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Using Digital Interventions to Support Individuals with Alcohol Use Disorder and Advanced Liver Disease: A Bridge over Troubled Waters

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Alcohol abstinence is the most important therapeutic goal for individuals with advanced liver disease (ALD), but commonly co-occurring alcohol use disorders (AUD) make it difficult to achieve (DiMartini et a, 2004). This challenge is perhaps best documented in the pre- and post-liver transplant period: around 30% of patients on a liver transplant list relapse with alcohol (Carboneau et al., 2010), and up to 50% can relapse in the first 10 years post-transplant (DiMartini et al., 2010). Tools to assist patients with ALD and AUD in initiating and maintaining abstinence have been limited: safe, tolerable, and effective pharmacotherapies for AUD are not widely used and treatment is often complicated by medical issues including malnourishment, physically debility, covert or overt hepatic encephalopathy, sleep and fatigue disorders, comorbid depression, and anxiety disorders.

To address these issues, some transplant centers have adopted multi-disciplinary team-based care focused on psychological and behavioral addiction support (Georgiou *et al. 2003*; Erim *et al. 2016*). In a recent systematic review of studies testing behavioral interventions for patients with liver disease and AUD, integrated cognitive behavioral therapy, motivational enhancement therapy, and comprehensive medical care resulted in higher rates of initiating alcohol abstinence (average 45.4%, range 25.4–74%) than the control groups (average 36.7%, range 19.7–50%) (Khan at al, 2017). Still, these behavioral interventions were not found to result in higher rates of abstinence maintenance.

Outreach efforts that extend support beyond the traditional medical setting may be able to help bridge the gap of support for individuals with ALD and AUD. McKay *et al.* (2016) randomized 252 participants with AUD who completed 3 weeks of intensive outpatient therapy to telephone monitoring and feedback, telephone monitoring with counseling, or treatment-as-usual (TAU). Telephone calls were offered weekly for the first 8 weeks, every other week for the next 44 weeks, and once per month for the final 6 months. Telephone counseling included a weekly presentation of their risk score, a review of current goals and the specific objectives that needed to be accomplished to reach each goal and encouragement

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for involvement in pro-recovery activities. Main findings were that all groups significantly reduced their alcohol consumption by 3-months and the counseling group had significantly greater reductions out to 18 months. Although promising, patient engagement was poor, with less than a third of the available telephone counseling session used by participants. As well, to provide this type of counseling requires resources not available in most health systems.

The Promise of Digital Interventions

Advances in computing and telecommunications make digital interventions possible. Ubiquity of mobile phones allow the ability to scale effective interventions to maximize public health impact. Digital interventions can offer greater convenience than in-person interventions, and when delivered through phones, can provide personalized support in real-world contexts, at times and in situations when it may be most needed (Marsch et al., 2014). Given the paucity of digital intervention studies focused on ALD and AUD, in this paper, we will more broadly review current evidence for digital interventions aimed at reducing alcohol consumption, outline key intervention features, discuss major gaps, and suggest future directions for digital intervention development.

Systematic Reviews of Digital Interventions for Alcohol and Other Substances

Most published digital intervention studies to date have tested desktop computer modalities that are designed to be used once, typically in an office or home setting. In a review of 16 randomized controlled trials, individuals exposed to Internet interventions drank on average 22 grams of ethanol less than controls and were significantly more likely to be adhering to low-risk drinking guidelines at post-treatment (RD 0.13, 95% CI: 0.09–0.17, $p<.001$). (Riper et al., 2014). A recent Cochrane review including 41 studies of 19,241 participants found that community-dwelling individuals using digital interventions drank approximately 23 grams of alcohol weekly (95% CI 15 to 30) less than participants who received no or minimal interventions at end of follow-up (Kaner et al., 2017). However, 5 studies of 390 participants comparing digital and face-to-face interventions found no difference in alcohol consumption at end of follow-up.

More recently, digital interventions delivered through mobile phones have begun to be tested, mainly using text messaging (SMS) or smartphone applications (apps), which are intended to be used repeatedly in an individual's natural environment to address the dynamic process of recovery from AUD. A systematic review of 11 studies testing SMS interventions (4 of which focused on alcohol) demonstrated improved clinical outcomes among individuals exposed to the SMS intervention (Tofighi et al., 2017). However, the heterogeneity of target populations, intervention components, and outcomes measures make results difficult to interpret, and therefore it is worth examining a few key studies that have used mobile digital interventions for individuals with AUD.

SMS-Based Intervention Studies for AUD

Agyapong *et al.* (2012, 2013) randomized patients with unipolar depression and AUD who completed an in-patient dual diagnosis treatment program to a SMS intervention (n=26) or control group (n=28). Starting on the day of discharge, patients in the intervention group received twice daily supportive messages for 12 weeks focused on dealing with stress, maintaining good mental wellbeing, promoting abstinence from alcohol, dealing with cravings, promoting adherence with medication, and providing general support. Intervention participants had significantly longer time to first drink (120 days) compared to control participants (62 days) as well as slightly higher days abstinent 88.3 (SD = 6.2) vs. 79.3 (SD = 24.1) p = 0.08. (2012). However, at 6-months there were no significant differences in abstinence between groups.

Lucht *et al.* (2014) recruited adults with alcohol dependence from an inpatient detoxification center in Germany who were assigned in blocks to either an interactive SMS intervention (n=42) or TAU (n=38). Over 8 weeks, the SMS intervention twice weekly sent “Dear Mr./Mrs. … Did you drink alcohol or do you need help?” which triggered a call from a therapist within 24 hours if positive or a supportive automated message if negative. Around 57% of the participants replied to at least 50% of the SMS prompts. At 8-weeks follow-up, 56% of intervention participants and 40% of TAU participants achieved low-risk consumption.

Muench et al. (2017) randomly assigned 152 help-seeking adults recruited online who had problematic drinking but were not currently in treatment to one of four different types of SMS interventions over a 12-week period. Interventions included weekly drink self-tracking mobile assessment messages, loss-framed messages, gain-framed messages, static tailored messages, and adaptive tailored messages. Main findings showed that although all active interventions reduced alcohol consumption compared with weekly drinking assessments, the intervention incorporating messages that were adaptive to goal achievement had largest effect size estimates. For this group, mean days per week abstinent went from 1 at baseline to 2 at 12-weeks follow-up.

There has only been one peer reviewed study to date exploring the use of a digital intervention for individuals with advanced liver disease and AUD. DiMartini *et al.* (2018) randomly assigned pre-liver transplant candidates with alcoholic liver disease who reported at least 1 drinking episode in the past year to either receive 3 messages per day for 4 weeks and 3 messages per week for 4 weeks including feedback on cravings, mood, identification of high-risk situations and coping (n=8) or no intervention (n=7). Main findings were that the SMS intervention was well received by participants and resulted in 0 out of 8 participants with positive urine alcohol at 8-weeks versus 2 control participants.

App- Based Intervention Studies for AUD

Gonzalez and Dulin (2015) reported results from a pilot trial where they recruited adults with AUD and at least some desire to reduce drinking and assigned them to a mobile app intervention that provided open access to 7 different psychoeducational modules, including support triggered by a user entering a geo-fenced area of past drinking (n = 28) or to a one-

time online Drinker's Check-up plus bibliotherapy (n = 26). Main findings were that there were increases in the percent days abstinent from baseline (~30%) to week 6 (~48%) in the intervention group only.

Gustafson *et al.* (2016) randomly assigned patients who met the criteria for alcohol dependence upon entering treatment at 3 residential programs to 8 months of an app-based intervention (n=170) or TAU (n=179). The app-based intervention incorporated daily ratings of abstinence confidence, weekly assessments of risk and protective factors related to relapse, triggered (geo-fencing) alerts, links to relevant resources, and suggestions of relevant coping skills. Among the 77% of participants who completed follow-up at 12-months, there was a higher percentage of consistent abstinence among intervention participants (52%) than TAU participants (40%).

Key Digital Intervention Components for Reducing Alcohol Consumption

We are just starting to understand what components are necessary to optimize digital intervention effects on alcohol consumption. One of the unique and potentially powerful features of mobile digital interventions is their ability to efficiently collect context- and time-varying data from individuals to inform just-in-time feedback and support. Most prior research has achieved this through experience sampling or ecological momentary assessment (EMA) methodology (Shiffman et al., 2008), but advances in computer miniaturization now allow the possibility of using portable sensor data (either from mobile phones or worn sensors) to infer behaviors (Mimura et al., 2015). In the following sections, we describe alcohol-related targets for digital interventions, behavior change techniques (BCTs) that could be useful to modify these targets, and design considerations for maximizing engagement and effectiveness.

Alcohol-Related Targets

Alcohol Consumption

By measuring drinking events longitudinally, one can get a more nuanced understanding of an individual's drinking patterns over time. Depending on what is needed to inform an intervention, one could collect as little as "Did a drinking event occur this past week?" to detailed information about each drink. Collecting real-time drinking information has been shown to be feasible within the context of a research study (Kuntsche et al., 2015), and may be more accurate than retrospective reports (Monk et al, 2015). However, we have found that it is very difficult to achieve high response rates in naturalistic drinking environments (Suffoletto et al., 2017). Ideally, the frequency of drinking assessments should be based on their expected periodicity, balanced with what is feasible and tolerable.

Another method for measuring alcohol consumption that could reduce the burden of self-reporting drinking events is through portable alcohol sensors. Barnett *et al.* (2014) had 66 heavy-drinking adults wear the Secure Continuous Remote Alcohol Monitoring (SCRAM) sensor for 1 to 28 days and found that SCRAM correctly identified 502/690 drinking episodes (72.8%), with higher detection rates when episodes involved greater than 5 drinks consumed. In a separate study, Alessi et al (2017) showed that 84% of 100 community-based

alcohol treatment outpatients used the SCRAM alcohol monitor for 12 weeks and 75% indicated that they would wear it for longer. Although these demonstrate feasibility and potential acceptability, it remains to be seen whether they could be useful in other populations or as part of clinical care.

Cognitive Processes

Consistent with the Relapse Prevention Model (Witkiewitz and Marlatt, 2004), important determinants of alcohol consumption include self-efficacy, motivations, craving, and affective states. There are several studies that have used EMA methodology to show both the feasibility of EMA to collect these time-varying determinants and the event-level relationships between them and alcohol consumption. Morgenstern *et al.* (2016) recruited 96 treatment-seeking problem drinkers to complete daily EMA surveys before, during, and after treatment for 7 weeks spread over a 9-month period, finding that daily fluctuations in motivation and self-efficacy significantly predicted drinking over the next 24 hours. Fazzino *et al.* (2013) recruited 246 heavy drinking adults to submit daily reports of craving and alcohol consumption to an interactive voice response telephone system for 180 days, finding that craving intensity predicted next day total drinks consumed. Dvorak *et al.* (2014) enrolled 74 moderate drinkers to respond to fixed and random prompts over a 21-day assessment period, finding a temporal association between negative mood and alcohol use on drinking days. Mohr *et al.* (2015) enrolled 47 moderate-to-heavy drinkers to report affect and alcohol consumption three times daily for 30 days, finding that greater negative and positive affect are related to greater daily alcohol consumption.

Individuals with ALD pose unique challenges related to measuring cognitive determinants of alcohol consumption using EMA. First, encephalopathy could impair an individual's ability to respond in an accurate way to assessments. Second, schedule demands related to medical care could impair ability to respond in a timely way to assessments. One potential solution to reduce user assessment burden and reliability of reporting is to use sensors to infer determinants like poor mood (Saeb S et al., 2015) and increased stress (Selvaraj et al, 2015).

Contextual Determinants

Social-ecological theories suggest that drinking is influenced both at the macro and micro level (Gruenwald et al., 2014). On a macro scale, distribution and density of alcohol outlets and bars can affect alcohol consumption and AUD (Ahern et al., 2015). On an individual scale, both drinking norms and alcohol cues influence event-level alcohol consumption. Context-specific perceived norms can refer to both the perception of alcohol consumption among co-located peers as well as the desire in a social situation to conform to certain drinking pressures (Larimer et al., 2011). One could use EMA to measure macro- or micro-social determinants including locations, social contacts, and peer drinking norms (O'Grady et al., 2011). One could also collect GPS coordinates from an individual's phone to identify entry into population-based or personal high-risk areas for drinking (Freisthler et al., 2014) or infer social density by sensing the number of Bluetooth signals (Chen et al., 2013). Given that cues associated with drinking can alter central and autonomic nervous system function in AUD, one could measure heart rate variability or cue-elicited biases, which have both been shown to predict relapse (Garland et al., 2012). These contextual determinants of

alcohol use may be less reliable in patients with ALD, as their medical comorbidities may preclude more social patterns of alcohol consumption and/or typical physiological responses to alcohol cues.

Behavior Change Techniques (BCTs)

In a Delphi review, Garnett *et al.* (2015) identified several important BCTs for AUD including goal-setting, action planning, and performance feedback. In a recent meta-analysis of digital behavioral interventions for AUD, larger effects were seen with provision of normative information or feedback on performance (Black et al., 2016). One BCT that could be especially useful for AUD is feedback on performance, which should match an individual's personal drinking goals (Sobell et al, 1992). For those already abstinent, the goals should be to prevent or lengthen time to initial lapse and expedite recovery from lapses. For those still drinking, the goals should be to reduce time to initiating alcohol reduction and assist stepping someone down over time to either a low-risk threshold or abstinence.

Feedback should ideally be designed to "celebrate small victories" to boost self-efficacy. Perhaps more importantly, failure to meet goals can be detrimental to long-term health engagement, especially in AUD with limit violation effects (Muraven et al., 2005). Therefore, digital interventions should focus on providing appropriate cognitive and affective support with goal failures including reframing failures as controllable and time-limited. For patients with ALD, the urgency and necessity of abstinence creates a tension between what someone can reasonably be able to achieve and what is needed to limit further hepatic damage.

Another potentially useful BCT is prompting of coping skills and/or repertoire. In one study, Dulin and Gonzalez (2017) recruited 28 adults who met criteria for AUD and were interested in changing their drinking to report strength of each craving, what triggered the craving, how they coped with the craving, and whether they drank in response to the cravings recorded. Results suggested that when use of coping strategies was reported, that there were lower subsequent rates of alcohol use. Strategies with the lowest reported rates of subsequent alcohol use included urge surfing, distraction, and viewing reasons for change. In a secondary analysis of a randomized trial of 507 participants entering 10 outpatient addiction treatment programs (Lévesque et al., 2017), a 12-week Internet intervention was associated with higher coping scores and higher coping scores were associated with increased likelihood of abstinence. These studies both provide support for prompting coping skills around high-risk occasions.

Other potentially useful BCTs include mindfulness training exercises (Kambo et al, 2017), attentional bias modification (Heitmann et al., 2017) and family/peer support, which has been shown to be important in retaining patients with liver disease in care (Grebley et al., 2010).

Design Considerations

Duration of engagement

Although AUD is considered a chronic disease, and likely requires longitudinal support, most studies to date have tested digital alcohol interventions lasting less than 12 weeks. The optimal duration of a digital intervention may vary between individuals, but should ideally balance what an individual finds useful with what an investigator believes is necessary to ensure adequately reinforced behaviors. Future designs could tailor duration to an individual's progress. For example, if a patient with ALD reports a certain length of abstinence, such as 12 weeks, then the intervention could allow voluntary breaks and/or initiate less intensive surveillance to identify if program re-entry is needed. This may be especially important for patients with ALD, who have other competing priorities related to co-morbid healthcare.

Mode of support

Support material can either be deployed within a digital modality or separately, with varying levels of complexity and human involvement. Perhaps the most basic form of support is a message, typically delivered in the form of a text via SMS technology or an app notification. One could also use graphical, brief tasks or video feedback to display progress reports, run skill-building simulations or present brief instructional content. Data collected from a digital intervention could also trigger a phone call from a counselor or an in-person meeting, supported by literature suggesting that adding human support to digital interventions results in greater therapeutic efficacy (Newman et al, 2011). Digital intervention support content should leverage source credibility and therapeutic alliance. Human support may be especially relevant for individuals with ALD who have established and close relationships with their transplant team.

Predicting drinking events

Ideally a digital intervention would be able to identify, at any moment, potential risk for a lapse. Scott *et al.* (2018) enrolled 43 participants who had completed substance use treatment and asked them to complete up to 5 randomly-prompted EMA assessments per day indicating the types of people, places, activities, and feelings over the past 30 min (including substance use). Multi-level models found that current use, negative affect, and craving were useful to predict varying probabilities of substance use (from 3% to 82%) over the following 5 EMA. Based on these preliminary models, it appears that digital interventions could be designed to be triggered specifically when a combination of risk factors like these are reported.

Phone sensors have also shown promise in informing predictive models for alcohol use. Our group enrolled 30 young adults with hazardous drinking, classifying 207 non-drinking, 41 low-risk, and 45 high-risk drinking episodes over a 28-day sampling period (Bae et al., 2017). A Random Forest machine-learning model using 30-min windows with 1 day of historical data performed best for detecting high-risk drinking, correctly classifying high-risk drinking windows 90.9% of the time. The most informative sensor features were related to time (i.e., day of week, time of day), movement (e.g., change in activities), device usage

(e.g., screen duration), and communication (e.g., call duration, typing speed). For patients with AUD and ALD, such passively-collected real-time data could allow efficient monitoring so that the transplant team could be alerted when risk prediction models indicate high potential for lapses.

Autonomy & Partnership

The growth of digital interventions has inspired debate and speculation on how they function both within individuals and society (Sharon, 2017). On one hand, they can assist patient engagement, turning individuals from passive recipients of care into actors. On the other hand, they promote surveillance (Lupton 2014), allowing others — health promoters, friends and followers — to be influencers of health behaviors. There is also concern that they unfairly place the burden of care on individuals as opposed to heath care systems and society.

Digital interventions should be designed to acknowledge the importance of individual autonomy and partnership. Autonomy could be operationalized by providing clear and ongoing consent procedures stressing voluntary use and explicit use of data elements, giving patients control over what data elements are collected and when. For example, a patient with ALD and AUD may decide that they want to track their alcohol consumption but do not want these data being transmitted to their doctor. Partnership between patients and health care teams include recognition that there may need to be compromise between what a patient wants to achieve versus what a healthcare provider perceives as important. For example, a digital intervention could ask both a patient and their doctor to choose an ideal timeline for drinking reduction and arbitrate the discrepancies to come up with a timeline that is acceptable to both stakeholders. For patients with ALD, this is complicated by the requirement at many centers for absolute abstinence to be considered an eligible candidate for transplant.

Conclusion

Alcohol abstinence is an important goal yet difficult for many individuals with liver disease. Existing behavioral interventions are limited in their ability to provide at-risk individuals the support they need between appointments. Digital interventions leveraging mobile phones, EMA methodology, and phone sensors could provide needed support targeted to temporal and contextual risks including determinants of alcohol relapse. It is up to intrepid scientists to continue to push the boundaries of what is possible to build the critical bridges needed to help individuals with ALD and AUD arrive safely on the shores of sobriety.

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