Section 4: Naturopathic Research

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HIGHLIGHTS

- The research paradigm employed to evaluate the effectiveness of naturopathy/ naturopathic medicine must be able to accommodate the complex and holistic nature of naturopathic practice if it is to provide accurate results that meaningfully inform policy and practice.
- Pragmatic clinical research methods apply a complex, person-centred approach to clinical trial design that may help determine fidelity to naturopathic practice.
- The naturopathic profession requires adequate infrastructure to further support research including research capacity building, consumer and practitioner engagement, and integration into health systems.
- The international naturopathic research community has demonstrated sustained commitment to codifying and synthesizing existing knowledge, generating new knowledge, and disseminating this knowledge to the wider clinical and research community.
- Naturopaths/NDs have published over 2000 peer-reviewed articles since 1987 with notable increases in the last 20 years.

Good research requires a balance between internal validity (i.e., appropriate study design to answer the research question) and external validity (i.e., relevance to the real world). As health research 'best practice' has evolved over time, methodological advancements aimed to improve internal validity have adversely impacted the external validity of the findings. This issue is particularly problematic in traditional and complementary medicine professions, such as naturopathy, due to its whole practice nature. Unlike the focus of popular clinical research designs, naturopaths/naturopathic doctors rarely treat a single health concern or set of symptoms in isolation. This creates a barrier for naturopaths/naturopathic doctors to applying new findings from such research within their clinical practice.

Despite these challenges, the naturopathic profession has a long tradition of generating new knowledge and naturopaths/naturopathic doctors have been described as early adopters of various forms of research while maintaining a strong connection to their naturopathic philosophies and principles. This commitment to, and interest in, research is also evidenced by the increasingly common incorporation of research departments within naturopathic educational institutions in many WHO Regions.

This overview is essential to understanding the research-based evidence associated with naturopathy/naturopathic medicine and the complexities of researching aspects of the naturopathic profession as a sophisticated and nuanced traditional system of medicine that combines modern research and traditional knowledge within a person-centred paradigm.

Researching Naturopathy as a Traditional System of Medicine (Chapter 14) overviews the contextual importance of recognizing naturopathy as a total system of traditional medicine when designing and conducting research investigating naturopathic treatments, therapies, and practices.

- Good research requires a balance between internal validity and external validity. This issue is particularly problematic in traditional and complementary medicine professions, such as naturopathy, due to its whole practice nature and has been identified by naturopaths/NDs as limiting the applicability to applying new research findings within their clinical practice.
- The naturopathic profession has a long tradition of generating new knowledge and naturopaths/NDs have been described as early adopters of various forms of research while maintaining a strong connection to their naturopathic philosophies and principles.

Challenges and Advancements for Naturopathic Clinical Research (Chapter 15) provides a closer exploration of the challenges and advancements that contemporary health research offers to naturopathic research, and the opportunities that naturopathic research can give to other areas of health research in return.

- Researching naturopathy/naturopathic medicine has historically presented several challenges due to the limitations of the randomized-controlled

trial design when evaluating complex interventions underpinned by philosophies and principles beyond the biomedical paradigm, but these challenges are being overcome by embracing widely accepted innovations in research design and methodology aimed at investigating person-centred interventions with multiple therapeutic elements.
- Pragmatic clinical research design allows for the inclusion of multi-modal interventions, real-world settings and flexibility in treatment delivery matching the approach taken in real-world naturopathic care.

Research Dissemination by the Global Naturopathic Research Community (Chapter 16) summarizes the peer-reviewed research article, *"Knowledge dissemination by the naturopathic profession: a bibliometric analysis of naturopath-authored, peer-reviewed publications"* and presents the results of the analysis conducted on naturopath-authored, peer-reviewed publications. The information from this analysis provides the foundation for the detailed summary of naturopathic clinical research presented in Sections 5 and 6 of this report.

- The international naturopathic research community has published peer-reviewed literature for over 30 years and has demonstrated sustained commitment to codifying existing knowledge, generating new knowledge, and disseminating this knowledge to the naturopathic and wider allied-health clinical and research communities.
- Naturopathic research is conducted in most of the educational institutions that have a naturopathic program, especially those in the United States of America, Canada, Australia, Germany, India, and New Zealand.

14 Researching Naturopathy as a Traditional System of Medicine

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HIGHLIGHTS

- Naturopathy/naturopathic medicine is a traditional system of medicine that is defined by philosophies and principles integrated with a biomedical understanding of health and disease.
- Naturopathy/naturopathic medicine embraces complexity in all levels of patient assessment, diagnosis, treatment, and management.
- The research paradigm employed to evaluate the effectiveness of naturopathy/ naturopathic medicine must be able to accommodate the complex and holistic nature of naturopathic practice if it is to provide accurate results that can meaningfully inform policy and practice.
- There are current research designs, such as pragmatic studies, that can accurately assess the effectiveness and efficacy of naturopathic practice.

According to the World Health Organization (WHO), a traditional system of medicine is characterized by a long history of practice and use [1]. Traditional systems of medicine encompass knowledge, skills, and therapeutics based on theories, beliefs and experiences indigenous to different cultures, and used in health maintenance, prevention, diagnosis, improvement or treatment of physical and mental illness [1]. Naturopathy is one such traditional system of medicine. Naturopathy/naturopathic medicine is a complete medical system of theory and practice indigenous to Europe that has evolved alongside and independent of biomedicine [2]. The naturopathic profession is defined by its philosophies *holism* and *vitalism* and is guided by seven principles as described in Chapter 2 *Naturopathic Philosophies and Principles* [3]. The naturopathic profession has evolved in response to the needs of modern communities, health care and health systems, whilst remaining consistent within its naturopathic philosophical foundations. This contemporary practice of naturopathy/naturopathic medicine draws on both traditional knowledge and modern scientific research [4, 5].

Naturopathic Research Considerations

Research examining naturopathic practice must account for the various components of its whole medicine system if it is to provide meaningful information for those within and outside of the profession. This need has also been raised in other areas of health research, such as public health [6] and primary care [7], where evidence-based medicine has been criticized for its poor applicability due primarily to its inability to account for complexity and nuance. In this section the implications of conducting clinical research that examines naturopathy/naturopathic medicine will be considered within the context of a naturopathic philosophical framework, within the context of naturopathy's guiding principles, naturopathy as a complex intervention and within the context of diverse knowledge sources.

Within the Context of a Naturopathic Philosophical Framework

As a traditional system of medicine, naturopathy/naturopathic medicine is defined by the application of its overarching philosophical frameworks in all aspects of naturopathic care, rather than its use of natural treatments and therapies [8, 9]. While the contemporary practice of naturopathy and naturopathic medicine has adapted to modern populations, health systems, and health conditions, the profession and its practice remains deeply grounded in its core philosophies and principles [3]. It is the integration of naturopathic philosophies and principles within a biomedical understanding of health and disease that defines naturopathic care.

Naturopathic researchers apply these philosophies and principles to the design of research studies examining the efficacy or effectiveness of naturopathic treatments. One such philosophy which has had an important influence on clinical research developed through the naturopathic lens is *holism*. Holism has enabled naturopathic researchers to be leaders in initiatives such as the development of whole practice research methodologies that are increasingly utilized in the evaluation of both traditional and complementary medical and conventional healthcare approaches [10]. While a belief of an ultimate connection in the natural world – a central feature of *holism* – was pivotal to the historical understanding of the natural world, from the 1600s the scientific gaze embraced the philosophies of reductionism and mechanism [11]. This shift served to simplify the world under investigation and enabled enormous growth in scientific knowledge. In this paradigm, complex systems were not investigated, instead, the smallest possible element was seen to provide answers to the problems of the whole [11, 12] and connections were viewed as linear causal chains [13]. Over time the limits of reductionism began to constrain scientific healthcare progress including the evolution in understanding biology and disease, and other topics specific to naturopathic practice that embraced complexity were similarly stifled [14, 15]. In response, science began to develop a transdisciplinary theory of complex systems in the 1900s – known as 'complexity science' – which is currently gathering momentum due partly to the availability of computer technology capable of handling large datasets. This interest is evident in health research as seen with the renewed recognition of the interrelatedness of physiological systems and organs, and the relevance of multi-modal interventions in healthcare [16].

The complexity science approach enables effective examination of naturopathic practice. Naturopathic case management – the assessment and treatment of individual patients – goes beyond specific and targeted interventions to encompass recognition of the human as a complex and adaptive system. Naturopathy/naturopathic medicine as a medical system is philosophically holistic and complex in nature and readily conceptualizes health and healing in a manner consistent with this complexity paradigm [17]. The naturopathic approach to case diagnosis, treatment and management is based on a view of integrated physiology [18]; of seeing the human organism as comprised of interacting organs and systems that, in combination, provide the functional capability of the organism and regulate health.

For this reason, the research paradigm employed to evaluate the effectiveness of naturopathy/ naturopathic medicine must be able to accommodate the complex and holistic nature of naturopathic practice if it is to provide accurate results that can meaningfully inform policy and practice. Whole systems research – as a clinical research methodology distinct from the science of researching specific, linear, and targeted interventions – is an important tool for a traditional system of medicine such as naturopathy/naturopathic medicine. A central focus of whole systems research is to address both the therapeutic and theoretical components of health care. Through the whole systems research approach, naturopathy/naturopathic medicine can be meaningfully explored in a way that accommodates the synergistic elements involved in naturopathic care and provides the flexibility needed to generate new knowledge that is reflective of traditional and contemporary practice [19]. Without full consideration of these frameworks, research evidence translates poorly to real-world contexts.

Within the Context of Naturopathy's Guiding Principles

Naturopathic practice is characterized by the application of care guided by overarching principles which views individualized treatments tailored to each patient through a person-centred approach [20]. When applied in clinical practice, naturopathic guiding principles have the capability to influence health care outcomes including reduced disease symptomology, improved patient health care experiences, satisfaction with care, and patient safety [18, 21]. This capability is already reflected in clinical research which reports that naturopathic care produces positive short- and long-term patient outcomes including increased patient empowerment leading to improved health behaviours and lifestyle choices [22]. These outcomes may be explained by the application of naturopathic principles that emphasize patient education (i.e., Doctor as Teacher), community education and preventive medicine (i.e., Health Promotion and Disease Prevention), and person-centred care (i.e., Treat the Whole Person) which may have a supportive role in the

management of non-communicable diseases [22]. Hence, naturopathic advancements within research also need to ensure that evaluation of naturopathic practice reflects the real-life practice of naturopathy/naturopathic medicine as guided by these principles. Yet, too often, the positive outcomes in naturopathic research have been assigned to the therapies themselves and not to the naturopathic approach to care, even when other professions have not been able to translate clinical research for therapies into successful outcomes for patients [23]. This perception has also led to resistance to the integration of naturopaths or naturopathic doctors within the biomedicine health systems, even when evidence shows clear and consistent benefit. However, these dual elements of naturopathic practice – the clinical approach and the therapies employed – cannot be easily separated and should instead be viewed as an interconnected whole medicine system.

Dominant research methodologies, and their limitations within the context of naturopathy [20], underscore the importance of identifying and applying emerging research paradigms and designs. These principles may not only guide practice, but also the naturopathic approach to conceptualizing, designing, and evaluating a clinical intervention. Naturopathic researchers have applied their commitment to see a fair balance between the internal study validity and the external validity of findings. In doing so, they have contributed to the innovation of research methodologies that, while still rigorous, may deviate from more common research practices to ensure the findings accurately reflect real-world naturopathic practice. Conversely, research conducted without consideration of naturopathic principles may have limited applicability to the realities of contemporary naturopathic care.

Naturopathy as a Complex Intervention

Naturopathy/naturopathic medicine is a system of health care with strong philosophical roots which continually evolves and adapts to population needs, regulatory context and health care settings [24]. As such, most naturopathic interventions are multifactorial in nature. Naturopaths/naturopathic doctors commonly employ an average of four different categories of treatments when providing care to their patients [25]. Furthermore, many of the treatments are themselves complex: herbal medicines, for example, are multifaceted compounds containing a mixture of active and synergistic ingredients; nutritional products often reflect a formulated combination of vitamins, minerals, and other nutrients or food- or plant-based ingredients. These layers of complexity – multiple, complex treatments prescribed in combination to achieve a variety of physiological, biochemical, or psychosocial outcomes – need to be carefully considered when evaluating the clinical effectiveness of naturopathic treatments.

The naturopathic therapeutic armamentarium has evolved over time through the inclusion of new therapeutic tools as they become available and the de-implementation of previous practices or treatments [24]. While informed by the continually growing body of health research, naturopaths'/naturopathic doctors' decisions to change the range of treatments they employ are also based on the degree to which the treatment aligns with naturopathic philosophies and principles. This contrasts with 'green allopathy' and functional medicine approaches which still apply the reductionist approach characterized by biomedicine but are defined largely by their use of natural substances instead of pharmaceutical or biomedicine agents in this model. However, green allopathy and functional medicine are also practiced without the support of the philosophical frameworks that are the core of naturopathic practice or the detailed knowledge of mechanism of action, nutritional biochemistry and herbal pharmacognosy that characterises naturopathic training. [26, 27]. Reductionism is still the dominant paradigm in contemporary health care, however, the World Health Organization's Declaration of Astana explicitly supports a transition away from the existing reductionist model and this bodes well for greater integration of naturopaths/naturopathic doctors into health systems globally, as they already focus on holistic, person-centred care [28]. There is also a growing area of research and scholarship that acknowledges complexity and a whole systems approach to health care is integral to critically evaluating the effectiveness of naturopathic care and producing new knowledge that can support evidence-based policy and health service delivery.

Within the Context of Diverse Knowledge Sources

Naturopaths/naturopathic doctors are trained to critically engage with naturopathic philosophical principles and frameworks to ensure optimal patient care while utilizing both traditional and contemporary evidence to inform clinical decisions. Research examining naturopathic practice must, therefore, also ensure it is informed by the knowledge and information sources that naturopaths/naturopathic doctors rely on when making clinical decisions. Such sources include traditional knowledge, contemporary education curriculum, research literature, and clinical wisdom and experience (see for more information Chapter 13 *Mobilization of Knowledge and Information in Naturopathic Clinical Practice*). Knowledge derived from traditional texts is valued by the naturopathic profession and can lead to the implementation or, in some instances, de-implementation of historical clinical practices [24]. Likewise, practice-informed research conducted within the whole system research framework

enables the generation of more pertinent, precise, and clinically relevant research questions that will improve patient and practice outcomes [29]. Without these aspects, the capability to reach the full potential of naturopathic research may be limited. As a traditional system of medicine, all elements of naturopathic philosophies, principles, practices, and knowledge must be considered when designing, examining, and interpreting naturopathic research.

Research Designs Relevant to Naturopathic Clinical Research

These important considerations notwithstanding, naturopathic clinical research can be conducted using commonly employed research designs. The most common of these is the randomized-clinical trial (RCT); a research design intended to help provide a clearer explanation of the clinical effect of a specific treatment. The RCT is accepted as the 'gold-standard' of clinical research through which a study population is carefully selected against pre-determined criteria and then randomly allocated to either receive an intervention, or a control. The control is most commonly an inactive substance, known as a *placebo*, but may also include the treatments that are usually provided for the condition, known as *standard care* or *usual care*, or a time delay in receiving the intervention during which time no intervention is provided, called a *waitlist control*. An RCT is designed to limit the variability between patients, setting and intervention and therefore provide a clear picture of the intervention's 'efficacy'. While RCTs have strong internal validity, the external validity of RCT research can be compromised. This differs from a *pragmatic clinical trial* which is more reflective of real-world practice including the characteristics of the patients and settings, as well as the variability in treatment prescription that can occur in routine clinical care. A pragmatic clinical trial provides evidence of 'effectiveness' and is commonly undertaken after evidence of efficacy has been shown through an RCT. These methods can be used to either research naturopathic care as a whole system or to investigate specific naturopathic treatments as complex or single interventions. Both RCTs and pragmatic clinical trials can also be employed to study treatments tailored to an individual's genetic or molecular characteristics, known as *precision-medicine*. However, not all clinical research compares the results of the intervention with a control group. Often, preliminary or pilot research involves only one study group who receives the intervention and, as such, is known as a *quasi-experimental* or *uncontrolled* trial. *Case reports* are also an important source of evidence for any health profession, and naturopathy is no different. Case reports can present the result of a single case, referred to as a *case study*, or multiple cases with a shared characteristic (e.g., presenting complaint, treatment used, etc.), known as a *case series*. Case reports provide a valuable mechanism for clinicians to document insights gathered from clinical practice to inform the wider research and health practitioner community [30, 31].

Other research methods are also relevant to naturopathic clinical research, even though they do not evaluate efficacy or effectiveness directly. Delphi studies, for example, are a research design aimed at gathering expert consensus on a topic, such as clinical treatment options which may be used to inform the design of an intervention for an RCT or pragmatic trial, based on the clinical expertise of naturopaths/naturopathic doctors with experience treating the condition of interest. Observational studies such as survey research may also be used to describe naturopaths'/naturopathic doctors' clinical experiences and observations and may serve to identify practice patterns and inform research priority areas. Even document analysis can be valuable as a research design for clinical research as it provides a robust method of critically engaging with traditional naturopathic texts to identify unexamined historical treatments and practices that warrant researcher attention. These are a few examples and, in line with complexity science principles, the accumulated value of all study designs in providing important insights into naturopathic clinical practice is greater than the contribution of any one study design on its own.

Summary

Naturopathy/naturopathic medicine is a traditional system of medicine that is defined by philosophies and principles, and embraces complexity in all levels of naturopathic assessment, case diagnosis, treatment, and management. Researchers must account for this complexity when designing and conducting research investigating naturopathy/naturopathic medicine. It is important that consumers have access to health services that meet their needs and are supported by quality evidence that reflects and is relevant to real-world context and practice. Policymakers and other stakeholders seeking to understand how best to optimize the health workforce and integrate naturopaths/naturopathic doctors into their policies, programs, and services for community benefit must consider research investigating naturopathic safety and effectiveness within the context of contemporary naturopathic practice.

Literature Cited

1. World Health Organisation. *Traditional, Complementary and Integrative Medicine*. 2021; Available from: https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab_1.
2. Koithan, M., Bell, I.R., Niemeyer, K., and Pincus, D., *A Complex Systems Science Perspective for Whole Systems of Complementary and Alternative Medicine Research*. Complementary Medicine Research, 2012. **19**(Suppl. 1): p. 7-14.
3. Hausser, T., Lloyd, I., Yánez, J., Cottingham, P., Newman-Turner, R., and Abascal, A. *WNF White Paper: Naturopathic Philosophies, Principles and Theories*. 2017; Available from: http://worldnaturopathicfederation.org/wp-content/uploads/2015/12/White-Paper_FINAL.pdf.
4. Steel, A. and Adams, J., *The interface between tradition and science: naturopath's perspective of modern practice*. Journal of Alternative and Complementary Medicine, 2011. **17**(10): p. 967-72.
5. Steel, A., Peng, W., Gray, A., and Adams, J., *The role and influence of Traditional and Scientific Knowledge in Naturopathic Education: A Qualitative Study*. Journal of Alternative and Complementary Medicine, 2018.
6. Wardle, J. and Oberg, E., *The Intersecting Paradigms of Naturopathic Medicine and Public Health: Opportunities for Naturopathic Medicine*. Journal of Alternative and Complementary Medicine, 2012. **17**(11): p. 1079-1084.
7. Stange, K.C. and Ferrer, R.L., *The Paradox of Primary Care*. Annals of family medicine, 2009. **7**(4): p. 293-299.
8. Wardle, J. and Sarris, J., *Clinical naturopathy: an evidence-based guide to practice*. 2014: Elsevier Health Sciences.
9. Dunn, J., Steel, A., Adams, J., Lloyd, I., De Groot, N., Hausser, T., and Wardle, J., *Characteristics of global naturopathic education, regulation, and practice frameworks: results from an international survey*. BMC Complementary Medicine and Therapies, 2021. **21**(1): p. 67.
10. Ijaz, N., Rioux, J., Elder, C., and Weeks, J., *Whole systems research methods in health care: A scoping review*. The Journal of Alternative and Complementary Medicine, 2019. **25**(S1): p. S21-S51.
11. Mazzocchi, F., *Complexity and the reductionism-holism debate in systems biology*. WIREs Systems Biology and Medicine, 2012. **4**(5): p. 413-427.
12. Tuffin, R., *Implications of complexity theory for clinical practice and healthcare organization*. BJA Education, 2016. **16**(10): p. 349-352.
13. Mills, P., Patel, S., Barsotti, T., Peterson, C., and Chopra, D., *Advancing Research on Traditional Whole Systems Medicine Approaches*. Journal of Evidence-Based Complementary & Alternative Medicine, 2017. **22**(4): p. 527-530.
14. Greene, J. and Loscalzo, J., *Putting the Patient Back Together – Social Medicine, Network Medicine, and the Limits of Reductionism*. New England Journal of Medicine, 2017. **377**(25): p. 2493-2499.
15. Launer, J., *Complexity made simple*. Postgraduate Medical Journal, 2018. **94**(1116): p. 611.
16. Sturmberg, J., Martin, C., and Katerndahl, D., *Systems and Complexity Thinking in the General Practice Literature: An Integrative, Historical Narrative Review*. The Annals of Family Medicine, 2014. **12**(1): p. 66.
17. Graham, K.D., Steel, A., and Wardle, J., *The Intersection between Models of Health and How Healing Transpires: A Metaethnographic Synthesis of Complementary Medicine Practitioners' Perceptions*. Journal of Alternative and Complementary Medicine, 2021.
18. Steel, A., Goldenberg, J., Hawrelak, J., Foley, H., Gerontakos, S., Harnett, J., Schloss, J., and Reid, R., *Integrative physiology and traditional naturopathic practice: results of an international observational study*. Integrative Medicine Research, 2020. **9**(4): p. 100424.
19. Verhoef, M., Lewith, G., Ritenbaugh, C., Boon, H., Fleishman, S., and Leis, A., *Complementary and alternative medicine whole systems research: Beyond identification of inadequacies of the RCT*. Complementary Therapies in Medicine, 2005. **13**(3): p. 206-212.
20. Schloss, J., McIntyre, E., Steel, A., Bradley, R., Harnett, J., Reid, R., Hawrelak, J., Goldenberg, J., Van De Venter, C., and Cooley, K., *Lessons from Outside and Within: Exploring Advancements in Methodology for Naturopathic Medicine Clinical Research*. The Journal of Alternative and Complementary Medicine, 2019. **25**(2): p. 135-140.
21. Myers, S. and Vigar, V., *The State of the Evidence for Whole-System, Multi-Modality Naturopathic Medicine: A Systematic Scoping Review*. The Journal of Alternative and Complementary Medicine, 2019. **25**(2): p. 141-168.
22. Steel, A., Tiveron, S., Reid, R., Wardle, J., Cramer, H., Adams, J., Sibbritt, D., and Lauche, R., *Do women who consult with naturopaths or herbalists have a healthy lifestyle?: a secondary analysis of the Australian longitudinal study on women's health*. BMC Complementary Medicine and Therapies, 2020. **20**(1): p. 349.
23. Stanbrook, M.B., *Can naturopaths deliver complementary preventive medicine?* Canadian Medical Association Journal, 2013. **185**(9): p. 747-747.
24. Reid, R., Steel, A., Wardle, J., and Adams, J., *Naturopathic Medicine for the Management of Endometriosis, Dysmenorrhea, and Menorrhagia: A Content Analysis*. The Journal of Alternative and Complementary Medicine, 2019. **25**(2): p. 202-226.
25. Steel, A., Foley, H., Bradley, R., Van De Venter, C., Lloyd, I., Schloss, J., Wardle, J., and Reid, R., *Overview of international naturopathic practice and patient characteristics: results from a cross-sectional study in 14 countries*. BMC Complementary Medicine and Therapies, 2020. **20**(1): p. 59.
26. Barker, J., *Naturopathic treatment of respiratory infections, in*

Townsend Letter for Doctors and Patients. 2005. p. 53+.
27. Hechtman, L., *Clinical Naturopathic Medicine*. 2012: Elsevier Australia.
28. World Health Organization and the United Nations Children's Fund (UNICEF). *Global Conference on Primary Health Care Declaration of Astana*. 2018; Available from: https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.pdf.
29. Ritenbaugh, C., Aickin, M., Bradley, R., Caspi, O., Grimsgaard, S., and Musial, F., *Whole systems research becomes real: new results and next steps*. Journal of Alternative and Complementary Medicine, 2010. **16**(1): p. 131-7.
30. Wardle, J. and Roseen, E., *Integrative medicine case reports: A clinicians' guide to publication*. Advances in Integrative Medicine, 2014. **1**(3): p. 144-147.
31. Fogarty, S. and Wardle, J., *Integrative medicine case series: A clinician's guide to publication*. Advances in Integrative Medicine, 2015. **2**(3): p. 147-151.

15 Challenges and Advancements for Naturopathic Clinical Research

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HIGHLIGHTS

- Contemporary health research and policy recognizes the importance of identifying the effectiveness and real-world outcomes of an intervention.
- Pragmatic clinical research methods apply a complex, person-centred approach to clinical trial design that may help determine fidelity to naturopathic practice.
- The naturopathic profession requires adequate infrastructure to further support research including research capacity building, consumer and practitioner engagement, and integration into health systems.
- Dedicated government funding for naturopathic research is needed to facilitate the naturopathic profession's interest and capability to conduct health quality research.

Respect for the dynamic interplay between a range of factors that shape health and wellbeing is inherent to the philosophy of naturopathy/naturopathic medicine as a whole system intervention and presents tensions, trade-offs, and challenges to effective application of the randomized controlled trial (RCT) design. Research pertinent to naturopathic practice begs adoption of other types of research methods appropriate for generating different types of evidence such as outcomes from real world practice, informed by clinical experience that is reflective of complex patients, conditions, and treatments [1-3]. This chapter is adapted from an article published in *The Journal of Alternative and Complementary Medicine's Special Focus Issue on Naturopathy* [4]. The goal of this chapter is to draw attention to key innovations in study design that are relevant to the future of naturopathic research. This chapter will explore what naturopathic research and researchers may offer the wider health research community and consider the advancements occurring within health research that are more aligned to the naturopathic approach to health care and hence will support future robust and rigorous naturopathic research.

Implications

There are several implications related to naturopathic research methodology that require careful consideration. One major challenge to conducting naturopathic research is the need for adequate infrastructure, which includes practitioner research capacity, consumer and practitioner engagement, and integration into health care systems, all of which are not fully developed within the naturopathic profession. The lack of integration of naturopathic health services in health care systems prevents access to resources to assist clinical research, such as health databases (e.g., e-health records) and practitioner databases (e.g., registration agencies). Creating practice-based research networks (PBRN) or academic networks [57] are potential solutions which enable researchers to access practitioners and their patients [58].

PBRNs will also help facilitate a research culture within naturopathy/naturopathic medicine by providing an opportunity for practitioners to participate in research within community-based practice [59]. Lack of clinician research capacity in many countries is a barrier

to conducting research such as pragmatic trials, translating research, codifying knowledge, and developing suitable research methods. Naturopaths/naturopathic doctors are, in some situations, adequately trained to adopt a researcher-practitioner model of practice in which research and clinical skills are equally valued. To enable naturopaths/naturopathic doctors to be involved in the research process there needs to be adequate educational infrastructure to increase research capacity. There is currently insufficient undergraduate, graduate, and postgraduate education in health and social science research methods for naturopathic practice [60]. This shortfall needs to be urgently addressed, otherwise lack of research skills will continue to be a significant barrier for naturopaths/naturopathic doctors to participate in and translate naturopathic research.

There is already a substantial volume of research examining naturopathic treatment and practices in a wide range of health conditions, but further research is still needed. Participatory community-based methods such as Delphi techniques could be used to engage naturopaths/naturopathic doctors and consumers to determine naturopathic research priorities [61, 62]. It is critical that naturopathic research is translatable to clinical practice and meaningful to health care consumers. Delphi techniques allow for clinician participation in design of the research process to ensure clinically meaningful outcomes and provide an opportunity to involve health consumers in research to ensure it is person-centered. Consensus methods such as Delphi techniques would also be suitable for identifying methods for research translation to both naturopathic practice and health care consumers. This participatory approach could be extended to assist with codifying knowledge, which includes developing clinical guidelines for naturopathic care. These methods could also facilitate the consolidation of traditional evidence into meaningful frameworks that are accessible to clinicians and the public. An example of this is described in an article that discusses the naturopathic approaches to irritable bowel syndrome [63].

Developing and evolving naturopathic research methodologies can be considered an iterative process that has the potential to influence health research more broadly. However, the advancements in health research methodologies more generally afford an opportunity for naturopathic research to align with established research designs while still answering clinically relevant and philosophically sensitive research questions. However, successful implementation of naturopathic research methodologies, and translation and dissemination of research will require a substantial paradigm shift in which naturopaths and naturopathic doctors adopt a greater level of responsibility for developing an evidence-base for naturopathic practice. Initiatives to support and evaluate knowledge mobilization [64] within the community of naturopathic medical research, education and practice may play a key, yet unexplored role [65]. Researchers in this field have an important leadership role to effectively facilitate this transformation, which will benefit health consumers, naturopathic practitioners, and the health care systems they serve. Naturopaths/naturopathic doctors who are not in the research field can also contribute by being part of research activities such as practice-based research networks; therefore, assisting in this paradigm shift and allowing the leaders in the field to move forward.

Similarly, government funding to support naturopathic research is also needed. In countries where naturopathic researchers have access to competitive government research funding, they are commonly achieving a greater degree of success than similar professions. For example, in Australia naturopaths have received more government funding from the National Health and Medical Research Council than any other TCIM profession, despite being the only TCIM profession not housed in a university for most of that time [66]. In the United States, naturopathic doctors have successfully attracted National Institute of Health funding for clinical research and capacity building, again surpassing the success of other TCIM professions with similar or greater integration into the health system. As such, the naturopathic research community shows the interest and capability to conduct high quality research that meets rigorous standards to which all health research is held when it has access to the required funding.

Contemporary Advances in Health Research

Clinical trials involving conventional healthcare interventions are generally centred around explanatory research utilizing the RCT model – historically, considered the highest recognized level of clinical evidence [5]. However, current opinions on explanatory research now recognize that although this type of research may ascertain causal relationships (efficacy) in an ideal or controlled situation, it does not accurately measure if the intervention is effective in an everyday healthcare setting (effectiveness) [6]. To be able to measure effectiveness, pragmatic trials need to be developed and implemented for translational science and application in real-world settings [5]. The spectrum between explanatory and pragmatic trials is not dichotomous but rather a continuum and the evidence generated by trials conducted according to each end of the continuum have value, with trials incorporating aspects of both in a variety of dimensions [7].

Recognition of the limitations of the RCT model has raised recognition of pragmatic research designs to evaluate the effectiveness of health care as it really occurs. The *Pragmatic-Explanatory Continuum Indicator Summary* (PRECIS-2) is an instrument that assists researchers in

developing trials for this particular purpose [8]. More importantly, the tool has been useful for articulating important aspects of design and intention, essentially framing what is sometimes a dynamic and disconnected process through the stages of research design, conduct, interpretation, and clinical application [9]. Being able to combine, develop and assess trials using the PRECIS-2 model supports researchers to develop trials that provide high level clinical evidence allowing for individualized clinical decision-making and the delivery of complex multi-modal interventions. In addition to the PRECIS-2, a *Template for Intervention Description and Replication* (TIDieR) checklist and guide was developed by an international team of experts to assist researchers to promote full and accurate descriptions of trial interventions [10].

Focusing on real world outcomes and effectiveness also increases the need for participatory/community-based involvement [11]. Equally, an observational or quasi-experimental (uncontrolled) trial may be advantageous when assessing application in a community-based setting. These types of research designs generally require a mixed methods approach that is person-centered rather than disease centered. Designing and implementing person-centered research has become more prominent in an era where policy-makers are emphasizing person-centered care [12]. Innovation in research methodology is a necessary response to these policy-driven demands. Fortunately, based on a recognition that clinical outcomes in clinical trials do not capture all important mediators and predictors of real-life clinical practice, several funding agencies including the National Institutes of Health (NIH) and the Patient-Centered Outcomes Research Institute (PCORI) in the USA have endorsed and led the development of research instruments and processes. This includes the Patient Reported Outcomes Measure Information System (PROMIS) [13] which is used to capture more holistic data on functional, social, emotional, and spiritual domains of health, and more directly involve patients in research.

Applying Health Research Advancements to Naturopathy

Certain aspects of naturopathic care are suited to clinical trials, however, the RCT model is not always applicable when assessing a naturopathic intervention due to the multifaceted approach to naturopathic care and the naturopathic focus on individuals as a complex system. Similar concerns about the emphasis on explanatory RCTs within the evidence-based medicine paradigm have been raised in other areas of health care, with criticisms and limitations described by medical doctors and allied health professionals [14-16]. The diversification of accepted health research methods to include pragmatic designs supporting assessment of complex person-centered interventions resulting from these concerns, provides important opportunities for naturopathic researchers focusing on real-world naturopathic practice. This type of research is important because patients who require a variety of different interventions due to complex disease status, are not normally included in certain trials since they do not fit the "optimal" requirements for that trial (e.g., too many potentially confounding health complications). In pragmatic trials, all patients who have the conditions of interest – regardless of their responsiveness, past compliance, and co-morbidities – can be enrolled [17]. Furthermore, the checklists and guidelines (e.g., PRECIS-2, TIDIER) that evolved in response to attempts by the health research community to better evaluate complex interventions, align well with the diverse practices inherent to naturopathic care.

Recent research evaluating treatments for low back pain provide excellent examples of multiple research methodologies applicable to naturopathic practice, including inclusion of education and self-care practices in randomized trials [18-21]; development and inclusion of multi-dimensional patient-reported outcome measures [22-24]; application of mixed-method designs to capture patients' experiences with the intervention [25, 26]; evaluating assessments of individual predictors of outcomes [27, 28] including experience of care [29, 30], inclusion of informed choice [31, 32], and expectations [33] as predictive factors for improved clinical outcomes. These research methodologies are richly aligned with naturopathic philosophy of *'holism'*, and principles of "Doctor as Teacher" *(docere)*, and "Treat the Whole Person" *(tolle totum)* and the naturopathic Therapeutic Order [34] because there is significant patient engagement, attention to education and self-reflection, as well as assessing aspects of the whole person as part of the intervention or outcome. Several of the approaches to data collection and outcome measurement described in this chapter have been applied to clinical research evaluating naturopathic practice. For example, a study in primary prevention of heart disease collecting data on the outcomes of highest priority to patients in addition to traditional Framingham risk scores [35]. Other examples include quasi-experimental research in type II diabetes collecting patient reported outcomes including self-efficacy and stress, in additional to clinical hemoglobin A1c changes [36], plus including qualitative elements in clinical trials to capture patients' experiences with care [37]. Other naturopathic research has been published that describes patients experiencing person-centered care when treated by a naturopath/naturopathic doctor [38]. For this reason, the person-centered research methods being developed within the broader health research community are particularly relevant to naturopathic research. In fact, instruments such as PROMIS and other patient-reported outcome measures afford researchers

an opportunity to capture changes to health status as experienced by the patients themselves.

The nature of naturopathic practice is complex to research in its totality. However, the pragmatic and person-centered research methods emerging from innovations in health research methods provide an approach to interrogate the complexity of practice while not requiring violation of fundamental naturopathic principles of practice allowing high external validity in the study design. In fact, these new research methods may help determine fidelity to complex naturopathic practices previously undervalued or overlooked in health research [39].

Strengthening Health Research Through the Naturopathic Approach

Not only do advances in health research methodology offer important opportunities to progress naturopathic research and benefit patients, but there are also areas where the unique characteristics of naturopathic philosophy and practice can impact on other areas of health research. The *tolle totem* principle of naturopathy – which focuses on treatment of all aspects of the individual – requires clinicians to acknowledge the complexity of disease etiology and pathophysiology [40, 41]. In doing so, naturopathic clinical understanding may open new avenues for researchers from other disciplines to explore. A recent example of this is the growing research interest in the clinical importance of gastrointestinal health in an array of health conditions [42-46] – a concept well-established within the naturopathic clinical approach [47]. There are undoubtedly many other areas where the insights and experience of naturopaths/naturopathic doctors may, once communicated to a wider audience through case reports and medical hypothesis articles, encourage more research breakthroughs that will benefit the community in ways yet unmeasured.

Such an opportunity to capture clinical insights as a basis for future research may not only assist the substantive topic in question, but it may also offer a practical method for recalibrating the balance within the evidence-based medicine triad; serving to bolster the attention given to clinical expertise and patient values through research [48-50]. As the naturopathic profession, both as clinicians and researchers, document and share their experience and clinical insights (both past and present), they will provide a model through which the 'clinician experience' pillar of evidence-based medicine can be operationalized [50]. This move to rebalancing the value placed on different types of knowledge has evolved globally in recent years, and scholars committed to mobilizing such knowledge between stakeholders have argued that this approach benefits all areas of society [51]. However, while building practitioner research capacity has demonstratable improvements in research quality and relevance [52], there remain barriers and challenges to fully engaging naturopaths/naturopathic doctors in this process, such as lack of access to clinician research support schemes available to other health professions.

Naturopaths/naturopathic doctors are well-placed to support new research by effectively and rapidly implementing practices developed through new areas of research such as precision or personalized medicine [53], thereby providing opportunities to better understand the real-world implications of the health technology as it develops. In fact, the emphasis on individualized treatments as a core philosophical element of naturopathic care [47] may mean that naturopaths/naturopathic doctors are more ideologically and logistically prepared to incorporate such personalized health care compared to other health professionals. However, despite a natural and opportune fit, issues with capacity, mentorship, training and support for naturopathic researchers and cross-disciplinary teams need to be addressed [54, 55].

There are gaps in the available health research methods and instruments which limit the robustness of some facets of naturopathic research. Current naturopathic researchers cannot meaningfully build the experience and knowledge of past (i.e., historical) naturopaths/naturopathic doctors into the design of research projects; without a rigorous framework to guide the analysis and appropriate use of traditional information sources (e.g., historical texts and ancestral or elder-based knowledge) [56]. They also need to develop instruments that measure the outcomes uniquely important in naturopathic clinical decision-making and treatment evaluation (e.g., vital force). In some instances, some relevant instruments may already exist that only require small modifications to capture nuances specific to naturopathic principles and practice. In other cases, the instruments will need to be developed in full.

Summary

Researching naturopathy/naturopathic medicine has historically presented several challenges due to the limitations of the randomized-controlled trial design when evaluating complex interventions underpinned by philosophies and principles beyond the biomedical paradigm, but these challenges are being overcome by embracing widely accepted innovations in research design and methodology aimed at investigating person-centred interventions with multiple therapeutic elements. This is evidenced in Section 5: *Effectiveness of Naturopathic Clinical Practice*, and Section 6: *Research in Naturopathic Therapeutics and Practices* where randomised-controlled trials have frequently been used by naturopathic researchers to evaluate naturopathy/naturopathic medicine and its treatments, but such trials commonly reflect

elements of pragmatic clinical research including multimodal interventions, real-world settings and flexibility in treatment delivery matching the approach taken in real-world care. The naturopathic research community is well positioned to contribute to the advancement of such designs and methodologies by applying their experience and perspective of complexity-based healthcare for the benefit of health research more generally.

Literature Cited

1. Bell, I.R. and Koithan, M., *Models for the study of whole systems.* Integrative Cancer Therapies, 2006. **5**(4): p. 293-307.
2. Mills, P.J., Patel, S., Barsotti, T., Peterson, C.T., and Chopra, D., *Advancing research on traditional whole systems medicine approaches.* 2017, SAGE Publications Sage CA: Los Angeles, CA.
3. Szajewska, H., *Evidence-based medicine and clinical research: both are needed, neither is perfect.* Annals of Nutrition and Metabolism, 2018. **72**(3): p. 13-23.
4. Schloss, J., McIntyre, E., Steel, A., Bradley, R., Harnett, J., Reid, R., Hawrelak, J., Goldenberg, J., Van De Venter, C., and Cooley, K., *Lessons from outside and within: Exploring advancements in methodology for naturopathic medicine clinical research.* The Journal of Alternative and Complementary Medicine, 2019. **25**(2): p. 135-140.
5. Merali, Z. and Wilson, J.R., *Explanatory versus pragmatic trials: An essential concept in study design and interpretation.* Clinical Spine Surgery, 2017. **30**(9): p. 404-406.
6. Califf, R.M. and Sugarman, J., *Exploring the ethical and regulatory issues in pragmatic clinical trials.* Clinical Trials, 2015. **12**(5): p. 436-441.
7. Neta, G. and Johnson, K.E., *Informing real-world practice with real-world evidence: the value of PRECIS-2.* BMC Medicine, 2018. **16**(1): p. 76.
8. Loudon, K., Treweek, S., Sullivan, F., Donnan, P., Thorpe, K.E., and Zwarenstein, M., *The PRECIS-2 tool: designing trials that are fit for purpose.* British Medical Journal, 2015. **350**: p. h2147.
9. Lipman, P.D., Loudon, K., Dluzak, L., Moloney, R., Messner, D., and Stoney, C.M., *Framing the conversation: use of PRECIS-2 ratings to advance understanding of pragmatic trial design domains.* Trials, 2017. **18**(1): p. 532.
10. Cotterill, S., Knowles, S., Martindale, A.-M., Elvey, R., Howard, S., Coupe, N., Wilson, P., and Spence, M., *Getting messier with TIDieR: embracing context and complexity in intervention reporting.* BMC Medical Research Methodology, 2018. **18**(1): p. 12.
11. Verhoef, M., Koithan, M., Bell, I.R., Ives, J., and Jonas, W., *Whole complementary and alternative medical systems and complexity: creating collaborative relationships.* Complementary Medicine Research, 2012. **19**(Suppl. 1): p. 3-6.
12. Jayadevappa, R., *Patient-centered outcomes research and patient-centered care for older adults: A perspective.* Gerontology & Geriatric Medicine, 2017. **3**: p. 2333721417700759.
13. Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., Amtmann, D., Bode, R., Buysse, D., and Choi, S., *The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005 – 2008.* Journal of Clinical Epidemiology, 2010. **63**(11): p. 1179-1194.
14. Cohen, A.M., Stavri, P.Z., and Hersh, W.R., *A categorization and analysis of the criticisms of evidence-based medicine.* International Journal of Medical Informatics, 2004. **73**(1): p. 35-43.
15. Greenhalgh, T., Snow, R., Ryan, S., Rees, S., and Salisbury, H., *Six 'biases' against patients and carers in evidence-based medicine.* BMC Medicine, 2015. **13**(1): p. 1-11.
16. Timmermans, S. and Mauck, A., *The promises and pitfalls of evidence-based medicine.* Health Affairs, 2005. **24**(1): p. 18-28.
17. Gaglio, B., Phillips, S.M., Heurtin-Roberts, S., Sanchez, M.A., and Glasgow, R.E., *How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research.* Implementation Science, 2014. **9**(1): p. 96.
18. Sherman, K.J., Cherkin, D.C., Wellman, R.D., Cook, A.J., Hawkes, R.J., Delaney, K., and Deyo, R.A., *A randomized trial comparing yoga, stretching, and a self-care book for chronic low back pain.* Archives of Internal Medicine, 2011. **171**(22): p. 2019-2026.
19. Saper, R.B., Lemaster, C., Delitto, A., Sherman, K.J., Herman, P.M., Sadikova, E., Stevans, J., Keosaian, J.E., Cerrada, C.J., and Femia, A.L., *Yoga, physical therapy, or education for chronic low back pain: a randomized noninferiority trial.* Annals of Internal Medicine, 2017. **167**(2): p. 85-94.
20. Turner, J.A., Anderson, M.L., Balderson, B.H., Cook, A.J., Sherman, K.J., and Cherkin, D.C., *Mindfulness-based stress reduction and cognitive behavioral therapy for chronic low back pain: similar effects on mindfulness, catastrophizing, self-efficacy, and acceptance in a randomized controlled trial.* Pain, 2016. **157**(11): p. 2434-2444.
21. Goertz, C.M., Long, C.R., Vining, R.D., Pohlman, K.A., Kane, B., Corber, L., Walter, J., and Coulter, I., *Assessment of chiropractic treatment for active duty, US military personnel with low back pain: study protocol for a randomized controlled trial.* Trials, 2016. **17**(1): p. 70.
22. Chen, C.X., Kroenke, K., Stump, T.E., Kean, J., Carpenter, J.S., Krebs, E.E., Bair, M.J., Damush, T.M., and Monahan, P.O., *Estimating minimally important differences for the PROMIS pain interference scales: results from 3 randomized clinical trials.* Pain, 2018. **159**(4): p. 775-782.
23. Ramasamy, A., Martin, M.L., Blum, S.I., Liedgens, H.,

Argoff, C., Freynhagen, R., Wallace, M., McCarrier, K.P., Bushnell, D.M., and Hatley, N.V., *Assessment of patient-reported outcome instruments to assess chronic low back pain*. Pain Medicine, 2017. **18**(6): p. 1098-1110.

24. Stief, F., Meurer, A., Wienand, J., Rauschmann, M., and Rickert, M., *Effect of lumbar spinal fusion surgery on the association of self-report measures with objective measures of physical function*. Gait & Posture, 2018. **61**: p. 7-12.
25. Keosaian, J.E., Lemaster, C.M., Dresner, D., Godersky, M.E., Paris, R., Sherman, K.J., and Saper, R.B., *"We're all in this together": a qualitative study of predominantly low income minority participants in a yoga trial for chronic low back pain*. Complementary Therapies in Medicine, 2016. **24**: p. 34-39.
26. Martin, M.L., Blum, S.I., Liedgens, H., Bushnell, D.M., McCarrier, K.P., Hatley, N.V., Ramasamy, A., Freynhagen, R., Wallace, M., and Argoff, C., *Mixed-methods development of a new patient-reported outcome instrument for chronic low back pain: part 1 – the Patient Assessment for Low Back Pain-Symptoms (PAL-S)*. Pain, 2018. **159**(6): p. 1045.
27. Sherman, K.J., Cherkin, D.C., Ichikawa, L., Avins, A.L., Barlow, W.E., Khalsa, P.S., and Deyo, R.A., *Characteristics of patients with chronic back pain who benefit from acupuncture*. BMC Musculoskeletal Disorders, 2009. **10**(1): p. 114.
28. Stein, K.M., Weinberg, J., Sherman, K.J., Lemaster, C.M., and Saper, R., *Participant Characteristics Associated with Symptomatic Improvement from Yoga for Chronic Low Back Pain*. Journal of Yoga & Physical Therapy, 2014. **4**(1): p. 151.
29. Evers, S., Hsu, C., Sherman, K.J., Balderson, B., Hawkes, R., Brewer, G., La Porte, A.-M., Yeoman, J., and Cherkin, D., *Patient Perspectives on Communication with Primary Care Physicians about Chronic Low Back Pain*. The Permanente Journal, 2017. **21**.
30. Goertz, C.M., Salsbury, S.A., Long, C.R., Vining, R.D., Andresen, A.A., Hondras, M.A., Lyons, K.J., Killinger, L.Z., Wolinsky, F.D., and Wallace, R.B., *Patient-centered professional practice models for managing low back pain in older adults: a pilot randomized controlled trial*. BMC Geriatrics, 2017. **17**(1): p. 235.
31. Sherman, K.J., Cherkin, D.C., Ichikawa, L., Avins, A.L., Delaney, K., Barlow, W.E., Khalsa, P.S., and Deyo, R.A., *Treatment expectations and preferences as predictors of outcome of acupuncture for chronic back pain*. Spine, 2010. **35**(15): p. 1471.
32. Tran, H.H., Weinberg, J., Sherman, K.J., and Saper, R.B., *Preference and expectation for treatment assignment in a randomized controlled trial of once-vs twice-weekly yoga for chronic low back pain*. Global Advances in Health Medicine, 2015. **4**(1): p. 34-39.
33. Hsu, C., Sherman, K.J., Eaves, E.R., Turner, J.A., Cherkin, D.C., Cromp, D., Schafer, L., and Ritenbaugh, C., *New perspectives on patient expectations of treatment outcomes: results from qualitative interviews with patients seeking complementary and alternative medicine treatments for chronic low back pain*. BMC Complementary Alternative Medicine, 2014. **14**(1): p. 276.
34. American Association of Naturopathic Physicians, *Definition of Naturopathic Medicine, in House of Delegates Position Paper*. 2011, American Association of Naturopathic Physicians,: Bethesda, MD.
35. Seely, D., Szczurko, O., Cooley, K., Fritz, H., Aberdour, S., Herrington, C., Herman, P., Rouchotas, P., Lescheid, D., and Bradley, R., *Naturopathic medicine for the prevention of cardiovascular disease: a randomized clinical trial*. Canadian Medical Association Journal, 2013. **185**(9): p. E409-E416.
36. Bradley, R., Sherman, K.J., Catz, S., Calabrese, C., Oberg, E.B., Jordan, L., Grothaus, L., and Cherkin, D., *Adjunctive naturopathic care for type 2 diabetes: patient-reported and clinical outcomes after one year*. BMC Complementary Alternative Medicine, 2012. **12**(1): p. 44.
37. Oberg, E.B., Bradley, R., Hsu, C., Sherman, K.J., Catz, S., Calabrese, C., and Cherkin, D.C., *Patient-Reported Experiences with First-Time Naturopathic Care for Type 2 Diabetes*. PloS one, 2012. **7**(11): p. e48549.
38. Foley, H. and Steel, A., *Patient perceptions of clinical care in complementary medicine: A systematic review of the consultation experience*. Patient Education and Counseling, 2016. **100**: p. 212-23.
39. Dodds, S.E., Herman, P.M., Sechrest, L., Abraham, I., Logue, M.D., Grizzle, A.L., Rehfeld, R.A., Urbine, T.J., Horwitz, R., Crocker, R.L., and Maizes, V.H., *When a Whole Practice Model Is the Intervention: Developing Fidelity Evaluation Components Using Program Theory-Driven Science for an Integrative Medicine Primary Care Clinic*. Evidence-Based Complementary and Alternative Medicine, 2013. **2013**: p. 11.
40. Bradley, R. and Oberg, E.B., *Naturopathic medicine and type 2 diabetes: a retrospective analysis from an academic clinic*. Alternative Medicine Review, 2006. **11**(1): p. 30-9.
41. Mills, P.J., Patel, S., Barsotti, T., Peterson, C.T., and Chopra, D., *Advancing Research on Traditional Whole Systems Medicine Approaches*. Journal of Evidence-Based Integrative Medicine, 2017. **22**(4): p. 527-530.
42. Huang, Y.J., Marsland, B.J., Bunyavanich, S., O'Mahony, L., Leung, D.Y.M., Muraro, A., and Fleisher, T.A., *The microbiome in allergic disease: Current understanding and future opportunities – 2017 PRACTALL document of the American Academy of Allergy, Asthma & Immunology and the European Academy of Allergy and Clinical Immunology*. Journal of Allergy and Clinical Immunology, 2017. **139**(4): p. 1099-1110.
43. Barin, J.G., Tobias, L.D., and Peterson, D.A., *The microbiome and autoimmune disease: Report from a Noel R. Rose Colloquium*. Clinical Immunology, 2015. **159**(2): p. 183-188.
44. Boulangé, C.L., Neves, A.L., Chilloux, J., Nicholson, J.K., and Dumas, M.-E., *Impact of the gut microbiota on inflammation, obesity, and metabolic disease*. Genome Medicine, 2016. **8**(1): p. 42.
45. Ferguson, J.F., Allayee, H., Gerszten, R.E., Ideraabdullah, F., Kris-Etherton, P.M., Ordovas, J.M., Rimm, E.B., Wang, T.J., and Bennett, B.J., *Nutrigenomics, the Microbiome, and Gene-Environment Interactions: New Directions in Cardiovascular Disease Research, Prevention, and Treatment: A Scientific*

Statement From the American Heart Association. Circulation: Cardiovascular Genetics, 2016. **9**(3): p. 291-313.
46. Alam, R., Abdolmaleky, H.M., and Zhou, J.-R., *Microbiome, inflammation, epigenetic alterations, and mental diseases*. American Journal of Medical Genetics Part B: Neuropsychiatric Genetics, 2017. **174**(6): p. 651-660.
47. Steel, A., Sibbritt, D., Schloss, J., Wardle, J., Leach, M., Diezel, H., and Adams, J., *An overview of the Practitioner Research and Collaboration Initiative (PRACI): a practice-based research network for complementary medicine*. BMC Complementary and Alternative Medicine, 2017. **17**(1): p. 87.
48. Szajewska, H., *Evidence-Based Medicine and Clinical Research: Both Are Needed, Neither Is Perfect*. Annals of Nutrition and Metabolism, 2018. **72 Suppl 3**: p. 13-23.
49. Bartlett, S.J., Barnes, T., and McIvor, R.A., *Integrating patients into meaningful real-world research*. Annals of the American Thoracic Society, 2014. **11 Suppl 2**: p. S112-7.
50. Leech, B., Schloss, J., and Steel, A., *Health services research as a framework for expanding a whole systems research agenda in complementary and integrative medicine: The example of intestinal permeability*. European Journal of Integrative Medicine, 2018. **17**: p. 22-25.
51. Boaz, A., Davies, H., Fraser, A., and Nutley, S., *What works now?: evidence-informed policy and practice*. 2019, Bristol, UK: Policy Press.
52. Wilson, P. and Sheldon, T.A., *Using Evidence in Health and Health Care, in What Works Now? Evidence Informed Policy and Practice*, A. Boaz, et al., Editors. 2019, Policy Press: Bristol, UK.
53. Larry Jameson, J. and Longo, D.L., *Precision Medicine – Personalized, Problematic, and Promising*. Obstetrical & Gynecological Survey, 2015. **70**(10): p. 612-614.
54. Menard, M.B., Weeks, J., Anderson, B., Meeker, W., Calabrese, C., O'Bryon, D., and Cramer, G.D., *Consensus Recommendations to NCCIH from Research Faculty in a Transdisciplinary Academic Consortium for Complementary and Integrative Health and Medicine*. Journal of Alternative and Complementary Medicine, 2015. **21**(7): p. 386-94.
55. Aucoin, M., Cooley, K., Knee, C., Tsui, T., and Grondin, D., *Naturopathy Special Interest Group Research Capacity and Needs Assessment Survey*. Journal of Alternative and Complementary Medicine, 2018.
56. Haines, J., Du, J.T., Geursen, G., Gao, J., and Trevorrow , E., *Understanding Elders' knowledge creation to strengthen Indigenous ethical knowledge sharing. In Proceedings of RAILS – Research Applications, Information and Library Studies, 2016, School of Information Management, Victoria University of Wellington, New Zealand*. Information Research, 2017. **22**(4).
57. Steel, A., Goldenberg, J.Z., and Cooley, K., *Establishing an international research collaborative for naturopathy: The International Research Consortium of Naturopathic Academic Clinics (IRCNAC)*. Advances in Integrative Medicine, 2017. **4**(3): p. 93-97.
58. Steel, A., Adams, J., and Sibbritt, D., *Developing a multi-modality complementary medicine practice-based research network: The PRACI project*. Advances in Integrative Medicine, 2014. **1**(3): p. 113-118.
59. Reid, R. and Steel, A., *The importance of the PRACI project for grass roots complementary medicine practice: a call for practitioner involvement*. Australian Journal of Herbal Medicine, 2015. **27**: p. 101+.
60. Steel, A. and McEwen, B., *The need for higher degrees by research for complementary medicine practitioners*. Australian Journal of Herbal Medicine, 2014. **26**(4): p. 136.
61. Goldenberg, J.Z., Ward, L., Day, A., and Cooley, K., *Naturopathic Approaches to Irritable Bowel Syndrome – A Delphi Study*. Journal of Alternative and Complementary Medicine, 2018.
62. Kezar, A. and Maxey, D., *The Delphi technique: an untapped approach of participatory research*. International Journal of Social Research Methodology, 2016. **19**(2): p. 143-160.
63. Goldenberg, J.Z., Steel, A., Day, A., Yap, C., Bradley, R., and Cooley, K., *Naturopathic approaches to irritable bowel syndrome: protocol for a prospective observational study in academic teaching clinics*. Integrative Medicine Research, 2018. **7**(3): p. 279-286.
64. Worton, S., Loomis, C., Pancer, S., Nelson, G., and Peters, D., *Evidence to impact: A community knowledge mobilisation evaluation framework*. Gateways: International Journal of Community Research and Engagement, 2017. **10**: p. 121-142.
65. Steel, A., Rapport, F., and Adams, J., *Towards an implementation science of complementary health care: some initial considerations for guiding safe, effective clinical decision-making*. Advances in Integrative Medicine, 2018. **5**(1): p. 5-8.
66. Wardle, J. and Adams, J., *Are the CAM professions engaging in high-level health and medical research? Trends in publicly funded complementary medicine research grants in Australia*. Complementary Therapies in Medicine, 2013. **21**(6): p. 746-749.

16 Research Dissemination by the Global Naturopathic Research Community

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HIGHLIGHTS

- The international naturopathic research community has demonstrated sustained commitment to codifying and synthesizing existing knowledge, generating new knowledge and disseminating this knowledge to the wider clinical and research community.
- Naturopaths/NDs have published over 2000 peer-reviewed articles since 1987 with notable increases in the last 20 years.
- The naturopathic profession has been increasingly engaged with evidence-based medicine since it was articulated in 1996.
- Naturopathic researchers have investigated a broad range of health conditions and a diverse array of naturopathic treatments.
- Naturopathic researchers utilize all types of research designs including randomized control trials, observational studies, reviews and case studies.
- Naturopathic researchers are publishing in high ranked journals in a range of subject areas.

The evolution and contemporary practice of the naturopathic profession occurs alongside substantial changes to the broader healthcare landscape. Most notable among these changes is prioritization of the best available evidence within clinical decision-making, described in 1994 as 'evidence-based medicine' (EBM) [1]. Key components to EBM are the generation of new knowledge and its dissemination and implementation within the clinical encounter [1, 2]. Historically, the primary platform for scientific knowledge dissemination favoured by EBM is through peer-reviewed academic journals. The peer-review process endeavours to ensure contributions to new knowledge are critically appraised by independent researchers prior to being shared with the wider community. While there are acknowledged limitations to the peer-review process [3, 4] and the translation of published articles to daily routine care [5], it is still a central component of knowledge generation and dissemination underpinning EBM.

This chapter presents the results of analysis from an article titled *"Knowledge dissemination by the naturopathic profession: a bibliometric analysis of naturopath-authored, peer-reviewed publications"* published in The Journal of Alternative and Complementary Medicine [6]. The information from this analysis provides the foundation for the detailed summary of naturopathic clinical research presented in Section 5: *Effectiveness of Naturopathic Clinical Practice* and Section 6: *Research in Naturopathic Therapeutics and Practices* of this Health Technology Assessment. This chapter adds to the evidence indicating exponential growth of the production of scientific content within traditional, complementary and integrative medicine (TCIM) journals [7] and for other TCIM professions [8], as it presents an examination of the published peer-reviewed journal articles authored by naturopathic researchers.

Implications

The evolution of knowledge generation and dissemination by naturopaths/naturopathic doctors globally has occurred organically for more than 30 years and the findings presented in this chapter provide insight into the implications for future research, policy, and practice for the naturopathic profession, as well as other health care professions, health care managers, policy- and decision-makers. The naturopathic profession has engaged philosophically [9-11] and practically [12-15] with EBM as evidenced by research centres having been established in naturopathic institutions; naturopaths/naturopathic doctors with research qualifications being housed in leading national and international research centres focused on naturopathy and related practices and professions (see Figure 16.1); and with the launch of an international leadership program for naturopathic researchers in 2015 [16]. The countries with substantive outputs of scholarly articles (USA, Australia, Canada, Germany and India) can be characterized by the presence of naturopathic institutions with some focus on research, or research centres that include naturopaths/naturopathic doctors with research qualifications.

To increase knowledge generation, evidence by publication of peer-reviewed articles, similar infrastructure and training should be made available to the naturopathic profession in other countries. Access to formal research qualifications may be limited in some countries due to variability in qualification level [17], however incorporating case report writing and other clinic-relevant research skills into the curriculum in those locations may still be achievable. However, the active participation of the naturopathic community in research where formal research qualifications are available to them suggests that government education and research agencies should consider broader incorporation of the naturopathic community in research and formal education initiatives.

The research active naturopathic community also needs to prioritize the attention given to specific topics to ensure it benefits the wider profession. The North American naturopathic community proposed a naturopathic research agenda in 2006 that recommended focusing on conditions with highest burden and significance, and those with the potential to advance patient care [13]. Given the transformation in the international landscape for the naturopathic profession in recent years, there may be value in revisiting this agenda with input from the global naturopathic research community.

Figure 16.1: Location of universities with naturopathic-focused research centers, chairs or departments, or naturopathic training institutions with research departments that have received government research funding

Methods

Literature search

A snowballing method was employed between June 2018 and July 2019 to identify research articles written by at least one naturopath/naturopathic doctor. Articles were included if: (1) at least one author held a naturopathic qualification recognized by the country where they were located; and (2) they were published in a peer-reviewed, indexed journal. Journals were defined as peer-reviewed and indexed if the journal's website outlined a peer-reviewing protocol within its publishing policy and if the journal was indexed in a scholarly database. No date restrictions were applied. Articles were excluded if the journal was indexed solely in broader databases that draw from non-scholarly sources, such as Google Scholar, or if the article was published before the author obtained naturopathic qualifications (e.g., the author was researching in another discipline before studying naturopathy).

The naturopathic researchers identified through referral were contacted and asked to provide a list of their publications to-date, along with other naturopathic practitioners who had also engaged in research. This process was repeated until no new referrals were received. In the event of no response after at least two attempts at contact, the naturopathic researcher's publications were searched for in PubMed, Google Scholar and ResearchGate. A request for publication lists was also sent by the World Naturopathic Federation (WNF) to naturopathic educational institutions.

Each publication list was systematically examined for articles meeting the eligibility criteria and citations for eligible articles were imported to an EndNote library, where duplicates were removed. The author lists of all eligible articles were examined for naturopathic qualifications and newly identified researchers were then contacted in the same snowballing method.

Data extraction

Data were extracted from the identified articles and input into an Excel spreadsheet.

Geography, affiliation and year of publication

Variables were created for the year the article was published, the WHO Region and country where the research was conducted, and the institutional affiliation and geographical location of each author. Where an article was written without reference to a specific geographic location (e.g., international reviews or commentary articles) the article was coded based on the primary affiliation of the lead author.

Article type or research design

Articles were also categorized based on the research design or article type (e.g., clinical trial/intervention study, editorial, case report). Observational studies were categorized either as a cluster of 'survey, interview, focus group or Delphi studies' or 'other observational/non-interventional studies. Studies reporting *in vivo, in vitro,* or *ex vivo* research were coded as 'basic science'.

Article topic

The primary topic focus of identified articles was determined by establishing which topic was most central to the article's aim or argument and broadly categorized as a: modality, treatment, speciality, condition, non-naturopathic treatment, public health/health services, basic science, education, or research methods/methodology. Any additional topics covered were separately coded as a secondary topic focus with binary variables for each of the above categories as well as health condition and treatment topic areas. Articles were also categorized based on whether they explicitly mentioned naturopathy.

Journal

The journals in which the identified articles were published were coded to individual variables.

Data analysis

Data were analysed in Stata 14.1 and initially explored via descriptive frequencies and percentages. Some data was then regrouped into new variables: (1) articles presenting original research (e.g., clinical trials, reviews/meta-analyses, observational studies, basic science, case reports, protocol papers) or other scholarly article types; (2) author affiliated with a naturopathic institution; and (3) 40 journals with the highest frequency of articles authored by naturopathic researchers.

The temporal changes in (1) original research compared to non-research articles; (2) study designs reported in original research articles; (3) original research published of researchers from different countries; and (4) articles published about the six most frequently reported health condition topics were examined descriptively. This temporal analysis excluded articles published in 2019 as our data did not cover the full year. Chi-square tests were used to interrogate associations between characteristics of articles published between 2006 and 2012, and between 2012 and 2018.

A backwards stepwise regression was conducted to identify the most parsimonious model of characteristics for five different article topics. These included the two most frequent health condition topics, the two most frequent treatment topics, and articles reporting a complex intervention. Unique baseline regression models were developed for each topic category. All the included variables were considered in this stage of analysis and

removed if appropriate as determined by a likelihood ratio test.

The Scimago Journal and Country Rank database (www.scimagojr.com) was used to identify the subject area of all journals in which the included articles were published. A binary variable was generated categorising each journal based on its allocation to the 'Complementary and Alternative Medicine' subject area or another subject area. The journal ranking for each subject area of the 40 journals most frequently identified as publishing articles authored by naturopathic researchers was also determined. Each of these 40 common journals was then coded according to whether it was in the first (Q1), second (Q2), third (Q3) or fourth (Q4) quartile of its allocated subject area. Where a journal was allocated to multiple subject areas, the highest quartile ranking was applied.

Results

Article characteristics

Naturopathic researchers from 22 countries published 2218 manuscripts in peer-reviewed indexed journals. The articles were published between 1987 and 2019 (median=2013) with 80.9% published in the last 10 years (since 2008). Table 16.1 reports the characteristics of included articles. Most articles were published by naturopathic researchers in the America (52.5%) and Western Pacific (28.3%) Regions with 37.2% of studies originating in the USA, 27.8% from Australia and 15.2% from Canada. At least one author identified an affiliation with a naturopathic institution in 32.4% of articles. The most common type of study design or article type were reviews and meta-analyses (23.2%), clinical trials or intervention studies (19.4%), observational studies (surveys, interviews, focus groups, Delphi studies) (17.9%) and commentary or opinion articles (15.6%).

Table 16.2 presents the topic areas of the identified articles. The article topics were predominantly a treatment or intervention (24.0%) a traditional medicine system such as naturopathy or traditional Chinese medicine (19.2%) or public health/health services research (15.8%). A range of health conditions were covered by the included articles. The most frequent health condition article topics were cancer and cancer-related conditions (14.3%) and mental health care and mental illness (12.3%). The most common treatment topic areas were botanical medicine (18.2%) and clinical nutrition (14.3%). Less than 10% explicitly identified naturopathy as related to the article topic (8.1%) or reported on a complex intervention (7.8%).

Temporal changes in the characteristics of published articles

Figure 16.2 presents temporal changes in a range of published article characteristics. Figure 16.2(a) shows an increase in the number of both original research articles and other non-research articles from 2004 onwards. This increase continues steadily through to 2018 for non-research articles but grows substantially for original research articles. Figure 16.2(b) demonstrates changes in the number of articles published about health conditions, focusing on the six most common health conditions identified through our analysis and representing 53.6% of the total included articles. A diversity of clinical topics has been the focus of the articles even in years where a relatively small number of articles were published. Articles about mental health and cancer have been published every year since 1998 and 1999 respectively. Neurological conditions have also been a topic of focus in articles as early as 1998. Female reproductive health has been discussed in articles since 1999 and gastrointestinal conditions since 1997.

The types of original research study designs reported in articles published between 1987 and 2018 indicate an increase in reviews and meta-analyses, and in survey, interview, focus group, and Delphi studies (see Figure 16.2(c)). Chi-square tests indicate a statistically significant difference (p=0.05) between the proportion of original research study designs published in 2006 compared with 2012, demonstrating a reduction in other observational/non-interventional studies (2006: 19.2%; 2012: 9.6%) and basic science (2006: 12.8%; 2012: 2.6%) and an increase in reviews and meta-analyses (2006: 25.5%; 2012: 34.8%). There was no statistically significant difference in original research study design types published in 2012 compared with 2018.

Figure 16.2(d) presents the proportional changes in the geographical location of naturopathic authors between 1987 and 2018. US-based authors published the most peer-reviewed articles between 1996 and 2006. Publications from Canada were identified from 2001 and increased in volume until 2008-9. Authors from India have articles published in 1997 but evidence of articles being published each year is not seen until 2006. Similarly, while there is some earlier publication of articles by Australia-based authors, regular article publication is not evident until 2002. Contributions from authors from Germany were not observed until 2010.

Chi-square tests indicate a statistically significant difference in the proportion of articles published by naturopathic researchers in 2006 compared with 2012 (p=0.006) whereby articles by authors from the USA and Canada increased in volume but reduced proportional

Table 16.1 (below): Characteristics of articles published by naturopathic researchers

Table 16.2 (right): Topic areas of articles published by naturopathic researchers

Characteristics	N	%
WHO Region		
African	8	0.4
Americas	1164	52.5
South-East Asia	204	9.2
European	195	8.8
Eastern Mediterranean	20	0.9
Western Pacific	627	28.3
Study location		
USA	825	37.2
Australia	616	27.8
Canada	338	15.2
India	203	9.2
Germany	185	8.3
Other	51	2.3
Naturopathic researcher location		
USA	823	37.1
Australia	647	29.2
Canada	389	17.5
Germany	204	9.2
India	194	8.8
New Zealand	6	0.3
South Africa	5	0.2
Argentina	1	0.05
Naturopathic institution affiliation	718	32.4
Study design or article type		
Reviews and meta-analyses	515	23.2
Clinical trial/interventional	431	19.4
Surveys, interviews and focus groups (includes Delphi)	396	17.9
Commentary and Opinion articles	347	15.6
Other observational/non-interventional	215	9.7
Letters to the Editor (and replies)	64	2.9
Basic sciences	57	2.6
Editorials	52	2.4
Study protocols	47	2.1
Monographs	15	0.7
Case reports and series	11	0.5
Medical hypotheses	11	0.5
Other	12	0.5

Article topics	N	%
Primary article topic		
Treatment or intervention	533	24.0
System of medicine (naturopathy, nutrition, homeopathy)	426	19.2
Public health/Health Services research	351	15.8
Research method/methodology	221	10.0
Medical speciality	114	5.1
Basic science	99	4.5
Conventional medicine treatment	34	1.5
Education	30	1.4
Health condition topic area		
Cancer and cancer-related condition	316	14.3
Mental health care and mental illness	273	12.3
Musculoskeletal condition	190	8.6
Neurological condition	151	6.8
Gastrointestinal condition	125	5.6
Female reproductive and sexual health	125	5.6
Cardiovascular condition	100	4.5
Endocrine condition	77	3.5
Infectious disease	71	3.2
Respiratory condition	59	2.7
Weight management	46	2.1
Dermatology condition	37	1.7
General wellness and preventive	32	1.4
Urogenital condition	24	1.1
Ageing and cognition-related disorders	20	0.9
Autoimmune condition	8	0.4
Treatment topic area		
Herbal/botanical medicine	403	18.2
Clinical nutrition inc. supplements/nutraceuticals	317	14.3
Explicitly focusing on naturopathy	179	8.1
Yoga	192	8.7
Counselling, Meditation and Mind-Body medicine	165	7.4
Applied nutrition inc. dietary prescription	106	4.8
Manual therapies	91	4.1
Lifestyle and behaviour changes	86	3.9
Acupuncture	53	2.4
Traditional Chinese medicine practices other than acupuncture	42	1.9
Laboratory, pathology or radiology testing	36	1.6
Hydrotherapy	16	0.7
Hormone prescribing	14	0.6
Homeopathy	11	0.5
Ayurvedic medicine other than yoga	11	0.5
Intravenous therapies	5	0.2
Wound care	2	0.1
Chelation therapy	1	0.05
Other naturopathic treatments	26	1.2

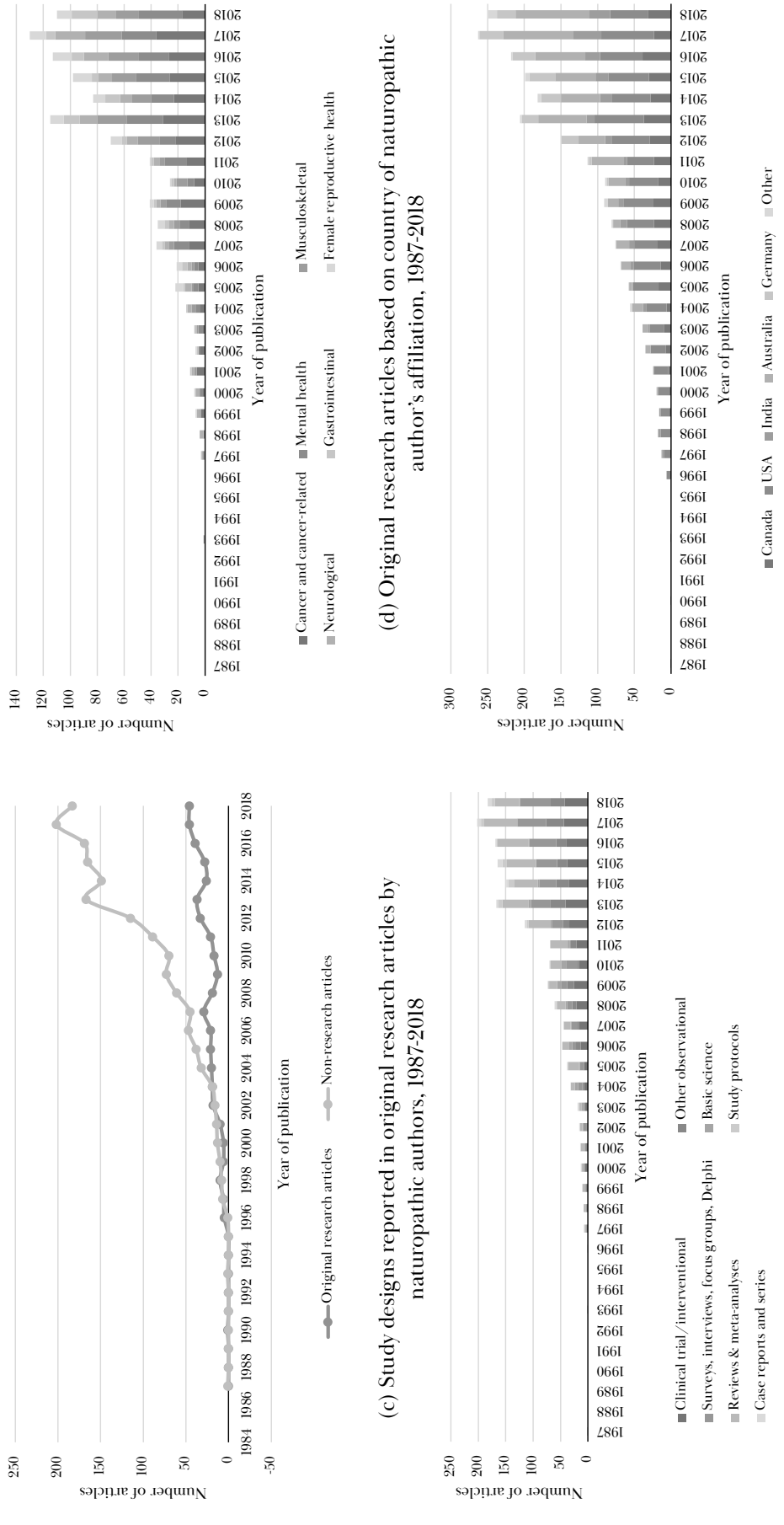

Figure 16.2: Changes in characteristics of peer-reviewed articles by naturopathic authors between 1987 and 2018

to the total number of articles published internationally due to an increase in articles published by authors from Germany and Australia. Between 2012 and 2018 the number of articles published by authors from India and Australia increased substantially while the number of articles published by authors in USA, Canada and Germany remained relatively constant resulting in a statistically significant change in proportional contribution to the total number of articles based on author's country ($p<0.001$).

Characteristics of articles focused on selected topic areas

The backwards stepwise logistic regression identified the characteristics most associated with articles focused on mental health, cancer, herbal medicine, clinical nutrition, and complex interventions (see Table 16.3). Articles focused on mental health were more likely to be conducted in Australia (OR 3.3) and focused on lifestyle behaviour (OR 2.5) or clinical nutrition (OR 1.6) and less likely to examine manual therapy (OR 0.3), be identified as naturopathic research (OR 0.4) or published by a researcher affiliated with a naturopathic institution (OR 0.6). Mental health articles reporting original research were less likely to report survey, interview, focus group or Delphi study research (OR 0.3), other observational or non-interventional research (OR 0.6) or reviews or meta-analyses (OR 0.7) compared to clinical trial or intervention studies.

Herbal medicine articles were more likely to be based empirically in Australia (OR 1.6) and less likely to come from Canada (OR 0.6) or Germany (OR 0.6). These articles were also more likely to cover skin complaints (OR 2.9) and included an author affiliated with a naturopathic institution (OR 2.3) but less likely to discuss neurological complaints (OR 0.5) or mention naturopathy in the manuscript (OR 0.2) compared to other articles. Herbal medicine articles were also more likely to report basic science (OR 5.3) and reviews or meta-analyses (OR 2.3) rather than clinical trials or interventional research but less likely to report surveys, interviews, focus groups and

Table 16.3: Characteristics of articles published by naturopathic researchers about selected topic areas

Research characteristic	Article topic focus				
	Mental health	Cancer	Herbal medicine	Clinical nutrition	Complex intervention
Research location	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Research located in Canada	–	–	0.6 (0.4-1.0)	–	4.9 (2.6-9.2)
Research located in Australia	3.3 (2.4-4.5)	0.1 (0.03-0.1)	1.6 (1.1-2.2)	–	–
Research located in Germany	–	0.5 (0.3-0.8)	0.4 (0.2-0.8)	0.2 (0.08-0.4)	–
Research located in India	–	–	–	0.1 (0.07-0.3)	–
Research located in New Zealand	–	–	–	–	11.2 (1.1-117.5)
Research topic or focus					
Lifestyle behaviour	2.5 (1.4-4.3)	2.0 (1.2-3.5)	–	–	–
Manual therapy	0.3 (0.1-0.9)	–	–	–	4.6 (1.8-11.7)
Clinical nutrition	1.6 (1.1-2.2)	–	–	–	–
Skin/Integumentary	–	–	2.9 (1.1-7.5)	–	–
Neurological	–	–	0.5 (0.3-1.0)	–	–
Musculoskeletal	–	–	–	0.4 (0.2-0.8)	–
Cancer	–	–	–	1.5 (1.0-2.1)	–
Ageing and cognition	–	–	–	4.6 (1.5-13.7)	–
Mental health	–	–	–	1.6 (1.1-2.3)	–
Naturopathic affiliation or recognition					
Researcher affiliated with a naturopathic institution	0.6 (0.4-0.8)	–	2.3 (1.7-3.1)	1.4 (1.0-1.9)	–
Identified as naturopathic research	0.4 (0.2-1.0)	0.4 (0.2-0.8)	0.2 (0.1-0.6)	–	133.8 (71.1-251.8)
Original research design					
Clinical trial/intervention study	Ref	Ref	Ref	Ref	Ref
Survey, interviews, focus groups and Delphi studies	0.3 (0.2-0.4)	–	0.5 (0.3-0.8)	0.2 (0.1-0.3)	4.2 (1.9-9.1)
Other observational/non-interventional study	0.6 (0.4-1.0)	2.0 (1.3-3.0)	0.4 (0.2-0.8)	0.5 (0.3-0.8)	3.3 (1.3-8.3)
Basic science	–	–	5.3 (2.9-10.0)	–	–
Reviews and meta-analysis	0.7 (0.5-1.0)	–	2.3 (1.6 -3.5)	0.7 (0.5-0.9)	–

Delphi studies (OR 0.3) or other observational/non-intervention studies (OR 0.4).

Compared to other articles, those focused on complex interventions were more likely to be located empirically in Canada (OR 4.9) or New Zealand (OR 11.2), to cover manual therapy (OR 4.6), and to explicitly mention naturopathy (OR 133.8). Articles about complex interventions were also more likely to be reporting survey, interview, focus group or Delphi studies (OR 4.2) or other observational or non-interventional research (OR 3.3) rather than clinical trials or intervention studies.

Journals publishing articles written by Naturopathic Practitioners

Almost half (48.4%; n=1074) of all included articles were published in 40 journals (see Table 16.4) and 56.9% of these were published in journals ranked Q1 for at least one subject area, with a further 16.1% published in Q2 journals (data not shown). The remaining one quarter were published in Q3 (22.9%) and Q4 (4.1%) journals.

The journals most frequently identified as publishing articles by naturopathic practitioners are included within the 'Complementary and Alternative Medicine' (CAM) subject area: *Alternative and Complementary Therapies* (n=141), *Journal of Alternative and Complementary Medicine* (n=127), *Advances in Integrative Medicine* (n=69) and *BMC Complementary and Alternative Medicine* (n=61). There was a significantly greater number of articles that explicitly mention naturopathy as a whole system published in journals within the 'CAM' subject area (75.9%) compared to journals from other subject areas (24.0%) (p<.001) (data not shown). Other journals publishing articles by naturopathic practitioners are Q1 for additional subject areas including: 'Medicine (miscellaneous)' (e.g., *PLoS* One [n=21], *The Cochrane Database of Systematic Reviews* [n=29], JAMA [n=11]); 'Oncology' and 'Cancer Research' (e.g., *Journal of Clinical Oncology* [n=29]); and 'Internal Medicine' (e.g., *Annals of Internal Medicine* [n=11]) among others.

Table 16.4: Most common 40 journals in which naturopathic researchers have published articles

Journal title		n	Journal ranking [Category (Quartile)]
1.	Alternative and Complementary Therapies	141	*Complementary and Alternative Medicine (Q3)*
2.	Journal of Alternative and Complementary Medicine	127	*Complementary and Alternative Medicine (Q1)*
3.	Australian Journal of Herbal and Naturopathic Medicine	70	*No data*
4.	Advances in Integrative Medicine	69	*Complementary and Alternative Medicine (Q3)*
5.	BMC Complementary and Alternative Medicine	61	*Complementary and Alternative Medicine (Q1)* *Medicine (miscellaneous) (Q2)*
6.	Complementary Therapies in Medicine	47	*Complementary and Alternative Medicine (Q1)* *Advanced and Specialized Nursing (Q1)* *Complementary and Manual Therapy (Q1)*
7.	Alternative Medicine Review	43	*Complementary and Alternative Medicine (Q1)*
8.	Journal of Clinical Epidemiology	33	*Epidemiology (Q1)*
9.	Evidence-based Complementary and Alternative Medicine	30	*Complementary and Alternative Medicine (Q1)*
10.	Integrative Cancer Therapies	29	*Complementary and Alternative Medicine (Q1)* *Oncology (Q2)*
11.	Journal of Clinical Oncology	29	*Cancer Research (Q1)* *Medicine (miscellaneous) (Q1)* *Oncology (Q1)*
12.	European Journal of Integrative Medicine	27	*Complementary and Alternative Medicine (Q2)*
13.	Alternative Therapies in Health and Medicine	26	*Complementary and Alternative Medicine (Q2)* *Medicine (miscellaneous) (Q3)*
14.	Explore	24	*Complementary and Alternative Medicine (Q2)* *Nursing (miscellaneous) (Q2)* *Chiropractics (Q2)* *Medicine (miscellaneous) (Q3)*
15.	PLoS One	21	*Medicine (miscellaneous) (Q1)* *Agricultural and biological science (miscellaneous) (Q1)* *Biochemistry, genetics and molecular biology (miscellaneous) (Q1)*
16.	International Journal of Yoga	19	*Medicine (miscellaneous) (Q4)*

17.	Complementary Therapies in Clinical Practice	20	*Complementary and Alternative Medicine (Q1)*
18.	The Cochrane Database of Systematic Reviews	17	*Medicine (miscellaneous) (Q1)* *Pharmacology (miscellaneous) (Q1)*
19.	Medical Journal of Australia	15	*Medicine (miscellaneous) (Q2)*
20.	Phytotherapy Research	15	*Pharmacology (Q2)*
21.	BMJ Open	13	*Medicine (miscellaneous) (Q1)*
22.	Journal of Complementary and Integrative Medicine	13	*Complementary and Alternative Medicine (Q2)* *Medicine (miscellaneous) (Q3)*
23.	Focus on Alternative and Complementary Therapies	12	*Complementary and Alternative Medicine (Q4)*
24.	Annals of Internal Medicine	11	*Internal medicine (Q1)* *Medicine (miscellaneous) (Q1)*
25.	Global Advances in Health and Medicine	11	*Medicine (miscellaneous) (Q2)*
26.	JAMA	11	*Medicine (miscellaneous) (Q1)*
27.	Cancer Research	10	*Cancer Research (Q1)* *Oncology (Q1)*
28.	FASEB Journal	10	*Biochemistry (Q1)* *Biotechnology (Q1)* *Genetics (Q1)* *Medicine (miscellaneous) (Q1)* *Molecular biology (Q1)*
29.	Indian Journal of Physiology and Pharmacology	10	*Pharmacology (Q4)* *Physiology (Q4)* *Physiology (medical) (Q4)*
30.	Journal of Evidence-based Complementary and Alternative Medicine	10	*Complementary and Alternative Medicine (Q2)*
31.	Orthopaedic Journal of Sports Medicine	10	*Orthopaedic and sports medicine (Q1)*
32.	Supportive Care in Cancer	10	*Oncology (Q2)*
33.	Systematic Reviews	10	*Medicine (miscellaneous) (Q1)*
34.	Trials	10	*Medicine (miscellaneous) (Q1)* *Physiology (medical) (Q1)*
35.	Canadian Journal of Clinical Pharmacology	9	*Medicine (miscellaneous) (Q2)* *Pharmacology (Q2)* *Physiology (Q3)* *Physiology (medical (Q3)*
36.	Indian Journal of Palliative Care	9	*Health policy (Q3)* *Public Health, Environmental and Occupational Health (Q3)*
37.	Integrative Medicine Research	9	*Complementary and Alternative Medicine (Q3)*
38.	Breast Cancer Research and Treatment	8	*Cancer Research (Q1)* *Oncology (Q1)*
39.	Pediatrics	8	*Pediatrics, Perinatology and Child Health (Q1)*
40.	Planta Medica	8	*Complementary and Alternative Medicine (Q1)* *Analytical chemistry (Q2)* *Drug discovery (Q2)* *Organic chemistry (Q2)* *Pharmaceutical science (Q2)* *Molecular medicine (Q3)* *Pharmacology (Q3)*

Discussion

This study presents the first bibliometric analysis of peer-reviewed articles indexed in journals and published by naturopathic researchers. It indicates naturopaths/naturopathic doctors have published over 2000 peer-reviewed articles since 1987 with notable increases in the last 20 years. This suggests the naturopathic profession has been increasingly engaging with EBM since it was articulated in 1996 [1]. Over the last 25 years there has been a proportional increase in observational study designs and case reports, a nominal increase in clinical trials and systematic reviews, and a decrease in basic science research. This change may reflect a shift in the health research community generally towards pragmatic, real-world evidence to inform practice and policy [12], though other factors such as funding agency priorities should also be considered. However, the analysis also found only 1 in 10 of these publications explicitly mention 'naturopathy'; a finding which may cause external stakeholders to erroneously perceive that there is limited research examining naturopathy/naturopathic medicine [18].

Naturopathic research is published in high ranked journals

Our data also shows naturopathic researchers are publishing in high ranked journals in a range of subject areas but most frequently publishing in journals within the 'CAM' subject area, particularly for articles explicitly mentioning naturopathy/naturopathic medicine. The reason behind this trend is unclear but may suggest a bias around publishing articles about naturopathy/naturopathic medicine within journals in other subject areas. While the scientific community has directed efforts to ameliorating publication bias – whereby delays or omissions in publishing study results skew the shared knowledge on a topic among the scientific and general community [3] – our data reflects challenges faced by authors attempting to publish articles in journals from diverse fields and may instead indicate confirmation bias on behalf of editors and peer-reviewers [4]. For this reason, naturopathic researchers writing articles explicitly about naturopathy/naturopathic medicine may only be successful in publishing within CAM-specific journals.

The correlation between naturopathic practice and naturopathic research

The articles in our study were frequently focused on cancer and cancer-related health conditions and mental health. These topic areas deviate somewhat from the practice characteristics of the international naturopathic community [19]. Based on a survey of 14 countries, patients most commonly seek naturopathic care for musculoskeletal (18.5%) and gastrointestinal (12.2%) conditions, although mental health concerns are also common (11.0%). In contrast, cancer was only reported as a primary concern in 4.6% of cases [19], however it is also worth noting that this previous survey only included naturopaths/naturopathic doctors providing generalist services and excluded naturopaths/naturopathic doctors that had a special clinical interest or focus on specific illness populations. As such, this difference may reflect the fact that naturopaths/naturopathic doctors providing care to individuals with cancer are more likely to provide specialised services for that population. Our analysis also identified a focus by naturopathic researchers on herbal medicine and clinical nutrition. While these treatments are commonly used by naturopaths/naturopathic doctors in clinical practice, the frequency that lifestyle behaviour and dietary changes are prescribed is the same [19] yet have not received the same attention in peer-reviewed articles by naturopathic researchers. This variation may be due to the naturopathic research community prioritising knowledge generation in areas unique to their profession rather than practices widely acknowledged as beneficial to public health, such as diet and lifestyle changes. It also may reflect the focus placed on herbal and nutritional prescription within naturopathic curricula in the countries producing the majority of the articles (Canada, USA, Australia) [20]. It may also reflect external influences on research funding decisions – for example research agency priority setting – which may not necessarily align with clinical areas of focus.

Limitations

This paper offers essential insight to a previously unexamined topic, yet limitations must be considered. While our methodology examines the research undertaken by authors with naturopathic qualifications, its scope does not include naturopathic research conducted by authors from other professions or disciplines, so cannot be considered a comprehensive collation of research relating to naturopathy. Equally, this research should be viewed in context of the 15 000 articles published in naturopathic journals recognized by naturopathic organizations as only one of those journals is indexed on a scholarly database and therefore met the inclusion criteria for this study [21]. As such, this study reports a very focused perspective on the naturopathic professions' commitment to knowledge generation and dissemination. Likewise, some of the authors included in our study have authored works not directly related to the naturopathic profession which were not excluded from our analyses. The snowballing method employed to identify relevant researchers relies on intra-professional networks which may have failed to identify some authors, however, the assistance of the WNF in contacting naturopathic institutions and other

international contacts was intended to ameliorate this substantially. Additionally, it was not within the scope of this paper to assess the level of evidence for naturopathic practice contained within this body of literature, which should be considered an important priority for further investigation.

Summary

The international naturopathic research community has produced peer-reviewed literature for over 30 years and has demonstrated sustained commitment to codifying and synthesising existing knowledge, generating new knowledge, and disseminating this knowledge to the wider clinical and research community. The diversity of topics covered in these publications is noteworthy, and reflects the varied treatments used, conditions managed, and populations supported by naturopathic care globally. In the last 20 years, the volume of peer-reviewed literature authored by naturopaths/naturopathic doctors has grown exponentially and much of this output is produced by naturopathic researchers affiliated with naturopathic educational institutions and research facilities. As the profession continues to mature within countries and internationally, the skills, experience and infrastructure offered by this history of research activity has the potential to significantly impact practice and policy if it is applied in a manner that meets the needs of the wider profession and healthcare more generally.

Literature Cited

1. Sackett, D.L., Rosenberg, W.M., Gray, J.M., Haynes, R.B., and Richardson, W.S., *Evidence based medicine: what it is and what it isn't*. 1996, British Medical Journal Publishing Group.
2. Brownson, R.C., Colditz, G.A., and Proctor, E.K., *Dissemination and implementation research in health: translating science to practice*. 2017: Oxford University Press.
3. Dickersin, K., *The Existence of Publication Bias and Risk Factors for Its Occurrence*. Journal of the American Medical Association, 1990. **263**(10): p. 1385-1389.
4. Mahoney, M.J., *Publication prejudices: An experimental study of confirmatory bias in the peer review system*.
5. Grimshaw, J.M., Eccles, M.P., Lavis, J.N., Hill, S.J., and Squires, J.E., *Knowledge translation of research findings*. Implementation Science, 2012. **7**(1): p. 50.
6. Steel, A., Foley, H., D'Souza, J., Adams, J., and Wardle, J., *Knowledge Dissemination by the Naturopathic Profession: A Bibliometric Analysis of Naturopath-Authored, Peer-Reviewed Publications*. Journal of Alternative and Complementary Medicine, 2021.
7. Ng, J.Y., *Insight into the characteristics of research published in traditional, complementary, alternative, and integrative medicine journals: a bibliometric analysis*. BMC Complementary Medicine and Therapies, 2021. **21**(1): p. 185.
8. Morin, C. and Gaboury, I., *Osteopathic empirical research: a bibliometric analysis from 1966 to 2018*. BMC Complementary Medicine and Therapies, 2021. **21**(1): p. 196.
9. Jagtenberg, T., Evans, S., Grant, A., Howden, I., Lewis, M., and Singer, J., *Evidence-based medicine and naturopathy*. The Journal of Alternative and Complementary Medicine, 2006. **12**(3): p. 323-8.
10. Steel, A., Rapport, F., and Adams, J., *Towards an implementation science of complementary health care: some initial considerations for guiding safe, effective clinical decision-making*. Advances in Integrative Medicine, 2018. **5**(1): p. 5-8.
11. Adams, J., Steel, A., and Reid, R., *A Holistic Approach to Implementation Science (IS): Broadening the IS Gaze to Traditional, Complementary and Integrative Medicine, in Public Health and Health Services Research in Traditional, Complementary and Integrative Health Care: International Perspectives*, J. Adams, et al., Editors. 2019, World Scientific: Singapore. p. 99-118.
12. Schloss, J., McIntyre, E., Steel, A., Bradley, R., Harnett, J., Reid, R., Hawrelak, J., Goldenberg, J., Van De Venter, C., and Cooley, K., *Lessons from outside and within: Exploring advancements in methodology for naturopathic medicine clinical research*. The Journal of Alternative and Complementary Medicine, 2019. **25**(2): p. 135-140.
13. Standish, L.J., Calabrese, C., and Snider, P., *The Naturopathic Medical Research Agenda: The Future and Foundation of Naturopathic Medical Science*. The Journal of Alternative and Complementary Medicine, 2006. **12**(3): p. 341-345.
14. Steel, A. and Adams, J., *Approaches to clinical decision-making: A qualitative study of naturopaths*. Complementary Therapies in Clinical Practice, 2011. **17**: p. 81-84.
15. Steel, A. and Adams, J., *The application and value of information sources in clinical practice: an examination of the perspective of naturopaths*. Health Information & Libraries Journal, 2011. **28**(2): p. 110-8.
16. Adams, J. and Steel, A., *Future-proofing the field of naturopathy research: nurturing international research leadership in an evolving profession*. The Journal of Alternative and Complementary Medicine, 2019. **25**(2): p. 133-4.
17. World Naturopathic Federation Education Committee. *Correlation between Education and Credentials*. 2018; Available from: www.worldnaturopathicfederation.org.
18. Steel, A., Bradley, R., and Wardle, J., *Naturopathic Research: Prevalent, Relevant, But Largely Hidden in Plain Sight*. Journal of Alternative and Complementary Medicine, 2019. **25**(2): p. 123-124.

19. Steel, A., Foley, H., Bradley, R., Van De Venter, C., Lloyd, I., Schloss, J., Wardle, J., and Reid, R., *Overview of international naturopathic practice and patient characteristics: results from a cross-sectional study in 14 countries*. BMC Complementary Medicine and Therapies, 2020. **20**(1): p. 59.
20. Wardle, J., Steel, A., Casteleijn, D., and Bowman, D., *An evidence-based overview of naturopathic practice in Australia*. Australian Journal of Herbal and Naturopathic Medicine, 2019. **31**(1): p. 9.
21. World Naturopathic Federation. *WNF Naturopathic Journal Report*. 2020; Available from: http://worldnaturopathicfederation.org/wp-content/uploads/2021/01/WNF_Survey_Journal_Articles.pdf.