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The Australian Traditional-Medicine Society Limited (ATMS) was incorporated in 1984 as a company limited by guarantee ABN 46 002 844 233.

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I would like to share some good political news with you.

Your active participation in our two most recent political lobbying campaigns - "I support natural medicine, and I vote" - and your mail pack to your local and federal members of Parliament - have both helped achieve two political victories for our profession. We now have continued consumer access in our community pharmacies to natural medicine products, and in particular to homeopathic medicines, despite the King Review’s recommendation to declare homeopathic medicines ‘non-therapeutic goods’, and stopped the ban on their manufacturers’ making therapeutic claims. These positive outcomes show how the will of the people can thwart negative political lobbying influences.

Another positive outcome has been in the development of collaborations with other professional associations, as we work together to expand our natural medicine industry. Along with our industry manufacturers, this is how we were able to recently set up a meeting with top Department of Health bureaucrats to state our case. We also participated in a new unification of five Australian professional associations with Chinese Medicine members, to once again lobby bureaucrats and politicians for greater access to Medicare provider support for statutorily registered acupuncturists.

To achieve these successes, your President, Treasurer and Chief Executive Officer have made numerous trips to Canberra for meetings with bureaucrats and parliamentarians, including cross-benchers, and attended political functions to make the case against the threatened withdrawal of the private health insurance rebate. They have argued the deleterious effect this would have on our small businesses and our clients’ choices for their access to health care services, and on Australia’s already over-burdened public health care system. In our private discussions with these bureaucrats and parliamentarians, they typically have interesting anecdotes to tell us about how natural medicine has helped them and their families. Our multiple approaches towards increasing parliamentarians’ awareness of the value and role of natural medicine in Australia will, we hope, make a difference when it comes time for them to vote on, and amend, new legislation for health fund rebates as attempts are made to pass it through the two Houses of Parliament later this year.

To reply to our critics, we have also presented the best scientific evidence we have been able to collate to these bureaucrats and politicians, to support our claims of the efficacy of natural medicine for preventative and wellness care. Our critics’ antagonism underlies various reports that have been published alleging that there is no good scientific evidence for natural medicine. In contrast, we are optimistic that the Commonwealth Ombudsman will later this year hand down his findings in our favour on our collaborative complaint against the negative NHMRC Report, published in 2015.

Next, I would like to share some good professional news with you.

Our Natural Medicine Week, held from 21-27 May 2018, was a singular success, with ATMS members advancing public awareness of the potential scope of natural medicine as an effective choice for health care services. More than eighty well patronised events were convened nationally.

Our “special events” for all members have also been going very well, such as the Transition to Practice: from the Classroom to the Clinic seminars which are aimed at supporting student members who are about to graduate, or who have recently done so. Our National Seminar Series on Healthy Ageing: Genomics through to Lifestyle have been very popular and well attended by practitioners of all modalities.

And lastly, now that the Federal Budget has been announced (early in May 2018), politicians are all into election mode, so our efforts on your behalf will be intensifying into the near future as we continue to assert ourselves politically and professionally in our crucial role as natural health care providers in Australia.

With my best wishes to all members for your professional and personal fulfillment,

Peter Berryman
President
As CEO of ATMS, I am pleased to write as the third Natural Medicine Week concludes. Our thanks go to members who organised Events and Special Offers right across Australia during Natural Medicine Week, 22 - 27 May 2018. As Peter Berryman noted in the ATMS President Report, more than 80 natural medicine events were coordinated across Australia during Natural Medicine Week.

This is an outstanding celebration of natural medicine! Natural Medicine Week highlights the important role practitioners play in local communities in maintaining overall health and wellbeing. Full details can be accessed at www.naturalmedicineweek.com.au.

Members can also follow ATMS and all things natural medicine across our popular social media platforms: Facebook: @atmsnatmed Instagram: @naturalmedicineweek LinkedIn: @atmsnatmed Twitter: @atmsnatmed

**Member portal launch**

ATMS is pleased to launch the new member portal in May 2018. Members can now use a dedicated login and password to access the member portal in atms.com.au. The member portal contains each member’s personal membership and professional information. To access the member portal, a member is required to have a unique email address assigned to their ATMS member number. Members who have a unique email address have been emailed a link to the new portal along with a personalised email and password. Any member requiring access can contact ATMS on 1800 456 855 or info@atms.com.au to obtain fresh access details.

The member portal contains personalised information for each ATMS member including: Member fee renewal status (including a live link to pay member fees online), Professional Indemnity insurance renewal date, first aid certificate renewal date, personal and clinic addresses, educational qualifications and accredited modalities. The portal allows a member to submit and upload changes and updates to this information.

Continuing Professional Education (CPE) remains a shared commitment between a member and ATMS and an essential component for ATMS Accredited Membership. An ATMS Accredited Member is committed to achieving 20 CPE points every year, in accordance with the ATMS CPE Policy.

The first responsibility for Continuing Professional Education is held by every ATMS Accredited Member. All Accredited Members should maintain comprehensive records of all CPE undertaken. Evidence of CPE is essential to ATMS Accredited Membership and is also essential to becoming and remaining a recognised provider with Health Funds. With the current uncertainty with Health Fund reform, ATMS urges members to maintain all current health fund recognition requirements before the proposed implementation of the final reforms in April 2019.

The launch of the member portal in May 2018 will begin the transition to the online automation of CPE records for ATMS members. This transition will see CPE activities conducted by ATMS in the 2017/2018 membership year begin to be uploaded to the membership portal by ATMS. From 1 July 2018, it is intended that all CPE conducted by ATMS for the 2018/2019 CPE year will be automatically uploaded to the member portal by ATMS. CPE activities not conducted by ATMS can be submitted via the member portal for assessment by ATMS for inclusion in a member’s CPE records.

This planned transition will prepare for all CPE records conducted by ATMS and submitted by a member for the 2018/2019 CPE year to be available in the member portal.

**Renewal of ATMS Accredited Membership**

The membership year for ATMS is 1 July to 30 June. Membership renewals have been prepared and distributed to members in May 2018, requesting payment for the coming financial year. Membership fees have been adjusted in accordance with ATMS Board policy, to increase Membership Fees by the inflation rate as at March each year, rounded up to the nearest $5. For the period 1 July 2018 to 30 June 2019, Membership Fees for Accredited Members will increase from $230 to $235 (both figures inclusive of GST).

To maintain professional standing, each Accredited Member of ATMS commits to four essential annual requirements:

- Completion of 20 Continuing Professional Education (CPE) points per financial year
- Current and continuous professional Indemnity Insurance of at least $1M (some health funds and national registration requirements require a greater minimum level of cover)
- Current and continuous senior first aid certificate
- Payment of membership fees for the current financial year

For any aspect of our membership and health fund administration, the ATMS team is available to be contacted on 1800 456 855 or info@atms.com.au.

My best wishes to all members for winter wellness and success,

**CEO**

Charles Wurf
ATMS is pleased to launch an ATMS special event, the PCOS Symposium 2018 in Sydney on Sunday 16 September.

In Australia, 1 in 10 women of childbearing age have been diagnosed with PCOS. Women with PCOS are frequent users of complementary therapies, but to date there has been no specialised training offered to natural medicine practitioners on PCOS (which is often missed diagnostically on both sides of medicine).

This conference aims to fill that gap by offering training to natural medicine practitioners on the relevant up-to-date medical information they need to help their clients overcome the condition once and for all.

We encourage all complementary health practitioners to attend including Naturopaths, Nutritionists, Herbalists, Homeopaths, Integrative Doctors, Traditional Chinese Medicine and Bodywork Therapists.

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- Lifestyle recommendations and the role of exercise physiology in the treatment of Polycystic Ovary Syndrome
- Deep diagnosis: Individual factors driving PCOS and how to treat them
- Optimising fertility for the PCOS patient

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Abstract
Cardiometabolic syndrome is a disease of unhealthy diet and lifestyle. It is a cluster of cardiometabolic risk factors, including elevated triglyceride levels, fasting plasma glucose level (hyperglycaemia), elevated blood pressure, increased waist circumference, and reduced high-density lipoprotein (HDL) cholesterol level. It is a multifactorial risk factor for cardiovascular disease and type 2 diabetes. Diet and nutrition play major roles in the prevention and management of chronic disease, especially cardiometabolic syndrome. Diets higher in fruits, vegetables, fibre, omega-3 polyunsaturated fatty acids, tree nuts, and potassium have been associated with a lower risk of cardiometabolic syndrome. This paper briefly introduces the effects of the Westernised diet, Mediterranean diet, Palaeolithic diet, glycaemic index diet, vegetarian diet, and the Dietary Approaches to Stop Hypertension (DASH) diet on the progression of cardiometabolic syndrome.

Introduction
Cardiovascular disease is the leading cause of morbidity and death worldwide. Metabolic syndrome is becoming hyperendemic and is a multifactorial risk factor for cardiovascular disease and type 2 diabetes. Cardiometabolic syndrome comprises the clustering of several cardiometabolic risk factors related to abdominal obesity and insulin resistance, with insulin resistance being one of the main drivers of cardiometabolic syndrome. Metabolic syndrome is diagnosed when any three of the following five risk factors are present: elevated triglyceride levels, reduced high-density lipoprotein (HDL) cholesterol level, elevated fasting plasma glucose level (hyperglycaemia), elevated blood pressure, and increased waist circumference (Table 1). Additionally, chronic inflammation, oxidative stress, endothelial dysfunction, and a hypercoagulable state have been associated with cardiometabolic disease.

Table 1. Definition of metabolic syndrome

<table>
<thead>
<tr>
<th>Metabolic syndrome is diagnosed when any 3 of the following 5 risk factors are present:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• triglycerides ≥1.69 mmol/l (150 mg/dL) or undergoing drug treatment for elevated triglycerides</td>
</tr>
<tr>
<td>• HDL cholesterol &lt;1.03 mmol/l (40 mg/dL) in males or &lt;1.29 mmol/L (50 mg/dL) in females or undergoing drug treatment for reduced HDL cholesterol</td>
</tr>
<tr>
<td>• fasting plasma glucose ≥5.5 mmol/L (100 mg/dL) or undergoing drug treatment for elevated glucose</td>
</tr>
<tr>
<td>• blood pressure ≥130 mmHg systolic or ≥85 mmHg diastolic or undergoing drug treatment for hypertension</td>
</tr>
<tr>
<td>• waist circumference &gt;102 cm in males or &gt;88 cm in females</td>
</tr>
</tbody>
</table>

Bradley McEwen | PhD, MHSc (Hum Nutr), BHSc, ND (Adv), DBM, DNutr, DSM, M.ATMS
There are numerous health consequences related to cardiometabolic syndrome. These include non-alcoholic fatty liver disease, obesity, overweight, high adiposity, reproductive dysfunction (such as polycystic ovary syndrome in females (PCOS) and erectile dysfunction in males), obstructive sleep apnoea, and certain forms of cancer.1 Metabolic syndrome is associated with a significantly increased risk of total mortality and cardiovascular morbidity5 and mortality.5, 6 People who are insulin-resistant have a tendency to lose the vasodilatory effect of insulin, leading to elevated blood pressure.3 It should be noted that excess abdominal fat is associated with insulin resistance. As a combination, excess abdominal fat and insulin resistance lead to an increase in the production of reactive oxygen species and inflammation leading to increased insulin resistance.3 The risk of coronary heart disease, myocardial infarction, and stroke is much higher in people who have cardiometabolic syndrome than in those without the syndrome.3 Hyperglycaemia is a well-established risk factor for cardiovascular disease, with research showing that impaired fasting glucose and impaired glucose tolerance are associated with increases in the risk for cardiovascular disease.7 Cardiometabolic syndrome is generally regarded as a pro-inflammatory and prothrombotic state.1 Inflammation drives insulin resistance and oxidative stress,9 further amplifying the condition. Although cardiometabolic syndrome is a chronic disease, in apparently healthy people cardiovascular risk is most frequently the result of multiple interacting risk factors.9 It should be noted that children and adolescents can also be affected by the components of cardiometabolic syndrome.1 Cardiometabolic syndrome is a disease of unhealthy diet and lifestyle. Diet and nutrition play major roles in the prevention and management of chronic disease, especially cardiometabolic syndrome.10 The goals of the management of cardiometabolic syndrome are to improve the diet, identify and correct nutritional deficiencies, increase physical activity, and achieve and maintain a healthy weight. Vegetarian and Mediterranean diets, and diets high in fruits, vegetables, fibre, omega-3 polyunsaturated fatty acids, tea and coffee (not sugar-sweetened), tree nuts, and potassium have been associated with a lower risk of cardiometabolic syndrome.1 This paper briefly introduces the impact of six diets (Westernised diet, Mediterranean diet, Palaeolithic diet, glycaemic index diet, vegetarian diet, and the Dietary...
Approaches to Stop Hypertension (DASH) diet on the progression of cardiometabolic syndrome.

**Westernised diet and cardiometabolic syndrome**

The Westernised diet is characterised by a higher intake of red and processed meats, sweets and desserts, potatoes, fries, refined grains, and high amounts of sugar and saturated fat. A diet high in these components, along with an intake of soft drinks, fried foods and a high-carbohydrate diet, has been associated with metabolic syndrome and cardiovascular disease, low-grade inflammation, insulin resistance, as well as higher cardiovascular mortality. The typical Western diet yields a net acid load and as a result, healthy adults consuming the standard Westernised diet sustain a chronic, low-grade metabolic acidosis. High intake of sugar has been associated with an increased risk of metabolic syndrome, cardiovascular disease, type 2 diabetes, dyslipidaemia, obesity, overweight, general weight gain, adiposity, and fatty liver disease. Refined sugars are essentially lacking in any vitamins, minerals, and fibre. The consumption of diets high in foods containing refined sugar reduces the total vitamin and mineral density of the diet by displacing foods that are more nutrient-dense. The Westernised diet has numerous negative effects on the parameters of cardiometabolic syndrome. It is recommended that those with cardiometabolic syndrome or those with components of the syndrome reduce or refrain from eating components of the Westernised diet.

**Mediterranean diet and cardiometabolic syndrome**

The Mediterranean diet is characterised by abundant fruit, vegetables, breads and other forms of cereals, beans, nuts, seeds and fish. Olive oil is the principal source of fat. Dairy products (principally cheese and yoghurt) and poultry are consumed in low to moderate amounts. Red meat is consumed in low amounts and (especially red) wine consumed in low to moderate amounts, normally with meals.

Adherence to the Mediterranean diet has been associated with a significant reduction in total mortality, with an inverse association with death due to coronary heart disease, lower risk of cardiovascular disease and of developing type 2 diabetes, and a lower risk of incident cardiovascular disease and stroke in women. High adherence to the Mediterranean diet has been associated with a reduced risk of metabolic syndrome. Significant inverse associations have been found for weight gain, overweight, obesity, waist circumference, significant lower average heart rate, blood pressure, low HDL cholesterol levels, and lower risk of depression. Additionally, the Mediterranean diet has been associated with a reduced risk of frailty syndrome in older women with type 2 diabetes. Furthermore, the Mediterranean diet has been associated with better scores in quality of life.

There have been discussions on whether adopting a diet from other countries can be transferable to another country, such as Australia. An Australian study investigated this effect and concluded that a diet that adhered to the principles of the traditional Mediterranean diet was associated with longer survival among Australians of either Greek or Anglo-Celtic origin.

The Mediterranean diet has beneficial effects in the management of cardiometabolic syndrome. Consuming the Mediterranean diet as a main diet for improving overall health and wellbeing can be recommended.

**Palaeolithic diet and cardiometabolic syndrome**

The Palaeolithic diet emphasises the intake of lean, non-domesticated meats, and non-cereal, plant-based foods. The plant-based foods included in the diet are fruits, beans, roots, and tubers, nuts, along with flowers and edible gums. The Palaeolithic diet was found to be low in sodium and contained very little sugar.

The Palaeolithic diet has shown improvements in reducing waist circumference, systolic and diastolic blood pressure, reduced triglyceride level, reduced fasting blood glucose levels, increased HDL cholesterol, decreased lipid accumulation in the liver, and improved peripheral insulin sensitivity. The Palaeolithic diet has beneficial effects in the management of cardiometabolic syndrome. Further research is needed because of limited data from clinical trials.

**Glycaemic index and glycaemic load and cardiometabolic syndrome**

The glycaemic index quantifies the glycaemic response to carbohydrates in different foods, while the glycaemic load is the mathematical result of the glycaemic index of the food and quantity (weight) of carbohydrate ingested. Foods and beverages with a high-glycaemic index, such as potatoes, white bread, white rice, low-fibre breakfast cereals, sweets, desserts, and sugar-sweetened beverages, have been linked to cardiovascular disease, type 2 diabetes, procoagulant activity, oxidative stress, inflammation, low-density lipoprotein oxidation, and weight gain. Research shows an association between a high glycaemic load diet and the presence of metabolic syndrome in obese children and adolescents. Studies in overweight or obese adults and children have found that low-glycaemic load diets were associated with marked weight benefits, loss of adiposity and reduced food intake. Low-glycaemic index and low-glycaemic load diets have been associated with a reduced risk of chronic diseases, such as cardiovascular disease and type 2 diabetes. A low carbohydrate diet has been associated with improved fasting plasma glucose, triglycerides, blood pressure, waist circumference, and body mass index.
A low glycaemic index diet has numerous benefits for elements of cardiometabolic syndrome. The diet can be recommended as a foundation diet for good health.

**Vegetarian diet and cardiometabolic syndrome**

A healthy vegetarian diet is composed of a variety of unrefined foods. Vegetarian diets encompass several diet types. These include semi-vegetarian (flexitarian), pesco-vegetarian, lacto-vegetarian, ovo-vegetarian, lacto-ovo-vegetarian, vegan, and raw food vegan diets. Semi-vegetarians include small amounts of meat, mainly from fish and poultry in their diet. Pesco-vegetarians consume some fish, in addition to foods of animal and plant origin. Lacto-vegetarians consume milk and dairy products. Ovo-vegetarian diets include eggs and lacto-ovo-vegetarians consume both dairy products, including milk, and eggs. Individuals who adhere to vegan diets exclude all meats and...
animal products. Vegetarian diets, including vegan diets, have numerous benefits for cardiovascular health, reduced blood pressure, improved glycaemic control (reduce glycated haemoglobin), reduced glucose levels, diverticular disease, reduced plasma lipids, and body weight. Studies have reported lower total cholesterol, LDL-cholesterol and blood pressure in vegetarians than in non-vegetarians. Consuming a predominantly plant-based diet is associated with a significantly lower risk of cardiovascular disease and type 2 diabetes. Additionally, mortality from ischaemic heart disease has been reported to be lower in vegetarians than in non-vegetarians. The intake of green leafy vegetables and vitamin C-rich fruits and vegetables has been inversely associated with the risk for cardiovascular disease. Consumption of vegetarian diets is associated with improved glycaemic control in people with type 2 diabetes. The protective effects of plant-based nutrition are likely to be mediated through their multiple beneficial nutrients, including monounsaturated fatty acids, polyunsaturated fatty acids (such as omega-3), antioxidant vitamins, minerals, phytochemicals, and fibre. Dietary fibre may slow glucose absorption from the intestine, which lowers the glycaemic index of carbohydrates.

The vegetarian diet has numerous health benefits. The DASH diet has numerous health benefits, especially for high blood pressure. This diet can be recommended for those with elevated blood pressure and components of cardiometabolic syndrome.

Conclusion
Cardiometabolic syndrome is a disease of unhealthy diet and lifestyle. Diet and nutrition play major roles in the prevention and management of chronic disease, especially cardiometabolic syndrome. A predominantly plant-based, Mediterranean-style, low-glycaemic index diet has numerous benefits in managing cardiometabolic syndrome and its individual components. Improving diet should be the foundation of any management plan of cardiometabolic syndrome and chronic disease.

REFERENCES
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Treating low back pain: The evidence

Sandra Grace | PhD, MSc(Res), Grad Cert Chiro Sports Med, Clinical Cert Chiro Paeds, DBM, Dip Acup, DBM, DC, DO, Dip Ed, BA

The Lancet is a weekly peer-reviewed general medical journal. It is one of the world’s oldest, best known and most highly regarded general medical journals. It has published many of the most important articles in the history of medicine. The Lancet published a series on Low Back Pain (LBP) in March 2018. The first paper by Hartvigsen et al. focused on the definition of low back pain and its causes and risks; the second, by Foster et al., collated current evidence for effective treatment. The third was a call to action for health practitioners to discard well entrenched but ineffective therapies and use only evidence-based ones. This series is mandatory reading for anyone who treats clients for low back pain.

Complementary medicine (CM) practitioners regularly treat clients with LBP. Consequently, it is important that they keep up to date with the latest evidence and adapt their practices accordingly.

Key points to be drawn from the Lancet series for CM practitioners:

- Take a case history to rule out red flags (indicators of rare but serious causes of LBP)
- First line treatment: Advise clients to stay active, exercise within their pain limits. (Some clients with persistent LBP may benefit from psychological therapies like cognitive behavioural therapy, mindfulness training, mind-body work).
- Educate clients about ways to minimise the risks associated with LBP.
- Second line treatment: If clients do not respond or stop responding to first line treatment, then other non-pharmacological therapies like massage, spinal manipulation, acupuncture and yoga are recommended.

CM practitioners who follow this regimen will be treating their clients with the best available evidence.

LBP – prevalence
Hartvigsen et al. define LBP as pain occurring between the lower ribs and the buttock creases. It can include pain and neurological symptoms that radiate into one or both legs. It is important to remember that it is a symptom and not a disease. LBP used to be thought of as isolated episodes, but it is now considered a prolonged condition that recurs. Recurrence is common. Most people with LBP recover on their own within about 6 weeks. Pain may still be present at 12 weeks but the intensity is usually reduced. For a small number of people, their LBP continues for months and years.

LBP is widespread. It is the greatest cause of disability worldwide and its incidence is expected to increase along with our ageing population. It is most prevalent in low and middle income countries where health systems lack the resources to manage the growing burden.

Causes and risks
There are many causes of LBP. These include biophysical factors (e.g. muscle co-ordination and size), co-morbidities, and poor mental health. But in most cases no cause of the pain can be found, that is, the LBP is ‘non-specific’. Serious causes of LBP are rare. They include vertebral fracture, axial spondylarthitis (ankylosing spondylitis), malignancy, cauda equinae and infection. Case histories are required to look for indicators of these serious red flag conditions (see Table 1). However, serious causes account for only 1% of acute LBP. Once these have been ruled out, diagnostic tests for other causes are unreliable. Note also that 80% of people with acute LBP have at least one red flag, despite the fact that only 1% have a serious condition. It is more reliable to observe the whole picture of the client’s state of health over time than to rely solely on red flags.
Risk factors include demanding physical work (e.g. heavy lifting and awkward postures), poor mental health, having had a previous episode of LBP, co-morbidities like asthma, diabetes and cardiovascular disease, sedentary lifestyle, obesity and smoking.

**Evidence-based treatment**
Clinical practice guidelines are based on systematic reviews of the available evidence. They make recommendations intended to provide clients with optimal care. Although a number of clinical guidelines for LBP have been published over the past 20 years, they continually evolve with emerging evidence. Consequently, their recommendations can vary. However, over time, key messages emerge. The following recommendations are based on clinical guidelines for the treatment of LBP from the UK, Denmark and the USA.

**Table 1. Red flags for serious causes of low back pain (adapted from Maher et al.)*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Red flag</th>
</tr>
</thead>
</table>
| Axial spondylarthitis (ankylosing spondylitis) | Morning stiffness  
Pain that wakes patient during early hours of the morning  
Improvement with exercise  
Alternating buttock pain  
Younger age |
| Cancer                                   | History of cancer  
Unexplained weight loss  
Over 50 years of age  
Pain at night or pain that fails to improve after 1 month |
| Vertebral fracture                        | History of trauma  
History of osteoporosis  
History of corticosteroid use  
Older age |
| Vertebral infection                       | Fever  
Recent infection  
Pain at rest  
Immunocompromised  
History of intravenous drug use |
| Cauda equine syndrome                     | Lower limb weakness or numbness  
Urinary retention  
Faecal incontinence  
Saddle anaesthesia  
Lower limb weakness or numbness |

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*Maher et al. 8*
The first line of treatment recommended by the findings of the Lancet series for patients with persistent non-specific LBP is to advise staying active, recommend exercises, and in some cases to refer to a psychologist for therapy (e.g. cognitive behaviour therapy) (see Table 2). There is no evidence yet for any superior efficacy of specific exercises, so practitioners should choose ones they judge to suit a particular patient’s condition, preference and capability. According to Almeida et al., chronic LBP guidelines are now endorsing exercises like Tai Chi, yoga, core muscle control, co-ordination and strengthening, and aerobic exercises like swimming and walking. Exercise is recommended alone and in combination with other multidisciplinary rehabilitation.

What are not recommended in these studies as first line treatments are NSAIDs and muscle relaxants, inactivity such as rest or bed-rest, imaging and surgery, all of which have been routinely prescribed for many years. In the Lancet Viewpoint paper the authors continually refer to the damaging effect of over-medicalisation as both an unfruitful avenue of therapy and a general societal threat, such as that currently faced by the USA of widespread opioid addiction.

Paracetamol is not recommended for either acute or persistent LBP; NSAIDs are supported only as second line treatments for both, and selective norepinephrine reuptake inhibitors only for persistent cases; skeletal muscle relaxants have only limited use in acute cases and are unsupported in persistent ones; opioids have limited use in selected patients only and must be used with caution on account of their addictive property; and glucocorticoids are not recommended at all.

### The role of complementary medicine

Manual and other complementary medicine (CM) and allied health therapists have key roles to play in treating LBP. Manual therapists - massage therapists, chiropractors, osteopaths and physiotherapists, along with acupuncturists, teachers of yoga and mindfulness are all recommended as second line treatment providers. Second line treatment is taken up when the first lines described above have failed to be effective or are no longer effective. Detractors of CM have long denied that evidence exists for its effectiveness in treating LBP, but the research reported in this series shows that, on the contrary, the evidence for it is sufficiently robust to be included in national clinical guidelines.

The Lancet is not alone in finding that CM therapies are more effective treatments for LBP than traditionally prescribed approaches. The Harvard Medical School, via its health blog, advises that heat, massage, acupuncture and spinal manipulation are the treatments of first choice for acute and sub-acute LBP, and exercise (such as stretching and strengthening core muscles), physical therapy, acupuncture and mindfulness training are those for chronic LBP. Also possibly helpful are tai chi, yoga, or progressive relaxation techniques. This advice is derived in large part from clinical practice guidelines issued by the American College of Physicians in April 2017, based on database searches of studies published between 2008 and 2016. It differs from the finding of the Lancet series that advice to stay active is the best first line treatment, but it also omits opioids, inactivity, imaging and surgery as effective approaches, and focusses on the benefits of CM treatment.

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**Table 2. Evidence for the treatment of low back pain, according to Clinical Guidelines UK, USA, Demark**

(adapted from Table 2 Foster et al. 

<table>
<thead>
<tr>
<th>Evidence-based treatment option</th>
<th>Acute low back pain Less than 6 weeks duration</th>
<th>Chronic low back pain More than 12 weeks duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First line treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client education and self-management</td>
<td>- Advice to stay active</td>
<td>- Advice to stay active</td>
</tr>
<tr>
<td></td>
<td>- Patient education</td>
<td>- Patient education</td>
</tr>
<tr>
<td><strong>Second line treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-pharmacological therapies</td>
<td>- Spinal manipulation</td>
<td>- Spinal manipulation</td>
</tr>
<tr>
<td></td>
<td>- Massage</td>
<td>- Massage</td>
</tr>
<tr>
<td></td>
<td>- Acupuncture</td>
<td>- Acupuncture</td>
</tr>
<tr>
<td>Pharmacology</td>
<td>- Non-steroidal anti-inflammatory drugs</td>
<td>- Non-steroidal anti-inflammatory drugs</td>
</tr>
<tr>
<td></td>
<td>- Muscle relaxants only for selected patients</td>
<td>- Selective norepinephrine reuptake inhibitors</td>
</tr>
<tr>
<td></td>
<td>- Opioids only for selected patients and to be used with caution</td>
<td>- Opioids only for selected patients and to be used with caution</td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Epidural glucocorticoid injection only for selected patients</td>
<td>- Discectomy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Laminctomy</td>
</tr>
</tbody>
</table>

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Exercise therapy could be considered as routine for persistent cases. Spinal manipulation, massage, and acupuncture are all recommended as second line or adjunctive treatments, particularly for persistent cases, along with yoga and mindfulness training. These are all evidence-based findings and support the clinical evidence garnered over many years of case histories by practitioners and their patients.
EXERCISE THERAPY COULD BE CONSIDERED AS ROUTINE FOR PERSISTENT CASES. SPINAL MANIPULATION, MASSAGE, AND ACUPUNCTURE ARE ALL RECOMMENDED AS SECOND LINE OR ADJUNCTIVE TREATMENTS, PARTICULARLY FOR PERSISTENT CASES, ALONG WITH YOGA AND MINDFULNESS TRAINING.

REFERENCES


Abstract

Introduction
There is mounting evidence indicating an association between vitamin D and Type 2 Diabetes (T2DM). Large epidemiological studies have found that low levels of vitamin D were associated with poor glycaemic control in DM patients, however, randomised controlled trials (RCTs) showed inconsistent results. This review aimed to assess the evidence of the association between vitamin D and glycaemic control in T2DM patients, specifically in RCTs.

Methodology
A search was performed in PUBMED in September 2017 to identify eligible studies. It was focused on RCTs relating to vitamin D interventions on glycaemic control in patients with T2DM. Study characteristics and general conclusions were extracted. The Jadad scale and van Tulder scale were used to assess the quality of the eligible studies.

Results
Sixteen RCTs were identified based on the selection criteria. All RCTs had a small sample size (8-45 each group), with subjects aged between 48.5 (±8) to 66.9 (±3.1) years. Vitamin D3 was used as an oral vitamin D supplement in most of the studies (12/16); two used vitamin D3 via injection; two used vitamin D fortified yoghurt. Four studies concluded that vitamin D had improved insulin sensitivity and glycaemia status among T2DM patients while eleven studies had reported no improvements. One study suggested a T2DM benefit using joint calcium and vitamin D supplementation.

Conclusion
The current review assessed the association between vitamin D and glycaemia control among T2DM patients from eligible RCTs. We concluded that the reviewed RCTs did not support that vitamin D was beneficial in glycaemic control among T2DM patients.

Keywords: type 2 diabetes, vitamin D, glycaemia control, insulin sensitivity, insulin resistance
Introduction
Diabetes has become a major health issue for many developed and developing countries. There are 347 million people affected by diabetes globally, and this number is expected to increase to 415 million by 2030 (1). Among those affected by diabetes, over 90% of people are diagnosed with Type 2 Diabetes (T2DM) based on data from the World Health Organization. There were 999,000 Australians (4.6%) reported to have diabetes in 2012, the majority (85.3%) of whom were T2DM. The prevalence of diabetes in Australia is expected to grow to 3.5 million by 2033 (2).

Diabetes mellitus is a chronic disease characterised by hyperglycaemia resulting from defects in insulin secretion, insulin function or both. It significantly affects an individual’s health and is associated with many complications, including damage to several organs, especially the eyes, kidneys, heart, nerves and blood vessels.

The treatment of T2DM involves achieving optimal blood glucose level and of other known risk factors that damage blood vessels or organs (3). The management of T2DM can be very challenging (4), as it requires medication and insulin use as well as lifestyle changes such as a healthy diet (5, 6) and increased physical exercise (7).

There is growing evidence indicating a link between vitamin D levels and T2DM. A large observational study from Finland found males with the highest serum vitamin D level had the lowest risk of developing diabetes (8). A similar result was found in women in a nested case-control study (9). A randomised trial conducted among non-diabetic but insulin-resistant South Asian women in New Zealand indicated that there was a significant improvement in insulin resistance by supplementing with vitamin D (10). This study suggested the importance of keeping a good 25(OH)D level (50-80 nmol/l) as a long-term maintenance, as it can benefit both insulin resistance and insulin sensitivity however not the secretion.

Another randomised clinical trial suggested that vitamin D slowed the increase in fasting glucose which could benefit T2DM patients (11). The association between 25(OH)D and insulin resistance is currently classified as evidence level II by the NMHRC (12). It was therefore decided to undertake a systematic review of randomised controlled trials (RCTs) examining the effects of vitamin D intervention on glycaemic control among T2DM patients.

Methodology
The search was performed in PubMed from its inception up to September 2017. The main aim was to identify eligible RCTs that assessed the efficacy of vitamin D supplementation on glycaemic control in T2DM patients.

Inclusion criteria
Included were all RCTs on human subjects with T2DM. Studies had to be published in English as a full-text original article. There was no restriction on vitamin D intervention type: studies using supplementary intervention such as vitamin D2 (ergocalciferol) or D3 (cholecalciferol), orally or through injection, or by lifestyle change such as sun exposure or dietary resources were all included. In addition, eligible studies had to report at least one of the following outcomes of glycaemia control: fasting plasma glucose (FPG); post-prandial glucose (PPG); haemoglobin A1c (HbA1c), insulin sensitivity (Quantitative Insulin Sensitivity Check Index, QUICKI), insulin secretion (homeostasis model assessment, HOMA-IR or beta cell function, HOMA-B). If there were more than one publication from the same research group that included similar or the same interventions, we included the study with the longer intervention period.

Exclusion criteria
Studies with a short trial period, that is less than or equal to one month, were excluded. Research designs other than RCTs such as reviews, cross-section studies and retrospective studies were also excluded. Studies involving children, pregnant women and/or participants with pre-diabetes, type 1 diabetes and gestational diabetes and/or participants with conditions such as chronic renal diseases and hyperparathyroidism were also excluded.

Data search and extraction
‘Vitamin D’, ‘diabetes’, ‘glycaemic control’ and related terms were used in the search, along with Vitamin D-related terms including ‘vitamin D3’ or ‘cholecalciferol’ or ‘vitamin D2’ or ‘ergocalciferol’, and diabetes-related terms including ‘diabetes’ or ‘type 2 diabetes’ or ‘T2DM’ or ‘hyperglycaemia’ or ‘hyperglycaemia’. ‘Human research’ and ‘clinical trials’ were added to the search criteria. Thirty-eight articles were initially retrieved and then, following an examination of the articles’ title and abstract based on the selection criteria, 16 eligible articles remained.

The full text of these articles was retrieved. Study characteristics such as location of study, study type, age of participants, intervention dosing, sample size, intervention pathway, study duration and targeted biomarker [FSP, PPG, HbA1c, insulin residence (HOMA-IR), beta cell function (HOMA-B), delta C-peptide (DCP), Quantitative Insulin Sensitivity Check Index (QUICKI)], positive biomarker which had a significant increase or decrease, and the general conclusion were extracted from the eligible studies and listed in a table.

Abbreviations:
- T2DM: Type 2 diabetes
- FPG, FSG: Fasting plasma glucose; Fasting serum glucose
- PPG: Post prandial glucose
- HbA1c: Haemoglobin A1c
- HOMA-IR: Homeostasis model assessment - insulin resistance
- HOMA-B: Homeostasis model assessment - beta cell function
- QUICKI: Quantitative Insulin Sensitivity Check Index
- DCP: Delta C-peptide
ARTICLE

Quality assessment
We used the Jadad scale and the Van Tulder scale to assess the quality of the eligible RCTs. The Jadad scale has five questions related to randomisation, blinding and related research design. The Van Tulder scale is designed to make assessments of RCTs on 11 components including randomization, allocation concealment, baseline characteristics, patient blinding, caregiver blinding, observer blinding, co-intervention, compliance, dropout rate, end-point assessment time point, and intention-to-treat analysis.

For both scales, the reviewer marked ‘Y’ (YES) and ‘N’ (NO) or ‘NK’ (NOT KNOWN) to answer each question. If the answer was ‘Y’, a score was given; ‘N’ or ‘NK’ received zero. The total score presents the quality of research. Total score >3 in Jadad scale or >5 in Van Tulder scale indicate a high quality study.

Sixteen RCTs were identified based on the inclusion and exclusion criteria. Among them, fifteen studies were randomised placebo-control studies, thirteen (4, 13-24) were double-blind design, two (25, 26) were single-blind design and one (27) was unclear. All RCTs had a small sample size (8-45 each group), with subjects aged between 48.5 (±8) to 66.9 (±3.1). Vitamin D3 (cholecalciferol) was used as an oral vitamin D supplement in most of the studies, two used vitamin D3 via injection (14, 20) and two used vitamin D fortified yoghurt (19, 25). The results are shown in Table 1.

Eligible studies were generally long-term studies with duration ≥ 3 months, with only two considered a short-term study (17, 18). Among them, four studies (15, 18-20) showed a positive change in glycaemia control, specifically in insulin sensitivity (HOMA-IR) (20), glycaemia status including serum insulin, FPG, HbA1c and HOMA (15, 18, 19). Tabesh et al. (17) used calcium and/or vitamin D as oral supplements and reported a positive result from conjoint supplementation of calcium and vitamin D in improving glycaemia status among T2DM patients. Nikooeyeh et al. (19) chose vitamin D and/or calcium fortified yoghurt as supplementary intervention and Jehle et al. (20) used 300,000IU vitamin D via injection: Authors of both studies concluded that vitamin D improved the glycaemic status and insulin sensitivity of T2DM patients.

Of the remaining eleven studies, none showed a significant improvement for glycaemia control (13, 14, 16, 21-28). Five of the included studies, however, showed a temporary improvement or suggested an association between vitamin D and glycaemic control. Kampmann et al. suggested a possible link between an adequate vitamin D level and insulin secretion, and it was noted that it was the only research study that used a hyperinsulinemic euglycaemic clamp to quantify beta cell response (21). Al-Sofiani et al. (13) suggested that vitamin D improved beta-cell activity in the vitamin D-deficient T2DM group with no significant changes in HbA1c or insulin sensitivity. Another study showed a temporary improvement on FPG and PPG at the 3-month period, but failed to show a difference again at the 6-month period (22). A significant reduction in HbA1c was shown but only among patients who had a baseline of HbA1c > 9.0 % (26), and a positive link of 25 (OH) D and fasting insulin was reported by Strobel, Reusch (24).

A 300,000 IU vitamin D injection was the highest dosing of vitamin D3 intervention among the 16 RCTs, and it indicated that vitamin D3 improved insulin sensitivity by increasing the HOMA-IR and HbA1c (15, 20). However, another study with large dosing (up to 20,000 IU, Oral) found no improvement in glycaemic control (28).

Quality assessment
According to the JADAD score, eleven RCTs were assessed as high quality with Jadad score ≥ 3. Details are shown in Table 2. Thirteen RCTs were considered as high quality studies based on Van Tulder scale with a total score >5; the remaining three studies all scored 5/11. Details are shown in Table 3.

Discussion
The current review analysed selected RCTs. However, several features may have caused inconsistent findings associated with the reviewed RCTs. These features include joint intervention of calcium and vitamin D, different dosing, vitamin D from sun exposure and diet sources, small sample size, baseline similarity, methodology and research design.

There were conflicting results among the four studies that used vitamin D and calcium as an intervention. A Korean study that used cholecalciferol and calcium as the intervention found no improvements on HOMA-IR, HbA1c or glycaemia control (23). However, Tabesh et al. (17) observed a significant decrease in serum insulin, HbA1c and a significant increase in QUICKI and HOMA-B in calcium + vitamin D group [calcium (1,000mg) and vitamin D (50,000IU)]. However no significant change was found between vitamin D and the placebo group.

Results
Sixteen RCTs were identified based on the selection criteria. Four studies concluded that vitamin D had improved insulin sensitivity and glycaemia status among T2DM patients while eleven studies reported no improvements. One study suggested a T2DM benefit of a conjoint calcium and vitamin D supplementation.

All studies were randomised placebo-control studies, with thirteen being double-blind design, two being a single blind design (26) and one unclear (27). All RCTs had a small sample size ranging from 8 to 45 per group, with subjects aged between 49.6 (±6.1) to 66.9 (±3.1). Vitamin D3 (cholecalciferol) was used as an oral vitamin D supplement in most of the studies, two used vitamin D3 via injection (14, 20) and two used vitamin D fortified yoghurt (19, 25). The results are shown in Table 1.

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<table>
<thead>
<tr>
<th>Author, country</th>
<th>Research design</th>
<th>Year</th>
<th>Intervention and sample size</th>
<th>Duration</th>
<th>Related target biomarker</th>
<th>Positive biomarker</th>
<th>General conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shab-Bidar et al. 2015</td>
<td>Single blind, randomized, placebo-controlled trial</td>
<td>2015</td>
<td>Iran</td>
<td>600 IU vitamin D3/d followed by 3000 IU vitamin D3 in plane 2 (N=45) vs. placebo (N=45), oral</td>
<td>3 months</td>
<td>Fasting serum glucose, HbA1c and QUICKI</td>
<td>Significant change in HbA1c (r=0.71, P&lt;0.001), QUICKI (r=0.009, P=0.001)</td>
</tr>
<tr>
<td>Sadjou et al. 2014</td>
<td>A randomized controlled double-blind clinical trial</td>
<td>2014</td>
<td>UAE</td>
<td>Placebo 66.7(9.7); 58.4±2.5 Vitamin D3 400 IU/d (N=13) vs. intervention: 53.8±9.2; 50.7±6.1 DY group: 500 IU vitamin D3 + 150 mg Cal (N=30) vs. placebo: 56.2±11</td>
<td>6 months</td>
<td>Fasting blood glucose, HbA1c, C-peptide</td>
<td>n/a</td>
</tr>
<tr>
<td>Elkassaby et al. 2014</td>
<td>Randomized, double blind, placebo-controlled clinical trial</td>
<td>2014</td>
<td>Iran</td>
<td>Placebo 35.8±2.6; 34.1±1.7 FPG lower at 3 months (D=0.40 vs. placebo +0.11mmol/L; P=0.06); PPG lower at 3 months (D=0.3 vs placebo +0.11mmol/L; P=0.03)</td>
<td>6 months</td>
<td>Delta C-peptide (DCP), FPG, PPG, HbA1c and HOMA-IR</td>
<td>Vitamin D has a transient improvement in glyceremia, but little to no therapeutic benefit in T2DM.</td>
</tr>
<tr>
<td>Ruy et al. 2014</td>
<td>Prospective, randomized, double-blind, placebo-controlled trial</td>
<td>2014</td>
<td>Korea</td>
<td>Vitamin D3 300,000 IU / (N=29) vs. placebo</td>
<td>2 months</td>
<td>Fasting insulin pulsatility, glucose-transported insulin sensitivity, QUICKI and fasting blood samples</td>
<td>n/a</td>
</tr>
<tr>
<td>Kampmann et al. 2014</td>
<td>Double blind, randomized placebo controlled trial</td>
<td>2014</td>
<td>Denmark</td>
<td>Vitamin D3 11,200 IU/d x 2 weeks then 5,600 IU/d x (N=8) vs. placebo (N=8), oral</td>
<td>3 months</td>
<td>FGTII, hyperosmolar hyperglycemic clamp, assessment of baseline high frequency insulin pulsatility, glucose-transported insulin sensitivity, QUICKI and fasting blood samples</td>
<td>No improvement in insulin resistance or HbA1C, might increase insulin secretion in T2DM patients.</td>
</tr>
<tr>
<td>Al-Saffar et al. 2014</td>
<td>A double blind, randomized, clinical trial</td>
<td>2014</td>
<td>USA/Saudi Arabia</td>
<td>Vitamin D3 100,000 IU (N=19), oral; vitamin C (N=12), oral</td>
<td>6 months</td>
<td>HOMA-IR &amp; QUICKI and HOMA-IR</td>
<td>Vitamin D-repletion improved B-cell activity in vitamin D—deficient T2DM with no significant changes in HbA1c or insulin sensitivity.</td>
</tr>
<tr>
<td>Tabesh et al. 2014</td>
<td>Parallel designed, double blind, randomized placebo-controlled clinical trial</td>
<td>2014</td>
<td>Iran</td>
<td>Placebo 55(10.7) Vitamin D3 10,000 IU/d x 2 weeks then 6,000 IU/d x 6 months (N=19) vs. placebo (N=24), oral</td>
<td>6 months</td>
<td>Vitamin D3 2,000 IU + calcium 200 mg/d (N=30) vs. placebo (calcium 200 mg/day) (N=32), oral</td>
<td>Fasting glucose, HbA1c, insulin, HOMA-IR and high-sensitivity C-reactive protein (hsCRP)</td>
</tr>
<tr>
<td>Jehle et al. 2014</td>
<td>Prospective, randomized, double-blind, placebo-controlled pilot study</td>
<td>2014</td>
<td>Swissland</td>
<td>Vitamin D3 300,000 IU / (N=29) vs. placebo (N=26), injection</td>
<td>6 months</td>
<td>HbA1c and HOMA-IR</td>
<td>Reduced HbA1c (3.9±1.5% vs +6.9±2.1%, P&lt;0.001); reduced HOMA-IR (-12.8±5.6% vs +10±5.4%, P&lt;0.032)</td>
</tr>
<tr>
<td>Yousef et al. 2014</td>
<td>Randomized double-blind placebo-controlled clinical trial study</td>
<td>2014</td>
<td>Iran</td>
<td>Placebo 400 IU/day (N=28) vs. placebo group (N=30)</td>
<td>2 months</td>
<td>HbA1c, insulin and HOMA-IR</td>
<td>A significant decrease in HbA1c (from 7.29±0.22 to 6.74 ± 0.18 %, P&lt;0.001) and insulin concentration (from 2.84 ± 0.97 pmol/L to 6.55 ± 0.28 µU/mL, P=0.020)</td>
</tr>
<tr>
<td>Nazari et al. 2013</td>
<td>Randomized, double-blind, placebo controlled clinical trial</td>
<td>2013</td>
<td>Iran</td>
<td>Vitamin D3 50,000IU/wk (N=30) vs. placebo (N=30), oral</td>
<td>3 months</td>
<td>HbA1c</td>
<td>HbA1c in male diabetic patients in interventional group was less than that of control group (p=0.0068)</td>
</tr>
<tr>
<td>Hechtman et al. 2012</td>
<td>Double blind, randomized clinical trial</td>
<td>2012</td>
<td>Iran</td>
<td>Placebo: 5.6±1.1; , Placebo: 5.6±1.1</td>
<td>3 months</td>
<td>Fasting blood sugar, HbA1c, HOMA and insulin</td>
<td>n/a</td>
</tr>
<tr>
<td>Nikzad等 et al. 2011</td>
<td>Double-blind, randomized clinical trial</td>
<td>2011</td>
<td>Iran</td>
<td>Placebo 35.8±2.6; 34.1±1.7</td>
<td>3 months</td>
<td>Fasting glucose, insulin, HOMA-index, delta C-peptide and HbA1c</td>
<td>Significant decrease in in serum insulin, glucose, insulin, HbA1c, DCS &amp; DSI &amp; FSG &lt;12.9±33.7 mg/dL (P=0.015) vs. PY &gt;9.6±4.9 mg/dL (P=0.035), HbA1c &lt;4.6±3.1% vs. &gt;4.6±3.1% (P&lt;0.001), HOMA-IR &lt;0.6±3.1% vs. &gt;0.4±3.1% (P&lt;0.001), an inverse correlation between changes in serum 25(OH)D and FSG (r=-0.208, P=0.05), a positive correlation between changes in serum C-peptide and QUICK (r=0.41, P=0.013)</td>
</tr>
<tr>
<td>Strubel et al. 2014</td>
<td>Placebo-controlled, randomized, double-blind study</td>
<td>2014</td>
<td>Germany</td>
<td>Placebo 33.8±4.2; Placebo: 33.8±4.2</td>
<td>3 months</td>
<td>Fasting insulin pulsatility correlated with 25OHD after 6 months in both groups (verum: r=0.23, P=0.492; placebo: r=0.23, P=0.492)</td>
<td>Fasting serum glucose, insulin, HbA1c, and HOMA-IR</td>
</tr>
<tr>
<td>Soric, Remter &amp; Smith 2012</td>
<td>Prospective randomized single-blind placebo-controlled study</td>
<td>2012</td>
<td>USA</td>
<td>Placebo 55.3±3.7</td>
<td>3 months</td>
<td>Fasting insulin pulsatility, glucose-transported insulin sensitivity, QUICKI and fasting blood samples</td>
<td>n/a</td>
</tr>
<tr>
<td>Patel, Porelys &amp; Liao 2010</td>
<td>Pilot prospective randomized trial, N/A control group</td>
<td>2010</td>
<td>USA</td>
<td>Placebo: 53.8±4.5</td>
<td>4 months</td>
<td>Fasting plasma glucose, HbA1c and QUICKI</td>
<td>n/a</td>
</tr>
<tr>
<td>Wittman et al. 2010</td>
<td>Double-blind, randomized parallel group, placebo-controlled trial</td>
<td>2010</td>
<td>UK</td>
<td>Placebo 66.7±9.7; 100,000 IU 65.3 (11.1); 200,000 IU 53.3 (9.1)</td>
<td>4 months</td>
<td>HOMA-IR, glucose and HbA1c</td>
<td>n/a</td>
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</table>
Using vitamin D fortified yoghurt as an intervention, Shab-Bidar, Neyestani (25) observed a significant change in HbA1c and QUICKI, but no significant change between groups. Similarly, Nikooyeh et al. (19) found a significant decrease in serum FSG, HbA1c and HOMA-IR in the vitamin D and/or vitamin D + calcium groups. They also observed an inverse correlation between serum 25(OH)D and FSG and concluded that vitamin D improved the glycaemic control in T2DM patients. It was noted that these two studies had a minimum vitamin D intake (500 IU/d), and the quality of these two studies were generally lower (scored 2 and 3 respectively, Jaded) than the previous two (scored 5, Jaded).

A study using calcium supplementation with 1,500mg/day for 8 weeks showed calcium had no effect on an insulin parameter (29). However, other studies showed a positive effect of vitamin D on beta-cell function and glucose tolerance which may have been due to the correction of calcium level and secondary hyperparathyroidism (30). Therefore, with calcium as the co-intervention, calcium’s effects on glycaemia should be considered when discussing the link between vitamin D and glycaemic control.

Vitamin D of different dosing showed inconsistent results. The largest dose used among the 16 RCTs was the 300,000IU vitamin D injection which occurred in two studies. One reported that vitamin D3 improved the insulin sensitivity by increasing the HOMA-IR and HbA1c (20), while the other failed to prove the association (15). Another study using oral vitamin D supplements of 100,000IU and 200,000IU found no improvement in glycaemic control (28). Most of the studies selected 500 to 6,000 IU vitamin D as the intervention dosage, the majority of which reported a negative link between vitamin D and glycaemic control in T2DM patients, but suggested a possible positive link between vitamin D and glycaemia (22), insulin sections (21) or insulin sensitivity (20).

The most common source of vitamin D in daily life is sun exposure, however there are no RCTs using sun exposure as an intervention. A current systematic review concluded that there is a significant gap between sun exposure and glycaemic outcomes (31). It also indicated that clinical trials using vitamin D supplementation may fail to capture the additional benefits of sun exposure. A recent study (32) showed a moderate level of evidence that sun exposure may prevent the development of T2DM. Hence more studies and RCTs are needed to explore the link between vitamin D via sun exposure and its impact on glycaemic control.

The National Health and Medical Research Council (NHMRC) suggested that sunlight is still the main approach for obtaining sufficient vitamin D and that dietary resources can replenish the level to a limited extent. More recently a study has suggested that the current data may underestimate the level of vitamin D3 in food since there is a discrepancy of vitamin D deficiency between calculation-based dietary data (71%) and actual serum 25(OH)D test data (19%) (33). This study also suggested that if we take 25(OH)D in animal-based food into consideration, there will be a 2-18 times higher level of vitamin D content, depending on the food type. Thus more studies are encouraged to explore the impact of dietary vitamin D on insulin sensitivity and glycaemic control.

Database bias is a limitation in the current review. Only one database (PUBMED) was used to conduct the article search and it is possible that some existing research studies may not have been included. Another criticism of this review is objective bias. Articles were selected and analysed by only one researcher thus there may have been subjective bias regarding article selection and analysis. A third limitation was the type of vitamin D intervention. Most of the studies used vitamin D3 through oral supplements and there were two studies that used injection. There were limited data of vitamin D2 or vitamin D gained via sun exposure or dietary resources to compare the differences. The fourth limitation was related to data extraction. Data such as ethnicity, gender, baseline fat mass index, outdoor physical exercise time, calcium intake from diet or supplements, vitamin D intake from diet or supplements could all affect the level of vitamin D, however, these features

Table 2. Quality assessment of RCTs as assessed by JADAD scale

<table>
<thead>
<tr>
<th>Author, Year, Country</th>
<th>Was the study described as random?</th>
<th>Was the randomization scheme described and appropriate?</th>
<th>Was the study described as double blind?</th>
<th>Was the method of double blinding appropriate?</th>
<th>Was there a description of dropouts and withdrawals?</th>
<th>JADAD SCORE</th>
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*Y=yes (1 score); N=No (0 score); **Total score > 3 indicate a high quality RCT.*
The authors declare no conflict of interest.

### ACKNOWLEDGEMENT & FUNDING SUPPORT
This project is supported by the ATMS Research Grant 2017.

### REFERENCES


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Table 3. Quality assessment of RCTs as assessed by VAN TULDER Scale

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<tr>
<th>Author, Year, Country</th>
<th>Randomisation adequate</th>
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<th>Care group blinding</th>
<th>Observer blinding</th>
<th>Outcome assessment time similar</th>
<th>Co-intervention accepted/ similar</th>
<th>Compliance acceptable in all-group</th>
<th>Drop out description &amp; acceptable</th>
<th>Include ‘intention to treat’ analysis</th>
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*Y=yes (1 score); N=No (0 score); NK=Not know (0 score); **Total score > 5 indicate a high quality RCT.


An evidence-based critical review of the botanicals bilberry fruit, black cohosh, bladderwrack and St John’s wort in clinical practice

Manuela Boyle | PhD, MHSc

Introduction

An evidence-based, patient-centred care approach to the use of natural medicines (i.e. vitamins, minerals and botanicals) focuses on the principle of ‘first do no harm’. It considers the best available indications of safety and efficacy, recognising that each person is an individual with different biopsychosocial dimensions. This paper proposes a review of some of the available evidence published in the literature on the herbs Bilberry fruit (Vaccinium myrtillus), Black cohosh (Actaea racemosa), Bladderwrack (Fucus vesiculosus) and St John’s Wort (Hypericum perforatum).

Bilberry

Bilberry is well known for the properties of its anthocyanidin and proanthocyanidin content. The active constituents are typically isolated from the berries and leaves of the bilberry plant, including anthocyanoside flavonoids (anthocyanins), vitamins, pectins and sugars, which are found in the berries, and quercetin, catechins, tannins, iridoids and acids, which are found in the leaves. The anthocyanosides are considered the most important of the pharmacologically active components. The concentration of anthocyanosides in the fresh fruit is approximately 0.1% to 0.25%, while concentrated bilberry extracts are usually standardised to 25% anthocyanosides. The berry’s anthocyanoside content increases as the fruit ripens, while the reverse is true of its leaf constituents. The chemistry and biological diversity of the anthocyanidins and anthocyanin (glycones and glycosides) have been extensively studied, although they constitute only between 0.1% and 0.25% in the fresh fruit. The catechin content of the fruit (tannin) on the other hand, is a lot higher, ranging from 5% to 10%. Tannins are polyphenolic compounds that have an affinity with proteins, and as such they are regarded as condensed anthocyanosides. When they meet the mucous membrane, tannins exert an astringent action, making bilberry ideal for treating diarrhoea.1 Bilberry is approved by Commission E, the German food and drug administration advisory board, for the treatment of non-specific, acute diarrhoea and mild inflammation of the mouth and throat.

Despite their high concentration, commercial products containing bilberry’s standardised extract have a safe therapeutic dose varying from 120mg to 480mg per day, which produces an actual daily anthocyanin dose of 60mg to 120 mg per day.2 Bilberry VMA (Vaccinium myrtillus, the anthocyanoside component of the extract) is usually standardised to contain 25% anthocyanidin. Research studies have shown that bilberry extracts containing anthocyanosides have strong antioxidant properties, maintain collagen fibres by promoting their biosynthesis, reduce capillary permeability, and inhibit platelet aggregation.3 Clinical evidence supports their use in peripheral vascular and ophthalmic disorders.4 Furthermore, anthocyanins may have a demonstrated protective effect on the vasculature of the connective tissues. As demonstrated by a study conducted by Erlund et al.3 the concentration of bilberry in connective tissue was five times higher than in plasma four hours after administration. The researchers demonstrated that the consumption and administration of bilberry helps to reduce low-grade
In a human clinical study reported by Mian et al.8 a diet rich in berries (n = 15) or a control diet (n = 1). Although there was no significant difference between the two groups in body weight and lipid metabolism, those who consumed daily 400g fresh bilberries showed a significant (p = 0.024) decrease in serum high-sensitivity C-reactive protein, IL-6, IL-12, and in LPS concentrations compared to the control group. In another study, Karlsten⁸ argued that bilberry anthocyanins can improve ischemia damage and preserve ischemic reperfusion injury. In a similar study, Morazzoni et al.⁷ reported the results of post-marketing surveillance data from 2,295 individuals who used a daily bilberry extract. Very minimal adverse effects were experienced (4% of the subjects overall), with only 1% complaining of gastrointestinal discomfort and less than 1% experiencing nausea or heartburn.

In a human clinical study reported by Mian et al.⁸ a diet rich in various types of berries was shown to reduce systolic blood pressure, particularly in individuals with an elevated baseline blood pressure. In this study, the consumption of moderate amounts of berries resulted in individuals with favourable changes in platelet function, blood pressure and HDL cholesterol, indicating that regular consumption of berries may play a role in preventing cardiovascular disease. Another investigation conducted by Zhu et al.⁹ involved a comparison between mixed-berry derived anthocyanins and a healthy diet comprising, in part, of regular bilberry consumption. The result of this study demonstrated that regular bilberry consumption improved various biomarkers of endothelial function, including flow-mediated dilation, soluble vascular adhesion molecule-1 and E-selectin. Therefore, it could be concluded that anthocyanin supplementation might help to improve endothelium-dependent vasodilatation and serum lipid profile, as well as to decrease inflammation in hypercholesterolemic individuals.

**Black cohosh**

In 1989 Commission E approved the use of black cohosh for its beneficial effect in dysmenorrhea, premenstrual discomfort and neurodegenerative issues associated with menopause. The somewhat narrow application of the standardised European isopropanolic preparation of this herb as a gynaecological remedy follows the response to consumers’ widespread concerns about the prolonged use of hormone replacement therapy. Due to the absence of phytoestrogenic isoflavones, the focus of research on black cohosh has moved toward its antiestrogenic and neuroendocrine properties. One of the most comprehensive studies was conducted by Kapur et al.¹⁰ who demonstrated that black cohosh extract has negligible effects on oestrogen receptors in the uterus and a significant beneficial effect on the balancing of the hypothalamic-pituitary axis. Further recent research has shown that black cohosh contains three types of hormonally active substances, one of which suppresses luteinising hormone (LH) secretion after prolonged administration, while the other two exert a weak oestrogen-like effect. LH surges are reported to cause flushing, and the suppression of this hormone by black cohosh has been shown to control the symptoms.¹¹

Numerous human clinical trials have further demonstrated the efficacy of black cohosh for menopausal symptoms. In one human trial, 36 women reported significant reduction in the severity and frequency of hot flushes, nervousness, irritability and depression after three months of black cohosh supplementation.¹² Further to this study, Borelli and Ernest² compared low dose oestrogen therapy to black cohosh supplementation in a double-blind study of 80 women with hot flushes (day and/or night) consistent with menopausal symptoms. After three months participants in the control group reported that their symptoms had significantly improved when compared to the experimental group. According to the authors, this improvement was due to the dopaminergic activity of the herb.

Commission E has approved the use of black cohosh as a treatment for menopausal symptoms and the World Health Organisation has similarly recognised its use for the treatment of profuse sweating, irritability and sleeping disorders. The Therapeutic Goods and Administration in Australia has made it mandatory that this herb carries a label warning about possible idiosyncratic hepatic reactions. The warning was based on a causal association between black cohosh and hepatitis. It is important to note that causality is at best considered scientifically questionable.

A study conducted by Antoine et al.¹³ demonstrated that black cohosh does not contain isoflavones with aromatase inhibition activity. The herb is primarily antiestrogenic, with receptor-binding tests negative for alpha or beta oestrogen receptors. It does not have oestrogenic effects on uterine tissue. Moreover, Lupu et al.¹⁴ have shown that black cohosh significantly inhibits oestrogen-induced proliferation, while enhancing the anti-metastatic effect of the drug tamoxifen. Despite the evidence in vivo and in vitro, the indications are still not clear regarding black cohosh’s safety in women presenting with hormone-sensitive malignancies such as breast cancer, uterine cancer, or endometriosis.¹⁵ Although the possible interaction between black cohosh and tamoxifen is still unclear, a human clinical
trial conducted on 136 breast cancer survivors aged 35-52 years has shown that the combined administration of tamoxifen and black cohosh reduced the number and severity of hot flushes.16

Bladderwrack

Bladderwrack contains about 0.1% of a volatile oil, cellulose, mucilage, mannite, colouring and bitter principles, and bromine compounds of sodium and potassium with iodine varying according to location and season. Iodine does not occur uncombined in nature, but it is widely distributed in the form of iodides and iodites, mainly sodium and potassium, in seawater, some seaweeds and various minerals. Research studies have shown that bladderwrack contains organic-bound iodine and it is therefore an ideal remedy to help stimulate thyroid function. A recent double-blind placebo-controlled human clinical trial on 25 healthy postmenopausal volunteers has shown that those who consumed 5 grams of seaweed daily demonstrated a small but significant increase in thyroid-stimulating hormone.17 The thyroid gland has an inbuilt mechanism that allows it to self-regulate when there is an excess of iodine. In healthy individuals, the effect of excess iodine is generally only transient, thyroid hormone synthesis being normalised over approximately 24 hours. In individuals presenting with an underlying thyroid disorder, the gland is not able to adapt to excessive iodine, which can lead to the onset of either hyperthyroidism or hypothyroidism. Research studies have shown that in individuals with a thyroidectomy, and those with autoimmune thyroiditis, including the elderly, the risk of developing iodine-induced thyroid dysfunction might be increased. Hypothyroidism or hyperthyroidism may be caused by supraphysiologic iodine exposure, either subclinical or overt.18

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As shown in a double-blind placebo-controlled pilot study, bladderwrack has a strong anticoagulant activity. In a human clinical trial reported by Fujimura et al., bladderwrack extract demonstrated a significant improvement in skin smoothness and elasticity due to the production of procollagen I and dermal wound repair, and by the inhibition of transforming growth factor (TGF)-beta1-induced fibroblast proliferation. An isolated case of possible poisoning associated with bladderwrack supplementation was recorded in a 54-year-old woman who experienced fatigue, nausea and vomiting following its prolonged use. All those symptoms were reversed once supplementation was discontinued.

St John’s wort

St John’s wort is one out of the nine genera belonging to the botanical family Clusiaceae Lindl (syn. Hypericaceae Juss.; APG III, 2009). The genus contains 484 species spread worldwide, one of which, Hypericum perforatum, is largely used in folk medicine with a long history as a vulnerary and for reducing mental affliction, including melancholy. As early as 1633, Gerard described St John’s wort as a very effective healing remedy for burns, wounds and snake bites. The popularity of this herb was so widespread that it was included in the Pharmacopoeia Londinensis in 1618. St John’s wort was later introduced into the homeopathic material medica by Muller in 1850 and almost simultaneously was included in the Homeopathic Pharmacopoeia of the USA for its capacity to treat nerve pain and traumatic injuries. Since the mid-1980s, several in vivo and in vitro research studies have shown that a standardised St John’s wort extract can be successfully used to treat mild to moderate depression. Commission E has further approved St John’s wort for the treatment of depression and contused injuries as well as for neuralgic pain, shingles and burns to the skin.

In 2000, some reports of possible interactions between St John’s wort and prescription drugs such as digoxin, cyclosporine and indinavir appeared in the literature. The data prompted researchers to review other potential interactions between this herb and a wider group of pharmaceutical drugs. Research studies caution the use of St John’s wort when used in conjunction with most pharmaceutical medications due to its effects on cytochrome P450 (CYP450) mixed-oxidase system, various conjugates and transferases, as well as transporter proteins that modulate drug efflux across intestinal, renal and biliary epithelia. Although numerous studies have reported interactions between St John’s wort and pharmaceutical drugs, the evidence varies significantly. For example, Fugh-Berman and Ernst reviewed published studies of St John’s wort interactions with drugs. Of these studies, 41 were rejected as unreliable and of the remaining group 11 reported possible interactions and only 2 were likely to indicate an interaction. An open-label, fixed schedule study on 12 participants reported by Wang et al. demonstrated that long-term use of St John’s wort activates selective induction of CYP3A in the intestinal wall, but does not alter the function of CYP2C9, CYP1A2, or CYP2D6. A systematic review comprising 16 studies (3 randomised controlled trials, 5 single-arm before-after studies, 6 cohort studies and 2 case reports) demonstrated that special precautions should be used when administering St John’s wort in conjunction with pharmaceutical drugs such as Voricazone (a triazole antifungal agent) that are metabolised via CYP450. In other studies, St John’s wort was found to reduce the effectiveness of benzodiazepines due to the shared metabolic pathway (CYP3A4), but not to influence the pharmacodynamics of the drug. Although the number of research studies dedicated to establishing interactions between St John’s wort and pharmaceutical drugs is expanding, it is important to note that these studies are likely to ignore the fact that drug disposition is unpredictably mediated by a wide variety of dietary compounds, food, herbs and beverages, as well as by genomic and lifestyle choices, making a meaningful screening virtually impossible to obtain. Additionally, apart from a few studies, most clinical trials have failed to present sound methodology and appropriate randomisation. Therefore, the variable effects of St. John’s wort on different conventional drugs, and the mechanism by which these effects may operate, remain largely inconclusive. As reported by Mills and Montori in the British Medical Journal better-designed pharmacokinetic studies are required to guide clinical practice.

St John’s wort is generally well tolerated, with a very low incidence of reported adverse reactions. Although some literature has been critical of the use of St John’s wort in breastfeeding, research studies are inconclusive. For example, in a double-blind placebo controlled human clinical study breastfeeding women showed no significant differences in adverse effects or lactation duration between the groups, apart from two reports of colicky infants in the St John’s wort group vs. one in the matched control group, and two cases of drowsiness and one of lethargy with St John’s wort group vs. no adverse effects in the matched control group. In this trial, there were no reported adverse events requiring medical treatment.
Conclusion
The use of botanicals in clinical practice is widespread and growing. Whether the use of herbal medicine is rooted in traditional or contemporary culture, its medicinal effects are still evidenced via randomised controlled trials. However, it is well demonstrated that the active ingredients of all botanicals are multi-chemical in nature, making pharmacological analysis more complex but not affecting the evidence. For conventionally trained clinicians, well-designed randomised controlled trials are of particular significance in their choice of prescriptions.

REFERENCES
Indigestion literally means impaired digestion and most people at some time in their lives will experience it. At any one time, it affects 15% of the population. The symptoms commonly associated with indigestion include abdominal distension, dyspepsia (sometimes used as a synonym for indigestion), eructation and flatulence. Indigestion itself is usually uncomplicated or ‘functional’, but may indicate the presence of problems such as gastroparesis, inflammatory bowel disease, coeliac disease, food allergy, intestinal ischemia, gastro-oesophageal reflux disease (GORD), gastritis, cholecystitis, cholelithiasis, heart disease or diabetes. There may also be an association with parathyroid, pancreatic, thyroid or kidney disease, helicobacter infection, peptic ulcer or cancer. It’s for the latter reason that unexplained indigestion of rapid onset, particularly in those over 55 years of age, should be investigated as a matter of priority.

Indigestion has also been linked to gastro-intestinal dysbiosis, anxiety, depression, food sensitivity, digestive enzyme dysfunction, alterations of gastric transit time, obesity, hiatus hernia, overeating, eating too quickly, the use of some medicines, exposure to dietary nitrates, and pregnancy. For some people suffering from indigestion, it may be aggravated by anxiety, smoking, eating too quickly, consuming alcohol or coffee, or the use of garlic, onions or fatty foods.

The medical treatment of functional indigestion often involves the use of non-steroidal anti-inflammatory drugs (which can also cause indigestion) or proton pump inhibitors. Antacids, H2 receptor antagonists and prokinetic agents have had a long history of use in this area but have been found to be ineffective.

There is some published evidence for the use of artichoke leaf, ginger, greater celandine, licorice, peppermint, and turmeric as herbal medicines in the management of functional indigestion, as well as caraway seeds. A 2002 systematic review found the combination of peppermint and caraway particularly useful. Anecdotally, dietary modification, lifestyle modification and the use of digestive enzymes have been found to be of some use in this area. Clearly, any intervention should first address the underlying cause of the indigestion.

Regardless of the cause of the problem, homeopathic treatment has a long history of successful use with people suffering from indigestion, and what follows are brief discussions of some of the more commonly prescribed medicines from this modality.

**Antimonium crudum**

Indigestion in this case is often accompanied by a thickly coated white tongue as well as dyspepsia, eructation that tastes of previously eaten food, and abdominal distension. Symptoms may arise from overeating. There is often a loss of appetite or a desire for acid or sour foods and a thirst for cold water. Nausea or vomiting may be present and the sufferer may appear to be irritable or anxious. Symptoms may be worse in the evenings, from overeating, from fatty foods and better from sitting up, eructation and flatulence.

**Anacardium orientale**

A good indicator here is indigestion with stomach pain that’s worse with an empty stomach and better from eating. Dyspepsia, an offensive halitosis and nausea are often also present. Symptoms are worse before a bowel movement and better from passing stools.

**Argentum nitricum**

Arg nit can be useful where a peptic ulcer is responsible for indigestion.
Nausea and vomiting of mucus may be noted as well as a painful and inflamed tongue tip, eructation and painful abdominal distension. A craving for sweets is usually present here but sweets often cause diarrhoea. Symptoms are worse at night and from sweets, and better from cold, eructation and flatulence.

**Arsenicum album**

Many of the symptoms seen in the Arsenicum presentation are burning in character and the indigestion in this instance is commonly associated with a burning dyspepsia which is relieved by hot applications. The sufferer may also have experienced feeling cold and weak, and may have experienced offensive diarrhoea, nausea and vomiting. The person may appear anxious and restless and though thirsty, only consumes small sips of liquid. A reduction in appetite may be noted to the extent that the sufferer can't tolerate the sight or smell of food and has a particular dislike for cold drinks. Symptoms are worse between midnight and 3 a.m., from cold, acid foods or melons, and better from warmth, from warm drinks and from having the head elevated.

**Bryonia**

Those who suffer from indigestion soon after eating, and where the indigestion is aggravated by motion or pressure, often do well with this medicine. A white coating on the tongue, a yellow tint to the skin and a history of liver disorders may be noted and the sufferer may complain of constipation, lethargy, a dry mouth, hypogeusia and a bitter taste in the mouth, and may appear to be irritable. There may be a desire for large amounts of cold water. Nausea and a faintness on rising from a sitting position may be experienced. Symptoms are worse from warm drinks, from motion, from touch, from moving the head, during warm weather and better from rest, strong pressure and cold.

**Calcarea carbonica**

Calc carb is frequently thought of for ailments experienced by people of a fair or chalky complexion who are overweight and sweaty, particularly around the head. The indigestion experienced here may occur with sour eructation and vomiting, an increase in appetite, as well as abdominal distension and a strong desire for cold drinks. Symptoms are worse from pressure, cold, exertion, starchy foods and milk and better for dry weather.

**Carbo vegetabilis**

Abdominal distension, eructation, delayed digestion, offensive flatulence, dyspepsia and indigestion may point the prescriber in the direction of Carbo veg. Cramping pain that causes the sufferer
to bend forward, and an aversion to milk and fatty foods, and generally slow digestion, may be found here. Symptoms are worse in the evening, from fatty foods, wine or spirits and in cold air, and better after eructation and from sitting up.

**Chamomilla**

Those who respond to this medicine will frequently be over-sensitive to pain, restless, and suffer from halitosis as well as indigestion accompanied by post-prandial bloating. The sufferer may complain of acid reflux and regurgitation of food. Symptoms are worse from anger, eructation, coffee and after eating, and better from the local application of heat and passive movements.

**Cinchona officinalis**

This medicine is also known as China. The need for it may be recognised by the presence of indigestion with sour eructations, flatulence, and abdominal distension not relieved by eructation or the passage of flatus. Typically the digestion here is slow to the extent that digested food appears to ferment. There may be an increase in appetite and a history of diarrhoea or vomiting. Symptoms are worse from milk, tea, from the slightest touch and after eating, and better from motion and from bending double.

**Graphites**

The indigestion in this case may be associated with offensive flatus, dyspepsia, abdominal distension and stomach pain. Symptoms are worse at night and from cold, and better from eating, consuming hot drinks, eructation and walking.

**Ignatia**

Indigestion sufferers who are inclined to be emotionally labile, crave acid foods and suffer from nocturnal stomach pain and flatulence, may respond well to Ignatia. Nausea and vomiting may be seen here. Symptoms are worse from emotion, from coffee and after eating, and better while eating, from a change in position, and pressure.

**Lycopodium**

The need for Lycopodium may be indicated by indigestion and abdominal distension that occurs soon after beginning to eat, as well as flatulent dyspepsia. The sufferer may begin a meal with a strong appetite but is soon too full to continue and frequently feels sleepy after eating. Digestion is slow, a burning eructation that rises to the pharynx may be experienced and there’s often a marked desire for sweets. Symptoms are worse in the late afternoon, from cabbage, beans, onions and peas, and better from warm drinks, motion, and in cool air.

**Natrum carbonicum**

Indigestion associated with flatulence, eructation, bloating immediately after a meal, and a sour or bitter taste in the mouth, are common pointers to this medicine. A spike in appetite at around 5am and a desire for sweet food as well as generally weak digestion, may also be noted here. Symptoms are worse from mental exertion, from heat, from drinking cold water or milk, and are better from motion.

**Nux vomica**

Nux is one of the medicines more commonly prescribed for those who suffer from indigestion. In this instance, indigestion often appears at around 1-2 hours after eating, particularly where the sufferer appears to be irritable, complains of dyspepsia, abdominal distension, bitter or sour eructations. There may be a strong desire for stimulants and fatty foods, a strong thirst and a sour taste in the mouth and the posterior portion of the tongue may be coated. The sufferer may be prone to overeating or drinking to excess, may be chilly, and may experience nausea after eating and a desire to vomit, but have difficulty in satisfying this urge. This person may also have difficulty in satisfying the urges to belch or pass stools. A general sensitivity to noise and light may be noted and the abdomen may be sensitive to pressure. Symptoms are worse from alcohol and stimulants, in the morning, from mental exertion or after a meal, and are better after passing stool or from a short sleep.

**Phosphorus**

Indigestion that’s associated with vomiting soon after eating or drinking, sour post-prandial eructation, a sour taste in the mouth, and an increased appetite soon after eating, often indicate the potential effectiveness of a prescription of Phosphorus. Symptoms are worse from physical or mental exertion, after salty or warm food or drink, and better from cold food or sleep.

**Pulsatilla**

The symptoms associated with this medicine include indigestion with frequent eructations that taste of the food recently consumed, abdominal distension, flatulence, dyspepsia, a bitter taste in the mouth, hypoguesia, thirstlessness, gastric reflux and a thick, white, rough coating of the tongue. These issues may be brought on by emotional trauma. Symptoms are worse from heat, from rest, from the consumption of fruit, pastruy, rich or fatty foods, and worse in the evening. Symptoms are better in the open air, from motion and from cold food and drinks.

**Sulphur**

The need for this may be indicated by the presence of indigestion with flatulent dyspepsia, offensive eructations, a strong desire for sweets and either a diminished or increased appetite. Symptoms are worse at around 11am, from the consumption of milk, from the warmth of a bed, and from standing, and better from warm, dry weather.

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The effectiveness of manual lymphatic drainage and low level laser in the treatment of a client with lipedema: an N-of-1 trial

Angela Balinski, Sandra Grace, Cathy Avila and Jo Bradbury

Introduction
An N-of-1 trial is a single or double blind randomised controlled trial with one participant. N-of-1 trials are particularly useful for clients of natural medicine practitioners because they can accommodate the holistic and customised treatments that commonly occur. This paper reports on the first of a series of N-of-1 trials sponsored by ATMS.

The participant
The participant was a 44 year old female with lipedema. Lipedema is a disorder of adipose tissue of unknown cause. It affects females primarily, typically beginning at puberty. It is characterized by fatty deposits in the hips and thighs. (1) A family history of lipedema is common. (2) In this study, the participant’s lipedema was confirmed by her GP.

Interventions
The participant was alternatively exposed to the intervention (manual lymphatic drainage (MLD) with low level laser therapy) and a comparator (MLD with sham laser therapy). MLD aims to direct lymphatic fluid away from oedematous tissues and reduce the volume of fluid in the limb. (3) It is well-tolerated and generally safe to use. (4) Low level (or non-thermal) laser is used to treat acute and chronic pain, and to relieve swelling and inflammation. (5) The laser is applied to the painful and/or fibrotic areas of the affected limb to increase the softness of the tissue and therefore the movement of fluid out of the tissue. Sham laser consisted of the same laser application but with the power turned off.

Outcome measures
Outcome measures included:

- 100mm Visual Analogue Scale (VAS): The participant marked the point on a line between ‘No pain’ and ‘Severe pain’ that represented their pain at the time. The data was collected at the same time each day.

- Patient Specific Functional Scale (PSFS): The participant listed four activities that she found difficult or unable to do because of her lipedema and scored the level of difficulty on a scale of 1-10.

- General Health Questionnaire (GHQ–12): This 12-item questionnaire was designed to assess the participant’s general health status.

Data analysis
The data was analysed using visual graphing of the pain scales, the PSFS and GHQ-12.

Trial procedures
The trial participant attended weekly clinic sessions for eight weeks. In Weeks 1 and 8 only assessments occurred. In Weeks 2-7 the participant received either manual lymphatic draining with laser therapy or manual lymphatic drainage with sham laser therapy in a randomised sequence.

Results
The maximum pain was rated as 22mm on a 100mm VAS scale occurring in Week 0 and 1; the minimum pain score was 0mm occurring in Weeks 1, 4 and 5. Daily pain assessments in the weeks of active laser treatment were compared with the weeks when sham laser was given. While the trend across the trial weeks was one of decreasing pain, there was no discernible difference between the effect when the active and sham laser treatments were applied together with the MLD, by any of the measures employed.

The four activities identified by the participant for the PSFS were running, walking or standing on her feet all day without compression tights, high intensity training at ‘boot camp’, and sitting for long periods. No change was reported in Weeks 3 (sham laser) and Week 6 (active laser treatment). The largest change was reported in Week 5, and at less than 1.3 (0.75 in Week 5) was below the minimum clinically relevant change of 1.3 described by Abbott and Schmitt (6) in lower limb pain. Table 1 shows the mean change in rating scores together with the percentage change.
Conclusion
This study was designed to provide the highest level of evidence of treatment efficacy for an intervention in an individual. Pain was identified by the client as the primary reason for her seeking treatment, even though her maximum pain level was low (22mm out of 100mm on the VAS). The results of this trial show that pain decreased over the duration of the trial, however, there was no discernible difference between using active or sham laser with MLD for this client.

Angela’s reflections
I began my research when I first noticed an ad in the ATMS journal asking if any practitioners would be interested in learning the clinical research skills required to work formally with a clinical research project, linked to a university. I have always been interested in this and felt that I had been researching most....
of my life as part of my practice, albeit informally.

The first place to start was turning clinical questions into research questions. When I was nursing or while I was treating clients with lymphoedema, remedial massage or flower essences I constantly asked myself:

Did the treatment work? Did the treatment help? If so, how long did it work for? Did the problem end straight after the treatment? Did it take several or many treatments to get a result? What were the problems associated with it working? What other factors did my client have that may have prevented them from using the treatment as prescribed or coming as often as needed?

Becoming involved in a formal study was enlightening as well as disheartening as I realised that my initial excitement was dampened when I began to understand what it takes to scientifically research a problem. This included conducting a literature review to collate the known knowledge, attending zoom meetings with researchers from Southern Cross University to design a study for my practice, modifying my idea to fit within the parameters of the trial and then performing the treatment protocols as set out in the trial.

Working with a university ethics committee also had its challenges. I had to find a client for the trial who fitted with the trial inclusion criteria. We needed a healthy client whose only medical diagnosis was lipedema. Most of the people I see have comorbidities that affect them in different ways. It seems we constantly modify our health goals for them with this in mind.

The trial commenced in the first week of November. It was an eight-week single blind N-of-1 trial. Associate Professor Sandra Grace was an excellent mentor and teacher who helped me with the step-by-step procedures and protocols that I had to attend to before commencing the trial. I think it is rare in University life to have such close and regular contact so I felt lucky to have had so much help. All the other researchers were excellent as well and I encourage any of you reading this to take up the opportunity to research whenever you can.

There seemed to be a lot of paperwork but once the trial was finished it seemed that the paperwork was very necessary as it began to outline all the different aspects of the pain management of the client with lipedema. It is helpful to collect as much relevant data as possible so that you get a clear picture of how the lipedema treatment and low level laser were affecting my client’s pain. Our data collection included a daily pain diary, a Patient Specific Scale and a General Health Questionnaire. My client found the data collection paperwork quite easy to follow. A lot of questions arose in my mind while I was doing the treatment but they had to be answered later as it was important that the treatments were conducted according to the protocol that had been approved for the trial.

An interesting aspect of research is that it sets out to answer a question and then ends with more questions - questions that need another trial to answer. Thank you ATMS and Southern Cross University for giving me this opportunity.

A poster (Figure 1) summarising the trial was presented at the Australasian Lymphology Association’s conference in Brisbane in May, 2018.

Acknowledgement

This project was sponsored by ATMS. It is part of a program designed to teach members how to run high quality trials in their practices.

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Breast cancer is likely to be the most commonly diagnosed cancer in Australia. While it primarily affects females, it is possible (although unlikely) for men to be affected. According to Australian Government statistics, it is estimated that approximately 18,000 females will be diagnosed with breast cancer in 2018. Advances in early diagnosis and treatments have significantly improved outcomes, with the five-year survival rate exceeding 90% (2009 – 2013 statistics). This figure keeps improving as newer treatments are developed and early diagnosis improves.

The risk factors for breast cancer are largely outside a person’s control. According to Cancer Australia, the main risk factors are being a woman, increasing age, having a strong family history of breast cancer and various hormonal factors. Whether or not a woman has children or has breast-fed may also be an influence, as is menstrual history. However, there are a few lifestyle changes that a person can make to reduce the risk of contracting breast (and other) cancers. These include reducing alcohol consumption, not smoking and doing regular physical activity. According to the US Centre for Disease Control and Prevention, maintaining a healthy weight (particularly after menopause), minimising combination hormone therapy (HRT) after menopause and avoiding ‘certain forms of oral contraceptive pills’ may also decrease the risk.

As naturopaths, we can encourage our patients to quit smoking, minimise alcohol consumption, remain physically active and provide dietary advice to maintain a healthy weight. We can also recommend that female patients see their GPs to have regular screening as well as learn self-examination techniques to detect suspicious lumps early. However, mammographic screening is not effective in the early detection of breast cancer for women under 40, as the breast tissue is dense, making accurate detection difficult. This is particularly problematic for women with especially dense breasts (more fibrous tissue) as the fibrous tissue can look similar to a tumour.

One thing naturopaths cannot do is use herbs to prevent, treat or cure breast cancer. While plants have a long history of use in cancer treatment, the term ‘cancer’ has been poorly defined in traditional or folk medicine. Traditional definitions of cancer may have included hard swellings such as abscesses, calluses, corns, warts or polyps, as well as non-malignant tumours. From 1955, the US National Cancer Institute screened over 114,000 plant extracts for anticancer activity and found less than four extracts in every thousand contained compounds.
that demonstrated efficiency. Out of all of the extracts studied only 26 proceeded to secondary testing. Out of these few, only taxanes from the Taxus brevifolia (Pacific Yew) received marketing approval from the US Food and Drug Administration. A synthetic form of this compound is used in the highly effective taxol family of drugs, including Paxlitaxel, used in breast cancer treatment.

There are several types of breast cancer. They are classified according to where the cancer is believed to have originated, whether it is invasive (has spread to other tissues) and the degree to which the disease has spread beyond the breast tissue. This guides the oncologist and surgeon in their treatment strategies, which may include surgery, chemotherapy, radiation therapy, post-treatment hormonal therapy or a combination.

Naturopaths, and other complementary health therapists, must ensure that they support the oncologist by not in any way interfering with the efficacy of the medical treatment. Due to the complexity of cancer treatments many herbal medicines and dietary supplements are known to or are believed to interact with medical therapies. Before any supplement is recommended it is important that the patient discuss it with their oncologist and follow their advice. It is also important that complementary medicine practitioners reinforce this message and guide patients to reliable sources of information, such as the Memorial Sloan Kettering Cancer Center’s database of herbs and supplements or the About Herbs App. This database provides evidence-based evaluations of common herbal and dietary supplements as well as potential interactions. Nevertheless, the oncologist, as primary physician, must be consulted and approve any supplements that the patient may take, whether professionally or self-prescribed.

Due to the complexity of cancer treatments many herbal medicines and dietary supplements are known to or are believed to interact with medical therapies. Before any supplement is recommended it is important that the patient discuss it with their oncologist and follow their advice.

Chemotherapy refers to drugs that are used to destroy cancer cells. Each patient offered chemotherapy will be given one or more of these drugs (either individually or in combination) according to an evidence-based treatment protocol. While these drugs are effective at destroying cancer cells, they also have significant side effects that can affect patients in different ways. Common side effects include nausea and vomiting, fatigue, hair loss, changes to bowel habits, weight change, mouth ulcers, skin or nail changes, menopausal symptoms (cessation of periods, hot flushes, vaginal dryness), depression or anxiety, sexual difficulties, nerve or muscle soreness, swelling, ‘chemo brain’ (feeling vague or in a fog), increased risk of infection, bleeding or bruising and allergic reactions. The oncologist usually manages these side effects using drug therapies.

Chemotherapy often causes changes in taste and appetite. The challenging aspect of this is that the changes can vary throughout the treatment, making it difficult to plan meals. As naturopaths, we can help our clients to manage their diets and make healthy eating choices. Chemotherapy puts a significant oxidative stress on the body, which affects the liver and other organs of elimination. While it is agreed that this oxidative stress may increase the side effects of chemotherapy and destroy other tissues, the evidence for the effectiveness of antioxidants is poor. In a 2008 study, only 33 of 965 articles reviewed demonstrated a sound evidence basis for their conclusions. Of these articles 24 reported some evidence of decreased toxicity side effects due to the use of antioxidants, nine studies reported no difference and one study reported increased toxicity.

This has to be weighed against the risk of antioxidant supplement-drug interactions with chemotherapy. The pharmacology of some chemotherapy drugs actually relies upon reactive oxygen species (free radicals) for their cytotoxic effects. This is also thought to be one of the mechanisms of action of radiotherapy. While free radicals may contribute to some cancers and ancillary cell damage, the use of antioxidants may diminish or even ‘quench’ the effect of chemotherapy and radiotherapy.
treatments. Each treatment generates its own reactive oxygen species, which may or may not adversely or beneficially interact with antioxidant supplements. Until there is evidence to support a specific interaction, the general rule is to avoid antioxidants because of the real risk of reducing the effectiveness of the treatment.12

Given that there is definite oxidative stress on the body, a good cleansing diet can be of benefit to support the treatments. This includes encouraging the patient to eat a variety of fresh fruits and vegetables in moderation, eating lean protein foods (fish, eggs and chicken), avoiding processed foods and minimising fatty foods (which themselves put a strain on the liver). While naturally occurring antioxidants in natural foods generally are acceptable, patients should avoid excessive consumption of ‘superfoods’ such as blueberry or pomegranate powders, green tea extracts and, for some such as blueberry or pomegranate, excessive consumption of ‘superfoods’ may or may not adversely or beneficially interact with chemotherapy, different types of physical therapies such as gentle cupping (using magnetic vacuum cups), magnets or heat/cold packs may be effective to a greater or lesser degree.

Treatments for cancer are not well tolerated and have many side effects so it is little wonder that patients will scour the Internet looking for ‘miracle’ cures. I have had patients report to me that eating asparagus ‘cured’ their prostate cancer and that they knew of a relative whose breast cancer was cured through meditation. It is possible that in these few isolated cases the cancer spontaneously resolved. Nevertheless, the overwhelming evidence is that cancer, even if detected early, can only be treated effectively through medical intervention. If a patient presents with any suspicious lump or changes to their breast or underarm axillary nodes, they should be referred to their GP immediately.

Our job as naturopaths is not to cure cancer. However we can support our patients through instilling healthy eating, exercise and lifestyle habits and providing sensible evidence-based advice about treatment options.

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Discussion

The results of the reviewed clinical trials indicate efficacy of short-term administration of saffron for treating mild to moderate depression. They also indicate saffron is as effective as the tricyclic antidepressant medication imipramine, and SSRI medications fluoxetine and citalopram for reducing depressive symptoms. These findings support those of two meta-analyses by Hausenblaus et al.41 and Lopresti and Drummond24 who determined saffron had similar efficacy to antidepressant medication and large treatment effects compared to placebo. It is also noteworthy that saffron demonstrated significant anti-anxiety effects in two of the trials conducted.43,44

Duration of treatment

Trial lengths of clinical studies assessing efficacy of saffron for depression varied from 4 to 12 weeks, with the majority of trials having a 6-week intervention period. Some of the clinical trials included within this review demonstrate significant benefits of saffron treatment after only one week.79,80,82,84 and statistically significant decreases in depression scale scores continued as treatment progressed. No long-term follow-up trials have been conducted so its efficacy after 12 weeks is unknown. These clinical trials have demonstrated that saffron may be effective as a first line therapy or adjunctive therapy for short term treatment of mild to moderate depression, and this quick effect of saffron may have particular clinical relevance since pharmaceutical antidepressant medication can take 4 to 6 weeks to reduce depressive symptoms.18-20 Saffron has been shown to be a safe alternative to antidepressant medication with few adverse effects at trialled therapeutic doses. Therefore long-term treatment may be an available option, but longer clinical trials are required. The longest clinical trial to date was for 14 months and used saffron as an intervention for early age-related macular degeneration.90 Another 22-week trial for Alzheimer’s disease compared saffron stigma (30 mg/day) to the acetylcholinesterase inhibitor Donepezil (10 mg/day) (n=54). It was well tolerated and had fewer side effects than pharmaceutical medication.97 Longer trials are therefore warranted.

Dosage and extract source

The majority of clinical trials assessing saffron for depression used a dosage of 30 mg/day; exceptions include the studies by Mazidi et al.45 (100 mg/day saffron) and Talaei et al.46 (30 mg/day crocin extract). The petal of saffron was used in two RCTs;80,83 all other studies used the stigma. Treatment efficacy of petal and stigma extracts were comparable, with no significant differences in HAM-D score changes. In a 6-week pilot double-blind RCT Akhondzadeh, Basti et al91 demonstrated that efficacy of saffron
petal was comparable to the stigma in reducing depressive symptoms at a dose of 30 mg/day. The antidepressant activity of saffron is attributed to several bioactive constituents including safranal, crocin and crocetin, however, crocin is not present in the saffron petal. Further studies have identified another bioactive constituent in the petal, kaempferol, which has antidepressant activity. The petal also contains phenolic compounds that have high antioxidant activity, and may contribute to its antidepressant effect. It would be beneficial to utilise the petal as it is less expensive than the stigma and it is easier to obtain larger quantities. Therefore, further clinical trials assessing antidepressant activity of the petal are warranted.

**Standardisation**

Six trials used saffron extracts standardised for safranal and/or crocin, while the remaining studies did not report standardisations for the active constituents. Two trials used extracts containing 0.30-0.35 mg safranal /15 mg capsule, three used SaffroMood, a dried hydroethanolic extract of saffron stigma standardised to 0.13-0.15 mg of safranal and 1.65-1.75 mg crocin/15 mg capsule, and one trial used 30 mg crocin extract. Treatment efficacy was not affected by standardisation as demonstrated by the comparable changes in HAM-D scores across all RCTs. However, standardisation is used as a quality control in phytotherapy, and allows for greater comparison across clinical trials. Quality control is a significant issue in phytotherapy with adulteration of herbal medicines common. This is especially the case with herbal medicines as expensive as saffron.

**Adverse effects and safety**

The main adverse effects of saffron reported in placebo-controlled RCTs were anxiety, nausea, headache and increased appetite. Compared to antidepressant trials, the effects of saffron were milder. Common side effects of antidepressant medication reported in the clinical trials include headache, constipation, dry mouth, vertigo, tremor, urinary retention and sexual dysfunction. Few adverse effects from saffron have been found in long-term studies up to 1 year in length. It is particularly noteworthy that clinical trials show that treatment with saffron extracts is effective for reducing sexual dysfunction in males and females taking SSRIs. Two 4-week clinical trials demonstrated that 30 mg/day saffron stigma significantly improved fluoxetine-induced sexual dysfunction in males (erectile dysfunction) and females (arousal, lubrication and pain) suffering mild to moderate depression. These trials highlight a significant benefit of using saffron for treating mild to moderate depression; it also appears safe as an adjuvant to antidepressant medication.

Saffron appears to be safe at the therapeutic doses prescribed for depression, although longer length trials are required to assess long-term safety. Daily doses of up to 1.5 g of saffron are thought to be safe, with some reports indicating adverse effects above 2 g/day including nausea, vomiting, diarrhoea and bleeding. However, adulteration was possible in some of these studies. Saffron has reportedly been used as an abortifacient at doses of 10 g. The LD50 value of saffron stigma is 1.6 g/kg and 6 g/kg for petal. These values are much higher than daily therapeutic doses, indicating saffron overdose is unlikely to occur. Saffron not only appears to be safe for treatment of depression, it may also effect positive effects on the cardiovascular system including reducing atherosclerosis, reducing blood pressure and correcting dyslipidemia.

In vivo and in vitro studies have demonstrated some effects of saffron on platelet aggregation and blood coagulation, these findings were not supported by clinical trials. Minor effects on bleeding time and international normalised ratio (INR) were observed in placebo-controlled trial of healthy volunteers ingesting 200 mg/day or 400 mg/day dried saffron stigma for 7 days but changes were not clinically significant. Ayatollahi et al. demonstrated no significant change on coagulation and clotting factors or fibrinogen after 1 week administration of 200 mg or 400 mg/day saffron. Mansoori et al. demonstrated saffron is a safe short-term adjuvant to SSRI medication, and had no significant effect on INR, platelet count, liver or kidney function or other haematological parameters. Mohamadpour et al. demonstrated one month administration of 20 mg/day crocin had no significant effect on haematological, biochemical, hormonal or urinary parameters in healthy adults.

**Mechanisms of action**

The mechanisms of saffron’s antidepressant action are not clear. However, evidence from preclinical trials suggests it may only have minimal impact on serotonin metabolism, and its main antidepressant actions are via the effect of the bioactive constituents (crocin, safranal, crocetin and kaempferol) on BDNF and sigma-1 and NMDA receptors in the brain. Saffron’s antidepressant ability may also arise from its anti-inflammatory, antioxidant, anti-inflammatory, HPA axis modulating actions and neuroprotective effects.

Deficits in monoamine neurotransmitters, particularly serotonin, were originally cited as the primary cause of depression but are now recognised as only one of several biological mechanisms. Based on current evidence, saffron appears to have limited effect on the serotonergic system. Georgiadou et al. proposed that crocins influence the serotonergic system and counteract obsessive-compulsive behaviour in mice by antagonising 5-HT2c receptors. Agha-Hosseini et al. demonstrated 30 mg/day saffron was effective in alleviating premenstrual syndrome (PMS) symptoms including depression. They hypothesised that its mechanism of action was through the serotonergic system, since dysregulation of this system during the luteal phase is believed to contribute to the majority of PMS symptoms.
Major depression has been associated with oxidative stress, and specifically lowered antioxidant enzymes such as GSH-Px, catalase and SOD. Saffron and its bioactive constituents safranal, crocin, and crocetin have been demonstrated to be powerful antioxidants by increasing SOD levels and glutathione availability, and decreasing markers of lipid peroxidation.

Immune system and inflammatory pathway activation are now recognised as major pathophysiological causes of depression. Saffron’s antidepressant activity may therefore be in part due to the strong anti-inflammatory effect of its bioactive constituents, crocin and crocetin. Saffron has been demonstrated to inhibit inflammatory cytokines including NF-κ, cyclooxygenase-2 (COX-2), IL-1, IL-6, and TNF-α. Depression is also associated with Th-1 (cell-mediated) immunity overactivation. Demonstrated in mice studies that saffron potentiated Th2 response, and therefore may be useful to regulate immune response in depression.

Individuals with depression often exhibit alterations in HPA axis activity. Clinical evidence suggests that the bioactive constituents safranal and crocin, reduce HPA response by lowering plasma corticosterone levels. HPA axis dysfunction can reduce BDNF levels, which affects neurogenesis and neuroplasticity and has been associated with depression. Crocin was shown to attenuate neurochemical and behavioural effects induced by malathion (a neurotoxic organophosphorus compound). This was hypothesised to have occurred due to its effect on BDNF. Crocin has also been demonstrated in mice studies to increase BDNF and cAMP response element binding protein (CREB).

Research has also demonstrated that saffron’s antidepressant action may be through the effect of its bioactive constituents on NMDA and sigma-1 receptors in the brain. Overactivation of these receptors can cause neuronal dysfunction and cell death (exocitoxicity). Lichtenberg et al. demonstrated that saffron extracts and trans-crocetin have antagonistic effects on NMDA and sigma-1 receptors. These findings were confirmed by Berger et al.

Limitations
The research demonstrating saffron’s efficacy for treating mild to moderate depression is promising. Clinical trials demonstrate that saffron is an efficacious antidepressant medication and more effective than placebo for short term treatment of mild to moderate depression. However, there are limitations to these studies, with all trials having short trial lengths (4 to 12 weeks) and small sample sizes (n = 20-68). No trials had follow-up assessments to assess long term efficacy of saffron for depression. Clinical trials with longer study duration are required as long-term treatment is often required in the management of depression. Most study outcomes were measured using only one subjective outcome measure (e.g. Beck’s Depression Inventory or Hamilton Depression Rating Scale) and future studies need more objective measures such as physiological markers of inflammation and oxidative stress which will also enhance the understanding of saffron’s antidepressant mechanism/s of action.

Nearly all studies to date have used a single daily dose of saffron of 30 mg/day. Further research is required to determine the most appropriate therapeutic dosages. The clinical trials to date have not demonstrated any significant differences in clinical outcomes between saffron stigma and petal or standardised and non-standardised saffron extracts but further investigation is required. Difference in the quality of the herb and quantity of bioactive constituents can affect the clinical efficacy of herbal preparations.

The clinical studies included in this review have assessed individuals aged 18 to 65 years with mild to moderate depression, and further studies are required to assess saffron’s efficacy in children, adolescents and the elderly population. Two studies suggest that saffron has positive effects in postpartum depression and depression associated with PMS108, and further investigation of saffron’s effectiveness for other types of depression such as bipolar depression, melancholic depression and dysthymic disorder should be further investigated. Furthermore, several clinical trials have indicated saffron is a safe and effective adjuvant to SSRI medication, suggesting its main mechanism of action is not via the serotonergic system. Further research is required to elucidate its pharmacokinetics as this will direct its clinical use with and without antidepressant medication.

Conclusion
Depression is a debilitating chronic illness which can lead to physical and social disability. Individuals with depression commonly experience frequent relapses and incomplete recovery despite pharmacotherapy intervention, and it is predicted to be the second leading cause of disability globally by 2020. Globally, depression affects 300 million people and in Australia nearly 9% of the population are affected. Due to safety concerns and side effects of many antidepressant medications, many individuals are seeking herbal medicine alternatives as first line therapy for depression.

Saffron has widespread traditional medicinal uses including the treatment of depression. Modern clinical trials indicate efficacy of short-term administration of saffron for treating mild to moderate depression compared to placebo. Saffron has also been shown to be as effective as antidepressant medication in treating the symptoms of mild to moderate depression with saffron being as well or better tolerated than antidepressant medication.

Studies to date have revealed a scientific basis for clinical use of saffron for depression. However, small sample sizes, short trial durations, lack of follow-up and use of self-reported depression
measures have weakened confidence in these studies. It is unclear whether the findings of these studies can be extrapolated to long-term treatment of mild to moderate depression or to other forms of depression. Clinical trials indicate that saffron is safe to use with antidepressant medication, specifically selective serotonin reuptake inhibitors, suggesting saffron has minimal impact on the serotonergic system. However, further research is required to establish the mechanisms of action that may be through its effect on brain-derived neurotrophic factor, and sigma-1 and N-methyl-D-aspartate receptors, as well as its anti-inflammatory, antioxidant and neuroprotective activity. Studies have shown no difference in efficacy of saffron stigma or petal, and standardised or non-standardised extracts, which could have implications for its widespread clinical use since the saffron petal is significantly cheaper than the stigma. Large-scale, well-controlled trials are required to determine the efficacy, dosage and safety of saffron for the treatment of mild to moderate depression.

References for Parts 1 and 2 are available from the Editor at atms. journal@westnet.com.au.

STUDIES TO DATE HAVE REVEALED A SCIENTIFIC BASIS FOR CLINICAL USE OF SAFFRON FOR DEPRESSION. HOWEVER, SMALL SAMPLE SIZES, SHORT TRIAL DURATIONS, LACK OF FOLLOW UP AND USE OF SELF-REPORTED DEPRESSION MEASURES HAVE WEAKENED CONFIDENCE IN THESE STUDIES.

Cooking for the Senses: Vegan Neurogastronomy

Jennifer Peace Rhind and Gregor Law.


Reviewed by Stephen Clarke.

The emerging science of neurogastronomy is yielding important understandings about the brain’s responses to foods that may shed light on the food choices that people make, and as a result pave their way to improved diet and nutrition. Flavour perception is extremely complex. It involves most of the senses, and especially that of smell. Jennifer Peace Rhind, one of the authors of this book, is a foremost researcher, write and practitioner in the relationship between aromas and human health. She has previously written two important books about aromas, one of which was reviewed in an earlier issue (Fragrance and Wellbeing: Plant Aromatics and Their Influence on the Psyche; JATMS 20.3). The present book owes its rationale to the thesis that recognising the part played by the brain’s flavour system can provide an understanding of the food choices people make. As food choice is one of the factors underlying eating disorders, understanding its basis in sensory perception might make a significant contribution to treating those disorders.

Cooking is a central element in the process of food choice. As the author says, “We are the only species on the planet which prepares food.” But this is far more than a cookbook. The recipes are not reached until the reader is over a hundred pages in. These first hundred or so pages are occupied by well-informed scholarly exploration of plant foods. There is a chapter on the sense modalities and the characteristics of food that underlie the experience of eating. In the chapter on understanding taste and flavour Rhind shows how the taste, smell, texture, visual appearance of food and even the sounds made by eating affect our affinities with foodstuffs. In the chapter on ingredients and flavours there is an absorbing account of the place in world cuisines of almost every variety of fruit and vegetable we eat: their contributions to nutrition, their tastes and textures and the methods of their preparation.

The recipes themselves form a delectable catalogue for vegans, although of course the reader doesn’t have to be a strict practitioner to enjoy plant-based meals. There are over one hundred recipes, in the categories of small plates; brunches, lunches and picnics; dinners and “gentle plates” (mains, essentially, though I have observed that my vegan friends are eclectic in the composition and order of their meals and don’t arbitrarily nominate particular courses as mains); “solace in the kitchen” (sauces, dressings and other pantry stand-bys); and desserts.

Rhind is a dedicated vegan gourmet. Her recipes are, as one would expect of this deep researcher of sensory experience, high-end adventures in taste. There are over one hundred of these adventures. They draw on all the major world cuisines and Rhind includes an interesting discussion of the predominant flavour characteristics of world regional foods. Gregor Law’s styling and photography complement all the recipes commendably. For Australian readers some, though not many, of the ingredients may be hard to source, and with imagination might be substituted by available ones. I spent quite some time hunting down elderflower cordial for my red quinoa bowl, but it proved to be time well spent. My vegan taster tells me that over all, this is the best collection of recipes she has come across.

There is an index covering the recipes themselves, the ingredients and the scholarly discussion. Rhind writes eloquently and clearly at all times. This book deserves to be used for both the recipes and its exposition of the science underlying them.
Many readers will be aware of requirements under the Privacy Act 1988 (Cth), especially since the changes from 12 March 2014, affecting the way client information is collected, used and stored. The changes included the introduction of 13 new Australian Privacy Principles (APPs), which apply to all health service providers and any business with an annual turnover of more than $3 million. This was the topic of an earlier Law Report in this Journal.

As a recap, the principles apply to any information that can be used to identify an individual. In the case of a therapist or sole trader these generally include name, address, credit card or bank details, occupation and employer, driver’s licence number and emergency contact details. Also included in the legislation is sensitive client information, which could be details about a person’s race, sex or health conditions.

Generally, small businesses do not need to comply with the Privacy Act unless they have an annual turnover of more than $3 million. However, some small businesses with an annual turnover of $3 million or less are required to comply with the Act’s privacy principles if they are a health service provider or a contractor to Commonwealth agencies.

The new laws require businesses to:

- Give an individual the option to remain anonymous or use a pseudonym
- Collect information only when necessary
- Always notify an individual when collecting and storing information
- Use personal information only for the purpose it was collected for. When no longer needed information should be disposed of.
- Never use personal information for the purpose of direct marketing, unless advised that the client is happy for this to happen
- Take all steps to protect information from misuse or interference, particularly in terms of cyber risks
- Take reasonable steps to destroy or permanently de-identify health information that is no longer needed.
- unauthorised disclosure, such as someone accidentally publishing the names of their clients on their website, or
- loss, such as leaving your iPhone containing client files in a café

These are defined as data breaches where a ‘reasonable person would conclude that [the breach] would be likely to result in serious harm to any of the [affected individuals]’. ‘Serious harm’ could include physical, psychological, emotional, economic and financial harm, as well as harm to reputation. An affected individual is someone who has been identified or can reasonably be identified.

At this stage we must decide whether an eligible data breach has occurred, that is, one that we need to report. This is where we decide if a reasonable person would think that the breach of data has caused serious harm to the identified person. In making an assessment of harm, an organisation needs to consider the nature and sensitivity of the personal information, whether the information is protected by security measures (e.g., encryption), who has obtained or accessed, or could obtain or access, the information, and the nature of the harm to affected individuals.
If you believe there has been some unauthorised access to your business where information has been compromised or stolen, you need to move promptly. This type of breach or theft may cause serious harm to someone and really damage your business in the process. Serious harm can include:

- Identity theft
- Threats to an individual’s physical safety
- Humiliation, damage to reputation or relationships
- Workplace or social bullying

If private information was broken into or stolen from your business, take note of it and of how your clients might be affected. First, you must prepare a statement about the data breach and send it to the Office of the Australian Information Commissioner (www.oic.gov.au). This can be done by filling in the Notifiable Data Breach Statement form.

Secondly, you need to tell affected clients about the incident, and how they should respond.

There are three different ways of notifying them:

- Tell each of the people affected
- Also, tell those who might be potentially at risk of serious harm
- If you can’t get in touch with these people, then publish a statement on your website and publicise it. This might include advertisements in newspapers, and on websites and social media platforms.

Failing to meet your privacy obligations can be costly in terms not only of monetary penalties but also of client complaints and reputational damage. Be prepared and have a data breach response plan in place as part of your risk management plan.

So some tips to help avoid a data breach:

- If you keep files at reception, make sure that they are kept in a locked cabinet and don’t leave the keys in there. Ideally, they should not be in the client area at all. Make sure that only people who need access to these files have a key.

- Don’t leave client records lying around waiting to be filed or actioned. This would include any correspondence about the client too. Keep your office area away from your client area.

- If you keep information on a notebook, phone or tablet/iPad, be careful when taking it out of the clinic. People regularly leave these behind in trains, cafes and taxis. Know where it is at all times. Always have a backup of your files elsewhere. Make sure that you password protect your files.

- Move inactive files into storage. This way you can comply with legal requirements, without cluttering your current files. Store them somewhere safe and dry, not at the back of your damp garage.

- If you need to destroy old files, it is best to shred them and ensure that everything is destroyed. If you can’t shred them, make sure they are de-identified by removing all names, addresses and contact details. Check for letters and reports that might have someone’s name on them. Dispose of them securely.

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Initially I worked as a massage therapist and as the additional qualifications were completed I included these new skills to employ remedial therapies, nutrition, herbalism and then naturopathy. That makes 32 years of continual practice in May this year.

These years were also spent with Marilyn, my partner, wife and mother of our three children in practice and for eleven of those years sharing a holistic clinic with Dr Rosslyn Morrison in Chatswood.

The major impact for me to change my career was the illness of one of our daughters. While we had fantastic surgical support and nursing assistance, the health system just failed to deliver any after-hospital care or really any strong advice on getting her back to normal. Fortunately, Marilyn was a registered nurse. She became interested and started studying herbalism which she directly applied to our daughter. Marilyn also continued her studies and completed the BSc Complementary Medicine some twelve years ago.

Anger and frustration are great initiators for change so after looking over her shoulder for a year or so I also took up the challenge. Together we forged a new working life and started our first clinic in May 1987.

Career history
I started practising in May 1987. Prior to this time, I was employed by the Australian Broadcasting Corporation in radio production and then in training and broadcast management. I resigned in 1987 to start naturopathy.

What are your future ambitions?
Well I am not going quietly into the night. Personally I want to work, part time, for at least the next ten years. For the last three years I have also been involved in teaching and clinic supervision for the Advanced Diploma in Naturopathy at WEA Newcastle. This was an adventure for me as I thought I would be overwhelmed by the students and the teacher’s knowledge and experience. It turned out to be a wonderful time of sharing both the theoretical and practical knowledge and experience and I would welcome the opportunity to be involved in teaching again - even if it meant upgrading the Certificate 4 Teaching and Assessment course I completed in November 2016.

What advice would you give to a new practitioner starting out?
Know your subject and develop a deep understanding of the effectiveness of our natural medicines. Employ observation as your first tool of the trade and good communications as the second. Try to be patient (I am the most impatient person on earth but at 69 I can at least take a deep breath). Don’t put your faith in advertising. Don’t spend money before you make it. Always work within your skill range and never fail to send a client onto another practitioner if required.

What do you like about being a natural medicine practitioner?
You would think broadcasting and naturopathy are like chalk and cheese. But the reality, for me, is that they are both holistic. In radio/TV production you start with an idea then apply research, scripting, interviewing, recording, editing and then broadcasting. In Naturopathy you follow a similar pathway. One major advantage I had was interviewing. After thousands of programs with the ABC it felt comfortable being in consultations with strangers and communicating with them to develop a naturopathic treatment to follow.

It is enormously rewarding having continuous positive client outcomes and being involved with the myriad of changes taking place in front of your eyes. Then there is the occasional minor miracle!! It is both a privilege and pleasure to be of service to our clients.

Morrison in Chatswood.

ATMS Member Interview
Ross Milford

PRACTITIONER PROFILE

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Marilyn and I will travel whenever we can and for the past 16 years we have been living near Dungog raising a rain forest. This will also turn out to be a wonderful time of sharing the teacher’s knowledge and experience. It turned out to be a wonderful time of sharing both the theoretical and practical knowledge and experience and I would welcome the opportunity to be involved in teaching again - even if it meant upgrading the Certificate 4 Teaching and Assessment course I completed in November 2016.

Marilyn and I will travel whenever we can and for the past 16 years we have been living near Dungog raising a rain forest. This will also continue. My private interests are to get back on radio at our local station, Radio Dungog 107.9, where I previously hosted a breakfast program and was the first president of the station when we started in 2010. For the last 14 years I have continued active involvement in our local Rural Fire Service, Flat Tops Brigade, now as a Crew Leader. We are also involved with our two grandchildren and, of course, the fun and games of family life.

Government policies?
In 1982 I completed a Graduate Diploma in Public Administration at KCAE. I was pressed into it by mentors who wanted to assist in my preparation for higher roles in the ABC of the time. It was just fantastic to be able to spend three years face to face with the problems of organisational structure, politics of work and the problems involved in the democratic involvement of public and private administration.

Thus the thorny question arises of whether to have registration or maintain the status quo. My summary of the situation, so far, is that the complementary health movement has been built on the backs of tens of thousands of good quality practitioners, teachers and educational institutions. This has transferred into strong positive support in the general public, and the fact that a student can now study at a degree level is a reflection by the government that there is an ongoing need in the community for our services. That alone is a huge advantage that cannot be squandered.

If registration was a simple issue I would be all for it - mainly to ensure that the quality and regulation of practitioners is improved and any unregistered practitioners are removed from practice. But it isn’t simple. The recent case of the Indian doctor who practised without a licence (or any training) for years in NSW shows that all the regulation in the world won’t prevent questionable characters getting under the net. So the real question to address is who benefits and why. That needs to be explored well before you go form links in Canberra. A common goal of bureaucrats is to improve their personal standing in the public service.

So don’t think I’m jaded, but I remember the last time a control was attempted and the clients and practitioners blocked the fax machines in Canberra until the politicians got the message that the public want the service of complementary practitioners. After all, they are our tax dollars they are spending and we do take pressure off Medicare.
Discussion: Sinew acupuncture is a potential alternative non-pharmacological therapy for KOA. This rigorous trial will expand our knowledge of whether sinew acupuncture reduces pain intensity and improves symptoms, functional movements, and quality of life of KOA patients.

Wan Q, Liu Z, Yang Y.


Background: Fine particulate matter (PM2.5) is a major risk factor for the development and progression of atherosclerosis. Puerarin, a natural extract from Radix Puerariae, possesses significant anti-atherosclerosis properties. However, the underlying molecular mechanisms responsible for the effect of puerarin on the VSMCs proliferation induced by PM2.5 remain unclear. The present study was designed to examine the effect of puerarin on PM2.5-induced VSMCs proliferation, and to explore the p38 mitogen-activated protein kinase (p38 MAPK) signal mechanism involved.

Methods: VSMCs viability was measured by CCK-8 assay, VSMCs proliferation was assessed by BrdU immunofluorescence, the levels of superoxide dismutase (SOD) and malonaldehyde (MDA) were assayed by colorimetric assay kits, the levels of nitric oxide (NO) and endothelin-1 (ET-1) were determined by nitrate reductase method and radioimmunoassay, the levels of vascular cell adhesion molecule-1 (VCAM-1), interleukin-6 (IL-6) and tumor necrosis factor-alpha (TNF-α) were measured by ELISA. The protein expressions of phospho-p38 MAPK (p-p38 MAPK) and proliferating cell nuclear antigen (PCNA) in the VSMCs were subjected by Western blot.

Results: Compared to the PM2.5-treated cells, in addition to inhibiting the PM2.5-induced VSMCs proliferation, puerarin also down-regulated the protein expressions of p-p38 MAPK and PCNA, decreased the levels of ET-1, VCAM-1, IL-6, TNF-α and MDA, increased the levels of NO and SOD. Moreover, the anti-proliferative effects of puerarin were significantly enhanced by the co-incubation of puerarin with SB203580, a selective inhibitor of p38 MAPK, as compared to the puerarin-treated cells.

Conclusion: These results suggest that puerarin might suppress the PM2.5-induced VSMCs proliferation via the inhibition of the p38 MAPK signaling pathway.


Objectives: The menopause is a natural biological process that is happened by a permanent regal stop due to the loss of performance. The aim of this research is to evaluate the effect of lavender aromatherapy on the menopause symptoms.

Study Design: This double-blind cross over clinical trial carried out on 100 menopause women (between 45 and 155 years old) referring to health centres in Ardabil in 2013-14. The samples blocked randomly, placed in two experimental (Lavender) and
control (diluted milk) groups. Lavender aroma is smelled two times daily for 20 min during 12 weeks by research subjects. Data were collected by Green questionnaire and the analysis of data carried out in SPSS v.16 by paired t-test.

Main Outcome Measures: The level of the symptoms has been decreased significantly after using lavender.

Results: Comparing the level of the symptoms before and after using lavender in experimental group suggested that the rate of the menopause symptoms has been decreased significantly (P = 0.000). The comparison of the mean of the menopause symptoms after intervention between two groups suggested that the menopause symptoms in the experimental group had a significant decrease comparing the control group (P = 0.000).

Conclusion: Using the lavender aromatherapy decreases menopause symptoms. According to the undesirable effect of the menopause symptoms on the quality of life of the menopausal women, these interventions may be instructed by midwives in the treatment and care centres as a health activity.

Herbal medicine


Background: Medicinal plants have been founded as traditional herbal medicine worldwide. Most of the plant’s therapeutic properties are due to the presence of secondary metabolites such as alkaloids, glycosides, tannins and volatile oil.

Methods: The present investigation analyzed the High-Pressure Liquid Chromatography (HPLC) fractions of Glycyrrhiza glabra (Aqueous, Chloroform, Ethanol and Hexane) against multidrug resistant human bacterial pathogens (Escherichia coli, Acinetobacter baumannii, Staphylococcus aureus and Pseudomonas aeruginosa). All the fractions showed antibacterial activity, were subjected to LC MS/MS analysis for identification of bioactive compounds.

Results: Among total HPLC fractions of G. glabra (n = 20), three HPLC fractions showed potential activity against multidrug resistant (MDR) bacterial isolates. Fraction 1 (F1) of aqueous extracts, showed activity against A. baumannii (15 ± 0.5 mm). F4 from hexane extract of G. glabra showed activity against S. aureus (10 ± 0.2 mm). However, F2 from ethanol extract exhibited activity against S. aureus (10 ± 0.3 mm). These active fractions were further processed by LC MS/MS analysis for the identification of compounds. Ellagic acid was identified in the F1 of aqueous extract while 6-aldehydo-isooophiopogonone was present in F4 of hexane extract. Similarly, Liquiritigenin was identified in F2 of ethanol.

Conclusions: Glycyrrhiza glabra extracts HPLC fractions showed anti-MDR activity. Three bioactive compounds were identified in the study. 6-aldehydo-isooophiopogonone and Liquiritigenin were for the first time reported in G. glabra. Further characterization of the identified compounds will be helpful for possible therapeutic uses against infectious diseases caused by multidrug resistant bacteria.

Welz AN, Emburger-Klein A, Menrad K.


Background: The use of herbal medicine, as one element of complementary and alternative medicine, is increasing worldwide. Little is known about the reasons for and factors associated with its use. This study derives insights for the use of herbal medicine in Germany regarding the usage aims, role played by the type of illness, reasons for preferred usage and sources of information.

Methods: Using a qualitative methodological approach, six focus groups (n = 46) were conducted. Two groups with young, middle-aged and elderly participants, respectively. After audiotaping and verbatim transcription, the data were analysed with a qualitative content analysis.

Results: We found that treating illnesses was the most frequently discussed aim for using herbal medicine over all age groups. Preventing illnesses and promoting health were less frequently mentioned overall, but were important for elderly people. Discussions on herbal medicine were associated with either mild/moderate diseases or using herbal medicine as a starting treatment before applying conventional medicine. In this context, participants emphasized the limits of herbal medicine for severe illnesses. Dissatisfaction with conventional treatment, past good experiences, positive aspects associated with herbal medicine, as well as family traditions were the most commonly-mentioned reasons why herbal medicine was preferred as treatment. Concerning information sources, independent reading and family traditions were found to be equally or even more important than consulting medicinal experts.
Conclusions: Although herbal medicine is used mostly for treating mild to moderate illneses and participants were aware of its limits, the combination of self-medication, non-expert consultation and missing risk awareness of herbal medicine is potentially harmful. This is particularly relevant for elderly users as, even though they appeared to be more aware of health-related issues, they generally use more medicine compared to younger ones. In light of our finding that dissatisfaction with conventional medicine was the most important reason for a preferred use of herbal medicine, government bodies, doctors, and pharmaceutical companies need to be aware of this problem and should aim to establish a certain level of awareness among users concerning this issue.

Method: The survey was conducted in January 2016 as part of the “TNS Gallup Health policy Barometer”. In total, 1728 individuals aged 16–92 years participated in the study, constituting an overall response rate of 47%. The survey included questions regarding opinions and attitudes towards health, health services and health politics in Norway.

Results: The majority of the participants (90.2%) would see a MD only if they were suffering from a chronic, non-life-threatening disease and were in the need of treatment. Men over the age of 60 with a university education tended to see a MD only. Only 9.8% of all respondents would in addition visit a CAM provider. Being an intentional user of a MD + CAM provider was associated with being a woman under the age of 60. The respondents believed that CAM providers have professional competence based on formal training in CAM. They also believed that individuals seeing a CAM provider have poor health and are driven by the hope of being cured. Further, that they have heard that others have good experience with such treatment.

Conclusion: Intentional use of CAM is associated with positive attitudes, trustworthiness, and presumed positive experiences in the CAM-patient-setting. Intentional CAM users also have the impression that CAM providers have professional competence based on formal training in alternative therapies.


Background: Complementary and alternative medicines (CAM) are sometimes used by individuals who desire to improve the outcomes of their fertility treatment and/or mental health during fertility treatment. However, there is little comprehensive information available that analyzes various CAM methods across treatment outcomes and includes information that is published in languages other than English.

Method: This scoping review examines the evidence for 12 different CAM methods used to improve female and male fertility outcomes as well as their association with improving mental health outcomes during fertility treatment. Using predefined key words, online medical databases were searched for articles (n = 270). After exclusion criteria were applied, 148 articles were analyzed in terms of their level of evidence and the potential for methodological and author bias.

Results: Surveying the literature on a range of techniques, this scoping review finds a lack of high quality evidence that complementary and alternative medicine (CAM) improves fertility or mental health outcomes for men or women. Acupuncture has the highest level of evidence for its use in improving male and female fertility outcomes although this evidence is inconclusive.

Conclusion: Overall, the quality of the evidence across CAM methods was poor not only because of the use of research designs that do not yield conclusive results, but also because results were contradictory. There is a need for more research using strong methods such as randomized controlled trials to determine the effectiveness of CAM in relation to fertility treatment, and to help physicians and patients make evidence-based decisions about CAM use during fertility treatment.


Background: Intentional use of complementary and alternative medicine (CAM) has previously only been researched in small, possibly biased, samples. There seems to be a lack of scientific information regarding healthy individual’s attitudes and presumed use of CAM. The aim of this study is to describe prevalence and characteristics of participants who intend to see a CAM provider compared to participants who intend to see a medical doctor (MD) only when suffering from a chronic, non-life threatening disease and in the need of treatment. Further to describe differences between the groups regarding expected reasons for CAM use and expected skills of CAM providers.

Method: This scoping review examines the evidence for 12 different CAM methods used to improve female and male fertility outcomes as well as their association with improving mental health outcomes during fertility treatment. Using predefined key words, online medical databases were searched for articles (n = 270). After exclusion criteria were applied, 148 articles were analyzed in terms of their level of evidence and the potential for methodological and author bias.

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Conclusion: Overall, the quality of the evidence across CAM methods was poor not only because of the use of research designs that do not yield conclusive results, but also because results were contradictory. There is a need for more research using strong methods such as randomized controlled trials to determine the effectiveness of CAM in relation to fertility treatment, and to help physicians and patients make evidence-based decisions about CAM use during fertility treatment.
Profile of osteopathic practice in Spain: results from a standardized data collection study.

Method: During the period between April 2014 and December 2015, a UK-developed standardized data collection tool was distributed to Spanish osteopaths who voluntarily agreed to participate in this cross-sectional study.

Results: Thirty-six osteopaths participated in this study and returned a total of 314 completed datasets. Of 314 patients, 61% were women and 39% were men, with a mean age of 40 years (SD 17.02 years, range 0 to 83 years). Forty-four percent were full-time salaried workers, and in 78% of cases, receiving osteopathic treatment was the patient’s own choice. Chronic spinal pain presentations were the most frequent reasons for consultation. Seventy-five percent of patients presented with a coexisting condition, mainly gastrointestinal disorders and headaches. The main treatment approach consisted of mobilization techniques, followed by soft tissue, cranial and high velocity thrust techniques. Improvement or resolution of the complaint was experienced by 93% of patients after a small number of sessions. Adverse events were minor and occurred in 7% of all cases.

Conclusion: This is the first study carried out in Spain analyzing the profile of patients who receive osteopathic care. The typical patient who receives osteopathic care in Spain is middle-aged, presents mainly with chronic spinal pain, and voluntarily seeks osteopathic treatment. Osteopathic treatment produces a significant improvement in the majority of cases with a low rate of minor adverse events reported.

Method: The measurement of Cr and lower limb muscle power during squat jump (SJ) and counter movement jump (CMJ) were performed before (PRE), immediately after (POST) and 3 hours after (POST 3h) a SMFR protocol (experimental condition). In the "control condition" testing session, the same measurements were performed without undergoing the SMFR protocol. Experimental and control conditions were tested in a randomized order.

Results: Cr at POST trended to increase as compared to PRE (+7.9±6.3%, p=0.002; and +10.0±8.7%, p=0.004, respectively). The rate of force development measured during CMJ also increased after SMFR, reaching statistical significance at 200 ms from force onset at POST 3h (+38.9%, p=0.024).

Conclusions: An acute use of foam roller for SMFR performed immediately prior to running may negatively affect the endurance running performance, while its use should be added before explosive motor performances that include stretch-shortening cycles.

Method: Experimental studies published in English were included; quasi-experimental research studies were also included in consideration of rare experimental studies in Korean. The search strategy sought to identify published research reports in the English language and covered all major databases up to 2016. The methodological quality of each study was assessed by 2 independent reviewers using a Scottish Intercollegiate Guidelines Network’s Methodology Checklist. Means and standard deviations were used for continuous variables, and standardized mean difference was used for variables of different scales. Heterogeneity was assessed using the I2 statistics after visual reviewing with forest plots.

Results: This study reviewed mainly the effect of tepid massage on temperature compared with the use of antipyretics, along with other factors.
adverse effects in relation with fever management. The results revealed no significant effect of tepid massage on temperature in febrile children. In addition, incidence rates of adverse effects including chills, goose pimples, and discomfort were higher in tepid massage groups.

**Conclusion:** This meta-analysis showed the need for re-verification of commonly used practice including the use of tepid massage and proper body temperature measurement.

**Nutrition**

**Zhang L, Zeng H, Cheng WH.**


Accumulation of genome and macromolecule damage is a hallmark of aging, age-associated degeneration, and genome instability syndromes. Although processes of aging are irreversible, they can be modulated by genome maintenance pathways and environmental factors such as diet. Selenium (Se) confers its physiological functions mainly through selenoproteins, but Se compounds and other proteins that incorporate Se non-specifically also impact optimal health. Bruce Ames proposed that the aging process could be mitigated by a subset of low-hierarchy selenoproteins whose levels are preferentially reduced in response to Se deficiency. Consistent with this notion, results from two selenotranscriptomic studies collectively implicate three low-hierarchy selenoproteins in age or senescence. Experimental evidence generally supports beneficial roles of selenoproteins in the protection against damage accumulation and redox imbalance, but some selenoproteins have also been reported to unexpectedly display harmful functions under sporadic conditions. While longevity and healthspan are usually thought to be projected in parallel, emerging evidence suggests a trade-off between longevity promotion and healthspan deterioration with damage accumulation. We propose that longevity promotion under conditions of Se deficiency may be attributed to 1) stress-response hormesis, an advantageous event of resistance to toxic chemicals at low doses; 2) reduced expression of selenoproteins with paradoxical functions to a lesser extent. In particular, selenoprotein H is an evolutionally conserved nuclear selenoprotein postulated to confer Se functions in redox regulation, genome maintenance, and senescence. This review highlights the need to pinpoint roles of specific selenoproteins and Se compounds in healthspan and lifespan for a better understanding of Se contribution at nutritional levels of intake to healthy aging.

**Hou YC, Wu CC, Liao MT, Shyu JF, Hung CF, Yen TH, Lu CL, Lu KC.**

**Role of nutritional vitamin D in osteoporosis treatment.** Clin Chim Acta. 2018 May 18; pii: S0009-8981(18)30244-4. doi: 10.1016/j.cca.2018.05.035

Osteoporosis is a systemic skeletal disorder characterized by a decrease in bone mass and microarchitectural deterioration of bone tissue. The World Health Organization has defined osteoporosis as a decrease in bone mass (50%) and bony quality (50%). Vitamin D, a steroid hormone, is crucial for skeletal health and in mineral metabolism. Its direct action on osteoblasts and osteoclasts and interaction with non-skeletal tissues help in maintaining a balance between bone turnover and bone growth. Vitamin D affects the activity of osteoblasts, osteoclasts, and osteocytes, suggesting that it affects bone formation, bone resorption, and bone quality. At physiological concentrations, active vitamin D maintains a normal rate of bone resorption and formation through the RANKL/OPG signal. However, active vitamin D at pharmacological concentration inhibits bone resorption at a higher rate than that of bone formation, which influences the bone quality and quantity. Nutritional vitamin D rather than active vitamin D activates osteoblasts and maintains serum 25(OH)D3 concentration. Despite many unanswered questions, much data support nutritional vitamin D use in osteoporosis patients. This article emphasizes the role of nutritional vitamin D replacement in different turnover status (high or low bone turnover disorders) of osteoporosis together with either anti-resorptive (Bisphosphonate, Denosumab et.) or anabolic (Teriparatide) agents when osteoporosis persists.
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**Notes:**
- •: Covered by fund
- ✓: Need to apply directly to fund
- *: ARHG are only recognising Remedial Therapists who are accredited for the modality and are approved for ARHG Provider status under their old criteria. For further details on ARHG requirements, please contact their office for current requirements.
- **ARHG** Health Fund: The ARHG Health Fund Information for further information.
Health Funds

ATMS is a ‘professional organisation’ within the meaning of section 10 of the Private Health Insurance Accreditation Rules 2011. This potentially allows ATMS accredited members to be recognised as approved providers by the various private health funds. Approved health fund provider status is, however, subject to each individual health fund’s eligibility requirements.

Consequently, membership of ATMS does not automatically guarantee provider status with all health funds. Please also note that several health funds do not recognise courses done substantially by distance education, or qualifications obtained overseas.

Additional requirements for recognition as a provider by health funds include:

- Clinic Address (Full Street Address must be provided - Please note that some health funds may list your clinic address on their public websites)
- Current Senior First Aid
- Current Professional Indemnity Insurance (some health funds require specific minimum cover amounts. Please refer to the individual health fund terms and conditions for further information)
- Compliance with the ATMS Continuing Education Policy along with any additional continuing education requirements stipulated by the health fund
- Current National Registration (where applicable)
- Compliance with the Terms and Conditions of Provider Status with the individual health funds.

ATMS must have current evidence of your first aid and insurance on file at all times.

When you join or rejoin ATMS, or when you upgrade your qualifications, you will need to fill out the ATMS Health Fund Application and Declaration Form available on the ATMS website. Once this is received, along with any other required information for health fund eligibility assessment, details of eligible members are sent to the applicable health funds on their next available listing. The ATMS office will also forward your change of details, including clinic address details to your approved health funds on their next available list. Please note that the health funds can take up to one month to process new providers and change of details as we are only one of many health professions that they deal with.

Lapsed membership, insurance or first aid will result in a member being removed from the health funds list.

As health funds change their provider eligibility requirements at any given time, upgrading qualifications may be necessary to be re-instated with some health funds.

TERMS AND CONDITIONS OF PROVIDER STATUS

Many of the Terms and Conditions of Provider Status for the individual health funds are located on the ATMS website. For the Terms and Conditions for the other health funds, it will be necessary to contact the health fund directly.

BEING A PROVIDER IMPLIES ACCEPTANCE OF THE TERMS AND CONDITIONS FOR THE HEALTH FUNDS.

Please note that whilst there is no law or regulation requiring patient clinical notes to be taken in English, many of the major health funds do require patient clinical notes to be taken in English. Failure to do this will be a breach of the Health Funds Terms and Conditions and may result in the practitioner being removed as a provider for that health fund.

For health funds to rebate on the services of Accredited members, it is important that a proper invoice be issued to patients. The information which must be included on an invoice is also listed on the ATMS website. It is ATMS policy that only Accredited members issue their own invoice. An Accredited member must never allow another practitioner, student or staff member to use their provider details, as this constitutes health fund fraud. Misrepresenting the service(s) provided on the invoice also constitutes health fund fraud. Health fund fraud is a criminal offence which may involve a police investigation and expulsion from the ATMS Register of Members.

It is of note that the health funds require practitioners to be in private practice. Some health funds will not recognise claims where accommodation, facilities or services are provided or subsidised by another party such as a public hospital or publicly funded facility. Rebates are only claimable for the face to face consultation (not the medicines or remedies); however this does not extend to mobile work including markets, corporate or hotels. Home visits are eligible for rebates for some health funds.

ONLINE OR PHONE CONSULTATIONS ARE NOT RECOGNISED FOR HEALTH FUND REBATES.

Please be aware that whilst a health fund may indicate that they provide a rebate for specific modalities, this rebate may only be claimable if the client has the appropriate level of health cover with that fund and has not exceeded any limits on how much they are eligible to claim back over a certain period of time.

Australian Health Management (AHM)

Names of eligible ATMS members will be sent to AHM each month. AHM’s eligibility requirements are listed on the ATMS website www.atms.com.au. ATMS members can check their eligibility by checking the ATMS website or by contacting the ATMS Office on 1800 456 855. Please contact AHM on 13 42 46 for your provider number.

Australian Regional Health Group (ARHG)

This group consists of the following health funds:

- ACA Health Benefits Fund Ltd
- Cessnock District Health Benefits Fund
- CUA Health Limited▼
- Defence Health ▼
- HBF (Including GMF Health)# ▼
- GMHBA ▼ (Including Frank Health Fund & Budget Direct)
- Health.com.au
- Health Care Insurance Limited#
If ATMS member 123 is accredited in Western herbal medicine, the ARHG provider number will be AT00123W.

1. If you are accredited in several modalities, you will need a different provider number for each modality (e.g. if ATMS member 123 is accredited for Western Herbal Medicine and Aromatherapy, the ARHG provider numbers are AT00123W and AT00123O.

ARHG - Remedial Massage and Chinese Massage

Remedial Massage and Chinese Massage therapists who graduated after March 2002 must hold a Certificate IV or higher from a registered training organisation.

Members who are accredited for Remedial Massage or Chinese Massage, will need to use the following letters.

M MASSAGE THERAPY
R REMEDIAL THERAPY

The letter at the end of your provider number will depend on your qualification, not the modality in which you hold accreditation*. All members who meet the ARHG eligibility requirements, who hold a Diploma of Remedial HLT50102, HLT50107 or HLT52015 or a Diploma of Chinese Remedial Massage HLT50102, HLT50107 or HLT50112 will be able to use both the ‘M’ and ‘R’ letters. It is recommended to use the ‘R’ as often as possible, but as not all health funds under ARHG cover ‘Remedial Therapy’, it will be necessary to use the ‘M’ at the end of the provider number for those funds only. All other eligible Remedial Massage Therapists who do not hold the Diploma of Remedial HLT50102, HLT50107 or HLT52015 or a Diploma of Chinese Remedial Massage HLT50102, HLT50107 or HLT50112 are required to use the ‘M’ at the end of their provider number.

*Members accredited for Remedial Therapies and approved for ARHG for this modality under their previous criteria will continue to be recognised under Remedial Therapy and will be fine to use the ‘R’ in their provider number. Should members in this situation lapse membership, first aid or insurance etc they will then be required to meet the current ARHG criteria.

HBF Health – Bowen Therapy, Kinesiology, Nutritional Medicine, Reflexology and Shiatsu

* For the additional modalities that HBF Health covers that are not listed above including Bowen Therapy, Kinesiology, Nutritional Medicine, Reflexology and Shiatsu, eligible providers will need to apply directly by completing the registration form available from our ATMS website.

CUA Health – Bowen Therapy, Kinesiology and Reflexology

* For the additional modalities that CUA Health covers that are not listed above including Bowen Therapy, Kinesiology and Reflexology, eligible providers will need to use the following to work out your provider number:

1. Add the letters AT which will be the start of your provider number
2. Then add the letter that corresponds to your accredited modality;
   B BOWEN THERAPY
   K KINESIOLOGY
   R REFLEXOLOGY
3. Then add your ATMS Number. If your ATMS number has five digits your provider number will now be complete. If it has two, three or four digits, you need to add enough zeros to the front to make it a five digit number (e.g. 123 becomes 00123).

If ATMS member 123 is accredited in Kinesiology, the CUA provider number will be ATK00123.

4. If you are accredited in several modalities, you will need a different provider number for each modality (e.g. if ATMS member 123 is accredited for Kinesiology and Reflexology, the CUA provider numbers are ATK00123 and ATR00123.

Details of eligible members, including member updates are sent to ARHG by ATMS monthly. The details sent to ARHG are your name, address, telephone and accredited discipline(s). These details will appear on the ARHG websites. If you do not wish your details to be sent to ARHG, please advise the ATMS office on 1800 456 855.

The ARHG provider number is based on your ATMS number with additional lettering. To work out your ARHG provider number please follow these steps:

1. Add the letters AT to the front of your ATMS member number
2. If your ATMS number has five digits go to step 3. If it has two, three or four digits, you need to add enough zeros to the front to make it a five digit number (e.g. 123 becomes 00123).
3. Add the letter that corresponds to your accredited modality at the end of the provider number;

A ACUPUNCTURE
C CHINESE HERBAL MEDICINE
H HOMEOPATHY
N NATUROPATHY
O AROMATHERAPY
W WESTERN HERBAL MEDICINE

Special condition applies for Remedial Massage

If ATMS member 123 is accredited in Western herbal medicine, the ARHG provider number will be AT00123W.
Health Partners – BOWEN THERAPY, KINESIOLOGY AND REFLEXOLOGY
^ For the additional modalities that Health Partners covers that are not listed above including Bowen Therapy, Kinesiology and Reflexology, eligible providers will need to use your ATMS member number as your provider number.

Reserve Bank Health Society -Reflexology
^ For the additional modalities that Reserve Bank Health Society covers that are not listed above including Reflexology, eligible providers will need to use the following to work out your provider number:

1. Add the letters AT which will be the start of your provider number
2. Then add the letter that corresponds to your accredited modality;
3. Then add your ATMS Number. If your ATMS number has five digits your provider number will now be complete. If it has two, three or four digits, you need to add enough zeros to the front to make it a five digit number (e.g. 123 becomes 00123).

If ATMS member 123 is accredited in Reflexology and Kinesiology, the Teachers Health provider number will be ATK00123.

Teachers Health– Bowen Therapy, Kinesiology, Reflexology And Shiatsu
^ For the additional modalities that Teachers Health covers that are not listed above including Bowen Therapy, Kinesiology, Reflexology and Shiatsu, eligible providers will need to use the following to work out your provider number:

1. Add the letters AT which will be the start of your provider number
2. Then add the letter that corresponds to your accredited modality;
3. Then add your ATMS Number. If your ATMS number has five digits your provider number will now be complete. If it has two, three or four digits, you need to add enough zeros to the front to make it a five digit number (e.g. 123 becomes 00123).

ADDITIONAL NOTE
# For all modalities that these funds (Health Care Insurance Limited, Queensland Country Health Fund Ltd, Railway and Transport Fund Ltd, Transport Health & Westfund) cover that are not listed above including Bowen Therapy, Kinesiology, Nutrition and Reflexology, eligible providers will need to use their ATMS number. Please refer to the Health Fund Table.

Australian Unity
Names and details of eligible ATMS members will be sent to Australian Unity each month. ATMS members will need to contact Australian Unity on 1800 035 360 to register as a provider, after filling out the Australian Unity Application Form located on the ATMS website to activate their provider status. This only needs to happen the first time. The provider eligibility requirements for Australian Unity are located on the ATMS website www.atms.com.au. Your ATMS number can be used as your Provider Number, or you can contact Australian Unity for your Australian Unity generated Provider Number. Please note that Australian Unity requires Professional Indemnity Insurance (to at least $2 million) and Public Liability Insurance (to at least $10 million).

BUPA
Names and details of eligible ATMS members will be sent to BUPA on a monthly basis. The provider eligibility requirements for BUPA are located on the ATMS website www.atms.com.au. The Provider eligibility requirements include an IELTS test result of an overall Band 7 or higher for TCM qualifications completed in a language other than English. BUPA will generate a Provider Number after receiving the list of eligible practitioners. BUPA advises ATMS of your Provider Number and ATMS will then advise those members directly.

Please note that BUPA requires all providers to have a minimum of $2 million Professional Indemnity Insurance. Also they now have a restriction of maximum four (4) clinic addresses for all modalities.

CBHS Health Fund Limited
Names and details of eligible ATMS members will be sent to CBHS each month. The details sent to CBHS are your name, address, telephone and accredited discipline(s). These details will appear on the CBHS website. If you do not want your details to be sent to CBHS, please advise the ATMS office on 1800 456 855. The provider eligibility requirements for CBHS are located on the ATMS website www.atms.com.au. Your ATMS number will be your Provider Number.

Doctors Health Fund
Names and details of eligible ATMS members will be sent to Doctors Health Fund each month. Please note that Doctors Health Fund only covers Remedial Massage. The provider eligibility requirements for Doctors Health Fund are located on the ATMS website www.atms.com.au. Your ATMS number will be your Provider Number.
Grand United Corporate (GU Health)

To register with Grand United Corporate, please apply directly to Grand United on 1800 249 966.

HCF

Names and details of eligible ATMS members will be sent to HCF on a weekly basis. The provider eligibility requirements for HCF are located on the ATMS website www.atms.com.au. HCF do not issue provider numbers nor use your ATMS number as your provider number. They do however require your ATMS membership details, including your ATMS number, to be clearly indicated on all invoices and receipts issued.

Health Partners – Bowen Therapy, Kinesiology and Reflexology

^ For the additional modalities that Health Partners covers that are not listed above including Bowen Therapy, Kinesiology and Reflexology, eligible providers will need to use your ATMS member number as your provider number:

Medibank Private

Names and details of eligible ATMS members will be sent to Medibank Private on a monthly basis. The provider eligibility requirements for Medibank Private are located on the ATMS website www.atms.com.au. Medibank Private requires Clinical Records to be taken in English. Medibank Private generates Provider Numbers after receiving the list of eligible practitioners from ATMS. Medibank Private sends these provider numbers directly to ATMS. ATMS will then forward this information to the provider. Please note that Medibank has placed a restriction of up to a maximum 3 clinic addresses that will be recognised for Remedial Massage. There are no restrictions on the number of recognised clinics for other modalities.

NIB

Names and details of eligible ATMS members will be sent to NIB on a weekly basis. The provider eligibility requirements for NIB are located on the ATMS website www.atms.com.au. NIB does accept overseas Acupuncture and Chinese Herbal Medicine qualifications which have been assessed as equivalent to the required Australian qualification by Vetassess. Your ATMS Number will be your provider number, unless your client wishes to claim online. Your client will need to contact NIB directly or search by your surname and postcode on the NIB website www.nib.com.au for your provider number for online claiming purposes.

HICAPS

ATMS members who wish to activate these facilities need to register directly with HICAPS. **HICAPS do not cover all health funds and modalities.** Please go to www.hicaps.com.au or call 1800 805 780 for further information.

FAQ

ABOUT YOUR INSURANCE

Based on enquiries and phone calls we receive from our ATMS clients in regards to the cover provided by CGU and GSA, we have put together a FAQ to assist with your own enquiries.

Q. How do I take out a NEW policy with GSA?
A. If you are a new client to GSA and require cover for Professional Indemnity and Public & Products Liability, please head to our website: www.gsaib.com.au/atms

Q. How can I renew my EXISTING policy with GSA?
A. GSA will provide four renewal notifications with a personalised link to your policy via email correspondence. This email allows you to renew your policy at a time which is convenient to you.

Q. Can additional names be included on my insurance policy?
A. The cover provided by CGU is for YOU as an Individual practitioner as well as your Business entity. Should you have employees under the Business entity, your staff are automatically covered under the business name. All other Individual members outside of this criteria are to hold their own insurance policy.

Q. Does the policy cover me to work as a mobile practitioner?
A. Yes, the policy provides cover for you to work Australia Wide. You do not have to notify GSA of your clinic address.

Q. Is the insurance premium payable via monthly instalments?
A. Payment must be paid in full at the time cover is taken out.

Q. Do I need to advise GSA if my contact details change?
A. Yes, all correspondence sent by GSA is via email. It is essential that GSA have your current email address and contact phone number on file. Simply email our office at atms@gsaib.com.au with any updates.

Q. What does Professional Indemnity cover me for?
A. Professional Indemnity insurance is designed for professionals who provide advice and or a service to their clients. It is designed to protect you against legal costs and claims for damages to third parties which may arise out of an act, omission or breach of your professional duty in the course of your business activities.

Q. What does Public & Products Liability cover me for?
A. Public Liability Insurance protects you and your business against the financial risk of being found liable to a third party for death or injury, loss or damage of property resulting from your negligence.

Q. What are the implications if my policy is not renewed by the date required?
A. It is a requirement of both ATMS and the Health Funds to maintain continuous insurance cover. It is critical that you renew your policy prior to it expiring to ensure you remain complaint.
Subclinical hypothyroidism (SCH) is one of the most common forms of thyroid disease and is typically diagnosed by the presence of increased circulating TSH with a normal free thyroxine (T4) and free tri-iodothyronine (T3) reading, as well as the presence of thyroid autoantibodies. Subclinical hypothyroidism may present with the classical symptoms of hypothyroidism (although is often asymptomatic in the early stages) and may also exacerbate other critical conditions such as diabetes, aortic calcification and impaired vascular function, atherosclerosis and myocardial and neuromuscular dysfunction.1,2 Whilst debated within the literature, there are compelling arguments to consider subclinical hypothyroidism for TSH readings greater than 2.5 mU/L, even in the absence of obvious symptoms, rather than 4.5 mU/L, as is currently widely accepted within the medical community.2 Historically, natural medicine practitioners have understood the value of assessing patients for what is ‘optimal’ rather than accepted as ‘normal’, and implementing preventive treatments for thyroid dysfunction at an early stage is understood to be an important part of practice.

Subclinical hypothyroidism, which often precedes progression to overt thyroid disease and thyroid autoimmunity, has very limited treatment options from the perspective of conventional medical care.1 Standard treatment involves hormone replacement therapy, however the effectiveness of such treatment is questionable, with a recent Cochrane review concluding that use of levothyroxine in SCH does not result in improved survival or cardiovascular morbidity; and importantly, does not improve symptoms to a greater degree than placebo.3 Considering that many patients can experience subclinical thyroid dysfunction for many years, and may in fact never progress to overt thyroid disease, effective management strategies are essential.

Fortunately, there are a multitude of natural medicine compounds and lifestyle interventions that aim to offer significant symptom relief and address the underlying causes.

A novel use for Withania in thyroid dysfunction

Withania has a rich history of traditional use and is frequently used for its adaptogenic properties – to regulate the HPA axis and increase resistance to stress. In addition, clinical trials support the use of Withania extracts in supporting multiple stress related presentations.4-8 Stress affects the immune system both directly and indirectly, through the activation of neural and endocrine systems. During periods of stress the resulting increase in glucocorticoids and catecholamines cause a shift to either Th1 or Th2 mediated immune activity which is associated with Hashimoto’s thyroiditis and Graves’ disease respectively.9 The adrenal axis also has well documented effects on thyroid function and there exists a negative relationship between cortisol and TSH. Both endogenous (stress related) and exogenous (pharmaceutical) corticosteroids suppress the HPT axis, while low cortisol levels increase the action of TSH, which suggests the existence of a physiologic feedback loop.2,10

Research Summary

A prospective, randomized, double-blind, placebo-controlled, pilot-study was conducted to evaluate the efficacy and safety of Withania root extract in SCH patients. Fifty patients met the inclusion criteria with TSH levels between 4.5 and 10 mU/L and normal T3 and T4 levels; and were randomized to receive 300mg Withania root extract (KSM-66) twice daily, equivalent to 7.5g dry herb daily.1 Treatment with KSM-66 resulted in a 41.5% increase in serum T3; a 19.6% increase in serum T4; and, a 17% reduction in serum TSH after 8 weeks of treatment. The differences compared to placebo were statistically significant. These results indicate a possible role for Withania in regulating the hypothalamic-pituitary-thyroid axis which may be explained through its HPA axis modulating properties. Withania’s anti-inflammatory and anti-dopaminergic properties may also play a role in the thyroid modulating effects of the KSM-66 extract.1

In an earlier study in which a Withania extract was used to assess its effect on

Disclaimer: The views and opinions expressed in these advertorials are those of the authors and do not necessarily reflect the opinions of ATMS or its Directors.
cognition in individuals with bipolar disorder, it was observed that in those with abnormal thyroid indices at baseline, Withania supplementation increased T4 levels in the treatment groups, whilst T4 levels tended to fall in the placebo group. Early animal data has also demonstrated thyroid enhancing properties from Withania administration.

**Further clinical support**

A holistic approach to management should also address the lifestyle and dietary factors contributing to disease progression. In addition, tyrosine, iodine, zinc, selenium, and vitamins A and D, are important nutritional co-factors which can be employed to address deficiencies; optimize thyroid hormone synthesis, conversion and activation; and modulate immune function.

For further research insights and information please contact technicalsupport@biomedica.com.au

**References**


Why is fascia currently such a hot topic?
The connective tissue has been underestimated for decades; we prefer to speak of the liver and not of the sheath surrounding the liver. The breakthrough for the fascia came in 2007 when the first Fascial Research Congress was held at the Harvard Medical School in the US. The significance of fascia since then has been widely discovered and demonstrated. Also, much new knowledge has been discovered, for example, the relationship between back pain and the neglected fascia.

Why do we need research on fascia?
Research is necessary. A lot has happened in recent years, for example, new measuring methods, such as with high-resolution ultrasound devices, make it even easier to work with patients in terms of quality and quantity. You can tell the patient that the stiffness of his connective tissue, for example, has improved by 8% since the last treatment.

What practical benefits can a therapist draw from research studies?
Some traditional methods have been confirmed by research; others have to be rewritten. For example, until recently, most manual therapists believed that the myofascial spiral line, as described by Tom Myers, ran throughout the body as a diagonal loop. Now, it has been established that there is only evidence of a fascial cross-linking above the iliac crest. This means when working on the the pelvic and leg area, you should focus more on the neuromuscular than a passive-fascial effect. It’s essential that a therapist keeps his/her knowledge up to date.

You recommended a regular Fascial Fitness training, Why?
Because we already know the importance of Fascia for our health, fitness, and figure. A well-trained fascia is tear-resistant and elastic. On the other hand, untrained fascia is brittle and get stuck together; we can lose our body shape, become less powerful and more prone to injury.

Will Fascial Training replace muscle training?
No, it is not so simple, especially fascia and muscles cannot be separated and cannot be trained individually. But having said that, training fascia needs specific movements. So it’s not either-or, but both. Fascial fitness does not take a lot of time, but you also do not want to overdo it. You only need to stimulate fascia properly once, and it will freshen up in the next 72 hours, produces new elastic collagen. Twice a week of a ten-minute regular workout is sufficient. Everyone can do this.

If you only train muscles, fascia can be tight and becomes brittle. Our bodies need to be resilient and agile as gazelles. Once the tissues stuck together or matted, it requires three to six months to restore. Lack of movement can make the Achilles tendon felt brittle. Frozen shoulder, a painful, stiff shoulder condition can have 30 percent of the connective tissues stuck in the shoulder area. If one bends over and cannot touch the floor with his hands, his leg and back fascia have lost their elasticity. This is the same for plantar fascia, i.e., the fascia under the foot. Scar tissues should be stretched and massaged, or lift the skin, fold in the hand, roll it or pull the scarred surface with cupping.

Not only scientists, physicians, and therapists have now recognized the importance of fascia, but also a bodybuilder. Therefore, they consume gelatin, which is cooked connective tissue. They might as well eat Jell-O, but that is not so attractive.

To learn more about Fascial Fitness Workshop in Sydney, Australia in November 2018, visit [www.fascialfitness.net.au/](http://www.fascialfitness.net.au/)
If you like the idea of continuing your practice unrestricted as you are now, continue reading.

The grisly process of stamping out homeopathy in Australia is well underway, with naturopathic medicines and other therapies to follow.

While the focus is currently on homeopathy, 16 other modalities are also under serious threat, threatening the livelihoods of suppliers, manufacturers and practitioners. That’s about everyone involved with CAM, including our patients.

The Australian Homeopathic Association and Complementary Medicines Australia, with support from ATMS and others, submitted a complaint about the NHMRC’s negative report on homeopathy two years ago. We expect a final determination from the Ombudsman soon.

The campaign is calling for a Senate Inquiry investigation into the inaccurate, negative government reports on homeopathy and 16 other natural therapies, which are being used to influence restrictive regulatory change on CAM therapies. As of 25th May, the campaign has 81,000 signatures. The goal is 100,000, to take it to the next level of political influence to protect CAM therapies from attacks by Skeptics and their influence on government.

This magic number aims to be achieved by June 30th 2018. Can we make an even stronger point and get more than 100,000 signatures? With your support, absolutely!

Send this message to your clients, staff, friends, family and ask them to contact their networks. International signatures count too.

Here’s how easy it is:

- It takes a few seconds to sign at www.yourhealthyourchoice.com.au
- Forward this message to your professional network
- Download a paper copy of the petition for your clinics and business for your clients and customers to sign (and email or post back to the address on the form)
- Email your clients – they are not happy when they realise their healthcare options could be restricted
- Put notices in newsletters & blogs about www.yourhealthyourchoice.com.au
- Share on Facebook (a ‘like’ must be supported by a sign-up)
- Share on Twitter - #yourhealthyourchoice

For an electronic version of this message to send out to clients please email nyema@karunahealthcare.com.au

If you like the idea of continuing your practice unrestricted as you are now, continue reading.

Your Health Your Choice campaign www.yourhealthyourchoice.com.au was established to attract political attention. Each signature, automatically generates a letter to your local MP.

Disclaimer: The views and opinions expressed in these advertorials are those of the authors and do not necessarily reflect the opinions of ATMS or its Directors.
Herb Growers and Herbal Extract medicine manufacturers work with the seasons, and its doubly so for manufacturers of Fresh Plant Tinctures. There is no drying the herb to use later, it must be processed with hours of harvest to capture all the actives, volatiles and energetics of the plant.

The 2017/2018 season is now nearly finished, with the root crops being harvested as this article is being written. Every year has its challenges and this year was characterised by below average rainfall. Low rainfall, in general, produces a good product, as the plant produces extra constituents to cope with the challenges. However, yields are affected, and certain crops like Scullcap, Gotu Kola and Yellow Dock really failed to thrive.

At this time of year, we sit down with Ronald and Marleen at Marleen Herbs Tasmania to review the year and plan for next year. Autumn is a great time to visit Tasmania, and the countryside had greened up after the first good rains of early April. Many of the perennial herbs were disappearing underground to rest for the winter. It’s also a good time to collect seed and as I arrived, Marleen and Emma came out of the fields with baskets of mature Echinacea purpurea flower heads full of seeds for next season.

Although a hard year, Marleen Herbs continues to mature as a herb farm. After establishment in 2010, the Van de Winckel family have worked hard to propagate up significant areas of over 110 different medicinal herbs. Woody species like Hawthorn, Olive, Poplar, Rosemary and Wormwood are gaining size with far better yields. Planting area continues to grow, and the purchase of additional land will see more area converted to Organic status.

PPC Herbs take all the Fresh Plant Tinctures produced and markets them to Herbalists and Healthcare professionals throughout Australia. With large amounts of Fresh Plant Tinctures now available commercially sales have increased significantly. Those not so familiar with this more European approach to Phyto-therapy have been keen to sample the exciting range. New offerings like Teasel, a popular choice for Lyme disease, have been warmly welcomed.

PPC Herbs also takes any excess stock as dried herb for our Traditional Extracts. This year 100% of our Echinacea purpurea, Sage, Rosemary, Thyme, Lavender and Golden Rod will come from this pristine certified organic Tasmanian farm.
The new greenhouse (pictured above) really helps with the propagation of young plants. The extra protection and warmth aids young cuttings and seedling establish themselves before being planted out. And of course, no organic herb farm is complete without its own bee hives (pictured) to pollenate the flowers and ensure good seed set for the next years planting.

Another sustainable practice at Marleen Herbs is the use of an electric tractor for cultivation and weed control. The tractor is recharged from the extensive array of solar panels at the farm.

In fact, most electricity for the farm is generated by solar, and the use of passive energy efficient systems can be seen in herb drying shed and the greenhouse with the stone wall acting as the thermal store.

Keys crops in 2018/2019 will include Chamomile, Dandelion, Lemon Balm, St Johns Wort, Passionflower and Lady’s Mantle. If you would like a sample of these Australian Grown, Certified Organic, Fresh Plant Tinctures, just send me an email to warren.morey@ppcherbs.com.au with your delivery address and contact number.

Disclaimer: The views and opinions expressed in these advertorials are those of the authors and do not necessarily reflect the opinions of ATMS or its Directors.
Imagine if your uniforms were designed by a fellow Practitioner, someone who knows what the uniform should perform like in an active job... Introducing 10 knots uniforms, designed by Practitioners for Practitioners.

- **Style and Comfort** – freedom to move, adjustable fit and superb cut.
- **Durable and breathable quality fabrics.** Natural Linen or Functional (Poly/Viscose).
- **Ethically designed and manufactured in Australia, stock held on site, no minimum order.**

Feel the difference, from AM to PM appointments you will look and feel fresh. … I designed your uniforms with a genuine desire to make a difference, aesthetically and practically.

**Australian School of Remedial Therapies**

admin@asrt.edu.au | www.asrt.edu.au | 02 9763 2388 | 0416 286 899

Established in Sydney in 1990 and founded and directed by Master Zhang Hao (B. ED, Dip. TCM, RM) the Australian School of Remedial Therapies offers nationally accredited vocational education training qualifications in Diploma of Remedial Massage and Diploma of (TCM) Remedial Massage. The school also regularly delivers the short CPE skill update workshops throughout the year which are specifically designed for professional massage therapists and health care workers.

If you like a caring, practical, fun and personalised training tradition and environment then try us!

**Bio-Medica Nutraceuticals**

info@biomedica.com.au | www.biomedica.com.au | 1300 884 702

BioMedica is an Australian owned company dedicated to the research, development and production of high quality, low excipient and efficacious practitioner formulations. Our products are developed by practitioners for practitioners. As a ‘Strictly Practitioner Only’ company, BioMedica is strongly dedicated to preserving and enhancing the role of the holistic practitioner. Our products are only sold to practitioners in a clinical setting, this has been our long standing policy since our inception in 1998, and remains firmly in place to this day. We also aim to provide highly relevant technical education materials and seminars, with practical research and insights that can be immediately integrated into clinical practice.

**Cathay Herbal**

orders@cathayherbal.com | www.cathayherbal.com | 1800 622 042

Established in 1986, Cathay Herbal is a company that is run by practitioners who constantly work to ensure they understand and meet the needs of you, the practitioner. All products sold by Cathay Herbal undergo rigorous development and investigation before being offered as part of their range. With one of the largest ranges of Chinese Classical formulas outside of China, they don’t just stock the popular ones. Cathay’s range is large and comprehensive. As well as the classical Black Pill range they also have many formulas available in tablet and capsules and a range of herbal granules, liquids and plasters.

**Core Body Therapy**

info@corebodytherapy.com.au | www.corebodytherapy.com.au | 0405 386 256

Core Body Therapy was developed in 2003 by Chris O’Brien, one of the most respected Myofascial Release Therapists and Teachers in the industry. A complete system of bodywork not offered in any other institution, our hands-on CPE courses will take your therapeutic bodywork deeper than traditional injury therapy moving beyond your initial training. Core Body Therapy recognises the need for small groups to give the highest quality training possible. We make sure you get plenty of one on one time for optimum learning. Our courses are geared towards dedicated, results oriented therapists seeking to further their practice.
PRODUCTS & SERVICES

**HESTA**

**Health World Limited**

www.healthworld.com.au | 07 3117 3300

Health World Limited is recognised as a Leading Natural Health Science Company and the innovators in Natural Health products and Healthcare professional education. Health World Limited and Metagenics have invested in cutting edge manufacturing technology and equipment in order to expand production of the highest quality Natural Medicines. This level of commitment ensures that Health World Limited produces products that you and your patient can trust for quality and effectiveness.

**Herbs of Gold Pty Ltd**

info@herbsofgold.com.au | www.herbsofgold.com.au | 02 9545 2633

Herbs of Gold has been dedicated to health since 1989, providing premium and practitioner strength herbal and nutritional supplements. Formulated by qualified, clinical and industry experienced naturopaths, herbalists and nutritionists, our formulations are based on current scientific research and traditional evidence. We take great care in all aspects of our business; right from the selection of raw materials through to the finished product, reviewing our environmental impact and sustainability of ingredients. All Herbs of Gold products meet stringent regulations for safety, quality and efficacy.

**Helio Supply Co**

tcm@heliosupply.com.au | www.heliosupply.com.au | 02 9698 5555

Helio Supply Co is a wholesaler of Acupuncture and TCM supplies. We distribute nationally as well as internationally and pride ourselves on our service to customers. Established in 2000, we are committed to providing educational opportunities, a practitioner support line and sourcing the best domestic and international equipment and materials.

**Oligoscan Australasia**

jon@karunahealthcare.com.au | www.oligoscan.net.au | 0455 6666 14

Oligoscan is sophisticated technology, yet easy to use. Using the hand held device it takes only a minute to run the rest. Practitioners familiar with hair mineral analysis can transition to Oligoscan to easily detect heavy metals (including antimony) and the minerals (including iodine). The Oligoscan is used worldwide by GPs, naturopaths, herbalists, homeopaths, chiropractors, pharmacists and nutritionists. With over 100 practitioners in Australasia, when you join the Oligoscan community you receive our Clinical Interpretation Guide and free access to our ongoing clinical webinars. You can also join the Oligoscan Facebook community and participate in clinical discussions with your colleagues. One on one mentoring program is available.

**Terra Rosa**

terrarosa@gmail.com | www.terrarosa.com.au | 0402 059 570

Terra Rosa specialised in educational massage DVDs and books. It has the largest collection of massage DVDs in Australia and the world, covering all modalities from Anatomy, Swedish Massage, Reflexology, Sports Massage to Myofascial Release and Structural Integration. We also provide the best in continuing education with workshops by international presenters including Orthopaedic Massage, Taping, Fascial Fitness and Myofascial Therapy.

**The Pharmaceutical Plant Company**

sales@ppcherbs.com.au | www.ppcherbs.com.au | 03 9762 3777

Where nature, science and health come together. PPC offers healthcare professionals a choice of either traditionally made herbal extracts from dried plant materials; or fresh plant tinctures that are all grown in Tasmania and processed within hours of harvest. PPC uses Organically certified herb where possible, with the entire Fresh Plant Tincture range being Australian Certified Organic. The Pharmaceutical Plant Company has 25 years experience in manufacturing and distributing traditional herbal extracts, fresh plant tinctures and listed medicines in Australia.

**The ATMS Products & Services Guide will appear in every issue of JATMS**

The cost is $150 for one issue or $500 for 4 consecutive issues. Listing comprises of – Logo, 100 word profile and contact information. If you wish to list your company, practice, products, services or training course to appear in the next Guide, please contact Yuri Mamistvalov on 0419 339 865.

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**HESTA**

Hesta@hesta.com.au | hesta.com.au | 1800 813 327

For more than 25 years, HESTA has focused on helping those in the health and community services sector reach their retirement goals. We now have more than 785,000 members, 155,000 employers and more than $28 billion in assets. HESTA’s community services sector reach their retirement goals. We now have more than 785,000 members, 155,000 employers and more than $28 billion in assets. HESTA's size means we can offer many benefits to members and employers. These include: low fees, a fully portable account, easy administration, access to low-cost income protection and death insurance, limited financial advice (at no extra cost), super education sessions and transition to retirement options. We also provide access to great value health insurance, banking and financial planning. For more information visit hesta.com.au or call 1800 813 327.

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Continuing Professional Education (CPE) is a structured program of further education for practitioners in their professional occupations.

The ATMS CPE policy is designed to ensure its practitioners regularly update their clinical skills and professional knowledge. One of the main aims of CPE is to keep members abreast of current research and new developments which inform contemporary clinical practice.

The ATMS CPE policy is based on the following principles:

- Easily accessible to all members, regardless of geographic location
- Members should not be given broad latitude in the selection and design of their individual learning programs
- Applicable to not only the disciplines in which a member has ATMS accreditation, but also to other practices that are relevant to clinical practice which ATMS does not accredit (e.g. Ayurveda, yoga)
- Applicable to not only clinical practice, but also to all activities associated with managing a small business (e.g. book-keeping, advertising)
- Seminars, workshops and conferences that qualify for CPE points must be of a high standard and encompass both broad based topics as well as discipline-specific topics
- Financially viable, so that costs will not inhibit participation by members, especially those in remote areas
- Relevant to the learning needs of practitioners, taking into account different learning styles and needs
- Collaborative processes between professional complementary medicine associations, teaching institutions, suppliers of therapeutic goods and devices and government agencies to offer members the widest possible choice in CPE activities
- Emphasis on consultation and co-operation with ATMS members in the development and implementation of the CPE program

ATMS members can gain CPE points through a wide range of professional activities in accordance with the ATMS CPE policy. CPE activities are described in the CPE policy document as well as the CPE Record. These documents can be obtained from the ATMS office (telephone 1800 456 855, fax (02) 9809 7570, or email info@atms.com.au) or downloaded from the ATMS website at www.atms.com.au.

It is a mandatory requirement of ATMS membership that members accumulate 20 CPE points per financial year. CPE points can be gained by selecting any of the following articles, reading them carefully and critically reflecting on how the information in the article may influence your own practice and/or understanding of complementary medicine practice. You can gain one (1) CPE point per article to a maximum of three (3) CPE points per journal from this activity:

- **Medhurst R.** Indigestion: background and management using homeopathy
- **Balinski et al.** The effectiveness of manual lymphatic drainage and low level laser in the treatment of a client with lipedema: an N-of-1 trial
- **McLean W.** A critical review of efficacy and safety of saffron (Crocus sativus) in the treatment of mild to moderate depression: Part 2
- **Neiger D.** Naturopathic support for breast cancer
- **Pagura I.** New developments in the area of privacy law

As part of your critical reflection and analysis, answer in approximately 100 words the following questions for each of the three articles:

1. What new information did I learn from this article?
2. In what ways will this information affect my clinical prescribing/techniques and/or my understanding of complementary medicine practice?
3. In what ways has my attitude to this topic changed?

Record your answers clearly on paper for each article. Date and sign the sheets and attach to your ATMS CPE Record. As a condition of membership, the CPE Record must be kept in a safe place, and be produced on request from ATMS.

*Continuing Professional Education*

- **McEwen B.** The impact of diet on cardiometabolic syndrome
- **Grace S.** Treating low back pain: the evidence
- **Yu et al.** Vitamin D on glycaemia control in type 2 diabetes patients: A systematic review of randomised clinical trials
- **Boyle M.** An evidence-based critical review of the botanicals bilberry fruit, black cohosh, bladderwrack and St John's wort in clinical practice
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For more information about our herbal extracts or herbal medicines visit [www.ppcherbs.com.au](http://www.ppcherbs.com.au) or contact us at sales@ppcherbs.com.au.

**Fresh Plant Tinctures**
- All Australian grown herbs
- Certified Organic by ACO
- Fresh plant material processed within hours of harvesting

**Herbal Extracts**
- Extensive range of 1:1 and 1:2 extracts
- Cold percolated from dried botanical material in the traditional manner

**Now**
- 110 Herbs
- NEW Lower Price

**Now**
- 130 Herbs
- Majority Australian Certified Organic and Wild-crafted