

Herbal Medications in College Health: Considerations & Evidence

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*No conflicts of interest

Disclosures

What I am not...

- Not an herbalist
- Not a naturopath
- Do not practice Eastern medicine

What I am...

- Family Physician
- Allopathic trained
- Do my best to practice evidence-based medicine
- In college health 2.5 years

What we won't be talking about...

- Medical marijuana

- (Nor non-medical uses of marijuana for that matter)



...and what we will (aka Objectives)

1. Herbals as supplements
 - FDA regulations differ from medications
 - Specific issues of safety
2. Herbal medication uses in college health
 - Key conditions for which herbals may be used
 - Summarize evidence re: efficacy for selected topics
 - Highlight any concerning safety issues
3. Sources of valid information regarding herbal medications

Going green w/ your meds?

- Herbal supplements are derived from plants, used for therapeutic purposes
- Assumption: natural = safe
 - Herbal supplements are still chemical
 - Can have own list of adverse effects
 - Can interact with other medications



Herbals & the FDA

- Herbals considered “supplements”
- Subjected to food regulations, not drug regulations
 1. Less standardization of content
 2. No pre-requisite for safety or efficacy prior to being marketed
 - FDA MedWatch program to monitor
 - Limits claims that can be made

Acai Berry Home

Free Trial Offers

Store

Acai Pills, Acai Capsules

Acai Berry Juice

Acai Berry Forums

Acai Berry Side effects

Acai Berry Diet

Acai Benefits

What is Acai?

Nutritional Info

Books and Literature

About Us

What is Acai Berry?

Note: US FDA Disclaimer



The acai berry (pronounced ah-sigh-ee) is a fruit that grows on the acai palm trees in the Amazon rain forest of Brazil. It is dark purple in color and about the size of a grape. It is extremely rich in nutrients. Natives of the Amazon region have made this berry a major part of their diet for hundreds of years.

Approximately 10% of the berry contains edible pulp and skin and the remaining 90% is the seed or pit. Most of the nutrients come from the pulp and skin and the seed is normally not eaten. The fruit tastes like a vibrant mix of berries and chocolate. With rich nutrients and great taste, it is not surprising that this food is becoming extremely popular.

Acai Berry, the new Superfood

Despite being extremely popular in Brazil, the acai berry has been relatively unknown in other parts of the world. However, recent media coverage of this amazing food has been touted on the Oprah Winfrey show, ABC, NBC and CBS news and other shows. It has also been featured in several books. In fact, Dr. Perricone calls this berry the number one superfood in his book "The Perricone Promise". The berry is extremely rich in antioxidants, amino acids and essential fatty acids. With 15-20 times the antioxidants as red grapes, it is one of best sources of antioxidants of any food. There are numerous benefits to acai. In summary, it can help:

- Promote weight loss
- Boost energy & stamina
- Support the immune system
- Promote more restful sleep
- Fight aging and inflammation

The FDA disclaimer

- The products and the claims made about specific products on or through this site have not been evaluated by the Bayside Laboratories or the United States Food and Drug Administration and are not approved to diagnose, treat, cure or prevent disease.
- The information provided on this site is for informational purposes only and is not intended as a substitute for advice from your physician or other health care professional or any information contained on or in any product label or packaging.
- You should not use the information on this site for diagnosis or treatment of any health problem or for prescription of any medication or other treatment.
- You should consult with a healthcare professional before starting any diet, exercise or supplementation program, before taking any medication, or if you have or suspect you might have a health problem.

What's a clinician to do?



- Ask students *specifically* about use of herbal meds
- Offer info about limitations of FDA regulations
- Know the evidence...
 - Check valid info sources for efficacy and give recommendations
 - Watch for warnings
 - Educate that hype and advertising are not the same as sound medical research

Cheryl's Approach

- Does this product work for the reason the student is seeking?
 - B grade with RCT data
- If so, is it safe?
- If not, is it safe?
- Pot'l harms: adverse effects—real or theoretical?
- Pot'l harm: wasted \$

Balancing benefits & risks



Examples:

- Kava for anxiety
- Melatonin for sleep disturbances
- High dose riboflavin for migraine prevention

A comment about evidence...

Validity for treatment

- Meta-analysis of RCTs
- Double blind RCT
- Controlled trial
- Cohort
- Case control

Relevance

- Human > animal
- Patient-oriented > disease oriented

3. Information sites about Herbals

- NIH drug information

 - <http://www.nlm.nih.gov/medlineplus/druginformation.html>

- Nat'l Center for Complementary & Alternative Medicine

 - <http://nccam.nih.gov/health/herbsataglance.htm>

 - Can register for updates

CF Commentary

 - Useful for clinicians, educators, patients

 - Information on efficacy (grade) and safety

 - Focus on validity, not necessarily relevance

 - Sometimes grade does not fully correlate w/ levels of evidence

Other evidence sources: original data

■ Cochrane Database

- Systematic reviews of RCTs on a wide variety of topics
- Group within focuses on alternative meds
- Worthwhile first look for any Q about treatment



■ PubMed Clinical Queries

- Therapy, systematic reviews
- Adds validity filters to your search to help retrieve better info

2. Audience query...

What herbals/alternative meds
are you being asked about?

What conditions do you see
students taking herbal meds for?

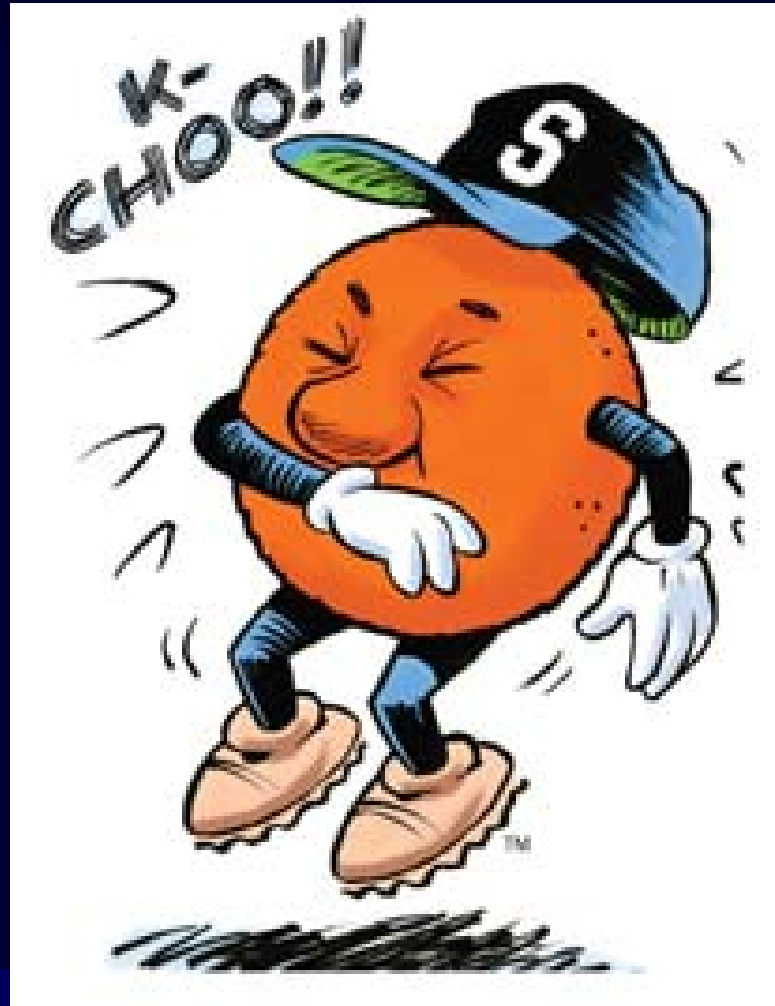
Why might college students use herbals?

- To prevent an illness
 - UTI, URI, heart disease
- To treat a condition
 - depression, sleep problems, infections, ADHD
- For enhancement of some sort
 - Improved memory, sexual performance, muscle building, weight loss, “general health”

Selected topics to be covered

- Handout covers broader range
 - More still likely to be encountered
- Selected handful of topics based on internal survey of frequency
 - URI prevention/treatment
 - Depression
 - UTIs
 - Body enhancement

Upper Respiratory Infections



Case 1: URI

- 19 y/o presents for ankle injury
- No PMHx, but taking vit C every day to prevent illness to limit illness, esp during midterms
- What do you tell him about herbals and preventing or treating URIs?

URIs & Echinacea

- Echinacea is the most commonly used herbal prep
- Touted to boost immune system
- Pot'1 to prevent and treat common cold

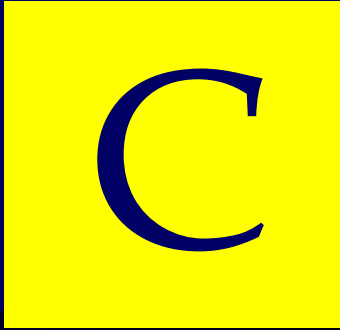


Echinacea & *Preventing* URIs: The Evidence

- Cochrane review, updated 2007
 - 3 RCTs—none found any benefit over placebo
- 2008 RCT, double blinded
 - 90 healthy adults treated bid x 8 wk
 - No difference in # sick days/person
 - No difference in adverse effects

NIH → B

based on NCCAM
inoculation study



C

Echinacea & *Treating* URIs: The Evidence

- Cochrane review, updated 2007
 - 16 RCTs echinacea vs placebo
 - Heterogeneity of preps
 - Benefit in 9, trend in 1, no difference in 6
 - Pooled data shows statistical benefit

Dose: 500-1000mg QD



B

Echinacea & Safety

- Safe and well tolerated in RCTs
 - Adverse effects minor, and not increased in echinacea group except rashes in one study of children
- No significant drug interactions

URIs & Vitamin C



- 1971 Linus Pauling
- Antioxidant, promotes well being and immune function
- Debate about accuracy of research, low dose vs high dose, dietary consumption vs supplemental
- Though vit C found in plants, mostly chemically made so technically not an herbal

Vitamin C & *Preventing* URIs: The Evidence

- Cochrane review, updated 2007
 - 30 RCTs using doses of >200mg/day involving 11,350 people
 - No benefit in prevention (RR 0.96)
 - Subset of high exercise, exposure to Arctic temps had RR 0.50
 - Modest statistical but not clinical reduction in duration of symptoms (8%)
- No newer RCTs



D

Vitamin C & *Treating* URIs: The Evidence

- Cochrane review, updated 2006
 - 7 RCTs with 3294 subjects
 - No benefit to duration or severity of URI sx



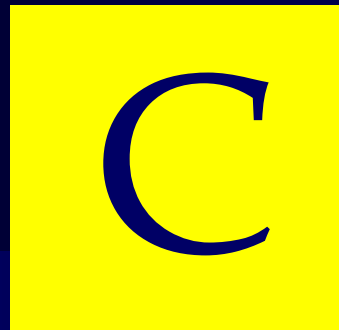
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Vitamin C & Safety

- Generally well tolerated in RCTs
- High doses (>2g/day) less tolerated
 - GI upset, flushing
 - Incr risk kidney stones
 - Abrupt discontinuation may lead to VitC def, so tapering rec'd

Garlic & URI prevention

- Cochrane review, updated 2009
 - Only 1 dbl blind RCT
 - 146 adults took garlic daily vs placebo x 3 months
 - Fewer total URIs, no difference in duration of illness if sick

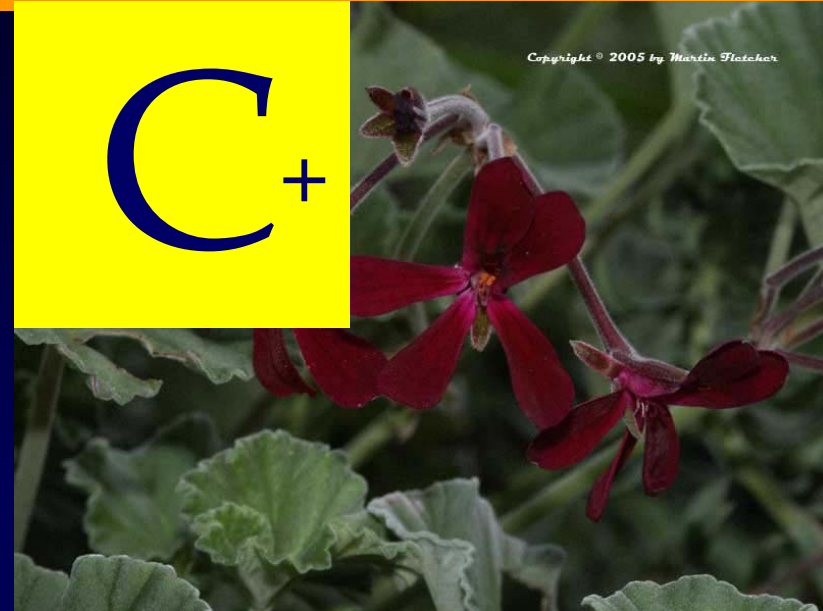


- Safety
 - Safe, well tolerated
 - Pot'l for halitosis!
 - Avoid before surgery given pot'l bleeding risk
 - Not proven to affect glucose



Pelargonium Sidoides & URI tx

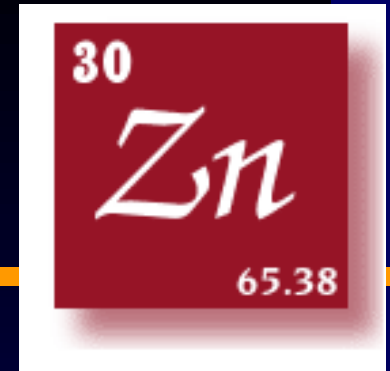
- 2008 Cochrane review
 - Significant heterogeneity but some benefit for treating acute bronchitis in adults
 - 1 unpublished study found benefit to adults in acute sinusitis
- 2 subsequent RCTs
 - 2009 adults w/ URIs found lower sx scores, fewer days off work
 - 2010 children/adol w/ bronchitis found overall lower sx scores



Safety

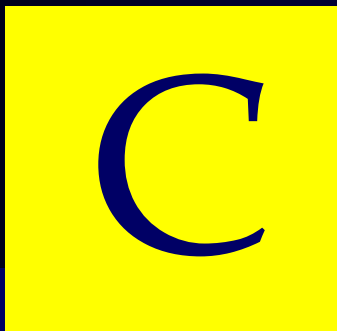
- Well tolerated and safe as noted within existing RCTs
- Not yet listed in NCCAM or NIH sites

Zinc & URIs



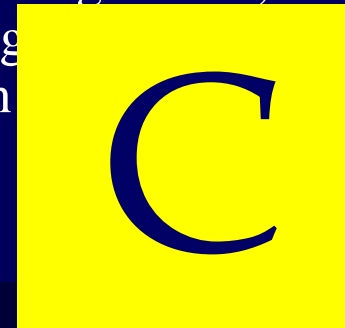
Prevention

- Systematic review
 - 2 RCTs for inoculated colds find no preventive benefit
 - 1 placebo controlled RCT of Zn supplementation in children found cold rate decreased from 1.7 to 1.2 over 7 month period



Treatment

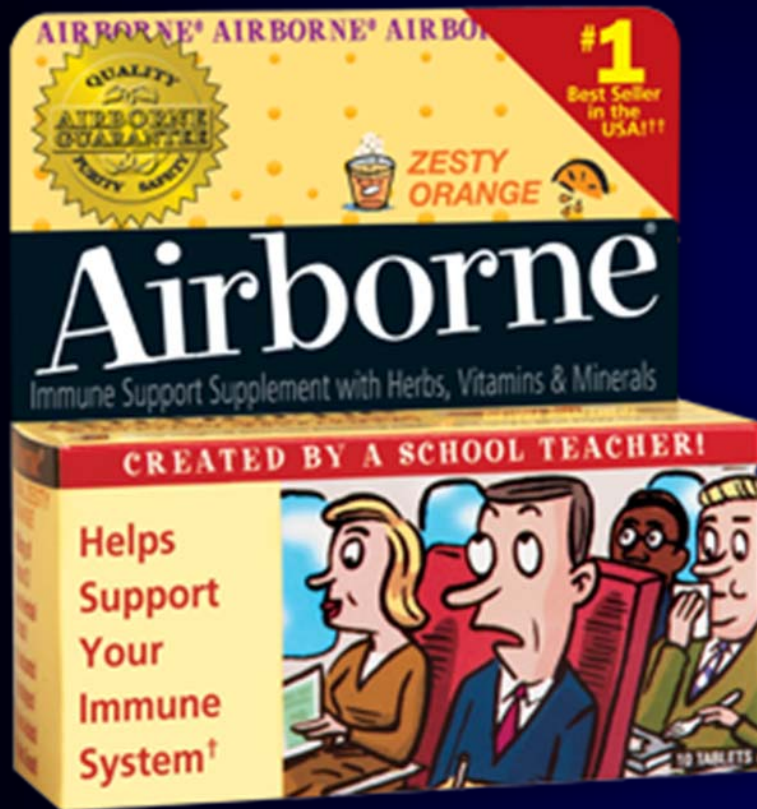
- Cochrane review, updated 1999
 - 8 RCTs; 4 finding no benefit, 4 improperly blinded did find modest benefit
- Pubmed search
 - Multiple RCTs w/ conflicting results; those finding benefit w/ design



Zn & Safety

- Less tolerated than placebo in RCTs
 - Mild, but lead to stopping med
 - Bad taste, nasal irritation
 - Concern of long term taste/smell distortion
- Case reports
 - Erosion of mucosal surfaces, hepatitis
- Avoid if kidney disease (renal excretion)

& how about...



- “Airborne contains a special blend of 17 vitamins, minerals and herbs, including Zinc, Ginger, Echinacea and a blast of Vitamin C!”
- NO STUDIES

H

Depression



Case 2: depression

- 26 y/o graduate student with mod depression, already in therapy. Family has had bad reactions to anti-depressants, so she's fearful of trying. Would prefer something natural.
- PMHx benign; routine GYN care, on OCPs for contraception
- How would you advise this patient?

Depression & St Johns Wort



- Also known as *Hypericum perforatum*
- Widely used as treatment for depression, esp in Europe
- Large RCT by NCCAM division of NIH

SJW & Depression: The Evidence

- Cochrane review, updated 2008
 - 18 RCTs SJW vs placebo in pts with major depression
 - Heterogeneity of results, beneficial effect
 - Large studies RR for response: 1.28
 - Smaller studies RR 1.87
 - (also 17 RCTs vs other anti-depressants finding equivalency in efficacy but more side effects/withdrawals in Rx group)
- 2010 RCT adults w/ depression & atypical features
 - Benefit in validated depression sx scores vs p

Dose: 300mg tid



B

SJW & safety

- Well tolerated in the research studies
 - Typical mild serotonin side effects: GI upset, sexual dysfunction, though better tolerated than Rx anti-depressants (TCAs and SSRIs)
- Possible serotonin syndrome if combined w/ other serotonin meds
 - Not to be combined w/ other SSRIs
 - Be aware of triptans, dextromethorphan also!
- Affects cytochrome P450, so caution advised when taking concurrent meds
 - Anti-epileptics, cyclosporin, HIV meds may be lowered; **Specific FDA warning re: lowered efficacy of indinavir**

SJW & OCPs:

a special consideration in college population

- Theoretical impact via Cyt P450
 - Advise back-up for of contraception
 - 1 study showing incr break through bleeding; case reports of unwanted pregnancy
- 1 small RCT lower hormone levels, “possible incr ovulation
- 2 larger RCTs no such effect; one measured ovulation
- Efficacy studies not finding any increased pregnancy rates reported.

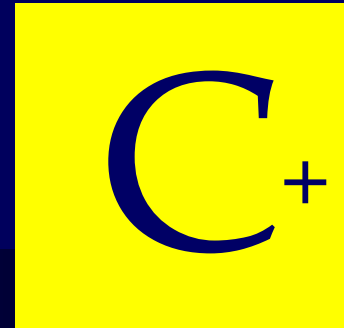
Depression & Fish Oil

- AKA omega-3;
Polyunsaturated fatty acids
 - EPA & DHA are specific types
- Not an herbal, but a supplement
- Observational association between low dietary intake of omega-3 PUFAs & depression



Omega-3 & Depression: The Evidence

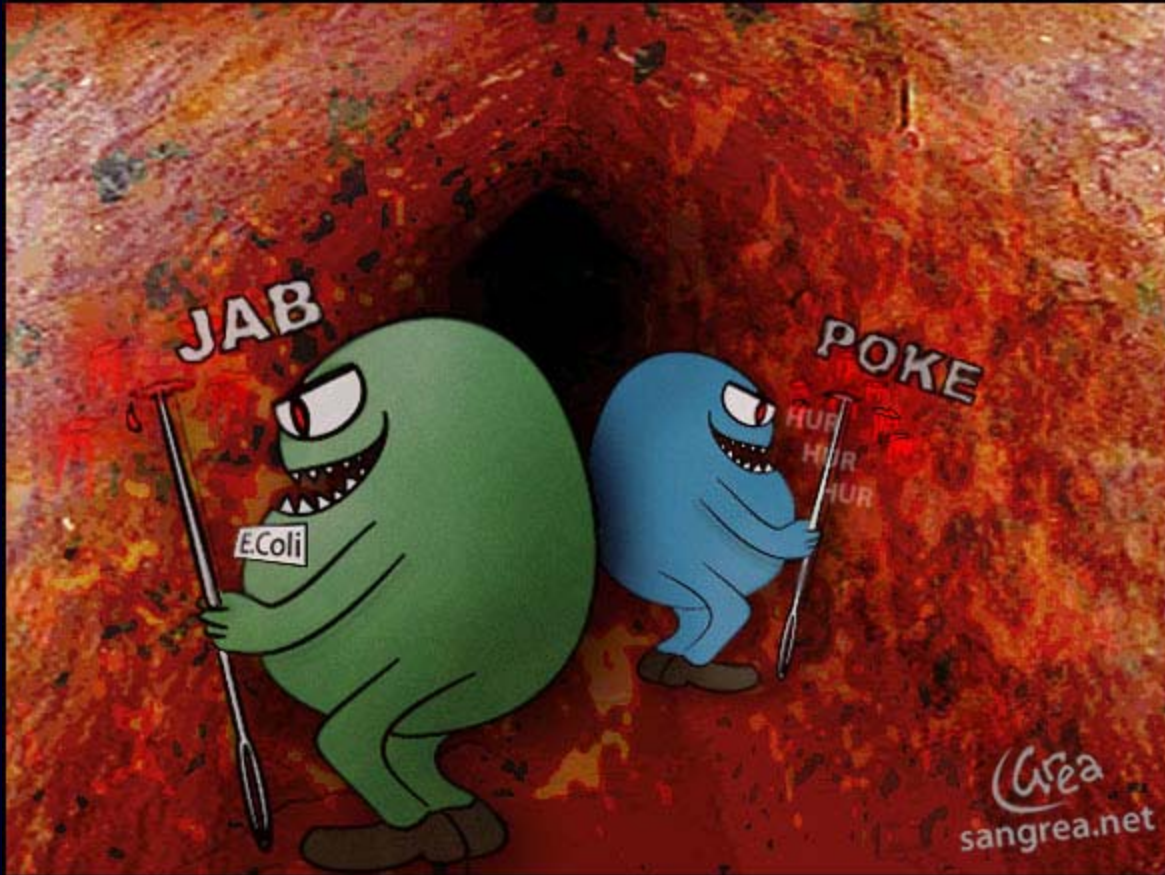
- No Cochrane reviews
- Pubmed search id'd a 2010 meta-analysis
 - Included 35 RCTs
 - Pooled data demo'd benefit for those w/ depression dx
 - (No benefit if nondepressed pts)
 - Concerns: heterogeneous, probable publication bias
- 3 RCTs
 - varying pop: childhood bipolar, women w/ psych distress, preventing peri-partum depression
 - Mixed results



Omega-3s & Safety

- Generally safe in doses up to 3g/day
 - No significant harms id'd in literature
 - Theoretical harm of very high dosing increasing bleeding risk
 - Greater concern of contaminants if consumed in fish products (mercury poisoning etc)
- Tolerability
 - Fish burps! Can be managed by freezing capsules

UTIs



The dreadful truth behind urinary tract infections

Case 3: UTI

- 19 y/o sophomore presents with dysuria & frequency. She comes to clinic Monday uncomfortable, having tried cranberry juice all weekend.
- ROS—no vaginal sx
- PMHx—only 2 UTIs in the past, one responded to cranberry juice; no h/o pyelo; no h/o STDs
- SHx—not currently sexually active; 1 lifetime partner
- How would you counsel her about cranberry juice?

Cranberries & UTIs



- Acidify urine?
- Reduce bacterial adhesion to bladder wall
- Touted as prevention and treatment of UTIs

Cranberries and UTI *prevention*: The Evidence

- Cochrane review, updated 2008
 - 10 RCTs, 1049 patients
 - Significant reduction in UTIs, RR 0.65
 - Specifically effective in women w/ recurrent UTIs
- 3 further placebo controlled RCTs for prevention
 - Children, spinal cord injury, older women
 - All showed benefit

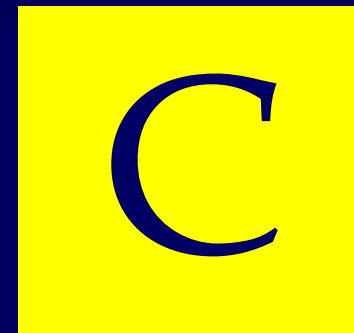
Dose: 3-16 oz cranberry
juice cocktail bid

B-

Cranberries and UTI *treatment*.

The Evidence

- Cochrane review, updated 2008
 - NO RCTs exist addressing cranberry products as treatment for UTI



Cranberry & Safety

- Generally safe; no harms id'd in studies
 - Pot'l for GI upset/diarrhea w/ large quantity consumption
 - Pot'l for kidney stones related to oxalate
- Do NOT use as substitute for eval/antibiotics for suspected bladder infection

Weight Loss



Case 4: weight loss

- 18 y/o 1st year from the midwest presents wanting to lose weight. Has been on many diets w/ minimal success, always gained weight back. Is considering buying Hoodia over the internet as her friends said that worked well.
- PE: BMI 25
- What do you tell her?

Bitter Orange & Weight loss



- Citrus aurantium
 - synephrine
- Chemical composition similar to ephedra/phenylephrine
- Extracts now used in place of ephedra in weight loss supplements since ephedra off the market

Bitter Orange & Weight Loss: The Evidence

- No Cochrane Reviews
- A 2004 meta-analysis
 - 1 study of 20 people x 6 wks, no benefit
 - did not address safety
- Additional RCT of 8 people
 - No benefit



C

Bitter Orange & Safety

- Limited data on safety
 - Existing small studies find no adverse effects but not powered enough to find them
 - Physical effects of appetite suppression also pot'l to incr HR, BP
 - Theoretical dangers similar to ephedra
 - Though the NCCAM working group's report noted possible harm and insufficient data
 - Caution use if known CV disease or on other meds affecting CV system

Acai Berry & Weight Loss

H

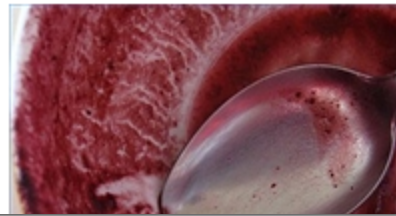


How to Use Acai Berry for Weight Loss



By Katherine Huether
eHow Contributing Writer

Article Rating: ★★☆☆☆ (240 Ratings)



I learned of a new superfood called Acai Berry that is used for weight loss. Since I'm always wary of big weight loss claims made by certain companies, I decided to do some research before I actually jumped on board.

The verdict? I've discovered that Acai Berry is

AS SEEN ON



No clinical trials id'd

the Power of Acai

Beware of Acai Berry Scams

While every acai product claims to be the magic weight loss pill, the truth is, not all acai berry supplements are equal. In fact, most supplements on the market right now are scams.



The Best Acai Product

As Seen on Rachel Ray



Certified Acai

Certified Acai is a really popular product, recommended by Top Doctors. We had 10 people of different body type to use Certified Acai for 30 days. Have a look at the results:



Hoodia & Weight Loss

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The screenshot shows a woman in a pink top and black shorts measuring her waist with a yellow tape measure, positioned between the two product offerings. The background features a light green and yellow color scheme.

- Also NO clinical trials for weight loss id'd

H

Muscle Building



Case 5: muscle building

- 22 y/o senior presents for STD screening. On PMHx exploration you discover he is taking 5g creatine supplement per day as part of his weight lifting routine.
- How do you counsel him about the supplement?

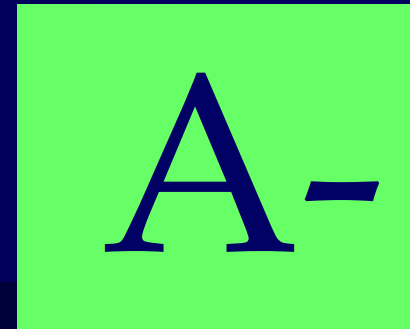
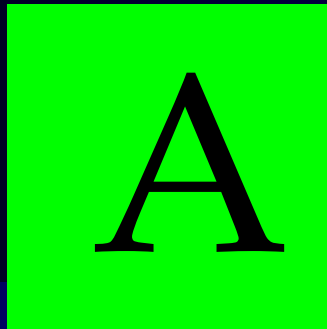
Creatine & Muscle building

- Supplement, not actually an herbal
- Touted as building muscles, increasing strength
- Anecdotally, used by many male college students, esp those who lift weights



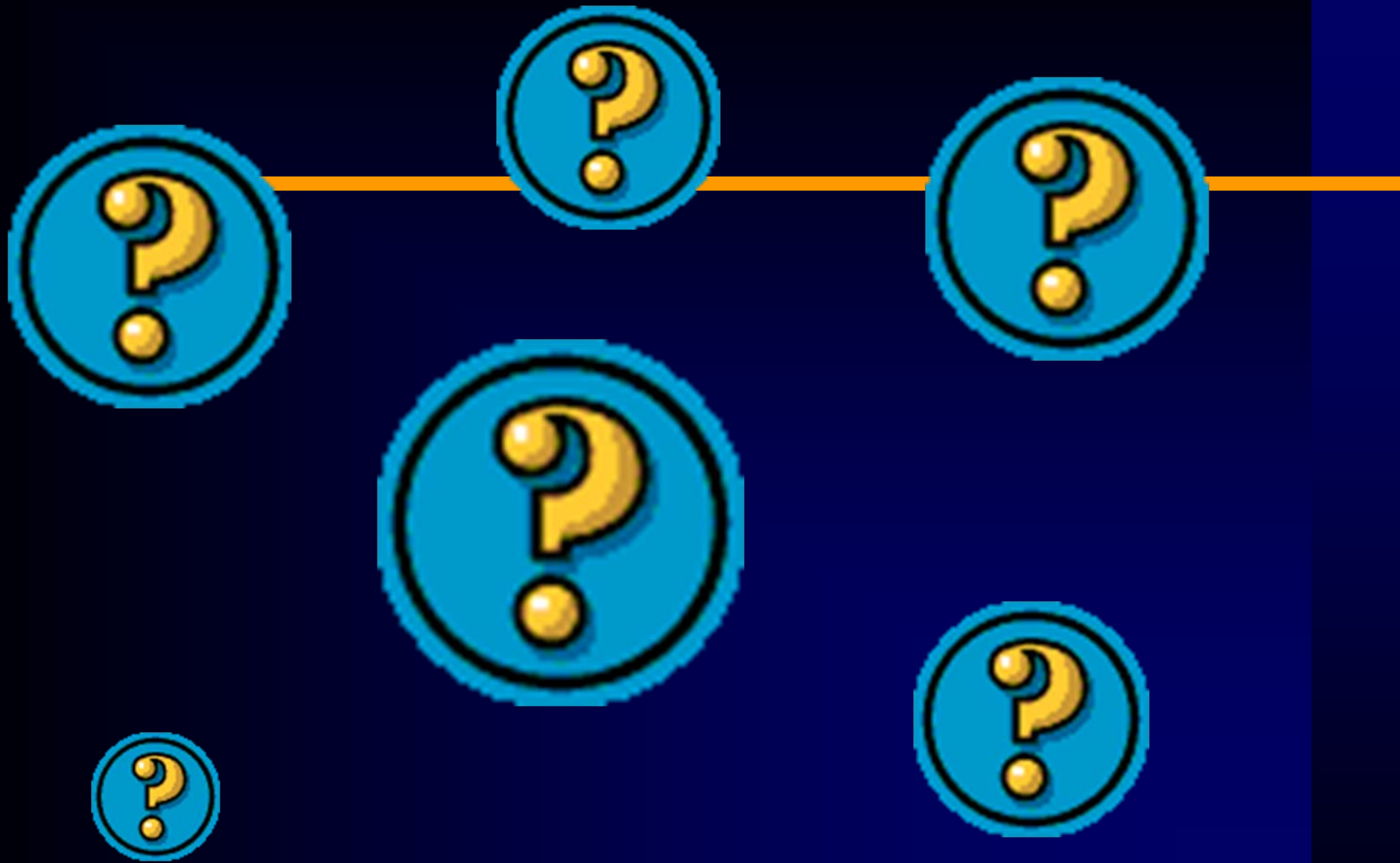
Creatine & Muscle Building: The evidence

- No cochrane reviews or meta-analyses
- Multiple RCTs
 - Heterogeneous populations, dosing, duration, outcome measurements
 - Gestalt: the majority--but not consistently--show some favorable outcomes



Creatine & Safety

- Concern re: pot'l harm to kidney
 - Those w/ renal disease advised to not use this supplement
 - Actual harm not born out in literature
 - Encourage good hydration if using
- Large quantities over long-term use → formaldehyde
 - Short term eval not finding incr'd levels



Case 6: cyclical breast pain

- 21 y/o for acute care visit. Med lists id's vit E supplementation as routine. You inquire about this use. She reports her GYN advised it for “general health.” GYN tells you it was recommended for managing breast tenderness before pt's periods.
- How do you address this?

Case 7: managing blood sugar

- Your uncle has type 2 diabetes and heard on the radio that cinnamon helps manage blood sugar.
- How do you respond?