

Complementary medicine & national prevention strategies

Submission to the
National Preventative Health Taskforce
in response to the discussion paper
Australia: The Healthiest Country by 2020

January 2009

Highlighting complementary medicine research

NICM is an Australian Government initiative, supported by the
NSW Government and hosted by the University of Western Sydney



NICM
THE NATIONAL INSTITUTE OF
COMPLEMENTARY MEDICINE

www.nicm.edu.au

Acknowledgements

NICM would like to acknowledge the assistance of Professor Paul A. Komesaroff in the preparation of this submission.

Foundation partners

The National Institute of Complementary Medicine was established in June 2007 with seed funding from the Australian Government through the Department of Health and Ageing and the NSW Government through the Office for Science and Medical Research, Department of State and Regional Development to provide leadership and support for strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians. Hosted by the University of Western Sydney at its Campbelltown campus, our role includes working with national and international partners to identify and develop sources of accurate information on complementary medicines and practices, including evidence of safety, efficacy and cost-benefits.

Introduction

The National Institute of Complementary Medicine (NICM) welcomes the commitment by the Australian Government to reforming the healthcare system to address the challenges presented by lifestyle behaviours and increased prevalence of chronic disease through a greater focus on health maintenance and disease prevention.

The Institute values the opportunity to contribute to the development of strategic directions to achieve these goals and endorses the approach adopted by the Taskforce in its first discussion paper. In particular, the need for:

- (i) Long-term cultural reform;
- (ii) A communal partnership approach;
- (iii) Multidimensional strategies, including information, education, incentives and targeted interventions that address the complex biological and social factors impacting on health risks, including obesity;
- (iv) Sustained and evidence based initiatives; and
- (v) A framework and infrastructure to coordinate effort and measure and report on performance and outcomes, including establishment of an agency to fulfil these roles on a national basis.

There is growing evidence for the value of complementary medicine in maintaining good health and the prevention and management of chronic disease associated with obesity, including diabetes and cardiovascular disease.¹ Complementary medicine interventions demonstrating safety, efficacy and cost-effectiveness should form part of the national preventative health framework, and those interventions showing strong potential included in preventative health research programs.

NICM was established with Commonwealth and State funding in June 2007 and is hosted by the University of Western Sydney. The Institute provides leadership and support for strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians. Its objectives include facilitating appropriate integration of complementary medicine within the Australian health system.

The Institute notes the stated intention of the Taskforce to work in collaboration with agencies focusing on prevention and would welcome opportunities to discuss our directions and programs and their alignment with Taskforce proposals.

¹ This submission comments particularly on the risk of obesity although complementary medicine interventions are available for other risks addressed by the Taskforce in its discussion paper.

Recommendations

That the Taskforce:

1. *Supports* research into the role of complementary medicine in preventing and managing obesity and other major health risk factors and associated impacts, having regard to the research priority development process being undertaken by NICM.
2. *Promotes*, in addition to safety, efficacy and cost-effectiveness, research into complementary medicine interventions that focuses on:
 - (i) The impact of interventions (or a combination of interventions) on achieving and maintaining wellness and on the incidence and progress of specific diseases associated with obesity, such as diabetes and cardiovascular disease.
 - (ii) Population studies on the factors affecting choice and take up of strategies to prevent or address obesity; and the impact and sustainability of interventions.
 - (iii) Targeted research with disadvantaged communities and workplaces at high risk of obesity and with a traditionally lower rate of use of complementary medicine (e.g. lower income groups).
 - (iv) Targeted research with disadvantaged communities at high risk of obesity that have a tradition in, but may not be utilising, complementary medicines.²
3. *Facilitates* inclusion of complementary medicine interventions demonstrating safety, efficacy and cost-effectiveness in the package of prevention reforms going forward.
4. *Supports* research into initiatives that utilise cultural mores to encourage activities to prevent and manage obesity that may fall outside traditional constructs of exercise (such as dancing).

² Complementary medicine is taken to include health and medical systems, practices and products not currently recognised a part of conventional or mainstream western medicine practiced by medical practitioners, nurses and allied health professionals and includes indigenous medicines and practices. For a full definition of complementary medicine, go to www.nicm.edu.au.

5. *Notes* work being undertaken by the Institute through partnerships to:
- (i) Strengthen research capacity and facilitate translation of research effort.
 - (ii) Develop and refine research priorities for complementary medicine, with an emphasis on wellness; nationally identified risks (including obesity) and major areas of disease burden.
 - (iii) Develop a minimum data set of measures relating to safety, efficacy and cost-effectiveness of complementary medicine interventions to ensure relevant and consistent approaches to health outcomes data collection.
 - (iv) Undertake economic modelling of selected complementary medicine interventions.
 - (v) Support basic and translational research through its collaborative research centre program and research into integrated healthcare practice.³
 - (vi) Develop resources and provide information about current evidence to consumers and clinicians to support informed decision making.
6. *Utilises* the knowledge and expertise within the complementary medicine research sector in developing and implementing initiatives, for example, development of wellness and outcome indices and measures.

³ Integrated care (or integrated medicine) is taken to mean complementary medicine (CM) used together with mainstream western medicine

Background

Complementary medicine is a significant and mostly privately funded component of the healthcare landscape which has substantial potential in achieving greater health and wellbeing at reduced cost; facilitating disease prevention and in addressing the burden of chronic disease.

The role of complementary medicine is reflected in developments such as the National Heart Foundation *Position Statement on Fish, fish oils, polyunsaturated acids and cardiovascular health*.

Other interventions demonstrating strong evidence of safety, efficacy and cost-effectiveness should form part of the national preventative health framework.

However, in order to capitalise on its most promising advantages in terms of health outcomes, consumers, clinicians and government alike require more clarity and certainty around the clinical benefits of many complementary medicine interventions, their comparative cost-effectiveness and the quality controls associated with their development and use. Pathways for intelligent and effective integration in clinical services are also needed. Strengthening the evidence base around complementary medicine through a focused research agenda will also contribute to the national innovation agenda through industry partnerships and development opportunities.

The National Institute of Complementary Medicine (NICM) was established with Commonwealth and State funding in June 2007 and is hosted by the University of Western Sydney. The Institute provides leadership and support for strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians.

As part of its brief, NICM is developing basic and translational research capacity, resources and partnerships to help build the complementary medicine research sector to a stage where it is robust, well co-ordinated and sufficiently established to be effectively participating in mainstream research processes and delivering clinical evidence and outcomes relevant to national priorities, including health outcomes and systemic reforms. The work of the Institute is undertaken in collaboration with a range of stakeholders, including mainstream and complementary medicine researchers and clinicians, government, industry, insurers, professional associations, foundations and corporations supporting health and medical research and consumers. The Institute wants to ensure that its efforts align with and contribute to the work of the Taskforce going forward.

NICM supports the directions and proposed package of measures proposed by the Taskforce. The Taskforce discussion paper *Australia: The Healthiest Country by 2020* clearly articulates the health and economic costs of obesity and associated health risks (diabetes, cardiovascular disease etc), so these will not be repeated here. The discussion paper persuasively argues for the need for a range of strategies to address obesity and other major health risks, and the need for these strategies to be collaborative, sophisticated, well-coordinated and both sustained and sustainable. The latter requires a strategic *action* research program and the capacity to define, measure, and report on challenges, effort and outcomes.

The proposed co-ordination agency is a sensible and welcome proposal to coordinate effort within and *across* risk factors that frequently share a common aetiology and response framework. Such an agency would also provide a mechanism to promote and build on the many excellent proposals already available.⁴

The complexity of factors influencing the development of obesity and responses to management strategies require an equally complex and multi-dimensional response. An evidenced based approach will also benefit from a sound understanding of available knowledge and a research framework including principles and priorities. These issues are dealt with in turn.

1. Multi-dimensional approach

The issues and circumstances confronting overweight people are in many ways analogous to those faced by these other disadvantaged groups. Like them, obese people identify themselves and are identified by others as members of a distinct community. They report common health needs and social and personal experiences related to their condition, many of which are subject to social and cultural influences; the quality of their health care is affected by their membership of this group.

However, there are important differences. Unlike many other minority groups obesity raises little public compassion or respect. Obese people often feel disempowered and isolated and tend not to associate deliberately with each other or provide mutual support and solidarity and there are few if any programmes providing economic and social support to people identified with the condition. It is possible that these differences will significantly inhibit attempts to mobilize the community to develop its own capacity to address its problems and therefore both exacerbate the predicaments of obese people and frustrated attempts to develop effective responses.

⁴ See, for example, *Time for Action*; The National Heart Foundation and The National Stroke Foundation; 2008.

Despite the widespread awareness of the health problems related to obesity medical and public health interventions have so far had little impact, most likely in part because of their failure of these interventions to address underlying causes, in part owing to the inadequacy of the biological and other strategies themselves and in part as a result of a failure to address the concerns of obese people themselves.

To help develop effective, precisely targeted interventions there is a need for a deep understanding of the physiology of obesity, the social and cultural influences shaping the obesity epidemic and the experiences of obese people, including their responses to attempts at public health campaigns and medical therapy.

Effective responses to the problem must reflect and acknowledge this complexity, and include both preventive and therapeutic dimensions. As the discussion paper rightly identifies, preventive strategies should include a focus on children and the influences to which they are exposed through television and the popular media, information received at school etc.

However, social marketing campaigns and limitations on advertising materials enforced through legal means will not address or contain underlying forces such as the impact of globalised culture and rampant consumerism. For this, more subtle cultural interventions that draw on local cultural strengths and empower both communities and individuals within them are needed. Such interventions will of necessity be long-term and ongoing process and will therefore require careful attention to the conditions for sustainability. To achieve this opportunities exist to establish links with other issues of contemporary social concern such as threats to the environment and the loss of localised community identities.

The response to the obesity epidemic must therefore take into account the dimensions of both culture and biology. Research into each of these requires specific and appropriate methodologies, as does the development of complex intervention strategies that operate in both domains. A detailed appreciation of the pre-existing literature regarding the cultural origins and impact of obesity and the role of biological, physical and mind-body approaches to the problem is an essential starting point for the development of such strategies.

2. Research priorities framework

Complementary medicine research is a strategic priority in Australia's National Health and Medical Research Council plan and one of the Institute's roles is to articulate national priorities in basic and translational complementary medicine research. In its first year of operation, NICM developed overarching research priorities, informed by national stakeholder consultations.

These priorities are research that:

- (i) Has the potential to impact positively on the health and wellbeing of all Australians. Emphasis is given to areas of high burden of disease where preliminary evidence is strong and demonstrates likelihood of positive impact.
- (ii) Elucidates safety, efficacy and cost effectiveness of complementary medicine and translates this into policy and practice.
- (iii) Investigates methodological issues relevant to the complex nature of complementary medicine, including development of methodological tools which may impact on our understanding of the whole practice, concepts and mechanisms underpinning complementary medicine.

Going forward, these higher level priorities need to be translated into a workable five year plan that will help better concentrate research effort both within the NICM collaborative centres and across the field more generally.

Establishing clear and agreed research priorities is a challenging task. Key considerations are the need for a timely, cost-effective and manageable process given the breadth of the field and volume of material, which have stalled past initiatives even into *single* disease areas. On advice from its Scientific Advisory Committee, NICM developed and is implementing a process to help develop the priorities that surmounts these challenges.

Preliminary work was undertaken in the second half of 2008 in the areas of cancer; cardiovascular disease; diabetes, obesity and metabolic syndrome; neurological disorders (dementia) and wellness promotion, with parallel work being undertaken by the NICM Collaborative Centre for Traditional Chinese Medicine. Examples of opportunities relating to obesity, diabetes and metabolic syndrome are included at Appendix 1.

The process being undertaken is not simply a list of potential areas of interest, and involves mapping current evidence for interventions against the burden of disease and nationally identified priorities and risks (e.g. obesity) and generating recommendations for areas of further work. These areas are then being mapped against mainstream and complementary medicine research strengths in the field in Australia and overseas with reference to the infrastructure, capacity and methodological requirements for undertaking the work and refined into a further set of priorities.

The process is also serving to identify and engage mainstream research and clinical networks in specific disease areas that will help lay the foundation for future partnerships.

Feedback on work to date through a broader consultation process will be undertaken in the first quarter of 2009. The findings will be presented at a forum in June 2009.⁵

⁵ The process being undertaken has also attracted international interest and a presentation will be given on the process and preliminary outcomes at the International Congress of Complementary Medicine Research being held in the USA in May 2009. Feedback will be incorporated into the Australian forum planned for June 2009.

Appendix one

Examples of opportunities: Complementary medicine in the management of obesity, diabetes and metabolic syndrome

The following provides examples of interventions of interest from preliminary work undertaken. The examples are not exhaustive or presented in any particular order of priority. The heading represents a heterogeneous collection of medical conditions and risk factors that both predispose to other conditions and reflect their outcomes. This includes disease areas also subject to the priority-setting process being undertaken by NICM, such as cancer, cardiovascular disease; and musculoskeletal conditions.

It should also be noted that some opportunities have been identified that NICM expects are in the province of or will be canvassed in more detail by other agencies. This includes for example, low-carbohydrate high-protein diets.⁶

1. Focus

Preliminary work in the prioritisation process has focused on:

- Treatment opportunities not currently satisfactorily dealt with by conventional medicine and specific disease complications in diabetes.⁷ The latter includes complications caused by long term medication use, side effects or disease progression (vascular ulceration, retinopathy, nephropathy, neuropathy and cardiovascular dysfunction. For example, after 15 years of diabetes, 70% of patients experience renal impairment).
- Reducing drug dependence.
- Preventing the onset of disease through novel approaches to pre-diabetes and obesity.
- In terms of herbal medicines, prioritising those ready for clinical evaluation, including studies of safety, efficacy and cost effectiveness, with quality control/standardisation essential.

⁶ A recent systemic review of 13 RCTs of low-carbohydrate/high-protein (LC/HP) diets in the management of obesity and its comorbidities has demonstrated that diets containing carbohydrate content ≤ 60 g/day, fat $\leq 30\%$ and protein $\geq 25\%$ of total energy are effective in reducing body weight at 6 months and in diminishing calculated cardiovascular disease risk at 1 year. More evidence and longer-term studies are needed to assess the cardiovascular benefits from the weight loss achieved using these diets including, the documentation of clinical endpoints. Several such studies are currently underway, e.g. St. Luke's-Roosevelt Hospital Center, Rockefeller University, New York, although much additional work remains to be done. [Hession M, Rolland C, Kulkarni U, Wise A, Broom J. Systemic review of randomized controlled trials of low-carbohydrate vs. low-fat/low-calorie diets in the management of obesity and its comorbidities. *Obes Rev* 2008; Aug 11]

⁷ The process has recognised, for example, that that biomedical research into vaccinations and stem cells in curing Type 1 diabetes is well covered.

2. Examples of interventions warranting further consideration

Examples (ingestive):

- Phytosterols (e.g. *Guggulsterone*, *Diosgenin*, *Campesterol*, *Sitosterol*, *Stigmasterol* and *Brassicasterol*) and fish oils in the management of blood lipids.
- Green tea, catechins and polyphenolic compounds for a range of anti-obesity effects.
- Whole herbs, including *Centella asiatica*, *Punica granatum*, Ginger, Ginseng, Bitter melon, *Salacia oblonga*.
- Grape seed extract - prevention of beta cell deterioration in early type 2 diabetes or pre-diabetes.

Examples (non ingestive):

- Yoga (Ayurvedic medicine), Qi Gong (Chinese medicine) and graded therapeutic exercise in the prevention of type 2 diabetes and management of obesity.

Examples of interventions identified for consideration in managing diabetic complications:

- Allithiamine – prevention of neuropathy.
- Lipoic acid – prevention of neuropathy.
- Ginseng and a range of Chinese herbs - general prevention of diabetes complications.

Examples of allied strategies

- Targeted information strategies to facilitate an *awareness* of complementary medicine and the *availability* and *usefulness* of specific interventions among people with diabetes (both Type 1 and Type 2) and health practitioners.
- Development of a register of qualified health professionals who could assist with accredited lifestyle programs to prevent type 2 diabetes.
- Development of clinical guidelines.

Examples of evidence and need for further research

Green tea

Green tea, green tea catechins, and epigallocatechin gallate (EGCG) have been demonstrated in cell culture and animal models of obesity to reduce adipocyte differentiation and proliferation, lipogenesis, fat mass, body weight, fat absorption, plasma levels of triglycerides, free fatty acids, cholesterol, glucose, insulin and leptin, as well as to increase beta-oxidation and thermogenesis. Studies conducted with human subjects report reduced body weight and body fat, as well as increased fat oxidation and thermogenesis and thereby confirm findings in cell culture systems and animal models of obesity. There is still a need for well-designed and controlled clinical studies to validate the existing and encouraging human studies. Since EGCG is regarded as the most active component of green tea, its specific effects on obesity should also be investigated in human trials.

Yoga

Data regarding the role of non-substance based clinical techniques in the prevention and management of obesity and its related conditions, with the possible exception of depression and other mental health conditions, are relatively limited. *Yoga* is a mind-body practice that usually incorporates *pranayam* (breathing exercise) *asanas* (postures), and meditation. Yoga originated in India but has long been popular in Asian countries and more recently in the West. Studies have suggested that regular yoga practice is associated with attenuated weight gain, especially among individuals who are already overweight. Also, adults with obesity have a lower prevalence of the use of yoga therapy, as with other forms of exercise. As well as possibly reducing (or limiting increases in) body-mass index, yoga practice may also be effective in reducing of the risk of some obesity-related conditions, such as diabetes mellitus, hypertension, and hyperlipidemia. To date, however, data in this field are very limited and there has been no systemic review of the extant studies or large scale trials.