Title: Ethical Challenges in Consumer Digital Psychotherapy

Authors: Nicole Martinez-Martin, JD, PhD
Stanford Center for Biomedical Ethics
Karola Kreitmair, PhD
Stanford Center for Biomedical Ethics

Corresponding author: Nicole Martinez-Martin, JD, PhD
Stanford Center for Biomedical Ethics
1215 Welch Road, Stanford, California, 94305
nicolemz@stanford.edu
Phone: (773) 980-6753
Abstract
This article focuses on the ethical challenges presented by digital psychotherapy services that are direct-to-consumer and do not involve oversight by a professional mental health provider. These services include apps that connect users to peer counseling and counseling steered by artificial intelligence and conversational agents. These services can potentially assist in improving access to mental health care for the many people who would otherwise not have the resources or ability to connect with a therapist. However, the lack of adequate regulation in this area exacerbates concerns over how safety, privacy, liability, and other ethical obligations to protect a client are addressed by these services. In the traditional therapeutic relationship, there are ethical obligations that serve to protect the interests of the client and provide warnings. In contrast, in a direct-to-consumer therapy app, there are not clear lines of accountability or associated ethical obligations to protect the user seeking mental health services. There is a need for increased oversight of direct-to-consumer non-professional psychotherapy services to better protect the consumer.
Digital mental health, also known as “mobile mental health,” spans medical and consumer domains and the technology encompasses “smartphones and associated technologies used to augment treatment, advance diagnosis and expand access” [1]. About 77% of people in the U.S. own smartphones [2], and thus there is considerable interest in leveraging smartphones, wearables and other digital technology to improve research and treatment, and reach the 60% of people with mental illness who currently go untreated [3,4]. One area in which digital technology is being used to provide treatment is with services that connect users to talk therapy [5, 6, 7], either direct-to-consumer or with some form of oversight by a licensed provider. There are hundreds of direct-to-consumer apps directed at providing mental health treatment tools [8], including a growing number of apps designed to be used in place of professional psychotherapy. Most of these apps have not been evaluated for safety or efficacy [7, 8, 9]. This article focuses specifically on the ethical challenges presented by digital psychotherapy services that are direct-to-consumer and do not involve oversight by a professional mental health provider. In digital talk therapy, the therapeutic relationship, i.e. the working alliance between therapist and client, [10] is the foundation of ethical obligations that serve to ensure trust and protect the interests of the client. Digital technology is set to have an impact on this relationship in ways that may on balance be positive, but are not entirely clear [6, 11,12, 13]. Using unlicensed providers or software to deliver direct-to-consumer talk therapy is a part of efforts to make such services more cost-effective and allow greater access to such services. People may feel more comfortable sharing personal information remotely, or with a bot rather than a human, thus making these services more likely to be accessed by certain types of patients [14,15]. However, there are three primary ethical challenges we discuss in relation to these services: ethical obligations arising from the therapeutic alliance, privacy and data management, and safety.

The digital mental health landscape is currently a “Wild West” [16], with minimal regulatory oversight [1, 9, 17]. While many digital mental health apps could technically be considered to be medical devices under FDA guidelines, and thus subject to regulation, in practice, the FDA has treated much of this technology as low-risk and thus not necessitating scrutiny [11, 18]. Nonetheless, the risks associated with digital mental health are not sufficiently understood, and only a small proportion of the thousands of mental health apps are supported by evidence-based studies [19]. Professional organizations such as the APA have made initial efforts to provide guidance to their members regarding appropriate standards for the use of digital technology in mental health practice [17, 20]. However, when digital psychotherapy tools are provided through direct-to-consumer services and thus not subject to the obligations associated with professional mental health providers, there is a need to examine this gap in accountability for possible harms that can arise in the direct-to-consumer digital therapeutic domain.

**Ethical Obligations in the Digital Realm**

Psychotherapy involves the sharing of deeply personal and sensitive information by the patient. Trust and respect are foundational to the therapeutic relationship [21]. The professional codes of ethics guiding psychiatrists, psychologists, therapists and other professionals who can provide counseling and psychotherapy contain obligations for the maintenance of confidentiality and privacy, competence, and safeguarding the interests of the client [22, 23]. Professional therapists generally have a duty to warn third parties of danger posed by the patient, and in most states are legally mandated to report certain kinds of abuse [24]. When there are questions of
malpractice or liability, professional obligations provide procedures for patients to report the therapist and also outline standards for evaluating that liability.

There are a variety of approaches being used to deliver psychotherapy with digital technology (see Table 1, below). The term “non-professional digital psychotherapy” is used to refer to the approaches in which the ethical duties and obligations of a professional mental health provider (such as a psychiatrist or licensed mental health therapist) do not clearly apply to the psychotherapy. These services include those involving people with some training in psychotherapeutic approaches (but who are not licensed mental health providers), peer counselors, as well as services in which the “therapist” is a software program.

While some services follow a subscription model, there are also freemium and ad-supported models. On the one hand, the free and lower-cost models allow more people to access such services. However, free and ad-supported models also can raise concerns about how the service may be monetizing the users’ sensitive behavioral data, in effect trading one’s behavioral data for therapy. There also needs to be attention to the possibility that ad-supported services could allow ad targeting of the user for traits such as anxiety, depression or mania.

Table 1: Types of digital mental health psychotherapy

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional therapist</td>
<td>• The service is used to connect the individual to a professional therapist, who provides talk therapy via the service</td>
</tr>
<tr>
<td></td>
<td>• Hybrid models in which the user interacts primarily with a peer group or self-help materials, but a clinician is available to provide guidance or therapy as needed</td>
</tr>
<tr>
<td>Trained non-professional</td>
<td>• The therapist has some educational background related to mental health and/or some training in a particular therapeutic tool, such as cognitive behavioral therapy, but is not a licensed professional clinician or therapist.</td>
</tr>
<tr>
<td>Peer</td>
<td>• The service connects the user to a peer counselor or peer discussion group.</td>
</tr>
<tr>
<td>Self-guided</td>
<td>• Tools give users information to guide them through a therapeutic process (such as writing down their feelings, monitoring their own behavior)</td>
</tr>
<tr>
<td>Psychotherapist software</td>
<td>• Service that involves software, such as a therapy bot or conversational agent, that interacts with user by text or voice for the purposes of mental health therapy</td>
</tr>
<tr>
<td></td>
<td>• A chatbot can be programmed to use cognitive behavioral tools to interact with people who are dealing with depression or anxiety. This approach shows particular promise for patients for whom sharing their problems with a person provokes additional anxiety [6].</td>
</tr>
</tbody>
</table>

Expanding access is a laudable goal, but there needs to be attention to ensuring adequate protection for the expanding proportion of people with mental health needs who will be receiving
therapy from services that have limited to no established ethical obligations as therapy providers. One concern is simply that consumers are sufficiently aware that these services are not subject to ethical obligations meant to safeguard the therapeutic process. A broader question is whether a certain level of ethical obligations for users, a certain percentage of whom may be adolescents or facing severe mental illness, need to be required for such services. For example, 7 Cups of Tea, a peer counseling service, “makes no representation or warranty” as to the accuracy of advice or abilities of the listeners on its service [27]. Furthermore, the non-professional digital psychotherapy services reviewed generally state in the user agreement that if a client makes a credible threat of harm to another person while using the service, the site bears no liability. While such a disclaimer of liability is not unusual for commercial enterprises generally, in the digital therapeutic domain, is there adequate protection of the interests of the users? Moreover, when the digital psychotherapy is conducted by bots and AI-powered psychotherapy programs, there is a question of accountability and oversight regarding the algorithms guiding the programs. When a service’s providers are aware that people occasionally will be engaging the AI or bot with emergent problems or risk of self-harm, there may need to be certain information or protocols built into such programs. If an algorithm predicts that a user poses a threat to self or others [25, 26], would there be a requirement and mechanism for reporting this problem to others? There needs to be more consideration of liability and accountability for how the algorithms are developed and deployed for therapeutic purposes [15].

Generally, direct-to-consumer services are not appropriate for clients with more complicated or severe mental disorders [8]. Most of these direct-to-consumer talk therapy services acknowledge that they are meant for users with less severe conditions, and have user agreements that advise that someone with severe mental illness or a mental health crisis should go elsewhere. One issue that arises is the extent to which users will be aware of and understand these limitations placed in the user agreement. A person with a severe mental illness or a minor in crisis may not have sufficient insight to know to go elsewhere, or ability to read through the dense language of a user agreement. It is also unclear what kind of follow-up direction or response such a client would receive if they continue to attempt to use the service. Furthermore, there is a basic question regarding what entity is determining which types of conditions are appropriate for non-professional direct-to-consumer psychotherapy services. For example, the service 7 Cups of Tea lists bipolar disorder, eating disorders and cutting as issues that non-professional “listeners” can address for clients. However, these conditions do not seem relatively less complicated mental health issues or have a low likelihood of harm for the client.

The users at 7 Cups of Tea can be as young as 13 years old, and listeners as young as 15 years of age [28]. It should be noted that 7 Cups of Tea requires parental permission for minors to use the service— but that permission is simply one click on a pop-up box, with no system for authentication. Although the set of disclaimers found in these services’ user agreements may satisfy legal requirements, they may fall short in providing the necessary foundation for a therapeutic interaction. There is a need for further empirical research into how consumers actually engage with these services in order to ascertain what types of oversight or standards are necessary in order to protect consumers.

**Safety**

When it comes to apps and devices that mainly serve to connect patients to different types of talk therapy, it can be tempting to view the digital technology simply as a new medium for established therapies — however, the medium can potentially affect the message. The mental
health apps that have empirical support validating safety and effectiveness generally involve oversight by licensed professionals [29, 30]. For non-professional digital psychotherapy, it is important to note that incorrect mental health advice can send clients down potentially harmful paths, and divert people from reaching appropriate mental health services [9, 31]. Many of these non-professional direct-to-consumer psychotherapy services present themselves explicitly as a substitute for professional therapy, and thus there needs to be adequate attention to the circumstances and parameters for which these claims may be safely made.

Digital services that utilize a peer or lay counseling model are identified as non-professional services that may raise ethical, even though there have long been peer counseling therapy models in the non-digital world, in part because the digital format can introduce features that impact safety or effectiveness, as well as expand the reach of such services under the veneer of being a proper substitute for professional therapy. Peer counselors have been effective at providing mental health assistance in real-world circumstances, such as for people who live in areas where they have limited options for professional help [32,33]. However, the studies of effective non-digital peer counseling involve programs that provide professional oversight of training, as well as ongoing professional feedback on the peer counseling practices [32,33]. There is a need for empirically-supported best practices and standards for direct-to-consumer digital versions of peer counseling in order to minimize risks to the users.

The potential for conflict between the design features of the technology and the goals of treatment also need to be better understood [9, 34]. An overarching goal for consumer mobile devices and apps, unsurprisingly, is to keep people using them. This is done with a variety of design options meant to activate the reward systems in the brain, such as constant alerts and notifications, color choices, and making participation seem like a game [35]. These features can provoke addiction and anxiety, particularly when people already feel isolated, depressed or lack social support [36, 37]. Moreover, when psychotherapy apps are direct-to-consumer, there may be financial incentives for developers to include additional features or ads to entice the user to keep checking the app [35]. On the one hand, the desire to use the app a useful feature in order to get people to increase their utilization of mental health services. However, there should be careful consideration of how to balance the design of apps that are engaging, but that do not promote compulsive or anxiety-provoking usage. An app that is effective for one mental health issue, may not be appropriate for another; there is a need to evaluate how certain populations or people with specific diagnoses might utilize and be affected by how the digital mental health service is designed [38]. Many minors may be attracted to direct-to-consumer mental health services [39, 40]. It is particularly important to consider guidelines for the safe use of these services by adolescents, because of the particular mental health needs of that age group, as well as potential differences in patterns of usage and impact of interventions [41]. The products developed by academic researchers are subjected to more rigorous testing, but may not have been designed to maximize an engaging user experience; in contrast, many private sector products may have more attractive design, but have not gone through rigorous tests [47]. This challenge is exacerbated by the lack of an agency or organization providing oversight of these mental health therapy services that are direct-to-consumer and utilize non-professional therapists or bots.

Privacy, Confidentiality & Data Management

Privacy is a major concern when it comes to protecting the interests of users of direct-to-consumer digital health technology. We live in a time where consumer data is valuable, and thus
the incentives for companies to mine consumer data from mental health apps are considerable [43]. It is important to protect users from unknowingly exchanging their personal data in return for mental health care. Data collected by apps can potentially be sold, or used by algorithms that affect the user in employment or educational settings, or physicians can request access to a patient’s social media and electronic communications to aid in diagnosis [12]. Particularly when paired with tools for predictive analytics, shared data may have consequences for users that they will not have foreseen [25]. It will be necessary to consider industry guidelines regarding which uses of data should be considered legitimate and what protections may need to be in place to protect consumer data in this setting. The informed consent process needs to ensure that users adequately understand the data management and storage practices of the service, as well as potential repercussions of the data being shared. It should be clear to users who will have access to the data, what kind of data is being collected and how it is being stored.

A professional psychotherapist would have obligations to keep client information confidential. Many non-professional psychotherapy services explicitly state, such as in their user agreement, that they do not have obligations such as confidentiality and are not responsible for protecting the interests of the user. However, many users might assume confidentiality applies in any therapeutic interaction and so it is particularly important to ensure users are aware when it does not. One service that offers talk therapy from peers or “listeners”, 7 Cups of Tea, states in its user agreement that all “chats or transcripts, being captured in any format, [can be] controlled, processed and shared by 7 Cups of Tea with third parties as designated solely by 7 Cups of Tea”. The lack of obligation for non-professional talk therapy services to be confidential or competent becomes more troubling particularly in light of the expected dramatic increase in use of direct-to-consumer psychotherapy tools [15, 26].

In particular, there need to be efforts to strengthen informed consent for such services. Basic measures include making sure that the reading level of the user agreement is not too high [44, 45]. There are also possible innovations for improving informed consent on digital technology platforms, such as slowing down the consent process with interactive screens or providing video/audio content to clarify risks and benefits [46]. Even beyond the question of whether users are sufficiently aware that these disclaimers are part of the user agreement, there may need to be a mechanism to ensure that ethical obligations such as confidentiality, competence or a duty to warn should apply to such services for public policy reasons, in order to make sure that people are receiving appropriate protections in a therapeutic interaction.

Conclusion

The incorporation of digital technology into mental health care is exciting and promises to improve diagnosis and access to treatment. Digital technology can make talk therapy services cheaper and easier to access. However, given the lack of regulation, there is a need to consider the ethical challenges of such technology when applied to direct-to-consumer non-professional psychotherapy services. Digital psychotherapy services have the potential to cause harm and divert individuals from more effective therapy. Moreover, services that are unsafe or violate user trust in terms of privacy or other ethical obligations also can affect the overall uptake of legitimate services. It will be necessary to involve stakeholder in the establishment of industry guidelines. For example, there may need to be requirements for how and where consumer data is stored that minimizes risks that sensitive user data can be accessed for purposes not intended by the user. There may also be a need for more regulatory oversight, particularly when it comes to privacy, safety and the accountability of providers. Improving informed consent for these
services will be necessary, so that users can understand the limitations and risks involved with such services. For certain uses, there also may be a need to improve the authentication of users, in order to ensure safety and appropriate mental health practices. Further empirical research into how these services are being used, as well as expectations of the users, is a key part of informing best practices and guidelines for using services for appropriate populations.

References


44. Cordasco KM. Obtaining Informed Consent From Patients: Brief Update Review. Agency for Healthcare Research and Quality (US); 2013.


Conflicts of Interest: None to Disclose