Alcohol 92 (2021) 25–34

Contents lists available at ScienceDirect

Alcohol

journal homepage: http://www.alcoholjournal.org/

Wrist-worn alcohol biosensors: Applications and usability in behavioral research

Yan Wang [a,*,1], Daniel J. Fridberg [b,1], Destin D. Shortell [c], Robert F. Leeman [d,e], Nancy P. Barnett [f], Robert L. Cook [a], Eric C. Porges [c]

[a] Department of Epidemiology, The University of Florida, Gainesville, FL, United States
[b] Department of Psychiatry and Behavioral Neuroscience, The University of Chicago, Chicago, IL, United States
[c] Center for Cognitive Aging and Memory, Department of Clinical and Health Psychology, The University of Florida, Gainesville, FL, United States
[d] Department of Health Education & Behavior, The University of Florida, Gainesville, FL, United States
[e] Department of Psychiatry, Yale School of Medicine, New Haven, CT, United States
[f] Department of Behavioral and Social Sciences, Brown University, Providence, RI, United States

ARTICLE INFO

Article history:
Received 29 July 2020
Received in revised form
2 December 2020
Accepted 19 January 2021

Keywords:
alcohol use
transdermal alcohol sensors
wearable alcohol biosensors

ABSTRACT

Wrist-worn alcohol biosensor technology has developed rapidly in recent years. These devices are light, easy to wear, relatively inexpensive, and resemble commercial fitness trackers. As a result, they may be more suitable for a wide range of clinical and research applications. In this paper, we describe three pilot projects examining the associations between reported drinking behavior and transdermal alcohol concentration (TAC) derived from a new, wrist-worn alcohol biosensor (BACtrack *Skyn*) in diverse participant groups and settings. Study 1 (N = 3) compared *Skyn*-derived TAC with that from an ankle-worn alcohol sensor (SCRAM *CAM*) and breath alcohol concentration (BrAC) in a laboratory setting. Study 2 (N = 10) compared *Skyn* TAC with BrAC during a naturalistic drinking episode in the field. Study 3 (N = 12) used the *Skyn* to monitor alcohol use in the field for 2 weeks. Studies 2 and 3 also collected usability and acceptability data from participants. The results of Study 1 showed that the *Skyn* produced a TAC curve that closely resembled that of the validated SCRAM *CAM* anklet. In Study 2, *Skyn* detected drinking for all 10 participants (peak BrAC range: 0.02–0.21) with an average delay of 35.6 ± 10.2 min after the start of self-reported drinking. In Study 3, *Skyn* reliably recorded continuous TAC data showing multiple drinking episodes over the monitoring period. Participants in Studies 2 and 3 both reported *Skyn* as highly acceptable. Collectively, the results of these pilot studies show that the *Skyn* was able to reliably detect drinking events in the laboratory and natural environments. We offer suggestions for further refinements of alcohol biosensors and accompanying analytic software that may facilitate adoption of these devices as cost-effective, user-friendly, and reliable tools to passively and accurately assess alcohol use in the field.

Introduction

Both research and clinical work in the field of human alcohol use depend upon accurate information regarding how much alcohol study participants or patients consume. Current practices often use self-report tools that are either retrospective, including the widely used Timeline Follow-back interview (TLFB) (Sobell & Sobell, 1992), or contemporaneous, such as ecological momentary assessment (EMA) (Shiffman, Stone, & Hufford, 2008). Both approaches aim to capture daily or, for EMA, near real-time alcohol consumption in a more granular manner (Fridberg, Faria, Cao, & King, 2019; Piasecki, 2019). However, self-report methods are significantly limited given that such approaches may fail to capture drinking behavior at higher levels of intoxication (Hultgren, Scaglione, Buben, & Turrisi, 2020), may underestimate or overestimate actual drinking behavior compared to objective measurement (Alessi, Barnett, & Petry, 2019; Merrill, Fan, Wray, & Miranda, 2020), and may interact with individual level factors such as social desirability bias (Davis, Thake, & Vilhena, 2010). As a result, there is a high degree of

* Corresponding author. Department of Epidemiology, University of Florida, 2004 Mowry Road, Gainesville, FL, 32610, United States. Tel.: +1 352 294 5942
E-mail address: ywang48@ufl.edu (Y. Wang).

[1] Co-first authors.

https://doi.org/10.1016/j.alcohol.2021.01.007
0741-8329/

interest in obtaining passive, objective measures of drinking behaviors in real-time (Wang, Fridberg, Leeman, Cook, & Porges, 2019).

Transdermal alcohol biosensors provide a promising potential solution to the inherent limitations of self-report. These devices monitor alcohol consumption by measuring a small fraction (less than 1%) of ingested alcohol that is excreted through the skin, expressed as transdermal alcohol concentration (TAC) (Barnett, 2015; Leffingwell et al., 2013; Swift, 2000). Data from alcohol biosensors can be used to provide objective data on alcohol use in near real-time, although TAC often lags behind the blood or breath alcohol concentration (BrAC) (Karns-Wright et al., 2017; Marques & McKnight, 2007). Recently, alcohol biosensors have advanced from larger devices used most often in criminal justice settings (e.g., the SCRAM Continuous Alcohol Monitoring/*CAM* anklet; AMS, Inc.) (Kilmer, Nicosia, Heaton, & Midgette, 2013) to discreet, wrist-worn devices resembling popular fitness trackers (Wang et al., 2019). In 2016, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) sponsored the Wearable Alcohol Biosensor Challenge to encourage the development of new, unobtrusive, and user-friendly biosensors for continuous monitoring of alcohol consumption in humans (NIAAA, 2016). Since then, several companies have developed wrist-worn biosensors and have made those devices available to researchers for testing and evaluation.

Previously, we reported preliminary data recorded from prototypes of two wrist-worn alcohol biosensors, the Quantac *Tally* (discontinued in 2017) and the BACtrack *Skyn* (the first-place winner of the NIAAA Wearable Alcohol Biosensor Challenge) (Wang et al., 2019). In 2019, BACtrack released a production version of the *Skyn* device for research use, and these units are now being tested in the field by our group and others. In this paper, we report new data from three pilot studies evaluating the application and acceptability of the production version of the *Skyn* biosensor. We identify some challenges facing researchers in the wearable alcohol biosensor field generally and conclude with our recommendations for areas of future research and hardware/software development.

The state of the wearable alcohol biosensor market in 2020

The wearable alcohol biosensor landscape has changed significantly since our prior report that reviewed prototypes of the newer generation of wrist-worn biosensors from three companies: Quantac Co., Milo, Inc., and BACtrack, Inc. (Wang et al., 2019). In 2017, Quantac Co., developers of the Tally alcohol biosensor, ceased business operations before releasing a final product. On March 1, 2019, the second-place winner of the NIAAA Wearable Alcohol Biosensor Challenge, Milo Sensors, Inc., rebranded their Proof alcohol biosensor as Ion. NIAAA awarded Milo Sensors, Inc. two Small Business Innovation Research awards in 2017 and 2019 to further develop their device (SBIR.gov, 2019). As of this writing, Milo is working with researchers in the alcohol field to further test and refine the *Ion* platform. In May 2019, BACtrack, Inc., announced that they had completed development on the *Skyn* and began shipping production units to researchers for use. They also provided an accompanying Apple iOS-based app for *Skyn* data transmission and a data portal for researchers to download data collected via *Skyn* devices. Fig. 1 provides a comparison of three biosensors – SCRAM *CAM*, BACtrack *Skyn* (newest model), and Milo *Ion*. Shortly after the *Skyn* production units became available, the authors conducted three separate pilot studies (one in the laboratory and two in the field) examining reported alcohol consumption and *Skyn*-derived TAC. The methods and results of these studies are presented below. While preliminary, the data illustrate examples of research questions that may be answered with these devices.

Pilot studies incorporating a new wrist-worn alcohol biosensor

Pilot study 1: Simultaneous measurement with wearable alcohol biosensors and portable breathalyzer in a laboratory setting

Aim and method

The first study reported in this paper was an internal test conducted when we first received the *Skyn* production units. The goal of this pilot study was to compare the ability of the BACtrack *Skyn* wrist biosensor and the SCRAM *CAM* anklet to capture alcohol consumption in a controlled laboratory alcohol administration paradigm. The laboratory session took place in a climate-controlled bar lab. Three unpaid healthy volunteers (researchers on our research team at the University of Florida, 2 males aged 37 and 38 years, weight = 97.5 kg and 88.4 kg, respectively; 1 female aged 36 years, weight = 54.4 kg) participated in the study. Due to the nature of this being an internal test of the *Skyn* device, no IRB approval was obtained for this study. All volunteers were told to refrain from eating for at least 5 h prior to the laboratory session and consumed a standard snack (~200 calories) upon arriving at the lab 30 min before consuming alcohol. Drinks were mixed from 40 percent ethanol whiskey in a 3:1 ratio of whiskey to soft drink. Ethanol dosing for each participant was determined using a Modified Widmark calculation (Watson, Watson, & Batt, 1981) and was targeted to reach a peak of 0.04 g/dL blood alcohol concentration (BAC). Participants were instructed to consume the mixed drink within 5 min. Breathalyzer (BrAC) readings were taken using a laboratory-grade breathalyzer (Alco-Sensor VXL, Intoximeters, Inc.) every 15 min until two consecutive readings of BrAC = 0.000 g/210 L of air were collected. TAC was recorded during the session via a BACtrack *Skyn* device placed on each participant's non-dominant wrist and by a SCRAM *CAM* placed on each participant's ankle. The sampling frequency for the *Skyn* and the SCRAM *CAM* were set to the manufacturer default rates of 20 s and 30 min, respectively. TAC output from the *Skyn* and SCRAM *CAM* were expressed in μg/L and g/1470 L of air, respectively. Temperature and motion data, expressed as degrees Celsius and *g* respectively, were recorded via the *Skyn*'s built-in sensors. Motion data were high-pass filtered (cutoff = 4 Hz) by the device, with a non-zero motion reading

Fig. 1. Comparison of SCRAM *CAM*, BACtrack *Skyn*, Milo *Ion* devices (from left to right)

indicating movement by the participant while wearing the device. Bearing in mind the delay in TAC relative to BrAC during alcohol consumption, all three participants wore the *Skyn* and SCRAM *CAM* for at least 5 h after their BrAC returned to 0.00 g/210 L of air to ensure that the devices captured the complete descending limb of the TAC curve.

Results and discussion

Alcohol consumption resulted in a rapid increase in BrAC for all participants, followed by a relatively delayed elevation in *Skyn*- and SCRAM *CAM*-derived TAC (Fig. 2). It should be noted that only one out of the three volunteers achieved the targeted BAC/BrAC level (0.04 g/dL). BrAC returned to baseline on average 135–180 min after the start of alcohol consumption, SCRAM *CAM* TAC returned to baseline on average after 150–180 min, and *Skyn* TAC indicated a more gradual return to baseline on average after 230–340 min. The results from this laboratory session demonstrated a much faster response in BrAC than TAC following alcohol consumption as expected (Marques & McKnight, 2007). Qualitatively, TAC derived from both the SCRAM *CAM* and *Skyn* showed similar patterns of delayed onset, a relatively flat peak, and gradual decline compared to BrAC. The *Skyn* data showed good agreement with the SCRAM *CAM* in its characterization of TAC, but *Skyn* data also showed considerable "noise" evidenced by rapid increases or decreases in TAC signal (see, e.g., panel 2 in Fig. 2). However, the *Skyn*'s rapid sampling rate (20 s at default and not currently changeable) may facilitate the use of data cleaning and filtering approaches to remove noise from TAC data collected by the device. Further, the rapid sampling rate may allow for the deconvolution of overlapping drinking events, although data processing methods to accomplish this task have not yet been established.

Pilot study 2: Measuring TAC using the Skyn during naturalistic drinking episodes

Aim and method

The aim of this pilot study was to examine the feasibility and acceptability of using the *Skyn* to monitor naturalistic alcohol use during real-world drinking episodes. This study was conducted in the Clinical Addictions Laboratory at the University of Chicago, and study procedures were approved by the institutional IRB. A different group of volunteers from Study 1 (N = 10; mean age = 29.5, standard deviation [SD] = 9.6 years, 60% female; self-reported binge drinking days = 4.5 ± 3.5 in the past month) wore the *Skyn* during a single drinking occasion in their natural environments. The only inclusion criterion for participation in this study was at least one self-reported past-month binge drinking day. For data reported in this paper, volunteers were personnel from the author's (DJF) laboratory who reported current alcohol consumption at least weekly and who were interested in personally testing the *Skyn* for this pilot study prior to a future formal study with outside participants. Participants were told their participation was totally voluntary and were not compensated for their participation. They were issued a *Skyn* to take home 12–48 h prior to the drinking event and were instructed to put the device on the wrist of their non-dominant hand 20 min prior to consuming alcohol to establish baseline TAC. They used a drink diary to record their alcohol consumption (time starting/finishing each drink and total number of standard drinks consumed) during the drinking episode, and most (n = 9) used a portable breathalyzer (BACtrack Mobile Pro, BACtrack, Inc.) to measure their BrAC at pre-drinking baseline and at intervals of approximately 30 min after finishing their first drink, until they went to sleep. As the goal of this study was to measure TAC in *ad libitum* drinking situations, participants were not instructed as to how much or how fast they should drink. As in a recent laboratory-based study (Fairbairn & Kang, 2019), we used the MATLAB changepoint detection function (findchangepts; Killick, Fearnhead, & Eckley, 2012) to detect the time from reported drinking onset to transdermally detected alcohol use for each participant. This function identifies an unknown number of changepoints in time series data via a model that minimizes the residual sum of errors with a penalty applied for each changepoint to avoid overfitting the model. Participants were told that they could remove the device from their wrist after concluding the drinking episode (e.g., for showering), but were encouraged to wear the device for at least 8 h after drinking ceased in order to allow TAC to return to baseline. At least 24 h after the end of the drinking episode, participants completed a brief survey assessing the usability and acceptability of using the *Skyn* and breathalyzer, respectively, during the real-world drinking episodes (Fridberg et al., 2019). The survey items were: 1) "Overall, the [BACtrack *Skyn*/breathalyzer] was easy to use"; 2) "The [BACtrack *Skyn*/breathalyzer] was intrusive"; 3) "Using the [BACtrack *Skyn*/breathalyzer] took too long"; 4) "I would recommend the [BACtrack *Skyn*/breathalyzer] to other potential participants"; and 5) "Overall, I was satisfied with using the [BACtrack *Skyn*/breathalyzer]".

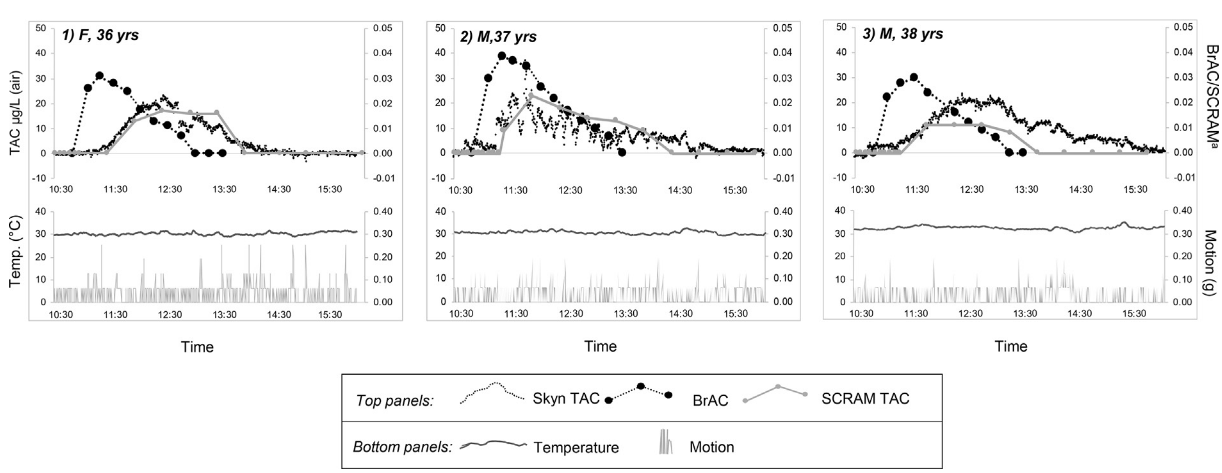

Fig. 2. Comparison of BACtrack *Skyn*, SCRAM *CAM*, and breathalyzer readings for three participants completing a laboratory alcohol challenge (target peak BAC = 0.04 g/dL). *Note:* Participants were instructed to consume the mixed drink within 5 min (10:30–10:35 AM) with a targeted BAC peak of 0.04 g/dL. Breathalyzer readings were taken every 15 min until it reached two zero readings. Motion and temperature data were recorded by the Skyn. [a]BrAC expressed as g/210 L of breath; SCRAM TAC expressed as g/1470 L of air.

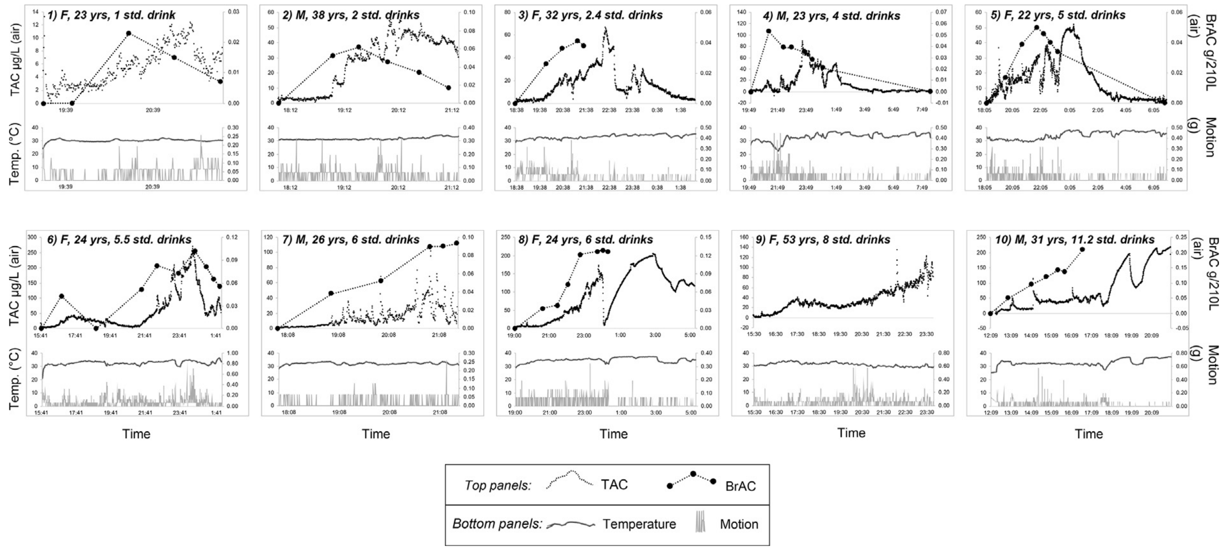

Fig. 3. *Skyn* TAC, temperature, motion, and breathalyzer BrAC from N = 10 participants during a real-world drinking episode in Study 2. *Note:* Participants were instructed to consume alcohol as they normally would and were not instructed to consume a specific amount of alcohol during the drinking event. Scale units differ across participants to better show the full range of alcohol consumption and TAC responses. BrAC data are missing for participant #9 as that individual did not have access to a portable breathalyzer during the drinking event.

Participants rated each item on a 1-to-5 point scale, with 1 = "strongly disagree" and 5 = "strongly agree".

Results and discussion

Participants consumed a mean of 5.2 ± 3.0 SD (range = 1–11.2) standard drinks during the real-world drinking events, with mean peak BrAC = 0.09 ± 0.06 SD (range = 0.02–0.21) g/210 L (participant 9 did not collect BrAC data). The top graph in each panel in Fig. 3 shows TAC/BrAC data during the course of the drinking event, while the bottom graph shows temperature and motion recorded by the *Skyn* during the same time period. Analysis of TAC data using the MATLAB changepoint function detected a drinking event for all 10 participants at mean = 35.6 ± 10.2 SD (range = 19.7–49.7) minutes after the start of the self-reported drinking event. Post-participation survey data (see Table 1) revealed that participants considered the *Skyn* to be highly useable, acceptable, and preferable to the breathalyzer on all outcomes including ease of use and intrusiveness (p values < 0.01).

Examination of the individual participant data presented in Fig. 3 highlights some notable features of the *Skyn*. Importantly, in this small pilot trial measuring TAC during real-world drinking episodes, the *Skyn* registered an elevation in TAC for all participants following as little as one standard drink (see, e.g., data from Participant 1 in Fig. 3). The mean time to detect a drinking event from TAC (approximately 36 min after drinking started) was in agreement with a recent study examining the ability of the *Skyn* to detect drinking under controlled laboratory conditions (Fairbairn & Kang, 2019). TAC tended to have the same general shape as the BrAC curve for all participants, but the Skyn data showed considerable "noise". There are possible explanations for the high variability in the TAC signal, including a loose fit of the bracelet and/or high amounts of movement. For instance, the rapid drop in the TAC signal between 23:00 and 1:00 in Participant 8's data (Fig. 3) coincided with a decrease in recorded body temperature, which could reflect that the bracelet had been removed or that it was loose. For participant 4, both increased movement and lower skin temperature at approximately 21:49 were associated with an obvious decrease in TAC (Fig. 3). Future studies could use data from other motion or environmental sensors to corroborate the output of *Skyn* and devise algorithms to evaluate when deviations in recorded TAC are due to motion or changes in environmental factors such as temperature.

In sum, the data from this small pilot study indicate that deploying the *Skyn* to assess real-world drinking behavior is acceptable and feasible. Examination of the data recorded by the wrist sensors shows that the *Skyn* can reliably detect alcohol use during diverse real-world drinking episodes. However, it is worth highlighting that the integrity of the data may be influenced by participant behavior such as movement and the degree to which the band is worn tightly on the wrist to prevent slipping. It remains to be seen whether newer model iterations of the *Skyn* and/or revising instructions given to participants (i.e., providing careful guidance to ensure the bracelet is worn snugly on the wrist and not moved during use) would reduce this source of noise.

Pilot study 3: Measuring TAC continuously over a 2-week period in the field

Aim and method

Data from the third pilot study were collected within a larger, ongoing validation study whose purpose is to evaluate the feasibility of using the *Skyn* to detect drinking events in adults with and without HIV over an approximately 2-week field period, as well as to examine the quality of data collected in this fashion. Participants are adults (aged 21 and above) living with or without HIV, who drank alcohol at least 5 days in the past 30 days with at least one occasion consuming three or more standard drinks. Exclusion criteria include individuals with a history of recent substance use treatment or those seeking treatment; urine-positive for illegal drugs except THC; past and current alcohol withdrawal; severe alcohol use disorder (DSM-5); meeting criteria for current nicotine dependence or current substance use disorder (excluding mild cannabis use disorder and mild/moderate alcohol use disorder); medical conditions (other than HIV) contraindicating alcohol; pregnancy/breastfeeding in women; and psychosis or other severe psychiatric conditions. The study protocol was approved by the University of Florida IRB, and all participants signed consent forms prior to their participation in the study. During the intake session,

Table 1
Mean (SD) acceptability ratings for the *Skyn* and portable breathalyzer during a real-world drinking episode (n = 10).

Item	*Skyn* (mean ± SD)	Breathalyzer (mean ± SD)	*t* value
1. Easy to use	4.89 ± 0.83	3.78 ± 0.33	4.26**
2. Intrusive	1.22 ± 0.44	3.67 ± 1.11	5.50**
3. Too long	1.22 ± 0.67	3.11 ± 1.05	5.38***
4. Would recommend	4.67 ± 0.24	3.33 ± 0.33	3.58**
5. Overall satisfied	4.78 ± 0.67	3.22 ± 0.97	4.13**

Note. See text for item wording and descriptions. Participants rated each item from 1 ("strongly disagree") to 5 ("strongly agree"). $^{**}p < 0.01$, $^{***}p < 0.001$.

participants receive training on how to use the *Skyn* device and its associated app for data uploading, and are instructed to wear the *Skyn* continuously during the 2-week assessment period and answer prompts to report their alcohol consumption using an ecological momentary assessment (EMA) smartphone app (mEMA™ by ilumivu Inc.). Participants can either report drinking during the daily EMA assessment (at 10:00 AM every day), which asks participants about their past 24-h alcohol consumption, or self-initiate an EMA assessment whenever they start drinking. Both formats of EMA assessments ask them to report the start and end times of their drinking, number of standard drinks, and type of drink(s). Participants were instructed to wear the *Skyn* at all times except when they showered/bathed/swam, as the *Skyn* is not waterproof. Also, they were instructed to charge the device every other day due to its 2–3-day battery life. At the end of the 2-week field period, participants return the *Skyn* biosensor to the lab and complete a brief 5-point Likert usability/acceptability questionnaire on the *Skyn* biosensor (including its app) and the EMA app that utilized items adapted from the System Usability Scale (Bangor, Kortum, & Miller, 2008; Brooke, 1996), as well as additional items developed by our team (e.g., "This technology made me drink less" and "This technology influenced my drinking"). Since both EMA and wrist biosensors can help researchers obtain continuous measurement of alcohol consumption in participants' naturalistic environment, we compared the acceptability/usability ratings of the *Skyn* device and its app with a widely used smartphone-based EMA app after the 2-week field period. In addition, participants responded to open-ended questions on the strengths, limitations, and desired features of the *Skyn* and its associated app.

Results and discussion

While data collection for this study is ongoing, Fig. 4 shows an example of *Skyn* data collected thus far from a healthy female, young adult (early 20s). The figure contains the full 2-week period data including TAC, temperature, and motion readings. This dataset was chosen as an example because there are clearly multiple drinking episodes and a period of potential noncompliance due to device removal. Data from the remaining participants collected so far are presented in the Supplemental Materials (Figures S1–S11).

The *Skyn* device recorded a relatively stable baseline TAC throughout with clear deviations primarily attributable to drinking episodes. A visual examination of the TAC curve shown in the upper panel of Fig. 4 suggests that at least eight drinking episodes occurred during the 2-week period with a notable peak (over 10 μg/L) and ascending/descending limbs characterizing each episode. The inset in Fig. 4 shows a 6-h period within the 2-week data collection period that contains the details of a complete drinking episode collected with EMA data. However, only three of these eight episodes were reported by the participant via EMA during this time period, highlighting the potential advantage of using biosensors to capture alcohol consumption passively, versus daily or event-contingent self-report that is associated with higher participant burden and dependent on participant compliance with reporting (Shiffman et al., 2008). On the other hand, it should be noted that there were two drinking episodes where the participant reported consuming one drink, but no significant elevation in TAC was observed. Nevertheless, heavier drinking episodes are often more concerning to researchers or clinicians.

It is challenging with the current raw *Skyn* data to determine whether elevations in TAC are drinking episodes or environmental exposure. For example, the light-orange shaded band in Fig. 4 is very likely an environmental exposure (e.g., use of hand sanitizer), because the peak of TAC is very steep and transient. To illustrate further the effects of environmental alcohol on TAC, Fig. 5 presents data recorded by one of the authors (YW) showing a steep and transient TAC peak following application of hand sanitizer. Automated methods for reliably detecting drinking episodes from *Skyn* TAC and distinguishing genuine alcohol consumption from environmental exposure are not widely available at this time and are needed to advance the field. These might include automated functions as described above using the Matlab changepoint function or defined according to criteria based on peak, absorption, and elimination rates as used with the SCRAM TAC data (Barnett, Souza, Glynn, et al., 2015; Roache et al., 2019).

As noted in Pilot Study 2 above, the temperature and motion readings (lower panel in Fig. 4) from the *Skyn* provide potentially useful information about participant activity and adherence. For example, there was a brief period between days 10 and 12 (the light-gray shaded band) when the temperature readings decreased about 10 °C from the average temperature throughout, and there were minimal to no motion recordings during this period. Furthermore, the participant's EMA report indicated that she consumed three drinks during that time, but TAC did not show a significant elevation. This suggests the participant took off the *Skyn* during that time. The *Skyn* biosensor is not waterproof, and so there are times when participants must remove the device, e.g., when showering or swimming. Indeed, Fig. 4 shows regular daily dips in the temperature curve, which may have indicated when the participant took the *Skyn* off to shower.

Data on the usability/acceptability of the *Skyn* biosensor have been completed by 12 participants so far. Results from the questionnaire showed no significant differences in ratings for the EMA and biosensor procedures on 12 of the 14 questions (see Table 2). The EMA procedure was rated significantly higher than the biosensor for agreement on one item ("Most people would learn it quickly"), although participants agreed with the statement for both devices, on average. Participants also significantly disagreed more with one item ("I felt self-conscious while using") in the case of EMA compared to the *Skyn* but, on average, participants disagreed with the statement for both devices. On average, participants also disagreed that either EMA or the *Skyn* influenced their behavior while drinking or made them drink less, suggesting that the devices can capture real-world drinking with minimal influence on behavior (i.e., reactivity) when participants are blinded to the TAC results.

Data from the open-ended questionnaire indicated that the most-liked features of the *Skyn* biosensor and its app included their ease of use and design. Seven out of 12 participants commented on

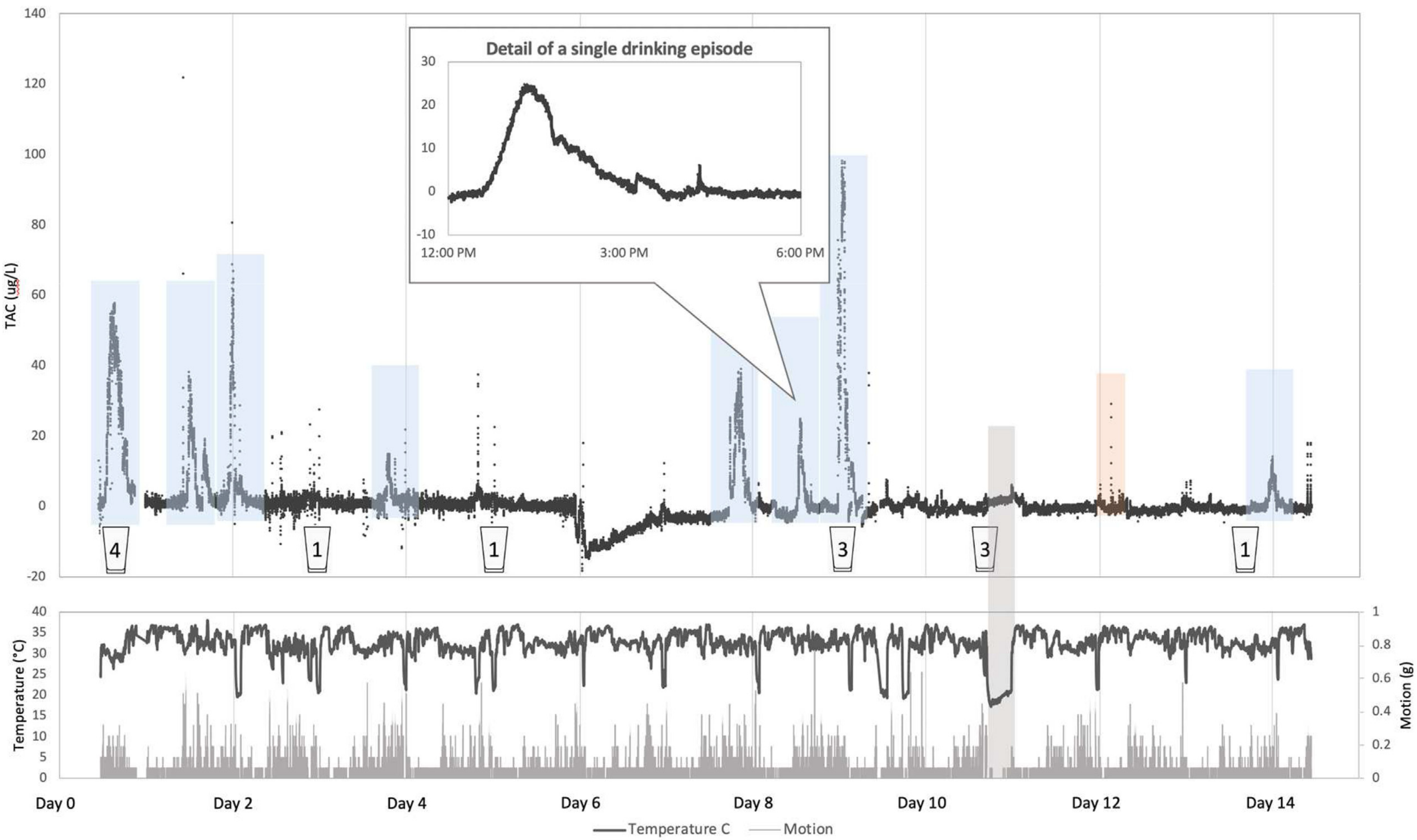

Fig. 4. *Skyn* data from one participant in a 2-week field period in Study 3. *Note:* The top panel of the figure shows the continuous TAC data obtained during the 2-week field period using the *Skyn* device. The bottom panel shows the continuous data of skin temperature (° C) and motion (in g's) obtained from the integrated temperature and motion sensors in the *Skyn* device. The inset shows the detail of a 6-h period that contains a complete drinking episode. The light-blue shaded parts of the TAC curve are possible drinking episodes detected by the *Skyn* device. The icons of glass with a number inside indicate the approximate timing and number of drinks reported in the EMA assessments. The light-gray shaded band shows a period of potential noncompliance where the participant may have taken off the *Skyn*. The light-orange shaded band shows a possible environmental exposure resulting in a peak of TAC readings. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

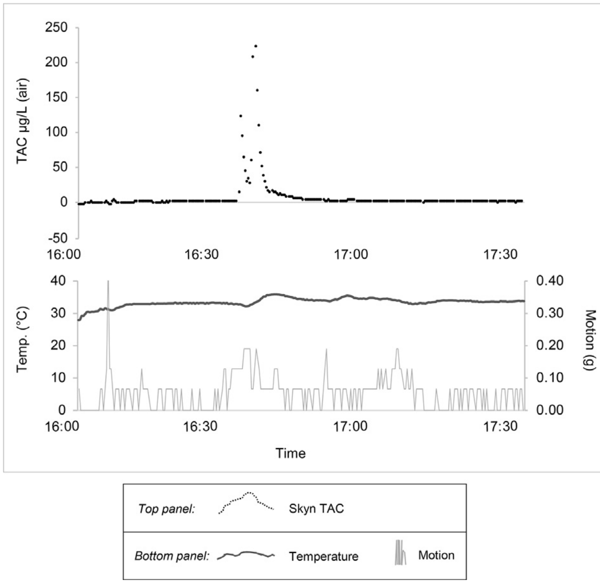

Fig. 5. An example of peak in *Skyn*-derived TAC after hand sanitizer use

the app's ease of use, with one person stating it was "simple [with] no complications", and another agreeing that the app was "easy and [they] never really had to think about it". Others commented that the app's "instructions were good", and the app was "easy to use [and] easy to sync [with the *Skyn* device]" with practice. However, three participants commented on difficulty pairing the *Skyn* device with the app in order to upload data. One participant stated, "it was hard to upload data [and] pairing did not work well". Another experienced an error while uploading that resulted in a loss of data. Considering the app is still in active development, future software updates may fix some of these concerns.

The design of the *Skyn* was described positively by eight out of 12 participants with statements that it was lightweight, comparable to a watch or bracelet, and comfortable to wear. The main recommendations for device improvement were to make the device waterproof (five out of 12 participants), to lengthen the battery life of the device and include a notification of battery level (four out of 12 participants), and to include notifications about the progress of data uploads and app pairing (four out of 12 participants). It should be noted that the most recent software revisions (version 2.0.8) provided by BACtrack address some of these issues and include notification of the data upload progress.

General discussion

There has been a long-standing demand for a user-friendly, non-invasive, continuous monitoring tool for alcohol consumption in the alcohol research and intervention fields. To date, research using non-invasive technology to monitor alcohol consumption has relied upon transdermal alcohol sensors, such as the WrisTAS by Giner Labs (Newton, Massachusetts, United States) and the SCRAM *CAM* (AMS Inc.). However, research applications of those devices have been limited, due in part to their high cost and relatively large size (Barnett, 2015; Greenfield, Bond, & Kerr, 2014; Leffingwell et al., 2013). Recent developments in the field of wrist-worn alcohol biosensors present new opportunities for researchers and clinicians interested in passively monitoring alcohol use in drinkers' natural environments. These newer devices are light, easy to wear, and resemble commercial fitness trackers (e.g., Fitbit). As a result, they may be more suitable for wider clinical and research applications. The results of the pilot studies described in this report support the utility of using the *Skyn* to detect drinking behavior in the laboratory and natural environments, the feasibility of deploying these devices in the field to measure naturalistic drinking behavior, and their acceptability to participants. Below, we discuss the main strengths, limitations, and potential applications of the *Skyn* biosensor based on findings from our pilot studies.

Summary of strengths

Detection of drinking

Our pilot data showed that the *Skyn* biosensor reliably detected alcohol use in both controlled laboratory and real-world settings (see Figs. 2–4). In some circumstances (see Pilot Study 3), the *Skyn* recorded alcohol consumption in the field that was not reported by participants, highlighting the potential advantages of the passive, biosensor-based monitoring approach over participant self-report to obtain a fuller picture of real-world drinking behavior. However, it should be noted that very low-level drinking may not be reliably detected (Pilot Study 2 showed one drink can be detected, but Pilot Study 3 showed some one-drink episodes were not detected) using biosensors (Barnett, Meade, & Glynn, 2014; Roache et al., 2015). As expected, the TAC curve generated by the *Skyn* resembled BrAC, including a relatively steeper ascending limb, peak, and a more gradual descending limb (see Figs. 2 and 3). Continuous use of the *Skyn* over a 2-week period demonstrated the ability of the device to detect drinking in the field and capture the details of multiple drinking episodes (see Fig. 4). Software is available that processes SCRAM *CAM* data using established criteria to identify drinking events (Barnett, Souza, Rosen, et al., 2015), but

Table 2
Mean (SD) acceptability ratings for the *Skyn* and EMA in 2-week field use (n = 12).

Item	EMA (M±SD)	BACtrack *Skyn* (M±SD)	*t* value
1. Would like to use frequently	2.75 ± 1.06	2.83 ± 1.27	−0.18
2. Easy to use	4.33 ± 0.78	3.75 ± 1.42	1.25
3. Most people would learn it quickly	4.50 ± 0.80	3.92 ± 1.08	2.24*
4. Felt very confident using it correctly	4.25 ± 1.14	4.42 ± 0.52	−0.48
5. Liked using it	3.08 ± 1.51	3.33 ± 1.37	−0.56
6. It influenced my drinking	2.67 ± 1.16	2.83 ± 1.27	−1.00
7. Satisfied with it	3.75 ± 1.14	4.17 ± 0.72	−1.60
8. Made me drink less	2.17 ± 1.19	2.08 ± 1.08	1.00
9. Would recommend to others who drink	3.00 ± 1.13	3.25 ± 1.06	−0.71
10. Unnecessarily complex	2.00 ± 0.95	2.17 ± 1.12	−0.69
11. Need technical support to use	1.92 ± 1.38	2.00 ± 1.04	−0.27
12. Cumbersome to use	2.08 ± 1.08	2.25 ± 1.06	−0.39
13. Needed to learn a lot before its use	2.25 ± 1.42	2.00 ± 1.13	1.39
14. Felt self-conscious	1.50 ± 1.00	2.08 ± 1.51	−2.55*

Note. Participants rated each item from 1 ("strongly disagree") to 5 ("strongly agree"). *$p < 0.05$

presently there are no established methods for detecting drinking episodes from *Skyn* data. Establishing alcohol detection criteria for the *Skyn* such as those developed for the SCRAM *CAM* is needed to distinguish drinking events from other perturbations in the data. For example, in the 2-week field study of the *Skyn* (see Pilot Study 3, Fig. 4), there are elevations in the TAC data that appear to correspond to behaviors other than drinking, such as removal of the *Skyn* or environmental exposures. More research is needed to systematically study wrist-sensor TAC readings to establish validity and reliability of methods for identifying drinking episodes and distinguishing them from other events (e.g., environmental alcohol) in the data.

Acceptability, feasibility, and reactivity

A notable strength of the *Skyn* was the high degree of acceptability reported across a range of conditions and participant populations as demonstrated in Pilot Studies 2 and 3. Our results show that wearing the *Skyn* was more acceptable to participants in our study than using a portable breathalyzer to take repeated breath alcohol measurements during naturalistic drinking events. Portable breathalyzers have several advantages (including their low cost, ease of interpretability of BrAC, and established accuracy), but also have significant limitations when deployed to assess naturalistic drinking behavior, including inaccurate readings due to residual mouth alcohol, significant participant burden related to taking multiple breathalyzer measurements over time (which may be especially important in research applications), and potential reactivity to unblinded BrAC readings. TAC may hold more appeal for participants as a measure of real-world alcohol use due to its passive and non-invasive nature. In turn, this may foster improved participant compliance with research and clinical protocols. Our results also showed that the *Skyn*'s acceptability was not significantly different from the acceptability of smartphone-based EMA with the exception of two questionnaire items (“Most people would learn it quickly”, “I felt more self-conscious while using”). In these two cases, the overall mean endorsement of the items was still within the same range of agreement or disagreement, respectively. These data suggest that using wrist biosensors to obtain continuous alcohol readings during participants' daily lives is highly acceptable, similar to current widely used EMA approaches in alcohol research (Fridberg et al., 2019; Piasecki, 2019). Based on usability scale ratings, participants indicated that wearing the *Skyn* passively without access to the TAC readings did not alter their drinking behavior. This suggests that wrist biosensors can monitor alcohol use with minimal perceived participant reactivity like EMA (Luczak, Rosen, & Wall, 2015; Piasecki, 2019), but this may also depend on the population characteristics and study goal (e.g., observation vs. intervention).

Limitations

Delay in detection of alcohol use

Broadly, the most prominent limitation of the *Skyn* biosensor is that TAC is inherently delayed relative to blood or breath alcohol measures due to the physiological process governing the TAC response (Swift, 2000). The average delay for *Skyn* to detect drinking was on average 36 min after the self-reported onset of alcohol use in our Pilot Study 2, which is slightly longer than what has been reported in a previous study conducted under controlled laboratory conditions (Fairbairn & Kang, 2019). Given the unavoidable nature of this delay, any applications that are dependent on “real-time” analysis (e.g., “just-in-time interventions”) of TAC will be subject to this limitation. In situations where “real-time” analysis is not required, the TAC delay relative to BAC can be addressed to a substantial degree, and it would be reasonable to expect that these methods will continue to improve. Further, future research may find that individual differences in this delay of TAC relative to BAC could reveal important and interesting individual differences in the way that participants process alcohol (Sirlanci, Rosen, Wall, & Luczak, 2019).

Sensitivity/reliability

Given that the newer generation of wrist biosensors has been available for only a short time, the length of time that these devices may be used before needing recalibration or service is unknown. SCRAM *CAM* requires regular replacement or service after one year of use (or when a problem is detected by the sensor's self-test that takes place at each reading) to ensure the sensor's accuracy. This is part of a pre-programmed maintenance schedule for the SCRAM *CAM*. A similar self-test function would be useful in these new wrist-worn biosensors to detect potential problems with the device. Future research on the sensitivity and reliability of wrist-worn alcohol biosensors over time is needed to ensure the accuracy and quality of data collected by these new devices. Relatedly, while data from the *Skyn's* temperature and movement sensors can be used to infer whether the device has been removed, there is no way to determine who is wearing the bracelet at a given time. The use of bracelets that are not secured to the wrist (like the SCRAM *CAM*, which has a locking clip that detects removal) will limit their use in studies with positive contingencies for not drinking (as in contingency management applications) or when there are negative contingencies for drinking (as in law enforcement uses).

Environmental considerations and challenges in the era of COVID-19

All transdermal alcohol biosensors measure ethanol directly and have a potential to produce false positive results due to environmental ethanol exposure. Ethanol-based hand sanitizer demand has dramatically increased in the context of the COVID-19 pandemic (New York Times, 2020), and with it the likelihood of its impact on alcohol biosensor data. Wrist-based biosensors, as compared to those elsewhere on the body (e.g., ankle), will likely be more vulnerable to regular use of ethanol-based hand sanitizer due to their proximity to users' hands. Such environmental exposure results in readings like the sharp peak we showed in Fig. 5. This problem may be mitigated in part by the *Skyn*'s rapid sampling rate, which should permit researchers to apply filtering approaches to the data more readily than sparsely sampled data (e.g., as used for SCRAM *CAM* data). It is worth noting that many of these concerns are not unique to alcohol biosensors. Alcohol biomarkers, such as ethyl glucuronide (*EtG*), have been reported to produce positive results (evidence of alcohol consumption) when hand sanitizers are used 20 times or more a day (Wurst et al., 2015). If contamination of TAC data by environmental alcohol can be minimized or automatically filtered by analytical software, wrist-worn alcohol biosensors present a promising way for researchers and clinicians to objectively monitor alcohol use remotely during the global pandemic.

Desirable features and future applications

Great strides have been made in the usability and functionality of wrist-worn alcohol biosensors. Based on our experience with the current generation of biosensors, future development of these devices will benefit from the consideration of two general uses. One use case involves their application in conjunction with a smartphone, which will allow for both a richer display of information (by way of the smartphone's display and other capabilities), as well as the ability of the smartphone to send data in real-time or near real-time to researchers and clinicians. This capacity facilitates drinking contingent interventions such as just-in-time adaptive interventions/JITAIS (Nahum-Shani et al., 2018). Thus, the inherent flexibility of smartphone technology will present researchers and clinicians with various opportunities for wrist-worn biosensor integration. For instance, an intervention could be devised wherein a pre-authorized notification is sent to the user's smartphone in the event that alcohol use is detected or if a specific TAC threshold is reached or exceeded.

A second use case involves biosensors measuring and logging TAC in the absence of a smartphone. In this case, the devices would be worn untethered for several days to weeks, with minimal interaction from the research subject. To increase subject compliance and capture their natural drinking behavior as accurately as possible, participant burden should be reduced to the absolute minimum, as should cues that their behavior is being monitored (Noland, 1959). To support this endeavor, a battery life and data storage capacity sufficient to handle at least one week of continuous recording would be desirable, and this may be achieved by taking less frequent samples of TAC (e.g., from sample every 20 s as the *Skyn* currently does to every 5 min). A device that is sturdy and able to resist sweat from exercise or water from bathing would also be highly desirable. In addition, the device should include a simple indicator that it is functioning properly, such as an indicator LED to denote power and recording status. Ideally, this confirmation would be elicited by the participant interacting with the device and not a continuous indication that may impact behavior. Of note, users can tap an LED on the BACtrack *Skyn* to check that the device is turned on, but at this time, neither the device nor the app display battery life.

Conclusions

Wrist-worn alcohol biosensors have great potential to improve research and clinical work involving real-world alcohol use and can be easily added to such protocols. Our preliminary experiences with the BACtrack *Skyn* provide initial support for the validity, feasibility, and acceptability of using such devices to capture naturalistic drinking episodes. Our studies are limited, with a small number of participants. Nevertheless, with further testing and refinement of the devices themselves and methods to identify drinking episodes using these devices and interpret TAC from them, researchers and clinicians may one day have a cost-effective, user-friendly, and reliable way to passively and accurately assess alcohol use in the field. This approach may be especially valuable in the current era, where concerns about disease transmissibility reduce enthusiasm for, or even prevent, face-to-face contact between patients and clinicians or between researchers and participants.

Acknowledgment

The studies were funded in part by grants from the National Institute on Alcohol Abuse and Alcoholism R21AA027191 (to YW), K01AA025306 and the McKnight Brain Research Foundation; the Center for Cognitive Aging and Memory at the University of Florida (to ECP), R21AA024901 (to DJF), R21AA026918 and UH3AA02614 (to RFL), U24AA022002 (to RLC), and T32AA025877 (to RLC, RFL, DDS).

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.alcohol.2021.01.007.

References

Alessi, S. M., Barnett, N. P., & Petry, N. M. (2019). Objective continuous monitoring of alcohol consumption for three months among alcohol use disorder treatment outpatients. *Alcohol, 81*, 131–138. https://doi.org/10.1016/j.alcohol.2019.01.008

Bangor, A., Kortum, P. T., & Miller, J. T. (2008). An empirical evaluation of the system usability scale. *International Journal of Human-Computer Interaction, 24*(6), 574–594.

Barnett, N. P. (2015). Alcohol sensors and their potential for improving clinical care. *Addiction, 110*(1), 1–3. https://doi.org/10.1111/add.12764

Barnett, N. P., Meade, E. B., & Glynn, T. R. (2014). Predictors of detection of alcohol use episodes using a transdermal alcohol sensor. *Experimental and Clinical Psychopharmacology, 22*(1), 86–96. https://doi.org/10.1037/a0034821

Barnett, N. P., Souza, T., Glynn, T. R., Luczak, S., Swift, R., & Rosen, G. (2015). *The transdermal alcohol sensor macro (TASMAC): A rapid data processing tool for use with the SCRAMx alcohol sensor*.

Barnett, N. P., Souza, T., Rosen, I. G., Luczak, S. E., Glynn, T. R., & Swift, R. (2015). *Transdermal alcohol sensor data macro (version X.X) [software]*. Retrieved from Brown University.

Brooke, J. (1996). SUS: A "quick and dirty" usability scale. In P. W. Jordan, & B. A. Thomas (Eds.), *Usability evaluation in industry* (pp. 189–194). London: Taylor & Francis.

Davis, C. G., Thake, J., & Vilhena, N. (2010). Social desirability biases in self-reported alcohol consumption and harms. *Addictive Behaviors, 35*(4), 302–311. https://doi.org/10.1016/j.addbeh.2009.11.001

Fairbairn, C. E., & Kang, D. (2019). Temporal dynamics of transdermal alcohol concentration measured via new-generation wrist-worn biosensor. *Alcoholism: Clinical and Experimental Research, 43*(10), 2060–2069. https://doi.org/10.1111/acer.14172

Fridberg, D. J., Faria, J., Cao, D., & King, A. C. (2019). Real-time mobile monitoring of drinking episodes in young adult heavy drinkers: Development and comparative survey study. *JMIR Mhealth and Uhealth, 7*(11), Article e13765. https://doi.org/10.2196/13765

Greenfield, T. K., Bond, J., & Kerr, W. C. (2014). Biomonitoring for improving alcohol consumption surveys: The new gold standard? *Alcohol Research, 36*(1), 39–45.

Hultgren, B. A., Scaglione, N. M., Buben, A., & Turrisi, R. (2020). Examining protocol compliance and self-report congruence between daily diaries and event-contingent ecological momentary assessments of college student drinking. *Addictive Behaviors, 110*, 106471. https://doi.org/10.1016/j.addbeh.2020.106471

Karns-Wright, T. E., Roache, J. D., Hill-Kapturczak, N., Liang, Y., Mullen, J., & Dougherty, D. M. (2017). Time delays in transdermal alcohol concentrations relative to breath alcohol concentrations. *Alcohol and Alcoholism, 52*(1), 35–41. https://doi.org/10.1093/alcalc/agw058

Killick, R., Fearnhead, P., & Eckley, I. A. (2012). Optimal detection of changepoints with a linear computational cost. *Journal of the American Statistical Association, 107*(500), 1590–1598.

Kilmer, B., Nicosia, N., Heaton, P., & Midgette, G. (2013). Efficacy of frequent monitoring with swift, certain, and modest sanctions for violations: Insights from south Dakota's 24/7 sobriety project. *American Journal of Public Health, 103*(1), e37–e43. https://doi.org/10.2105/AJPH.2012.300989

Leffingwell, T. R., Cooney, N. J., Murphy, J. G., Luczak, S., Rosen, G., Dougherty, D. M., et al. (2013). Continuous objective monitoring of alcohol use: Twenty-first century measurement using transdermal sensors. *Alcoholism: Clinical and Experimental Research, 37*(1), 16–22. https://doi.org/10.1111/j.1530-0277.2012.01869.x

Luczak, S. E., Rosen, I. G., & Wall, T. L. (2015). Development of a real-time repeated-measures assessment protocol to capture change over the course of a drinking episode. *Alcohol and Alcoholism, 50*(2), 180–187. https://doi.org/10.1093/alcalc/agu100

Marques, P., & McKnight, A. S. (2007). *Evaluating transdermal alcohol measuring devices*. Retrieved from: https://rosap.ntl.bts.gov/view/dot/1793.

Merrill, J. E., Fan, P., Wray, T. B., & Miranda, R., Jr. (2020). Assessment of alcohol use and consequences: Comparison of data collected via timeline followback interview and daily reports. *Journal of Studies on Alcohol and Drugs, 81*(2), 212–219. https://doi.org/10.15288/jsad.2020.81.212

Nahum-Shani, I., Smith, S. N., Spring, B. J., Collins, L. M., Witkiewitz, K., Tewari, A., et al. (2018). Just-in-Time adaptive interventions (JITAIs) in mobile health: Key components and design principles for ongoing health behavior support. *Annals of Behavioral Medicine, 52*(6), 446–462. https://doi.org/10.1007/s12160-016-9830-8

National Institute of Alcohol Abuse and Alcoholism [NIAAA]. (2016). *NIAAA selects winners of its wearable alcohol biosensor challenge*. Retrieved from: https://www.niaaa.nih.gov/news-events/news-releases/niaaa-selects-winners-its-wearable-alcohol-biosensor-challenge.

New York Times. (2020). *'Where do I find your hand sanitizer?' sorry, we have none*. Retrieved from: https://www.nytimes.com/2020/02/29/business/coronavirus-hand-sanitizer.html.

Noland, E. W. (1959). Hawthorne Revisited. By Henry A. Landsberger. Ithaca, New York: The New York State School of Industrial and Labor Relations, 1958, 132 pp. $3.50. *Social Forces, 37*(4), 361–364. https://doi.org/10.2307/2574186

Piasecki, T. M. (2019). Assessment of Alcohol Use in the Natural Environment. *Alcoholism: Clinical and Experimental Research, 43*(4), 564–577. https://doi.org/10.1111/acer.13975

Roache, J. D., Karns-Wright, T. E., Goros, M., Hill-Kapturczak, N., Mathias, C. W., & Dougherty, D. M. (2019). Processing transdermal alcohol concentration (TAC) data to detect low-level drinking. *Alcohol, 81*, 101–110. https://doi.org/10.1016/j.alcohol.2018.08.014

Roache, J. D., Karns, T. E., Hill-Kapturczak, N., Mullen, J., Liang, Y. Y., Lamb, R. J., et al. (2015). Using Transdermal Alcohol Monitoring to Detect Low-Level Drinking. *Alcoholism: Clinical and Experimental Research, 39*(7), 1120–1127. https://doi.org/10.1111/acer.12750

SBIR.gov. (2019). *Milo sensors*. Retrieved from: https://www.sbir.gov/node/1206115.

Shiffman, S., Stone, A. A., & Hufford, M. R. (2008). Ecological momentary assessment. *Annual Review of Clinical Psychology, 4*, 1–32. https://doi.org/10.1146/annurev.clinpsy.3.022806.091415

Sirlanci, M., Rosen, I. G., Wall, T. L., & Luczak, S. E. (2019). Applying a novel population-based model approach to estimating breath alcohol concentration (BrAC) from transdermal alcohol concentration (TAC) biosensor data. *Alcohol, 81*, 117–129. https://doi.org/10.1016/j.alcohol.2018.09.005

Sobell, L. C., & Sobell, M. B. (1992). Timeline Follow-Back. In R. Z. Litten, & J. P. Allen (Eds.), *Measuring alcohol consumption: Psychosocial and biochemical methods* (pp. 41–72). Totowa, NJ: Humana Press.

Swift, R. (2000). Transdermal alcohol measurement for estimation of blood alcohol concentration. *Alcoholism: Clinical and Experimental Research, 24*(4), 422–423.

Wang, Y., Fridberg, D. J., Leeman, R. F., Cook, R. L., & Porges, E. C. (2019). Wrist-worn alcohol biosensors: Strengths, limitations, and future directions. *Alcohol, 81*, 83–92. https://doi.org/10.1016/j.alcohol.2018.08.013

Watson, P. E., Watson, I. D., & Batt, R. D. (1981). Prediction of blood alcohol concentrations in human subjects. Updating the Widmark Equation. *Journal of Studies on Alcohol, 42*(7), 547–556. https://doi.org/10.15288/jsa.1981.42.547

Wurst, F. M., Thon, N., Yegles, M., Schrueck, A., Preuss, U. W., & Weinmann, W. (2015). Ethanol Metabolites: Their Role in the Assessment of Alcohol Intake. *Alcoholism: Clinical and Experimental Research, 39*(11), 2060–2072. https://doi.org/10.1111/acer.12851