



SUBMISSION

RESPONSE TO THE *NATIONAL PREGNANCY CARE GUIDELINES* (*NUTRITION, PHYSICAL ACTIVITY AND WEIGHT*) CONSULTATION

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Prepared by: The Naturopaths and Herbalists Association of Australia

In partnership with: Australian Research Centre in Complementary and Integrative Medicine - University of Technology Sydney, School of Pharmacy – University of Sydney, and School of Pharmacy and Pharmacology – University of Tasmania.



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1 BACKGROUND

1.1 ABOUT THE NHAA

The NHAA is the peak professional association for the naturopathy and Western herbal medicine profession in Australia. Established in 1920, it is also the oldest professional association of complementary therapists in the country. The NHAA represents around 2,000 practitioners and is a member of the World Naturopathic Federation (WNF) which represents practitioners globally.

Our members provide primary care services to people suffering both acute and chronic disease. We use a combination of therapies, including diet, exercise, stress management, supplementation and herbal medicine formulations to deliver holistic treatments. We work alongside other health professionals to support conventional treatment. We play an important role in public health, including the quality use of medicines by Australian consumers.

The primary aims of the NHAA are to:

- Promote, protect and encourage the learning, knowledge and service delivery of naturopathic and Western herbal medicine
- Disseminate such knowledge through available media and networks
- Encourage the highest ideals of professional and ethical standards
- Promote naturopathic and Western herbal medicine as safe and effective public healthcare
- Engage with legislative tools and their representatives as they relate to the practice of naturopathic and Western herbal medicine in Australia

The vision of the NHAA is:

- Practitioners and the practice of naturopathic medicine and Western Herbal medicine are fully integrated into the primary healthcare system in Australia
- The NHAA is recognised as the peak body for naturopathic and Western Herbal medicine
- Naturopathic and Western Herbal medicine is accessible to all
- The integrity of the profession of naturopathic and Western Herbal medicine is maintained
- The standards and quality of education of the professions continue to be promoted
- Career opportunities and research pathways for naturopathic and Western Herbal medicine professionals are developed and maintained
- The integration of traditional knowledge and evolving science is continued

The NHAA publishes the quarterly *Australian Journal of Herbal & Naturopathic Medicine (AJHNM)*. The AJHNM publishes material on all aspects of medical herbalism and naturopathic practice including philosophy, phytochemistry, pharmacology and clinical application of medicinal plants. The NHAA also holds annual seminars throughout Australia, with the Herbal and Naturopathic International Conference held biennially (recently in March 2019 the *11th Herbal & Naturopathic International Conference* kicked off the NHAA's 100th year Celebrations). Since its inception, the NHAA and its members have been at the forefront of naturopathic and Western Herbal medicine and have been influential in areas ranging from education and practice to ethical, regulatory and industry standards.

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2 RESPONSE TO THE PREGNANCY CARE GUIDELINES CONSULTATION

2.1 THE ROLE OF NATUROPATHS IN THE CARE OF PREGNANT WOMEN IN AUSTRALIA

Naturopathy is a traditional system of medicine originating from Europe.¹ Almost all Australian naturopathic practitioners regularly prescribe lifestyle modifications (99.2%), nutritional supplements (97.8%), herbal medicines (tablets: 90.8%; liquid herbal medicines: 88.4%) dietary changes (90.1%), and physical activity (82.5%) as therapeutic tools in the management of health conditions in their patients.² Furthermore approximately 7.2% of Australian pregnant women report consulting a naturopath for pregnancy-related health concerns³ and 70.1% of naturopaths in Australia reporting regularly ('sometimes' or 'often') treating pregnant women.² Additional analysis has explored the practice behaviours of naturopaths who regularly treat pregnant women had similar practice behaviours to other naturopaths in Australia.⁴ For this reason, the current review of the nutrition, physical activity and weight components of the National Pregnancy Care Guidelines is of great interest to the Australian naturopathic profession.

2.2 COMMENTS AND RECOMMENDATIONS

2.2.1 Overall document

The National Pregnancy Care Guidelines (Nutrition, Physical Activity and Weight) is an important document to support the provision of evidence-based care to pregnant women in Australia. Overall, the proposed revisions to the Guidelines strengthens the document. We have, however, identified some two specific points which we believe require close attention from the Expert Working Group prior to finalizing this document. These relate specifically to the 'Probiotics' and 'Herbal Preparations' sections.

2.2.2 Probiotics

The World Health Organisation (WHO) defines probiotics as "*live microorganisms which when administered in adequate amounts confer a health benefit on the host*". In order to be listed as a probiotic supplement, the WHO criteria have to be met, and supported by sufficient published scientific evidence to support a health benefit. Probiotics are named and studied according to their genus, species and strain. Therefore, the term probiotic can only be considered an 'umbrella term' for multiple microbes with some shared but not well defined clinical use.

Therefore, general meta-analyses are usually not recommended on probiotics, as therapeutic differences between species and strains will be obscured when one assumes all probiotics are the same and treat them as a single agent in an analysis.⁵⁶ Each strain of probiotic must be considered as a potentially unique therapeutic agent, different in action than other strains – even those within the same species. The probiotic literature is replete with examples of these strain-specific differences.^{78,910} Thus, some probiotic strains will be effective where others are not; and some will be more effective for specific conditions than others. Analysing all probiotics as if they are a single agent will obscure such differences in conditions like Group B Streptococcus colonisation, bacterial vaginosis, and gestational diabetes.

Accurate probiotic meta-analyses can be done where these differences are taken into account, by performing sub-group analyses on specific strains for example,¹¹ or strain-specific meta-analyses.¹² Furthermore, specific species and strains of probiotics administered at specific stages of gestation have been shown to reduce the incidence of eczema in infants at a higher risk of developing the condition.¹³¹⁴¹⁵ In addition, recent evidence suggests that specific species and strains of probiotics taken in the 2nd and or 3rd trimester of pregnancy may improve insulin resistance in women with gestational diabetes.¹⁶¹⁷¹⁸ For the evidence guide to be more accurate and clinically useful, it is essential that strain level data is examined and discussed in the guidelines. In addition, this section could include information on the sources and benefits of probiotic bacteria in foods and drinks.

With this in mind, we recommend the following to the Expert Working Group:

Undertake an extensive review of the literature reporting on the effects of probiotic use on pregnancy health outcomes is commissioned. The results of this review could inform detailed content that provides clinicians on the appropriate and safe use of probiotic use in pregnancy.

2.2.3 Herbal Preparations:

We propose that there are two areas requiring further attention in the nutritional considerations section as it relates to herbal preparations.

The first pertains to an appropriate engagement with the evidence of safety of herbal products. As with pharmaceuticals, there are ethical challenges associated with the conduct of clinical trials in populations of pregnant women. As such, safety data is largely based on animal studies and observational epidemiological research. Due to limitations to herbal medicine commercialisation, alongside ubiquitous and perennial availability and use of herbal preparations, most research examining the safety of herbal preparations is drawn from epidemiological research rather than animal studies.

Observation studies have been collated and analysed in a clinical text which assessed 123 herbs against the pharmaceutical safety criteria. The text reports 11 herbs in category A; 24 in category B1; 47 in category B2; 17 in category B3; 13 in category C; eight in category D and three in category X.¹⁹ Additional reviews examining herbal medicine safety during pregnancy identify diverse risk levels and adverse effects, with significant variations between individual herbal medicines.²⁰ Such diversity often occurs between herbal species within the same genus. For example, the level of active constituents vary significantly between *Echinacea angustifolia* and *Echinacea purpurea*. This variability extends to the part used, e.g. aerial parts (i.e. flowering tops) and the roots. In this regard, herbal preparations should be viewed as a class of medicine, rather than a homogenous group of treatments.

For this reason, health professionals providing advice to any member of the community with regards to the use of herbal medicine to manage specific health complaints should be adequately trained. At a minimum, trained in Latin binomial, common names, botanical description, part(s) used, primary relevant constituents, actions, indications, cautions, contraindications, regulatory status in Australia, clinically relevant herb/drug/nutrient interactions, preparation forms, and dosage. This should be delivered as part of a minimum of a degree-level qualification with a core focus on herbal medicine pharmacology,

pharmacognosy and treatment and inclusive of a minimum of 400 hours of supervised clinical experiences involving diagnosis and treatment of health conditions using herbal medicines.ⁱ

For this reason, we recommend the following sentence be added to the beginning of the section on herbal preparations.

“Each herbal preparation needs to be considered as a potentially unique therapeutic agent, different in action from any other herbal medicine; even those within the same genus or produced from different parts of the same plant. The use of herbal preparations by pregnant women should be supervised by an appropriately qualified health professional.”

Secondly, we propose there are two herbal medicines that warrant explicit mention in the guidelines that are currently overlooked. The first of these is Raspberry Leaf (*Rubus idaeus*). While current research does not describe the prevalence of *R. idaeus* use by Australian pregnant women, approximately 52.5% of Australian midwives have recommended *R. idaeus* to the women in their care.²¹ As the target audience for the Guidelines is maternity care providers, we argue that attention to this herbal medicine is important. The current research evidence regarding the clinical effect or safety of *R. idaeus* use during pregnancy is limited. Small studies have examined clinical effects of *R. idaeus* but significant methodological limitations preclude firm clinical guidelines being based on their findings. However, there is also limited evidence to indicate safety concerns associated with *R. idaeus*,¹⁶ although it is allocated to Category A based on animal studies.¹⁵ In light of these gaps in clinical evidence, we recommend the following statement be added to the guidelines (addition is underlined):

“There is insufficient evidence on the efficacy and safety of Echinacea, elderberry, and raspberry leaf during pregnancy (Holst et al 2014, Balbontin et al 2019)”

We also propose specific mention of *Hypericum perforatum* (St John’s Wort). *H. perforatum* is often recommended by midwives for postpartum depression.²² One in five Australian women with children aged 24 months or less are diagnosed with depression. More than half of these women report that their diagnosed depression was perinatal, representing an estimated 111,000 Australian mothers being diagnosed with depression, and of these 56,000 with perinatal depression.²³

Meta-analyses of extensive clinical research including 3038 patients confirms the efficacy of *H. perforatum* is comparable to selective serotonin reuptake inhibitors for mild-moderate depression.²⁴ Research has demonstrated that pharmaceutical antidepressants, such as

ⁱ Details of minimum education standards for herbal medicine and naturopathic practitioners in Australia are outlined in NHAHA Course Accreditation System (CAS) (<https://www.nhaa.org.au/education/course-accreditation-system-cas>) and Australian Register of Naturopaths and Herbalists Education Standards (<http://www.aronah.org/course-accreditation/>)

selective serotonin reuptake inhibitors, increase the risk of preterm birth.²⁵ In contrast, a study examining the use of *H.perforatum* by pregnant women found no increased risk of preterm birth.²⁶ A further systematic review of animal studies investigating *H.perforatum* in pregnancy and lactation identified significant methodological limitations which limit the use of these studies to inform clinical decision-making regarding *H.perforatum* in pregnancy.²⁷ There is also no clinical research examining the efficacy of *H.perforatum* in the management of perinatal depression.²⁸ However, there is strong justification for its inclusion in the Guidelines given its widely reported benefits in generalised depression alongside the high prevalence of perinatal depression in Australian women. As such, we propose an additional statement be added to the Guidelines as follows:

“The efficacy of Hypericum perforatum (St John’s Wort) is comparable to selective serotonin reuptake inhibitors in the management of mild to moderate depression with less reported adverse effects in the general population (Ng et al, 2017). However, there is little clinical research examining the efficacy of H. perforatum in perinatal depression (Deligiannidis and Freeman, 2014). The evidence about the safety of H.perforatum use in pregnancy is incomplete. With only one available human study, reporting no increased risk of preterm birth (Kolding et al 2015), and methodological weaknesses in available rodent studies (Avila et al, 2018) the use of existing evidence to inform guidelines for pregnant women is limited. Pregnant women’s use of H.perforatum for depression should be undertaken with caution and supervised by an appropriately qualified health professional.”

2.3 CONCLUSION

The NHAHA supports the current review of the National Pregnancy Care Guidelines (Nutrition, Physical Activity and Weight). We would like to particularly highlight the following point:

- Advice pertaining to herbal and nutritional products must be based on a sophisticated and nuanced understanding of the treatments being examined and the relevant research evidence.
- Health professionals providing advice to pregnant women regarding herbal preparations should be adequately trained.

The NHAHA appreciates the opportunity to contribute to the ongoing development of the Guidelines and in doing so, continue to support the health and wellbeing of pregnant women in Australia.

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- ¹ World Naturopathic Roots Committee. (2017). *WNF White Paper: Naturopathic Philosophies, Principles and Theories*. Retrieved from Canada: http://worldnaturopathicfederation.org/wp-content/uploads/2015/12/White-Paper_FINAL.pdf
- ² Steel, A., Schloss, J., Leach, M., & Adams, J. (2020). The naturopathic profession in Australia: A secondary analysis of the Practitioner Research and Collaboration Initiative (PRACI). *Complementary Therapies in Clinical Practice*, <https://doi.org/10.1016/j.ctcp.2020.101220>.
- ³ Steel, A., Adams, J., Sibbritt, D., Broom, A., Gallois, C., & Frawley, J. (2012). Utilisation of complementary and alternative medicine (CAM) practitioners within maternity care provision: results from a nationally representative cohort study of 1,835 pregnant women. *BMC pregnancy and childbirth*, 12(1), 146.
- ⁴ Unpublished data from the Practitioner Research and Collaboration Initiative (PRACI) practice-based research network. Analysed by A. Steel (amie.steel@uts.edu.au). Data available on request.
- ⁵ Marteau, P. (2011). "Evidence of probiotic strain specificity makes extrapolation of results impossible from a strain to another, even from the same species." *Annals of Gastroenterology & Hepatology* 2(1): 34-36.
- ⁶ McFarland, L. V., C. T. Evans and E. J. C. Goldstein (2018). "Strain-Specificity and Disease-Specificity of Probiotic Efficacy: A Systematic Review and Meta-Analysis." *Front Med (Lausanne)* 5: 124.
- ⁷ Bibiloni, R., P. F. Perez and G. L. De Antoni (1999). "Will a high adhering capacity in a probiotic strain guarantee exclusion of pathogens from intestinal epithelia." *Anaerobe* 5: 519-524.
- ⁸ Tallon, R., S. Arias, P. Bressollier and M. C. Urdaci (2007). "Strain- and matrix-dependent adhesion of *Lactobacillus plantarum* is mediated by proteinaceous bacterial compounds." *J Appl Microbiol* 102(2): 442-451.
- ⁹ Bao, Y., Y. Zhang, Y. Zhang, Y. Liu, S. Wang, X. Dong, Y. Wang and H. Zhang (2010). "Screening of potential probiotic properties of *Lactobacillus fermentum* isolated from traditional dairy products." *Food Control* 21(5): 695-701.
- ¹⁰ Dietrich, C. G., T. Kottmann and M. Alavi (2014). "Commercially available probiotic drinks containing *Lactobacillus casei* DN-114001 reduce antibiotic-associated diarrhea." *World journal of gastroenterology* 20(42): 15837-15844.
- ¹¹ McFarland, L. V., C. T. Evans and E. J. C. Goldstein (2018). "Strain-Specificity and Disease-Specificity of Probiotic Efficacy: A Systematic Review and Meta-Analysis." *Front Med (Lausanne)* 5: 124.
- ¹² Hawrelak, J. A., D. L. Whitten and S. P. Myers (2005). "Is *Lactobacillus rhamnosus* GG effective in preventing the onset of antibiotic-associated diarrhea: a systematic review and meta-analysis." *Digestion* 72: 51-56.
- ¹³ Zuccotti G, Meneghin F, Aceti A, et al. Probiotics for prevention of atopic diseases in infants: systematic review and meta-analysis. *Allergy*. 2015;70(11):1356-1371. doi:10.1111/all.12700
- ¹⁴ Bertelsen RJ, Brantsæter AL, Magnus MC, et al. Probiotic milk consumption in pregnancy and infancy and subsequent childhood allergic diseases. *J Allergy Clin Immunol*. 2014;133(1):165-71.e718. doi:10.1016/j.jaci.2013.07.032

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- ¹⁵ Wickens K, Stanley TV, Mitchell EA, et al. Early supplementation with *Lactobacillus rhamnosus* HN001 reduces eczema prevalence to 6 years: does it also reduce atopic sensitization?. *Clin Exp Allergy*. 2013;43(9):1048-1057. doi:10.1111/cea.12154
- ¹⁶ Kijmanawat A, Panburana P, Reutrakul S, Tangshewinsirikul C. Effects of probiotic supplements on insulin resistance in gestational diabetes mellitus: A double-blind randomized controlled trial. *Journal of diabetes investigation*. 2019 Jan;10(1):163-70.
- ¹⁷ Pan J, Pan Q, Chen Y, Zhang H, Zheng X. Efficacy of probiotic supplement for gestational diabetes mellitus: a systematic review and meta-analysis. *The Journal of Maternal-Fetal & Neonatal Medicine*. 2019 Jan 17;32(2):317-23.
- ¹⁸ Han MM, Sun JF, Su XH, Peng YF, Goyal H, Wu CH, Zhu XY, Li L. Probiotics improve glucose and lipid metabolism in pregnant women: a meta-analysis. *Annals of Translational Medicine*. 2019 Mar;7(5).
- ¹⁹ Mills S and Bone K 2005 *The Essential guide to Herbal Safety*, Elsevier, Philadelphia, USA
- ²⁰ Balbontín Y, Stewart D, Shetty A, Fitton , McLay J, 2019 Herbal Medicinal Product Use During Pregnancy and the Postnatal Period: A Systematic Review, *Obstetrics and Gynecology*, 133(5): 920–932.
- ²¹ Mollart L, Skinner V, Adams J, Foureur M. Midwives' personal use of complementary and alternative medicine (CAM) influences their recommendations to women experiencing a post-date pregnancy. *Women Birth*. 2018;31(1):44-51. doi:10.1016/j.wombi.2017.06.014
- ²² Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2018.
- Available from: <https://www.ncbi.nlm.nih.gov/books/NBK501922/>
- ²³ Adhikari, P., & Cooper-Stanbury, M. (2012). Perinatal depression: Data from the 2010 Australian national infant feeding survey. AIHW. <https://www.aihw.gov.au/reports/primary-health-care/perinatal-depression-data-from-the-2010-australia/related-material>
- ²⁴ Ng, Q. X., Venkatanarayanan, N., & Ho, C. Y. X. (2017). Clinical use of *Hypericum perforatum* (St John's wort) in depression: a meta-analysis. *Journal of affective disorders*, 210, 211-221.
- ²⁵ Lund N, Pedersen L, Henriksen T, 2009 Selective serotonin reuptake inhibitor exposure in utero and pregnancy outcomes *Archives of Pediatrics and Adolescent Medicine* 163(10):949-54.
- ²⁶ Kolding L, Pedersen L, Henriksen T, Olsen J, Grzeskowiak L, 2015 *Hypericum perforatum* use during pregnancy and pregnancy outcome, *Reproductive Toxicology* Vol 58 pp. 234–237
- ²⁷ Avila, C., Whitten, D., & Evans, S. (2018). The safety of St John's wort (*Hypericum perforatum*) in pregnancy and lactation: A systematic review of rodent studies. *Phytotherapy Research*, 32(8), 1488-1500.
- ²⁸ Deligiannidis, K. M., & Freeman, M. P. (2014). Complementary and alternative medicine therapies for perinatal depression. *Best practice & research Clinical obstetrics & gynaecology*, 28(1), 85-95.