

Systematic Review of Outcomes Studies of Whole Practice Naturopathic Medicine

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Background

Individualized diagnosis & combined treatment modalities according to the system's principles and guidelines are the rule in naturopathic practice. Naturopathic doctors in Canada and the US in licensed jurisdictions, as a specific discipline, receive training to a common standard resulting in practice distinct from naturopathy in unregulated jurisdictions or other countries. Evaluating this whole practice as a system is more likely to validly assess potential benefits of the practice than studies of clinical intervention subsets.

Objectives

We seek to represent the general landscape and outcomes of clinical studies of naturopathic practice, with research intervention models consistent with naturopathic whole practice (rather than single therapeutic modalities) including observational studies in licensed North American naturopathic medicine to generate hypotheses for future study and to identify gaps in knowledge.

Methods

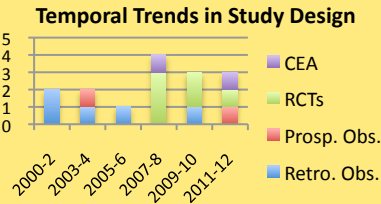
In a systematic review by PRISMA guidelines, we gathered and assessed longitudinal clinical studies in which N.Am. licensed naturopathic doctors had access to the range of therapeutic & diagnostic tools in their scope of practice--as in observational studies--or to well-described models of current whole practice. In designed models of practice, at least 2 treatment modalities were required to be permitted. Results from the search in MEDLINE and from consulting content experts are reported here. Final results will include AMED, CINAHL, EMBASE, the Cochrane Library, gray literature and emerging data. The review, inclusion criteria and search strings are pre-registered with PROSPERO.

Conclusions

Formal whole practice studies in naturopathic medicine are a recent phenomenon in N.Am. All studies meeting criteria showed signals of benefit, sometimes quite strong, but also have methodological weaknesses. The review provides evidence of effectiveness and cost savings in chronic diseases in the observed or validly-modeled practice of trained and licensed naturopathic doctors.

Search Outcomes

The MEDLINE search provided 319 citations which yielded 12 qualifying clinical studies after redundant review. A yet unpublished randomized controlled trial (RCT) & cost-effectiveness analysis (CEA) from informants were added to produce 6 RCTs typically vs usual care, 2 observational prospective studies of which one was comparative, 1 retrospective comparative, 4 retrospective case series, and 2 CEAs in 2 of the RCTs. All studies were in chronic disease with 4 in musculoskeletal, 4 CVD/diabetes, & 4 in "other" conditions.



Study Quality

The 6 RCTs were assessed with the Cochrane Risk of Bias tool by 2 reviewers (right). Downs & Black criteria are applied below to all 13 clinical studies. In both assessments, red indicates methodological weaknesses. Weaknesses in blinding are associated with challenges to hiding complex whole practice interventions.

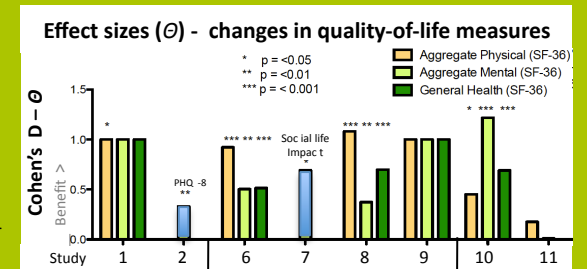
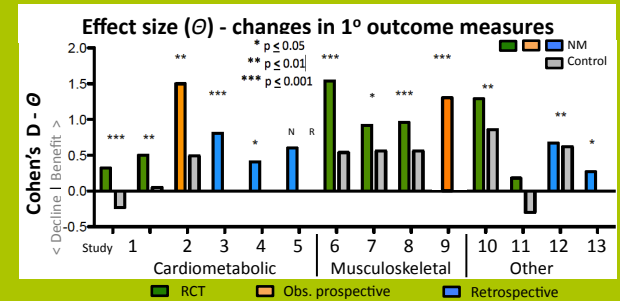
Study	Reporting (11)	External Validity (9)	Int. Validity Bias (7)	Int. Validity Confounding (6)	Power (3)
Bradley 2007	11	0	9	4	0
Cooley 2008	10	1	6	4	0
Ritenbaugh 08	10	1	2	5	0
Szczurko 2009	11	0	7	0	0
Seely 2006	11	1	7	6	1
Seely 2012	10	1	4	5	0
Secor 2004	6	2	3	1	0
Bradley 2012	11	2	4	2	0
Millman 2000	5	2	3	1	1
Cramer 2004	9	3	3	3	1
Bradley 2006	4	2	1	0	0
Bradley 2009	9	3	3	1	0
Bradley 2010	9	3	3	2	0

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bradley 2007	●	●	●	●	●	●	●
Cooley 09	●	●	●	●	●	●	●
Ritenbaugh 08	●	●	●	●	●	●	●
Seely 2012	●	●	●	●	●	●	●
Shinto 08	●	●	●	●	●	●	●
Szczurko 07	●	●	●	●	●	●	●
Szczurko 09	●	●	●	●	●	●	●

Clinical Outcomes

Clinical outcomes from the 13 studies of all designs showed some degree of benefit in every condition. At right are shown changes by effect size of 14 primary outcomes from 13 studies with changes in Cohen's d = Δx/sd.

Study	Condition	Primary Outcome	Length	PMID
1 Seely 2012	CVD risk	Framingham Risk	1 yr	
	Metabolic Syndr	Metabolic Syndrome	1 yr	
2 Bradley 2012	Diabetes	HbA1c	1 yr	22512949
3 Bradley 2010	Hypertension	Blood Pressure	μ9 mo	21799695
4 Bradley 2009	Diabetes	HbA1c	μ27 mo	19500011
5 Bradley 2006	Diabetes	% with improvement	>6 mo	16597192
6 Szczurko 2009	Rot. Cuff Tendonitis	Pain VAS	12 wk	19644905
7 Ritenbaugh 08	Temporomand JD	Avg Facial Pain VAS	~9 m	18564953
8 Szczurko 2007	Low Back Pain	Oswestry Score	>8 wk	17878954
9 Secor 2004	Pain	Pain VAS	3+ vts	15253855
10 Cooley 2009	Anxiety	Beck Anxiety Inv.	12 wk	19718255
11 Shinto 2008	Multiple Sclerosis	Disability Status Scale	6 mo	18532899
12 Cramer 2003	Menopause sympt	% pts with sympt	μ5.9 vts	14490029
13 Millman 00	Hepatitis C	Serum ALT	>1 mo	10956381



Consonant with expectations of comprehensive naturopathic treatment & health enhancement, a quality-of-life measure was used in 8 of the 13 studies. All 8 studies showed improvements with naturopathic care.

14 Herman 2012	CVD risk; study 1	QALY, Tot social costs	1 yr	
15 Herman 2008	LBP; study 8	QALY, Tot social costs	1 yr	18383988

Cost Outcomes

Two cost-effectiveness analyses were performed in conjunction with two clinical trials by the same team in Canadian postal workers: Herman 08 and 12 in Szczurko (LBP) and Seely (CVD Risk) respectively. Both CEAs revealed societal and employer savings. Herman 08 on LBP also showed participant savings and significant benefit in quality-adjusted life years.