Abstract: The invention relates to a novel mask for delivering light and/or aroma therapy to a user; the use of said mask for the delivery of light and/or aroma therapy to a user; and a method for treating a psychological disorder comprising the use of said mask for the delivery of light and/or aroma therapy to a user.
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Device for olfactory and visual stimulation

Field of the Invention

The invention relates to a novel mask for delivering light and/or aroma therapy to a user; the use of said mask for the delivery of light and/or aroma therapy to a user; and a method for treating a psychological disorder comprising the use of said mask for the delivery of light and/or aroma therapy to a user.

Background of the Invention

A mental disorder is a psychological pattern or anomaly, which may often be reflected in abnormal behaviour, which is not considered part of normal development. There are many different categories of mental disorder, and many different facets of human behaviour and personality that can become disordered. Two such examples include anxiety and depression.

Anxiety or fear that interferes with normal functioning may be classified as an anxiety disorder, and commonly recognized categories include specific phobias, generalized anxiety disorder, social anxiety disorder, panic disorder, agoraphobia, obsessive-compulsive disorder and post-traumatic stress disorder.

Other affective (emotion/mood) processes can also become disordered. Mood disorder involving unusually intense and sustained sadness, or despair, is known as major depression (also known as unipolar or clinical depression). Milder but still prolonged depression can be diagnosed as dysthymia. Bipolar disorder (also known as manic depression) involves abnormally "high" or pressured mood states alternating with normal or depressed mood.

It is predicted that Common Mental Disorders affect 1 in 6 British adults every week. Over half of these have a mixed anxiety and depressive disorder (Deverill et al, 2009). In the USA, in any given one-year period, 13 million to 14 million people (which equates to approximately 6.6% if the US population)
experience the illness (Kessler et al, 2003); globally, more than 350 million people of all ages suffer from depression (WHO, 2012) and the annual incidence in UK rate is 36 per 1000 (NICE, 2004). This contributes to substantial financial burden on healthcare systems, with the total cost of services for depression in England in 2007 estimated to be £1.7 billion, while lost employment as a consequence of suffering depression increased this total to £7.5 billion. By 2026, these figures are projected to be £3 billion and £12.2 billion, respectively (McCrone et al, 2008).

The underlying causes of mental disorders varies and are often unclear, with a continuum of illness making diagnosis complex and with many cases going unrecognised. In many cases, there is no single accepted or consistent cause currently established. The likely course and outcome of mental disorders varies, depending on numerous factors related to the disorder itself, the individual as a whole, and the social environment. Whilst some disorders are chronic, others may be more transient in nature and may be accompanied by additional symptoms such as elevated blood pressure and heart rate.

Seasonal Affective Disorder (SAD) is a sub-category of depression or mood disorders, in which people who have normal mental health throughout most of the year experience depressive symptoms at a certain time of the year, most commonly in the late autumn and winter (winter depression) and more rarely in late spring and summer (summer depression). Connections between human mood and the seasons are well documented, even in healthy individuals. Symptoms of SAD mimic those of other depressive disorders and may consist of difficulty in waking, morning sickness, tendency to oversleep and over eat, lack of energy, difficulty concentrating on or completing tasks, withdrawal from friends, family, and social activities, decreased sex drive, and suicide. This may lead to more severe forms of depression.

The prevalence of SAD is reported as ranging from 0.4 to 12% (Blazer et al., 1998 and Dam et al., 1998): 4-6% people in USA, -7% in UK, 2% (10% with
milder symptoms) in Northern Europe suffer from SAD. However, a variation in estimates occurs as a consequence of inherent variability according to the diagnostic test used. For example, in the UK different diagnostic tests have indicated a prevalence of SAD of 5.6% to 10.7% (Thompson et al, 2004).

There are many different treatments for classic (winter-based) seasonal affective disorder, including light therapy with sunlight or bright lights, antidepressant medication, cognitive-behavioural therapy, ionized-air administration, and carefully timed supplementation of the hormone melatonin.

Light therapy is an established treatment for SAD and mood disorders (Golden et al, Am J Psychiatry 2005; Pail et al, Neuropsychobiol 2011), having been used for over 20 years with reasonable effectiveness. It has also been shown to be effective in other kinds of depression such as Major Depressive Disorder (MDD) (Lieverse et al, Arch Gen Psychiatry 2011). It is the recommended first-line treatment of the majority of cases of SAD, with improvements in symptoms observed with as little as 20 minutes of bright light exposure. It is believed this positive effect is attributed to photoperiod-related alterations in the duration of melatonin secretion, which is thought to affect the seasonal mood cycles of SAD.

Conventional light therapy utilises a lightbox, which emits a significant number of lumens - much greater than a standard incandescent lamp. Bright white "full spectrum" light at 10,000 lux, blue light at a wavelength of 480 nm at 2,500 lux or green (actually cyan or blue-green) light at a wavelength of 500 nm at 350 lux are commonly used. Therapy involves the patient sitting at a prescribed distance from the light box for periods, where 30-60 minutes are often recommended. Effective doses of light therapy vary depending on the individual, with studies showing effective doses ranging between 3,000 lux 2 hours/day for 5 weeks to 10,000 lux 30 minutes/day for 8 weeks.
However, a number of factors exist, such as the type of light, its mode of delivery and also the schedule of delivery, which are all thought to be important in determining effectiveness of light therapy in the treatment of SAD. Further, conventional light box therapy is often deemed inconvenient to most users due to the required time commitment.

Alternatively, odour has been demonstrated to induce a range of emotions in humans including happiness, surprise, anger, disgust, fear, sadness (Alaoui-Ishmaili et al, 1997; Vernet-Maury et al, 1999; Herz; 2005; Johnson, 2011) and, in general, the mood induced is congruent with the hedonics of the stimulus (Ehrlichman and Bastone, 1992). Therefore, a pleasant odour tends to induce a positive mood. Further, olfactory stimulus has the capacity to alter physiological parameters such as blood pressure, heart rate, respiration and skin conductance. In animal and human studies lavender has been shown to exhibit a sedative effect (Buchbauer et al, 1993; Ghelardini et al, 1999) and has been used in humans as a treatment for agitated behaviour as a consequence of dementia (Holmes et al., 2002). Many other odours have been demonstrated to affect human psychology and physiology, for example lemon odour has been shown to reduce depression and also reported depressive mood (Komori et al, 1995; Schiffman, 1991).

Herein disclosed is a device that simultaneously delivers light and olfactory stimulation to a user. An example of proof of concept is herein demonstrated through positive observations upon various physiological and psychological parameters that are known to associate with improved mood. Further, the disclosed device produces cyclic light and olfactory stimulation, which can be adjusted such that stimuli are sensed at maximum levels during use, thereby having greatest effect in enhancing mood. Advantageously, the device disclosed herein generates a positive effect upon mood, which has implications in the treatment of mood disorders such as depression, including SAD, and anxiety.
Sensory information is integrated in the orbitofrontal cortex of the brain, including Brodmann area (BA) 11 (Kringelbach, 2005). This area neighbours the subgenual anterior cingulate cortex (BA 25), an area implicated in major depressive disorder (MDD), and is functionally connected to it. BA25 is overactive in depression and deep brain stimulation of BA25 has been found to treat MDD (Mayberg et al., 2005). Without wishing to be bound to theory, the hypothesis proposed herein is that activation of neighbouring BA11 by multiple sensory stimuli will achieve similar consequences to deep brain stimulation and impact upon MDD and related depressive disorders.

Statements of Invention

According to a first aspect of the invention there is provided a mask adapted to be worn over the eyes of a user, wherein said mask comprises:

a) at least one light source for delivering light to a user; and

b) at least one aroma supply in fluid communication with a delivery channel or conduit which terminates in at least one opening positioned, when worn, near or adjacent the nose of a user.

In a preferred embodiment of the invention said mask is provided as a pair of goggles or as a helmet.

More preferably still said aroma supply comprises housing for accommodating an aroma. Preferably, said housing accommodates a disposable or re-usable cartridge or container in which said aroma is stored. Yet more preferably still, said cartridge or container comprises at least one outlet means which, ideally, is sealable, typically using a valve, whereby the release of said aroma from said cartridge or container can be selectively controlled. This control may be manual or via the use of appropriate circuitry. Yet more preferably still, said aroma supply comprises a pressure generating device such as an agitator, or fan, or suction device whereby passage of said aroma along said channel or conduit can be pressure assisted. More ideally still, said aroma supply comprises a timing mechanism whereby either or both the release of aroma...
from said housing and/or the assisted passage of said aroma along said channel or conduit can be timed, thus, the timing mechanism is in operational communication with said sealable outlet means and/or said pressure generating means.

In a yet further preferred embodiment of the invention said cartridge or container comprises a removable cap whereby the contents of said cartridge or container can be accessed and replaced, thus ensuring the re-use of a selected aroma or the substitution of an alternative aroma.

In a yet a further embodiment still, said cartridge further comprises an electronic chip for storing programs relating to the use of said aroma supply and/or said light source and, in particular, the synchronised use of said light source and said aroma supply. In this way, the supply of a particular aroma via said valve can be coupled to a specific administration program and/or light program such that the synchronized use of same can be varied depending upon the nature and effect of the chosen aroma stimulus.

In yet a further preferred embodiment of the invention said light source is positioned, when worn, to be visible to a user either directly or indirectly. In the former instance said light a source is positioned so as to be in the field of view of a user, in the latter instance a diffraction device and/or a refractive device and/or a reflective device is/are provided for altering or controlling the path of travel of said light so that it is ultimately viewable by a user. More preferably still, said light source is in operational communication with the timing mechanism of said aroma supply or, alternatively, with a separate timing mechanism whereby the emittance of light is selectively controlled and/or synchronized with the delivery of said aroma.

In yet a further preferred embodiment of the invention said mask is provided with a battery supply and/or a socket for connecting the mask to a mains supply
whereby the light source and/or the pressure generating device can be powered.

In yet still a further preferred embodiment of the invention said mask is provided with an electronic chip for storing programs relating to the use of said light source and/or said aroma supply and, in particular, the synchronised use of said light source and said aroma supply. Accordingly said chip is in operational communication with said components of said mask, in particular said light source and said aroma supply and, ideally, said pressure generating device and said sealable outlet.

More ideally still, said aroma supply is positioned, when worn, on said mask toward the rear of same. Alternatively said aroma supply is positioned, when worn, remote from said mask and so, in one embodiment, on the arm of a user.

In a further embodiment at least one of, including any combination of, said power/battery supply, aroma supply, pressure generating device and electronic chip and its programmes are positioned remote from said mask, ideally in a separate housing that is in operational communication with said mask whereby the light and aroma stimuli can be controlled.

In yet a further preferred embodiment of the invention said mask is adapted to provide an administration cycle for synchronising the delivery of light and aroma therapy to a user of said mask wherein;

a) light is delivered in repetitive rising and declining phases;

b) aroma is delivered in repetitive rising and declining phases; and

c) the intensity peaks of said light delivery cycle according to a) occurs at the same time as the intensity peak of said aroma delivery cycle according to b).

Those skilled in the art will appreciate the mask is adapted to provide said administration cycle by the storage of programs on said chip(s) for selectively
controlling the timing and amplitude of the delivery of said aroma and/or light stimulus.

In a preferred embodiment of the invention, said rising phase of said aroma delivery is undertaken at at least two flow velocities or speeds and so occurs in a step wise manner. Ideally, said rising phase of said aroma delivery is undertaken at two speeds and so occurs in a single step-wise manner. In further ideal embodiments of the invention said aroma delivery is undertaken at greater than two flow velocities or speeds and so occurs in a number of steps. In contrast, ideally, the declining phase of said aroma delivery occurs in a single step such that the delivery ceases as abruptly as possible.

In yet a further preferred embodiment still, said light is delivered in a saw tooth (or triangular wave) cycle and so upon rising to a peak immediately declines to zero before immediately rising again to said peak.

In yet a further preferred embodiment said light is delivered in a sine wave and so upon gradually rising to a peak gradually declines to zero before gradually rising again to said peak.

In yet a further preferred embodiment said declining phase of said light cycle begins at the same time as the declining phase of said aroma cycle.

According to a further aspect of the invention there is provided the use of said mask for the delivery of light and/or aroma therapy to a user.

According to a yet further aspect of the invention there is provided a method for treating a psychological disorder comprising the use of said mask for the delivery of light and/or aroma therapy to a user.

Throughout the description and claims of this specification, the words "comprise" and "contain" and variations of the words, for example "comprising"
and "comprises", mean "including but not limited to" and do not exclude other moieties, additives, components, integers or steps. Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

All references, including any patent or patent application, cited in this specification are hereby incorporated by reference. No admission is made that any reference constitutes prior art. Further, no admission is made that any of the prior art constitutes part of the common general knowledge in the art.

Preferred features of each aspect of the invention may be as described in connection with any of the other aspects.

Other features of the present invention will become apparent from the following examples. Generally speaking, the invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including the accompanying claims and drawings). Thus, features, integers, characteristics, compounds or chemical moieties described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be applicable to any other aspect, embodiment or example described herein, unless incompatible therewith.

Moreover, unless stated otherwise, any feature disclosed herein may be replaced by an alternative feature serving the same or a similar purpose.

An embodiment of the invention will now be described with reference to the Examples below and to the drawings in which:

**Figure 1** shows a rear elevation perspective view of the goggle form of the mask in accordance with a preferred embodiment of the invention;
Figure 2 shows a front elevation perspective view of the goggle form of the mask in accordance with a preferred embodiment of the invention;

Figure 3 shows an exploded version of the different components of the aroma supply shown in figures 1 to 2;

Figure 4 shows the mask according to a preferred embodiment of the invention when worn by a subject;

Figure 5 shows a perspective view of the mask in accordance with a further embodiment of the invention;

Figure 6. Light and odour stimulus cycle. Light was delivered as a saw tooth intensity cycle rising to a maximum of 2500 lux and falling to near 0 lux every 30 sec. Odour was delivered at low to high speed followed by a refractory period. Both stimuli were presented in synchrony for the requisite time period;

Figure 7. The effect of 10 min exposure to light (2500 lux) and odour (vanillin, 5%) on blood pressure. There was a significant reduction in systolic pressure (p=0.014, n=16);

Figure 8. The effect of 15 min exposure to light (2500 lux) and odour (lemon essential oil) on skin conductance. There was a significant reduction in skin conductance (p<0.0001, n=59);

Figure 9(a). EEG alpha asymmetry. The effect of 10 min exposure to light (2500 lux), pleasant odour (vanillin and PEA) and light + odour on alpha wave asymmetry. The subjects (n=46) were divided into positive and negative on the basis of their alpha wave asymmetry (alpha power at F8 minus alpha power at F7). Alpha wave power is expressed per 10sec époque;
Figure 9(b). EEG alpha asymmetry following repeated sessions. The effect of 15 min exposure to light and smell (vanillin) on alpha wave asymmetry. EEG was recorded from subjects with a negative asymmetry (n=5) on two separate occasions. There was a significant increase (2-factor Anova, p<0.05) in the asymmetry index (Al) during the first session that was maintained to the second session;

Figure 10. Effect of odour and light stimuli on PANAS. [A] The exposure of subjects to 10 min stimulation with light and pleasant odour (PEA) had the effect of significantly (* p<0.05, n=15) reducing the negative affect (NA) without changing the positive affect (PA). [B] Separating the high scorers on the Becks Depression Inventory (BDI) showed that those with high scores had a larger negative affect (NA) on PANAS and that there was a significant reduction in NA following exposure to light and odour (PEA), * p<0.05, n=4;

Figure 11. Effect of odour and light stimuli on POMS. [A] The exposure of subjects to 10 min stimulation with light and pleasant odour (PEA) had a significant (* p<0.05, n=15) effect on total mood disturbance (TMD), anger-hostility (AH), confusion-bewilderment (CB), fatigue-inertia (Fl) and tension-anxiety (TA) (n=15). [B] light and vanillin had a significant effect on TMD (p<0.01). Fl, TA, and dejection-depression (DD) (b), (n=17);

Table 1. The statistical effects light and odour on the Profile of Mood States (POMS).

Referring to figure 1, there is shown a mask 1 in the form of a headband, thus it is generally circular in cross section and of a size that sits comfortably on the head of a user. Mask 1 comprises a front section 2, a rear section 3 and sides 4.
In this particular embodiment, mask 1 takes the form of a pair of goggles although those skilled in the art will appreciate that alternative versions of the mask can be used to achieve the same effect. Mask 1 thus has a front light source 2a positioned within the eye wells of the goggles. Light source 2a emits light directly into the field of view of a user. In alternative embodiments of the invention the light source may be located remote from the user's field of view and is directed to a user's field of view using at least one light guide.

The light source 2a is an equivalent UV-free light stimulus that emits up to 2500 lux when in close proximity (2-4 cm) to the eyes. This light was delivered by LEDs, 24 in total, 12 per eye. Forward voltage per LED 3.2V @ 10mA, LED drive voltage 3.2V x 6 = 19.2V, drive current 10mA x 4 = 40mA. Total LED power 24 x 3.2V x 10mA = 19.2V x 40mA = 0.77W.

The outer surface 2b of the eye wells is opaque so that the user's attention is not distracted by external visual stimuli. However, in certain embodiments it is possible that the outer surface is transparent, this is particularly true where the light source is located remote from the user's field of view and is directed using a light guide. Associated with light source 2a is a light diffuser (not shown) in order to deliver uniform light stimulus to the user. Conventional diffusers are used for this purpose such as mirror gratings or such as Fresnel lens structures.

Additionally, front section 2 comprises one or a series of openings 2c located adjacent to the nose bridge 2d of the goggles. These are best seen in Figure 2. These openings are connected to a channel 2e that runs along the lower edge of front section 2 and the middle of sides 4 terminating at rear 3 in an aroma supply 3a. This channel is also shown in figure 2.

As shown, the supply of aroma is therefore located toward the rear of the mask.
Now referring to figure 3, the individual components of the aroma supply 3a are shown in an exploded view. Aroma supply 3a comprises a housing 3b which is fashioned to sealingly, but removably, engage with a cartridge or container 3c. Inside cartridge 3c is an absorbent pad onto which a selected scent has been absorbed. In use a range of such cartridges are provided each one having a different scent or aroma. Thus the nature of the olfactory experience can be varied according to the nature of the cartridge that is selected.

For this study the odours were: vanillin (5% in dipropylene glycol (DPG)) and phenylethyl alcohol (PEA, 10% in DPG), obtained from Sigma-Aldrich (Dorset, UK) and lemon essential oil (ISO 855:2003) obtained from Neal’s Yard (Gillingham, Dorset, UK) although other odours and aromas may also be used.

Although not shown the cartridge 3c is provided with at least one outlet. Additionally, aroma supply 3a comprises a pressure generating device, herein depicted as a fan 3d to facilitate or drive the flow of said aroma through said outlet and along channels 2e.

In an alternative aspect of the invention, the cartridge 3c is provided with at least one outlet that has an associated valve or manually operated cap, although not shown, governing when the cartridge is open to emit aroma or closed to contain it. Additionally, aroma supply 3a comprises a pressure generating device, herein depicted as a fan 3d to facilitate or drive the flow of said aroma along channels 2e.

The mask 1 comprises a power supply, such as a battery pack 3e and/or connecting socket 3f for connection to a mains supply to power the light source 2a and/or pressure generator device 3d. In this embodiment the power sources are positioned with the housing 3b, however, in alternative embodiments they may be provided elsewhere such as along sides 4.
Further, the mask is provided with an electronic chip 3g for storage of programs relating to the use of the light source and/or aroma supply, in particular, the provision of light and aroma and, specifically, synchronising these two stimuli according to pre-determined or user specified cycles. Ideally, said electronic chip 3g is in operational communication with other components of the mask (not shown) such as, where present, the cartridge valve.

The mask may also comprise a switch 3h, such that the light and/or aroma supply can be turned on or off by the user.

Referring to figure 4, the mask according to a preferred embodiment of the invention can be seen in use positioned on the user.

Referring to figure 5 there is shown a perspective view of an alternative mask, wherein the mask is provided as a visor 5a. This embodiment has the features described above and so channels 2e terminate on the rear side of the visor near to the nose of a wearer.

Further, in this particular embodiment, the aroma supply is located remote from the mask and is worn on the arm of the user. Attachment straps 5b are provided to secure the aroma supply 3a in this position. Additionally, side channels 2e converge into an extension tube 5c thus enabling the aroma to travel from the aroma supply 3a to the visor.

In yet a further embodiment the power supply, aroma supply and fan are located remotely from said mask and situated in a free standing box. Tubes allow the aroma to travel to the mask and wires connect the power supply to the visor and control the administration cycle.

In use, the user places mask 1 over their eyes so that the aroma channel openings 2c terminate adjacent to the nose. The user then switches on the device 3h, such that the power supply 3e/3f activates the light source 2a.
delivering light stimuli, directly or indirectly, to the eyes of the user. At the same time, the aroma supply 3a delivers the chosen olfactory stimulus, or aroma, through the delivery channel 2e to the channel openings 2c, thereby delivering stimulus to the olfactory receptors in the nose of the user. Switching on the power supply also activates the fan 3d, which assists flow of the aroma from cartridge 3c to the user.

As will be appreciated by those skilled in the art, the provision of an electronic chip 3g containing stored programs for activation of light source/fan, permits control of the duration, synchrony and cycling of the light and aroma stimulus according to the specific requirements of the user.

In the depicted embodiment, circuitry was designed to allow the device to be switchable between: (i) fan only, (ii) light only, (iii) fans and light continuous and (iv) fans and light to be driven, in synchrony with an oscillatory cycle specified by the administration program.

An exemplary program is shown in figure 6 where light is delivered in repetitive rising and declining cycles in a saw-tooth (triangular) manner and aroma is also delivered in repetitive rising and declining cycles; further the intensity peaks of the light delivery cycle occurs at the same time as the intensity peak of the aroma delivery cycle. Moreover it can be seen that the rising cycle of said aroma delivery is undertaken at two speeds and so occurs in a step wise manner. Finally, the declining phase of the light cycle begins at the same time as the declining phase of the aroma cycle.

Testing of the device

**Stimulus Cycle**

It is known that humans exhibit peripheral adaptation and central habituation to a continuous, constant stimulus. Thus, within 30-60sec, a constant olfactory
stimulus would no longer be perceived. Recovery from adaptation/habituation requires at least 30 sec and this therefore determined the duration of the smell stimulus. To avoid adaptation/habituation stimuli were presented on a 1 min cycle and the light and odour stimuli were delivered in synchrony with a 30 sec rising phase and a 30 sec falling phase (figure 5). A saw tooth waveform was selected for the sake of the simplicity of the electronic circuit but a sine wave would be preferable.

Biometric testing

a) Blood pressure

Blood pressure was measured using a sphygmomanometer (also referred to as a sphygmometer). Using an upper arm cuff monitor (OMRON M10-IT, Boots, UK), placed on the right arm of the participant systolic/diastolic, blood pressure was taken before and after the administration of the visual and/or olfactory stimuli.

b) EEG

EEG electrodes were positioned on the left and right lateral frontal areas (F7 and F8 respectively, International 10-20 System of Electrode Placement). These were referenced to linked mastoids (A1 and A2). Another electrode placed in the centre of the head, at Fpz, was grounded. The electrodes were connected to a laboratory interface (CED1401, CED, Cambridge) via a preamplifier (CED1902, CED, Cambridge) and stored on a computer for subsequent power spectrum analysis with Spike 2 (CED, Cambridge).

c) Skin conductance

Skin conductance serves as an index of autonomic arousal (Taylor and Epstein, 1967) and is often used as an objective measure of psychological stress (Jacobs et al., 1994). Skin conductance was monitored using a conductance meter (Cambridge Electronic Design CED2502SA) designed to make direct measurements of the conductivity between two electrodes.
attached to the body (first and third fingers of one hand). The unit generates a continuous output of skin conductance \((1/\text{resistance})\). Increasing skin conductance indicates increasing autonomic arousal which correlates with a rise in stress. Conversely, a decrease in skin conductance correlates with increased relaxation.

**Psychometric testing**

**a) POMS test**

The Profile of Mood States test (POMS) was administered before and after exposure to the stimuli. The POMS inventory, developed by McNair, Lorr and Droppleman (1971), has been used extensively for the assessment of mood in many environments. The factor structure of the POMS, representing six dimensions of the mood construct -- Tension, Depression, Anger, Vigor, Fatigue, Confusion -- and the associated tables of normative values were derived from psychiatric outpatients and normal college students (McNair et al, 1971).

**b) PANAS test**

Positive and Negative Affect Schedule (PANAS) consists of two 10-item scales for PA and NA, respectively. The PANAS questionnaire is a 5-point, unipolar intensity scale of 10 positive words and 10 negative words. Each word is marked with the appropriate response to the word based on how one has been feeling. Each word can be marked 'not at all', 'a little', 'moderately', 'quite a bit', or 'extremely.' These two general dimensions account for most of the variance in self-rated affect-together they account for roughly one-half to three-quarters of the common variance in mood terms (Watson et al, 1988).

**User Participants**

Participants were students aged 18-28 years old from Cardiff University who had volunteered for the experiment. Laboratory conditions: humidity = 35-40%, temperature 22±1°C.
1. Test participant is seated and given the Information Sheet explaining the experiment.
2. Participant signs a Consent Form and completes a Medical Questionnaire
3. Complete 1st PANAS, POMS tests
4. Set up biometric equipment and connect to test participant
5. Apply device according to the invention
6. Record blood pressure
7. Start the biometric equipment
8. Record baseline (no stimulus) - 90secs
9. Apply, in sequence, each of 4 conditions randomly (control, light, smell, light+smell) and record for 90secs with 30sec gap between each condition
10. Remove device according to the invention
11. Record blood pressure
12. Remove biometric recording equipment
13. Complete 2nd PANAS, POMS tests

**RESULTS**

**Biometric Testing**

Exposure to a 10 min stimulation with light (2500 lux) and vanillin (5%) caused a significant reduction in systolic blood pressure from $109.47 \pm 2.94$ mmHg to $104.41 \pm 2.11$ mm Hg ($p<0.05$; $n=16$, Fig. 7). Although there was a reduction in diastolic blood pressure from $73.88 \pm 2.17$ mm Hg to $71.53 \pm 1.85$ mm Hg this was not significant (Figure 7).

In another experiment, exposure to a 15 min stimulation with light (2500 lux) and lemon essential oil caused a significant reduction skin conductance, ANOVA $F(2,16)=14.42$, $p<0.0001$ (Figure 8). The skin conductance returned to normal values after the exposure to the light and odour stimuli. There is no significant difference between the before and after values.
The frontal alpha wave asymmetry was computed by measuring the power in the alpha waveband and subtracting the value at electrode F7 from that at F8. This asymmetry (F8-F7) can be positive or negative. Interestingly there were more subjects in the negative group (N=30) than in the positive group (N=14).

The subjects were exposed to four conditions in random order; control, light, smell (vanillin), light+smell, and the resulting data were analysed separately on the basis of whether the subjects' asymmetry in control was in the negative or positive group. There was a statistically significant difference between the positive and negative groups (Figure 9(a); repeated measures ANOVA F(1, 42) = 47.921, p<0.001). Furthermore there was a statistically significant different effect of treatment (condition) in both cases; a large effect for negatives (high F7 alpha) p=0.0003 (2-tailed t-test) and a smaller effect for positives (low F7 alpha), p=0.011 (Figure 9(a)). Indeed, for the negatives at the p<0.001 level there was a particularly statistically significant different effect of treatment (condition) (high F7 alpha), (2-tailed t-test) (Figure 9(a)).

When subjects (n=5) with a negative asymmetry index (Al) (high F7 alpha) were exposed to the light and smell (vanillin) stimuli for 15 minutes on two separate occasions there was a reversal of the asymmetry on the first session that was maintained for the second session (Fig. 9(b)). A two-way ANOVA demonstrated a significant effect for time x session (p<0.01). A negative asymmetry is generally an indication of negative affect. Therefore, a reduction in this negative asymmetry indicates a change in the direction of positive affect.

**Psychometric testing**

A ten minute treatment with light and a pleasant aroma, phenylethyl alcohol (PEA) had a positive effect on the PANAS score (Figure 10a). In particular the negative affect (NA) was significantly (p<0.05) reduced from 12.93±1.93 to 10.87±0.31 (n=15) (Figure 10b). There was no significant effect on the positive affect (PA) (figure 10a). If the subjects were then separated on the basis of
their scores on the Beck's Depression Inventory (BDI) then the high scorers (>10) exhibited a larger reduction in response to light and odour treatment for NA, from 16.75±2.50 to 10.75±0.75 (p<0.05, n=4) (Figure 10b).

The effect of this treatment (light + odour) on the Profile of Mood States (POMS) was tested and both PEA and vanillin were found to produce significant effects (Figure 1). The total mood disturbance (TMD) was significantly reduced in both cases, from 46.4±2.9 to 41.9±4.5 (p<0.05, n=15) in light plus PEA and from 43.3±2.1 to 41.2±1.5 (p<0.01, n=17) in light plus vanillin (Table 1). In light with PEA, AH, CB, FI and TA were all reduced (p<0.05). In light + vanillin, DD, FI and TA were significantly reduced (p<0.01, see Table 1).

**Discussion**

It is herein demonstrated the effects of treatment of human subjects with a combination of light plus pleasant odour. The two sensory stimuli were delivered individually and in combination. Our results show that a ten minute exposure to both stimuli presented simultaneously was found to reduce blood pressure and skin conductance whilst the effect on EEG alpha waves suggests a change in the direction of positive affect. Further, light and odour treatment reduced negative affect in the PANAS test and reduced total mood disturbance in the POMS test. This indicates that this treatment reduced anxiety and depression.

In conclusion, we have demonstrated that light and olfactory stimuli through use of the device according to the invention, when given simultaneously, generate a positive effect on mood and physiological state which can be used in the treatment of psychological disorders such as depression and anxiety.

Table 1. Effect of light in combination with PEA and vanillin on mood as measured by the POMS inventory.

<p>| PEA (n=15) |</p>
<table>
<thead>
<tr>
<th></th>
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**Vanillin (n=17)**

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Legend: TMD = total mood disturbance, AH = anger-hostility, CB = confusion-bewilderment, DD = dejection-depression, Fl = fatigue-inertia, TA = tension-anxiety. se = standard error of the mean, p = probability.

### References


The NHS Information Centre.
(www.ic.nhs.uk/pubs/psychiatricmorbidity07)


WHO (2012) Fact sheet N°369,
Claims

1. A mask adapted to be worn over the eyes of a user, wherein said mask comprises:
   a) at least one light source for delivering light to a user; and
   b) at least one aroma supply in fluid communication with a delivery channel or conduit which terminates in at least one opening positioned, when worn, near or adjacent the nose of a user.

2. The mask according to claim 1 wherein said mask is provided as a pair of goggles or as a helmet.

3. The mask according to claim 1 or 2 wherein said aroma supply comprises a housing for accommodating an aroma.

4. The mask according to claim 3 wherein said housing accommodates a disposable or re-usable cartridge in which said aroma is stored.

5. The mask according to claim 4 wherein said cartridge comprises at least one outlet means.

6. The mask according to claim 5 wherein said outlet means is sealable whereby the release of said aroma from said cartridge or container can be selectively controlled.

7. The mask according to any preceding claim wherein said aroma supply comprises a pressure generating device.

8. The mask according to claim 7 wherein said pressure generating device is an agitator, fan, suction device whereby passage of said aroma along said channel or conduit can be pressure assisted.
9. The mask according to any preceding claim wherein said aroma supply comprises a timing mechanism.

10. The mask according to claim 9, when dependent on claims 6 or 7, wherein said timing mechanism is in operational communication with said sealable outlet means and/or said pressure generating device.

11. The mask according to any one of claims 4 - 10 wherein said cartridge further comprises an electronic chip in operable communication with said aroma supply wherein said chip stores programs relating to the use of said aroma supply.

12. The mask according to any preceding claim wherein said light source is positioned, when worn, to be visible to a user either directly or indirectly.

13. The mask according to claims 9-12 wherein said light source is in operational communication with the timing mechanism of said aroma supply.

14. The mask according to claim 12 wherein said light source comprises a timing mechanism whereby the emittance of light is selectively controlled and/or synchronized with the delivery of said aroma.

15. The mask according to any preceding claim wherein said mask further comprises a battery supply and/or a socket for connecting the mask to a mains supply whereby said light source and/or said pressure generating device can be powered.
16. The mask according to any preceding claim wherein said mask further comprises an electronic chip for storing programs used to control the use of said light source and/or said aroma supply.

17. The mask according to claim 16 wherein said chip is in operational communication with at least one of said light source, aroma supply and/or pressure generating device.

18. The mask according to any preceding claim wherein said aroma supply is positioned, when worn, on said mask toward the rear of same.

19. The mask according to claims 1-17 wherein at least one of: said aroma supply, battery supply or socket, pressure generating device and/or electronic chip and its programmes is/are positioned, when worn, remote from said mask.

20. The mask according to claim 19 wherein at least one of: said aroma supply, battery supply or socket, pressure generating device and/or electronic chip and its programmes is/are positioned in a further housing that is in operational communication with said mask whereby the light and/or aroma stimuli can be controlled.

21. The mask according to any preceding claim wherein said mask is adapted to administer light and aroma therapy to a user in a synchronized manner wherein:
   a) light is delivered in repetitive rising and declining phases;
   b) aroma is delivered in repetitive rising and declining phases; and
   c) the intensity peaks of said light delivery cycle according to a) occurs at the same time as the intensity peak of said aroma delivery cycle according to b).
22. The mask according to claim 21 wherein said rising phase of said aroma delivery is undertaken at least two speeds.

23. The mask according to claim 21 wherein said rising phase of said aroma delivery is undertaken at two speeds.

24. The mask according to any one of claims 21-23 wherein said declining phase of said aroma delivery is undertaken in one step to zero.

25. The mask according to any one of claims 21-24 wherein said light is delivered in a saw tooth cycle and so upon rising to a peak immediately declines to zero before immediately rising again to said peak.

26. The mask according to any one of claim 21-24 wherein said light is delivered in a sine wave and so upon gradually rising to a peak gradually declines to zero before gradually rising again to said peak.

27. The mask according to any one of claims 21-26 wherein the declining phase of said light cycle begins at the same time as the declining phase of said aroma cycle.

28. The use of the mask according to any one of claims 1-27 for the delivery of light and/or aroma therapy to a user.

29. A method for treating a psychological disorder comprising the use of the mask according to claims 1-27 for the delivery of light and/or aroma therapy to a user.
Figure 6

Light pattern:
- max
do
- off

Fan pattern:
- on speed 2
- on speed 1
- off
- 15s 15s 30s
Figure 7

Blood pressure

Before ❧ BP systolic ❧ After

Figure 8

Skin conductance

Before ❧ During ❧ After

Before ❧ During ❧ After
EEG

Figure 9(a)

Effect of repeat sessions on negative AI subjects

Figure 9(b)
Figure 10
A. (a) Effect of PEA on POMS (n=15)

B. (b) Effect of vanillin on POMS (n=17)
### A. CLASSIFICATION OF SUBJECT MATTER

**INV.** A61N5/06  
**ADD.** A62B18/00    A61M16/06

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

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<td>wo 2012/106775 AI (RESMED LTD [AU]; HOLEY LIAM [AU]; ARMITSTEAD JEFFREY PETER [AU]; FARR) 16 August 2012 (2012-08-16) paragraphs [0008] - [0015], [0030] - [0035], [0053] - [0073], [0099], [0100], [0113] figure 1</td>
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### C. DOCUMENTS CONSIDERED TO BE RELEVANT

- **X** Further documents are listed in the continuation of Box C.  
- **X** See patent family annex.

**"A"** document defining the general state of the art which is not considered to be of particular relevance  
**"B"** earlier application or patent but published on or after the international filing date  
**"L"** document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
**"O"** document referring to an oral disclosure, use, exhibition or other means  
**"P"** document published prior to the international filing date but later than the priority date claimed

**"T"** later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
**"X"** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
**"Y"** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
**"Z"** document member of the same patent family

Date of the actual completion of the international search: 22 July 2015  
Date of mailing of the international search report: 30/07/2015

Name and mailing address of the ISA/  
European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040  
Fax: (+31-70) 340-3018

Authorized officer: Lohmann, Stefan
## DOCUMENTS CONSIDERED TO BE RELEVANT

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Form PCT/ISA/210 (continuation of second sheet) (April 2005)
INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. □ Claims Nos.: 28, 29
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. □ Claims Nos.: (continuation of first sheet (2))
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. □ Claims Nos.: (continuation of first sheet (2))
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. □ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of additional fees.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 28, 29

4. □ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 28, 29

Remark on Protest

□ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

□ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

□ No protest accompanied the payment of additional search fees.
**INTERNATIONAL SEARCH REPORT**

**Information on patent family members**

**International application No**

PCT/GB2015/051194

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