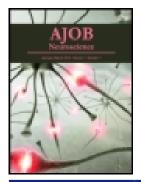


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Is There an App for That?: Ethical Issues in the Digital Mental Health Response to COVID-19

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ABSTRACT

Well before COVID-19, there was growing excitement about the potential of various digital technologies such as tele-health, smartphone apps, or AI chatbots to revolutionize mental healthcare. As the SARS-CoV-2 virus spread across the globe, clinicians warned of the mental illness epidemic within the coronavirus pandemic. Now, funding for digital mental health technologies is surging and many researchers are calling for widespread adoption to address the mental health sequelae of COVID-19. Reckoning with the ethical implications of these technologies is urgent because decisions made today will shape the future of mental health research and care for the foreseeable future. We contend that the most pressing ethical issues concern (1) the extent to which these technologies demonstrably improve mental health outcomes and (2) the likelihood that wide-scale adoption will exacerbate the existing health inequalities laid bare by the pandemic. We argue that the evidence for efficacy is weak and that the likelihood of increasing inequalities is high. First, we review recent trends in digital mental health. Next, we turn to the clinical literature to show that many technologies proposed as a response to COVID-19 are unlikely to improve outcomes. Then, we argue that even evidence-based technologies run the risk of increasing health disparities. We conclude by suggesting that policymakers should not allocate limited resources to the development of many digital mental health tools and should focus instead on evidence-based solutions to address mental health inequalities.

Well before the COVID-19 pandemic, there was growing excitement about the potential of various digital technologies, especially smartphone apps, to revolutionize mental healthcare (e.g. Insel 2018). As the SARS-CoV-2 virus spread across the globe, representative headlines warned that "COVID-19 could spark a mental-health tsunami" (Urback 2020), that lockdowns would create a "mental illness epidemic within the coronavirus pandemic" (Miller 2020), and that we could see an "echo pandemic' among traumatized health workers" (Harris 2020). And indeed, a CDC study in June 2020 found that a staggering 40% of Americans reported considerably elevated adverse mental health conditions, a significant increase compared to the same period in 2019 (Czeisler et al. 2020). All of this has unfolded against a backdrop where demand for mental health services already outstripped the supply of available clinicians. Thus, many researchers are sounding the alarm that the mental health fallout from COVID-19 will persist long after

KEYWORDS

Bioethics; mental health; psychiatry; artificial intelligence

vaccines are distributed, further straining the existing mental health infrastructure for years to come (Galea, Merchant, and Lurie 2020; Kathirvel 2020).

In response, interest in (and funding for) digital mental health technologies is surging, to the point that Ben-Zeev (2020) has claimed "the digital mental health genie is out of the bottle." A reckoning with the ethical and social implications of these technologies is urgent because decisions made today will shape the future of mental healthcare for the foreseeable future. We contend that the existing bioethics literature on digital mental health technologies has neglected fundamental ethical questions related to efficacy and justice. That is, the extent to which these technologies demonstrably improve mental health outcomes, and the likelihood that wide-scale adoption will exacerbate the existing health inequalities laid bare by the pandemic. We will argue that the evidence for efficacy is weak and that the likelihood of increasing inequalities is high.

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Here is the plan for the paper. In the Section entitled "What is digital mental health?," we briefly summarize recent trends in digital mental health. In the Section entitled "DMH as a response to COVID-19," we note the growing calls for widespread adoption of digital mental health tools to address the mental health sequelae of COVID-19. In the Section entitled "Efficacy, justice, and the DMH response to COVID-19," we develop two responses. First, we carefully assess recent meta-analytic evidence from the clinical literature to argue that many technologies proposed as a response to the pandemic are unlikely to improve mental health outcomes. Second, we argue that even evidence-based digital mental health tools run a high risk of increasing health disparities. We conclude by recommending that policymakers should not allocate limited resources to the development of many digital mental health tools. Rather, they should focus instead on evidence-based solutions to address mental health inequalities.

WHAT IS DIGITAL MENTAL HEALTH?

To begin, a quick terminological clarification will be helpful. In order to account for the diverse approaches in this field, we follow the World Health Organization (2019),¹ and use "Digital Mental Health" (DMH, henceforth) as a catchall term.² A recent scoping review found four main application areas for digital mental health technologies including (1) detection and diagnosis; (2) prognosis, treatment and support; (3) public health, and; (4) research and clinical administration (Shatte, Hutchinson, and Teague 2019). In what follows, we provide a brief summary of some recent developments in these areas, with a focus on (1) and (2). Smartphone apps play an outsized role here because they are often touted as a solution to the problem of increased demand mentioned above, owing to their ubiquity and scalability.³

Smartphone Apps

Before COVID-19, much excitement and funding were generated around approaches in the smartphone app category and these trends are also likely to persist after the pandemic.⁴ According to one estimate, there are over 10,000 mental health smartphone apps commercially available, though that number is likely even higher now (Carlo et al. 2019). Much of this work has fallen under the heading of "digital phenotyping," following a series of influential articles by Tom Insel, former director of the National Institute of Mental Health (NIMH).⁵

To cite just a few examples of the ways smartphone apps are used for treatment and support, consider "PTSD Coach," a free smartphone app for anyone who has experienced trauma, "FOCUS," which is geared toward patients with schizophrenia; "Sleepio," which helps patients suffering from insomnia (Anthes 2016);"Lantern," "Joyable," "MoodGYM," and "Ginger.io" which connect users with cognitive and behavioral therapists (Topol 2019); "7 Cups" describes itself as "the world's largest emotional support system" which "connects users to caring listeners for free emotional support" and has over one millions installs; "Youper" is described as "a pocket AI therapist which

¹In their (2019) guidelines on digital interventions, the WHO defines digital health as "a broad umbrella term encompassing eHealth [electronic health: 'the use of information and communications technology in support of health and health-related fields'], which includes mHealth [mobile health: 'the use of mobile wireless technologies for health'], as well as emerging areas, such as the use of advanced computing sciences in 'big data', genomics and artificial intelligence." Given the broad scope, this terminology best captures the variety of approaches in digital *mental* health as well.

²We should also note at the outset that developments in this field proceed at a breakneck pace, much faster than the traditional academic publishing cycle. In our experience researching this topic, it is not unusual that a digital mental health application will be introduced on the market, and then be re-branded, bought-out by a competitor, or disappear altogether within the timespan of a few months. Thus, our examples in this section are best understood as a snapshot of DMH technology from a particular point in time (namely, Summer/Fall 2020). Nonetheless, we made every effort to ensure our analyses will remain relevant to future developments in this area.

³Of course, one of the defining features of the COVID-19 pandemic has been the rapid shift and adoption of tele-health generally, and telemental health specifically (e.g. use of phone, text, or video communication involved in the delivery of mental health services on platforms such as Doxy, Teladoc, or Mend). Before COVID-19, these services were often promoted as an effective means of providing mental health services to low-resources areas (Kaonga and Morgan 2019) and traditionally under-served populations, including rural areas (e.g. Myers 2019; Speyer et al. 2018), indigenous communities (Hensel et al. 2019), and geriatric patients (Gentry, Lapid, and Rummans 2019). While telemental health certainly fits under the broad umbrella of DMH, in contrast to some smartphone apps, many standard tele-health approaches lack health services (see Section 3.3 below for further discussion).

⁴For example, according to SensorTower the world's top 10 combined English-language mental wellness apps "accumulated close to 10 million downloads, up 24.2 percent from the installs they generated in January 2020" (Chapple, 2020). It of course remains to be seen if these trends will continue after the pandemic, but this rapid increase is undoubtedly significant.

⁵Digital phenotyping is described as a family of "approaches in which personal data gathered from mobile devices and sensors are analyzed to provide health information." (Martinez-Martin et al. 2018, 1). According to Insel, smartphones provide "an objective, passive, ubiquitous device to capture behavioral and cognitive information continuously," with the potential to "transmit actionable information to the patient and the clinician, improving the precision of diagnosis and enabling measurement based care at scale" (Insel 2017, 1215). In turn, these approaches promise to "revolutionize how we measure cognition, mood, and behavior," and "transform the diagnosis and treatment of mental illness globally by enabling passive, continuous, quantitative, and ecological measurement-based care" (Martinez-Martin et al. 2018, 4).

is always there to talk," with over one million installs; "Sanvello" is described as "the #1 app for stress, anxiety, and depression with over 3 million users." Examples of smartphone apps in the administrative category include "PE Coach" or "DBT Coach," which help clinicians to facilitate therapy by providing homework assignments for clients.

Still other apps promise to improve detection and diagnosis by running in the background of a user's smartphone and collecting data about general scrolling, typing, and tapping patterns. An application called DeepMood, for example, predicted depression on the basis of key presses and movements on the smartphone keyboard (Cao et al. 2017). Academic researchers are deploying these tools as well: Jacobson, Summers, and Wilhelm (2020) used a digital phenotyping approach combining machine learning methods with passively collected smartphone data about participants' movement (via accelerometer) and social contact (via call and text records) to predict social anxiety symptoms.

Smartwatches, smartrings, and fitness trackers (e.g. AppleWatch, Oura, FitBit) are increasingly being deployed in response to COVID-19, and can also be integrated with the kinds of apps described above. For example, Youper allows users to "integrate mindfulness sessions with Google Fit to make self-help and self-care easy." Importantly, these wearable technologies also contain sensors not found in smartphones which could be relevant for mental health, including thermometers, and photoplethysmography sensors (PPG) which use infrared light to measure changes in blood circulation, from which signals such heart rate variability can be derived (Castaneda et al. 2018).

Finally, in what has been called a "landmark decision" (Robbins 2020), the FDA has approved for the first time a video game app therapeutic – "EndeavorRx" developed by Akili Interactive Labs – meant to be prescribed to children with ADHD.⁶

Social Media

Given how much time many people spend on social media, digital approaches which can leverage the mental health-relevant data generated there have the potential to fill in gaps in the "clinical whitespace," or the time between structured, formal interactions with healthcare systems (Coppersmith et al. 2017). Of course, one of the primary ways users access social media is through smartphone apps. Some early work in this vein was conducted De Choudhury et al., who analyzed linguistic features from Facebook and Twitter posts to predict the onset of Major Depressive Disorder and postpartum depression (De Choudhury et al. 2014), and also constructed a general social media depression index (De Choudhury, Counts, and Horvitz, 2013).

In a recent review, Chancellor and de Choudhury (2020) describe 75 published studies which used various forms of social media data for inferring various mental health statuses. Most of the studies used data from Twitter, Reddit, and Weibo. By far, the most studied condition was depression, followed by suicide, schizophrenia, eating disorders, anxiety, stress, PTSD, and bipolar disorder.

Some of the highest-profile work attempts to deploy text mining methods to predict suicide. Coppersmith et al. (2018), for example, utilize data from Twitter posts to aggregate risk scores from individual posts to predict a given user's suicide risk. It is worth noting, however, that data gathered from social media is not limited to text. In addition to psycholinguistic information contained in the text of social media posts, researchers can also extract mental health relevant signals from user-posted photos, in addition to meta-data such as the number, timing, and frequency of posts, geo-location, interactions with other users (e.g. follows, re-tweets, likes, replies, group memberships, etc.), or user network structures.

Natural Language Processing (NLP)

The example of text mining social media posts is part of a family of broader DMH applications which deploy computational methods on various speech and text corpora to investigate different aspects of mental health. These range from administrative tasks such as recording clinical notes, to diagnosis of mental disorders based on subtle syntactic features, to chat-bot delivered therapy, to automated reviews of clinical literature (Shatte, Hutchinson, and Teague 2019; Dreisbach et al. 2019).

For our purposes, one influential study in this area illustrates the predictive and diagnostic potential of DMH. Bedi et al. (2015) attempted to predict the onset of psychosis in high-risk youths. The researchers conducted open-ended interviews and then transcribed them into text. Using measures of semantic coherence, use of determiners (e.g. "that," "what," "whatever," "which") and phrase length, their machine

⁶Interestingly, the game was in regulatory limbo for the past two years waiting on a decision from the FDA. But by the time the green light was given on June 15, 2020, the game was already available online, due to the FDA's decision in April 2020 to relax regulations on low-risk mental health devices during the COVID-19 pandemic.

learning classifier yielded 100% accuracy in predicting transition to psychosis, which outperformed the standard clinical ratings, which yielded only 79% accuracy. Corcoran et al. (2018) replicated and extended these findings with a larger sample, achieving 83% accuracy. Bedi et al. (2015, 2) note that "improving the capacity to predict psychosis among high-risk populations would have important ramifications for early identification and preventive intervention, potentially critically altering the long-term life trajectory of people with emergent psychotic disorders." This sense of optimism for improving outcomes through early diagnosis is pervasive in the DMH literature and we will have more to say about it in the Section entitled "Efficacy, justice, and the DMH response to COVID-19" below.

DMH AS A RESPONSE TO COVID-19

By March 2020, the global spread of COVID-19 required governments to impose sweeping public health interventions to reduce physical human contact in order to flatten the epidemiologic curve. Shortly thereafter, the U.S. government suspended some telehealth rules and regulations to quickly respond to social distancing requirements.⁷ These measures were widely lauded for being responsive to the safety needs of both health care professionals and patients (Shore, Schneck, and Mishkind 2020). As Mosnaim et al. (2020) put it: "More changes in the adoption and administration of remote health care occurred in the first 20 days of March than in the previous 20 years to meet the health care crisis."

Researchers have, however, also expressed worries about the longer-term knock-on effects of social distancing, including increased anxiety, depression, serious mental illness, suicide and self-harm. (Reger, Stanley, and Joiner 2020), in addition to alcohol and substance abuse, gambling, domestic and child abuse, along with psychosocial risks such as social disconnection, lack of meaning, feelings of entrapment, cyberbullying, feeling burdensome, financial stress, bereavement, loss, unemployment, homelessness, and relationship breakdown (Holmes et al. 2020). According to Zhou et al. (2020, 1), "the Chinese, Singaporean, and Australian governments have highlighted the psychological side effects of COVID-19, and have voiced concerns regarding the long-term impacts of isolation and that the fear and panic in the community could cause more harm than COVID-19."

A steady stream of articles and commentaries has since called for the wide-scale deployment of the tools described in the Section entitled "What is digital mental health?" as a response to this growing crisis. For example, Torous et al. (2020, 1) proclaimed: "although the world today must 'flatten the curve' of spread of the virus, we argue that now is the time to 'accelerate and bend the curve' on digital health. Increased investments in digital health today will yield unprecedented access to high-quality mental health care." Wind et al. (2020) called the COVID-19 pandemic, "the 'black swan' for mental health care and a turning point for e-health." Robbins (2020) argued that the coronavirus pandemic "sets up a potential breakout moment for virtual mental health care." Sust et al. (2020) urged mental health professions to "turn the crisis into an opportunity" by using digital mental health strategies. And indeed, one recent estimate suggests that broader uses of digital health technology during the pandemic drove a record \$3.1B in investment (Day et al. 2020).

This much should be clear: We are at a turning point for DMH. Policymakers are proposing measures which could make permanent many digital health measures initially put in place as emergency responses to the pandemic. Choices made today will shape the future of mental healthcare for the foreseeable future. But which ethical considerations should guide these weighty decisions? We contend that they need to be (1) guided by evidence of efficacy and (2) responsive to the structural health inequalities laid bare by the pandemic.

EFFICACY, JUSTICE, AND THE DMH RESPONSE TO COVID-19

The existing literature on the ethics of DMH tends to focus on the different ethical standards between commercial and academic settings (Martinez-Martin and Kreitmair 2018; Torous and Roberts 2017), threats to autonomy (Burr and Morley 2020), transparency and accountability (Martinez-Martin et al. 2018), data protection and data privacy (Chiauzzi and Wicks 2019; Morley et al. 2020), informed consent

⁷For example, Medicare quickly modified its policies to allow clinicians to use non-standard telehealth technologies such as FaceTime or Skype (Wilser 2020) and also allowed clinicians to bill for them (Figueroa and Aguilera 2020). Likewise, the Health Insurance Portability and Accountability Act (HIPAA) Rules, immediately expanded the remote communication channels that health care professionals can use with patients, even if such channels do not fully comply with HIPAA (HIPAA) Office for Civil Rights (OCR) 2020). Many states also waived the requirement of requiring psychiatrists to provide services only to patients within the states they are licensed to practice in, so they can now provide such services out of state (Gautam et al. 2020).

(Martinez-Martin and Kreitmair 2018; Morley et al., 2020), cultural differences (Tekin 2020), among others.

Our central claim is that while these ethical considerations are important, they overlook a more fundamental ethical question which must be addressed in guiding the response to the pandemic: *Do DMH technologies demonstrably improve mental health outcomes*? If they do not, then many of these other ethical considerations will be moot. That is, if DMH technologies are highly unlikely to improve mental health outcomes (or if there is a risk of worsening such outcomes), then their widespread deployment as a response to the pandemic should be resisted on those grounds. And even if evidence does support the use of DMH, further questions about *who* benefits will still need to be addressed.

Efficacy and DMH

It is striking that, despite the existence of hundreds (if not thousands) of studies,8 there is no sustained engagement by bioethicists with the questions of whether and how DMH tools improve mental health outcomes, and for whom. The problem is obvious: Information about safety and efficacy is critical when weighing tradeoffs. People might be willing to take on certain data privacy risks, for example, in using a DMH app if there is a high probability that use of that app would significantly improve their mental health. But if the probability of improvement is low (or highly uncertain), then the data privacy risks might not be justifiable. In order to properly address such tradeoffs when making decisions about how to respond to the mental health fallout from COVID-19, we need to carefully examine the existing body of empirical evidence.

Specific answers to the question "Does DMH improve mental health outcomes?" will, of course, vary as function of the specific mental illness and the technology being considered. Moreover, mental health outcomes could be improved directly (by treatment or support) or indirectly (by early detection and diagnosis leading to better downstream treatments or support).

Still, for many of the technologies reviewed in the Section entitled "What is digital mental health?," an overarching theme is clear: We simply don't know if these technologies improve (or worsen) mental health outcomes, directly or indirectly, because *the vast* *majority are not supported by empirical evidence.* This is especially true for many smartphone apps, AI chatbots and wearables.

To cite one of many examples, Larsen et al. (2019) reviewed the claims made by the 73 most highly rated mental health apps from the Google Play and iTunes app stores. They found that less than half of the app descriptions employ scientific language, and of the apps describing *specific* scientific techniques, over 30% referred to techniques with no empirical support. Crucially, only two apps provided *direct evidence* associated with app use.

There are, however, DMH technologies which have been rigorously evaluated with respect to mental health outcomes and we explore these in detail. We bring up the examples above to emphasize that such rigorous evaluation is the exception rather than the rule.

Below, we focus mostly on smartphone apps for two reasons. First, this literature contains high-quality evidence directly assessing mental health outcomes. Second, the ubiquity and scalability of smartphone apps make them highly attractive candidates to address the mental health sequalae of COVID-19. While there is high-quality evidence directly assessing mental health outcomes for the kinds of tele-health approaches described above, these approaches tend to lack the scalability required to serve as effective responses to the pandemic (see footnote 3 above, also the Section entitled "Efficacy and Scalability" below).

Within the literature exploring the efficacy of smartphone apps, it would be easy to cherry-pick a handful of studies showing that some smartphoneapp-delivered therapy is more effective than traditional face-to-face therapy. It would be equally easy to cherry-pick a different handful of studies showing that some smartphone-app-delivered therapy makes users worse off than doing nothing at all. For this reason, we attempt to provide a balanced, big-picture view, using only the highest quality evidence from the field - meta-analyses of randomized controlled trials – to guide our ethical analyses.

Meta-analysis 1

Firth, Torous, Nicholas, Carney, Rosenbaum et al. (2017) conducted the first systematic evaluation of the empirical evidence for using smartphones to treat anxiety. The authors note that anxiety disorders are among the most prevalent mental health conditions across the globe, affecting nearly 30% of the population per year. They also tout familiar promises about

⁸For example, a recent meta-review by Lecomte et al. (2020) reported retrieving over 2,500 potential papers and 24 meta-analyses related to DMH.

smartphone interventions as highly scalable and personalizable. Their meta-analysis covered 9 Randomized Controlled Trials (RCTs) with a total of 1,581 participants, 880 of which were in various smartphone treatment conditions, and 701 of which were in various control conditions.

The most coarse-grained analysis found a pooled effect size (i.e. the standardized mean difference between treatment and control conditions across all 9 RCTs) of g = 0.325, with a 95% Confidence Interval (CI) ranging between 0.17 and 0.48, which is conventionally interpreted as a small-to-moderate effect.⁹

While the overall effect seems promising, more fine-grained sub-group analyses raise important concerns. When smartphone interventions were compared with "passive" waitlist controls (i.e. no engagement with a smartphone app) the effects were much larger (g=0.45) than when the smartphone interventions were compared with "active" controls (i.e. using a non-anxiety-treatment smartphone app) (g=0.19).

In a theme that is present across many studies, when researchers employ a rigorous, active control condition (such as listening to music) which accounts for user attention and engagement with their smartphone, the effects of the interventions (in this case, for anxiety) are negligible or non-existent. Similarly small results were found for studies which integrated smartphone interventions within a broader therapeutic context (e.g. in concert with face-to-face therapy, medications, etc.), but crucially, *stand-alone smartphone apps which directly targeted anxiety did not differ significantly from controls.*

Meta-analysis 2

Firth, Torous, Nicholas, Carney, Pratap, et al. (2017) conducted the first systematic evaluation of the empirical evidence for using smartphones to treat depression. This meta-analysis contained twice the number of interventions and participants, owing to the recent

explosion of interest in DMH approaches to depression. Thus, 18 RCTs employing 22 different smartphone-delivered interventions, covering 3,414 participants were reviewed.

The most coarse-grained analysis found a similar pooled effect size as in the anxiety studies (g = 0.38, 95% CI: 0.24-0.52). But again, digging beneath the surface into the sub-group analyses provides important qualifications. Effect sizes for interventions with compared with looser, inactive controls were significantly larger (g = 0.55, 95% CI: 0.38-0.74) than the effect sizes for interventions compared with tighter, active control conditions (g = 0.21,95% CI: 0.10-0.33). While this is somewhat promising, the authors also note that "the only populations in which smartphone interventions significantly reduced depressive symptoms were those with self-reported mild-to-moderate depression" (296).

Meta-analysis 3

As evidence of how quickly DMH is growing, consider that since the publication of Firth et al.'s metaanalyses, almost 50 more RCTs were published and included in the Linardon et al. (2019) meta-analysis, which included 66 RCTs with 77 smartphone interventions for a range of mental health problems including anxiety, depression, stress, and post-traumatic stress disorder, among others. As with the meta-analyses above, only English language RCTs were included.

Consistent with results above, the pooled effect size for 54 trials comparing smart-phone interventions and all control conditions for depression is g = 0.28 (95% CI: 0.21–0.36), but sub-group analyses looking at smartphone interventions against "active" control conditions revealed a statistically insignificant effect size of g = 0.13 (95% CI: -0.07 to 0.34), which ought to dampen some enthusiasm about the Firth, Torous, Nicholas, Carney, Pratap et al. (2017) results.

Similar patterns obtained for generalized anxiety. The pooled effect size for 39 studies comparing smartphone interventions against all controls was g=0.30(95% CI: 0.20–0.40). But again, when looking at "active" controls, the effect size drops to a statistically insignificant g=0.09 (95% CI: -0.21 to 0.39). Stress levels assessed in 27 comparison also exhibited the same patterns of results: The overall pooled effect g=0.35 (95% CI: 0.21–0.48) diminishes to a statistically insignificant g=0.21 (95% CI: -0.46 to 0.88) when compared with active controls.

⁹Following Cohen (1992), effect sizes around 0.8 are considered large, effect sizes around 0.5 are moderate, and effect sizes around 0.2 are small. There are, however, perennial debates about the relationship between such measures of statistical significance on the one hand, and clinical significance on the other. In terms of interpreting the metaanalytic results reported here, a concrete example may be helpful. The 17-item Hamilton Depression Rating Scale, with a range from 0 to 52 points, is "the most commonly used depression rating scale and is the recommended scale by psychiatrists worldwide" (Jakobsen, Gluud, and Kirsch 2020, 2). A decrease of three points on this scale (e.g. a score of 47 at baseline, and then a score of 44 after an intervention) corresponds to a standardized mean difference of 0.5. A drop of seven points on the scale corresponds to an effect size of around 0.8. For more context, Hieronymus et al. (2020) estimate that commonly prescribed antidepressants have an effect size of approximately 0.3 compared with placebos.

Meta-analysis 4

In this recent meta-analysis and systematic review, Weisel et al. (2019) focus specifically on standalone smartphone apps for a variety of mental health conditions including depression, anxiety, substance use, self-injurious thoughts and behaviors, and sleep problems. Their analysis covers 19 RCTs involving 3,681 participants.

The results for apps targeting depression are consistent with the meta-analyses above. In the present analysis, six comparisons (n = 796) yielded a significant pooled effect of g = 0.33 (95% CI 0.10–0.57) with larger effect sizes observed when interventions were contrasted with passive controls g = 0.41 (95% CI 0.24–0.59), and, once again, non-significant effects for active controls g = 0.17 (95% CI –0.00 to 0.42).

The pooled effect sizes for all the other conditions were, at best, small and statistically insignificant. For example, unlike previous findings, there was no significant difference between smartphone interventions and (any) control conditions for anxiety (g=0.30, 95% CI -0.1 to 0.7).

Strikingly, suicidal ideation was assessed in four comparisons (n = 286), and the negative effect size estimate (g = -0.14, 95% CI -0.37 to 0.1) suggests that, at best, smartphone interventions may do little to nothing, but at worst, they might sometimes lead to *more* suicidal ideation. Similar results were observed for three comparisons of self-injury (n = 225, g = -0.04, 95% CI -0.31 to 0.22), three comparisons of drinking behavior (n = 1040, g = -0.03, 95% CI -0.22 to 0.17), and one PTSD comparison (n = 49, g = -0.05, 95% CI -0.6 to 0.51). This suggests that not only might standalone apps for these conditions not improve outcomes very much, *they may sometimes lead to worse outcomes*.

These results lead the authors to conclude that "there remains a lack of generalizable evidence to support particular standalone smartphone apps for mental health as a substitute to conventional mental health treatment," which, in turn, highlights "the need for discussing the potential harm of currently available apps, which might keep users away from evidencebased interventions while bearing a substantial risk of being ineffective" (Weisel et al., 2019, 8).

Interpretations and Qualifications

While we have aimed to carefully present the best available evidence, some further qualifications are still necessary. First, it bears repeating that the overwhelming majority of DMH apps available on the market are not evidence-based. So, the small number of appbased interventions considered here are but a drop in the ocean. Still, there are several important methodological issues within this subset of apps which have been subject to empirical assessment. As many authors point out, a persistent risk of bias in the literature is due to difficulties with adequately blinding participants.¹⁰

A related issue is that "digital placebo effects" are not well-characterized (Torous and Firth 2016). Placebo effects play an important role in mental healthcare generally and this consideration looms especially large, given that many intervention effects of smartphone apps all but disappear when compared with active controls.

Finally, an overarching consideration is the presence of trial bias. To see this, consider some of the results reported in Baumel, Edan, and Kane (2019). "Real world" data (as opposed to data collected in research settings) for app use suggests that only between 0.5 and 28.6% of users continue to use mental health apps after six weeks, whereas systematic reviews of research trials report completion rates of 50-100%. For example, only 0.5% of the MoodGym apps' native users completed a non-compulsory final assessment, where 22.5% completed it in a research trial (Fleming et al., 2018). Similarly for the PTSD Coach app: some participants in the trial reported using the app throughout the day, in different contexts, for 4 weeks. But in "real world" usage without interactions with researchers, almost half of the participants stopped using the app after one week (Owen et al., 2015).

Baumel, Edan, and Kane (2019) obtained independent and objective use data for mental health apps from SimilarWeb Pro, a mobile analytics company. They contrasted this "real world" data with data from 13 published research trials using the same apps and found that the median usage rate was over four times higher in the latter than the former.

Despite this underwhelming evidence for direct efficacy, it is possible that smartphone apps or other DMH tools could improve mental health outcomes in other, less direct ways. For example, many of the NLP and data mining applications described in the Section entitled "What is digital mental health?" deliver highly accurate predictions which promise earlier diagnosis and detection of disorders ranging from schizophrenia

¹⁰After all, if one signs up for a research study about the effects of a smartphone app on mental health, but one never uses an app (as in a waitlist control), or one just listens to music (as in an "active" control), it would not be difficult to determine that one was not in an intervention condition.

to Alzheimer's. While many impressive results have been reported in this vein, DMH proponents often gloss too quickly over the myriad barriers that stand between the kinds of predictions generated by various data mining approaches, and the kinds of interventions that improve patient well-being.11 To see this, recall the Bedi et al. (2015) study from the Section entitled "Natural Language Processing (NLP)." No one would argue on the basis of their findings that a patient could decrease their risk of a psychotic episode by using longer phrases in their speech or altering their usage of words like "that" or "which."¹² And even if the only aim were to identify possible targets for early intervention, in the cases of psychosis-related conditions, there are very few effective treatments and interventions to which these early-identified patients could be referred (Friesen 2019). In fact, following Burr et al. (2020), it seems just as likely that the widespread use of these predictive techniques could lead to epidemiological inflation, diminishment of patient autonomy, and shifts in the distribution of responsibility for the maintenance of public mental health.

Putting it all together, the evidence from the four meta-analyses above suggests that for the very small number of mental health apps that have been rigorously studied, the treatment effects are negligible to non-existent when considering the most relevant and informative comparisons with active controls. When this lack of efficacy is considered alongside pervasive methodological shortcomings (e.g. trial bias), unacknowledged difficulties in translating machine predictions to clinical interventions, as well as long-standing ethical concerns about data privacy, threats to autonomy, lack of transparency, and insufficient regulatory oversight, the case for smartphone apps as a response to the mental health fallout from COVID-19 is on thin ice.

Efficacy and Scalability

As we have seen throughout, perhaps the most touted features of smartphone mental health interventions are their ubiquity and scalability. It is unsurprising then, in light of the kinds of headlines described in the Introduction, that they are portrayed as an attractive solution to the mental health fallout from COVID-19. And yet, the gaps described above severely limit the kinds of generalizability and scalability at the heart of many DMH proponents' arguments for wide-scale adoption as а response to the pandemic.

There are, of course, other forms of DMH which do enjoy more empirical support. As Torous et al. (2020, 1) have pointed out, the temporary relaxation of many telehealth rules and regulations noted in the Section entitled "DMH as a response to COVID-19" was "made possible because of the strong and clear evidence base for the efficacy of telehealth and decades of high-quality research."¹³

The problem, however, is that the forms of DMH (e.g. tele mental health) which enjoy the most robust empirical support are also the least scalable, and therefore the least likely to address the wide-ranging mental health sequelae from the pandemic.¹⁴ Indeed, as many clinicians have pointed out recently, tele-health is not a "turnkey" or "plug and play" affair. Extensive resources are required to establish the requisite digital infrastructure and competencies.

On the flip side, DMH solutions like therapy apps or AI chatbots claim to provide resource-effective alternatives. But the vast majority of these tools have not been subjected to empirical scrutiny. For those that have, the evidence suggests that most are about as effective as active controls, such as listening to music. Crucially, the evidence we reviewed above *does* support the limited efficacy of some apps for adjunctive or stepped-up care roles, but such concessions undermine their very motivation as a response to the pandemic: scalability.

As policymakers are faced with difficult decisions about how to allocate limited resources for mental health, they will have to weigh many different considerations related to cost- and time-effectiveness, along

¹¹For a striking example of this gap between machine prediction and clinical intervention, see Elish & Watkins's (2020) in-depth study of the Sepsis Watch AI tool deployed at the Duke Health. Their analysis shows that even with (relatively) straightforward conditions like sepsis, there exist tremendous difficulties in translating Al-driven predictions into improved clinical outcomes. Such difficulties are likely to be even more pronounced in the mental health context.

¹²One might object here that such NLP projects are more aimed at research than clinical application. However, when NLP researchers claim, as they often do, that such research can, for example, "greatly facilitate targeted early intervention" and "provide previously unavailable information for clinicians on which to base treatment and prognostic decisions" (Bedi et al., 2015, 6), it seems fair to raise this criticism, especially when the myriad difficulties of translating computational research into improved psychiatric outcomes are not discussed in any depth. See Velupillai et al. (2018) for an analysis of the many difficulties outcome contexts.

¹³Here, they reference Yellowlees and Shore (2018). Studies examining the efficacy of telehealth via phone- or video-calling vs. face-to-face therapy tend to point in the same direction for depression (Berryhill et al. 2019), PTSD (Acierno et al. 2017), and the use of internet-based cognitive behavioral therapy more generally (Andersson et al. 2019).

¹⁴In fact, these forms of tele-health may even be less time- and costeffective than traditional face-to-face therapies, at least at first, given various struggles with internet connection issues, scheduling, interface functionality, and the like. Thanks to an anonymous reviewer for suggesting this point.

with a range of opportunity costs. Our analysis suggests that one particularly salient tradeoff will be between efficacy and scalability. That is, there seems to be an inverse relationship between the scalability of DMH tools and their likelihood of improving mental health outcomes.

In turn, this presents a thorny problem: If the mental health fallout from the pandemic over the coming years is as widespread as is currently being predicted, then there will be an even greater shortage of mental health services relative to demand. Subsequently, we predict that calls for various DMH solutions to this problem will grow even louder. While the hype generated around DMH would have us believe that smartphone apps, AI chatbots, and the like are perfectly positioned to address this growing problem, the empirical evidence suggests that while these tools may indeed be able to achieve the requisite scale, they are highly unlikely to improve mental health outcomes – directly or indirectly – at that scale.

Here, then, is one conclusion. In light of cuts to mental health budgets, limited public health resources should not be allocated to the longer-term development and deployment of smartphone-app mental health interventions, as alluring and transformative as they might seem.¹⁵ This is especially true when such resources could be directed to (admittedly less sleek) established and evidence-based forms of tele-mental health. This is not to say that DMH tools have no place in the post-pandemic mental health ecosystem. To the contrary, we support the evidence-based deployment of these tools as adjuncts, or in steppedup care settings. But we remain skeptical of the recent and more ambitious assessments of the transformative potential of these technologies as a response to the pandemic.

Justice and DMH

Mental illness makes up 13-16% of the total global burden of disease, and it was well-known before the

pandemic that this disease burden is disproportionately high in low-income areas (Collins et al. 2011; Ngui et al. 2010; Vigo, Thornicroft, and Atun 2016). Similarly, Cook et al. (2017) report significant disparities in racial and ethnic minority groups' access to various mental health services compared to Whites. And for Blacks and Hispanics, these disparities widened between 2004 and 2012. It is with these kinds of findings in mind that a widely-cited position paper in Lancet Psychiatry predicted that the pandemic would "exacerbate healthcare disparities and will probably disproportionately affect socially disadvantaged patients," and that "health systems will be faced with widespread demand to address these COVID-19related mental health needs" (Moreno et al. 2020, 1).

It is too early to say for certain whether these predictions will be borne out. However, recent evidence from a carefully designed longitudinal study has shown a significant increase in mental distress in the UK population attributable to COVID-19 which has "not affected all groups equally" such that "established health inequalities persist" (Pierce et al. 2020, 884). Czeisler et al. (2020) reported a broadly similar pattern of results in the US, with disproportionately worse mental health outcomes experienced by racial/ ethnic minorities, essential workers, and unpaid adult caregivers.

Many DMH interventions explicitly target these disparities, but there is a persistent risk that they may exacerbate the very problems they aim to fix. Scholars from many disciplines have examined this risk through the lens of the *digital divide*. In the present context, there are at least three manifestations of the digital divide relevant to the DMH response to COVID-19.

The first refers to the unequal access to DMH tools between those that can afford mobile technologies and reliable high-speed internet access and those who cannot. (Anthes 2016, 23). A second concerns unequal engagement with DMH tools between those are digitally literate (or motivated to become more digitally literate) and those who are not (Terrasse, Gorin, and Sisti 2019). A third is what McCarthy (2016) calls a "big data divide" and refers to the disparity between organizations that have the financial and technical means to collect, link, and analyze big data as opposed to those who lack such resources and capabilities. Organizations with greater access to higher volumes and higher quality mental health relevant data are thus able to develop tools and uncover insights that more "data poor" organizations are not. As McCarthy (2016, 1132) points out, perhaps unsurprisingly, these

¹⁵To reiterate a point made above, evidence-based considerations do support the limited use of smartphone apps in stepped-up care settings, for example, and the same point might be made about the use of these technologies as "stopgap" solutions amid a public health emergency. This is fine as far as it goes. But we worry that many DMH proponents are advocating for much more than these short-term, emergency measures. Anticipating the themes of the next section, there is a real risk that, without persistent critical oversight, what starts as a short-term, "stopgap" solution slowly becomes the "new normal" in such a way that existing health inequalities are exacerbated: The relatively well-off in society get evidence-based, face-to-face therapies while the less well-off get automated chatbot therapists. Indeed, in a recent op-ed, Green (2020) observes precisely this dynamic, albeit in the context of primary education, in proposals for so-called "learning pods."

various digital divides are driven by customary markers of inequality such as "income, education, race, gender, and area of residence."

All of this raises the worry that even the best evidence-based DMH tools have the potential to lock-in vicious cycles of digital inequality, whereby those with fewer digital resources and lower digital literacy will be excluded from advances in evidence-based DMH technology. This in turn makes it less likely that their mental health issues will be improved, which could lead to further disadvantages of resources and literacy, and so on.

The heart of the concern raised in the Section entitled "Efficacy and Scalability" is that limited public health resources should not be allocated to DMH technologies which are not likely, on the basis of existing empirical evidence, to improve mental health outcomes. Keeping in mind the qualifications from the Section entitled "Interpretations and Qualifications," this covers many, but not all, of the DMH approaches reviewed in the Section entitled "What is digital mental health?" Importantly, evidence-based considerations *do* support the use of tele mental health as a response to the pandemic (scalability issues notwithstanding). In turn, however, this raises several questions about digital divides which must be reckoned with.

As we mentioned, telehealth is not a simple switch that clinicians can turn on or off. As Torous and Wykes (2020, 1) note, developing effective "webside manner" requires a substantial investment of resources:

The benefits of increased access to telehealth services are apparent for telepsychiatry, but in the present crisis, these benefits can only be realized if these digital tools are used by clinicians who have the appropriate training and guidance and know these services are accepted by organizations providing services and payers. *The need for training among health care professionals is the number 1 priority* (emphasis added).

A corollary here is that organizations with the requisite resources (money, time, supervision, infrastructure, etc.) are better positioned to switch to telehealth than those with fewer resources. Surprisingly, some recent reporting has suggested that while many practices quickly adopted telehealth at the outset of the pandemic, many are now abandoning it. More specifically, organizations with more than 100 clinicians were able to shift 16% of their pre-pandemic visits to telehealth visits, while organizations with 20 or fewer clinicians were barely able to shift 5% (Mehrotra, Linetsky, and Hatch 2020). Perhaps less surprising is that many of these smaller organizations often serve less privileged populations.

The worries about widening digital divides should be clear: mental health practices with more resources, serving more well-off patients, are more likely to provide high quality telehealth during and after the pandemic than those practices with fewer resources, serving less well-off patients. In turn, this makes it less likely that the less well-off will see improvements in their mental health, and again, on down the spiral.

Moreover, as Wetsman (2020) has documented, many design choices in telehealth interfaces are made by English speakers for English speakers. So while telehealth may be effective for social distancing reasons, and while some populations may prefer it, for the 25 million people in the US who have limited English language skills, some forms of telehealth could prove more of a barrier than a benefit.¹⁶ And because these populations are more likely to be poor and work in jobs at higher risk of COVID-19 exposure, the potential for widening health inequalities is ever present.

Similarly, elderly people are among the highest-risk for serious illness or death from COVID-19 (Centers for Disease Control and Prevention (CDC) 2020), suffer from high rates of social isolation and loneliness (Holt-Lunstad, Robles, and Sbarra 2017), and crucially for our purposes, *are also among the least likely to benefit from advances in DMH*.

Data from the Pew Research Center shows that only 42% of adults age 65 or older have smartphones and only 51% of adults age 65 or older have high-speed internet at home (Anderson and Perrin 2017). While these numbers are likely somewhat higher now, the fact remains that many DMH tools are not designed with elderly users in mind, and there are substantial barriers for the elderly to engage with and benefit from them (Seifert, Reinwand, and Schlomann 2019).

Against the backdrop of the stark, preexisting health disparities laid bare by the pandemic (e.g. Chowkwanyun and Reed 2020; Yancy 2020), these worries about resource inequalities among providers and various language and digital literacy barriers among patients force a serious consideration of whether widescale adoption of DMH will narrow or widen these gaps. We think there is a substantial risk that the gaps will widen.

But more than that, we must also seriously consider whether some DMH tools might themselves be perpetuating the very problems they aim to solve.

¹⁶These worries are pronounced in other forms of DMH as well, especially NLP applications which are trained only or primarily on English speakers' voice, text, social media posts, etc.

Consider that Facebook deploys algorithms to assess the suicide risk of users on its platform (Gomes de Andrade et al. 2018). When the algorithm and a moderator identify crisis situations, police officers are often dispatched to conduct wellness checks. In 2018 alone, Facebook initiated 3,500 such wellness checks. But as the tragic cases of D'Andre Campbell, Ejaz Ahmed Choudry, and Chantel Moore illustrate, for Black and Indigenous communities, wellness checks can be fatal: all were shot and killed during wellness checks by police in Canada between April and June 2020.

Here, then, is another conclusion. At the very least, we need to ensure that DMH tools do not exacerbate various forms of inequality. And to the extent that DMH tools are deployed, we also need to ensure that the necessary resources, such as clinician training, digital literacy, reliable broadband, access to steppedup care, etc., are made available to bring their use inline with evidence-based standards. This, of course, requires longer-term investments aimed at addressing the structural barriers which generated various health disparities in the first place. Unfortunately, there's not an app for that.

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