Review

Impact of Electronic Health Records on Information Practices in Mental Health Contexts: Scoping Review

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Abstract

Background: The adoption of electronic health records (EHRs) and electronic medical records (EMRs) has been slow in the mental health context, partly because of concerns regarding the collection of sensitive information, the standardization of mental health data, and the risk of negatively affecting therapeutic relationships. However, EHRs and EMRs are increasingly viewed as critical to improving information practices such as the documentation, use, and sharing of information and, more broadly, the quality of care provided.

Objective: This paper aims to undertake a scoping review to explore the impact of EHRs on information practices in mental health contexts and also explore how sensitive information, data standardization, and therapeutic relationships are managed when using EHRs in mental health contexts.

Methods: We considered a scoping review to be the most appropriate method for this review because of the relatively recent uptake of EHRs in mental health contexts. A comprehensive search of electronic databases was conducted with no date restrictions for articles that described the use of EHRs, EMRs, or associated systems in the mental health context. One of the authors reviewed all full texts, with 2 other authors each screening half of the full-text articles. The fourth author mediated the disagreements. Data regarding study characteristics were charted. A narrative and thematic synthesis approach was taken to analyze the included studies' results and address the research questions.

Results: The final review included 40 articles. The included studies were highly heterogeneous with a variety of study designs, objectives, and settings. Several themes and subthemes were identified that explored the impact of EHRs on information practices in the mental health context. EHRs improved the amount of information documented compared with paper. However, mental health–related information was regularly missing from EHRs, especially sensitive information. EHRs introduced more standardized and formalized documentation practices that raised issues because of the focus on narrative information in the mental health context. EHRs were found to disrupt information workflows in the mental health context, especially when they did not include appropriate templates or care plans. Usability issues also contributed to workflow concerns. Managing the documentation of sensitive information in EHRs was problematic; clinicians sometimes watered down sensitive information or chose to keep it in separate records. Concerningly, the included studies rarely involved service user perspectives. Furthermore, many studies provided limited information on the functionality or technical specifications of the EHR being used.

Conclusions: We identified several areas in which work is needed to ensure that EHRs benefit clinicians and service users in the mental health context. As EHRs are increasingly considered critical for modern health systems, health care decision-makers should consider how EHRs can better reflect the complexity and sensitivity of information practices and workflows in the mental health context.

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KEYWORDS

electronic health records; psychiatry; mental health; electronic medical records; health informatics; mental illness; scoping review; clinical decision support

Introduction

Background

Electronic health records (EHRs) are being adopted in many health systems to improve the collection, sharing, and use of health care information [1]. Such information practices play a critical role in providing safe and high-quality care [2,3]. EHRs promise more integrated and connected health services, which are recognized by the World Health Organization and many governments as essential for sustainable, effective health systems [4-6]. Owing to the complex array of services that support service users, the fragmentation of care and limited information sharing are common in the mental health context [7]. Limited information sharing among health care services affects the planning and provisioning of appropriate care, such as medication management and reconciliation [8,9]. It can also negatively affect service users' experience of mental health care, especially when it leads to them having to retell their stories multiple times [10]. However, information sharing also comes with risks for service users, such as the stigma associated with mental health conditions [11]. Thus, mental health information tends to be considered highly sensitive information, requiring extra protection [12].

Information is critical to modern health care, especially mental health care, and health records are vital tools for documenting, organizing, and using information [8,13]. When health care professionals provide care to service users, they undertake a range of information practices, including seeking, using, documenting, and sharing information [14]. Health records play a critical role in such practices. Coiera [15] outlined that a health record has many functions, including enabling communication among staff through the information in the record, providing a central source of information for care, acting as an informal workspace for capturing ideas, and being a historical archive that can inform future care. Mental health records are especially complex because many entries can be included in the record [16,17].

EHRs are a core health informatics tool for the improvement of health care quality, partly through improved information quality and accessibility [15]. EHRs are, in one sense, a digitized version of the health care record but are also much more in that they introduce new practices and workflows [18-21]. For example, EHRs have been found to affect how information is documented in clinical records by introducing structured data entry forms and disrupting the collection of narrative information [22-25]. Internationally, the uptake of EHRs in the mental health context has been much slower than in other health contexts [26-29]. A recent scoping review on the effective implementation of electronic medical records (EMRs) in mental health settings also identified limited research on this topic [30]. Apart from the barriers faced by all health settings in adopting EHRs, such as interoperability, time impacts, and workflow changes, there may be particular issues in the mental health context that require investigation [31].

Information sharing relies on a range of information behaviors and practices by clinicians and service users [32,33]. Information behavior has been used to capture the range of human behaviors related to seeking and using information [34]. In comparison, information practice considers how information behaviors are embedded and shaped by organizational contexts and interactions [34]. Østensen et al [35] defined information practice as "a socially constructed practice that determines how information is produced, organised, disseminated, distributed, reproduced and circulated in the community, and which specific types of information are legitimized."

Going forward, we purposively use the term *information practice* rather than the more widely used term *information behavior*. Adopting this language aligns with our understanding that social and organizational rules and norms shape how clinicians practice information sharing [36-40]. Using the concept of information practice allows us to reflect on how particular issues in the mental health context, such as sensitive information and stigma, influence information practices.

Mental health care involves various sensitive information practices, such as people sharing a range of sensitive and potentially stigmatizing information, from personal trauma to behavioral patterns [9,41]. This information can also be considered stigmatizing, both publicly and within health care settings. Stigma is a common theme across a number of studies exploring the experiences of service users in the mental health context [42-44]. For example, it has been found that people with diagnoses such as borderline personality disorder experience stigma from health professionals, which affects their care [45]. Health care professionals in the mental health context are also aware of the sensitivity of mental health information [9,46]. Several commentaries have raised concerns about how sensitive information is recorded in EHRs and its implications for privacy and security [47-50].

The documentation of mental health information is another information practice that is an issue in EHR use in the mental health context. Mental health services are more likely to rely on narrative information [51]. For example, Kobus et al [51] pointed out that although most medical conditions rely on quantitative measures, depression relies partly on reviewing narrative progress notes. However, one of the reasons for adopting an EHR is to standardize data collection through structured data fields [24]. The lack of standardized information formats in the mental health context is a potential barrier to EHR uptake [52,53]. There is also great diversity in how mental health information is documented and used across professions, which complicates the standardization of mental health information [54]. Although diagnostic codes are available for mental health conditions, it is not easy to establish a clear diagnosis and associated diagnostic codes in the mental health context [55-57].

A final issue that has been raised in the literature as a concern for the adoption of EHRs in mental health contexts is the impact it could have on the therapeutic relationship [58,59]. Therapeutic relationships are critical for providing mental health care [60,61]. Adding an EHR to clinical encounters, which may bring new information practices, has been raised in different care settings as a potential barrier to establishing and maintaining a therapeutic relationship [62]. Shank et al [63] found that mental health clinicians worried that EHRs would divert their attention from service users and negatively affect the therapeutic relationship.

Research on the use of EHRs in the mental health context is at a low stage of maturity, with a diverse array of studies responding to different contextual issues. Thus, a scoping review is necessary to understand the literature [64]. This scoping review aims to identify the impact of EHRs, implemented in the mental health context, on information practices. Furthermore, it aims to explore how, in the use of EHRs, sensitive information, data standardization, and impacts on the therapeutic relationship have been considered, if at all.

The review had the following objectives and research questions:

1. In mental health contexts, what impact do EHRs have on information practices, and how do these changes affect other aspects of care?
2. In mental health contexts, how have sensitive information, data standardization, and therapeutic relationships been managed when using EHRs?

A Note on Language

We chose to use the term *service user* to represent people accessing and using mental health services and chose not to use terms such as *client* as this suggests that people voluntarily use services, which is not always the case in mental health contexts. Terms such as *patient* can be considered as disempowering for people who access services. We acknowledge that the terminology in this space is not settled and that others may consider different terms more appropriate.

The title of this paper refers to the *mental health context*. We chose this term to capture the broad range of clinical and nonclinical services that people may access when experiencing mental health issues [65].

Throughout this paper, we have raised terms such as *mental health data* and *mental health information*. These terms are not clearly defined in the literature, and we will return to this issue in the *Discussion* section.

Methods

Overview

The scoping review is a method of synthesizing research and can support various methods, objectives, and study types [64,66,67]. Unlike systematic reviews, scoping reviews do not attempt an exhaustive review of all relevant studies but rather aim for a breadth of evidence. Owing to the relatively recent uptake of EHRs in mental health care, it is appropriate to conduct a scoping review of this emerging evidence to consider a broad definition of EHRs and a range of study types.

This scoping review was informed by the Arksey and O'Malley [67] framework for scoping reviews. We were also informed by the PRISMA-ScR (Preferred Reporting Item for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist and explanation [68]. However, some criteria were not relevant to our study because of the thematic synthesis approach we used to analyze the included studies. Our approach to this scoping review has been to explore the literature on EHRs and describe what it tells us about the impact of EHRs on information practices in the mental health context. Unlike some scoping reviews, we chose not to map the trends in the literature. As different jurisdictions are moving at different speeds in their adoption of EHRs, and due to the breadth of the topic, we did not view the mapping of trends as feasible or helpful in this specific review.

Inclusion and Exclusion Criteria

Overview

We included studies that have examined EHRs in the adult mental health context, either by being based in mental health settings or being used by or for people with a mental health diagnosis. Nonclinical services (eg, housing services) providing services to people with mental illness were also included in this review, in keeping with the definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [69].

We included studies that mentioned using EMRs, EHRs, or any associated terms such as health information systems. Häyrinen et al [70], in a review of the literature, found that there are many terms used to describe EHRs, with various functions, formats, users, settings, and purposes. We acknowledge that EHRs, EMRs, and other terms are different but interlinked systems. An EMR is generally considered to be a record of a person's health encounters in a specific health setting. In contrast, an EHR is usually a compilation of summary information from across EMRs in a region, country, or health system [71]. However, these definitions are not always made clear or defined in the literature, and thus, we did not adopt a specific definition in this paper. There is no one gold standard definition of an EHR or EMR, with peak health informatics organizations using the same definition for both terms [72]. Going forward, we have used the term EHR as an umbrella term to represent the information systems used to manage service users' health information by and for health services.

This review included any primary evidence that explored the use of EHRs in the mental health context published before April 2021. We excluded studies that focused on children's health care in acknowledgment that this field raises several unique issues, such as the involvement of parents, which is worthy of a specific review. We excluded studies during the full-text screening that were not relevant to EHRs, the mental health context, or information practices. Studies that focused on clinicians' perceptions of EHRs in general rather than the EHR that was implemented were also excluded. The case studies were evaluated on a case-by-case basis, depending on the level of detail provided. We excluded studies that described only the design and development of an EHR.

Several types of EHRs provide service users access to their health information, such as personal EHRs, patient portals, and initiatives such as OpenNotes. We excluded these from this review as they raise unique issues regarding how service users access and use their health information. We acknowledge that systems such as OpenNotes will have implications for our study questions. However, we consider these systems to be more thematically aligned with patient portals and personal EHRs, which would benefit from a separate review. Readers interested in this topic should read the recent scoping review by Zhang et al [73] on the use of patient portals in mental health settings.

Types of Studies, Information Sources, and Search Strategy

Embase, Scopus, and PsycINFO were searched using a combination of key terms, an example of which is provided in Textbox 1. The search strategy was developed iteratively alongside the identification of key terms in the literature and hand searching of reference lists. This search was initially undertaken in late 2018 and then updated in December 2020, with new papers continually identified until April 2021, when the final draft was completed. No date limitation was applied in the initial search as we wanted to identify all relevant health informatics literature, which ranged across several decades [74]. Papers not published in English were excluded. The first author (TCK) read a subset of articles from the initial search to develop further search terms, which were then applied across PubMed, CINAHL, SocINDEX, and Web of Science. We also searched research repositories: Google, Google Scholar, Grey Literature Report, TROVE, OPEN Grey, and Social Care Online.

Textbox 1. Example search strategy run on Embase.

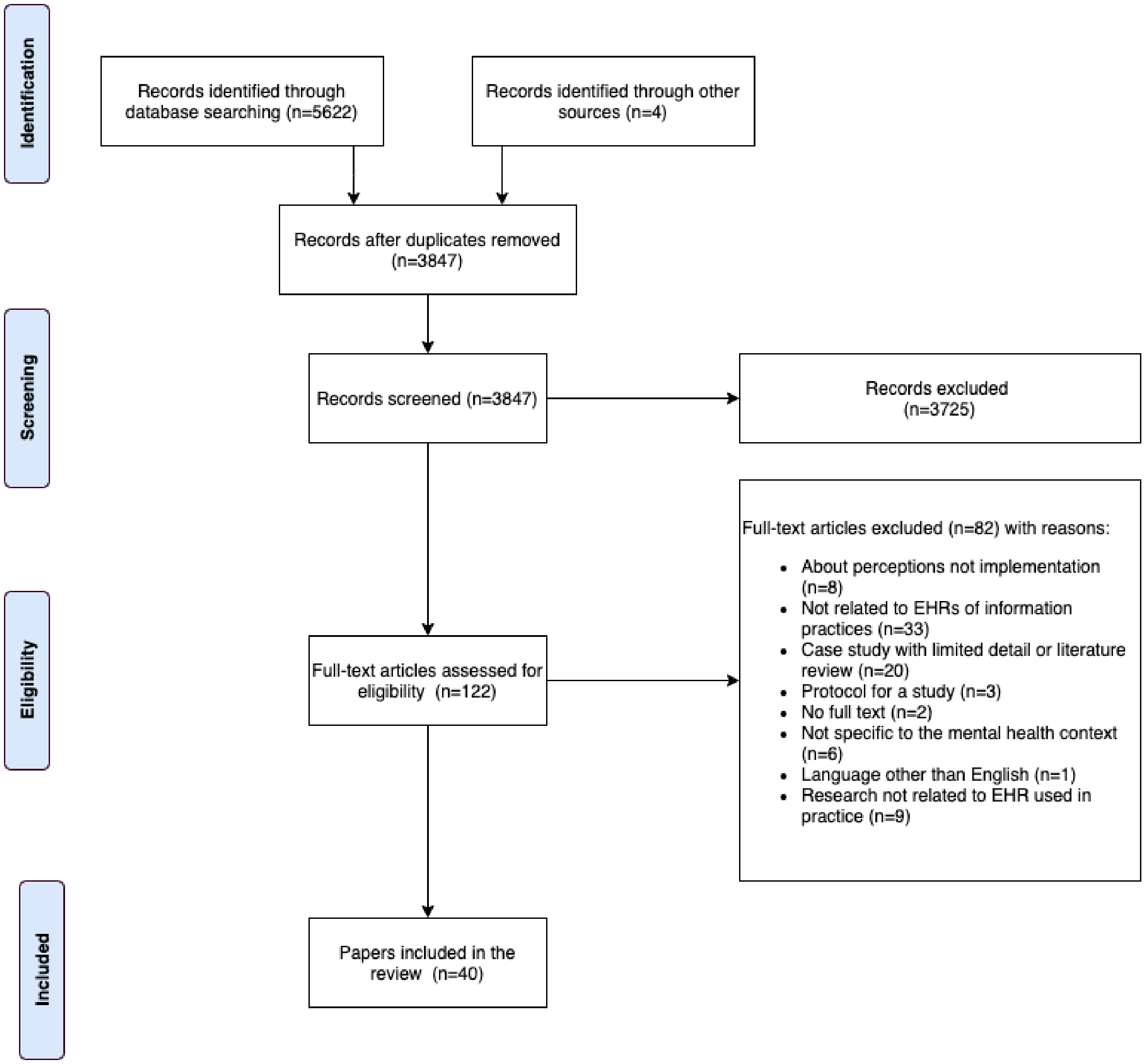
Search number and search term

1. Electronic health record/
2. Electronic medical record*
3. Electronic patient record*
4. EHR
5. EPR
6. Health information system
7. Health Information Exchange
8. Mental Disease
9. Mental Illness
10. Mental health care
11. Behavio?l health care
12. Mental health service*
13. 1 OR 2 OR 3 OR 4 OR 5 OR 6
14. 7 OR 8 OR 9 OR 10 OR 11
15. 12 AND 13

Study Selection

We identified 3847 nonduplicate articles. The titles and abstracts were screened against the inclusion criteria by TCK. Approximately 3.17% (122/3847) of articles were considered potentially relevant and were retrieved from the full text. TCK reviewed all 122 full-text articles, with SG and MP each independently reviewing half of the full-text articles. Differences were resolved by discussion and mediation by KG. Of the 122 articles reviewed in the full text, 82 (67.2%) were excluded, and 40 (32.8%) were included (Figure 1).

Figure 1. PRISMA (Preferred Reporting Item for Systematic Reviews and Meta-Analyses) diagram. EHR: electronic health record.



Charting the Results

To provide an overview of the study characteristics, we charted the objectives, study design, research method, study participants, country, study setting, EHR description, year of publication, and theories used in the included studies in a spreadsheet.

Owing to the breadth of the study types and objectives, covering a range of qualitative and quantitative methodologies, we followed Lakshman et al [75] in adopting both a textual narrative and thematic synthesis approach to analyzing the included studies. The textual analysis involved tabulating the study findings alongside their characteristics and conclusions. We adopted a thematic synthesis approach to analyze the qualitative papers included in this review. This method involved coding the text, developing descriptive themes, and generating analytical themes [76,77]. Following the method by Thomas and Harden [76], we initially developed descriptive themes by coding both direct participant quotes and researcher interpretations. We approached this by free-coding findings in an unstructured mind map, which we used to develop descriptive themes. Our research questions framed this coding process so that we coded anything related to information practices or the issues outlined in the *Introduction* section. We also considered the factors that shaped the way information was collected or shared in the presence of an EHR or the outcomes of changes in information practices. We intended for these descriptive themes to stay as close to the original findings as possible.

Next, we used our review questions to develop the analytical themes. We integrated the quantitative data we had extracted during the textual analysis during this process. Thomas and Harden [76] described this process as potentially controversial as it relies on the researcher’s judgment and insight. This iterative process aimed to capture the descriptive data developed in the initial analysis. The analysis identified 6 major themes describing the impact of EHRs on information practices in the mental health context. Of these themes, 5 had subthemes that explored specific topics relevant to the theme.

Study Characteristics

Overview

The studies included in this review were highly heterogeneous. This heterogeneity reflects one of the strengths of a scoping review in that it was inclusive of many study types. The following sections describe the characteristics of the included studies. Owing to the heterogeneity of study types and limited use of standardized terms, comparisons between studies were limited. Table 1 outlines the key study characteristics.

Table 1. Study characteristics (N=40).

Characteristics	Values, n (%)
Study design	
Quantitative	21 (53)
Qualitative	11 (28)
Mixed methods	8 (20)
Research method[a]	
Surveys	15 (38)
Interviews or focus groups	7 (18)
Chart reviews	5 (13)
Cross-sectional or secondary data use	5 (13)
Quality improvement	3 (8)
Ethnographic or observational	6 (15)
Descriptive case studies	1 (3)
Study sample	
Clinicians or health care professionals	26 (65)
Administrator, IT[b], or management	9 (23)
Service users	4 (10)
No participants (eg, record review)	13 (33)
Countries	
United States	27 (68)
United Kingdom	8 (20)
Canada	2 (5)
Other	3 (8)

[a] Some studies included multiple methods and thus were counted twice.

[b] IT: information technology.

Study Design and Research Method

A range of study designs and research methods were represented in the included studies. Most were quantitative (21/40, 53%) [78-98], with qualitative (11/40, 28%) [99-109] and mixed method studies (8/40, 20%) [110-117] also included. We categorized studies based on the broad category of research methods, including surveys (15/40, 38%) [78,80-85,89,92,95-97,110,113,116], qualitative interview/focus group studies (7/40, 18%) [100-104,110,111], chart review of specific EHRs (5/40, 13%) [85-87,114,117], cross-sectional analysis of EHR data or comparison with other secondary data (5/40, 13%) [90,91,93,95,98], quality improvement initiatives (3/40, 8%) [79,88,111], ethnographic or observational (6/40, 15%) [99,105-108,112], and descriptive case studies (1/40, 3%) [109].

The objectives of the included studies varied. We compared the objectives and research questions of the included studies and grouped them according to similar topic areas, as outlined in Table 2 (some studies had multiple objectives). We also included the publication years in Table 2 to showcase how certain topics were not confined to any specific period.

Table 2. Topics of included studies and related publication dates.

Topics of included studies	Publication years of included studies
Exploring the adoption of EHRs[a] in the mental health care context	2015 [116] and 2018 [94]
Evaluation of an EHR implementation	2009 [78], 2010 [107], 2011 [108], 2012 [99], 2017 [79], and 2018 [110]
Exploring the use of EHRs to provide mutual access to psychiatric records	2013 [80] and 2015 [81]
Exploring the impact of EHRs on the therapeutic relationship or person-centered care	2010 [82], 2011 [84] 2017 [101], 2019 [111], 2020 [83], and 2020 [85]
Exploring the use of EHRs in integrated or collaborative care contexts	2012 [113], 2012 [113], 2015 [112], 2015 [81], and 2018 [86]
Comparing documentation in EHRs with documentation in paper records	2007 [87], 2016 [88], and 2018 [114]
Exploring service users' experiences or satisfaction with care when an EHR is present	2018 [110] and 2020 [90]
Exploring the barriers, facilitators, workarounds, and usability of EHRs in the mental health context	2010 [103], 2011 [108], 2012 [113], 2012 [99], 2013 [109], 2014 [100], 2015 [116], 2015 [112], 2017 [115], 2017 [101], and 2021 [102]
Exploring the impact of EHRs on health care professionals' information practices and behavior	2004 [105], 2010 [106], and 2016 [104]
Exploring clinicians' satisfaction and perspectives of EHRs	2009 [89], 2015 [92], and 2018 [110]
Exploring information availability or documentation of specific diagnoses in EHRs	2013 [117], 2016 [91], 2016 [95], 2016 [96], 2019 [93] 2020 [98], and 2020 [97]

[a] EHR: electronic health record.

Participants

In most studies that involved direct data collection from human participants, such as EHR evaluations, the participants were health care professionals. The type of health care professional was not always reported or was generalized as *medical professionals*. Overall, primary health care clinicians, physicians, psychiatrists, psychologists, social workers, and nurses were well-represented across the studies. Some studies (9/40, 23%) included administrative, management, or information technology staff [78,97,99-103,108,112]. Only 10% (4/40) of studies involved service users [82,83,108,110]. Table 3 provides more details regarding the types of participants in the included studies.

Table 3. Participant roles reported in included studies (N=40).

Participant role	Included studies reporting this role, n (%)	Reference
Primary health care professional	4 (10)	[81,97,110,112]
Physician	6 (15)	[92,99,102,106,107,115]
Psychiatrist	7 (18)	[80,89,96,99-101,103]
Psychologist or psychology technicians	9 (23)	[78,89,92,96,103-105,111,116]
Behavioral health clinicians or mental health clinicians	5 (13)	[83,101,102,110,112]
Nurse, psychiatric nurse, or nurse practitioner	11 (28)	[78,84,89,96,99,100,102,103,105,114,115]
Social workers or social assistants	7 (18)	[92,96,100,103-105,111]
Pharmacists	3 (8)	[78,99,102]
Other allied health professionals	5 (13)	[99,100,105,107,111]
Other clinical or health care staff	12 (30)	[78,85,89,96,97,99-101,107,108,110,111]
Administrative staff	5 (13)	[78,102,103,107,112]
Information technology staff	4 (10)	[97,99,100,108]
Implementation teams	4 (10)	[99,100,107,108]
Service users	4 (10)	[82,83,108,110]
No participants (eg, secondary data and chart review)	13 (33)	[79,86-88,90,91,93-95,98,109,113,117]

Countries

Most studies took place in the United States (27/40, 68%) [80-83,85-90,92-98,101,102,104,106,110-113,115,116], followed by the United Kingdom (8/40, 20%) [78,84,99,100,105,107,108,117]. Canada (2/40, 5%) [79,114], France (1/40, 3%) [103], Brazil (1/40, 3%), and Ireland (1/40, 3%) [91] were also represented in the included studies. There were no clear differences in the approaches or methods across jurisdictions. The limited number of studies in countries outside the United States and the heterogeneity of study types limited any comparison.

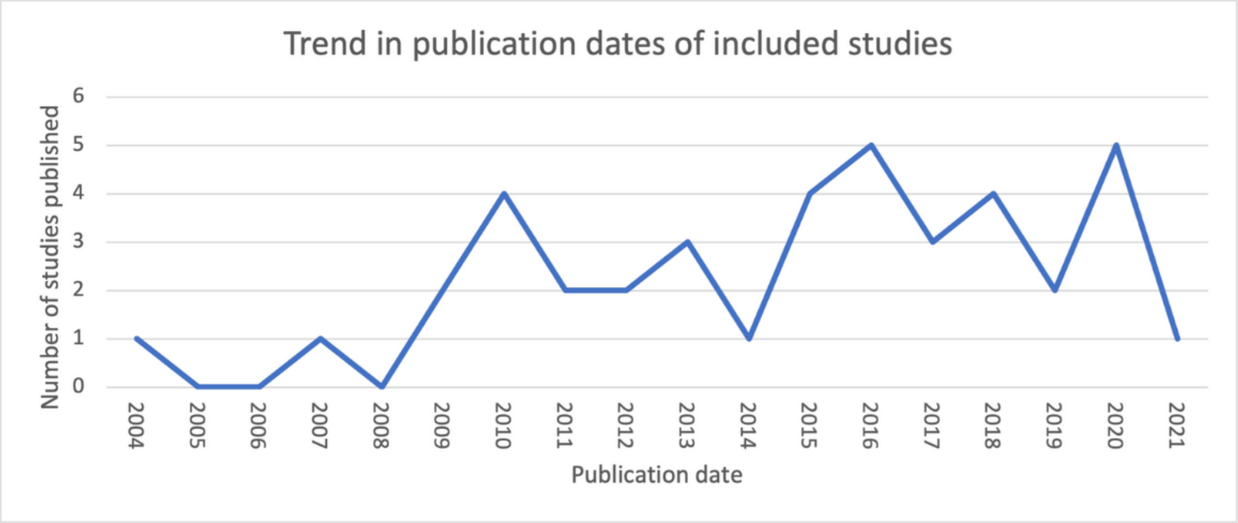
Settings

A variety of health care settings were represented in the included studies, ranging from psychiatric hospitals to community mental health settings. The type of setting was not reported to support easy comparison. These settings are outlined in Multimedia Appendix 1 [54,77-113,115,116] using terminology from the included studies.

Year of Publication

The included studies ranged in publication date from 2004 to 2021 (Figure 2). Although our search strategy had no date restrictions, the terminology used in the search may have shaped what studies were included. Older systems such as computerized patient records may not have been identified. This search strategy was deemed appropriate as these systems did not align with the more recent conceptualizations of what an EHR includes. In general, there has been an increase in the literature on this topic since 2004. Interestingly, many of the issues and topics identified in the *Results* section do not appear to be constrained to a certain period. We would expect to see advancements in EHR infrastructure being reflected in the themes and issues raised in the included studies. This lack of visible change may be because of the low reporting of EHR functions and technical features, limiting the opportunity to see major trends in how EHRs have advanced over time in the mental health context. Table 2 outlines the key topics and publication dates of the included studies.

Figure 2. Trend in publication year of the included studies.



EHR System Used

We noted the name of the EHR and whether it was custom built or off the shelf. We also assessed whether the EHR functions or technical details had been reported. We did not expect all the studies to report this information, such as studies drawing on the secondary analysis of data. We first identified studies that expected to report the details of the EHR in their methods sections, such as the evaluations of specific EHRs (28/40, 70%) [78,79,81-84,87-89,91,92,95,99-111,114,115,117]. Of these 28 studies, 16 (57%) either named the EHR or provided details as to whether it was custom built or off the shelf [78,79,83,84,89,95,99-102,105-108,110,117]. One of the studies pointed to other publications in which the details of the EHR were reported [103]. Of the studies that reported details of the EHRs used, we tried to establish whether they were off-the-shelf commercial EHRs or custom-built EHRs. Some papers did not provide these details, and we searched for further information on the web to categorize those EHRs. Of the 16 studies that reported on the EHR, 3 (19%) were custom built [89,106,117], 12 (75%) were off the shelf [78,79,83,84,95,99-102,107,108,110], and 1 (6%) was unclear [105]. The common off-the-shelf models were RiO [84,99,100,107,108] and EPIC [95,110]. Some studies outlined that commercial off-the-shelf EHRs have been adapted for the mental health context, such as through the addition of mental health–specific modules [102,110]. However, most studies did not clearly state whether and how off-the-shelf EHRs had been customized for the local context.

Of the 28 studies that we expected to report EHR details in their methods sections, only 7 (25%) discussed the functions of the EHR [79,81,84,89,103,105,110]. Sometimes, functions could be assumed from the results sections. No studies reported on the technical aspects of an EHR. Owing to the limited reporting of EHR types and functions, a comparison across studies was not feasible. The only theme that arose from these studies was that in the United Kingdom, many National Health System services used the same EHR (RiO), whereas, in the United States, there was more variety.

Several studies involved the collection of data on the type of EHRs that services were using, such as cross-sectional surveys of health services. We expected these studies to report details of the EHR in their results sections (8/40, 20%) [80,85,96,97,112,113,116]. Of these 8 studies, 3 (38%) reported on the names or types of EHR used by the included health services [97,112,116], and 2 (25%) reported some details of the functions [80,112], which were mainly related to those who could access the EHR. The included studies reported a variety of off-the-shelf and custom EHRs. For example, in the survey by Cellucci et al [116], they found that most psychology clinics used a commercial system, whereas a small number used custom-designed systems. Another example was the survey by Wu et al [97], which found 17 different off-the-shelf EHRs used by services in the US National Drug Abuse Treatment Clinical Trials Network. Multimedia Appendix 1 lists the EHRs reported in each study.

Theory

The included studies rarely referred to any underlying theory being used. Of the 40 studies, 2 (5%) of studies that reported using theories from the field of information behavior [104,105], 3 (8%) studies reported using sociotechnical theories [99,107,108], and 2 (5%) studies used the Technology Acceptance Model [110,116]. Approximately 3 (8%) of the 40 other studies also discussed the use of different theories [78,79,115].

Quality of the Studies

Scoping reviews do not incorporate an evaluation of the quality of the included studies, although some authors may consider it appropriate to do so [68]. This scoping review included a diversity of studies that no single evaluation method could appropriately address. A significant quality issue that we identified was the lack of detail regarding the EHRs, such as their functionality. The quality criteria for health informatics papers by Talmon et al [118] recommend studies that include information about the system in use.

Results

Overview

In the following sections, we report the findings of the textual narrative and thematic synthesis of the 40 included studies. The analysis led to the development of 6 main themes and several subthemes. The quotes that support the themes are provided in Multimedia Appendix 2 [79,81,86,88,98-100,104,105,107,110,111].

Supports Better Management of Most Information

This theme relates to how EHRs were found to support certain information practices, such as documentation and information accessibility. However, although EHRs show improvements over paper records, there are still issues with the completeness of documentation, especially of mental health information.

Documentation of Information

Several studies reported an improvement in the completeness of documentation in EHRs compared with paper records [78,87-89,102,113-115]. Electronic documentation also addressed issues of legibility that were common in paper records [88,89,99,108]. Improved documentation may partly be because of EHRs promoting accountability in documentation practice and prompting clinicians for certain information [87,105,114]. Approximately 2 (5%) of the 40 studies suggested a greater coupling of policy and practice guidelines within EHRs compared with paper records as the guidelines could be embedded in the EHR, such as through templates [79,105]. These templates provided less discretion regarding how information collection policies were followed. Although EHRs improved documentation compared with paper records, they still showed poor documentation of certain information [87,95]. Tsai and Bond [87] found that past psychotropic medications, prior hospitalizations, and clinical outcomes were regularly missing in EHRs. Bell et al [117], in scanning an EHR to identify drug- and alcohol-related issues, discovered that relevant information was more likely to be found in free-text progress notes, although structured forms were available. An interesting issue raised by participants in the study of EHR use in an integrated care trial by Cifuentes et al [112] was that new types of health care professionals could bring new types of data that the EHR was not designed to collect.

Some studies have found that EHRs create conditions that might negatively affect the documentation. Ser et al [100] found, in interviews with staff across 2 mental health hospitals, that long delays can occur between information collection and documentation in the EHR. Meredith [78] found, from a survey of community mental health teams, that both an EHR and paper record were used side by side, leading to some information not being documented in the EHR.

The benefits of improving documentation came with an increased time burden for clinicians [100,101,103,111,113]. This time burden was related to issues such as simple documentation tasks requiring multiple steps in the EHR [103]. Matthews [101] found that templates may speed up documentation but create challenges if clinicians need to navigate multiple screens and menus. Increased time spent documenting information in EHRs may lead to time savings when reviewing clinical notes in the future [81,110]. For example, Bhe et al [81] reported that 97% (28/29) of primary care physicians who had received access to psychiatric notes in the EMR reported increased efficiency in encounters with psychiatric service users.

Missing Mental Health Data

Several studies found that mental health information was regularly missing from EHRs, documented in the wrong place, or underdocumented in specific contexts [93,95-98,106]. For example, Gleeson et al [91] found that relying on diagnostic codes in an EHR would have missed 92.4% (110/119) of the mental health diagnoses. However, the information needed to make a diagnosis was available in other parts of the record. The same issue was found in the US Veterans Affairs EHR, where 40.9% (45/110) of people with a posttraumatic stress disorder diagnosis did not have it recorded [96]. Similarly, Madden et al [95] found that many psychiatric services for people with diagnoses of depression or bipolar disorder were missing from the EHR data when compared with health insurance claims. Gibson et al [104], in exploring how clinicians search for information in an EHR, found that when information is not present, clinicians may assume the opposite. For example, if the information on noncompliance with treatment is not present, clinicians may assume that the service user is compliant.

There are many reasons why mental health information may be missing in EHRs. Zhou et al [106] found that psychosocial information may be communicated verbally between clinical team members and not recorded in an EHR immediately, if at all. This practice may be because of psychosocial information being viewed as too subjective to be initially recorded in the EHR [106]. Wu et al [97] found that substance use disorders were not thoroughly captured in EHRs, partly because of the continued use of paper records for that specific part of the health service. Furthermore, in non–mental health services, mental health–related information collection may occur informally and may not be officially recorded in the EHR [106]. Madden et al [95] found that missing mental health data could result from service users seeking mental health care outside their regular health service. Missing information may also be because of the stigma, as discussed further in the following sections.

Access and Availability of Information

The use of EHRs appeared to improve legibility, timely access, and the availability of information [84,87,89,99,108,109,115]. These improvements allowed information to be found more easily when responding to concerns or issues [99,115]. The availability of information also benefited administrative staff, such as health information managers, who could easily look up mental health information [102]. Improved access to information was also viewed as contributing toward safer and higher quality care [99,102,116]. Boyer et al [103] reported that 74.8% (86/115) of health care professionals interviewed in a psychiatric hospital reported improved access to service user information with an EHR. However, not all information is available on EHRs [112]. Clinicians may have to go through a complex process of identifying what information they need and where they can access that information [104]. Clinicians may also struggle with navigating the EHR because of the amount of information it contains, which is an issue when EHRs do not include search functions [104,106].

Finally, information may be collected for several purposes. The availability of information for one purpose, such as providing care, may not necessarily mean availability for another purpose, such as reporting [100]. Larrison et al [94] found that for community mental health agencies, "capturing data to improve reporting capabilities" was a key motivation for implementing an EHR.

Creates New Structures That Shape Information Collection

This theme reflects the finding that the adoption of the EHRs introduced new structures that shape information collection. These structures standardize and formalize information collection and raise several issues, especially in the mental health context, where unstructured narrative information is used extensively.

Standardized Information

The issue of data standardization arose in several articles, where data fields in the EHR were not suitable for mental health information. Structured fields cannot easily capture the *gray* narrative information common in mental health contexts, and trying to fit data into structured fields can have implications for care [101]. Two common issues were restrictive templates that took away from the narrative format of mental health notes [101,113] and essential templates or data fields missing from the EHR [99,106,112]. Common information collection forms used for mental health care, such as care plans and mental health screening tools, were missing in several EHRs [101,109,113]. When forms were missing, individual clinicians had to decide how to record the information [106]. In some cases, clinicians created standalone tools, such as spreadsheets to collect data. However, this further fractured information in EHRs, unless work was undertaken to integrate the information [112]. EHR formats not being suitable for the mental health context also led to data being captured in other parts of the record, such as free-text boxes or laboratory value areas, which can affect future uses of the data [100,101,109,117]. In addition, the extensive use of free text can make EHRs challenging to navigate [109].

Some of the reasons why standardization did not suit the mental health context included the level of personalization needed in the mental health contexts [111] and that some mental health information is subjective and could be perceived in different ways by different health services [106]. The use of diagnostic codes in an EHR may also create extra work when service users do not clearly fit any one diagnostic code [99]. Specific models of care may also require greater flexibility and personalization of the information collected [111]. An example of this is found in a study on person-centered care planning by Stanhope and Matthews [85,111], who found that standard forms in the EHR were barriers to person-centered care.

Standardization is not necessarily a negative process, and Takian et al [99] found that the standardization of letters sent to people's general practitioners was viewed as beneficial. Clinicians have also recognized the benefits of data management tools to improve the searchability, visibility, and accessibility of information [103,108].

Standardization was also raised as a broader systems issue, where EHRs could not be tailored to specific organizations or settings. This issue was raised in a few studies that adopted commercial EHRs [101,110,111]. In a series of studies from the UK National Health Service (NHS), where uniform EHRs were being adopted, services wanted to tailor the standard solution to their unique needs and the changing priorities of their communities [99,100,107,108].

Informal Versus Formal Documentation

The 8% (2/40) of studies that explored the process that clinicians go through to document information found an element of informality in how mental health information was collected before a specific judgment was made and recorded in the EHR [105,106]. Hardstone et al [105] described how mental health clinicians used informal information practices to develop ideas before they were formalized in the health record. Paper records appeared to enable this informal documentation. In contrast, this provisionality enabled by paper records is limited by EHRs, where the information entered is viewed as a finalized account. Compared with a paper record, recording in an EHR had a greater sense of finality and permanence, which did not align with the informal discussion and sharing of assessments in integrated care settings [105]. Hardstone et al [105] outlined how EHRs may tightly embed rules around who can access records and when, which limits the flexibility to work on notes collaboratively. Zhou et al [106] found that EHRs did not have the functionality to capture provisional information.

Supports Information Sharing and Communication

This theme captures how EHRs supported the components of integrated care, including information sharing and communication among professionals.

Communication Among Service Providers

The specific functions of EHRs may support information sharing and communication among service providers. The functions of EHRs that improve communication include the ability to assign tasks or notes to other clinicians [104], the use of messaging systems [92,101], and shared care plans [112]. These functions that allow clinicians to share information about service users can support the tailoring of care, reduction of unnecessary assessment, and reduction in the number of times service users have to retell the theory story [101]. However, not all EHRs had these functions [112]. There is some evidence that EHRs can improve service users' experience of integrated care. Hu et al [90] found that EHR adoption was significantly associated with improved service user experience for "care transition" and "discharge information" in psychiatric hospitals. Jetelina et al [110] also found a significant improvement in service users' perceptions of integrated care after the implementation of a mental health–specific EHR. However, EHRs that support integrated care may have to be situated in a model of care [85].

Interoperability Between EHRs and Services

Interoperability was raised as an issue across several contexts in the included studies. Several papers acknowledged that integrated EHRs are not always linked with all relevant mental health services [99,100,107,115]. An issue raised in implementing a national EHR in the UK NHS [100,107] was drawing boundaries regarding what services and clinicians can access the EHR. Ser et al [100] outlined how some local community services' information systems were not integrated into the EHR, although these services played a significant role in providing mental health care. Robertson et al [107] also acknowledged that individuals may receive care from many services that are not always contained within a specific geographic region, which an EHR was designed to include. Furthermore, some EHRs lacked interoperability within and among health services [112]. Workarounds for the lack of interoperability identified by Cifuentes et al [112] included printing information from one EHR and scanning it into another EHR or duplicating documentation, which created delays and extra work.

Disrupts Information Management Workflows That Affect the Therapeutic Relationship

This theme explores how EHRs disrupt information practice workflows and raise concerns regarding therapeutic relationships.

Workflow Disruption

Nonalignment of EHRs with workflows was raised in several studies [84,100,103,108,116]. For example, 34.6% (9/26) of psychology training clinics represented in the study by Cellucci et al [116] raised "the difficulty of getting EMR to do what they wanted" as a barrier to implementation. Boyer et al [103] found that 73% (84/115) of interviewed health care professionals in a psychiatric hospital raised the issue of workflow in connection with reduced efficiency, specifically, the challenge of balancing service user care needs and using the EMR. Workflow misalignments led to less time for direct care, which was viewed as affecting the therapeutic relationship [87,100,103].

Sheikth et al [108], Takian et al [99], and Edwards et al [84], in examples of the RiO EHR from the UK NHS, outlined how mental health presentations were complex and varied and required long and detailed assessments. Participants raised that it would not be feasible to try and get people in a crisis setup near a computer so that they could input notes simultaneously [108]. This situation may lead to information having to be inputted later, which could have a broader impact on the operations of the hospital [108]. Participants in the study by Ser et al [100] outlined the challenge of balancing EHR use and supporting people in a crisis, which is common in the mental health context. In clinical therapy, Matthews [101] found that some specific psychological therapies that are more structured may be appropriate for EHR documentation, such as cognitive behavioral therapy.

Matthews [101] and Ser et al [100] found that the EHR interface and design were more medically orientated and designed for contexts in which service users could be treated and discharged and did not need ongoing care. They also found that EHRs missed key mental health functions such as treatment planning and mental health screening. Workarounds were developed to overcome these EHR issues; however, they could be time consuming and require extra work [101]. In comparison, participants in the study by Jung et al [102] who used an EHR specifically designed for mental health contexts commented that they appreciated the EHR being designed for their workflow, including multidisciplinary documentation functions. Administrative staff, including health information managers, valued the ability to make changes to the templates in the EHR where necessary [102]. Similar findings were apparent in the research by Jetelina et al [110], where a mental health–specific add-on to an EPIC brand of the EHR system was evaluated. The tool improved screening and had good acceptability by clinicians.

The Therapeutic Relationship

The findings regarding the impact of EHRs on therapeutic relationships were mixed. Stewart et al [82] found no significant impact on the therapeutic relationship in a survey of people accessing outpatient psychiatric services where EHRs were used. In interviewing health care professionals at a psychiatric hospital, Boyer et al [103] found that 47% (54/115) were concerned about the triangulation of the therapeutic relationship with the inclusion of an EMR. Interestingly, Matthews [83] found that clinicians rated EHRs as more disruptive to care than service users did. This difference could be explained by the finding that clinicians used a number of strategies to integrate EHR into a session to minimize disruption for service users [83]. Conversely, EHRs have been seen as strengthening the therapeutic relationship by opening the documentation process to service users for discussion and better tailoring care to service users' needs [101].

User Design, Computer Literacy, and the Learning Curve

Several studies have reported that EHRs' complex user interface designs contributed to workflow disruption [99,101,102,111,113,115]. This complexity was related to navigating multiple screens and menus and working with complex templates. Matthews [101] found that clinicians had to navigate various parts of the EHR (screens, menus, and tabs) to record information and that templates did not always follow a structured order that was relevant to the session's progress. Some of these issues may also be specific to the type of clinician. Jung et al [102] found that nurses who had the broadest range of access within the EHR experienced confusion because of the number of modules and the amount of information available to them. Issues with user interface design led to increased time burden for clinicians when documenting information in the EHR [100,101]. Alerts in the EHR were raised as issues in 8% (2/40) of the included studies [102,115]. Some studies reported frequent system crashes or technical glitches such as server issues, which severely affected EHR use and care provision [100,101,111,113]. Participants in the study by Takian et al [99] reported issues logging in and out of systems, especially as legacy systems were running alongside the EHR.

Low computer literacy was raised as a reason why clinicians may find the user interface of the EHR complex [100-102].

Clinicians may also have variable computer skills, specific skills such as typing, and general skills in using technology [88,100-102,107]. For some clinicians, the learning curve can be quite significant [110]. Sheikh et al [108] also found that EHRs may be designed for one type of clinician rather than for many health care professionals and administrative staff using the EHR. Several studies raised the importance of high-quality training to address usability issues [99,102,116].

Challenges Clinician’s Management of Sensitive Information

This theme relates to how EHRs raise issues regarding the management of sensitive information and how reducing access to certain parts of the EHR was a common approach to managing issues of sensitive information.

Sensitive Information

Several studies acknowledged that information collected in the mental health context could be particularly sensitive, such as information on traumatic personal events [80,89,93,97,103,113]. EHRs may lead to sensitive information collected by clinicians being more widely available to other clinicians, thus challenging the confidentiality between service users and clinicians [88,100,103]. Several studies explored how specific conditions, including posttraumatic stress disorder [96], substance use [97], mental health diagnoses among people living with HIV [98], and sexual trauma [93], were documented in EHRs. These topics were generally contextualized as sensitive, which affected their documentation. In studies that explored clinicians’ documentation practices, an approach clinicians took to sensitive information was generalizing it or *watering it down* [89,100]. Another approach was excluding this information from the EHR or keeping a *shadow record* or paper record for mental health information [89,96]. A finding from the study by Zhou et al [106] points to the subjectivity in clinicians’ decisions regarding when to document mental health information.

In some cases, concerns about sensitive information were related to a lack of clarity regarding the legal requirements regarding privacy and confidentiality [113] and the need for further training on these topics [116]. Psychiatric health care professionals in the study by Boyer et al [103] raised the issue of balancing the need to record sensitive information for the provision of care with the risk that it may be used to create a *profile* of service users for other purposes.

Mutual Access to Psychiatric Information

A common indirect way that sensitive information was raised as an issue was by sectioning mental health records in the EHR [80,86,89,97,113]. By sectioning the record, nonpsychiatric clinicians could not access mental health notes or could only access them with a password or if they were willing to *break the glass* and have their access recorded. For example, Bhe et al [81] reported that psychiatrists were given the option of creating two separate notes in the EHR, one accessible by other psychiatric clinicians and one for nonpsychiatric clinicians.

There is evidence that mutual access to psychiatric information supported the provision of mental health care. Bhe et al [81] found that primary care clinicians valued access to psychiatric information as it enabled them to provide care relevant to someone’s psychiatric needs, such as by considering the side effects of medication. Mutual access to mental health records may also support care coordination between mental health care and primary health care providers [86,113]. Colaiaco et al [86] found, in practices with a mutual EHR, that 46% (19/41) of reviewed service users’ primary care records showed some contact between primary health care and mental health care clinicians compared with only 11% (11/100) in practices with no mutual EHR. Furthermore, 100% (24/24) of the reviewed records in services with a mutual EHR had medication information updated across mental health and primary care providers’ records compared with 57% (31/54) in nonmutual EHR services.

This study does not seek to consider the clinical implications of EHRs. However, we would be remiss not to mention a finding from the study by Kozubal et al [80] that there was a significant relationship between increased accessibility (nonpsychiatric clinicians’ ability to access psychiatric records) and reduced readmission rates.

Raises Legal Concerns for Clinicians Regarding Their Information Responsibilities

The final theme regarding legal issues, particularly those related to privacy and mental health laws, appeared in far fewer studies than we had anticipated. There was little congruence among the references to legal concerns, with a variety of different concerns raised across the included studies. Reitz et al [113] found that the use of EHRs raised concerns about compliance with relevant information privacy laws. Ser et al [100] found that clinicians expressed concerns about whether EHRs aligned with their requirements under relevant mental health legislations. In the study by Jung et al [102], administrative staff, such as health information managers, outlined how the EHR supported compliance with relevant regulations by reducing the reporting burden. Clinical staff also reported wanting alerts relevant to their legal requirements when people were being treated under the relevant mental health laws [102]. Participants in the survey by Cellucci et al [116], representing psychology training clinics, identified the need for training on ethical issues, confidentiality, and security standards. Participants in the study by Matthews [101] outlined how state regulations and standards shaped the design and use of EHRs.

Discussion

Principal Findings

This scoping review aimed to explore how EHRs in the mental health context affected the information practices of health care professionals and how these changes affected other aspects of care. Issues relevant to the mental health context, such as the management of sensitive information, data standardization, and therapeutic relationships, were also explored. We found that EHRs can improve some information practices but need to be designed appropriately for specific workflows and information types in the mental health context. Beyond the design of EHRs, the redesign of health service workflows and clinician training may be needed to ensure that EHRs can be used effectively in the mental health context. Information collected in the mental health context is considered more sensitive than other types of clinical information. Greater guidance may be needed regarding how sensitive information is managed in EHRs to ensure that it is documented and used appropriately. In the following sections, we consider how the findings of this review link back to the broader literature on EHRs.

The documentation of clinical information is a critical information practice that informs current and future care [119-121]. The findings of this review point to improvements in the relative quantity of the information documented when using an EHR compared with paper records. However, information was still missing from EHRs, which may affect future care. Furthermore, a common issue for clinicians was the inflexibility of the fields in EHRs and the time required to input data. This issue may be partly because of the greater coupling of policy and process with tools for documentation, such as templates. Mamykina et al [121] has raised this focus on templates and structures in EHRs as an outcome of viewing clinical documentation as a *composition* activity. However, through a time-and-motion study, they found that clinical documentation was a synthesis activity involving clinicians accessing several informal and formal information sources that they synthesized into clinical documents. This reflects the finding from this review that informal documentation is a necessary precursor to formal documentation and contributes to the synthesis of the final documentation. Mamykina et al [121] argued that tools for composition, such as templates, differ from tools for synthesis, which should promote access to various information sources, such as informal notes that previously could be written and edited within the paper document. This finding may explain why certain information is missed in the structured documentation in EHRs, although it was available in other free-text sections.

The focus on the standardization and the formalization of documentation exposed a critical tension between current approaches to health informatics and contemporary mental health care. An objective of EHRs is the standardization of health information to allow for health information exchange and data analytics [122,123]. In comparison, mental health care involves the documentation of a large amount of narrative information, much of which resists standardization [16,51]. An increasing focus on recovery models of mental health care that prioritize service user–defined measures and outcomes may create further tensions with standardized data collection [124]. Concerns have also been raised about EHRs impeding clinicians' ability to understand a service user's entire story [125]. These issues were discussed in 1998 regarding the need for an informatics framework specific to mental health [126]. Future research and EHR design need to establish which standardized information is relevant for the mental health context and how best to present narrative information to capture service users' stories.

The issue of standardization found in this review is not unique to mental health in that paper records, in general, provide more opportunities than EHRs for recording narrative information [127]. The many benefits promised by EHRs in terms of decision support, streamlined reporting, and supporting research are premised on the need for structured data entry [24]. However, narrative information is highly valued by clinicians. This may reflect why clinicians used narrative information, even when structured fields were available. Our findings and research in other contexts indicate that clinicians prefer documentation methods that align with their workflows and allow them to record more details about clinical encounters [24,128-130]. Narrative information provides opportunities for clinicians to convey information such as uncertainty, unique aspects of cases, and nuances in the service user's appearance, which is not supported by structured documentation [24]. A potential solution to the tension between unstructured and structured documentation is the application of software to unstructured clinical notes that can extract relevant data into structured fields. For example, natural language processing could be applied to free-text narratives to fill structured EHR fields [24,127].

The management of sensitive information was raised as a key concern in the adoption of EHRs. The definitions of and overlap between sensitive information and mental health information are unclear. The National Committee on Vital and Health Statistics [131] outlined the complexity of defining mental health information in that it can be collected in a variety of clinical settings and may be scattered throughout a person's health record. Data about physical health, collected in mental health settings, may also be considered mental health information. However, there appears to be a subsection of mental health information classified as *sensitive* for several reasons, such as the stigma related to certain diagnoses. There is also a relationship between standardization and sensitive information, with some studies in this review finding that sensitive information may be captured in free-text notes but not in standardized fields. Perhaps free text provides more nuances in documenting this type of information. For example, Cairns et al [132], in a study of social workers using a shared record, found that they had concerns about reporting subjective information that other people could wrongly interpret. One of the potential issues with incorrect or vague documentation in the mental health context is that it could feed into incorrect risk assessments [133]. Risk assessments in mental health can have significant implications for people's health outcomes and their human rights if a risk assessment leads them to be involuntarily treated [133].

Shared decision-making has become a key approach for promoting autonomy in health care decision-making, especially in the mental health context [134]. This can be seen in the practices of clinicians inviting service users to be involved in deciding what information to document in their health record, which is known as collaborative documentation [91]. Inviting service users to participate in decisions about what information goes into their EHR and how to document sensitive information could help address concerns that clinicians might have about privacy or stigma. Pisciotta et al [135] found that clinicians and service users in mental health settings avoided discussing notes because they worried about each other's responses. Pisciotta et al [135] also found that service users want clinicians to be open to discussing what is written about them and have opportunities to collaborate in documenting information. Collaborative documentation may also address concerns about the therapeutic alliance if workflows are redesigned to accommodate EHRs and service users. Maniss and Pruit [136] outlined how collaborative documentation involves clinicians documenting service user information alongside service users and creating opportunities for their input and approval. However, as was found in the included studies, the current EHR design is not aligned with the complexity of some mental health contexts where service users may arrive in a crisis. Thus, the adoption of collaborative documentation may need to happen alongside other service changes to ensure that EHRs can be more easily integrated into service users' care.

The findings related to the relationship between information practices and therapeutic relationships require more research, especially from the service user perspective. It has been suggested that most information practices are invisible to service users [137] unless there are active efforts to make them visible. However, these practices and how they are shaped using EHRs will affect service users' experience of care through impacts on the therapeutic relationship or the time available for direct care. Much research has focused on service users' perspectives concerning the privacy and confidentiality of EHRs [12]; however, the actual impact on the experience of care has received limited attention. There is a growing body of evidence exploring the role of computers in clinical encounters, which may capture some of these experiences [138,139]. The impact of computers on the interaction between clinicians and service users can be shaped by factors such as the clinician's skill in using the computer and the way clinicians embed computers in their practice [140]. Findings from the study by Pearce et al [141] showed that computers had become part of a *triadic relationship* with clinicians and service users, which is not necessarily a negative outcome. Future work should explore how EHRs as sociotechnical systems affect the care provided and service users' experience of these impacts.

Comparison With Prior Work

Overview

There are several reviews related to different elements of EHRs, which generally support the findings of this review. In a systematic review of the impact of EHRs on documentation time, Baumann et al [23] found that EHRs were associated with increased documentation time for hospital staff. The interaction between service users and clinicians was also raised as potentially threatened by the use of EHRs [142]. Workflow issues were also identified by Gephart et al [143] in a systematic review of nurses' experiences of EHR. They found that EHRs created unexpected changes in the accepted workflows. Strudwick and Eyasu [144], in a review of the literature on EHRs used by nurses in mental health settings, also identified the unique nature of the mental health context. They found that nurses were conscious of the privacy and confidentiality risks posed by the ease of access enabled by EHRs. A recent scoping review on EMR implementations in mental health settings by Zurynski et al [30], which also included studies in children and adolescents and several review studies not specific to the mental health context, also found issues with documentation, workflows, and usability.

The issue of usability that was raised in this study has been confirmed by previous reviews exploring navigation in EHRs [143,145,146]. Roman et al [145] found that navigation between EHR screens was a regularly identified usability issue that could be addressed through shortcuts, dashboards, and integration of information into single screens. Training has also been found to enable the acceptance and use of EHRs [146,147]. McGinn et al [142], in a systematic review of barriers to and facilitators of EHR implementation, also found that usability could be both a barrier to and a facilitator of EHR use.

An increasing number of studies have identified new secondary uses for the data collected in EHRs [148]. These secondary uses include applications in psychiatric phenotyping [149] and methods for predicting suicidal behavior [150]. The potential impact of this secondary data use makes it increasingly urgent to address the issues raised in this study. Secondary data use in the mental health context requires further ethical consideration, especially as new data sources are being introduced into the health care system, such as data from wearables [151,152].

Relevance of Findings for EHR Designers

One of the key issues identified in this review was that EHRs were not appropriately designed for the mental health context. Thus, we will target our recommendations for those who design and develop EHRs.

Designers must ensure that they understand clinicians' information practices in the mental health context. There are examples of EHR usability frameworks such as the TURF (task, user, representation, and function) framework [153], which can guide EHR design. A key point raised by the TURF framework is the need to understand the complexity of a task independent of how it is implemented in a specific setting. Our review found that many EHRs were not designed to address the complexity of the mental health context. This issue could be because of designers and developers not understanding the essential elements of certain tasks and how these should be represented in the design of the EHR. Our review also found that many EHRs are missing data fields relevant to mental health and provide limited ways of managing narrative data. Thus, improving the customizability of EHR workflows may be useful. Alternatively, several preset workflows could be provided for different types of service users or clinical contexts. The study by Jetelina et al [110] provides an example in which an add-on for an EPIC EHR was developed containing specific features for the mental health context. Designers should also consider the computer literacy of their end users and what relevant training and support may be needed.

The time burden experienced by clinicians when documenting information in EHRs raises questions about the systems' user experience design. This time burden is not just an issue in the mental health context, with O'Brien et al [154] describing the broader issue as *death by data entry*. This is a critical issue for clinicians and is associated with increased odds of burnout [155,156]. This could be addressed in several ways, including through research, policy initiatives, and design methods [157]. Our findings suggest that further research is needed for workflows in the mental health context and how EHR functions can support rather than disrupt these workflows. Addressing this issue should also lead to greater end user involvement in designing, developing, and implementing EHRs in the mental health context [158]. Improving clinician training may also support the use of EHRs [99,100].

Relevance of Findings for Clinicians

A key issue found in this review was the poor documentation of mental health information in EHRs. Missing information is detrimental to both the care of service users and clinicians' work. It appears that there is a perception among clinicians that mental health information, being particularly sensitive, should be documented differently from other information. We would advise clinicians to consider approaches such as collaborative documentation in which service users are involved in discussions about what to document. If there is doubt about how to word certain sensitive information, clinicians should ask the service user and consider the implications for future clinical encounters and the service user's experience if certain information is missing or misinterpreted.

Relevance of Findings for Health Service Managers and Health Policy Makers

From this initial evidence on EHRs in the mental health context, it would be advisable for health service managers to scope their options when adopting an EHR. Services should start by identifying their information and workflow needs before choosing an EHR. Some EHRs designed specifically for the mental health context are more appropriate than generic EHRs. Otherwise, specific add-ons that meet the workflow and information needs of the mental health context may be considered. Furthermore, well-executed training is necessary to ensure that clinicians have appropriate computer skills to manage the complex user interfaces that some EHRs present.

We would advise policy makers to support the adoption of EHRs only when they are designed for local contexts. In Australia, the Victorian Royal Commission into Mental Health Services has recently recommended that information systems should be used to improve care in the mental health context [159]. We would advise that further research is needed to identify the mechanisms by which EHRs will lead to the assumed outcomes and any barriers or structural issues to achieving these assumed outcomes.

Relevance of Findings for Service Users

It was concerning that there was minimal involvement of service users in the included studies. The issues identified in this review will have implications for service users. These impacts may be related to disrupted workflows or sensitive information being recorded incorrectly. Many service user groups are taking great interest in the digitization of the health system, and we would encourage them to continue this involvement, especially with a focus on EHR development.

Relevance of Findings for Future Research

Future researchers should report on the types and functions of the EHRs they are studying. This would enable greater comparison between contexts. Adopting a standard approach to describing EHRs such as the Health Care Information and Management Systems Society's [160] EMR Adoption Model may support comparison across studies. Furthermore, more details about the setting of the research should be provided. Health information technology is a global business, and companies providing EHRs to the United States also provide them to other countries. Providing more details about the setting of implementation and the type of EHR would support evidence synthesis that other jurisdictions can also rely on.

Future research should also include service user perspectives on EHRs and information practices. Researchers should consider adopting co-design or participatory methods to involve service users in research about EHRs. It would also be advisable to involve peer workers within health services in the design of EHRs as they may see how these EHRs have been used in practice. Researchers should also involve more health information managers and other administrative staff. These stakeholders play a critical role in supporting the correct management of information in health care settings.

The field of research on EHRs in the mental health context is still at a low stage of maturity, and this, in part, reflects the maturity of EHR use in the mental health context. Future research should include high-quality evaluations of EHRs in the mental health context for both implementation and sustained use. This research will pave the way for systematic reviews that can provide insights into how EHRs affect processes and clinical outcomes in the mental health context. We would also recommend further studies on the usability of EHRs or that usability analysis be included in other study designs.

Notably, we could not conduct a temporal analysis of the included papers. Recent decades have seen considerable advancements in the fields of health informatics and digital health [161]. It would make sense that these advances should be reflected in the included papers. We might expect to see improvements in interoperability because of the increasing adoption of solutions such as the Fast Health care Interoperability Standard [162]. We may also expect to see improvements in the documentation of standard information using clinical terminologies such as the Systematized Nomenclature of Medicine [163]. However, these advances were not discussed in the included papers. We can speculate why this was the case. It might be that these innovations have not penetrated the mental health context or affected the issues we have identified. However, what is needed in future research is a greater focus on the technical aspects of digital health research. Future studies should aim to report the technical aspects of EHRs in practice to enable greater visibility of how EHR innovations penetrate real-world applications.

Finally, a further piece of research that should be considered is how digital health or information system theory can accommodate the findings of this review and others related to the use of EHRs. A few of the included studies drew upon the theory in their work; however, more work could be conducted to extend this work. We have reflected that many of our findings could be considered using an *Activity Theory* lens, and we would welcome discussions and collaborations to further this thinking.

Limitations

This scoping review is limited, in part, because of the nature of the field. The combination of no standard EHR definition and poor reporting of the systems used in the included studies has made it difficult to assess how specific themes related to specific types of EHRs. This review examines information practices, which is one of the many potential research topics that could be addressed in this space. Other studies should examine clinical outcomes. We expected to find more studies reporting on legal and ethical concerns, and in hindsight, a more tailored search may have been needed. There was limited information on the technical aspects (such as interoperability standards) of the EHRs used in the included studies. This limited information affected our ability to comment on whether the technical elements of the EHR contributed to our findings. The United States' focus of the included studies also limits the applicability of the findings to other jurisdictions, especially those related to health system structure and culture.

Conclusions

EHRs in the mental health contexts have been slow to materialize. This review found that EHRs in the mental health context affect clinicians' information practices, which have implications for how care is provided. The core of mental health services is the therapeutic relationship, which requires a unique workflow that is currently not supported by many EHRs. In addition, because of the narrative nature of mental health care, the standardized data underpinning many EHRs may not align with the information needs and practices of the mental health context. Finally, although health information is recognized as personal information, mental health information is seen as especially sensitive for several reasons. This understanding of mental health information may lead to underreporting, generalizing, or watering down certain details when documenting in EHRs. EHRs need the capacity to support information sharing in a nuanced way to manage sensitivity and stigma in the mental health context. Future research should involve service users to explore how the impact of EHRs on information practices also affects their experience of care.

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Authors' Contributions

TCK performed the conceptualization, writing of the original draft, and investigation of this paper. SG, MP, and KG each reviewed, edited, and provided supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Included studies.
[DOCX File , 28 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Quotes to support themes.
[DOCX File , 23 KB-Multimedia Appendix 2]

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Abbreviations

EHR: electronic health record
EMR: electronic medical record
NHS: National Health Service
PRISMA-ScR: Preferred Reporting Item for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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Corrigenda and Addenda

Correction: Tracking Healthy People 2020 Internet, Broadband, and Mobile Device Access Goals: An Update Using Data From the Health Information National Trends Survey

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In “Tracking Healthy People 2020 Internet, Broadband, and Mobile Device Access Goals: An Update Using Data From the Health Information National Trends Survey” (J Med Internet Res 2019;21(6):e13300) the authors made the following updates.

The authors were notified of data errors in two of the Health Information National Trends Survey (HINTS) cycle datasets (HINTS 4, Cycle 3 and HINTS 4, Cycle 4); the errors were in the weights provided for use in the analysis of these data [1].

These weights primarily affected logistic regression analyses, reported in Table 2 of the originally published article. This previous version of Table 2 is in Multimedia Appendix 1. Following the HINTS error notice [1], the authors reran the logistic regression analyses. The corrected version of the article includes the following updated Table 2.

In rerunning this analysis, only one difference was found that resulted in changes in the conclusion. Namely, geography is significant, with those in rural settings having significantly lower odds of having internet access via a mobile phone compared to their urban counterparts (OR = 0.80; 95% CI: 0.65-0.98; *P*=.033). This finding was not reported as significant in the original analysis, due to the above-mentioned error in the HINTS data sets [1]. All other conclusions remain consistent with those reported in the original publication.

In the section “Internet Access via Cellular Network” in the *Results*, the first sentence in the second paragraph originally read as follows:

> *Most of the sociodemographic variables within our multivariable model were statistically significant after adjusting for survey year, save for geography (Table 2).*

It has been corrected as follows:

> *Most of the sociodemographic variables within our multivariable model were statistically significant after adjusting for survey year (Table 2).*

Table 2. Weighted multivariate logistic regression model of predictors of having internet access via mobile phone among those who reported having internet access. Data from the National Cancer Institute's Health Information National Trends Survey (HINTS) administrations between 2008 and 2017 (n=14,794).

Variable	Predictors of internet access via cell phone				
	Odds ratio (95% CI)	Beta coefficient	SE beta	Adjusted Wald F	*P* value
Sex				1.32	.252
Female	Ref[a]	Ref	Ref		
Male	1.08 (0.95, 1.22)	0.7	0.06		
Age				166.15	<.001
18-34	Ref	Ref	Ref		
35-49	0.43 (0.36-0.51)	–0.84	0.09		
50-64	0.20 (0.17-0.24)	–1.61	0.10		
65-74	0.08 (0.06-0.10)	–2.52	0.11		
>75	0.04 (0.03-0.05)	–3.24	0.16		
Race and ethnicity				4.07	.008
Non-Hispanic White	Ref	Ref	Ref		
Hispanic	1.25 (1.00-1.56)	0.23	0.11		
Non-Hispanic Black	1.39 (1.09-1.77)	0.33	0.12		
Non-Hispanic Other	0.83 (0.63-1.10)	–0.18	0.14		
Education				5.26	.002
Less than high school	Ref	Ref	Ref		
High school graduate	1.03 (0.65-1.64)	0.03	0.24		
Some college	1.42 (0.89-2.27)	0.35	0.24		
College graduate	1.47 (0.93-2.31)	0.38	0.23		
Income (US $)				14.06	<.001
<$20,000	Ref	Ref	Ref		
$20,000 to <$35,000	0.98 (0.73-1.30)	–0.02	0.15		
$35,000 to <$50,000	1.07 (0.83-1.39)	0.07	0.13		
$50,000 to <$75,000	1.33 (1.04-1.70)	0.28	0.13		
$75,000 +	1.92 (1.50-2.46)	0.65	0.12		
Geography				4.60	.033
Urban	Ref	Ref	Ref		
Rural	0.80 (0.65-0.98)	–0.23	0.11		
HINTS [b] Survey Year				126.77	<.001
HINTS 3 (2008)	Ref	Ref	Ref		
HINTS 4 Cycle 1 (2011)	17.86 (13.17-24.21)	2.88	0.15		
HINTS 4 Cycle 2 (2012)	21.59 (16.06-29.02)	3.07	0.15		
HINTS 4 Cycle 3 (2013)	29.45 (21.32-40.69)	3.38	0.16		
HINTS 4 Cycle 4 (2014)	30.45 (22.24-41.69)	3.42	0.16		
HINTS 5 Cycle 1 (2017)	51.31 (37.54-70.11)	3.94	0.16		

[a] Ref: reference group.

[b] HINTS: Health Information National Trends Survey.

In addition, the corresponding author's email address has been changed from *greenberg.alexandra@mayo.edu* to *worisek.alexandra@gmail.com*, as the author is no longer affiliated with Mayo Clinic College of Medicine and Science.

The correction will appear in the online version of the paper on the JMIR Publications website on May 26, 2022 together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Multimedia Appendix 1

Originally published Table 2.
[PNG File , 731 KB-Multimedia Appendix 1]

Reference

1. HINTS Data Errors, Remediation, and Recommendations. Health Information National Trends Survev. URL: https://hints.cancer.gov/data/data-remediation.aspx [accessed 2022-05-19]

Abbreviations

HINTS: Health Information National Trends Survey

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Commentary

Through the Narrative Looking Glass: Commentary on “Impact of Electronic Health Records on Information Practices in Mental Health Contexts: Scoping Review”

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Abstract

The authors of “Impact of Electronic Health Records on Information Practices in Mental Health Contexts: Scoping Review” have effectively brought to our attention the failure of the electronic health record (EHR) to represent the human context. Because mental health or behavioral disorders (and functional status in general) emerge from an interaction between the individual’s characteristics and the social context, it is essentially a failure to represent the human context. The assessment and treatment of these disorders must reflect how the person lives, their degree of social connectedness, their personal motivation, and their cultural background. This type of information is best communicated both through narrative and in collaboration with other providers and the patient—largely because human social memory is organized around situation models and natural episodes. Neither functionality is currently available in most EHRs. Narrative communication is effective for several reasons: (1) it supports the communication of goals between providers; (2) it allows the author to express their belief in others’ perspectives (theory of mind), for example, those who will be reading these notes; and (3) it supports the incorporation of the patient’s personal perspective. The failure of the EHR to support mental health information data and information practices is, therefore, essentially a failure to support the basic communication functions necessary for the narrative. The authors have rightly noted the problems of the EHR in this domain, but perhaps they did not completely link the problems to the lack of functionality to support narrative communication. Suggestions for adding design elements are discussed.

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KEYWORDS

electronic health records; psychiatry; mental health; electronic medical records; health informatics; mental illness; scoping review; clinical decision support

Introduction

Through their scoping review of mental health data and the electronic health record (EHR), the authors of “Impact of Electronic Health Records on Information Practices in Mental Health Contexts: Scoping Review” have brought to center stage the failure of the EHR to represent the human context [1]. Mental health or behavioral disorders (and functional status in general) emerge from an *interaction* between the individual’s characteristics and the social context. As a result, the assessment and treatment of these disorders must reflect how the person lives, their degree of social connectedness, their personal motivation, and their cultural background—in other words: the human context. This failure of the EHR to support both information data (eg, missing or “fuzzy” data) and information practices (processes) for mental health information is a feature, not a bug. Specifically, EHRs have systematically avoided supporting text data—partially because electronic text is seen as hard to use [2] and due to the belief that structured data is more accurate. However, it is not just that providers *prefer* to tell the patient’s story in narrative rather than structured data forms [3] or that mental health data is “soft” data, it is that it is much too difficult to get a sense or gist of the patient’s situation through structured data and is much less cognitively efficient. In other words, accuracy is in the eye of the beholder. Some studies have noted the narrative is more accurate for mental health data, even if different text is used as descriptors [4]. One reason for the power of the narrative is that memory is organized around situation models and episodic mental representations, which are best communicated in story form [5]. Humans can grasp a situation much more rapidly through a story than through a list of facts [5]. Putting together "pieces" of data to get a gist of the patient's situation is significant work, whereas distilled information has better comprehension and is associated with better decision-making [6]. Narrative communication is effective for several reasons: (1) it supports the communication of goals between providers; (2) it allows for the author to express their belief in others' perspectives (theory of mind), for example, those who will be reading these notes; and (3) it supports the incorporation of the patient's personal perspective.

Goals

Documenting and tracking clinical goals is at the heart of care processes and communication in general [7]. The clinical goals for mental health patients almost always involve some aspect of context (which, in turn, requires specific descriptions of that context). The question "is the therapeutic treatment working?" requires data about the patient's work situation, personal relationships, or the patient's motivation [8].

Communication

Communicating mental health information to other providers is complex because people of many different roles care for these patients compared to patients with other disorders. Documentation must then be "tailored" to the audience and to the perspectives of differing roles (theory of mind), which requires significant amounts of working memory [9].

Patient Preferences

The patient's preferences are often idiosyncratic, embedded in the social context, and specific to location and time. The EHR is a limited representation of patient preference data. A story about the patient's wishes is generally the most effective way of communicating preferences and planning care [10].

Conclusion

The failure of the EHR to support mental health information data and information practices is, therefore, really a failure to support the basic communication functions necessary for the narrative. The authors have rightly noted the problems of the EHR in this domain, but perhaps they did not completely link the problems to the lack of functionality to support narrative communication. Links to the clinical goals of other clinicians, a specific location for the patient's story, temporal links to clinical episodes, and the ability to annotate the clinical notes of others in order to understand one's impressions would help communicate the patient's story. Improving the use of natural language processing and building ontologies of context would also help. Additionally, addressing these functions would also address several of the issues raised in the review, specifically, missing data, sensitive data, and collaborative decision-making information. Future work in the arena of EHRs could create tools and spaces for narrative, patient preferences, collaborative discourse, and shared collaborative documentation [11].

Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health record

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Original Paper

Online Video Teletherapy Treatment of Obsessive-Compulsive Disorder Using Exposure and Response Prevention: Clinical Outcomes From a Retrospective Longitudinal Observational Study

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Abstract

Background: Exposure and response prevention, a type of cognitive-behavioral therapy, is an effective first-line treatment for obsessive-compulsive disorder (OCD). Despite extensive evidence of the efficacy of exposure and response prevention (ERP) from clinical studies and in real-world samples, it is still underused as a treatment. This is likely due to the limits to access to care that include the availability of adequately trained therapists, as well as geographical location, time, and cost barriers. To address these, NOCD created a digital behavioral health treatment for OCD using ERP delivered via video teletherapy and with technology-assisted elements including app-based therapy tools and between-session therapist messaging.

Objective: We examined treatment outcomes in a large naturalistic sample of 3552 adults with a primary OCD diagnosis who received NOCD treatment.

Methods: The treatment model consisted of twice-weekly, live, face-to-face video teletherapy ERP for 3 weeks, followed by 6 weeks of once-weekly brief video teletherapy check-ins for 30 minutes. Assessments were conducted at baseline, at midpoint after completion of 3 weeks of twice-weekly sessions, and at the end of 6 weeks of brief check-ins (endpoint). Longitudinal assessments were also obtained at 3, 6, 9, and 12 months after endpoint.

Results: Treatment resulted in clinically and statistically significant improvements, with a 43.4% mean reduction in obsessive-compulsive symptoms (g=1.0; 95% CI 0.93 to 1.03) and a 62.9% response rate. Treatment also resulted in a 44.2% mean reduction in depression, a 47.8% mean reduction in anxiety, and a 37.3% mean reduction in stress symptoms. Quality of life improved by a mean of 22.7%. Reduction in OCD symptoms and response rates were similar for those with mild, moderate, or severe symptoms. The mean duration of treatment was 11.5 (SD 4.0) weeks, and the mean total therapist time was 10.6 (SD 1.1) hours. Improvements were maintained at 3, 6, 9, and 12 months.

Conclusions: In this sample, representing the largest reported treated cohort of patients with OCD to date, video teletherapy treatment demonstrated effectiveness in reducing obsessive-compulsive and comorbid symptoms and improved quality of life. Further, it achieved meaningful results in less than half the total therapist time compared with standard once-weekly outpatient treatment, an efficiency that represents substantial monetary and time savings. The effect size was large and similar to studies of in-person ERP. This technology-assisted remote treatment is readily accessible for patients, offering an advancement in the field in the dissemination of effective evidence-based care for OCD.

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KEYWORDS

digital behavioral health; cognitive-behavioral therapy; CBT; exposure and ritual prevention; ERP; EX/RP; digital health; telehealth; cognitive therapy; obsessive compulsive disorder; OCD; clinical outcomes; teletherapy; remote therapy; telemedicine; obsessive compulsive; symptom; comorbid symptom; comorbidity; comorbidities; video therapy; virtual therapy; clinical outcome; patient outcome; online therapy; mobile health; mHealth; app based; health app; technology assisted; messaging

Introduction

Obsessive-compulsive disorder (OCD) is a prevalent and disabling psychiatric disorder, affecting 2.3% of individuals during their lifetimes [1]. Typically chronic if untreated, OCD is markedly detrimental to one's quality of life [2]. Yet, OCD can be treated effectively with psychotherapy or pharmacological interventions [3]. Exposure and response prevention (ERP), also known as exposure and ritual prevention, is a type of cognitive-behavioral therapy (CBT) that consistently demonstrates efficacy for OCD in numerous controlled trials and is also effective in less controlled clinical settings [3-7]. Based on this research evidence, ERP is considered a first-line treatment for OCD [8,9].

However, ERP requires specialty-trained therapists and thus is not readily available to everyone with OCD because of limited numbers of trained therapists, as well as cost and geographical limitations [10]. Indeed, the majority of individuals with OCD and related anxiety conditions are unable to access evidence-based psychotherapy [11]. Moreover, ERP typically requires over 25 hours of therapist time per patient [12] to achieve meaningful results; thus, when delivered in its most common format of once-weekly outpatient therapy, it could take 6 or more months.

To address the challenges of delivering ERP in terms of barriers to access and associated cost and time, NOCD has developed a digital behavioral health treatment program using video teletherapy. Remote ERP for OCD, delivered by video or telephone, has been demonstrated to significantly improve OCD symptoms [13]. Two head-to-head comparisons with in-person treatment in adults and adolescents show only small differences in outcome [14,15]. One of the several vital advantages of remote treatment is that therapists can readily interact with patients in the specific settings that most trigger their obsessional thoughts, images, or urges, for example in the home. This allows for administering in-session exposures that otherwise could be difficult or impossible to reproduce in an office setting. Although therapists in traditional face-to-face treatments can visit patients' homes and other nonoffice settings to administer exposures and help patients practice response prevention, this is logistically challenging and inefficient due to the travel times involved. Moreover, as of 2022, approximately 83% of the world's population (6.5 billion) owns a smartphone [16], and this grows yearly.

NOCD's treatment approach was inspired by a treatment previously tested in an open clinical trial [17] (N=33) that used the NOCD app integrated with brief in-person therapy. This trial tested a treatment protocol designed to minimize therapist time while increasing therapy intensity compared with once-weekly ERP sessions. It is possible that greater symptom reduction earlier in treatment, which may occur with more intensive treatment, could portend better ultimate clinical outcomes [18-20]. In a 2020 trial conducted by Gershkovich et al [17], there were high satisfaction ratings: 68.2% were "very" and 31.8% "mostly" satisfied with the services received. The treatment resulted in a mean reduction in OCD symptoms of 38.9%, with a response rate (≥35% reduction in OCD symptoms) of 52%. Mean therapist time was 6.7 (SD 1.52) hours total per patient.

We designed a treatment model for NOCD to treat patients with OCD using exposure and response prevention, with similar intensity, and to be able to reach as many as possible in the general community. To provide accessibility, all sessions were conducted remotely with video teletherapy. To provide additional support, enhance adherence, and potentially improve efficacy, every patient had access to between-session contact with their therapist via messaging. Further, a large online OCD community was available for further support through group message boards and scheduled support group sessions. In addition, peer support from individuals who had completed NOCD treatment was available to patients prior to starting treatment. The objective of this study was to examine treatment outcomes in a large naturalistic sample of 3552 adults with a primary OCD diagnosis who received NOCD treatment from January 1, 2020, to June 30, 2021.

Methods

Diagnostic Evaluations and Inclusion and Exclusion Criteria

Patients initially contacted the NOCD intake team as self-referrals or as referred from their health plans. They underwent diagnostic assessments by licensed clinical psychotherapists, who had received standardized training from NOCD in the evaluation and treatment of OCD using ERP. The diagnostic assessment consisted of a comprehensive clinical evaluation, including biopsychosocial elements of their history, and a standardized, semistructured diagnostic evaluation using the Diagnostic Interview for Anxiety, Mood, and Obsessive Compulsive and Related Neuropsychiatric Disorders (DIAMOND) [21]. Individuals who met DIAMOND criteria for OCD (consistent with Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [22]) as their primary disorder were treated. The majority of those who scored a 7 ("extreme") on the DIAMOND clinician-rated severity scale were referred to higher levels of care, including intensive outpatient programs, partial hospitalization programs, or residential treatment programs (exceptions were made on a case-by-case basis for a small number of individuals [n=16] whom the therapist and clinical leadership deemed may benefit from treatment by NOCD). Other situations that resulted in referral at the time of diagnostic assessment included active substance use disorders or comorbid uncontrolled psychiatric disorders or symptoms (eg, mania, psychosis, or active suicidality), deemed to potentially interfere with treatment, on a case-by-case basis. Although the current analysis is of patients 18 years and older, NOCD treated those 5 years of age and older (results from the child and adolescent cohort are forthcoming). There was no upper limit on age. Medicated or unmedicated individuals were treated.

Treatment Model

The NOCD treatment model consisted of twice-weekly 60-minute remote ERP video sessions for 3 weeks. After this, patients had 6 weeks of once-weekly 30-minute video “check-in” sessions to guide ongoing ERP homework assignments conducted by the patients.

Therapists were trained and instructed to follow this framework for treatment but were allowed some flexibility to add sessions, if needed. In addition, between sessions, all patients had access to as-needed asynchronous text messaging with their therapists 5 out of 7 days per week to obtain guidance with exposures and response prevention. Patients had 24 hours per day and 7 days per week access to the online NOCD community, consisting of a forum of individuals around the world self-identified as having OCD, providing support and advice through online (monitored) postings. The NOCD app was available for patients to use during treatment; it provided tools for patients, in collaboration with their therapists, to create exposure hierarchies and do exposure exercises. Patients could also read and post messages in the NOCD community through the app.

All sessions were conducted via Zoom (US Health Insurance Portability and Accountability Act–compliant version). Patients could join the sessions via any personal computer or portable electronic device. For billing purposes, both the therapist and patient needed to be on video throughout the session. Aside from their electronic device, there was no other hardware required for either patients or therapists. Therapists were trained to not proceed with sessions if adequate sound and video quality could not be achieved, and in these scenarios, to reschedule in a timely manner. Additionally, during traditional daytime business hours (when most sessions were held) there was live technical support available to therapists to assist patients with troubleshooting if there were connectivity issues.

Therapists had Master’s, PhD, or PsyD degrees, and were licensed in the states in which they provided remote treatment. Therapists received training by NOCD to conduct ERP and were provided ongoing group and individual supervision by experienced NOCD clinical leadership team members. All NOCD therapists received 3 days of intensive training on OCD, ERP, and application of ERP to OCD. After this training, there are several assessments that all clinicians must pass, including quizzes, a mock diagnostic session, a mock education session, and mock ERP sessions. As therapists go live, the clinical leadership team observes them in their first through fourth sessions randomly to see live examples of their diagnostic skills, provision of psychoeducation, and proficiency in the development of ERP hierarchies. The full-time therapists attend 2 hours per week of clinical supervision or case consultation as well as a 3-, 6-, 9-, and 12-month clinical advising review of their cases.

Assessments

Assessments were emailed to patients as links and were conducted at the initial diagnostic assessment, at treatment midpoint (after 6 twice-weekly therapy sessions), and the endpoint (after 6 weekly 30-minute check-in sessions). The use of patient-rated scales as the outcome variables of interest reduced the risk of therapist bias that may occur with clinician-rated scales. Follow-up assessments were sent to patients at the therapy visit closest in time to 3, 6, 9, and 12 months after their endpoint assessment. The majority of these follow-up sessions were 30-minute brief check-in sessions, as most had transitioned to less frequent visits (30-minute check-ins twice monthly to once every 3 months).

Dimensional Obsessive-Compulsive Scale (DOCS) [23] is a 20-item self-report measure of OCD symptom severity across four domains: contamination, responsibility for harm or mistakes, unacceptable thoughts, and incompleteness or symmetry. The DOCS has shown good psychometric properties, including strong convergent validity with the Yale-Brown Obsessive Compulsive Scale (r=0.54) and the Obsessive-Compulsive Inventory—Revised (r=0.69), and is sensitive to the effects of treatment.

The DIAMOND severity scale [21] is a 2-item clinician-rated assessment of the overall severity of an individual’s emotional distress and functional impairment related to OCD symptoms. The clinician makes separate ratings of an individual’s emotional distress and functional impairment on a scale ranging from 1 (Normal) to 7 (Extreme), and the higher of the two ratings is taken as the total severity score.

Depression, Anxiety, and Stress Scales (DASS-21) [24] is a 21-item self-report measure of symptoms of depression, anxiety, and stress. It has been widely used in previous research and has consistently shown good psychometric qualities.

Quality of Life Enjoyment and Satisfaction Questionnaire—Short Form [25] is a 14-item self-report assessment of quality of life across a variety of life domains. It has demonstrated good psychometric properties in previous research.

Statistical Analyses

All data were deidentified prior to analysis. We analyzed data for those patients who completed at least the initial and the endpoint outcome assessments for the DOCS, the primary outcome measure. The majority also had a midpoint assessment. Data analysis was conducted using a linear mixed model (in part to handle missing data) with assessment time point as a fixed factor, patient as a random factor, and DOCS as the primary dependent variable. Secondary outcome analyses for the DASS-21 subscales of depression, anxiety, and stress, and the Quality of Life Enjoyment and Satisfaction Questionnaire—Short Form, were analyzed using the same model. A tertiary outcome was follow-up symptom severity ratings on the DOCS at 3, 6, 9, and 12 months from the endpoint assessment; this was also conducted using linear mixed models with assessment time point as a fixed factor (initial, 3-month, 6-month, 9-month, and 12-month time points), patient as a random factor, and DOCS as the primary dependent variable. Statistical significance was determined using an alpha of .05. Outcome analyses were conducted using SPSS version 27.0.0.0 (IBM Corp). We calculated Hedges g effect sizes using R (R Foundation for Statistical Computing).

Ethical Considerations

The analysis conducted in this study did not require research ethics board review as it does not meet the criteria for Human Subject Research as defined by federal regulations for human subject protections, 45 CFR 46.102(e); this is a secondary analysis of de-identified data from clinical records, obtained and analyzed retrospectively, and was not the result of a research intervention or interaction.

NOCD's Privacy Policy complies with the UK Data Protection Act of 2018, as well as the European Union's General Data Protection Regulation privacy law. All patients who are treated by NOCD must accept NOCD's Privacy Policy, which discusses how personal data are used, by whom, and for what purpose.

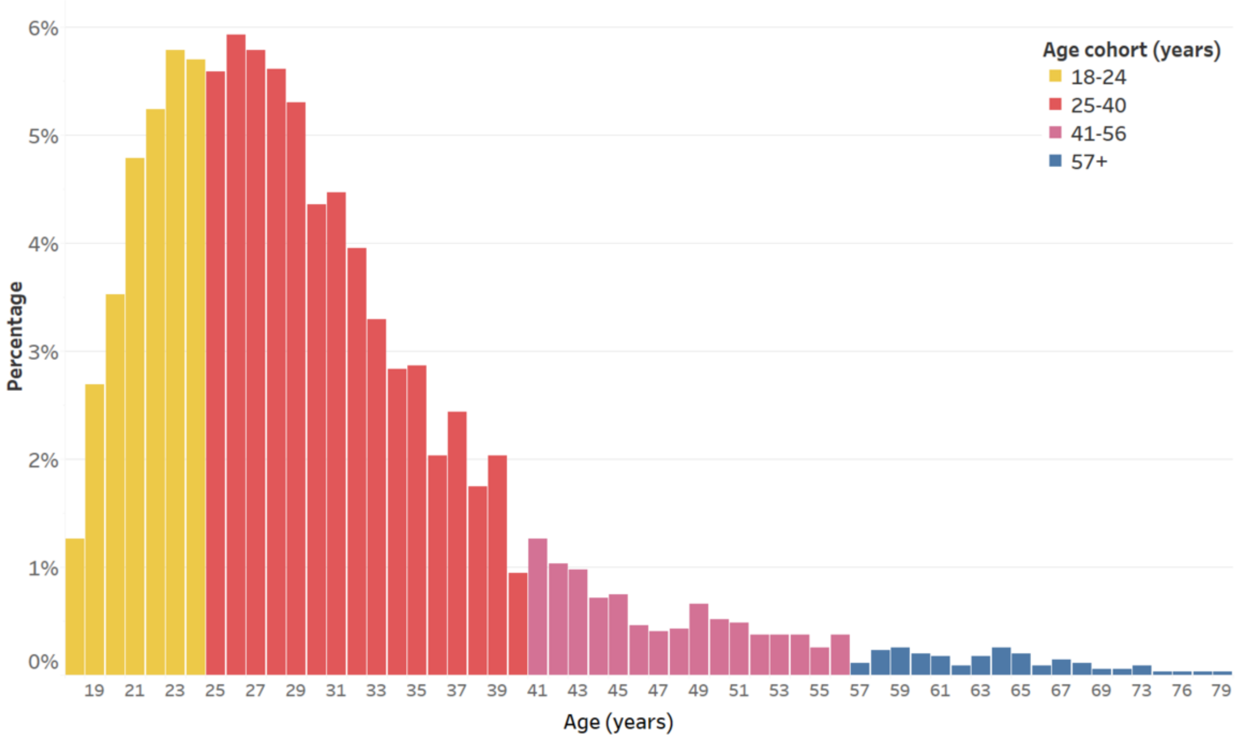
Results

Sample

We analyzed data collected from patients who started treatment between January 1, 2020, and June 30, 2021. (It is important to note that this date range was chosen to capture outcomes from when NOCD started enrolling substantial numbers of patients until the treatment protocol introduced minor changes in late August 2021; individuals who started as late as June 30, 2021, for example, would have finished treatment before these came into effect.)

We analyzed data from adults (aged ≥18 years) with a diagnosis of OCD who had at least an initial and endpoint assessment with the primary outcome measure, the DOCS. Data from 3552 patients who met these criteria were analyzed. Those who had fewer than 5 sessions were excluded (representing <0.1% of the sample), as this indicated that the treatment was likely interrupted, and outcomes were not available. The mean age was 29.9 (SD 9.3) years, range 18-79 years (Figure 1). In terms of gender, 55.88% (1985/3552) identified as female and 37.56% (1334/3552) identified as male (6.56% [233/3552] indicated nonbinary or another gender-expansive identity or did not provide this information). Regarding comorbidities, 36.4% (1293/3552) had a comorbid anxiety disorder, 32.8% (1165/3552) had a comorbid mood disorder, 10.3% (366/3552) had a comorbid OCD-related disorder, 5.3% (188/3552) had a trauma and stress-related disorder (posttraumatic stress disorder or acute stress disorder), 1.8% (64/3552) had a substance use disorder, 11.2% (398/3552) had another comorbid disorder, and 62% (2202/3552) had no comorbid disorders (Table S3 in Multimedia Appendix 1).

Figure 1. Age distribution.



NOCD App Use, Messaging, and NOCD Web-Based Community Posts

The app was used by 3529/3552 (99.4%) of patients at least once, and 3515/3552 (99%) sent at least one text message. Further, 1932/3552 (45.6%) made at least one community post. The mean number of app usages was 454.7 (SD 852.8), and the mean number of community posts was 55.8 (SD 282.0).

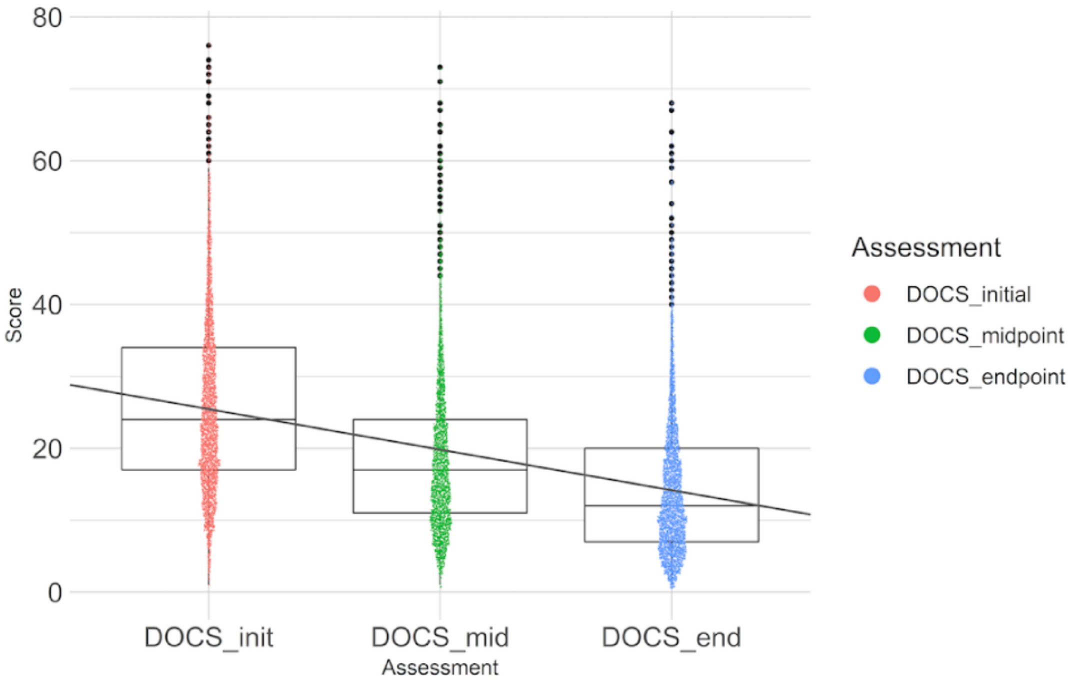
Treatment Duration

The mean treatment duration was 11.54 (SD 3.96) weeks (median=10.71, mode=9), the mean number of therapist sessions was 13.0 (SD 1.3; median=13.0, mode=13), and the mean number of therapist hours was 10.6 (SD 1.1; median=10.5, mode=10.5). Of the total 3552 sample, 53% (n=1883) had >14 sessions before the 3-month follow-up; of these, the mean number of 60-minute sessions was 7.7 (SD 2.0; the mean for those with 13 sessions was 7.0, SD 1.0) and the mean number of 30-minute check-in sessions was 9.1 (SD 1.7; the mean for those with 13 sessions was 5.8, SD 0.9). This amounts to a mean total of 16.8 (SD 2.2) sessions in those with >14 sessions; the majority of the additional sessions, if they were conducted, were check-in sessions.

OCD Symptom Results

NOCD treatment resulted in a significant decrease in patient-rated OCD symptoms (DOCS scores; $F_{6646.02}$=2810.08, *P*<.001; initial to endpoint Hedges g=1.0: "large" effect size). On the total sample level, DOCS scores improved from a mean of 26.0 (SD 12.3) to a mean of 14.7 (SD 9.8), representing a mean 11.3-point decrease (43.4%). On the individual patient level, the median DOCS score improvement was 45%. Note that we report the median for the individual score change rather than the mean, as it is a better representation of the central tendency for percentage change for these data. This is due to the fact that individuals' scores can worsen more than 100% but cannot improve more than 100%, which can result in a skewed distribution (Figure 2).

Figure 2. Changes in obsessive-compulsive disorder symptoms as assessed by the Dimensional Obsessive-Compulsive Scale (DOCS) with treatment (*P*<.001 for DOCS_mid compared with initial scores and *P*<.001 for DOCS_end compared with initial scores).



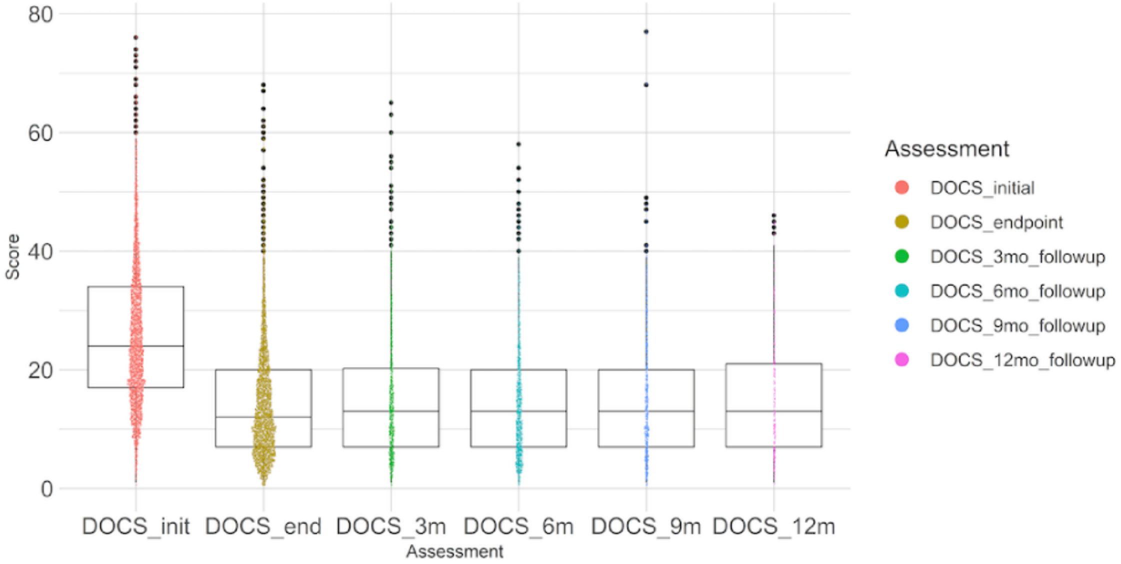
By midpoint, there were also statistically significant improvements; DOCS scores improved to a mean of 18.6 (SD 10.6), representing a mean 7.3-point decrease (28.2%). On the individual patient level, median DOCS score improvement was 30.8%.

Further, 62.9% (2234/3552) met the criteria as full "responders," defined as a ≥35% reduction in OCD symptoms [26]. A total of 74.2% (2636/3552) met the criteria as achieving either partial (25%-35% reduction) or full response.

Follow-up Scores at 3, 6, 9, and 12 Months

Of the whole 3552 sample, 1633 (46%) did a 3-, 6-, 9-, or 12-month follow-up. At 3, 6, 9, and 12 months post the endpoint assessment, most patients had maintained their improvements in all symptom and quality of life domains. This was evidenced by mean DOCS, DASS depression, DASS anxiety, DASS stress, and QLESQ-SF scores at 3, 6, 9, and 12 months, which were similar to scores at the endpoint of treatment and remained significantly different from the initial assessment (Figure 3 and Tables S1 and S2 in Multimedia Appendix 1).

Figure 3. Longitudinal follow-up of obsessive-compulsive disorder symptoms as assessed by the Dimensional Obsessive-Compulsive Scale (DOCS; *P*<.001 for DOCS_end, DOCS_3m, DOCS_6m, DOCS_9m, and DOCS_12m compared with initial scores).



Depression, Anxiety, Stress, and Quality of Life Results

Treatment resulted in significant improvements on the DASS depression ($F_{6647.79}$=972.91, *P*<.001; initial to endpoint Hedges g=0.66), DASS anxiety ($F_{6659.83}$=1162.76, *P*<.001; initial to endpoint Hedges g=0.76), DASS stress ($F_{6645.12}$=1387.22, *P*<.001; initial to endpoint Hedges g=0.87), and the QLESQ-SF ($F_{6156.13}$=1140.66, *P*<.001; initial to endpoint Hedges g=0.76) (Figure 4 and Tables 1 and 2).

Figure 4. Changes in depression, anxiety, stress, and quality of life with treatment. DASS: Depression, Anxiety, and Stress Scales; DEPR: depression; QLESQ: Quality of Life Enjoyment and Satisfaction Questionnaire; ***P*<.001 compared with initial scores.

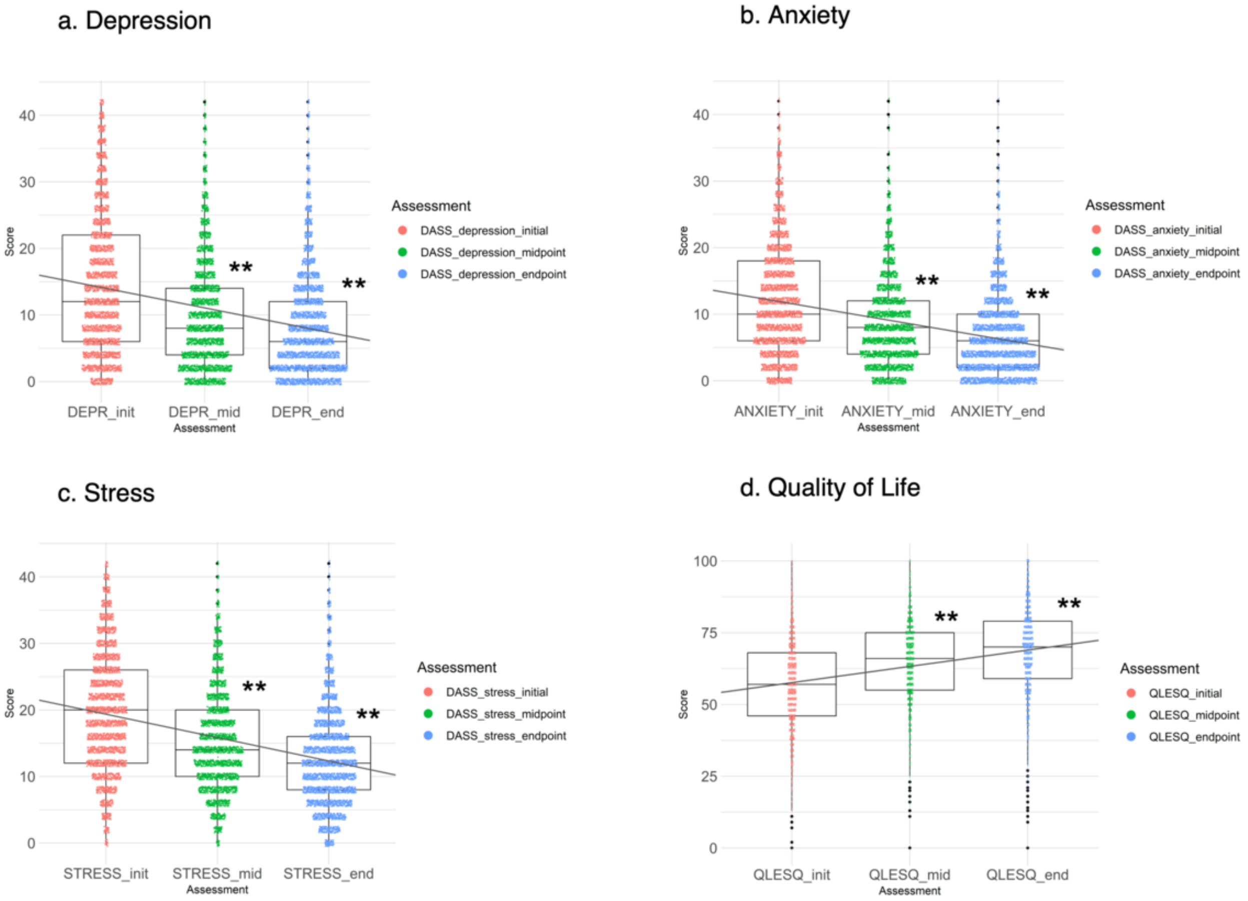


Table 1. Clinical assessments by treatment time point.

Outcome scale and assessment time point	Valid, n	Missing, n	Mean	SD	Mean 95.0% CI, lower bound	Mean 95.0% CI, upper bound	Median	Median 95.0% CI, lower bound	Median 95.0% CI, upper bound
DOCS[a]									
Initial	3552	0	26.0	12.3	25.5	26.4	24	24	25
Midpoint	3037	515	18.6	10.6	18.2	19.0	17	17	18
Endpoint	3552	0	14.7	9.8	14.4	15.0	12	12	13
DASS[b] **depression**									
Initial	3551	1	14.5	10.4	14.1	14.8	12	12	14
Midpoint	3032	520	10.2	8.7	9.9	10.5	8	8	10
Endpoint	3526	26	8.4	7.9	8.1	8.6	6	6	8
DASS anxiety									
Initial	3551	1	12.1	8.3	11.8	12.4	10	10	12
Midpoint	3033	519	8.6	6.7	8.4	8.8	8	8	10
Endpoint	3528	24	6.5	5.9	6.3	6.7	6	6	8
DASS stress									
Initial	3550	2	19.7	8.8	19.	19.9	20	20	22
Midpoint	3033	519	15.1	7.7	14.9	15.4	14	14	16
Endpoint	3528	24	12.6	7.3	12.4	12.9	12	12	14
QLESQ[c]									
Initial	3469	83	57.1	16.2	56.6	57.7	57	57	59
Midpoint	2764	788	64.5	14.9	63.9	65.0	66	66	68
Endpoint	3295	257	68.4	15.1	67.9	69.0	70	70	71

[a] DOCS: Dimensional Obsessive-Compulsive Scale.

[b] DASS: Depression Anxiety and Stress Scale—21.

[c] QLESQ: Quality of Life Enjoyment and Satisfaction Questionnaire—Short Form.

Table 2. Changes in OCD,[a] depression, anxiety, and stress symptoms and quality of life by assessment time point.

Outcome scale and assessment	Score change	SE	Score change 95% CI, lower bound	Score change 95% CI, upper bound	Percentage change	*df*	*t*	Sig.[b]	Hedges g effect size	Hedges g 95% CI, lower bound	Hedges g 95% CI, upper bound
DOCS[c]											
Midpoint	–7.4	0.2	–7.7	–7.0	–28.4	6680.86	–45.71	<.001	0.66	0.63	0.69
Endpoint	–11.3	0.1	–11.6	–11.0	–43.4	6583.44	–73.97	<.001	1.00	0.93	1.03
DASS[d] depression											
Midpoint	–4.4	0.1	–4.7	–4.1	–30.4	6696.36	–29.16	<.001	0.48	0.45	0.51
Endpoint	–6.2	0.1	–6.4	–5.9	–42.5	6571.51	–42.96	<.001	0.66	0.62	0.69
DASS anxiety											
Midpoint	–3.6	0.1	–3.9	–3.4	–29.9	6715.28	–29.11	<.001	0.50	0.46	0.53
Endpoint	–5.6	0.1	–5.9	–5.4	–46.4	6572.55	–47.65	<.001	0.76	0.72	0.80
DASS stress											
Midpoint	–4.6	0.1	–4.9	–4.3	–23.4	6702.45	–32.23	<.001	0.59	0.55	0.63
Endpoint	–7.0	0.1	–7.3	–6.8	–35.8	6554.35	–51.96	<.001	0.87	0.83	0.91
QLESQ[e]											
Midpoint	7.7	0.3	7.2	8.2	13.5	6227.25	29.47	<.001	0.55	0.52	0.59
Endpoint	11.6	0.2	11.1	12.1	20.3	6107.25	46.98	<.001	0.76	0.72	0.79

[a] OCD: obsessive-compulsive disorder.

[b] Sig.: significance probability.

[c] DOCS: Dimensional Obsessive-Compulsive Scale.

[d] DASS: Depression Anxiety and Stress Scale–21.

[e] QLESQ: Quality of Life Enjoyment and Satisfaction Questionnaire—Short Form.

Post Hoc Analysis of Outcomes Stratified by Starting Clinician-Rated Severity Level

To determine how treatment response differed by different initial severity levels of OCD, we used the DIAMOND scale at the initial assessment to stratify patients into three groups of severity ratings: "Mild" (severity score of 2 or 3), "Moderate" (severity score of 4 or 5), or "Severe" (severity score of 6 or 7). Moreover, of the 3552 patients, 596 (17%) were missing DIAMOND severity scale scores. Of these, there was a median 46.86% reduction in DOCS scores and a 64.3% response rate. For DOCS scores, on the individual patient level, the Mild group (n=679, 19%) had a median 50.0% reduction, the Moderate group (n=2079, 59%) a median 42.9% reduction, and the Severe group (n=198, 6%) a median 44.6% reduction. Response rates from the DOCS were 68.8% for Mild, 60.7% for Moderate, and 61.6% for Severe.

Discussion

Patients with OCD treated with digital teletherapy using ERP show significant improvement in symptoms. OCD symptoms were reduced by 43.4%. Moreover, 62.9% (2234/3552) were classified as full responders, and 74.2% (2636/3552) had partial or full response. Treatment also resulted in improvements in the common comorbid symptoms of depression, anxiety, and stress and resulted in a significant improvement in quality of life. This provides evidence that a single, focused OCD treatment can result in an overall reduction of multiple disabling and distressing symptoms and improve the lives of patients. This is notable considering the fact that OCD is a chronic illness that individuals on average have for 11 years before receiving treatment [27]. Long-term follow-up data at 3-, 6-, 9-, and 12 months post treatment showed overall maintenance of gains from the initial treatment period.

These results demonstrate not only the magnitude of the effect of this treatment model on OCD and comorbid symptoms but also its efficiency in terms of cost and time savings. The time frame of these improvements was less than 12 weeks and less than 11 total therapist hours, on average. This is less than half the total therapist time and less than half of the duration of traditional once-weekly outpatient ERP [12]. This has the potential for substantial cost savings for patients and third-party payors such as health insurers.

This treatment format was inspired by a treatment previously developed and tested [17] to provide evidence-based ERP treatment for OCD, in a manner that is efficient in terms of total therapist time. The OCD symptom reduction results in the current NOCD-treated sample are similar to those achieved in that study. Yet, direct comparisons are limited by the fact that the current sample was from a "real-world" clinical setting rather than a controlled research setting with more selective inclusion and exclusion criteria. Other differences that preclude direct comparisons include, but are not limited to, the fact that NOCD used the patient-rated DOCS scale, whereas the previous study used the clinician-rated Yale-Brown Obsessive-Compulsive Scale [28] as the primary outcome measure. Further, NOCD treatment consisted of face-to-face teletherapy rather than in-person therapy.

There are other important additional elements of treatment in the NOCD model that impact patient experience and may have influenced outcomes. Additional support for patients was available between sessions through patient-therapist SMS messaging. Patients also had 24-hour access to NOCD's web-based support community, consisting of messaging boards from others with OCD and organized around common OCD subtypes. This allows people to find others who experience similar symptoms, which can help reduce the sense that their OCD symptoms are a rare or unique type of OCD and therefore difficult to treat or may not even be OCD. This can be an important experience for those with OCD, given the broad and heterogeneous content of obsessional thoughts [29]. In addition, only a limited number of subtypes such as those involving contamination or washing, checking symptoms, and ordering or symmetry are typically described in the literature and are widely known, so certain OCD symptoms might be missed or misidentified by clinicians, family members, and patients themselves. In addition, patients had peer support from former patients who had completed NOCD treatment. When used, this would occur in the interval between contacting the initial call center for NOCD and their first diagnostic appointment with their therapist. The peer support may encourage people to follow through with scheduling and attending their first assessment meeting and beginning treatment. This additional support may be particularly useful due to the fact that ERP can be challenging for individuals to engage in; this is because, by necessity, ERP's therapeutic mechanisms are predicated on inducing distress (exposures) and eliminating behaviors that temporarily relieve distress (response prevention) but that perpetuate the cycle of obsessions and compulsions. Future investigations will quantify if, and to what degree, these additional digital and personal treatment elements affected clinical outcomes and patient experience.

Technology assistance likely played an important role in this treatment's ability to both engage and treat a large number of patients in wide-ranging geographic locations and to achieve a high mean rate of symptom improvement and a high rate of treatment response. Teletherapy using video allows people in remote locations to access treatment and to be able to complete, in-session, in vivo exercises in places and situations that are most relevant to, or triggering of, their symptoms. Previous studies of remote therapy demonstrate effect sizes that are similar to controlled studies of in-person treatment (see the meta-analysis [13]). The effect size for OCD symptom severity reduction in the current analysis of g=1.0 ("large" effect size) (95% CI .93 to 1.03) is similar to that found in a recent meta-analysis of controlled studies of ERP vs psychological placebo (g=1.13, 95% CI 0.71 to 1.55; 10 studies) [5]. Importantly, the current results are observed in a cohort that is one to two orders of magnitude larger than previous controlled ERP studies [5], providing strong evidence that virtual face-to-face ERP can be at least as effective as in-person ERP.

While most previous studies of ERP *efficacy* have come from clinical research trials, a meta-analysis of *effectiveness* studies of CBT in real-world clinical settings found an effect size for reduction of OCD symptoms across 11 studies of d=1.32 (95% CI: 1.19 to 1.45) [7]. A study published more recently examined CBT outcomes in an outpatient setting and found a mean 47.09% reduction in OCD symptoms on the Obsessive-Compulsive Inventory—Revised (n=451 at baseline and n=235 post treatment, effect size d=1.18) [30]. However, some differences limit direct comparisons to the current results because other studies used different OCD outcome rating scales (primarily the clinician-rated Yale-Brown Obsessive-Compulsive Scale or the patient-rated Obsessive-Compulsive Inventory—Revised rather than the DOCS) and had much smaller sample sizes.

Aside from video teletherapy, there are other technology-based features of this treatment that may have enhanced patient engagement. This includes integrated SMS messaging that allowed for increased continuity of treatment; patients could obtain advice and assistance when doing homework assignments in between sessions or when encountering unexpected situations that lead to obsessions and distress. This both helps keep treatment momentum and helps patients feel a more continuous sense of support. Further, the NOCD app has built-in tools for creating ERP hierarchies for exposure treatment planning. In addition, there are tools such as distress ratings to track progress during exposures and to track exposure-to-exposure progress, all of which can be visualized graphically by the patients and therapists. In this sample, almost all used the NOCD app and almost half made at least one post in the online community, with an average of approximately 56 posts per person. The specific effects of these technology features, as well as the effects of peer support and online community support, can be measured and evaluated in future analyses.

Another finding of note in this analysis was that symptom improvements were relatively similar for those with mild, moderate, and severe OCD symptoms. Overall mean symptom improvements were thus not driven only by those, for example, on the milder end of the symptom severity spectrum. Rather, the treatment model works well for those with a wide range of baseline symptoms, including those with severe OCD.

There are several limitations of this analysis, which are mostly due to its observational nature. Data were missing for some patients for certain rating scales (Table 1). Although all therapists received training in conducting ERP from NOCD's curriculum and learned the overall structure of the treatment model, therapy sessions were not videotaped to ensure treatment fidelity and consistency from therapist to therapist, as in a research study. However, therapists were regularly audited in terms of outcomes, patient feedback, and patient retention and were assisted in improving in any of these areas if necessary. Another limitation to the generalizability of the results is that the treatment model allowed for some flexibility; for example, therapists sometimes extended treatment beyond the 3 weeks of twice-weekly therapy or 6 weeks of once-weekly brief therapy check-ins if they deemed it important for patient improvement.

Another limitation is the use of the DOCS as the primary OCD outcome measure. As a patient-rated measure, it depends on patients' understanding of their symptoms in the framework of OCD. This could be problematic if patients do not recognize that some of their experiences are OCD symptoms, or if they believe that some experiences are OCD symptoms when they are not, which can result in erroneously low or high scores, respectively. This is a limitation, however, of all OCD rating scales to varying degrees. In addition, the majority of those whom therapists determined in the initial diagnostic assessment to have "extreme" OCD symptoms on the DIAMOND severity scale (aside from n=16 for whom exceptions were made on a case-by-case basis) were not treated and were instead referred to a higher level of care. Thus, although outcomes were similar for those with mild to severe cases, there is less certainty about generalization to those with extreme OCD severity. Another limitation is that 3-, 6-, 9-, and 12-month follow-up data were not available for many who completed the treatment. Thus, it remains unknown whether the proportions of those for whom 3-, 6-, 9-, and 12-months follow-up data were not provided represented individuals who were doing worse and sought other treatment, or were doing much better and did not see the need to continue these sessions. Further, even for those who provided data during this follow-up period, some may have engaged in other concurrent treatments.

In sum, ERP delivered in a technology-assisted video teletherapy treatment format results in clinically significant symptom and quality of life improvements in a real-world sample, on a large scale. This can provide a readily accessible means of obtaining effective, evidence-based treatment of OCD. Further, the relatively efficient treatment that is delivered can represent substantial cost savings for patients and third-party payors over traditional weekly outpatient face-to-face ERP.

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Conflicts of Interest

JDF, NRF, JK, PBM, AR, TF, SL, JEJ, LT, and SMS report personal fees from NOCD Inc during the conduct of the study.

Multimedia Appendix 1

Supplemental document that contains visualizations of analysis pertaining to characterization of the data in terms of demographics and tables.
[DOCX File , 3055 KB-Multimedia Appendix 1]

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Abbreviations

CBT: cognitive-behavioral therapy
DASS: Depression, Anxiety, and Stress Scales

DIAMOND: Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders
DOCS: Dimensional Obsessive-Compulsive Scale
ERP: exposure and response prevention
OCD: obsessive-compulsive disorder

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Original Paper

A Gamified Personalized Normative Feedback App to Reduce Drinking Among Sexual Minority Women: Randomized Controlled Trial and Feasibility Study

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Abstract

Background: Sexual minority women disproportionately engage in heavy drinking and shoulder the burden of alcohol dependence. Although several intensive interventions are being developed to meet the needs of treatment-seeking sexual minority women, there remains a lack of preventive interventions to reduce drinking and its consequences among women not yet motivated to reduce their alcohol consumption.

Objective: We aimed to examine the feasibility and efficacy of reducing alcohol-related risks via personalized normative feedback (PNF) on alcohol use and coping delivered within LezParlay, a social media–inspired digital competition designed to challenge negative stereotypes about lesbian, bisexual, and queer (LBQ)–identified sexual minority women.

Methods: Feasibility was assessed by examining engagement with LezParlay outside the context of an incentivized research study, assessing the characteristics of the LBQ women taking part, and examining the competition's ability to derive risk-reducing actual norms as well as levels of acceptability and perceived benefits reported by participants. Intervention efficacy was examined by randomizing a subsample of 499 LBQ alcohol consumers (ie, drinkers) already taking part in the competition to receive sexual identity–specific PNF on alcohol use and coping, alcohol use only, or control topics over only 2 rounds of play. Changes in alcohol use and negative consequences were examined 2 and 4 months after the delivery of treatment PNF.

Results: A total of 2667 diverse LBQ women played ≥1 round of LezParlay. The competition attracted large numbers of moderate and heavy drinkers; however, risk-reducing actual norms could still be derived from competition rounds and featured in PNF. Efficacy results revealed that drinkers who received PNF on alcohol use and both alcohol use and coping had similar reductions in their weekly drinks (P=.003; P<.001), peak drinks (P<.001; P<.001), and negative consequences (P<.001; P<.001) relative to those who received PNF on control topics at the 2-month follow-up. However, at the 4-month follow-up, reductions in alcohol consumption outcomes faded among those who received alcohol PNF only (weekly: P=.06; peak: P=.11), whereas they remained relatively robust among those who received PNF on both alcohol use and coping (weekly: P=.02; peak: P=.03). Finally, participants found the competition highly acceptable and psychologically beneficial as a whole.

Conclusions: The LezParlay competition was found to be a feasible and efficacious means of reducing alcohol-related risks in this population. Our findings demonstrate the utility of correcting sexual identity–specific drinking and coping norms to reduce alcohol-related risks among LBQ women and suggest that this approach may also prove fruitful in other stigmatized health disparity populations. To engage these populations in the real world and expand the psychological benefits associated with PNF, our findings also point to packaging PNF within a broader, culturally tailored competition designed to challenge negative group stereotypes.

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KEYWORDS
sexual minority women; alcohol; intervention; social norms; gamification; mobile phone; smartphone

Introduction

Background

Relative to women who identify as heterosexual, experience only opposite-sex attractions, and only have sex with men, research has reliably documented more frequent and intense alcohol consumption [1-3], as well as a greater likelihood of negative alcohol-related consequences and alcohol dependence [2-4], among sexual minority women, a population that includes women who psychologically identify as lesbian, bisexual, or queer (LBQ), in addition to those who report having sex with women and experiencing same-sex attraction [5,6]. Although several culturally tailored interventions are currently being developed to meet the needs of heavy drinking sexual minority women seeking treatment for alcohol use disorder (AUD) [7,8], to date, there remains a lack of preventive, culturally tailored interventions to reduce alcohol-related harm among alcohol-consuming sexual minority women *who are not yet* motivated to reduce their drinking. Seeking to address this void, this study evaluates the degree to which an evidence-based personalized normative feedback (PNF) intervention embedded within a culturally tailored digital competition can engage LBQ-identified sexual minority women and reduce their alcohol-related risks.

Antecedents to Heavy Drinking Among Sexual Minority Women and Targets for Intervention

Consistent with the sexual minority stress model [9], extant research has linked greater alcohol consumption and negative consequences among sexual minority women to the internalization of sexual minority stigma [10-12] and experiences of harassment, discrimination, and violence due to sexual minority status [13-15]. These findings have informed the recent development of 2 stigma-coping–focused digital programs designed for heavy drinking sexual minority women seeking treatment for AUD only [7] and both AUD and poor mental health [8]. Although these programs hold promise for sexual minority women motivated to seek help, they appear unlikely to attract or engage the larger population of sexual minority women who do not view their mental health or drinking as problematic.

Recent research suggests that to motivate reductions in drinking among those not seeking treatment, it may be beneficial to target the elevated perceptions of sexual identity–specific drinking norms [16-20], which appear to be a consequence of the central role that alcohol use plays in queer socialization contexts [21-24]. Indeed, qualitative accounts from LBQ-identified women suggest that the position of bars and nightclubs as central hubs for queer socialization may lead young LBQ women to view heavy drinking as a normative *rite of passage* [23,24]. Findings from survey studies also suggest that the high visibility of alcohol use in physical and web-based LBQ community spaces may lead LBQ women to perceive heavy drinking as more characteristic or *typical* of LBQ peers than heterosexual women [20]. They tend to substantially overestimate how much and how often LBQ peers drink [16,17,19] and the frequency with which they drink to cope with sexual minority stigma [25].

Web-Based PNF Interventions

In other heavy drinking populations found to overestimate peer-drinking norms, alcohol-related risks have been reduced through PNF, a brief intervention strategy that only requires members of a social group to answer survey questions about their perceptions of the *typical* group member's drinking and then report on their own consumption [26-28]. Group members then receive individualized graphical reports highlighting discrepancies between their perceptions of peers' drinking, peers' actual drinking, and their own drinking [28,29]. To date, research has yet to investigate whether delivering PNF on LBQ-specific drinking and coping norms is an effective means of reducing alcohol-related risks among LBQ drinkers. However, supporting the promise of PNF for this population, in university and military samples, this strategy has been found particularly effective in reducing alcohol consumption among women [30,31], individuals for whom the reference peer group or community is important to their overall sense of self [32], those reporting coping motivations for drinking [33,34], and heavy drinkers not yet aware that their consumption exceeds normative standards [35].

Reaching LBQ Drinkers With PNF on Alcohol Use and Stigma Coping

Despite the potential promise of PNF, previous work suggests that LBQ women may comprise a population that is particularly difficult to reach, recruit, and retain in transparent health interventions. For instance, a review of community-based interventions targeting various health risk behaviors in this population identified low response rates, small sample sizes, and problems with attrition as significant challenges to evaluation efforts, reflecting broader difficulties with intervention engagement [36]. Recruitment and engagement concerns are also magnified in the PNF context, as this strategy is most effective in reducing alcohol-related risks among individuals who do not view their drinking as excessive or see themselves as in need of intervention. Moreover, very few PNF interventions have been delivered to populations not attached to institutions or workplaces, and researchers have struggled to implement PNF interventions outside study settings where participation is mandatory or participants are promised compensation at the point of recruitment [37-39].

Seeking to remedy these implementation challenges and extend promising gamified intervention work with college students [40-42], PNF on alcohol use and stigma-coping behaviors was delivered to LBQ drinkers within *LezParlay*, a culturally tailored digital competition designed to challenge negative stereotypes about LBQ women and increase visibility (Figure 1). In brief, the competition comprised 8 monthly rounds wherein LBQ users guessed about the behaviors, attitudes, and experiences of age group and sexual identity–matched peers; wagered points on their guesses being true based on the responses of other users; and reported on their own corresponding behaviors, attitudes, and experiences. At the end of each month, players were SMS text messaged private URLs at which they could view detailed results (ie, PNF) on all or a subset of the round's questions. All actual norms presented in the detailed results (ie, PNF) were transparently derived from the responses of the players in each subgroup. Users' scores reflected the accuracy of their LBQ peer perceptions, and each round's top scorer won a variable cash prize. A complete overview of the digital competition and detailed descriptions of the theory-informed game mechanics and deep-structure cultural adaptations leveraged to bolster appeal and engagement are available in this project's protocol paper [43].

Figure 1. The initial version of LezParlay tested in this trial was a device-responsive HTML5 web application that delivered personalized normative feedback on a number of lesbian, bisexual, and queer stereotypes and health-related topics within the context of a monthly competition.

YOU'VE HAD ABOUT THE SAME NUMBER OF UHAUL RELATIONSHIPS AS OTHER PLAYERS YOUR AGE.. HERE'S HOW YOU STACK-UP OVERALL

HOW MANY POINTS DO YOU WANT TO BET ON 4 BEING THE AVERAGE NUMBER OF UHAULS AMONG LESBIAN PLAYERS IN THEIR 30s?

This Study

Informed by the Accelerated Creation-to-Sustainment model for the rapid development and evaluation of real-world–ready digital health interventions [44-46], a registered hybrid trial [43] simultaneously examined the degree to which LBQ women would be engaged in the LezParlay competition in the real world (when there was no study framing and participation incentives were not offered) and evaluated whether delivering PNF on alcohol use and stigma coping within the competition would meaningfully reduce alcohol use and negative consequences among participating LBQ drinkers. As shown in Textbox 1, this study examined 5 key questions related to LezParlay's feasibility and efficacy as an alcohol intervention strategy.

Textbox 1. Key feasibility and efficacy questions addressed in this study.

Feasibility

1. Were lesbian, bisexual, and queer (LBQ) women engaged by the LezParlay competition in the absence of traditional study incentives?
2. Could risk-reducing actual drinking norms be generated in real time from users' responses to round questions?
3. Did LBQ drinkers taking part in LezParlay find the competition acceptable and psychologically beneficial? What ideas for improvements were submitted?

Efficacy

1. Did personalized normative feedback (PNF) designed to correct LBQ peer-drinking norms reduce alcohol-related risks among LBQ drinkers?
2. Did PNF on both LBQ peer-drinking and stigma-coping norms better reduce alcohol-related risks than PNF on LBQ peer-drinking norms alone?

Methods

Participants and Procedure

Broader Competition

LezParlay was advertised to LBQ women as it would be in the real world—as a free, web-based competition designed to test LBQ stereotypes and increase visibility. Despite no traditional study incentives being offered at the point of recruitment or sign-up, 2677 LBQ women took part in the competition between December 2018 and July 2019 and played ≥1 of the 8 monthly rounds. LezParlay's informational landing page received 4099 unique views during recruitment and competition periods, with digital advertising campaigns responsible for the bulk of these views. Specifically, promotional campaigns on the HER Social app, a popular dating and social networking app for LBQ women, were responsible for 34.01% (1394/4099) of the total landing page visits, whereas campaigns on Facebook or Instagram and Google Search accounted for 32.01% (1312/4099) and 22.98% (942/4099) of the total visits, respectively. Of the 4099 landing page visitors, 2008 (48.99%) advanced directly to create a user account [43] on the LezParlay competition web app. In addition, 669 user accounts were created organically by users who did not view the landing page first but were directly invited to the LezParlay web app by a friend taking part in the competition. Figure 2 provides a visual breakdown of LezParlay users by US metropolitan area, and Table 1 presents basic user characteristics.

Figure 2. Geodensity of LezParlay users across US metropolitan areas.

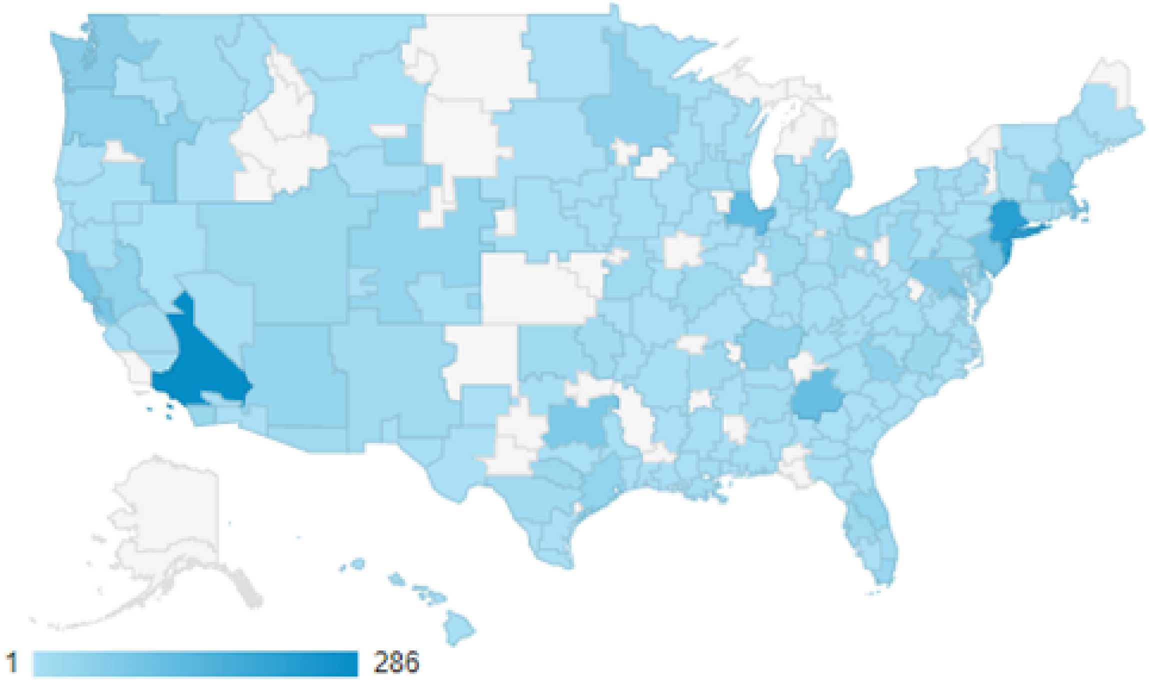


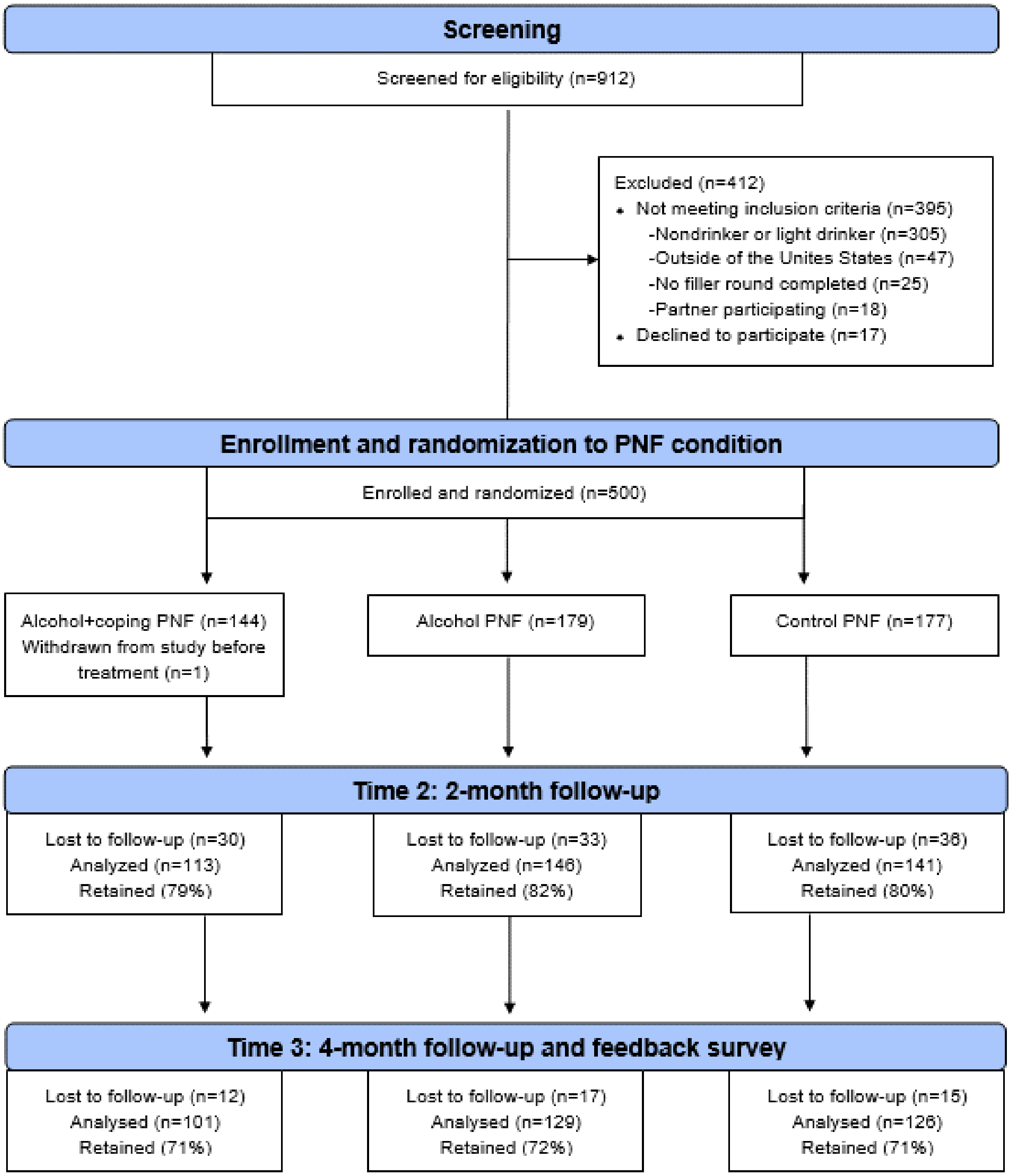
Table 1. Characteristics of LezParlay users (N=2667).

Characteristic	Participants, n (%)
Sexual identity	
Lesbian	1446 (54.22)
Bisexual	669 (25.08)
Queer	562 (21.07)
Age group (years)	
<18	107 (4.01)
18-24	401 (15.04)
25-34	1284 (48.14)
35-44	562 (21.07)
54-65	240 (9)
≥66	80 (3)
Relationship status	
Single	1205 (45.18)
In a relationship	857 (32.13)
Married	455 (17.06)
It’s complicated	161 (6.04)
Device used	
Mobile phone	2266 (84.96)
Tablet	54 (2.02)
Computer	347 (13.01)

Evaluation Study (Randomized Controlled Trial)

The third monthly round of LezParlay inquired about alcohol use and LBQ stigma exposure and served as the screening instrument and baseline assessment (time point [T1]) for the randomized controlled trial (RCT). As players completed this round, a subsample of 500 LBQ drinkers meeting the eligibility criteria were invited to take part in an evaluation study wherein they were incentivized to play subsequent rounds and complete a feedback survey following the competition. A total of 1337 LBQ women completed the round with 912 users covertly screened for eligibility based on their responses to round questions about alcohol use (ie, reporting drinking ≥3 days per week or consuming ≥3 drinks on their heaviest drinking occasion) and other app data (eg, geolocation in the United States, at least one previous round played, and no partner participating) before the 500 spots in the evaluation study were filled. As described in greater detail elsewhere [43], at the point of study enrollment, participants were covertly randomized to receive 1 of 3 sequences of PNF delivered at the end of the third and fourth monthly rounds: alcohol + coping, alcohol + control, or control topics only. Reductions in drinking and negative consequences were assessed 2 (time point 2 [T2], June 2019) and 4 (time point 3 [T3], August 2019) months later. Following completion of a postcompetition feedback survey, participants were debriefed regarding the research questions and the nonrandom nature of the topics on which they received detailed results in 2 of the 8 competition rounds. A CONSORT (Consolidated Standards of Reporting Trials) diagram summarizing the flow of participants through the RCT portion of the trial is presented in Figure 3 (see also Multimedia Appendix 1 for this trial’s CONSORT E-HEALTH checklist). Mirroring the larger user base, the evaluation study drinkers were diverse in terms of their geographic locations, representing 44 US states and 221 different counties and age groups, sexual identities, races, and ethnicities.

Figure 3. Flow of the evaluation showing study participants through screening, enrollment, and follow-ups. PNF: personalized normative feedback. T1: time point 1; T2: time point 2; T3: time point 3.



Ethical Considerations

Human subjects approval for this research was granted by the Loyola Marymount University institutional review board (protocol #LMUIRB2018SU14) on August 14, 2018. All procedures [43] were in accordance with the ethical standards of the US Department of Health and Human Services Office for Human Research.

Measures

Competition Engagement

Data collected by Google Analytics and the application examined the total number of users who signed up to participate in the LezParlay competition and detailed users' average number of logins, number of rounds completed, and most visited areas of the app.

Demographics

All users reported their sexual identity and relationship status at competition sign-up. Age in years, race, and ethnicity were also reported by the evaluation study participants at the point of study enrollment.

Perceived Norms for Alcohol Use and Negative Consequences

Three items modeled after the Quantity, Frequency, Max measure [47] assessed perceived LBQ peer alcohol use norms for the average number of drinks consumed in a typical week (2 items), maximum (or peak) number of drinks consumed on one occasion (1 item), and the number of negative alcohol-related consequences experienced (1 item). The perceived norm for weekly drinks comprised 2 items that prompted users to report their perception of the number of days per week the typical user drank (0-7 days) and the typical user's average number of drinks consumed per drinking day (0 to ≥12 drinks). The product of these 2 items was computed to create a variable indicative of users' perceived norm for weekly drinks. For the peak drinking norm, users reported the typical user's maximum number of drinks consumed on one occasion (0 to ≥12 drinks). To assess the perceived norm for negative consequences, users were presented with a list of 8 negative consequences (eg, had a hangover or illness, got in a physical or verbal fight, had problems with a significant other, missed a social engagement or event, had problems with friends or family, performed poorly at work or school, had problems with money, and had an unwanted or regrettable sexual experience) and were then asked to report the number they thought the typical user experienced due to drinking or partying. At all 3 time points, items assessing norms referenced the previous 2 months, and the sexual identity and age group of the typical user in these questions were piped to match each user's own sexual identity and age group (eg, "Over the past two months, on average, on how many days per week did the typical [lesbian] user in her [30s] drink?").

Own Alcohol Use and Negative Consequences

Users' own weekly drinks, peak drinks on one occasion, and negative consequences in the past 2 months were assessed using items that paralleled norm items (eg, "Over the past two months, on average, on how many days per week did YOU drink?") at the same time points and presented the same response options (ie, 0-7 days; 0 to ≥12 drinks; 0-8 negative consequences).

Interpersonal Stigma Exposure

Interpersonal stigma exposure was assessed at T1 with two items adapted for the in-game context from a widely used measure of sexual minority stigma [48]: (1) "During the past 2 months, how many times have you been physically harmed due to your sexual identity?" (2) "During the past 2 months, how many times have you been verbally harassed or threatened (online or in person) due to your sexual identity?" More than 75% of users' responses were concentrated in the range of 0 to 1. Therefore, items were first recoded to reflect this binary (ie, 0=this did not happen; 1=this happened once or more times) and then summed to produce a score between 0 and 2. This measure was included as a covariate in statistical models evaluating efficacy due to sexual minority status–related violence and harassment being the experiences most consistently linked to alcohol consumption and negative alcohol-related consequences among sexual minority women [13-15].

LezParlay Acceptability

The postcompetition feedback survey prompted study participants to rate numerous aspects of the competition (the stereotype challenge concept, topics and questions, detailed results, leaderboards, the ability to browse player profiles, the ability to submit questions, the ability to bet points on the accuracy of guesses, SMS text messages, and email communications) on Likert-type scales ranging from *did not like at all* (rating=0) to *liked very much* (rating=5). Total acceptability scores were computed by summing the ratings.

LezParlay Perceived Benefits

A single item in the feedback survey asked evaluation study participants to select yes or no in response to the question, "Did you find taking part in LezParlay to be psychologically beneficial?" Those selecting *yes* in response were invited to enter text describing their perceived benefits.

LezParlay Ideas for Improvement

A final free-response question asked evaluation study participants to share any ideas they had for ways in which LezParlay could be improved (ie, "Do you have any ideas for how LezParlay could be improved? What would you like to see in the next version?").

Analysis Plan

Evaluating Feasibility

Descriptive statistics examined the level of engagement with the LezParlay app (ie, total number of sign-ups and average number of rounds played), initial levels of alcohol use among players, competition-derived actual norms for treatment topics, competition acceptability among drinkers taking part in the RCT, and the proportion of drinkers taking part in the RCT reporting perceived psychological benefits. Qualitative responses to items assessing the perceived benefits associated with LezParlay and ideas for improvement were examined using a generic inductive qualitative coding approach [49,50]. This iterative approach is similar to grounded theory but is more commonly used in the program evaluation literature, where the coding objective tends to be summarizing phenomena for basic understanding rather than building theory. As this approach can be prone to reflecting the biases of a single coder, multiple coder perspectives were sought, with a lesbian-identified senior researcher (SCB), a gay male–identified senior researcher (JWL), and 2 heterosexual female research assistants taking part in the coding process. For psychological benefits, coding sought to condense the raw text descriptions submitted by participants into a summary of common benefit categories. First, the 2 senior researchers (SCB and JWL) conducted independent, initial readings of participant responses, with each aiming to identify no more than 10 unique categories of benefits. As responses were generally short, although many described >1 benefit, it was decided a priori that each response could receive up to 3 category classifications. The senior researchers then met, compared categories, agreed upon common category themes, and identified several pairs of categories that were extremely similar and could be condensed into a single category. This process culminated in 6 shared benefit categories. Next, 2 research assistants independently classified all responses according to the 6 categories, with each response coded for a maximum of 3 benefits. Interrater reliability was high (κ=0.91), and discrepancies were resolved through discussion. A similar approach was used to code participants’ ideas for improving LezParlay. However, as the research team only sought to identify the most agreed-upon or frequently submitted ideas for improvement to inform the next version of the app, all 4 coders independently grouped participant responses in terms of similarity. No discrepancies in groupings were observed between coders, and similar responses were tallied for summary purposes.

Evaluating Efficacy

Preliminary analysis of RCT data examined the distributions of alcohol-related variables, the nature of missing data, and the characteristics of participants lost to follow-up (*t* tests). One-way ANOVAs and chi-square tests also established conditional equivalency for demographic characteristics, interpersonal stigma, perceived alcohol use norms, and alcohol use behaviors assessed at T1. Examination of attrition suggested that missingness was random rather than systematic. As such, 3 multilevel models, each with maximum likelihood estimation to deal with data missing at random, a random intercept component, and an unstructured covariance matrix, were conducted in SAS (version 9.4) to assess the effects of treatment PNF (alcohol PNF and alcohol + coping PNF) on respective changes in weekly drinks, peak drinks, and negative consequences relative to control PNF. In all 3 models, predictors included study condition (alcohol PNF and alcohol + coping PNF vs control PNF) and time (T2 and T3 vs T1). To determine whether there were changes in drinking outcomes over time related to PNF treatment, condition × time interaction terms were included in each model. Covariates also included in the models were age, sexual identity (bisexual and queer vs lesbian), race (White vs non-White), ethnicity (non-Hispanic or Latino vs Hispanic or Latino), relationship status (single vs in a relationship or married), and exposure to interpersonal LBQ stigma. Post hoc Tukey tests were then conducted to determine the nature of significant condition × time effects.

Results

Research Question 1: Were LBQ Women Engaged by the LezParlay Competition?

Yes, despite no traditional study incentives being offered at recruitment, sign-up, or initial round completion, 2667 LBQ women signed up and played ≥1 round. Furthermore, the average user logged into the LezParlay app 2 times during the competition following initial sign-up; completed 1.97 rounds; and, on average, spent 4.15 minutes on the app per login (no SDs available). The LezParlay web application also recorded 54,072 total page visits among logged in users, with the most frequented sections of the app devoted to browsing the social media–inspired profiles of other users, followed by playing monthly rounds, viewing detailed results (ie, PNF), and viewing leaderboards.

Research Question 2: Was It Feasible to Derive Risk-Reducing LBQ Actual Drinking Norms From In-Round Questions?

Yes, of the 1337 LezParlay users who completed the round where alcohol use was first assessed, 254 (19%) reported no alcohol consumption or light drinking (≤2 drinks per week), and 346 (25.88%) reported moderate drinking (3-7 drinks per week and ≤3 drinks on any day). Notably, ≤7 drinks per week and ≤3 drinks per day are the upper limits for low-risk drinking among women, as defined by the National Institute on Alcohol Abuse and Alcoholism [51], as these patterns of consumption equate to low risks for alcohol dependence and development of alcohol-related health problems. Higher levels of risk were also well represented in LezParlay, with 55.12% (737/1337) of the users who completed this round consuming ≥8 drinks per week or ≥4 drinks on any day, thereby meeting the National Institute on Alcohol Abuse and Alcoholism’s definition of high-risk drinking [51]. Conferring elevated risks for AUD and alcohol-related health problems, the average number of drinks consumed per week among these users ranged from 8 to 56 drinks, and peak drinks consumed on a day ranged from 4 to ≥12 drinks for the 2-month period referenced in the game questions. However, as LezParlay users were so diverse in their patterns of alcohol consumption, the broader composition of alcohol use among users was sufficient for generating risk-reducing actual norms to deliver to drinkers in the evaluation study. As is typically the case in traditional PNF interventions, the lower levels of consumption among nondrinkers and low-risk drinkers attenuated the higher levels of consumption among high-risk users. Round-derived actual norms featured in treatment PNF are presented in Table 2.

Table 2. Competition-derived actual norms presented in treatment personalized normative feedback.

Norms	Age groups (years)		
	21-29	30-39	≥40
Round 3: alcohol use actual norms[a]	n=627	n=498	n=212
Drinking days per week, mean	2	2	1.5
Drinks per occasion, mean	2.5	2	2
Weekly drinks, mean	5	4	3
Peak drinks on one occasion, mean	4	3	3
Negative consequences, mean	2	1.5	1
Round 4: coping actual norms[a]	n=503	n=414	n=186
Times drank alcohol to cope, %	18	17	16
Time used drugs to cope, %	12	9	9
Times exercised or meditated to cope, %	55	61	49
Times sought social support to cope, %	53	50	62

[a] As no sexual identity differences were observed for alcohol use or coping behaviors, participants received the same age group–specific lesbian, bisexual, and queer actual norms for these topics as a function of condition assignment.

Did PNF on Alcohol Use Delivered Within the Competition Reduce Alcohol-Related Risks Among LBQ Drinkers? Was It More Beneficial to Deliver PNF on Both Drinking and Coping Behaviors Than on Drinking Behaviors Alone?

Retention in the RCT was adequate, with 80.2% (400/499) of the evaluation study participants retained at T2 and 71.3% (356/499) at T3. Participants lost to follow-up were younger (t_{497}=4.48; *P*<.001) and non-Hispanic White (t_{497}=4.13; *P*<.001). Attrition, in this case, was considered random rather than systematic, given that the *average* participant in the study was both younger and non-Hispanic White, and attrition was not significantly associated with any other study variables. Beyond attrition, there were no other missing data among participants. As shown in Table 3, tests of conditional equivalency revealed no significant between-condition differences for any of the variables at baseline.

The results for multilevel models, predicting weekly drinks, peak drinks on one occasion, and negative alcohol-related consequences are presented in Table 4. The condition × time effects in each model were significant, indicating that treatment PNF conditions predicted significant changes in outcomes over time, controlling for baseline covariates (ie, sexual identity, race, ethnicity, age, relationship status, and interpersonal stigma exposure).

As presented in Table 5 and Figure 4, post hoc analyses probing interaction effects for each outcome revealed that participants in both treatment PNF conditions significantly decreased their weekly drinks from T1 to T2 relative to participants receiving PNF on control topics, but significant differences in weekly drinks were retained only at T3 between the alcohol + coping PNF and control PNF conditions. Similarly, both treatment PNF conditions predicted significant decreases in peak drinks consumed from T1 to T2 relative to control PNF; however, only the differences between the alcohol + coping and control PNF conditions met the threshold for significance at T3 (*P*=.06 for alcohol PNF vs control PNF). Finally, participants in both treatment PNF conditions significantly decreased the negative consequences they experienced relative to controls from T1 to T2 and from T2 to T3.

Table 3. Baseline demographics, psychosocial characteristics, drinking norms, and alcohol use of evaluation study participants overall and by condition assignment.

Characteristics	Overall (N=499)	Control PNF[a] (n=177)	Alcohol PNF (n=179)	Alcohol + coping PNF (n=143)
Sexual identity, n (%)				
Lesbian	290 (58.1)	94 (53.1)	108 (60.3)	89 (62.2)
Bisexual	115 (23)	48 (27.1)	39 (21.8)	29 (20.2)
Queer	94 (18.8)	35 (19.8)	32 (17.9)	25 (17.5)
Relationship status, n (%)				
Single	209 (41.9)	80 (45.2)	69 (38.5)	60 (41.9)
Ethnicity, n (%)				
Hispanic/Latino	123 (24.6)	40 (22.6)	46 (25.7)	37 (25.8)
Race, n (%)				
American Indian/Alaskan Native	13 (2.6)	4 (2.3)	5 (2.8)	4 (2.7)
Asian American	39 (7.8)	17 (9.6)	16 (8.9)	6 (4.1)
Black/African American	70 (14)	26 (14.7)	25 (14)	19 (13.2)
Hawaiian/Pacific Islander	1 (0.2)	0 (0)	0 (0)	1 (0.6)
White	268 (53.7)	99 (55.9)	91 (50.8)	78 (54.5)
Multiracial	53 (10.6)	15 (8.5)	23 (12.8)	15 (10.4)
Other	55 (11)	16 (9)	19 (10.6)	14 (20)
Age (years), mean (SD)	29.87 (7.32)	29.47 (7.03)	30.37 (7.75)	29.73 (7.15)
T1[b] interpersonal stigma, mean (SD)	0.61 (0.69)	0.66 (0.69)	0.56 (0.66)	0.62 (0.70)
T1 perceived drinking norms, mean (SD)				
Norm–weekly drinks	13.94 (9.37)	13.84 (9.44)	14.07 (10.35)	13.89 (7.92)
Norm–peak drinks	6.31 (2.18)	6.16 (2.27)	6.36 (2.07)	6.43 (2.20)
Norm–consequences	2.88 (1.74)	2.84 (1.65)	3.01 (1.84)	2.73 (1.72)
T1 alcohol use, mean (SD)				
Weekly drinks	9.15 (7.51)	9.13 (7.90)	8.96 (8.19)	9.43 (6.00)
Peak drinks	5.79 (2.34)	5.74 (2.43)	5.76 (2.37)	5.87 (2.19)
Consequences	2.52 (1.89)	2.45 (1.95)	2.55 (1.86)	2.58 (1.89)

[a] PNF: personalized normative feedback.

[b] T1: time point 1.

Table 4. Multilevel model results for outcomes (weekly drinks, peak drinks, and negative alcohol-related consequences).

Outcomes	Weekly drinks		Peak drinks		Consequences	
	b (SE)	*P* value	b (SE)	*P* value	b (SE)	*P* value
Alcohol PNF[a]	0.41 (0.74)	.58	0.13 (0.22)	.54	0.2 (0.16)	.24
Alcohol + coping PNF (reference: control PNF)	0.14 (0.78)	.86	0.16 (0.23)	.49	0.13 (0.17)	.47
Time 2	0.65 (0.39)	.09	0.19 (0.14)	.19	0.71 (0.12)	<.001
Time 3 (reference: time 1)	−0.50 (0.40)	.22	−0.05 (0.15)	.73	0.64 (0.13)	<.001
Alcohol PNF × time 2	−2.72 (0.54)	<.001	−1.61 (0.20)	<.001	−1.03 (0.18)	<.001
Alcohol PNF × time 3	−1.64 (0.57)	.004	−0.59 (0.21)	.005	−0.90 (0.18)	<.001
Alcohol + coping PNF × time 2	−3.39 (0.58)	<.001	−1.67 (0.22)	<.001	−1.00 (0.19)	<.001
Alcohol + coping PNF × time 3	−2.03 (0.61)	.01	−0.71 (0.23)	.02	−0.98 (0.20)	<.001
Queer	−1.88 (0.78)	.02	−0.29 (0.22)	.19	−0.48 (0.16)	.01
Bisexual (reference: lesbian)	−1.26 (0.72)	.08	0.40 (0.20)	.05	−0.03 (0.15)	.83
Non-White (reference: White)	0.75 (0.65)	.25	0.23 (0.18)	.21	0.51 (0.13)	.001
Hispanic or Latinx (reference: non-Hispanic or Latinx)	−0.68 (0.77)	.38	0.02 (0.22)	.93	−0.28 (0.15)	.07
Age	−0.05 (0.04)	.20	−0.04 (0.01)	.001	−0.04 (0.01)	<.001
Single (reference: coupled or married)	2.30 (0.62)	.002	0.61 (0.18)	.01	0.41 (0.13)	<.001
Interpersonal stigma exposure	1.85 (0.43)	<.001	0.38 (0.12)	.002	0.45 (0.09)	<.001

[a] PNF: personalized normative feedback.

Table 5. Tukey post hoc test results probing PNF[a] condition × time interactions.

PNF condition comparisons	Weekly drinks		Peak drinks		Consequences	
	b (SE)	*P* value	b (SE)	*P* value	b (SE)	*P* value
T1[b]						
Alcohol vs control	−0.41 (0.74)	.58	−0.13 (0.22)	.54	−0.20 (0.16)	.24
Alcohol + coping vs control	−0.14 (0.78)	.86	−0.16 (0.23)	.49	−0.13 (0.17)	.47
Alcohol vs alcohol + coping	0.27 (0.78)	.73	−0.03 (0.23)	.91	0.07 (0.17)	.69
T2[c]						
Alcohol vs control[d]	2.31 (0.77)	.003	1.48 (0.23)	<.001	0.83 (0.18)	<.001
Alcohol + coping vs control[d]	3.25 (0.82)	<.001	1.51 (0.25)	<.001	0.86 (0.19)	<.001
Alcohol vs alcohol + coping	0.94 (0.82)	.25	0.04 (0.25)	.88	0.03 (0.19)	.87
T3[e]						
Alcohol vs control[d]	1.24 (0.79)	.12	0.46 (0.24)	.06	0.70 (0.19)	.002
Alcohol + coping vs control[d]	1.90 (0.84)	.03	0.55 (0.26)	.03	0.86 (0.20)	<.001
Alcohol vs alcohol + coping	0.66 (0.84)	.43	0.10 (0.26)	.71	0.15 (0.20)	.44

[a] PNF: personalized normative feedback.

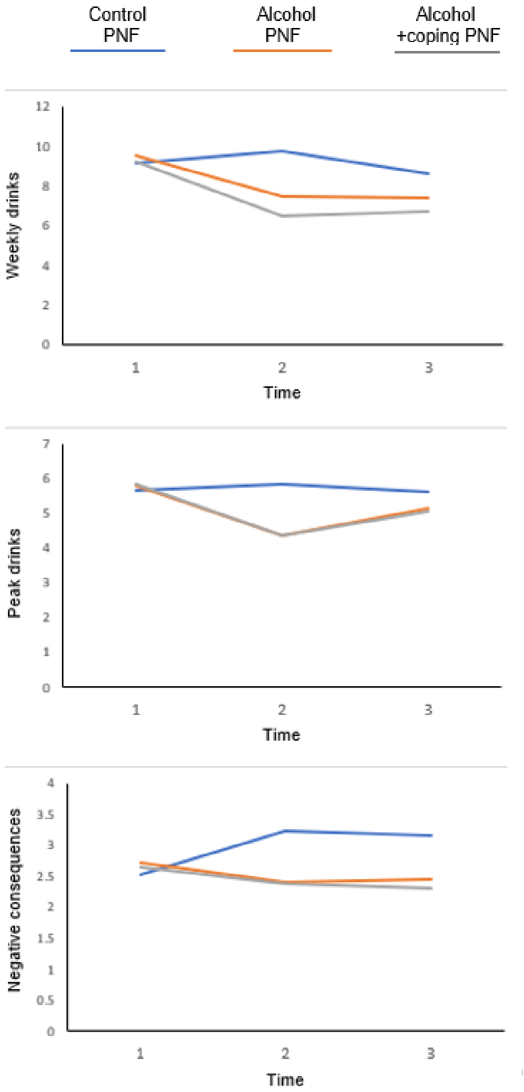
[b] T1: time point 1.

[c] T2: time point 2.

[d] Across outcomes, Cohen *d* effect size estimates for significant treatment versus control comparisons ranged from 0.20 to 0.33 at T2 and 0.12 to 0.22 at T3.

[e] T3: time point 3.

Figure 4. Personalized normative feedback (PNF) condition as a function of time for each outcome.



Did LBQ Drinkers Find the Competition Acceptable and Psychologically Beneficial? What Ideas for Improvements Did They Submit?

Overall, drinkers in the evaluation study found the LezParlay competition to be highly acceptable, with the average participant rating competition aspects between *liked* and *liked very much* (mean 41.26, SD 3.84; out of a maximum score of 50). Table 6 presents descriptive statistics for individual acceptability items. Notably, the highest-rated aspect was *receiving detailed results each round* (mean 4.51, SD 0.56). The exploratory 1-way ANOVA and correlational analyses also determined that acceptability ratings were not significantly associated with participants' study condition ($F_{2,355}$=0.41, P=.67) or baseline measures of alcohol outcomes (r ranged from 0.02 to 0.04; P ranged from .64 to .68).

Of the 356 participants who completed the feedback survey, 331 (93%) reported finding the LezParlay competition to be psychologically beneficial. Furthermore, 85.5% (283/331) of the participants that indicated benefits entered text to describe the experienced benefits. Qualitative coding resulted in 6 common categories of benefits reported by participants: knowledge and social comparison, community connection and identity strength, stigma reduction, introspection and self-confrontation, entertainment and fun, and mood enhancement. Table 7 presents the proportion of total responses that reflected each benefit category and representative responses of benefits in each category.

Notably, although benefits associated with social comparison and self-confrontation in the domain of drinking may be experienced in a traditional PNF alcohol intervention, benefits associated with community connection and identity strength, stigma reduction, entertainment, and enhanced mood and outlook would not be experienced in the context of traditional PNF. Presumably, these extra psychological benefits described by participants were related to LezParlay's social media–inspired web-based community features, the broad challenging of negative LBQ stereotypes via PNF, and the competition-fostering constellation of game mechanics.

In response to the optional item inquiring as to how LezParlay could be improved, 47.5% (169/356) of participants submitted a total of 307 individual ideas for improvement. The most frequently submitted ideas revealed that participants most commonly desired a native (iOS and Android) smartphone app for the competition (112/307, 36.5%); more frequent rounds (eg, weekly rather than monthly) with faster results delivery (74/307, 24.1%); increased opportunity for interaction between players (eg, a chat feature or direct messaging that could be turned on and off; 43/307, 14%); increased ease of inviting friends and the ability to earn bonus points for referring friends (24/307, 7.8%); the ability to go back and change previously submitted guesses or point wagers before a round closing (12/307, 3.9%); the connection of results to informational articles or community resources (11/307, 3.6%); additional questions about race, gender identity, and sexual identity–based biases within the community (9/307, 2.9%); worldwide promotion and additional results comparing the behaviors and experiences of LBQ players in different countries or regions (4/307, 1.3%); and the ability to see the community thumbnail photo collage of LBQ users being guessed about on the *guess question* screen rather than on a previous screen (4/307, 1.3%).

Table 6. LezParlay competition acceptability ratings by item (N=356).

Acceptability item	Rating, mean (SD)[a]
The “stereotype challenge” concept	4.37 (0.56)
The topics and questions	4.01 (0.56)
Receiving the detailed results each round	4.51 (0.56)
Browsing players profiles	3.62 (0.66)
Submitting and voting on questions	3.95 (0.59)
Betting points on your guesses being correct	4.34 (0.62)
Receiving SMS text message reminders	4.12 (0.58)
Receiving email reminders	4.27 (0.50)
Viewing the top scorer leaderboards	3.89 (0.60)
Competing for money and receiving gift cards	4.09 (0.55)

[a] Response options ranged from 1=disliked very much to 5=liked very much.

Table 7. Categories of psychological benefits described by participants and representative responses (n=283).

Benefit category	Total, n (%)	Representative responses and user characteristics
Knowledge and social comparison	184 (65)	• “I work at an LGBTQ community center and it really helped having data to influence our programs and identify topics/issues to discuss in our women's group meetings.” [Queer, 41 years] • “Let me learn more about the lgbtq community and see that I drink way more than average lol fail” [Lesbian, 38 years]
Community connection and identity strength	96 (33.9)	• “Being in my 50s and feeling sort of invisible these days this competition really helped me feel connected to something again” [Lesbian, 52 years] • “It was so great for me although it's hard to describe how/why exactly...felt connected and in the know...also felt more confident and secure in my identity.” [Queer, 25 years]
Stigma reduction	88 (31)	• “This really helped me reduce biases that I had internalized without even realizing it!” [Queer, 26 years] • “Cool to see that some of the negative ways we get portrayed in the media are totally off.” [Lesbian, 36 years]
Introspection and self-confrontation	66 (23.3)	• “This really helped me see that I need to get my shit together in several areas” [Lesbian, 33 years] • “Made me question some of my own tendencies and behaviors. Came to see that I was doing what I thought everyone else was doing which wasn't even the truth...” [Lesbian, 28 years]
Funa and entertainment	54 (19)	• “Loved the competition, betting, prizes, and leaderboards... so so fun” [Lesbian, 51 years] • “It was so fun and I was able to get my lesbian roommate to play with me...we got super competitive about scores and had a blast!” [Bisexual, 37 years]
Mood and outlook enhancement	40 (14.1)	• “...helped my mental health and gave me a more positive outlook on all things queer.” [Queer, 29 years] • “It was a source of enjoyment. Getting the results always put me in such a good mood...even when I was wrong about stuff...” [Lesbian, 23 years]

Discussion

Principal Findings

LezParlay leveraged gamification and deep cultural adaptations to deliver a PNF alcohol intervention to LBQ women, a difficult-to-engage population for whom alcohol-related risks are high, but efficacious evidence-based intervention and prevention programs are lacking [3,52]. Reflecting the widespread appeal and cost-efficacy afforded by LezParlay's framing as a competition designed to challenge negative LBQ stereotypes, a very large and diverse group of LBQ women signed up to take part in the competition despite the lack of traditional study incentives being offered for sign-up or initial round play. Furthermore, more than half of the LBQ users who completed the round in which alcohol use was first assessed exceeded established drinking guidelines for women and thus were an ideal population for PNF intervention. LBQ women taking part in LezParlay substantially overestimated LBQ-specific peer norms for drinking, experiencing negative consequences, and engaging in maladaptive coping behaviors in response to stress and stigma consistent with previous survey study findings [16-19]. In summary, the markedly lower levels of consumption among alcohol abstainers and low-risk drinkers also taking part in the round attenuated the levels of consumption among heavier drinkers, allowing risk-reducing actual drinking norms (presented in PNF) to be organically generated in real time from users' round data.

This novel approach to PNF intervention also demonstrated efficacy in reducing drinking and its negative consequences. Relative to LBQ drinkers randomized to receive PNF on control topics in the competition, those who received treatment PNF on drinking or both drinking and coping similarly and substantially reduced their weekly drinks, peak drinks consumed on one occasion, and number of negative consequences 2 months later. For these outcomes, effect sizes associated with LezParlay treatment arms at the 2-month follow-up were consistent with or exceeded the short-term effects associated with treatment arms of traditional, remotely delivered PNF alcohol interventions in other populations [53-55]. Thus, in the short term, the impact of additional treatment PNF on coping behaviors beyond alcohol PNF was negligible. However, at the 4-month follow-up, relative to control PNF, the reductions in quantity of consumption outcomes (ie, weekly drinks and peak drinks) associated with the alcohol-only PNF condition faded, whereas they remained relatively robust in the alcohol + coping condition. There are 2 potential explanations for this finding. First, as previous research has found drinking to cope to be a strong overall predictor of alcohol consumption among LBQ women [56,57], correcting LBQ coping norms may have changed participants' own coping behaviors to be more adaptive, which, with passing time, impacted alcohol use outcomes. However, given the design of this trial, wherein coping PNF corrected norms for coping-motivated drinking (among other behaviors) and was delivered 1 month following the initial treatment PNF on alcohol use, it is possible that coping PNF had little effect on participants' subsequent coping behaviors. Rather, the portion of coping PNF that corrected norms for coping-motivated drinking may have acted as a broader *booster* to alcohol PNF, further reinforcing the idea that LBQ peers do not drink as much as one previously thought. Thus, although efficacy findings from this initial trial are promising and suggest that both alcohol and coping PNF are beneficial, additional research will be needed to fully understand the mechanisms (ie, correcting coping norms or reinforcing actual alcohol use norms) by which coping PNF influences drinking in this population.

In addition to being a feasible and effective means of delivering PNF to this population, LBQ drinkers also found the LezParlay competition to be both highly acceptable and psychologically beneficial. Notably, the detailed results (ie, PNF) were the most liked aspect of LezParlay, and ratings were not significantly associated with study condition or baseline alcohol consumption. Thus, those receiving fewer and more health-related results as a function of condition and those entering the study as lighter and heavier drinkers similarly enjoyed receiving the PNF delivered. These findings suggest that future versions of the competition might also correct additional types of alcohol and coping-related norms or expand the topics on which PNF is delivered to other areas of physical and mental health without detracting from acceptability or engagement. Most participants also reported that they psychologically benefited from taking part in the competition, and descriptions of benefits reflected learning and social comparison, community connection and identity strength, stigma reduction, enhanced mood or outlook, and entertainment. Many of these benefits map onto LezParlay's social media–inspired web-based community features, the constellation of game mechanics, and the broad challenging of negative LBQ stereotypes and, importantly, extend far beyond the psychological benefits associated with traditional PNF alcohol interventions. Finally, participants submitted several actionable ideas for ways in which the LezParlay app, user experience, and competition format could be improved. These insights will inform the next version of LezParlay.

Implications for Intervention Research and Practice

To date, alcohol interventions developed for sexual minorities have tended to be clinical, intensive, and focused on affirming sexual identities, aiding individuals in understanding sexual minority stress processes, and providing resources to help individuals cope with stigma more adaptively [52,58,59]. Although these approaches hold much promise for individuals seeking treatment, other findings suggest that the central and highly visible positions that bars and nightclubs occupy in sexual minority communities may diminish community members' recognition of their heavy drinking as problematic and motivation to change, thereby deterring or delaying treatment seeking [60-62]. However, very few, if any, previous evidence-based interventions have been designed to motivate reductions in drinking among sexual minorities who do not view their drinking as problematic or experience other barriers to intensive treatment programs. To our knowledge, this study is the first to demonstrate that correcting sexual minority–specific drinking and coping norms via PNF is effective in reducing drinking in a sexual minority population. Although more research is needed, these findings suggest that the impact of PNF is not diminished by violence and harassment due to sexual minority status and that this approach may similarly reduce alcohol-related risks in other populations of sexual minority adolescents and adults. Importantly, for LBQ women, this gamified, incognito, brief intervention also provides a valuable complement to more intensive programs being developed to meet the needs of self-aware LBQ women already motivated to reduce their consumption [7] and those seeking culturally tailored treatment for AUD and comorbid mental health problems [8].

The present findings also bring clarity to confusion in the substance use literature around the appropriateness and utility of social norms interventions for health disparity populations [18]. For instance, because it is well-known that LBQ women disproportionately drink and experience consequences relative to heterosexual women, there is often confusion as to whether delivering PNF on LBQ-specific actual alcohol use norms would have the effect of increasing or reducing drinking. As evident from this trial's findings, increasing drinking should not be a concern with this approach to the extent that LBQ women overestimate the drinking of other LBQ women; that is, similar to college students known to drink disproportionately drink relative to noncollege students and military populations known to drink more than their civilian peers, PNF reduces alcohol use in these heavy drinking populations despite disparate out-group comparisons. This type of intervention is effective because perceived in-group drinking norms are both highly relevant to the self and substantially overestimated.

This study's feasibility findings also provide an innovative answer to challenges related to reaching and engaging stigmatized minority populations with PNF in the real world. LezParlay delivered the core components of a PNF intervention within a fun, culturally tailored digital competition designed to challenge negative stereotypes about the target population. This gamified, incognito intervention approach was found to be highly engaging, acceptable, and psychologically beneficial among alcohol-consuming LBQ women and meaningfully reduced their alcohol-related risks. Although more research is needed, the stereotype challenge concept, along with the injection of established game mechanics and cultural themes, may have similar utility in reaching other high-risk stigmatized minority groups with PNF on drinking and other health risk behaviors. Finally, looking past PNF, findings from this study also suggest that challenging negative identity-related stereotypes and including web-based community features may also prove fruitful in minority, stress-informed digital health and mental health programs targeting internalized stigma, loneliness, and isolation [8,63,64].

Limitations and Future Directions

As the initial step in a new direction for alcohol intervention development, the key limitations associated with this study include the relatively short duration of the follow-up period, organic assessment of baseline and follow-up alcohol outcomes within rounds of the competition at T1 and T2, and assessment of acceptability and psychological benefits only among LBQ drinkers involved in the RCT. Thus, future evaluation efforts should follow participants for a longer duration (6-24 months), incorporate survey-based baseline and follow-up assessments, and examine the acceptability and psychological benefits among nondrinkers and other LBQ players not involved in the efficacy portion of the trial. An additional limitation to be remedied in future research is this trial's lack of an assessment-only control condition. Although randomizing participants to receive PNF on either treatment or control topics, as was done in this study, reflects the gold standard trial design in the PNF intervention literature, it may not be optimal when PNF is delivered within a culturally tailored digital competition focused on challenging negative group stereotypes. That is, participants in all 3 PNF conditions described unanticipated, far-reaching psychological benefits associated with broader participation in the competition, including stigma reduction, community connection, and identity strength. As these factors are theorized to diminish the degree to which sexual minority stress negatively impacts health risk behavior [65,66], it is possible that they alone may have reduced drinking across PNF conditions to some degree. To fully determine the impact of the LezParlay competition app as an alcohol intervention strategy, it will be important for future trials to also include an assessment-only control group with no exposure to PNF or the competition app. Future trials using such an expanded design should examine internalized stigma, LBQ identity strength, and community connection, in addition to perceived norms for treatment topics as potential mediators of conditional effects on drinking and negative consequences. Similarly, it will also be important to examine internalized, structural, and interpersonal forms of sexual minority stigma as potential moderators of direct and indirect effects.

Although this efficacious initial version of LezParlay was a standalone intervention focused exclusively on correcting descriptive drinking and coping norms, exciting directions for future research also lie in the prospect of incorporating additional components to further reduce alcohol-related risks and increase wellness more broadly. For example, future research may seek to evaluate the utility of including a judgment-based reflective injunctive alcohol normative feedback component that builds on promising pilot findings among college students [41]. The competition's multiround format also provides a natural environment for examining the utility of PNF on dynamic or *trending* health-related norms [67,68] focused on group-based changes in behavior or attitudes over time. Furthermore, the competition's ability to attract and engage LBQ women in the absence of traditional study incentives also suggests that it could play a future role in implementing more intensive health interventions that have found it difficult to engage this population [36]. Thus, another important direction for future research is to examine the degree to which LezParlay could fruitfully serve to attract LBQ women and motivate behavior change as part of a larger multicomponent intervention targeting multiple health behaviors. For instance, within the competition, PNF could target additional health behaviors, and after motivating behavior change through norms correction, the app could link at-risk users to intensive web-based intervention components or local health promotion programs that correspond to these behaviors.

Conclusions

The results of this hybrid trial provide initial support for the feasibility and efficacy of LezParlay as a culturally tailored, gamified, PNF alcohol intervention for LBQ women, thereby narrowing costly disparities in alcohol intervention research and practice. The reductions in alcohol use and negative consequences associated with PNF on drinking and coping delivered within LezParlay demonstrate the utility of PNF as an alcohol intervention strategy for a stigmatized minority health disparity population. These findings should behoove substance use researchers developing interventions for sexual minorities to consider such sexual identity–specific peer norms as potential intervention targets. Furthermore, to overcome engagement challenges associated with delivering PNF to non–treatment-seeking members of stigmatized minority groups and broaden the psychological benefits associated with this strategy, the findings underscore the value of packaging PNF within a broader culturally tailored competition designed to challenge negative group stereotypes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 25450 KB-Multimedia Appendix 1]

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Abbreviations

AUD: alcohol use disorder
CONSORT: Consolidated Standards of Reporting Trials
LBQ: lesbian, bisexual, and queer
PNF: personalized normative feedback
RCT: randomized controlled trial
T1: time point 1
T2: time point 2
T3: time point 3

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Viewpoint

Improving Research Patient Data Repositories From a Health Data Industry Viewpoint

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Abstract

Organizational, administrative, and educational challenges in establishing and sustaining biomedical data science infrastructures lead to the inefficient use of Research Patient Data Repositories (RPDRs). The challenges, including but not limited to deployment, sustainability, cost optimization, collaboration, governance, security, rapid response, reliability, stability, scalability, and convenience, restrict each other and may not be naturally alleviated through traditional hardware upgrades or protocol enhancements. This article attempts to borrow data science thinking and practices in the business realm, which we call the data industry viewpoint, to improve RPDRs.

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KEYWORDS

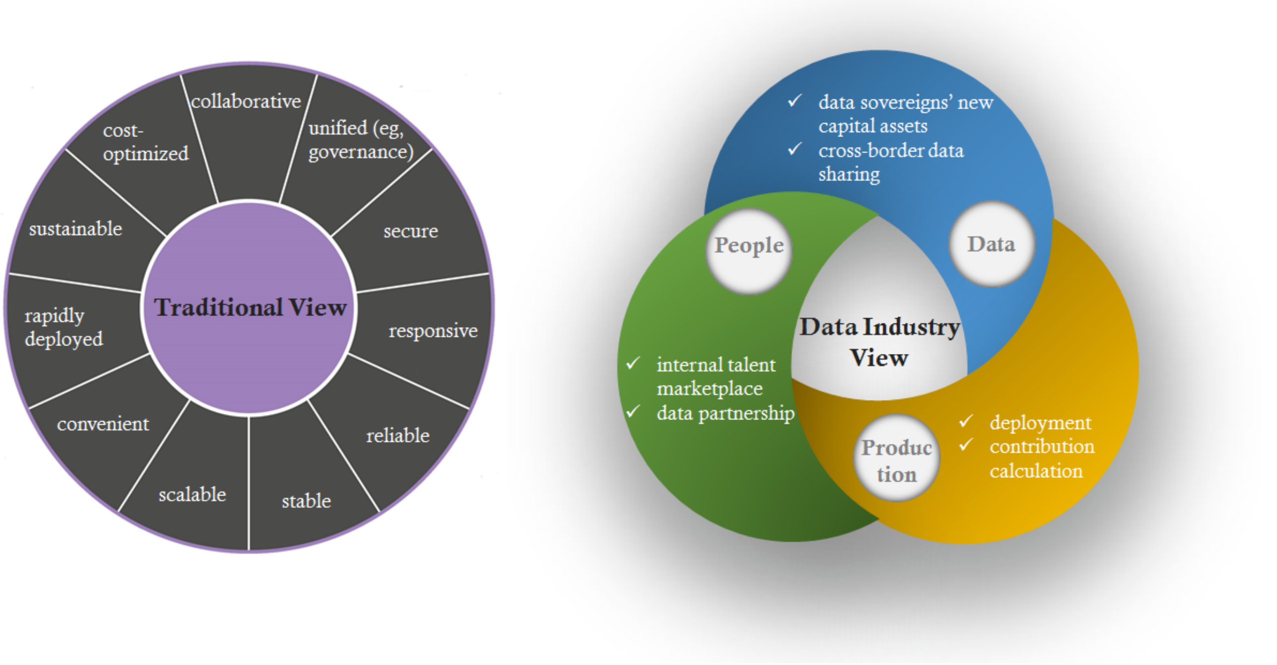
data science; big data; data mining; data warehousing; information storage and retrieval

Introduction

Research Patient Data Repositories (RPDRs, eg, Integrating Biology & the Bedside [i2b2]) and their rapid organic evolution are critical to linking disparate and high-dimensional patient data for a wide range of applications in research. One goal for RPDRs’ evolution in clinical and translational science is to subsume biomedical data science infrastructures and infrastructural health data science [1,2], such as rapid pharmacovigilance [3] and the delivery of real-world evidence at the point of care to actualize the learning health care system [4]. The path to achieving this goal may be tortuous since problems may not emerge until fundamental issues are resolved. Biomedical data science aims to use data technology of any kind to advance medical society as a transdisciplinary ecosystem [4,5] by unifying different disciplines beyond their traditional boundaries to address a common problem. The complexity of the data science ecosystem increases the difficulty of improving RPDRs. Improving RPDRs, therefore, requires a wide variety of new functions and capabilities in the administrative, organizational, and educational areas, including data integration, management, education, support, tooling, governance, optimization, and alignment across missions [3,6].

The effort to establish and sustain biomedical data science infrastructures would benefit if it borrowed thinking and best practices from the data industry [7]. Data industry thinking includes perspectives on data-driven research, innovation, industrialization, and opportunities. We hypothesize that data industry thinking may reshape prevailing views of how people interact with data value and data production in the context of RPDRs (Figure 1).

Figure 1. Comparison between traditional and data industry viewpoints of Research Patient Data Repositories.



Data Production: Deployment Challenges and Contribution Calculations

Data production involves the generation, storage, and curation of data from data-centric human (social, economic, and scientific) activities. Intuitively speaking, it is the process of combining various analyzable data inputs for consumption. The consumption process starts with incoming raw materials used for the preparation of semifinished (eg, pretrained word embeddings) and finished data products (eg, a service). The raw data and data products are "nonrivalrous" in nature, meaning they can be used by multiple users at once without depletion of the resource. Data products can act as reusable resources [8], assets [9], or capital [10] to accelerate research.

When considering data production in RPDRs, some previously unseen problems may arise, such as deployment. Campion Jr et al [11] reported that deployment challenges are widespread in the existing RPDRs: "a number of tools commonly but not uniformly implemented"; for example, i2b2 enables investigators to obtain deidentified patient counts without SQL programming [12]. Many incorrectly think of deploying a data science or analytical model as the last stage of the process. Starting with the algorithm first, and only at the end of the project thinking about how to insert it into the process, is where many deployments fail [13]. Scientists can readily interact with RPDRs to access the underlying electronic health record (EHR) data. RPDRs should additionally provide a solution for fully and successfully implementing analytical and artificial intelligence models from experimentation to production. The first tools to consider to mitigate deployment challenges are tools for handling structured and unstructured EHR data, such as exploratory analysis and data self-governance tools. Exploratory data analysis is an important data industry best practice step focused on gaining insights from raw data prior to training learning models. Exploratory analysis tools that go beyond basic initial data analysis tasks (like SQL programming, ie, sort, filter, aggregate, correlate, group, derive attributes) are essential for handling tasks that previously were manual, heuristic-based, or simply impossible [14]. The transformation of unstructured clinical notes which contain summaries (eg, history of present illness) that describe and illustrate the longitudinal course of specific clinical events or situations experienced by patients into an appropriate data representation (eg, annotated corpus of pretrained word embeddings or a hierarchical representation with multiple levels of granularity) can offer RPDRs enhanced machine intelligence for downstream analysis and reduce duplicated preprocessing efforts to make this data computable [15]. Data self-governance models like Databox [16] can support data sharing that meets study eligibility criteria documented in RPDRs. These default tools can be customized as digital "errand runners" [17] to replace deeply occupational tasks that are tedious, time-consuming, and not artistic.

Data product sharing should be encouraged by the data sovereigns of RPDRs [18], including cross-border data flows. Multilevel data products, such as models, code, intermediate results, annotated training corpora, enclaves, experimental findings, presentations, preprints, and retrieved literature citations can be found throughout the entire life cycle of medical research and are helpful for accelerating complementary efforts. We recommend transplanting contribution margin–based pricing from the data industry to RPDRs to facilitate data sharing. These contributions include but are not limited to reuse frequency, shareable integrity, quantity versus speed in question and answer responses, and compliance practices. Contribution calculations can support employee engagement in the RPDR community and serve as an accelerator for scientific discovery.

People: Internal Talent Marketplace and Data Partnerships

We suggest that RPDR processes and structures be optimized based on the organizational structure, how stakeholder power is exercised, how stakeholders communicate their needs, how decisions are made, and how decision-makers are held accountable. Data production relies on the efforts of a community of interdisciplinary users, including data scientists, enterprise information technology personnel, clinicians, researchers, informaticists, data engineers, data analysts, annotators, and other data product enhancers. The data partnerships' teams rely on an organization's brand to undertake and complete data production. These teams can freely use RPDR data within organizations, and products or services carried out by these teams will be shared within the company. When the velocity of data partnerships in a market exceeds that of an organization, inefficiencies will cause the organization to lose competitive advantages. As markets evolve, an organization will inevitably choose to focus on cost (ie, replacing human labor with machines) or evolve their organizational structure. Flattening the organizational hierarchy so that people can work together “more equally” will lead to increased efficiencies from equitable data partnerships and the rise of the internal talent marketplace. As an upgraded version of a “principal investigator,” a data partnership might not just rely on grants but also on contributions. In essence, the organization has evolved into a market with relatively small competition. Crowdsourcing within an organization is an alternative for these teams to achieve their goals and with it, the rise of the internal talent marketplace is achieved. The internal talent marketplace takes advantage of the increased flexibility of the gig economy and marketplace-based platforms without requiring changes to employment categories. It matches internal employees and, in some cases, a pool of contingent workers to short-term projects and work. Thus, under ideal next-generation RPDRs, these trends among employees can result in collaborative translational medicine by maintaining an innovation ecosystem through teamwork, trust, reliability, and collaboration.

Conclusions

Best practices in RPDRs tend to focus on core infrastructural and methodological needs, such as machine-readable standards, data access platforms, search and discoverability, claim validation, and insight generation [19]; we argue that the complementary data industry viewpoint is relevant and apposite. From this point of view, RPDRs must consider production deployment and contribution calculations, the establishment of internal talent marketplaces and data partnerships, as well as data sovereigns’ new capital assets and cross-border data sharing, as they reveal issues that are not typically addressed. Only with innovative deployed tools, the wide availability and use of diverse data products, and achievable foresight will the future of ideal next-generation RPDRs be truly accessible.

Authors' Contributions

All authors provided substantial contributions to paper conception and edits and approved the final version of the manuscript.

Conflicts of Interest

JP reports receiving personal fees from Summary Medical Inc and DispatchHealth and equity from Summary Medical Inc outside the submitted work. DB reports receiving grants and personal fees from EarlySense, personal fees from CDI Negev, equity from Valera Health, equity from CLEW Medical, equity from MDClone, personal fees and equity from AESOP, personal fees and equity from FeelBetter, and grants from IBM Watson Health, outside the submitted work.

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Abbreviations

EHR: electronic health record
RPDR: Research Patient Data Repositories

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