

Elsevier required licence: © <2017>. This manuscript version is made available under the CC-BY-NC-ND 4.0 license <http://creativecommons.org/licenses/by-nc-nd/4.0/>

1 Establishing an international research collaborative for naturopathy:
2 the International Research Consortium of Naturopathic Academic
3 Clinics

4

5 Abstract

6 Naturopathy is a system of healthcare through which practitioners apply core philosophies, theories
7 and principles to integrate medical knowledge with natural treatment options. In recent years the
8 naturopathic community has developed a stronger international coherence. Alongside this growing
9 connectivity in the global naturopathic profession, there have been a number of calls for more
10 systematic research attention to be devoted to naturopathy as a substantive research topic, as well
11 as a need for the naturopathic profession to hone a culture of research and evidence-based
12 practices and skillsets. Progress in this area has been made through the development of more
13 pragmatic and whole systems naturopathic research. One aspect which is currently missing in the
14 global naturopathic research landscape despite this growing pattern of practice-based, whole
15 systems research is the application of international multicentre research projects. In response, we
16 have established a research consortium for naturopathic academic clinics in four countries and
17 across multiple world regions. This paper serves to overview the mission, scope and membership of
18 the research consortium and explore some of the research designs and questions which it may
19 support.

20

21 Keywords: naturopathy; pragmatic research; clinical research; complementary therapies; integrative
22 medicine; multicentre clinical trials

1 Background

2 Naturopathy is a “system of healthcare with a deep history of traditional philosophies and practice”¹
3 through which practitioners integrate medical knowledge with natural treatment options.¹ While
4 naturopathy originated in Germany, the profession is now practiced in every region of the world.² As
5 a profession, naturopathy is defined by core philosophies, theories and principles.¹ These elements
6 manifest in a clinical practice approach to treatment that is holistic and as such naturopathy is
7 characterised by this approach more so than the specific treatments prescribed by the practitioner.³

8 In recent years the naturopathic community has developed a stronger international coherence, most
9 clearly in evidence through the formation of the World Naturopathic Federation (WNF).⁴ The efforts
10 of the WNF to date have been extensive and include the first attempts to understand the practice
11 approach of naturopaths internationally as well as measure the coherence in the naturopathic
12 practice in different countries. The first reports produced by the WNF identify consistency in the
13 application and practice of naturopathic principles and philosophies.⁵

14 More recent research by the WNF indicates there is consistency in the inclusion of naturopathic
15 definitions, history, philosophy and theories in naturopathic education programs worldwide.⁶ Other
16 subject areas which are covered in all known naturopathic programs are basic sciences, clinical
17 sciences, naturopathic disciplines and clinical practicum.⁶ However, there is some diversity in the
18 amount of time dedicated to each subject area within the naturopathic curriculum of each
19 educational institution. There is also variability in other aspects of the naturopathic programs
20 including the number of contact hours and the diagnostic methods and treatments taught within
21 naturopathic courses. Despite these differences, there is some consistency in naturopathic training
22 programs within and between world regions. For example, there are naturopathic academic
23 institutions in North America, Asia and Western Pacific world regions that offer naturopathic
24 programs 4000 hours or longer and represent the most lengthy programs for the profession
25 globally.⁶ The most common naturopathic modalities taught in these regions are nutrition and
26 botanical medicine.⁶

27 The emerging strengths in naturopathic research globally

28 There have been a number of calls for more systematic research attention to be devoted to
29 naturopathy as a substantive research topic, as well as a need for the naturopathic profession to
30 hone a culture of research and evidence-based practices and skillsets.⁷⁻⁹ Alongside these calls,
31 important initiatives such as the Practitioner Research and Collaboration Initiative (PRACI)¹⁰ have
32 arisen which support the study of the real life practice of naturopathy and outcomes of naturopathic
33 care.¹¹ PRACI has the capacity to support sub-studies employing a range of research designs and

1 methods including clinical trials, observational studies, qualitative projects and case series/studies.¹²
2 However, despite its valuable contribution to naturopathic practice-based research - both current
3 and future - the infrastructure of PRACI is restricted to the study of naturopathy in Australia.¹²
4 Whole systems research has received increasing attention and support from health researchers
5 including among those focusing on complementary medicine clinical care.¹³⁻¹⁵ Whole systems
6 research has evolved alongside the movement towards pragmatic research in the wider health
7 research community,^{16,17} and can be considered a variation on the popular pragmatic research with a
8 goal of being more applicable to real world settings.¹⁷ Of note, is that not all comparative
9 effectiveness research is pragmatic and that randomized controlled trials may indeed be pragmatic
10 in so far as they incorporate real world elements, such as broader inclusion criteria, and the use of
11 complex interventions.¹⁸⁻²⁰ Whole systems research emphasises the importance of evaluating the
12 outcomes of complex treatment approaches that have foundations on a system of care rather than
13 centring on a specific treatment intervention.¹³ In line with this, whole systems research has also
14 been promoted as a clinical research framework which may have relevance to the study of
15 naturopathy¹⁴ whereby it is argued to hold value due to naturopathy's principles-based system of
16 care. Early signs suggest this approach may have some value, when applied correctly, to evaluating
17 the effects of the complex dynamics inherent within naturopathic clinical care with a number of
18 studies examining the outcomes of naturopathic care for a range of health conditions (e.g. Seely
19 2013²¹).¹⁵ However, these studies have primarily been single centre studies based in North America¹⁵
20 and as such have a limited value in informing policy or practice in other world regions.²²

21 [The need for international multicentre naturopathic research](#)

22 One aspect which is currently missing in the global naturopathic research landscape despite this
23 growing pattern of practice-based, whole systems research is the application of international
24 multicentre research projects. The wider health research community emphasise the randomised
25 clinical trial and comparative effectiveness study as the premier clinical research designs for
26 answering questions of efficacy and effectiveness respectively.²³ Yet there is still a requirement that
27 findings from any clinical study are replicated in other settings before the finding is accepted and
28 supported. While single centre trials do have a number of advantages related to expediency and
29 logistics, these studies are also at risk of limited external validity, implausible effect size, and
30 unequal allocation of resources.²⁴ As a result, it is not unusual for single centre trials to be
31 contradicted by subsequent studies.²⁴

32 In an attempt to offset the limitations of single centres trials, there are increasing calls within health
33 and medical research for the conduct of multicentre clinical studies (i.e. any clinical trial where there

1 is more than one site through which the study is conducted) as they are argued to provide additional
2 rigour to the existing clinical trial study design.^{24,25} Multicentre clinical trials strengthen the external
3 validity of research findings, provide more sensitive information regarding effect size, and may
4 compensate for issues regarding clinician blinding.²⁴ Furthermore, the value of multicentre research
5 is not limited to clinical trials, encompassing observational studies and other research designs which
6 benefit from data collected in a clinical setting.²⁶

7 Academic teaching clinics may be uniquely positioned to serve as research nodes for international
8 multicentre whole systems naturopathy research. The advent of comparative effectiveness research
9 (CER) as an important research design within health research and policy environments has presented
10 a number of implications and opportunities for academic centres as sites for pragmatic research.²⁷
11 These include challenges to professional cultural views (e.g the interface between tradition and
12 science;²⁸ delineating culturally relevant evidence-based interventions²⁹), availability of and access to
13 resources, and training of both faculty and students in applicable research methods. Many of the
14 naturopathic teaching institutions have academic faculty, research departments and ethics officers
15 which can be leveraged by their clinics for logistical, administrative, and ethical oversight support.
16 Early work conducted at some of the existing naturopathic academic clinics has demonstrated
17 capacity, interest and experience in research that is foundational to CER, health services research,
18 and electronic data collection and management.³⁰⁻³² Also, as the primary training centres for future
19 naturopathic clinicians, integration with regular and embedded research programs may help
20 strengthen an already growing culture of research in the international naturopathic community.²⁹

21 Therefore, we have established a research consortium for naturopathic academic clinics in four
22 countries and across two world regions. This paper serves to overview the structure of the research
23 consortium and explore some of the research designs and questions which it may support.

24 [Establishing the International Research Consortium of Naturopathic Academic Clinics](#)

25 The research consortium was first conceived in January 2017 during planning meetings for a
26 collaborative research project which was undergoing expansion from the United States into Australia
27 and Canada. The project expansion was inspired by the research team's involvement in the
28 International Naturopathy Research Leadership and Capacity Building Program run by the Australian
29 Research Centre in Complementary and Integrative Medicine (University of Technology Sydney).

30 As a direct result of these collaborative discussions a benefit was identified for the establishment of
31 infrastructure which supports a multicentre international study design for the conduct of this and
32 any future research project in naturopathy. Our proposed solution is an International Research
33 Consortium of Naturopathic Academic Clinics (IRCNAAC). The Consortium aims to bring together

1 naturopathic educational institutions with common goals and in so doing amplify the benefits of
2 collaboration across institutional and geographical boundaries. The structure of the Consortium
3 centres on a core mission to which all members subscribe, a clear scope of activity, and defined
4 criteria for membership.

5 [Mission](#)

6 The purpose of the Consortium covers three core areas (see Figure 1). Firstly, we are committed to
7 advancing international research in the naturopathic profession. Alongside important advances such
8 as the World Naturopathic Federation, the Consortium matches the growing strength in the
9 international naturopathic community. As links between practitioner communities in different
10 countries develop and strengthen, simultaneous links between researchers in these countries is not
11 only advantageous but vital for advancement of the profession.

12 Secondly, we intend to support collaborative relationships between researchers affiliated with
13 naturopathic academic clinics. Building on the important foundations of the International
14 Naturopathy Leadership and Capacity Building Program this initiative will support the formation of
15 relationships between naturopathic educational institutions in general, and naturopathic academic
16 clinics in particular. The international naturopathic academic community will benefit from the
17 increased collaboration and connection which is facilitated by the structure of the Consortium. In
18 part the manifestation of this mission will also include leveraging the research strength within some
19 naturopathic academic institutions to support and grow naturopathic research capacity and activity
20 in other institutions less developed in research skills and infrastructure.

21 Lastly, but no less importantly, we commit to enabling the efficient conduct of international
22 multicentre research projects through naturopathic academic clinics. The advantages of
23 international research projects in naturopathy has already been described, as have the logistical
24 challenges often faced by research teams looking to establish international multicentre trials. It is
25 hoped that the Consortium will reduce the burden on researchers planning trials in more than one
26 country.

27 [Scope: Area and Method of Cooperation](#)

28 While collaboration is at the core of the Consortium's mission, the member organisations are first
29 and foremost educational institutions for the next generation of naturopathic practitioners. For this
30 reason, we have defined clear areas and methods of cooperation which are respectful of each
31 member's independence. The area of cooperation includes any research project offered by any of
32 the members determined to be desirable and feasible for developing cooperative relationships. The
33 methods of cooperation include, subject to the approval of each member, research activities or

1 programs such as research collaborations, exchange programs, resource sharing, and joint
2 applications for funding.

3 Criteria for Membership

4 The Consortium operates through formal relationships between educational institutions which
5 provide supervised clinical training in naturopathy. Institutions are eligible to join the Consortium if
6 they offer training programs for naturopaths which comply with their respective regional
7 accreditation requirements and the standards for Education Membership set by the World
8 Naturopathic Federation.

9 Founding Members

10 The formation of the consortium was the impetus of representatives of Endeavour College of
11 Natural Health in Australia, Bastyr University in the United States of America, and The Canadian
12 College of Natural Medicine in Canada. These members developed the Memorandum of
13 Understanding document which forms the foundation of the Consortium and extended an invitation
14 to other institutions in their regions. The outcome of this work is a Consortium that spans two world
15 regions, four countries and represents eight naturopathic educational institutions (see Table 1).
16 Plans are in place to extend this membership to include a third world region.

17 Research Opportunities

18 As the program unfolds and initial research trials are executed, we expect lessons learned, the
19 adoption of methodological advances, and centralized resource use to maximize the efficiency of
20 future trials.³³ As institutional experience grows within and is shared among the centres, we expect
21 the feasibility and productivity of the respective research programs to grow exponentially. Research
22 designs foundational to understanding and mapping the profession such as patient and practice
23 characteristics^{12,34} as well as assessments of knowledge/attitudes,³⁵⁻³⁹ engaging experts through
24 Delphi studies or for guideline generation,^{40,41} can all be applied or compared at the international
25 level. We anticipate improved ease and efficiency of planning and conducting large-scale prospective
26 outcome-focussed research similar to the ongoing Canadian/US Integrative Oncology Study
27 (CUSIOS),⁴² as well as a wide variety of other relatively underutilized terrain such as mixed methods
28 and qualitative research.⁴³ The involvement of academic centres has been a key infrastructure
29 requirement for supporting practice-based research networks,^{16,17,44} as well as adopting best-
30 practices and tools for planning and conducting clinical trials within the context of networks like
31 IRCNAC.⁴⁵ Our Consortium is positioned to play an important catalysing role in the evolution
32 prospective research in naturopathic medicine not only within the member organisations, but within
33 the countries and regions where these organisations are located.

1 Support from the International Profession

2 The members of the World Naturopathic Federation voted at the 3rd General Assembly in Phoenix,
3 Arizona (USA) to support and endorse the IRCNAC. This decision was based on the value and
4 significance this initiative is expected to contribute to advancing new knowledge in naturopathy at
5 an international level.

6 Conclusions

7 Naturopathy is a growing profession in the midst of professionalization and development. Its leaders
8 have underscored the importance of instilling an evidence and research-based culture with the
9 recognition of the limitations of single agent trials in this whole systems based form of medicine. It is
10 our belief that the Collaboration supports this aim and provides an important step in developing the
11 infrastructure and culture needed for the development of a high-quality evidence base respectful of
12 the needs of a whole systems based profession.

1 References

- 2 1. World Naturopathic Federation. About Naturopathy. 2015 (accessed 20 June 2017).
- 3 2. World Naturopathic Federation. 2016 Naturopathic Numbers Report. Canada: World
4 Naturopathic Federation, 2016.
- 5 3. Sarris J, Wardle J. Clinical naturopathy: an evidence-based guide to practice: Elsevier Health
6 Sciences; 2014.
- 7 4. World Naturopathic Federation. About WNF. 2015 (accessed 20 June 2017).
- 8 5. World Naturopathic Federation. World Naturopathic Federation Report: Findings from the
9 1st World Naturopathic Federation survey. Canada: World Naturopathic Federation, 2015.
- 10 6. World Naturopathic Federation. WNF - Naturopathic Roots Report: Findings from the
11 Naturopathic Roots Committee Survey. Canada: World Naturopathic Federation, 2016.
- 12 7. Steel A, Adams J. The role of naturopathy in pregnancy, labour and post-natal care:
13 broadening the evidence-base. *Complementary therapies in clinical practice* 2011; **17**(4): 189-92.
- 14 8. Sibbritt D. The decline of herbal medicine/naturopathy consultations: How research can help
15 further the profession. *Australian Journal of Herbal Medicine* 2014; **26**(1): 8.
- 16 9. Standish LJ, Calabrese C, Snider P. The naturopathic medical research agenda: the future and
17 foundation of naturopathic medical science. *Journal of Alternative & Complementary Medicine* 2006;
18 **12**(3): 341-5.
- 19 10. Steel A, Adams J, Sibbritt D. Developing a multi-modality complementary medicine practice-
20 based research network: The PRACI project. *Advances in Integrative Medicine* 2014; **1**(3): 113-8.
- 21 11. Reid R, Steel A. The importance of the PRACI project for grass roots complementary
22 medicine practice: A call for practitioner involvement. *Australian Journal of Herbal Medicine* 2015;
23 **27**(3): 101.
- 24 12. Steel A, Sibbritt D, Schloss J, et al. An Overview of the Practitioner Research and
25 Collaboration Initiative (PRACI): a practice-based research network for complementary medicine.
26 *BMC complementary and alternative medicine* 2017; **17**(1): 87.
- 27 13. Verhoef MJ, Lewith G, Ritenbaugh C, Boon H, Fleishman S, Leis A. Complementary and
28 alternative medicine whole systems research: beyond identification of inadequacies of the RCT.
29 *Complementary therapies in medicine* 2005; **13**(3): 206-12.
- 30 14. Ritenbaugh C, Aickin M, Bradley R, Caspi O, Grimsgaard S, Musial F. Whole systems research
31 becomes real: new results and next steps. *The Journal of Alternative and Complementary Medicine*
32 2010; **16**(1): 131-7.
- 33 15. Oberg EB, Bradley R, Cooley K, et al. Estimated effects of whole-system naturopathic
34 medicine in select chronic disease conditions: a systematic review. *Alternative & Integrative*
35 *Medicine* 2015.
- 36 16. Loudon K, Zwarenstein M, Sullivan F, et al. The PRECIS - 2 tool has good inter - rater
37 reliability and reasonable discriminant validity. *Journal of Clinical Epidemiology*.
- 38 17. Thorpe KE, Zwarenstein M, Oxman AD, et al. A pragmatic–explanatory continuum indicator
39 summary (PRECIS): a tool to help trial designers. *Journal of Clinical Epidemiology* 2009; **62**(5): 464-75.
- 40 18. Fønnebø V, Grimsgaard S, Walach H, et al. Researching complementary and alternative
41 treatments—the gatekeepers are not at home. *BMC medical research methodology* 2007; **7**(1): 7.
- 42 19. Rothwell PM. External validity of randomised controlled trials:“to whom do the results of
43 this trial apply?”. *The Lancet* 2005; **365**(9453): 82-93.
- 44 20. Witt CM. Efficacy, effectiveness, pragmatic trials—guidance on terminology and the
45 advantages of pragmatic trials. *Complementary Medicine Research* 2009; **16**(5): 292-4.
- 46 21. Seely D, Szczurko O, Cooley K, et al. Naturopathic medicine for the prevention of
47 cardiovascular disease: a randomized clinical trial. *Canadian Medical Association Journal* 2013;
48 **185**(9): E409-E16.

- 1 22. Wardle J. The Australian government review of natural therapies for private health
2 insurance rebates: What does it say and what does it mean? *Advances in Integrative Medicine* 2016;
3 **3**(1): 3-10.
- 4 23. Sox HC, Goodman SN. The methods of comparative effectiveness research. *Annual review of*
5 *public health* 2012; **33**: 425-45.
- 6 24. Bellomo R, Warrillow SJ, Reade MC. Why we should be wary of single-center trials. *Critical*
7 *care medicine* 2009; **37**(12): 3114-9.
- 8 25. Wallace S, Myles P. Solving the challenges of large multicenter trials in Anesthesia. *HSR*
9 *proceedings in intensive care & cardiovascular anesthesia* 2009; **1**(3): 46.
- 10 26. Sandy J, Kilpatrick N, Persson M, et al. Why are multi-centre clinical observational studies
11 still so difficult to run? *Br Dent J* 2011; **211**(2): 59-61.
- 12 27. Rich EC, Bonham AC, Kirch DG. The implications of comparative effectiveness research for
13 academic medicine. *Academic Medicine* 2011; **86**(6): 684-8.
- 14 28. Steel A, Adams J. The interface between tradition and science: naturopath's perspective of
15 modern practice. *J Altern Complement Med* 2011; **17**(10): 967-72.
- 16 29. Goldenberg JZ, Burlingham B, Gultinan J, Oberg E. Shifting attitudes towards research and
17 evidence-based medicine within the naturopathic medical community: The power of people, money
18 and acceptance. *International Journal of Naturopathic Medicine* 2012; **6**(1): 663.
- 19 30. Chamberlin SR, Oberg E, Hanes DA, Calabrese C. Naturopathic Practice at North American
20 Academic Institutions: description of 300,483 visits and comparison to conventional primary care.
21 *Integrative medicine insights* 2014; **9**: 7.
- 22 31. Kennedy DA, Bernhardt B, Snyder T, Bancu V, Cooley K. Complementary medical health
23 services: a cross sectional descriptive analysis of a Canadian naturopathic teaching clinic. *BMC*
24 *complementary and alternative medicine* 2015; **15**(1): 37.
- 25 32. Leung BM, Flower G, Cooley K, et al. Assessing the utility of an electronic research database
26 to capture whole systems practice at two naturopathic outpatient teaching clinics. *Journal of*
27 *Evidence-Based Complementary & Alternative Medicine* 2013; **18**(3): 170-5.
- 28 33. Broom A, Adams J. Current issues and future directions in complementary and alternative
29 medicine (CAM) research. *Complementary Therapies in Medicine* 2007; **15**(3): 217-20.
- 30 34. Adams J, Robinson N. Public health and health services research in integrative medicine: an
31 emerging, essential focus. *European Journal of Integrative Medicine* 2013.
- 32 35. McMurtry A, Wilson K, Clarkin C, et al. The development of vaccination perspectives among
33 chiropractic, naturopathic and medical students: a case study of professional enculturation.
34 *Advances in Health Sciences Education* 2015; **20**(5): 1291-302.
- 35 36. Ijaz N, Boon H, Welsh S, Meads A. Supportive but "worried": perceptions of naturopaths,
36 homeopaths and Chinese medicine practitioners through a regulatory transition in Ontario, Canada.
37 *BMC Complementary and Alternative Medicine* 2015; **15**(1): 312.
- 38 37. Braun LA, Spitzer O, Tiralongo E, et al. The prevalence and experience of Australian
39 naturopaths and Western herbalists working within community pharmacies. *BMC Complementary*
40 *and Alternative Medicine* 2011; **11**(1): 41.
- 41 38. Cooley K, Tummon-Simmons L. P31 Attitudes and knowledge towards interprofessionalism
42 among naturopathic students. *BMC complementary and alternative medicine* 2017; **17**(Suppl 1): 322.
- 43 39. Goldenberg JZ, Day A, Sasagawa M, Ward L, Cooley K. P225 Establishing naturopathic dietary
44 interventions for irritable bowel syndrome: an e-Delphi protocol. *BMC complementary and*
45 *alternative medicine* 2017; **17**(Suppl 1): 317.
- 46 40. Okoli C, Pawlowski SD. The Delphi method as a research tool: an example, design
47 considerations and applications. *Information & management* 2004; **42**(1): 15-29.
- 48 41. Brouwers MC, Makarski J, Kastner M, Hayden L, Bhattacharyya O. The Guideline
49 Implementability Decision Excellence Model (GUIDE-M): a mixed methods approach to create an
50 international resource to advance the practice guideline field. *Implementation Science* 2015; **10**(1):
51 36.

1 42. Canadian College of Naturopathic Medicine. The Canadian/US Integrative Oncology Study
 2 (CUSIOS). 2016 (accessed 30 Jun 2017).
 3 43. Pritzker S, Hui KK. Building an Evidence-Base for TCM and Integrative East-West Medicine: A
 4 Review of Recent Developments in Innovative Research Design. *Journal of Traditional and*
 5 *Complementary Medicine* 2012; **2**(3): 158-63.
 6 44. Green LA, White LL, Barry HC, Nease DE, Hudson BL. Infrastructure Requirements for
 7 Practice-Based Research Networks. *The Annals of Family Medicine* 2005; **3**(suppl 1): S5-S11.
 8 45. Dolor RJ, Schmit KM, Graham DG, Fox CH, Baldwin LM. Guidance for Researchers Developing
 9 and Conducting Clinical Trials in Practice-based Research Networks (PBRNs). *Journal of the American*
 10 *Board of Family Medicine : JABFM* 2014; **27**(6): 750-8.

11 *Figure 1: Mission of the International Research Consortium of Naturopathic Academic Clinics*



12

13

14

1 *Table 1: Foundational members of the International Research Consortium of Naturopathic Academic Clinics*

Consortium member	Clinic	Location	Number of patient visits*
Endeavour College of Natural Health	Wellnation Clinic	Adelaide, South Australia, Australia	4500
		Brisbane, Queensland, Australia	
		Gold Coast, Queensland, Australia	
		Melbourne, Victoria, Australia	
		Perth, Western Australia, Australia	
Bastyr University	The Bastyr Center for Natural Health	Seattle, Washington, USA	43,000
		San Diego, California, USA	
The Canadian College of Naturopathic Medicine	Robert Schad Naturopathic Clinic	Toronto, Ontario, Canada	35,000
Wellpark College of Natural Therapies	Prema Clinic	Albany, Auckland, New Zealand	300
South Pacific College of Natural Medicine	Paua Clinic	Ellerslie, Auckland, New Zealand	600
Southern School of Natural Therapies & Australasian College of Natural Therapies	Think Wellbeing Centre	Fitzroy, Victoria, Australia	2000
		Pymont, New South Wales, Australia	
		Brisbane, Queensland, Australia	
Southwest College of Naturopathic Medicine and Health Sciences	SCNM Medical Center	Tempe, Arizona, USA	16,000
National University of Natural Medicine	NUNM Health Centers	Portland, Oregon, USA	12,500

2 *Estimated number of patient visits for the naturopathic academic clinic in one calendar year