




A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS OF HEALTH RELATED ISSUES WITHIN AN ABORIGINAL CONTEXT

Michael Saini, PhD and Ashley Quinn, PhD, MSW

NATIONAL COLLABORATING CENTRE
FOR ABORIGINAL HEALTH



CENTRE DE COLLABORATION NATIONALE
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For further information or to obtain additional copies, please contact:

National Collaborating Centre for Aboriginal Health
3333 University Way
Prince George, BC, V2N 4Z9
Tel 250 960 5250 Fax 250 960 5644
Email nccah@unbc.ca
www.nccah-ccnsa.ca

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EXECUTIVE SUMMARY



Objective

The objective of this systematic review was to describe the frequency and design of randomized controlled trials (RCTs) specifically addressing Aboriginal health. The purpose was to determine the extent that RCTs have been used as a research methodology within Aboriginal communities, to explore the types of health-based interventions assessed using RCTs, and to assess the relevancy and applicability of RCTs within Aboriginal communities.

Methodology

The review included electronic searching of databases up to 2010. The databases searched included MEDLINE; Psychological Abstracts (PsycINFO, PsycLIT, ClinPsychological subset); EMBASE; ASSIA (applied social sciences); ERIC; CINAHL; Social Work Abstracts; Social Sciences Abstracts; Social Service Abstracts; Dissertation Abstracts International (DAI); Bibliography of Native North Americans; America: History and Life; CSA FRANCIS (Humanities & Social Sciences); International Bibliography of the Social Sciences (IBSS) and Library and Archives Canada: Aboriginal Peoples. Studies were included in this review if they: 1) addressed an Aboriginal health problem; 2) had a formal description of methods and results; 3) and used an RCT to compare the health effects of an intervention using a control group.

Results

Twenty-two (22) studies were identified that met the inclusion criteria. They addressed a number of health-related issues, including obesity, diabetes, mental health issues, parenting, child conduct problems, and substance use. The majority of studies were conducted in the United States and Australia, with few exceptions in Canada.

Conclusions

Results of this review of RCTs of health-related issues in Aboriginal communities build on the work by Morris (1999) who found and reviewed 13 RCTs related to Aboriginal health in Australia more than a decade ago. No Canadian RCTs of health-related issues in Aboriginal communities were found prior to 1999. Given the general explosion of RCTs in health sciences in the past decade and the dearth of studies within Aboriginal communities found in this review, this suggests that Aboriginal peoples are underrepresented in RCTs of health issues. Rather than sidestepping Aboriginal communities, researchers should consider participatory methods for conducting RCTs with Aboriginal communities to increase the cultural relevance of these designs and to enhance the process and implementation of RCTs for optimal recruitment, engagement and retention of participants in trials, while being sensitive to the social values and cultural traditions of Aboriginal communities.



1. BACKGROUND



Aboriginal¹ people represent approximately 3.8% of Canada's total population with over 50 percent under the age of 24 (Statistics Canada, 2006). Despite the negative effects of colonization and policies such as residential schools and the Indian Act, many Aboriginal communities have made impressive improvements in their overall health and well-being (Ontario Aboriginal Health Advocacy Initiative, 2003). Disadvantageous socioeconomic conditions created and maintained by colonization and marginalization are often cited as primary factors for the current lower health outcomes experienced in many Aboriginal communities (ibid.). Prior to contact with Europeans, historical documents suggest that Aboriginal peoples were in good health (Royal Commission on Aboriginal Peoples, 1996), and it was not until the contact period that many became ill and died from infectious diseases that were foreign to them, such as influenza, polio, measles, smallpox and diphtheria (ibid.). As reported in the Royal Commission on Aboriginal Peoples (1996):

Skeletal remains of unquestionably pre-Columbian date... are, barring a few exceptions, remarkably free from disease. Whole important scourges [affecting Europeans during the colonial period] were wholly unknown... There was no plague, cholera, typhus, smallpox or measles. Cancer was rare, and even fractures were infrequent.... There were, apparently, no nevi [skin tumours]. There were no troubles with the feet, such as fallen arches. And judging from later acquired knowledge, there was a much greater scarcity than in the white population of... most mental disorders, and of other serious conditions (p.103).

Since contact with Europeans, Aboriginal communities have struggled with higher levels of health conditions than the Canadian population as a whole (Ontario Aboriginal Health Advocacy Initiative, 2003). Currently, Aboriginal peoples have the poorest health levels in Canada. For example, they have shorter life expectancies and higher infant mortality rates, and are more likely to experience inadequate nutrition, insufficient housing, unsafe sanitation, unemployment, poverty, racism

¹ The term "Aboriginal" refers to individuals who identify with at least one Aboriginal group, i.e. First Nations (North American Indian), Métis or Inuit, and/or those who report being a Treaty Indian or a Registered Indian as defined by the Indian Act of Canada and/or who are members of an Indian Band or First Nation (Statistics Canada, 2006).

and marginalization, all significant factors that predict determinants of health and well-being (ibid.). Given the disparities in factors that predict health and well-being between Aboriginal and non-Aboriginal Canadians, it would seem logical that there would be a number of clinical trials within Aboriginal communities to find the most effective interventions to remedy these disparities (Morris, 1999).

1.1 The Use of Randomized Controlled Trials for Evidence-Based Practice

The advent of evidence-based practice has meant that practitioners and policy makers are increasingly using results of rigorous and high-quality studies to correctly identify interventions that can either prevent health-related risks for targeted communities or effectively intervene to ameliorate health-related outcomes (Littell, Corcoran & Pillai, 2008). As a result, there has been a steady increase in effectiveness-based studies to assess health-related outcomes and the promotion of promising health-related practices. There has also been a recent commitment by a number of organizations to transfer evidence gleaned from effectiveness-based studies and reviews to inform practice and policy decisions. The Cochrane Collaboration, for example is a non-profit organization of over ten thousand volunteers in over 90 countries worldwide to review the effects of health care interventions through randomized controlled trials (RCTs) and systematic reviews (Cochrane Collaboration, 2008).

Explanatory RCTs are considered the 'gold standard' for evaluating intervention efficacy because the methodology allows for the determination of a cause and effect relationship between the treatment and pre-defined outcomes (Fink & McCloskey, 1990), which require pre- and post-test comparisons of intervention participants and control groups. There is general

agreement that studies using a tightly controlled experimental design are the most promising for detecting estimates of treatment effect because they are the least prone to biases (Chalk & King 1998; Rubin, 2008) and will provide the best evidence of a causal relationship between an intervention and an outcome (Petticrew & Roberts, 2006). RCTs address limitations in non-random control trials and cross-sectional studies because they account for confounding factors by converting known and unknown covariates to random variables. The randomization element of RCTs (being randomly assigned to intervention groups) ensures there are no systematic differences between participants in all intervention groups that may affect the outcome. The intervention type (experimental treatment, control – treatment as usual [TAU] or alternative treatment) remains unknown to participants and clinicians alike for the duration of the trial, thereby limiting the influence of bias (preconceived views) on the assessment of outcomes. Not only can RCTs demonstrate the value of an intervention, activity or product, they can also measure the added benefit of a simple or complex intervention.

Unfortunately, many have taken evidence-based practice to mean that practice and policy should be based solely on the evidence produced by RCTs. As Ramchandani, Joughin and Zwi (2001) suggest, "this narrow approach, whilst not one envisaged by the original proponents of evidence-based medicine (Sackett, Rosenberg, Gray, Haynes & Richardson, 1996), is a common misunderstanding of the paradigm" (p. 60). Gambrill (1999) asserts that "evidence-based practice (EBP) draws attention to the kind of evidence needed to rigorously test different kinds of practice-related claims. What is needed to critically appraise data regarding a question depends on what kind of question it is" (p. 344). Although RCTs have been considered the 'gold standard' for questions of effectiveness, there are serious gaps in

indiscriminately applying RCTs to health-related interventions, as many interventions are not amenable to research designs involving RCTs. For example, RCTs may be more amenable to individual treatment approaches than population-based interventions (Ogilvie, Egan, Hamilton & Petticrew, 2005). RCTs are also not ideal for exploring process and implementation factors, nor are they the best design for exploring participants' experiences of their involvement in the interventions included in RCTs.

Pragmatic RCTs are also becoming increasingly relevant to health science research and the number of studies using this approach has grown during the last 15 years. Pragmatic RCTs are considered "more relevant to policymakers than efficacy trials because they generally use the same criteria of effectiveness as those used by policymakers – namely, user perceptions, important and visible outcomes, usual health service planning entities, and typical service limitations" (Treweek et al., 2006: 1127). Unlike explanatory RCTs that primarily use laboratory conditions, pragmatic RCTs focus on testing two comparable interventions at their optimal levels in a natural, real-life setting (routine clinical practice) to determine if one intervention is better than another, and the degree of beneficial impact in real life clinical practice (Godwin et al., 2003; Roland & Torgerson, 1998; Schwartz & Lellough, 1967).

Including contextual factors and participant withdrawal into the analyses, pragmatic RCTs are able to "absorb" all withdrawals that occur under practical conditions (Schwartz & Lellough, 1967: 643). Intention-to-Treat analysis includes analyzing all participants in the original intervention group assigned, even if participants withdraw from the study or change groups (Roland & Torgerson, 1998). Instead of rigorously controlling for and ensuring intervention compliance as in explanatory RCTs, pragmatic RCTs

measure intervention compliance in the analysis as an outcome (Godwin et al., 2003). While explanatory RCTs focus on maintaining internal validity by rigorously controlling all variables, often at the cost of external validity where the results are not generalizable to the larger population, pragmatic RCTs are challenged to maintain a balance between internal and external validity (Fransen et al., 2007; Godwin et al., 2003). Please see Abernethy et al., (2006) and Fransen et al. (2007) for full accounts of how the integrity of internal and external validity was established and addressed in two pragmatic RCT methodologies.

Similar to explanatory RCTs, pragmatic RCTs also use randomization into intervention groups to control for selection bias and an independent assessor who is blind to treatment assignment to control for biased outcome assessment (Roland & Torgerson, 1998). Explanatory RCTs focus on capturing intervention effects on a homogeneous population while pragmatic RCTs reflect “the variations between patients that occur in real clinical practice

and therefore aims to inform therapeutic choices among prescribing physicians” (Helms, 2002: 5). Furthermore, pragmatic RCTs do not assess one outcome or subset of outcomes such as in explanatory RCTs; rather they consider a wide range of health gains that are not as easily measured in explanatory RCTs (Helms, 2002). The Trial Protocol Tool (Trewick et al., 2006) was developed through the Pragmatic Randomized Controlled Trials in Health Care (PRACTIHC) to assist researchers and investigators in writing research protocols for pragmatic RCTs. The tool brings together and combines the current knowledge on research protocols with contemporary research examples into one source, with additional useful resources including a sample size calculator, a basic Gantt chart builder, checklists, leaflets, brochures, and articles (Trewick et al., 2006). Emphasizing the importance of good research protocols to high-quality RCTs, researchers are encouraged to utilize the Trial Protocol Tool in their own teaching and research, enabling high-quality written protocols.

1.2 Randomized Controlled Trials in Aboriginal Communities

There remains a substantial debate about whether RCTs are feasible to study health issues relevant to Aboriginal communities and if methods are inconsistent with Aboriginal cultural and traditional worldviews (Morris, 1999; Blackstock, 2009). However, not including Aboriginal communities in effectiveness-based interventions to assess health outcomes limits the transferability of knowledge gained from these studies and further marginalizes Aboriginal communities from the knowledge regarding the benefits and limitations of health-based interventions. Rather than sidestepping Aboriginal communities from health-based research studies, researchers should consider ways to conduct research that meets the values, expectations and traditions of Aboriginal communities to increase the cultural relevance of research (Blackstock, 1999).

RCTs are not entirely absent as a method in studies involving Aboriginal peoples (Boyd-Ball, 2003; Sibthorpe et al., 2002), yet, we know very little about the use of RCTs in Aboriginal communities. The use of RCTs can provide valuable insight for assessing health-based interventions applicable for Aboriginal peoples living in communities. Results from RCTs can help community leaders and administrators make decisions about types of facilities, programming needs, and the allocation of scarce resources (Kenny, 2002). The critical question is not whether RCTs should play a role in health-based decisions, but how to efficiently and effectively establish this role with First Nations, Inuit and Métis communities and peoples.





2. PURPOSE



The purpose of this review of RCTs within Aboriginal communities is to describe the frequency and design of RCTs specifically addressing Aboriginal health. This review will determine the extent that RCTs have been used as a

research methodology within Aboriginal communities, explore the types of health-based interventions assessed using RCTs, and assess the relevancy and applicability of RCTs within Aboriginal communities.

3. METHODOLOGY

This review of RCTs was guided by protocols and standards established by the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008). A systematic review is an application of precise, transparent and replicable procedures that limit bias in the collection, critical appraisal, summary, and analysis of all relevant studies on a topic (Wade, Turner, Rothstein, & Lavenberg, 2006). The Cochrane and Campbell Collaborations are international networks of researchers, practitioners, and others working to develop, maintain and disseminate systematic reviews on the effects of prevention and intervention programs in the areas of social welfare, crime and justice, and education.

The protocol developed by these collaborations uses conventional systematic review methods that involve sensitive searching, systematic screening, and independent quality assessment. Published and unpublished materials relevant to the topic of interest are retrieved using an iterative electronic search strategy of applying and modifying key terms. Published materials include journal articles, reference lists, conference proceedings, and government documents. Unpublished or grey literature, such as informally published conference papers and research reports, may also be included and are located through contacting key authors and examining individual issues of key journals.

3.1 Search Strategy for Identification of Relevant Studies

In order to be comprehensive, various information retrieval strategies were utilized during the systematic review process. Electronic searching of databases included MEDLINE; Psychological Abstracts (PsycINFO, PsycLIT, ClinPsychological subset); EMBASE; ASSIA (applied social sciences); ERIC; CINAHL; Social Work Abstracts; Social Sciences Abstracts; Social Service Abstracts; Dissertation Abstracts International (DAI); Bibliography of Native North Americans; America: History and Life; CSA FRANCIS (Humanities & Social Sciences); International Bibliography of the Social Sciences (IBSS) and Library and Archives Canada: Aboriginal Peoples. Multiple search terms were used for each database to locate potential studies and were focused on three specific areas: Indigenous people in Canada and internationally; RCTs; and, health care and the delivery of health services. For a list of example search terms, please refer to Appendix A.

Based on the information retrieval strategy, 1116 titles were retrieved and of these, 380 were excluded because they were duplicates (see Table 1). The remaining 736 titles were screened based on the inclusion criteria by the first author of this review and a trained research assistant. The full article was reviewed if the study met the following inclusion criteria: 1) addressed an Aboriginal health problem; 2) had a formal description of methods and results; and 3) used a randomized controlled trial to compare the health effects of an intervention with a control group. A single author reviewed and extracted summary data from the included articles in order to maintain consistency. The term “Aboriginal” in

this review refers to First Nations, Inuit and Métis peoples. Indigenous is used interchangeably with Aboriginal, usually in international contexts. Where sources refer to specific groups, such as First Nations, the terminology of the source was retained. The decision to include international studies instead of limiting the review to the Canadian context was made in order to locate all potential RCTs that have been conducted within Aboriginal communities. Given that Morris (1999) completed a similar review of studies published prior to 1999 in Australia, the current information retrieval included RCTs published subsequent to Morris’s (1999) study up to the year 2010 to explore what, if any, progress had

been made since that time. Additional searches were conducted to retrieve RCTs completed prior to 1999 with and/or in Aboriginal communities² in Canada, but none were found.

3.2 Data Extraction

Summary data were extracted from each article that met the inclusion criteria (see Appendix B). The most important features of the study were extracted including: the location of the study; the sample; the health-related issue; the intervention, design, and major results; and the strengths and limitations of the study.

Table 1: Results of Electronic Database Searches

Electronic Database	# Hits
MEDLINE	395
PsycINFO	41
EMBASE	509
ASSIA (applied social sciences)	8
ERIC	8
CINAHL	130
Social Work Abstracts	0
Social Sciences Abstracts	7
Social Services Abstracts	3
Dissertation Abstracts International (DAI)	15
Bibliography of Native North Americans	0
Library and Archive Canada: Aboriginal Peoples	0
Results	1,116
Total Duplicates	380
Actual Total (without duplicates)	736

² The search for RCTs did not distinguish between studies that were “with” versus “in” Aboriginal communities, or that included Aboriginal people but were not conducted in Aboriginal communities; for example, urban Aboriginal RCTs. The distinction of these is addressed in the results of the paper.



4. RESULTS



Twenty-two (22) studies were identified that met the inclusion criteria. All studies included in this review were published after Morris' (1999) review of thirteen RCTs involving Aboriginal communities. In combining the results from this current review with the RCTs found in Morris' (1999) review, the results suggest that only 35 such RCTs have been published worldwide in the past four decades.³ A search on Medline (health sciences) for "RCT" in the general population suggests that there are considerably more RCTs published every year compared to those found within Aboriginal communities (see Table 2).

4.1 Location of Studies

The majority of studies were conducted in the United States and Australia, with only six studies found in Canada (Christofides, Schauer, Sharieff, & Zlotkin 2005; Bhattacharyya, 2007; Harrison & Veronneau, 2010; Lawrence et al., 2008; Martens, 2001; Tobe et al., 2006). Based on these Canadian studies, the Aboriginal peoples represented in these RCTs included Ojibway-Cree First Nation communities in Ontario, the Sagkeeng First Nation Ojibwa communities in

Manitoba, the First Nation People registered with the Battlefords Tribal Council in Saskatchewan, and one Inuit community in Nunavut Territory. No Métis communities were included in the RCTs. As well, no studies were conducted west of Saskatchewan or east of Ontario, and only one was conducted in the North. The limited use of RCTs across Canada severely hinders the generalizability and transferability of knowledge gained from RCTs across Aboriginal communities; this represents a substantial gap in our understanding of the evidence of health-based interventions in these communities. Given the heterogeneity of Aboriginal peoples and communities, there is a need to consider the potential effectiveness of health-related interventions within local contexts and across demographic considerations.

4.2 Participants Included in the RCTs

Thirteen of the twenty-two studies involved children, while the remaining involved adults as participants. In comparison to Morris' (1999) study which found twelve of the thirteen RCTs were

³ Morris's (1999) review included studies published between 1973 and 1998.

Table 2: “RCT” as a Keyword Searched in Medline and Included Studies by Year

Year	# Hits in Medline	RCTs with Aboriginal communities
2000	3,067	0
2001	3,820	1
2002	4,423	1
2003	4,950	2
2004	5,430	2
2005	5,458	2
2006	5,895	3
2007	5,517	3
2008	6,163	2
2009	6,968	3
2010	7,370	3
Total	59,061	22

conducted with Aboriginal children, the current review suggests that more attention is now being placed on the health needs of adults compared to a decade ago. The number of participants varied from 16 to 5240, which reflects that RCTs are being conducted at the individual (Christofides et al., 2005; Govula, Kattelman, & Ren, 2007; Kattelman, Conti, & Ren, 2009; Martens, 2001; Walkup et al., 2009), community (Bhattachryya, 2007; Couzos, Lea, Mueller, Murray, & Culbong, 2003; Davies et al., 2003; Harrison & Veronneau, 2010; Himes & Ring, 2003; Lawrence et al., 2008; Stevens et al., 2003), and population-based (Calver et al., 2005) levels of analysis.

4.3 Types of Health Outcomes

The RCTs included in this review all addressed important health problems and made significant contributions to the literature regarding Aboriginal health. Studies addressed a number of health-related issues, including obesity, diabetes, cholesterol management, iron deficiency,

mental health issues, prenatal care, chronic suppurative otitis media, parenting, child conduct problems, and substance use. The variability of health-related outcomes addressed with Aboriginal populations suggests that RCTs can be applied to a variety of settings and for a variety of interventions.

4.4 Types of Interventions

Although the cultural relevancy of the interventions was not clear in many of the studies, there were a number of RCTs that were transparent about how the interventions had been modified to be culturally adaptive to the local community. Kattelman et al. (2009), for example, assessed the effectiveness of culturally adapted educational lessons based on the Medicine Wheel model for nutrition. Likewise, Govula et al. (2007) assess a culturally adapted nutrition curriculum on fruit and vegetable consumption with lessons based on the “Medicine Wheel Nutrition for Native Americans.”

Turner, Richards, and Sanders (2007) include a culturally sensitive adaptation of the mainstream Group Triple-P intervention for parents to help manage child behaviours. Others have attempted to be more culturally sensitive by including trained Aboriginal community members as intervention facilitators (Sibthorpe et al., 2002; Valery et al., 2010; Walkup et al., 2009). Barlow et al. (2006) assess the effectiveness of prenatal care, including child care knowledge and skills, and introduce several cultural adaptations, including style, graphics, delivery, and content. Cultural adaptation was achieved in this study through a community-based participatory process where community members were given the opportunity to provide input into the design of the intervention.

4.5 Use of the Control Group

The use of a control group in RCTs poses challenges in community settings because the idea of randomly assigning participants to wait for an intervention or to receive care as usual may not be accepted by the community (Turner et al., 2007). Turner et al. (2007) suggest that researchers need to incorporate flexibility to adapt or alter their research design into their evaluation projects to make them viable if originally negotiated procedures become unacceptable within a community. Although there is a general concern that RCTs can manipulate individuals into placebo groups (Andersson, 2008), the use of health-based RCTs among Aboriginal peoples most often provide the ‘control group’ with usual care or delayed intervention (after post-test), thereby not withholding care from the control group (Bhattachryya, 2007; Lawrence et al., 2008; Martens, 2001; Nagel, Robinson, Condon, & Trauer, 2009; Sawchuk et al., 2008). Lawrence et al. (2008), for example, conducted a RCT of childhood caries in twenty First Nations communities in the Sioux Lookout Zone in Northwestern

Ontario by providing all caregivers with oral health counseling, while children in the treatment group additionally received fluoride varnish. Likewise, Sawchuck et al. (2008) randomly assigned participants into either the activity monitoring control or the activity monitoring with a pedometer intervention. In Martens' (2001) RCT of breastfeeding education in Sagkeeng First Nation Ojibwa community in Manitoba, 22 students in the intervention group received the education sessions and then the same intervention was provided to 23 students in the control group at post-test to ensure all participants eventually received the same education.

4.6 Involvement of Community Members

Candace Uhlik (2006) suggests that there is a continuum of approaches for including Aboriginal peoples and communities in the research process. On one end of the continuum, researchers involve the full participation of Aboriginal peoples living in the community as planners, implementers, analyzers, and reporters of research results. On the other end, Aboriginal peoples are not directly involved in the research process, but they

are nevertheless directly or indirectly affected by the methods used in the study, the results, and by subsequent action taken. Even in these situations, researchers should consult with Aboriginal representatives, since the process and/or the outcomes of the research will likely affect the lives of Aboriginal communities and peoples.

The results of this review found that there was a range of involvement of Aboriginal peoples and communities in the research process. Participation ranged from research subjects to being fully engaged in the research process within a participatory research approach. For the most part, community members were consulted or informed of the research. Christofides et al. (2005), for example, obtained consent forms from First Nation communities and the Chief Council. RCTs that used a community participatory approach research model noted that participants seemed satisfied with their involvement in the research and were more likely to engage in the process. Couzos et al. (2003) used a community controlled model of research that shifted the balance of control towards those being researched. Engagement and active involvement of the community were considered vital for the success of the RCTs in these communities.

4.7 Integration of Qualitative Interviews

Studies that included qualitative interviews seemed to benefit from the additional information provided by the participants regarding the interventions and the process of being involved in the study. Davies et al. (2003), for example, reports that by conducting interviews at the end of the intervention, additional information about what works best with families can be gathered and evaluated, then applied to future prevention research and practice. Sibthorpe et al. (2002) highlighted that patients who were approached about their drinking were embarrassed or resentful, and did not want to discuss their drinking habits. Interviews with staff similarly revealed a discomfort among Aboriginal health workers with approaching patients about their drinking, with many of them expressing concerns about the ethics of randomly allocating the study groups. They thought the research project was a hassle.

4.8 Quality of RCTs

Although challenges of conducting RCTs within Aboriginal communities were noted, the design and process of the studies appeared appropriate in most cases. Reporting on the process and implementation of the studies seems to have greatly improved from a decade ago (Morris, 1999). Studies included in this review are generally consistent in reporting recruitment procedures, sampling, the process of randomization, theoretical basis for interventions, fidelity of interventions, rates of compliance, and rates of attrition and retention. There continues, however, to be limited reporting of the role of the community, ethical issues regarding randomization and the use of control groups, the cultural adaptation of the interventions to the local context, and issues regarding sustainability of the interventions within Aboriginal communities.



5. DISCUSSION



In efforts to better understand the current health conditions of Aboriginal communities, there has been a growing recognition of distinct health-based Aboriginal research approaches so that these methods include the histories, socio-cultural realities, health conditions and lived experiences of Aboriginal communities and peoples (Aboriginal Education Research Centre, 2007; Tuhiwai Smith, 1999). Despite this recognition, there has been little attention devoted to providing a methodological process for RCTs to provide space for the voices of Aboriginal communities and peoples while assessing the overall effectiveness of health-based interventions. While more community members are now involved as co-researchers and partnerships between Aboriginal communities and researchers are now more common, it remains rare for RCTs to be initiated, driven and implemented by Aboriginal communities. Central to the purpose of conducting research within Aboriginal communities should be to ensure that the research process is performed in ways that are considered ethical, respectful, applicable, sympathetic, authentic, beneficial and relevant to the experiences of Aboriginal peoples (CIHR, 2007; Porsanger, 2004). Ethical guidelines for research with Aboriginal communities have been established (CIHR, 2007; Schnarch, 2004) and these seem to work

well with qualitative research. However, these guidelines do not adequately address methodological issues arising from the use of RCTs within Aboriginal communities.

It is important that criteria and guidelines be created for doing research with Aboriginal peoples that are culturally relevant and credible. It is also important to ensure that the development of methods for conducting RCTs in Aboriginal communities are consistent with general standards for conducting randomized controlled trials (CONSORT: Consolidated Standards of Reporting Trials) in order to increase the validity of these methods to assess the effectiveness of interventions. To increase the cultural relevance of RCTs within Aboriginal communities, there are several methodological issues that need to be resolved. These include:

- prioritizing RCTs given the scarce resources to conduct these complex research designs
- the process for involving all stakeholders
- issues regarding the level of randomization (individual, community, population)
- ethical issues regarding withholding the intervention to the 'control group'
- issues regarding the involvement of community members as facilitators of the interventions under study

- the involvement of community members in the assignment of participants to treatment and control groups
- the involvement of community members in data collection and analysis
- issues regarding the feasibility and relevancy of culturally adapting interventions to the local community
- issues regarding the sustainability of interventions at the end of the studies, and
- the resources needed to sustain the interventions beyond the research study.

Results of this review of RCTs of health-related issues in Aboriginal communities build on the work by Morris (1999) who found and reviewed 13 studies more than a decade ago. Given the general explosion of RCTs in health sciences in the past decade and the dearth of studies within Aboriginal communities found in this review, Aboriginal peoples continue to be underrepresented in the evaluation of health-based interventions. Although the twenty-two RCTs included in this review represent an almost two-fold increase from Morris' (1999) last known review of published studies, the results are a modest gain considering the thousands of RCTs published every year in the health sciences. There is a comparative lack of RCTs involving Aboriginal communities. Since Aboriginal communities continue to struggle with higher levels of health conditions compared to the Canadian population as a whole (Ontario Aboriginal Health Advocacy Initiative, 2003), it is imperative that more research be conducted to determine what works to resolve health disparities within Aboriginal communities.

RCTs are considered valuable to Aboriginal communities when they are developed in active collaboration with the community, and the methods can provide generalizable and valid information on the health and well-being of Aboriginal peoples. Results from RCTs can help community leaders and administrators

make practical decisions about the types of programs needed and to allocate scarce resources to programs that have been shown to be effective in local communities (Kenny, 2002). Glor (1987) found that applying holistic frames of reference to quantitative work can be frustrating as they arise from epistemologies in opposition. However, quantitatively-based evaluations of public programs and policy can substantiate the impact of holistically based innovations, thus providing evidence for further funding and support.

5.1 Limitations

There are several limitations to this review that should be acknowledged. First, although a comprehensive search strategy was used, it may not necessarily be inclusive. Given that as many as 50 percent of completed studies are never published (Sherer, Dickersin, & Langenberg, 1994), these unpublished studies may have been overlooked using this search strategy. Researchers may be less inclined to publish negative results or studies of weaker quality (Morris, 1999).

As well, RCTs may be limited in Aboriginal communities by perceptions within the communities about them. Andersson (2008) suggests some Aboriginal leaders have rejected the use of RCTs within their communities as they have been considered "distasteful, with ethical concerns about withholding an intervention and tricking people with placebos" (p. 203-204). He suggests that a new approach is needed to integrate Aboriginal worldviews within RCTs to ensure the health needs of Aboriginal communities are adequately addressed with the most advanced and relevant evidence. As Andersson (2008) states:

There is a widespread, but mistaken, belief that disclosure is necessary for RCTs, that knowledge bearers of Indigenous spiritual knowledge must give this information to the researchers or public. This is

understandably unpalatable for Indigenous advocates, who argue that Indigenous spirituality should not be dissected by Western scientists, that traditional medicine should not be handed over to those who practise the modern measurement sciences. In fact, the scientific value of an RCT is enhanced if the researchers do not know what exactly the intervention is. They need only know which individuals or communities were exposed to this intervention, and which not. And they need a clear way of measuring the outcomes — increased resilience or decreased effects of the erosion of resilience (p. 204).

Morris (1999) notes that the lack of RCTs in Aboriginal communities may reflect the belief of community members, researchers and funding bodies that it is inappropriate to be spending money looking for solutions to health problems arising from colonization, unsatisfactory health-related policies, marginalization, and socioeconomic disadvantages experienced by Aboriginal communities. He also notes that while structural issues must be considered given the disadvantages faced by Aboriginal peoples, failure to include Aboriginal communities in RCTs can result in a twofold marginalization whereby these communities must cope not only with the stresses of poverty, but may also be denied access to improvements in health-related services, programs and resources. It appears that the same is true ten years later.



6. CONCLUSION



The results of this review of RCTs of health-related interventions with Aboriginal communities demonstrate that there is no consistent approach for addressing these issues and there is substantial variability across studies. Given the importance of RCTs in helping to improve the health and well-being of Aboriginal peoples, it is imperative that guidelines be developed that specifically address the issues relevant to conducting RCTs within Aboriginal communities. Such efforts can clarify misconceptions, hesitations and concerns expressed by community members, researchers and funding bodies, thereby making it more feasible to conduct RCTs with Aboriginal communities to better understand health conditions.

Couzos et al. (2003) suggested the establishment of a RCT community-controlled model, which includes new standards for conducting RCTs with Aboriginal communities for health-based research so that they can become more actively involved in the research process. In accordance with CONSORT (Consolidated Standards of Reporting Trials) standards (Moher, Schulz, & Altman, 2001), Couzos et al. (2003) identified additional principles that should characterize the RCT methodology within Aboriginal community-based research. In summary, the research agenda should be established by the community and

based on their needs “because scarce research funds should be directed to areas most likely to improve health inequities” (Couzos, Traven, Murray, & Culbong, 2005). For community control to be achieved within RCT designs, communities must be active members of the research process at the onset and be fully engaged throughout the duration of the project. Also, the planning of the RCT must be carefully considered for relevancy and applicability to the community, as well as ensuring that the design is realistic given community expectations and resources available to support the project. In addition, there needs to be adequate attention to the cultural sensitivity of the intervention and its sustainability once the research is completed. Cultural sensitivity includes working with community members to ensure that the intervention has been adequately adapted to the socio-cultural context of the community to ensure that it is consistent with local traditions, teachings, community structures and worldviews. Sustainability means there must be a commitment on the part of all stakeholders to continue providing services to community members beyond the end of the study. It is critical that local community-based leadership and communication networks are harnessed throughout the project to ensure the community is in the best position to sustain the intervention once the research

is completed. Lastly, it is critical that ownership of intellectual property is vested in community-representative bodies, that communities are enabled to document their experiences, and that research leads to actions promoting policy changes.

The involvement of Aboriginal peoples in the creation of knowledge about their health outcomes is critical given the longstanding misuse, abuse and mistreatment of Aboriginal peoples involved in research and the health inequalities they face. Evidence has ultimately shown that research on Aboriginal peoples has often been counterproductive to improving health conditions (Anderson, Young, Markovic, & Manderson, 2001). Participatory methods are being explored and utilized for conducting RCTs with Aboriginal communities in order to increase their cultural relevance and thus enhance the process and implementation of RCTs for optimal recruitment, engagement and retention of participants in trials, while being sensitive to the social values and cultural traditions of Aboriginal communities. For example, a research framework has been developed to “measure the impact of community-

led interventions to reduce domestic violence in Aboriginal communities” (Andersson, Shea, Amaratunga, McGuire, & Sioui, 2010). This research is guided by a community participatory approach in which community-based Aboriginal researchers will be trained and will lead the RCT project. Please refer to Andersson et al. (2010) for a rich discussion of this methodological approach to conducting RCTs with Aboriginal communities. Ethical protocols and an example data sharing agreement template are also included at the end of this article, which can help Aboriginal researchers and communities develop similar research protocols and RCTs for their own community members. This research emphasizes building partnerships with communities and establishing protocols to formulate evidence-based community-led interventions in order to develop and test culturally appropriate methods to measure and reduce domestic violence in Aboriginal communities. Overall, conducting RCTs within Aboriginal Communities requires the technical skills needed to develop, implement and evaluate health-related interventions, as well as sensitivity and space for Aboriginal worldviews, traditions and culture.





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APPENDICES



Appendix A: Example Search Terms

[(Aborigine or Aboriginal* or Aboriginal Population* or Torres Strait Islander or Maori or American Indian* or North American Indian* or Indian* or Alask* Nativ* or Native Hawaiian* or Hawaii Nativ* or Native American* or American Samoan or Eskimo* or Inuit* or Aleut* or Métis or First Nation* or Indigenous).mp. [mp=title, original title, abstract, name of substance word, subject heading word] AND (RCT or random assign* or random control or controlled clinical trial* or control group* or Evaluation stud* or double-blind or placebo).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier] AND exp Community Health Nursing/ or exp Dental Health Surveys/ or exp Family Health/ or exp Consumer Health Information/ or exp Education, Public Health Professional/ or exp Allied Health Occupations/ or exp "Delivery of Health Care"/ or exp Adolescent Health Services/ or exp Community*

Health Services/ or exp Comprehensive Health Care/ or exp Health/ or exp Environmental Health/ or exp Attitude to Health/ or exp Health Behavior/ or exp Health Education/ or exp American Public Health Association/ or exp Community Health Aides/ or exp Community Mental Health Centers/ or exp Community Mental Health Services/ or exp Dental Health Services/ or exp Child Health Services/ or exp Health Educators/ or exp Health Education, Dental/ or exp Community Health Centers/ or exp "Delivery of Health Care, Integrated"/ or exp "Attitude of Health Personnel" or Community Health Nursing or Dental Health or Family Health or Consumer Health or Public Health or Allied Health or Delivery of Health Care or Adolescent Health or Community Health or Comprehensive Health Care or Health or Child Health or Substance use or smoking or poverty or determinants of health)]

Appendix B: RCTs Within Aboriginal Communities (2000-2010)

Source	<ul style="list-style-type: none"> Barlow et al., (2006).
Aboriginal Peoples and Communities	<ul style="list-style-type: none"> One Apache and 3 Navajo communities in the United States.
Sample	<ul style="list-style-type: none"> 53 pregnant American Indian adolescents. (28 intervention, 25 control group). Follow-up data for 19 intervention and 22 control participants.
Health Issue	<ul style="list-style-type: none"> Prenatal care, including child care knowledge and skills.
Intervention	<ul style="list-style-type: none"> Paraprofessionals delivered 41 prenatal and infant care lessons in participants' homes from 28 weeks' gestation to 6 months post partum. The home-visiting intervention was modeled on "Healthy Families America."
Design	<ul style="list-style-type: none"> Randomized controlled trial. Randomization stratified by site was determined by the Randomization.com Website. Concealed from the key investigators and on-site educators at all times.
Results	<ul style="list-style-type: none"> Mothers in the intervention had significantly higher parent knowledge scores at 2 months. Intervention group mothers scored significantly higher on maternal involvement scales at 2 months post partum and scores approached significance at 6 months post partum.
Strengths	<ul style="list-style-type: none"> The educators (n=4) were bilingual American Indian women who had a job history in tribal health and human services, passed background screening, and had been teen mothers themselves or had special interest in this population. Cultural adaptations, including style, graphics, delivery, and content – were achieved through a community-based participatory process.
Limitations	<ul style="list-style-type: none"> Parenting knowledge and involvement could be indicators for capacity but the links are not yet proven. There were a notable number of dropouts, particularly in the intervention arm (9 of 28 intervention mothers vs 3 of 25 controls).

Source	<ul style="list-style-type: none"> Bhattacharyya (2007).
Aboriginal Peoples and Communities	<ul style="list-style-type: none"> Oji-Cree reserves in Sioux Lookout Zone, Ontario Canada.
Sample	<ul style="list-style-type: none"> n=153 patients in the intervention communities, n=158 patients in the control groups.
Health Issue	<ul style="list-style-type: none"> Cholesterol management in diabetic patients in reserves in Northern Ontario.
Intervention	<ul style="list-style-type: none"> Diabetes clinical practice guidelines in remote aboriginal communities.
Design	<ul style="list-style-type: none"> A sequential, mixed method controlled before-after intervention trial. Two communities were randomized to receive an interactive education workshop intervention and audit and feedback identifying diabetic patients with elevated cholesterol, while the other 2 communities had usual care.
Results	<ul style="list-style-type: none"> Providers identified a range of factors leading to indecision in prioritization of processes of diabetes care. Prioritized key points derived from this were well received (though poorly understood) by nurses, but rejected by doctors because they de-individualized care. The audit and feedback was accepted by all providers, and they felt that following up patients did not significantly increase their workload.
Strengths	<ul style="list-style-type: none"> Explored the barriers to implementation of diabetes clinical practice guidelines in remote aboriginal communities. A range of primary care providers participated in in-depth interviews and focus groups to explore barriers to diabetes care. These results informed a controlled before-after intervention trial.
Limitations	<ul style="list-style-type: none"> The small number of randomized clusters, which may not have controlled for unmeasured confounders and could have led to significant baseline imbalance. The abstractors were not blinded to allocation of the communities, which could have biased their measurements in favour of a treatment effect.

Source	· Caballero et al. (1998).
Aboriginal Peoples and Communities	· American Indian communities in the United States: Gila River Indian Community of Arizona (Akimel O'odham), Tohono O'odham Nation, Navajo Nation (Dine), Oglala Sioux Tribe (Oglala Lakota), Rosebud Sioux Tribe (Sicangu Lakota), San Carlos Apache Tribe (Dee'), and the White Mountain Apache Tribe (Ndee').
Sample	· 41 schools in 7 American Indian communities (1,704 children).
Health Issue	· Obesity (percentage body fat).
Intervention	· Evaluated the effectiveness of a school-based, multicomponent intervention for reducing percentage body fat in American Indian schoolchildren. · The intervention had 4 components: classroom curriculum, food service, physical activity, and family involvement.
Design	· Randomized, controlled, school-based trial.
Results	· The program produced significant positive changes in fat intake and in food- and health-related knowledge and behaviors. · The intervention showed positive but no statistically significant trend in the level of physical activity during school time.
Strengths	· Approval of the study by school, community, and tribal authorities. · The intervention approach combined constructs from social learning theory and principles of American Indian culture and practices. Several indigenous learning modes (eg, story telling) were also incorporated into the intervention.
Limitations	· More intense or longer interventions may be needed to significantly reduce adiposity in this population.

Source	· Calver et al. (2005).
Aboriginal Peoples and Communities	· Aboriginal and Torres Strait Islander Australians located in the most northern part of the Western Australian outback.
Sample	· 478 intervention and 6,736 control. · The intervention group stratified random sample of Aborigines aged 15-80 years at time 1. The control consisted of Aboriginal people on the registers who were aged 15-80 years at time 1.
Health Issue	· Hazard of death (all causes, alcohol-related and injury-related). · The hazard of cancer (total cancer and alcohol-related): and the rate of hospital separation (any separation, alcohol-related and injury-related, both first-time and multiple).
Intervention	· To examine the impact of a multi-component health assessment on mortality and morbidity.
Design	· A population-based randomized controlled trial using linked hospital, cancer and death records.
Results	· The intervention group had an increased rate of contact with health services following their involvement in the research assessment. · Higher rate of first-time hospitalization and an increased rate of detection of alcohol-related cancers, but no consistent difference was seen in overall mortality.
Strengths	· Consultation with communities and provision of feedback on research results was undertaken.
Limitations	· Lack of detailed process evaluation of the intervention and the possible contamination of an unknown proportion of the control group by some aspects of the community feedback following the research. · The external validity of this conclusion is limited to Aboriginal populations living in remote regions such as the far north of Western Australia.

Source	· Christofides et al. (2005).
Aboriginal Peoples and Communities	· Cree communities on the west side of James Bay, Ontario and one Inuit community in Nunavut Territory.
Sample	· 102 non-anemic children aged 4 to 18 months from three communities were randomized to receive sprinkles containing 30 mg Fe/day (NR=49) or placebo (NR=53) for six months.
Health Issue	· Iron Deficiency.
Intervention	· To determine the acceptability and safety of micro-encapsulated-iron sprinkles, a new powdered form of iron packaged in a single-serving sachet for prevention of IDA.
Design	· a double-blind randomized controlled trial design was used to measure the acceptability and safety of iron supplement sprinkles.
Results	· Results suggest that sprinkles may provide a safe and acceptable option to the current standard of care (i.e. ferrous sulphate drops) for the provision of iron in Canadian Aboriginal populations.
Strengths	<ul style="list-style-type: none"> · There were no differences in adherence, SF, anthropometric status or side effects between groups. · Consent from First Nations communities was obtained from hospital boards and the chief and councils. Community and individual informed consent were obtained.
Limitations	<ul style="list-style-type: none"> · Conflict of interest as one of the authors has the intellectual copyright of sprinkles. · Over a six-month period, participants adhered on average approximately 60 percent of the time to the recommended use of sprinkles.

Source	· Couzos et al. (2003).
Aboriginal Peoples and Communities	· 8 Aboriginal communities in northern Western Australia and Queensland.
Sample	· 111 Aboriginal children, n=55 treatment n=56 control.
Health Issue	· Chronic suppurative otitis media (CSOM), a chronic infection of the middle ear.
Intervention	· Otological ciprofloxacin with framycetin gramicidin, examethasone eardrops together with povidone-iodine ear cleaning as treatments for chronic suppurative otitis media (CSOM) in Aboriginal children.
Design	· Aboriginal community-controlled, community-based, multicentre, double-blind, randomized controlled trial.
Results	<ul style="list-style-type: none"> · Ciprofloxacin ear drops were 47% more likely to cure CSOM in Aboriginal children after a single course of twice-daily treatment than combined framycetin gramicidin and dexamethasone ear drops. · Twice-daily ear cleaning and topical ciprofloxacin is effective at community-level in achieving cure for CSOM.
Strengths	<ul style="list-style-type: none"> · All Aboriginal Community Boards approved the study with written consent. · The 'community-controlled' model of research relating to Aboriginal peoples health is a form of 'participatory' research that shifts the balance of control towards those being researched.
Limitations	<ul style="list-style-type: none"> · Whether the antiseptic effect of ear cleaning contributed overall to clinical cure remains unknown. · Follow-up too short to detect changes in hearing or TM healing.

Source	· Davis et al. (2003).
Aboriginal Peoples and Communities	· Participating schools included public, parochial, tribal contract and grant schools, and government schools under the Bureau of Indian Affairs located in New Mexico, Arizona, Utah, and South Dakota.
Sample	· 1,704 American Indian third to fifth grade students from 41 schools (21 intervention, 20 controls) in seven American Indian communities.
Health Issue	· Healthful eating and increasing physical activity.
Intervention	· Pathways, a multisite school-based study aimed at promoting healthful eating and increasing physical activity. · The intervention schools received four integrated components: a classroom curriculum, food service, physical activity, and family modules. The curriculum and family components were based on Social Learning Theory, American Indian concepts, and results from formative research.
Design	· Randomized field trial.
Results	· There were significant increases in knowledge and cultural identity in children in intervention compared to control schools with a significant retention of knowledge over the 3 years, based on the results of repeating the third and fourth grade test items in the fifth grade.
Strengths	· A culturally appropriate school intervention can promote positive changes in knowledge, cultural identity, and self-reported healthful eating and physical activity in American Indian children and environmental change in school food service. · The Pathways staff included individuals who were members of participating American Indian communities.
Limitations	· Researchers may find it helpful to monitor Family Events to determine which events were enjoyed the most and which activities are practical to implement. · By conducting interviews at the end of the Family Events, additional information about what works best with families could be gathered and evaluated and then applied to future prevention research and practice.

Source	· Govula et al. (2007).
Aboriginal Peoples and Communities	· Northern Plains Indian reservations.
Sample	· 33 students from 6 classes in 3 rural elementary schools were assigned to an intervention group (n=12) and a control group (n=21) in accordance with time requirements to travel from one school to another and with the physical education class schedule.
Health Issue	· Fruit and vegetable consumption.
Intervention	· 6-lesson, culturally adapted nutrition curriculum on fruit and vegetable consumption. · The nutrition lessons consisted of three lessons from MyPyramid and three lessons from Medicine Wheel Nutrition for Native Americans.
Design	· This quasi-experimental pilot study assessed the effectiveness of a six-lesson, culturally adapted nutrition curriculum on fruit and vegetable consumption.
Results	· The change in intake from baseline to completion between groups was significantly different for total fruit and vegetable serving per day, and total vegetable serving per day but not for total fruit. · At completion, there were a significantly greater number of students who scored 75% or more on the knowledge questionnaire (100% in intervention, 14% in control group).
Strengths	· This study indicates that culturally appropriate educational intervention is a potential tool to increase fruit and vegetable intake and nutrition knowledge in American Indian children. · The nutrition lessons were developed by authors (CG and KK) with input from Lakota tribal members.
Limitations	· The study was conducted with a sample of a limited size. · Participants were assigned to their respective group based on logistical determinants that such as distance between schools and timing of classes, rather than randomization.

Source	· Harrison & Veronneau (2010).
Aboriginal Peoples and Communities	· Aboriginal (Cree) mothers and infants in eastern James Bay in Quebec, Canada.
Sample	· 272 of the original target sample size of 309 mothers were recruited over a two-and-a-half year period.
Health Issue	· Children's dental health status and family dental health practices.
Intervention	· Motivational Interviewing, to control dental caries in young Aboriginal children.
Design	· The communities were randomly allocated to test or control group by a random "draw" over community radio.
Results	· Mothers in the test or MI communities had later stages of pregnancy than mothers in control communities (22.4 vs. 17.7 weeks), and mothers with other children in the MI communities were less likely to have had another child with a tooth extraction (34 vs. 49%).
Strengths	<ul style="list-style-type: none"> · Aboriginal women were hired from the 9 communities to recruit expectant and new mothers to the trial, administer questionnaires, and deliver the counseling to mothers in the test communities. · The process of community consultation was one of several complex issues that arose during the planning of the trial. · Prior to undertaking the trial, extensive discussions throughout the community were undertaken. · Cree dental assistants who worked part-time in community dental clinics worked on this project.
Limitations	· Randomization of individual mothers within each community was inappropriate for this study because of the close-knit nature of the communities and the risk of contamination.

Source	· Himes & Ring (2003).
Aboriginal Peoples and Communities	· American Indian communities in the United States: Gila River Indian Community of Arizona (Akimel O'odham), Tohono O'odham Nation, Navajo Nation (Dine), Oglala Sioux Tribe (Oglala Lakota), Rosebud Sioux Tribe (Sicangu Lakota), San Carlos Apache Tribe (Dee'), and the White Mountain Apache Tribe (Ndee').
Sample	· 41 schools in 7 American Indian communities (1,704 children).
Health Issue	· Obesity (percentage body fat).
Intervention	<ul style="list-style-type: none"> · Evaluated the effectiveness of a school-based, multicomponent intervention for reducing percentage body fat in American Indian schoolchildren. · The intervention had 4 components: classroom curriculum, food service, physical activity, and family involvement.
Design	· Randomized, controlled, school-based trial.
Results	· Pathways intervention brought about significantly smaller mean intakes of total fat and saturated fat as percentages of calories compared with controls.
Strengths	· The Pathways intervention successfully reduced the intake of percent calories from fat and saturated fat, at school lunch and over the whole day.
Limitations	· Unclear whether communities were involved in the research process and whether this had any influence on the study.

Source	· Kattelman et al. (2009).
Aboriginal Peoples and Communities	· The Northern Plains Indians of the Cheyenne River Sioux Tribe in western South Dakota, United States.
Sample	· 114 adults aged 18 to 65 years, with type 2 diabetes.
Health Issue	· Diabetes and obesity.
Intervention	· Culturally adapted educational lessons based on the Medicine Wheel Model for Nutrition in addition to their usual dietary education. · The education group received six nutrition lessons based on the Medicine Wheel Model for Nutrition. The usual care group received the usual dietary education from their personal providers.
Design	· Eligible participants were stratified by gender and body mass index (BMI) and were randomized using a computer generated random number chart into a six month dietary education intervention (ED) or usual care control group (UC).
Results	· The education intervention was not able to empower the participants to make the dietary changes. · The culturally based nutrition intervention promoted small but positive changes in weight.
Strengths	· The high level of participation in this trial was one of the successes of the study. Ninety percent of those enrolling completed the trial and greater than 92% of the education participants attended 4 out of the 6 education lessons.
Limitations	· The diet and lifestyle intervention tailored specifically to Northern Plains Indians may not have allowed sufficient time both in duration and frequency for comprehension and adoption of dietary behavior changes in this specific population.

Source	· Lawrence et al. (2008).
Aboriginal Peoples and Communities	· 28 Ojibway-Cree First Nations communities. · Twenty First Nations communities in the Sioux Lookout Zone (SLZ), Northwest Ontario, Canada.
Sample	· 1,275, 6 months to 5-year-old children from the SLZ communities were enrolled.
Health Issue	· Childhood caries.
Intervention	· Fluoride varnish (FV) and caregiver counseling in preventing early childhood caries (ECC) in Aboriginal children. · All caregivers received oral health counseling, while children in one group received FV twice per year and the controls received no varnish.
Design	· The trial used a cluster randomization design. · The clusters were the 20 randomly selected SLZ communities and the unit of randomization was the community itself with all eligible participants in each community receiving the same intervention.
Results	· Findings support the use of FV at least twice per year, in conjunction with caregiver counseling, to prevent ECC, reduce caries increment and oral health inequalities between young Aboriginal and non-Aboriginal children.
Strengths	· Community dental assistants served as translators when necessary. · At the final, 24-month follow-up, 952 children were seen, representing a 75% retention rate (no community dropped out of the study).
Limitations	· Six teams of dental hygienists and recorders were flown into the participating communities for an average stay of 10 days but no mention of cultural sensitivity. · People living in the same community or children attending the same school may be more similar than those in different communities or schools for reasons unrelated to the intervention being tested.

Source	· Martens (2001).
Aboriginal Peoples and Communities	· Sagkeeng First Nation, Ojibwa community in Manitoba, Canada.
Sample	· 22 eligible students in the intervention group (10 males and 12 females) and 23 in the control group (11 males and 12 females).
Health Issue	· Breastfeeding.
Intervention	· Adolescent breastfeeding educational session.
Design	· Randomized pretest-posttest control group design. A retention test to measure overall retained learning was given to all students 10 days later.
Results	<ul style="list-style-type: none"> · Breastfeeding beliefs increased from pretest to posttest for intervention subjects but not for controls. · Learning was gender specific, with females experiencing increases in breastfeeding beliefs, decreases in bottle-feeding beliefs, and a trend to increased breastfeeding attitudes. · Males showed small, inconsistent learning effects.
Strengths	· The intervention group received the session first; the control group received the session following the posttest.
Limitations	· Small sample. Unclear whether communities were involved in the research process and whether this had any influence on the study.

Source	· Nagel et al. (2009).
Aboriginal Peoples and Communities	· Aboriginal/Torres Strait Islanders.
Sample	· A total of 49 patients with mental illness and 37 carers were recruited to a randomized controlled trial that compared MCP (n=24) with a clinical control condition (treatment as usual, n=25).
Health Issue	· Chronic mental illness.
Intervention	<ul style="list-style-type: none"> · Culturally adapted brief intervention for Indigenous people with chronic mental illness. · The early treatment group received MCP at baseline and the late treatment group received delayed treatment at six months.
Design	· A mixed methods design in which an exploratory phase of qualitative research was followed by a nested randomized controlled trial.
Results	<ul style="list-style-type: none"> · The results revealed improvements in participants' well-being as compared with treatment as usual (TAU). Improved outcomes were sustained over 18 months. · The evidence presented suggests these are positive strategies on what works to overcome Indigenous disadvantage.
Strengths	<ul style="list-style-type: none"> · Psycho-education resources and a brief intervention, motivational care planning (MCP), were developed and tested in collaboration with aboriginal mental health workers in three remote communities in northern Australia. · The program/activity was adapted to be culturally appropriate for Indigenous Australians. · The entire subpopulation was invited to participate in the program/activity. Participatory methods were included in this report. · The qualitative research methods included in this study are key informant interviews and focus groups.
Limitations	<ul style="list-style-type: none"> · Low sample numbers might suggest poor generalizability of the results. · Participatory methods were not included in this report.

Source	· Sawchuk et al. (2008).
Aboriginal Peoples and Communities	· American Indians.
Sample	· 125 American Indians aged 50-74 years at the Seattle Indian Health Board in 2005.
Health Issue	· Physical inactivity is common among older populations and American Indians.
Intervention	· Two methods for increasing physical activity and walking among American Indian elders.
Design	· A two arm randomized trial to increase physical activity. · Participants were randomized into either an activity monitoring (n=63) or activity monitoring with a pedometer (n=62) arm over a six-week period.
Results	· There were no group differences in self-reported physical activities and well-being. The 6-min walk test yielded no between-group differences. · All participants increased the frequency of leisure walking ($p < 0.01$), frequency of all exercise-related activities ($p < 0.01$), frequency of moderate-intensity exercise activities ($p < 0.01$), and improved weekly caloric expenditure for all exercise activities ($p < 0.05$) by the end of the trial.
Strengths	· Pedometers did not confer enhanced performance on the physical activity outcomes beyond those achieved through self-monitoring. Physical activity can be promoted among at-risk groups in a brief, inexpensive manner in primary care.
Limitations	· Exercise prescription and culturally relevant enhancement strategies may optimize physical activity outcomes for elder American Indians.

Source	· Sibthorpe et al. (2002).
Aboriginal Peoples and Communities	· Aboriginal/ Torres Strait Islanders.
Sample	· Only 16 clients were recruited for follow-up in six-months, and the trial was terminated.
Health Issue	· Alcohol use.
Intervention	· Brief intervention for hazardous alcohol use among Indigenous Australians.
Design	· Randomized controlled trial in an urban Aboriginal Medical Service (AMS) as a joint AMS-university partnership. · Because of low numbers of potential participants being screened, the RCT was abandoned.
Results	· The key points to emerge from the study are that alcohol misuse is a difficult issue to manage in an Indigenous primary health care setting.
Strengths	· Authors followed up with qualitative interviews to explore the demise of the RCT.
Limitations	· RCTs involving inevitably complex study protocols may not be acceptable or sufficiently adaptable to make them viable in busy, Indigenous primary health care settings.

Source	· Simmons et al. (2008).
Aboriginal Peoples and Communities	· New Zealand Maori in Te Wai o Rona.
Sample	· 5,240 non-pregnant Maori family members without diabetes from 106 rural and 106 urban geographical clusters.
Health Issue	· Prevention of diabetes.
Intervention	· Personal trainer (Maori Community Health Worker, MCHW) approach among Maori in New Zealand.
Design	· A randomized cluster-controlled trial of intensive lifestyle change. · A pilot study (Vanguard Study) cohort of 160.
Results	· During the Vanguard Study, participants and MCHW found the messages, toolkit and delivery approach acceptable. · Those with IGT/IFG diagnosed (n=27) experienced significant weight loss after screening and during the Vanguard Study. · Significant weight loss occurred during the Vanguard Study among all participants.
Strengths	· Community-wide prevention programs are feasible among Maori and are likely to result in significant reductions in the incidence of diabetes.
Limitations	· How to translate this to implementation across whole communities remains unclear.

Source	· Stevens et al. (2003).
Aboriginal Peoples and Communities	· American Indian communities in the United States: Gila River Indian Community of Arizona (Akimel O'odham), Tohono O'odham Nation, Navajo Nation (Dine), Oglala Sioux Tribe (Oglala Lakota), Rosebud Sioux Tribe (Sicangu Lakota), San Carlos Apache Tribe (Dee'), and the White Mountain Apache Tribe (Ndee').
Sample	· 41 schools in 7 American Indian communities (1,704 children).
Health Issue	· Obesity (percentage body fat).
Intervention	· Evaluated the effectiveness of a school-based, multicomponent intervention for reducing percentage body fat in American Indian schoolchildren. · The intervention had 4 components: classroom curriculum, food service, physical activity, and family involvement.
Design	· Randomized, controlled, school-based trial.
Results	· The combined exposure to a classroom curriculum, a food service program, a physical education program, and a family-targeted program did result in changes in some aspects of children's knowledge, self-efficacy, intentions, and reported behaviors related to diet and physical activity. The intervention did not uniformly affect these constructs in both boys and girls.
Strengths	· The Pathways study is unique among all these studies in that it investigated the effects of a multifaceted, school based intervention in American Indian children. · This study is the first to develop and evaluate culturally relevant and age-appropriate instruments for assessing psychosocial determinants related to diet and physical activity in American Indian elementary schoolchildren.
Limitations	· Children in the sample were living in nonurban areas, ranging from geographically isolated communities to rural areas just beyond the suburbs of a large city. The applicability of these findings to American Indian children living in urban areas and attending nonreservation schools is unknown. Environmental approaches and active family involvement deserve further study.

Source	· Tobe et al. (2006).
Aboriginal Peoples and Communities	· First Nations people registered with the Battlefords Tribal Council Indian Health Services.
Sample	· 50 subjects were randomly assigned to the treatment strategy and 49 to the control strategy.
Health Issue	· Hypertension and type 2 diabetes.
Intervention	<ul style="list-style-type: none"> · Community-based treatment strategy implemented by home care nurses for controlling hypertension in First Nations people with existing hypertension and type 2 diabetes. · In the intervention group, a home care nurse followed a predefined treatment algorithm of pharmacologic antihypertensive therapy. · In the control group, treatment decisions were made by each subject's primary care physician.
Design	<ul style="list-style-type: none"> · Randomization was performed by means of opaque sealed envelopes using a permuted block design, stratified by the 7 reserves. · Envelopes were opened by the home care nurse in the presence of the physician and patient at the end of the baseline visit.
Results	<ul style="list-style-type: none"> · The reduction in systolic blood pressure was 7.0mm Hg greater in the intervention group than in the control group, but this difference was not statistically significant. · The addition of a home care nurse to implement a treatment strategy for blood pressure control was more effective in lowering diastolic than systolic blood pressure compared with home care visits for blood pressure monitoring alone and follow-up treatment by a family physician.
Strengths	· High rates of blood pressure control in the community were achieved in both groups.
Limitations	<ul style="list-style-type: none"> · There may have been a halo effect because patients in the intervention group and the control group shared family physicians. · There were insufficient family physicians in the region to randomize by practice. · Unclear whether communities were involved in the research process and whether this had any influence on the study.

Source	· Valery et al. (2010).
Aboriginal Peoples and Communities	· Thursday Island and Horn Island, and in Bamaga, Torres Strait region of northern Australia.
Sample	· 88 children, aged 1-17 years, with asthma diagnosed by a respiratory physician (intervention group, 35; control group, 53; 98% Indigenous children).
Health Issue	· Asthma outcomes (number of unscheduled visits to hospital or a doctor because of asthma exacerbation in the 12 months' follow-up).
Intervention	<ul style="list-style-type: none"> · All children had an asthma education session with trained Indigenous health care workers using the adapted asthma booklets. · The intervention group had three additional education sessions with trained Indigenous health care workers at 1, 3 and 6 months after the baseline visit.
Design	· Children were randomly allocated to: (i) three additional asthma education sessions with a trained IHCW, or (ii) no additional asthma education. Both groups were re-assessed at 12 months.
Results	<ul style="list-style-type: none"> · Reduction in school days missed for children in the intervention group (less than 7 compared to 7-14 for control group). · Better understanding of asthma and action plans for carers of children in the intervention group. · Improved quality of life and function severity index for both groups.
Strengths	<ul style="list-style-type: none"> · Response and follow-up rates were high, limiting the potential for selection bias. · Provides a model for addressing the gap in health outcomes between Indigenous and non-Indigenous Australians. · Culture- specific study in an affluent country of an education intervention by IHCWs for Indigenous children.
Limitations	<ul style="list-style-type: none"> · As study enrolment was slower than anticipated, they modified the intervention allocation based on estimates of asthma prevalence. · Limited power to detect small differences between the groups with certainty. · All children had an "intervention" at baseline: the specialist assessment and an education session with a trained IHCW. This potentially diminished the impact of additional asthma education sessions by IHCWs.

Source	· Valery et al. (2006).
Aboriginal Peoples and Communities	· Indigenous children at the Alice Springs Hospital in the Northern Territory.
Sample	· 392 Aboriginal children with 436 episodes of diarrhea. · Aboriginal children (aged < 11 years) hospitalized for acute diarrhea at Alice Springs Hospital, Northern Territory, April 2001-July 2002.
Health Issue	· Acute diarrhea.
Intervention	· The role of zinc and vitamin A supplementation in the recovery of Indigenous children hospitalized for acute diarrhea.
Design	· A randomized controlled 2 by 2 factorial trial of supplementation with zinc and vitamin A.
Results	· Supplementation with zinc, vitamin A, or combined zinc and vitamin A had no significant effect on duration of diarrhea or rate of re-admission compared with placebo. · The number of re-admissions did not differ significantly between those receiving vitamin A or zinc and the relevant placebo groups.
Strengths	· Informed consent was obtained from the carer(s) by an Indigenous research officer or a member of the research team before enrolment.
Limitations	· This finding may not apply to children with malnutrition, for whom other studies suggest a benefit. · Larger trials incorporating more comprehensive data on the vitamin A and zinc status as well as nutritional status of study populations might help to explain the different results in different populations.

Source	· Walkup et al. (2009).
Aboriginal Peoples and Communities	· Navajo and White Mountain Apache reservations.
Sample	· Expectant women aged 12 to 22 years (n=167).
Health Issue	· Post-natal care.
Intervention	· Paraprofessional-delivered, home-visiting intervention among young, reservation-based American Indian mothers on parenting knowledge, involvement, and maternal and infant outcomes. · 25-visit "Family Spirit" intervention addressing prenatal and newborn care and maternal life skills (treatment) · 23-visit breast-feeding/nutrition education intervention (active control).
Design	· Randomized (1:1) to one of two paraprofessional-delivered, home-visiting interventions.
Results	· At 6 and 12 months postpartum, treatment mothers compared with control mothers had greater parenting knowledge gains. · At 12 months postpartum, treatment mothers reported their infants to have significantly lower scores on the externalizing and less separation distress in the internalizing domain. · No between-group differences were found for maternal involvement, home environment, or mothers' stress, social support, depression, or substance use.
Strengths	· Researchers engaged in local and cross-tribal advisory boards. · Completed pilot study to assess whether intervention feasible and relevant for American Indian mothers. · Through the use of community-based participatory research methods, this study breaks new ground in designing, implementing, and evaluating paraprofessional delivered in-home interventions.
Limitations	· Attrition rates particularly among treatment group mothers were higher than anticipated. High attrition rates were likely related to participant factors such as Family Spirit intervention time burden and transient living status post-delivery. · The attrition prevention protocol for this study did not include maintaining contact with participants or reengaging mothers who missed multiple consecutive sessions.

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NATIONAL COLLABORATING CENTRE
FOR ABORIGINAL HEALTH
CENTRE DE COLLABORATION NATIONALE
DE LA SANTÉ AUTOCHTONE

FOR MORE INFORMATION:
UNIVERSITY OF NORTHERN BRITISH COLUMBIA
3333 UNIVERSITY WAY, PRINCE GEORGE, BC V2N 4Z9

1 250 960 5250
NCCAH@UNBC.CA
WWW.NCCAH-CCNSA.CA