Realising the technological promise of smartphones in addiction research and treatment: An ethical review

Realising the technological promise of smartphones in addiction research and treatment: An ethical review

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ABSTRACT

Background: Smartphone technologies and mHealth applications (or apps) promise unprecedented scope for data collection, treatment intervention, and relapse prevention when used in the field of substance abuse and addiction. This potential also raises new ethical challenges that researchers, clinicians, and software developers must address. **Aims:** This paper aims to identify ethical issues in the current uses of smartphones in addiction research and treatment. **Methods:** A search of three databases (PubMed, Web of Science and PsycInfo) identified 33 studies involving smartphones or mHealth applications for use in the research and treatment of substance abuse and addiction. A content analysis was conducted to identify how smartphones are being used in these fields and to highlight the ethical issues raised by these studies. **Results:** Smartphones are being used to collect large amounts of sensitive information, including personal information, geo-location, physiological activity, self-reports of mood and cravings, and the consumption of illicit drugs, alcohol and nicotine. Given that detailed information is being collected about potentially illegal behaviour, we identified the following ethical considerations: protecting user privacy, maximising equity in access, ensuring informed consent, providing participants with adequate clinical resources, communicating clinically relevant results to individuals, and the urgent need to demonstrate evidence of safety and efficacy of the technologies. **Conclusions:** mHealth technology offers the possibility to collect large amounts of valuable personal information that may enhance research and treatment of substance abuse and addiction. To realise this potential researchers, clinicians and app-developers must address these ethical concerns to maximise the benefits and minimise risks of harm to users.

Keywords: smartphones, mHealth, addiction, substance abuse, ethics, research, treatment.

INTRODUCTION

Smartphones are a powerful and ubiquitous technology that combines mobile computing with telecommunication capabilities (Mosa, Yoo, & Sheets, 2012). In 2011, there were over 6 billion phone subscriptions reaching 87% of the world's population (ITU, 2011). A recent survey found that 43% of global respondents have a smartphone (Poushter, 2016). For countries such as Australia or the United States, this figure approaches three-quarters (Poushter, 2016). There is growing interest in the use of smartphones and other mobile technologies for conducting research on drug use and addiction and intervening to reduce drug use and its harmful effects (Kuntsche & Labhart, 2014; Meurk, Hall, Carter, & Chenery, 2014).

The ability of smartphones to run third party software applications (or apps) has generated interest in their use for research in substance abuse and addiction. Smartphones overcome many of the traditional limitations of addiction research that rely upon pen and paper surveys or diaries and retrospective recall. Although gathering retrospective self-report may be cost-efficient and convenient, it has been found to underestimate substance abuse (Kuntsche & Labhart, 2014). Self-reported drug use can be under-reported if participants are unwilling to reveal the true amount consumed. It may also be subject to recall bias when users only remember some of their total drug consumption (Kuntsche & Labhart, 2014). Surveys of drug use generally underrepresent heavy substance abusers in the population (Kuntsche & Labhart, 2014). Less intrusive smartphone technologies can encourage a wider section of the population to participate in surveys. Less time is taken to fill out lengthy questionnaires and diaries, and prompts can be sent throughout the day to collect a greater range of data at more regular intervals (Kuntsche & Labhart, 2014).

Smartphones are also being looked at for use in healthcare settings to improve diagnosis and personalise treatment (Mosa et al., 2012). Smartphones may enable clinicians and other health care professionals to deliver clinically important information in a uniquely timely way. For example, data collected by a smartphone could trigger clinically relevant messages to the user prior to any drug use (Luxton, McCann, Bush, Mishkind, & Reger, 2011). The use of smartphone technologies for this purpose has been termed *mHealth* (Tamony, Holt, & Barnard, 2015).

mHealth falls within the broader field of electronic research or *e-research* (Kypri & Lee, 2009; Miller & Sønderlund, 2010). E-research is commonly used to study human participants from populations difficult to identify, recruit and retain in research and treatment. Advantages of mHealth and e-research in non-therapeutic research (e.g. epidemiological, social and behavioural, humanities research) (Barratt, 2012; Meurk et al., 2014; Miller, Johnston, McElwee, & Noble, 2007; Shearer et al., 2007), include: increased participant comfort and perceived anonymity that encourages more honest disclosure; improved consent processes (Ford Ii et al., 2015; Monney, Penzenstadler, Dupraz, Etter, & Khazaal, 2015; R. Patel et al., 2015); reduced research costs; and fewer data errors (Miller et al., 2007; Monney et al., 2015). These approaches have also proven beneficial with human participants in therapeutic research domains (i.e. prevention, treatment and other interventions) include greater capacity to recruit participants for clinical studies, more efficient intervention delivery, improved monitoring of adherence to treatment protocols (Vahabzadeh, Lin, Mezghanni, Epstein, & Preston, 2009), and capacity to produce significant intervention effects (Amstadter, Broman-Fulks, Zinzow, Ruggiero, & Cercone, 2009; Neil, Batterham, Christensen, Bennett, & Griffiths, 2009).

For both research and treatment of addiction, smartphone monitoring of substance use or treatment is possible through passive data collection or via direct input from patients. Smartphone apps can prompt and record a patient's self-reported drug consumption and cravings, commonly referred to as Ecological Momentary Assessment (EMA) (Serre, Fatseas, Swendsen, & Auriacombe, 2015). Smartphone technologies may passively record patterns of movement within the environment, for example, via global positioning systems (GPS), wireless local area networks (or Wi-Fi), Bluetooth, accelerometers, gyroscopes, pressure-sensors, proximity-sensing magnetometers, barometers, humidity sensors, temperature sensors, and ambient light sensors (Luxton et al., 2011). Microphones and cameras are able to record images and sounds, including personal conversations, in the vicinity of the phone (Pei et al., 2013). From these data it is possible to deduce rich social information about an individual, including their identity, gender, age, marital status, social status, where they live, where their children go to school, health, sex life, religion, mood, and whether they visit a therapist, and if so how often, or how regularly they visit drinking or gambling establishments (A. Carter, Liddle, Hall, & Chenery, 2015; Gasson, Warwick, Kosta, Royer, & Meints, 2011; King, 2011; Pei et al., 2013; Shilton, 2009).

Physiological information such as heart rate, blood pressure and substance concentration levels may be measured using additional sensors. Remote monitoring devices, for example, are being developed to continuously monitor physiological responses or precursors to cravings or relapse in persons being treated for addiction (Boyer, Smelson, Fletcher, Ziedonis, & Picard, 2010; Yu et al., 2012). Smartphones can also be adapted to directly monitor physiological responses to drug consumption, such as sensor bands that are able to detect electro-dermal activity, body motion and skin temperature (Boyer et al., 2012). This information may be linked to other electronic databases, either commercially available or through agreement with other government agencies (e.g. personal medical records). Algorithms may then be developed to identify behavioural patterns indicative of treatment progress, such as treatment response and triggers for cravings and behaviour that increases the risk of relapse (Ahsan et al., 2013). In order for the technology to provide effective treatments, robust research will need to be conducted. Given the sensitive information being collected and intrusive nature of the equipment, a number of ethical issues arise.

Ethical issues

mHealth raises novel ethical issues for research because it differs from traditional means of human participant recruitment, consent, data collection, and analysis (A. Carter et al., 2015). mHealth methods alter the nature, dynamics and potential consequences of research participation and are evolving rapidly. The potential negative consequences of participation in mHealth research are particularly salient for those with stigmatised disorders or behaviour, such as those with a drug addiction or who use illicit drugs (Meurk et al., 2014).

There are also concerns surrounding the clinical applications of mHealth technology for addiction or substance abuse treatment. Confidentiality and informed consent procedures may need to be revised to consider storage locations and security. Given the wide market available and possibility for corporate interest, evidence of safe and effective treatments may need to be highlighted prior to distribution among potentially vulnerable users. The speed of growth of the smartphone app market appears to have outpaced the medical fraternity's ability to address these ethical challenges (Boyce, 2012).

The pace of development is "forcing researchers and research regulators to rethink and re-evaluate such fundamental research ethics issues as privacy, informed consent, ownership, recruitment, public versus private space, research and scientific integrity itself" (Buchanan & Hvizdak, 2009, p. 37). The World Health Organization has recognised the need for greater consideration of the ethical use of electronic or mobile research and health. Unfortunately, progress in developing ethical guidance has been slow. A recent NHMRC Australian Health Ethics Committee (AHEC) consultation paper on ethical issues in alcohol and drug research acknowledged: "The National Statement was published before the ethical issues raised by these developments became apparent so it currently provides no specific guidance for Internet-based or other forms of online research" (NHMRC, 2011, p. 27). This is particularly the case for mobile technologies. Although recent guidelines have been outlined on the use of digital data in research (Clark et al., 2015), ethical guidelines are still required to clarify best practice in the use of mHealth technology (A. Carter et al., 2015).

It is important that ethical regulation of the research and clinical use of smartphones keeps pace with the rapid developments in these technologies. Traditional ways of ensuring the confidentiality and privacy of research data collected on drug use and behaviour are not sufficient to deal with the sophisticated array of personal data that are collected via smartphone technologies. Research teams and clinicians must understand these ethical implications if they are to maximise the promise of this technology and minimise any unintended harms. These ethical concerns depend on how the technology is being used, and the sorts of safeguards that are put in place. The use of appropriate technical safeguards during the development of apps can mitigate many of these concerns (e.g. by the use of secure in-boxes, maximising user control over data recorded, transmission of data using secure methods, and providing access to devices for those that do not have them) (A. Carter et al., 2015). The current lack of ethical guidelines in this area can "result in researchers acting with less consideration, and even behaving unethically towards their study subjects" (Bober, 2004, p. 308).

In order to better understand the ethical issues raised by the use of smartphones in addiction research and treatment, this paper aims to review the ways in which smartphone technologies are currently being employed in the field. From this ethical review, we will conclude with a set of recommendations for the development and use of mHealth apps for researchers and clinicians in the field of substance abuse and addiction.

METHODS

A search of three electronic databases (PubMed, PsycInfo and Web of Science) was performed by HC using the following terms: ("substance use" OR "substance abuse" OR "drug dependence" OR addict* OR alcohol* OR smok* OR tobacco OR cannabis OR marijuana OR heroin OR cocaine OR opioid OR opiate) AND (mHealth OR smartphone OR iPhone OR "mobile phone app") NOT ("smartphone addiction").Eighty-four articles were downloaded to an Endnote database for further analysis of eligibility. Titles and abstracts of the articles were examined to identify studies fulfilling the following criteria: 1) involving mHealth apps or smartphones (defined as mobile phones with on board sensors, internet capability and the ability to run third party apps); 2) for use in the research or treatment of substance abuse or addiction. Articles not fulfilling these criteria were excluded (n = 22). Full-text analysis excluded a further 30 publications because they either did not fulfil the inclusion criteria, provided only a case report or general review of the topic or re-published data (Epstein et al., 2009; McTavish, Chih, Shah, & Gustafson, 2012). Article reference lists were screened

identifying one additional study (Yu et al., 2012). The final analysis comprised of 33 unique papers describing 35 mHealth/mobile phone applications (see Figure 1).

[**Figure 1** Trial Flow Diagram.]

Data Analysis

The data was transcribed into the Statistical Package for Social Sciences (SPSS) Version 23.0 software to be analysed quantitatively and also tabulated in Microsoft Word for qualitative analysis. Of the 33 studies included in this analysis, 10 used smartphone technology to collect research data from participants (*Research apps,* see Table S1) and 23 focused on the treatment or management of addiction and substance abuse (*Clinical apps,* see Table S2). A content analysis identified the following relevant themes: substance investigated, study aims and design, information recorded as part of the study, how information was stored and transferred from the smartphone, and the ethical considerations highlighted in the study. We then examined the ethical concerns raised by these themes and assessed the measures suggested in the literature to mitigate these concerns. We then conducted an ethical analysis employing a pluralistic principlist approach (Beauchamp & Childress, 2009) to identify additional ethical concerns that warrant further consideration by researchers, clinicians, and app developers.

RESULTS

Substance Investigated

Approximately half of the apps focused on tobacco abuse and one-third involved alcohol use (see Table 1); two examined heroin addiction, and one cocaine abuse. Three studies examined addiction in general, either covering a range of substances or not specifying the substance of addiction.

[**Table 1** Substance of focus.]

Study Design and Aim

The majority (37.1%) of studies analysed were randomised controlled trials (RCT) of clinical smartphone apps. Approximately one-third (31.4%) were observational studies of intervention effects on participants' behaviour; seven of these were cohort studies and four were case-control studies. One-quarter of the applications reviewed were feasibility studies. Two papers were reviews of commercially available applications.

Five distinct aims of the apps were identified (see Table 2). Over half aimed to induce or support behaviour change, such as smoking cessation, or reduced alcohol consumption. Other applications aimed at: preventing the user from relapsing to drug use; assisting the user to monitor their consumption; and encouraging medication adherence in the treatment of alcohol abuse.

More than half of the 10 research applications used text messaging and EMA protocols to assess relationships between cravings, substance use, mood or proximity to retail outlets for alcohol or tobacco. One study tested the reliability and validity of a mobile phone based breath carbon-monoxide meter, while another aimed to investigate the prevalence of smoking in vehicles. Two studies used smartphone apps to study the effects of alcohol on cognition: one used games to

measure alcohol intoxication and compared this with blood alcohol concentration; the other examined the effectiveness of a program to increase executive functioning of alcohol abusers.

[**Table 2** Purpose of application.]

Personal Information Recorded

The apps collected a range of demographic and personal information (see Table 3). A majority required users to record their regular consumption habits, daily drug use, cravings, or triggers of cravings. Over half of the apps obtained personal demographic information that included age, gender, ethnicity, education level and employment. Users' locations were tracked using GPS or other geo-locating sensors by more than one-fifth of the applications and three included devices that measured physiological data. Three obtained this information via user self-report. Six apps collected information on participants' medical history or their use of prescribed medications. More than one-third of apps collected information on users' goals for recovery, such as personal motivations or reasons for abstinence.

[**Table 3** Type of information collected.]

Data Storage and Transfer

One-quarter of the studies did not address storage security or methods of transferring the information from the device. Almost half (48.6%) utilised 'secure' online storage banks, such as 'the cloud', and wireless or 3G servers to transfer this information (Ahsan et al., 2013; BinDhim, McGeechan, & Trevena, 2014; Hertzberg et al., 2013; Reitzel et al., 2014; Renner, 2012; Struik & Baskerville, 2014). The remainder either stored information on local devices (25.7%). In terms of transfer of information, over half of the studies transferred data using online pathways and approximately one-fifth (22.9%) transferred information using localised, offline devices.

Ethical Considerations

After reviewing the literature, we identified the following ethical issues as emerging themes: protecting the privacy of the information collected (assessed by attempts to ensure user anonymity, encryption of data, consideration of storage and transfer security, password protection, private inboxes, and user control); ensuring equal access to the technology for all individuals; and providing appropriate clinical information to the individual (including recommendations for supportive resources for substance abuse treatment) (see Table 4).

Privacy

Over one third of the applications reported implementing processes that aimed to preserve user anonymity (e.g. unidentified usernames, de-identification of the data). Eleven apps used data encryption methods, where data is scrambled to make it indecipherable by third parties and one-fifth used password-protection. Twenty apps provided users with an element of control over the utility of the app. For example, a number of apps sought to maintain user privacy by providing the participant with the ability to turn off alerts at certain times (Keoleian, Stalcup, Polcin, Brown, & Galloway, 2013; Kirchner et al., 2013; McTavish et al., 2012; van Mierlo et al., 2014). One application allowed the user to switch off location services when desired (McTavish et al., 2012), potentially reducing the amount of unnecessary data collected and the possibility of a third-party identifying the user through data profiling (Gasson et al., 2011).

Of the 18 applications that used text messaging, only three incorporated a separate or private inbox for the user (e.g. (Hasin, Aharonovich, & Greenstein, 2014; Haug, Kowatsch, Castro, Filler, & Schaub, 2014)). To ensure privacy from third party access, if the device is lost or stolen, a small number of apps used password protection (e.g. (Hertzberg et al., 2013; Renner, 2012; van Mierlo et al., 2014)).

Equal access to the technology

Fourteen of the studies reviewed took steps to ensure that individuals in the lower socioeconomic population had access to mHealth technology. A range of methods were observed, such as providing the participant with a smartphone device (Dulin, Gonzalez, & Campbell, 2014; Ingersoll et al., 2014; Johnson, Barrault, Nadeau, & Swendsen, 2009), recruiting participants from treatment centres (Epstein et al., 2009; Johnson et al., 2009; Watkins et al., 2014) or focusing primarily on individuals of lower income (Reitzel et al., 2014; Wen et al., 2014). Yet more than half of the studies required participants to own a smartphone device or have access to the Internet (Keoleian et al., 2013; Whittaker, 2011) in order to be eligible to participate.

Communication of clinical information

Over half of the studies provided external support resources for participants, through either clinical treatment as part of the study (Boyer et al., 2012; Epstein et al., 2009; Ingersoll et al., 2014; McTavish et al., 2012), personal care or online interactive resources (Dulin et al., 2014; McTavish et al., 2012). However, almost half of the studies did not provide any resources or clinically relevant information for users. Finally, six apps were developed alongside not-for-profit, independent organisations, such as Quit Victoria (Ploderer, Smith, Pearce, & Borland, 2014) or the Cancer Council (Borland, Balmford, & Benda, 2013; Buller, Borland, Bettinghaus, Shane, & Zimmerman, 2014).

[**Table 4** Ethical issues considered.]

DISCUSSION

A range of research methods were observed in the 33 unique studies of smartphone technologies in addiction research and treatment and it was encouraging to find the most common being randomised controlled trials, the 'gold standard' research method. Yet, despite some in-depth, potentially identifiable information being collected about the user, many studies may have overlooked the reliability of their security measures. Such oversight has implications on the participant's privacy and informed consent. Given the potential vulnerability of the population in question, ethical issues may arise when using mHealth technology for treating substance abuse related to the equal availability of smartphone technology for all, communication of clinically relevant information, evidence of safety and effectiveness of the app as well as the process of app design.

Privacy

The most prominent ethical concern with mHealth technology is protecting the privacy of users' personal information. The mHealth apps we reviewed collected a range of sensitive information, such as users' demographic characteristics, drug use, mood or cravings. From such data, it may be possible for a third party to identify persons engaging in criminal behaviours (e.g. consumption or purchase of illicit drugs), the locations at which they did so, and the details of others who may also be involved. Given the sensitivity of the information collected, researchers, clinicians and app developers have an ethical obligation to take steps to ensure that third parties cannot access such

information and to be aware of the limitations of their promises to protect users' privacy. We are unable to discern from this study whether the informed consent process met these recommendations. The inability to ensure anonymity and guarantee privacy is seldom acknowledged in the mHealth literature. Although a breach of a user's privacy may be viewed as unlikely, this is an area that requires greater attention.

Data storage and transfer

Despite collecting information about potentially illegal behaviours, many studies either did not address storage security, or utilised online storage banks where the level of security is unknown. The risks of such storage locations need to be addressed. Researchers and clinicians cannot guarantee that information stored online will not be accessed by third parties, despite password protection, as recent high profile breaches of cloud storage illustrate (Chu et al., 2013; "Cloud hack on celebrities," 2014; Timberg, 2014). Furthermore, entrusting data with third-party networks, via transmission or storage, can increase the possibility of hacking. There is also a question about data ownership by telecommunication companies and cloud storage providers through which the data is transmitted or stored (e.g. Internet service providers (ISP), Google, Amazon) (He, Naveed, Gunter, & Nahrstedt, 2014).

Third-party access

There are limits to the extent to which researchers, clinicians and app-developers can guarantee the privacy of participant information, despite using off-line, secure storage. Drug use is often illicit and may be of interest to both criminal and civil courts (e.g. Family Courts in custody disputes). If presented with a subpoena, researchers and clinicians are legally required to hand over participant information that is recorded on drug-related apps. Furthermore, many drug users are engaged in illegal behaviour (by definition in using an illegal drug), and frequently come under the surveillance of the authorities. If there is suspicion that they have engaged in illegal activities, law enforcement officials have the authority to demand access to smartphone data, which may record proof of illegal activity of study participants (e.g. their illicit drug use or property crimes) or others (e.g. the location of their drug dealers).

In addition to carrying larger volumes of personal data, mobile phones are often permanent accompaniments that are easily visible and accessible by third parties. Despite efforts to reduce the risk of third parties accessing the app or user information, the simple presence of an app on a phone may be enough to disclose that the person has an addiction. These are salient issues where users may be subject to significant stigmatisation and social discrimination (e.g. by employers, educators, insurers). Steps should be taken to mitigate unintended discovery of the app or the data recorded. These limitations should also be acknowledged through transparent and robust informed consent procedures (see below).

User anonymity

A number of app designers have taken steps to ensure that the data they collect does not identify the user. For example, anonymous usernames were employed and specific details were removed from the data that could uniquely identify a person (e.g. personal address) (Ploderer et al., 2014; Stoner & Hendershot, 2012; van Mierlo et al., 2014). Although these attempts may increase user

anonymity, they can be ineffective if the app passively collects geo-location data, as was found for two apps (BinDhim et al., 2014; Boyer et al., 2012).

Data encryption methods were utilised by some apps, where data is scrambled so that it is indecipherable by third parties. Yet the security of this procedure is uncertain as it is possible for codes to be broken or cracked with modern computing methods (Wei, Murugesan, Kuo, Naik, & Krizanc, 2013). Although most of the apps that used encryption methods also de-identified the data collected (Ahsan et al., 2013; BinDhim et al., 2014; Boyer et al., 2012; Gajecki, Berman, Sinadinovic, Rosendahl, & Andersson, 2014; Gamito et al., 2014; Renner, 2012; Stoner & Hendershot, 2012; van Mierlo et al., 2014), collecting a wide range of data, including geo-location, renders it possible to construct a data profile that may identify the user (Gasson et al., 2011).

Some features included in a number of apps may threaten users' privacy. For example, alerts employed by smartphones to collect research data may attract the attention of third parties (B. L. Carter et al., 2008; Dulin et al., 2014; Johnson et al., 2009). Such approaches may increase the privacy and control a participant has over their data and the intrusiveness of the app, but at the cost of reducing its research value if data are missed. This trade off must be carefully balanced during research design and ethical review.

Informed Consent

It is imperative that participants in smartphone research or users of mHealth apps for treatment of addiction are fully informed of the potential risks to their privacy and the limitations on researchers and clinicians' ability to protect this privacy. Presently, the technological and legal implications of these devices may be difficult for both participants and researchers to comprehend. For example, researchers who used an mHealth app for individuals recovering from alcohol dependence conducted focus groups to examine users' perceptions of GPS tracking (D. Gustafson et al., 2011). Most users were quite open to location tracking, provided the data were only shared with their permission. Despite the limited ability to protect privacy of information on illicit substance use, the researchers did not clarify the limits to privacy or describe the amount of information that may be gleaned from the devices.

Some long-term dependent drug users may have cognitive or learning impairments that interfere with their ability to understand the ethical implications raised by the technologically sophisticated use of smartphone apps. Researchers and clinicians must take this into consideration by designing informed consent procedures that explain this technologically complex information in ways that facilitate comprehension (e.g. by using visual aids and testing comprehension). Furthermore, as the legal situation is different in different countries, researchers and clinicians should be aware of the laws affecting their area.

Equal Access to mHealth Technology

The expense of buying smartphones and telephone plans may prevent vulnerable populations from accessing mHealth services or participating in research. This can amplify inequities in access to healthcare. While there has been a rapid growth in mobile phone coverage in recent years, some segments of the population still lack access (Labrique, Kirk, Westergaard, & Merritt, 2013). A recent study on mobile phone use in substance abuse patients found that although the majority owned a

mobile phone, only half had smartphone capabilities and three-quarters were on pay-as-you-go contracts (Milward, Day, Wadsworth, Strang, & Lynskey, 2015). mHealth applications that require internet access and costly data transmission may be unaffordable and thus inaccessible for significant portions of the drug dependent population.

More than half of the studies reviewed required participants to own a smartphone device or have access to the Internet in order to be eligible to participate. These requirements exclude individuals who may not have access to smartphone technology. Given that drug users tend to be over-represented in lower socioeconomic populations, there is an ethical imperative to ensure that these patients are not prevented from benefitting from mHealth monitoring (Labrique et al., 2013). Furthermore, study results will be skewed if such a population is ignored and as a result those in most need of rehabilitation or support are excluded from participating in important research or from receiving treatment benefits.

Communication of Clinical Information to Participants

A critical decision in using smartphones for clinical purposes is how to communicate results to users. The provision of immediate and ubiquitous feedback of information has the potential to empower and assist patients to better manage their health and to improve clinician/patient relationships (Boyce, 2012). This issue was only considered by a small number of studies. One, for example, provided detailed personalised feedback in the form of graphs and summaries and, after 30 days, patients met with counsellors to ensure that they understood the feedback (Hasin et al., 2014). Other apps fulfilled this ethical requirement by providing users with features mapping their self-reported progress in the form of monetary or health benefits trackers (BinDhim et al., 2014; Bricker et al., 2014; Struik & Baskerville, 2014). To be clinically meaningful, however, the findings must be scientifically robust and presented in a way that the patient understands.

At a minimum, apps must provide information on clinical services and resources available to the person both via and external to the app. It is not only important that app developers and researchers facilitate access to clinical information and services, but also that they are factual and maximise benefits to the user.

Evidence of Safety and Effectiveness

In order to minimise any risk of harms to the users, app-developers should provide evidence of the safety and effectiveness of the apps before making them available to the public. This urgent need was recognized by the World Health Organization and other leading health agencies in the Bellagio call to action on global eHealth evaluation that called for rigorous evaluation “to generate evidence and promote the appropriate integration and use of technologies...to improve health and reduce health inequalities” (The Bellagio eHealth Evaluation Group, 2011, p. 1). One app, for example, included alerts to warn users when they were entering a location where they may be at risk of a relapse to drinking (Dulin et al., 2014). Without evidence of safety and effectiveness, alerts such as this may unintentionally remind the user of an opportunity to use their drug and induce craving.

Although some apps were developed alongside independent organisations, many that are publicly available are created by commercial developers who are not subject to the same ethical guidelines as university or hospital-based researchers (Abroms, Westmaas, Bontemps-Jones, Ramani, &

Mellerson, 2013). Given the simplicity and cost-effectiveness of mHealth solutions, decision-makers may overlook the lack of robust empirical evidence in deciding whether to use them (Boyce, 2012). The implementation of untested mHealth interventions may result in failed projects, wasted resources, and poorer health outcomes for those using these services. In order to benefit the user, it is imperative that the mHealth apps used by researchers, clinicians, universities and hospitals are supported by rigorous evidence of safety and efficacy (Boyce, 2012).

App Design and Development

The development and investigation of these apps requires engagement with users and other stakeholders to identify their concerns and develop processes that protect the participant and maximise the utility and effectiveness of the intervention. Focus groups were employed throughout the development process for a number of papers developing apps for smoking cessation (Giroux, Bacon, King, Dulin, & Gonzalez, 2014; Ybarra, Holtrop, Prescott, & Strong, 2014). Although important for enhancing user access and utility, issues related to participant privacy were not addressed. Researchers and app developers need to consider ethical issues when designing mHealth technology for addiction research and treatment purposes. A consideration of these issues should not be left until after an app has been designed. This will not optimally meet the ethical challenges, mitigate any risk of harm for users, or maximise participant autonomy. We propose a number of recommendations for the development and use of such technology for substance abuse and addiction (see Box. 1).

Limitations and Future Directions

The present paper has reviewed the literature on the use of mHealth technology for research and treatment of substance abuse or addiction. We have identified a number of ethical concerns and have provided recommendations for researchers, clinicians and app developers that would contribute to ensuring user privacy is maintained and standard ethical principles are not violated with the fast-developing technology. Due to the nature of the research, however, some limitations are acknowledged. The present review was limited to the use of smartphones published in academic journals only. This may have excluded commercially available apps that were not being tested by researchers. A review of apps available on commercial platforms is recommended for future research. The use of smartphones in addiction research and treatment involves complex, technically specific research and knowledge. We believe that multidisciplinary working groups are needed to examine the complex technical issues involved in ensuring the ethical use of smartphone apps in research and treatment, and to develop a set of easily understood guidelines for both researchers and clinicians about the minimum standard ethical requirements for the design and use of this promising technology.

Ethical Consideration	Recommendations
Data storage and transfer	Serious consideration should be given to where the data is stored and how it is transmitted from the device. Online transmission and storage should be avoided in favour of localised storage units that can only be accessed by authorised personnel. Only data relevant to the aims of the study or purpose of the application should be collected.
Data ownership	If data is to be stored on third party networks, clear guidelines should be provided prior to data collection that outlines to all parties who has rights to access the data and which parties own the data.
Third-party access	Password protection or private inbox features should be utilised to prevent accidental third party access to the app/device. Individuals should be informed of the potential for third parties to access their data, through legal means, or hacking.
User anonymity	Data encryption methods can reduce likelihood of third-party access to information but their limitations must be relayed to the user. Users need to be made aware if de-identification processes are not possible. Where possible, users should be given power to control how much information is collected and when.
Informed consent	mHealth users need to be informed of the risks and benefits of the technology in a way that is clear and understandable. This includes limits to confidentiality and privacy, for example, court orders or subpoena.
Access to mHealth technologies	Strategies need to be used to ensure that individuals from minority groups, such as lower socioeconomic populations or those with a disability, have equal access to the benefits of mHealth technology. Provision of devices to research participants will include those most in need and ensure a more representative sample.
Communication of clinically relevant results	Feedback of clinically relevant information should be relayed to the user in a manner that they understand but only when there is strong empirical evidence to support the findings. Users should also be provided with access to external resources for evidence-based, clinical support for their addiction.
Evidence of safety and effectiveness	Interventions encompassed in mHealth technology should only be utilised if prospectively shown to be safe, effective and of benefit to the consumer.
Regulation of mHealth products	A regulatory process is needed to carefully evaluate mHealth apps and require evidence of safety, effectiveness, and ethical conduct before routine public distribution and clinical use.

Box 1 Recommendations for researchers, clinicians, and app developers when using and designing mHealth technology for therapeutic and non-therapeutic addiction research.

CONCLUSIONS

Smartphone and mHealth technology provide unique possibilities for collecting valuable information about research and for the treatment of substance abuse and addiction. Given the wide scope of personal information that can be collected, the promise of these technologies also raise a number of ethical issues. Our analysis suggests that there is a lack of awareness of the ethical issues raised by their use, the implications for how the apps are developed, and how both research and clinical treatments are conducted. Given the sensitivity of information being collected (e.g. illegal behaviours), it is an ethical imperative for researchers, app-developers and clinicians to protect the rights and privacy of the users. There is currently a lack of attention to where information is being stored, the level of security involved, and how it is being transferred (He et al., 2014; Su, 2014). App-developers and researchers need to ensure that apps are designed in a way that reduce the risk of personal information being accessed by third parties and maximises user anonymity. There is great potential of mHealth technology, yet it is imperative that we first address these ethical considerations to ensure that we capitalise on the possible benefits of these technologies while minimising the potential risks to the users.

Tables and Figures

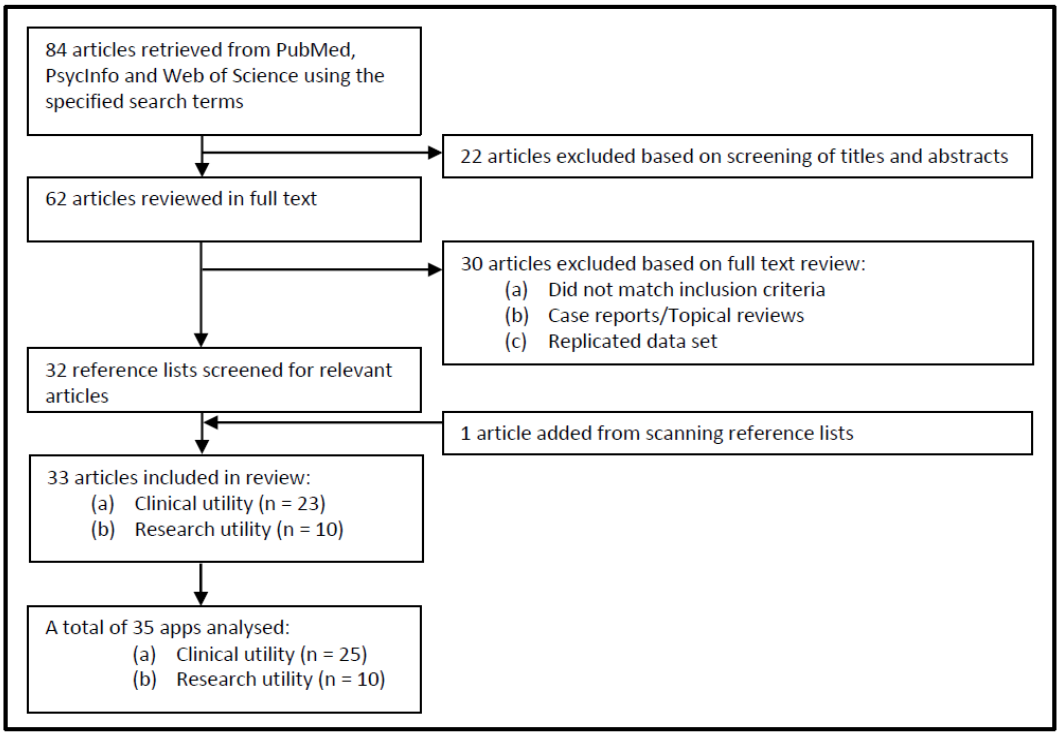

Figure 1 Flow diagram for literature search and study inclusion.

Table 1 Substance focus.

Substance	*N* (%)	References
Tobacco	17 (48.6%)	(Ahsan et al., 2013; BinDhim et al., 2014; Borland et al., 2013; Bricker et al., 2014; Buller et al., 2014; B. L. Carter et al., 2008; Haug et al., 2014; Hertzberg et al., 2013; Kirchner et al., 2013; Meredith et al., 2014; V. Patel, Nowostawski, Thomson, Wilson, & Medlin, 2013; Ploderer et al., 2014; Reitzel et al., 2014; Struik & Baskerville, 2014; van Mierlo et al., 2014; Watkins et al., 2014; Whittaker, 2011)
Alcohol	12 (34.3%)	(Bendtsen & Bendtsen, 2014; Dulin et al., 2014; Gajecki et al., 2014; Gamito et al., 2014; Hasin et al., 2014; Haug et al., 2014; Kauer, Reid, Sanci, & Patton, 2009; Matsumura, Yamakoshi, & Ida, 2009; McTavish et al., 2012; Renner, 2012; Stoner & Hendershot, 2012; Yu et al., 2012)
Heroin	2 (5.7%)	(Boyer et al., 2012; Epstein et al., 2009)
Cocaine	1 (2.9%)	(Freedman, Lester, McNamara, Milby, & Schumacher, 2006)
General	3 (8.6%)	(Campling, 2011; Ingersoll et al., 2014; Johnson et al., 2009)

Table 2 Purpose of mHealth applications.

Purpose	*N* (%)	References
Behaviour change	18 (51.4%)	(Ahsan et al., 2013; Bendtsen & Bendtsen, 2014; BinDhim et al., 2014; Borland et al., 2013; Bricker et al., 2014; Buller et al., 2014; Dulin et al., 2014; Hasin et al., 2014; Haug et al., 2014; Hertzberg et al., 2013; Ingersoll et al., 2014; Ploderer et al., 2014; Renner, 2012; Struik & Baskerville, 2014; van Mierlo et al., 2014; Whittaker, 2011; Yu et al., 2012)
Relapse prevention	3 (8.6%)	(Boyer et al., 2012; Campling, 2011; McTavish et al., 2012)
Medication adherence	1 (2.9%)	(Stoner & Hendershot, 2012)
Monitor consumption	5 (14.3%)	(Gajecki et al., 2014; Gamito et al., 2014; Kauer et al., 2009; Matsumura et al., 2009; V. Patel et al., 2013)
Research only	8 (22.9%)	(B. L. Carter et al., 2008; Epstein et al., 2009; Freedman et al., 2006; Johnson et al., 2009; Kirchner et al., 2013; Meredith et al., 2014; Reitzel et al., 2014; Watkins et al., 2014)

Table 3 Type of information collected.

Type of Information Collected	*N* (%)	References
Demographics	20 (57.1%)	(Ahsan et al., 2013; BinDhim et al., 2014; Borland et al., 2013; Bricker et al., 2014; Buller et al., 2014; B. L. Carter et al., 2008; Epstein et al., 2009; Gajecki et al., 2014; Gamito et al., 2014; Haug et al., 2014; Hertzberg et al., 2013; Johnson et al., 2009; Kauer et al., 2009; Kirchner et al., 2013; Matsumura et al., 2009; McTavish et al., 2012; Reitzel et al., 2014; Struik & Baskerville, 2014; van Mierlo et al., 2014; Watkins et al., 2014)
Location		
Self-Reported	3 (8.6%)	(Epstein et al., 2009; Freedman et al., 2006; V. Patel et al., 2013)
GPS tracking	8 (22.9%)	(BinDhim et al., 2014; Boyer et al., 2012; Dulin, Gonzalez, King, Giroux, & Bacon, 2013; Kirchner et al., 2013; McTavish et al., 2012; Reitzel et al., 2014; Struik & Baskerville, 2014; Watkins et al., 2014)
Consumption habits	26 (74.3%)	(Ahsan et al., 2013; Bendtsen & Bendtsen, 2014; BinDhim et al., 2014; Borland et al., 2013; Bricker et al., 2014; Buller et al., 2014; Campling, 2011; B. L. Carter et al., 2008; Dulin et al., 2014; Epstein et al., 2009; Freedman et al., 2006; Gajecki et al., 2014; Haug et al., 2014; Hertzberg et al., 2013; Johnson et al., 2009; Kauer et al., 2009; McTavish et al., 2012; Reitzel et al., 2014; Renner, 2012; Struik & Baskerville, 2014; van Mierlo et al., 2014; Watkins et al., 2014; Whittaker, 2011; Yu et al., 2012)
Cravings/Triggers	24 (68.6%)	(Ahsan et al., 2013; BinDhim et al., 2014; Borland et al., 2013; Boyer et al., 2012; Bricker et al., 2014; Buller et al., 2014; B. L. Carter et al., 2008; Dulin et al., 2014; Epstein et al., 2009; Freedman et al., 2006; Hasin et al., 2014; Haug et al., 2014; Ingersoll et al., 2014; Johnson et al., 2009; McTavish et al., 2012; Reitzel et al., 2014; Renner, 2012; Stoner & Hendershot, 2012; Struik & Baskerville, 2014; van Mierlo et al., 2014; Watkins et al., 2014; Whittaker, 2011; Yu et al., 2012)
Physiological response	3 (8.6%)	(Boyer et al., 2012; Meredith et al., 2014; Yu et al., 2012)
Medical history	6 (17.1%)	(Borland et al., 2013; Bricker et al., 2014; Buller et al., 2014; Gamito et al., 2014; Johnson et al., 2009; van Mierlo et al., 2014)
Daily drug use	30 (85.7%)	(Ahsan et al., 2013; Bendtsen & Bendtsen, 2014; BinDhim et al., 2014; Borland et al., 2013; Bricker et al., 2014; Buller et al., 2014; Campling, 2011; A. Carter, Liddle, J., Hall, W., Chenery, H., 2015; Dulin et al., 2014; Epstein et al., 2009; Freedman et al., 2006; Gajecki et al., 2014; Hasin et al., 2014; Haug et al., 2014; Hertzberg et al., 2013; Ingersoll et al., 2014; Johnson et al., 2009; Kauer et al., 2009; Matsumura et al., 2009; McTavish et al., 2012; Meredith et al., 2014; Ploderer et al., 2014; Reitzel et al., 2014; Renner, 2012; Stoner & Hendershot, 2012; Struik & Baskerville, 2014; van Mierlo et al., 2014; Watkins et al., 2014; Whittaker, 2011)
Goals for recovery	13 (37.1%)	(Ahsan et al., 2013; BinDhim et al., 2014; Borland et al., 2013; Bricker et al., 2014; Buller et al., 2014; Campling, 2011; Hasin et al., 2014; Haug et al., 2014; McTavish et al., 2012; Stoner &

	Hendershot, 2012; Struik & Baskerville, 2014; van Mierlo et al., 2014)

Table 4 Ethical issues considered.

Ethical consideration	N (%)	References
Privacy		
User anonymity	13 (38.2%[a])	(Ahsan et al., 2013; BinDhim et al., 2014; Borland et al., 2013; Freedman et al., 2006; Gajecki et al., 2014; Gamito et al., 2014; Haug et al., 2014; Matsumura et al., 2009; V. Patel et al., 2013; Renner, 2012; Stoner & Hendershot, 2012; van Mierlo et al., 2014)
Data encryption	11 (32.3%[b])	(Ahsan et al., 2013; BinDhim et al., 2014; Boyer et al., 2012; Gajecki et al., 2014; Gamito et al., 2014; Haug et al., 2014; Meredith et al., 2014; Renner, 2012; Stoner & Hendershot, 2012; Struik & Baskerville, 2014; van Mierlo et al., 2014)
Password protection	7 (24.1%[c])	(Boyer et al., 2012; Hasin et al., 2014; Haug et al., 2014; Hertzberg et al., 2013; V. Patel et al., 2013; Renner, 2012; van Mierlo et al., 2014)
User control	20 (69.0%[d])	(Bendtsen & Bendtsen, 2014; BinDhim et al., 2014; Bricker et al., 2014; Campling, 2011; B. L. Carter et al., 2008; Gajecki et al., 2014; Haug et al., 2014; Hertzberg et al., 2013; Ingersoll et al., 2014; Kauer et al., 2009; McTavish et al., 2012; Ploderer et al., 2014; Reitzel et al., 2014; Renner, 2012; Struik & Baskerville, 2014; van Mierlo et al., 2014; Watkins et al., 2014; Whittaker, 2011; Yu et al., 2012)
Private inbox	3 (16.7%[e])	(Buller et al., 2014; Hasin et al., 2014; Haug et al., 2014)
Equity in access	14 (46.7%[f])	(Boyer et al., 2012; A. Carter, Liddle, J., Hall, W., Chenery, H., 2015; Dulin et al., 2014; Epstein et al., 2009; Freedman et al., 2006; Gamito et al., 2014; Hasin et al., 2014; Ingersoll et al., 2014; Johnson et al., 2009; Kauer et al., 2009; McTavish et al., 2012; Reitzel et al., 2014; Watkins et al., 2014; Yu et al., 2012)
Support resources	19 (55.9%[g])	(Bendtsen & Bendtsen, 2014; Bricker et al., 2014; Buller et al., 2014; Dulin et al., 2014; Epstein et al., 2009; Freedman et al., 2006; Gajecki et al., 2014; Hasin et al., 2014; Haug et al., 2014; Hertzberg et al., 2013; McTavish et al., 2012; Ploderer et al., 2014; Reitzel et al., 2014; Struik & Baskerville, 2014; van Mierlo et al., 2014; Watkins et al., 2014; Yu et al., 2012)

[a]One application was coded as not applicable (NA) for this ethical consideration as personal information was not collected (Meredith et al., 2014). [b]One application was coded as NA for this ethical consideration as it was not invasive to the users privacy (V. Patel et al., 2013). [c]Six applications were coded as NA for this ethical consideration as the apps were used in controlled experimental conditions (Freedman et al., 2006; Gamito et al., 2014; Matsumura et al., 2009; Meredith et al., 2014; Reitzel et al., 2014; Watkins et al., 2014). [d]Six applications were coded as NA for this ethical consideration as they were either used in controlled experimental conditions or were not invasive to the users privacy (Epstein et al., 2009; Freedman et al., 2006; Gamito et al., 2014; Matsumura et al., 2009; Meredith et al., 2014; V. Patel et al., 2013). [e]17 applications were coded as NA for this ethical consideration as messaging was not included in the features (Ahsan et al., 2013; BinDhim et al., 2014; Bricker et al., 2014; Epstein et al., 2009; Freedman et al., 2006; Gamito et al., 2014; D. H. Gustafson et al., 2014; Hasin et al., 2014; Hertzberg et al., 2013; Matsumura et al., 2009; Meredith et al., 2014; V. Patel et al., 2013; Ploderer et al., 2014; Reitzel et al., 2014; Stoner & Hendershot, 2012; Struik & Baskerville, 2014; Watkins et al., 2014). [f]Five applications were coded as NA for this ethical consideration as they were part of exploratory/feasibility studies (Ahsan et al., 2013; Matsumura et al., 2009; Meredith et al., 2014; V. Patel et al., 2013; Struik & Baskerville, 2014). [g]One application was coded as NA for this ethical consideration as the users of the app were not being studied for their personal substance abuse (V. Patel et al., 2013).

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