Don't Touch That Drink! Making Serious Cognitive Testing More Engaging for Use in Substance Consumer Contexts

Megan Young (BPsych)

A report submitted as a partial requirement for the degree of Bachelor of Psychology with Honours at the University of Tasmania, 2019.

Statement of Sources

I declare that this report is my own original work and that contributions of others have been duly acknowledged.

Megan Young

17/10/2019

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Acknowledgements

Foremost, I would like to thank my supervisor, Associate Professor Raimondo Bruno for his hard work, guidance and constant support throughout this year. Thank you for battling the horrific task of organising my data files ready for analysis, I am truly grateful. You are a fabulous researcher and your knowledge of all things statistics has never failed to surprise me. To Matthew Gretton, the creator of the soon to be famous Whack-a-Bottle! Thank you for creating such a fun and engaging cognitive test – it gave hope to my participants in their darkest times of participating and I'm sure they are forever grateful.

A huge appreciation to my research partners, Erin and Tanya. Thank you for making the enduring hours in the lab enjoyable and always being there for support. You are both such kind and caring girls and I feel privileged that I was able to work with you both – I wish you both endless success in life.

To my beautiful friends – Dina, Nikki and Shara. You have been such amazing friends to me, supporting me in every decision I make and always being my number one fans. Thank you for your constant support and love throughout the last four years of my degree. I wouldn't have been able to get through it without you – I will cherish our friendship forever. A special thanks to Dina, who made the submission of this thesis possible after countless technical difficulties. You are truly amazing! My thesis and I are forever in debt to you.

To my brother Connor – although your dog contributed greatly to my sleep deprivation, your support and encouragement has not gone unnoticed. And lastly, to my selfless parents, Trevor and Julie. Thank you for your unconditional love and support. I am forever grateful for all you have done for me and I promise to look after you well when you are old and delirious.

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Word Count: 9,994

Abstract

Inhibitory control (IC) is crucial in the ability to resist and impede habitual substance use. Workforce surveys have indicated a strong interest in the assessment of IC during substance use treatment. However, these are poorly utilised due to cost, accessibility and poor appeal. We have developed a brief, interactive IC task for smartphones and tablets. Our proposed measure uses a go/no-go paradigm; go-stimuli are bottles of healthy drinks and no-go stimuli are bottles of alcoholic drinks. Two studies were conducted to validate the task: a seven-day test-retest study, comprising both this test and traditional IC tasks in healthy adults (N=68, 40 females); and an acute alcohol dosing study designed to determine sensitivity to intoxication (BrAC=0.05%, 0.08%; N=37, 22 females). The WAB demonstrated weak to moderate magnitude correlations with existing measures of IC and minimal learning effects on repeat assessment. Participants also reported greater acceptability of the WAB than a traditional IC measure. Finally, the WAB was a more sensitive measure to acute alcohol intoxication. Overall, the WAB demonstrates good face validity, equivalent reliability and greater sensitivity than traditional IC measures. Further development of the task is required to reduce ceiling effects and ensure that it is a valid IC measure.

Recent research has emphasised the importance of assessing cognition in substance dependence (Kwako, Momenan, Litten, Koob, & Goldman, 2016). For successful treatment to occur, substance-dependent individuals require the ability to integrate new information to modify habitual drug-seeking cognitions and behaviours (Brady, Gray, & Tolliver, 2011). However, the ability to perform these cognitive and behavioural modifications require intact cognition (Perry & Lawrence, 2017). It has been consistently demonstrated that substance-dependent individuals present with significant cognitive deficits (Brady et al., 2011). As a result, treatment success is compromised and continual substance use is maintained (Aharonovich et al., 2006). This relationship between cognitive deficits and poorer treatment outcomes is a key contributor to individuals remaining stuck in a cycle of dependence (Kwako et al., 2016).

Addictions Neuroclinical Assessment Framework

A neurobiological framework of addiction has been proposed; the Addictions Neuroclinical Assessment (ANA). This consists of three core neurofunctional domains; incentive salience, negative emotionality and executive function (EF) (Kwako et al., 2016). Kwako et al. (2016) claim that these domains explain the aetiology of addictive disorders and how their interactions lead to impulsive and compulsive behaviour. It is argued that the daily cycle of addiction consists of three phases, with a particular ANA domain being fundamental at each stage; incentive salience representing binge-intoxication, negative emotionality representing withdrawal-negative affect, and EF representing preoccupation-anticipation (Figure 1) (Koob & Le Moal, 2001). The persistent cycle of these stages and interaction of these three domains maintains the habitual behaviours, negative emotional states and anticipation associated with substance use, further facilitating the pathological state of addiction (Kwako et al., 2016).

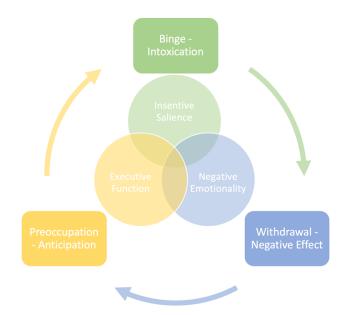


Figure 1. Addiction cycle and relevant ANA domains (Kwako et al., 2016).

In the context of addiction, substances garner an incentive salience – a drive towards that stimuli through positive reinforcement (Kwako et al., 2017). Following chronic use of a substance, the absence of the drug produces an increase in negative emotionality (i.e., dysphoria). It is claimed that such negative affects drive continued substance use in an attempt to self-medicate these states (Kwako et al., 2016). This is maintained through negative reinforcement, whereby consumption of the substance temporarily reduces the negative emotionality or withdrawal state, perpetuating continued use (Koob & Volkow, 2016).

A core component in the development and maintenance of addiction is executive dysfunction (Hester & Garavan, 2004). The ANA domain of EF constitutes a broad family of higher-order cognitive abilities that exert top-down control over mental processes that drive goaloriented behaviour (Alvarez & Emory, 2006). Impairments in EFs are widely apparent in substance use (Dominguez-Salas, Diaz-Batanero, Lozano-Rojas, & Verdejo-Garcia, 2016) and have been suggested to result from a loss of top-down control over mental processes in the prefrontal cortex (Kwako et al., 2016). This dysfunction in the pre-frontal cortex has been shown to directly impact incentive salience and negative emotionality via glutamatergic and dopaminergic neuronal connections, further facilitating the cycle of addiction (Koob & Volkow, 2016).

Executive Function

A particular area of interest for this study is the ANA domain of EF. EF is claimed to comprise of three core functions, including inhibition, WM, and cognitive flexibility (Diamond, 2013). This is supported by Miyake et al.'s (2000) three-factor model of EF, which demonstrates that these three core functions operate as separate processes, however, moderate correlations also exist between them, indicating that they have a reliance on a common underlying construct, namely EF.

EFs have been consistently shown to be pertinent for the circumvention of maladaptive behaviours (Day, Kahler, Ahern, & Clark, 2015), with strong EF abilities being claimed to be protective against initiation of substance misuse (Perry & Lawrence, 2017). Consequently, it has been suggested that individuals with EF deficits may be at a higher risk of developing substance use problems (Finn, Justus, Mazas, & Steinmetz, 1999), have an increased susceptibility of further EF decline during substance use (Day et al., 2015), and have poorer treatment outcomes with limited success in remaining abstinent (Noel et al., 2002).

Dysfunctions in EF have been extensively documented among individuals using addictive substances (Day et al., 2015; Dominguez-Salas et al., 2016; Jovanovski, Erb, & Zakzanis, 2005; Smith, Mattick, Jamadar, & Iredale, 2014). A comprehensive review by Spronk, van Wel, Ramaekers, and Verkes (2013) of 63 studies investigating the long-term cognitive effects of cocaine found that long-term cocaine use is associated with EF dysfunction in most domains, with the strongest deficits evident in response inhibition (Standardised mean difference (SMD)=0.64, 95% CI [0.44, 0.84]) and decision making (SMD = 0.53, 95% CI [0.32, 0.75]). In addition, meta-analytic evidence and systematic reviews have also demonstrated widespread deficits in EF in alcohol dependency (Stavro, Pelletier, & Potvin, 2013), chronic opiate use (Baldacchino, Balfour, Passetti, Humphris, & Matthews, 2012), methamphetamine dependency (Dean, Groman, Morales, & London, 2013), and chronic ecstasy use (Roberts, Jones, & Montgomery, 2016).

Impairments in EF are not only apparent in substance dependence, but are also evident during recreational substance use, with the level of impairment differing between recreationaland substance-dependent populations (Ersche, Clark, London, Robbins, & Sahakian, 2006). This is supported by Vonmoos et al. (2013) who found that dependent cocaine users had significantly poorer cognitive functioning (d=1.04) compared to recreational cocaine users (d=0.48), suggesting that regular, dependent cocaine use produces greater impairments in EFs. Additionally, it is argued that remaining abstinent, or reducing substance use can improve EF prospectively (Schulte et al., 2014). A longitudinal study by Vonmoos et al. (2014) demonstrated that decreased cocaine use was associated with small improvements in EF (d=0.14). It was also found that cocaine users who ceased use reversed the deficits in EF, with their EF performance improving to levels consistent with psychostimulant-naïve controls (Vonmoos et al., 2014).

Deficits in EF have also been argued to contribute to difficulty in maintaining therapeutic adherence and abstinence in substance dependence (Dominguez-Salas et al., 2016). Table 1 illustrates the associations between EF and aspects of treatment outcome. As shown in Table 1, there is substantial variability among studies. This is in part due to the diversity of measures used to assess each EF domain and the differing sensitivity of each measure (Day et al., 2015).

Additionally, the heterogeneity of sex in study samples, such as male/female ratios, have also been argued to contribute to the inconsistencies in the literature (Aragues, Jurado, Quinto, & Rubio, 2011). This is supported by van der Plas, Crone, van den Wildenberg, Tranel, and Bechara (2009) who found that the EF domain of decision making was significantly more impaired in females dependent on methamphetamine or cocaine compared to males dependent on the same substances. This suggests that caution is needed when interpreting the results of studies, as the proportion of males and females included may skew the findings.

Table 1

Executive Functions As Predictors Of Treatment Outcome in Substance Dependence

| Domain | Study | N | Measure | Substance | Effect size | Main findings | Predictors of outcome |
|-----------------------|--|-----|--|---------------------|------------------|--|------------------------|
| Working memory | Dean et al. (2009) | 60 | N-back Task | Methamph etamine | <i>d</i> = 0.58 | Less errors on the N-back task was significantly related with increased attendance at treatment | Treatment retention |
| | Verdejo- García et al. (2012) | 131 | Letter Number Sequencing (WASI) | Cocaine | <i>d</i> = 0.12 | No effect | Treatment retention |
| | Noel et al. (2002) | 22 | Alpha-span Task | Alcohol | <i>d</i> = 1.13 | Relapsed participants had poorer performance on the Alpha-span task compared to abstainers | Relapse |
| Inhibitory control | Brewer, Worhunsky, Carroll, Rounsaville, and Potenza (2008) | 20 | Stroop Colour Word Interference | Cocaine | <i>r</i> = -0.46 | There was a moderate negative correlation found between treatment retention and the Stroop effect for cocaine-dependent individuals | Treatment retention |
| | Verdejo- García et al. (2012) | 131 | Delis– Kaplan Stroop Test | Cocaine | <i>r</i> = 0.10 | Patients performance on Stroop inhibition was significantly associated with increased retention in treatment | Treatment retention |

| Schmitz et al. (2009) | 75 | Delayed Memory task | Cocaine | <i>d</i> = 0.01 | No effect | Treatment retention |
|---------------------------|-----|--|---------------------------------------|-----------------|--|---------------------------------------|
| Winhusen et al. (2013) | 182 | Comalli- Kaplan Stroop Test | Methamph etamine and Cocaine | <i>d</i> = 0.13 | No effect | Treatment retention |
| Fagan et al. (2015) | 120 | Stroop Colour Word Interference | Cocaine | <i>d</i> = 0.02 | Higher Stroop Colour-Word <i>T</i> -score predicted better treatment adherence | Treatment retention |
| Mitchell et al. (2013) | 32 | Stroop Colour Word Interference | Cocaine | r =0.78 | The Stroop effect was positively associated with the number of self- reported days of abstinence during treatment | Treatment retention |
| Schmitz et al. (2009) | 75 | Immediate Memory task | Cocaine | <i>d</i> = 0.19 | No effect | Treatment retention |
| Rupp et al. (2016) | 43 | Go/no-go Task | Alcohol | <i>d</i> = 0.24 | Poor GNG response inhibition predicts increased treatment dropout/relapse | Relapse and treatment retention |
| Passetti et al. (2011) | 80 | Go/no-go | Opiates | <i>d</i> = 0.27 | No effect | Relapse |
| Noel et al. (2002) | 20 | Hayling Task | Alcohol | <i>d</i> = 1.01 | At two months follow-up, relapsers had higher overall error scores than abstainers | Relapse |

| | Passetti et al. (2011) | 80 | Go/no-go Task | Opiates | <i>d</i> = 0.23 | No effect | Relapse |
|--------------------------|---|-----|---------------------------------|---------------------|------------------|---|------------------------|
| | Czapla et al. (2016) | 165 | Go/no-go Task | Alcohol | <i>d</i> = 0.71 | Poor performance on GNG predicted increased rate of relapse | Relapse |
| | Kennedy, Gross, Ely, Drexler, and Kilts (2014) | 35 | Stroop Interference Task | Cocaine | d = 0.40 | No effect | Relapse |
| Decision making | Chen, Chen, and Wang (2015) | 42 | Iowa Gambling Task | Methamph etamine | <i>d</i> = 0.88 | Participants who dropped out of treatment had lower total scores; higher selections from high reward- high risk decks and lower selections from low reward low risk decks, compared to participants who remained in treatment | Treatment retention |
| | Passetti, Clark, Mehta, Joyce, and King (2008) | 43 | Information Sampling Task | Opiates | <i>d</i> =0.11 | No effect | Relapse |
| | Stevens et al. (2015) | 70 | Iowa Gambling Task | Poly-drug Use | <i>d</i> = 0.69 | Poorer performance on the task predicted relapse at 3 months | Relapse |
| Cognitive flexibility | Desfosses, Meadows, Jackson, and Crowe (2014) | 21 | Wisconsin Card Sort Test | Alcohol | <i>r</i> = -0.54 | Strong inverse correlation between dropout rate and scores on task | Treatment retention |

| | Chen et al. (2015) | 42 | Wisconsin Card Sort Task | Methamph etamine | <i>d</i> =0.15 | No effect | Treatment retention |
|-------------|---|----|--------------------------------|---------------------------------------|-----------------|---|---------------------|
| | Clark et al. (2014) | 45 | Wisconsin Card Sort Test | Alcohol and Methamph etamine | <i>d</i> = 0.67 | Poorer performance was predictive of higher incidence of relapse | Relapse |
| | Aharonovich, Brooks, Nunes, and Hasin (2008) | 20 | Wisconsin Card Sort Task | Cannabis | <i>d</i> = 0.16 | No effect; Cannabis abstinence was unrelated to cognitive flexibility | Relapse |
| Impulsivity | Washio et al. (2011) | 36 | Delay Discounting Task | Cocaine | <i>d</i> = 0.83 | Steeper delayed discounting was significantly associated with shorter durations of cocaine abstinence | Relapse |

Note. GNG = Go/No-go Task.

Despite the discrepancies in the literature, it is claimed that deficits in EF can limit successful treatment outcomes for individuals suffering from substance dependence (Day et al., 2015). This is supported by the findings in Table 1, illustrating that EF deficits can be associated with poor therapeutic retention rates and greater likelihood of relapse. A potential mechanism explaining this association is that the treatments currently implemented in substance dependence require high cognitive engagement and involve individuals to perform complex mental processes (Perry & Lawrence, 2017). These treatments commonly require substance-dependent individuals to implement behavioural change (i.e., leaving the room when presented with cues that elicit drug cravings) and modify dysfunctional thinking (i.e., challenge negative thinking that is triggered by drug cravings) (Sofuoglu, DeVito, Waters, & Carroll, 2013). However, many of the cognitive processes needed for success in these treatments are the very cognitive domains that are impaired in substance use (Day et al., 2015). Resultantly, the cognitive and behavioural changes that are necessary for abstinence are unable to be initiated and maintained, therefore further perpetuating the vicious cycle of addiction (Perry & Lawrence, 2017).

Inhibitory Control in Substance Use

The capacity to delay, disrupt or withhold a behavioural reaction is a critical component of EF (Rey-Mermet & Gade, 2018). Inhibitory control (IC) is the ability to inhibit a prepotent response, instead utilising a response that is more appropriate or desirable (Diamond, 2013). For example, imagine you are driving along the highway and you need to change lanes to overtake a car in front of you. As you start to change lanes you suddenly see that there is a car in your blind spot; your automatic response would be to continue switching lanes, but your ability to inhibit that response, and stay within the same lane, is what is referred to as you IC. IC can be measured using a variety of tasks, with Table 2 outlining these. However, the Stop Signal Task (SST) and Go/no-go (GNG) task are the most consistently used measures of IC in research (Spinola, Maisto, White, & Huddleson, 2017).

In the context of addiction, IC is crucial in the ability to resist and impede habitual substance use once established (i.e., resist drug-taking behaviour in response to drug cravings) (Day et al., 2015). As such, dysfunction in IC is argued to contribute to the development and preservation of substance use through an inability to restrain maladaptive drug-seeking behaviours (Moeller, Bederson, Alia-Klein, & Goldstein, 2016). Consequently, poor IC is argued to contribute to an individual's vulnerability to addiction (Koob & Volkow, 2016).

Meta-analytic evidence and systematic reviews have demonstrated that impairments in IC are well-established in substance use and dependence (Luijten et al., 2014; Stavro et al., 2013; Wright, Lipszyc, Dupuis, Thayapararajah, & Schachar, 2014). Despite the varying neurochemical profiles of addictive substances, the abundance of literature suggesting an IC deficit in substance use/dependence indicates that IC dysfunction is a reliable defining feature of addiction (Table 3) (Charles-Walsh, Furlong, Munro, & Hester, 2014b). This is supported by a comprehensive meta-analysis of 97 studies examining inhibition in substance use, which found that deficits in IC were apparent for heavy use/dependence on methamphetamine (g=0.72), MDMA (g=0.35), cocaine (g=0.47), tobacco (g=0.25), and alcohol (g=0.53) (Smith et al., 2014). However, no IC deficit was found for dependence on cannabis (g=0.01) or opiates (g=0.06) (Smith et al., 2014).

Table 2

Measures of Inhibitory Control

| Task | Description | Main Dependent Variable | Form of Inhibition | Length of Time | Cost | Accessibility |
|---|---|-------------------------------|--------------------------|-------------------|--|-----------------------------------|
| Go/no-go (GNG) Task | A simple task is performed (i.e. pressing a button if the letter M is presented), unless a no-go stimulus is presented (i.e., the letter X) where participants have to withhold their response. | Error rates | Automatic inhibition | 0-00 | Open- source (computer) or \$\$\$\$ | No norms, research focussed |
| Stop Signal Task (SST) | An ongoing task is performed (i.e., pressing a button if a X is presented and pressing a button if a O is presented), unless a stop signal (i.e., two red lines) appear where participants have to withhold their response. The time between the stop signal and presentation of the stimulus is manipulated so that participants <i>should</i> only successfully withhold their response when a stop signal is presented in 50% of trials. The better participants perform, the longer the delay is between the presentation stimulus and the stop signal. | Stop signal reaction time | Controlled inhibition | 0 - 0 0 | Open- source (computer) or \$\$\$\$ | No norms, research focussed |
| Hayling Sentence Completion Task | The task consists of two sets of fifteen sentences. In each sentence the last word of the sentence is missing. In the first set of sentences an examiner reads each sentence | Reaction time | Automatic inhibition | 00 | \$\$\$ | Restricted (B) |

aloud and the participant simply responds with the word that would complete the sentence. In the second set of sentences the same procedure occurs, however, the participant respond with a word (i.e., that would not appropriately complete the sentence (i.e., suppresses the appropriate word).

| Immediate | IMT: Participants are presented a sequence |
|-------------|---|
| and Delayed | of five-digit numbers (i.e., 53723) on a |
| Memory | computer screen, one at a time. Participants |
| Task | are required to respond when two identical |
| (IMT/DMT) | numbers are presented in sequence. |
| | Numbers may be presented in three forms: |
| | target stimulus (i.e., five-digit number is |
| | identical to the preceding five-digit number); |
| | catch stimulus (i.e., five-digit number differs |
| | from the preceding five-digit number by |
| | only one digit); filler stimulus (i.e., random |
| | five-digit number). |
| | |

DMT: A sequence of distractor numbers (i.e., five-digit numbers) are presented inbetween each five-digit number that is required to be compared to the previous in the sequence. Participants are required to ignore these distractor numbers and complete the task as per the IMT. Automatic

inhibition

Error rates

 $\bigcirc \bigcirc$

Opensource (computer) No norms, research focussed

| Stroop Colour Word Task | The colour of a word is printed in a congruent colour (i.e., the word <i>yellow</i> is printed in the colour yellow) or incongruent colour (i.e., the word <i>yellow</i> is printed in the colour blue). Participants are required to name the <i>colour</i> of the ink that the word is printed in and to inhibit reading the word. | Reaction times | Ignore response interference | ٢ | Nil to \$\$\$ | Norms in specialist tests; kit is restricted (C) ^b |
|--|---|-------------------|------------------------------------|------|--|---|
| Flankers | Participants are required to respond to a central stimulus (i.e., arrow or letter) while ignoring flanking stimuli. Flanking stimuli may be congruent (i.e., MMM) or incongruent (i.e., TMT). | Error rates | Ignore response interference | 0-00 | Open- source (computer) or \$\$\$\$ | No norms, research focussed |
| Conners's Continuous Performance Test - III | Participants press the space bar when they are presented with any letter apart from the letter X. Participants are required to withhold their response when they are presented with the letter X. | Error rates | Automatic inhibition | 00 | \$\$\$\$ | Restricted (B) for norms ^a |
| Simon Task | Participants are required to respond to visual stimuli (i.e., pressing the <i>right</i> button if a circle is presented or pressing the <i>left</i> button if a square is presented). The stimuli are presented on either the <i>right</i> or <i>left</i> hand side of the screen, which can be congruent (i.e., stimuli presented on the <i>right</i> hand side of the screen and <i>right</i> button must be | Reaction time | Ignore response interference | 0-00 | Open- source (computer) or \$\$\$\$ | No norms, research focussed |

pressed) or incongruent (stimuli presented on the *left* side of the screen and the *right* button must be pressed).

| Antisaccade | Participants are required to fixate on a stationary (i.e., small dot). A stimulus will then be presented on either the right or left side of that stimulus. Participants are required to make a saccade (i.e., quickly move both eyes) in the direction away from the stimulus (i.e., if a stimulus was presented on the <i>right</i> side of the fixation dot participants would be required to move their eyes towards the <i>left</i> . | Error rates | Ignore response interference | U | \$\$\$\$ | No norms, research focussed |
|--------------------------------|---|------------------------------|------------------------------------|---|----------|-----------------------------------|
| CANTAB: Stop Signal Task | Participants respond to an arrow stimulus by pressing a button (i.e., left or right) that corresponds with the direction that the arrow stimulus is pointing. Participants are required to respond as quickly as possible, unless an auditory signal (i.e., beep) occurs, where participants have to withhold their response. The time between the stop signal and presentation of the stimulus is manipulated so that participants <i>should</i> only successfully withhold their response when a stop signal is presented in 50% of trials. The better participants perform, the longer the | Stop signal reaction time | Controlled inhibition | | \$\$\$\$ | Norms, research focused |

delay is between the presentation stimulus and the stop signal.

Note. One clock = <10 mins; two clocks = >10 mins; dollar value: each \$ = a zero (i.e. 300 =\$\$; 1100 =\$\$\$).

aRestricted (B) = Use is restricted to Allied Health or Special Education Professionals. This restriction also applies to, but is not limited to Undergraduate and Master's degrees in speech pathology, occupational therapy, physiotherapy and may include special education, medical and behavioural science

^bRestricted (C) = Use is restricted to Registered Psychologists; Controlled inhibition = response needs to be inhibited after its initiation; automatic inhibition = a prepared response is withheld that has not been initiated.

The ANA suggests that EF deficits are *central* to the cognitive processes occurring in people who are experiencing substance use disorder (Kwako et al., 2016). Despite this, Smith et al.'s (2014) meta-analysis found an *in-substantial effect* of an IC deficit for some classes of drugs; cannabis and opiates. A potential mechanism explaining this could be that different addictive substances have particular neuromodulator properties that produce relatively stronger or weaker impairments in specific EF domains, due to the precise brain regions they target (Jovanovski et al., 2005). Both cannabis and opiates have been shown to produce their effects through similar processes; through secondary modulation of dopamine via the opioid system in the reward pathway compared to the direct dopaminergic effects of cocaine and methamphetamine (Fernandez-Serrano, Perez-Garcia, & Verdejo-Garcia, 2011). Hence, the comparable neuromodulator properties of these substances could explain why a lack of IC impairment was found in Smith et al.'s (2014) meta-analysis, suggesting that IC is not a primary deficit of cannabis and opiates.

However, on closer review of Smith et al.'s (2014) meta-analysis it is apparent that there is a dearth of research investigating IC deficits in opiate users. Only five studies were included in the present meta-analysis, with four out of the five studies containing small user group sample sizes (n<32) (Constantinou et al., 2010; Forman et al., 2004; Fu et al., 2008; Yang et al., 2009). It also is apparent that these studies included no, or only a small proportion of female opiate users, suggesting that the effect found could be sex-specific rather than applying generally to opiate users. Although Smith et al. (2014) included a larger proportion of studies that investigated IC in cannabis-dependent individuals (N=11), the majority of these studies also included small user group sample sizes, with varying proportions of female inclusion. It is possible that the small sample sizes and heterogeneity of sex inclusion between studies has influenced the statistical

power to detect small to moderate effect sizes, meaning there is a potential that effects have been missed (Smith et al., 2014).

Dysfunctions in IC have also been claimed to be associated with more frequent use, larger dosages, and more failed attempts to reduce and control use (Weafer & Fillmore, 2008). Consequently, impaired IC is argued to be predictive of impulsive behaviour and risk of relapse in substance use disorders (Dominguez-Salas et al., 2016). Table 1 illustrates the predictive outcomes of IC in substance dependence. It is clearly evident that dysfunctions in IC predict poor treatment efficacy (Thoma et al., 2011), treatment retention (Wilcox, Dekonenko, Mayer, Bogenschutz, & Turner, 2014), and abstinence during treatment (Rupp et al., 2016).

Table 3

Studies of Substance Use Investigating Inhibitory Control Performance

| Substance | Study | п | % females | Type of substance use | Measure | Effect size | Main findings |
|---------------------|---|----|--------------|-----------------------|---|-----------------|---|
| Cocaine | Pike, Stoops, Fillmore, and Rush (2013) | 30 | 43 | Regular users | Attentional Bias- Behavioural Activation Task | <i>d</i> = 0.84 | Participants allocated to the cocaine image condition produced significantly more inhibitory errors on the no-go targets compared to participants allocated to the neutral cue condition |
| | Zhang, Hu, Bednarski, Erdman, and Li (2014) | 35 | 0 | Dependent | Stop Signal Task | <i>g</i> = 0.47 | Cocaine dependent patients had longer SSRT compared to controls |
| | Bell, Foxe, Ross, and Garavan (2014) | 27 | 11 | Abstinent | Go/no-go Task | <i>g</i> = 0.05 | No effect |
| Methamph etamine | Tabibnia et al. (2011) | 43 | 44 | Dependent | Stop Signal Task | g = 0.65 | Methamphetamine dependent- participants had worse response inhibition (prolonged SSRT) compared to controls |
| | Monterosso, Aron, Cordova, Xu, and London (2005) | 11 | 36 | Dependent | Stop Signal Task | <i>g</i> = 1.53 | Methamphetamine dependent- participants had worse response inhibition (prolonged SSRT) compared to controls |

| | Leland, Arce, Miller, and Paulus (2008) | 19 | 11 | Dependent | Go/no-go Task | <i>g</i> = 0.58 | Methamphetamine dependent- participants made more commission errors compared to controls |
|---------|--|---------|----|----------------------------|-----------------------------------|-----------------|---|
| Tobacco | Charles-Walsh, Furlong, Munro, and Hester (2014a) | 37 | 30 | Dependent | Stop Signal Task | <i>d</i> = 0.03 | No effect; there was no difference in SSRT between nicotine- dependent individuals and controls following 3 hours of abstinence |
| | Charles-Walsh et al. (2014a) | 22 | 50 | Dependent | Stop Signal Task | <i>d</i> = 0.97 | Inhibitory control performance was significantly poorer following 10-h nicotine abstinence. |
| | Nestor, McCabe, Jones, Clancy, and Garavan (2011) | 33 | 36 | Dependent and abstinent | Go/no-go Task | <i>g</i> = 0.96 | Current smokers had poorer response inhibition compared to controls and ex-smokers |
| Opiates | Constantinou et al. (2010) | 32 | 38 | Dependent and abstinent | Go/no-go Task | <i>d</i> = 0.34 | No effect |
| | Liao et al. (2014) | 26 4 | 0 | Abstinent | Stop Signal Task | <i>d</i> = 1.46 | Opiate dependent participants had prolonged SSRT compared to controls |
| Alcohol | Salgado et al. (2009) | 31 | 16 | Dependent | Continuous Performance Task | <i>g</i> = 0.87 | Alcohol dependent patients made more commission errors compared to controls |
| | Czapla et al. (2016) | 94 | 19 | Dependent | Go/no-go Task | <i>d</i> = 0.54 | Alcohol-dependent participants had significantly higher rate of |

| | | | | | | | controls |
|----------|--|----|----|---------------|---------------------|-----------------|---|
| Cannabis | Jutras-Aswad et al. (2012) | 50 | 26 | Dependent | Stop Signal Task | <i>g</i> = 0.25 | No effect |
| | Pope, Gruber, Hudson, Huestis, and Yurgelun-Todd (2001) | 74 | 26 | Heavy users | Stroop Task | <i>g</i> = 0.16 | No effect |
| MDMA | Roberts, Fairclough, Fisk, Tames, and Montgomery (2013) | 20 | 50 | Regular users | Go/no-go Task | <i>d</i> = 0.44 | No effect; response inhibition did not significantly differ between MDMA users and drug naïve controls |
| | Roberts and Garavan (2010) | 20 | 50 | Regular users | Go/no-go Task | <i>g</i> = 0.01 | No effect |

Note. n and % of females includes only substance taking/abstinent participants and does not include controls.

commission errors compared to

Inhibitory Control and Alcohol Use

Some substances produce impairments in EF acutely as well as chronically. Alcohol is a good example of this. It is claimed that alcohol disrupts functioning of the prefrontal cortex, producing disinhibiting effects on behaviour, which can lead to impulsivity (Weafer & Fillmore, 2008). Resultantly, alcohol's disinhibiting effects produce dysfunctions in IC, causing a reduced ability to inhibit maladaptive behaviour (Day et al., 2015). This is thought to facilitate alcohol's abuse potential through binge-drinking, as urges to drink are unable to be inhibited (Weafer & Fillmore, 2012).

Zoethout, Delgado, Ippel, Dahan, and Van Gerven (2011) claim that IC is a useful functional biomarker of acute alcohol intoxication. The disinhibiting effects of alcohol on IC are well-established, with Table 4 summarising the evidence for this. Despite this, Table 4 also illustrates a proportion of studies that have produced null findings. It was found that lower doses of alcohol (0.2-0.5 g/kg) were not sufficient to produce impairments in IC function (Dougherty, Marsh-Richard, Hatzis, Nouvion, & Mathias, 2008; Volkow et al., 2006). This is supported by Zoethout et al. (2011) who illustrated that the current tasks used to measure IC are only primarily sensitive to detecting impairment at higher doses of alcohol (>0.8 g/kg), indicating that they are less suitable at lower alcohol doses (Zoethout et al., 2011).

| Task | Study | n | % females | Type of alcohol use | Alcohol dose (g/kg; BrAC %) | Effect size | Main findings |
|---------------------|---|----|--------------|--|-----------------------------------|-----------------|---|
| Task Sk an Sp | Mulvihill, Skilling, and Vogel- Sprott (1997) | 48 | 50 | Social drinkers | Men: 0.62 Women: 0.54 | <i>d</i> = 1.25 | Alcohol disrupted inhibitory control in both men and women |
| | Fillmore and Weafer (2004) | 24 | 50 | Social drinkers | 0.65 | <i>d</i> = 0.96 | When responses were pre-potent, males had higher impairment of inhibitory control under the influence of alcohol compared to females |
| | Weafer and Fillmore (2008) | 26 | 46 | Social drinkers | 0.65 | <i>d</i> = 1.54 | Alcohol impaired inhibitory control evident by increased <i>p</i> -failures compared to control |
| | Marczinski, Combs, and Fillmore (2007) | 32 | 50 | Binge drinkers and non-binge drinkers | 0.65 | <i>d</i> = 0.68 | Inhibitory control was further impaired in binge drinkers compared to non- binge drinkers |
| | Weafer and Fillmore (2008) | 26 | 46 | Social drinkers | 0.65 | <i>d</i> = 1.01 | Greater impairments in inhibitory control was associated with increased ad lib consumption |

Table 4The Effects of Alcohol on Inhibitory Control

| Continuous Performance Test | Bjork, Hommer, Grant, and Danube (2004) | 130 | 26 | Dependent | n/aª | n/a ^b | Alcohol-dependent patients demonstrated increased rate of commission errors, but not omission errors |
|-----------------------------------|--|-----|----|----------------------------------|--------------------------|------------------|--|
| | Salgado et al. (2009) | 31 | 16 | Dependent | n/aª | <i>d</i> = 0.87 | Alcohol-dependent patients reported more commission errors than healthy controls |
| Stop Signal Task | Spinola et al. (2017) | 75 | 52 | Moderate to heavy drinkers | 0.65 | <i>d</i> = 0.29 | No effect; this dose of alcohol was not sufficient to produce impairments in inhibitory control in moderate to heavy drinkers |
| | Guillot, Fanning, Bullock, McCloskey, and Berman (2010) | 185 | 49 | Social drinkers | 0.05% and 0.1 % | <i>d</i> = 0.04 | No effect; inhibitory control performance was not significantly impaired between 0.05% BrAC and 0.1% BrAC |
| | Dougherty et al. (2008) | 90 | 50 | Social drinkers | 0.2, 0.4, 0.6 and 0.8 | n/a ^b | No effect; there was no significant difference in inhibitory control between peak BrAC and any of the other alcohol conditions or between control |
| | Fillmore and Vogel- | 35 | 0 | Social drinkers | 0.62 | <i>d</i> = 1.13 | Alcohol impaired inhibitory control |

| | Sprott (1999) | | | | | | |
|--------------------------------|---|----|----|--|--------------|---|---|
| | Peacock, Cash, and Bruno (2015) | 19 | 0 | Social drinkers | 0.08% | <i>d</i> = 0.34 | There was no significant difference in SSRT between alcohol and placebo conditions |
| Stroop Task | Volkow et al. (2006) | 20 | 40 | Moderate drinkers | 0.25 and 0.5 | 0.25: d = 0.27 0.5: d = 0.19 | No effect; these doses of alcohol were not sufficient to produce impairments in inhibitory control |
| | Schweizer et al. (2005) | 20 | 0 | Social drinkers | 0.65 | BrAC ascending: d = 0.90 BrAC descending: d = 1.02 | Participants in the alcohol group had increased response times on the BrAC ascending limb and also made more errors on the descending limb compared to controls |
| Random Letter Generation | Montgomer y, Fisk, Murphy, Ryland, and Hilton (2012) | 41 | 51 | Light social drinkers and heavy social drinkers | n/aª | <i>d</i> = 0.66 | Heavy drinkers had poorer inhibitory control compared to light drinkers |
| Sustained Attention to | Naim-Feil, Fitzgerald, Bradshaw, | 24 | 54 | Abstinent | n/aª | <i>d</i> = 0.90 | Alcohol-dependent participants demonstrated poorer inhibitory control performance compared to controls |

| Response | Lubman, | | | | | | |
|----------|-------------|----|----|-------------|-----------|-----------------|--|
| Task | and | | | | | | |
| | Sheppard | | | | | | |
| | (2014) | | | | | | |
| | Dry, Burns, | 28 | 43 | Experienced | 0.05% and | 0.05%: | Participants in the alcohol condition |
| | Nettelbeck, | | | drinkers | 0.10% | <i>d</i> = 1.06 | made significantly more errors of |
| | Farquharson | | | | | 0.10%: | commission at both 0.05% and 0.10% |
| | , and White | | | | | <i>d</i> = 1.06 | compared to controls |
| | (2012) | | | | | | |

Note. n and % of females includes only substance taking/abstinent participants and does not include controls; BrAC = breath alcohol concentration; SSRT = stop signal reaction time. ^an/a: participants were not under the influence of alcohol at the time of testing; n/a^b : effect size was unable to be calculated due to the

study not providing sufficient statistics

Conversely, Table 4 also illustrates a portion of studies that have demonstrated no IC deficit even at moderate to high doses of alcohol (0.6-0.8 g/kg) (Dougherty et al., 2008; Spinola et al., 2017), with Guillot et al. (2010) demonstrating that BrAC of 0.1% produced no significant impairments in IC. On closer review, Table 4 shows that the studies which have produced null findings at higher alcohol doses all measured IC using the SST. This suggests that the SST may lack sensitivity to detect IC deficits under acute alcohol impairment. Spinola et al. (2017) supports this, claiming that the disparity in the literature could be due to the differences in the sensitivity of IC measures used.

Wright et al. (2014) claim that the SST and GNG task measure distinctive aspects of IC. As illustrated in Table 2, the SST is claimed to measure controlled inhibition, where a response needs to be inhibited after its initiation (Littman & Takacs, 2017); and the GNG task which is claimed to measure automatic inhibition, where a prepared response that has not been initiated is withheld (Smith et al., 2014). Wright et al. (2014) suggests that cancellation of an already initiated response is more cognitively demanding and requires higher EFs than withholding a planned response which has not been initiated. This could account for why moderate doses of alcohol impair IC measured with the GNG tasks but not SSTs, indicating that the GNG task may be a more sensitive to acute impairments from alcohol. This is supported by research investigating IC impairment at moderate alcohol doses (0.65 g/kg) in social drinkers, illustrating that IC is further impaired using the GNG task (d=0.85), compared to the SST (d=0.52) (Birak, Higgs, & Terry, 2011). Despite Birak et al.'s (2011) small sample size (N=24), meta-analytic evidence further supports this, demonstrating that the weighted mean effect size for alcohol dependence on GNG tasks is substantially larger (g=0.53) compared to SSTs (g=0.39) (Smith et al., 2014).

Inhibitory Control and Working Memory

Deficits in IC have been argued to be associated with impairments in other cognitive domains as a result of neuroadaptations from chronic substance consumption (Day et al., 2015). As previously discussed, EF is claimed to be composed of three fundamental domains; IC, WM and cognitive flexibility (Figure 2) (Diamond, 2013). It has been consistently demonstrated that there are moderate to strong magnitude correlations between IC and WM (Chambers, Garavan, & Bellgrove, 2009; Hester & Garavan, 2004; Looby, Norton-Baker, & Russell, 2018), suggesting that IC and WM contain a substantial proportion of common variance. This is further supported by Miyake et al.'s (2000) confirmatory factor analysis of EFs, where a positive, strong relationship between IC and WM was found (r=.63, 95% CI [.09, .76]).

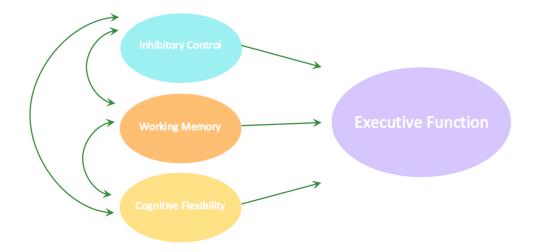


Figure 2. Model of Executive Functioning adapted from Miyake et al. (2000).

Engle, Conway, Tuholski, and Shisler (2016) claim that EF processes run on a limited reserve. This is explained by the limited resource model of executive functioning, which proposes that individuals who experience dysfunctional behaviour have poor EF abilities when their WM capacity is taxed or exhausted (Looby et al., 2018). Subsequently, it is claimed that if WM is taxed or exhausted, the ability to inhibit impulsive behaviour and distractions is also limited (Looby et al., 2018). This is argued to be a result of actively maintaining your goal in mind to identify what will facilitate or hinder the achievement of that goal and what may need to be inhibited (Diamond, 2013). Hence, a deficit in either WM or IC produce subsequent impairments in each other (Hester & Garavan, 2004), indicating that these two constructs simultaneously support each other (Diamond, 2013). Despite this, debate still exists around whether IC and WM are in fact separate cognitive processes or part of an integrated system (Friedman & Miyake, 2004; Noel et al., 2013).

Developing a New Task of Inhibitory Control: Whack-a-Bottle

Neuroscience-based frameworks; such as the ANA and Impaired Response Inhibition and Salience Attribution (iRISA) model of substance use disorder, as well as the broader Research Domain Criteria Initiative (RDoC), Cognitive Neuroscience Treatment Research to Improve Cognition in Schizophrenia (CNTRICS) and the National Institute of Mental Health's consensus measures for Phenotypes and eXposures (PhenX), emphasise the importance of assessing EFs as a predictor of functional outcome (Kwako et al., 2016). Specifically, they all include the assessment of IC, with general consensus indicating that the SST and GNG task are gold standard measures (Table 5).

Workforce surveys have indicated a strong interest in assessment of IC during substance use treatment (Collins, 2018). However, these are poorly utilised due to current, valid measures of IC being expensive, restricted and not accessible to frontline workers (Table 2) (Day et al., 2015). These measures are also tedious to complete, have poor appeal to participants, and are susceptible to practice effects (Weafer, Baggott, & de Wit, 2013).

Neuroscience-based Assessment Frameworks and Tasks of Inhibitory Control

| Neuroscience-based Assessment Frameworks | Description | Tasks of Inhibitory Control |
|---|--|--|
| Addictions Neuroclinical Assessment (ANA) | The ANA is a neuroscience-based framework for addictive disorders that encompasses three functional domains that are derived from the neurocirculatory of addiction; incentive salience, negative emotionality and executive functions. | SSTGNG |
| Impaired Response Inhibition and Salience Attribution (iRISA) | The iRISA is a neuroscience-based framework that identifies the disruptions in the neurocirculatory of addiction and emphasises the importance of inhibitory control in the addiction cycle. | SSTGNGStroop Task |
| Research Domain Criteria Initiative (RDoC) | RDoc is a research framework that focuses on psychiatric disorders. | AntisaccadeSSTGNGFlankers |
| Cognitive Neuroscience Treatment Research to Improve Cognition in Schizophrenia (CNTRICS) | CNTRICS is a neuroscience-based framework with the primary goal of developing measurements that can be implemented in treatments to improved impaired cognition in schizophrenia. | SSTSwitching Stroop |

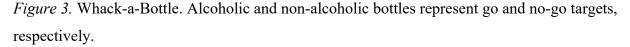
PhenX Toolkit is an online catalogue of
SST
standardised measures that have been
GNG
developed for a variety of domains. It includes
a group of measures that focus on the
assessment of substance dependence and abuse.

Note. SST=Stop Signal Task; GNG = Go/no-go task

Recently, a 'serious games' movement has emerged, aiming to develop engaging tools for cognitive assessment. 'Serious games' promote users to interact at a deeper level with a cognitive test through novel engagement and motivational properties (i.e., receiving/losing points) typically used in recreational computer games (Connolly, Boyle, MacArthur, Hainey, & Boyle, 2012). Hence, putting neuropsychologically informed tests within this framework fosters engagement and improves the attractiveness of the cognitive measures. Consequently, we have developed a brief, interactive IC task for smartphones and tablets based on a 'serious games' approach to enhance user engagement.

Our proposed measure of IC is based on a whack-a-mole concept; a version of a GNG paradigm and is subsequently named 'Whack-a-Bottle' (WAB) (Figure 3). Instead of moles, gostimuli are bottles of healthy drinks (water, orange juice) and no-go stimuli are bottles of alcoholic drinks (beer, wine), which appear randomly, one at a time. The simple and random nature of the task safeguards the WAB's susceptibility to learning effects as strategy generation is limited. Additionally, the WAB's software is compatible with most Android devices, allowing it to be portable and easily accessible. Our goal is to make the WAB freely available to clinicians and the research community to promote accessibility to frontline workers.





Since impaired IC is a defining feature of substance use and dependence (Table 3), the use of alcoholic no-go stimuli in the WAB was implemented to foster inhibitory control training (ICT) in substance consuming populations. ICT aims to strengthen IC through repeated inhibition of a prepotent response to salient stimuli (Luijten et al., 2014). Houben, Nederkoorn, Wiers, and Jansen (2011) have demonstrated that significant reductions in weekly alcohol intake were found when heavy drinkers were trained to inhibit alcohol-related no-go stimuli, compared to when alcohol-related stimuli were paired with the go condition in a modified beer-GNG task. In addition, recent meta-analytic evidence has illustrated moderate reductions in alcohol consumption following ICT (d=0.43) (Jones et al., 2016). Meta-analytic evidence has also shown

that reductions in harmful behaviours (i.e., alcohol consumption) were larger for GNG training (d=0.50), compared to SST training (d=0.26), further supporting the findings that the GNG task is a more sensitive measure of IC (Allom, Mullan, & Hagger, 2016).

The primary aim of this study is to validate the WAB against traditional, gold standard measures to determine whether it is a valid and sensitive measure of IC. Due to the WAB being based on a GNG paradigm, it is hypothesised that the task will demonstrate strong correlations with traditional measures of IC. Specifically, it is hypothesised that the WAB will demonstrate large magnitude correlations with the SST and Flanker GNG task. As IC and WM are claimed to have a substantial proportion of common variance (Miyake et al., 2000), it is further hypothesised that the WAB, and other tasks of IC, will demonstrate convergent validity, in that they will establish moderate magnitude correlations with other executive tasks of WM. Additionally, due to the random nature of the task, it is also hypothesised that the WAB will produce minimal learning effects in a repeated measures context. Since the WAB has been specifically developed for substance consuming populations, study two aims to test the effects of acute alcohol intoxication on IC. On the basis of previous findings (Table 4), it is hypothesised that if the WAB is a valid measure of IC, then it should be sensitive to impairment from alcohol.

Method: Study One

Study one investigated whether the WAB is a valid measure of IC, and stable over repeated assessment.

Participants

The current study recruited 68 participants (28 males) (M_{age} =41.1, *SD*=13.7, range=20-64) from the general community through social media. Participants were deliberately stratified across the adult age range in order to ensure that the results from this study were generalisable

across the age range where the WAB is hoped to be applied (adult substance use treatment, where 75% of clients are in the 20-49 age range (Australian Institute of Health and Welfare, 2019). Eligibility criteria included English as a primary language, age between 20-64, and normal or corrected-to-normal vision. Exclusion criteria included current mental health problems (i.e. self-report), major physical health problems, and prescribed current sedating psychoactive medication. Participants were reimbursed \$10 per testing session (\$20 total) for their time.

Materials

Inhibitory control measures. *Whack-a-Bottle (WAB).* This is a GNG task adapted from a whack-a-mole game. Instead of moles, go-stimuli are bottles of healthy drinks (water, orange juice) and no-go stimuli are bottles of alcohol (beer, wine). The aim of the game is to 'hit' the healthy drinks and avoid hitting the alcoholic drinks. There are 100 trials, with 1.2 seconds per each trial, with an 84% probability of a drink presented being a 'go' stimuli (i.e., stimuli requiring a response) and 16% probability of an alcoholic drink (stimuli requiring response to be withheld). There are 50ms between trials. Two primary measures of IC were utilised; percent of IC errors and score (participants are given 10 points per correct 'go' response within 1200ms, and an additional 5 points if responses are made within 500ms of stimuli onset; participants are penalised 100 points for every no-go response; scores are displayed on-screen). Score is another way of measuring IC that takes into consideration reaction time and errors, hence it may capture speed/accuracy trade-offs.

Flanker Task (GNG). In this task, stimuli consist of five arrows with a central target arrow pointing left or right flanked on both sides either by two squares (neutral), two arrows pointing in the same direction (congruent), or opposite direction (incongruent). Participants respond to the direction of the central arrow. Stimuli remain on screen until participants respond

or 1000ms has elapsed. Congruent, neutral, and incongruent trials each comprise 30% of 80 total trials. On 10% of trials a NoGo trial occurs, where suppressor flankers ('X') indicate to withhold a response. The outcome measure was the number of IC errors on No Go trials.

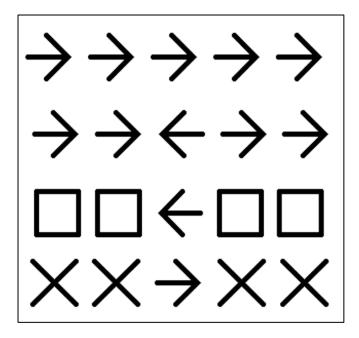


Figure 4. Example targets from the Flanker GNG Task. In all cases participants need to respond by determining if the central arrow points to the left or the right. The surrounding stimuli might be congruently pointing arrows, incongruently pointing arrows, or neutral stimuli (squares). When the surrounding stimuli are Xs, the participant has to *not* respond.

Stop Signal Task. Following 500ms presentation of a central fixation point, participants press a left or right square as fast as possible when 'X' or 'O' (go signal – stimuli a and b in the figure below). Stop-signal trials, requiring withholding of response, consist of a stimulus (two red lines) that initially occurs 250ms after letter onset (termed stop-signal delay (SSD)). SSD increased 50ms following failure to inhibit and decreased by 50ms following correct inhibition. There are 48 trials (25% stop-signal). Stop Signal Reaction Time (SSRT) is estimated by subtracting SSD from average go signal response time (Aron & Poldrack, 2006). The outcome

variables was SSRT in ms.

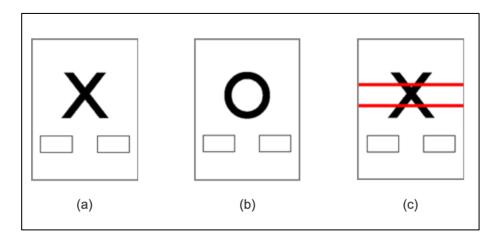


Figure 5. Example stimuli in the Stop Signal Task. Participants need to press one button if they see a X on the screen (a) or a different button if they see a O on the screen (b) as quickly as possible. On a small number of trials, a few milliseconds after the X or O appear, two red lines will appear. In these cases the participant will need to *not* respond.

Working memory measure (convergent validity). N-back Task. Participants are

presented a sequence of letter stimuli one at a time, at a rate of one per second. For each stimulus, they need to decide if the current stimulus is the same as the one presented N trials ago. Participants completed a 1, 2, and 3-back version of the task in sequence. There were 12 targets in the 1-back task; and 24 targets in the 2- and 3-back tasks, with targets randomly presented at a probability of 10%. Outcome variable was percent correct.

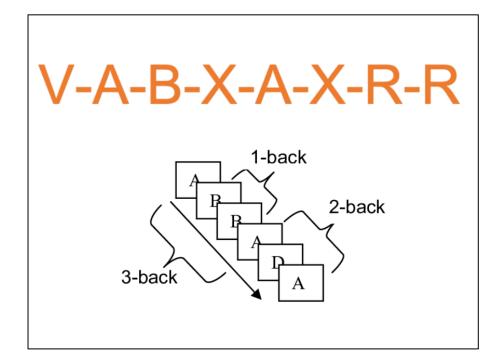


Figure 6. Example of the N-back task. In each level of difficulty of the task, letters are displayed on screen one at a time, one per second. In the easiest version (1-back) participants have to respond whenever the new letter is the same as the one they saw 1 stimuli previously (i.e., they would press the button the second time the R was presented in the orange list above). In more difficult versions, the participants need to press a button whenever the new stimuli match the one presented 2- (or more) 'back'. For example, in the 2-back level of difficulty, in the orange sequence above, participants would respond to the second X.

Covariate. *Wechsler Test of Adult Reading (WTAR).* The WTAR is a series of 50 words that have irregular grapheme-to-phoneme correspondence. Participants are asked to read aloud a list of words; correctness of pronunciation is recorded. The scale is co-normed with the Wechsler Adult Intelligence Scale and provides a brief estimate of verbal intelligence (*r*=0.75 with WAIS Verbal IQ) (Wechsler, 2001).

User Experience Questionnaire (short form). The short version of the User Experience Questionnaire (UEQ-S) was included to gather subjective consumer opinions towards the user experience of the WAB and to compare these to a comparative, traditional IC task; SST. The UEQ-S includes two scales; pragmatic quality (i.e., usability/functionality; 4 items) and hedonic quality (i.e., engagement/enjoyment; 4 items). Each item is measured using a seven-level semantic differential (two terms with polar opposite meanings at low and high anchors). The scale has normative data from instruments such as businesses software, web services and social media, from over 280 studies of software user experience reports.

Procedure

The University of Tasmania Social Science Human Research Ethics Committee approved the project (Approval #H0018073: Appendix A). Eligible participants (Appendix B) completed two 30-45 minute sessions, conducted approximately seven days apart (minimum of 5, maximum 14 days); informed consent was received in session one (Appendix C and D). To control for diurnal variability, the second session was conducted at approximately the same time of day. Prior to commencement of the cognitive test battery, the cognitive tests were explained both verbally and using instruction sheets; a demographic survey (Appendix E) was also completed. The cognitive test battery was standardised between sessions, with the cognitive tests administered in the following order: (1) WTAR (first session only); (2) WAB; (3) Flanker GNG; (4) N-back; (5) SST. The second session also administered the UEQ-S after completion of both the WAB and the SST to determine participant acceptability of each task. All cognitive tasks were completed on a 7" Android tablet.

Design and Analysis

Technical malfunction resulted in demographic, UEQ-S and session one WAB data to not be recorded for one participant. To assess construct validity, a correlational approach was adopted, assessing cross-sectional relationships between the measures. Three different measures of IC (WAB; SST; Flanker GNG) and one measure of WM (N-back task) were administered. Five continuous dependent variables (DVs) were utilised (percent of IC errors and score on the WAB; number of IC errors on Flanker GNG; SSRT on the SST; % correct on the N-back). Baseline correlations between the WAB and the other two validated measures IC were used to test the hypothesis that the WAB will demonstrate strong construct validity. Likewise, baseline correlations between the IC tasks and a measure of WM (N-back) tested the hypothesis that the WAB correlates with other processes known to relate to the IC construct.

Correlations between test and retest for each cognitive measure was also utilised to assess for consistency across assessment time points. These were assessed using correlation analyses and were interpreted using Pearson's correlation coefficient (r); ^{+/-}0-0.10=trivial, ^{+/-}0.10-0.29=weak, ^{+/-}0.30-0.49=moderate, ^{+/-}0.50-1.00=strong (Akoglu, 2018). Learning effects on repeat testing was assessed using paired samples *t*-tests to determine significant differences between test and retest for the cognitive measures as well as calculating effect sizes. Bayes factors were also used to determine the evidence in favour of the null hypotheses. Paired samples *t*-tests were used to assess significant differences between user experience for the SST and WAB. Statistical analyses were conducted on JAMOVI v1.1.3.0. Effect sizes were interpreted as 0.2=small, 0.5=moderate, 0.8=large (Cohen, 1992).

Results: Study One

Sample Characteristics

The sample comprised of adults across the age range with average levels of intellectual functioning and high levels of education (Table 6). The sample had low levels of gaming experience in the past week, with 46% not spending any time on games, indicating that it is unlikely that this would have influenced participants' performance.

| Sample Char | racteristic | | | Mean (SD) | Range |
|--------------|---------------|--------------------|----------|--------------|--------------|
| Age | | | | 41.1 (13.7) | 20.8 - 63.8 |
| % Males | | | | 41% | |
| Age groups | | Free | luencies | | |
| | | Males | Females | _ | |
| | 20-29 | 11 | 11 | 23.4 (1.92) | 20.8 - 28.8 |
| | 30 - 39 | 2 | 8 | 35.3 (2.61) | 31.3 - 38.8 |
| | 40 - 49 | 5 | 10 | 44.8 (2.79) | 40.6 - 49.4 |
| | 50 - 59 | 8 | 9 | 56.0 (2.65) | 50.9 - 59.9 |
| | 60 - 64 | 2 | 2 | 61.4 (2.05) | 60.1 - 63.8 |
| Intellectual | functioning (| WTAR) ^a | | 112.0 (7.53) | 87.0 - 124.0 |
| Gaming (hor | urs per week) |) | | 2.8 (4.61) | 0.00 - 20.0 |

Demographic Characteristics (N=67)

Note. Mean age is not representative because ten participants did not correctly fill out their specific age on the demographic questionnaire. However, age group data was completed for all participants.

^aWechsler Test of Adult Reading (WTAR); standardised score is 100 and scores are normed based on age. WTAR score <70 is indicative of intellectual functioning disorder (Wechsler, 2001).

Whack-a-Bottle Norms

Recruitment was stratified across the age-range to provide normative data for

standardised assessment (Table 7).

Normative Data for Score and Percent of Inhibitory Control Errors on Whack-a-Bottle

| Whack-a- | -Bottle Measures | | | | | | |
|----------|------------------|----|-------|------|-----------|------------------|-------------|
| | | | Score | | Percent o | f Inhibitory Con | trol Errors |
| | | n | Mean | SD | n | Mean | SD |
| Age-grou | ps | | | | | | |
| 20-29 | | | | | | | |
| | Males | 11 | 1886 | 901 | 11 | 0.12 | 0.12 |
| | Females | 11 | 1385 | 558 | 11 | 0.12 | 0.12 |
| 30-39 | | | | | | | |
| | Males | 2 | 1140 | 226 | 2 | 0.04 | 0.05 |
| | Females | 8 | 998 | 140 | 8 | 0.02 | 0.04 |
| 40-49 | | | | | | | |
| | Males | 5 | 1404 | 646 | 5 | 0.03 | 0.05 |
| | Females | 10 | 1113 | 446 | 10 | 0.04 | 0.04 |
| 50-59 | | | | | | | |
| | Males | 8 | 786 | 62.8 | 8 | 0.02 | 0.03 |
| | Females | 9 | 819 | 106 | 9 | 0.02 | 0.04 |
| 60-64 | | | | | | | |
| | Males | 2 | 685 | 332 | 2 | 0.22 | 0.12 |
| | Females | 2 | 850 | 28.3 | 2 | 0.00 | 0.00 |

Note. Means, *SDs*, and *n* for both males and females in each age-group.

Manipulation Checks

Whack-a-Bottle. Percent correct on the WAB was used to assess the validity of the task. Across both test and retest, the mean performance of participants was above 95%, indicating that participants performed the task correctly (Table 8).

Stop Signal Task. The SST uses a staircase procedure to modify SSD following correct performance and requires the proportion of IC errors to be close to 50% for accurate calculation of the SSRT. Across both test and retest, the percent of responses remained above 50%, indicating that delayed responses on the SST did not interfere with the validity of the SSRT results (Table 8).

Table 8

Mean (SD) Performance of Percent Correct on Whack-a-Bottle and Percent of Responses on the Stop Signal Task

| Manipulation Checks | Test | Retest |
|------------------------|-------------|-------------|
| - | Mean (SD) | Mean (SD) |
| Whack-a-Bottle: | | |
| | 98.1 (0.03) | 97.0 (0.04) |
| Percent correct % | | |
| Stop Signal Task: | | |
| Percent of responses % | 64.8 (0.01) | 66.6 (0.12) |

Note. Mean and SDs represented as percentages.

Correlations

Does the Whack-a-Bottle Task correlate well with traditional measures of inhibitory

control? Positive, trivial to weak magnitude non-significant correlations between measures of IC

errors on the WAB and Flanker GNG task were seen at both test (r=0.16) and retest (r=0.01; Table 9). Significant, moderate magnitude inverse correlations were found between WAB IC errors and SSRT at test (r=-0.31) and retest (r=-0.45). Using the more global measure of WAB score, there was a positive, small non-significant relationship with IC errors on the Flanker GNG task at test (r=0.12), falling to trivial and inverse on retest (r=-0.03). Significant, moderate inverse correlations were found between global WAB score and SSRT at test (r=-0.37) and retest (r=-0.36). In contrast, IC errors on the Flanker GNG task had significant but weak relationships with SSRT at test (r=-0.26), falling to trivial and non-significant at retest (r=-0.02).

Do measures of inhibitory control correlate with tasks of working memory? There were insubstantial relationships between WM performance (percent correct on N-back) and IC measures on either the WAB or the Flanker GNG task (r < |0.1|; Table 9). A similar lack of relationship was identified between WM performance and SSRT (r < |0.1|). Using the more global measure of WAB Score, there was a positive, small significant relationship with WM performance at test (r=0.25), although this was not replicated at retest (r=0.01).

Correlations Between Cognitive Measures

| Cognitive Measures | 1. | 2. | 3. | 4. | 5. |
|---|------------|--------|----------|-------|-------|
| 1. Whack-a-Bottle score | - | 0.33** | -0.36** | -0.03 | 0.01 |
| 2. Whack-a-Bottle inhibitory control errors | 0.35** | - | -0.45*** | 0.01 | 0.13 |
| 3. Stop Signal Reaction Time | -0.37** | -0.31* | - | -0.02 | -0.05 |
| 4. Inhibitory control errors Flanker GNG | 0.12 | 0.16 | -0.26* | - | -0.05 |
| 5. N-back Percent Correct | 0.25^{*} | -0.01 | -0.06 | -0.05 | - |

Note. Correlations for test (baseline) on the lower diagonal; correlations for retest on the upper diagonal. N = 67 for all Whack-a-Bottle measures due to the baseline measure of one participant to not be recorded; N = 68 for all other cognitive measures. GNG = Go/No-go.

* p < .05. ** p < .01, *** p < .001.

Are Measures of Inhibitory Control Stable Over Time? 1: Test-Retest Correlations.

Typical acceptable values of test-retest reliability of scales in psychological research has been suggested to be 0.7 by Nunnally (1970). As demonstrated in Table 10, IC measures on the WAB and the Flanker GNG task fell short of this criterion (r=0.41 and r=0.50 respectively). The more global measure of WAB score performed similarly (r=0.53). SSRT, however, performed better (r=0.75).

Table 10

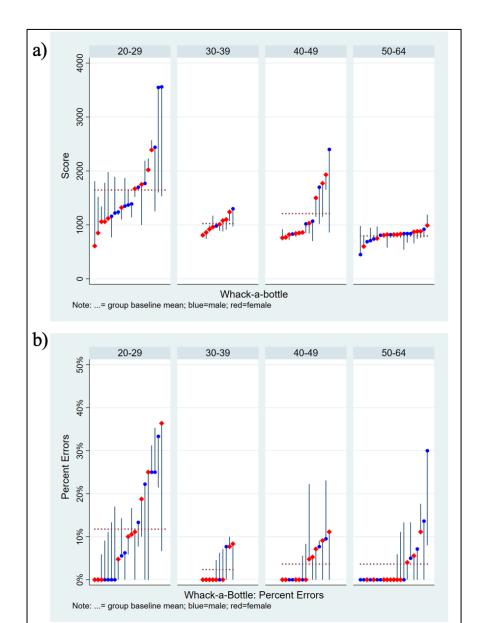
Correlations Between Test and Retest for Measures of Inhibitory Control

| | Test - | Retest |
|--|--------|--------|
| Cognitive Measures | r | р |
| Whack-a-Bottle score | 0.53 | <.001 |
| Whack-a-Bottle inhibitory control errors | 0.41 | <.001 |
| Stop Signal Reaction Time | 0.75 | <.001 |
| Inhibitory control errors Flanker GNG | 0.50 | <.001 |

Note. For all Whack-a-Bottle measures N = 67; for all other cognitive measures N = 68; GNG = Go/No-go.

Are Measures of Inhibitory Control Stable Over Time? 2: Learning Effects.

There were no indications of meaningful learning effects for either WAB IC errors or the global score measure, with non-significant, small magnitude increases on both measures (errors: d=0.05; score: d=0.17). In addition, Bayes Factors indicated strong evidence in favour of the null hypothesis of no change in performance (Table 11). However, examining individual level change, Figure 7 illustrates that a substantial number of participants made no IC errors on the



WAB (54% at test; 56% at retest; 34% making no errors at either test or retest).

Figure 7. Individual change on retest for the Whack-a-Bottle task. a) score; b) percent of inhibitory control errors. Lines represent change on retest; dotted line represents group baseline mean; blue dots represent males; red dots represent females.

However, IC errors on the Flanker GNG task demonstrated a statistically significant, moderate magnitude improvement in performance between test and retest (d=0.48), with

participants making less IC errors on retest. Bayes factors suggest strong support for a difference in performance overtime (Table 11). Examination of individual level change (Figure 8b) suggests that the majority of change between test and retest was positive (57%). Only a small minority of participants made no IC errors on this task (13% at test; 25% at retest; 1% making no errors at either test or retest).

Conversely, SSRT on the SST demonstrated a statistically significant, moderate magnitude reduction in performance between test and retest (d=-0.31), with participants' performance worsening on retest. Additionally, Bayes Factors suggest that there is a reasonable evidence to support a difference in reduced performance overtime (Table 11), indicated by a Bayes Factor just above 0.3. Examination of individual level change (Figure 8a) suggests that the majority of change between test and retest was negative (60%).

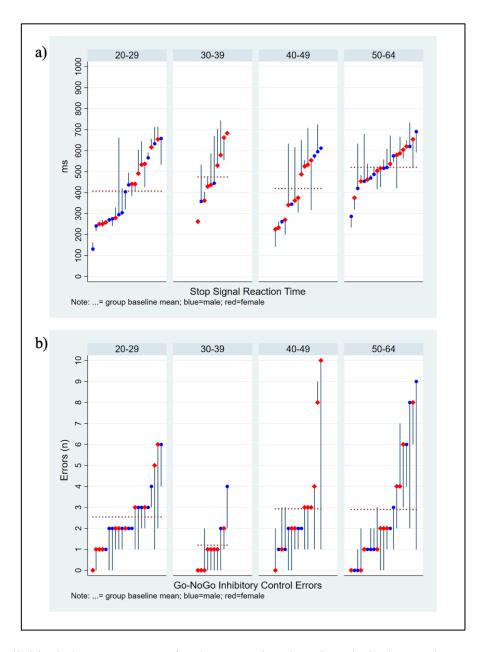


Figure 8. Individual change on retest for the Stop Signal Task and Flanker Go/No-go Task. a) stop signal reaction time on the Stop Signal Task; b) number of inhibitory control errors on the Go/No-go task. Lines represent change on retest; dotted line represents group baseline mean; blue dots represent males; red dots represent females.

| Cognitive measure | Test | Retest | | | | | | |
|-----------------------|------------------|------------------|-------|----|-------|-------|---------------|--------------------|
| | Mean (SD) | Mean (SD) | t | df | р | d | $BF_{01}{}^a$ | Learning Effect |
| WAB score | 1190.15 (607.78) | 1101.48 (446.14) | 1.37 | 66 | .177 | 0.17 | 3.08 | No |
| WAB PE | 0.06 (0.09) | 0.06 (0.08) | 0.40 | 66 | .687 | 0.05 | 6.90 | No |
| SSRT | 454.94 (140.96) | 489.71 (170.67) | -2.53 | 67 | .014 | -0.31 | 0.39 | Likely |
| Flanker GNG IC errors | 2.54 (2.30) | 1.56 (1.65) | 3.94 | 67 | <.001 | 0.48 | 0.01 | Yes |
| N-back PC | 0.68 (0.13) | 0.72 (0.12) | -2.58 | 67 | .012 | -0.31 | 0.35 | Likely |

Descriptive Statistics and Tests of Change in Cognitive Task Performance Over a Seven-Day Retest Period

Note. N = 67 for all Whack-a-Bottle measures due to the baseline measure of one participant to not be recorded; N = 68 for all other cognitive measures. GNG = Go/No-go; Whack-a-Bottle=WAB; percent of inhibitory control errors = PE; stop signal reaction time = SSRT; inhibitory control errors = IC errors; Go/No-go = GNG; percent correct = PC.

^a $BF_{01} > 3$ indicates strong evidence in favour of no change; $BF_{01} < 0.3$ indicates strong evidence in favour of change.

User Experience Questionnaire-Short.

Participants substantially preferred the WAB to a more traditional assessment of IC (i.e., SST) on both pragmatic (d=1.30) and hedonic scales (d=0.52) of the UEQ-S (Table 12). Using UEQ norms, mean participant ratings for pragmatic quality for the WAB were in the top 10% of results ('excellent' range), in the third quartile (50-75%, 'above average' range) for hedonic quality, and in the second quartile (75-90%, 'good' range) for overall rating (Figure 9).

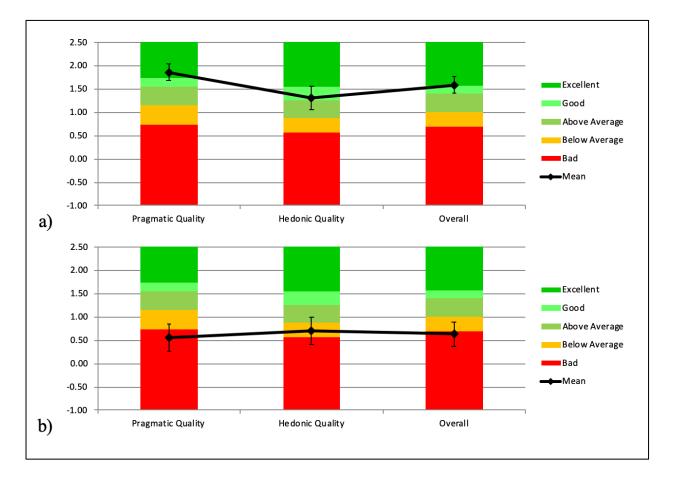


Figure 9. Mean scores of the a) Whack-a-Bottle and b) Stop Signal Task in relation to a benchmark data set. Error bars represent 95% confidence intervals. Benchmark data set is based on >280 studies of software user experience reports.

| Paired Samples t-Test Between the Whack-a-Bo | ttle Task and Stop Signal Task on the | User Experience Ouestionnaire - Short |
|--|---------------------------------------|---------------------------------------|
| | I I I I I I I I I I I I I I I I I I I | \mathcal{L} |

| Comparison | WAB | SST | | | | 95% | CI | |
|-------------------|--------------|--------------|------|----|-------|-------|-------|------|
| | Mean (SD) | Mean (SD) | t | df | р | Lower | Upper | d |
| Pragmatic Quality | 23.42 (2.89) | 18.24 (4.85) | 9.49 | 66 | <.001 | 4.09 | 6.27 | 1.30 |
| Hedonic Quality | 21.15 (4.12) | 18.79 (4.93) | 3.66 | 66 | .001 | 1.07 | 3.66 | 0.52 |
| Overall UEQ | 44.57 (6.04) | 37.03 (6.12) | 7.30 | 66 | <.001 | 5.48 | 9.60 | 1.24 |

Note. Pragmatic and Hedonic refer to the two scales on the User Experience Questionnaire – Short Form. WAB = Whack-a-Bottle; SST = Stop Signal Task.

Method: Study Two

Study two examined whether the WAB was sensitive to the effects of alcohol intoxication.

Participants

The current study recruited 37 participants (22 females) aged between 18-31 years-old (M=22.84, SD=3.12) from the general community through social media. Participants were reimbursed \$50 for their time. Eligibility criteria included: (1) age between 18-31, as individuals within this age range are the most likely to binge drink and be susceptible to alcohol-related harms (Australian Institue of Health and Welfare, 2017); (2) English as a first language; (3) completed high school; (4) normal or corrected-to-normal vision; (5) regular sleeping patterns; (6) frequent alcohol consumption to ensure safety of alcohol doses administered (minimum consumption of two standard alcoholic beverages on one occasion in the preceding month); (7) and body mass index between 18.50 and 31.0 to minimise the differential rate of alcohol abortion due to body mass (Foster & Marriott, 2006).

Participants were excluded from the study for: (1) recent illicit drug use (preceding six months); (2) regular tobacco use; (3) history of a significant medical/psychological conditions; (4) significant psychological distress (Kessler Psychological Scale; K10 score \geq 30 indicates clinical levels of psychological distress) (Kessler et al., 2002); (5) history of alcohol or drug abuse or dependence disorder; or use of alcohol at hazardous or harmful levels (Alcohol Use Disorder Identification Test score \geq 16 indicates likely alcohol dependence; AUDIT) (Babor, Higgins-Biddle, Saunders, & Monteiro, 2001).

Materials and Apparatus

Cognitive test battery. The same cognitive test battery as described in study one was

utilised. The same standardised order of the cognitive tests was also used for each BrAC target; the SST was not administered at BrAC 0.05% ascending to reduce administration time.

Breath alcohol concentration. Participant's Breath Alcohol Concentration (BrAC) was measured using Andatech AlcoSense Prodigy S police-grade breathalysers. This device meets Australian standards; AS3547.

Procedure

The Tasmanian Health and Medical Human Research Ethics Committee approved the project (Approval #H0016125: Appendix F). Eligible participants (Appendix G) were asked to attend a four-five hour laboratory session, abstaining from alcohol for 24 hours and food for 4 hours prior to attending. Weight and height were measured and a preliminary breath alcohol assessment was conducted to exclude on-arrival intoxication; informed consent was also obtained (Appendix H and I). Before commencement of the cognitive test battery, the cognitive tests were explained both verbally and using instruction sheets. Participants then undertook the cognitive test battery at a BrAC of 0.00%.

Participants were then administered an alcoholic beverage following National Institute on Alcohol Abuse and Alcoholism guidelines (NIAAA, 2004); a combination of vodka, 300mls of soda water and 100mls of sugar-free raspberry flavoured syrup. The quantity of alcohol administered to each participant was calculated according to the Widmark equation (Figure 10) (Dry et al., 2012), allowing for the target of 0.08% BrAC to be reached. Participants were given ten minutes to orally consume their alcoholic beverage. They were instructed to avoid retaining the beverage in their mouths for longer than five seconds as retention of mouth alcohol can influence breathalyser sensitivity (Spector, 1971). Water was used to rinse participant's mouth after they had consumed their beverage to further eliminate alcohol mouth retention. Immediately after, a post-consumption breath assessment was taken. Breath alcohol concentration assessments were completed every ten minutes post-consumption to track participants breath alcohol ratings. Participants completed the cognitive test battery at 0.05% BrAC, again at 0.08% BrAC on the ascending limb of the alcohol curve, and lastly at 0.05% BrAC on the descending limb of the alcohol curve.

Alcohol Dose (mg) = $W\rho(C_1 + \beta t)$

| W | Body | weight o | of part | icipant | (kg) |
|----|------|--|---------|---------|------|
| •• | 204 | ······································ | - por | | (D/ |

- ρ Distribution of alcohol in the body
- C₁ Target breath alcohol concentration (BrAC; g/100mL)
- *t* Time (Hours) from dose
- β Rate of alcohol elimination. Set at 0.015g/100mL/hour

Note: Final alcohol dose (mg) was divided by 0.8 to achieve a dose in millilitres.

Figure 10. Widmark equation used for calculating quantity of alcohol dose required to achieve 0.08% target breath alcohol concentration based off sex, weight and height of participant (Dry et al., 2012).

Participants were required to stay within the testing facility until they reached three consecutive breath alcohol ratings of 0.03% or below (if they held a full drivers licence) or a breath alcohol rating of 0.00% (if they held a provisional drivers licence and intended on driving).

Design and Analysis

Technical malfunction resulted in the data for one participant to not be recorded for the SST, Flanker GNG and N-back task. Dependent variables were percent of IC errors and score on the WAB; number of IC errors on Flanker GNG; SSRT on the SST; % correct on the N-back. Mixed Linear Models (MLM) for repeated measures with restricted maximum likelihood

estimation (REML) and a diagonal covariance structure were conducted on IBM SPSS v23. Target BrAC (0.00%, 0.05% ascending, 0.08% peak, 0.05% descending) was included as a fixed and repeated effect. Sex and the interaction between target BrAC and sex were also included as fixed effects. 'Participants' was included as a random effect to account for intra-individual variation. To account for differences in general cognitive function, participants' WTAR score was included as a covariate for all measures. Benjamini-Hochberg adjusted pairwise comparisons were used to check for differences in dependent variables across target BrAC. Alpha levels were maintained at p < .050.

The sensitivity of each task to impairments of alcohol was examined by calculating the effect sizes for the magnitude of the difference between baseline (0.00 BrAC) and 0.05 BrAC ascending and descending; and between baseline (0.00 BrAC) and 0.08 BrAC, for each of the three IC measures (WAB; Flanker GNG; SST). Effect sizes were calculated using Hedges' g, as it accounts for the bias in small samples compared to Cohen's d (Hedges, 1981).

Results: Study Two

Sample Characteristics

The sample consisted of young adults who reported average levels of intellectual functioning, low psychological distress and strong educational background, with all participants completing year 12 schooling. All participants were regular drinkers and reported drinking two or more standard drinks in the last fortnight.

Demographic Characteristics (N=37)

| Sample Characteristic | Mean (SD) | Range |
|---|---------------|------------|
| Age (years) | 22.84 (3.12) | 18.0-31.0 |
| % Male | 41% | |
| Harmful Alcohol Use (AUDIT) ^a | 6.57 (2.80) | 1.0-14.0 |
| Psychological Distress (K10) ^b | 15.03 (3.97) | 10.0-28.0 |
| Intellectual functioning (WTAR) ^c | 113.00 (7.09) | 92.0-126.0 |
| Body Mass Index ^d | 23.88 (3.13) | 18.5-31.2 |
| Average number of standard drinks in the last fortnight | 10.10 (9.50) | 2.0-50.0 |
| Sleep patterns ^e (hours per weeknight) | 7.88 (0.89) | 5.0-9.0 |
| (hours per weekend night) | 8.42 (1.09) | 6.0-12.0 |

^aThe Alcohol Use Disorder Identification Test (AUDIT; Babor et al., 2001) is a measure of alcohol dependency. Scores range from 0 - 40, with scores ≥ 16 indicative of harmful or hazardous alcohol use. ^bThe Kessler Psychological Scale (K-10) is a measure of psychological distress, with scores ranging from 10 - 50. K10 scores ≥ 30 indicate clinically significant levels of psychological distress. ^cWechsler Test of Adult Reading (WTAR); standardised score is 100 and scores are normed based on age. WTAR score <70 is indicative of intellectual functioning disorder (Wechsler, 2001). ^dThe healthy Body Mass Index (BMI) range is between 18.5-24.9; scores above 25.0 are considered overweight and above 30 are considered obese (World Health Organization, 2019). ^cHealthy adults require on average 7 - 9 hours sleep per night for normal functioning (National Sleep Foundation, 2016).

Breath Alcohol Concentration (BrAC)

Since BrAC was zero at baseline, only mean BrAC for each target BrAC post-beverage

administration was calculated. At each target BrAC, intra-individual variation was observed

(Figure 11). At the 0.05% ascending target BrAC 'timepoint', mean BrAC was 0.057%

(SD=0.01); 0.075% (SD=0.01) at the 0.08% target BrAC timepoint and 0.049% (SD=0.00) at the

0.05% BrAC descending timepoint.

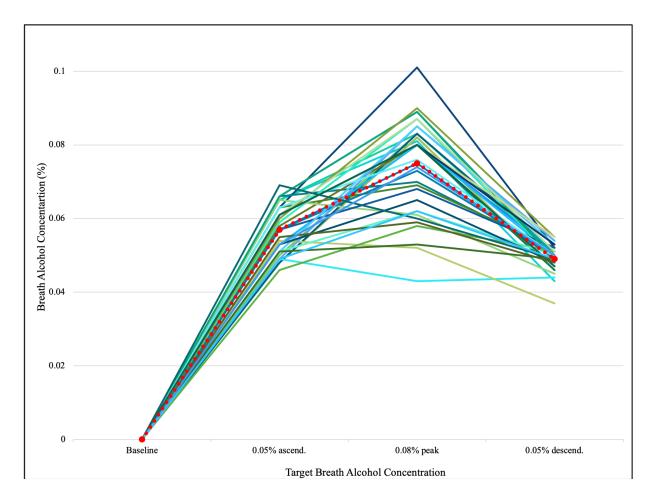


Figure 11. Mean and individual breath alcohol concentrations (BrAC) attained at each target BrAC. Individual lines represent each participant's attained BrAC at each target BrAC timepoint. Mean BrAC of all participants at each target BrAC is represented with the red dotted line.

Manipulation Checks

Whack-a-Bottle. Percent correct on the WAB was used to assess the validity of the task. Across each target BrAC, the mean performance of participants was above 96%, indicating that participants performed the task correctly (Figure 12).

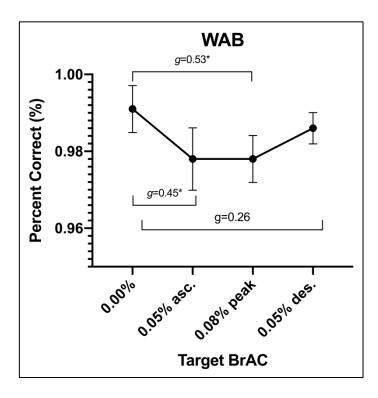


Figure 12. Means with 95% confidence intervals for percent correct on the Whack-a-Bottle Task at each target breath alcohol concentration (BrAC).

Stop Signal Task. The SST uses a staircase procedure to modify SSD following correct performance and requires the proportion of IC errors to be close to 50% for accurate calculation of the SSRT. Across each target BrAC, the percent of responses remained above 50%, indicating that delayed responses on the SST did not interfere with the validity of the SSRT results (Figure 13).

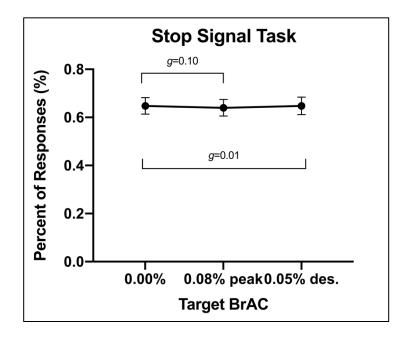


Figure 13. Means with 95% confidence intervals for percent of responses on the Stop Signal Task at each target breath alcohol concentration (BrAC).

Inhibitory Control Measures: Sensitivity to Alcohol Intoxication

Whack-a-Bottle. There were statistically significant main effects of target BrAC for both IC errors and the overall global score (Table 14), indicating that alcohol intoxication influenced performance on these measures. A significant main effect of sex was found only for WAB score and no statistically significant target BrAC x sex interactions were found. Since the sensitivity of each WAB measure to acute alcohol intoxication was the primary focus of the study, follow-up pairwise comparisons at each target BrAC were performed (Figure 14). For IC errors, there were moderate magnitude (g~0.7) impairments from baseline performance seen at all target BrAC levels (Figure 16). For global score, significant and moderate magnitude impairments from baseline were seen at 0.05% BrAC ascending (g=0.87) and at 0.08% BrAC (g=0.51) (Figure 16). No significant impairments were apparent by 0.05% descending timepoint (g=0.14).

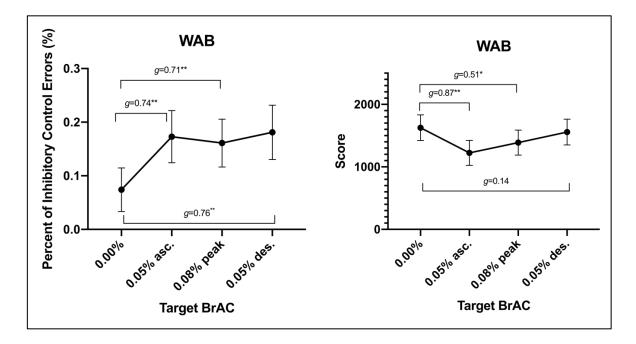


Figure 14. Means for each Whack-a-Bottle measure at each target breath alcohol concentration (BrAC). a) Whack-a-Bottle percent correct; b) Whack-a-Bottle percent of inhibitory control errors; c) Whack-a-Bottle score. Error bars indicate 95% confidence intervals.

Flanker GNG. No statistically significant main effect of target BrAC for IC errors was found (Table 14), indicating that alcohol intoxication did not influence performance. Additionally, no significant main effect of sex was found. There was a significant target BrAC x sex interaction, although follow up pairwise comparisons found no significant difference between males and females across target BrAC. The sensitivity of IC errors to acute alcohol intoxication was investigated using follow-up pairwise comparisons at each target BrAC (Figure 15b). No significant impairments were apparent at all target BrAC levels (ps > .206), indicating that IC errors on the Flanker GNG is not sensitive to alcohol impairment (Figure 16).

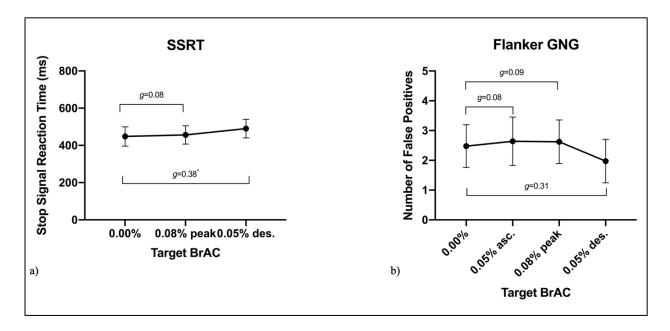


Figure 15. Means for each traditional inhibitory control measure at each target breath alcohol concentration (BrAC). a) stop signal reaction time on the Stop Signal Task; b) number of false positives on the Flanker Go/No-go task. Error bars indicate 95% confidence intervals.

Stop Signal Task. There was a statistically significant main effect of target BrAC for SSRT (Table 14), indicating that alcohol intoxication influenced performance. A significant main effect of sex was also found, however, there was no significant target BrAC x sex interaction. Follow up pairwise comparisons were conducted to determine the sensitivity of SSRT to acute alcohol intoxication (Figure 15a). There was no significant impairment from baseline seen at 0.08% BrAC (g=0.08), while a significant, small impairment was apparent at 0.05% descending timepoint (g=0.38) (Figure 16).

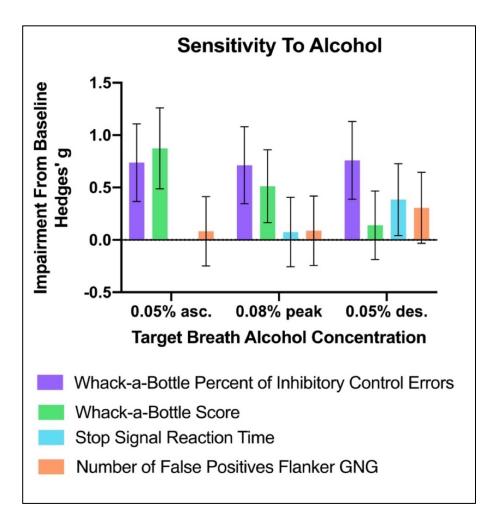


Figure 16. Hedge's *g* effect size for each outcome measure of inhibitory control. Error bars indicate 95% confidence intervals. The Stop Signal Task was not administered at 0.05 ascending BrAC.

Table 14

| | | Target BrAC | | Sex | | Target BrAC x Sex | | | | |
|----------------|---------------------------|-------------|--------|-------|------|-------------------|------|------|--------|------|
| Cognitive task | | F | df_2 | р | F | df_2 | р | F | df_2 | p |
| WAB: | | | | | | | | | | |
| | WAB score | 11.22 | 41.54 | <.001 | 4.58 | 34.01 | .040 | 0.82 | 41.54 | .490 |
| | Percent errors | 11.93 | 42.65 | <.001 | 0.01 | 34.80 | .930 | 0.57 | 42.65 | .635 |
| SST: | | | | | | | | | | |
| | SSRT | 3.33 | 39.35 | .046 | 4.80 | 32.35 | .036 | 0.62 | 39.35 | .544 |
| Flanker GNG: | | | | | | | | | | |
| | Inhibitory control errors | 2.33 | 43.71 | .087 | 1.22 | 33.22 | .278 | 2.85 | 43.71 | .048 |

Interactions and Main Effects of BrAC Target and Sex for Inhibitory Control Measures

Note. Denominator degrees of freedom= df_2 ; numerator degrees of freedom (df_1) for Target BrAC and Target BrAC x Sex = 3 for all cognitive tasks; numerator degrees of freedom (df_1) for Sex = 1 for all cognitive tasks. Whack-a-Bottle=WAB; Stop Signal Task = SST; stop signal reaction time = SSRT; Flanker Go/No-go = Flanker GNG; percent of inhibitory control errors = percent errors.

Correlations

Does the Whack-a-Bottle Task correlate well with traditional measures of inhibitory control under alcohol impairment? There were positive, weak magnitude relationships between measures of IC errors on the WAB and Flanker GNG at both baseline (r=0.19) and peak 0.08% target BrAC (r=0.21) (Table 15). Significant, moderate magnitude inverse correlations were found between WAB IC errors and SSRT at both baseline (r=-0.36) and peak 0.08% target BrAC (r=-0.42). Using the more global measure of WAB score, there was an inverse, trivial nonsignificant relationship with IC errors on the Flanker GNG task at baseline (r=-0.05), increasing to a weak relationship at peak 0.08% target BrAC (r=-0.13). Non-significant, trivial correlations were found between global WAB score and SSRT at both baseline (r=-0.02) and peak 0.08% target BrAC (r=0.05). In contrast, IC errors on the Flanker GNG task had a non-significant, moderate inverse relationship with SSRT at baseline (r=-0.31), falling to weak at peak 0.08% target BrAC (r=-0.17).

Do measures of inhibitory control correlate with tasks of working memory under alcohol impairment? There was a weak inverse relationship between WM performance (percent correct on N-back) and WAB IC errors at baseline (r=-0.11), falling to positive and trivial at peak 0.08% BrAC (r=0.02). There were insubstantial relationships between WM performance SSRT and IC errors on the Flanker GNG at both baseline and 0.08% target BrAC (r<|0.1|; Table 15). Using the more global measure of WAB Score, there were positive, non-significant weak relationships with WM performance at baseline (r=0.19) and 0.08% target BrAC (r=0.24).

Table 15

Cognitive Measures 1. 2. 3. 4. 5. 1. Whack-a-Bottle score -0.02 -0.04 -0.05 0.19 -2. Whack-a-Bottle inhibitory control errors 0.16 -0.36* 0.19 -0.11 -3. Stop Signal Reaction Time 0.05 -0.42* -.31 0.09 -4. Inhibitory control errors Flanker GNG 0.21* -0.13 -0.17 -0.04 -0.02 0.03 5. N-back Percent Correct 0.24 0.09 _

Correlations Between Cognitive Measures at Baseline and at Peak (0.08%) Target Breath Alcohol Concentration

Note. Correlations for baseline, 0.00% target breath alcohol concentration on upper diagonal; correlations for peak, 0.08% target breath alcohol concentration on the lower diagonal. GNG = Go/No-go * p < .05. ** p < .01.

Discussion

The primary aim of the present studies was to assess the performance of the WAB against traditional, gold-standard measures of IC. This was achieved by conducting two laboratorybased, experimental studies. Study one investigated the test-retest reliability of the WAB, while also determining its construct validity by examining the correlations between the WAB and traditional measures of IC, as well as tasks of WM to determine convergent validity. Results did not support the hypothesis that the WAB would demonstrate large magnitude correlations with existing measures of IC, with only weak to moderate magnitude correlations found. The hypothesis that the WAB and traditional measures of IC would moderately correlate with tasks of WM was not supported, with only trivial to weak magnitude correlations found. However, results indicated that the WAB is stable over repeated assessment, supporting the hypothesis of minimal learning effects between test and retest. Additionally, study two investigated the WAB's sensitivity to acute alcohol impairment. Results supported the hypothesis that the WAB is stable of the WAB is a more sensitive measure than traditional IC tasks.

Table 16

| | WAB | Flanker GNG | SST | |
|-------------------------------|------------------|---|-------------------------|--|
| Construct validity | | | | |
| With Flanker GNG | Weak | - | Weak | |
| With SST | Moderate | Weak | - | |
| Convergent validity | | | | |
| With N-Back | Trivial - weak | Trivial | Trivial | |
| Stability on repeated testing | | | | |
| Test-retest correlations | Moderate | Moderate | Strong | |
| Learning effects | No | Yes | Likely | |
| Sensitivity to alcohol | | | | |
| At 0.05% BrAC | Moderate - large | <small< td=""><td>small</td></small<> | small | |
| At 0.08% BrAC | Moderate | <small< td=""><td><small< td=""></small<></td></small<> | <small< td=""></small<> | |

Note. Pearson's correlation coefficient (*r*) representing construct and convergent validity as well as test - retest correlations: $^{+/-}0 - 0.10 = \text{trivial}$, $^{+/-}0.10 - 0.29 = \text{weak}$, $^{+/-}0.30 - 0.49 = \text{moderate}$, $^{+/-}0.50 - 1.00 = \text{strong}$. Hedge's *g* effect sizes represent sensitivity to alcohol intoxication: 0.2 = small, 0.5 = moderate, 0.8 = large. WAB = Whack-a-Bottle; Flanker GNG = Flanker Go/No-go; SST = Stop Signal Task; BrAC = Breath Alcohol Concentration.

Does the Whack-a-Bottle Correlate Well with Traditional Measures of Inhibitory Control?

The WAB produced trivial to moderate magnitude correlations between the Flanker GNG and SST in study one (Table 9). Similarly, the Flanker GNG and SST illustrated a weak magnitude relationship. Comparable magnitude correlations were also observed in study two at both baseline and 0.08% BrAC (Table 15), indicating that the relationships between the IC measures remained relatively stable over each study.

These findings indicate that the IC measures utilised in the present research do not

correlate well together, regardless of their commonality. This is consistent with a large body of literature that has demonstrated similar poor inter-correlations between measures of IC (Rey-Mermet, Gade, & Oberauer, 2018). This is supported by Friedman and Miyake (2004) who illustrated only weak magnitude correlations between the Stroop and SST (r=0.15, p<.05), and Stroop and Antisaccade (r=0.23, p<.05). Tiego, Testa, Bellgrove, Pantelis, and Whittle (2018) further supports this, demonstrating a moderate magnitude relationship between IC errors on a GNG task and SSRT (r=0.39, p<.001). Consequently, the consistently weak to moderate correlations illustrated between measures of IC calls into question the reliability of IC as a psychometric construct (Rey-Mermet et al., 2018).

Bartholow et al. (2018) claims that that the low inter-correlations illustrated between IC measures could be a result of IC as a construct demonstrating task-specific variance. This could explain why only weak to moderate magnitude relationships were found between the IC measures in the present study (Table15). Further, this could account for why the Flanker GNG task and WAB only weakly correlated together, even though both tasks are based off comparable GNG paradigms. A potential mechanism explaining this task-specific variance is the task impurity problem, whereby performance on a task not only reflects the intended EF (in this case IC), but also reflects other cognitive processes that are specific to that task (Miyake et al., 2000).

Since the traditional GNG task utilised in the present research was developed using a flanker paradigm, there is the potential that this task also measures attentional processes rather than selectively focusing on IC (Aschenbrenner & Balota, 2017). This is supported by the Flanker GNG task requiring the capacity to selectively attend to a central target while ignoring highly salient, but irrelevant flankers (Brydges et al., 2012). Although the present study was only investigating the number of IC errors made on the Flanker GNG task, it is possible that the

employment of the flanker paradigm has also resulted in the measurement of attentional processes, which consequently could be masking the existence of an underlying commonality between the WAB and Flanker GNG (Miyake et al., 2000). This could also explain the relatively weak relationships found between the Flanker GNG task and other measures of IC; WAB and SST (Table 9). Hence, the task impurity problem is likely attenuating the magnitude of the correlations between the IC measures.

Does the Whack-a-Bottle and Other Measures of Inhibitory Control Demonstrate Convergent Validity with Tasks of Working Memory?

Trivial to weak magnitude relationships were found between WM performance (percent correct on N-back) and measures of IC (Table 9). Comparable magnitude correlations were also observed in study two at both baseline and 0.08% BrAC (Table 15), indicating that the relationships between WM and IC performance remained relatively stable over each study. Our findings of trivial to weak magnitude correlations between the N-back and measures of IC is inconsistent with previous findings. Research consistently illustrates significant moderate to strong correlations between WM measures (i.e., N-back; Letter Memory Task; Backwards Digit Recall) and traditional tasks of IC (i.e., GNG task; SST; Stroop task; Antisaccade) (Earhart & Roberts, 2014; Friedman et al., 2016; Miyake et al., 2000). This is further supported by Tiego et al. (2018) where significant moderate inverse relationships were found between the Backwards Digit Recall and the GNG task (r=-0.34, p<.001), and also between the SST and Listening Recall (r=-0.35, p<.001).

As previously discussed, debate still exists in the literature regarding whether IC and WM are in fact separate cognitive processes or part of an integrated system (Noel et al., 2013). This is supported by Friedman and Miyake (2004) who have illustrated trivial magnitude relationships

between the Antisaccade and the Random Number Generation task (r=0.09), and between the SST and Reading Span Recall (r=-0.03), suggesting that IC and WM do not have a common variance. Our findings support the notion that IC and WM are in fact relatively separate processes, as indicated by the trivial to weak magnitude relationships that are illustrated between the WM and IC measures (Table 9). However, it should be noted that the task impurity problem, as previously discussed, could also be contributing to the lack of commonality between these two constructs (Miyake et al., 2000).

Does the Whack-a-Bottle Have Good Test-Retest Reliability?

Consistent with our hypothesis, the WAB IC measures produced no learning effects over repeated assessment as indicated by Bayesian and paired samples *t*-tests (Table 11). Since the WAB utilises a random nature (i.e., bottles appear randomly), it is likely that strategy generation is limited, hence learning effects are unlikely to occur. The WAB also demonstrated moderate magnitude test-retest correlations, indicating that performance was relatively stable across retest; the magnitude of these correlations were equivalent with the Flanker GNG task, but were reduced compared to the SST (Table 10).

A potential reason for these findings is that the WAB demonstrated ceiling effects (Table16; Figure 7b), with a large proportion of participants having perfect performance on the task, hence making no IC errors. It is likely that these ceiling effects are attenuating the testretest correlations between the WAB, possibly explaining the reduced magnitude test-retest correlation compared to the SST. There also is the potential that these ceiling effects have masked the presentation of practice effects over repeated assessment. This is because the ceiling effects create an upper limit on the ability of the WAB to change from test to retest, as participants cannot improve on perfect performance. The Flanker GNG and SST also demonstrated moderate and strong magnitude test-retest correlations, respectively. These findings are consistent with a large body of research that has demonstrated that performance on a range of IC tasks (i.e., SST; GNG; Stroop; Antisaccade; Flanker) is associated with performance across a test-retest period (Friedman & Miyake, 2004; Friedman et al., 2016; Rey-Mermet et al., 2018). Specifically, Bender, Filmer, Garner, Naughtin, and Dux (2016) has illustrated strong magnitude test-retest correlations for SSRT (r=0.60), GNG commission errors (r=0.62), Stroop congruency effect (r=0.57), and Flanker RT (r=0.75).

Despite performance remaining consistent across test-retest, it is consistently demonstrated that performance on current IC measures significantly improves over repeated assessment (Beglinger et al., 2005; Langenecker, Zubieta, Young, Akil, & Nielson, 2007; Schapkin, Falkenstein, Marks, & Griefahn, 2007). Weafer et al. (2013) further supports this, demonstrating that paired samples *t*-tests revealed significant differences between test and an eight day retest on the SST (d=0.60), indicating that performance on the task improved on repeated assessment. This is partly consistent with our findings, with the Flanker GNG demonstrating learning effects over repeated assessment (Table 11), suggesting that when undertaking the task, participants' adopted task strategies, hence improving their performance on subsequent testing due to learning (Figure 8b). However, performance on the SST was shown to significantly worsen over the test-retest period (Table 11). Although inconsistent with past research (Soreni, Crosbie, Ickowicz, & Schachar, 2009), this unexpected finding illustrates that performance on the SST is not stable over repeated assessment (Figure 8a), indicating that the task is not appropriate for subsequent use and that it may be falsely sensitive to IC impairment on repeated assessment.

Did Participants Enjoy Whack-a-Bottle More Than Traditional Measures of Inhibitory Control?

Participants reported a better user experience with the WAB compared to a comparative, traditional measure of IC; SST (Figure 9). It is likely that the 'serious games' approach used in the development of the WAB has enhanced engagement of the cognitive test through a more dynamic and interactive display. Sounds, bright colours, feedback (i.e., game scores) and motivational properties (i.e., receiving points for correct responses and losing points for incorrect responses) have improved the appeal of the cognitive test to participants, hence improving the acceptability of task.

Is the Whack-a-Bottle Sensitive to Impairment From Acute Alcohol Intoxication?

The WAB is a more sensitive measure to alcohol impairment across target BrAC than other traditional measures of IC; SST and Flanker GNG (Figure 16). A potential reason that could explain the greater sensitivity of the WAB is that the WAB utilised a greater number of trials in comparison to the traditional measures of IC. Subsequently, the WAB produced a greater number of opportunities to make IC errors, with 16 no-go trials presented compared to 12 stop signals in the SST and 8 no-go trials in the Flanker GNG; it should be noted that these tasks contain a small amount of trials as they have been designed to be extremely brief (Cash, Peacock, Barrington, Sinnett, & Bruno, 2015). Hence, this could explain the WAB's greater sensitivity to IC impairment across target BrAC because participants' had a greater likelihood of making IC errors compared to the other IC tasks. Despite this, even under alcohol impairment, people still tended to make no IC errors on the WAB (Table 17), suggesting that the WAB's difficulty needs to be increased in order to be a more accurate measure of IC.

The greater number of trials on the WAB also influences the strength of the prepotent

response as more go trials are presented compared to the SST and Flanker GNG tasks. The WAB produces a 84% probability that a go stimuli will be presented, while the SST and Flanker GNG have a 75% and 72% probability, respectively. Subsequently, the WAB may elicit a stronger prepotent response compared to the traditional measures of IC. Bartholow et al. (2018) argues that strong prepotency is pertinent to elicit sensitivity to IC impairment. Hence, the stronger prepotent response produced in the WAB could be a possible factor that is contributing to the task's greater sensitivity under alcohol impairment.

The differing sensitivity between the IC tasks could also be influenced by the distinctive aspects of inhibition that are measured (Bartholow et al., 2018). As shown in Table 4, the GNG task has consistently been shown to have increased sensitivity to the acute effects of alcohol compared to the SST. This is likely due to the SST requiring higher EFs to perform the task due to it measuring controlled inhibition, where a response needs to be inhibited after its initiation, rather than automatic inhibition in GNG tasks, where a prepared response is withheld that has not been initiated, which is less cognitively demanding (Littman & Takacs, 2017). This potentially explains why the SST did not detect significant impairments in SSRT at peak 0.08% BrAC and was associated with a trivial magnitude effect size (Figure 15a). However, a small magnitude significant impairment was detected at 0.05% descending target BrAC. These findings are partly consistent with the majority of research (Table 4; Cash et al., 2015) that has found that the SST is not sensitive to alcohol impairment across the alcohol curve. Although a significant impairment was observed at 0.05% descending target BrAC, it is possible that this reflects fatigue effects under alcohol intoxication (Bartholow et al., 2018).

Although the Flanker GNG task is also based off a GNG paradigm, it is claimed to measure more attentional processes rather than solely measuring inhibition (Aschenbrenner &

Balota, 2017). Consequently, the Flanker GNG task is argued to be a less sensitive measure of IC (Bender et al., 2016). This could explain for why no IC deficit was detected across target BrAC in the Flanker GNG (Figure 15b) compared to the WAB. The absence of a IC deficit measured using the Flanker GNG could also be a result of practice effects. As shown in Table 11, the Flanker GNG exhibited strong evidence of learning effects over repeated assessment. Subsequently, the repeated completion of the task over each target BrAC could have resulted in task learning, leading to alcohol induced impairments in IC to be masked. This is supported by Figure 15b illustrating that less IC errors were made at 0.05% descending target BrAC compared to baseline. Hence, it is possible that practice effects have weakened the sensitivity of the Flanker GNG task.

Limitations and Future Directions

While methodologically sound, the reliability of the results obtained for the WAB are limited due to a large proportion of participants making no IC errors on the task, hence producing ceiling effects (Table 17). In comparison to the Flanker GNG, the WAB produced a substantially larger proportion of ceiling effects, with over 50% of participants making no IC errors on both test and retest. The discrepancy between the WAB and Flanker GNG indicates that the difficulty of the two tasks are not comparable.

Table 17

| | Number of no inhibitory control errors | | | | | | |
|-------------------------|--|--------|--------------------|--|--|--|--|
| Inhibitory control task | Test | Retest | Alcohol impairment | | | | |
| Whack-a-Bottle | 53.7% | 55.9% | 17.1% | | | | |
| Flanker Go/no-go | 13.2% | 25.0% | 12.6% | | | | |

Percent of No Inhibitory Control Errors on the Whack-a-Bottle and Flanker Go/No-Go Tasks

Note. Alcohol impairment includes 0.05% ascending, 0.08% peak, and 0.05% descending breath alcohol concentration.

These ceiling effects have the potential to attenuate the correlations between the WAB and other measures of IC, as well as the test-retest correlations on the WAB. This is a result of ceiling effects artificially depressing the magnitude of correlations by restricting the distribution range of the dataset (Goodwin & Leech, 2006). Consequently, this could explain for the trivial to moderate magnitude correlations illustrated between the WAB and traditional measures of IC, as well as accounting for the weaker magnitude test-retest correlations exhibited by the WAB. Hence, it is likely that the magnitude of the correlations found are not representative of their true value if comparable ceiling effects were found between the Flanker GNG and WAB.

Although the ceiling effects on the WAB are potentially reducing the reliability of the results obtained from this research, it is now apparent that further development of the task is required to reduce these ceiling effects. This is supported by Table 17, which illustrates that the drop in the percent of perfect performance on the WAB under alcohol intoxication strongly argues for making the task more difficult. This can be achieved by increasing the number or speed of trials and/or decreasing stimulus presentation time, which can be easily managed in task configuration settings.

Future research should aim to replicate the present findings with a more difficult version of the WAB to further validate the psychometric quality of the task against comparative, traditional IC measures and to obtain normative data for standardised assessment. Additionally, future research should investigate the use of the WAB for ICT in substance-dependent individuals, whereby IC is strengthened through repeated inhibition of a prepotent response to salient stimuli (Luijten et al., 2014). As previously discussed, ICT has been shown to reduce alcohol consumption when no-go targets are repeatedly paired with alcohol-related stimuli (Jones et al., 2016). Hence, the WAB has been specifically developed to foster ICT in substance-dependent individuals through the use of alcohol-related no-go targets. Since the WAB is compatible with most Android devices, the practicality of its use in ICT is further enhanced through the portability of the task, as treatment retention is poor in substance-dependent individuals (Wilcox et al., 2014).

Conclusion and Implications

The present study examined the psychometric quality of the WAB against traditional gold standard measures; SST and Flanker GNG, to determine whether it was a valid and sensitive measure of IC. Results revealed that the WAB demonstrates good face validity and equivalent reliability with traditional measures of IC. The WAB also demonstrated minimal learning effects over repeated assessment, while comparative IC measures revealed that performance was not stable across test-retest. However, it is likely that the substantial proportion of participants displaying no IC errors on the WAB could be attenuating the magnitude of the correlations between the tasks and obscuring the potential for learning effects. Hence, reliability could be improved by further development of the task to reduce ceiling effects. Finally, it was demonstrated that the WAB was a more sensitive measure to acute alcohol impairment across target BrAC than other traditional measures of IC, with large magnitude deficits in IC performance found at ascending, peak and descending BrACs.

These findings illustrate that the WAB has the potential to be a sensitive and robust measure of IC that could be used for research purposes and in treatment contexts for ICT in substance dependent populations. The WAB has been specifically developed using a 'serious games' approach to be free, portable and brief, with automated scoring and interpretation. Its simplicity allows for no specialist knowledge to be required for administration, making it freely accessible to clinicians and the research community. Hence, the practicality of the WAB accommodates the needs of researchers and clinicians, while also enhancing the engagement of its consumers through motivational properties. However, before use in these contexts, further development of the task is required to ensure it is a robust IC measure.

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 doi:10.1111/j.1365-2125.2010.03846.x

Appendices

Appendix A

Ethics approval: Study One

Sent via email

From: ss.ethics@utas.edu.au Sent: Monday, 20th May 2019 8:22AM To: Raimondo Bruno Cc: Matthew Gretton; Erin Van Der Kley; Tanya Wilson; Megan Young Subject: H0018073 Validation of brief mobile/tablet based assessments of processing speed, inhibitory control and impulsivity

Dear AssocProf Bruno

Ethics Ref No: H0018073 Project title: Validation of brief mobile/tablet based assessments of processing speed, inhibitory control and impulsivity

The above Minimal Risk application has been approved by the Chair of the Tasmania Social Sciences Human Research Ethics Committee, on behalf of the full committee. Approval is for four years and conditional upon receipt of an annual Progress Report. Ethics approval for this project will lapse if a Progress Report is not submitted.

A copy of the approval letter is attached for your records.

The Ethics Committee wishes you all the best with the project.

If you have any questions, please contact <u>SS.Ethics@utas.edu.au</u> or 03 6226 6254.

Kind regards Jude

Jude Vienna-Hallam Executive Officer, Social Science HREC Research Integrity and Ethics Unit I Research Division University of Tasmania Building 1, 1st Floor, 301 Sandy Bay Road Hobart TAS 7001 Telephone: 03 6226 2608 www.utas.edu.au/research-admin/reasearch-integrity-and-ethics-unit-rieu

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Appendix B

Screening Questionnaire: Study One

| | ntial |
|--|-------|
| | |
| | |

Pre-Screening Survey

Please complete the survey below.

Thank you!

Researchers at UTAS have developed some new cognitive tasks that can be used on smartphones or tablets. We want to make these freely available for other researchers and for clinical purposes. Before we can unleash them, we need to make sure that the new tasks on mobile phones/tablets work in the same way as pencil and paper-based and other versions of the tasks.

Participation will involve 2 x 45-30 minute sessions, run at the University of Tasmania Sandy Bay Campus. Sessions are conducted approximately 1 week apart.

You will be reimbursed \$20 at the end of the second session.

Thank you for your interest.

| Please complete the information below. | |
|---|--|
| What is your age group? | 20-29 30-39 40-49 50-59 60-64 other |
| What is your gender? | |
| Do you have any problems with your eyesight that aren't corrected by glasses or contacts? | ⊖ Yes ⊖ No |
| Do you have any concerns about your memory or attention span? | ⊖ Yes ⊖ No |
| Do you have any major health issues currently? | ⊖ Yes ⊖ No |
| Are you taking any prescribed medications currently (not including contraception) | ⊖ Yes ⊖ No |
| please specify the medication(s) | |
| Do you have any current mental health problems? | ⊖ Yes ⊖ No |
| What is your main language? | ○ English ○ Other |
| Have you previously completed the Transdermal Alcohol and Cognition Study? | ☐ Yes ☐ No ☐ Unsure |



Page 2 of 2

Thank you answering the screening questionnaire, we appreciate your assistance. The researchers will be in contact with you as quickly as possible to confirm whether you are eligible to participate

What is your email address?

What is the best phone number to contact you on?

Please indicate which days would suit you best for completing these sessions

☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday ☐ Sunday

Appendix C

Information sheet: Study One

Validation of brief mobile/tablet based assessments of processing speed, inhibitory control and impulsivity

Invitation

This is an independent study conducted by Associate Professor Raimondo Bruno, in the School of Medicine (Psychology) at the University of Tasmania. Other researchers involved in the study include Dr Matthew Gretton, who programmed one of the tasks, and Tanya Wilson, Edin Van Der Kley and Megan Young as part of their research for the degree of Honours in psychology.

1. What is the purpose of this study?

We have developed **three** new tests that can be used on mobile smartphones or tablets. They will look at processing speed, inhibitory control, and impulsivity. We want to make these freely available for other researchers and for clinical purposes. Before we can put these new tests out to be used, we need to make sure that the new tests on mobile phones/tablets work in the same way as pencil and paper-based and other versions of the tasks. We also need to make sure that they give a reliable measure of people's processing speed, inhibitory control and impulsivity – and by that we mean that it should give you similar results if you repeat the test. Once we have tested these, then we will be able to confidently use the new test in research studies and make them available for others to use.

Processing speed is basically a measure of how quickly your brain can deal with information and make decisions. For example, working out if something on a computer screen is an X or a Y; or seeing if there is a match among a group of images. Processing speed is an important part of cognition (thinking) because it is a skill that is necessary for performing well in a number of different areas. For example, how well you can work with information in working memory (such as doing maths problems in your head) depends on how quickly you can process information. This new test is based on a very well used task that is usually done with pencil and paper. We have made a new and harder version that works on mobile phones so that we can measure processing speed in real world contexts. In the future, we're hoping to use this task to do things like measure processing speed over the work day in people who work with complicated machinery; to measure processing speed over the course of an evening out while people are drinking alcohol; or over the course of attending music festivals.

Inhibitory control is how good you are at stopping responses once you've started. For example, like when you have started to move into a different lane while driving but suddenly notice a car in your blind spot, so you shift back into your original lane. The ability to do this skill is really important for a number of areas, but in particular things like being able to withstand cravings and staying abstinent when you're trying to stop smoking or drinking. The existing measures for this are good but both expensive and pretty boring for people to complete. We have developed a new measure that we hope is more interesting, based on the traditional 'whack-a-mole' game.

Impulsivity is about whether your decisions are focused on immediate reward or what is better for you in the long term. Like, for example, when you are hungry and need to choose between satisfying but unhealthy foods (like hot chips) and less satisfying but more health foods (like fruit). We have made a short version of a questionnaire that asks about preferences for immediate vs long term rewards.

2. Why have I been invited to participate?

We're inviting any adults between 20 and 64 who are healthy and not taking any medications that are willing to help us validate these tasks.

We're not just asking people who are university students to take part, but if you are involved with the University of Tasmania, you should know that if you don't want to take part in this study, that is OK, and it is not going to have any impact on the way you are treated by the University. If you start taking part in this study, and decide that you don't want to continue, that's not going to have any impact on how the University will treat you either.

3. What will I be asked to do?

There's two parts to this study. Each part will take between 30 and 45 minutes.

After making sure that you are eligible to take part, you will be given some tests of cognition (thinking). These might ask you to pronounce some unusual words out loud (like 'yacht'), to pick the direction of an arrow on screen as quickly as possible, to work out whether there are matches in a group of images. Each of these are pretty short (2-4 minutes) and are designed to be tricky.

Then you will complete the three new tasks:

Processing speed: What you will need to do is to work out, as quickly as possible, if any of a group six images on screen are an exact match to either of two target images. There will be a lot of these trials, and about half of them will be matches and half of them won't match.

Inhibitory control: This is just like a game of 'whack-a-mole'. Here, different sorts of bottles will pop up on a screen, one at a time. As quickly as possible you have to smash any bottles of healthy drinks (like water or oange juice). Every now and then, a bottle of alcohol (beer or wine) will pop up, and you have to avoid hitting those ones. You will have around 100 trials to get as many points (for hitting the right targets) as possible.

Impulsivity: Here you just need to answer a bunch of 'would you rather'-type questions. For example, you might be asked "Would you prefer \$54 today or \$55 in 117 days?". All you have to do is pick whether you would, hypothetically, prefer to have the money today or to wait for the larger option. There are no 'right' or 'wrong' answers, we're just interested in your opinion. You can take regular breaks (we'll remind you about this option).

About a week later, we'd like you to invite you to come back and do the same tasks again. This might seem a little pointless, but knowing how much people's performance changes after they have done the task is critically important if we are going to use the test in repeated studies. It is important to know that it's up to you whether you want to do any of these bits of the study, and if you are only ok with some parts and not others, that's ok, you can still take part in the bits of the study that you are comfortable with.

4. Are there any possible benefits from participation in this study?

The main benefit from taking part in this study is making a contribution to science by making sure that the tests we use are valid.

We appreciate your time and inconvenience in contributing to research, and we are able to provide reimbursement of \$10 for each of the sessions (\$20 in total, paid once you've completed both parts). If you decide to do only one part, we will of course provide the amount of payment for the part you complete.

5. Are there any possible risks from participation in this study?

These tests are all designed to be challenging, but it is unlikely that you would find them stressful or that they would cause you to be upset. It might feel a bit annoying if you make a

mistake but the tests are all designed to be challenging enough so that **everybody** is going to make mistakes somewhere.

We are going to keep your personal details confidential. The consent forms with identifying information (such as your contact details) are kept separately from all other information from this study (such as the questions about your substance use). They are stored securely at the University. All information from the study is stored only with a study ID (e.g. CTX777). As soon as you complete the study, any link between your identifying information and study ID is securely destroyed, making it very difficult for an individual person to be identified by their data.

6. What if I change my mind during or after the study?

As noted above, it is completely fine for you to decide not to answer any questions that you're not comfortable with. That won't affect your relationship with the University. The same applies if you start the study and then decide that it is not for you. You don't need to explain why. If you decide to withdraw, you will still receive reimbursement for your time involved in the study, on a pro-rata basis.

If you decide that you don't want to be part of the study, and you let us know before the end of your participation in the study, we'll be able to work out which data is yours and we can delete all records and securely destroy any consent forms. If you let us know after you have finished all the parts of the study, we won't be able to remove your data because we would have destroyed the links between your identifying information and the study ID.

7. What will happen to the information when this study is over?

Identifying information will be destroyed as soon as any individual participant completes their part of the study. All the information about performance on the different tasks are stored only using study ID. This will be stored in an electronic database, on secured University of Tasmania servers, and password protected. Hard copies (of your consent form with no link to a study ID) are stored in locked filing cabinets in University of Tasmania storage archives. Both electronic and hard copy data will be destroyed five years after the first publication from this study. A reminder: any information obtained for the purpose of this study that can identify you will be destroyed as soon as you have completed your part in the study or withdrawn your consent. All information, regardless of whether it is identifying or not, will be treated as confidential and always securely stored.

The data from the tests doesn't provide any useful diagnostic information – it is mainly just information about reaction times. Where it is used in research is to test for *changes* as people

get tired, or consume alcohol, or are prescribed medications and the like. Because of this, we are not planning on providing any feedback about your performance to you.

8. How will the results of the study be published?

Study findings will be presented in formal publications and in conference presentations. Only group level analyses will be reported, so there is no way that a particular individual could be identified in any publication. The results will be available on the university of Tasmania publications repository, WARP (<u>https://rmdb.research.utas.edu.au/public/rmdb/q/warp_home</u>) or specifically

here: <u>https://rmdb.research.utas.edu.au/public/rmdb/q/indiv_detail_warp_trans/3812#research-</u> <u>tab-5</u>. You can also contact Raimondo Bruno directly here: Raimondo.Bruno@utas.edu.au

9. What if I have questions about this study?

If you have questions about the study, you can contact Raimondo Bruno at 03 6226 2240 or <u>Raimondo.Bruno@utas.edu.au</u>. This study has been approved by the Tasmanian Social Sciences Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, please contact the Executive Officer of the HREC (Tasmania) Network on +61 3 6226 6254 or email <u>human.ethics@utas.edu.au</u>. The Executive Officer is the person nominated to receive complaints from research participants. Please quote ethics reference number [H0018073].

Thank you for your interest in the study, and your time in reading this information sheet. This is for you to keep. If you want to take part in this study, there is a consent form for you to complete. This will be stored separately from the test results.

Appendix D

Consent Form: Study One

Validation of brief mobile/tablet based assessments of processing speed, inhibitory control, and impulsivity

Consent form for participants

1. I agree to take part in the research study named above.

2. I have read and understood the Information Sheet for this study.

3. The nature and possible effects of the study have been explained to me.

4. I understand that the study involves completion of a number of brief tests, on computers, and pencil and paper, of my thinking.

5. I also understand that I will be asked to come to a second session to repeat these tasks, in order to measure how test performance holds up over time.

6. I understand that participation involves no foreseeable risks.

7. I understand that all my data will be labelled only with a study ID, not my name or any other identifying information, and that any link between my name and Study ID will be destroyed as soon as I have completed my role in the study, whether that be by completion of both sessions or if I decide to discontinue for any other reason.

8. I understand that all research data will be securely stored by study ID only on the University of Tasmania premises for five years from the publication of the study results, and will then be securely destroyed.

9. Any questions that I have asked have been answered to my satisfaction.

10. I understand that the researcher(s) will maintain confidentiality and that any information I supply to the researcher(s) will be used only for the purposes of the research.

11. I understand that the results of the study will be published so that I cannot be identified as a participant.

12. I understand that my participation is voluntary and that I may withdraw at any time without any effect.

I understand that I will not be able to withdraw my data after completing all parts of the study, as any links with identifying information will have been destroyed. Before this point, I am able to withdraw my data if I so wish.

Participant's name:

Participant's signature:

Date: _____

Statement by Investigator

I have explained the project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

If the Investigator has not had an opportunity to talk to participants prior to them participating, the following must be ticked.

The participant has received the Information Sheet where my details have been provided so participants have had the opportunity to contact me prior to consenting to participate in this project.

Investigator's name:

Investigator's signature:

Date: _____

Appendix E

Demographic Survey: Study One

| Please complete the survey below. | | | |
|--|---|---|--|
| Thank you! | | | |
| As a participant in this study, pleas | se answer the | questions below. Thank you! | |
| What is your birthdate? | | · · · | |
| What is the highest level of education you have completed? | | Did not complete high school Year 10 Year 12 TAFE/training Currently completing university degree University degree (inc. honours) Postgraduate degree (Masters, PhD) | |
| Do you have a sleep disorder or sleeping difficulties? | | ○ Yes ○ No | |
| | ns you | | |
| please describe these (inc any medication take) Have you ever had or are you now | | a any of the following? Yes | |
| take) Have you ever had or are you now Fits or convulsions | suffering from | Yes | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy | suffering from | Yes | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness | suffering from | Yes O O | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness Concussion | suffering from No ○ ○ ○ | Yes O O O | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness Concussion Loss of consciousness | suffering from No ○ ○ ○ | Yes 0 0 0 0 0 | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness Concussion Loss of consciousness Severe head injury | suffering from No ○ ○ ○ ○ | Yes 0 0 0 0 0 0 0 | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness Concussion Loss of consciousness Severe head injury Diabetes | suffering from | Yes 0 0 0 0 0 0 0 0 0 | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness Concussion Loss of consciousness Severe head injury Diabetes Hypertension | suffering from No ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ | Yes 0 0 0 0 0 0 0 0 0 0 0 0 0 | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness Concussion Loss of consciousness Severe head injury | suffering from | Yes 0 0 0 0 0 0 0 0 0 | |
| take) Have you ever had or are you now Fits or convulsions Epilepsy Regular giddiness Concussion Loss of consciousness Severe head injury Diabetes Hypertension Heart Condition Other serious physical health | suffering from No ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ | Yes 0 0 0 0 0 0 0 0 0 0 0 0 0 | |

Confidential

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| How often do you smoke tobacco? | Never Monthly Fortnightly Weekly Daily or almost daily | |
|--|--|--|
| Approximately how many hours did you spend playing computer games last week (includes mobile phone games)? | | |

Appendix F

Ethics approval: Study Two

Sent via email

From: human.ethics@utas.edu.au Sent: Monday, 6th May 2019 10:22AM To: Raimondo Bruno Cc: Amy Peacock; Olivia Maynard; Jane Akhurst; Thomas Norman; Erin Van Der Kley; Tanya Wilson; Megan Young Subject: Notification of Amendment Approval: H0016125 Longitudinal Study on Alcohol, Harm and Cognitive Performance in the Festival Environment

Dear AssocProf Bruno,

Ethics Ref: H0016125 Title: Longitudinal Study on Alcohol, Harm and Cognitive Performance in the Festival Environment

This email is to confirm that the following amendment was approved by the Executive Officer on behalf of the Tasmania Health and Medical Human Research Ethics Committee on 6/5/2019:

Amendment Additional Staff: Erin Van Der Kley, Megan Young, Tanya Wilson Information Sheet PITP Information Sheet - Apr2019

All committees operating under the Human Research Ethics Committee (Tasmania) Network are registered and required to comply with the National Statement on Ethical Conduct in Human Research (NHMRC 2007).

This email constitutes official approval. If your circumstances require a formal letter of amendment approval, please let us know.

Should you have any queries please do not hesitate to contact me.

Kind regards

Gina Zappia Ethics Officer Office of Research Services University of Tasmania Private Bag 01 Hobart TAS 7001

Email: Human.Ethics@utas.edu.au http://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu

Appendix G

Screening Questionnaire: Study Two

Confidential UTAS Transdermal Alcohol and Cognition Study

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Thank you for your interest in participating in this research. The purpose of this study is to investigate the relationship between transdermal alcohol concentration, breath alcohol concentration and cognitive performance. Participation will involve attending one 240 minute experimental session at the Psychology Research Centre, Hobart campus, University of Tasmania.

In this session participants will consume a maximum of six standard alcoholic drinks. Participants will then complete computerised behavioural laboratory tasks. Breath alcohol concentration (BrAC) and transdermal alcohol concentration (TAC) will be monitored using hand held breathalysers and transdermal leg bracelets, respectively. Both of these devices are safe and considered non-invasive. At the end of the experimental session, participants will remain at leisure at the Psychology Research Centre until two consecutive BrAC measurements of 0.03% or less are recorded. Participants will be reimbursed \$50 for participation.

We are currently seeking healthy participants who: are aged 18-35, have English as a first language, have completed Year 12, have normal or corrected-to-normal vision, have normal sleep patterns, have no history of any significant neurological condition (including epilepsy), have no significant current physical condition, have no current diagnosis of a significant psychological condition or intellectual disability, regularly consume alcohol, are not regularly taking prescription medication, are not currently using illicit drugs and are able to attend the Hobart campus of the University of Tasmania for one 240 minute session.

If you are still interested and eligible to participate in this research, please complete the following online screening questionnaire. Please note that all information will be kept confidential and securely stored. You can close this browser window at any point during the questionnaire if you are no longer interested in participating. Once again, thank you for your interest in our research. We appreciate your assistance.

| What is your age in years? | | |
|---|---|--|
| What is your sex? | Male Female Other | |
| What is your e-mail address? This is so we can contact you. | | |
| What is the phone number you are most easily reached on? | | |
| What was the highest grade of school you completed? | | |

Confidential

| | Page 2 |
|---|---|
| Which state do you currently live in? | |
| ls English your first language? | ⊖ Yes ⊖ No |
| Which type of drivers license do you currently hold? | No license Learners license Provisional license Full license |
| Health | |
| Do you have any difficulties with vision? | ○ Yes ○ No |
| Are these difficulties corrected with glasses/contacts? | ○ Yes ○ No |
| Do you have a sleep disorder or any sleeping difficulties? | ⊖ Yes ⊖ No |
| On average, how many hours do you sleep on a weekend? | |
| On average, how many hours do you sleep on a weeknight? | |
| Do you work night shifts (e.g., 10pm - 6am) or double shifts (e.g., 8am until midnight)? | ⊖ Yes ⊖ No |
| How many times per week do you work night shifts? | |
| Have you ever had or are you now suffering from any of the following? | Fits or convulsions Epilepsy Regular giddiness Concussion Severe head injury Loss of consciousness Diabetes Hypetension Gastro-oesophageal reflux condition Heart condition Substance abuse/dependence disorder |
| 18. Do you have any other serious physical conditions? | ⊖ Yes ⊖ No |
| Are you currently pregnant or breastfeeding? | ⊖ Yes ⊖ No |
| Are you currently suffering from anxiety or depression? | ⊖ Yes ⊖ No |
| Do you have any other serious mental health conditions? | ○ Yes ○ No |

17/10/2019 9:13am

REDCap

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| What is your approximate height in cm? | |
|--|---|
| | (Note that 1ft = 30.5cm. Please write "I don't know" if you're not sure.) |
| What is your approximate weight in kg? | |
| | (Note that $1 \text{kg} = 2.2$ pounds. Please write "I don't know" if you're not sure.) |
| During the last 30 days, about how often did you feel tired out for no good reason? | None of the time A little of the time Some of the time Most of the time All of the time |
| During the last 30 days, about how often did you feel nervous? | None of the time A little of the time Some of the time Most of the time All of the time |
| During the last 30 days, about how often did you feel so nervous that nothing could calm you down? | None of the time A little of the time Some of the time Most of the time All of the time |
| During the last 30 days, about how often did you feel hopeless? | None of the time A little of the time Some of the time Most of the time All of the time |
| During the last 30 days, about how often did you feel restless or fidgety? | None of the time A little of the time Some of the time Most of the time All of the time |
| During the last 30 days, about how often did you feel so restless you could not sit still? | None of the time A little of the time Some of the time Most of the time All of the time |
| During the last 30 days, about how often did you feel depressed? | None of the time A little of the time Some of the time Most of the time All of the time |
| During the last 30 days, about how often did you feel that everything was an effort? | None of the time A little of the time Some of the time Most of the time All of the time |

Page 4 of 6

| During the last 30 days, about how often did you feel so sad that nothing could cheer you up? | None of the time A little of the time Some of the time Most of the time All of the time |
|--|---|
| During the last 30 days, about how often did you feel worthless? | None of the time A little of the time Some of the time Most of the time All of the time |
| Alcohol Use | |
| Have you consumed an alcoholic drink in the last fortnight (14 days)? | ⊖ Yes ○ No |
| How many standard alcoholic drinks have you consumed in the last fortnight? | |
| The following questions ask about your alcohol us alcohol quantities are provided in standard drinks confidential. | |
| How often do you have a drink containing alcohol? | Never Monthly or less 2 to 4 times a week 4 or more times a week |
| How many standard drinks containing alcohol do you have on a typical day when you are drinking? | ○ 1 or 2 ○ 3 or 4 ○ 5 or 6 ○ 7 to 9 ○ 10 or more |
| How often do you have six or more standard drinks on one occasion? | Never Less than monthly Monthly Weekly Daily or almost daily |
| How often during the last year have you found that you were not able to stop drinking once you had started? | Never Less than monthly Monthly Weekly Daily or almost daily |
| How often in the last year have you failed to do what was normally expected of you because of drinking? | Never Less than monthly Monthly Weekly Daily or almost daily |

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REDCap

| How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session? | Never Less than monthly Monthly Weekly Daily or almost daily |
|--|---|
| How often during the last year have you had a feeling of guilt or remorse after drinking? | Never Less than monthly Monthly Weekly Daily |
| How often during the last year have you been unable to remember what happened the night before because of your drinking? | Never Less than monthly Monthly Weekly Daily |
| Have you or someone else ever been injured because of your drinking? | No Yes, but not in the last year Yes, in the last year |
| Has a relative or friend or a doctor or other health worker ever been concerned about your drinking or suggested you cut down? | No Yes, but not in the last year Yes, during the last year |
| Other Drug Use | |
| How often do you smoke tobacco? | ○ Never |
| | Monthly Fortnighly Weekly Daily or almost daily |
| Have you used cannabis in the last month? | Monthly Fortnighly Weekly |
| | Monthly Fortnighly Weekly Daily or almost daily Yes |
| Have you used cannabis in the last month? Have you used any form of illicit drugs in the past | Monthly Fortnighly Weekly Daily or almost daily Yes No Yes |
| Have you used cannabis in the last month? Have you used any form of illicit drugs in the past month? Are you currently regularly taking prescription | Monthly Fortnighly Weekly Daily or almost daily Yes No Yes No Yes Yes |
| Have you used cannabis in the last month? Have you used any form of illicit drugs in the past month? Are you currently regularly taking prescription medication for medicinal or recreational purposes? | Monthly Fortnighly Weekly Daily or almost daily Yes No Yes No Yes Yes |
| Have you used cannabis in the last month? Have you used any form of illicit drugs in the past month? Are you currently regularly taking prescription medication for medicinal or recreational purposes? Statement of Study Restrictions Have you participated in another study within the last three months for which you had to consume any | Monthly Fortnighly Weekly Daily or almost daily Yes No Yes No Yes Yes Yes |

| idential | | Page 6 |
|--|---------------|--------|
| Are you willing to drink up to six standard alcoholic drinks during the experimental session? Please note that you will not be informed of the specifc quantity of alcohol administered in the beverage until conclusion of the session. | ⊖ Yes ⊖ No | |
| Prior to the session, participants will be asked to abstain from: | ⊖ Yes ⊖ No | |
| Food for 4 hours Caffeine for 8 hours Alcohol for 24 hours Prescription medication for 24 hours Illicit drugs during the course of participation Can you agree to abstain from these items for the | | |
| specified time? | | |
| Are you willing to remain in the laboratory until you breath alcohol concentration is recorded at .03% or less? Provisional license holders who are intending to drive will have to remain in the laboratory until their breath alcohol concentration is at .00%. If not intending to drive provisional license holders will have to remain in the laboratory until their breath alcohol concentration reaches .03% and be required to organise alternative transportation after the session. In addition to food and drink, DVDs and magazines will be provided in the interim. | ○ Yes ○ No | |
| | | |

researchers will be in contact with you as quickly as possible to confirm whether you are eligible to participate. Please email Thomas Norman at utastransdermalstudy@gmail.com if you have any queries or would like a copy of the information sheet.

Please indicate which days would best suit you for completing the experimental session:

| Monday |
|-----------|
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Appendix H

Information Sheet: Study Two



School of Medicine University of Tasmania

> Information Sheet

Alcohol Intoxication, Transdermal Alcohol Assessments and Cognitive Performance

Version 4, April 2019

Introduction

You are invited to participate in a study examining the relationship between transdermal alcohol assessments, cognitive performance and alcohol intoxication. This research is being conducted by Thomas Norman, as partial fulfilment of a Doctor of Psychology degree. Thomas is being supervised by Associate Professor Raimondo Bruno and Dr Amy Peacock from the School of Medicine (Psychology), University of Tasmania. In addition, this research will be part of the research conducted by Erin van der Kley, Megan Young and Tanya Wilson for their Honours in Psychology. The key researchers can be contacted as following: Thomas Norman

(Thomas.Norman@utas.edu.au) or Raimondo Bruno (Raimondo.Bruno@utas.edu.au).

What is the purpose of the study?

The purpose of this study is to investigate the degree to which transdermal alcohol concentration relates to alcohol intoxication and cognitive performance (e.g., reaction time, accuracy, decision-making,) outcomes.

Who can participate?

We are currently seeking participants who are:

- Male or female
- •Aged 18 years or over
- •Completed Year 12
- •Normal or corrected-to-normal vision
- Normal sleep patterns

- •Healthy (no history of significant neurological disorder or current psychiatric disorder, significant intellectual disorder, alcohol/drug dependence, regular tobacco use, or chronic health problems)
- •Regular alcohol consumers (minimum consumption of 2 standard alcoholic drinks on one occasion in the preceding month)
- •Not currently using illicit drugs (i.e., use in the preceding six months)
- •Able to attend the Hobart campus of the University of Tasmania for one three hour session conducted between 9am and 7pm.

What does participation in the study involve?

This research will be conducted in the Perception Laboratory at the School of Psychology, University of Tasmania (Hobart). Interested individuals will complete a brief screening questionnaire that collects data about demographics (e.g., age, sex), medical history, pregnancy/breastfeeding status (females only), psychological wellbeing, reading ability, use of alcohol and other drugs. Eligible participants will be asked to attend one three hour session at the psychopharmacology laboratory.

If participants are deemed eligible, they will be invited to participate in a laboratory session. During this session, participants will be dosed with alcohol (up to .05 breath alcohol concentration) and asked to complete a series of cognitive tasks on a tablet. A breathalyser will be used to monitor participants' breath alcohol concentration throughout the duration of the study. They will be fitted with a continuous alcohol monitoring bracelet around their ankle, which will be worn during the course of the session and taken off before they leave. This bracelet can be taken off at any time if the participant wishes to do so. Session length is dependent on the time taken for the participant to record two consecutive breath alcohol readings of .03% or less (.00% for Provisional licence holders intending to drive). Depending on the individual's rate of alcohol absorption and elimination this time may vary and therefore some sessions may take longer than three hours to complete.

What are the restrictions regarding participating?

Participants will be asked to abstain from alcohol and over-the-counter medication for 24 hours prior to the laboratory session. Participants will be asked to abstain from illicit drugs and tobacco for the duration of participation.

At the end of the laboratory session, participants will remain at leisure (with food and entertainment provided) until they attain two consecutive breathalyser recordings of 0.03% or less measured 15 minutes apart.

Participants holding their provisional driver licence, who are intending to drive will be required to remain in the laboratory until two consecutive BrAC measurements are recorded at .00%. Participants holding their provisional licence who are not intending to drive, will be able to leave the laboratory at .03% BrAC if they sign a declaration in which they agree to be escorted by a nominated guardian to their place of residence and accompanied for a two hour period following session completion. The nominated guardian must be an adult aged 18 years or older who: (i) holds their provisional or full driver licence (ii) directly collects the participant from the research premises and meets the researcher in-person, and (iii) signs a declaration agreeing to escort the

participant directly to their place of residence and accompany the participant for the two hour period following session completion. The researcher reserves the right to retain participants in the laboratory until .03% BrAC for those holding their full driver licence and .00% BrAC for those holding their provisional licence when it is deemed unsafe for the participant to leave at .03% BrAC.

What are the benefits of participating?

Your participation will help us enhance our knowledge of the effects of alcohol on transdermal readings and on cognitive performance outcomes. This knowledge can be used to help educate people and the scientific community regarding the potential outcomes and utility of these measures in alcohol-related research.

What are the risks associated with participating?

There are no anticipated risks of this research. However, if in the unlikely event you experience negative side-effects, please inform the experimenter and the necessary assistance will be sought and provided. We ask that participants refrain from consuming alcohol or operating heavy machinery for four hours post-laboratory session.

Is there any monetary reimbursement for participation?

Participants will be reimbursed \$50 for participation in the session.

How do I volunteer to participate? What if I want to withdraw from participating?

Participation in this study is voluntary. By signing the attached consent form, you are indicating that you are aware of the nature of the study and wish to participate. While we would be pleased to have you participate, we respect your right to decline. There will be no consequences to you if you decide not to participate. If you decide to discontinue participation at any time, you may do so without providing an explanation. However you will be required to remain in the laboratory until your breath alcohol concentration measurement equals 0.03% or less on two separate occasions measured 15 minutes apart.

What will happen to the information I provide?

All information collected will be kept confidential. Each participant will be assigned a code and individual participant data will be identifiable only by that code. All of the data will be stored on password protected secure computers or in a locked cabinet in the School of Psychology for a minimum of five years after the publication of any academic journal articles, at which point all questionnaires will be destroyed using a paper shredder and electronic data will be deleted. The screening questionnaire will be securely destroyed immediately on completion of the study and that any information provided by the participant on the questionnaire will be identifiable only by participant number, kept confidential, and viewed only by the experimenter.

Who do I contact if I have any queries?

If you would like to discuss any aspect of this study please contact Thomas Norman (Thomas.Norman@utas.edu.au). Alternatively, you can contact Dr Raimondo Bruno on (03) 6226 2240 or email Raimondo.Bruno@utas.edu.au.

How do I find out the results of the study?

A summary of the results will be available on the Research webpage of the School of Psychology, University of Tasmania (http://fcms.its.utas.edu.au/scieng/psychol/). Results of the study can also be provided by Thomas Norman (Thomas.Norman@utas.edu.au).

Who do I contact if I have a complaint about the study?

This study has been approved by the Tasmanian Social Science Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote H0016125.

Who do I contact if I wish to speak to someone about my alcohol or drug use, or mental health?

As aforementioned, a number of simple screening questionnaires will be administered assessing psychological functioning and alcohol and other drug use. Whilst it is not anticipated that these questionnaires will cause distress, please do not hesitate to let the researcher know if you do not wish to fill them in. If you are concerned about your drinking or mental health, please contact the Tasmanian Alcohol Drug Information Service 1800 811 994 or Lifeline 13 11 14 (both services available 24 hours a day).

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

Appendix I

Consent Form: Study Two



School of Psychology University of Tasmania

Consent Form

Alcohol Intoxication, Transdermal Alcohol Assessments and Cognitive Performance

1.I have read and understood the 'Information Sheet' for this project.

2. The nature and possible effects of the study have been explained to me.

3.I understand that the study involves attending the Cognitive Neuroscience Laboratory for one four to five hour session. This can be completed on a mutually convenient day of your choosing.

4.<u>I understand that my height, weight, reading ability, psychological wellbeing, demographic information, drug and alcohol use history and pregnancy/breastfeeding status (females only) will be assessed to ensure my eligibility for participation. I understand that in the session I will complete measures of cognitive performance and alcohol use, as well as having my height and weight measured.</u>

5.I understand that I will be asked to

sign a declaration and complete a breath alcohol concentration measurement (via a breathalyser) to confirm my abstinence at the start of the laboratory session.

6.I understand that in the laboratory session I will receive a beverage containing alcohol. I understand that I will be given enough alcohol to receive a breath alcohol reading of .05. I understand that after beverage consumption, I will be asked to

complete a number of laboratory cognitive-behavioural performance tasks during which my behavioural responses will be recorded. I understand that my breath alcohol concentration will be recorded throughout the laboratory session.

7.I understand that I will be asked to remain in the laboratory until my blood alcohol concentration equals 0.03% or less on two occasions measured 15 minutes apart. I acknowledge that I have been advised to refrain from drinking alcohol or operating a vehicle or other heavy machinery for four hours after the end of the experimental session.

8.I understand that if I hold a provisional driver licence and I intend to drive I will be required to remain in the laboratory until my breath alcohol concentration is .00% on two consecutive occasions. I understand that if I hold a provisional driver licence and do not intend to drive I will be able to leave the laboratory at .030% BrAC after signing a declaration in which I agree to be escorted by my nominated legal adult to my place of residence and be accompanied for a two hour period following session completion. I

understand that the nominated legal guardian must be an adult aged 21 years or older who: (i) holds their provisional or full driver licence (ii) directly collects me from the research premises and meets the researcher in-person, and (iii) signs a declaration agreeing to escort me directly to my place of residence and accompany me for the two hour period following session completion. Furthermore, I understand that the researcher reserves the right to retain participants in the laboratory until .03% BrAC for those holding their full driver licence and .00% BrAC for those holding their provisional licence when it is deemed unsafe for the participant to leave at .03% BrAC. I acknowledge that I have been advised to refrain from drinking alcohol or operating a vehicle or other heavy machinery for four hours after the end of experimental sessions.

9. I understand that I will be fitted with a continuous alcohol monitoring bracelet during the sessions, but that I may take this off at any time and for any reason.

10.I understand that I will be provided reimbursement to the sum of \$50 for participation. If I withdraw from the study prior to concluding all sessions I will not be eligible for monetary reimbursement, unless the withdrawal is due to an unexpected adverse event.

11.I understand that, while there are no anticipated risks associated with this study, I should inform the experimenter immediately if any unexpected negative side-effects are experienced. I understand the experimenter will immediately cease the session and seek the necessary assistance. <u>I understand that I can contact the researchers, Lifeline or the Tasmanian Drug Information Service should I experience any adverse (phone numbers have</u>

been provided on the information sheet).

12.I understand that the researchers will maintain my confidentiality and that any information I supply to the researcher(s) will be used only for the purposes of the research. My data will only be identifiable by an individual numerical participant code.

13.I understand that the screening questionnaire will be securely destroyed immediately on completion of the study and that any information I provide will be

identifiable only by my participant number, kept confidential, and viewed only by the experimenter.

14.I understand that all research data will be securely stored on the University of

Tasmania premises for at least five years, and will then be securely destroyed when no longer required.

15.I agree that research data gathered from me for the study may be published provided that I cannot be identified as a participant.

16.I agree to participate in this investigation and understand that I may withdraw at any time without any effect, and if I so wish, may request that any data I have supplied to date be withdrawn from the research.

17. Any questions that I have asked have been answered to my satisfaction.

 Name of Participant

 Signature of Participant

 Date

Statement by Investigator

I have explained the project & the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

If the Investigator has not had an opportunity to talk to participants prior to them participating, the following must be ticked.

The participant has received the Information Sheet where my details have been provided so participants have the opportunity to contact me prior to consenting to participate in this project.

Name of Investigator ______ Signature of Investigator ______ Date _____