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PREFACE

Introduction

The library of the Central Council for Research in Homoeopathy has been circulating “Current Health Literature Awareness Service” (CHLAS). The main objective is to disseminate precise information/citation about scientific articles published in various journals/magazine subscribed by this Council.

Scope

This volume covers articles on AYUSH & other systems and Allied Sciences

Arrangement of Entries

The articles are indexed under the name of the authors, arranged in alphabetical order. The entries have been made in the following order:

- Author
- Title
- Name of Journal
- year of publication; Volume (issue no.): pagination
- Abstract

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(Meenakshi Bhatia)
Librarian Incharge
AYUSH & Other Systems


Abstract:

Objectives: This study aims to explore pregnant and postpartum women's understanding of the meaning of traditional and complementary medicine (T&CM) and how that may affect their T&CM use.

Methods: A cross-sectional study was conducted using self-administered questionnaires. Data collected from 374 women were analysed and represented via descriptive statistics.

Results: Out of the 374 participants, 285 (76.2%) reported using at least one type of T&CM to conceive, during pregnancy or in the postpartum period. The majority of the participants identified that T&CM is all about plants or natural products without chemicals or drugs (n = 267, 71.4%, p < .001). The category of T&CM with the highest usage was biological based therapies (n = 272, 95.4%), while the lowest was energy therapies (n = 8, 2.8%). The most commonly used T&CM was the traditional Malay massage (n = 170, 59.6%). The main sources of information and recommendations for using T&CM came from their family members or friends (n = 199, 69.8%). Almost half of the participants incurred minimum expenditures of MYR100 and below on the T&CM used (n = 137, 48.1%) and there was no significant difference between pregnant and postpartum women (p = .056).

Conclusion: This study reveals that many women are practising T&CM when trying to conceive and during pregnancy and the postpartum period even though they are aware that there is insufficient evidence on its safety and efficacy. Therefore, further studies are needed in order to gain sufficient clinical evidence that could be used to structure better guidelines for T&CM practices and services in Malaysia.


Abstract:

This study examined (1) the agreement of acupuncture experts with textbook prescriptions and among themselves, and (2) the association between similar traditional diagnoses and textbook acupuncture prescriptions, examining whether pragmatic practice (i.e., modifying prescriptions according to personal clinical practice) alters such
an association. A computational analysis quantified the diagnosis-prescription association from a textbook. Eight acupuncture experts were independently interviewed. Experts modified the textbook prescriptions according to their pragmatic practice. Experts mostly agreed (19–90%) or strongly agreed (0–29%) with the textbook prescriptions, with no-better-than-chance agreement on their ratings (Light’s $\kappa = 0.036$, CI95% = [0.003; 0.081]). The number of manifestations in traditional diagnoses weakly explains the variability (Spearman’s $\rho = 0.260$, $p = 0.038$) of the number of acupoints in prescriptions. The association between similar traditional diagnoses and acupuncture prescriptions is strong in the textbook ($\gamma = 0.720$, CI95% = [0.658, 0.783]), whereas pragmatic practice had little effect on this association ($\gamma = 0.724$–0.769).


Abstract:

Background: Many patients with depression fail to achieve remission after several consecutive treatments. Vitamin D deficiency is prevalent and new research suggests that it may have an impact on mood, primarily through an effect on neurotransmitters. Numerous observational studies suggest a relationship between low levels of vitamin D and increased incidence and severity of mood disorders. A small number of pilot studies have been undertaken but lack rigorous methodology required to draw conclusions about a clinical role for this nutrient in treatment resistant depression.

Methods: This study was designed as a randomized, double-blind, placebo controlled intervention study administering a weekly (bolus) dose of 28 000IU of Vitamin D3 or placebo to 125 patients with non-remitted depression adjunct to current antidepressant medication. Patients were followed weekly for eight weeks plus a one month follow up. Outcomes measured included depression severity, serum vitamin D levels and safety. Due to slow recruitment during the first season, amendments were made. These included extending the age range to 18–75 and removing the requirement for failing to respond to one pharmacologic antidepressant agent. The protocol was amended to reduce the burden on participants by changing the in-office visits to bi-weekly. Three additional tertiary psychiatric clinics were also added as trial sites.

Results: Over three recruitment period years (fall/winter), a total of 148 participants completed screening, 24 (16.2%) of whom qualified to participate in the study. Use of too many or no psychiatric medications, comorbid exclusionary psychiatric conditions, current use of a vitamin D supplement, and lack of participant compensation were the predominant reasons for ineligibility or unwillingness to participate. 9 participants were successfully enrolled in the study, 7 (77.8%) of whom completed the trial as per the protocol. After the third season, futility was declared based on inability to enroll participants. The sample size of enrolled participants (7/125, 5.6%) lacks power to conduct a full assessment of findings.

Discussion: High accessibility of vitamin D, as well as a growing lack of equipoise in patients and clinicians about the potential ubiquitous benefits of vitamin D for Canadians, not just for mood disorders, resulted in a large proportion of ineligible
potential participants. Limited funding provided to studies on natural health products hampered recruitment. The labile and fluctuating nature of non-remitted depression as well as frequent co-morbid conditions creates additional challenges for conducting trials in this population. Future studies assessing vitamin D in depression should consider our experiences in design and conduct of research. Innovations in clinical trial design such as preference trials or accepting patients already using vitamin D but not achieving an optimal target value are potential solutions to some of these challenges.


**Abstract:**

**Aims:** To examine the effects of aromatherapy massage on anxiety and sleep quality in patients undergoing colorectal surgery in the preoperative period.

**Background:** In recent years, there has been an increase in the number of studies conducted on aromatherapy massage. It is stated that studies conducted on aromatherapy massage for anxiety and sleep quality reveal contradictory results and that more research is required on the issue.

**Design:** A randomized controlled trial.

**Methods:** Eighty patients undergoing colorectal surgery were randomly assigned to experimental and control group. To the experimental group (n = 40), aromatherapy massage was applied in accordance with the “Back Massage Guide” using 5% lavender oil (Lavandula Hybrida) for ten minutes before surgery and the morning of surgery. The control group received standard nursing care in compliance with the hospital procedure. Data were obtained by the State Anxiety Inventory (SAI) and Richard-Campbell Sleep Questionnaire (RCSQ). Results were analyzed using the t-test, Chi-square test or Fisher’s exact test.

**Results:** There was no baseline difference between the groups. A statistically significant difference was found between the experimental and control group in terms of the SAI and RCSQ mean scores recorded on the morning of surgery. It was determined that the SAI and RCSQ mean score of the experimental group after aromatherapy massage on the morning of surgery decreased when compared to that of the evening before surgery.

**Conclusions:** It was found that aromatherapy massage with lavender oil increased the sleep quality and reduced the level of anxiety in patients with colorectal surgery in the preoperative period.


**Abstract:**
Objective: To determine the frequency of use of different types of CAM among patients who attended outpatient general practices (GP).

Methods: CAM use, type, reason, administration, satisfaction, and disclosure to physician were documented by interviewing 360 patients.

Results: A total of 192 individuals (53.3%) reported that they were using or had used at least one form of CAM therapy (a total of 343 CAM therapies). The five most commonly used CAM therapies were, respectively, vitamin supplements (105 subjects, 54.7%), traditional herbal products (80 cases, 41.7%), mineral supplements (58 cases, 30.2%), herbal medicines (49 cases, 25.5%) and dietary therapies (18 cases, 9.4%); 240 therapies (70%) were self-prescribed.

Conclusion: A substantial number of the patients had used CAM on their own; one-third of these patients did not have sufficient knowledge about the therapies used. Health care providers should be aware of this practice by the patients and seek information about CAM usage.


Abstract:

Objectives: Despite expanded legalization and utilization of medical cannabis (MC) internationally, there is a lack of patient-centered data on how MC is used by persons living with chronic conditions in tandem with or instead of prescription medications. This study describes approaches to use of MC vis-à-vis prescription medications in the treatment of selected chronic conditions.

Design: Participants completed semi structured telephone interviews with open-ended questions. Content analysis of qualitative data identified themes and subthemes relating to patient approaches to using MC products.

Participants: Thirty persons (mean age = 44.6 years) living with a range of chronic conditions (e.g., rheumatoid arthritis, Crohn’s disease, spinal cord injury/disease, and cancer) who had qualified for and used MC in Illinois.

Results: Participants described a range of approaches to using MC, including (1) as alternatives to using prescription or over-the-counter medications; (2) complementary use with prescription medications; and (3) as a means for tapering off prescription medications. Motives reported for reducing or eliminating prescription medications included concerns regarding toxicity, dependence, and tolerance, and perceptions that MC improves management of certain symptoms and has quicker action and longer lasting effects.
**Conclusions:** MC appears to serve as both a complementary method for symptom management and treatment of medication side-effects associated with certain chronic conditions, and as an alternative method for treatment of pain, seizures, and inflammation in this population. Additional patient-centered research is needed to identify specific dosing patterns of MC products associated with symptom alleviation and produce longitudinal data assessing chronic disease outcomes with MC use.


Chatterjee Sujit. 2 Cases of cancer of GIT. *National Journal of Homeopathy 2018; 221 20(02): 11-16p.*


**Abstract:**

**Background:** The majority of studies of integrative treatment for colorectal cancer (CRC) have been published in Chinese journals. These studies indicate potential benefits, but concerns have been raised over the quality of trials published in Chinese journals. The CONSORT statement provides a guide for study reporting that has been endorsed by more than 400 international journals. Previous studies have used the CONSORT checklist to assess the quality of randomized controlled trials (RCTs).

**Objectives:** This study focused on RCTs of integrative and traditional medicine for CRC published in Chinese journals and assessed: (1) the overall quality of reporting with a focus on methodological aspects; (2) change over time; and (3) the influence of study funding, level of institution conducting the trial, rank of the journal, and the length of the article.

**Design:** Searches of seven databases identified RCTs. Quality was assessed using CONSORT 2010 with adaptations to facilitate scoring. Additional codes were added for publication year, hospital rank, report length, and status of the journal. Scores of each checklist item, total scores, and scores for eight items associated with RCT methodology were calculated.

**Results:** Eighty-one studies were included in the main analyses. The RCT methodology subgroup scores were significantly higher in studies: with public funding, conducted by authors from university hospitals, published in higher ranked journals, and in longer articles.

**Conclusions:** Few Chinese journals mention CONSORT in their author guidelines. In these RCTs on CRC better reporting of RCT methodology was associated with ranking of the journal as “core,” public funding of the RCT, and first or correspondent author from a university hospital but the quality of reporting had not significantly improved in
15 years. As the volume of scientific information produced in China grows, it is imperative that there is growth in the quality of this information.

**Chhatlani Chandresh Kumar, Goswami Amiya Nanda. Study and security audit of software for Homoeopathy doctors. Homoeopathy The Friend of Health 2018; 6(2): 5-14p.**

**Abstract:**

There are number of software in homoeopathy namely RADAR, CARA, HOMPATH, POLYCRES, ORGANUM and day to day more are being introduced. However, the security in terms of hacking the data and cracking the software exists. Once can sue these software without purchasing. This research paper conveys various techniques of testing of software, so that homeopathic software could become more secured and could do not loose its privacy. An enhanced frame work is also proposed.

**Clarke Tainya C. Use of Complementary Health Approaches Among U.S. Adults with a Recent Cancer Diagnosis. Journal of Alternative and Complementary Medicine 2018, 24(2): 139-45p.**

**Abstract:**

**Objective:** The object of this study was to explore the use of complementary health approaches among U.S. adults with a cancer diagnosis in the past 5 years and distinguish use for general wellness from use specifically for treatment.

**Methods:** Using data from the 2002, 2007, and 2012 National Health Interview Survey, the study included 1359 persons with a cancer diagnosis of selected cancers in the past 5 years. Participants were asked about their use of complementary health approaches for general reasons and cancer treatment in the past 12 months. Responses were aggregated into the use of any complementary approach as well as examined by mode of practice.

**Results:** Overall, 35.3% of persons with a cancer diagnosis used complementary health approaches in the past 12 months. These persons were more likely to have used a biologically based approach (22.8%) compared with other approaches. Persons with breast cancer were significantly more likely to use any complementary health approach (43.6%) compared with those with other recently diagnosed cancers. Few persons with a cancer history (2.3%) used complementary approaches specifically for cancer treatment. However, prevalence of use for treatment varied by cancer type (0.4%–6.8%).

**Conclusions:** This study highlights differences in the use of various types of complementary health approaches for different reasons among persons with recent diagnoses of some of the most commonly diagnosed cancers in the United States.

**Abstract:**

**Objective:** To determine if U.S. female veterans had demonstrable improvements in neck pain after chiropractic management at a Veterans Affairs (VA) hospital.

**Methods:** This was a retrospective cross-sectional study of medical records from female veterans attending a VA chiropractic clinic for neck pain from 2009 to 2015. Paired t-tests were used to compare baseline and discharge numeric rating scale (NRS) and Neck Bournemouth Questionnaire (NBQ) scores with a minimum clinically important difference (MCID) set at a 30% change from baseline.

**Results:** Thirty-four veterans met the inclusion criteria and received a mean of 8.8 chiropractic treatments. For NRS, the mean score improvement was 2.7 (95%CI, 1.9–3.5, p < .001). For the NBQ, the mean score improvement was 13.7 (95%CI, 9.9–17.5, p < .001). For the MCID, the average percent improvement was 45% for the NRS and 38% for the NBQ.

**Conclusion:** Female veterans with neck pain experienced a statistically and clinically significant reduction in NRS and NBQ scores.


**Abstract:**

**Objectives:** Chronic pain is a common problem in the United States, one for which there is a dearth of effective treatments. Nonpharmacological options are a promising alternative, especially for Spanish-speaking Latinos. This pilot study would like to assess the feasibility of an adapted Integrative Medical Group Visit (IMGV) curriculum for a Spanish-speaking Latino chronic pain population.

**Design and Intervention:** We translated and adapted the curriculum of the IMGV for a Spanish-speaking Latino chronic pain population. We then tested the feasibility of using this model with two pilot groups (N = 19) using a pre–postdesign.

**Subjects:** This intervention was targeted for underserved Spanish-speaking Latino patients with chronic pain.

**Settings/Location:** This study took place at a safety net academic teaching hospital, the Boston Medical Center, and at a community health center located in a majority Latino neighborhood, the East Boston Neighborhood Health Clinic.

**Outcome measures:** We used the validated Spanish translations of the Patient-Reported Outcomes Measurement Information System (PROMIS-29) (short version),
Personal Health Questionnaire (PHQ-8), and Perceived Stress Scale (PSS-10). We also gathered qualitative information through focus groups and in-depth interviews.

**Results:** Using PROMIS measures, there was a statistically significant reduction in pain interference ($p = 0.01$), fatigue ($p = 0.01$), and depression ($p = 0.01$). Qualitative data also indicated the participants felt they benefited from the visits and having care in Spanish was unique.

**Conclusions:** This model offers a promising nonpharmacological option for Spanish-speaking patients with chronic pain and could offer an alternative for addressing disparities for this population.


**Abstract:**

**Objective:** About one-third of service members returning from post-9/11 deployment in Afghanistan and Iraq report combat-related mental health conditions, but many do not seek conventional treatment. Mind–body therapies have been offered as alternative approaches to decreasing post-traumatic stress disorder (PTSD), but no review of studies with veterans of post-9/11 operations was found. The objective of this study was to fill that gap.

**Design:** A systematic literature review was conducted following the preferred items for systematic reviews and meta-analyses (PRISMA) guidelines. PubMed MeSH terms were used to capture articles reporting on the military population (veteran and veterans) with PTSD who received a portable mind–body intervention (e.g., mindfulness, mind–body therapy, and yoga). PubMed/MEDLINE and PsycINFO were searched. Studies were included if participants were a mixed group of war veterans, as long as some post-9/11 veterans were included. In addition, participants must have had a diagnosis of PTSD or subthreshold PTSD, and the PTSD must have been attributable to combat, rather than another event, such as sexual trauma or natural disaster.

**Results:** Of 175 records identified, 15 met inclusion criteria. Studies reported on seated or gentle yoga that included breath work, meditation, mantra repetition, or breathing exercises. For 14 of the 15 studies, study retention was 70% or higher. Overall, studies reported significant improvements in PTSD symptoms in participants in these interventions. Although each study included post-9/11 veterans, about 85% of participants were from other conflicts, predominantly Vietnam.

**Conclusion:** Although findings were positive, future studies are needed to evaluate the short- and long-term impact of mind–body therapies on larger samples of post-9/11 veterans and to address research questions related to broadening service member and veteran participation in these therapies.

**Dehghan Mahlagha, poor Amanollah Fatehi, Mehdipoor Roghayeh et al. Does abdominal massage improve gastrointestinal functions of intensive care patients**

Abstract:

**Introduction:** Gastrointestinal dysfunction is one of the most common problems among patients hospitalized in intensive care units. Currently, medicinal and non-medicinal methods are being used to prevent gastrointestinal problems. Among non-medicinal methods, abdominal massage is considered as a relatively acceptable method. The present study aims to examine the effect of abdominal massage on gastrointestinal functions of the intensive care patients with an endotracheal tube.

**Materials and methods:** In this clinical trial, 70 intensive care patients with an endotracheal tube were chosen by convenience sampling and allocated to an intervention or a control group randomly. In the intervention group, a 15-min abdominal massage was conducted twice a day for three days, while the control group received only routine cares. The abdominal circumference, gastric residual volume, times of defecation, and frequency of constipation were measured.

**Results:** Gastric residual volume decreased significantly in the intervention group and increased significantly in the control group; however, there was no significant difference between two groups (P = .15). There was a significant difference between two groups regarding abdominal circumference and it was decreased in the intervention group (P < .001). The defecation times significantly increased in the intervention group (P = .002). After the intervention, the prevalence of constipation was significantly decreased in the intervention group (P = .008).

**Conclusion:** The results revealed that abdominal massage could improve gastrointestinal functions in enterally fed patients with an endotracheal tube. It is suggested to use abdominal massage as an adjunct therapy for improving gastrointestinal functions in intensive care patients.

**Devarajan Latha. Integrated approach to IBS and APD. National Journal of Homeopathy 2018; 221 20(02): 29-32p.**


Abstract:

This work is about the dietary supplements for the people who suffer with breast cancer. Here the article is started with small information about the breast cancer followed by detailed information of the advisable diet. This work is done with two purposes, for the physician as a brush up of their knowledge.


Abstract:
Oncologists tend to avoid the use of supplements during chemotherapy. To understand
the safety issue, a literature review was conducted to evaluate safety and possible
benefits of taking curcumin during chemotherapy. Curcumin was chosen because of its
wide use in the public and because of the availability of clinical trials utilizing curcumin
during chemotherapy. Curcumin is considered a “pan-assay interference compound,”
creating false leads in drug discovery assays. The pharmacodynamics of curcumin
presents many challenges for a therapeutic agent, including poor bioavailability and
rapid metabolism and excretion. The proposed molecular targets for curcumin include
inhibition of nuclear factor kappa B and inhibition of cyclooxygenase-2. Clinical trials
investigating the efficacy of curcumin treatment for cancer have been conducted in
patients with colorectal cancer (CRC), pancreatic cancer, breast cancer, prostate cancer,
multiple myeloma, lung cancer, and head and neck cancer. Outcomes revealed that
while curcumin was not effective, it was well tolerated and safe. Recently, there have
been several Phase I and Phase II trials combining curcumin with chemotherapeutic
agents. Two trials investigated the effect of curcumin given concurrently with
gemcitabine for advanced pancreatic cancer patients. One trial investigated the effect
of curcumin given concurrently with docetaxel in advanced breast cancer patients.
Another trial investigated the role of curcumin given concurrently with docetaxel and
prednisone in castration-resistant prostate cancer patients. The results again indicate
the safety of curcumin, but no added benefit of adding curcumin to the chemotherapy
regimen. The literature review demonstrated that curcumin is well tolerated up to 6–8 g
in research. While there are many promising in vivo and in vitro trials on the potential
benefits of curcumin for treatment of cancer in conjunction with chemotherapy, to date
there is no evidence that combining curcumin with chemotherapeutic agents is effective
for treating cancer in humans. The lack of effect may be due to the target diseases that
are treatment resistant such as advanced pancreatic cancer and advanced breast
cancer. Also, curcumin has many difficult properties such as poor solubility and rapid
metabolism. Currently, there are developments of analogues, liposomal products, and
nanoparticles that may overcome the current challenges of curcumin. Future studies
should utilize these evolving technologies.


Abstract:
In this world of digital evolution, despite the dramatic and overwhelmingly positive
changes in life style, there are increasing challenges for health issues. The thorniest
issue among all is acid peptic disorders. There are many polytheists medicines which
are helpful to combat such diseases, but there are many useful medicines which are
overlooked either from ignorance, favoritism or other reasons. So I want to focus light
on ten such useful but ducked medicines from Boericke’s Materia Medic afro acid peptic
disorders.


Abstract:
Nails are the mirror of our personality as well as never failing guide as they give ideas
regarding the local as well as systemic diseases. Nail disorders are mots commonly
encountered conditions in our day-to-day clinical practice. In order to see the effectiveness of homeopathic medicines for various nail disorders a prospective observational study was carried out on 5 randomly selected cases and results were found very favorable.


Abstract:

Background: The use of complementary and alternative medicine (CAM) for chronic diseases such as multiple sclerosis (MS) is becoming an increasingly important issue for those affected. Especially in Germany there are only a few studies dealing with CAM, as yet. The aim of this study was to assess the prevalence, the methods used, the subjective benefits as well as physician/patient communication.

Methods: A structured questionnaire including demographic and disease-specific data, CAM use, perceived benefits as well as physician/patient communication was sent to real and web-based self-help groups for MS in Germany.

Results: 343 answers could be evaluated. 77.3% of the participants were females. The mean age was 45.0 ± 11.9 years and the duration of the disease was 12.0 ± 9.6 years. 81.9% said they were using CAM, nearly half (44.8%) used it alternatively to conventional medicine. The average number of CAM-methods used were 3.6. The most popular methods were vitamin supplements, Yoga/Thai chi/Qi Gong, relaxation techniques and meditation. Approximately half (139/49.5%) of CAM users disclosed this to their treating neurologist. Yet, 37.6% have doubts on the competence of the respective physician.

Conclusion: Patients with MS have a strong interest in CAM. Usage as alternative therapy is widespread and puts patients at risk of progress of the disease. As patient/physician communication on the topic is increasing, neurologists should be attentive to guiding their patients through safe complementary methods.


Abstract:

Introduction: There is growing interest in mind-body skills (MBS) education and online interprofessional elective MBS training for health professionals. We conducted this study to understand a) the demand among different health professionals for an online MBS course; b) engagement with different MBS topics; and c) planned behavior changes.

Methods: We examined registrations from May 1 through August 31, 2014 for a new online MBS elective, analyzing the percentage of registrants who engaged with one or more of 12 modules by September 30, 2014. We also reviewed written comments about planned behavior change.
**Results:** The 693 registrants included physicians, nurses, social workers, dietitians, psychologists, and others. The two most popular topics were “Introduction: to Stress, Resilience, and Relaxation Response” and “Autogenic Training”. Half of registrants (57%) engaged with at least one module and 9% completed all 12 modules within the study period. Nearly all (90%) of those who completed evaluations planned to use the technique they learned for themselves, introduce it to patients, or both.

**Discussion:** Online elective MBS training attracts diverse health professionals and leads to plans for personal and professional behavior change. Additional research is necessary to understand the impact of different amounts and kinds of MBS training on professionals’ resilience, burnout, and quality of care.


**Huberty Jennifer, Matthews Jeni, Leiferman Jenn A et al. Use of complementary approaches in pregnant women with a history of miscarriage.** *Complementary Therapies in Medicine 2018; 36: 1-5p.*

**Abstract:**

**Objectives:** To describe the use of complementary approaches in pregnant women with a history of miscarriage and to investigate whether a miscarriage is associated with the use of complementary approaches during their pregnancy.

**Design:** A cross-sectional survey was distributed to pregnant women residing in the United States (N = 890).

**Results:** Women who had a history of miscarriage, were Caucasian, were college educated, reported a high income, had low depression scores, and had low anxiety scores (all P < 0.001) were more likely to use complementary approaches. In pregnant women with a history of miscarriage (N = 193), the most frequently reported complementary approaches used were prayer (22.3%), yoga (15%), massage (14.5%), chiropractic (13%), and meditation (11.4%). Finally, after adjustment for age, race, education, and income, the odds of using a complementary approach in women with a history of miscarriage was 1.8 (95% CI: 1.3, 2.5, P < 0.001) as compared with women without a history of miscarriage (model 1). Associations persisted after additional adjustment for depression, anxiety, and stress; the odds of using a complementary approach in women with a history of miscarriage was 1.7 (95% CI: 1.2, 2.4, P < 0.001) (model 2), compared with women without a history of miscarriage.

**Conclusions:** Findings from this study may help inform future studies for pregnant women with a history of miscarriage and may also provide information about appropriate strategies in which health care providers can refer their patients.

Abstract:

Objective: To investigate the effect of olfactory stimulation with essential oils on cardiovascular reactivity during the “moving beans” rehabilitation task in stroke patients with anxiety.

Methods: Twenty-eight stroke patients participated in this study. Blood pressure and heart rate were measured before and after finger movement tasks (e.g., moving beans and the Purdue pegboard test). Olfactory stimulation with lavender oil, grapefruit oil, and distilled water were conducted during finger tasks. Anxiety was assessed using the State Trait Anxiety Inventory (STAI)-Y2 before the finger movement tasks.

Results: There were no significant changes in blood pressure or heart rate activity in both finger movement tasks when stimulation of lavender oil, grapefruit oil, and distilled water was applied. However, the change values of Δ diastolic blood pressure (DBP) associated with the moving beans task indicated a significant interaction between olfactory stimulations and the groups of STAI-Y2 scores (high vs low) (p = 0.03), without main effects in the olfactory stimulations and the groups of STAI-Y2 scores.

Conclusion: Olfactory stimulation with lavender and grapefruit oil may repress the exaggerated DBP response during the moving beans task in stroke patients with higher levels of trait anxiety symptoms.


Abstract:

Objectives: To clarify the status of home care massage services provided to patients. This will help in understanding how many patients utilize this service and the circumstances under which treatment is provided.

Design: A retrospective study.

Setting: Fifty-four acupuncture, moxibustion, and massage clinics. Participants were patients who had received home care massage for six months or more. We collected a total of 1587 responses from these 54 massage clinics; of these, 1415 responses (mean age = 79.1 ± 11.5 years) were valid (valid response rate 89.2%).

Main outcome measures: Actual patients and actual care services.

Results: The most common disorder observed among patients who utilized home care massage services was cerebrovascular disease (at approximately 36%), while the second most common were arthropathy-related disorders (16.3%). Although most patients received massage, approximately 30% received manual therapy (e.g. manual correction) and hot fomentation as part of thermotherapy. Notably, only around 10% of patients
received massage alone; the majority received treatment in combination with range of motion and muscle-strengthening exercises.

**Conclusions:** This study helped to clarify the actual state of patients receiving home care massage and the details of the massage services provided. This study clearly showed the treatment effectiveness of massage, which can be used by home medical care stakeholders to develop more effective interventions.


**Abstract:**

**Objectives:** Various exercise strategies have been suggested to address movement deficits in order to improve motor function and quality of life for individuals in the early or moderate stages of Parkinson disease. The purpose is to evaluate the effects of an aquatic Ai Chi intervention on balance, gait speed and quality of life of patients.

**Design and intervention:** Twenty-nine people with Parkinson disease participated in this pilot study. People were randomized into (1) aquatic Ai Chi program (experimental group) and (2) a dry land conventional Western physical therapy intervention (control group). Twenty-two twice-weekly sessions were performed with the 14 patients assigned to the experimental group, during the same period of time as the control group (same number of sessions), who received dry land therapy.

**Main outcomes measures:** Visual Analogue scale (VAS), The Timed Get up and Go test, Five Times Sit-to-Stand test, single leg standing, Yesavage test and Parkinson’s Disease Questionnaire (PDQ-39). A descriptive analysis was performed on all study variables.

**Results:** The results showed a significant effect on time – of a high effect which indicates that the VAS scores (F 1.3; p < 0.001), Five time (F = 1.8; p = 0.001) and Get up and Go (F = 1.7; p < 0.001) significantly decreased in time, independent of the treatment group. In contrast, no significant differences were found in the results shown on the PDQ-39 scale, finding only changes in the section of social support (p < 0.001 F = 18.63).

**Conclusions:** The results of this 11-week controlled pilot trial suggest that aquatic Ai Chi applied twice weekly may potentially reduce Parkinsonian symptoms as measured on different motor symptoms, bradykinesia and rigidity.


**Abstract:**
**Objective:** Urolithiasis is a common medical condition affecting the urinary tract. Typical symptoms reported by patients include colic pain and hematuria. Some patients may undergo surgical intervention or lithotripsy to remove the stones. In this case, we demonstrated that Chinese herbal medicine (CHM) was an effective modality to remove stones in a patient with urolithiasis.

**Clinical features and outcome:** A 47-year-old man suffered from right flank pain and hematuria for three months and was diagnosed with an upper third ureteral stone obstruction with right hydronephrosis. He had received extracorporeal shock wave lithotripsy (ESWL) three times before his first CHM visit, but it was unsuccessful. Therefore, he sought CHM for further intervention. His symptoms subsided, and the image study showed complete removal of the ureteral stone after regular therapy with Zhi Bai Di Huang Wan (Graphical abstract for this article) combined with Lygodii spora (Graphical abstract for this article), Curcumae radix (Graphical abstract for this article), Endothelium Corneum Gigeriae Galli (Graphical abstract for this article), Lysimachiae herba (Graphical abstract for this article), Orthosiphon stamineus (Graphical abstract for this article) for approximately four months. Neither complications nor side-effects were noted during the CHM treatment.

**Conclusions:** In this case, we concluded that CHM may be an effective alternative therapy for the treatment of ureteral stones, and furthermore, may also be applied as an option to salvage failed ESWL procedures.


Lauche Romy, Fuller Nicholas R, Cramer Holger et al. Associations between complementary medicine, satisfaction with body weight and shape, and the use of methods to lose or control weight: Results of a national survey of 8009 Australian women. *Complementary Therapies in Medicine 2018; 36: 100-06p.*

**Abstract:**

**Objective:** This study aimed to determine whether the use of complementary medicine (CM) is associated with body satisfaction and weight management methods in Australian women.

**Methods:** Women aged 34–39 years from the Australian Longitudinal Study on Women’s Health were surveyed regarding satisfaction with their body weight and shape, and the use of weight management methods. Associations with CM use were analysed using logistic regression modelling.

**Results:** Women using CM less likely wanted to lose weight; and were more likely to cut down on fats and/or sugars, use low glycaemic diets, diet books and ‘other’ methods (OR: 1.33–2.83) compared to CM non-users. Women using herbal medicine products ‘sometimes’ were more likely to use meal replacements/slimming products (OR: 1.50–1.67) compared to non-users.
Discussion: Australian women using CM are more likely to be satisfied with their body weight and shape, and to use a range of weight management approaches compared to CM non-users.


Abstract:

Objective: To generate a multidisciplinary stakeholder-informed definition of integrative health care (IHC).

Methods: A mixed-method study design was used, employing the use of focus groups/semi-structured interviews (phase-1) and document analysis (phases 2 and 3). Phase-1 recruited a purposive sample of Australian health consumers/health providers. Phase-2 interrogated websites of international IHC organisations for definitions of IHC. Phase-3 systematically searched bibliographic databases for articles defining IHC. Data were analysed using thematic analysis.

Results: Data were drawn from 54 health consumers/providers (phase-1), 23 IHC organisation webpages (phase-2) and 23 eligible articles (phase-3). Seven themes emerged from the data. Consensus was reached on a single, 65-word definition of IHC.

Conclusion: An unambiguous definition of IHC is critical to establishing a clearer identity for IHC, as well as providing greater clarity for consumers, health providers and policy makers. In recognising the need for a clearer description, we propose a scientifically-grounded, multi-disciplinary stakeholder-informed definition of IHC.


Abstract:

Objective: The purpose of this case report was to elucidate how Chinese herbal medicine (CHM) was used safely in this patient undergoing interferon beta (IFNβ-1a) treatment and was associated with reduction in the side effects the patient had experienced when using IFNβ-1a treatment alone.

Clinical features and outcome: A 30-year-old man was diagnosed with MS in December 2014. For two years, he suffered from severe flu-like symptoms as side effects of IFNβ-1a treatment. He subsequently received treatment with Chinese herbal medicine. During a two-month period of treatment with CHM, the patient responded well, with most of the symptoms induced by IFNβ-1a ameliorated. The fever subsided. Incidence rates of dizziness and headaches were reduced. The health condition compared to the prior year increased by 50%. According to CCMQ and SF-36 assessments, CHM had the beneficial effects of recovering the yin-yang balance,
harmonizing the qi, and regulating the blood state; essentially, improving the patient’s comfort level and quality of life.

**Conclusions:** IFNβ-1a injections will damage qi and cause blood stasis in MS patients, thereby causing various side effects and weakening the body’s immune system. Bu-Zhong-Yi-Qi-Tang, associated with Salvia miltiorrhiza, Ligusticum chuanxiong, Angelica dahurica and Polygonum multiflorum Thunb., is an effective prescription to ameliorate such symptoms and signs in patients with MS.


**Abstract:**

**Objectives:** To assess the experiences of a veteran initiated horticultural therapy garden during their 28-day inpatient Substance Abuse Residential Rehabilitation Treatment Program (SARRTP).

**Design:** Retrospective study.

**Setting:** Veterans Affairs Medical Center (VAMC), Salem, Virginia, USA

**Interventions:** Group interviews with veterans from the last SARRTP classes and individual interviews with VAMC greenhouse staff in summer of 2016.

**Outcome measures:** Time spent in garden, frequency of garden visits, types of passive and active garden activities, words describing the veterans’ emotional reactions to utilizing the garden.

**Results:** In 3 summer months of 2016, 50 percent of the 56 veterans interviewed visited and interacted with the gardens during their free time. Frequency of visits generally varied from 3 times weekly to 1–2 times a day. Amount of time in the garden varied from 10 min to 2 h. The veterans engaged in active and/or passive gardening activities during their garden visits. The veterans reported feeling “calm”, “serene”, and “refreshed” during garden visitation and after leaving the garden.

**Conclusions:** Although data was secured only at the end of the 2016 growing season, interviews of the inpatient veterans revealed that they used their own initiative and resources to continue the horticulture therapy program for 2 successive growing years after the original pilot project ended in 2014. These non-interventionist, therapeutic garden projects suggest the role of autonomy and patient initiative in recovery programs for veterans attending VAMC treatment programs and they also suggest the value of horticulture therapy as a meaningful evidence-based therapeutic modality for veterans.


**Abstract:**
**Objective:** The present systematic review aimed to verify the effect of resistance and combined training on the inflammatory profile of breast cancer survivors.

**Design:** The searches were made on the platforms PsycINFO, PubMed, Cochrane, Science Direct and Scopus, from 1996 to 2017, using the keywords: cancer survivors, cancer treatment, cancer patients, breast cancer, inflammation, inflammatory profile, immune function, resistance training, strength training, weight training, physical activity, concurrent training and combined training. References of selected articles were also considered. Seven studies fulfilled the criteria adopted for analysis.

**Results:** None of these studies have shown reduced inflammatory markers in breast cancer survivors undergoing combined or isolated resistance training.

**Conclusions:** It is not yet possible to conclude which resistance and/or combination training protocol is capable of improving the short-term inflammatory profile in this population. Future studies should seek to establish how structural training variables (intensity, volume, density, intra- and inter-series recovery, among others) act on anti-inflammatory processes in breast cancer survivors.


**Abstract:**

A close examination of the incident reports to the Food and Drug Administration (FDA) regarding homeopathic teething tablets reveals a lack of evidence either for the FDA advisories regarding them or the media reports claiming that hundreds of infants were harmed soon after ingesting them. Many of the incident reports were requests for information from concerned parents, while the rest lacked a temporal association with ingestion or failed to rule out confounding medications or health conditions. The only other recent example of alleged harm from a homeopathic product was the case of Zicam®, withdrawn from the market after users reported loss of their sense of smell. Two views of Zicam are examined—that it was a supplement falsely labeled homeopathic or that it was an outlier among bona fide homeopathic medicines—neither of which would implicate the safety of homeopathic medicines in general. A recent *New England Journal of Medicine* perspectives piece is addressed: it calls for homeopathy to be regulated more stringently, as pharmaceuticals are. This article agrees that additional regulations and enforcement are needed. However, they should be limited to minor adjustments to make homeopathy more accessible to consumers and to minimize fraudulent products. This article asserts that homeopathy is already safer and can be more effective than pharmaceuticals, while current regulations of pharmaceuticals have failed to ensure their safety or effectiveness. The low risk–benefit ratio of homeopathy is asserted based on its minimal risk and its potential great benefit to consumers and the healthcare system as a whole, including cost savings, reducing antibiotic usage in humans and animals, and providing a rapid response to an epidemic. Finally, a proposed “new therapeutic order” is recommended in which safe holistic modalities such as homeopathy are used first, with drugs and surgery used only as a last resort.

**Abstract:**

**Objectives:** To evaluate the impact of yoga training in patients with chronic obstructive pulmonary disease (COPD).

**Method:** A literature search was performed in PubMed, Cochrane Library, Embase, CINAHL, and Web of Science for relevant studies published before June 2017. Quality assessment, sensitivity analysis and heterogeneity were performed. Stata12.0 software was used for statistical analysis.

**Results:** Ten studies were eligible for this analysis. There were significantly greater improvements in 6MWD (p = 0.000), Borg scale scores (p = 0.018), FEV1 Value (p = 0.013), PaCO2 (p = 0.037), SGRQ scores (p = 0.000) and CAT scores (p = 0.009) in yoga training patients. No statistically significant difference was observed in the FEV1/FVC (p = 0.75), FEV1 predicted value (p = 0.057) and FVC (p = 0.05).

**Conclusions:** This meta-analysis indicates that yoga training can be an acceptable and appropriated adjunctive rehabilitation program for COPD patients.


**Abstract:**

**Objective:** Cupping therapy has a long history in traditional medicine especially in Asian countries. It was controversial whether cupping induced blisters are beneficial to healing effects, and the formation and content in the blisters remain unexplored. We aimed to identify and compare the molecular components of the blister fluid from the cupping therapy and the scalds to explore the necessary of inducing cupping induced blisters.

**Methods:** Fluid sample of blisters from fifteen patients receiving cupping therapy (Cupping group) and scald burns (Scald group) were collected in this study. Proteins from the blisters were separated by two-dimensional electrophoresis (2D-gel) and further analyzed by mass spectrometry. In addition, the changes in particular proteins were confirmed by Western blotting.

**Results:** The protein components are significantly different between blister from cupping therapy and scalds. The immune responses, oxidative stress and metabolic related proteins (Ig lambda-2 chain C regions, Ig gamma-1 chain C region, hemopexin, prdx2, calmodulin, succinyl-CoA ligase and tetranectin) were increased, whereas the hemoglobin subunit beta was decreased in the Cupping group compared with the Scald group.

**Conclusions:** Cupping induced blisters contain several proteins which relate to the activation of certain immune pathways including anti-oxidation, anti-apoptosis, tissue
repairing and metabolic regulation. This proteomic analysis may indicate a significant clue to the mechanism study of cupping.


Abstract:

**Purpose:** To examine the acute effects of pre-competition massage on acceleration and sprint performance in collegiate track and field athletes.

**Methods:** Seventeen collegiate male (n = 9) and female (N = 8) track and field athletes participated in the study. Athletes were assigned to a counterbalanced, repeated measures designed experiment testing four treatment conditions of a pre-competition massage, dynamic warm-up, combination of a massage and warm-up, and a placebo ultrasound.

**Results:** The reliability between treatments was very high (ICC range: 0.94–0.98) and displayed a high internal consistency (Cronbach α = 0.96). Inter-item correlations for treatments were strong at all time intervals (20-m r = 0.74–0.90; 30-m r = 0.87–0.95; 60-m r = 0.88–0.95). There were no significant differences between the four treatments and performance (p = 0.70). Massage decreased 60-meter sprint performance in comparison to the traditional warm-up, although the combination of the massage and warm-up appeared to have no greater difference than the warm-up alone.

**Conclusions:** Massage prior to competition remains questionable due to a lack of effectiveness in improving sprint performance. Further, pre-competition massage may not be more effective as a pre-event modality, over a traditional warm-up.


Abstract:

The aim of this study was to obtain data of gait parameters on predicting long-term outcome of hippotherapy. In 20 participants (4–19 years; GMFCS levels I to III) with cerebral palsy (CP), gait and balance abilities were examined after 10-m walking test using a portable motion recorder. Hippotherapy was associated with increased Gross Motor Function Measure (GMFM)-66 at 1 year from the baseline (P < 0.001). Hippotherapy increased stride length, walking speed, and mean acceleration and decreased horizontal/vertical displacement ratio over time (P < 0.05). Stride length and mean acceleration at 6 weeks predicted the elevation of GMFM-66 score. These data
suggest that 1-year outcome of hippotherapy on motor and balance functions can be assessed from the early phase by serial monitoring of the gait parameters.


Abstract:

Background: Over 80% of head and neck cancer patients suffer from radiotherapy-induced xerostomia (dry mouth). Xerostomia affects cancer patients' quality of life, and xerostomia sometimes persists throughout the patients' lifetime. This review aimed to evaluate the effectiveness and safety of Chinese herbs in relieving radiotherapy induced xerostomia.

Methods: Systematic searches were conducted on 6 databases (English and Chinese). Studies published up till May 2017 were considered for inclusion.

Results: A final 14 RCTs (total 994 head and neck cancer patients undergoing radiotherapy) compared Chinese herbs with no herbs, were included in analysis. Very low to moderate quality of evidence found Chinese herbal treatment may relief radiotherapy-induced xerostomia and other related complications (such as oral mucositis and loss of appetite) in head and neck cancer patients.

Conclusion: There is limited evidence that Chinese herbal treatment may relief radiotherapy-induced xerostomia and other related complications in head and neck cancer patients.


Abstract:

Background: Knee osteoarthritis is considered as one of the most prevalent musculoskeletal disorders which leads to joint degeneration and consequently disability in activities of daily living. This study aimed to evaluate the effects of aromatherapy massage with lavender essence on activities of daily living of patients with knee osteoarthritis.

Methods: This is a single-blinded, randomized clinical trial. A total of 90 patients with osteoarthritis of the knee referring to the outpatient rheumatology clinics affiliated to Birjand University of Medical Sciences were selected via convenience sampling method. The participants were randomly assigned into three groups: intervention group (aromatherapy massage with lavender essential oil), placebo group (massage with almond oil) and control group (without massage). The activities of daily living of patients was evaluated according to the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) at baseline, immediately after the intervention, 1 week,
and 4 weeks after the intervention. Data were analyzed using SPSS statistical software version 16.

**Results:** The activities of daily living of patients were significantly improved immediately and 1 week after the intervention in the intervention group compared with their initial status (p < .001) and that of the control group (p < .001 and p = .03 respectively). However, 4 weeks after the intervention, there was no significant difference between the groups according to the Western Ontario and McMaster Universities Osteoarthritis index (p = .95).

**Conclusion:** Aromatherapy massage with lavender essential oil may reduce the incidence of activities of daily living disability in patients with osteoarthritis of the knee. However, further studies are required to confirm findings of this study.


**Abstract:**

**Objectives:** To quantify different aspects of the quality of reporting of herbal medicine clinical trials, to determine how that quality is affecting the conclusions of meta-analyses, and to target areas for improvement in future herbal medicine research reporting.

**Study design:** The Electronic databases PubMed, Academic Search Premier, ScienceDirect, and Alt HealthWatch were searched for meta-analyses of herbal medicines in refereed journals and Cochrane Reviews in the years 2000–2004 and 2010–2014. The search was limited to meta-analyses of randomized controlled trials involving humans and published in English. Judgments and descriptions within the meta-analyses were used to report on risks of bias in the included clinical trials and the meta-analyses themselves.

**Results:** Out of 3264 citations, 9 journal-published meta-analyses were selected from 2000 to 2004, 116 from 2010 to 2014, and 44 Cochrane Reviews from 2010 to 2014. Across both time frames and categories of publication, <42% of the trials included in the meta-analyses described adequate randomization; <19% described concealment methods; <26% described double blinding; <29% described outcome assessment blinding, ≤53% discussed incomplete data, and <36% were nonselective in their reporting. Less than 54% of trials reported on adverse events and 64% of meta-analyses did not include a single trial with a low risk of bias. Taxonomic verification and chemical characterization of test products were infrequent in trials. Only 40% of meta-analyses considered publication bias and, of those that did, 90% found evidence for it. Cochrane Reviews were more likely than other sources to make negative conclusions of efficacy or to defer conclusions because of the absence of high quality trials.

**Conclusions:** Meta-analyses of herbal medicines include a significant number of clinical trials that do not meet the recommended standards for clinical trial reporting. This quantitative assessment identified significant publication bias and other bias risks that
may be due to inadequate trial design or incomplete reporting of outcomes. Suggested improvements to herbal medicine clinical trial reporting are discussed.


**Abstract:**

**Objective:** To evaluate the effects of oral rosemary on memory performance, anxiety, depression, and sleep quality in university students.

**Methods:** In this double-blinded randomized controlled trial, the 68 participating students randomly received 500 mg rosemary and placebo twice daily for one month. Prospective and retrospective memory performance, depression, anxiety and sleep quality of the students were measured using Prospective and Retrospective Memory Questionnaire, Hospital Anxiety and Depression Scale, and Pittsburgh Sleep Quality Inventory at baseline and after one month.

**Results:** The scores of all the scales and subscales except the sleep latency and sleep duration components of Pittsburgh Sleep Quality Inventory were significantly decreased in the rosemary group in comparison with the control group after one month.

**Conclusions:** Rosemary as a traditional herb could be used to boost prospective and retrospective memory, reduce anxiety and depression, and improve sleep quality in university students.

**Oh Yun Ah, Park Sin Ae, Ahn Byung Eun. Assessment of the psychopathological effects of a horticultural therapy program in patients with schizophrenia. Complementary Therapies in Medicine 2018; 36: 54-58.**

**Abstract:**

**Objectives:** This study assessed the psychopathological effects of participation in a 10-session horticultural therapy program in patients with schizophrenia.

**Design:** The study design was pre and post test design of experimental and control groups.

**Setting:** Twenty-eight Korean patients with schizophrenia, recruited from a mental health clinic and two mental health rehabilitation centers in Suwon, South Korea, were voluntarily assigned to either a control group (average age: 33.4 ± 9.4 years) or a horticultural therapy group (average age: 42.1 ± 13.0 years).

**Interventions:** The participants in the horticultural therapy group participated in a 10-session horticultural therapy program designed around various plant cultivating activities. The horticultural therapy program involved sessions once a week from April 2017 to June 2017.
Main outcome measures: A psychiatrist evaluated the psychopathological symptoms of schizophrenic patients in both groups. To assess the clinical psychopathological effects, the Korean version of the Positive and Negative Syndrome Scale (PANSS) and Brief Psychiatric Rating Scale (BPRS) were used.

Results: The horticultural therapy group significantly improved in terms of positive, negative, and general symptoms on the PANSS after the 10-session horticultural therapy program. Moreover, the horticultural therapy group significantly improved in terms of clinical symptoms of schizophrenia in BPRS after the 10-session horticultural therapy program. However, there was no change in the PANSS and BPRS scores in the control group.

Conclusions: This study showed the potential of horticultural therapy in improving psychopathological symptoms in psychiatric patients. Future studies should investigate the effects of long-term horticultural therapy program on the chronic symptoms of patients with schizophrenia.


Abstract:

We investigate the effects of a massage therapy program (MTP) in cortisol concentration (CC), intensity of pain, quality of life and perceived stress index of fibromyalgia patients. Volunteers (n = 24, aged 26–55 years) were treated with MT, twice a week for three months. They answered the Fibromyalgia Impact Questionnaire (FIQ), Perceived Stress Questionnaire (PSQ) and McGill Pain Questionnaire (MPQ-Br), and collected saliva to evaluate CC before and after the end of each month. The MT had improvement in quality of life, according to the FIQ results, and promoted reduction in PSQ values after the second (PSQ2-0.62 ± 0.04vsPSQ0-0.71 ± 0.04) and third month (PSQ3–0.64 ± 0.04vsPSQ0-0.71 ± 0.04). The MTP also promoted reduction in pain after the third month (MQP-Br1-44.50 ± 2.15vsMQP-Br4–35.38 ± 3.71). Despite PSQ reduction, the CC were not affected by the program. This pilot suggests that this treatment improved quality of life, reduced perceived stress index and pain in these volunteers.


Abstract:

Objectives: This study aimed at finding out the effects of reflexology on pain, anxiety levels after abdominal hysterectomy.

Design & methods: The study was performed on women hospitalized in the intensive care unit and gynecology services of Ege University Hospital in İzmir after abdominal hysterectomy between September 2013 and September 2014. This study was designed
and conducted as a randomized controlled trial. The study sample consisted of 63 female patients: 32 in the experimental group and 31 in the control group. The postoperative daily monitoring sheet, Spielberger State Anxiety Inventory (SAI), was employed to collect research data and “visual analog scale” to evaluate pain levels.

**Results:** The female patients’ average age was found to be 47.23 ± 4.71. The three-day monitoring showed a significant difference between the experimental and control groups in terms of average pain levels and anxiety scores after reflexology (p < 0.05).

**Conclusion:** Foot reflexology may serve as an effective nursing intervention to increase the well-being and decrease the pain of female patients after abdominal hysterectomy, and nurses should be aware of the benefits of reflexology.


**Abstract:**

Passiflora incarnata is marketed in many countries as anxiolytic herbal supplement. Herbal medicines are natural products, but it doesn't mean they are always safe, especially during pregnancy. Passiflora incarnata extract was not teratogenic in experimental studies. However, there are no data available on possible effects on human pregnancy. Here we report five pregnant women with depression and/or anxiety who used passiflora incarnata in pregnancy. We observed one pregnancy resulting in neonatal death, two pregnancies with premature rupture of membranes, two infants with meconium aspiration syndrome and one infant with persistent pulmonary hypertension. No birth defects and no growth or developmental abnormalities for the live born infants were reported at 6 months of age. This observation is important since there have been no human reports about the use of passiflora incarnata in pregnant women. Pregnant women exposed to passiflora incarnata should be monitored, unless further data are available.


**Abstract:**

**Objectives:** Multimorbidity is common, but often poorly managed, among the rapidly growing population of older adults. The existing guidelines followed by physicians frequently lead to polypharmacy and a complex treatment burden. The objective of this study was to explore what benefits are perceived by older adults with multimorbidity as a result of long-term, regular acupuncture treatment.

**Design:** A qualitative design with inductive thematic analysis of semistructured interviews.
**Settings/Location:** Participants were recruited from a no-cost, college-affiliated acupuncture clinic for low-income older adults in an urban, racially/ethnically diverse neighborhood in southern California.

**Participants:** Fifteen patients aged 60 years and older suffering from at least two chronic conditions.

**Results:** Five themes were identified: (1) mind-body effects, (2) the enhanced therapeutic alliance, (3) what they liked best, (4) the conventional healthcare system, and (5) importance of regular schedule. A notable mind-body effect, reported by a substantial number of participants, was medication reduction. Participants also cited changes in mood, energy, and well-being as important benefits. In addition, they voiced widespread dissatisfaction with conventional healthcare. Keeping up regular treatments as a way to deal with new complaints and encourage a healthier lifestyle was seen an important aspect of care at the clinic.

**Conclusions:** This cohort of older adults with multimorbidity valued acupuncture as a way to reduce medication as well as a means to maintain physical and mental health. In addition, they developed a strong trust in the clinic's ability to support the totality of their health as individuals, which they contrasted to the specialized and impersonal approach of the conventional medical clinic.


**Parthasarathy Vishpala. Homoeopathy: To convert a non believer is the name of the game.** *National Journal of Homeopathy 2018; 221 20(02): 17-21p.*


**Abstract:**

Nails are hard and meant for protection and are in the first layer of suppression. Though comparatively nails are least important but has their own importance. Homoeopathy omits nothing. According to nature, nothing exists without a prior cause, similarly nails disorders may have something prior to this. Hahnemann says treat the patient not the disease, similarly nail disorders also be treated holistically, then only cure attained. Here in this article let us see how homeopathy deals with in Grown Nails.

**Rajalakshimi MA. Healing autism with homeopathy.** *Medicina Futura Homoeopathica 2018; 6(2): 13-18p.*


**Rezaei Nodehi Masoud, Shorofi Seyed Afshin, Bagheri Nesami Masoumeh et al.** Effect of pleasant olfactory mental imagery on the incidence and extent of

Abstract:

**Background and purpose:** Atelectasis is the most common pulmonary complication after open heart surgery. This study was intended to examine the effects of pleasant olfactory mental imagery on postoperative atelectasis in patients undergoing open heart surgery.

**Materials and methods:** This is a randomized controlled clinical trial. The sample consisted of 80 patients who were randomly assigned to either practice olfactory mental imagery (test group) or receive routine care (control group). A card with the image of roses was given to patients and they were asked to look at the image, visualize the scent of roses in the mind, and then sniff as much as possible, hold their breath for 2 s and eventually exhale slowly through the nose. This procedure was consecutively repeated five times. After a fifteen-minute break, patients proceeded to practice olfactory mental imagery with other fruit images (banana, apple, and lemon). The test group executed the olfactory mental imagery for two hours in the morning and two hours in the afternoon on postoperative days 1 and 2. The control group received the routine ICU care. A questionnaire collected information on sociodemographic characteristics and clinical parameters. Chest radiographs were used to diagnose atelectasis, which were evaluated by the hospital radiologist.

**Results:** No statistically significant differences were observed between the two groups regarding sociodemographic, medical and surgical information. The incidence of atelectasis in the test group (40%, n = 16) was significantly lower than in the control group (67.5%, n = 27) on postoperative day 2 (p = 0.02).

**Conclusion:** Our findings suggest that olfactory mental imagery can improve respiratory function and reduce the risk of atelectasis in patients with cardiac surgery.


Abstract:

We estimated prevalence rates of complementary and alternative medicine (CAM) use by reason for use (treatment, wellness, or both), and examined perceived benefits of using CAM among U.S. adults with migraines/severe headaches. The 2012 National Health Interview Survey, which represents non-institutionalized adults with migraines/severe headaches (n = 4447 unweighted), were used. Of the study sample, 41.3% used some form of CAM in the past year. Nearly a third of them (29.6%) used CAM for wellness only and 59% used CAM for both wellness and treatment. In given six self-reported perceived benefits, those who used CAM for wellness only and for a combination of both treatment and wellness had higher likelihoods of reporting benefits for all categories (p < 0.05), except for better sleep, when compared to those who used CAM for treatment only. CAM
use was associated with an improvement in several health-related quality of life outcomes in U.S. adults with migraines/severe headaches.


Abstract:

Objectives: This study examined the effect of spiritual counseling on the spiritual well-being of Iranian women with cancer.

Design and setting: a randomized clinical trial was conducted on 42 female cancer patients who were randomized to either an 8-week spiritual counseling intervention (n = 21) or a control group that received routine education/care (n = 21). Spiritual well-being (SWB) was assessed before and after the 8-week spiritual counseling program using Paloutzian and Ellison’s (1983) Spiritual Well-Being Scale (SWBS).

Results: There were no significant differences on SWBS and its two subscales scores (RWB and EWB) between intervention and control groups at baseline (p > .05). After intervention, there was a significant mean difference in SWB (p = .001), RWB (p = .013) and EWB (p = .001) in two groups.

Conclusions: Spiritual counseling is associated with significant improvements in SWB in Iranian women with cancer. Interventions that acknowledge the spiritual needs of these patients should be incorporated into conventional treatments.


Abstract:

Objectives: The study aimed to investigate the prevalence of CAM users among asthmatic patients in a tertiary care South Indian hospital.

Methods: Prospective, cross sectional study was conducted in 394 asthmatic patients.

Results: 30.4% of the patients used CAM therapies. The most commonly used CAM treatment was herbal medicine followed by pranayama (controlled breathing exercises). Most of the CAM users were found to be in lower middle class. The baseline characteristics of the CAM users and the non CAM users were found to be similar except for education and socioeconomic status (p < .008). Among the CAM users, none of the patients disclosed about their CAM treatment to their pulmonologists.
**Conclusion:** Patients must be educated about CAM therapies and they must be advised to discuss all their treatment related issues with treating clinicians. Healthcare professionals should be familiar with the merits and demerits of using CAM therapy so that they could provide proper guidance to their patients.


**Abstract:**

**Objectives:** Mucuna pruriens (MP) seeds contain levodopa (up to 2% by weight) and have been used in traditional Indian medicine to treat an illness named “Kampavata,” now understood to be Parkinson’s disease (PD). Studies have shown MP to be beneficial, and even superior, to levodopa alone in treating PD symptoms. Commercial products containing MP are readily available from online and retail sources to patients and physicians. Products often contain extracts of MP seeds, with significantly higher levodopa content than the seeds. However, MP products have limited regulatory controls with respect to quality and content of active ingredient. The aim of this study was to apply a quantitative method to determine levodopa content in readily available MP products that might be used by patients or in research studies.

**Design:** Levodopa present in six commercial MP products was quantified by solvent extraction followed by reversed-phase high-performance liquid chromatography (HPLC) coupled to fluorescence detection (FD). Certificates of analysis (COA) were obtained, from manufacturers of MP products, to assess the existence and implementation of specifications for levodopa content.

**Results:** HPLC-FD analysis revealed that the levodopa content of the six commercial MP products varied from 6% to 141% of individual label claims. No product contained levodopa within normal pharmacopeial limits of 90%–110% label claim. The maximum daily dose of levodopa delivered by the products varied from 14.4 to 720 mg/day. COAs were inconsistent in specifications for and verification of levodopa content.

**Conclusions:** The commercial products tested varied widely in levodopa content, sometimes deviating widely from the label claim. These deficiencies could impact efficacy and safety of MP products used by PD patients and compromise the results of scientific studies on MP products. The HPLC-FD method described in this study could be utilized by both manufacturers and scientific researchers to verify levodopa content of MP products.
Abstract:

Objective: This study aims at analyzing the effect of music on pain and anxiety felt by women in labor during their first pregnancy.

Method: When the pregnant women in the experimental group progressed into the active phase of the labor, they were made to listen to music in Acemasiran mode with earplugs for 3 h (20 min of listening with 10-min breaks).

Findings: It was observed that after the first-hour women indicated that their pain was statistically less in the experimental group. Trait anxiety scores of the women in labor were similar for experimental and control groups. Following the practice, state anxiety average scores became lower in favor of the experimental group and the correlation was statistically significant.

Conclusion: In order to facilitate women's coping with labor pain and improve their wellbeing with the activity during the labor, musicotherapy, a non-pharmacological method, is an effective, simple and economical method.


Abstract:

Acupuncture (ACU) is becoming a more common practice among hypertensive individuals. However, the reported therapeutic effects of ACU in lowering brachial blood pressure (BP) are ambiguous. Therefore, evaluating more sensitive markers of arterial functioning might unveil the protective effects of ACU on hypertension. We examined the effects of an 8-week ACU therapy intervention on vascular hemodynamics and stiffness in middle-age hypertensive individuals. Participants were randomly assigned to either ACU (n = 23) or a control group (n = 22). Brachial and aortic BP, wave reflection (AIx) and arterial stiffness (SI) were measured before and after 8 weeks. There was a significant group x time interaction (P < 0.05) for brachial and aortic BP, AIx and SI which significantly decreased (P < 0.05) following ACU but not after control. ACU led to reductions in brachial and aortic BP, wave reflection and arterial stiffness in middle-age hypertensive individuals. ACU might be effective in the prevention and treatment of hypertension.

**Abstract:**

**Objectives:** The effect of tongue cleaning on digestive power is mentioned in Ayurvedic information sources. However, no study has yet evaluated this. We aimed to evaluate the effects of tongue cleaning on digestive power from Ayurvedic viewpoint, and on oral health-related quality of life (OHRQoL) in healthy adults.

**Design:** Randomized cross-over.

**Interventions:** We recruited healthy adults aged 20–60 years. After randomization, the immediate intervention group started tongue cleaning with a tongue scraper every morning for 4 weeks, and then waited for 4 weeks. The delayed intervention group initially waited for 4 weeks, and then started tongue cleaning in the same way.

**Main outcome measures:** We assessed the outcomes using the questionnaire on digestive power from Ayurvedic viewpoint, and the General Oral Health Assessment Index for OHRQoL. We estimated the effects of tongue cleaning using generalized estimating equations (GEE). We also conducted a sensitivity analysis, by comparing the changes in outcomes during the first 4 weeks of both groups.

**Results:** Of 58 participants, 57 completed the study. In GEE analysis, tongue cleaning showed improvement in some components of Ayurvedic digestive power represented by fecal and body conditions. For example, the odds ratio for improvement of constipation was 2.80 (95% CI: 1.04–7.58). The General Oral Health Assessment Index score was significantly increased by 4.33 points (95% CI: 2.18–6.48) after tongue cleaning. In sensitivity analyses, the trends of the results were similar to the main GEE analyses.

**Conclusions:** Tongue cleaning may be an effective method to improve digestive power and OHRQoL.


**Abstract:**

**Background:** The composition of intestinal microbiota is very important in human health. Gastrointestinal disturbances are among the symptoms commonly reported by individuals diagnosed with chronic diseases, such as inflammatory bowel disease, autism, and chronic fatigue syndrome. The effects of probiotics and prebiotics for dysbiosis have been reported in many studies. Bowel nosodes are homeopathic remedies made from human gut microbiota.

**Objective:** Bowel nosodes made from the intestinal bacteria of European patients from the 1900s were administered to Japanese patients suffering from gastrointestinal
disturbances, such as constipation and diarrhea, to determine their therapeutic efficacy.

Methods: Twenty-eight outpatients from Yoko Clinic (11 males, 17 females; age range, 4–72 years) were enrolled in this study. One nosode remedy was selected for each case. Patients took six pills for 2 days. After a month, the effect of each treatment was evaluated using the Glasgow Homeopathic Hospital Outcome Scale (grade +4 to −4).

Results: Patient number of each grade was +4 (N = 2), +3 (N = 4), +2 (N = 7), +1 (N = 3), 0 (N = 7), with no negative grades. Of the 23 patients analyzed, 69.6% showed some type of improvement, and no harmful effects from taking bowel nosodes were observed; 26% of patients showed major improvement or were “cured.”

Conclusion: It is difficult to find correct constitutional remedies as they often require high-level techniques and time. Since there are only 11 main bowel nosode remedies, they are easier to choose from and cheaper to use and develop than classical constitutional remedies. Herein, 69.6% of dysbiotic patients taking bowel nosodes showed improvements, and no harmful effects were reported by any patient. These results suggest that the homeopathic bowel nosodes are a useful method for controlling gastrointestinal disturbances.


Abstract:

Background and aim: Premenstrual Syndrome (PMS) is a health problem which begins approximately one week before menstruation in women occurs as a set of physical and psychological symptoms. This study aimed to determine the effect of aromatherapy on coping with premenstrual syndrome in university students.

Methods: A randomized controlled trial design was used. This study included 40 students in the intervention and 37 students in the control groups. Data was collected by questionnaire form and PMS scale. The intervention and control groups were followed up for 3 cycles in terms of PMS symptoms. The method of inhalation aromatherapy by lavender oil was applied for 5 sessions on average for each cycle.

Results: When PMS mean scores of the intervention and control groups during 3 follow-up periods were compared, it was found that there is a statistically significant difference between intervention and control groups (p < 0.05). It was determined that there is a statistically significant difference between the groups in terms of PMS scale and sub-dimensions of anxiety, depressive affect, nervousness, pain, bloating, depressive thoughts mean scores of pre-test and 3rd follow-up (p < 0.05),

Conclusions: It was concluded that inhalation aromatherapy can be used for coping with PMS. It is recommended that the students suffering from PMS problems should be informed on the inhalation therapy by lavender oil.


**Abstract:**

**Objective:** Yoga has been shown to improve muscle strength, flexibility, and balance. However, the impact of meditation on dynamic factors such as gait, reactive balance and proprioception has yet to be examined. The purpose of this study was to test if a novel yoga meditation program (YoMed) is as effective as a standard proprioceptive training in improving proprioception, balance and power in older individuals who have fallen.

**Design:** Sixteen older persons were randomly assigned to either the YoMed Group (YM) or Proprioception Training Group (PT). Each group received 45 min of training, 3 days per week, for 6 weeks. Pretest and post-test outcome measures were used to quantify the comparative effects of the interventions.

**Setting:** Research Laboratory.

**Interventions:** Yoga meditation and proprioceptive training.

**Main outcome measures:** The Balance Error Scoring System (BESS), the Tenetti Balance and Gait Assessment, dynamic posturography, joint position sense, joint kinesthesia and leg extensor power.

**Results:** The primary findings of the study were that neither the YM or PT intervention groups showed statistical improvements in any variable with the exception of the dynamic posturography overall score (DMA), which showed a significant improvement by the YM group (d = 1.238; p = 0.049). Additionally changes in a number of variables that did not reach significance demonstrated effect sizes in the medium to high range.

**Conclusion:** These results indicate the potential for the YoMed program to be used as a clinical intervention in older individuals. Given these results a longer study using a larger sample size and individuals at higher risk of falling is warranted.


**Abstract:**

**Objective:** The existing eligible randomized controlled trials (RCTs) were critically appraised for the effectiveness and safety of Chinese herbal medicine Dengzhan Shenmai for ischemic stroke.
**Design:** Systematic review and meta-analysis (CRD42016042914, http://www.crd.york.ac.uk/PROSPERO).

**Methods:** Six electronic databases were searched from inception to May 2016. Risk ratio (RR) and mean difference (MD) with a 95% confidence interval (CI) were used as effect estimates using RevMan 5.3. Meta-analysis was performed where data were available. A summary of finding table was generated by the GRADEpro (version 3.6).

**Results:** We identified 14 RCTs involving 5206 participants. Majority of the included trials were of high risk of bias in methodological quality. For acute ischemic stroke, adding DZSM capsule to conventional therapy achieved higher Barthel Index scores (MD 22.37, 95% CI 21.34–23.40), lower neurological function deficit scores (MD –3.73, 95% CI –5.27 to –2.19) and lower recurrence rate (RR 0.22, 95% CI 0.10, 0.46). For patients in their convalescence (or sequelae) stage of ischemic stroke, DZSM capsule was superior in improving quality of life (MD 28.8, 95% CI 7.10–50.50) and recurrence rate (RR 0.71, 95% CI 0.51–0.99) compared to placebo. No trials reported serious adverse events.

**Conclusion:** DZSM capsule appears to improve neurological function, quality of life, and reduce recurrence rate based on conventional therapy for ischemic stroke. DZSM capsule seems generally safe for clinical application. However, the findings of benefit are inconclusive due to generally weak evidence, and further large, rigorous trials are still warranted.


**Abstract:**

Herbal medicines have long been used to treat and prevent viral respiratory infections (VRI). Here, a broad survey of these herbs is provided. The effects and benefits of a wide array of antiviral herbs are discussed in depth. The benefit of most of these herbs having built-in immune-stimulating and inflammation-modulating effects means that they can help prevent immune overreaction (“cytokine storm”) to VRI while still helping the immune system cope better with the infections. The scientific basis supporting these contentions are discussed. Major herbs with clinical trial evidence that they help resolve VRI reviewed in detail include Sambucus nigra (black elder) fruit, BNO 1016 (Sinupret®) formula, Andrographis paniculata (kalmegh), Pelargonium sidoides (African geranium), má huáng tāng (maō-tō, ephedra decoction), and antiwei formula. The failure of research on Echinacea angustifolia (narrow-leaved purple coneflower), particularly by using far too low of doses, is reviewed. An individualized approach to formulating for VRI patients is presented, followed by a review of the evidence that various herbs, notably Panax ginseng (Asian red ginseng), Panax quinquefolius (American ginseng), Camellia sinensis (green tea), and Allium sativum (garlic), can prevent VRI.

Abstract:

**Objectives:** To examine the effectiveness of a 12-week lifestyle program on cardiometabolic, behavioral, and psychological outcomes among overweight Hispanic children and adolescents.

**Design:** A case series study with pre- and post-test analyses.

**Subjects/Settings/Location:** A convenience sample of high-risk pediatric primary care patients (n = 22; 6 girls, 16 boys; M age = 11.73 ± 1.39 years) and their guardians in the Southeast United States.

**Intervention:** Twice per week 60 min (total of 24 h) of moderate-to-vigorous intensity boxing exercise training, 12 h of nutrition education for guardians, and a 30-min pediatrician appointment.

**Outcome measures:** Cardiometabolic (height [m], weight [kg], waist circumference [cm], body-mass index [BMI], BMI-z, BMI%, cholesterol [mg/dL], triglycerides [mg/dL], glucose [mg/dL], and low-density lipoprotein and high-density lipoprotein cholesterol [mg/dL]), behavioral (objective free time physical activity [PA] and sedentary time [min/day]), and psychological (self-determined exercise motivation) outcomes were measured/calculated, and paired-samples t-tests were conducted.

**Results:** A significant reduction was observed in waist circumference t(17) = −2.57, p = 0.020, d = 0.64; BMI% t(15) = −2.53, p = 0.023, d = 0.20; fasting glucose t(15) = −6.43, p < 0.001, d = 1.67; and amotivation (−) t(17) = −2.29, p = 0.036, d = 0.64; whereas a significant increase was identified in moderate t(10) = 4.01, p = 0.002, d = 1.23 and vigorous t(10) = 3.41, p = 0.007, d = 1.07 intensity PA; intrinsic motivation t(17) = 2.71, p = 0.015, d = 0.38; and introjected regulation t(17) = 2.74, p = 0.014, d = 0.64.

**Conclusions:** A 12-week lifestyle program can be effective in improving selected health markers among overweight Hispanic children and adolescents. The positive changes in fasting glucose, BMI, and waist suggest that the participants are currently at lower risk for both type 2 diabetes and cardiovascular disease as a result of the Confidence, Ownership, Responsibility, and Exercise program.


Abstract:

Juggling-exposure therapy has been employed in the management of anxiety and post-traumatic stress disorder. However, there is little evidence of the effectiveness of juggling-exposure in improving emotional states in subclinical conditions. This study aimed at evaluating the effect of a course of juggling on emotional states, sleep quality and blood pressure among medical students at a critical stage of their academic training. Blood pressure, psychometric and quality of sleep assessments were performed pre- and post-examination period for two groups of students: juggling-exposed (n = 9) and non-juggling-exposed (n = 11). Juggling exposure consisted of practice-drills for one
hour per week during the period spanning the student’s scheduled exams. Comparisons were made between quantitative measures that were collected pre- and post-the course of juggling drills. Differences in scores and measures were expressed as percentage-change and compared between non-juggling and juggling groups. Overall, there was a decrease in depression and anxiety scores between the pre-to post-exam periods. This decrease was statistically significant for both non-juggling and juggling groups with respect to anxiety, but only the juggling-exposed group had a significant reduction regarding depression scores. However, when calculated as percentage-change over the pre-to post-exam period, there was no significant difference in any of the parameters for either of the two groups. Practicing juggling drills had an influence on emotional states.


Abstract:

Objective: In spite of supportive care for people affected by cancer being well recognized as a priority for research, there is little solid evidence of the effectiveness of psychological interventions using mindfulness for those with advanced cancer. This systematic review aims to describe, evaluate and synthesize the acceptability and potential benefits of mindfulness-based interventions (MBIs) for the psychological well-being of people with advanced cancers.

Methods: Eight databases were searched and terms related to advanced stages of cancer and mindfulness were combined systematically to identify relevant published literature. Inclusion criteria were studies with adults only and all types of cancer at stages III and IV. There was considerable variety in the MBI treatment packages including in the extent and centrality of mindfulness in the interventions.

Results: Of 312 identified studies, only 8 included MBIs for people with advanced cancer rather than their families or carers. Results from these studies suggests that MBIs are acceptable and beneficial to the advanced cancer population, improving quality of life, use of mindfulness skills, acceptance of their cancer situation and reduction in depression and anxiety. Some adaptations were recommended however regarding delivery, simplified briefer MBIs, abbreviated session time, flexibility concerning locality of treatment and a minimized questionnaire burden for this group.

Conclusions: MBI packages reviewed in this study had evidence of acceptability and of effectiveness, indicating potential benefit for this population. Individualized, including home-based interventions may be optimal to allow critically ill patients to participate in treatment. In future, MBIs adapted to the needs of various advanced cancer patients are recommended to address the gap in the field and improve health care.
**Allied System**


*Changing culture to end FGM. Lancet 2018; 391(10119): 401p.*


**Abstract:**

**Background:** Arthroscopic sub-acromial decompression (decompressing the sub-acromial space by removing bone spurs and soft tissue arthroscopically) is a common surgery for subacromial shoulder pain, but its effectiveness is uncertain. We did a study to assess its effectiveness and to investigate the mechanism for surgical decompression.

**Methods:** We did a multicentre, randomised, pragmatic, parallel group, placebo-controlled, three-group trial at 32 hospitals in the UK with 51 surgeons. Participants were patients who had subacromial pain for at least 3 months with intact rotator cuff tendons, were eligible for arthroscopic surgery, and had previously completed a non-operative management programme that included exercise therapy and at least one steroid injection. Exclusion criteria included a full-thickness torn rotator cuff. We randomly assigned participants (1:1:1) to arthroscopic subacromial decompression, investigational arthroscopy only, or no treatment (attendance of one reassessment appointment with a specialist shoulder clinician 3 months after study entry, but no intervention). Arthroscopy only was a placebo as the essential surgical element (bone and soft tissue removal) was omitted. We did the randomisation with a computer-generated minimisation system. In the surgical intervention groups, patients were not told which type of surgery they were receiving (to ensure masking). Patients were followed up at 6 months and 1 year after randomisation; surgeons coordinated their
waiting lists to schedule surgeries as close as possible to randomisation. The primary outcome was the Oxford Shoulder Score (0 [worst] to 48 [best]) at 6 months, analysed by intention to treat. The sample size calculation was based upon a target difference of 4·5 points (SD 9·0). This trial has been registered at ClinicalTrials.gov, number NCT01623011.

**Findings:** Between Sept 14, 2012, and June 16, 2015, we randomly assigned 313 patients to treatment groups (106 to decompression surgery, 103 to arthroscopy only, and 104 to no treatment). 24 [23%], 43 [42%], and 12 [12%] of the decompression, arthroscopy only, and no treatment groups, respectively, did not receive their assigned treatment by 6 months. At 6 months, data for the Oxford Shoulder Score were available for 90 patients assigned to decompression, 94 to arthroscopy, and 90 to no treatment. Mean Oxford Shoulder Score did not differ between the two surgical groups at 6 months (decompression mean 32·7 points [SD 11·6] vs arthroscopy mean 34·2 points [9·2]; mean difference −1·3 points [95% CI −3·9 to 1·3, p=0·3141]). Both surgical groups showed a small benefit over no treatment (mean 29·4 points [SD 11·9], mean difference vs decompression 2·8 points [95% CI 0·5–5·2], p=0·0186; mean difference vs arthroscopy 4·2 [1·8–6·6], p=0·0014) but these differences were not clinically important. There were six study-related complications that were all frozen shoulders (in two patients in each group).

**Interpretation:** Surgical groups had better outcomes for shoulder pain and function compared with no treatment but this difference was not clinically important. Additionally, surgical decompression appeared to offer no extra benefit over arthroscopy only. The difference between the surgical groups and no treatment might be the result of, for instance, a placebo effect or postoperative physiotherapy. The findings question the value of this operation for these indications, and this should be communicated to patients during the shared treatment decision-making process.

**Funding:** Arthritis Research UK, the National Institute for Health Research Biomedical Research Centre, and the Royal College of Surgeons (England).


**Abstract:**

The realisation of human potential for development requires age-specific investment throughout the 8000 days of childhood and adolescence. Focus on the first 1000 days is an essential but insufficient investment. Intervention is also required in three later phases: the middle childhood growth and consolidation phase (5–9 years), when infection and malnutrition constrain growth, and mortality is higher than previously recognised; the adolescent growth spurt (10–14 years), when substantial changes place commensurate demands on good diet and health; and the adolescent phase of growth and consolidation (15–19 years), when new responses are needed to support brain maturation, intense social engagement, and emotional control. Two cost-efficient packages, one delivered through schools and one focusing on later adolescence, would provide phase-specific support across the life cycle, securing the gains of investment in
the first 1000 days, enabling substantial catch-up from early growth failure, and leveraging improved learning from concomitant education investments.


Abstract:

**Background:** Internationally, the clinical outcomes of routine mental health services are rarely recorded or reported; however, an exception is the English Improving Access to Psychological Therapies (IAPT) service, which delivers psychological therapies recommended by the National Institute for Health and Care Excellence for depression and anxiety disorders to more than 537 000 patients in the UK each year. A session-by-session outcome monitoring system ensures that IAPT obtains symptom scores before and after treatment for 98% of patients. Service outcomes can then be reported, along with contextual information, on public websites.

**Methods:** We used publicly available data to identify predictors of variability in clinical performance. Using β regression models, we analysed the outcome data released by National Health Service Digital and Public Health England for the 2014–15 financial year (April 1, 2014, to March 31, 2015) and developed a predictive model of reliable improvement and reliable recovery. We then tested whether these predictors were also associated with changes in service outcome between 2014–15 and 2015–16.

**Findings:** Five service organisation features predicted clinical outcomes in 2014–15. Percentage of cases with a problem descriptor, number of treatment sessions, and percentage of referrals treated were positively associated with outcome. The time waited to start treatment and percentage of appointments missed were negatively associated with outcome. Additive odd ratios suggest that moving from the lowest to highest level on an organisational factor could improve service outcomes by 11–42%, dependent on the factor. Consistent with a causal model, most organisational factors also predicted between-year changes in outcome, together accounting for 33% of variance in reliable improvement and 22% for reliable recovery. Social deprivation was negatively associated with some outcomes, but the effect was partly mitigated by the organisational factors.

**Interpretation:** Traditionally, efforts to improve mental health outcomes have largely focused on the development of new and more effective treatments. Our analyses show that the way psychological therapy services are implemented could be similarly important. Mental health services elsewhere in the UK and in other countries might
benefit from adopting IAPT's approach to recording and publicly reporting clinical outcomes.

**Funding:** Wellcome Trust.


**Abstract:**

**Background:** Large-scale and contemporary population-based studies of heart failure incidence are needed to inform resource planning and research prioritisation but current evidence is scarce. We aimed to assess temporal trends in incidence and prevalence of heart failure in a large general population cohort from the UK, between 2002 and 2014.

**Methods:** For this population-based study, we used linked primary and secondary electronic health records of 4 million individuals from the Clinical Practice Research Datalink (CPRD), a cohort that is representative of the UK population in terms of age and sex. Eligible patients were aged 16 years and older, had contributed data between Jan 1, 2002, and Dec 31, 2014, had an acceptable record according to CPRD quality control, were approved for CPRD and Hospital Episodes Statistics linkage, and were registered with their general practice for at least 12 months. For patients with incident heart failure, we extracted the most recent measurement of baseline characteristics (within 2 years of diagnosis) from electronic health records, as well as information about comorbidities, socioeconomic status, ethnicity, and region. We calculated standardised rates by applying direct age and sex standardisation to the 2013 European Standard Population, and we inferred crude rates by applying year-specific, age-specific, and sex-specific incidence to UK census mid-year population estimates. We assumed no heart failure for patients aged 15 years or younger and report total incidence and prevalence for all ages (>0 years).

**Findings:** From 2002 to 2014, heart failure incidence (standardised by age and sex) decreased, similarly for men and women, by 7% (from 358 to 332 per 100 000 person-years; adjusted incidence ratio 0·93, 95% CI 0·91–0·94). However, the estimated absolute number of individuals with newly diagnosed heart failure in the UK increased by 12% (from 170 727 in 2002 to 190 798 in 2014), largely due to an increase in population size and age. The estimated absolute number of prevalent heart failure cases in the UK increased even more, by 23% (from 750 127 to 920 616). Over the study period, patient age and multi-morbidity at first presentation of heart failure increased (mean age 76·5 years [SD 12·0] to 77·0 years [12·9], adjusted difference 0·79 years, 95% CI 0·37–1·20; mean number of comorbidities 3·4 [SD 1·9] vs 5·4 [2·5]; adjusted difference 2·0, 95% CI 1·9–2·1). Socioeconomically deprived individuals were more likely to develop heart failure than were affluent individuals (incidence rate ratio 1·61, 95% CI 1·58–1·64), and did so earlier in life than those from the most affluent group (adjusted difference −3·51 years, 95% CI −3·77 to −3·25). From 2002 to 2014, the socioeconomic gradient in age at first presentation with heart failure widened. Socioeconomically deprived individuals also had more comorbidities, despite their younger age.
Interpretation: Despite a moderate decline in standardised incidence of heart failure, the burden of heart failure in the UK is increasing, and is now similar to the four most common causes of cancer combined. The observed socioeconomic disparities in disease incidence and age at onset within the same nation point to a potentially preventable nature of heart failure that still needs to be tackled.

Funding: British Heart Foundation and National Institute for Health Research.


Abstract:

**Background:** The Zika virus epidemic and associated congenital infections have prompted rapid vaccine development. We assessed two new DNA vaccines expressing premembrane and envelope Zika virus structural proteins.

**Methods:** We did two phase 1, randomised, open-label trials involving healthy adult volunteers. The VRC 319 trial, done in three centres, assessed plasmid VRC5288 (Zika virus and Japanese encephalitis virus chimera), and the VRC 320, done in one centre, assessed plasmid VRC5283 (wild-type Zika virus). Eligible participants were aged 18–35 years in VRC19 and 18–50 years in VRC 320. Participants were randomly assigned 1:1 by a computer-generated randomisation schedule prepared by the study statistician. All participants received intramuscular injection of 4 mg vaccine. In VRC 319 participants were assigned to receive vaccinations via needle and syringe at 0 and 8 weeks, 0 and 12 weeks, 0, 4, and 8 weeks, or 0, 4, and 20 weeks. In VRC 320 participants were assigned to receive vaccinations at 0, 4, and 8 weeks via single-dose needle and syringe injection in one deltoid or split-dose needle and syringe or needle-free injection with the Stratis device (Pharmajet, Golden, CO, USA) in each deltoid. Both trials followed up volunteers for 24 months for the primary endpoint of safety, assessed as local and systemic reactogenicity in the 7 days after each vaccination and all adverse events in the 28 days after each vaccination. The secondary endpoint in both trials was immunogenicity 4 weeks after last vaccination. These trials are registered with ClinicalTrials.gov, numbers NCT02840487 and NCT02996461.

**Findings:** VRC 319 enrolled 80 participants (20 in each group), and VRC 320 enrolled 45 participants (15 in each group). One participant in VRC 319 and two in VRC 320
withdrew after one dose of vaccine, but were included in the safety analyses. Both vaccines were safe and well tolerated. All local and systemic symptoms were mild to moderate. In both studies, pain and tenderness at the injection site was the most frequent local symptoms (37 [46%] of 80 participants in VRC 319 and 36 [80%] of 45 in VRC 320) and malaise and headache were the most frequent systemic symptoms (22 [27%] and 18 [22%], respectively, in VRC 319 and 17 [38%] and 15 [33%], respectively, in VRC 320). For VRC5283, 14 of 14 (100%) participants who received split-dose vaccinations by needle-free injection had detectable positive antibody responses, and the geometric mean titre of 304 was the highest across all groups in both trials.

**Interpretation:** VRC5283 was well tolerated and has advanced to phase 2 efficacy testing.

**Funding:** Intramural Research Program of the Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Jaffe Susan. CDC faces leadership changes, potential spending cuts. *Lancet 2018; 391(10121): 644-45p*


**Abstract:**

The 2013–16 Ebola virus disease outbreak in west Africa was associated with unprecedented challenges in the provision of care to patients with Ebola virus disease, including absence of pre-existing isolation and treatment facilities, patients’ reluctance to present for medical care, and limitations in the provision of supportive medical care. Case fatality rates in west Africa were initially greater than 70%, but decreased with improvements in supportive care. To inform optimal care in a future outbreak of Ebola virus disease, we employed the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology to develop evidence-based guidelines for the delivery of supportive care to patients admitted to Ebola treatment units. Key recommendations include administration of oral and, as necessary, intravenous hydration; systematic monitoring of vital signs and volume status; availability of key biochemical testing; adequate staffing ratios; and availability of analgesics, including opioids, for pain relief.


**Abstract:**

**Background:** Type 2 diabetes is a chronic disorder that requires lifelong treatment. We aimed to assess whether intensive weight management within routine primary care would achieve remission of type 2 diabetes.

**Methods:** We did this open-label, cluster-randomised trial (DiRECT) at 49 primary care practices in Scotland and the Tyneside region of England. Practices were randomly
assigned (1:1), via a computer-generated list, to provide either a weight management programme (intervention) or best-practice care by guidelines (control), with stratification for study site (Tyne-side or Scotland) and practice list size (>5700 or ≤5700). Participants, carers, and research assistants who collected outcome data were aware of group allocation; however, allocation was concealed from the study statistician. We recruited individuals aged 20–65 years who had been diagnosed with type 2 diabetes within the past 6 years, had a body-mass index of 27–45 kg/m², and were not receiving insulin. The intervention comprised withdrawal of antidiabetic and antihypertensive drugs, total diet replacement (825–853 kcal/day formula diet for 3–5 months), stepped food reintroduction (2–8 weeks), and structured support for long-term weight loss maintenance. Co-primary outcomes were weight loss of 15 kg or more, and remission of diabetes, defined as glycated haemoglobin (HbA1c) of less than 6·5% (<48 mmol/mol) after at least 2 months off all antidiabetic medications, from baseline to 12 months. These outcomes were analysed hierarchically. This trial is registered with the ISRCTN registry, number 03267836.

Findings: Between July 25, 2014, and Aug 5, 2017, we recruited 306 individuals from 49 intervention (n=23) and control (n=26) general practices; 149 participants per group comprised the intention-to-treat population. At 12 months, we recorded weight loss of 15 kg or more in 36 (24%) participants in the intervention group and no participants in the control group (p<0·0001). Diabetes remission was achieved in 68 (46%) participants in the intervention group and six (4%) participants in the control group (odds ratio 19·7, 95% CI 7·8–49·8; p<0·0001). Remission varied with weight loss in the whole study population, with achievement in none of 76 participants who gained weight, six (7%) of 89 participants who maintained 0–5 kg weight loss, 19 (34%) of 56 participants with 5–10 kg loss, 16 (57%) of 28 participants with 10–15 kg loss, and 31 (86%) of 36 participants who lost 15 kg or more. Mean bodyweight fell by 10·0 kg (SD 8·0) in the intervention group and 1·0 kg (3·7) in the control group (adjusted difference −8·8 kg, 95% CI −10·3 to −7·3; p<0·0001). Quality of life, as measured by the EuroQol 5 Dimensions visual analogue scale, improved by 7·2 points (SD 21·3) in the intervention group, and decreased by 2·9 points (15·5) in the control group (adjusted difference 6·4 points, 95% CI 2·5–10·3; p=0·0012). Nine serious adverse events were reported by seven (4%) of 157 participants in the intervention group and two were reported by two (1%) participants in the control group. Two serious adverse events (biliary colic and abdominal pain), occurring in the same participant, were deemed potentially related to the intervention. No serious adverse events led to withdrawal from the study.

Interpretation: Our findings show that, at 12 months, almost half of participants achieved remission to a non-diabetic state and off antidiabetic drugs. Remission of type 2 diabetes is a practical target for primary care.

Funding: Diabetes UK.

Abstract:

Background: Extended-release naltrexone (XR-NTX), an opioid antagonist, and sublingual buprenorphine-naloxone (BUP-NX), a partial opioid agonist, are pharmacologically and conceptually distinct interventions to prevent opioid relapse. We aimed to estimate the difference in opioid relapse-free survival between XR-NTX and BUP-NX.

Methods: We initiated this 24 week, open-label, randomised controlled, comparative effectiveness trial at eight US community-based inpatient services and followed up participants as outpatients. Participants were 18 years or older, had Diagnostic and Statistical Manual of Mental Disorders-5 opioid use disorder, and had used non-prescribed opioids in the past 30 days. We stratified participants by treatment site and opioid use severity and used a web-based permuted block design with random equally weighted block sizes of four and six for randomisation (1:1) to receive XR-NTX or BUP-NX. XR-NTX was monthly intramuscular injections (Vivitrol; Alkermes) and BUP-NX was daily self-administered buprenorphine-naloxone sublingual film (Suboxone; Indivior). The primary outcome was opioid relapse-free survival during 24 weeks of outpatient treatment. Relapse was 4 consecutive weeks of any non-study opioid use by urine toxicology or self-report, or 7 consecutive days of self-reported use. This trial is registered with ClinicalTrials.gov, NCT02032433.

Findings: Between Jan 30, 2014, and May 25, 2016, we randomly assigned 570 participants to receive XR-NTX (n=283) or BUP-NX (n=287). The last follow-up visit was Jan 31, 2017. As expected, XR-NTX had a substantial induction hurdle: fewer participants successfully initiated XR-NTX (204 [72%] of 283) than BUP-NX (270 [94%] of 287; p<0·0001). Among all participants who were randomly assigned (intention-to-treat population, n=570) 24 week relapse events were greater for XR-NTX (185 [65%] of 283) than for BUP-NX (163 [57%] of 287; hazard ratio [HR] 1·36, 95% CI 1·10–1·68), most or all of this difference accounted for by early relapse in nearly all (70 [89%] of 79) XR-NTX induction failures. Among participants successfully inducted (per-protocol population, n=474), 24 week relapse events were similar across study groups (p=0·44). Opioid-negative urine samples (p<0·0001) and opioid-abstinent days (p<0·0001) favoured BUP-NX compared with XR-NTX among the intention-to-treat population, but were similar across study groups among the per-protocol population. Self-reported opioid craving was initially less with XR-NTX than with BUP-NX (p=0·0012), then converged by week 24 (p=0·20). With the exception of mild-to-moderate XR-NTX injection site reactions, treatment-emergent adverse events including overdose did not differ between treatment groups. Five fatal overdoses occurred (two in the XR-NTX group and three in the BUP-NX group).

Interpretation: In this population it is more difficult to initiate patients to XR-NTX than BUP-NX, and this negatively affected overall relapse. However, once initiated, both medications were equally safe and effective. Future work should focus on facilitating induction to XR-NTX and on improving treatment retention for both medications.

Funding: NIDA Clinical Trials Network.

**Abstract:**

**Background:** Glucocorticoid treatment is recommended as a standard of care in Duchenne muscular dystrophy; however, few studies have assessed the long-term benefits of this treatment. We examined the long-term effects of glucocorticoids on milestone-related disease progression across the lifespan and survival in patients with Duchenne muscular dystrophy.

**Methods:** For this prospective cohort study, we enrolled male patients aged 2–28 years with Duchenne muscular dystrophy at 20 centres in nine countries. Patients were followed up for 10 years. We compared no glucocorticoid treatment or cumulative treatment duration of less than 1 month versus treatment of 1 year or longer with regard to progression of nine disease-related and clinically meaningful mobility and upper limb milestones. We used Kaplan-Meier analyses to compare glucocorticoid treatment groups for time to stand from supine of 5 s or longer and 10 s or longer, and loss of stand from supine, four-stair climb, ambulation, full overhead reach, hand-to-mouth function, and hand function. Risk of death was also assessed. This study is registered with ClinicalTrials.gov, number NCT00468832.

**Findings:** 440 patients were enrolled during two recruitment periods (2006–09 and 2012–16). Time to all disease progression milestone events was significantly longer in patients treated with glucocorticoids for 1 year or longer than in patients treated for less than 1 month or never treated (log-rank p<0·0001). Glucocorticoid treatment for 1 year or longer was associated with increased median age at loss of mobility milestones by 2·1–4·4 years and upper limb milestones by 2·8–8·0 years compared with treatment for less than 1 month. Deflazacort was associated with increased median age at loss of three milestones by 2·1–2·7 years in comparison with prednisone or prednisolone (log-rank p<0·012). 45 patients died during the 10-year follow-up. 39 (87%) of these deaths were attributable to Duchenne-related causes in patients with known duration of glucocorticoids usage. 28 (9%) deaths occurred in 311 patients treated with glucocorticoids for 1 year or longer compared with 11 (19%) deaths in 58 patients with no history of glucocorticoid use (odds ratio 0·47, 95% CI 0·22–1·00; p=0·0501).

**Interpretation:** In patients with Duchenne muscular dystrophy, glucocorticoid treatment is associated with reduced risk of losing clinically meaningful mobility and upper limb disease progression milestones across the lifespan as well as reduced risk of death.

**Funding:** US Department of Education/National Institute on Disability and Rehabilitation Research; US Department of Defense; National Institutes of Health/National Institute of Arthritis and Musculoskeletal and Skin Diseases; and Parent Project Muscular Dystrophy.

**Modjarrad Kayvon, Lin Leyi, George Sarah L et al. Preliminary aggregate safety and immunogenicity results from three trials of a purified inactivated Zika virus**

Abstract:

Background: A safe, effective, and rapidly scalable vaccine against Zika virus infection is needed. We developed a purified formalin-inactivated Zika virus vaccine (ZPIV) candidate that showed protection in mice and non-human primates against viraemia after Zika virus challenge. Here we present the preliminary results in human beings.

Methods: We did three phase 1, placebo-controlled, double-blind trials of ZPIV with aluminium hydroxide adjuvant. In all three studies, healthy adults were randomly assigned by a computer-generated list to receive 5 μg ZPIV or saline placebo, in a ratio of 4:1 at Walter Reed Army Institute of Research, Silver Spring, MD, USA, or of 5:1 at Saint Louis University, Saint Louis, MO, USA, and Beth Israel Deaconess Medical Center, Boston, MA, USA. Vaccinations were given intramuscularly on days 1 and 29. The primary objective was safety and immunogenicity of the ZPIV candidate. We recorded adverse events and Zika virus envelope microneutralisation titres up to day 57. These trials are registered at ClinicalTrials.gov, numbers NCT02963909, NCT02952833, and NCT02937233.

Findings: We enrolled 68 participants between Nov 7, 2016, and Jan 25, 2017. One was excluded and 67 participants received two injections of Zika vaccine (n=55) or placebo (n=12). The vaccine caused only mild to moderate adverse events. The most frequent local effects were pain (n=40 [60%]) or tenderness (n=32 [47%]) at the injection site, and the most frequent systemic reactogenic events were fatigue (29 [43%]), headache (26 [39%]), and malaise (15 [22%]). By day 57, 52 (92%) of vaccine recipients had seroconverted (microneutralisation titre ≥1:10), with peak geometric mean titres seen at day 43 and exceeding protective thresholds seen in animal studies.

Interpretation: The ZPIV candidate was well tolerated and elicited robust neutralising antibody titres in healthy adults.

Funding: Departments of the Army and Defense and National Institute of Allergy and Infectious Diseases.


Abstract:

Background: Canakinumab, a monoclonal antibody targeting interleukin-1β, reduces inflammation and cardiovascular event rates with no effect on lipid concentrations. However, it is uncertain which patient groups benefit the most from treatment and
whether reductions in the inflammatory biomarker high-sensitivity C-reactive protein (hsCRP) correlate with clinical benefits for individual patients.

Methods: The Canakinumab Anti-Inflammatory Thrombosis Outcomes Study (CANTOS) used computer-generated codes to randomly allocate 100,611 men and women with a history of myocardial infarction to placebo or one of three doses of canakinumab (50 mg, 150 mg, or 300 mg) given subcutaneously once every 3 months. In a prespecified secondary analysis designed to address the relationship of hsCRP reduction to event reduction in CANTOS, we evaluated the effects of canakinumab on rates of major adverse cardiovascular events, cardiovascular mortality, and all-cause mortality according to on-treatment concentrations of hsCRP. We used multivariable modelling to adjust for baseline factors associated with achieved hsCRP and multiple sensitivity analyses to address the magnitude of residual confounding. The median follow-up was 3.7 years. The trial is registered with ClinicalTrials.gov, number NCT01327846.

Findings: Baseline clinical characteristics did not define patient groups with greater or lesser cardiovascular benefits when treated with canakinumab. However, trial participants allocated to canakinumab who achieved hsCRP concentrations less than 2 mg/L had a 25% reduction in major adverse cardiovascular events (multivariable adjusted hazard ratio [HRadj]=0.75, 95% CI 0.66–0.85, p<0.0001), whereas no significant benefit was observed among those with on-treatment hsCRP concentrations of 2 mg/L or above (HRadj=0.90, 0.79–1.02, p=0.11). For those treated with canakinumab who achieved on-treatment hsCRP concentrations less than 2 mg/L, cardiovascular mortality (HRadj=0.69, 95% CI 0.56–0.85, p=0.0004) and all-cause mortality (HRadj=0.69, 0.58–0.81, p<0.0001) were both reduced by 31%, whereas no significant reduction in these endpoints was observed among those treated with canakinumab who achieved hsCRP concentrations of 2 mg/L or above. Similar differential effects were found in analyses of the trial prespecified secondary cardiovascular endpoint (which additionally included hospitalisation for unstable angina requiring unplanned revascularisation) and in sensitivity analyses alternatively based on median reductions in hsCRP, on 50% or greater reductions in hsCRP, on the median percent reduction in hsCRP, in dose-specific analyses, and in analyses using a causal inference approach to estimate the effect of treatment among individuals who would achieve a targeted hsCRP concentration.

Interpretation: The magnitude of hsCRP reduction following a single dose of canakinumab might provide a simple clinical method to identify individuals most likely to accrue the largest benefit from continued treatment. These data further suggest that lower is better for inflammation reduction with canakinumab.

Funding: Novartis Pharmaceuticals.

Sinharay Rudy, Gong Jicheng, Barratt Benjamin et al. Respiratory and cardiovascular responses to walking down a traffic-polluted road compared with walking in a traffic-free area in participants aged 60 years and older with chronic lung or heart disease and age-matched healthy controls: A randomised, crossover study. Lancet 2018; 391(10118): 339-49p.
Abstract:

Background: Long-term exposure to pollution can lead to an increase in the rate of decline of lung function, especially in older individuals and in those with chronic obstructive pulmonary disease (COPD), whereas shorter-term exposure at higher pollution levels has been implicated in causing excess deaths from ischaemic heart disease and exacerbations of COPD. We aimed to assess the effects on respiratory and cardiovascular responses of walking down a busy street with high levels of pollution compared with walking in a traffic-free area with lower pollution levels in older adults.

Methods: In this randomised, crossover study, we recruited men and women aged 60 years and older with angiographically proven stable ischaemic heart disease or stage 2 Global initiative for Obstructive Lung Disease (GOLD) COPD who had been clinically stable for 6 months, and age-matched healthy volunteers. Individuals with ischaemic heart disease or COPD were recruited from existing databases or outpatient respiratory and cardiology clinics at the Royal Brompton & Harefield NHS Foundation Trust and age-matched healthy volunteers using advertising and existing databases. All participants had abstained from smoking for at least 12 months and medications were taken as recommended by participants’ doctors during the study. Participants were randomly assigned by drawing numbered disks at random from a bag to do a 2 h walk either along a commercial street in London (Oxford Street) or in an urban park (Hyde Park). Baseline measurements of participants were taken before the walk in the hospital laboratory. During each walk session, black carbon, particulate matter (PM) concentrations, ultrafine particles, and nitrogen dioxide (NO2) concentrations were measured.

Findings: Between October, 2012, and June, 2014, we screened 135 participants, of whom 40 healthy volunteers, 40 individuals with COPD, and 39 with ischaemic heart disease were recruited. Concentrations of black carbon, NO2, PM10, PM2.5, and ultrafine particles were higher on Oxford Street than in Hyde Park. Participants with COPD reported more cough (odds ratio [OR] 1·95, 95% CI 0·96–3·95; p<0·1), sputum (3·15, 1·39–7·13; p<0·05), shortness of breath (1·86, 0·97–3·57; p<0·1), and wheeze (4·00, 1·52–10·50; p<0·05) after walking down Oxford Street compared with Hyde Park. In all participants, irrespective of their disease status, walking in Hyde Park led to an increase in lung function (forced expiratory volume in the first second [FEV1] and forced vital capacity [FVC]) and a decrease in pulse wave velocity (PWV) and augmentation index up to 26 h after the walk. By contrast, these beneficial responses were attenuated after walking on Oxford Street. In participants with COPD, a reduction in FEV1 and FVC, and an increase in R5–20 were associated with an increase in during-walk exposure to NO2, ultrafine particles and PM2.5, and an increase in PWV and augmentation index with NO2 and ultrafine particles. In healthy volunteers, PWV and augmentation index were associated both with black carbon and ultrafine particles.

Interpretation: Short-term exposure to traffic pollution prevents the beneficial cardiopulmonary effects of walking in people with COPD, ischaemic heart disease, and those free from chronic cardiopulmonary diseases. Medication use might reduce the adverse effects of air pollution in individuals with ischaemic heart disease. Policies
should aim to control ambient levels of air pollution along busy streets in view of these negative health effects.

**Funding:** British Heart Foundation.


**Abstract:**

**Background:** Staphylococcus aureus bacteraemia is a common cause of severe community-acquired and hospital-acquired infection worldwide. We tested the hypothesis that adjunctive rifampicin would reduce bacteriologically confirmed treatment failure or disease recurrence, or death, by enhancing early S aureus killing, sterilising infected foci and blood faster, and reducing risks of dissemination and metastatic infection.

**Methods:** In this multicentre, randomised, double-blind, placebo-controlled trial, adults (≥18 years) with S aureus bacteraemia who had received ≤96 h of active antibiotic therapy were recruited from 29 UK hospitals. Patients were randomly assigned (1:1) via a computer-generated sequential randomisation list to receive 2 weeks of adjunctive rifampicin (600 mg or 900 mg per day according to weight, oral or intravenous) versus identical placebo, together with standard antibiotic therapy. Randomisation was stratified by centre. Patients, investigators, and those caring for the patients were masked to group allocation. The primary outcome was time to bacteriologically confirmed treatment failure or disease recurrence, or death (all-cause), from randomisation to 12 weeks, adjudicated by an independent review committee masked to the treatment. Analysis was intention to treat. This trial was registered, number ISRCTN37666216, and is closed to new participants.

**Findings:** Between Dec 10, 2012, and Oct 25, 2016, 758 eligible participants were randomly assigned: 370 to rifampicin and 388 to placebo. 485 (64%) participants had community-acquired S aureus infections, and 132 (17%) had nosocomial S aureus infections. 47 (6%) had meticillin-resistant infections. 301 (40%) participants had an initial deep infection focus. Standard antibiotics were given for 29 (IQR 18–45) days; 619 (82%) participants received flucloxacillin. By week 12, 62 (17%) of participants who received rifampicin versus 71 (18%) who received placebo experienced treatment failure or disease recurrence, or died (absolute risk difference −1·4%, 95% CI −7·0 to 4·3; hazard ratio 0·96, 0·68–1·35, p=0·81). From randomisation to 12 weeks, no evidence of differences in serious (p=0·17) or grade 3–4 (p=0·36) adverse events were observed; however, 63 (17%) participants in the rifampicin group versus 39 (10%) in the placebo group had antibiotic or trial drug-modifying adverse events (p=0·004), and 24 (6%) versus six (2%) had drug interactions (p=0·0005).

**Interpretation:** Adjunctive rifampicin provided no overall benefit over standard antibiotic therapy in adults with S aureus bacteraemia.
Funding: UK National Institute for Health Research Health Technology Assessment.


Abstract:

**Background:** Bruton tyrosine kinase is a clinically validated target in mantle cell lymphoma. Acalabrutinib (ACP-196) is a highly selective, potent Bruton tyrosine kinase inhibitor developed to minimise off-target activity.

**Methods:** In this open-label, phase 2 study, oral acalabrutinib (100 mg twice per day) was given to patients with relapsed or refractory mantle cell lymphoma, until disease progression or unacceptable toxicity. The primary endpoint was overall response assessed according to the Lugano classification, and safety analyses were done in all participants. This trial is registered with ClinicalTrials.gov, number NCT02213926.

**Findings:** From March 12, 2015, to Jan 5, 2016, 124 patients with relapsed or refractory mantle cell lymphoma were enrolled and all patients received treatment; median age 68 years. Patients received a median of two (IQR 1–2) previous therapies. At a median follow-up of 15·2 months, 100 (81%) patients achieved an overall response and 49 (40%) patients achieved a complete response. The Kaplan-Meier estimated medians for duration of response, progression-free survival, and overall survival were not reached; the 12-month rates were 72% (95% CI 62–80), 67% (58–75), and 87% (79–92%), respectively. The most common adverse events were primarily grade 1 or 2 and were headache (47 [38%]), diarrhoea (38 [31%]), fatigue (34 [27%]), and myalgia (26 [21%]). The most common grade 3 or worse adverse events were neutropenia (13 [10%]), anaemia (11 [9%]), and pneumonia (six [5%]). There were no cases of atrial fibrillation and one case of grade 3 or worse haemorrhage. The median duration of treatment was 13·8 months. Treatment was discontinued in 54 (44%) patients, primarily due to progressive disease (39 [31%]) and adverse events (seven [6%]).

**Interpretation:** Acalabrutinib treatment provided a high rate of durable responses and a favourable safety profile in patients with relapsed or refractory mantle cell lymphoma. These findings suggest an important role for acalabrutinib in the treatment of this disease population.

Funding: Acerta Pharma, a member of the AstraZeneca Group.


Abstract:
**Background:** MiStent is a drug-eluting stent with a fully absorbable polymer coating containing and embedding a microcrystalline form of sirolimus into the vessel wall. It was developed to overcome the limitation of current durable polymer drug-eluting stents eluting amorphous sirolimus. The clinical effect of MiStent sirolimus-eluting stent compared with a durable polymer drug-eluting stents has not been investigated in a large randomised trial in an all-comer population.

**Methods:** We did a randomised, single-blind, multicentre, phase 3 study (DESSOLVE III) at 20 hospitals in Germany, France, Netherlands, and Poland. Eligible participants were any patients aged at least 18 years who underwent percutaneous coronary intervention in a lesion and had a reference vessel diameter of 2·50–3·75 mm. We randomly assigned patients (1:1) to implantation of either a sirolimus-eluting biodegradable polymer stent (MiStent) or an everolimus-eluting durable polymer stent (Xience). Randomisation was done by local investigators via web-based software with random blocks according to centre. The primary endpoint was a non-inferiority comparison of a device-oriented composite endpoint (DOCE)—cardiac death, target-vessel myocardial infarction, or clinically indicated target lesion revascularisation—between the groups at 12 months after the procedure assessed by intention-to-treat. A margin of 4·0% was defined for non-inferiority of the MiStent group compared with the Xience group. All participants were included in the safety analyses. This trial is registered with ClinicalTrials.gov, number NCT02385279.

**Findings:** Between March 20, and Dec 3, 2015, we randomly assigned 1398 patients with 2030 lesions; 703 patients with 1037 lesions were assigned to MiStent, of whom 697 received the index procedure, and 695 patients with 993 lesions were assigned to Xience, of whom 690 received the index procedure. At 12 months, the primary endpoint had occurred in 40 patients (5·8%) in the sirolimus-eluting stent group and in 45 patients (6·5%) in the everolimus-eluting stent group (absolute difference −0·8% [95% CI −3·3 to 1·8], p_{non-inferiority}=0·0001). Procedural complications occurred in 12 patients (1·7%) in the sirolimus-eluting stent group and ten patients (1·4%) in the everolimus-eluting stent group; no clinical adverse events could be attributed to these dislodgements through a minimum of 12 months of follow-up. The rate of stent thrombosis, a safety indicator, did not differ between groups and was low in both treatment groups.

**Interpretation:** The sirolimus-eluting bioabsorbable polymer stent was non-inferior to the everolimus-eluting durable polymer stent for a device-oriented composite clinical endpoint at 12 months in an all-comer population. MiStent seems a reasonable alternative to other stents in clinical practice.

**Funding:** The European Cardiovascular Research Institute, Micell Technologies (Durham, NC, USA), and Stentys (Paris, France).

