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EDITORIAL

Reporting and understanding the safety and adverse effect profile of mobile apps for psychosocial interventions: An update

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Abstract

Recent years have seen a rapidly increasing trend towards the delivery of health technology through mobile devices. Smartphones and tablet devices are thus becoming increasingly popular for accessing information and a wide range of services, including health care services. Modern mobile apps can be used for a variety of reasons, ranging from education for the patients and assistance to clinicians to delivery of interventions. Mobile phone apps have also been established to benefit patients in a scope of interventions across numerous medical specialties and treatment modalities. Medical apps have their advantages and disadvantages. It is important that clinicians have access to knowledge to make decisions regarding the use of medical apps on the basis of risk-benefit ratio. Mobile apps that deliver psycho social interventions offer unique challenges and opportunities. A number of reviews have highlighted the potential use of such apps. There is a need to

describe, report and study their side effects too. The adverse effects associated with these apps can broadly be divided into: (1) those resulting from the security and safety concerns; (2) those arising from the use of a particular psycho social intervention; and (3) those due to the interaction with digital technology. There is a need to refine and reconsider the safety and adverse effects in this area. The safety profile of a mobile PSI app should describe its safety profile in: (1) privacy and security; (2) adverse effects of psychotherapy; and (3) adverse effects unique to the use of apps and the internet. This is, however, a very new area and further research and reporting is required to inform clinical decision making.

Key words: Mobile; Psycho social; Side effects; Health; Media; Security; Privacy

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Core tip: Mobile apps offer unique opportunities and risks when used for delivering psychosocial interventions. While there is some evidence to inform clinicians and patients of the efficacy of these apps, only limited information is available on their risk profiles. The side effects of mobile psychosocial apps might be due to the privacy and security issues, side effects of a particular therapy that is being delivered or due to the use of excessive use of internet or the apps. There is a need for clinicians and patients to report the side effects in these areas.

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INTRODUCTION

Recent advances in mobile devices and faster Internet connectivity of these devices has led to a new era in health technology. Smartphones and tablet devices are thus becoming increasingly popular for accessing information and a wide range of services, including health care services. Modern mobile phones offer stable and versatile platforms that allow delivery of a variety of services. Mobile apps can support a variety of routine medical tasks, ranging from education and assistance to clinicians to helping and supporting the patients. These apps have also been established to benefit patients by providing a range of interventions across most medical specialties. Medical apps are used by clinicians to access medical knowledge. All these mobile apps have their advantages and disadvantages. In this article, we will only focus on the mobile apps that are used for delivering psychosocial interventions. A mobile psychosocial intervention (mPSI) app means a software used on a mobile platform to deliver a psychosocial intervention. These will include apps such as Breathe and Relax, PTSD Coach and the Big White Wall.

As with many interventions, the decision to use a mobile app in a particular clinical situation should be dependent on clinician perceived risk-benefit ratio. These decisions require health care professionals to have a good understanding of the intended benefits, limitations and risks of the medical apps in order to make an informed app usage decision. We have recently argued that providing accurate information in easy to understand language about development and initial testing should be an essential part of the mPSI app[1]. This information will help both patients and clinicians in making informed decisions. We have also suggested that the risks and adverse effects of psychosocial interventions are an important part of a description of the maps[1]. It is important that the person using these apps is fully aware of the safety profile and adverse effects of these apps. This is especially important within persons suffering from mental illness, as they may be more vulnerable to the adverse effects from these apps compared to the general population. The adverse effects associated with these apps can broadly be divided into: (1) those resulting from the security and safety concerns; (2) those arising from the use of a particular psychosocial intervention; and (3) those due to the interaction with digital technology. Most writers in this area have focused on security and privacy, an understandable concern[2-4]. We will briefly describe these here. Other adverse effects such as those resulting from the interaction with these devices have received little attention and will be described in more details[5].

SECURITY AND PRIVACY ISSUES

When conducting any form of health research, it is imperative for researchers to follow the principles set out by the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects[6]. These guidelines ensure the safety of participants, the right by participants to withdraw from the study, recruitment of participant's security, privacy and confidentiality.

Mobile applications with a low level of security or privacy can cause serious issues, and can have severe implications for users and organizations alike. But can the mobile environment ever be considered secure? Past security incidents including vulnerabilities found in well-known mobile apps and malware attacks on mobile platforms suggest that the mobile environment is far from secure despite advances in security measures in cyberspace[4]. Rapid growth of mobile devices with position sensors has made Location-based Services readily accessible. These mobile devices send user's

location information to the third party location servers, which can be accessed by other service providers. Those aware of this, might feel continuously tracked[3]. This might have serious implications for most persons suffering from any psychiatric disorders with increased anxiety and paranoia.

Perera[7] described a number of safeguards which can be used to ensure data security on mobile devices. To ensure protection mobile devices should be accessible *via* a pin; it is recommended that rather than a four digit pin an alphanumeric passcode is used. In addition, functionality, whereby data is wiped from the device after 10 failed passcode attempts would further protect data[7]. Furthermore, encryption of mobile devices, enabling remote wiping of data held on the device and storing data in the cloud instead of the mobile device are key strategies in ensuring data security[7].

Another factor which needs considering is the number of notifications and alerts which are programmed into mPSI apps. Firstly, the notification iconography may need to be discreet/private as not to cause any distress to participants in the case of someone accidentally viewing the icon; this may infer the individual is undergoing therapy and may be stigmatizing. Individuals should be given control in the use of the mobile device, and it should not be seen as an intrusion into their daily life.

Lewis *et al*[2] suggest that these risk factors can be broken down into internal and external risk factors. Although internal risk factors may be reduced through appropriate regulation, external risk factors can only be eliminated through proper training and education. The same authors have also suggested a two-dimensional "app-space" where an app can be located depending on a variety of factors. The authors suggest that based on combined chances of harm and complexity, an app will fall into one of four categories: (1) requiring only local inspection; (2) requiring a more formal risk assessment; (3) requiring professional review of a full profile; and (4) those requiring formal regulation and review by governmental bodies such as the United States Food and Drug Administration Agency due to their high probability of causing harm". In a recent opinion paper[1], we have reported that the mPSI apps can be divided into three types: (1) type 1, intervention delivered by a human therapist through eMedia (*e.g.*, telephone-delivered problem solving by a therapist, Avatar Therapy); (2) type 2, intervention based on a manualized, well-established therapy delivered through eMedia (*e.g.*, CBT delivered from a website that is based on a manual); and (3) type 3, a new intervention that did not exist before, and is not based on previous theory or on therapeutic principles (*e.g.*, electronic dispensing). These criteria need a further definition that relates to the risks attached.

ADVERSE EFFECTS DUE TO PSYCHOSOCIAL INTERVENTIONS

Since a classic paper of Bergin[8] on the description of the possibility of a psychological treatment producing negative effects, clinicians and researchers had low interest in this area[9]. This is a re-emerging area and research has just started in this area. But it has been estimated that between 3% and 15% of the recipients experience unwanted effects. These rates are similar to those of pharmacotherapy[10]. There are only a few reported studies comparing the adverse effects of psychosocial interventions, for example, Klingberg *et al*[11] reported an RCT, which compared CBT for psychosis with Cognitive Remediation Therapy. Both groups experienced nearly the equal adverse effects. Lambert *et al*[12] has suggested that between 5% and 10% of all patients undergoing psychotherapy deteriorate.

Recently, the need for expanded monitoring of negative effects in clinical trials of psychotherapy has been discussed, resulting in different suggestions on how to define and measure the negative effects. Linden[10] presented a comprehensive checklist dividing negative effects into different categories. These include: (1) deterioration; (2) adverse events; (3) severe adverse events; (4) novel symptoms; (5) dropout; (6) nonresponse; (7) unwanted events; and (8) suicide attempts and deaths by unnatural means.

ADVERSE EFFECTS UNIQUE TO APPS AND INTERNET USE

There are a number of adverse effects that are unique to the use of mobile apps and the internet. These include reduced face to face communication which probably can result in inadequate social skills (however, it can be argued that future generations might not need social skills as we know these). This is particularly important as most psychotherapeutic interventions aim to enhance communication and social skills. The "virtual" interactions may result in reduced problem-solving skills in the real world. There are also possible adverse effects of using the internet for increased periods which can contribute to increased levels of inactivity and sedentary behaviors which have been reported to increase the risk of obesity[13].

Information overload (or worse still inappropriate information) can lead to cognitive problems. Similarly, insomnia, depression and anxiety are common among heavy net users[14]. It is important that these factors are highlighted due to the way individuals are using apps and the internet, but also due to the increasing availability of internet on mobile devices.

One of the key adverse effects of the internet is internet addiction, with a study by Boysan *et al*[15] in the United Kingdom reporting that out of 2257 university students 3.2% were addicted to the internet. Furthermore, Ko *et al*[14] suggested the heightened comorbidity of psychiatric disorders and internet addiction, with more research needed to better understand this phenomenon. Another possible adverse effect of internet usage is the potential for online sexual

grooming and exploitation of children, due to factors such as anonymity which may provide an environment for perpetrators to engage in sexually motivated behaviours[16].

More specific to the area of apps, mobile devices which run mPSI apps produce electromagnetic fields which have been suggested as being carcinogenic by the World Health Organisation (WHO) with the WHO conducting a formal risk assessment of this potential adverse reaction, due 2016[17]. Furthermore, it has also been found that another possible adverse effect of apps is high frequency usage. A study by Thomée *et al*[18] found an increased risk factor for mental health outcomes in young adults with high frequency use associated with stress, sleep disturbances and symptoms of depression at one-year follow up. In addition, there has also been research suggesting increased risk of ocular problems, with viewing mobile phone screens causing eye strain[19]. Other complications have also been found in relation to viewing mobile device screens, with Wood *et al*[20] reporting that exposure to self-luminous screens on mobile devices have the potential to increase the likelihood of sleep disorders due to factors such as melatonin suppression, particularly in the blue light spectrum. It is also important that individuals feel no pressure in replying to the mPSI app notifications and alerts, as there may be a risk of increasing paranoia and anxiety.

It is important that these adverse effects are systematically observed, and data are recorded in any psychosocial intervention studies. This will require both qualitative and quantitative studies. The qualitative studies will help us to understand patient experience, which has rarely been studied in psychosocial interventions using mobile apps. Furthermore, adverse effects should be reported to regulatory bodies such as the FDA and MHRA. Naeem *et al*[1] proposed a framework for understanding that mPSI apps use lessons learned by the pharmaceutical industry to ensure the safety of mPSI apps through rigorous testing and evaluation.

CONCLUSION

There is a need to refine and reconsider the safety and adverse effects in this area. The use of mPSI interventions offers unique opportunities and risks. The safety profile of a mobile PSI app should describe its safety profile in: (1) privacy and security; (2) adverse effects of psychotherapy; and (3) adverse effects unique to the use of apps and the internet.

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