The effect of brief mindfulness training on distress tolerance, heart rate variability and alcohol consumption

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:

Name: Öykü Damla Irez

Date: 17.06.2016

Overview

This thesis examines the effectiveness of brief experimental mindfulness training in reducing alcohol craving and consumption in relation to distress tolerance and heart rate variability (HRV) among harmful/hazardous drinkers.

Part one presents a literature review examining the effects of mindfulness on HRV. The review of 16 studies concluded that mindfulness is associated with HRV and increased HRV in a high frequency range was observed in both healthy individuals and in patient groups. Methodological limitations of the current literature and recommendations for future research are discussed.

Part two is an empirical study involving a randomized controlled design examining the effects of brief mindfulness training on distress tolerance, heart rate variability and alcohol consumption. The results indicated that there was a significant increase in HRV in the relaxation group but no significant change in the mindfulness group. Participants who had increased HRV consumed less alcohol immediately after training, but interestingly only the participants in the mindfulness group consumed less alcohol after seven days. The increase in distress tolerance was similar between groups. This paper is part of a joint theses project with another Trainee Clinical Psychologist, Shirley Serfaty (2016). Her study involved a cue reactivity procedure to examine the effects of mindfulness on craving and negative affect.

Part three provides a critical appraisal of the empirical study. It discusses methodological issues such as challenges with developing mindfulness/relaxation scripts, choice of behavioural and physiological measures and maintaining superior follow up rates. It also includes a brief discussion of my interest in the field of mindfulness and my experiences of conducting this research.

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Finally, I want to dedicate this thesis to my beloved grandma. I wish you had been here to read it.

Part 1: Literature Review

The effects of mindfulness on heart rate variability: A systematic review

Abstract

Aim: To review the existing literature looking into the effects of mindfulness on HRV.

Methods: A systematic search was conducted in PsychINFO, Embase and Medline electronic databases. The review included studies using mindfulness or closely related practices reporting HRV outcomes. Sixteen studies consisting of a total of 993 participants (37.2% male; mean age 34.5 years) met the inclusion criteria, 13 studies involved healthy population and three studies involved clinical population. The Cochrane Collaboration's tool for assessing risk of bias was used to assess the methodological quality of the included studies.

Results: Overall 12 out of 16 studies (75%) suggest that there is evidence that mindfulness has an effect on modulating HRV while four studies failed to do so. The majority of these studies (eight studies including healthy population and two studies including clinical population) reported increased HRV in high frequency range (HF-HRV), which can be interpreted as a favorable effect of mindfulness on PNS activity. Mixed findings were reported for HRV in low frequency range.

Conclusions: The majority of the studies demonstrated that mindfulness is associated with HRV and increased HRV in high frequency range was observed in both healthy individuals and in patient groups. However, taking heterogeneity and methodological issues into consideration, the results of the studies should be approached with caution. Therefore future research should try to address the methodological limitations of the current literature.

Introduction

In some countries across the world, meditation has been a long established traditional practice dating back centuries (Ospina et al., 2007). In the last 40 years it has also received significant interest from Western countries in improving physical and mental well-being. There are various meditation practices. They share some characteristics but differ in the way they are practiced. Meditation is classified into two main styles: focused attention and open monitoring (Lutz, Slagter, Dunne, & Davidson, 2008). Focused attention meditation includes selective attention to a chosen object that can take different forms, such as sensations of breathing, repetition of a mantra or an image. Transcendental meditation, loving-kindness mediation, some forms of Zen and Qi Gong are the examples of focused attention meditation practices. Open monitoring meditation on the other hand does not require focusing on a particular object. Rather, it involves being attentive to any physical sensations or emotional experiences that arise in the present moment. Mindfulness and Vipassana are mainly considered as open monitoring meditation (Cahn & Polich, 2006). However, other meditation practices such as Acem meditation and integrative body-mind training (IBMT) also highlight open monitoring.

Mindfulness is described as non-judgmental observation of the present-moment experience. It involves two important components: sustaining one's attention on the present moment and holding an attitude of openness and acceptance of this experience (Bishop et al., 2004). Evidence suggests that mindfulness improves emotion regulation by encouraging a stance towards thoughts, feelings and physical sensations that is not characterized by avoidance, but rather, openness, curiosity and acceptance (Bishop et al, 2004; Lutz et al., 2008). Mindfulness is described as increased self-regulation and it is thought to improve emotion regulation

by helping to change one's relationship with unpleasant experiences. By encouraging an observational stance towards distressing experiences and exploration of bodily sensations, there is less of a tendency to *act* on physical and psychological discomfort; instead, tolerance is cultivated (Brewer, Elwafi, & Davis, 2012). Individuals become distressed when they continue to judge or analyse their experiences and the distress can be lessened if the individual is able to let go of their usual reactions to the experiences and be in the present moment (Kabat-Zinn, Lipworth, & Burney, 1985). Mindfulness practice and non-judgmental awareness can help to change the way individuals relate and respond to unpleasant experiences by reducing the tendency to respond automatically (Morrison, Madden, Odum, Friedel, & Twohig, 2014). As a consequence, the distressing experience becomes less intense and exerts less control over behavior (Brewer et al., 2012).

Mindfulness-based interventions are commonly used in the treatment of both physical and mental health problems. There is a growing body of evidence suggesting that people who suffer from depression, chronic pain and borderline personality disorder, benefit from mindfulness-based interventions (Kabat-Zinn et al., 1985; Linehan, Heard, & Armstrong, 1993; Teasdale et al., 2000). Baer's (2003) meta-review supports these findings, suggesting that mindfulness can be beneficial in a range of different conditions such as depression and anxiety. Mindfulness has also been integrated in the treatment of post-traumatic stress disorder, generalized anxiety disorder and substance abuse (Marlatt, 2002; Wells, 2002; Wolfsdorf & Zlotnick, 2001).

In recent years, studies examining the psychophysiology of mindfulness have increased. The studies looking into the effects of mindfulness on emotion regulation have supplemented self-report measures with measures of autonomic regulation of

cardiac activity such as heart rate variability (Arch & Craske, 2006). A human heart beats around 100.000 times in a day and 2.5 billion times in a lifetime (Shaffer, McCraty, & Zerr, 2014). Heart rate variability (HRV) is the variation of a time interval between heartbeats and is an important biomarker for autonomic nervous system activity. Beyond many vital functions of the body, the autonomic nervous system regulates involuntary actions such as heart rate and respiratory rate. The autonomic nervous system (ANS) has two main divisions; the sympathetic nervous system (SNS) and the parasympathetic nervous system (PNS). The SNS controls the 'fight or flight' response of the body, while the PNS controls the 'rest and digest' functions. "A healthy heart is not a metronome" (Shaffer et al., 2014) and it has natural fluctuations arising from the activities of both SNS and PNS. This normal variation of the heart rate occurs during the activities of the autonomic nervous system, to adapt and react to the various demands of the body. Electrocardiograms (ECG) are the tools to measure activities of the heart and their data also helps to produce HRV indices in time and frequency domains by using appropriate software. Time domain HRV indices such as RMSSD (root mean square of successive differences) and SDNN (standard deviation of NN intervals) are calculated on the normal-normal (NN) or 'RR' intervals during continuous ECG recording. RR corresponds to the interval between the R peaks at QRS complex represented on ECG. The frequency domain analysis defines HRV in three categories; high frequency (HF) HRV, low frequency (LF) HRV and very low frequency (VLF) HRV. The frequency ranges of HF, LF and VLF are 0.15-0.4 Hertz (Hz), 0.15-0.4 Hz and 0.003-0.04 Hz respectively (Task force, 1996). LF-HRV indicates both sympathetic and parasympathetic modulation of HRV while HF-HRV predominantly indicates parasympathetic modulation, mediated by the vagus nerve.

This vagally mediated HF-HRV is associated with respiratory sinus arrhythmia which is the natural fluctuations in heart rate during the breathing cycle, as heart rate increases and decreases in tandem with respiration (Berntson, Cacioppo, & Quigley, 1993; Dexter, Yang, & Levy, 1992).

Research has indicated that physical health problems such as cardiovascular disorders are linked with low levels of HRV and it predicts mortality after myocardial infarction (Kleiger, Miller, Bigger, & Moss, 1987). HRV is also associated with psychological health and HF-HRV is considered a reliable measure of PNS activity on heart rate. Reduced HF-HRV indicates low PNS activity and is a sign of poor psychological health (Libby, Worhunsky, Pilver, & Brewer, 2012). Research has demonstrated that patients suffering from depression, bipolar disorder, post-traumatic stress disorder, general anxiety disorder and panic disorder have reduced HRV (Cohen et al., 1997; Cohen et al., 2003; Nahshoni et al., 2004; Thayer, Friedman, & Borkovec, 1996). Reduced HRV is also associated with difficulties in reaching a relaxed state following stress and this shows that HRV is linked with emotion regulation (Segerstrom & Nes, 2007). Different emotions can lead to different degrees of physiological responses, which are produced mostly by the autonomic nervous system. HF-HRV is a marker of a flexible autonomic system as it adapts necessary bodily responses with linked emotions (e.g. during feelings of calmness the body relaxes) (Appelhans & Luecken, 2006). In other words HRV is a marker of flexible adjustment and improved emotional regulation capacity.

Self-regulation is an important characteristic of mindfulness, which suggests that HF-HRV could be a physiological marker of mindfulness. This brings about the question of whether people who practice mindfulness have higher HRV. There are studies assessing the effects of mindfulness on HRV but they have reported mixed

findings. Amihai and Kozhevnikov (2015) conducted a review of the effects of different meditative traditions on ANS. Unlike our review they also included studies reporting galvanic skin response and neuroimaging outcomes. Their review specifically pointed to the evidence that Vajrayana practices lead to increased sympathetic activity while Theravada practices lead to increased parasympathetic activity. Their review also addressed the cultural and philosophical differences between different meditation practices. However, Amihai and Kozhevnikov's review was not conducted systematically and did not focus on mindfulness meditation specifically. To the best of my knowledge, no systematic review has been published on mindfulness and HRV. Therefore, the goal of this systematic review is to summarize and evaluate the existing literature looking into the effects of mindfulness on HRV.

Method

2.1   Search methods for identification of studies

A systematic search was conducted in PsychINFO, Embase and Medline electronic databases with the following search terms. The search was restricted to human studies and articles published in English.

Title/abstract search: "heart rate variabilit*" OR "vagus" OR "vagal" OR "respiratory sinus arrhythmia" OR "autonomic" OR "parasympathetic" OR "sympathetic"

AND

Title/abstract search: "mindfulness" OR "meditation"

This search yielded a total of 731 hits (190 from PsychINFO, 347 from Embase and 194 from Medline).

2.2 Inclusion and exclusion criteria

The systematic review included randomised controlled trials and non-randomised controlled studies and before-and-after studies examining the effects of mindfulness on HRV. Studies were included if they reported HRV data and used control condition(s). Studies involved both healthy and clinical populations ($\geq$18 years old). This review included studies using mindfulness, or closely related practices that employ open monitoring (Vipassana, Acem meditation and IBMT).

The review excluded studies involving focused attention meditation such as Transcendental meditation (Cunningham, Brown, & Kaski, 2000; Paul-Labrador et al. 2006; Travis, 2001; Travis & Pearson, 2000; Travis & Wallace, 1997; Travis et al., 2009), mantra meditation (Steinhubl et al., 2015), loving-kindness meditation (Kemper & Shaltout, 2011; Kok et al., 2013), movement-based meditations (Qi Gong, Tai Chi, Yoga) (Kamath, 2013; Peng et al., 1999), Autogenic meditation (Kim, Kang, Lee, Kim, & Whang, 2013; Kim, Rhee, & Kang, 2014), Chan meditation (Lo & Chang, 2013), Kundalini yoga, Cyclic meditation (Patra & Telles, 2010; Sarang & Telles, 2006).

Some types of Zen meditation such as Su-soku meditation are also considered as focused attention meditation. Therefore studies reporting Su-soku meditation were also excluded (Cysarz & Bussing, 2005; Lee et al., 2015; Lehrer, Sasaki, & Saito, 1999; Murata et al., 2004; Takashi et al., 2005).

2.3 Screening and data synthesis

731 titles and abstracts screened for inclusion and exclusion criteria, 513 articles were excluded as they failed to meet major inclusion criteria (e.g. not related to meditation and HRV). This initial assessment process led to retrieval of 218 articles. After removing duplicates, 88 papers potentially meeting the inclusion

criteria were identified. Reference lists of the selected studies were also screened but no additional articles were identified. A total of 88 studies were reviewed and after applying the inclusion/exclusion criteria 72 papers were removed. This left sixteen studies (Figure 1).

The details of the 16 included studies are presented in Table 1. The table includes name of the authors and publication year, study descriptions (RCT or non-RCT), type of mindfulness meditation, control condition(s), sample size, mean age, HRV measure, main results and a comment section which included methodological issues such as experience of meditators. This review used a narrative synthesis and critically evaluated the methodological quality of the studies.

2.4   Quality assessment

The Cochrane Collaboration's tool for assessing risk of bias was used to assess the methodological quality of the included studies (Ryan, Hill, Prictor, & McKenzie, 2013). The same quality assessment was also used in a systematic review assessing the effects of yoga on HRV (Posadzski, Kuzdzal, Lee, & Ernst, 2015). We included six domains of Cochrane Collaboration's tool; selection bias (sequence generation and allocation concealment); performance bias (blinding of participants); detection bias (blinding of assessors); attrition bias (addressing incomplete data) and reporting bias (selective outcome reporting). Cochrane collaboration's tool has also a domain of "other risk of bias" which allows to report any other bias other than six basic criteria. We did not include this domain as there were no additional concerns of bias to be reported. Each study was assessed by the scores of 'Low risk', 'High risk' or 'Unclear risk' of bias.

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  ┌──────────┐   ┌──────────┐   ┌──────────┐
  │ Embase   │   │ PsychINFO│   │ Medline  │
  │ 347      │   │ 190      │   │ 194      │
  └────┬─────┘   └────┬─────┘   └────┬─────┘
       │              │              │
  ┌────┴─────┐   ┌────┴─────┐   ┌────┴─────┐
  │   98     │   │   51     │   │   69     │
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Embase
347

PsychINFO
190

Medline
194

98

51

69

218

Excluded
duplicates:
130

88

Excluded = 72
• not open monitoring meditation (30)
• not adult population (i.e. adolescents, older adults) (6)
• not reporting HRV data (23)
• no control condition (5)
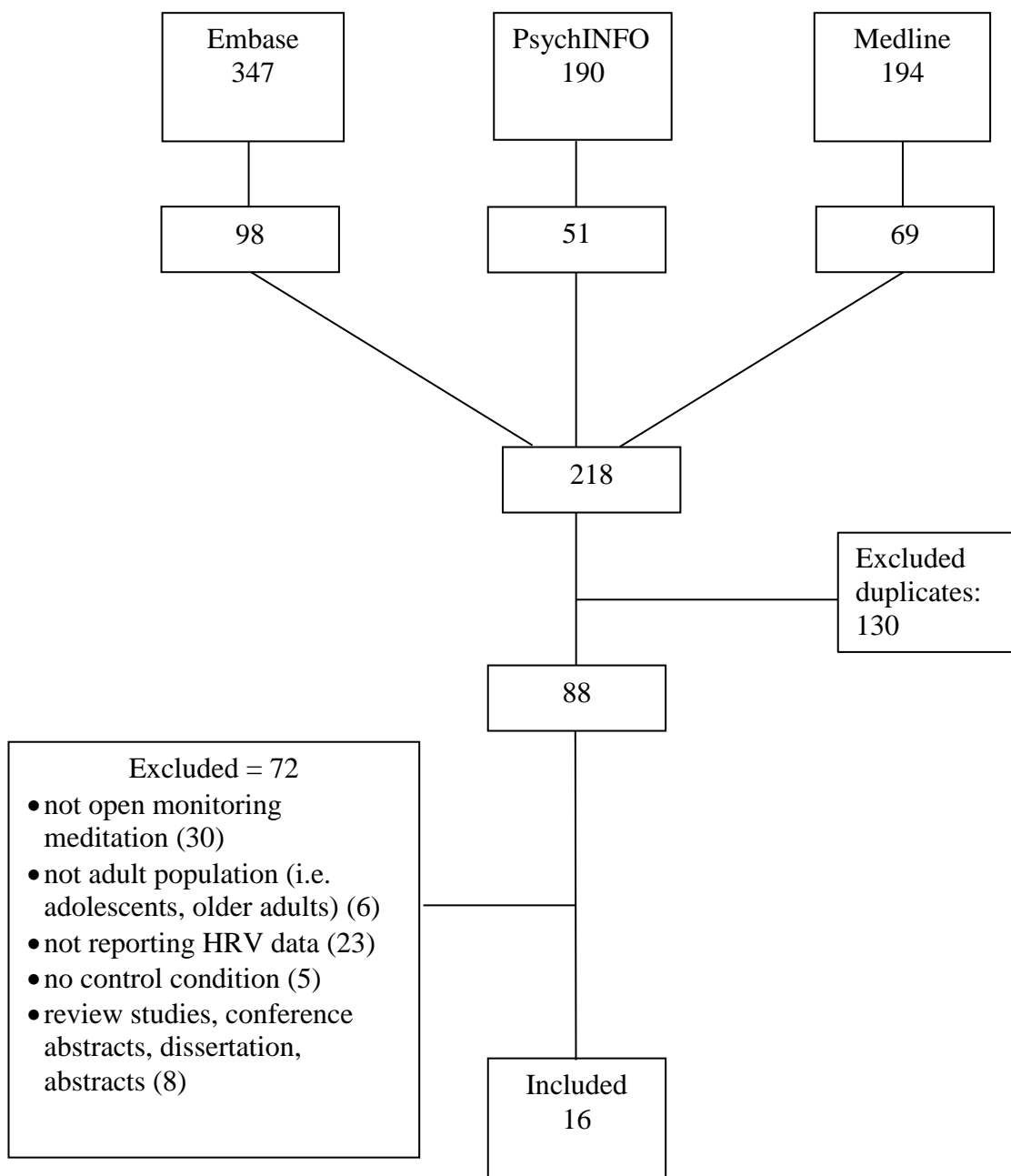• review studies, conference abstracts, dissertation, abstracts (8)

Included
16

Figure 1. Flowchart of literature search process

Results

3.1 Overview of studies

All studies clearly reported their aims and hypotheses, except two studies, which only reported their aims (Ditto, Eclache, & Goldman, 2006; Nesvold et al., 2011).

Table 1. *Characteristics of the 16 included studies*

Study	Study description	Conditions	Sample size (mean age or age group)	HRV measure	Main results/ between group differences	Comment (participant characteristic and HRV measurement time point)
Amihai & Kozhevnikov (2014)	Pre-post Within subjects	A) Vipassana meditation B) Rig-pa meditation C) Rest	19 adults (44.3)	1. HF 2. LF/HF	1. Increase ($p < 0.05$) (A vs. C) Decrease ($p < 0.05$) (B vs. C) 2. Decrease ($p < 0.05$) (A vs. C) n.s. (B vs. C)	- Experienced meditators - HRV measured during meditation/rest condition.
Azam et al. (2015)	RCT Parallel groups	A) Brief audio guided mindfulness meditation ($n = 31$) B) Resting condition consisting of an audio description of scientific and historical information on mindfulness meditation ($n = 29$)	60 healthy adults (21.12)	1. lnHF	1. Increase ($p < 0.000$) (A vs. B - control participants) n.s. (A vs. B - perfectionists)	- Perfectionist group scored high on PCI and control group scored low on PCI - Novice meditators - Stress induction (PRT) before mindfulness/control condition. HRV measured during stress induction and mindfulness.

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Table 1. *continued*

Study	Study description	Conditions	Sample size (mean age or age group)	HRV measure	Main results/ between group differences	Comment (participant characteristic and HRV measurement time point)
Delgado et al. (2010)	RCT Parallel groups	A) Mindfulness (n = 15) B) Relaxation (n = 17)	32 healthy females (18-24 years)	1. HF	1. n.s. (A vs. B)	- Participants scored high on PSWQ. - Intense white noise accompanied by pleasant/neutral/unpleasant pictures and this followed by self-induced worry period before mindfulness/relaxation. HRV assessed before and after the intervention.
Delgado-Pastor et al. (2013)	Pre-post Within subjects	A) Vipassana meditation B) Random thinking	10 healthy males (20-61)	1. HF 2. LF 3. LF/HF	1. n.s. (A vs. B) 2. n.s. (A vs. B) 3. Increase ($p < 0.034$) (A vs. B)	- Experienced meditators - Auditory oddball task pre-post meditation/random thinking. HRV measured before and after the intervention.
Delgado-Pastor et al. (2015)	RCT Parallel groups	A) Mindfulness interoceptive training (n = 15) B) Mindfulness cognitive training (n = 12) C) Control (n = 14)	41 healthy females (21.5)	1. RSA 2. RMSSD	1. Increase ($p < 0.03$) (A vs. C) Increase ($p < 0.03$) (A vs. B) n.s. (B vs. C) 2. Increase ($p < 0.09$) (A vs. C) n.s. (A vs. B)	- Participants scored high on PSWQ. - Self-induced worry period before mindfulness training. HRV measured before and after the intervention.

Table 1. *continued*

Study	Study description	Conditions	Sample size (mean age or age group)	HRV measure	Main results/ between group differences	Comment (participant characteristic and HRV measurement time point)
Ditto et al. (2006)	RCT Parallel groups	Study 1 A) Body scan meditation (*n* = 10) B) Progressive muscular relaxation (*n* = 10) C) Waitlist (*n* = 12)	32 healthy adults (21.6)	1. RSA	1. Increase (*p* < 0.032) (A vs. B and C)	- Novice meditators - HRV measured before and one month after intervention.
		Study 2 A) Mindfulness meditation (*n* = 15) B) Control audiotape (*n* = 10)	30 healthy adults (19.2)	1. RSA 2. LF	1. Increase (*p* < 0.002) (A vs. B) 2. Increase (*p* < 0.008) (A vs. B)	- Novice meditators - HRV measured before and one week after intervention.
Garland et.al (2010)	RCT Parallel groups	A) MORE (n = 27) B) ASG (n = 26)	53 alcohol dependent adults (40.3)	1. RMSSD	1. Increase (p = 0.03) (A vs. B)	- HRV measured during baseline, stress cues, alcohol cues and recovery period. Before and after MORE/SG.
Garland et al. (2014)	RCT Parallel groups	A) MORE (n = 20) B) SG (n = 29)	49 adults (chronic pain and daily opioid users) (40.3)	1. HF	1. Increase (p < 0.004) (A vs. B)	- HRV measured during dot probe task. Before and after MORE/SG.

Table 1. *continued*

Study	Study description	Conditions	Sample size (mean age or age group)	HRV measure	Main results/ between group differences	Comment (participant characteristic and HRV measurement time point)
Howells et al. (2014)	Non-randomised controlled trial Parallel groups	A) MBCT (n = 12) B) Control group (n = 9)	21 adults (12 Bipolar I disorder, 9 healthy control) (33.	1. HF 2. LF	1. Decrease (p < 0.05) (A vs. B) 2. Decrease (p < 0.05) (A vs. B)	- HRV measured during visual matching task before and after MBCT.
Krygier et al. (2013)	Pre-post Within subjects	A) Vipassana (Anapana exercise, mindfulness of breathing) B) Rest	36 healthy adults (43.8)	1. lnHF 2. HFnu 3. THM	1. Increase ($p = 0.006$) pre-Vipassana (A vs. B) n.s. post-Vipassana (A vs. B) 2. n.s. pre-Vipassana (A vs. B) Increase (p=0.019) post-Vipassana (A vs. B) 3. n.s. pre-Vipassana (A vs. B) Decrease (0.004) post-Vipassana (A vs.B)	- Baseline and meditation HRV measured pre and post 10 days Vipassana.
Libby et al. (2012)	Pre-post Within subjects	A) Mindfulness B) Rest	28 healthy adults (48.00)	1. HF	1. n.s. (A vs. B)	- Novice and experienced meditators. - HRV measured during mindfulness/rest.

Table 1. *continued*

Study	Study description	Conditions	Sample size (mean age or age group)	HRV measure	Main results/ between group differences	Comment (participant characteristic and HRV measurement time point)
Lumma et al. (2015)	Pre-post Within subjects	A) Mindfulness meditation (Breathing Meditation) B) Observing-thoughts meditation C) Loving-kindness meditation	156 healthy adults (41.17)	1. HF	1. n.s. (A vs. B vs. C)	- Novice meditators - HRV measured pre-post at week 3 and week 13.
Nesvold et al. (2011)	Pre-post Within subjects	A) Acem meditation B) Rest	27 healthy adults (34-63)	1. HF 2. LF	1. Increase ($p < 0.0013$) (A vs. B) 2. Increase ($p < 0.0014$) (A vs. B)	- Experienced meditators - HRV measured during meditation/rest.
Tang et al. (2009)	RCT Parallel groups	A) IBMT ($n = 46$) B) Relaxation ($n = 40$)	86 healthy adults (21.45)	1. HFnu	1. Increase ($p < 0.001$) (A vs. B)	- Novice meditators - HRV measured before and after IBMT/relaxation.
Watford et al. (2015)	RCT Parallel groups	A) Mindfulness intervention (n = n.r.) B) Control (Radio gardening programme Control) (n = n.r.)	70 healthy adults (19.31)	1. HRV vagal ratio	1. Increase ($p = 0.05$) (A vs. B)	- Novice meditators - Automated span task pre mindfulness/control condition followed by negative/positive emotional stimuli. HRV measured during mindfulness/control condition.

Table 1. *continued*

Study	Study description	Conditions	Sample size (mean age or age group)	HRV measure	Main results/ between group differences	Comment (participant characteristic and HRV measurement time point)
Wolever et al. (2012)	RCT Parallel groups	A) Mindfulness meditation ($n = 96$) B) Viniyoga stress reduction program ($n = 90$) C) Control ($n = 53$)	239 healthy adults (42.9)	1. HRV coherence ratio	1. Increase ($p < 0.05$) (A vs. C)	- Novice meditators - HRV measured before and 12 weeks after intervention.

ASG = alcohol dependence support group; HF = high frequency; HFnu = HF (normalized unit); HRV = heart rate variability; IBMT = integrative body-mind training;
LF = low frequency; LF/HF = LF HF ratio; log HF = log transformed HF; MBCT = mindfulness based cognitive therapy; MBSR = mindfulness based stress reduction;
MORE = mindfulness-oriented recovery enhancement; n.s. = not significant; PCI = Perfectionism Cognitions Inventory; PRT = Pattern recognition task; PSWQ = Penn
State Worry Questionnaire; *RCT = randomized controlled trial; RMSSD = root mean square of the successive difference; RSA = respiratory sinus arrhythmia;*
SG = Support group; sig = significant; THM =Traube-Herring-Mayer waves.

3.2   Study Designs

This review included nine RCT's (Azam et al., 2015; Delgado et al., 2010; Delgado-Pastor et al., 2015; Ditto et al., 2006; Garland, Gaylord, Boettiger, & Howard, 2010; Garland et al., 2014; Tang et al., 2009; Watford et al., 2015; Wolever et al., 2012) and seven non-RCT's (Amihai & Kozhevnikov, 2014; Delgado-Pastor, Perakakis, Subramanya, Telles, & Vila, 2013; Howells et al., 2014; Krygier et al., 2012; Libby et al., 2012; Lumma et al., 2015; Nesvold et al., 2011). Ten studies used a between-group design and six studies used a within-group design (Amihai & Kozhevnikov, 2014; Delgado-Pastor et al., 2013; Krygier et al., 2012; Libby et al., 2012; Lumma et al., 2015; Nesvold et al., 2011).

Most of the studies had two conditions and five studies had three conditions (Amihai & Kozhevnikov, 2014; Delgado-Pastor et al., 2015; Ditto et al., 2006; Lumma et al., 2015; Wolever et al., 2012).

3.3   Sample characteristics

The studies included a total of 993 participants and across the studies the mean age was 34.5 years (SD=7.02) of which 37.2% were male. The range of sample sizes was 10 to 239 (See Table 1 for further demographic information). Only one study mentioned power analysis to calculate sample size (Azam et al., 2015). Eight studies reported that participants were reimbursed, received course credit or stated that the participants were volunteers (Azam et al., 2015; Delgado-Pastor et al., 2013; Delgado et al., 2010; Ditto et al., 2006; Garland et al., 2010; Garland et al., 2014; Watford et al., 2015; Wolever et al., 2012). The monetary compensation ranged from $10 (Ditto et al., 2006) to $200 (Garland et al., 2014). Remaining studies did not report this information.

Most of the studies reported inclusion and exclusion criteria except Ditto et al. (2006) and Krygier et al. (2012). Eight of the studies excluded participants on the

basis of cardiovascular disease, as it interferes with ANS function (Amihai & Kozhevnikov, 2014; Azam et al., 2015; Delgado et al., 2010; Delgado-Pastor et al., 2013; Delgado-Pastor et al., 2015; Nesvold et al., 2011; Tang et al., 2009; Watford et al., 2015). Six studies reported number of excluded participants (Delgado-Pastor et al., 2015; Delgado-Pastor et al., 2013; Delgado et al., 2010; Watford et al., 2015) and two of these studies provided additional figures for participant flow (Azam et al. 2015; Wolever et al., 2012). Six studies recruited participants with specific characteristics based on the Perfectionism Cognitions Inventory (Azam et al., 2015), Penn State Worry Questionnaire (Delgado-Pastor et al., 2015; Delgado et al., 2010), daily cigarette consumption (Libby et al., 2012), diagnosis of euthymic bipolar I disorder (Howells et al., 2014), diagnosis of alcohol dependence (Garland et al., 2010) and diagnosis of recurrent pain and daily use of opioid analgesics (Garland et al., 2014). Six of the studies recruited novice meditators (Azam et al., 2015; Ditto et al., 2006; Lumma et al., 2015; Tang et al., 2009; Watford et al., 2015; Wolever et al., 2012;) while three of the studies recruited experienced meditators (Amihai & Kozhevnikov, 2014; Delgado-Pastor et al., 2013; Nesvold et al., 2011). Libby et al. (2012) recruited both novice and experienced meditators. The remaining six studies did not report the level of meditation experience of participants.

Nine of the studies provided detailed demographic information including ethnicity, education, employment and income. The remaining seven studies only reported age and gender.

Two of the studies asked participants to abstain from caffeine, alcohol, illicit substances, nicotine and exercise prior to the testing session as these factors are known to influence ANS (Ditto et al., 2006; Krygier et al., 2012). The abstinence period ranged from 2 hours (Ditto et al., 2006) to 24 hours (Krygier et al., 2012).

Three of the studies reported the data collection time. Nesvold et al. (2011) and

Howells et al. (2014) collected HRV data between 09:00 and 13:00 whereas Krygier

et al. (2012) collected data between 15:00 and 18:00 to control the diurnal effects on

HRV.

3.4   Meditation and control procedures

The content of the meditation techniques are provided in Table 2. Eight

studies used mindfulness meditation and the length of the meditation varied across

studies. The studies involved included a range of meditation practice durations.

Some involved instructions intended to generate a state of open awareness within a

single experimental session only. Other studies emphasized 'training' in the more

formal sense, with practice occurring within and between sessions over several

weeks (Delgado et al., 2010; Delgado et al., 2015; Garland et al., 2010; Garland et

al., 2014; Howells et al., 2014; Krygier et al., 2013; Lumma et al., 2015; Wheeler et

al., 2014; Wolever et al., 2012).

Six studies delivered the instructions in a standardized format. Five of these

studies used audio-recorded meditation instructions (Azam et al., 2015; Ditto et al.,

2006; Libby et al. 2012; Tang et al., 2009; Watford et al., 2015) and one study used

written instructions (Delgado-Pastor et al., 2013). Five of the studies delivered the

treatment in groups and the intervention was delivered by a range of professionals:

an experienced mindfulness meditation teacher (Wolever et al., 2012), a qualified

mediation teacher (Lumma et al., 2015), a therapist experienced in delivering

cognitive therapy and MBCT (Howells et al., 2014), and a social worker with

experience in mindfulness meditation (Garland et al., 2010; Garland et al., 2014).

The remaining five studies (Amihai & Kozhevnikov, 2014; Delgado et al., 2010;

Delgado-Pastor et al., 2015; Krygier et al., 2013; Nesvold et al., 2011) did not provide information about the format of their instructions.

Ten studies reported that they matched manipulations between groups in terms of length, structure of the session (e.g. brief explanation first, then meditation), time of the day (Amihai & Kozhevnikov, 2014; Azam et al., 2015; Delgado et al., 2010; Delgado-Pastor et al., 2013; Delgado-Pastor et al., 2015; Ditto et al., 2006; Garland et al., 2010; Garland et al., 2014; Libby et al., 2012; Tang et al., 2009; Watford et al., 2015). Two studies reported using manipulation check involving a scale in which participants rated how well they followed the instructions (Libby et al., 2012) and reported their success in engaging with the task (Delgado-Pastor et al., 2013). Only one study assessed the credibility of the intervention, by means of a scale derived from the attitudes towards treatment measure (Borkovec & Nau, 1972) to assess participants' expectations of the benefits from the intervention (Garland et al., 2010).

Nine studies had active comparison conditions such as relaxation, yoga, loving-kindness meditation, and alcohol support group. Three studies had inactive control conditions (no treatment and waitlist) in addition to active comparison groups (Delgado-Pastor et al., 2015; Ditto et al., 2006; Wolever et al., 2012).

Table 2. *Details of mindfulness condition*

Study	Description of mindfulness condition	Duration
Amihai & Kozhevnikov (2014)	"Theravada practitioners were asked to perform 15 minutes of Shamatha (Kasina) meditation (with a focus on the breath) followed by 15 minutes of Vipassana. Tibetan Vajrayana practitioners were asked to perform 15 minutes of Deity meditation after the rest condition, followed by 15 minutes of Rig-pa meditation."	30 minutes
Azam et al. (2015)	"Participants were asked to remain seated in a relaxed and upright manner with eyes closed. Audio recording was played featuring mindfulness instructions emphasizing attention to breathing sensations and a reorientation to breathing sensations once there was awareness of thoughts, emotions, bodily sensations, and/or external stimuli."	10 minutes
Delgado et al. (2010)	"Attention was focused on awareness of participants' present mental and emotional state with the intention of accepting the affective value of the experience, whether positive, neutral, or negative. Whenever attention wandered from present state to past or future thoughts, attention was returned to the present by using breathing as an anchor: participants had to focus attention on the sensation of breath entering and leaving the body only at the nostrils or abdomen; respiration had to be smooth and natural, with no intention of controlling or manipulating it. After session three, the participant's attention was also directed to interoceptive consciousness of all parts of the body, scanning sensations from feet to head with openness and equanimity, accepting all sensations beyond their affective valence and noting their transitory nature; priority areas were the abdomen, thorax, neck and head. After session five, the meditation practice also incorporated the possibility of briefly labelling the present experience (i.e., 'thinking', 'wandering', 'worrying', 'remembering', 'anticipating', etc.); this labelling had to be free of any judgement or analysis, solely a direct re-cognition of the experience of the present mental state."	Twice a week1 hour sessions for 5 weeks
Delgado et al. (2013)	"The meditation task was structured in three sub-periods (a) Anapana: an initial 10-minute period of self- regulation of attention focused on breathing sensations (sensations from air entering and leaving the body at the nostrils), (b) Vipassana: a central 15-minute period of focusing attention on sensations from all parts of the body while maintaining the non-reactivity and acceptance attitude, and (c) Metta: a final 5-minute period focused on generating feelings of compassion and unconditional love to all living beings."	30 minutes
Delgado et al. (2015)	Mindfulness interoceptive training - "The participants were guided to recognise and accept their current overall bodily and emotional-affective states. Then they were guided to focus their attention on the 'here and now' with an attitude of openness, curiosity, and interest in what was currently happening in terms of the experience of sensations. Additionally, the participants were given the suggestion to	Twice a week 1 hour sessions for 5 weeks

scan their bodily sensations from their feet to their head with openness and equanimity while noting the changeable and transitory nature of these sensations."

Mindfulness cognitive training – "The participants were instructed to recognise and accept their current overall mental state. Then they were instructed to focus their attention on the 'here and now' with an attitude of openness, curiosity, and interest regarding what was happening in their minds in terms of mental processes. Additionally, the participants were invited to become aware of how thoughts arose and vanished in their minds, to adopt an attitude of acceptance and equanimity, and to note the changeable and transitory nature of their thoughts."

Ditto et al. (2006)	"Guided body scan. Listeners are asked to attend to various parts of their body and their breathing, gently observing these areas and allowing other thoughts to recede."	20 minutes
Garland et al. (2010)	Mindfulness-oriented recovery enhancement (MORE), adapted from mindfulness based cognitive therapy (MBCT). "MORE involves mindful breathing and walking meditations".	10 weeks
Garland et al. (2014)	"MORE participants were asked to engage in daily 15-min mindfulness practice sessions at home guided by a CD. During the meditation session, participants were instructed to mindfully attend to the colors, textures, and scents of a bouquet of fresh flowers and to absorb and appreciate the emotions of contentment and joy arising from this savoring practice."	8 weeks
Howells et al. (2014)	MBCT. No further information on mindfulness exercises.	8 weeks
Krygier et al. (2013)	"Tasks included a 5-minute resting baseline recording in which participants were instructed to simply sit quietly with their eyes open, and a 5-minute eyes closed Anapana (mindfulness of breathing) meditation exercise, in which participants were instructed to breath naturally and to be mindful of each breath as it enters and leaves the body."	10 days
Libby et al. (2012)	Mindfulness of the breath instructions. "Please pay attention to the physical sensation of the breath wherever you feel it most strongly in the body. Follow the natural and spontaneous movement of the breath, not trying to change it in any way. Just pay attention to it. If you find that your attention has wandered to something else, gently but firmly bring it back to the physical sensation of the breath."	5 minutes
Lumma et al. (2015)	"During breathing meditation exercise, participants were asked to focus their attention on their in-breath and out-breath. In case participants lost the focus on the breath they were asked to refocus their attention on their breath. During the observing-thoughts meditation participants were asked to focus their attention on the coming and going of their own thoughts. In case participants lost the focus on their thoughts they were asked to refocus their attention back to their thoughts."	20 minutes daily (5 times per week) for 13 weeks

Nesvold et al. (2011)	"Acem meditation is a nondirective technique wide-spread in Scandinavia. It is based on a Western approach, and psychological understanding of the elicited mental processes. Acem meditation does not require volitional direction of attention towards specific subjective states of mind, nor any attempts to control the current mental content. Thus, it is practised with a free mental attitude, similar to some mindfulness meditations, and allows any emerging thought, memory, emotion, or sensation to pass through the awareness of the practitioner. Further, it allows spontaneous normal breathing."	20 minutes
Tang et al. (2009)	"IBMT involves several body–mind techniques including: (i) body relaxation, (ii) breath adjustment, (iii) mental imagery, and (iv) mindfulness training. In the training session, subjects followed the compact disc with body posture adjustment, breathing practice, guided imagery, and mindfulness training accompanied by a music background."	20 minutes per day for 5 days
Watford et al. (2015)	"Mindfulness intervention (a) described the concept of mindfulness followed by an experiential exercise of mindful breathing and (b) described the way in which mindfulness principles apply to emotional experiences followed by another experiential exercise in which participants were instructed to be mindful of their emotions."	15 minutes
Wolever et al. (2012)	"Mindfulness at Work is a stress management program based upon the principles and practices of mindfulness meditation. The Mindfulness at Work program teaches mindfulness practices that explicitly target work-related stress, work-life balance, and self-care. These practices are relatively brief (5-15 min) and are specifically designed to be used at work."	12 weeks (14 hours)

3.5 Outcomes

3.5.1 Type of HRV indices reported in the studies

The majority of the results were reported in HRV frequency domain. Two studies reported RMSSD, a measure in time domain (Ditto et al., 2006; Garland et al., 2010). The studies mostly reported HF-HRV and LF-HRV in absolute power (ms^2) while some studies reported HRV in normalized units (HFnu) (Libby et al., 2012; Krygier et al., 2012; Tang et al., 2009). Four studies log transformed their data to remove skewness and reported lnHF (Azam et al., 2015; Ditto et al., 2006; Howells et al., 2014; Krygier et al., 2012). The study by Krygier et al. (2012) reported the THM measure (Traube–Hering–Mayer waves), a measure in the low frequency spectrum. The LF/HF ratio, an indicator of sympathovagal balance (Malliani, Pagan, Lombardi, & Cerutti, 1991) was reported in two studies (Azam et al., 2015; Delgado-Pastor et al., 2013). Another two studies reported RSA values, which correspond to HF-HRV values (Delgado-Pastor et al., 2015; Ditto et al., 2006). Watford et al. (2015) reported HRV vagal ratio, an analogous measure to HF-HRV values as per Biopac HRV analysis (Biopac Systems, Goleta, CA, Biopac AcqKnowledge 4 software Guide). Wolever et al. (2012) reported HeartMath's heart rate coherence ratio (McCraty, Atkinson, Tomasino, & Bradley, 2009).

3.5.2 The effects of mindfulness meditation on HRV in healthy populations

Thirteen studies included healthy participants. Nine studies reported an increase in HRV (Amihai & Kozhevnikov, 2014; Azam et al., 2015; Delgado-Pastor et al., 2015; Ditto et al., 2006; Krygier et al., 2012; Nesvold et al., 2011; Tang et al., 2009; Watford et al., 2015; Wolever et al., 2012). Among these, one recent study examining the effects of brief mindfulness training on emotion regulation, reported that HRV vagal ratio (akin to HF-HRV) increased in mindfulness participants

compared to control condition (Watford et al., 2015). Similarly, Azam et al. (2015) examined HRV compared to resting baseline, stress, and post-stress conditions in perfectionists and controls. It was reported that the perfectionists showed no significant change in HF-HRV after mindfulness meditation while the control group showed increased HF-HRV. This result suggests that perfectionism is related to decreased vagal tone and this is an obstacle to achieve a mindful state. Another study examining the effect of mindfulness in the treatment of worry investigated the interoceptive and cognitive elements of mindfulness training, reporting HRV increase in both frequency and time domain HRV values (Delgado-Pastor et al., 2015). The mindfulness interoceptive group showed an increase in RSA and RMSSD while no significant difference was found between the mindfulness cognitive group and the control group. This indicates that only the mindfulness interoceptive group showed significant improvement in physiological measures of autonomic regulation compared to the mindfulness cognitive group.

Ditto et al. (2006) examined the effects of body scan meditation on HRV and reported the results of two different studies in one paper. Study 1 showed that participants who practiced body scan meditation had greater RSA compared to control groups. Different groups of participants, which acted as their own control, took part in the study 2 and a greater RSA and LF-HRV were reported. A large study of mindfulness in a workplace included HRV measures to explore the impact of the mindfulness training on autonomic function (Wolever et al., 2012). Findings demonstrated that participants involved in the 'Mindfulness at Work' program showed greater HRV coherence ratio in comparison to control participants.

Two studies used Acem meditation and IBMT, which are similar to mindfulness as they also highlight open monitoring. The study by Tang et al. (2009)

examined HRV at rest, during IBMT and after 5 days of IBMT and relaxation. The IBMT group demonstrated a significant increase in HFnu compared to the relaxation group, which indicates the activation of PNS and the inhibition of SNS after the mindfulness training. Nesvold et al. (2011) found a similar result when they examined the effects of Acem meditation on HRV compared with rest condition for the experienced meditators. It was observed that both HF-HRV and LF-HRV showed an increase after meditation.

Another two studies examined the effects of Vipassana on HRV. Amihai and Kozhevnikov (2014) compared experienced Therevada and Vajrayana meditation practitioners. During the open monitoring stages of both Theravada meditation (Vipassana) and Vajrayana meditation (Rig-pa), findings demonstrated that Theravada practitioners showed an increase in HF-HRV (Vipassana vs. resting baseline) and they also showed a decrease in LF/HF ratio which is a consistent outcome due to increase in HF-HRV. The same study reported a decrease in HF-HRV by Vajrayana practioners (Rig-pa vs. resting baseline) and the authors explained this outcome by the differences between the neurophysiological mechanisms of Theravada and Vajrayana meditations. Similarly, Krygier et al. (2012) examined the effects of Vipassana on HRV pre-post 10 days of Vipassana training and Anapana (mindfulness of breathing exercise of Vipassana) versus rest condition, both in the beginning and after each Vipassana training. The findings demonstrated no significant main effect of time for pre-post 10 days Vipassana training on HRV measures. Regarding the effects of Anapana compared to resting baseline, lnHF increased at pre-Vipassana while no significant difference was found for the same condition at post-Vipassana. HFnu and THM had no significance change for Anapana compared to resting baseline at pre-Vipassana, however HFnu

increased and THM decreased post-Vipassana. The authors pointed out the difficulties in elucidating absolute and normalized HRV measures as well as the effects of low frequency modulation to other HRV measures.

Four studies reported no significant changes in HRV indices after mindfulness mediation. Lumma et al. (2015) investigated the influence of different kinds of meditation styles (breathing meditation, loving-kindness meditation and observing-thoughts meditation) on cardiac activity. This was a one-year longitudinal study, in which all the participants practiced each type of meditation on a daily basis for 3 months. While breathing meditation is similar to mindfulness meditation, both loving-kindness meditation and observing-thoughts meditation are categorized as a focused attention type of meditation. No significant difference was found between all three types of meditation for HF-HRV. However, loving-kindness meditation and observing-thoughts meditation showed a decrease in HF-HRV after three months of training. The authors suggest both loving-kindness meditation and observing-thoughts meditation increased SNS activity over training but the breathing meditation did not influence the cardiac activity. Libby et al. (2012) examined HRV in nicotine dependents and reported no statistically significant result for HRV (mindfulness/rest). However, it was suggested that the participants were significantly more likely to demonstrate increased HF-HRV as 20 of 28 participants showed an increase in HF-HRV while 8 participants showed decrease in HF-HRV and the authors underlined that the direction of change favoured increase in HF-HRV. Delgado et al. (2010) also reported no significant results for the modulation of HRV between the mindfulness and relaxation group. Another study by Delgado-Pastor et al. (2013), which included experienced Vipassana meditators, reported no significant difference for HF-HRV and LF-HRV between the stages of Vipassana and random

thinking. However the study reported a significant increase in LF/HF ratio, which is a controversial outcome as it indicates increased SNS activity contrary to the expected effect of meditation. The authors explained this controversy based on the arguments that LF-HRV is primarily determined by PNS but not by the SNS (Reyes del Paso, Langewitz, Lambertus, Mulder, Van Roon, & Duscher, 2013).

3.5.3 *The effects of mindfulness meditation on HRV in clinical populations*

Three studies included various clinical populations (Garland et al., 2010; Garland et al., 2014; Howells et al., 2014). Howells et al. (2014) tested the effects of eight weeks MBCT on HRV for 12 participants with bipolar disorder (BD) and compared this to a control group of nine people having no prior psychiatric history. The findings show that emotional processing is impaired in individuals with BD and they exhibit higher HRV. The study reported decreased HF-HRV and LF-HRV values after MBCT compared to baseline, which can be an indication that MBCT improved emotional processing in individuals with BD.

Two studies tested the effects of MORE (Mindfulness-Oriented Recovery Enhancement) on HRV (Garland et al., 2010; Garland et al., 2014). Garland (2010) examined HRV after 10 weeks of MORE for alcohol dependent participants and increased RMSSD (pre-post intervention) was reported for MORE participants compared to the control group. A further study by Garland et al. (2014) reported increased HF-HRV in chronic pain patients with opioid use problems after eight weeks of MORE intervention, relative to control participants. Both studies by Garland suggest that increased HRV results in high frequency range, and demonstrate evidence for the favorable effects of mindfulness-based treatments.

3.6   Quality Assessment

Table 3 presents the quality assessment based on the six criteria selected from the Cochrane Handbook ratings. The columns show the ratings for risk of bias (ROB) as high ROB, low ROB or unclear ROB. Non-RCT studies were rated as "High risk" for the domains of random sequence generation and allocation concealment as required. However the studies reporting counterbalancing were rated as 'Unclear risk' of bias in the same domains. Figure 2 illustrates the risk of bias summary presented as a percentage in all included studies.
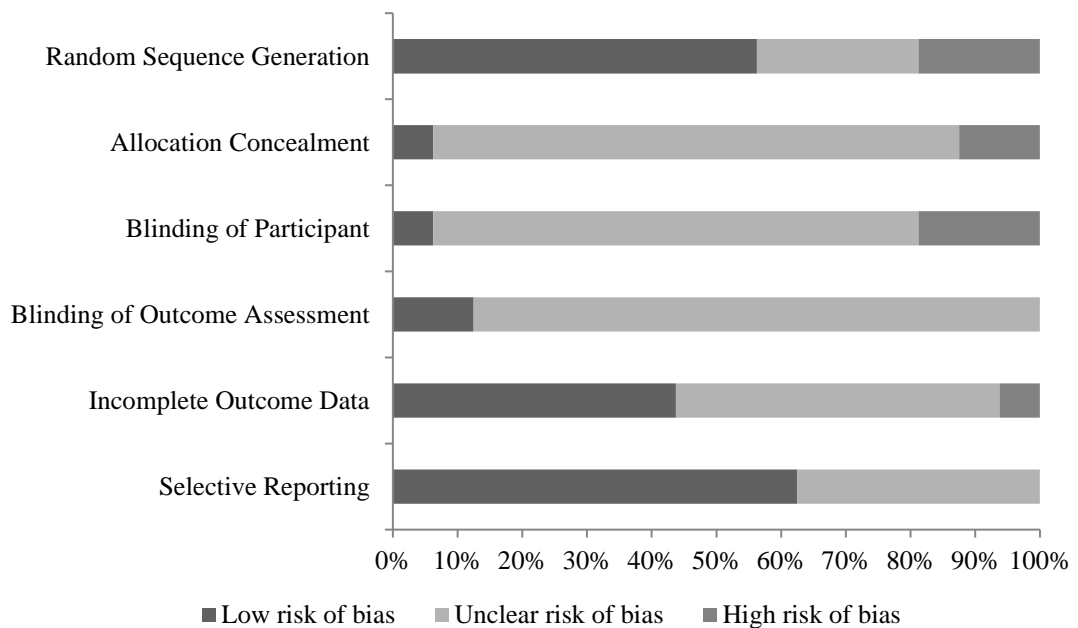

Figure 2. Risk of bias summary

Table 3. *Cochrane Handbook Ratings*

Author (Date)	Random Sequence Generation	Allocation Concealment	Blinding of Participant	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Reporting
Amihai & Kozhevnikov (2014)	**H**	**H**	**U**	**U**	**U**	**U**
Azam et al. (2015)	**L**	**L**	**L**	**U**	**L**	**L**
Delgado et al. (2010)	**L**	**U**	**U**	**U**	**L**	**L**
Delgado P. et al. (2013)	**U**	**U**	**U**	**U**	**L**	**L**
Delgado P. et al. (2015)	**L**	**U**	**U**	**U**	**L**	**L**
Ditto et al. (2006)	**L**	**U**	**U**	**U**	**U**	**U**
Garland et al. (2010)	**L**	**U**	**U**	**L**	**L**	**L**
Garland et al. (2014)	**L**	**U**	**U**	**U**	**U**	**L**
Howells et al. (2014)	**H**	**H**	**H**	**U**	**U**	**L**
Krygier et al. (2013)	**U**	**U**	**H**	**U**	**H**	**L**
Libby et al. (2012)	**U**	**U**	**U**	**U**	**U**	**L**
Lumma et al. (2015)	**U**	**U**	**U**	**L**	**U**	**U**
Nesvold et al. (2011)	**H**	**H**	**H**	**U**	**U**	**U**
Tang et al. (2009)	**L**	**U**	**U**	**U**	**U**	**U**
Watford et al. (2015)	**L**	**U**	**U**	**U**	**L**	**U**
Wolever et al. (2012)	**L**	**U**	**U**	**U**	**L**	**L**

Note: H=high ROB, L=low ROB, U=unclear ROB

Discussion

The aim of this systematic review was to summarize and critically evaluate studies examining the effects of mindfulness on HRV. Overall, this review of 16 studies suggests that mindfulness has an effect on modulating HRV as 75 % of studies (12 out of 16) presented evidence favoring the effect of mindfulness in altering HRV while four studies failed to do so.

Nine out of 13 studies (69%), which included healthy participants, reported statistically significant results for the effect of mindfulness on HRV. Eight of these studies reported increase in HRV in high frequency range (HF-HRV, RSA, RMSSD), which can be interpreted as a positive modulatory effect on PNS activity. Beyond the increases in the high frequency range, three of these studies reported an increase (Ditto et al., 2006; Nesvold et al., 2011; Wolever et al., 2012) and two studies reported a decrease (Amihai & Kozhevnikov. 2014; Krygier et al., 2012) in low frequency range (LF-HRV, THM, heart rate coherence ratio), which is more likely related with SNS activity.

In comparison to 13 studies in healthy populations, there were only 3 studies which included clinical population. Two of these studies reported a favorable effect of mindfulness, as the participants showed increased HF-HRV and RMSSD compared to the control group (Garland et al., 2010; Garland et al., 2014). On the other hand the study by Howells (2014) reported decreased HF-HRV and LF-HRV. The origin of the modulations at HRV frequency components is controversial. There is a growing body of evidence showing that HF-HRV is based on PNS activity, however, the interpretation of LF-HRV is more complex. Regarding the autonomic balance hypothesis, HF-HRV is the marker of cardiac parasympathetic tone, while LF-HRV is the marker of cardiac sympathetic tone, assuming that they reflect the

reciprocal activities of PNS and SNS to regulate cardiac activity (Malliani et al., 1991). The marker of sympathovagal balance (LF/HF ratio) is based on this hypothesis, and it indicates the relative dominance of PNS and SNS to the cardiac activity (Reyes Del Paso et al., 2013; Shaffer et al., 2014; Taskforce, 1996). However LF-HRV being the marker of SNS as well as the concept of sympathovagal balance (LF/HF ratio) was challenged by some studies arguing that the relationship between SNS and PNS is complex, non-linear and often non reciprocal and both can simultaneously produce cardiac activity (Berntson et al., 1997; Billman, 2013; Shaffer et al., 2014; Task Force, 1996). Additionally recent evidence suggests that LF-HRV is mainly determined by PNS activity, which highlights the importance of the PNS activity on the autonomic regulation of heart (Reyes Del Paso et al., 2013). In this context, we observed the studies reporting LF-HRV have mixed findings; for example the studies by Nesvold (2011) as well as Ditto (2006) reported increase in both HF-HRV and LF-HRV, which can be attributed to both sympathetic and parasympathetic activities. Under normal circumstances, the increase in HF-HRV is likely to produce a decrease in LF-HRV or vice versa. Similarly, in two studies reporting LF/HF ratio (Amihai & Kozhevnikov, 2014; Delgado-Pastor et al., 2013), the results by Amihai and Kozhevnikov (2014) were in the expected direction, which the Vipassana meditators showed increased HF-HRV and decreased LF/HF ratio in line with the increased parasympathetic activity, however Delgado-Pastor (2013), who also examined Vipassana meditators reported increased LF/HF ratio, which can be attributed to an increased sympathetic activity.

Classification of meditation practices based on focused attention and open monitoring has been extensively used in meditation research. However, Amihai and Kozhevnikov (2014) suggest that this classification does not represent the

complexity of meditation practices and that some meditation practices include both focused attention and open monitoring. Instead they offer another categorization of meditation practices, relaxation and arousal. They add that this categorization is more clear-cut, as meditation can either result in relaxation or arousal response but not both. Amihai and Kozhevnikov (2014) found that HF-HRV increased in the Theravada meditators and HF-HRV decreased in the Vajrayana meditators. They explain this with the differences in neurophysiological mechanisms between Therevada meditation (relaxation response) and Vajrayana meditation (arousal response). Lumma et al. (2015) similarly reported that it is not the breathing meditation but the loving-kindness meditation and observing-thoughts meditation produced reduced HF-HRV which can be explained that the meditation exercise can produce arousal response and increase sympathetic activity, this can be reflected as either decreased HF-HRV or increased LF-HRV.

The studies demonstrated that HF-HRV increased after mindfulness meditation in both novice (Azam et al., 2015; Ditto et al., 2006; Tang et al., 2009; Watford et al., 2015; Wolever et al., 2012) and experienced meditators (Amihai & Kozhevnikov, 2014; Nesvold et al., 2011). Lumma et al. (2015) including novice meditators and Delgado-Pastor et al. (2013) involving experienced meditators reported no significant differences in altering HRV. Increased HF-HRV in novice meditators suggests that individuals can reach to a mindful state after brief instructions. This is also in line with the literature that suggests brief mindfulness training improved mood and cardiovascular functioning (Broderick, 2005; Zeidan, Johnson, Gordon, & Goolkasian, 2010).

4.1 Methodological quality of the included studies

The report about meditation practices for health concluded that the quality of meditation research is poor due to difficulties in designing good quality RCT studies (Ospina et al., 2007). Most of the studies included in this review were conducted after this report, and attempted to conform to the recommendations made by Ospina et al., (2007) about improving study design. For example, the majority of the studies included active comparison groups and matched manipulations between groups. In addition, most of the studies delivered mindfulness instructions in a standardized format and nine studies reported randomization. However, only Azam et al. (2015) reported allocation concealment from participants. No studies reported double blinding, although such methodological characteristics are difficult to implement in meditation research (Ospina et al., 2007). Other methodological weaknesses include lack of assessment of participants' compliance and expectancy, insufficient information about participants' meditation experience and lack of use of power analysis to calculate sample size.

4.2 Recommendations for future research

Future research should try to address the methodological limitations of the current literature by designing studies, which execute randomization, participant and experimenter blinding and clear reporting of participants' attrition rates. The complexity of meditation practice makes it difficult to standardize the meditation techniques and design RCTs. Therefore, future research should also try to overcome the heterogeneity of this field by describing the meditation techniques clearly and reporting participants' meditation experience. Moreover, there are also methodological issues regarding HRV measurement. The variations in heart period are affected by multiple autonomic factors (Heathers, 2014) and the origin of HRV

modulations is controversial (Billman, Huikuri, Sacha, & Trimmel, 2015). This makes the interpretation of HRV measures difficult and therefore there is a need for methodological improvements as well as a revision of standards and recommendations for HRV measurements (Heathers, 2014; Nunan, Sandercock, & Brodie, 2010).

4.3   Limitations of the systematic review

This systematic review has some limitations. Although a comprehensive search was performed, it is possible that not all the relevant studies were included in our systematic review as only one reviewer carried out the search process. This may have also introduced bias in the selection of studies and in the rating of the methodological quality. Additionally, heterogeneity of sample characteristics, variety of meditations and control groups was an obstacle and for this reason meta-analysis was not conducted.

This review excluded studies published in languages other than English and this possibly increased the risk of bias in our results. It is likely that we have missed some untouched evidence in other languages for example studies from India and China, where many mediation techniques originated.

In conclusion, the majority of the studies demonstrated that there are findings, which show the effectiveness of mindfulness on changing HRV for both healthy and clinical populations. However, several methodological issues suggest that the results of these studies should be approached with caution as the effects may have been overestimated or generalizability not yet established.

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Part 2: Empirical Paper

The effect of brief mindfulness training on distress tolerance, heart rate

variability and alcohol consumption

Abstract

Aim: To investigate the effects of brief experimental mindfulness training on alcohol craving and consumption in relation to distress tolerance and heart rate variability (HRV).

Methods: Sixty-eight harmful/hazardous drinkers were randomly allocated to a mindfulness group (n=34) or a matched placebo (relaxation) group (n=34) using double-blind procedures. Dependent variables were distress tolerance, HRV, craving and drinking behaviour (at the end of the experiment and at the seven day follow up).

Results: The participants in the relaxation group showed increased HRV after training. Participants who had increased HRV consumed less alcohol immediately after training but only the mindfulness group consumed less alcohol after seven days. However, the increase in distress tolerance was similar between groups and there was no significant relationship between distress tolerance and drinking outcomes.

Conclusions: Mindfulness training led to a greater reduction in alcohol consumption among harmful/hazardous drinkers. Increased HRV is a biomarker of heightened self-regulation and related to reduced alcohol use. Overall, these findings can be beneficial in improving mindfulness-based interventions targeting alcohol use.

Introduction

Excessive alcohol use can cause serious health problems, as well as significant social and economic harms. Alcohol misuse is associated with a variety of medical problems including liver cirrhosis, high blood pressure, heart disease and some cancers. Every year, there are approximately 3.3 million alcohol-related deaths worldwide (World Health Organization, 2014). In the UK alone, there were over 8500 alcohol-related deaths in 2014 (Office for National Statistics, 2016). Today in the UK, it is estimated that around nine million adults consume alcohol and approximately 1.6 million people are alcohol dependent (Public Health England, 2014). There are around 1.2 million alcohol-related admissions to hospitals, and the overall cost of alcohol-related harm to the NHS is estimated to be £3.5bn a year in England alone (Public Health England, 2014). In addition, based on UK government data, excessive alcohol use leads to 1 million violent crimes a year (Home Office, 2011). Estimations suggest that the cost of alcohol-related harm to society is around £21 billion a year (Home Office, 2012).

Given that excessive alcohol use is associated with such pervasive problems, there has been extensive work aiming to characterize the psychological processes in addictive behaviour. A number of theories have been developed to explain the aetiology and maintenance of alcohol use disorders. Negative affect has been emphasized in some of these theories as an important factor in the onset, maintenance and relapse of alcohol problems (Baker, Piper, McCarthy, Majeskie, & Fiore, 2004; Brown, Lejuez, Kahler, Strong, & Zvolensky, 2005; Zvolensky, Feldner, Eifert, & Brown, 2001). Moreover, negative affect is both caused by and, in turn, instigated by craving (Zvolensky et al., 2001). In other words, craving can be experienced as distressing and in order to change that unpleasant state, craving often

results in drinking (Brewer, Elwafi, & Davis, 2012; Murphy & MacKillop, 2014). The negative affect model suggests that low tolerance for negative affect, rather than negative affect per se, plays an important role in the maintenance of alcohol dependence. Therefore treatments that aim to improve tolerance of negative affect (distress tolerance) could be key to promoting abstinence.

Current pharmacotherapies and psychosocial treatments for addictive behaviour tend to target craving. For example, behavioural treatments for alcohol generally aim to achieve abstinence through skills learning including general strategies for coping, ways to avoid cues and substituting drinking with other activities. Cognitive-behavioural treatments (CBT) also enhance skills through self-monitoring, identification of craving patterns and addressing maladaptive thinking patterns. A reasonable evidence base has built up around the use of CBT for substance use disorders and is applicable to problematic drinking (Longabaugh & Magill, 2011). However, no routinely used treatment specifically targets the central link between negative affect and craving, and given that negative affect often precedes relapse, this may be an important reason why treatments produce disappointing outcomes. Consequently, there is still a need for more effective alcohol cessation treatments.

In the past three decades, mindfulness-based treatments have gained in popularity among clinical researchers who recognized the need to tackle experiential avoidance in psychiatric conditions, including addictive disorders (Bowen et al., 2009; Brewer et al., 2009; Witkiewitz, Marlatt, & Walker, 2005). Mindfulness is defined as non-judgmental observation of the present-moment experience. It involves two important components: sustaining one's attention on the present moment and holding an attitude of acceptance (Bishop et al., 2004). Although there are some

differences between specific mindfulness practices, the main aim is to help the individual to take a different stance towards their thoughts and feelings, one that is not characterized by (experiential) avoidance, but rather, openness, curiosity and acceptance.

In relation to alcohol use disorders, mindfulness can help to increase individuals' tolerance for craving and to reduce their habitual responses (Witkiewitz et al., 2005). As craving can be unpleasant, especially when precipitated by withdrawal, this can lead individuals to drink in order to change this negative state. Alternatively, as alluded to above, craving can support, and be supported by, negative feelings of depression and anxiety. Instead of avoiding the unpleasant state (e.g. by drinking alcohol), mindfulness encourages individuals to observe the craving experience itself and to explore how craving feels in their bodies. In this way individuals do not act on their physical sensations; instead they experience how to tolerate them (Brewer et al., 2012). Mindfulness practice and non-judgmental awareness can also help to change the way individuals relate and respond to their cravings by reducing the tendency to respond impulsively (Morrison, Madden, Odum, Friedel, & Twohig, 2014). As a secondary consequence, cravings become less intense and exert less control over behaviour (Brewer et al., 2012).

Recent studies have explored how mindfulness can be used to treat alcohol use disorders. Clinical studies have reported mixed findings regarding the effects of mindfulness-based practices on addiction. Bowen et al. (2009) reported that mindfulness practices increased acceptance and reduced craving and alcohol use. Another study by Brewer et al. (2009) on alcohol and cocaine dependence had promising results as they found that mindfulness was equally effective as CBT in reducing alcohol use. Although some studies reported significant results, others have

not reported a reduction in alcohol craving (Garland, Gaylord, Boettiger, & Howard, 2010) and reduced substance use (Bootzin & Stevens, 2005).

Given the mixed findings of previous studies and the limited number of experimental studies examining the effects of mindfulness, additional experimental studies are essential to investigate the mechanisms by which mindfulness may exert a beneficial effect on craving. Investigation of a number of conceptually related psychophysiological constructs may prove to be useful in this regard.

1.1   Distress Tolerance, addiction and mindfulness

Distress tolerance refers to the trait capacity for enduring physical and/or emotional aversive states (Simons & Gaher, 2005; Zvolensky, Vujanovic, Bernstein, & Leyro, 2010) and plays an important role in the development of psychopathology, including substance addiction (Zvolensky et al., 2010). Individuals with low distress tolerance are at greater risk to abuse substances (Zvolensky et al., 2010) and on the contrary increased distress tolerance is considered as a protective factor from the development of psychopathology (Simons & Gaher, 2005). Research suggests that distress tolerance is related to different stages of substance use; onset, maintenance and relapse (e.g. being able to tolerate discomfort during abstinence). For example, Brown, Lejuez, Kahler, & Strong (2002) found that individuals who have a tendency for negative affect during nicotine cessation and those who find it difficult to tolerate physical discomfort are more likely to experience early relapses. Abrantes et al. (2008) also found that smokers with low distress tolerance are at greater risk of early relapses. Specific to alcohol use, research has indicated that adolescents with low distress tolerance tend to drink alcohol more frequently (Daughters et al., 2009; Howell, Leyro, Hogan, Buckner, & Zvolensky, 2010; Simons & Gaher, 2005).

Distress tolerance can be assessed by self-report measures and behavioural

measures. Self-report measures assess perceived capacity to tolerate distress, whereas behavioural measures, assess distress tolerance while an individual is experiencing physical/psychological stress induced by the experimental tasks (Gorka et al., 2012). One way of measuring distress tolerance in behavioural terms is the breath holding task (BHT; Brown et al., 2002), the performance of which is a predictor of addiction treatment outcomes (Sütterlin et al., 2013). Research suggests that the longer the period one can hold one's breath, the longer the period one can abstain from smoking (Brown et al., 2002). Similarly, Abrantes et al. (2008) found that individuals with low distress tolerance showed higher levels of negative affect and were more likely to relapse. These results are in line with earlier studies by Hajek showing that breath holding duration is positively correlated with smoking abstinence (Hajek, Belcher, & Stapleton, 1987).

In relation to mindfulness interventions and distress tolerance, a study by Hayes and colleagues investigated the effects of acceptance-based intervention on pain caused by a cold-pressor task. The results show that acceptance-based intervention increased tolerance to pain (Hayes, Strosahl, & Wilson, 1999). Similarly mindfulness interventions for alcohol use disorders also target distress tolerance in relation to tolerating distressing aspects of craving. However, no previous studies on mindfulness have investigated the relationship between distress tolerance and drinking outcomes.

1.2 Heart rate variability, craving and mindfulness

Recent studies investigating the effects of mindfulness on emotion regulation have included measures of heart rate variability (HRV) in addition to self-report measures (Arch & Craske, 2006). HRV is the variation of a time interval between heartbeats and is a reliable biomarker for autonomic nervous system (ANS) activity.

HRV in a high frequency range (HF-HRV) is an important measure of parasympathetic nervous system (PNS) activity and RMSSD (root mean square of successive differences) is the approximate time domain correlate of HF-HRV (Task Force, 1996). It is a marker of flexible adjustment and improved emotional regulation capacity as ANS adapts necessary bodily responses with linked emotions (e.g. during feelings of calmness muscles relax) (Appelhans & Luecken, 2006). Conversely diminished HRV is an indicator of low PNS activity and poor psychological health (Libby, Worhunsky, Pilver, & Brewer, 2012).

Studies have found that HF-HRV is closely linked to heightened self-regulation in smokers (Libby et al., 2012). In addition, nicotine dependence is associated with low levels of HF-HRV (Kupari, Virolainen, Koskinen, & Tikkanen, 1993), whereas high HF-HRV is linked with abstinence (Minami, Ishimitsu, & Matsuoka, 1999). In relation to alcohol use, a meta-analysis indicates that alcohol dependence is related to reduced HRV (Quintana, McGregor, Guastella, Malhi, & Kemp, 2013). A systematic review demonstrated that alcohol-dependents had decreased HRV compared to non-dependent individuals and it was also found that HRV reduced further during alcohol withdrawal but increased following abstinence (Karpyak, Romanowicz, Schmidt, Lewis, & Bostwick , 2014).

Mindfulness meditation increased HF-HRV in both healthy (Ditto, Eclache, & Goldman, 2006; Tang et al., 2009) and clinical populations (Garland et al., 2014). Relaxation exercises, on the other hand, increased HF-HRV in healthy population (Sakakibara et al., 1994; Sarang & Telles, 2006) but not in clinical groups (panic, social anxiety, obsessive-compulsive and generalized anxiety) (Pittig, Arch, Lam, & Craske, 2013).

An increase in HF-HRV suggests a potential link between the practice of developing particular mental states characterized by low arousal and reduced cigarette consumption (Brewer et al., 2009). This result is in line with the study by Libby et al. (2012), which demonstrated that mindfulness increased HF-HRV in smokers and was associated with a significant reduction in smoking. Garland et al. (2010) found that HF-HRV increased after mindfulness in alcohol dependent individuals. However they did not report a significant reduction in alcohol craving. These mixed findings suggest that there is a need for studies that directly investigate the link between changes in HF-HRV as a result of mindfulness practice and alcohol related outcomes.

1.3   The present study

This thesis was conducted as part of a research programme on the effects of 'micro-interventions' on drug use behaviour and other outcomes related to the psychological flexibility model (e.g. Beadman, Das, Freeman, Scragg, West, & Kamboj, 2015). The goal of this two-part study (the other part of the study was carried out by a D.Clin.Psy. trainee, Shirley Serfaty, which is presented separately; Serfaty, 2016) was to investigate the effectiveness of brief experimental mindfulness training followed by self-guided practice for a week in reducing alcohol craving and consumption in relation to distress tolerance and HF-HRV. Mindfulness training was compared to a closely matched relaxation control condition.

We hypothesized that mindfulness training would be associated with a greater increase in distress tolerance over two time points within the same session when compared to the control condition (relaxation).

We were interested in exploring the effects of mindfulness and relaxation on HRV and exploring the relationship between distress tolerance, HRV and drinking

behaviour at the end of experimental session (taste test) and over a seven day follow up period.

Method

2.1   Joint Theses

This D.Clin.Psy. thesis was a joint theses project with another Trainee Clinical Psychologist, Shirley Serfaty. We conducted the same experimental procedure on different days. Shirley's thesis involved a cue reactivity procedure to examine craving and negative affect in response to standardised mindfulness instructions and a relaxation control condition. In the cue reactivity paradigm participants were exposed to alcohol cues while their physiological responses were measured (HR and blood pressure).

We were both responsible for data collection and management, but analysed our primary outcomes separately. The write-up of this thesis was independent.

2.2   Design

The present study used two 2x2 mixed (between and within-groups) design. The between-groups variable was the training group (mindfulness vs. relaxation), and the within-groups variable was time (pre vs. post and follow up measures). The time variable was a repeated measure of time points at: baseline and follow up also pre-intervention (T1) and post-intervention (T2). The dependent variables consisted of distress tolerance, HRV, craving and drinking behavior. Figure 1 shows the time points.

Screening and baseline measures

$\downarrow$

Pre-intervention tests (T1)

$\downarrow$

Training conditions (mindfulness versus relaxation)

$\downarrow$

Post-intervention tests and state measures (T2)

$\downarrow$

Follow-up measures
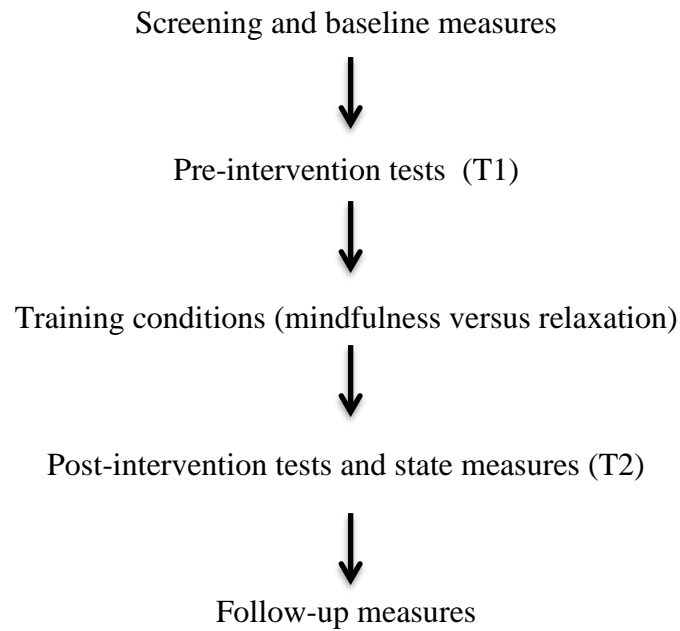
Figure 1. Time points

2.3   Participants

Participants were selected from a pre-clinical population of drinkers who are at risk of developing problematic use. They were selected on the basis of having hazardous or harmful drinking patterns (assessed by a score of ≥ 8 on The Alcohol Use Disorder Identification Test, AUDIT; Babor, Higging-Biddle, Saunders, & Monteiro, 2001) and drinking more than the weekly alcohol limits recommended by the Department of Health (14 + units for women and 21 + units for men). Other inclusion criteria included being aged between 18-50 years old and being fluent in English. Exclusion criteria included having no serious current mental health problems (i.e. those who require ongoing treatment) and no acute or chronic respiratory illnesses. Participants were also asked about their preferred alcoholic beverage. Only beer drinkers were included in the study, in order to ensure that a single cue-reactivity procedure (exposure to a glass of beer) would be suitable for all participants.

Participants were randomly allocated to mindfulness or relaxation training by using an online random number table generator (www.random.org). The study was conducted under double-blind conditions (both experimenters and participants were unaware if they had been assigned to an active or a control condition). The randomisation code was provided by the supervisor.

2.4   Power analysis

The power calculation for the current study was informed by previous research using a similar design and objectives (Szasz et al., 2012). Although this study investigated nicotine rather than alcohol, the design was thought to be more important than the substance, as craving is a transdiagnostic construct. Szasz et al. (2012) investigated the effects of different emotion regulation strategies on nicotine craving and found a medium-large effect size (η^2=0.13). Taking these findings into account, power was calculated using G*Power3 (Faul, Erdfelder, Lang & Buchner, 2007) with alpha specified at 0.05 and power at 0.8. Taking these findings into account, sample size for a mixed between-within subjects ANOVA was calculated using G*Power3 (Faul, Erdfelder, Lang & Buchner, 2007) with alpha specified at 0.05 and power at 0.8. This estimated a sample size of 72 (36 in each group). The achieved sample size in the present study was 68 (34 in mindfulness and 34 in relaxation training).

2.5   Measures

Most measures used in this study were standardized questionnaires. Alternative methodologies (e.g. self-devised questionnaires) are outlined in the appendices.

2.5.1 Screening measure

The Alcohol Use Disorder Identification Test (AUDIT). This is a clinical screening tool used to identify hazardous and harmful alcohol use, as well as possible alcohol dependence (Babor et al., 2001). AUDIT consists of 10 items regarding the frequency and quantity of recent alcohol use and alcohol dependence symptoms. Items are rated on a 5-point Likert scale ranging from 0-4 with higher scores reflecting greater hazardous alcohol use. The cut-off score is 8, which indicates hazardous or harmful drinking. The AUDIT has been demonstrated to have good reliability and validity (Babor et al., 2001).

2.5.2 Physiological measure (ECG recording)

During the mindfulness and relaxation training, the heart rate variability of the participants was measured. An electrocardiogram (ECG) signal was detected and recorded using a wearable heart rate monitor with a sampling rate of 1kHz (Firstbeat Bodyguard 2). ECG electrodes were attached below the right collarbone and the bottom of the left ribcage at the start of the experiment to avoid interruption once the experiment started, and recording continued throughout. At the end of the experiment, the ECG electrodes were detached and data uploaded onto a dedicated computer to which the device was time-locked. The key measurement time-points were before and during the training session. In relation to HRV data, the start of the recording was determined from the time indicated on the computer, which was recorded during the experiment and was used to identify the appropriate intervals for analysis of the inter-beat interval data. This data was measured online, recorded by hand source data and was analysed offline using the Kubios package (http://kubios.uku.fi/).

2.5.3 *Drinking-related and relevant trait measures*

Timeline Follow Back (TLFB). This is a drinking assessment tool that obtains retrospective estimates of daily drinking (Sobell & Sobell, 1992). Participants were asked to recall how many units of alcohol they consumed over the last 7 days. In order to aid their recall, participants were asked to use their diary to help them to think of any special events when they might have consumed alcohol more (e.g. parties). If they were not sure of the exact units of alcohol consumed, they were encouraged to give their best guess. Participants were also presented a guide explaining number of units for different alcoholic beverages. TLFB has been shown to have high test-retest reliability and validity across clinical and general populations (Sobell, Sobell, Klajner, Pavan, & Basian, 1986).

The Drinking Motives Questionnaire-Revised (DMQ-R). This is a self-report measure that identifies motivation for drinking (Cooper, 1994). It has four dimensions of motivation for drinking: coping, social, conformity and enhancement of pleasurable feelings. 20 items are scored on a 5-point Likert scale, 1 (almost never/never) to 5 (almost always/always). DMQ-R has shown good to excellent test and re-test reliability in a sample of undergraduates (Grant, Stewart, O'Connor, Blackwell, & Conrod, 2007).

Five Facets Mindfulness Questionnaire (FFMQ). This is a self-report measure of trait mindfulness (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). It consists of 39 items and includes five aspects of mindfulness: non-reactivity, observing, acting with awareness, describing, non-judging of experience. Items are scored on a 5-point Likert scale 1 (never or very rarely true) to 5 (very often or always true). FFMQ has been demonstrated to have adequate to good reliability and validity (Baer et al., 2008).

The Hospital Anxiety and Depression Scale (HADS). The HADS was used as a baseline trait measure (Zigmond & Snaith, 1983). It is a 14-item questionnaire that assesses levels of anxiety and depression. It has two subscales: seven items to measure depression and seven items to measure anxiety. Items are scored on a 4-point Likert scale ranging from 0-3. For each subscale the total score ranges from 0-21 and is categorised as follows: 0-7 indicates normal, 8-10 indicates borderline and 11-21 indicates abnormal levels of anxiety and depression. The HADS has shown good reliability and validity (Zigmond & Snaith, 1983).

The State-Trait Anxiety Inventory (STAI). This self-report measure of trait and state anxiety consists of two questionnaires of 20 items each, which are rated on a 4-point Likert scale 1 (not at all) to 4 (very much so). STAI has shown very good test-retest reliability and adequate validity (Spielberger & Vagg, 1984).

The Alcohol Craving Questionnaire-Short Form-Revised (ACQ-SF-R). This is a self-report measure of alcohol craving in the current context (Singleton, Henningfield, Tiffany, 1994). ACQ-SF-R has four factors: compulsivity, expectancy, purposefulness and emotionality. It consists of 12 items. Items are rated on a 7-point Likert scale from 1 (strongly disagree) to 7 (strongly agree). ACQ-SF-R demonstrated moderate to strong reliability and validity (Raabe, Grusser, Wessa, Podschus, & Flor, 2005).

Affect Grid. This is a single-item self-report measure that assesses affect in two dimensions: pleasure-displeasure and arousal-sleepiness (Russell, Weiss, & Mendelsohn, 1989). Both pleasure and arousal scores range from 1 to 9: 1 (pleasure) to 10 (displeasure) and 1 (arousal) to 10 (sleepiness). The pleasure score was the number of the column marked, counting from the left. The arousal score was the number of the row marked, counting from the bottom. In the cue reactivity procedure

(which is the focus of Shirley Serfaty's thesis), mood was assessed at different time points repeatedly and therefore we used the affect grid, as it is brief and well-suited to repeated assessments. In this study participants were provided written instructions on how to use it and asked, "Please rate your mood as it is right now". The participant placed a single mark on the grid. The Affect grid has demonstrated adequate reliability and validity (Russell et al., 1989).

2.5.4   Pre measures

Taste test. This is an objective, behavioural measure of alcohol consumption. In the current study a similar procedure was followed as outlined by Field and Eastwood (2005). Participants were presented with 275 ml of chilled alcohol free beer (Becks brand) and instructed to drink as much as they wish to (they were blind to the alcohol free nature of the drink). Alcohol free beer was used in order not to interfere with the mindfulness training. They were instructed to make judgments about the drink in four continuums (unpleasant-pleasant, tasteless-strong, bitter-sweet, flat-gassy) by ticking along each line on a visual analogue scale provided on the computer. The dependent variable was the amount of drink consumed, and this was measured after the experiment (Field & Eastwood, 2005; Hobbs, Remington, & Glautier, 2005).

Breath-holding task (BHT). It is a behavioural measure of distress tolerance with good test-retest reliability (Sütterlin et al., 2013). In this study a similar procedure was followed as outlined by Brown et al. (2002) and Sütterlin et al. (2013). In this task participants were asked to hold their breath for as long as possible after a full, normal exhalation (Sütterlin et al., 2013). While holding their breath they were asked to keep their eyes closed and instructed to hold their breath for as long as possible, even when they had the urge to breathe; this increased their distress levels

(Sütterlin et al., 2013). Participants were monitored and nose clips were used to prevent breathing through the nose. They were timed until they could no longer hold their breath. The BHT outcome was total breath holding time in seconds.

2.5.5. *Post strategy measures*

Credibility and Expectancy Questionnaire (CEQ). Devilly and Borkovec's (2000) questionnaire was adapted for the present study. Instructions about mindfulness or relaxation training were followed by the credibility questionnaire in order to assess the credibility of each training exercise. The credibility factor included questions such as 'How logical does this strategy seem to you if it was used as a way of helping people to cut down/stop drinking?' The expectancy factor items like 'How much do you really feel that this strategy will help you to reduce your cravings?' The original scale consists of six items, but we only included four questions, as two questions in the expectancy factor were not considered relevant to brief mindfulness/relaxation training. Additionally, the phrase 'this therapy' was changed to 'this strategy'.

Toronto Mindfulness Questionnaire (TMS). This is a self-rated scale that assesses state mindfulness (Lau et al., 2006). It can be administered immediately after or during mindfulness exercise. TMS consists of 13 items, which are rated on a 5-point Likert scale ranging from 0 (not at all) to 4 (very much). TMS assesses two qualities of mindfulness: curiosity and decentering. TMS has been shown to be a valid and reliable measure of mindfulness (Lau et al., 2006).

Relaxation/tension measure. The equivalent of the TMS for the relaxation training was a single item question to assess participants' level of relaxation. Participants were asked to indicate their level of tension on a 10-point Likert scale: 1 (absolutely no tension) to 10 (extremely tense) (Vinci et al., 2014).

Manipulation check. Participants were asked six true/false questions to assess how much they had followed the instructions. The manipulation check consisted of two questions related to mindfulness, including qualities such as noticing, observing and allowing their craving to stay. The remaining three questions were related to relaxation (e.g. breathing calmly and releasing tension to reduce my craving). There was also one generic question "I was given a specific strategy to use to cope with cravings".

The Taste test and BHT were re-administered post intervention using the same procedure as acute indices of change in drinking behaviour and distress tolerance*.*

2.5.6 Follow-up measures

Participants were asked to practise the mindfulness/relaxation techniques for the next seven days whenever they craved alcohol. At the one week follow-up, participants were emailed the following measures:

TLFB. The same TLFB tool used, additionally participants were emailed the instructions and the unit guide.

ACQ-SF-R. As above

Affect grid. As previously explained. Participants were emailed the instructions.

Assessment of practice. Participants were emailed a three item questionnaire in order to assess their compliance with their assigned strategy (mindfulness or relaxation). They were asked to specify the number of days they practised the strategy on a 5-point Likert scale; 1 (0 days) to 5 (7 days). They were also asked the duration that they had practised their assigned strategy per day on a 5 point Likert scale; 1 (0 minutes) to 5 (15+ minutes).

2.6   Procedure

2.6.1   Participant recruitment

Ethical approval was obtained from the UCL Research Ethics Committee (Project ID 0760/002; Appendix 1). Participants were recruited via advertisements on online websites: Sona Systems, Call for Participants, Experimatch, Gumtree and social media (e.g. Facebook). Participants who were interested in taking part were emailed the screening questionnaire link to assess their eligibility. Participants who did not complete the questionnaire were sent reminders, and if they did not reply it was assumed that they were no longer interested in taking part in the study. Participants who were not eligible to take part in the study were sent a thank you email. The eligible participants were emailed more information about the study and were notified of the date they needed to attend the experiment. The day before the experiment eligible participants were contacted via phone or email to remind them the time of their attendance and they were also asked to abstain from alcoholic drinks before the experiment. Testing sessions were conducted between 17:00-21:00 during weekdays to control the diurnal effects on craving and HRV. For each participant the experiment lasted for approximately 1.5 hrs.

2.6.2   Testing procedure

On the day of the experiment the participants were given the information sheet (Appendix 2) and informed consent was obtained (Appendix 3). Prior to testing, a breathalyser was used to make sure that participants had not consumed any alcoholic drinks before the testing session.

Participants were instructed to fit the ECG device (written instructions and a pictorial guide were also provided). They were asked to provide socio-demographic information (gender, ethnicity, age, education level, employment). Participants were

then administered baseline questionnaires including TLFB, FFMQ, STAI, ACQ-SF-R and the Affect Grid. This was followed by the taste test to assess their current alcohol consumption and BHT to measure their immediate distress tolerance levels. Participants were then randomly allocated to mindfulness or relaxation training. The mindfulness/relaxation recordings each lasted 15 minutes.

2.6.3 *Strategy instructions*

The instructions consisted of three sections: 1) explanation of the strategy, its usefulness, and the rationale for practising it in relation to craving, 2) strategy practice, 3) the main task in which participants practised the strategy in more detail and depth. Instructions were audio recorded and presented in a standardised format in order to reduce experimenter effects. Both instructions were closely scripted, similar in complexity and number of craving related cue words as well as the order of the instructions, duration and the number of words. Readability scores (FlescheKincaid grade level; Kincaid, Fishburne, Rogers & Chissom, 1975) suggest that both scripts were well-matched in terms of complexity and readability (mindfulness: 9.07 and relaxation: 8.93).

Mindfulness training. The main aim of the exercise was not to get rid of the experience of craving but to experience craving in a different way and learn that those feelings can be accepted rather than acted upon. In the task participants were instructed to imagine their favourite alcoholic drink to induce craving. The recording was informed by Kabat-Zinn's guided meditations (Williams, Teasdale, Segal, & Kabat-Zinn, 2007) and also Bowen and Marlatt's (2009) 'urge surfing' mindfulness technique that is specific to cravings in smokers.

Relaxation training. The main aim of the exercise was to reduce craving and change the feelings of craving into less unpleasant ones through releasing tension in

their body. In the task participants were instructed to imagine their favourite alcoholic drink in order to induce craving (the same as the mindfulness script). Then they were asked to release tension in their body where they experience craving (e.g. 'I am managing my craving by calming my abdomen'). The relaxation recording was informed by Vinci et al. (2014).

The mindfulness and relaxation scripts are presented in Appendix 4 and Appendix 5.

In each training explanation of the strategy was followed by the credibility/expectancy questionnaire in order to assess participants' beliefs about the strategy. After participants finished listening to the recordings they were asked to complete the compliance check to assess how much they had followed the instructions. Following this, participants were asked to complete the post-test measures including the TMS, relaxation/tension measure, taste test and BHT.

At the end of the experiment participants were debriefed and they were asked to practise their assigned strategy everyday for approximately 15 minutes for one week, whenever they crave an alcoholic drink. They were also provided with a cue card that included a brief summary of their strategy (mindfulness or relaxation) (Appendix 6). Participants were emailed reminders to use their assigned strategy, two days and four days after attending the experiment. Participants were then emailed the follow-up measures including the TLFB, ACQ-SF-R, Affect grid and assessment of practice questionnaire seven days after the experiment. Once participants completed the follow-up measures, they were reimbursed £20 for their time.
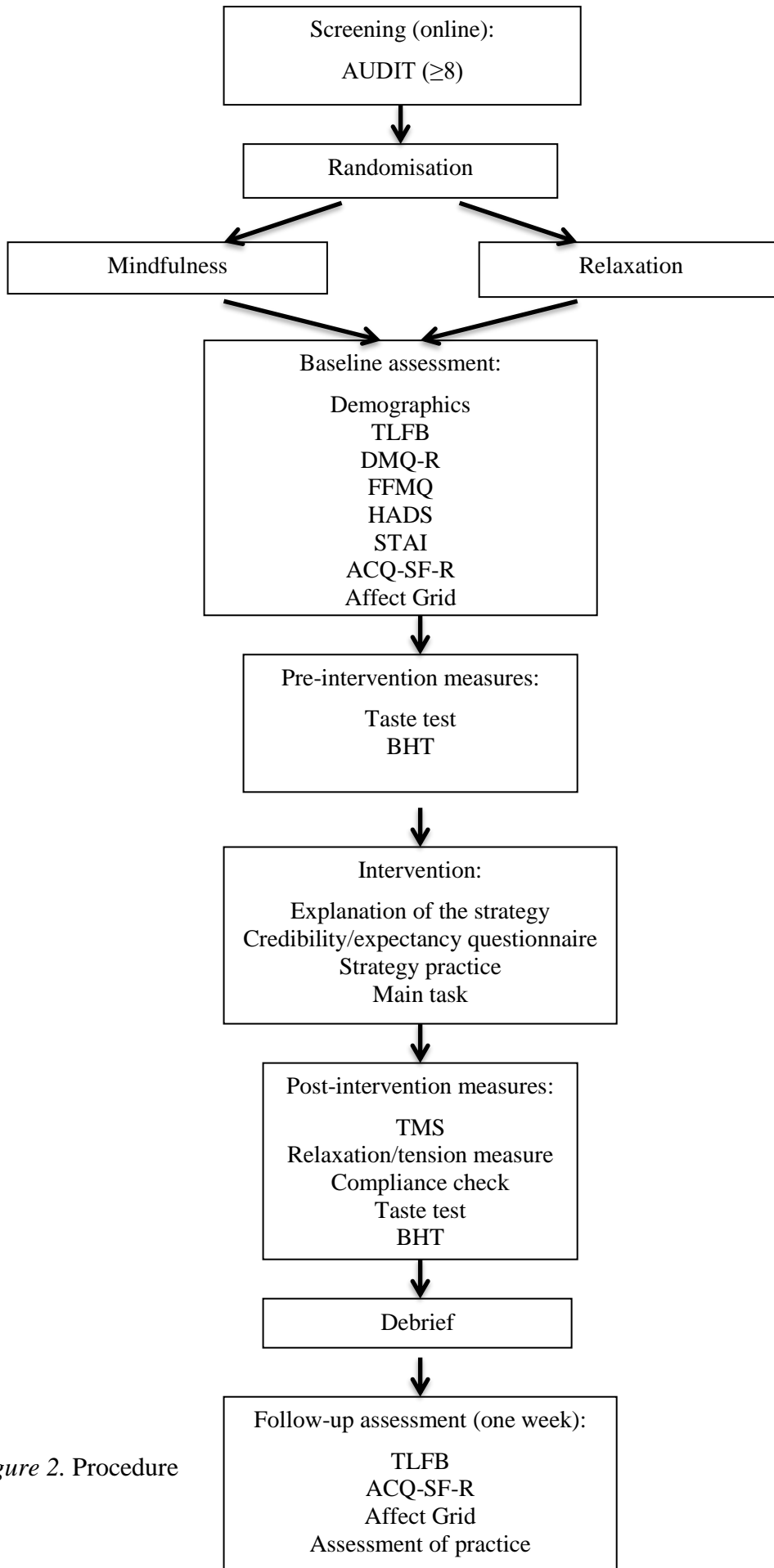
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                    ┌─────────────────────────────┐
                    │   Screening (online):       │
                    │                             │
                    │   AUDIT (≥8)                │
                    └─────────────────────────────┘
                                  │
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                    │      Randomisation          │
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                          ↙               ↘
        ┌──────────────────┐         ┌──────────────────┐
        │   Mindfulness    │         │    Relaxation    │
        └──────────────────┘         └──────────────────┘
                          ↘               ↙
                    ┌─────────────────────────────┐
                    │   Baseline assessment:      │
                    │                             │
                    │   Demographics              │
                    │   TLFB                      │
                    │   DMQ-R                      │
                    │   FFMQ                       │
                    │   HADS                       │
                    │   STAI                       │
                    │   ACQ-SF-R                   │
                    │   Affect Grid               │
                    └─────────────────────────────┘
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                    ┌─────────────────────────────┐
                    │   Pre-intervention measures:│
                    │                             │
                    │   Taste test                │
                    │   BHT                        │
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                    ┌─────────────────────────────┐
                    │   Intervention:             │
                    │                             │
                    │   Explanation of the strategy│
                    │   Credibility/expectancy questionnaire│
                    │   Strategy practice         │
                    │   Main task                 │
                    └─────────────────────────────┘
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                                  ▼
                    ┌─────────────────────────────┐
                    │   Post-intervention measures:│
                    │                             │
                    │   TMS                        │
                    │   Relaxation/tension measure│
                    │   Compliance check          │
                    │   Taste test                │
                    │   BHT                        │
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                    │         Debrief             │
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                    │ Follow-up assessment (one week):│
                    │                             │
                    │   TLFB                       │
                    │   ACQ-SF-R                   │
                    │   Affect Grid               │
                    │   Assessment of practice    │
                    └─────────────────────────────┘
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Figure 2. Procedure

2.7   Piloting

The scripts were reviewed by 20 trainee clinical psychologists (10 for relaxation and 10 for mindfulness). Each volunteer was asked to rate the script:

1) To what extent did the instructions focus on the experience of craving?

2) To what extent did the instructions encourage the participants to relax in response to the experience/be mindful of their experience?

The piloting confirmed that the scripts were clear, focused on craving and encouraged relaxation or mindfulness. The experimental procedure was also piloted on four people and this resulted in minor amendments (e.g. wording of the instructions and order of tasks).

2.8   Analysis

Normality tests were carried out to make sure data met the assumptions for parametric testing. Raw data were inspected for outliers using boxplots for the mindfulness and relaxation groups separately. Detected outliers were replaced with adding/subtracting 1 to the next highest/lowest non-outlier values in their respective group (Field, 2005). The analysis was repeated with replaced outliers and the results were similar. This suggests that the findings are reliable and not largely influenced by a small number of cases.

Independent t-tests were performed to make sure both the mindfulness and relaxation groups were similar in demographics, drinking characteristics and baseline measures. BHT, HRV and levels of craving (ACQ-SF) and drinking (TLFB, taste test) were analysed using a 2×2 mixed-ANOVA, with intervention (mindfulness vs. relaxation) as the between-subjects factor and the time (pre vs. post measures) as the within-subjects factor.

The α level was 0.05 except for adjustments for post hoc and multiple between-group comparisons of baseline measures where it was adjusted to α = 0.01 to reduce the probability of making a Type I error.

1.13 % of the total data was missing. Missing BHT and HRV data was due to a technical fault and it was not replaced.

Results

3.1   Demographics

Table 1 and 2 outline demographic information and drinking characteristics for the mindfulness and relaxation groups.

Table 1. *Demographic data*

Demographic Variable	Mindfulness N (%)	Relaxation N (%)
Gender		
Female	17 (50)	17 (50)
Male	17 (50)	17 (50)
Ethnicity		
White	29 (85.3)	24 (70.6)
Asian	3 (8.8)	2 (5.9)
Black	0 (0)	2 (5.9)
Chinese or other	1 (2.9)	5 (14.7)
Mixed	1 (2.9)	1 (2.9)
Occupation		
Student	25 (73.5)	29 (85.3)
Employed	9 (26.5)	5 (14.7)

Table 2. *Age, years of education, drinking characteristics and other baseline measures*

	Mindfulness (*n* = 34)	Relaxation (*n* = 34)
	M (*SD*)	M (*SD*)
Age	24.59 (6.77)	23.09 (4.97)
Years of education	15.53 (1.69)	15.47 (1.48)
Number of drinking units per week	22.31 (6.81)	21.22 (5.72)
AUDIT score	16.41 (4.99)	17.21 (4.61)
TLFB score	27.66 (16.96)	23.94 (11.71)
ACQ score	3.70 (1.00)	4.03 (0.81)
Mindfulness and mood variables		
DMQR score		
Social subscale	3.73 (0.86)	3.95 (0.67)
Coping subscale	2.48 (1.08)	2.75 (0.93)
Enhancement subscale	3.28 (0.85)	3.72 (0.83)
Conformity subscale	1.61 (0.71)	1.84 (0.89)
FFMQ score	3.32 (0.47)	3.21 (0.46)
STAI score	2.07 (0.60)	2.28 (0.63)
HADS		
Anxiety subscale	7.41 (4.55)	8.09 (3.86)
Depression subscale	3.65 (3.56)	3.91 (2.77)
Affect Grid		
Pleasure subscale	6.48 (0.91)	6.35 (1.25)
Arousal subscale	4.55 (1.72)	4.71 (1.79)

3.1.1 *Baseline group characteristics*

As presented in Table 1 and 2, there were no differences between mindfulness and relaxation groups in key demographics and drinking related variables. The groups did not differ on any of the alcohol-variables (t values $\leq$2.17) or mood and mindfulness variables (t values $\leq$1.43).

3.2 Credibility and expectancy

There were no differences between mindfulness ($M = 5.26$, $SD = 1.34$) and relaxation ($M = 5.09$, $SD = 1.13$) on the credibility questionnaire; $t(66) = 0.587$, $p = 0.560$. The expectancy of the training to reduce cravings also did not differ between mindfulness ($M = 4.35$, $SD = 1.35$) and relaxation ($M = 4.29$, $SD = 1.95$); $t(66) = 0.145$, $p = 0.885$.

3.3 Manipulation check

The mindfulness group ($M = 4.79$, $SD = 1.22$) did not differ from relaxation group ($M = 4.64$ $SD = 0.93$) on the manipulation check, $t(65) = 0.592$, $p = 0.556$. In order to assess participants' level of mindfulness/relaxation, TMS and relaxation/tension measures were administered immediately after the strategy. As presented in table 3, there were no group differences in state mindfulness $t(65) = 1.363$, $p = 0.178$ and relaxation $t(65) = 1.351$, $p = 0.181$.

Table 3. *Means and standard deviations for state mindfulness and relaxation*

Variable	Mindfulness (N = 34)	Relaxation (N = 34)
	M (*SD*)	*M* (*SD*)
TMS score	32.59 (6.41)	30.48 (6.22)
Decentering	16.82 (4.33)	15.24 (4.27)
Curiosity	15.76 (4.32)	15.24 (4.65)
Tension score	3.65 (2.60)	3 (1.73)

3.4   Use of strategy after a week

All participants provided data after seven days of participating in the experiment. There were no differences in the number of days participants practised their assigned strategy between mindfulness ($M = 3.12$, $SD = 0.62$) and relaxation ($M = 3.21$, $SD = 0.85$); $t(65) = -0.522$, $p = 0.603$ on their reported use of the strategy.

3.5   Distress tolerance

There was a trend-level main effect of Time, ($F(1, 64) = 3.911$, $p = 0.052$, $\eta_p^2 = 0.058$), suggesting that breath holding duration increased at time point two compared to time point one. There was no main effect of Group ($F(1, 64) = 0.007$, $p = 0.934$, $\eta_p^2 = 0.00$) and no Time x Group interaction ($F(1, 64) = 1.583$, $p = 0.213$, $\eta_p^2 = 0.024$), suggesting that the increase in distress tolerance was similar between the mindfulness and relaxation groups.

Table 4. *Means and standard deviations for BHT scores (in seconds)*

BHT score	Mindfulness (N = 33)	Relaxation (N = 33)
	M (*SD*)	*M* (*SD*)
Pre training	31.61(10.63)	32.66 (12.05)
Post training	33.73 (11.38)	33.13 (10.95)

3.6   Heart rate variability

There was a significant Time x Group interaction ($F(1, 57) = 7.266$, $p < 0.01$, $\eta_p^2 = 0.113$) and main effect of Time, ($F(1, 57) = 14.973$, $p < 0.001$, $\eta_p^2 = 0.208$), reflecting a large increase in RMSSD from time-point one to time-point two. There was no significant main effect of Group ($F(1, 57) = 0.238$, $p = 0.628$, $\eta_p^2 = 0.004$). As shown in Figure 3, this result suggests that the relaxation group led to a greater increase in RMSSD. Post-hoc t-test analysis further revealed that there was a

significant increase in RMSSD in the relaxation group, $t(25) = 3.648$, $p < 0.001$, but no significant change in the mindfulness group $t(32) = 1.097$, $p = 0.281$.
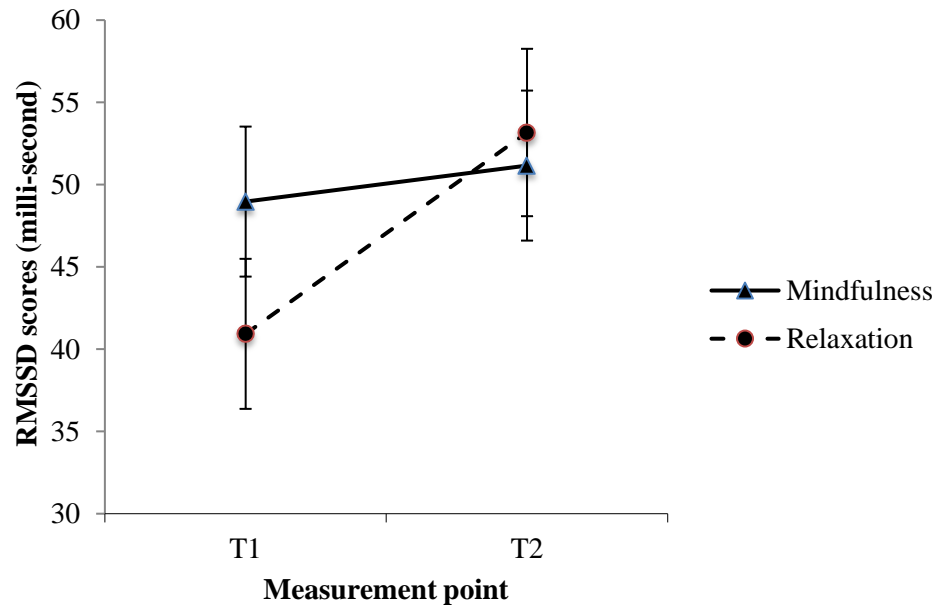
Figure 3. Mean +/- SEM for RMSSD in mindfulness and relaxation groups at T1 and during training T2.

3.7 Craving and alcohol consumption

3.7.1 Craving

Craving was assessed by ACQ-SF at baseline and follow up. There was a significant main effect of Time ($F(1, 66) = 54.564$, $p < 0.001$, $\eta_p^2 = 0.453$), indicating that craving scores reduced by day 7. The main effect of Group was not significant ($F(1, 66) = 2.883$, $p = 0.094$, $\eta_p^2 = 0.042$) and there was no significant Time x Group interaction ($F(1, 66) = 0.004$, $p = 0.953$, $\eta_p^2 = 0.000$), indicating that the reduction in craving was similar in both groups.

Table 5. *Means and standard deviations for ACQ-SF scores*

ACQ-SF score	Mindfulness (*N* = 34)	Relaxation (*N* = 33)
	M (*SD*)	*M* (*SD*)
Baseline	3.79 (1.00)	4.03 (0.81)
Seven days follow up	2.91 (0.92)	3.23 (0.89)

3.7.2 Immediate drinking behaviour (taste test)

There was a significant main effect of Time (F(1, 65) = 4.551, p = 0.037, η_p^2 = 0.065), showing that the immediate alcohol consumption reduced at the end of the training. However there was no significant main effect of Group (F(1, 65) = 2.435, p = 0.124, η_p^2 = 0.036) and no significant Time x Group interaction (F(1, 65) = 1.077, p = 0.303, η_p^2 = 0.016) suggesting that the reduction in alcohol consumption was similar between the experimental and control group.

Table 6. *Means and standard deviations for taste test scores (grams of alcohol)*

Taste test score	Mindfulness (*N* = 34)	Relaxation (*N* = 33)
	M (*SD*)	*M* (*SD*)
Pre training	58.34 (34.81)	50.45 (23.75)
Post training	55.56 (37.38)	42.38 (16.98)

3.7.3 Alcohol consumption over a seven day follow-up period

There was a significant main effect of Time (F(1, 66) = 19.699, p < 0.001, η_p^2 = 0.230). There was no significant main effect of Group (F(1, 66) = 0.039, p = 0.843, η_p^2 = 0.001) but there was a significant Time x Group interaction (F(1, 66) = 5.175, p = 0.026, η_p^2 = 0.073) with a larger reduction in drinking in the mindfulness group. Post-hoc t-test analysis also revealed that there was a significant reduction in the

mindfulness group $t(33) = 4.565$, $p < 0.001$, but no significant change in the

relaxation group $t(33) = 1.596$, $p = 0.120$.

Table 7. *Means and standard deviations for TLFB (drinking units)*

TLFB score	Mindfulness (N = 34)	Relaxation (N = 34)
	M (*SD*)	*M* (*SD*)
Baseline	27.66 (16.96)	23.94 (11.71)
Seven days follow up	18.25 (12.21)	20.94 (10.55)

3.8. Exploratory correlational analysis

3.8.1 *The relationship between change scores in BHT and drinking outcomes*

There was no significant relationship between BHT and the taste test in neither the mindfulness group ($r = -0.039$, $p = 0.803$), nor the relaxation group *($r = -0.130$, $p = 0.405$)*. Similarly no relationship was found between BHT and TLFB in the mindfulness group ($r = 0.148$, $p = 0.404$) and relaxation group *($r = -0.186$, $p = 0.323$)*.

3.8.2 *The relationship between HRV and drinking outcomes*

Change in RMSSD and change in immediate drinking in the taste test was negatively correlated in the mindfulness group *($r = -0.561$, $p = 0.001$)*, suggesting that participants whose RMSSD increased during mindfulness drank less immediately after the training. The correlation between RMSSD and taste test drinking in the relaxation group was $r = -0.351$ ($p = 0.086$). Since the two correlation coefficients were not significantly different from one another ($p = 0.3$), this suggests that an increase in RMSSD may be a general mechanism for reduced acute drinking. RMSSD was not significantly related to follow up drinking levels in the mindfulness group *($r = -0.245$, $p = 0.170$)* and relaxation group *($r = -0.021$, $p = 0.917$)*.
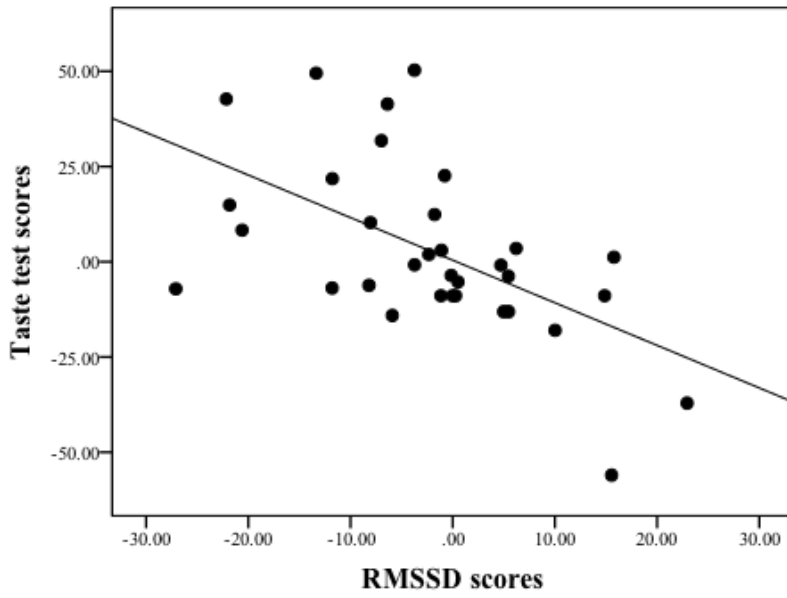
Figure 4. The correlation between RMSSD and taste test drinking in the mindfulness group.
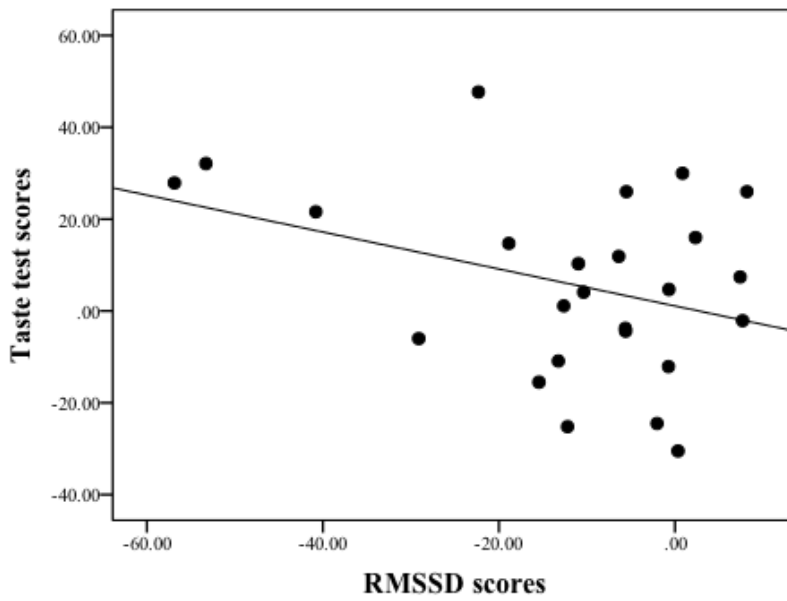
Figure 5. The correlation between RMSSD and taste test drinking in the relaxation group.

Discussion

The goal of the present study was to investigate the effect of brief mindfulness training in reducing alcohol craving and consumption among hazardous/harmful drinkers. Mindfulness training was compared to a closely matched relaxation control condition. We were mainly interested in the effects of mindfulness training on distress tolerance and HRV. We also examined the effects of the training on immediate drinking levels as well as a seven-day follow up period.

4.1   Distress tolerance

We expected a greater increase in distress tolerance in the mindfulness group compared to relaxation, as mindfulness encourages individuals to accept and observe the distressing craving experience rather than trying to avoid it (Brewer et al., 2012; Brown et al., 2002). Contrary to our hypothesis the increase in distress tolerance was similar between mindfulness and relaxation groups. In contrast Hayes et al. (1999) found beneficial effects of acceptance-based strategies in increasing pain tolerance. Clearly, one explanation for this inconsistency could be the methodological differences between the studies in terms of the strategy used as well as the measure of distress tolerance. However, it is worth noting that our control condition was a closely matched placebo (relaxation) strategy. The results indicate that there were no group differences between state mindfulness and relaxation, which suggests that the strategies may not have been experientially different for participants. This may explain the similar increase in distress tolerance in both groups.

Another study comparing mindfulness with guided imagery found that only mindfulness improved pain tolerance as measured by the cold-pressor task (Kingston, Chadwick, Meron, & Skinner, 2007). Unlike our study, which used a 'micro intervention' lasting 15 minutes in a single session, Kingston et al. (2007)

used six 1-h sessions. It is possible that a significant increase in distress tolerance cannot be accomplished with a brief 15-minute mindfulness training session. Indeed, Sharpe, Perry, Rogers, Refshauge, & Nicholas (2013) also compared mindfulness with a relaxation exercise (each was 12-minutes) and failed to show an increase in pain tolerance in both groups. Our results suggest that a 15-minute mindfulness training does not increase distress tolerance more than the relaxation exercise. This shows that the duration of the strategy can be important in observing a change between groups.

4.1.1 *The relationship between distress tolerance and drinking outcomes*

Previous research on BHT and smoking outcomes found individuals who can hold their breath for a longer time period are able to abstain from smoking for longer (Abrantes et al., 2008; Brown et al., 2002; Hajek et al., 1987). Similarly, in our study we expected that breath holding duration would be negatively correlated with immediate alcohol consumption (taste test) and alcohol consumption after a seven day follow up (TLFB). Contrary to our predictions there was no significant relationship between breath holding duration and drinking outcomes. This might be due to our study population, as previous research included smokers whereas our study included hazardous/harmful drinkers.

4.2   Heart rate variability

The results indicated that there was a significant increase in HRV in the relaxation group but no significant change in the mindfulness group. This result suggests that only relaxation had a positive effect by activating PNS and/or inhibiting SNS. Although relaxation is also associated with higher levels of HF-HRV (Dolbier & Rush, 2012; Sakakibara, Takeuchi, & Hayano, 1994), previous studies comparing mindfulness and relaxation reported a greater increase in HF-HRV in the

mindfulness group (Ditto et al., 2006; Tang et al., 2009). These results are in contrast to our findings. Methodological differences between studies might explain this discrepancy. Tang et al. (2009) used a 20-minute mindfulness practice every day for five days whereas Ditto et al. (2006) examined the effect of 20-minute mindfulness practice every day over a month. Both Tang et al. (2009) and Ditto et al. (2006) recruited healthy participants whereas our study recruited hazardous/harmful drinkers. Garland et al. (2010) recruited alcohol dependent individuals and found that RMSSD increased after mindfulness practice. However it is also methodologically different to our study. Garland et al. (2010) delivered a 10-week mindfulness practice in a group setting whereas we used 15-minute audio-recorded mindfulness instructions. Their control group was an alcohol support group, whereas our control group was a relaxation strategy. It is important to note that HRV starting point in our study was higher in the relaxation group than the mindfulness group and this may have influenced the degree of change.

Regardless of the methodological differences between studies, the interpretation of HRV components is difficult. HRV measures are complex as heart periods are affected by multiple autonomic factors (Heathers, 2014) and the origin of HRV modulations and the exact contributions of PNS and SNS to ANS are controversial (Billman, Huikuri, Sacha, & Trimmel, 2015). Recent studies highlight the substantial need for methodological improvements in research measurement of HRV, revision of standards, and recommendations for HRV measurements (Heathers, 2014; Nunan, Sandercock, & Brodie, 2010).

4.2.1 *The relationship between HRV and drinking outcomes*

Based on the previous study by Libby et al. (2011) we expected a change in HRV scores would be negatively correlated with change in immediate alcohol consumption (taste test) and alcohol consumption after a seven day follow up (TLFB). Libby et al. (2011) found that increased HRV after mindfulness was associated with a significant reduction in smoking at follow up. Garland et al. (2010) failed to show an association between HRV and craving in dependent drinkers. In line with our predictions, participants who had increased HRV consumed less alcohol immediately after training. This result tentatively suggests that the relationship is significant between HRV and drinking outcomes among hazardous/harmful drinkers, but not in dependent drinkers. Future research comparing hazardous/harmful and dependent drinkers is needed to clarify this further.

4.3   Strengths and Limitations

There are several strengths of the current study. First, we used behavioural and physiological measures in addition to self-report measures to examine the mechanisms through which mindfulness may be effective in reducing craving and alcohol consumption, as recommended by previous studies (Bowen & Marlatt, 2009). Secondly, both participants and experimenters were blind to the study conditions. Thirdly, our strategy instructions included practice and experiential exercises as recommended by previous research (Murhphy & McKillop, 2014). We used audio-recorded instructions to reduce experimenter effects. Unlike other studies on craving, which compared mindfulness with distraction-based strategy (Murhphy & McKillop, 2014), no-instruction control group (Bowen & Marlatt, 2009), suppression strategy (Rogojanski et al., 2011) we used a closely matched

relaxation instruction. The use of credibility/expectancy questionnaire showed that participants perceived both strategies as equally credible. Finally, we had no attrition at follow up. The methodological strengths of the present study may have reduced the likelihood of spurious results in relation to mindfulness.

There were also limitations in the current study. First, our study was slightly underpowered to detect small effects. Secondly, participants were drinking at a hazardous/harmful level but were not seeking treatment. Therefore caution should be taken when generalising these findings to treatment seekers in the community. Thirdly, the testing session was conducted in person whereas follow up was remote. We were therefore not able to assess the effects of mindfulness and relaxation on distress tolerance and HRV after one week. Finally, missing HRV data in the relaxation group might have affected the HRV analysis.

4.4   Clinical implications

Overall, the results of this study could have clinical implications in the development of effective alcohol cessation treatments that target the link between negative affect and craving. Current behavioural treatments and cognitive-behavioural treatments focus on skills enhancement through avoiding cues or self-monitoring (Longabaugh & Magill, 2011) and unlike mindfulness they do not target negative affect, which is key in reducing relapse rates. The results of this study suggest that both mindfulness and relaxation are potentially effective in reducing craving and immediate alcohol consumption among harmful/hazardous drinkers. However, an additional control group (no intervention) would be needed to confirm this. Interestingly, the mindfulness group led to a greater reduction in alcohol consumption after seven days.

Distress tolerance increased in both groups. This result is potentially

promising as increased distress tolerance can be a protective factor for hazardous/harmful drinkers from developing alcohol use disorder. Increased capacity to tolerate discomfort during abstinence will likely reduce relapse rates and increase the success of alcohol cessation treatments. However it is difficult to conclude this without another control condition as distress tolerance might increase with practice in general (from the first to second time). Future research is needed to clarify this mechanism further.

Participants who had increased HRV consumed less alcohol immediately after the training. This supports the previous findings stating that increased HRV is a biomarker for heightened self-regulation (Libby et al., 2012). This study extends previous positive results with smokers to hazardous/harmful drinkers. Clinically, this is important as heightened self-regulation is linked with abstinence (Minami et al., 1999), and this finding can be useful in improving mindfulness-based interventions for alcohol use disorders.

Our study investigated the mechanisms of mindfulness through exploring a number of conceptually related psychophysiological constructs (distress tolerance, HRV). Understanding some of the specific beneficial components of mindfulness on alcohol use could help to improve alcohol cessation treatments. However, there is still need for future research to clarify further the mechanisms of mindfulness in reducing craving and alcohol consumption. Future research should also attempt to differentiate the effects of mindfulness and relaxation on alcohol use in relation to distress tolerance and may consider including a treatment seeking population.

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Part 3: Critical Appraisal

Introduction

In this section I will discuss methodological issues and challenges associated with this project. I will also briefly discuss my interest in the field of mindfulness and my experiences of conducting this research.

1.   Interest in mindfulness

My professional interest in mindfulness emerged when I started practising meditation. Having personal experience of practising mindfulness helped me in my clinical practice. For example, during my first year of clinical psychology training I co-facilitated a mindfulness group in an inpatient unit and was able to use my own experience in group discussions (e.g. normalising the challenges of attaining focused attention). In the same placement I was also interested in participants' experiences of attending the mindfulness group and carried out focus groups to explore their experiences, which has also become a part of my service related research project. In the second year of my training I tailored my mindfulness and Acceptance and Commitment Therapy (ACT) skills in my individual and group work with clients experiencing a range of physical health difficulties (e.g. chronic pain). Although I did not have any experience of working with people who suffer from alcohol use disorders, I was keen to take part in the study, which examined the effect of mindfulness on different psychophysiological constructs such as heart rate variability and drinking behaviour among hazardous/harmful drinkers. I feel that having personal and professional experience gave me the chance to use my understanding of mindfulness as well as experience and skills in the research process, specifically around developing the mindfulness script.

2. Methodological issues

2.1 Recruitment

As previously mentioned, with a sample of 68 our study was slightly underpowered to detect small effects based on the original effect size calculation. More recently, a study with greater relevance to the current study (Beadman, Das, Freeman, Scragg, West, & Kamboj, 2015) suggested that a large effect size could be expected from our design, and as such, the study was more than adequately powered. Nonetheless, achieving this sample was a challenge from the outset as our sample required to have very specific characteristics (i.e. drinking more than the recommended guidelines) who had to attend an experimental session. This meant that we had to start recruitment earlier than planned to be able to reach our required sample size.

Overall, more than 300 participants were interested in taking part in the study, and were emailed the screening questionnaire individually, but this was a time consuming process. This could have been achieved more efficiently through an automated process as suggested by a previous D.Clin.Psy. trainee (Beadman, 2014), since the participants were screened online rather than in a face-to-face interview. In the screening questionnaire participants were asked about their preferred alcoholic beverage and only beer drinkers were included in the study. We could have specified in our advertisement that the study recruited beer drinkers only, which could have saved us time.

2.2 Development of Strategy scripts

Previous scripts informed our recordings (e.g. Williams, Teasdale, Segal, & Kabat-Zinn, 2007; Bowen & Marlatt, 2009; Vinci et al., 2014) and we have also taken into consideration the suggestions by a meta-analysis and involved experiential

features in our strategies rather than providing a rationale only (Levin, Hildebrandt, Lillis, & Hayes, 2012; Murhphy & McKillop, 2014).

Research suggests that using well matched active control conditions are particularly important in mindfulness research in order to rigorously assess the effects of mindfulness (Davidson & Kaszniak, 2015). In the present study matching both scripts in terms of complexity, the number of craving related cue words, the number of words and the duration was a laborious task and required numerous drafts and reviews by the supervisors, and the resulting amendments. This process was important to assess the real effect of the strategies regardless of other factors (e.g. length, complexity). Moreover, the scripts were reviewed separately by 16 doctoral level clinical psychologists in training who confirmed that both scripts achieved their aim of encouraging mindfulness or relaxation as intended. Additionally, we used credibility/expectancy questionnaires to check participants' beliefs about the strategy. Both strategies were perceived as equally credible to cut down on drinking, and useful to manage their cravings. Manipulation check is particularly important in this field, as the concept of "mindfulness" and "acceptance" can be unclear to participants practising it for the first time (Levin et al., 2012). As recommended, we used manipulation check and this proved that the participants were able to follow the instructions. Future research might also consider asking participants to provide a qualitative description of the training that they were assigned.

2.3   *Behavioural and physiological measures*

Breath holding task. The Breath holding task (BHT) was used as a behavioural measure of distress tolerance. We preferred a behavioural measure to a self-report measure (e.g. Distress Tolerance Scale, Simons & Gaher, 2005) as we aimed to explore participants' distress tolerance levels in the present moment rather

than their distress tolerance levels as a trait. Additionally, self-report measures may not accurately represent individuals' distress tolerance levels as they assess participants' perceived capacity to tolerate distress, and they could be biased by social desirability (Glassman et al., 2016). On the other hand, behavioural measures are more objective but they can possibly be affected by participants' motivation to persist in the task by factors unrelated to distress tolerance (e.g. demand characteristics in which the participant performs according to the experimenter's expectations) (Simons & Gaher, 2005). This might have affected the subjects' performance in our study as some of the participants wanted to know the duration of their breath holding and whether it was shorter/longer after the task. We attempted to reduce demand characteristics by minimising our interpersonal contact with participants during the task. Therefore written instructions were provided and a stopwatch was not shown to participants. Moreover, our study was double-blinded, which reduced the possibility of participants guessing our hypotheses.

Distress tolerance is defined as the trait capacity for enduring physical and/or emotional aversive states (Zvolensky, Vujanovic, Bernstein, & Leyro, 2010). However, distress tolerance measurement literature lacks consistency, as different measures focus on specific features of the construct and they have been used interchangeably (Glassman et al., 2016). For example, BHT and the cold-pressor task (Keogh, Bond, Hanmer, & Tilston, 2005) focus on physical distress tolerance, whereas the mirror tracing task (Strong et al., 2003) is a cognitive distress tolerance measure, and the Distress Tolerance Scale (DTS; Simons & Gaher, 2005) assesses perceived emotional distress. Nicotine and alcohol dependency are comparable constructs (Batel et al., 1995), therefore in our study BHT was the choice of measure for distress tolerance as it has been used in smoking abstinence research (Hajek et al.,

1987; Brown et al., 2002). We also preferred BHT because unlike other measures (e.g. Carbon dioxide breathing challenges; Zvolensky et al., 2001), BHT requires no special equipment and it is easy to administer. BHT assesses capacity to tolerate physiological distress but possibly does not reflect emotional distress tolerance. However, negative affect is also an important component of craving. Therefore, future research might consider using a self-report measure of emotional distress tolerance (e.g. Distress Tolerance Scale) in addition to behavioural measures of physiological distress. This could help compare the results of self-report and behavioural measures and understand different components of distress tolerance (physiological vs. emotional) in relation to craving.

BHT could have been particularly stressful for some participants and could have possibly involved some risks to their physical health. However, previous research and our own consultation with a cardiopulmonary physician at UCH suggests that this is a very low risk procedure if participants have no respiratory problems and are seated during the task. Therefore, we screened out any respiratory problems prior to the testing session and participants were seated during the task as suggested.

Another consideration was the order of the tasks. We initially administered BHT before the taste test but after piloting we decided to administer BHT after the taste test in order not to affect the participants' drinking level after a distressing experience.

Heart rate variability. The origin of heart rate variability (HRV) is controversial, as the modulation of heart rate is affected by multiple autonomic factors and the interpretation of HRV measures is difficult due to its complicated nature (Heathers, 2014, Billman et al., 2015). HRV measurement can be influenced

by many factors such as the intake of nicotine and caffeine before data collection, as well as cardioactive and/or psychiatric medication use (Quintana & Heathers, 2014; Sjoberg & Saint, 2011; Sondermeijer et al., 2002; Kemp et al., 2010). In our study we excluded participants who required ongoing treatment (including psychiatric medication use) for their mental health problems. However, we did not specifically exclude participants on the basis of cardiovascular diseases, as additional exclusion criteria could have been practically difficult since we recruited participants with specific characteristics (i.e. harmful/hazardous drinkers). Future research focusing on HRV might take this into account, and also consider asking participants not to consume nicotine or caffeine prior to data collection. Age and physical activity levels, circadian effects and alcohol use are among the factors affecting HRV (Quintana & Heathers, 2014). In the present study we conducted the testing sessions at the same time of day (17:00-21:00) in order to minimise variability of HRV due to time-of-day effects. As suggested by Task Force (1996) we analysed HRV for a period of five minutes, which was measured before and during the mindfulness/relaxation training. The recording continued throughout the experiment to avoid interruption (Task Force, 1996; Quintana et al., 2016). Participant acclimatisation to the testing environment is another important issue as posture (standing vs. seated) and test anxiety may affect HRV (Chan et al., 2007; Quintana & Heathers, 2014). Therefore, we did not select the baseline HRV at the beginning of the testing session, rather we selected the last five minutes of the baseline assessment period. Regardless of these factors as well as interpretation difficulties we were faced with some practical difficulties during our HRV measurement. For example, we had some missing data, which was due to battery failure and insufficient memory of the heart rate monitor as well as poor electrode contact. As the memory capacity of the

heart rate monitor was insufficient, periodically we uploaded the data onto the computers. However, this might have been problematic on the rare occasion that the testing session lasted longer than expected (e.g. more than 1.5hrs). We also provided a pictorial guide and written instructions to participants about how to fit the heart rate monitor (e.g. "make sure that the electrodes are snugly attached to the skin") in order to reduce the possibility of data loss due to poor electrode contact.

Beyond the methodological issues and interpretation difficulties, the recent study by Quintana et al. (2016) addressed the paucity of standardised reporting of methodology in the studies involving HRV. They proposed the Guidelines for Reporting Articles on Psychiatry and Heart rate variability (GRAPH) and explained the necessity of such guidelines in HRV research in psychiatry and related fields, to improve the interpretation of HRV measures, reproducibility and enable valid meta-analyses. Our data collection and analysis was informed by an earlier set of guidelines (Task Force, 1996), although future research might consider following GRAPH recommendations.

2.4 Follow up

We had no attrition in the follow up. This was one of the primary strengths of this study. Similar studies report varying levels of attrition at follow-up (e.g. Litvin, Kovacs, Hayes, & Brandon, 2012; Rogojanski, Vettese, & Antony, 2011) and often use unsuitable methods for dealing with cases lost to follow-up. It is likely that we achieved improved retention relative to a very similar study published by the team (Beadman et al., 2015). That study also used email reminders (after two days and four days of attending the experiment) but reimbursed participants before the study (follow-up) had finished. In the current study, payment for participation was contingent on completing the entire study (including follow up). This is in line with

previous research that shows payment after attendance reduces attrition rates (Festinger & Dugosh, 2012). Research also indicates that higher payments and the mode of payment (cash/bank transfer rather than vouchers) increases follow up attendance among substance abusing participants (Festinger et al., 2008). As such, this methodological feature should be repeated in similar research in the future.

3.   Reflections on the research process

In my previous research experience during my MSc. in Mental Health Studies, as well as voluntary research positions, I was mainly responsible for the implementation and write up of the project. In this study I learned a lot from my supervisors' expertise by actively taking part in designing the study (e.g. deciding on the use of specific measures and the order of tasks). Working with a co-researcher was helpful primarily in data collection, as it enabled us to increase our sample size. Supporting each other in the initial testing session also helped us to increase our confidence in carrying out the testing sessions independently.

Heart rate variability - which was one of the main elements of my project - was a new psychophysiological construct to me. Since I did not have a medical background or interest in cardiology, it took me a while to fully understand what HRV is, how it is linked with physical and psychological well-being and how the data are analysed. Moreover, I have also become more aware of the interpretation difficulties of HRV, as the contributions of sympathetic and parasympathetic nervous systems to HRV are controversial. Despite the challenges, it was a rewarding process as I discovered how HRV can be a biomarker for psychological health.

4.   Conclusion

This critical appraisal discussed various methodological issues such as challenges with developing strategy scripts, decision making around specific

measures, as well as some strengths such as successful follow up rates.

Overall, the present study examined the mechanisms of mindfulness through exploring a number of conceptually related psychophysiological constructs such as distress tolerance and HRV. The results demonstrated both mindfulness and relaxation increased distress tolerance and HRV, and the mindfulness group led to a greater reduction in alcohol consumption among harmful/hazardous drinkers. As increased distress tolerance and HRV are linked with abstinence, these findings can be beneficial in improving mindfulness-based interventions targeting alcohol use. Future research could attempt to clarify further the mechanisms of mindfulness in reducing craving and alcohol consumptions, and differentiate the effects of mindfulness and relaxation on alcohol use.

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Appendices

Appendix 1: Ethics Approval

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Amendment Approval Request Form

1	**Project ID Number:** 0760/002	**Name and Address of Principal Investigator:** Dr Sunjeev Kamboj, Research Dept Clinical, Educational and Health Psychology

2	**Project Title:** Craving changes? How do verbal and visuospatial strategies modify craving experiences in heavy smokers and drinkers

3	**Type of Amendment/s (tick as appropriate)** ☒ Research procedure/protocol (including research instruments) ☐ Participant group ☐ Sponsorship/collaborators ☒ Extension to approval needed (extensions are given for one year) *TO JULY 2016.* ☒ Information Sheet/s ☐ Consent form/s ☐ Other recruitment documents ☐ Principal researcher/medical supervisor* ☐ Other * *Additions to the research team other than the principal researcher, student supervisor and medical supervisor do not need to be submitted as amendments but a complete list should be available upon request.

4	**Justification** (give the reasons why the amendment/s are needed) We request adding an experiment to enable two DClinPsy students to examine how craving - and its physiological correlates - is affected by mindfulness instructions in heavy social drinkers. The instructions to participants are only slightly different from the currently-used 'distancing' instructions. However, the main amendment relates to the use of physiological measures and a 'breath-holding task'. Specifically, we aim to incorporate objective measures of addiction-related behaviour as outcome measures. Firstly, 'distress tolerance (DT)' which will be assessed using the breath-holding task (see below). In smokers, performance on this procedure is associated with relapse, such that those with low levels distress tolerance (shorter breath-holding times) relapse more quickly after a quit attempt (Hajek et al., 1987). On the other hand, interventions that aim to enhance distress tolerance in smokers may reduce the tendency to relapse (Brown et al., 2008). Our understanding of the role of DT in addiction remains in its infancy however, with few studies demonstrating its impact on outcomes other than relapse in smokers. For example, it is possible that mindfulness, which involves simple, non-judgemental attention directed at ongoing bodily experience, may enhance DT and have secondary effects on addictive behaviours, cognition and craving (e.g. Brown et al., 2008). Moreover, DT may have relevance to addictive-behaviours other than smoking (e.g. heavy drinking). Secondly, we aim to record continuous ECG from participants, to assess how (i) heart rate variability (HRV) indices differ in response to relaxation and mindfulness and (ii) how these indices change when participants are exposed to alcohol cues before and after the relaxation/mindfulness procedures. Thirdly, blood pressure will be recorded before and after exposure to beer cues and before and after mindfulness/relaxation using a Beurer BM40 unit, which has a cuff that attaches to the upper arm. The overall aim in the current study is to examine the relationship between (i) effectiveness of mindfulness as a strategy for coping with alcohol craving and (ii) changes in physiology and DT before and after mindfulness (or relaxation control). By adding these objective measures of distress tolerance (breath holding) and physiological indices or affect regulation (HRV and blood pressure), this study will examine mechanism of change for procedures that may reduce alcohol craving. As in our previous studies, participants (n=100) will be healthy volunteers who are at risk of developing

alcohol problems. However, unlike our previous studies we do not aim to exclude participants on the basis of scores ≥ 20 on the Alcohol Use Disorder Identification Test (AUDIT; Babor et al, 2001) as we have found the prevalence of such scores is very high among respondents, especially students. Nonetheless, we will continue to exclude participants with likely alcohol dependence (as assessed by high scores on the dependency items on the AUDIT). These participants will be offered information on potential sources of help for moderating drinking. An additional primary exclusion criterion is the presence of acute or chronic respiratory illnesses (see breath holding task below).

Mindfulness and relaxation instructions:
Mindfulness instructions will involve asking participants to pay attention to their moment-to-moment experience and will be based on existing, widely available instructions. Primarily, participants will be asked to focus on all bodily sensations (the 'breath and body exercise' as described in Kabat Zinn, 2006; Williams and Penman, 2011) in an accepting, non-judgemental way and to approach craving sensations in a similar manner. As with our previous studies, relaxation instructions will closely match to mindfulness instructions (e.g. in complexity of language, use of craving terms, length of script), using the term "relax [body part]" to replace "attend to [body part]."

Breath-holding task:
Prior to and after mindfulness or relaxation, participants will be asked to perform the breath-holding task (BHT; Brown et al., 2002) as a behavioural index of distress tolerance. In the task participants are seated and asked to hold their breath for as long as possible after a full, normal exhalation (Sütterlin et al., 2013). While holding their breath they will be asked to keep their eyes closed and instructed to hold their breath for as long as possible, even when they have an initial urge to breathe (Sütterlin et al., 2013). The duration of breath holding will be recorded from the time of normal exhalation to subsequent first inhalation.

Physiological recording:
Heart rate (inter-beat interval) will be recorded continuously using a FirstBeat portable ECG device. Participants will attach the electrodes underneath their clothing themselves, with printed instructions provided by the experimenter. One electrode is attached directly to the FirstBeat unit, which is itself attached under the right collar bone; the other electrode is attached by a short wire to the FirstBeat unit and is attached under the left ribcage. This is a completely painless procedure. In our existing experiments we find that participants are able to do this with ease and without inconvenience. ECG recordings will be taken from the start of the experiment, although the key periods of interest will be (i) before and during exposure to verbal and visual beer cues and (ii) before and during mindfulness/relaxation.

Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation)
As in our previous studies, participants (n=100) will be healthy volunteers who are at risk of developing alcohol problems. However, unlike our previous studies we do not aim to exclude participants on the basis of scores ≥ 20 on the Alcohol Use Disorder Identification Test (AUDIT; Babor et al, 2001) as we have found the prevalence of such scores to be very high among respondents, especially students. Many respondents who have a high total score on the AUDIT simultaneously have low scores on the alcohol dependence items of the AUDIT. We propose continuing to exclude participants with likely alcohol dependence, but will base this exclusion on high scores on the dependency items of the AUDIT rather than the total score. Those identified with likely dependence will be offered information on potential sources of help for moderating drinking. An additional primary exclusion criterion is the presence of acute or chronic respiratory illnesses (see breath holding task below).

5   Mindfulness and relaxation instructions:
Mindfulness instructions will involve asking participants to pay attention to their moment-to-moment experience and will be based on existing, widely available instructions. Primarily, participants will be asked to focus on all bodily sensations (the 'breath and body exercise' as described in Kabat Zinn, 2006; Williams and Penman, 2011) in an accepting, non-judgemental way and to approach craving sensations in a similar manner. As with our previous studies, relaxation instructions will closely match to mindfulness instructions (e.g. in complexity of language, use of craving terms, length of script), using the term "relax [body part]" to replace "attend to [body part]."

Breath-holding task:
Prior to and after mindfulness or relaxation, participants will be asked to perform the breath-holding task (BHT; Brown et al., 2002) as a behavioural index of distress tolerance. In the task participants are seated and asked to hold their breath for as long as possible after a full, normal exhalation (Sütterlin et al., 2013). While holding their breath they will be asked to keep their eyes closed and instructed to hold their breath for

as long as possible, even when they have an initial urge to breathe; this will increase the distress levels (Sütterlin et al., 2013). The duration of breath holding will be recorded from the time of normal exhalation to subsequent first inhalation.

Physiological recording:
Heart rate (inter-beat interval) will be recorded continuously using a FirstBeat portable ECG device. Participants will attach the electrodes underneath their clothing themselves, with printed instructions provided by the experimenter. One electrode is attached directly to the FirstBeat unit, which is itself attached under the right collar bone; the other electrode is attached by a short wire to the FirstBeat unit and is attached under the left ribcage. This is a completely painless procedure. In our existing experiments we find that participants are able to do this with ease and without inconvenience. ECG recordings will be taken from the start of the experiment, although the key periods of interest will be (i) before and during exposure to verbal and visual beer cues and (ii) before and during mindfulness/relaxation.

6	**Ethical Considerations** (insert details of any ethical issues raised by the proposed amendment/s) Previous research and our own consultation with a cardiopulmonary physician at UCH suggests that the breath holding task is a very low risk procedure if participants have no respiratory problems and are seated during the task. The task is designed to cause some distress in order to assess tolerance for distress. Participants will be made aware of this at screening and before the experiment starts, and reminded that they are free to withdraw from the experiment at any time. It should be noted however that the duration of the breath holding, and by extension the distress, is necessarily very timelimed and ultimately very largely determined by the participant's choice.
7	**Other Information** (provide any other information which you believe should be taken into account during ethical review of the proposed changes)

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.
- For student projects I confirm that my supervisor has approved my proposed modifications.

Signature: ████████

Date: 20`/03/2015

FOR OFFICE USE ONLY:

Amendments to the proposed protocol have been … *Approved* by the Research Ethics Committee.

Signature of the REC Chair, Professor John Foreman: ████████

Date: 24/3/2015.

Appendix 2: Participant information sheet

<u>**Information Sheet for Craving for Alcohol? The Effect of a Brief Strategy on Craving Experience and Alcohol Use**</u>
You will be given a copy of this information sheet.
Title of Project: Craving for alcohol? The effect of a brief strategy on craving experience and alcohol use

This study has been approved by the UCL Research Ethics Committee (Project ID Number): 6520/001

Name	Shirley Serfaty
	Damla Irez
Work address	Research Department of Clinical, Educational and Health Psychology University College London, Gower Street, London. WC1E 6BT
Contact details	Email: ███████████████████ Telephone: ███████████
	███████████████████ Telephone: ███████████

Details of Study: This study examines strategies for managing craving experiences associated with alcohol use. These experiments will help us discover more about the psychological processes that underpin the experience of craving, which in the long-term, may help in the development of psychological treatments for addictions.

Who can take part? If you are generally healthy and regularly drink twice as much as the government recommended guidelines for alcohol consumption (which are 14 units for women and 21 units for men) and are between 18-50 years old, fluent in English, have no current psychological and physical illness that requires ongoing treatment. You must also have healthy lung functioning to take part as we require participants to hold their breath as part of the experiment.
What will happen to me if I take part?
The experiment involves taking part in a brief strategy that is delivered through audio recording. You will be given some questionnaires to measure your cravings, mood and alcohol consumption. You will be asked about your reactions to alcohol stimuli before and after listening to some audio instructions. We will also measure various bodily reactions. These include blood pressure, which will be assessed using a standard blood pressure cuff and monitor. Heart rate will be measured using two sticky probes which you attach to your skin beneath your clothes (the experimenter will show you instructions on how to do this). The probes will be attached under the right collar bone and under the left ribcage.

To measure taste reactions to different beverages, we will ask you to consume a drink (which may be beer or a soft drink) and a measure of lung functioning will be taken by asking you to hold your breath for as long as possible while seated.

We expect all of the procedure above will take up to one and a half hours. We will ask you to practice the techniques taught in the experiment for a week, every day, for approximately 15 minutes. In 2 and 4 days from now we will remind you to use the technique. We will contact you a week later, asking about your experience of practicing the techniques, as well as requesting you to complete 4 questionnaires online (regarding cravings and alcohol consumption). You may contact the researcher at any time after the study if you experience any difficulties.

You will be paid £20 once you complete the last set of questionnaires, a week after attending the laboratory at UCL.

Are there any risks in taking part?

There are no known risks in completing the questionnaires or procedures except for potentially experiencing mild discomfort with holding your breath.

Are there any benefits to taking part?

You may find the strategies helpful for managing craving experiences. However, this is not certain. Nevertheless, your participation will help us gain a better understanding of the experience of craving and people acting on craving, which may lead to better strategies for managing these challenging experiences. In addition, some people find the tasks involved in the experiment can be interesting and enjoyable.

Please discuss the information above with others if you wish, or ask us if there is anything that is not clear or if you would like more information.

It is up to you to decide whether to take part or not; choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time and without giving a reason.

All data will be collected and stored in accordance with the Data Protection Act 1998.

All information which is collected about you during the course of the research will be kept strictly confidential and will be securely stored electronically, using a numbered code so that you cannot be identified. Only researchers directly involved in the study will have access to the data. All data will be stored in accordance with the Data Protection Act 1998. The data will be used only for informing the research question in this study and the results of the research will be disseminated in peer-reviewed scientific journals, but you will in no way be identifiable from such publications.

Appendix 3: Informed consent

<div style="border:1px solid black; padding:1em;">

Informed Consent for Craving for Alcohol? The Effect of a Brief Strategy on Craving Experience and Alcohol Use

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Project: **Craving for alcohol? The effect of a brief strategy on craving experience and alcohol use**

This study has been approved by the UCL Research Ethics Committee (Project ID Number): 6520/001

Thank you for your interest in taking part in this research. Before you agree to take part, the person organising the research must explain the project to you.

If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you to decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

Participant's Statement

I

- have read the notes written above and the Information Sheet, and understand what the study involves

- understand that if I decide at any time that I no longer wish to take part in this project, I can notify the researchers involved and withdraw immediately.

- consent to the processing of my personal information for the purposes of this research study.

- understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.

- agree that the research project named above has been explained to me to my satisfaction and I agree to take part in this study.

Signed: Date:

</div>

Appendix 4: Mindfulness script

Introduction

In this recording you will learn about a strategy for managing craving or urges to drink alcohol. This strategy can be used whenever you experience a difficult feeling, but here we are thinking specifically about how to manage craving for alcohol. First there will be an explanation about what this strategy involves and then you'll have a chance to practice it briefly before the main task.

Explanation of the strategy

When we notice a strong desire for something, like a favourite food or drink, especially if it's right in front of us, it is often the case that we will simply eat or drink it without too much thought. This is a kind of automatic response. We do not notice how full or hungry we are but just respond to stimuli automatically. A similar thing can happen with alcohol, leading to over-drinking and occasionally to more serious alcohol problems. We may be responding automatically to external events such as seeing someone drinking, or we may be responding automatically to internal negative feelings in our bodies.

A craving or urge to drink alcohol is generally experienced as a feeling in the body that can be accompanied by thoughts like "I could really do with a drink right now". Craving is often related to stress and negative feelings, like anxiety. Experiencing craving, stress and uncomfortable bodily sensations can lead automatically to drinking. Being in touch with and aware of your feelings and bodily sensations can help you experience craving in a different way. Noticing what sensations are currently being felt in your body can help you experience craving as temporary events in the body. Paying attention to the exact experiences and processes that are going through your body can help you tolerate them without having to act on them.

Some people find that noticing, paying attention to and accepting what's going on inside their minds and bodies without trying to change these experiences - can help them experience craving in a different way – in a way that does not lead to automatic drinking. The main benefits of noticing and focusing on your thoughts and bodily sensations are believed to lie in a greater ability to accept that unpleasant and strong feelings and thoughts wax and wane, like waves.

You begin to realise that you do not have to get caught up in them – you can just allow unpleasant feelings to come, to stay for as long as they will, and eventually, change or even disappear. The key thing is allowing yourself to fully experience bodily reactions and thoughts without trying to get rid of them and without automatically responding to them. This can be achieved by the simple method of observing your thoughts and feelings with curiosity without analysing or judging them. This leads to greater acceptance of difficult feelings.

Strategy Practice

Let's see how this approach might work in practice. Start by letting your eyes gently close or fix them on a point on the floor in front of you. Take a moment and notice the sensations of sitting on the chair. Maybe notice the parts of your body in contact with the chair [pause]. Notice the sensations in those parts of your body. Notice the sensations in your legs and in your feet where they make contact with your shoes and the floor [pause 5 seconds]. Notice sensations in other parts of your body. Now imagine that there is a drink in front of you: your favourite alcoholic drink. Please really concentrate on this image of your favourite drink, get caught up in it, bring it to life as if it's right in front of you, and give it your full attention. Imagine holding the drink; the smell of the drink; its colour. Now imagine bringing it to your lips and taking a sip. Imagine how it feels in your mouth and throat as you swallow. Immerse yourself in this experience and the different sensations {pause}. As you keep this image in mind you may notice some craving or urges to drink. As you notice these feelings, focus your attention inward on those feelings. Allow your attention to wander throughout your body. Notice where in your body you experience the craving or any difficult feeling and what the sensations are like. Notice each area where you experience the urge and any difficult feeling, and simply tell yourself what you are experiencing. For example, you might say "I feel my craving in my abdomen" or "I feel my craving in my chest".

Try to focus on the area in your body where you are experiencing the craving most strongly. Notice the exact sensations in that area. How does it feel? Is it hot, cold, tingly, or numb? Perhaps there is another word to describe the feeling that you are noticing? Are your muscles tense or relaxed? How large an area of your body is involved? Notice the sensations, stay with them and describe them to yourself. [pause] Notice how the sensations change in your body: how they change in shape or location or intensity. Do not struggle against the feelings; allow them and follow the way they shift and change. The purpose of this exercise is not to make the craving go away but to experience craving in a different way and learn that these feelings can be accepted and tolerated rather than acted upon.

Main task

Now we are going to practice the strategy again with a bit more detail and depth. While doing this exercise, your attention will probably wander from time to time, as you get caught up in different, unrelated thoughts. This is quite normal and it may happen repeatedly [pause]. Each time you notice your mind wandering; take a second to notice this and bring yourself back to the task at hand [pause 5 seconds]. To start, let your eyes gently close, or fix them on a point in front of you. Try to sit in a way that ensures that you are awake and alert. The idea is not necessarily to become relaxed. The main idea is to be awake and attentive. This will enable you to fully notice and focus on the body. As before, take a moment now to notice the

sensation of sitting in the chair [pause].Try to notice where parts of your body contact the chair, and your feet on the ground [pause 5 seconds].

Now take a slow and deep breath and direct your attention to focus on the physical sensations of your breath [pause 5 seconds]. You don't need to do anything special with your breathing. Simply notice the rise and fall of your chest or abdomen with each breath [pause 5 seconds]. As you breathe in notice the cool air coming into your nostrils [pause], and the warm air as you breathe out.

Now again, imagine that there is a drink in front of you: your favourite alcoholic drink. Concentrate on the image, get caught up in it and bring it to life as if it's right in front of you. Imagine the smell and sight of your favourite drink. Now imagine bringing it to your lips and taking a drink. Immerse yourself in this experience and the different sensations {pause}. Be aware of whatever you are experiencing at the moment as you imagine this scene, even if it is difficult or unpleasant sensations, thoughts or emotions. In fact it is important especially in such moments to be open hearted and non-reactive as you notice the sensations the best you can [pause]. Let go of the tendency that we all have to want things to be different from how they are right now, and allow things to be exactly as you find them [5 seconds pause]. As you keep this image in mind you may start to feel some craving or urges to drink. As you notice these feelings, focus your attention inward on those feelings. Allow your attention to wander through your body. Notice where in your body you experience the craving or any difficult feelings and what the sensations are like. Notice each area where you experience the urge and any difficult feelings and simply tell yourself what you are experiencing. For example, you might say to yourself "I feel my craving in my abdomen" or "I feel my craving in my chest". Focus on one area where you are experiencing the urge most vividly. Notice the exact sensations in that area. How does it feel? Is it hot, cold, tingly, or numb? Perhaps there is another word to describe the feeling you are noticing? Are your muscles tense or relaxed? How large an area of your body is involved? Notice the sensations, stay with them and describe them to yourself. [pause] Notice also how the sensations change in your body: how they change in shape or location or intensity. Do not struggle against the feelings; allow them and follow the way they shift and change.

Repeat the focusing with each part of your body that experiences the craving. Pay attention to and describe to yourself the changes that occur in the sensations. Notice how the urges come and go. Remember, the purpose of this exercise is not to make the craving go away but to experience it in a different way and learn that these feelings can be accepted and tolerated rather than acted upon [30 secs].

And now bring your attention back to the room, open your eyes if they were closed. Notice what you can see, notice what you can hear [pause].

Appendix 5: Relaxation script

Introduction

In this recording you will learn about a strategy for managing craving or urges to drink alcohol. This strategy can be used whenever you experience a difficult feeling, but here we are thinking specifically about how to manage craving for alcohol. First there will be an explanation about what this strategy involves and then you'll have a chance to practice it briefly before the main task.

Explanation of the strategy

When we notice a strong desire for something, like a favourite food or drink, especially if it's right in front of us, it is often the case that we will simply eat or drink it without too much thought. This is a kind of automatic response. We do not notice how full or hungry we are but just respond to stimuli automatically. A similar thing can happen with alcohol, leading to over-drinking and occasionally to more serious alcohol problems. We may be responding automatically to external events such as seeing someone drinking, or we may be responding automatically to internal negative feelings in our bodies.

A craving or urge to drink alcohol is generally experienced as a feeling in the body that can be accompanied by thoughts like "I could really do with a drink right now". Craving is often related to stress and negative feelings, like anxiety. Experiencing craving, stress and uncomfortable bodily sensations can lead automatically to drinking. Softening the muscles in your body and calming and unwinding your mind can help you reduce your craving. Releasing tension in your body can help you reduce the intensity of your stress, anxiety and cravings. Easing-up and de-stressing the tension in your body, and reaching a state of tranquillity can help you to control them without having to act on them.

Some people find that calming and unwinding what's going on inside their minds, and releasing and easing up the tension from their bodies, can help them to reduce their craving levels in a way that does not lead to automatic drinking. The main benefits of easing-up and de-stressing your mind and the tension in your body are believed to lie in a greater ability to calm the unpleasant and strong feelings and thoughts.

You begin to develop the ability to release tension from your body and mind and find that unpleasant feelings gradually change and decrease, and eventually they maybe even disappear. The key thing is transforming your bodily reactions and thoughts to more calming experiences so that they are less unpleasant and you do not have to automatically respond to them. This can be achieved by the simple method of soothing your thoughts and loosening up any tension from your muscles. This leads to changing difficult feelings into less unpleasant ones.

Strategy practice

Let's see how this approach might work in practice. Start by letting your eyes gently close or fix them on a point on the floor in front of you. Take a moment to adopt a calm state of mind and a relaxed posture. Make sure you are sitting in a comfortable position in the chair and unwind your mind [pause]. Loosen up any stiffness that you feel in your body. Start by releasing tension from the muscles in your legs and feet and then ease and soften other parts in your body [pause 5 seconds].

Now imagine that there is a drink in front of you: your favourite alcoholic drink. Please really concentrate on this image of your favourite drink, get caught up in it, bring it to life as if it's right in front of you, and give it your full attention. Imagine holding the drink; the smell of the drink; its colour. Now imagine bringing it to your lips and taking a sip. Imagine how it feels in your mouth and throat as you swallow. Immerse yourself in this experience and the different sensations {pause}. As you keep this image in mind you may start feeling craving and urges to drink. As you have these feelings, focus on calming your body. Allow your body to feel more and more loose and at ease. Wherever you experience craving or any difficult feeling in your body, just loosen and untense that region….. Now see if there is another part of your body where you're experiencing an urge and simply tell yourself to loosen that part of your body. For example, you might say "I am managing my craving by calming my abdomen" or "I am managing my craving by loosening any tension in my chest". Try to untense the area in your body where you are experiencing the craving most strongly. Start by taking a few slow and deep breaths….. Breathe in through your nostrils and breathe out from your mouth. As you breathe out, release any tension that you may be experiencing. Allow the muscles to feel more and more loose and floppy in other parts of your body.

Calm each area where you experience tension and difficult feelings [pause]. Continue to take slow and deep breaths… As you breathe out unwind your mind and release any further tension felt in your body. Allow any feelings to change to more calming and less unpleasant ones.
The purpose of this exercise is to reduce the craving and change the feelings of the craving into less unpleasant ones, through releasing tension all over the muscles in the body and calming the mind.

Main task

Now we are going to practice the strategy again with a bit more detail and depth. While doing this exercise, your attention will probably wander from time to time, but as long as you continue to relax, this is fine. In fact, this is quite normal and it may happen repeatedly [pause]. Just allow your body to continue to be calm and your mind to continue to unwind [pause 5 seconds]. To start, let your eyes gently close, or fix them on a point in front of you. Try to sit in a way that ensures that you are comfortable and tranquil. The idea is not necessarily to be awake and attentive.

The main idea is to be calm and at ease. This will enable you to fully release tension from your body and unwind your mind. As before, take a moment now to adopt a calm state of mind [pause]. Make sure you sit in a comfortable position in the chair, and loosen up any tension that you feel in your body [pause 5 seconds].

Now take a slow and deep breath. As you breathe in, allow your belly to rise, and to fall as you breathe out, if that feels comfortable [pause 5 seconds]. You don't need to do anything special with your breathing. Simply breathe in from your nostrils and breathe out from your mouth [pause 5 seconds.] Calm as the cool air comes into your nostrils [pause], and as you breathe out warm air.
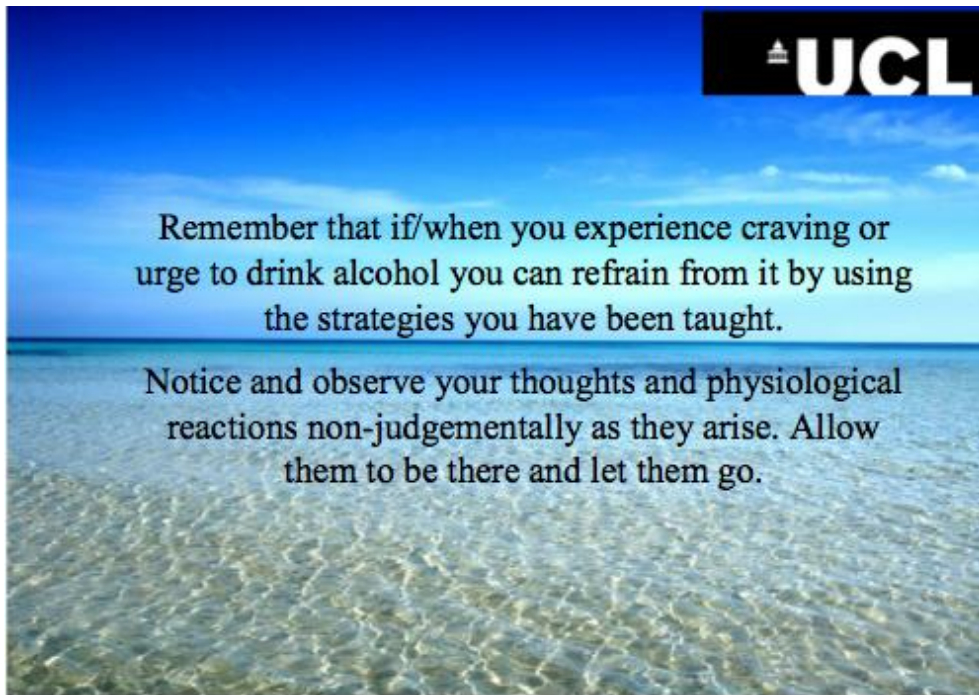
Now again, imagine that there is a drink in front of you: your favourite alcoholic drink. Concentrate on this image, get caught up in it and bring it to life as if it's right in front of you. Imagine the smell and sight of your favourite drink. Imagine bringing it to your lips and taking a drink. Immerse yourself in this experience and the different sensations {pause}. As you imagine this scene you may experience difficult or unpleasant sensations, thoughts or emotions. Try to wind down your mind and release any tension from your body completely. It is important especially in such moments to ease any stiffness in your muscles and any thoughts that may be distressing in your mind [pause]. If you feel tension try and calm down and make yourself feel more at ease and de-stressed, in order to allow things to be less unpleasant. [5 seconds pause]. As you keep this image in mind you may start to feel some craving and urges to drink. As you have these feelings, focus on calming your body. Allow your body to feel more and more loose and at ease. Wherever you experience craving or any difficult feelings in your body, just loosen and untense that region….. See if there is another part of your body where you're experiencing an urge or any difficult feelings and simply tell yourself to calm that part of your body. For example, you might say to yourself "I am managing my craving by calming my abdomen" or "I am managing my craving by loosening my chest". Untense the area where you are experiencing the urge most vividly. Take taking a few slow and deep breaths…..As you breathe out, release any tension that you may experience. Allow your muscles to feel more and more loose and floppy in other parts of your body. Calm each area where you experience tension and difficult feelings [pause]. Continue to take slow and deep breaths… As you breathe out continue to unwind your mind and release any further tension felt in your body. Allow any feelings to change to more calming and less unpleasant ones.

Repeat releasing the tension from each part of your body that experiences the craving. Calm down your entire body and let the muscles loosen up gradually. Take a few more deep breaths in order to reduce the urge. Remember, the purpose of this exercise is to reduce the craving and change the feelings of craving into less unpleasant ones, through releasing tension all over the muscles in the body and calming the mind [30 secs].

And now bring your attention back to the room, open your eyes if they were closed. You can stretch the different parts of your body [pause].

Appendix 6: Cue cards

Mindfulness:

Remember that if/when you experience craving or urge to drink alcohol you can refrain from it by using the strategies you have been taught.

Notice and observe your thoughts and physiological reactions non-judgementally as they arise. Allow them to be there and let them go.

Relaxation:

Remember that if/when you experience craving or urge to drink alcohol you can refrain from it by using the strategies you have been taught.

Take a few deep breaths and release any tension in your body as it arises. Allow your muscles to feel more and more calm.

Appendix 7: Taste test visual analogue scale

Instructions

Please rate your experience by placing a single checkmark (like this: X) along each line that best fits your experience of tasting the drink. You can continue to taste the drink between items to ensure your rating is accurate for each item.

The drink was…

1. **Unpleasant ___:____: ___:___:___:___:___ Pleasant**

2. **Tasteless ___:____: ___:___:___:___:___ Strong tasting**

3. **Bitter ___:____: ___:___:___:___:___ Sweet**

4. **Flat ___:____: ___:___:___:___:___ Gassy**

Appendix 8: Credibility and expectancy questionnaire

We would like you to indicate below how much you believe, right now, that the strategy that you have just heard about will help you to manage alcohol cravings. Please answer the questions below.

<u>**Credibility**</u>

1. **At this point, how logical does this strategy seem to you if it was to be used as a way of helping people to cut down/stop drinking?**

    Not at all logical   Somewhat logical   Very logical

    1   2   3   4   5   6   7   8   9

2. **At this point, how successful do you think this will be in helping *you* to manage your cravings?**

    Not at all useful   Somewhat useful   Very useful

    1   2   3   4   5   6   7   8   9

3. **How *confident* would you be in recommending this to a friend who wants to cut down or stop drinking?**

    Not at all confident   Somewhat confident   Very confident

    1   2   3   4   5   6   7   8   9

<u>**Expectancy**</u>

1. **At this point, how much do you really *feel* that this strategy will help you to reduce your cravings?**

    Not at all   Somewhat   Very much

    1   2   3   4   5   6   7   8   9

Appendix 9: Relaxation/tension measure

Please rate your level of tension at this point.

Absolutely no tension   Somewhat tense   Extremely tense
1   2   3   4   5   6   7   8   9

Appendix 10: Manipulation check

Thinking about the strategy you have just taken part in, please circle the appropriate answer.

In the strategy:

1. **I was given a specific strategy to use to cope with cravings**　　　True/False

2. **I was instructed to breathe calmly in order to reduce my craving**　　　True/False

3. **I was instructed to try to allow my craving to stay as it is *without* trying**　　True/False
   to change it

4. **I was instructed to unwind my mind when I feel craving**　　　True/False

5. **I was instructed to accept my thoughts without trying to get rid of them**　　True/False

6. **I was instructed to release tension in my muscles when I feel craving**　　True/False

Appendix 11: Assessment of practice

Please rate the questions below. We are interested in your most accurate responses. Your responses will not affect the payment that you will receive.

1. **How many days have you practised the techniques and exercises that you were taught during the past week?**

   0   1-2   3-4   5-6   7

2. **How long on average have you practised each day?**

   0 minutes   1-5 minutes   6-10 minutes   11-14 minutes   15+ minutes

3. **If and when you have practised the exercises, did you feel that you were fully engaged with the exercise?**

   Not at all   A little   Somewhat   Quite a bit   Very much

Appendix 12: Information on joint theses

This D.Clin.Psy. thesis was a joint theses project with another Trainee Clinical Psychologist, Shirley Serfaty. We worked together to obtain ethical approval for our project. Under the supervision of Dr. Sunjeev Kamboj, Shirley and I worked on designing the experimental procedure and selecting the appropriate measures. We worked together to create the scripts for mindfulness and relaxation and matched both scripts in terms of complexity, the number of craving related cue words, and the number of words.

We conducted the same experimental procedure on different days. Shirley's thesis involved a cue reactivity procedure to examine craving and negative affect in response to standardised mindfulness instructions and a relaxation control condition. In the cue reactivity paradigm, participants were exposed to alcohol cues while their physiological responses were measured (HRV and blood pressure).

We were both responsible for data collection and management but analysed our primary outcomes separately. The write-up of this thesis was independent.