Towards a consensus around standards for smartphone apps and digital mental health

Mental disorders impact one in four people worldwide, yet access to care is challenging for those who suffer from them[1]. Mental health apps offer the potential to overcome access barriers for the nearly three billion people projected to own a smartphone by 2020.

Although there are over 10,000 mental health apps commercially available, there are few resources available to help end users (patients, clinicians and health care organizations) to evaluate the quality and suitability of these products. Thus, there is an urgent need for an agreement about appropriate standards, principles and practices in research and evaluation of these tools.

We represent leaders in mHealth research, industry and health care systems from around the globe, and we seek here to promote consensus on implementing these standards and principles for the evaluation of mental health apps. At a minimum, standards should include consideration of: a) data safety and privacy, b) effectiveness, c) user experience/adherence, d) data integration. Our consensus on the challenges and recommendations in each of these areas is presented below.

Data safety and privacy. Given the climate today regarding the misuse of online data such as email and social media, mental health apps must ensure that data storage, use and sharing practices fulfill health care standards for handling patient health information data[2]. Like with all sensitive health data, smartphones-based sensor data such as global positioning system (GPS), voice, keyboard usage, photos, video and overall phone usage behavior are features that many mental health apps collect, posing significant privacy challenges[2,3].

Our recommendations are: a) agreed upon standards for data storage, use and sharing are needed; b) data storage, use and sharing policies must be made transparent to users of the app; c) if data are shared with external partners (e.g., researchers), the partner's storage, use and sharing plans must be shared with the end user; d) the end user must have the option to "opt out" of sharing his/her information; e) any language regarding data storage, use and sharing must be written at a maximum of a 6th grade reading level; f) technical security reviews and data audits are necessary to guarantee that apps follow the standards they set out and ensure that new vulnerabilities are quickly identified.

App effectiveness. Most mental health apps that are sold as therapeutic tools have not undergone rigorous evaluation, but instead claim that they are evidence based because they are informed by evidence based treatments[4]. Even when apps do have an evidence base, changes in technology may mean that app updates need to be re-evaluated for their efficacy. Small cosmetic changes, platform changes and aspect changes do not likely require a retest of an intervention, as long as the therapeutic principle that has been evaluated remains intact.

Particularly where the aim is to increase reach, engagement and adherence rather than efficacy, A/B testing may be most appropriate. However, significant changes, such as adding a new therapeutic principle or substantial changes to that principle, must demonstrate efficacy through the same evaluation pathways as novel therapeutics.

Our recommendations are: a) newly adapted therapeutic principles, which should be identified and defined, must undergo controlled clinical trials to determine their efficacy and effectiveness; b) small changes to an app with an evidence base need not undergo another clinical trial, but any major change requires a re-evaluation of app effectiveness; c) a nosology for mental health apps[5] and guidelines to match the necessary level of evidence for each app's use cases and risks[6] should be developed.

User experience/adherence. Many patient end users stop using a health app two weeks after download[7]. Clinician end user adherence is influenced by familiarity with technology and app match to the clinician's therapeutic expertise. Lack of adherence is likely a function of app usability, as the input of clinician and patient end users is often missing when a mental health app is designed, resulting in apps that do not align with the preferences and goals of the intended users[6].

Our recommendations are: a) user-centered/user experience (UX) design methods should be employed when creating an app; this includes involving the intended end user in the development, and conducting as-is workflow analysis to ensure that the app is useful and usable, and that it fits into the fabric of the person's life, not producing unnecessary burden to the end user; b) when usability is evaluated, developers should report use statistics to all end users; c) standards concerning best practice in user design research for mental health apps should be articulated.

Data integration. Apps should allow appropriate electronic health record (EHR) integration and sharing of health information with clinicians. One challenge is that EHRs have non-uniform data integration requirements and not all support use of application programming interface (API) for data exchange. In the US, there is a strong move towards allowing patients access to their electronic health record information via SMART Health IT (https://apps.smarthealthit.org/), an open, standards-based technology platform that enables innovators to create apps that run across platforms. However, there are few agreed upon internal data standards to facilitate this level of interoperability.

Our recommendations are: a) mental health apps that are intended to be used in conjunction with health care systems should employ methods to ensure interoperability with electronic health records; b) mental health apps will need to document the processes they use to ensure the secure exchange of information between platforms; c) internal data standards for

interoperability are needed, much like those outlined in http://www.openmhealth.org/.

As mHealth transitions towards medical care in the mental health field, now is the critical moment for researchers, clinicians, service-users, policy makers and funders to guide that transition and ensure that these tools meet rigorous standards, as is required of any novel therapeutic.

Movement in this direction is taking place. In the US, the Food and Drug Administration has announced that it is moving away from evaluating individual apps, and focusing its regulatory efforts on the app makers. Additionally, US professional groups like the American Psychiatric Association and the American Medical Association are creating app evaluation frameworks[8]. In the UK, the National Health Service has recently re-opened the App Library in beta phase, providing recommendations for apps across a range of conditions including mental health, and the British Standards Institute has published standards for health app development. In the European Union, the National Institute of Health and Care Excellence (NICE) is actively developing standards for apps and other technology based behavioral change interventions.

We thus make a final recommendation that these organizations, and others, come together to set universal standards for mental health app quality control, and that those standards include at a minimum the review of data security, app effectiveness, usability, and data integration.

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1. World Health Organization. The world health report 2001 – Mental health: new understanding, new hope. Geneva: World Health Organization, 2001.
2. Huckvale K, Prieto JT, Tilney M et al. BMC Med 2015;13:214.
3. Kramer DB, Fu K. JAMA 2017;318:2077-8.
4. Larsen ME, Nicholas J, Christensen H. PLoS One 2016;11:e0152285.
5. Hollis C, Falconer CJ, Martin JL et al. J Child Psychol Psychiatry 2017; 58:474-503.
6. Mohr DC, Weingardt KR, Reddy M et al. Psychiatr Serv 2017;68:427-9.
7. Dorsey ER, McConnell MV, Shaw SY et al. Acad Med 2017;92:157-60.
8. Torous JB, Chan SR, Gipson SY et al. Psychiatr Serv 2018;69:498-500.

AVATAR therapy: a promising new approach for persistent distressing voices

AVATAR therapy was invented and first described by J. Leff and colleagues[1]. The therapy involves a three-way conversation between therapist, patient and a digital simulation ("avatar") of one of his/her hallucinated voices. The avatar comprises a visual representation of the agent that the patient believes is responsible for the voice and uses a speech transformation software to change the therapist's voice into a close match of the vocal characteristics (e.g., tone and pitch) of the voice that the patient has chosen for the therapy.

Therapy takes place over 6-8 short sessions of approximately 45 min, of which around 15 min are spent in dialog with the avatar, and the rest reviewing the experiences of the previous week, planning the session and reviewing the experience after the dialog is complete. The therapist, sitting in a room remotely from the patient, speaks either as him/herself or in his/her transformed voice as the avatar. The patient sits in front of a monitor on which the avatar appears. Starting with verbatim copies of what the patient reports hearing from his voices, the therapist adjusts what the avatar says according to the unfolding dialog, in which the patient is encouraged to confront the avatar and, through the dialog, to get to a point where it is no longer intimidating and may even become encouraging and supportive.

The origins of the approach lie in dialogic therapies[2-4] and is based on the observation that voices are best understood not simply as misattributions of internal thoughts, but represent hallucinated social entities that have personal relevance, meaning and purpose[5,6]. Thus, the content of therapy is based on a formulation that takes account of the person's beliefs about the identity, power and malevolence of the voices. It includes consideration of whether the voice is of someone he/she knows and whether what it says echoes earlier difficulties in relationships, as for example experiences of being bullied, shamed or humiliated.

The therapy proceeds in two broad phases[7]. The first three sessions focus on assertively standing up to the avatar and rejecting its onslaught. The content of the second phase (sessions 4 through 6) is more variable, as it is based on a formulation of what needs to change in the relationship and what might persuade the avatar to take a more conciliatory and accepting view of the person. Strategies to improve self-esteem have turned out to be a key target, both as an end in themselves and in the understanding of the origin and maintenance of the voice.

There have now been two pilot studies comparing AVATAR therapy to a waiting list control[1,8] and one powered controlled