Complementary Medicine: Exploring the Issues

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http://www.medreach.com.au

Short Course (Session 3), July 1, 2014, National Seniors Centre

Issues that could be explored

- What is complementary &/or alternative medicine?
- Who uses it, why and what for?
- Regulation of products and practitioners;
- The current review of the private health insurance rebate for natural therapies;
- How do we know if it works: what is evidence?
  - Evidence for and against specific products &/or therapies for certain conditions;
  - Sources of good information about complementary medicine, and
  - Using complementary medicine wisely.
But first a new video from the TGA


Specific products &/or therapies: Evidence?
You wanted to know about:

<table>
<thead>
<tr>
<th>Product / therapy</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saw Palmetto</td>
<td>Benign prostatic hypertrophy</td>
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<td>Omega-3 fatty acids (fish oil)</td>
<td>Preventing cardiovascular disease</td>
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<td></td>
<td>Rheumatoid arthritis</td>
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<td>Calcium &amp; Vitamin D</td>
<td>Osteoporosis</td>
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<td>Cranberry juice</td>
<td>Recurrent urinary tract infections</td>
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<td>Acupuncture</td>
<td>Back pain</td>
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<tr>
<td>Bilberry and grape seed extract</td>
<td>Help with eyesight</td>
</tr>
</tbody>
</table>

Sources of good information about CM

- **Summarised evidence:**
  - National Center for Complementary and Alternative Medicine
    - http://nccam.nih.gov/health/decisions
  - Medline Plus
  - The Cochrane Library
    - http://www.thecochranelibrary.com
  - PubMed Health
  - Healthdirect Australia

- **Original clinical trials**
  - PubMed
Saw Palmetto: Benign prostatic hypertrophy

30 caps $11.99
320 mg extract equiv to dry fruit (3.2g) 3200 mg, standardised to contain fatty acids 288 mg
Take one, 12 hrly

30 caps $24.36
160 mg extract equiv to dry fruit (1.6g) 1600 mg, standardised to contain fatty acids 144 mg
Take one, 12 hrly

30 tabs $26.40
66 mg extract equiv to dry leaf 660 mg standardised to fatty acids 39.6 mg plus other ingredients
Take one, daily

Saw Palmetto: Claims

- **Cenovis® Prostate Health Saw Palmetto 3200:**
  - Formulated to provide relief from the symptoms of medically diagnosed benign prostatic hypertrophy (BPH).

- **Nature's Own**
  - Saw Palmetto is a recognised herbal remedy for symptomatic relief of medically diagnosed benign prostatic hypertrophy.

- **Blackmores Proseren® Saw Palmetto:**
  - A standardised extract of the herb saw palmetto which has been shown to relieve the symptoms of medically diagnosed benign prostatic hypertrophy.

- **Caruso's ProstateEZE MAX**
  - An Australian preliminary clinical trial recently found 87.8% of the 32 active trial participants experienced improvements in their medically diagnosed Benign Prostatic Hypertrophy, symptoms over 3 months.
Several small studies suggest that saw palmetto may be effective for treating BPH symptoms.

However, a 2011 NCCAM-co-funded study in 369 older men demonstrated that saw palmetto extract administered at up to three times the standard daily dose (320 mg) did not reduce the urinary symptoms associated with BPH more than placebo.

A 2009 review of the research concluded that saw palmetto has not been shown to be more effective than placebo for this use.

In 2006, an NIH-funded study of 225 men with moderate-to-severe BPH found no improvement with 320 mg of saw palmetto daily for 1 year versus placebo.

There is not enough scientific evidence to support the use of saw palmetto for reducing the size of an enlarged prostate or for any other conditions.

http://nccam.nih.gov/health/palmetto/ataglance.htm

Saw Palmetto:

- The use of plants and herbs (phytotherapy) for the treatment of lower urinary tract symptoms associated with BPH is common and has been growing steadily in most Western countries.
- The extract of the berry of the American saw palmetto, or dwarf palm plant, Serenoa repens (SR), which is also known by its botanical name of Sabal serrulatum, is one of several phytotherapeutic agents available for the treatment of BPH.
- The update of this review included 32 randomized controlled trials involving 5666 men.
- Compared with placebo, Serenoa repens, at double and triple the usual dose, provides no improvement for nocturia, peak urine flow, and symptom scores for men with benign prostatic hyperplasia.


ProstateEZE Max: : Australian preliminary clinical trial?

Saw Palmetto: Australian preliminary clinical trial?


• A phase II randomised double-blind placebo-controlled clinical trial investigating the efficacy and safety of ProstateEZE Max: a herbal medicine preparation for the management of symptoms of benign prostatic hypertrophy.

• Authors: Coulson S, Rao A, Beck SL, Steels E, Gramotnev H, Vitetta L. The University of Queensland, School of Medicine, Centre for Integrative Clinical and Molecular Medicine, Brisbane, QLD 4102, Australia.


ProstateEZE Max: Australian preliminary clinical trial?

• The trial evaluated the efficacy and safety of ProstateEZE Max for the management of BPH

• The product contained the herbal extracts:
  – Cucurbita pepo (Pumpkin seed) (160 mg), Epilobium parviflorum (Willow herb) eq. 500 mg dry herb), lycopen (found in tomatoes 2.1 mg), Pygeum africanum (eq 15 g dry stem) and Serenoa repens (palmetto) eq. 660 mg dry leaf.

• It was conducted on 57 otherwise healthy males aged 40-80 years that presented with medically diagnosed BPH.

• Participants were assigned to receive 3 months of treatment (1 capsule per day) with either the herbal preparation (n = 32) or a matched placebo capsule (n = 25).

• The primary outcome measure was the international prostate specific score (IPSS) measured at baseline, 1, 2 and 3 months. The secondary outcomes were the specific questions of the IPSS and day-time and night-time urinary frequency.
ProstateEZE Max: Australian preliminary clinical trial?

Abstract:

- There was a significant reduction in IPSS total median score in the active group of 36% as compared to 8% for the placebo group, during the 3-months intervention ($p < 0.05$).
- The day-time urinary frequency in the active group also showed a significant reduction over the 3-months intervention (7.0–5.9 times per day, a reduction of 15.6% compared to no significant reduction change for the placebo group (6.2–6.3 times per day) ($p < 0.03$).
- The night-time urinary frequency was also significantly reduced in the active group (2.9–1.8), 39.3% compared to placebo (2.8–2.6 times) 7% ($p < 0.004$).

The problem with $p$ values:

- The current consensus is that if $p$ is less than .05, a study has reached the holy grail of being statistically significant, and therefore likely to be published.
- Over .05 and it’s usually back to the drawing board.
- However, it’s been contended that using .05 is a key reason why false claims are published and many published results fail to replicate. Some advocate requiring .005 or even .001 as the criterion for statistical significance.
- But this would require larger and more expensive studies.
- A confidence interval gives us the best estimate of the true effect, and also indicates the extent of uncertainty in our results. Confidence intervals also us to integrate results from a number of experiments into a meta-analysis.

http://theconversation.com/the-problem-with-p-values-how-significant-are-they-really-20029
ProstateEZE Max: Australian preliminary clinical trial?

International prostate specific symptom score (IPSS) median at 3 months.
Each question scored from 0 (not at all) to 5 (almost always)
Score 0-7 mild symptoms; 8-19 moderate; 20-35 severe symptoms.

<table>
<thead>
<tr>
<th>Item</th>
<th>Treated (n=32)</th>
<th>Placebo (n=25)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensation bladder not emptied</td>
<td>1.5</td>
<td>3</td>
<td>0.06</td>
</tr>
<tr>
<td>Cannot hold for 2 hours</td>
<td>3</td>
<td>3</td>
<td>0.29</td>
</tr>
<tr>
<td>Stop and start during urination</td>
<td>1</td>
<td>2</td>
<td>0.06</td>
</tr>
<tr>
<td>Difficult to postpone urination</td>
<td>3</td>
<td>3.5</td>
<td>0.07</td>
</tr>
<tr>
<td>Weak stream</td>
<td>3</td>
<td>3.5</td>
<td>0.10</td>
</tr>
<tr>
<td>Push or strain to urinate</td>
<td>1</td>
<td>1</td>
<td>0.20</td>
</tr>
<tr>
<td>How often do you get up at night</td>
<td>2</td>
<td>2.5</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Total score (difference = -4)</td>
<td>12.5</td>
<td>16.5</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>
Complementary Medicine: Exploring the Issues

Pygeum africanum in BPH: A systematic review

- The literature on P. africanum for the treatment of BPH is limited by the short duration of studies and the variability in study design, the use of phytotherapeutic preparations, and the types of reported outcomes.
- The evidence suggests that P. africanum modestly, but significantly, improves urologic symptoms and flow measures.
- Further research is needed using standardized preparations of P. africanum to determine its long-term effectiveness and ability to prevent complications associated with benign prostatic hyperplasia.

Conventional treatment of BPH

- Conventional medicines
  - Alpha 1-blockers such as tamsulosin relax the muscles of the bladder neck and prostate. This rapidly allows easier urination.
  - Finasteride and dutasteride lower levels of hormones produced by the prostate. These drugs also reduce the size of the gland, increase urine flow rate, and decrease symptoms of BPH over 3 to 6 months.
  - Side effects of both drugs can include ejaculation disorders and decreased sex drive.
  - Tamsulosin and dutasteride are available as a combined capsule (duodart).
  - Mean improvements in IPSS scores (after 2-4 years) were -6.3 units for combination therapy (n=1610), -5.3 units for dutasteride monotherapy (n=1623) and -3.8 units for tamsulosin monotherapy (n=1611) – 4 year randomized, double-blind, multinational, CombAT trial.
- Surgery
  - Transurethral resection of the prostate (TURP): This is the most common and most proven surgical treatment for BPH. TURP is performed by inserting a scope through the penis and removing the prostate piece by piece. Side effects include impotence and less commonly incontinence.
  - Less invasive therapy such as laser prostatectomy or microwave thermotherapy are also used.
Clinical trial information

- **Registration:**
  - Prospective.
  - Enforced & monitored by funding bodies, journals and professional societies.

- **Summary results:**
  - Published on register within one year of the trial’s completion (currently FDA only).

- **Journal publication:**
  - But negative results often either not submitted for publication or not accepted.

- **Full clinical study report to made publically available:**
  - Currently produced only for regulatory and licensing purposes but “commercial-in-confidence”.

Make clinical trials count:

http://www.alltrials.net
Omega-3 fatty acids (fish oil): Heart disease

- **5 Things To Know About Omega-3s for Heart Disease**
  - Experts agree that fish rich in omega-3 fatty acids should be included in a heart-healthy diet (at least 2-3 times a week).
  - Omega-3s in supplement form have not been shown to protect against heart disease.
  - Omega-3 supplements may interact with drugs that affect blood clotting.
  - Fish liver oils (which are not the same as fish oils) contain vitamins A and D as well as omega-3 fatty acids; these vitamins can be toxic in high doses.
  - Talk to your health care provider before using omega-3 supplements.

Omega-3 fatty acids: Rheumatoid arthritis

- A meta-analysis was conducted of randomized controlled trials (RCTs) that examined the effects of omega-3 polyunsaturated fatty acids (PUFA) on clinical outcomes in RA patients.
- Ten RCTs involving 183 RA patients and 187 placebo-treated RA controls were included in this meta-analysis.
- The analysis showed that omega-3 PUFAs reduced nonsteroidal anti-inflammatory drug (NSAID) consumption (p = 0.011).
- Tender joint count (p = 0.128), swollen joint count (p = 0.241), morning stiffness (p = 0.221), and physical function (p = 0.314) showed a trend to improve more in patients treated with omega-3 PUFAs than in placebo-treated controls, but they did not reach statistical significance.
- This meta-analysis suggests that the use of omega-3 PUFAs at dosages > 2.7 g/day for > 3 months reduces NSAID consumption by RA patients. Further studies are needed to explore the clinical effects of omega-3 PUFAs in RA.

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Omega-3 fatty acids: Rheumatoid arthritis

Fish Oils

Please note: Some of these pages use the term 'arthritis'. Arthritis is sometimes used as a generic term for musculoskeletal conditions.

This page provides general information about the use of fish oils supplements as a treatment for arthritis. It includes information about who may benefit from taking fish oils, how much to take and where to find more information.

What are fish oils?
Fish oils are oils found in the tissues of fish. They contain a certain type of fat called omega-3.

What are omega-3 fats?
Omega-3 fats are a type of fat that may be important for good general health. Our bodies cannot produce omega-3 fats so they must be obtained from food. Omega-3 fats are mostly found in oily fish and certain nuts and seed oils.

Calcium & Vitamin D: Preventing osteoporosis

Exercise

Weight-bearing exercises

People who exercise are less likely to suffer broken bones. Regular weight-bearing exercises can help you to stay strong and healthy. They can also help you to stay independent longer.

Exercise can improve your quality of life by improving your mood and self-esteem. It can also help you to maintain your independence and reduce the risk of falls and fractures.

Resistence exercises

Resistence exercises can improve your strength, balance and coordination. They can also help you to maintain your independence and reduce the risk of falls and fractures.

Healthy eating

Choosing a healthy, balanced diet is recommended for everyone. It can help prevent many conditions, including heart disease, diabetes and many forms of cancer, as well as osteoporosis.

Calciuim is important for maintaining strong bones. 1000mg of calcium per day is recommended for women over 40 and men over 50. Calcium is found in a number of different foods including dairy foods, green leafy vegetables, and fish.

If you can’t get the recommended amount of calcium from your diet you may need to take a calcium supplement. This will depend on your age and sex. You can find more information on calcium supplements and their use at the Cancer Council website.


http://www.omega3facts.org


http://www.aarp.org

http://www.aarp.org/health/supplements-benefits/index.htm
Calcium & Vitamin D: Preventing osteoporosis

The groups at greatest risk of vitamin D deficiency in Australia are dark-skinned and veiled women (particularly in pregnancy), their infants, and older persons living in residential care.

Recommended sun exposure Melbourne (face, hands & arm)
Dec-Jan (10:00 or 14:00) 6-8 min
Jul-Aug (12:00) 25 min

Cranberry extract

- Helping you to reduce the frequency of recurrent cystitis
- Blackmores Cranberry 15000 is a concentrated high potency cranberry extract that may help to reduce the frequency of recurrent cystitis.
- Cranberry contains active constituents called proanthocyanidins which have been found to discourage bacteria from sticking to the bladder wall.
- It helps mask urinary odours associated with incontinence
- The capsule can be pulled apart and contents sprinkled over food or into drinks.

$26.60, 60's
Cranberry extract

- Swisse Ultiboost Cranberry contains PACran®, a premium quality cranberry extract to support urinary tract health and help reduce the frequency of cystitis.
- Cranberries are a rich source of antioxidants and possess unique anti-adhesion qualities that protect the urinary tract against the bacteria that causes cystitis. Swisse Ultiboost Cranberry can help with cystitis symptoms and may help reduce the recurrence of cystitis.
- PACran® is a clinically proven, standardised, high potency cranberry extract and is a unique combination of the whole cranberry fruit pulp. Clinical trials support the use of PACran® to maintain urinary tract health.

Swisse Ultiboost Cranberry: Evidence

- O'May C. Tufenkji, N. (2011) The swarming motility of Pseudomonas aeruginosa is blocked by cranberry proanthocyanidins and other tannin-containing materials Applied and Environmental Microbiology 77:9:3061-3067
- Vidal, D. (2011) A randomized double blind placebo controlled trial to evaluate the efficacy of cranberry powder as a prophylactic against recurrent urinary tract infection (UTI) in women PhytoPharm Congress presentation

$18.39, 30's

This updated review includes a total of 24 studies (six cross-over studies, 11 parallel group studies with two arms; five with three arms, and two studies with a factorial design) with a total of 4473 participants.

Prior to the current update it appeared there was some evidence that cranberry juice may decrease the number of symptomatic UTIs over a 12 month period, particularly for women with recurrent UTIs. The addition of 14 further studies suggests that cranberry juice is less effective than previously indicated.

Although some of small studies demonstrated a small benefit for women with recurrent UTIs, there were no statistically significant differences when the results of a much larger study were included.

Given the large number of dropouts/withdrawals from studies (mainly attributed to the acceptability of consuming cranberry products particularly juice, over long periods), and the evidence that the benefit for preventing UTI is small, cranberry juice cannot currently be recommended for the prevention of UTIs.

Other preparations (such as powders) need to be quantified using standardised methods to ensure the potency, and contain enough of the 'active' ingredient, before being evaluated in clinical studies or recommended for use.
• Acupuncture is known to treat a wide range of disorders including:
  – **Musculoskeletal disorders** such as **osteoarthritis**, **sciatica**, lumbago, weak back, **low back pain**, rheumatoid arthritis, gout, tenosynovitis, shoulder and neck pain, **cervicobrachial syndrome**, ‘**frozen shoulder**’, and ‘**tennis elbow**’.
  – The disorders above which appear in **bold** have been recognised by the World Health Organisation (December 1979) as having been successfully treated by acupuncture. The disorders which do not appear in bold above are other common disorders which have been found to respond well to acupuncture.

Acupuncture

• It's difficult to compare acupuncture research results from study to study and to draw conclusions from the cumulative body of evidence.
• This is because studies may use different acupuncture techniques (e.g., electrical vs. manual), controls (“placebo” or “sham”) and varied outcome measures.
• An emerging theme in acupuncture research is the role of the placebo.
• For example, a 2009 systematic review of research on the pain-relieving effects of acupuncture compared with placebo (simulated) or no acupuncture was inconclusive.
• The reviewers found a small difference between acupuncture and placebo and a moderate difference between placebo and no acupuncture but the effect of placebo acupuncture varied considerably.


Acupuncture Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Sham Procedure</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bannan et al</td>
<td>Two needles inserted into sham points, nine guide tubes on traditional points</td>
<td>Traditional slightly better than sham</td>
</tr>
<tr>
<td>Witt et al</td>
<td>Superficial needling at sham points</td>
<td>Traditional better at eight weeks, not at 52 weeks</td>
</tr>
<tr>
<td>Schneid et al</td>
<td>Minimal depth needling at nontraditional points</td>
<td>No difference between sham and traditional</td>
</tr>
<tr>
<td>Foster et al</td>
<td>Nonpenetrating needling, traditional points</td>
<td>No benefit for sham or traditional acupuncture</td>
</tr>
<tr>
<td>Suarez-Almazor et al</td>
<td>Minimal penetration at nonmeridian points</td>
<td>No difference between sham and traditional</td>
</tr>
<tr>
<td>Back Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leibing et al</td>
<td>Superficial insertion, nontraditional points</td>
<td>No difference between sham and traditional</td>
</tr>
<tr>
<td>Mobberger et al</td>
<td>Superficial insertion into nontradional points</td>
<td>Traditional better than sham</td>
</tr>
<tr>
<td>Brinkhaus et al</td>
<td>Superficial insertion, nontraditional points</td>
<td>No difference between sham and traditional</td>
</tr>
<tr>
<td>Meiko et al</td>
<td>Superficial insertion, nonacupuncture points</td>
<td>No difference between sham and traditional</td>
</tr>
<tr>
<td>Cherkin et al</td>
<td>Tactile stimulation of point, traditional points</td>
<td>No difference between sham and traditional</td>
</tr>
</tbody>
</table>

http://www.the-rheumatologist.org/details/article/873613 ls. Acupuncture for Pain a Placebo Treatment.html
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U3A City Short Course, June-July, 2014

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Acupuncture

- Acupuncture for chronic low back pain in long-term follow-up: a meta-analysis of 13 randomized controlled trials:
  - The authors compared acupuncture with sham acupuncture and other treatments.
  - Overall, 2678 patients were identified from thirteen randomized controlled trials.
  - Compared with no treatment, acupuncture achieved better outcomes in terms of pain relief, disability recovery and better quality of life, but these effects were not observed when compared to sham acupuncture.
  - Acupuncture is an effective treatment for chronic low back pain, but this effect is likely to be produced by the nonspecific effects of manipulation.

Bilberry and grape seed extract for vision

- Bilberry (Vaccinium myrtillus) is a relative of the blueberry, and its fruit is commonly used to make pies and jams.
- It has been used for nearly 1,000 years as a folk or traditional remedy for diarrhoea, menstrual cramps, eye problems, varicose veins, venous insufficiency and other circulatory problems.
- Some claim that bilberry fruit improves night vision, but clinical studies have not shown this to be true.
- There is not enough scientific evidence to support the use of bilberry fruit or leaf for any health conditions.
Bilberry and grape seed extract for vision

- The leaves and fruit of the grape (Vitis vinifera) have been used medicinally since ancient Greece.
- Studies have found that some compounds in grape seed extract may be effective in relieving symptoms of chronic venous insufficiency.
- Small randomized trials have found beneficial effects of grape seed extract for diabetic retinopathy (an eye problem caused by diabetes) and for vascular fragility (weakness in small blood vessels). Larger trials are needed to confirm these findings.
- NCI is also funding studies to evaluate whether grape seed extract is effective in preventing breast cancer in postmenopausal women and prostate cancer.

$27.69
Bilberry and grape seed extract for vision

Issues that could be explored

- What is complementary & or alternative medicine?
- Who uses it, why and what for?
- Regulation of products and practitioners;
- The current review of the private health insurance rebate for natural therapies;
- How do we know if it works: what is evidence?
- Evidence for and against specific products & or therapies for certain conditions;
- Sources of good information about complementary medicine, and
- Using complementary medicine wisely.
Sources of good information about CM

- Summarised evidence:
  - National Center for Complementary and Alternative Medicine
    - http://nccam.nih.gov/health/decisions
  - Medline Plus
  - The Cochrane Library
    - http://www.thecochranelibrary.com
  - PubMed Health
  - Healthdirect Australia

- Original clinical trials
  - PubMed

Using complementary medicine wisely

- To use CM wisely:
  - ALWAYS tell your health practitioners about ALL the medicines you take.
  - Ask your practitioner for advice, especially:
    - Evidence of efficacy from well conducted clinical trials concerning the specific product recommended,
    - Possible side-effects and potential interactions with your existing therapy.
  - Search for independent information from trusted sources:
    - See previous slide
    - Also consumer sites e.g.
    - Check the CRP and TGA complaint register to see if complaints about a product’s claims have been upheld:
      - www.tga.com.au
  - Be very skeptical about promotional claims.
Remember: CM are no substitute for a good diet and exercise

http://www.shapeup.gov.au/start-shaping-up

Finally: use all health care interventions (not just CM) wisely

http://www.youtube.com/watch?v=FqQ-JuRDkJ8; http://www.choosingwisely.org;
http://www.youtube.com/watch?v=ZPWTPXvmC_w