Contents

Review

Benefits of Digital Health Resources for Substance Use Concerns in Women: Scoping Review (e25952)
Lena Quilty, Branka Agic, Michelle Coombs, Betty-Lou Kristy, Jill Shakespeare, Adrienne Spafford, Reena Besa, Shadini Dematagoda, Alina Patel, Rebecca Persaud, Leslie Buckley ................................................................. 2

Original Papers

Factors Predicting Trial Engagement, Treatment Satisfaction, and Health-Related Quality of Life During a Web-Based Treatment and Social Networking Trial for Binge Drinking and Depression in Young Adults: Secondary Analysis of a Randomized Controlled Trial (e23986)
Samineh Sanatkar, Milena Heinsch, Peter Baldwin, Mark Rubin, Jenny Geddes, Sally Hunt, Amanda Baker, Kathryn Woodcock, Terry Lewin, Kathleen Brady, Mark Deady, Louise Thornton, Maree Teesson, Frances Kay-Lambkin ......................................................... 15

Design and Implementation of an Informatics Infrastructure for Standardized Data Acquisition, Transfer, Storage, and Export in Psychiatric Clinical Routine: Feasibility Study (e26681)
Rogério Blitz, Michael Storck, Bernhard Baune, Martin Dugas, Nils Opel ............................................................................. 28

Needs and Experiences of Users of Digital Navigation Tools for Mental Health Treatment and Supportive Services: Survey Study (e27022)
Elizabeth Stafford, Teri Brister, Ken Duckworth, Natali Rauseo-Ricupero, Sarah Lagan ................................................................. 46
Benefits of Digital Health Resources for Substance Use Concerns in Women: Scoping Review

Lena Quilty1,2, PhD; Branka Agic1,2, MD, PhD; Michelle Coombs3, PhD; Betty-Lou Kristy4; Jill Shakespeare1, MSW; Adrienne Spafford5, BCom; Reena Besa1, MLS; Shadini Dematagoda1, BSc; Alina Patel1,2, MA; Rebecca Persaud1, BSc; Leslie Buckley1,2, MD, MPH

1Centre for Addiction and Mental Health, Toronto, ON, Canada
2University of Toronto, Toronto, ON, Canada
3The Jean Tweed Treatment Centre, Toronto, ON, Canada
4Centre for Innovation in Peer Support, Support House, Oakville, ON, Canada
5Addictions and Mental Health Ontario, Toronto, ON, Canada

Corresponding Author:
Lena Quilty, PhD
Centre for Addiction and Mental Health
1025 Queen Street West
Toronto, ON, M6J 1H1
Canada
Phone: 1 4165358501
Email: Lena.Quilty@camh.ca

Abstract

Background: Digital health resources are being increasingly used to support women with substance use concerns. Although empirical research has demonstrated that these resources have promise, the available evidence for their benefit in women requires further investigation. Evidence supports the capacity of interventions that are sex-, gender-, and trauma-informed to improve treatment access and outcomes and to reduce health system challenges and disparities. Indeed, both sex- and gender-specific approaches are critical to improve health and gender equity. Violence and trauma are frequent among those with substance use concerns, but they disproportionately affect those who identify as female or women, further underscoring the need for trauma-informed care as well.

Objective: The objective of this investigation was to evaluate the evidence supporting the efficacy or effectiveness of online or mobile interventions for risky or harmful substance use in adults who identify as female or women, or who report a history of trauma.

Methods: This scoping review is based on an academic search in MEDLINE, APA PsycINFO, Embase, Cochrane Central, and CINAHL, as well as a grey literature search in US and Canadian government and funding agency websites. Of the 7807 records identified, 465 remained following title and abstract screening. Of these, 159 met all eligibility criteria and were reviewed and synthesized.

Results: The 159 records reflected 141 distinct studies and 125 distinct interventions. Investigations and the interventions evaluated predominantly focused on alcohol use or general substance use. Evaluated digital health resources included multisession and brief-session interventions, with a wide range of therapeutic elements. Multisession online and mobile interventions exhibited beneficial effects in 86.1% (105/122) of studies. Single-session interventions similarly demonstrated beneficial effects in 64.2% (43/67) of study conditions. Most investigations did not assess gender identity or conduct sex- or gender-based analyses. Only 13 investigations that included trauma were identified.

Conclusions: Despite the overall promise of digital health interventions for substance use concerns, direct or quantitative evidence on the efficacy or effectiveness of interventions in females or women specifically is weak.

(JMIR Ment Health 2021;8(6):e25952) doi:10.2196/25952
KEYWORDS
women; female; gender-specific; digital health; internet; mobile app; technology; technology interventions; technology-based intervention; web-based intervention; substance use concerns; trauma

Introduction

Background
Despite the higher prevalence of substance misuse and substance use disorders in men compared with women, a substantial proportion of women do experience harms associated with substance use. Moreover, research suggests that substance use and associated harms have been increasing in women over time. For example, the frequency and volume of alcohol use in women increased substantially from the 2000s to 2010s [1,2]. Cannabis use has exhibited an increase over even shorter time periods, and recent estimates suggest that 10% of women in Canada self-reported having a dependence on some form of illicit drug [1,3]. Substance use in women is further associated with staggering personal and societal costs. In particular, it is strongly linked to mental health concerns, including depression and suicidal thoughts and behaviors [4], as well as physical health concerns, including morbidity and mortality [5]. Substance misuse has associated health impacts on maternal health, fetal and neonatal morbidity, prematurity, and small for gestational age. It also leads to parenting deficits related to psychological and environmental concerns [6,7]. Overall, societal costs associated with substance use are widespread and growing, as illustrated by increasing hospitalizations due to substance use [8] and increasing loss in productivity, which is estimated to be over Can $15 billion [7].

Sex-, Gender-, and Trauma-Informed Supports for Substance Use Concerns

Despite an increase in substance use among women, women are generally underrepresented in treatment settings [9]. Research has suggested that women are less inclined to seek treatment until negative consequences become severe [10,11]. Additionally, research has demonstrated that women experience specific barriers to care, from psychological barriers, such as stigma and discrimination, to practical barriers, such as decreased opportunity due to caregiving roles and responsibilities, relationship abuse and violence, etc [12]. Women are more likely to be principal caregivers to children and other family members, and concerns regarding the potential involvement of child protection services or other social services as a result of seeking support can be a particularly powerful deterrent. These barriers can thus delay treatment seeking, such that women presenting to specialized services exhibit both acute and complex needs to impact both treatment engagement and outcomes.

Evidence supports the capacity of interventions that are sex-, gender-, and trauma-informed to improve treatment access and outcomes and to reduce health system challenges and disparities. Indeed, both sex- and gender-specific approaches are critical to improve health and gender equity, attending to the biological factors that impact the response to substances and biological treatments, as well as the gendered experiences of substance use challenges and their management [13]. Trauma is critical to consider in this context. While specifics may vary, trauma is generally defined as an emotional consequence of a deeply distressing or disturbing event [14] that has overcome an individual’s ability to cope [13]. An elevated prevalence of substance use among those with a history of trauma supports a strong overall association between trauma exposure and substance misuse [15]. Strikingly, 75% of women and more than 25% of men who enter treatment for substance use disorders report histories of abuse and trauma [15-17]. Those with a history of trauma have been shown to experience more complications in treatment for substance use disorders, with higher levels of distress, lower treatment adherence, and longer courses, when compared with those without a history of trauma [18]. Despite high prevalence rates and significant implications, trauma is not frequently assessed or addressed in the treatment of substance use disorders [19]. Thus, although trauma and substance use concerns frequently co-occur, adults who identify as female or women are disproportionately affected by trauma and the impact of trauma on care. This health disparity further underscores the need for sex-, gender-, and trauma-informed interventions.

Current evidence-based best practice guidelines have therefore highlighted the importance of gender- and trauma-informed treatments for substance use concerns in women. Gender-informed practices include integrated treatment approaches addressing a wide range of women’s needs (eg, physical, social, and mental health needs, and child-centered services such as prenatal services, parenting programs, and child care) and are associated with improvements in recovery, parenting skills, and emotional health [20]. Trauma-informed practices, in turn, follow the principles of trauma awareness/acknowledgment; maintaining trust and safety; promoting choice and collaboration; maintaining focus on strength/skills building; attending to cultural, historical, and gender issues such as intimate partner violence; peer support; and mutual self-help. Trauma-informed care is also associated with improved service user experiences and clinical outcomes [21].

It is notable then that the gender- and trauma-informed practices most appropriate to women with substance use difficulties primarily comprise integrated psychosocial interventions, most commonly provided in-person and in group formats. Yet, in many jurisdictions, this model of care delivery is not possible to maintain during the COVID-19 global pandemic. Similar to other health care settings, substance use treatment centers serving women are increasingly turning to digital health solutions to provide support, particularly while physical distancing measures are necessary to protect public health. Digital health solutions may in fact overcome numerous barriers to care experienced by women and provide a valuable addition to the health system even beyond the current crisis.

In a recent review, Nesvåg and McKay [22] evaluated the feasibility and therapeutic benefits of digital interventions to...
prevent and treat substance use concerns. This review located 28 unique interventions, which were categorized as simple or complex based on the number of features. Simple interventions were generally mobile apps integrated within other services and supports, whereas complex interventions were more frequently delivered as stand-alone interventions, using a personal computer and/or a mobile app format. A large proportion of participants (70%-90%) found the interventions to be useful, and more than half of the studies found small to medium positive effects in comparison to a control group. This review supported the feasibility of digital health resources for substance use concerns, but found less consistent support for their efficacy or effectiveness. In a review centered on women of childbearing age, Hai et al [23] evaluated the efficacy of technology-based interventions for substance use, with a focus on randomized controlled trials. This review located 15 trials, and a meta-analysis of 13 trials supported the efficacy of the digital health interventions for alcohol use concerns specifically compared with control conditions.

This review extends the foundational work in several ways. First, Hai et al [23] specifically focused on studies conducted in women of childbearing age, precluding an evaluation of differential effects across sex or gender. Second, both Hai et al [23] and Nesvåg and McKay [22] specifically focused on randomized controlled trials; however, initial investigations as well as investigations with a focus on effectiveness and/or implementation outcomes in real-world settings may utilize different research designs. Third, previous reviews have not systematically extracted data regarding the trauma endorsed by samples, limiting the capacity to determine the degree to which this crucial clinical feature is integrated into research designs, analyses, and interpretations. The current investigation therefore conducted a scoping review to evaluate the nature of the evidence for the efficacy and/or effectiveness of digital health resources to treat substance use and/or associated risks or harms. Consistent with recommendations [24], we conducted a scoping review to evaluate the types of available evidences in the field, which we envisioned would therefore either act as a precursor to a systematic review or support the analysis of knowledge gaps, contingent upon the results. We therefore implemented a search strategy including a wide range of research designs and the United States using Google from July to August 2020. The full MEDLINE search strategy is available in Supplementary Appendix 1.

The scoping review was conducted to answer the following research questions:

1. What digital health resources have been evaluated in those who identify as female/women or those reporting a history of trauma, regardless of sex or gender?
2. What digital health resources have empirical support for their efficacy/effectiveness in those who identify as female/women or those reporting a history of trauma, regardless of sex or gender?

For the purpose of this study, a scoping review was defined as a type of research synthesis that aims to “map the literature” on a particular topic or research area and provide an opportunity to identify key concepts; gaps in the research; and types and sources of evidence to inform practice, policymaking, and research [29]. Through answering the above questions our objective was to evaluate the nature of the evidence base for the efficacy and/or effectiveness of digital health resources for reducing substance use and/or associated harms in those identifying as female/women or in those reporting a history of trauma, regardless of sex or gender.

Stage 2: Identifying Relevant Studies

A comprehensive search strategy was developed by a librarian (RB) in consultation with the research team. The following databases were searched from inception: MEDLINE (including Epub ahead of print, in-process, and other nonindexed citations), APA PsycINFO, Embase, Cochrane Central, and CINAHL. No language limits were applied at this stage. For the searches, combinations of controlled vocabulary in the form of database-specific subject headings and relevant free-text keywords were included. The database searches were conducted in June 2020. The full MEDLINE search strategy is available for viewing in Multimedia Appendix 1.

In addition, nonpeer reviewed (grey) literature was also retrieved. The research team conducted a web search of Canadian and US Government and Funding Agencies in Canada and the United States using Google from July to August 2020. These searches were conducted using variations of the following (including but not limited to): “substance use,” “drug use,” “alcohol use,” or “addiction;” “online intervention,” “digital health;” “eHealth,” or “mobile health;” and “women” or “female.”
Stage 3: Study Selection

Studies were selected according to the following eligibility criteria:

1. Language: We included articles in English.
2. Date: We included articles from database inception to the date of extraction (June 30, 2020).
3. Publication type: We only considered original research articles, including secondary analyses. Dissertations, commentaries, conference proceedings, letters, editorials, and reviews were excluded to ensure presence of sufficient methodology and data needed to map and evaluate the nature of the evidence.
4. Sample: We considered adults aged 18 years or older, who endorsed or exhibited risky or harmful substance use. Similar to previous reviews [22,23], we did not include nicotine or caffeine. A minimum of 20% of participants was required to identify as female and/or women, or to report a trauma history, regardless of sex or gender. Although in many contexts, a higher proportion would be more appropriate and/or necessary to ensure power of sex- or gender-based analyses, this lower limit permits broad sampling of evidence to evaluate current practices.
5. Setting: We considered all settings (eg, health care, forensic, and educational).
6. Design: We included all prospective designs (eg, single vs multiple arms and augmentation vs stand-alone intervention). Randomization or a comparison/control group was not required.
7. Intervention: We considered web- or mobile-based interventions targeting substance use or substance use disorder symptoms. All theoretical orientations and durations of treatments were included; however, formats that were computer-based, but not online, or that were interactive were excluded (eg, telephone, video, and text-based interactive psychosocial interventions with a clinician and social networking/platforms such as peer support discussion boards).
8. Outcomes: We considered substance use or substance use disorder symptoms. Outcomes that were focused only on acceptability or feasibility were excluded.

Following the initial extraction and removal of duplicates, two research staff independently (1) screened the titles and abstracts of all unique records, (2) conducted full-text reviews for all records not excluded, and (3) extracted data from included studies. Team members demonstrated substantial agreement during title and abstract screening (96% agreement; $\kappa=0.74$) and during the full-text review (92% agreement; $\kappa=0.84$). Discrepancies were resolved by consensus, with the support of a member of the investigation team as needed (LQ).

Stage 4: Charting the Data

Procedures were consistent with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews (PRISMA-ScR) guidelines [30]. The following data were extracted from records included in synthesis: study design features (eg, setting and randomized controlled trial), sample features (eg, size and demographic information), intervention (eg, duration and components), outcomes (eg, instruments and indicators), and bias and fidelity indicators. Two research staff independently extracted data, and discrepancies were resolved by consensus.

Stage 5: Collating, Summarizing, and Reporting the Results

The Cochrane Risk of Bias Tool was used to evaluate bias at the study level across the following six domains: sequence generation, allocation concealment, blinding, incomplete data, selective reporting, and overall risk [31]. Each domain was given a rating of high, low, or some concerns of bias.

Results

Study Identification

The study selection process is illustrated in Figure 1. We located a total of 8617 published and 1773 grey literature records. A total of 7807 records remained after removing duplicates, and then, 465 remained following the screening of titles and abstracts. Records excluded at this first stage most commonly did not report original data or did not include critical design (eg, not original research and not a prospective design), sample (eg, adults with harmful/risk substance use), or intervention features (eg, online/mobile intervention targeting substance use or harms). Of the 465 remaining records, 306 were excluded because they did not include original (n=68) or prospective (n=10) research; did not include an adult sample (n=9) endorsing substance use risk or harms (n=69) with the minimum proportion of females/women or trauma (n=17); or did not include online or mobile interventions (n=93) targeting substance misuse (n=23). A total of 159 records were therefore included in this review. These 159 records reflected 141 distinct studies, including 125 distinct interventions.
Study Characteristics

The study characteristics are provided in Table 1. In-depth characteristics of the included studies are described in Multimedia Appendix 2 and Multimedia Appendix 3, and the intervention characteristics are shown in Multimedia Appendix 4. The majority of studies were conducted in the United States (94/161, 58.4%). The other locations were the European Union (38/161, 23.6%), United Kingdom (7/161, 4.3%), Australia and New Zealand (11/161, 6.8%), Canada (7/161, 4.3%), and others (<4%). Studies included one to six conditions (mean 2.3, median 2), with the majority (n=149) randomizing participants to conditions. The majority of studies included control conditions (n=115), including treatment as usual (n=31), assessment only (n=20), waitlist (n=12), and other control conditions specifically relevant to the research question. Sample sizes ranged from 13 to 4165 (mean 453, median 217), and sample types included clinical (50/159, 31.4%), community (56/159, 35.2%), college/university (40/159, 25.2%), and veteran samples (7/159, 4.4%) and others (5/159, 3.1%). The mean age of the participants ranged from 18 to 53 years (mean 31.83, median 34). The majority of studies were focused on alcohol use, risks, and/or harms (109/159, 68.5%), although a substantial minority focused on multiple substances or any substance (28/159, 17.6%), cannabis specifically (12/159, 7.5%), opioids specifically (4/159, 2.5%), or other specific substances (<3% each).
Table 1. Characteristics of the included studies (N=159).

<table>
<thead>
<tr>
<th>Parameters and characteristics</th>
<th>Studies, n (%)a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study metadata</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Study design</strong></td>
<td></td>
</tr>
<tr>
<td>Randomized controlled trial</td>
<td>122 (76.3%)</td>
</tr>
<tr>
<td>Secondary analyses</td>
<td>18 (11.3%)</td>
</tr>
<tr>
<td>Single-arm studies</td>
<td>19 (11.9%)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>94 (58.4%)</td>
</tr>
<tr>
<td>Canada</td>
<td>7 (4.4%)</td>
</tr>
<tr>
<td>European Union</td>
<td>38 (23.6%)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>7 (4.4%)</td>
</tr>
<tr>
<td>South America</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Australia and New Zealand</td>
<td>11 (6.8%)</td>
</tr>
<tr>
<td>Asia</td>
<td>3 (1.9%)</td>
</tr>
<tr>
<td><strong>Population characteristics</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td></td>
</tr>
<tr>
<td>≤100</td>
<td>41 (25.6%)</td>
</tr>
<tr>
<td>101-500</td>
<td>66 (41.3%)</td>
</tr>
<tr>
<td>501-1000</td>
<td>39 (24.4%)</td>
</tr>
<tr>
<td>&gt;1000</td>
<td>14 (8.8%)</td>
</tr>
<tr>
<td><strong>Mean age (years)</strong></td>
<td>31.83</td>
</tr>
<tr>
<td><strong>Percentage women/female</strong></td>
<td></td>
</tr>
<tr>
<td>≤10%</td>
<td>3 (1.9%)</td>
</tr>
<tr>
<td>11%-50%</td>
<td>95 (59.4%)</td>
</tr>
<tr>
<td>51%-99%</td>
<td>54 (33.8%)</td>
</tr>
<tr>
<td>100%</td>
<td>8 (5.0%)</td>
</tr>
<tr>
<td><strong>Study characteristics</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Target substance</strong></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>110 (69.2%)</td>
</tr>
<tr>
<td>Cannabis</td>
<td>12 (7.6%)</td>
</tr>
<tr>
<td>Opioids</td>
<td>4 (2.5%)</td>
</tr>
<tr>
<td>Any substance</td>
<td>28 (17.6%)</td>
</tr>
<tr>
<td>Other substances</td>
<td>5 (3.1%)</td>
</tr>
<tr>
<td><strong>Conducted sex- and gender-based analyses</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>27 (17.0%)</td>
</tr>
<tr>
<td>No</td>
<td>123 (77.3%)</td>
</tr>
<tr>
<td>N/Ad</td>
<td>9 (5.7%)</td>
</tr>
<tr>
<td><strong>Assessed gender</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19 (12.0%)</td>
</tr>
<tr>
<td>No</td>
<td>140 (88.0%)</td>
</tr>
<tr>
<td><strong>Assessed trauma</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13 (9.1%)</td>
</tr>
</tbody>
</table>
Intervention Characteristics

Digital health resources included multisession interventions (122/190, 64.2%) with multiple components or modules, such as screening and assessment, motivational enhancement, psychoeducation, and cognitive and behavioral skills building. Multisession interventions were available online (82/122, 67.2%), on mobile devices (mobile apps [25/122, 20.5%] and text [13/122, 10.7%]), and in a combination of both online and mobile methods (2/122, 1.6%). A substantial minority comprised single-session interventions (68/190, 35.8%), which were primarily available online (67/68, 99%) rather than on mobile devices (mobile apps [1/68, 2%]). There were no single-session interventions that were provided over text or that comprised a combination of both online and mobile methods. Each of these broad categories of digital health resources will be discussed in turn below. The digital health intervention duration ranged from one session (n=68) to 12 months, with other frequent durations including 4 weeks (n=7), 8 weeks (n=10), and 12 weeks (n=28). A substantial minority did not report or include a follow-up period (n=35). Follow-up durations ranged from 2 weeks to 2 years, with the most frequent periods including 1 month (n=37), 3 months (n=49), and 6 months (n=52). Overall, interventions were primarily in the English language (150/190, 78.9%), although others were available in multiple languages (6/190, 3.2%) or other specific languages such as Swedish (15/190, 7.9%) and others (German [6/190, 3.2%], Norwegian [2/190, 1.1%], Spanish [3/190, 1.6%], other [5/190, 2.6%]; all <4%). In line with the study focus as reviewed above, the majority of interventions themselves targeted alcohol use, risks, and/or harms (95/124, 76.6%) in their content, with a substantial minority including a treatment targeting multiple substances or any substance (15/124, 12.1%), cannabis specifically (11/124, 8.9%), or other specific substances or substance combinations (<2% each).

Study Quality or Bias

Overall, the majority of studies were found to exhibit features associated with some concerns of bias (93/160, 58.1%), with 11.9% (19/160) associated with high bias and 30.0% (48/160) associated with low bias, according to the Cochrane Risk of Bias Tool (Figure 2). More specifically, 68.1% (109/160) of studies were evaluated to have low bias associated with the randomization process (Domain 1), suggesting that adequate processes were put in place within these studies to minimize issues with randomization. The 39 studies associated with some concerns reported limited information on randomization methods or the concealment of assigned interventions, while the 12 with high bias did not randomize participants.
Domain 2 examined the risk of bias due to deviations from the intended interventions. Approximately 48% (76/160, 47.5%) of studies were evaluated as having some concerns of bias in this domain, mostly due to the use of analyses that were not appropriate to estimate the effect of assignment to the intervention, or the lack of adequate information regarding deviations from the planned protocol. The 22.5% (36/160) of studies with high bias tended to have issues regarding both of these points, whereas the 30.0% (48/160) of studies with low bias used intention-to-treat analyses to estimate the effect of assignment and had adequate blinding measures in place.

Domain 3 examined risk of bias due to missing outcome data, with 71.9% (115/160) of studies being evaluated as having low bias. Low bias in this domain signified that outcome data were available for nearly all participants or that adequate measures were put in place to evaluate bias due to missing outcome data. The 12.5% (20/160) of studies with some concerns were evaluated as such if it was possible that the results were biased by missing outcome data, such that study withdrawal occurred due to participants’ health status, whereas the 15.6% (25/160) of studies with high bias were evaluated as such if it was likely that study withdrawal occurred for this reason.

Domain 4 examined risk of bias in measurement of the outcome variables. Approximately 77% (123/160, 76.9%) of studies were evaluated to have low bias in this section, due to appropriate outcome measures being used and appropriate blinding if outcomes were assessed by outcome assessors or participant blinding if outcomes were assessed using self-report measures. The 17.5% (28/160) of studies evaluated as having some concerns in this domain were characterized by some likelihood that measures of outcomes could have been influenced by the intervention received, and the 5.6% (9/160) of studies rated as having high bias in this domain were found to have inadequate information in this regard.

Domain 5 examined risk of bias in the selection of the reported results. Approximately 61% (98/160, 61.3%) of studies were rated as having some concerns in this domain, particularly due to lack of prespecified analysis plans. The 37.5% (60/160) of studies with low risk of bias were found to have prespecified analysis plans and report all outcome measures and analyses in accordance with these plans. The 1.3% (2/160) of studies evaluated as having high risk of bias were found to be potentially selective in reporting outcome measurements and analyses, based on the results. All domains were coded according to a standardized scoring algorithm. Detailed information regarding the risk of bias for each study is presented in Multimedia Appendix 5. See Multimedia Appendix 6 for the references for all studies.

**Study Outcomes**

Overall, studies concluded that digital health resources for substance use or associated harms were efficacious or effective (155/190, 81.6%). The proportion of participants who identified as female or women ranged from 7% to 100% (mean 48%, median 46%; six studies were below 20%, but were eligible as over 20% endorsed trauma). In the vast majority of cases, participants identified as female, as only 16 studies explicitly assessed gender identity. Many studies appeared to use the terms sex and gender interchangeably (n=41). For example, indicating that gender was assessed (rather than sex) and specifying that reported genders were female and male. Sex- and gender-based analyses were conducted in only 17.0% (27/159) of studies, with 77.4% (123/159) of studies not conducting such analyses and 5.7% (9/159) not applicable (ie, no females or women were included in the sample, or the sample included only females or women). Thus, although digital health resources were found to
be efficacious or effective in general, this was quantitatively confirmed for females or women in only 13.7% (26/190) of studies, with 81.1% (154/190) of studies not reporting relevant analyses and 5.3% (10/190) finding that the intervention was not effective for female or women participants. Only 13 of the studies reported that at least 20% of participants had a trauma history, and only seven of these reported that at least 20% of participants were female or women, and reported trauma (ie, six studies included at least 20% of participants with a trauma history, but less than 20% were female or women; these studies were nevertheless retained to present the nature of the evidence for those who have been exposed to violence or trauma). These studies included two studies of single-session interventions as follows: BSAFER (developed for any substance [32]; demonstrated effectiveness at a 3-month follow-up in a small sample) and VetChange (developed for alcohol [33]; demonstrated effectiveness over 1, 3, and 6 months). Two studies evaluated a mobile app (A-CHESS) developed for any substance and delivered over 6 to 8 months, which demonstrated effectiveness in an entirely female sample [34], as well as a mixed sample [35], although sex- or gender-based analyses were not conducted in the latter. Another study evaluated a mobile text message intervention for alcohol in young adults following emergency room treatment, with improvements at a 3-month follow-up [36]. Finally, two widely investigated interventions (CBT4CBT and TES) developed for any substance and delivered over 12 weeks were evaluated in samples involving females and trauma, and although both interventions were effective, sex- or gender-based analyses were not conducted [37,38].

A total of 122 study conditions comprised online multisession interventions, primarily targeting alcohol (n=53) or any substance (n=19), although more targeted interventions for cannabis and opioids were present as well. These interventions included both openly available and commercial products, which varied in their provision of screening, assessment, or monitoring; however, most included psychoeducation, goal setting, cognitive and behavioral skills training, and links to resources. Primary outcomes were most frequently substance consumption, although substance use harms or substance use disorder symptoms were also included. Overall, 87% (73/84) of these relatively intensive interventions exhibited acute impacts on primary outcomes following up to 8 or 12 weeks of treatment; in some cases, these were retained in subsequent follow-up assessments.

Mobile interventions included both apps (n=27) and text-based messaging interventions (n=13). Mobile apps targeted alcohol (n=21) and any substance (n=4) or cannabis (n=3), and 87% (73/84) of these apps demonstrated improvements in the primary outcomes after approximately 4 to 12 weeks of use. Text-based messaging interventions targeted alcohol (n=9) or cannabis (n=1), and 85% (11/13) demonstrated benefits following 2 to 12 weeks of use.

A total of 67 study conditions evaluated brief interventions, which were primarily delivered online (n=66) as compared to via a mobile device (n=1). The majority of these brief interventions addressed harmful or risky alcohol use, with only a small number addressing general drug use (n=10) or cannabis use (n=3). These brief interventions frequently took the form of noncommercial programs that provided initial screening and personalized normative feedback, as well as psychoeducation and resources. The primary outcome was most frequently substance consumption, primarily quantity or frequency (eg, number of standard alcoholic drinks per week and binge or heavy drinking frequency). Approximately 64% (43/67) of these brief interventions did exhibit short-term impacts on the primary outcomes.

**Discussion**

**Principal Results**

The empirical investigations of the efficacy or effectiveness of digital health resources for adults who identify as female or women, or who report a history of trauma, appear to be principally conducted in the United States and Europe, with the majority in the English language. These investigations and the interventions evaluated predominantly focused on alcohol use or associated harms/risks, although a substantial minority of investigations was broadly applicable to substance use in general. The majority of studies randomized participants to study conditions, with a range of active and control conditions evident across studies. Similar to other reviews of psychosocial interventions, a substantial proportion of investigations was judged to have some concerns associated with bias, primarily related to participant or assessor blinding, lack of intent-to-treat analysis, or lack of a reported prespecified or registered analytical plan. Lower bias was evident regarding randomization, missing data, and outcome measurement.

The digital health resources evaluated included multisession and brief (ie, single) session interventions, with a wide range of therapeutic elements. Across all interventions, the primary outcome was most frequently substance use quantity and frequency. More intensive online and mobile interventions, frequently several months or more in duration and including numerous therapeutic components, exhibited moderate to strong effects in the vast majority of studies. Brief interventions, which consisted of a single session of varied duration (but most commonly less than 1 hour), demonstrated efficacy in most studies, although it was notable that these effects decreased over longer follow-ups in many studies.

Overall, studies that included a substantial proportion of adults who identified as female or women concluded that digital health resources for substance use or associated harms were efficacious or effective (155/190, 81.6%). A minimum threshold of 20% of the sample identifying as female or women, or endorsing trauma, was implemented to ensure the relevance of evidence reviewed to the research question. This eligibility requirement resulted in the exclusion of a limited number of records (n=17), which shared many of the study and intervention features described above. Notably, in many contexts, a much higher proportion would be required to conduct sex- or gender-based analyses and to support generalizability to our target populations. In fact, the majority of studies did include 40% or more of participants who were female or women, with larger proportions more common in community and trainee samples. Yet, most investigations did not assess gender identity, and many used sex and gender terms interchangeably. Further, sex- or
gender-based analyses were not conducted in the majority of studies (n=113); thus, direct or quantitative evidence for the efficacy or effectiveness of interventions in females or women specifically is weak.

Evidence for adults reporting a history of trauma was even more limited. Only 13 studies were found that met this liberal inclusion criterion, and even then, the association between trauma history and clinical outcomes was not evaluated. There is a critical need to assess and report trauma in the evaluation of digital health resources in this context to identify those most likely to be of benefit to adults with a trauma history. Of note, the current results appear unlikely to be the result of lower access to individuals with past or current experiences of violence and trauma. Among women presenting to treatment, significantly higher rates of sexual abuse have been observed in comparison to community samples of women meeting criteria for the diagnosis of substance use disorders, suggesting that experiences of trauma may play a role in the process of treatment initiation [10,39]. In fact, 61% of people in a population of treatment-seeking men and women specifically cited the experience of a recent traumatic event as the reason for seeking treatment for their substance misuse, demonstrating a clear need for a trauma-focused approach [39].

Comparison With Prior Work

Similar to the current investigation, previous systematic reviews and meta-analyses have highlighted the large number of digital interventions for alcohol, with a preponderance of brief interventions with small immediate benefits but low evidence for longer-term clinically significant effects [40]. Evidence for digital interventions for other substances is promising but more limited [41]. The most recent and focused investigation of digital health resources for women with substance use disorders focused on the childbearing age. Notably, the current broader synthesis noted that, in fact, there appears to be a dearth of studies in older adult samples as well as studies in other important groups. For example, studies in samples across the lifespan, across racial backgrounds, and with other important social determinants of health and those who face barriers to care (eg, rural communities, homeless or houseless individuals, forensic samples, and adults of varied physical and mental abilities) are critical to conduct. Thus, although a range of sample types was evident in the current review, future research would benefit from extending across the lifespan and including other types of samples with more varied demographic and clinical features.

Limitations

This investigation focused on a specific category of digital health resources, which necessarily limits its scope. The consideration of virtual psychotherapy, digital recovery support networks, and other forms of resources would be a valuable extension of this work. Similarly, this investigation focused on adults reporting or exhibiting substance use risks or harms, and interventions targeting substance use or associated risks or harms, which would preclude larger-scale population health interventions targeting a broader range of lower-risk individuals as well as interventions with lifestyle or health/wellness foci. Focused reviews of these broader groups and interventions would benefit a range of stakeholders. This review focused on adults who identify as female or women and neglected other sex and gender groups. Thus, increased attention to treatment outcomes across the gender continuum is needed. Finally, the incorporation of other key identity features, particularly those related to race, culture, and ethnicity, is critical to examine how the intersections of these different components of identity are linked to treatment outcomes. Very limited research in this area has been conducted to date, highlighting this key gap.

Conclusions

This project represents a synthesis of available evidence for digital health resources for adults who identify as female or women with substance use concerns. Although substance use has been increasing in these individuals, adults who identify as female or women are underrepresented in in-person clinical services and exhibit unique treatment barriers, preferences, and needs. Importantly, trauma is elevated in this group, highlighting the clinical priority of interventions that are sensitive to not only gender-specific psychoeducation and skills building, but also trauma-informed approaches. Although this synthesis simultaneously provides promising support for the therapeutic benefit of digital health resources for this priority population, it also highlights critical clinical and research priorities. Increased assessments of both sex and gender identities, and the implementation of sex- and gender-based analyses are critical in future empirical investigations of digital health resources. Increased integration of trauma and other key participant features is also needed to contribute to the further development of these interventions. Trauma, intersectionality, and key social determinants of health are critical to understand not only the value of these resources but also how to successfully implement them in varied geographical regions and health systems.

Acknowledgments

This project was supported by operating funds from the Canadian Institutes of Health Research (CIHR), who approved the research proposal, including the objectives and methodology, but had no involvement in the research design, conduct, analysis, interpretation, or reporting.

Conflicts of Interest

None declared.

Multimedia Appendix 1

https://mental.jmir.org/2021/6/e25952
Search strategy for MEDLINE.
[DOCX File, 121 KB - mental_v8i6e25952_app1.docx]

Multimedia Appendix 2
Study demographic characteristics.
[DOCX File, 174 KB - mental_v8i6e25952_app2.docx]

Multimedia Appendix 3
Study design characteristics.
[DOCX File, 153 KB - mental_v8i6e25952_app3.docx]

Multimedia Appendix 4
Intervention characteristics.
[DOCX File, 85 KB - mental_v8i6e25952_app4.docx]

Multimedia Appendix 5
Risk of bias.
[DOCX File, 57 KB - mental_v8i6e25952_app5.docx]

Multimedia Appendix 6
References for articles included in the scoping review.
[DOCX File, 61 KB - mental_v8i6e25952_app6.docx]

References


©Lena Quilty, Branka Agic, Michelle Coombs, Betty-Lou Kristy, Jill Shakespeare, Adrienne Spafford, Reena Besa, Shadini Dematagoda, Alina Patel, Rebecca Persaud, Leslie Buckley. Originally published in JMIR Mental Health (https://mental.jmir.org), 07.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Mental Health, is properly cited. The complete bibliographic information, a link to the original publication on https://mental.jmir.org/, as well as this copyright and license information must be included.
Factors Predicting Trial Engagement, Treatment Satisfaction, and Health-Related Quality of Life During a Web-Based Treatment and Social Networking Trial for Binge Drinking and Depression in Young Adults: Secondary Analysis of a Randomized Controlled Trial

Samineh Sanatkar1,2, PhD; Milena Heinsch1, PhD; Peter Andrew Baldwin3, MPsychol, PhD; Mark Rubin4, PhD; Jenny Geddes1, BSc, MPsych, MAPS; Sally Hunt1,4, PhD; Amanda L Baker1, PhD; Kathryn Woodcock3, BA (Hons); Terry J Lewin1, BCom (Hons); Kathleen Brady5, MD, PhD; Mark Deady3, PhD; Louise Thornton2, PhD; Maree Teesson2, FAHMS, FASSA; Frances Kay-Lambkin1,2, BSc (Hons), PhD

1Centre for Brain and Mental Health Research, School of Medicine and Public Health, The University of Newcastle, Callaghan, Australia
2The Matilda Centre for Research in Mental Health and Substance Use, The University of Sydney, Camperdown, Australia
3Black Dog Institute, UNSW Sydney, Randwick, Australia
4School of Psychology, The University of Newcastle, Callaghan, Australia
5Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, SC, United States

Corresponding Author:
Samineh Sanatkar, PhD
Centre for Brain and Mental Health Research
School of Medicine and Public Health
The University of Newcastle
University Drive
Callaghan, 2308
Australia
Phone: 61 02 9065 9179
Email: samineh.sanatkar@uon.edu.au

Abstract

Background: Mental health and alcohol use problems are among the most common causes of disease burden in young Australians, frequently co-occur (comorbidity), and lead to significant lifetime burden. However, comorbidities remain significantly underdetected and undertreated in health settings. Digital mental health tools designed to identify at-risk individuals, encourage help-seeking, or deliver treatment for comorbidity have the potential to address this service gap. However, despite a strong body of evidence that digital mental health programs provide an effective treatment option for a range of mental health and alcohol use problems in young adults, research shows that uptake rates can be low. Thus, it is important to understand the factors that influence treatment satisfaction and quality-of-life outcomes for young adults who access e-mental health interventions for comorbidity.

Objective: In this study, we seek to understand the factors that influence treatment satisfaction and quality-of-life outcomes for young adults who access e-mental health interventions for comorbid alcohol and mood disorders. The aim is to determine the importance of personality (ie, Big Five personality traits and intervention attitudes), affective factors (ie, depression, anxiety, and stress levels), and baseline alcohol consumption in predicting intervention trial engagement at sign-up, satisfaction with the online tool, and quality of life at the end of the iTreAD (Internet Treatment for Alcohol and Depression) trial.

Methods: Australian adults (N=411) aged between 18 and 30 years who screened positive for depression and alcohol use problems signed up for the iTreAD project between August 2014 and October 2015. During registration, participants provided information about their personality, current affective state, alcohol use, treatment expectations, and basic demographic information. Subsequent follow-up surveys were used to gauge the ongoing trial engagement. The last follow-up questionnaire, completed at 64 weeks, assessed participants’ satisfaction with web-based treatment and quality-of-life outcomes.
Results: Multiple linear regression analyses were used to assess the relative influence of predictor variables on trial engagement, treatment satisfaction, and quality-of-life outcomes. The analyses revealed that the overall predictive effects of personality and affective factors were 20% or lower. Neuroticism constituted a unique predictor of engagement with the iTreAD study in that neuroticism facilitated the return of web-based self-assessments during the study. The return of incentivized follow-up assessments predicted treatment satisfaction, and state-based depression predicted variance in quality-of-life reports at study completion.

Conclusions: Our findings suggest that traditional predictors of engagement observed in face-to-face research may not be easily transferable to digital health interventions, particularly those aimed at comorbid mental health concerns and alcohol misuse among young adults. More research is needed to identify what determines engagement in this population to optimally design and execute digital intervention studies with multiple treatment aims.


International Registered Report Identifier (IRRID): RR2-10.1186/s12889-015-2365-2

(JMIR Ment Health 2021;8(6):e23986) doi:10.2196/23986

KEYWORDS
digital mental health; personality; negative affect; study engagement; life quality

Introduction

Background
Mental health and alcohol use disorders are the leading causes of disability among young adults globally [1,2]. This trend is reflected in Australia, with alcohol misuse and poor mental health reported as the primary contributors to disease burden among Australian youth, including young adults [3]. The burden of disease increases when substance use and mental health disorders co-occur. For example, comorbidity of alcohol use disorder and major depressive disorder is associated with elevated risks of alcohol dependence, higher instances of attempted suicide, and lower levels of functioning and life satisfaction [4,5]. Consequently, treatment prognoses for this population tend to be relatively poor [6,7].

Complicating the path to recovery, young Australians in their teens and 20s see their general practitioners or mental health professionals less frequently than their older counterparts [8]. Recent research found that across 1306 adults presenting for assessment of their general practitioners, comorbid alcohol use and major depressive disorders were correctly detected in only 21% of cases [9]. This situation highlights the need to improve the identification of comorbid disorders because high nondetection rates constitute a major barrier to access appropriate and timely treatment.

Digital technologies offer a promising opportunity to identify comorbid disorders and enhance access to high-quality mental health care for young adults [10,11]. Digital services can function as stand-alone programs or in conjunction with face-to-face or web-based clinical support. These types of services are acceptable to young people and align with recent findings that young people use digital apps for numerous purposes (including supporting their health and well-being) at a greater rate than any other age group [12]. Previous research indicates that 44% of Australians aged between 16 and 25 years use the internet to access health information [13]. A recent review found that face-to-face help-seeking among young people aged between 12 and 25 years may improve after using computerized mental health programs and services [14]. However, sustained engagement with digital interventions has proved difficult, and limited participation and high attrition rates are common [11]. This is concerning because the amount of exposure to an intervention is often an important prerequisite for intervention outcomes [15].

Studies that have evaluated engagement in digital health interventions suggest that it may be an important contributor to participant satisfaction and quality of life at the conclusion of a research study or treatment program. For example, in a post hoc analysis of a randomized controlled trial evaluating the effectiveness of an online support group on primary care patients’ mental health, Geramita et al [16] found that those who engaged more frequently with a study-specific online support group reported significant improvements in health-related quality of life 6 months after the trial phase had ended compared with participants who had engaged the least. Consequently, evaluating engagement with mental health treatment protocols has been identified as critical for improving intervention impact and success [17]. Although engagement with digital interventions is not identical to engagement in clinical trials of these interventions, dropout rates in clinical trials can reflect disengagement rates with digital interventions in naturalistic settings when sample bias and trial push factors are kept to a minimum [18-20].

Person-based characteristics can predict engagement with health treatment protocols and intervention success in younger adult samples. In particular, personality patterns, such as high levels of conscientiousness and low levels of neuroticism, predicted adherence to study protocols in trials for smoking cessation therapy, asthma control, and health-related quality of life [21-23]; whereas negative emotional states and unfavorable attitudes toward treatments can negatively influence engagement and treatment satisfaction displayed by young adults in clinical trials across a variety of health conditions [24-29]. Personality patterns of low conscientiousness, high neuroticism, and extraversion have consistently been associated with problematic levels of alcohol consumption among adolescents and young adults [30], indicating that personality may influence both the formation of and recovery from health-related complications in...
young adulthood. This highlights the usefulness of considering young adults’ personality, affect, and treatment beliefs as predictors of engagement with study protocols. Clarifying the unique role played by each of these factors may help to remedy the poor uptake of web-based mental health interventions [11,31].

Objectives

This study aims to examine the relative importance of personality factors (ie, conscientiousness and neuroticism), negative emotional states (ie, stress, anxiety, and depression), recent alcohol use, and treatment expectations in predicting engagement with a web-based mental health study designed to reduce depressive symptoms and incidences of heavy episodic drinking *(binge drinking)* in young adulthood. In addition, we examined the predictive strength of personality, negative emotions, alcohol consumption, treatment expectations, and study engagement on participants’ self-reported treatment satisfaction and quality of life at the end of the web-based mental health study. Specifically, it was hypothesized that a pattern of low neuroticism, high conscientiousness, lower emotional distress, lower alcohol consumption, and greater expectations of treatment success at sign-up would predict higher levels of subsequent study engagement, treatment satisfaction, and quality-of-life ratings at the last assessment point. It was further predicted that higher study engagement levels during the trial would predict greater treatment satisfaction and quality of life at the last assessment point. To our knowledge, this is the first study to assess these predictors simultaneously within a randomized controlled trial design that evaluates the effectiveness of a web-based mental health program to reduce the severity of comorbid substance use disorder and major depression among young Australian adults. In doing so, our study seeks to contribute to the literature on web-based mental health program acceptance among young adults in line with the recommendations of Clarke et al [11].

Methods

Overview

The iTreAD (Internet Treatment for Alcohol and Depression) trial study protocol was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12614000310662) and approved by the UNSW Sydney Human Research Ethics Committee (HC13299). The protocol has been previously published [32].

Participants and Procedures

Recruitment to iTreAD occurred between August 2014 and October 2015. Following an initial screener, a total of 421 eligible candidates from Australia (aged between 18 and 30 years) who reported current depressive symptoms and alcohol misuse and had internet access completed the informed consent process and baseline survey and were randomly allocated to one of three conditions: (1) web-based self-assessments, (2) web-based self-assessments with an additional digital mental health program, or (3) web-based self-assessments, digital mental health programs, and an additional clinician-guided digital forum (refer Kay-Lambkin et al [32] for further details on the study design). In total, 10 participants subsequently withdrew their consent to participate in the iTreAD study and were removed from the analysis. The final sample consisted of 411 participants, of which 135 were allocated to the web-based self-assessment control group, 131 to the web-based self-assessment and digital mental health program group, and 145 to the joint web-based self-assessment, digital mental health program, and clinician-guided forum group. Most participants were female (252/411, 61.3%) and had a mean age of 23 (SD 3.67) years.

The overall study duration was 64 weeks. During this time, all participants were asked to complete 12 monthly web-based self-assessments and four follow-up surveys at 26, 39, 52, and 64 weeks after their initial baseline assessment. Participants were reimbursed up to Aus $20 (US $15.44) for their baseline assessment and for each follow-up assessment they completed, regardless of participation rates in any of the three study conditions. No reimbursement was provided for the 12-monthly web-based self-assessments. Only participants allocated to either of the two treatment groups gained access to their respective web-based intervention components.

Measures

Personality

Conscientiousness was measured using the 9-item Conscientiousness subscale of the Big Five Inventory (BFI) [33], which asks participants to rate their agreement with statements such as, “I see myself as someone who does a thorough job.” Neuroticism was measured using the 2-item Neuroticism subscale of the BFI short form [34], which asks participants to rate their agreement with statements such as, “I see myself as someone who gets nervous easily.” Both the long and short forms of the BFI have been found to be reliable and valid measures of the Big Five trait dimensions [33-36].

Negative Affective States

Recent experiences of negative affective states were measured using the Depression, Anxiety, and Stress Scale-21 items (DASS-21) [37]. The DASS-21 has been demonstrated to have good psychometric properties in clinical, nonclinical, and adolescent samples and has been used in previous research assessing affective states of web-based intervention users [38-40]. An example item for depression is, “I couldn’t seem to experience any positive feeling at all.”

Alcohol Consumption

Heavy drinking and probable alcohol dependence were assessed using the 3-item Consumption Short Form of the Alcohol Use Disorders Identification Test-Concise (AUDIT-C) [41]. The AUDIT-C is a valid and reliable measure to screen for possible alcohol use disorders similar to the AUDIT long form [41,42]. An example item is, “How often did you have six or more drinks on one occasion?” with responses ranging from 0 (never) to 4 (daily). Overall AUDIT-C scores range from 0 to 12, with a score of 3 or above warranting further assessment of whether an alcohol use disorder may be present.
Treatment Expectations and Satisfaction

Treatment expectations at the beginning of the study were measured by asking participants, “By the end of treatment, how much improvement in binge drinking and depression do you think could occur as a result of internet delivered treatment?” Participants responded to this question in increments of 10 points ranging from the lowest (0-10) to highest expected improvement (91-100). Treatment satisfaction at the end of the study was measured using the general 8-item Client Satisfaction Questionnaire [43], which has demonstrated concurrent validity among Australians seeking treatment for alcohol and substance abuse [44]. An example item for client satisfaction is, “In an overall general sense, how satisfied are you with the service you received?”

Study Engagement

We considered returned web-based self-assessments (0-12) and follow-up questionnaires (0-4) as indicators of participants’ engagement with the iTreAD study. Web-based self-assessments were part of the iTreAD treatment protocol because reflecting on one’s recent mood and alcohol consumption was thought to have a mild therapeutic effect [45], and the completion of follow-up questionnaires constituted an indicator of study adherence. Thus, the self-assessments and follow-up questionnaires captured elements of treatment and study protocol engagement in the iTreAD trial. No other engagement indices were shared across the experimental and control groups.

Quality of Life

Participants’ health-related quality of life was assessed using the 20-item standard version of the Assessment of Quality of Life questionnaire (AQoL-6D) [46]. The instrument considers various physical and psychological indicators of quality of life and general functioning. The validity of its components has been confirmed in Australian adult samples [47]. An example item is, “How often do you feel in control of your life?” Higher scores on the AQoL-6D were indicative of lower perceived quality of life.

Analytic Plan

With regard to the primary outcomes of the iTreAD trial, multilevel regression models revealed significant decreases in depression severity and binge drinking episodes throughout the study; however, these improvements did not vary by treatment condition (Kay-Lambkin et al, unpublished data, April 2021). This pattern of results suggested that there were no systematic differences between groups in the outcome measures, either at baseline or as a result of any intervention. Therefore, we collapsed the three trial conditions across all outcome measures to retain a sufficiently powered sample size for the analysis regarding study engagement. After collapsing across groups, 390 participants completed all relevant measures at registration. A total of 190 participants completed the treatment satisfaction questionnaire, and 191 participants completed the quality-of-life assessment at the last assessment point at 64 weeks. This reduction in available data was because of the study attrition and optional completion of the questionnaire components. Using G*Power 3.1 (Heinrich Heine University Düsseldorf) [48], power calculations indicated that a sample size of 205 was required to detect small-to-medium effects typical in personality research with α of .05, a power of 0.80, and 9 predictor variables. These power calculations indicated that the treatment satisfaction and quality-of-life analyses were slightly underpowered and would be more suitable for detecting medium-sized effects.

Predictor variables were identified based on the literature, indicating a likely impact on engagement. These variables were the personality traits of conscientiousness and neuroticism, the negative affective states of depression, anxiety, stress, alcohol use, and treatment expectations at the outset of the study. The BFI subscales of neuroticism and conscientiousness were used to describe personality trait dimensions. The DASS-21 subscales of depression, anxiety, and stress were used as predictor variables of negative affect. AUDIT-C scores were used to indicate alcohol consumption levels, and the single-item measure “By the end of treatment, how much improvement in binge drinking and depression do you think could occur as a result of internet delivered treatment?” assessed at baseline was used as a proxy for treatment expectations. The total number of returned study questionnaires (ie, web-based self-assessments and follow-up questionnaires) were computed to describe indices of study engagement. The sum scores of the 8-item Client Satisfaction Questionnaire and AQoL-6D were used to measure treatment satisfaction and quality of life, respectively, at the end of the study.

Multiple linear regression analyses were performed using SPSS Statistics for Windows, version 25 (IBM Corporation) to assess the extent to which baseline levels of personality, negative affect, alcohol consumption, and treatment expectations might predict subsequent study engagement and to assess the ability of personality, negative affect, alcohol consumption, treatment expectations, and study engagement to predict treatment satisfaction and quality of life at the end of the study. The resulting prediction models reveal the unique and combined contributions of the predictor variables that help explain the proportion of the total variance of each outcome variable. As we considered three outcomes, we tested a total of three model predictions.

Results

Sample Characteristics

Table 1 presents the descriptive and between-group statistics of the iTreAD study participants. There were no significant differences in key variables between groups, including treatment satisfaction at the end of the study (mean 23.90, SD 5.17; F2,196=2.14; P=.12), except for engagement. On average, participants in the control condition returned around two additional questionnaires (mean 6.51, SD 4.19) from the web-based self-assessment component compared with participants in experimental conditions 1 (mean 3.75, SD 3.87) and 2 (mean 4.43, SD 4.19; F2,408=16.59; P<.001). It is possible that these differences were because of limited engagement options in the control condition (ie, questionnaire assessment only), whereas the experimental conditions offered web-based activities in addition to the questionnaire completion options.
Table 1. Scale response anchors: means, SDs, and between-group statistics on key variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Scale anchors</th>
<th>Control group (n=135)</th>
<th>Experimental group 1 (n=131)</th>
<th>Experimental group 2 (n=145)</th>
<th>F test (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range</td>
<td>Mean (SD)</td>
<td>n (%)</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>n (%)</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>n (%)</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)(^b)</td>
<td>18-30</td>
<td>23.2 (3.59)</td>
<td>129 (95.6)</td>
<td>23.6 (3.67)</td>
<td>134 (92.4)</td>
<td>0.71 (2, 388)</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>1-5</td>
<td>3.35 (0.66)</td>
<td>128 (94.8)</td>
<td>3.25 (0.65)</td>
<td>138 (95.2)</td>
<td>0.82 (2, 391)</td>
</tr>
<tr>
<td>Neuroticism</td>
<td>1-5</td>
<td>3.84 (1.06)</td>
<td>127 (95.1)</td>
<td>3.87 (1.02)</td>
<td>138 (95.2)</td>
<td>0.03 (2, 390)</td>
</tr>
<tr>
<td>Depression</td>
<td>0-42</td>
<td>25.2 (9.53)</td>
<td>133 (98.5)</td>
<td>26.43 (8.5)</td>
<td>144 (99.3)</td>
<td>0.58 (2, 404)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0-42</td>
<td>16.72 (8.78)</td>
<td>133 (98.5)</td>
<td>17.88 (8.74)</td>
<td>144 (99.3)</td>
<td>0.78 (2, 404)</td>
</tr>
<tr>
<td>Stress</td>
<td>0-42</td>
<td>23.56 (8.30)</td>
<td>133 (98.5)</td>
<td>24.97 (8.51)</td>
<td>144 (99.3)</td>
<td>1.05 (2, 404)</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td>0-12</td>
<td>7.66 (1.99)</td>
<td>135 (100)</td>
<td>7.55 (2.16)</td>
<td>143 (98.6)</td>
<td>0.11 (2, 406)</td>
</tr>
<tr>
<td>Treatment expectation</td>
<td>0-100</td>
<td>46.23 (22.04)</td>
<td>130 (96.3)</td>
<td>47.44 (21.77)</td>
<td>138 (95.2)</td>
<td>0.38 (2, 394)</td>
</tr>
<tr>
<td>Self-assessments</td>
<td>0-12</td>
<td>6.51 (4.19)</td>
<td>135 (100)</td>
<td>3.75 (3.87)</td>
<td>145 (100)</td>
<td>16.59 (2, 408)</td>
</tr>
<tr>
<td>Follow-ups</td>
<td>0-4</td>
<td>2.35 (1.61)</td>
<td>135 (100)</td>
<td>1.92 (1.73)</td>
<td>145 (100)</td>
<td>2.21 (2, 406)</td>
</tr>
<tr>
<td>Treatment satisfaction(^c)</td>
<td>8-32</td>
<td>22.9 (5.72)</td>
<td>72 (53.3)</td>
<td>24.56 (4.84)</td>
<td>70 (48.3)</td>
<td>2.14 (2, 196)</td>
</tr>
<tr>
<td>Quality of life(^d)</td>
<td>20-99</td>
<td>39.51 (9.63)</td>
<td>73 (54.1)</td>
<td>40.28 (11.24)</td>
<td>70 (48.3)</td>
<td>0.48 (2, 197)</td>
</tr>
</tbody>
</table>

\(^a\)Responses to items were optional. Actual numbers ranged from 57 to 145 per group.
\(^b\)Age, personality, emotional distress, and treatment expectation statistics were computed at registration.
\(^c\)Treatment satisfaction and quality of life were assessed at trial completion after 64 weeks postbaseline.
\(^d\)Lower scores on the quality-of-life measure indicate higher life quality.

Table 2 lists Pearson correlations between variables. Conscientiousness showed consistent weak-to-moderate negative correlations with neuroticism, depression, anxiety and stress levels, and alcohol consumption (r ranged between −0.20 and −0.26) and was associated with higher levels of study engagement (the correlation with self-assessment returns was r=0.12 and with follow-up returns was r=0.11) and higher reported quality of life at the end of iTreAD at 64 weeks (r=−0.25). Conversely, higher initial reported stress and anxiety levels as well as alcohol consumption were negatively associated with web-based self-assessment returns (r=−0.15 and r=−0.12, respectively), and higher initial levels of alcohol consumption were negatively associated with returns of follow-up assessments (r=−0.14). Neuroticism and negative affect at baseline showed moderate correlations with decreased quality of life at the 64-week follow-up (r ranged between 0.23 and 0.41). In addition, lower perceived quality of life was associated with lower levels of treatment satisfaction at the 64-week follow-up (r=−0.20). Treatment satisfaction was positively correlated with the number of returned follow-up assessments (r=0.18) in this study.
Table 2. Pearson correlations between key variablesa.

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Conscientiousness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Neuroticism</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Anxiety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Stress</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Alcohol consumption</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Treatment expectation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Self-assessments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Follow-ups</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Treatment satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Quality of lifec</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aPersonality, emotional distress, and treatment expectation statistics were computed at registration; treatment satisfaction and quality of life were assessed at trial completion 64 weeks postbaseline. Responses to items were optional. Actual n ranged between 192 and 415.

bNot applicable.

cLower scores on the quality-of-life measure indicated higher life quality.

Regression Models

For model 1, personality, negative affect, alcohol consumption, and treatment expectation variables were included as predictors of iTreAD study engagement, as indicated by the return of web-based self-assessments (Table 3) and follow-up questionnaires (Table 4). The models predicting self-assessment ($F_{7,382}=3.09; P=.003$) and follow-up returns ($F_{7,382}=2.61; P=.01$) were significant. However, the predictors only accounted for about 5% of the variance in study engagement ($R^2=0.05$), indicating that personality, negative affect, alcohol consumption, and expectations of treatment success together played a minor role.
role in determining continuous study participation. Neuroticism remained a statistically significant predictor of study engagement, although its unique predictive power was low. Neuroticism alone accounted for approximately 2% of the variance in web-based self-assessments. In other words, an increase of about one point (0.71) in the neuroticism dimension was predictive of returning an additional web-based self-assessment.

**Table 3.** Standard regression results for personality, negative affect, and treatment expectations predicting engagement with web-based self-assessments (n=390)\(^a\).

<table>
<thead>
<tr>
<th>Model</th>
<th>b (SE)</th>
<th>(\beta)</th>
<th>Pearson (r)</th>
<th>(sr) (^b)</th>
<th>Structure coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>1.81 (1.93)</td>
<td>N/A(^c)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>0.67 (0.34)</td>
<td>.10</td>
<td>0.12</td>
<td>0.10</td>
<td>0.500</td>
</tr>
<tr>
<td>Neuroticism(^d)</td>
<td>0.71 (0.24)</td>
<td>.18</td>
<td>0.05</td>
<td>0.15</td>
<td>0.203</td>
</tr>
<tr>
<td>Depression</td>
<td>0.02 (0.03)</td>
<td>.04</td>
<td>−0.07</td>
<td>0.03</td>
<td>−0.289</td>
</tr>
<tr>
<td>Anxiety</td>
<td>−0.07 (0.03)</td>
<td>−.14</td>
<td>−0.14</td>
<td>−0.10</td>
<td>−0.595</td>
</tr>
<tr>
<td>Stress</td>
<td>−0.05 (0.04)</td>
<td>−.10</td>
<td>−0.11</td>
<td>−0.07</td>
<td>−0.474</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td>−0.06 (0.11)</td>
<td>−.03</td>
<td>−0.11</td>
<td>−0.03</td>
<td>−0.319</td>
</tr>
<tr>
<td>Treatment expectation</td>
<td>0.01 (0.01)</td>
<td>.07</td>
<td>0.05</td>
<td>0.06</td>
<td>0.228</td>
</tr>
</tbody>
</table>

\(^a\)\(R^2=0.05;\ adjusted \ R^2=0.04.\)

\(^b\)\(sr\): the semipartial correlation.

\(^c\)N/A: not applicable.

\(^d\)\(P<.01.\)

Model 2 (presented in Table 4) examined the predictive strength of personality, negative affect, treatment expectations, and study engagement on participants’ satisfaction with the iTreAD program. Contrary to expectations, the overall model only approached significance \((F_{9,180}=1.90; P=.06)\), indicating that the variance of satisfaction with the treatment program could not be explained by the prediction model. However, the study engagement variable of follow-up assessments showed a significant association with treatment satisfaction in the overall model. The return of follow-up assessments explained 2.5\% of the variance in treatment satisfaction, whereby the completion of about 2 (1.6) additional questionnaires was predictive of a 1-point increase in treatment satisfaction.

**Table 4.** Standard regression results for personality, negative affect, and treatment expectations predicting engagement with follow-up questionnaires (n=390)\(^a\).

<table>
<thead>
<tr>
<th>Model</th>
<th>b (SE)</th>
<th>(\beta)</th>
<th>Pearson (r)</th>
<th>(sr) (^b)</th>
<th>Structure coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>1.81 (0.75)</td>
<td>N/A(^c)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>0.23 (0.13)</td>
<td>.09</td>
<td>0.11</td>
<td>0.09</td>
<td>0.519</td>
</tr>
<tr>
<td>Neuroticism(^d)</td>
<td>0.18 (0.09)</td>
<td>.12</td>
<td>0.04</td>
<td>0.10</td>
<td>0.164</td>
</tr>
<tr>
<td>Depression</td>
<td>0.01 (0.01)</td>
<td>.04</td>
<td>−0.05</td>
<td>0.03</td>
<td>−0.243</td>
</tr>
<tr>
<td>Anxiety</td>
<td>−0.02 (0.01)</td>
<td>−.09</td>
<td>−0.09</td>
<td>−0.07</td>
<td>−0.435</td>
</tr>
<tr>
<td>Stress</td>
<td>−0.01 (0.02)</td>
<td>−.06</td>
<td>−0.07</td>
<td>−0.04</td>
<td>−0.313</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td>−0.08 (0.04)</td>
<td>−.10</td>
<td>−0.13</td>
<td>−0.10</td>
<td>−0.617</td>
</tr>
<tr>
<td>Treatment expectation</td>
<td>0.01 (0.00)</td>
<td>.08</td>
<td>0.08</td>
<td>0.08</td>
<td>0.393</td>
</tr>
</tbody>
</table>

\(^a\)\(R^2=0.05,\ adjusted \ R^2=0.03.\)

\(^b\)\(sr\): the semipartial correlation.

\(^c\)N/A: not applicable.

Personality, negative affect, treatment expectations, and study engagement were used to predict the self-reported quality of life at study cessation in model 3 (Tables 5 and 6). The prediction model was significant \((F_{9,181}=6.34; P<.001)\). The combined predictors accounted for approximately 20\% of the variance in quality of life \((R^2=0.20; adjusted \ R^2=0.20)\). Only depression scores at baseline had a significant influence on subsequent quality-of-life ratings and, given the other variables in the model, only accounted for about 3\% of the variance in quality of life. In other words, a 0.3-point increase on the DASS-21 depression measure uniquely accounted for a 1-point increase on the AQoL-6D (ie, a 1-unit decrement in life quality).
Table 5. Standard regression results for personality, negative affect, treatment expectations, and study engagement predicting treatment satisfaction (n=190)\(^a\).

<table>
<thead>
<tr>
<th>Model</th>
<th>b (SE)</th>
<th>(\beta)</th>
<th>Pearson r</th>
<th>(sr) (^b)</th>
<th>Structure coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>16.78 (3.88)</td>
<td>N/A(^c)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>0.32 (0.63)</td>
<td>.04</td>
<td>0.06</td>
<td>0.04</td>
<td>0.194</td>
</tr>
<tr>
<td>Neuroticism</td>
<td>0.23 (0.43)</td>
<td>.05</td>
<td>0.05</td>
<td>0.04</td>
<td>0.180</td>
</tr>
<tr>
<td>Depression</td>
<td>−0.06 (0.05)</td>
<td>−.11</td>
<td>−0.07</td>
<td>−0.09</td>
<td>−0.252</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0.03 (0.06)</td>
<td>.06</td>
<td>0.05</td>
<td>0.04</td>
<td>0.167</td>
</tr>
<tr>
<td>Stress</td>
<td>0.03 (0.07)</td>
<td>.04</td>
<td>0.03</td>
<td>0.03</td>
<td>0.099</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td>−0.10 (0.19)</td>
<td>−.04</td>
<td>−0.09</td>
<td>−0.04</td>
<td>0.310</td>
</tr>
<tr>
<td>Treatment expectation</td>
<td>0.03 (0.02)</td>
<td>.13</td>
<td>0.13</td>
<td>0.13</td>
<td>0.446</td>
</tr>
<tr>
<td>Self-assessments</td>
<td>−0.14 (0.11)</td>
<td>−.11</td>
<td>−0.00</td>
<td>−0.10</td>
<td>0.003</td>
</tr>
<tr>
<td>Follow-ups(^d)</td>
<td>1.63 (0.54)</td>
<td>.25</td>
<td>0.20</td>
<td>0.22</td>
<td>0.677</td>
</tr>
</tbody>
</table>

\(^a\)\(R^2=0.09;\) adjusted \(R^2=0.04.\)
\(^b\)\(sr: the semipartial correlation.\)
\(^c\)N/A: not applicable.
\(^d\)\(P<.01.\)

Table 6. Standard regression results for personality, negative affect, treatment expectations, and study engagement predicting quality of life (n=191)\(^a\).

<table>
<thead>
<tr>
<th>Model</th>
<th>b (SE)</th>
<th>(\beta)</th>
<th>Pearson r</th>
<th>(sr) (^b)</th>
<th>Structure coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>38.40 (7.23)</td>
<td>N/A(^c)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>−1.94 (1.17)</td>
<td>−.12</td>
<td>−0.25</td>
<td>−0.11</td>
<td>−0.502</td>
</tr>
<tr>
<td>Neuroticism</td>
<td>0.65 (0.81)</td>
<td>.06</td>
<td>0.25</td>
<td>0.05</td>
<td>0.506</td>
</tr>
<tr>
<td>Depression(^d)</td>
<td>0.30 (0.09)</td>
<td>.27</td>
<td>0.39</td>
<td>0.22</td>
<td>0.802</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0.08 (0.11)</td>
<td>.07</td>
<td>0.34</td>
<td>0.05</td>
<td>0.688</td>
</tr>
<tr>
<td>Stress</td>
<td>0.17 (0.13)</td>
<td>.14</td>
<td>0.39</td>
<td>0.08</td>
<td>0.788</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td>−0.19 (0.36)</td>
<td>−.04</td>
<td>0.10</td>
<td>−0.03</td>
<td>0.202</td>
</tr>
<tr>
<td>Treatment expectation</td>
<td>−0.03 (0.03)</td>
<td>−.06</td>
<td>−0.01</td>
<td>−0.06</td>
<td>−0.014</td>
</tr>
<tr>
<td>Self-assessments</td>
<td>0.19 (0.20)</td>
<td>.07</td>
<td>−0.04</td>
<td>0.06</td>
<td>0.084</td>
</tr>
<tr>
<td>Follow-ups(^d)</td>
<td>−1.74 (1.01)</td>
<td>−.13</td>
<td>−0.16</td>
<td>−0.11</td>
<td>−0.331</td>
</tr>
</tbody>
</table>

\(^a\)\(R^2=0.24;\) adjusted \(R^2=0.20;\) lower scores on the quality-of-life measure indicated higher quality of life.
\(^b\)\(sr: the semipartial correlation.\)
\(^c\)N/A: not applicable.
\(^d\)\(P<.01.\)

Discussion

Principal Findings

We hypothesized that a combination of personality traits (conscientiousness and neuroticism), recent feelings of negative affect (depression, anxiety, and stress), recent alcohol use, and expectations of treatment effectiveness could predict subsequent study engagement within a young adult–focused web-based intervention trial (iTreAD). We further hypothesized that personality, negative affect, alcohol use, treatment expectations, and study engagement would predict treatment satisfaction and self-reported quality of life at the end of iTreAD. We expected that conscientiousness, treatment expectations, and study engagement would exert a positive influence on study engagement and outcomes, whereas neuroticism, negative affect, and greater alcohol consumption at baseline would pose obstacles to study engagement and derive any intended benefit. This study sought to extend the existing literature by combining these predictive factors into a single model to test the overall magnitude of influence and discern the unique contributions of predictor variables.

As there were no previous studies known to us that had assessed predictors of engagement, treatment satisfaction, and quality-of-life outcomes simultaneously, we had no a priori expectations regarding the shared and unique contributions of predictor variables in explaining outcomes. Our results indicated...
that the combined effects of personality, negative affect, alcohol use, and attitudes in predicting study engagement were relatively low. Although conscientiousness, anxiety, stress, and alcohol consumption showed significant zero-order correlations with our measures of study engagement, only 5% of the variance in study engagement exhibited by young Australian adults could be attributed to personality, negative affect, alcohol use, and treatment expectations at the time of study registration, when considering all predictor variables. This is a clinically important finding, indicating that this range of presenting characteristics supporting engagement in mental health services in previous research was not as salient in a population of young adults with comorbid depression and alcohol use problems. It is well recognized that comorbid substance use and mental disorders are among the strongest factors associated with nonengagement with mental health treatment [49], and young people represent a particular subgroup of our community who are among the hardest to engage in treatment [6]. Although treatment engagement is a complex and multidimensional issue, a review of people with mental illness highlighted the potential for digital tools to remove many of the traditional barriers to access mental health treatment, to encourage ongoing psychoeducation, to outreach to people in environments in which they feel comfortable and safe, and to promote autonomy and empowerment [6]. These issues may be particularly important for young people considering treatment for sensitive mental health problems and for people with comorbidities who may experience service fragmentation and disconnection when seeking care. It may be that the digital environment offered our study population an opportunity that overcame some of these typical predictors of engagement. Future research should seek to understand digital tools in this context, particularly given that our study still reported high levels of attrition over time.

Among the predictors of study engagement, and contrary to expectations, only elevated neuroticism levels at baseline seemed to be associated with increased numbers of monthly web-based self-assessments returned. Previous studies demonstrated that neuroticism could indeed be beneficial for performance because of individuals’ increased tolerance for negative affect [50], which may have played a supportive role in participants’ willingness to complete self-assessments in this study. These findings resemble what previous researchers have coined healthy neuroticism, where a combination of neurotic self-awareness and conscientious decision making indicates engaging in favorable health behaviors such as increased doctor visits and fewer risky behaviors such as alcohol consumption and smoking [51-54]. Importantly, Weston and Jackson [52] found that healthy neurotics were more successful than other personality types in implementing effective behavior change after disease onset, suggesting that awareness of a chronic condition facilitated healthful actions particularly well in this group. Hence, it is possible that among treatment-seeking young people, moderate levels of neuroticism are beneficial to increase the chances of ongoing engagement with a digital mental health intervention study.

Concerning treatment satisfaction, the prediction model did not yield statistical significance, indicating that our predictors did not explain substantive variance in treatment satisfaction. Reductions in the adjusted R-squared value compared with the initial R-squared value indicated that the variables entered were in fact detrimental to explaining variance in treatment satisfaction. Although the overall model did not reach the statistical level of significance, it is worth noting that, in line with zero-order correlations, completion of incentivized follow-up assessments was uniquely predictive of satisfaction ratings at the conclusion of the study. Participants were invited to complete follow-up assessments 26, 39, 52, and 64 weeks after study registration and were reimbursed each time they returned a follow-up assessment. It is possible that the ongoing reflection on symptom scores combined with positive reinforcement through the incorporation of a tangible monetary reward system facilitated satisfaction with the study overall. This may hint toward the utility of supervision and blended care models, where some clinician guidance takes place alongside digital mental health therapy. Furthermore, personality, emotional distress, the severity of alcohol consumption, and even treatment allocation did not seem to affect satisfaction with the trial negatively. Satisfaction ratings with the study were good across all the conditions. These results warrant further exploration of factors influencing young adults’ satisfaction with web-based treatment components in particular, given the increasing focus on providing web-based health tools to young, digitally native populations [14].

Most notably, personality, affect, treatment expectation, and engagement variables together predicted about one-fifth of the variance in quality-of-life responses at the end of the iTreAD study. Although there were numerous moderate-sized zero-order associations with quality of life, when all predictors were included within one model (and with this, the sizable correlations between the predictor variables were accounted for), only depression remained a unique contributor to the variance in quality of life. These results underscore that depressive symptoms are a robust contributor to poor functioning in young people facing problems with alcohol and deserve attention in the design and delivery of digital mental health interventions.

Strengths and Limitations

Although the strength of this analysis lies in the simultaneous inspection of predictive factors, several limitations warrant consideration. First, our study’s engagement measures were somewhat limited in scope. Although our study engagement variables captured both treatment and trial engagement, only one common aspect of the treatment protocol (monthly web-based self-assessments) could be considered for the analysis. Ideally, web-based treatment engagement metrics would comprise several treatment components, such as the number of log-ins and module completion rates within the digital mental health intervention [55]. Power requirements prevent such an approach in our analyses; however, future research should attempt to uncover person-based predictors of web-based treatment engagement using more content-valid engagement measures. Second, although the decision as to which variables to include in this analysis was informed by the existing literature, the results revealed that the overall contribution of personality, affect, alcohol use, and expectations in predicting markers of treatment success were small, indicating that other, more

https://mental.jmir.org/2021/6/e23986
important factors determined engagement in this digital treatment trial. Third, because of the optional completion of study components and study attrition, analyses including variables assessed at the conclusion of the study (ie, treatment satisfaction and quality of life) were slightly underpowered and thus needed to be interpreted with caution.

Conclusions
Taken together, our findings suggest that web-based mental health trials should continue to consider and aim to treat initial levels of depression to optimally improve quality-of-life experiences at the conclusion of the intervention period. In addition, neuroticism may constitute a positive predictor of subsequent engagement with the treatment protocol, and study adherence incentivized through monetary rewards may indicate improved satisfaction with the digital service overall.

Digital mental health interventions have the potential to become an integral part of health promotion strategies aimed at young people [11]. However, to meet this objective, web-based treatments need to capture their target audience’s demands and deliver health information and mental health support in a comprehensive, effective, and engaging way. Our findings suggest that traditional predictors of engagement observed in face-to-face and even some web-based research may not be easily transferable to evaluate digital health interventions, particularly those aimed at comorbid mental health concerns and alcohol misuse among young adults.

Future research should continue to assess which factors and their combinations reliably and substantially predict young adults’ engagement with digital mental health tools. As a next step, similar to face-to-face psychotherapy recommendations [56], supervised and tailored approaches to digital health and mental health promotion may yield the most engaging prospect as interventions can be personalized and delivered in a manner that suits the person undertaking web-based treatment [15].

Conflicts of Interest
None declared.

References


17. Yeager CM, Benight CC. If we build it, will they come? Issues of engagement with digital health interventions for trauma recovery. Mhealth 2018;4:37 [FREE Full text] [doi: 10.21037/mhealth.2018.08.04] [Medline: 30363749]


**Abbreviations**

- **AUDIT-C**: Alcohol Use Disorders Identification Test-Concise  
- **AQoL-6D**: Assessment of Quality of Life questionnaire  
- **BFI**: Big Five Inventory  
- **DASS-21**: Depression, Anxiety, and Stress Scale-21 items  
- **iTreAD**: Internet Treatment for Alcohol and Depression
Factors Predicting Trial Engagement, Treatment Satisfaction, and Health-Related Quality of Life During a Web-Based Treatment and Social Networking Trial for Binge Drinking and Depression in Young Adults: Secondary Analysis of a Randomized Controlled Trial

JMIR Ment Health 2021;8(6):e23986
URL: https://mental.jmir.org/2021/6/e23986
doi:10.2196/23986
PMID:34096873
Design and Implementation of an Informatics Infrastructure for Standardized Data Acquisition, Transfer, Storage, and Export in Psychiatric Clinical Routine: Feasibility Study

Rogério Blitz¹, PhD; Michael Storck¹, PhD; Bernhard T Baune²,³,⁴, Prof Dr, MPH, MBA, FRANZCP; Martin Dugas¹,⁵*, Prof Dr; Nils Opel²,⁶,⁷*, MD

¹Institute of Medical Informatics, University of Münster, Münster, Germany
²Department of Psychiatry, University of Münster, Münster, Germany
³The Florey Institute of Neuroscience and Mental Health, University of Melbourne, Melbourne, Australia
⁴Department of Psychiatry, Melbourne Medical School, University of Melbourne, Melbourne, Australia
⁵Institute of Medical Informatics, Heidelberg University Hospital, Heidelberg, Germany
⁶Institute for Translational Psychiatry, University of Münster, Münster, Germany
⁷Interdisciplinary Centre for Clinical Research of the Medical Faculty, University of Münster, Münster, Germany

* these authors contributed equally

Corresponding Author:
Nils Opel, MD
Department of Psychiatry
University of Münster
Albert-Schweitzer-Str. 11
Münster, 48149
Germany
Phone: 49 2518358160
Email: n_opel01@uni-muenster.de

Abstract

Background: Empirically driven personalized diagnostic applications and treatment stratification is widely perceived as a major hallmark in psychiatry. However, databased personalized decision making requires standardized data acquisition and data access, which are currently absent in psychiatric clinical routine.

Objective: Here, we describe the informatics infrastructure implemented at the psychiatric Münster University Hospital, which allows standardized acquisition, transfer, storage, and export of clinical data for future real-time predictive modelling in psychiatric routine.

Methods: We designed and implemented a technical architecture that includes an extension of the electronic health record (EHR) via scalable standardized data collection and data transfer between EHRs and research databases, thus allowing the pooling of EHRs and research data in a unified database and technical solutions for the visual presentation of collected data and analyses results in the EHR. The Single-source Metadata ARchitecture Transformation (SMA:T) was used as the software architecture. SMA:T is an extension of the EHR system and uses module-driven engineering to generate standardized applications and interfaces. The operational data model was used as the standard. Standardized data were entered on iPads via the Mobile Patient Survey (MoPat) and the web application Mopat@home, and the standardized transmission, processing, display, and export of data were realized via SMA:T.

Results: The technical feasibility of the informatics infrastructure was demonstrated in the course of this study. We created 19 standardized documentation forms with 241 items. For 317 patients, 6451 instances were automatically transferred to the EHR system without errors. Moreover, 96,323 instances were automatically transferred from the EHR system to the research database for further analyses.

Conclusions: In this study, we present the successful implementation of the informatics infrastructure enabling standardized data acquisition and data access for future real-time predictive modelling in clinical routine in psychiatry. The technical solution presented here might guide similar initiatives at other sites and thus help to pave the way toward future application of predictive models in psychiatric clinical routine.
Introduction

Scientific Background

Psychiatric disorders represent one of the leading causes of disability worldwide. In the challenge to provide advanced treatment and prevention strategies for psychiatric disorders, previous research has focused on better understanding of the neurobiological basis of affective disorders [1]. However, the translation of such findings into clinical application remains an unresolved problem up to now. For this reason, the focus of psychiatric research has shifted from sole neurobiological characterization at the group level toward the application of multivariate machine learning methods trained on multimodal data for individualized prediction of clinical outcomes [2,3]. Multivariate machine learning applications have been proven to be innovative and powerful tools in translational psychiatric research. In this regard, the successful utilization of machine learning algorithms for individualized predictions of treatment response [4-6], depression severity [7], disease risk [8], differential diagnosis [9,10], and relapse risk [11] has yielded the first promising results. However, up to now, several obstacles have prevented the successful transfer of individual predictive modeling to routine clinical application, as discussed in recent reviews [12-15]. In this regard, the gap between homogeneous well-characterized samples acquired in experimental studies [16] and heterogeneous unvalidated data from day-to-day clinical routine has proven to be a major obstacle in the translation of predictive models to routine application. Hence, ecologically valid predictive models would require access to standardized real world data collected at the point of care [17].

Importantly, large-scale studies reporting the successful application of multivariate models trained on data from electronic health records (EHRs), including features such as diagnosis and procedures, laboratory parameters, and medications for the prediction of suicide risk or weight gain following antidepressant treatment have demonstrated the capacity and generalizability of predictive models trained on real-world data [18-20]. Further extension of EHRs via standardized collection of predictive variables such as known risk factors might further enhance the potential of this novel data entity for predictive analytics in psychiatry [21,22]. Standardized electronic collection of patient-reported outcomes that has previously been shown to improve clinical outcomes such as survival in patients with cancer represents another possibility to enrich EHR data. Similarly, combining data from EHRs with research data might provide new opportunities for the discovery and validation of psychiatric endophenotypes as demonstrated via recent validation of a polygenic risk score in a Danish population study [23]. However, future application of predictive models for personalized diagnostic and treatment requires their validation via clinical trials that, in turn, critically depend on the availability of the informatics infrastructure for the application of predictive models in routine care. The required informatics infrastructure should facilitate the acquisition of standardized real world data at the point of care, potential enrichment with patient-reported outcomes or research data, and subsequent access to data for clinicians and researchers. However, while these technical requirements are already available in selected clinical settings, for example, in the United States [24], they are up to now absent in the clinical working environment of psychiatry hospitals in many European countries. More concretely, ORBIS, the EHR system that is the market leader in Germany, Austria, and Switzerland, does not currently support standardized form metadata, clinical data, or annotated data sets. Our approach thus addresses the currently unmet need to (1) implement the technical requirements for standardized data acquisition and analysis in one of the most widely used EHR systems in Europe and (2) to specifically design a technical solution, including appropriate data collection routines, for the domain of clinical psychiatry.

This study aims to present the design and implementation of the technical requirements to address the aforementioned challenges with the ultimate goal of providing the basis for a successful future translation of predictive models to routine application in psychiatric disorders. The implementation of the outlined technical solution will ultimately allow the evaluation of the potential of predictive models for the clinical management of psychiatric disorders under real-world conditions. In detail, we present the design and implementation of the informatics infrastructure, including technical solutions for (1) extension of the EHR via standardized electronic collection of patient-reported outcomes, (2) data transfer between EHRs and research databases, (3) pooling of EHRs and research data in a unified database, and (4) visual presentation of the analyses results in the EHRs.

Objective of This Study

The main objective of this study was the design and successful implementation of the informatics infrastructure required to train and validate predictive models in day-to-day clinical application in psychiatry as part of the SEED 11/19 study [25]. Our study consisted of the following steps in detail:

1. Implementation of standardized documentation forms in EHRs.
2. The set-up of an interface for direct data transfer between clinical documentation systems and a database for predictive analysis.
3. The set-up of a unified database that allows pooling of clinical data with further research data for predictive analysis.
4. Visual presentation of relevant data entities and results of predictive analysis in EHRs at the point of care.
Methods

Setting
The Münster University Hospital in Germany is a tertiary care hospital with 1457 beds and 11,197 staff who treated 607,414 patients (inbound and outbound) in 2019 [26]. The department for psychiatry and psychotherapy at the University Hospital treated 1341 cases in the study period from February 25, 2019 to July 31, 2020 (1042 cases in 2018 [27,28]). Validation was carried out by 25 doctors and 61 specialists from the health care sector.

System Details
The EHR system ORBIS by Dedalus Healthcare is used at Münster University Hospital in more than 40 clinics and is the market leader in Germany, Austria, and Switzerland with over 1300 installations [29]. The EHR system has an 8700 GB Oracle database, 7938 users, and 1927 user sessions per day (status at July 2020) at Münster University Hospital. No standardized metadata form, clinical data, and annotated data sets are supported.

Requirement Engineering
To address the study aims, the following requirements were identified through focus groups including physicians and researchers at Münster University Hospital in Germany.

1. Extension of the EHR via standardized data collection: At first sight, the widely established usage of electronic documentation systems in clinical routine might supplement the notion of a fast translation of predictive models. However, until now, the majority of clinical data is still acquired and stored in an unstructured way that cannot be directly used for predictive modeling. Extension of EHR data via standardized forms of data collection in routine care is therefore required to provide a sufficient database for the development of predictive models. Importantly, the technical solution should be flexible and allow to update the content of the collected EHR data. Content-wise, in an initial step, standardized extension of EHR data should include assessment of symptomatology in order to allow both patient stratification at baseline as well as outcome measurement following intervention. Furthermore, standardized assessment of known risk factors, including life events and sociodemographic data, appears meaningful.

2. Data transfer: Routine EHR data storage systems are usually strictly separated from research databases for safety reasons and hence are not directly accessible for predictive analyses. Training and validation of predictive models based on EHR data requires the set-up of interfaces and a database in which EHR data can be transferred and subsequently stored in a standardized way. In line with our study aim, the technical solutions should be scalable and allow data transfer in real time. EHR data transferred and stored in the database must be accessible for researchers in order to allow the development of predictive models.

3. Combination of EHRs and research data: Again, since routine EHR data storage systems are strictly separated from research databases, pooling of EHR and research data is not possible within state-of-the art EHR databases. Pooling EHR with research data in a unified database would also be accessible for researchers in order to combine each patient’s EHR and research data, a unified scalable research database is needed that allows the integration of EHRs and research data acquired via experimental studies.

4. Presentation of standardized data within the EHR: Once collected, clinically useful standardized data as well as results of any analysis must be transferred back to the main EHR system in real time and presented to the clinician at the point of care.

Solution Requirements
An informatics infrastructure enabling real-time clinical predictive modeling based on the single-source architecture was derived from the named requirements. Custom metadata must be supported. The Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM) (version 1.3.2) was used as a flexible standard for exchange and archiving of metadata within the framework of clinical studies [30,31]. Mobile apps must be able to communicate with the architecture. Automatic data transfer into the database of the EHR system and from the EHR system to a research database was carried out via a communication server. ODM files were transported automatically to the database of the EHR system with Health Level 7 (HL7) messages [32]. NextGen Connect [33] was used as a communication server. HL7 version 2.5 and message type ORU^R01 were used. The plausibility and completeness of form data were validated by the clinical users.

Analysis of Technical and Clinical Feasibility
The technical feasibility was demonstrated by the implementation of an infrastructure that enables clinical predictive modeling in real time. Java version 1.8.0_181 [34], JavaScript ECMAScript 6 [35], TypeScript version 3.7.2 [36], and the proprietary language of the EHR system were used as programming languages. MongoDB Java Drivers version 3.9.1 [37] and Json-lib version 2.4 [38] were used as third-party libraries. MongoDB version 4.2.3 [39] was used as a research database, Docker version 19.03.13 [40] for operating system–level virtualization, and Red Hat Enterprise version 7.8 [41] as research server. The clinical feasibility was determined by piloting the architecture in the clinic for psychiatry and psychotherapy and for a prospective analysis of the clinical documentation forms used. The clinical users of the system were 25 doctors and 61 health care sector specialists. The stakeholder of the study at Münster University Hospital is the Institute for Translational Psychiatry, Department of Psychiatry. Evaluation began on February 25, 2019 and ended on July 31, 2020. EHR data from daily clinical routine (e.g., laboratory data, diagnostic codes) and self-reports/patient-reported outcomes that were experimentally collected as an extension of the clinical routine documentation as part of the SEED research project were examined. The following evaluation criteria were analyzed: (1) measurement of data completeness in the created documentation forms, (2) measurement of data completeness...
in the research database, (3) monitoring of system stability, and (4) monitoring of data transfer. SPSS Statistics version 25 (IBM Corp) [42] was used for descriptive data analysis. Adobe Photoshop version 11.0 [43] and Microsoft Visio version 16.0.4849.1000 [44] were used to depict the workflow.

Results

System Architecture

The Single-source Metadata ARchitecture Transformation (SMA:T) was used as the software architecture [45]. SMA:T is an extension of the EHR system of the Münster University Hospital and uses module-driven software development [46] to generate standardized applications and interfaces. Every SMA:T form has a generic built-in interface for exchanging standardized data. Embedded applications [45] were used as the application type. These are linked to an ODM file in the EHR database, from which a documentation form is generated. All metadata and clinical data are available in the ODM developed by CDISC version 1.3.2. Patient-reported outcomes are recorded via Mobile Patient Survey (MoPat) [47,48] on mobile devices (generation 6 iPads) and via the web application Mopat@home (a modified version of the tablet-based web app MoPat) [49] for follow-up assessments following discharge from inpatient treatment. Collected data are transferred to the communication server via an HL7 message and from there to the database of the EHR system. Data are sent in the OBX-5 segment of the HL7 message. SMA:T provides database storage. A reference to the imported clinical data is saved. Clinical data are automatically inserted by SMA:T when the documentation form is opened for the first time. A unique ID from the HL7 header is used for this purpose. Each ID is linked to an imported clinical record. The structure of the architecture is shown in Figure 1. Data transfer to the research database takes place via the researcher module from SMA:T. This provides a front end to the EHR system and an extension of the communication server for data transfers. Both prospective and retrospective standardized data exports of EHR data points are supported, specifically, vital signs, laboratory data, medication data, and administrative data. Each data export can be customized by individual parameters. The following parameters are supported: name of data export, export interval, database query, destination parameters for electronic data capture systems, or research databases. MongoDB and RedCap [50] are currently provided as destination templates in the EHR system. The destination portfolio can easily be expanded with interface functions of SMA:T. The research database is embedded in a Docker container of a virtualized Red Hat Enterprise Linux server. The data flow from EHR to electronic data capture is shown in Figure 2. The software architecture is shown in Figure 3.
Figure 1. Unified Modeling Language sequence diagram of the data collection workflow. In process steps 1-3, the patient completes the forms and sends data to the communication server. In process steps 4-8, the communication server sends data to the electronic health record system and creates a blank documentation form. This form is populated with imported data. In process steps 9-13, SMA:T creates the documentation form with metadata and imported data. EHR: electronic health record; HL7: Health Level 7; MoPat: Mobile Patient Survey; ODM: operational data model; SMA:T: Single-source Metadata ARchitecture Transformation.
Figure 2. Unified Modeling Language sequence diagram of the data extraction workflow. In process steps 1-8, a study query is created with SMA:T and a generic operational data model file is saved in the database of the electronic health record system. In process steps 9-18, a generic Mirth Channel is created based on the study query. In process steps 19-20, data points are automatically extracted from the electronic health record system and transferred to the study database using operational data model standard format. EDC: electronic data capture; EHR: electronic health record; HDD: Hard Disc Drive; HL7: Health Level 7; LOC: Lines Of Code; MoPat: Mobile Patient Survey; ODM: operational data model; SMA:T: Single-source Metadata ARchitecture Transformation.
System Implementation

The implementation of the architecture is divided into 4 areas: data collection, data transfer, data storage, and data visualization. Agile methods were used for Project Life Cycle and Development Cycle [51].

Data Collection

SMA:T provides 2 options for data collection, namely, the EHR system in clinical routine and dedicated web applications. Data input via web applications can be designed freely. In this study, EHR data generated as part of clinical routine documentation comprised, among others, laboratory data, medication, information on diagnosis, time of admission, and length of stay and are presented in detail in Table 1. MoPat [47,48] was selected for the collection of patient-reported outcomes. After input of the patient case ID, staff handed the patient an iPad with the MoPat app. Patients were then guided through a series of documentation forms comprising different questionnaires and they entered data on the mobile device (Figure 4). The iPad was then returned to the medical staff. Further details regarding the collection of patient-reported outcomes during inpatient treatment have previously been described [25]. In brief, the self-reports applied in this study are based on well-established questionnaires and scales in the domain of psychiatry and clinical psychology. In addition, to the retention of single item information, sum scales were calculated based on the recommendations provided in the original manuals and references [52-58]. In addition, Mopat@home was used for the collection of patient-reported outcomes following discharge. To this end, patients were sent an email, which provided a link to a website in which the above referenced questionnaires were presented and could be filled out [49].

Figure 3. SEED software architecture of the Münster University Hospital. EHR: electronic health record; MoPat: Mobile Patient Survey; SMA:T: Single-source Metadata ARchitecture Transformation; *supports custom applications.
Table 1. Research documentation used in the Department of Psychiatry.

<table>
<thead>
<tr>
<th>Name of the documentation form</th>
<th>Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEED ClinicalData Admission Date &amp; Time</td>
<td>4</td>
</tr>
<tr>
<td>SEED ClinicalData Classification</td>
<td>2</td>
</tr>
<tr>
<td>SEED ClinicalData Diagnosis-Related Groups/Diagnosis</td>
<td>3</td>
</tr>
<tr>
<td>SEED ClinicalData Electroconvulsive Therapy</td>
<td>11</td>
</tr>
<tr>
<td>SEED ClinicalData Laboratory Assessments</td>
<td>7</td>
</tr>
<tr>
<td>SEED ClinicalData Medication</td>
<td>5</td>
</tr>
<tr>
<td>SEED ClinicalData Patient</td>
<td>4</td>
</tr>
<tr>
<td>SEED ClinicalData Vital Signs</td>
<td>3</td>
</tr>
</tbody>
</table>

Figure 4. One item of Beck Depression Inventory presented in the MoPat app (clinic for psychiatry and psychotherapy at Münster University Hospital).

Data Transfer

SMA:T provides 2 types of data transfer in the present scenario, that is, data transfer into the EHR system and transfer into the electronic data capture system. MoPat sends data to the EHR system via the communication server of the University Hospital. Data are saved in the ClinicalData structure of the ODM format. The ODM document is embedded in an HL7 message. Each HL7 message creates a form in the EHR system. The header of the HL7 message determines which form is automatically created. Data transfer to the electronic data capture takes place via SMA:T interfaces. Both retrospective and prospective data exports in real time are supported. When a study query was activated via the EHR frontend, metadata and corresponding structured query language statements were read by the SMA:T extension of the communication server. SMA:T uses its code library and channel framework to generate unique Mirth channels. These send a database query to the EHR system and transfers the output directly to the electronic data capture system. Both metadata (clinical documentation form) and clinical patient data are provided by SMA:T in the ODM format. Data records are combined into an ODM document. In this study, SMA:T converts the resulting XML-based ODM document into JavaScript Object Notation format [59] (JODM format [60]). The JavaScript Object Notation schema [61] of JODM [60] is open source and currently limited to Study and ClinicalData nodes, including all subnodes of the ODM in version 1.3.2.
**Data Storage**

Data storage addresses metadata and clinical data. Metadata of clinical documentation forms are stored centrally in the SMA:T database. The SMA:T database model is part of the EHR database model. Metadata and clinical data are available in the ODM format. MoPat also supports ODM format; therefore, the same data model can be used for both systems. Clinical data are clearly identified by unique object identifiers and the associated object identifier on the documentation form.

**Data Presentation**

Usability principles were applied to visualize data [62-64]. A one-column layout was implemented according to the requirements of the 10 web form design guidelines [65]. Those forms are displayed via SMA:T within the EHR system (see Multimedia Appendix 1 and Multimedia Appendix 2). SMA:T supports item-based real-time notifications as well as centralized notification services to display analysis results in real time.

**Technical and Clinical Feasibility**

As part of the study, 11 customized documentation forms with 202 items were created for the clinic for psychiatry and psychotherapy (Table 2): Beck Depression Inventory [66], Big Five Inventory (BFI-2-S) [67], Big Five Inventory (BFI-2-XS) [68], Childhood Trauma Questionnaire [69], Family Mental History [70], Hamilton Depression Scale [71], Narcissistic Admiration and Rivalry Questionnaire [72], Symptom Checklist-90 Somatization Scale [73], sociodemographic questionnaire [74], questions on individual disease course [75], and questions on somatic comorbidities [76]. Data models without license restrictions are available in the portal of medical data models. A documentation form is a document from the EHR system (see Multimedia Appendix 1) and consists of several items. An item consists of an input field and the associated label. For example, 1 item from Multimedia Appendix 1 is the drop-down box labeled A; 5866 instances of several items were created by the patients with Mopat@home and automatically transferred to the research database via SMA:T (Table 7).

<table>
<thead>
<tr>
<th>Name of the documentation form (n=11)</th>
<th>Items (n=202)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>23</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-S)</td>
<td>35</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-XS)</td>
<td>20</td>
</tr>
<tr>
<td>Childhood Trauma Questionnaire</td>
<td>34</td>
</tr>
<tr>
<td>Family Mental History</td>
<td>14</td>
</tr>
<tr>
<td>Hamilton Depression Scale</td>
<td>25</td>
</tr>
<tr>
<td>Narcissistic Admiration and Rivalry Questionnaire</td>
<td>9</td>
</tr>
<tr>
<td>Symptom Checklist-90 Somatization Scale</td>
<td>14</td>
</tr>
<tr>
<td>Sociodemographic questionnaire</td>
<td>5</td>
</tr>
<tr>
<td>Questions on individual disease course</td>
<td>18</td>
</tr>
<tr>
<td>Questions on somatic comorbidities</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 2. Routine documentation used in the Department of Psychiatry.
Table 3. Number of instances created for each documentation form: the counts of patients, patient cases, and users are shown.

<table>
<thead>
<tr>
<th>Name of the documentation form</th>
<th>Cases</th>
<th>Patients</th>
<th>Instances</th>
<th>Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>380</td>
<td>307</td>
<td>1266</td>
<td>50</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-S)</td>
<td>358</td>
<td>303</td>
<td>559</td>
<td>25</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-XS)</td>
<td>258</td>
<td>217</td>
<td>692</td>
<td>19</td>
</tr>
<tr>
<td>Childhood Trauma Questionnaire</td>
<td>313</td>
<td>303</td>
<td>354</td>
<td>33</td>
</tr>
<tr>
<td>Family Mental History</td>
<td>315</td>
<td>305</td>
<td>343</td>
<td>31</td>
</tr>
<tr>
<td>Hamilton Depression Scale</td>
<td>350</td>
<td>296</td>
<td>516</td>
<td>42</td>
</tr>
<tr>
<td>Narcissistic Admiration and Rivalry Questionnaire</td>
<td>357</td>
<td>302</td>
<td>558</td>
<td>20</td>
</tr>
<tr>
<td>Symptom Checklist-90 Somatization Scale</td>
<td>360</td>
<td>303</td>
<td>564</td>
<td>18</td>
</tr>
<tr>
<td>Sociodemographic questionnaire</td>
<td>315</td>
<td>305</td>
<td>344</td>
<td>26</td>
</tr>
<tr>
<td>Questions on individual disease course</td>
<td>315</td>
<td>305</td>
<td>342</td>
<td>26</td>
</tr>
<tr>
<td>Questions on somatic comorbidities</td>
<td>313</td>
<td>303</td>
<td>328</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 4. Data quality of patient-based documentation regarding score calculation.

<table>
<thead>
<tr>
<th>Name of the documentation form</th>
<th>Instances</th>
<th>Scores</th>
<th>Missing data&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>1266</td>
<td>1238</td>
<td>28</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-S)</td>
<td>559</td>
<td>540</td>
<td>19</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-XS)</td>
<td>692</td>
<td>656</td>
<td>36</td>
</tr>
<tr>
<td>Childhood Trauma Questionnaire</td>
<td>354</td>
<td>320</td>
<td>34</td>
</tr>
<tr>
<td>Hamilton Depression Scale</td>
<td>516</td>
<td>502</td>
<td>14</td>
</tr>
<tr>
<td>Narcissistic Admiration and Rivalry Questionnaire</td>
<td>558</td>
<td>550</td>
<td>8</td>
</tr>
<tr>
<td>Symptom Checklist-90 Somatization Scale</td>
<td>564</td>
<td>554</td>
<td>10</td>
</tr>
</tbody>
</table>

<sup>a</sup>Missing data frequency is determined by missing data entries.

Table 5. Data on the completeness of the documentation forms.<sup>a</sup>

<table>
<thead>
<tr>
<th>Name of the documentation form</th>
<th>Items</th>
<th>Completed items</th>
<th>Uncompleted items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>29,118</td>
<td>29,015</td>
<td>103</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-S)</td>
<td>19,565</td>
<td>19,519</td>
<td>46</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-XS)</td>
<td>13,840</td>
<td>13,739</td>
<td>101</td>
</tr>
<tr>
<td>Childhood Trauma Questionnaire</td>
<td>12,036</td>
<td>11,985</td>
<td>51</td>
</tr>
<tr>
<td>Family Mental History</td>
<td>4802</td>
<td>4354</td>
<td>448</td>
</tr>
<tr>
<td>Hamilton Depression Scale</td>
<td>12,384</td>
<td>12,076</td>
<td>308</td>
</tr>
<tr>
<td>Narcissistic Admiration and Rivalry Questionnaire</td>
<td>5031</td>
<td>5012</td>
<td>19</td>
</tr>
<tr>
<td>Symptom Checklist-90 Somatization Scale</td>
<td>7896</td>
<td>7879</td>
<td>17</td>
</tr>
<tr>
<td>Sociodemographic questionnaire</td>
<td>1720</td>
<td>1715</td>
<td>5</td>
</tr>
<tr>
<td>Questions on individual disease course</td>
<td>6156</td>
<td>5453</td>
<td>703</td>
</tr>
<tr>
<td>Questions on somatic comorbidities</td>
<td>1640</td>
<td>1095</td>
<td>545</td>
</tr>
</tbody>
</table>

<sup>a</sup>In this context, completeness means that the documentation form contains values in all data points.
Table 6. Number of retrospectively transferred research documentation forms (electronic health record to electronic data capture).a

<table>
<thead>
<tr>
<th>Name of the documentation form</th>
<th>Instances in electronic health records</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEED ClinicalData Admission Date &amp; Time</td>
<td>245</td>
</tr>
<tr>
<td>SEED ClinicalData Classification</td>
<td>8260</td>
</tr>
<tr>
<td>SEED ClinicalData Diagnosis-Related Groups/Diagnosis</td>
<td>1163</td>
</tr>
<tr>
<td>SEED ClinicalData Electroconvulsive therapy</td>
<td>452</td>
</tr>
<tr>
<td>SEED ClinicalData Laboratory Assessments</td>
<td>22,886</td>
</tr>
<tr>
<td>SEED ClinicalData Medication</td>
<td>14,244</td>
</tr>
<tr>
<td>SEED ClinicalData Patient</td>
<td>245</td>
</tr>
<tr>
<td>SEED ClinicalData Vital Signs</td>
<td>48,828</td>
</tr>
</tbody>
</table>

aElectronic health record data were extracted with generic study queries in the Single-source Metadata ARchitecture Transformation system.

Table 7. Number of instances created with Mopat@home for each documentation form.

<table>
<thead>
<tr>
<th>Name of the documentation form</th>
<th>Instances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>65</td>
</tr>
<tr>
<td>Big Five Inventory (BFI-2-S)</td>
<td>64</td>
</tr>
<tr>
<td>Childhood Trauma Questionnaire</td>
<td>65</td>
</tr>
<tr>
<td>Family Mental History</td>
<td>65</td>
</tr>
<tr>
<td>Narcissistic Admiration and Rivalry Questionnaire</td>
<td>64</td>
</tr>
<tr>
<td>Symptom Checklist-90 Somatization Scale</td>
<td>66</td>
</tr>
<tr>
<td>Sociodemographic questionnaire</td>
<td>66</td>
</tr>
<tr>
<td>Questions on individual disease course</td>
<td>65</td>
</tr>
<tr>
<td>Questions on somatic comorbidities</td>
<td>65</td>
</tr>
</tbody>
</table>

Discussion

Answers to the Study Questions

The aim of this study was the design and implementation of an informatics infrastructure enabling standardized data acquisition at the point of care and subsequent accessibility of clinical data for analytic purposes, which is required for future application of predictive models in day-to-day clinical routine in psychiatry. In this study, we have shown the overall technical feasibility of the implemented solution. Standardized documentation forms were implemented to extend EHR data domains and to improve data quality in the EHR system. An automated transfer of data into the EHR system and the research database was implemented, thus enabling the pooling of EHR data with already existing research data from ongoing cohort studies. This system was accepted by clinical staff from the Department of Psychiatry of Münster University Hospital in Germany. Widespread use of documentation forms could be demonstrated. Standardized electronic data collection in the EHR at the point of care was successfully implemented. The latter solution can similarly be applied for the presentation of results from predictive models.

Strengths and Weaknesses of This Study

The major strengths of this study are standardized acquisition, transfer, storage, and export of data in real time with a generic informatics infrastructure. This system fulfills the prerequisites for future predictive modelling in clinical routine in psychiatry [85-87]. Standardized data transfer in ODM format provides scalability in the context of complex medical data structures. The Define-XML standard, an extension of the ODM standard, is mandated by regulatory authorities such as Food and Drug Administration for metadata [88]. Compliance with regulatory standards is the major advantage of our infrastructure regarding future clinical studies. The data format had to be converted due to the research database, which is a limitation. MongoDB was chosen for rapid analysis of large amounts of data in previous work [89]. Standardized automatic data transfer into research databases was possible for both retrospective and prospective research questions. The data of the EHR system was responsible for the number of documentation forms for the retrospective export. Data export can be configured centrally from the EHR system in compliance with local data protection regulations. Our approach is scalable because ORBIS EHR systems are used in more than 1300 hospitals in Germany, Austria, and Switzerland. The evaluation concentrated on technical and clinical feasibility. Limitations include the lack of elaborated standardized evaluations of the user experience of the system by clinical staff. Moreover, further evaluation is necessary in order to assess the sustainable benefit in everyday clinical practice. Although the feasibility and acceptability of the implemented data input interface has been demonstrated in a recent publication [24] and the wide-spread use of the implemented data presentation format in the EHR indicates
acceptability, it appears important to note that no further feedback from clinicians (ie, in the form of structured interviews or questionnaires) has been acquired, which limits the informative value regarding user satisfaction. This important issue should therefore be addressed by future works based on elaborated user feedback. Of note, the projected acquisition of data from several hundred cases per year based on our set-up results in a database of modest scale was comparable to that by successfully established deep learning models in other fields of medicine [90]. Yet, it appears important to take into account that the current state-of-the-art machine learning approaches in psychiatric research are based on cohorts with smaller sample sizes that were acquired over a period of multiple years [91-93]. The present initiative that aims to train predictive models on data from clinical routine documentation thus offers a perspective to significantly increase sample sizes in machine learning research in psychiatry. The training of predictive models as well as their validation in clinical applications is not within the scope of this study but will be the focus of subsequent work building on the technical infrastructure outlined in this study. Importantly, as our standardized data acquisition protocol covers established risk factors and symptom profiles that have in part already been successfully used for predictive analytics in psychiatric cohort studies [91,93], it appears reasonable to assume their predictive validity for the intended prediction of symptom trajectories and functional outcomes in future work.

Results in Relation to Other Studies

Through our study, we extend a previous line of research on predictive modeling based on EHR data. While previous studies have demonstrated empirical evidence for the predictive validity of EHR data in psychiatric use cases [18-20], to the best of our knowledge, our study is the first to not only report on the design but also on the successful implementation and technical feasibility of the informatics infrastructure for standardized acquisition, transfer, storage, and access of real world data for analytic purposes in psychiatric care, which is the basic requirement for the application and validation of predictive models in future clinical studies. Although we are not aware of any other study that has reported successful implementation of a comparable informatics infrastructure in psychiatric clinical routine, several preliminary reports should be taken into account. Complementary to the work presented in this study, Khalilia et al [94] described a Fast Healthcare Interoperability Resources (FHIR) web modeling service that was tested on a pilot intensive care unit dataset. A multi-source approach was used. No binding standard is used for clinical studies; instead, the standard Observational Medical Outcomes Partnership Common Data Model was applied [95] and an FHIR server and database are required for this system, which might limit potential implementations at multiple sites, considering that many EHR systems currently do not yet use an FHIR server. Of note, we are aware of several large-scale efforts aiming to translate predictive models into psychiatric practice [96] that, once implemented, might serve as a future base for comparison of system stability and performance. Importantly, the presented infrastructure represents a flexible solution that allows compatibility with existing initiatives and concepts of data standardization such as the Common Data Elements repository of the National Institutes of Health [97]. The choice of the ODM as the data standard implies the automatic provision of a metadata provider for each item. Thus, data points can be enriched with additional codes based on standards such as the Systematized Nomenclature of Medicine Clinical Terms or the Unified Medical Language System [98,99]. The integration takes place via the alias node or the SMA:T schema extension of the ODM. This makes it possible to enrich the survey data with additional metadata. International standardizations are hence compatible with the operating data model based on a 1-1 mapping of item definition nodes.

Generalizability of This Study

The informatics infrastructure for standardized data acquisition, transfer, storage, and export in real time for future predictive modelling outlined in this study is an important step in the complex process toward the implementation of machine learning and clinical decision support solutions in routine care. Our study shows that this approach is technically feasible. Owing to the standardization, this concept is also scalable for other medical areas. Data warehouse applications of a heterogeneous hospital landscape can be implemented with this software architecture. In addition to local artificial intelligence applications, multi-site implementations of the architecture could also transfer pseudonymized data points into a global predictive model. The implementation of national and international predictive models in medicine would be possible.

Future Work

Artificial intelligence systems rely on high-quality data. In the future, artificial intelligence applications might send real-time evaluations directly back into the EHR system. Clinical staff could access and respond to calculated predictions. Selected data will be provided in a modular dashboard. Medical device regulation needs to be taken into account for implementation of such systems. Direct data transfer back from the clinic would be possible. Real-time adjustments of the prediction models would thus be possible. Standardization of clinical routine documentation via SMA:T can provide high-quality structured data points. It is planned to augment this database with further research data from existing cohort studies, for example, covering neuroimaging and genetic data. Specific prediction models can be trained in this way with the same architecture. Generic model pipelines can be set up. Model clusters can be set up to answer complex medical questions. Basically, SMA:T forms a solid technical infrastructure for the implementation of artificial intelligence solutions in medicine. Scheme extensions of the ODM standard can be implemented to optimize communication between systems. Observational and interventional studies are warranted to evaluate the predictive validity of machine learning models in psychiatric routine. For multi-center studies, SMA:T needs to be reimplmented in the respective EHR environments to process CDISC ODM files. A software blueprint is available [45]. If SMA:T and MoPat are already in use, the architecture can be set up within a short time frame of approximately 1 week. The generic concept of the architecture enables the reuse of our data models, database queries, and server architecture. Retrospective database queries might have to be reimplemented.
in the EHR environments. The necessary data can be used from our repository on GitHub [100]. Another important consideration is the potential future enrichment of EHR data with mobile assessments, including ecological momentary assessments and passive sensor data derived from smartphones. Recent reports on successful real-time prediction of depressive symptoms based on ecological momentary assessment data supplement this notion [101]. Thus, future studies should explore technical solutions that allow data transfer between EHRs and patients’ smartphones. Future work will evaluate the predictive potential of the acquired data entities by training and validating machine learning models for an individual level prediction of treatment response, functional outcome, and depression relapse. In accordance with findings from previous machine learning approaches in psychiatric cohort studies, in a first step, well-established predictive algorithms such as support vector machines will be trained on features covering risk and symptom profiles, sociodemographic variables, medication, and treatment history [7,91,93]. Yet importantly, as opposed to previous cohort studies, the technical infrastructure outlined in this study will allow to train and validate predictive models in naturalistic patient samples in routine care.

Conclusions
The presented informatics infrastructure enabling standardized data acquisition, transfer, storage, and export in real time for future predictive modelling in clinical routine in psychiatry is technically feasible. The outlined architecture provides a technical basis for the application, first and foremost, and the validation of clinical decision support systems and artificial intelligence applications in clinical studies.

Acknowledgments
We are deeply indebted to all the participants of this study. This study was supported by a grant from BMBF (HiGHmed 01ZZ1802V). Funding was provided by the Interdisciplinary Center for Clinical Research (IZKF) of the medical faculty of Münster (Grant SEED 11/19 to NO) as well as the “Innovative Medizinische Forschung” (IMF) of the medical faculty of Münster (Grants OP121710 to NO).

Authors’ Contributions
RB and NO drafted the manuscript. RB developed the software architecture and conducted the statistical analyses. NO was responsible for the formulation of the overarching research goal and aims, the study design, conception, development of the methodology, management and coordination responsibility for the research activity planning and execution, data acquisition and design, creation of data models, and data analysis. NO and MD acquired financial support for the conduction of this study. MS supported programming and the implementation of computer code. All authors contributed to the interpretation of data. All authors critically reviewed and substantially revised the final manuscript.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Beck Depression Inventory documentation form created with Single-source Metadata ARchitecture Transformation.
[PNG File, 37 KB - mental_v8f6e26681_app1.png ]

Multimedia Appendix 2
Symptom Checklist-90 Somatization Scale documentation form created with Single-source Metadata ARchitecture Transformation.
[PNG File, 119 KB - mental_v8f6e26681_app2.png ]

References


36. What is TypeScript? TypeScript. URL: https://www.typescriptlang.org/ [accessed 2021-05-25]
46. REDCap. URL: https://www.project-redcap.org/ [accessed 2021-05-25]


88. FDA resources for data standards. US Food and Drug Administration. URL: https://www.fda.gov/industry/fda-resources-data-standards [accessed 2021-05-25]


98. Systematized Nomenclature of Medicine. URL: https://www.snomed.org/ [accessed 2021-05-25]


100. Seed project. GitHub. URL: https://github.com/764374625489/Seed [accessed 2021-05-25]


Abbreviations

CDISC: Clinical Data Interchange Standards Consortium
EHR: electronic health record
FHIR: Fast Healthcare Interoperability Resources
HL7: Health Level 7
MoPat: Mobile Patient Survey
ODM: operational data model
SMA:T: Single-source Metadata ARchitecture Transformation

©Rogério Blitz, Michael Storck, Bernhard T Baune, Martin Dugas, Nils Opel. Originally published in JMIR Mental Health (https://mental.jmir.org), 09.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Mental Health, is properly cited. The complete bibliographic
information, a link to the original publication on https://mental.jmir.org/, as well as this copyright and license information must be included.
Needs and Experiences of Users of Digital Navigation Tools for Mental Health Treatment and Supportive Services: Survey Study

Elizabeth Stafford¹, MPH; Teri Brister¹, LPC, PhD; Ken Duckworth¹, MD; Natali Rauseo-Ricupero², LCSW; Sarah Lagan², BA

¹The National Alliance on Mental Illness, Arlington, VA, United States ²Beth Israel Deaconess Medical Center, Boston, MA, United States

Abstract

Background: Despite a recent proliferation in web-based and digital resources that are designed to assist users in finding appropriate mental health treatment and supportive services, it can be overwhelming, confusing, and difficult for an individual or family member to access and use an appropriate navigation tool. As digital resources are increasingly sought after, there is an urgent need for a clearer understanding of digital navigation tools in order to help link individuals with the tool that is best suited to their needs.

Objective: The objective of this study was to determine the needs of individuals seeking mental health treatment and supportive services and to quantify their experiences and satisfaction with available digital navigation tools.

Methods: A survey was offered via an email newsletter and social media posting throughout the extended membership of the National Alliance on Mental Illness, which includes both individuals with a mental health condition and their family members and support networks. A 13-item anonymous survey, which consisted of multiple-choice and open response options, was developed to measure participants’ past use of and experiences with web-based, mobile, and phone-based navigation tools. The survey was available from April 9 through May 21, 2020.

Results: A total of 478 respondents completed the survey; the majority of respondents were female (397/478, 83.1%) and aged ≥35 years (411/478, 86%). Younger respondents were more likely to report seeking mental health services for themselves, while older respondents were more likely to be searching for such services on behalf of a family member. The majority of respondents seeking such services on behalf of a family member (113/194, 58.2%) required a combination of mental health treatment and supportive services. Furthermore, two-thirds of respondents (322/478, 67.4%) used a navigation tool to find treatment or services. The majority of respondents who provided feedback about their experiences with navigation tools (224/280, 80%) reported difficulties, with data availability and accuracy being the most commonly reported issues.

Conclusions: The survey results suggest that issues with data availability and accuracy in available navigation tools remain a major barrier for locating timely and appropriate mental health treatment and supportive services within the population of individuals seeking such services. Particularly for individuals seeking care on behalf of a family member, improving the accuracy of and users’ experiences with navigation tools could have a major impact on effectively connecting people to treatment and support services.

(JMIR Ment Health 2021;8(6):e27022) doi:10.2196/27022

KEYWORDS
mental health; supportive services; perception; quality; satisfaction; needs; digital tools; directories; navigation
**Introduction**

Approximately 1 in 5 adults and 1 in 7 adolescents in the United States experience a mental health condition each year [1,2]. Although there has been significant progress in reducing the stigma around seeking care, ensuring parity in insurance coverage, and developing new therapeutic models, many individuals continue to struggle in isolation when attempting to enter and navigate a complex and fractured care system. Each of the over 60 million people with a mental health condition has a unique set of experiences and needs that do not always fit neatly into the array of services that are available to them. Beyond talk therapy, which has become increasingly accessible through advances in telehealth [3], and medication, which can often be prescribed by a primary care physician [4], many people are in immediate need of specialized services, such as crisis care or partial hospitalization programs [5,6]. Additionally, coordinated care for chronic physical health issues [7], housing and legal support, or straightforward guidance and reassurance may be needed as people navigate their overall health care path [8].

In the context of the global COVID-19 pandemic, historic protests against systemic racism and injustice and significantly heightened political tensions, rates of anxiety, depression, and trauma-related stress have skyrocketed [9]. These overlapping crises have brought to light the flaws in our current systems of care. For many individuals, treatment can be inaccessible, unaffordable, and unsuited to their specific needs [1,10,11]. In 2019, approximately 43% of US adults with a mental illness who did not receive needed services stated that they could not afford the cost of treatment, 33% did not know where to go for help, and 20% simply could not afford to invest the necessary time for finding and receiving treatment [1]. For researchers and providers who are invested in reducing this disparity and increasing access to and the appropriate use of mental health services, it is critical to understand how people currently seek out and access treatment and support options.

Health care–focused technology solutions have proliferated in recent years. A recent study of downloadable apps for personal mental health management and support reported more than 1400 individual products in the Google Play and iTunes stores [12]. Insurance providers who offer Affordable Care Act marketplace and Medicare Advantage plans are required to publish provider directories [13,14], and many insurers and health systems offer web-based provider search and appointment scheduling tools. However, successfully connecting to appropriate services can be challenging, even with the aid of a directory or search tool. Users may be unsure about what service is the most appropriate for their specific needs and how to parse information on the internet about a diversity of specialties and treatment modalities with overly technical names and descriptors [15]. Provider directories are prone to inaccurate or out-of-date information [16]. Mental health providers are less likely to participate in insurance network plans and, consequently, may change their offerings and availability at will [17]. Amid a flood of information, users who are likely already experiencing considerable stress may be overwhelmed and left without clear guidance.

Current efforts for simplifying this search process and supporting user decision making include the development of e-hubs—web-based directories of local resources and community services that enable users to efficiently search for and organize potential treatment and support options. With the recent rise in web-based mental health tools, more comprehensive e-hubs have emerged to support access to web-based resources such as web-based forums, self-help videos, and support groups [18,19]. It is particularly relevant that these web-based navigation resources and e-hubs have been community [19] and expert driven [18]. Although the availability and complexity of these navigation tools has increased, no single e-hub is recognized as a gold-standard model.

The COVID-19 pandemic has highlighted the importance of accessible mental health services [20] and has resulted in a surge in the demand for web-based treatment options. Despite the clear potential that digital navigation tools have for improving accessibility to both web-based and in-person resources, research on this topic is sparse and often limited to the experiences of younger adults [21]. Continued progress requires a more complete understanding of how people search for mental health treatment and related services and how satisfied they are with their experiences of using different tools. Thus, in this survey study, we aimed to assess how people seeking mental health resources use and perceive technology-based navigation resources. As we were aware of prior research suggesting that information on interventions is the most important [22] and that older adults are becoming increasingly comfortable with operating web-based platforms [23], we hypothesized that overall satisfaction with digital navigation tools would be high. However, given the diversity of the needs and experiences of users and the difficulty of maintaining accurate informational resources across a variety of platforms, quantifying the actual experience of users is critical.

**Methods**

The National Alliance on Mental Illness (NAMI) is a nonprofit, national advocacy group based in the United States. By using a nationwide network of state and local community–based affiliates, NAMI provides education, awareness, and advocacy programs to support the mission of empowering individuals with mental illness and their family members to lead productive and fulfilling lives. An integral part of this work is the operation of the NAMI HelpLine—an information and support center that is staffed by individuals with lived experiences of mental illness. The HelpLine served over 150,000 individuals in 2019 through phone calls, emails, social media interactions, web-based resources, and letters [24]. Throughout the first half of 2020, the HelpLine received a record number of inquiries and requests, which were in large part due to concerns about COVID-19 and stress-related mental health concerns.

In order to better serve the needs of the community and improve service delivery, NAMI conducted a web-based, anonymous survey to assess individuals’ needs and experiences when searching for mental health resources. This voluntary survey was promoted through NAMI’s national leadership email newsletter and the NAMI Facebook and Twitter accounts. The
survey was available from April 9 through May 21, 2020. The eligibility requirements included any adult (aged ≥18 years) located in the United States who had searched for mental health treatment or services for themselves or someone else via the internet.

The survey consisted of 13 questions, including demographic questions, questions about the types of mental health services sought, questions about the types of tools used, and questions about prior experience with navigation tools. Multimedia Appendix 1 outlines the questions that were asked in the survey as well as the type of responses available.

Results

A total of 520 individuals completed the survey, and 478 individuals met the eligibility requirements. A large portion of respondents (397/478, 83.1%) were female, 14.6% (70/478) were male, and 1.5% (7/478) were gender nonbinary or self-described their gender identity. Half of the respondents were aged ≥55 years (242/478, 50.6%), 35.4% (169/478) of individuals were aged 35-54 years, and 13.4% (64/478) of participants reported that they were between the ages of 18 and 34 years. Most participants (403/478, 84.3%) self-identified as White or Caucasian, 6.3% (30/478) of participants self-identified as Black or African American, 2.5% (12/478) reported a self-described identity, 2.1% (10/478) self-identified as mixed or multiracial, 1.7% (8/478) self-identified as Asian or Pacific Islander, and 1% (5/478) self-identified as Native American or Alaska Native. Demographics are detailed in Table 1.

Table 1. Demographic characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristics of survey respondents</th>
<th>Values, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>397 (83.1)</td>
</tr>
<tr>
<td>Male</td>
<td>70 (14.6)</td>
</tr>
<tr>
<td>Nonbinary or self-described</td>
<td>7 (1.5)</td>
</tr>
<tr>
<td>Unreported</td>
<td>4 (0.8)</td>
</tr>
<tr>
<td><strong>Race and ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Asian or Pacific Islander</td>
<td>8 (1.7)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>30 (6.3)</td>
</tr>
<tr>
<td>Native American or Alaska Native</td>
<td>5 (1)</td>
</tr>
<tr>
<td>White or Caucasian</td>
<td>403 (84.3)</td>
</tr>
<tr>
<td>Mixed or multiracial</td>
<td>10 (2.1)</td>
</tr>
<tr>
<td>Self-described</td>
<td>12 (2.5)</td>
</tr>
<tr>
<td>Unreported</td>
<td>10 (2.1)</td>
</tr>
<tr>
<td><strong>Age category (years)</strong></td>
<td></td>
</tr>
<tr>
<td>18-34</td>
<td>64 (13.4)</td>
</tr>
<tr>
<td>35-54</td>
<td>169 (35.4)</td>
</tr>
<tr>
<td>≥55</td>
<td>242 (50.6)</td>
</tr>
<tr>
<td>Unreported</td>
<td>3 (0.6)</td>
</tr>
</tbody>
</table>

A total of 67.4% (322/482) of respondents reported that they used a web-based platform, phone-based directory, or mobile app to find mental health services. Older adults were less likely to use navigation tools compared to younger adults, with 37.2% (90/242) of those aged ≥55 years reporting that they had never used a web-based platform, phone-based directory, or mobile app to find mental health services, as shown in Table 2. Younger respondents (aged 18-34 years) were less likely to seek support by using the phone-based HelpLine or a phone-based directory compared to middle- and older-aged individuals. While 21.9% (90/411) of respondents aged ≥35 years reported seeking resources by using the phone-based HelpLine or a phone-based directory, only 7.8% (5/64) of younger participants used a phone-based directory, and 12.5% (8/64) of younger participants used a mobile app to seek resources. Younger respondents (55/64, 85.9%) and middle-aged respondents (aged 35-54 years; 115/169, 68%) were more likely to report searching for resources for themselves, while older individuals (aged ≥55 years) were more likely to report searching for resources on behalf of a family member or another individual who required support (131/242, 54.1%).
Table 2. Use of navigation tools by age.

<table>
<thead>
<tr>
<th>Tool sought and used, n (%)</th>
<th>All respondents</th>
<th>Respondents aged 18-34 years</th>
<th>Respondents aged 35-54 years</th>
<th>Respondents aged ≥55 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web-based search platform</td>
<td>289 (60.4)</td>
<td>45 (70.3)</td>
<td>112 (66.3)</td>
<td>131 (54.1)</td>
</tr>
<tr>
<td>Mobile app</td>
<td>48 (10)</td>
<td>8 (12.5)</td>
<td>18 (10.7)</td>
<td>22 (9.1)</td>
</tr>
<tr>
<td>Phone-based HelpLine or directory</td>
<td>97 (20.3)</td>
<td>5 (7.8)</td>
<td>38 (22.5)</td>
<td>52 (21.5)</td>
</tr>
<tr>
<td>No tool used, n (%)</td>
<td>156 (32.6)</td>
<td>17 (26.6)</td>
<td>48 (28.4)</td>
<td>90 (37.2)</td>
</tr>
<tr>
<td>Seeking on behalf of self, n (%)</td>
<td>281 (58.8)</td>
<td>55 (85.9)</td>
<td>115 (68)</td>
<td>111 (45.9)</td>
</tr>
<tr>
<td>Seeking on behalf of another, n (%)</td>
<td>197 (41.2)</td>
<td>9 (14.1)</td>
<td>54 (32)</td>
<td>131 (54.1)</td>
</tr>
<tr>
<td>Total responses, n</td>
<td>478</td>
<td>64</td>
<td>169</td>
<td>242</td>
</tr>
</tbody>
</table>

In total, 48.2% (228/473) of respondents reported only seeking resources that were related to treatment (talk therapy, outpatient psychiatry, inpatient care, or crisis care), while 49.9% (236/473) reported seeking a combination of treatment and support resources (social worker or community resource officer, housing, and legal or financial assistance). Across all age groups, those who were seeking resources on behalf of someone else were the most likely to be seeking a combination of treatment and supportive services (113/194, 58.2%; Table 3). The top three resources that respondents reported seeking were talk therapy (362/473, 76.5%), outpatient psychiatry (361/473, 76.3%), and crisis care (250/473, 52.9%), as depicted in Figure 1. The highest rated concern reported was whether a service was covered by their insurance. The lowest rated concerns, which are illustrated in Figure 2, included transportation, cultural considerations, and respect for gender identity.

Table 3. Type of service sought among individuals seeking services on behalf of themselves versus those seeking services on behalf of another.

<table>
<thead>
<tr>
<th>Responses</th>
<th>All respondents</th>
<th>Seeking on behalf of self</th>
<th>Seeking on behalf of another</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total responses, n</td>
<td>473</td>
<td>279</td>
<td>194</td>
</tr>
<tr>
<td>Treatment only, n (%)</td>
<td>228 (48.2)</td>
<td>151 (54.1)</td>
<td>77 (39.7)</td>
</tr>
<tr>
<td>Support service only, n (%)</td>
<td>9 (1.9)</td>
<td>5 (1.8)</td>
<td>4 (2)</td>
</tr>
<tr>
<td>Combination of treatment and support services, n (%)</td>
<td>236 (49.9)</td>
<td>123 (44)</td>
<td>113 (58.2)</td>
</tr>
</tbody>
</table>

Figure 1. The most common services sought by survey respondents.
Of the 280 survey respondents who provided details about their experiences with navigation tools, 224 (80%) indicated that they had experienced frustration or difficulty. The most commonly reported difficulties were about data availability and quality; approximately half of respondents who reported experiencing issues with navigation tools indicated that their search results did not contain enough information (118/280, 42.1%) or that the information provided was incorrect or out of date (132/280, 47.1%), as detailed in Table 4. Older adults who reported using navigation tools (103/132, 78%) were not significantly more likely than younger age groups (31/42, 74%) to report difficulties ($P=.57$), but participants who were seeking services on behalf of a family member or someone else (89/106, 84%) were somewhat more likely to experience issues compared to those seeking services for themselves (135/174, 77.6%; Table 5). However, the difference was not statistically significant ($P=.20$). For individuals playing caregiver roles, the availability of comprehensive and user-friendly navigation tools is especially relevant, as the services that are needed tend to be more complex in nature.

Table 4. Difficulties with navigation tools by age.

<table>
<thead>
<tr>
<th>Responses</th>
<th>All respondents</th>
<th>Respondents aged 18-34 years</th>
<th>Respondents aged 35-54 years</th>
<th>Respondents aged ≥55 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provided details about the use of a navigation tool, n</td>
<td>280</td>
<td>42</td>
<td>104</td>
<td>132</td>
</tr>
<tr>
<td><strong>Any difficulty, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tool was confusing</td>
<td>224 (80)</td>
<td>31 (73.8)</td>
<td>88 (84.6)</td>
<td>103 (78)</td>
</tr>
<tr>
<td>Specific need was not covered</td>
<td>95 (33.9)</td>
<td>14 (33.3)</td>
<td>37 (35.6)</td>
<td>43 (32.6)</td>
</tr>
<tr>
<td>Geographic area was not covered</td>
<td>53 (18.9)</td>
<td>7 (16.7)</td>
<td>21 (20.2)</td>
<td>24 (18.2)</td>
</tr>
<tr>
<td>Not enough information provided</td>
<td>118 (42.1)</td>
<td>22 (52.4)</td>
<td>45 (43.3)</td>
<td>51 (38.6)</td>
</tr>
<tr>
<td>Information provided was incorrect or out of date</td>
<td>132 (47.1)</td>
<td>25 (59.5)</td>
<td>47 (45.2)</td>
<td>59 (44.7)</td>
</tr>
<tr>
<td><strong>No difficulty, n (%)</strong></td>
<td>56 (20)</td>
<td>11 (26.2)</td>
<td>16 (15.4)</td>
<td>29 (22)</td>
</tr>
</tbody>
</table>
Table 5. Difficulties with navigation tools among individuals seeking services on behalf of themselves versus those seeking services on behalf of another.

<table>
<thead>
<tr>
<th>Responses</th>
<th>Seeking on behalf of self</th>
<th>Seeking on behalf of another</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provided details about the use of a navigation tool, n</td>
<td>174</td>
<td>106</td>
</tr>
<tr>
<td><strong>Any difficulty, n (%)</strong></td>
<td>135 (77.6)</td>
<td>89 (84)</td>
</tr>
<tr>
<td>Tool was confusing</td>
<td>32 (18.4)</td>
<td>18 (17)</td>
</tr>
<tr>
<td>Specific need was not covered</td>
<td>54 (31)</td>
<td>41 (38.7)</td>
</tr>
<tr>
<td>Geographic area was not covered</td>
<td>31 (17.8)</td>
<td>22 (20.8)</td>
</tr>
<tr>
<td>Not enough information provided</td>
<td>72 (41.4)</td>
<td>46 (43.4)</td>
</tr>
<tr>
<td>Information provided was incorrect or out of date</td>
<td>81 (46.6)</td>
<td>51 (48.1)</td>
</tr>
<tr>
<td>No difficulty, n (%)</td>
<td>39 (22.4)</td>
<td>17 (16)</td>
</tr>
</tbody>
</table>

**Discussion**

The results from our web-based survey showed that two-thirds (322/478, 67.4%) of adults seeking mental health treatment or support services used web-based, phone, and app-based tools to find resources and information, but the majority (224/280, 80%) experienced difficulties and dissatisfaction largely due to out-of-date and incorrect information. The use of these tools varied with age, with younger people being more likely to use navigation tools, especially web-based platforms or mobile apps, and more likely to seek mental health services for themselves as opposed to seeking such services for someone else.

The survey results suggest that existing digital navigation resources do not meet the demands of users. Although widespread internet access and increased comfort with web-based tools has resulted in the increased visibility of web-based mental health resources, a lack of reliable curation has led to an accumulation of out-of-date and incorrect information. These results suggest that a focus on the quality of content may be the most important next step in this research area. Offering some degree of personalization in insurance coverage matching services also appears to be a crucial factor—one that is not commonly available to date. Furthermore, web-based resources must account for the different needs and priorities within user populations. For instance, a previous study suggested that older adults (aged ≥65 years) were more willing to engage with digital tools after receiving digital skills training and a demonstration of a tool’s value [25]. However, an alternative study found significant variance in older individuals’ (aged ≥65 years) use and perceptions of the benefits of digital tools; the differences were more aligned with racial identity and socioeconomic status than with age [26].

The results from the survey conducted in our study did not show a meaningful difference in the percentages of older adults who found that navigation tools were confusing to use.

The primary limitation of this study lies in the generalizability of the results. As the survey was conducted via a web-based platform and promoted through digital communication channels, it can be assumed that all participants had reliable internet access and at least a moderate level of comfort with using the internet. Participants with a connection to NAMI may have been more likely than the general population to have past experiences with seeking mental health services and support, and many (eg, those seeking inpatient treatment) were likely to be individuals or family members of an individual with a serious mental illness. Our findings may consequently have limited generalizability to individuals seeking services and support for less intensive and more common mental health conditions. The participant population was heavily weighted toward older White females, indicating that issues affecting members of minority communities are underrepresented. The survey did not collect information on socioeconomic status or geographic location, of which both are factors that may significantly influence users’ needs for and experiences with seeking services. Finally, this study was conducted from April to May 2020 (ie, early stage of the COVID-19 pandemic), and we expect that the concerns and experiences of those seeking mental health care may have changed, as the pressures and constraints of the ongoing pandemic have continued to affect both mental health needs and the accessibility of related services. Finally, this study was only offered in English; therefore, it is not representative of many patients and families who read in other languages.

In summary, there remains a need for improved digital navigation resources and e-hubs, as existing services do not meet the needs and expectations of users. As more mental health resources move to web-based platforms, ensuring that services remain easily searchable and accessible will only become more important.

**Conflicts of Interest**

None declared.

Multimedia Appendix 1
Finding mental health services: Survey on experiences and needs.
References


Abbreviations

NAMI: National Alliance on Mental Illness

©Elizabeth Stafford, Teri Brister, Ken Duckworth, Natali Rauseo-Ricupero, Sarah Lagan. Originally published in JMIR Mental Health (https://mental.jmir.org), 09.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Mental Health, is properly cited. The complete bibliographic information, a link to the original publication on https://mental.jmir.org/, as well as this copyright and license information must be included.