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Review article

Lavender and sleep: A systematic review of the evidence

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Abstract

Introduction and aim: Poor quality sleep affects a large proportion of the UK population. Surveys of health-seeking behaviour suggest a preference for self-care remedies while essential oil aroma inhalation is a popular aromatherapy application. Anecdotally, lavender oil has sedative or sleep enhancing properties and is believed to cause few side effects. The aim of this review was to systematically search the literature and examine the evidence on lavender (*Lavandula* sp.) aroma inhalation (as a possible self-care intervention) to improve sleep architecture (initiation, maintenance and quality).

Methods: Major medical databases including AMED, BNI, Cochrane CENTRAL, EMBASE, MEDLINE, PsycINFO and PubMed, specialist complementary and alternative medicine databases and trials registers were searched systematically up to April 2012. All controlled human trials in which lavender oil aroma inhalation was used as single intervention were retrieved. Only those published in English were appraised in detail. *Results:* No previous systematic review focusing on lavender in sleep was identified. Eight eligible studies were found of which 4 were randomised controlled trials, 1 was counterbalanced and 3 were non-randomised controlled trials. Most studies had small samples and methodological limitations. Results suggested lavender oil may be of small to moderate benefit.

Discussion/conclusion: Early results appear promising but they should be viewed with caution. More scientifically rigorous and adequately powered trials are needed to investigate the true effect of lavender oil aroma inhalation on sleep. Due to the clinical significance of waking function as influenced by sleep, the use of wake outcome measures should also be considered.

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Keywords: Lavandula; Lavender; Aroma; Essential oil; Sleep initiation and maintenance disorders; Insomnia

Introduction

Poor quality sleep and its management

Inadequate sleep has been shown to affect mood, neurocognitive function, performance and homeostasis [1–5]. Even moderate deficit can produce similar effects to total sleep deprivation on life and health quality [5,6]. It is estimated that poor sleep architecture (in the form of non-clinical insomnia, problems with initiation, maintenance or early awakening) affects one third of the population in the UK [7,8]. Therefore it seems likely that many health practitioners will encounter such patients [9].

Sleep hygiene (including behavioural modification and environmental change) offers one treatment strategy but evidence has yet to demonstrate its efficacy [10]. Behavioural approaches with variable efficacy include cognitive based therapies [11]. Primary care prescription of these approaches appears limited in part due to lack of availability [9,11].

Conventional treatments include drugs to induce or prolong sleep [12]. However, quality of sleep may remain poor and side-effects such as dependence and increased drug tolerance may occur [12–16]. Dependence may be psychological in that the patient is reluctant to discontinue medication while withdrawal effects though often of short duration, may be prolonged in some cases [12]. Some of the problems, such as carry over effects, were related to the long-acting benzodiazepines such as diazepam (Valium[®]) and nitrazepam (Mogadon[®]). These have been alleviated to some extent by the introduction of shorter acting benzodiazepines (e.g. temazepam) and the 'Z' drugs (zopiclone, zolpidem, and zaleplon) but it is still unclear whether improvement in insomnia continues after drug therapy has been discontinued [12]. Consequently, treatment preferences appear to tend towards non-pharmacological interventions

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[17]. Research into alternative, safe and non-pharmacological interventions with minimal side-effects is therefore relevant particularly in the context of burgeoning use of over-the-counter (OTC) sleep remedies [18].

Lavender and aromatherapy

Aromatherapy is one of the more popular complementary and alternative medicine (CAM) modalities in the UK [19]. Fragrance aromatherapy involves the inhalation of pure essential oil derived from plants, whereas aromatherapy massage may also involve cutaneous absorption [20]. Administration methods for the aroma include vaporisation via an oil burner or hot water and the application of small quantities of the oil to clothing or pillows [21].

Over 200 species of Lavender (*Lavandula*) are reported to exist [22]. Lavender oil is created by steam-distillation of the flowering heads [13]. Key active components are linalyl acetate and linalool which occur in varying amounts depending on species [22]. *Lavandula angustifolia* is the most commonly used lavender oil in practice [13]. Many historical and herbal medicine texts make references to its analgesic and, sedative properties [23,24].

The true mode of action of fragrance aromatherapy remains unknown. Reported effects may be due to an amygdala response initiated by psychological associations to an aroma or due to an actual physiological change via absorption of pharmacologically active components [25]. Results from several animal model studies indicate a possible sedative effect validated by the almost certain absence of psychological effect [26–29]. A sedative effect appears, at least in part, due to one of the major constituents of lavender oil, linalool, a monoterpene [29]. Lavender oil has been reported to act on gamma aminobutyric acid (GABA) pathways, inhibiting binding at the GABA A receptor channel with reversible inhibition of GABA-induced currents and an overall depressant effect on neurotransmission [30].

Rationale for this study

In summary, many people suffer from transiently poor sleep, a step away from insomnia (clinically defined as poor sleep in excess of one month) [31]. Repercussions include poor productivity and increased utilisation of primary health-care services [32]. Health-seeking behaviour trends indicate a preference for self care remedies [33]. Essential oils are believed to be safe with few known side-effects [34]. A previous systematic review of complementary medicine and insomnia addressed a range of therapies [35]. Because of the broad scope of the review, the searches were limited to four major databases, and trials were required to have a sample size of at least 30 and a Jadad score over 5. Consequently, only one trial of lavender was located and no trials met the inclusion criteria.

Increased use of OTC products, anecdotal evidence supporting lavender oil inhalation for sleep and the absence of any systematic reviews focused on lavender in sleep problems indicated that this review was timely. The aim of this review was to systematically search the literature and examine the evidence on lavender (*Lavandula* sp.) aroma inhalation (as a possible self-care intervention) to improve sleep architecture (initiation, maintenance and quality).

Methods

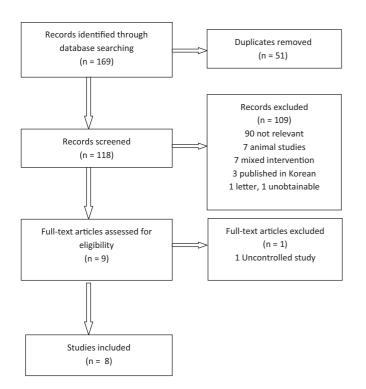
Scope

Studies were only included if lavender oil was administered by inhalation rather than ingested, or applied topically. All lavender species and methods of aroma inhalation delivery were included. Studies were excluded where combined interventions such as lavender oil massage or adjunct treatments such as acupuncture were used. Animal studies were excluded due to issues regarding the generalisability of results to human models particularly with regards to administration and dosage [36,37]. Controlled trials were taken to mean any design where a control was included for comparison [38]. Uncontrolled studies were excluded in a best evidence approach [38]. Studies of the effects of lavender on all aspects of sleep and sleep outcomes were included. Resource limitations mediated the identification but not full translation and appraisal of studies published in languages other than English.

Search strategy and selection of studies

A comprehensive search for clinical studies was performed initially between October 2010 and May 2011 by one reviewer (KF). The following electronic databases were searched from inception: The Allied and Complementary Medicine Database (AMED), Cochrane CENTRAL, EMBASE, PsycINFO and PubMed. For all databases except PubMed a search strategy using the textwords (lavender OR lavandula) and (sleep OR insomnia) was used. For PubMed the search strategy included the following MeSH terms: Lavandula [MesH] OR lavender oil [supplementary concept] AND Sleep [MesH] OR Sleep initiation and maintenance disorders [MesH]. Additional strategies included keyword searching using Google Scholar and citation searching. Terms used were lavender, Lavandula, and sleep. The search was repeated and extended by the second reviewer (KP) in April 2012. The additional sources searched included: British Nursing Index, MEDLINE, trials databases (Current Controlled Trials and clinicaltrials.gov), specialist resources (HerbMed, Natural Medicines Database, Memorial Sloan-Kettering Cancer Center "About Herbs" database and MD Anderson Cancer Center's Complementary/Integrative Medicine Education Resources (CIMER)).

Titles and abstracts were reviewed to identify relevant studies, which were retrieved if eligible or if eligibility remained unclear. Each set of search results was screened by one of two reviewers working independently. Trial designs were classified according to the Centre for Research and Dissemination (CRD) definitions [39].



Process for the selection of studies

Fig. 1. Process for the selection of studies.

Data extraction and appraisal

The absence of a formal framework for non-randomised studies mediated the development of a bespoke tool for systematic data extraction. This was devised using key criteria from Greenhalgh's framework for evaluating randomised controlled trials (RCTs) and Marshall's structure for systematically critiquing research papers [37,40]. The following data were extracted: aim, trial design, sample population (number, characteristics and recruitment methods), Lavender oil intervention/method of application, control intervention(s), outcome measures, data collection methods and results.

Eligible studies were then evaluated for quality and validity, focusing on sample size, patient allocation and blinding, and confounding factors [41]. Data extraction and appraisal was carried out by one reviewer (KF) and checked by the second (KP).

Results

No systematic reviews investigating lavender oil aroma inhalation for sleep were found. One systematic review investigating the evidence base for aromatherapy in general and another reviewing aromatherapy for dementia were found but no eligible studies were identified from these [20,42]. A total of 169 citations were screened for relevant trials. The selection process is shown in Fig. 1. The excluded studies were: animal studies [26–29,43–45], studies using mixed interventions (aromatherapy massage [15,46,47], lavender oil added to a bath [48–50], lavender used with another oil [51]), an uncontrolled study [52] studies not published in English [53–55], a letter [14] and a citation with no further details available [56].

A total of eight eligible controlled studies were found [16,57–63]. Four were randomised controlled trials, 1 was counterbalanced and 3 were non-randomised controlled trials. An overview of the characteristics of the studies is presented in Table 1.

Overview of eligible studies

Three broad categories of studies were identified; three trials were conducted under strict controlled laboratory conditions, one under partially controlled conditions and four in a clinical environment.

Studies conducted under controlled laboratory conditions

Samples

Three studies examined healthy populations screened for sleep pathology, medications and lack of a sense of smell [58–60]. Two populations were sampled from college campuses (mean age of 19–20 years old) [58,59]. Arzi et al. [60] provided no recruitment details but the mean age of participants was 28 years. All were small trials (N=20–45).

Intervention

Trials were conducted in laboratory conditions where the sleep environment was strictly controlled. Two studies used specialised odour delivery equipment [58,60]. The intervention administration was supervised by a researcher in the other [59]. Controls were; water, no aroma or alternative aromas. Considerable diversity was found amongst the other intervention variables.

Outcomes and results

All three studies used objective outcomes to measure sleep quality. Goel et al. [59] and Arzi et al. [60] recorded polysomnographic sleep (PSG), coded according to the Rechtschaffen and Kales' criteria, until recently considered the gold standard for sleep scoring [64]. Inter-rater reliability was high. Both studies reported some positive objective outcomes favouring lavender oil: increased deep sleep and a trend towards reduced wake frequency respectively. Raudenbush et al. [58] measured sleep actigraphy including sleep efficiency, movement, total sleep time and sleep latency. In this study, no significant beneficial effects were observed for lavender oil.

Two studies used the Profile of Mood States (POMS) questionnaire to measure self-reported subjective sleep quality. POMS scores revealed reduced vigour in one study [58] and statistically significant increase in vigour upon waking in the other study [59]. No adverse reactions were reported.

Table 1 Lavender and sleep: study characteristics and quality appraisal.

Study	Study design	Sample	Intervention	Control/comparison	Sleep outcome measures	Results	Quality appraisal
Hudson [63] UK	Quasi- experimental (non-randomised, non-concurrent control group) Single aroma	<i>N</i> =31 Elderly hospital patients admitted for acute medical reasons (many with dementia)	Treatment; 1 drop of LO on the participant's pillow at night repeated for 1 week Brand/species reported <i>Study</i> <i>environment</i> : hospital ward	Control: usual care for 1 week (patients admitted subsequently with similar diagnoses)	Subjective: Assessment of % nights recorded by nurses as good sleep and % days as good days	Higher % of nights assessed as good sleep with LO than no LO (72% vs 64%). Good days (79% vs 26%). No significance testing	No randomisation or blinding reported Attrition unknown. No inter-rater reliability tests Confounding variables: medication, environment. Subsequent pre-post study in 9 long-term patients also reported positive results but some inconsistencies in results
Borromeo [57] USA	Randomised, cross over trial Pseudo randomised sampling Single aroma	N=25 Patients admitted to CCU of a large tertiary hospital. <i>Excluded:</i> chronic sleep problems, day time sleepers	Treatment; 1 drop LO to cotton ball on participants pillow case for 1 night Brand/species reported Study environment: CCU	Control; distilled water (same protocol) Washout period = 15 h	Subjective; RCSQ (depth, latency/onset, awakenings, time asleep, sleep quality each assessed on 0–100 VAS scale) daily at 6 am	No significant difference in mean RCSQ scores (<i>p</i> < 0.25)	Randomised treatment order No blinding reported Attrition reported Underpowered Confounding variables: medication, environment
Raudenbush et al. [58] USA	Randomised three armed cross over trial Multiple aroma study	N=20 College students (10 male, 10 female). Mean age 19.8 years <i>Excluded</i> sleep pathologies, abnormal sleep patterns	Treatment 1; 15 ml of LO diffused via a variable oxygen concentrator Total of 3 nights Brand reported <i>Study</i> <i>environment:</i> controlled experimental sleep room	Treatment 2; 15 ml jasmine oil (same protocol) Control; no odour (same protocol) Washout = 2–7 days)	<i>Objective</i> : Sleep monitor device to assess sleep latency/onset, efficiency, movements, total sleep time, DSST (cognition) upon waking <i>Subjective</i> : POMS upon waking	No significant effects of LO except POMS score for vigour upon waking lower than control ($p < 0.05$) (sleep, DSST and anxiety improved with jasmine)	Randomisation: no details Assessor blinding: self-assessed Attrition unknown

Table 1 (Continued)

Study	Study design	Sample	Intervention	Control/comparison	Sleep outcome measures	Results	Quality appraisal
Goel et al. [59]	Controlled cross over trial with	N=31	Treatment; LO inhaled from vial	First night adaptation session	<i>Objective</i> : Polysomnographic	Small but significant	Randomisation unclear but
USA	counterbalancing	Healthy sleepers recruited via	intermittently between 23.10 and	Control; distilled	sleep recording using R&K to	increase in slow wave (deep) sleep	counterbalanced Blinding; sleep
	Single aroma	college campus and local advert	23.40. Total of 3 nights.	water (same protocol)	score sleep Subjective: SSS	with LO (<i>p</i> < 0.005),	scorers blinded Good inter-rater
		(16 male, 15 female). Mean age 20.5 years.	Brand reported	Washout = 23 h	(scale 1 = wide awake, 7 = sleep onset	POMS vigour higher with LO at $0800 \ (p < 0.05)$	reliability Attrition unknow
		<i>Excluded</i> : extreme morningness or eveningness	Study environment: experimental sleep room		soon) at 2350 & 0800 POMS at 2300, 2312, 2342, 0800	SSS changes not significant	
Lewith et al. [16]	Pilot randomised crossover trial	N=10	Treatment; 6–8 drops LO diffused	Placebo; almond oil (same	Subjective: PSQI baseline and post	Trend towards improvement in	Randomisation; computerised
117	C' 1	Individuals with	via vaporiser	protocol)	intervention	PSQI with LO	Blinding; data
UK	Single aroma	PSQI global score > 5 recruited via university campus and	overnight (for 1 week) Brand/species	Washout = 1 week	(questions on duration, disturbance, latency/onset, day	(reduction of 2.5, p = 0.07), no significant change in control	analysts Attrition reported Baseline characteristics
		adverts (5 male, 5 female). Mean	reported		dysfunction,	B&N confirmed	comparable
		age: 37.4 years and 40.4 years	Study environment:		efficiency, quality, medication, total score $0-21, > 5$	equipose	Confounding variables: compliance
		<i>Excluded</i> : sleep pathology	participants home		poor sleep, 3 clinically significant	HCAMQ; no relationship to outcomes	unknown, environment uncontrolled,
					change) <i>Other:</i> B&N for equipoise (pre/post		treatment not standardised
					intervention) HCAMQ for beliefs		

Arzi et al. [60] Israel	Quasi- experimental parallel group design Multiple aroma	N=45(35 after exclusions) No recruitment information (24 male, 21 female). Mean age 27.8 years <i>Excluded:</i> sleep apnoea, abnormal sleep habits	Treatment 1; LO odour via nasal mask by olfactometer, 12–27 odour stimuli per night (varying length) (14) Brand reported <i>Study</i> <i>environment</i> : Sleep lab	Treatment 2; vetiver oil (10) Treatment 3; vanillin aroma (15) Treatment 4; Ammonium sulphide aroma (6)	<i>Objective</i> : PSG sleep recording, R&K to score sleep	Trend towards reduced wake frequency following LO aroma ($p < 0.083$) No other significant results for LO	Not described as randomised Blinding not reported Good inter-rater reliability Attrition not reported
Moeini et al. [61] Iran	Quasi- experimental controlled trial Simple randomised sampling Single aroma	N=64 CCU patients from two university hospitals (34% female in LO group, 41% female in control). Mean age 55.7 years (LO), 52.8 years (control)	Treatment; 2 drops of LO on cotton wool near patient's pillow from 9 pm to 6 am (3 nights) Brand reported <i>Study</i> <i>environment:</i> CCU	Control; usual care (3 nights)	Subjective: SMHSQ (latency/onset, depth, awakenings, sleep time, quality, morning clear headedness, satisfaction converted into a total score between 11 and 44, higher scores denote poorer sleep)	Improved mean SMHSQ score within LO group (mean reduction 6.15, $p < 0.001$) and significantly different from control ($p < 0.001$)	Randomisation not reported Blinding; data collectors Baseline sleep characteristics compared Attrition not reported Confounding variables: environment, medication
Chien et al. [62] Taiwan	Randomised controlled trial Single aroma	N=67 Recruited from communities in Taiwan via sleep hygiene programme (CPSQI>5, all female). Mean age 51.1 years (test group); 50.9 (control)	Treatment: 0.25 ml LO inhaled via ultrasonic aromatherapy diffuser for 20 min twice weekly for 12 weeks. Brand reported <i>Study</i> <i>environment</i> : controlled room	Control: as for treatment without aroma	Subjective: CPSQI (>5 poor sleep) Objective: heart rate variability analysis	Improved mean CPSQI score in LO group but not in the control group $(-4.90$ vs. -0.26 , p < 0.001)	Randomisation computerised Blinding not reported Baseline sleep characteristics comparable Attrition reported Confounding variables: timing of intervention

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Key: B&N, Borkovec & Nau questionnaire; CPSQI, Chinese Pittsburgh Sleep Quality Index; DSST, digital-symbol substitution test; HCAMQ, Holistic Complementary and Alternative Medicine Questionnaire; LO, lavender oil; POMS, Profile of Mood States; PSQI, Pittsburgh Sleep Quality Index; RCSQ, Richards-Campbell Sleep Questionnaire; R&K, Rechtschaffen and Kales' criteria; SMHSQ, St Mary's Hospital Sleep Questionnaire; SSS, Stanford Sleepiness Scale.

Studies conducted under partially controlled conditions

Sample

The trial by Chien et al. [62] involved women aged between 45 and 55 years suffering from poor sleep who were recruited from communities in Taipei through a sleep hygiene programme. Sixty-seven women were recruited, of whom 60 completed the study.

Intervention

An ultrasonic aromatherapy diffuser into which 0.25 ml lavender oil and 50 ml of water was introduced was used to deliver the inhalation for a 20 min period. The women were sitting in a temperature-controlled, quiet but bright room and encouraged to relax. The treatment was carried out between 17:00 and 23:00 h twice weekly. The control involved a similar procedure excluding the lavender oil.

Outcomes and results

After 12 weeks of treatment, total sleep scores based on the Chinese version of the PSQI (CPSQI) significantly decreased indicating improved sleep in the treatment but not the control group. Heart rate variability was also found to reduce but this was a short-term effect.

Studies conducted in a natural environment

Samples

Three of the four studies in this group were hospital based, where morbidity and the environment affect sleep [57,61,63]. Two studies [57,61] examined coronary care unit (CCU) patients (randomly sampled) with ischaemic heart disease or unstable angina. People with chronic sleep problems were excluded from one study [57]. For Moeini et al. [61] additional exclusions were a dose in excess of 10 mg oxazepam, a benzodiazepine, (or equivalent) daily and atopy. Hudson [63] investigated 31 elderly patients, some with dementia, with no exclusions. A follow-up study involving 9 patients was also reported in the same paper but no control group was involved in this stage [63].

Lewith et al.'s trial [16] differed in that a general population sample was used and the intervention self-administered at home. A PQSI score of >5, indicating insomnia, was required on entry. All participants were healthy and hypersensitivity free.

Intervention

Lavender oil (1–2 drops) was applied to the participant's pillow between 1 and 7 consecutive nights in the hospital studies, with a control of usual care or water. In Lewith et al.'s study, lavender oil or an almond oil placebo was self-administered for 7 nights using an aroma diffuser [16]. Where specified, the species used was *L. angustifolia* [16,57,63].

Outcomes and results

Three studies used well validated subjective questionnaires to measure quality of sleep; PQSI [16], Richards-Campbell Sleep Questionnaire (RCSQ) [57], St Mary's Hospital Sleep Questionnaire (SMHSQ) [61]. In Hudson's study [63] nurses completed subjective sleep observations. Three studies reported a positive trend favouring lavender oil, with the largest (n = 64) [61] reporting statistically significant improvements in mean sleep scores.

Evaluation of methodological quality

Sample size and trial design

Initial results appear positive towards lavender oil aroma inhalation for improving sleep in six of the eight studies. However, samples were small potentially impacting on the validity of results (n = 10-67). A cross-over design was used in four studies [16,57–59], in which participants received both, or all, interventions therefore providing their own control [39]. The three largest trials [60–62] used a parallel design and Hudson's study [63] used a control group recruited a week later. Interventions with temporary effects and short-term outcomes suit crossover trials providing appropriate washout periods are adhered to, to counter carry-over effect [39,65,66]. Washouts appeared adequate in all trials reporting favourable outcomes except for one in which several odours were applied during one night [60]. Lewith et al.'s study [16] was a pilot, therefore no power calculation was done. No studies reported adverse reactions.

Randomisation

A quasi-experimental trial design was used in the two largest trials [60,61]. Use of non-randomised methods for participant allocation may challenge the validity of significant outcomes due to undetermined confounding factors [39,67,68,69]. However, comparability at baseline can counterbalance the impact of selection bias [36]. Moeini et al. [61] confirmed similarity of the groups at baseline improving validity. Random allocation in cross-over trials occurs with treatment sequence rather than intervention group [70]. This was achieved in all the cross-over studies except one which used the related technique of counterbalancing [59]. Therefore, allocation bias was not deemed a major threat to validity in these studies.

Blinding

Blinding represents an additional strategy to moderate systematic bias [71]. Raudenbush et al. [58] and Goel et al. [59] reported that participants were not told odours were being presented. However, in Goel's study participants held the vial so would have been aware of an odour, while participants waking during Raudenbush's trial would also have been aware of an aroma. Although inadequate blinding may influence participants' reporting, objective outcomes are less at risk of distortion [72,73]. Objective sleep quality outcomes were contradictory with Raudenbush et al. [58] reporting no significant effect. Goel et al. [59] reported a small but significant increase in deep sleep (stages 3 and 4), validated by sleep recorder blinding and interrater reliability of 95.2%. As participant blinding presents a challenge in aroma trials, alternative blinding strategies take on a greater significance [74,75]. Three trials employed assessor or data collector blinding [16,59,61]. However, in Moeini et al.'s study [61] lavender oil aroma may have been detectable to assessors due to the uncontrolled study environment. In the remaining trials blinding was either not attempted or not reported

[57,62,63]. As the outcomes favouring lavender oil were subjective, lack of blinding may have been a significant threat to validity.

Controls

All trials employed a placebo or control to ascertain intervention effectiveness. However, finding a credible placebo or control for an intervention such as a familiar aroma with well known purported benefits is challenging for trial design [76,77]. Standard care, water or no intervention clearly indicates the active intervention to participants. Lewith et al.'s study [16] was the only study to attempt to mitigate this using the validated Borkovec and Nau Questionnaire [78] to test for equipoise between almond oil (placebo) and lavender oil pre and post intervention. As no other strategies were employed by trials it is not possible to gauge the impact that placebo credibility (or lack of) may have had on outcomes. For the trials investigating multiple aromas this may have been less of an issue [58,60]. However, aroma comparability is not known [25].

Discussion

Randomised and non-randomised controlled trials investigating the effect of lavender oil aroma inhalation on a variety of sleep outcomes were the subject of this review. The methodological quality of the eligible studies varied considerably. Blinding in particular was employed with varying effectiveness. Nevertheless, reporting of a small to moderate benefit favouring lavender oil across a cross-section of study populations was found. Of the two studies which found no difference between lavender oil and control, one was reported to have been underpowered. In terms of specific effects on sleep initiation, maintenance and quality, the results reported in the included studies do not provide sufficient detail to assess these individually. Several studies used outcome measures which included these aspects but reported mean composite scores. Analysis of PSG recordings in two studies suggested an increase in deep sleep and reduced wakenings due to lavender but both studies were short-term studies based in sleep laboratories.

The apparently low reporting of adverse reactions could imply tolerability and safety. However, most studies failed to provide attrition details which may have masked these and the studies only involved small numbers of participants. Further well designed trials are needed to establish the true causal implication of observed effects and document adverse reactions. Gaps in current knowledge identified appear to be the suitability of outcome tools to measure quality of sleep, lavender oil aroma inhalation's mode of action and a rationale for intervention standardisation (in terms administration method, quantity and duration of exposure).

Scientifically rigorous trials are a relatively new phenomenon in aromatherapy research partially due to funding and recruitment challenges [79–81]. Most studies found were underpowered and few were true RCTs. The use of a cross-over design appeared a useful strategy to increase validity and limit regression to the mean. Encouragingly, the trial with the most robust study design [16] registered results in favour of lavender oil inhalation, suggesting potential as an early intervention strategy for those with poor quality sleep, and lending credence to the results of others. However, this study was a pilot and the authors were cautious about the significance of results.

Animal model studies indicate lavender oil may have a sedative effect as post inhalation key constituents linalool and linalyl acetate have been found in blood plasma [27,28,43]. Comparable doses would be unsuitable in human studies [22]. Dosage standardisation and rationale regarding dosage was largely absent in the studies reviewed therefore preventing analysis. If lavender oil aroma acts as a mild hypnotic, current evidence does little to clarify its mode of action.

Conversely, associations with lavender oil's aroma may trigger a cerebral response via the amygdala, highlighting the need to quantify expectancy on outcomes [20,25]. The use of the Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) to record participants' health beliefs pre-intervention was a relevant strategy to separate expectancy and treatment effect [16,82]. However, the HCAMQ could benefit from improved construct validity [82–84]. Placebo credibility is also vital to attenuate expectancy [25,80]. The Borkovec & Nau (B&N) questionnaire [78] used by Lewith et al. [16] has been used in number of CAM trials and can establish equipoise [85–87].

Subjective (self-reported questionnaires) and objective (PSG sleep recording or actigraphy) outcomes were used to examine sleep quality. Disparity between the two, even within the same trial, prevented comparison. In aroma trials, subjective outcomes may produce overly optimistic results [25]. Most were positive in the trials found. Nevertheless, subjective outcomes remain clinically relevant due to their resemblance to methods used in primary care for sleep investigation and the subjective nature of sleep quality [88,89].

PSG recording is generally considered the gold standard for efficacy research investigating sleep and minimises the effect expectancy [90]. However, its sensitivity and suitability remain questionable due to the additional burden placed on participants which may obstruct sleep and there is little consensus on nights needed for normal sleep to occur [88,91]. Few positive objective outcomes were reported in the trials found.

Reduction of daytime functioning is a significant consequence of poor sleep [88,92]. Raudenbush et al.'s study [58] was the only study to use actigraphy to measure the sleep wake continuum. With greater validity it could provide a relevant outcome for future research when combined with subjective measures [88,91].

Implications for practice

Studies found fell into two broad categories each of which differ in purpose and clinical relevance [93]. In the several trials, stringent sampling criteria recruited primarily healthy sleepers, treatment durations tended to be short (over-night) and strict experimental conditions increased internal validity but reduced generalisability [58–60]. Conversely, in the remaining trials the relatively uncontrolled experimental conditions increased external validity but influenced treatment outcomes [16,57,61–63].

Lewith et al. were the only group to investigate lavender oil aroma inhalation as a self care intervention to aid sleep but unfortunately the aroma device noise affected compliance [16]. Other pragmatic trials saw the lavender oil being administered on or near participants' pillows; a technique potentially suitable for self-care that requires further exploration [57,61,63].

Health-seeking behaviour of individuals with sub-clinical insomnia indicates a proclivity for self-help strategies before seeking professional medical advice [33]. Preferences for nonpharmacological interventions indicate that lavender oil may have greater acceptability [9]. With evidence of only a moderate benefit for lavender oil inhalation the potential of adverse reactions should dictate suitability of use [79]. A cursory literature search indicated these may be rare. Two accounts of headaches and dizziness were found. One resolved upon cessation and the other concerned a participant with a migraine history [94,95]. One case of airborne contact dermatitis was reported, possibly due to long-term use of an aroma oil burner [96]. These relatively few findings appear consistent with low reporting of adverse reactions. However, underpowered studies and attrition bias may be a cause [79]. The safety of long-term use of lavender oil aroma inhalation is unknown, particularly with regards to toxicity or sensitisation [97]. The assessment by the Natural Medicines Comprehensive Database of lavender oil when inhaled as part of aromatherapy is that it is 'possibly safe' indicating that there is some evidence showing its safety but the evidence is limited [98].

For the most part, use of lavender oil aroma inhalation appears to be self-prescribed [99,100]. With regards to safety, the variable quality and composition of lavender oil is a concern [101,102]. In the studies evaluated, the quality is likely to have varied between different countries. Furthermore, the composition of different species can also vary [22]. Further research could benefit from standardisation. Standards for lavender oil have been published, the specification being based on various constituents, of which linalool (range 25–38%) and linalyl acetate (25–45%) are the most significant [103]. Health consumers should be advised to purchase the best quality oil available or seek the advice of a qualified aromatherapist.

Limitations of this study

The framework used for data collection and appraisal was developed for this study. It has not been validated elsewhere but provided detail that a simple scoring system such as the Jadad score may have ignored [104,105]. Data extraction was conducted by one researcher and checked by a second rather than two researchers working independently. Meta-analysis was not possible, due to the variable study designs and outcomes; therefore it was not possible to draw definitive recommendations based on pooled data. Systematic searching also identified a cohort of studies published in languages other than English. Resource constraints prevented the translation of these studies but it appears from examination of the abstracts that two of three studies published in Korean were relatively small, uncontrolled, pre-post studies [53–55]. Furthermore, the findings of all three studies were positive and so would not contradict the findings

of this review. No further details could be found for a possible study published in Japanese in 1986 [56].

Conclusions and recommendations

The aim of this review was to examine the evidence for lavender oil aroma inhalation as a possible self care intervention to promote sleep. Systematic searching of the literature identified relevant studies which were subsequently evaluated for quality. Findings were suggestive of a small benefit for lavender oil compared to control. However, methodological inadequacies, small sample sizes, short duration, and challenges related to blinding, mean that results should be viewed with caution. Variability of administration methods and sleep outcome measures, lack of information regarding dose rationale, and variation between efficacy and effectiveness trials also impede comparison. As a result no definitive conclusions can be made regarding the efficacy of lavender oil aroma for sleep.

Nevertheless, this review identified key issues for research such as the largely unresolved issue of participant blinding, effect of expectancy bias and suitability of sleep outcomes measures. Encouragingly, one of the trials explicitly attempted to quantify placebo credibility and expectancy bias to increase validity providing potential strategies for future research [16]. As lavender oil inhalation appears to be primarily self-prescribed, the documentation and reporting of serious adverse reactions is of paramount importance [106]. In view of these findings larger, more scientifically rigorous trials may be warranted. Exclusion of participants with plant sensitivities, allergies and atopy in many trials suggests reasonable contraindications to use. Future studies may benefit from further exploration of methods for selfadministration. In addition simultaneous use of objective and subjective sleep outcomes with the inclusion of daytime function may provide more clinically useful outcomes.

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Conflict of interest

Neither author has a conflict of interest with the contents of this paper.

References

- Pilcher JJ, Walters AS. How sleep deprivation affects psychological variables related to college students' cognitive performance. Journal of American College Health 1997;46:121–6.
- [2] Heuer H, Spijkers W, Kiesswetter E, Schmidtke V. Effects of sleep loss, time of day, and extended mental work on implicit and explicit learning of sequences. Journal of Experimental Psychology: Applied 1998;4:139–62.
- [3] Harrison Y, Horne JA. One night of sleep loss impairs innovative thinking and flexible decision making. Organizational Behavior and Human Decision Processes 1999;78:128–45.
- [4] Van Dongen HP, Maislin G, Mullington JM, Dinges DF. The cumulative cost of additional wakefulness: dose–response effects on neurobehavioral

functions and sleep physiology from chronic sleep restriction and total sleep deprivation. Sleep 2003;26:117–26.

- [5] Durmer JS, Dinges DF. Neurocognitive consequences of sleep deprivation. Seminars in Neurology 2005;25:117–29.
- [6] Reynolds CF, Serody L, Okun ML, Hall M, Houck PR, Patrick S, et al. Protecting sleep, promoting health in later life: a randomized clinical trial. Psychosomatic Medicine 2010;72:178–86.
- [7] Lack LC, Thorn SJ. Sleep disorders: their prevalence and behavioral treatment. In: Byrne DG, Caddy GR, editors. Behavioral medicine: international perspectives, vol. 2. New Jersey: Alex Publishing; 1991.
- [8] Sharpley AL, Attenburrow MEJ, Cowen PJ. Assessment and treatment of insomnia (including a case control study of patients with primary insomnia). International Journal of Psychiatry in Clinical Practice 1997;1:107–17.
- [9] Edinger JD, Sampson WS. A primary care "friendly" cognitive behavioral insomnia therapy. Sleep 2003;26:177–82.
- [10] Stepanski EJ, Wyatt JK. Use of sleep hygiene in the treatment of insomnia. Sleep Medicine Reviews 2003;7:215–25.
- [11] Chesson AL, Anderson WM, Littner M, Davila D, Hartse K, Johnson S, et al. Practice parameters for the nonpharmacologic treatment of chronic insomnia. An American academy of sleep medicine report. Standards of practice committee of the American academy of sleep medicine. Sleep 1999;22:1128–33.
- [12] Wilson SJ, Nutt DJ, Alford C, Argyropoulos SV, Baldwin DS, Bateson AN, et al. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders. Journal of Psychopharmacology 2010;24(11):1577–601.
- [13] Wheatley D. Medicinal plants for insomnia; a review of their pharmacology, efficacy and tolerability. Journal of Psychopharmacology 2005;19:414–21.
- [14] Hardy M, Kirk-Smith MD, Stretch DD. Replacement of drug treatment for insomnia by ambient odour. Lancet 1995;346:701.
- [15] Cannard G. Complementary therapies: on the scent of a good night's sleep. Nursing Standard 1995;9:21.
- [16] Lewith GT, Godfrey AD, Prescott P. A single-blinded, randomized pilot study evaluating the aroma of *Lavandula augustifolia* (*sic*) as a treatment for mild insomnia. Journal of Alternative and Complementary Medicine 2005:11:631–7.
- [17] Vincent N, Lionberg C. Treatment preference and patient satisfaction in chronic insomnia. Sleep 2001;24:411–7.
- [18] Gyllenhaal C, Merritt SL, Peterson SD, Block KI, Gochenour T. Efficacy and safety of herbal stimulants and sedatives in sleep disorders. Sleep Medicine Reviews 2000;4:229–51.
- [19] Hunt KJ, Coelho HF, Wider B, Hung SK, Terry R, Ernst E. Complementary and alternative medicine use in England: results from a national survey. International Journal of Clinical Practice 2010;64:1496– 502.
- [20] Holt FE, Birks TPH, Thorgrimsen LM, Spector AE, Wiles A, Orrell M. Aroma therapy for dementia. Cochrane Database of Systematic Reviews 2003;(3), <u>http://dx.doi.org/10.1002/14651858.CD003150</u>. Art. No. CD003150.
- [21] Price S, Price L. Aromatherapy for health professionals. London: Churchill Livingstone; 1995.
- [22] Cavanagh HM, Wilkinson JM. Biological activities of Lavender essential oil. Phytotherapy Research 2002;16:301–8.
- [23] Moss M, Cook J, Wesnes K, Duckett P. Aromas of rosemary and lavender essential oils differentially affect cognition and mood in healthy adults. International Journal of Neuroscience 2003;113:15–38.
- [24] Holmes C, Ballard C. Aromatherapy in dementia. Advances in Psychiatric Treat 2004;10:296–300.
- [25] Howard S, Hughes BM. Expectancies, not aroma, explain impact of lavender aromatherapy on psychophysiological indices of relaxation in young healthy women. British Journal of Health Psychology 2008;13:603–17.
- [26] Guillemain J, Rousseau A, Delaveau P. Neurodepressive effects of the essential oil of *Lavandula angustifolia* Mill. Annales Pharmaceutiques Francaises 1989;47:337–43.

- [27] Buchbauer G, Jirovetetz L, Jager W, Dietrich H, Plank C. Aromatherapy: evidence for sedative effects of the essential oil of lavender after inhalation. Zeitschrift für Naturforschung 1991;46:1067–72.
- [28] Lim WC, Seo JM, Lee CI, Pyo HB, Lee BC. Stimulative and sedative effects of essential oils upon inhalation in mice. Archives of Pharmacal Research 2005;28:770–4.
- [29] Linck VM, da Silva AL, Figueiró M, Piato AL, Herrmann AP, Dupont Birck F, et al. Inhaled linalool-induced sedation in mice. Phytomedicine 2009;16:303–7.
- [30] Huang L, Abuhamdah S, Howes MJ, Dixon CL, Elliot MS, Ballard C, et al. Pharmacological profile of essential oils derived from *Lavandula angustifolia* and *Melissa officinalis* with anti-agitation properties: focus on ligand-gated channels. Journal of Pharmacy and Pharmacology 2008;60(11):1515–22.
- [31] Walsh JK. Drugs used to treat insomnia in 2002: regulatory-based rather than evidence-based medicine. Sleep 2004;27:1441–2.
- [32] Simon GE, VonKorff M. Prevalence, burden and treatment of insomnia in primary care. American Journal of Psychiatry 1997;154:1417–23.
- [33] Morin CM, LeBlanc M, Daley M, Gregoire JP, Merett C. Epidemiology of insomnia: prevalence, self-help treatments, consultations, and determinants of help-seeking behaviour. Sleep Medicine 2006;7:123–30.
- [34] Vickers A [editorial] Why aromatherapy works (even if it doesn't) and why we need less research. British Journal of General Practice 2000;50:444–5.
- [35] Sarris J, Byrne GJ. A systematic review of insomnia and complementary medicine. Sleep Medicine Reviews 2011;15(2):99–106.
- [36] Cawthorn A. A review of the literature surrounding the research into aromatherapy. Complementary Therapies in Nursing and Midwifery 1995;1:118–20.
- [37] Greenhalgh T. How to read a paper: the basics of evidence based medicine. 4th ed. Oxford: Wiley-Blackwell Publishing; 2010.
- [38] Norris SL, Atkins D. Challenges in using nonrandomized studies in systematic reviews of treatment interventions. Annals of Internal Medicine 2005;142:1112–9.
- [39] Centre for Reviews and Dissemination. Systematic reviews: CRD's guidance for undertaking reviews in health care. York: University of York; 2008. Available from: http://www.york.ac.uk/inst/crd/systematic-reviews_book.htm [accessed 04.05.11].
- [40] Marshall G. Critiquing a research article. Radiography 2005;11:55-9.
- [41] White A, Schmidt K. Systematic literature reviews. Complementary Therapies in Medicine 2005;13:54–60.
- [42] Cooke B, Ernst E. Aromatherapy: a systematic review. British Journal of General Practice 2000;50:493–6.
- [43] Bradley BF, Starkey NJ, Brown SL, Lea RW. Anxiolytic effects of *Lavan-dula angustifolia* odour on the Mongolian gerbil elevated plus maze. Journal of Ethnopharmacology 2007;111:517–25.
- [44] Gilani AH, Aziz N, Khan MA, Shaheen F, Jabeen Q, Siddiqui BS, et al. Ethnopharmacological evaluation of the anticonvulsant, sedative and antispasmodic activities of *Lavandula stoechas* L. Journal of Ethnopharmacology 2000;71:161–7.
- [45] Kim Y, Kim M, Kim H, Kim K. Effect of lavender oil on motor function and dopamine receptor expression in the olfactory bulb of mice. Journal of Ethnopharmacology 2009;125:31–5.
- [46] Soden K, Vincent K, Craske S, Lucas C, Ashley S. A randomized controlled trial of aromatherapy massage in a hospice setting. Palliative Medicine 2004;18:87–92.
- [47] Williams TI. Evaluating effects of aromatherapy massage on sleep in children with autism: a pilot study. Evidence-based Complementary and Alternative Medicine 2006;3:373–7.
- [48] Field T, Field T, Cullen C, Largie S, Diego M, Schanberg S, et al. Lavender bath oil reduces stress and crying and enhances sleep in very young infants. Early Human Development 2008;84:399–401.
- [49] Ikue K, Yumiko S, Miwa O, Chizuri O. The influence of using aromatherapy on sleep in patients in HCU. The results of practicing aroma bathing with lavender oil. Medical Journal of Hiroshima Prefectural Hospital 1999;31:161–6.
- [50] Moriya K. The effect of foot bathing with lavender oil on the nocturnal sleep. Aroma Research 2000;1:62–9.

- [51] Lee SH. Effects of aroma inhalation on fatigue and sleep quality of postpartum mothers. Korean Journal of Women's Health Nursing 2004;10:235–43.
- [52] Daoud WA, Ngan M, Cheuk K. Biodegradable poly(L-lactic acid)lavender nanocapsules: synthesis, controlled release, and application in remedy of sleep disorder. Journal of Nanoscience and Nanotechnology 2010;10:1255–60.
- [53] Lee YJ, Park MJ, Kim EJ, Kim SM. The effect of lavender fragrance on sleep of institutionalized elderly. Journal of the Korean Gerontological Society 2002;3:159–72 [in Korean].
- [54] Lee KH, Park KM, Ryu MK. The effects of aromatherapy with lavender essential oil on sleep disturbance and depression of middle aged women. Journal of the Korean Society of Maternal and Child Health 2002;6:23–37 [in Korean].
- [55] Lee IS, Lee GJ. Effects of lavender aromatherapy on insomnia and depression in women college students. Taehan Kanho Hakhoe 2006;36:136–43 [in Korean].
- [56] Azumi T. Sleepy effect of bedding with perfume. Fragrance Journal 1986;8:191–5 [in Japanese].
- [57] Borromeo AR. The effect of aromatherapy on patient outcomes of anxiety and sleep quality in coronary care units. PhD dissertation. Texas: Texas Woman's University; 1998.
- [58] Raudenbush B, Koon J, Smith J, Zoladz P. Effects of odorant administration on objective and subjective measures of sleep quality, post-sleep mood and alertness, and cognitive performance. North American Journal of Psychology 2003;5:181–92.
- [59] Goel N, Kim H, Lao RP. An olfactory stimulus modifies nighttime sleep in young men and women. Chronobiology International 2005;22:889–904.
- [60] Arzi A, Sela L, Green A, Givaty G, Dagan Y, Sobel N. The influence of odorants on respiratory patterns in sleep. Chemical Senses 2010;35:31–40.
- [61] Moeini M, Khadibi M, Bekhradi R, Mahmoudian SA, Nazari F. Effect of aromatherapy on quality of the sleep in ischemic heart disease patients hospitalized in intensive care units of heart hospitals of Isfahan University of Medicinal Sciences. Iranian Journal of Nursing and Midwifery Research 2010;15:234–9.
- [62] Chien LW, Cheng SL, Liu CF. The effect of lavender aromatherapy on autonomic nervous system in midlife women with insomnia. Evidencebased Complementary and Alternative Medicine 2012;2012:740813.
- [63] Hudson R. The value of lavender for rest and activity in the elderly patient. Complementary Therapies in Medicine 1996;4:52–7.
- [64] Moser D, Anderer P, Gruber G, Parapatics S, Loretz E, Boeck M, et al. Sleep classification according to AASM and Rechtschaffen & Kales: effects on sleep scoring parameters. Sleep 2009;32(2):139–49.
- [65] Elbourne DR, Altman DG, Higgins JP, Curtin F, Worthington HV, Vail A. Meta-analysis involving cross-over trials: methodological issues. International Journal of Epidemiology 2002;31:140–9.
- [66] Ernst E. Understanding research in complementary and alternative medicine. Cambridge: EMS Publishing (formerly Holistic Therapy Books); 2007.
- [67] Torgerson DJ, Torgerson CJ. Avoiding bias in randomised controlled trials in educational research. British Journal of Educational Studies 2003;51:36–45.
- [68] Stolberg HO, Norman G, Trop I. Fundamentals of clinical research for radiologists: randomized controlled trials. American Journal of Roentgenology 2004;183:1539–44.
- [69] Deeks JJ, Dinnes J, D'Amico R, Sowden AJ, Sakarovitch C, Song F, et al. Evaluating non-randomised intervention studies. Health Technology Assessment 2003;7(27).
- [70] Brown BW. The crossover experiment for clinical trials. Biometrics 1980;36:69–79.
- [71] Furberg CD, Soliman EZ. Double-blindness protects scientific validity. Journal of Thrombosis and Haemostasis 2008;6:230–1.
- [72] Kjaergard LL, Villumsen J, Gluud C. Reported methodologic quality and discrepancies between large and small randomized trials in meta-analyses. Annals of Internal Medicine 2001;135:982–9.
- [73] Wood L, Egger M, Gluud LL, Schulz KF, Jüni P, Altman DG, et al. Empirical evidence of bias in treatment effect estimates in controlled

trials with different interventions and outcomes: meta-epidemiological study. British Medical Journal 2008;336:601–5.

- [74] Jüni P, Altman DG, Egger M. Systematic reviews in health care: assessing the quality of controlled clinical trials. British Medical Journal 2001;323:42–6.
- [75] Barker Bausell R. Are positive alternative medical therapy trials credible? Evaluation and the Health Professions 2009;32:349–69.
- [76] Freudenheim JL. Study design and hypothesis testing: issues in the evaluation of evidence from research in nutritional epidemiology. American Journal of Clinical Nutrition 1999;69:1315S–21S.
- [77] Nahin RL, Straus SE. Research into complementary and alternative medicine: problems and potential. British Medical Journal 2001;322:161–4.
- [78] Borkovec TD, Nau SD. Credibility of analogue therapy rationales. Journal of Behavior Therapy and Experimental Psychiatry 1972;3(4): 257–60.
- [79] Shekelle PG, Morton SC, Suttorp MJ, Buscemi N, Friesen C. Challenges in systematic reviews of complementary and alternative medicine topics. Annals of Internal Medicine 2005;142:1042–7.
- [80] Nguyen QA, Paton C. The use of aromatherapy to treat behavioural problems in dementia. International Journal of Geriatric Psychiatry 2008;23:337–46.
- [81] Evans I, Thornton H, Chalmers I. Testing treatments: better research for better healthcare. London: Pinter & Martin; 2010.
- [82] Hyland ME, Lewith GT, Westoby C. Developing a measure of attitudes: the holistic complementary and alternative medicine questionnaire. Complementary Therapies in Medicine 2003;11:33–8.
- [83] Erci B. Attitudes towards holistic complementary and alternative medicine; a sample of healthy people in Turkey. Journal of Clinical Nursing 2007;16:761–8.
- [84] Kersten P, White PJ, Tennant A. Construct validity of the holistic complementary and alternative medicines questionnaire (HCAMQ) – an investigation using modern psychometric approaches. Evidence-based Complementary and Alternative Medicine 2011;2011:396327.
- [85] Choi PY, Tweed A. The holistic approach in acupuncture treatment: implications for clinical trials. Journal of Psychosomatic Research 1996;41:349–56.
- [86] White P, Lewith G, Hopwood V, Prescott P. The placebo needle, is it a valid and convincing placebo in use for acupuncture trials? A randomised, single-blind, cross-over pilot trial. Pain 2003;106:401–9.
- [87] Whale CA, Maclaran SJ, Whale CI, Barnet M. Pilot study to assess the credibility of acupuncture in acute exacerbations of chronic obstructive pulmonary disease. Acupuncture in Medicine 2009;27: 13–5.
- [88] Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. Journal of Clinical Sleep Medicine 2008;4:487–504.
- [89] Harvey AG, Stinson K, Whitaker KL, Moskovitz D, Virk H. The subjective meaning of sleep quality: a comparison of individuals with and without insomnia. Sleep 2008;31:383–93.
- [90] Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, Morin CM. Recommendations for a standard research assessment of insomnia. Sleep 2006;29:1155–73.
- [91] Morin CM. Measuring outcomes in randomized clinical trials of insomnia treatments. Sleep Medicine Reviews 2003;7:263–79.
- [92] Weaver TE. Outcome measurement in sleep medicine practice and research. Part 1: assessment of symptoms, subjective and objective daytime sleepiness, health-related quality of life and functional status. Sleep Medicine Reviews 2001;5:103–28.
- [93] Flay BR, Biglan A, Boruch RF, Castro FG, Gottfredson D, Kellam S, et al. Standards of evidence: criteria for efficacy, effectiveness and dissemination. Prevention Science 2005;6:151–75.
- [94] Maddocks-Jennings W. Critical incident: idiosyncratic allergic reactions to essential oils. Complementary Therapies in Nursing and Midwifery 2003;10:58–60.
- [95] Kim JT, Wajda M, Cuff G, Serota D, Schalme M, Axelrod DM, et al. Evaluation of aromatherapy in treating postoperative pain: pilot study. Pain Practice 2006;6:273–7.

- [96] Schaller M, Korting HC. Allergic airborne contact dermatitis from essential oils used in aromatherapy. Clinical and Experimental Dermatology 1995;20:143–5.
- [97] Burfield T. Safety of essential oils. International Journal of Aromatherapy 2000;10:16–29.
- [98] Natural medicines comprehensive database. Stockton, CA: Therapeutic Research Faculty; 2010, http://naturaldatabase.therapeuticresearch.com/ [accessed 21.05.12].
- [99] Vickers A, Zollman C. ABC of complementary medicine: massage therapies. British Medical Journal 1999;319:1254–7.
- [100] MacLennan AH, Wilson DH, Taylor AW. The escalating cost and prevalence of alternative medicine. Preventive Medicine 2002;35:166–73.
- [101] Lis-Balchin M. Possible health and safety problems in the use of novel plant essential oils and extracts in aromatherapy. Perspectives in Public Health 1999;119:240–3.

- [102] Bleasel N, Tate B, Rademaker M. Allergic contact dermatitis following exposure to essential oils. Australasian Journal of Dermatology 2002;43:211–3.
- [103] Lis-Balchin M. Aromatherapy science: a guide for healthcare professionals. London: Pharmaceutical Press; 2006.
- [104] Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, et al. Assessing the quality of reports of randomized clinical trials: Is blinding necessary? Controlled Clinical Trials 1996;17: 1–12.
- [105] Pilkington K, Kirkwood G, Rampes H, Richardson J. Yoga for depression: the research evidence. Journal of Affective Disorders 2005;89: 13–24.
- [106] Pilkington K, Boshnakova A. Complementary medicine and safety: a systematic investigation of design and reporting of systematic reviews. Complementary Therapies in Medicine 2012;20:73–82.