3 User's Guide*. 2023, Cary, NC: SAS Institute Inc.
42. Faverio, M. and O. Sidoti, *Teens, social media and technology 2024*. 2024, Pew Research Center.
43. van Veen, T., et al., *Potential of mobile health technology to reduce health disparities in underserved communities*. West J Emerg Med, 2019. **20**(5): p. 799-802.
44. Ramos, G., et al., *State of the science: Using digital mental health interventions to extend the impact of psychological services*. Behav Ther, 2024. **55**(6): p. 1364-1379.
45. Magwood, O., et al., *Mobile apps to reduce depressive symptoms and alcohol use in youth: A systematic review and meta-analysis: A systematic review*. Campbell Syst Rev, 2024. **20**(2): p. e1398.

Table 1. Features of the Connected for Wellness Mobile Application for Youth and Caregivers

Feature (English and Spanish)	Description	Examples
Pathways	Brief videos and quick tips on wellbeing topics	Getting Better Sleep Improving Communication Grief and Loss Social Connectedness Relaxation

		Managing Emotions Academic Stress Mental Health Help-Seeking
Self-Assessments 	Short questionnaires to gauge sleep and wellbeing (for youth and caregivers), and social determinants needs (for caregivers)	World Health Organization (WHO)-5 PROMIS sleep items Social Determinant of Health questions
Directory 	Site specific, local, and national resources with direct dial, map, and information about resources	Hotlines Helplines Clinic or school specific mental health and social resources located on-site Community resources (Findhelp)

Toolbox 	Over 500 wellbeing activities and suggestions that can be saved in “toolbox”	Brief suggestions based on wellbeing frameworks that include domains of physical, psychological, emotional, spiritual, relational, professional, and cultural wellbeing
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Table 2: Cascade of Care Operational Definitions

Table 2: Cascade of Care Model Based on Connected for Wellness Triage Outcomes		
Step	Rate	Operational Definition
a. Youth at site	(a)	Total number of youth enrolled at a high school campus or on patient panel at primary care clinic site
b. Need Identified	(b/a)	Subset (a) who have completed mental health and social determinants of health needs identification at school or primary care clinic
c. Matched to Service(s)	(c/b)	Subset of youth with need (b) who receive a referral
d. Initiated Services	(d/c)	Subset of those referred to services (c) who have started services (e.g., first treatment session)
e. Engaged in Services (e/d)	(e/d)	Subset of those who initiate services (e) who have ongoing sessions (3 or more visits)

Supplementary Files

Untitled.

URL: <http://asset.jmir.pub/assets/7aad25252d88e7ba69a065ae4873bbf.docx>

Existing Peer-Review Reports from Funding Agencies (for protocols/proposals only)s

NIH Peer review report for this funded study.

URL: <http://asset.jmir.pub/assets/36f3bf7953525cead82b29fd3736b353.pdf>