Successful Implementation of IM PBR

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UC San Diego Health System
Translating “Integrative Medicine” into Practice-based Research

• Case report: MBSR in HTN
• Case series: Naturopathy in HTN
• Quasi-Experimental, Mixed-methods Research: Naturopathy in Diabetes
• Prospective Observational Research in Practice: Naturopathy in Diabetes and CVD
• Semi-Pragmatic trial: Multi-modal Lifestyle Intervention for Primary Prevention of CVD
Self-directed Mindfulness Training and Improvement in Blood Pressure, Migraine Frequency, and Quality of Life

Abstract

Background: Interest in case studies has undergone a resurgence concurrent with increasing prioritization of illustrations of patient-centered care. However, substantial inclusion of the patient in these reports remains limited. Here, a doctor and patient collaborate to present a case report of self-directed mindfulness training and the subsequent changes in blood pressure, migraine frequency, and quality of life.

Methods: After receiving encouragement from her naturopathic doctor, the patient initiated an 8-week program in mindfulness training following the Kabat-Zinn protocol and logged her daily blood pressure and symptoms before and after meditation sessions over an 11-week period.

Results: Patient-reported outcomes included decreased perceived stress, increased focus, and a newfound sense of centeredness and calm. Changes in objective outcomes were clinically and statistically significant, including reductions in mean systolic and diastolic blood pressure between week 1 and week 11 (P = 0.001 and P ≤ 0.005 for systolic and diastolic, respectively, by paired, 2-sided t-tests). Self-reported frequency of chronic migraine was also reduced. Critical to the patient’s success was that mindfulness training was first approached in a simple, accessible manner prior to embarking on a deeper, extended experience.

Discussion and Conclusion: Self-directed mindfulness training can have a meaningful impact on both subjective and objective health outcomes. It may take years of encouragement from a healthcare provider before a patient is ready to adopt a mind-body practice; it is important to recognize and counsel patients with messages appropriate to their stage of change and self-efficacy. Additionally, case studies that combine the voice of the clinician and the patient can provide useful illustrations of truly patient-centered care.

SINOPSIS

Investigación: El interés en los estudios de casos clínicos ha experimentado un resurgir coincidente con el aumento del énfasis en la ejemplificación de la atención centrada en el paciente. Sin embargo, la inclusión del paciente de forma sustancial en estos estudios sigue siendo limitada. En el presente estudio, un médico y su paciente colaboraron para presentar un caso clínico de formación autodirigida en la atención plena y los posteriores cambios en la tensión arterial, la frecuencia de las migrañas y la calidad de vida.

Métodos: Tras ser animada a ello por su médico naturista, la paciente inició un programa de 8 semanas sobre formación en la atención plena siguiendo el protocolo de Kabat-Zinn, y registró su tensión arterial diaria y sus síntomas antes y después de las sesiones de meditación durante un periodo de 11 semanas.

Resultados: Los resultados indicados por la paciente incluyeron una disminución del estrés percibido, un aumento de la concentración, y una nueva sensación de concentración y en calma. Los cambios en los resultados objetivos...
Blood pressure changes

Figure 1a Systolic blood pressure over 11 weeks of MBSR.
Abbreviations: MBSR, mindfulness-based stress reduction; SBP, systolic blood pressure.

Figure 1b Diastolic blood pressure over 11 weeks of MBSR.
Abbreviations: DBP, diastolic blood pressure MBSR, mindfulness-based stress reduction.

Value of including patient’s voice:
Qualitative elements in a case report...

“I feel like I have a new tool to deal with an aging mother in another state, the uncertainty of our modern world, and with the students and staff I work with who are experiencing their own traumatic life events. Just as regular physical exercise has become important to my daily routine and ultimately health and well-being, mindfulness practice is now part of my daily life and has already had effects on my health and well-being.”

<table>
<thead>
<tr>
<th>Topic</th>
<th>Item</th>
<th>Checklist item description</th>
<th>Reported on Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>1</td>
<td>The words “case report” should be in the title along with the area of focus</td>
<td></td>
</tr>
<tr>
<td>Key Words</td>
<td>2</td>
<td>2 to 5 key words that identify areas covered in this case report</td>
<td></td>
</tr>
<tr>
<td>Abstract</td>
<td>3a</td>
<td>Introduction—What is unique about this case? What does it add to the medical literature?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>The main symptoms of the patient and the important clinical findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3c</td>
<td>The main diagnoses, therapeutics interventions, and outcomes</td>
<td></td>
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<tr>
<td></td>
<td>3d</td>
<td>Conclusion—What are the main “take-away” lessons from this case?</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td>4</td>
<td>One or two paragraphs summarizing why this case is unique with references</td>
<td></td>
</tr>
<tr>
<td>Patient Information</td>
<td>5a</td>
<td>De-identified demographic information and other patient specific information</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Main concerns and symptoms of the patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>Medical, family, and psychosocial history including relevant genetic information (also see timeline)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>Relevant past interventions and their outcomes</td>
<td></td>
</tr>
<tr>
<td>Clinical Findings</td>
<td>6</td>
<td>Describe the relevant physical examination (PE) and other significant clinical findings</td>
<td></td>
</tr>
<tr>
<td>Timeline</td>
<td>7</td>
<td>Important information from the patient’s history organized as a timeline</td>
<td></td>
</tr>
<tr>
<td>Diagnostic Assessment</td>
<td>8a</td>
<td>Diagnostic methods (such as PE, laboratory testing, imaging, surveys)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8b</td>
<td>Diagnostic challenges (such as access, financial, or cultural)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8c</td>
<td>Diagnostic reasoning including other diagnoses considered</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8d</td>
<td>Prognostic characteristics (such as staging in oncology) where applicable</td>
<td></td>
</tr>
<tr>
<td>Therapeutic Intervention</td>
<td>9a</td>
<td>Types of intervention (such as pharmacologic, surgical, preventive, self-care)</td>
<td></td>
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<tr>
<td></td>
<td>9b</td>
<td>Administration of intervention (such as dosage, strength, duration)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9c</td>
<td>Changes in intervention (with rationale)</td>
<td></td>
</tr>
<tr>
<td>Follow-up and Outcomes</td>
<td>10a</td>
<td>Clinician and patient-assessed outcomes (when appropriate)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10b</td>
<td>Important follow-up diagnostic and other test results</td>
<td></td>
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<tr>
<td></td>
<td>10c</td>
<td>Intervention adherence and tolerability (How was this assessed?)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10d</td>
<td>Adverse and unanticipated events</td>
<td></td>
</tr>
<tr>
<td>Discussion</td>
<td>11a</td>
<td>Discussion of the strengths and limitations in your approach to this case</td>
<td></td>
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<tr>
<td></td>
<td>11b</td>
<td>Discussion of the relevant medical literature</td>
<td></td>
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<tr>
<td></td>
<td>11c</td>
<td>The rationale for conclusions (including assessment of possible causes)</td>
<td></td>
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<tr>
<td></td>
<td>11d</td>
<td>The primary “take-away” lessons of this case report</td>
<td></td>
</tr>
<tr>
<td>Patient Perspective</td>
<td>12</td>
<td>When appropriate the patient should share their perspective on the treatments they received</td>
<td></td>
</tr>
<tr>
<td>Informed Consent</td>
<td>13</td>
<td>Did the patient give informed consent? Please provide if requested</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>
Case Series in HTN: Design & Setting

• Retrospective, observational case series for patients meeting 3 inclusion criteria:
  – Assessed w/ HTN by ICD-9 code (401.xx)
  – Minimum six month duration of care
  – Minimum 2 objective measures in the medical chart, e.g. blood pressure

• Outpatient care delivered between 2001-2006 at the academic clinic of a naturopathic medicine school

• Primary outcomes baseline BP measures vs. last observation (1°) plus longitudinal trends for change (2°)
Baseline Sample Characteristics

<table>
<thead>
<tr>
<th>Population Characteristic</th>
<th>Mean (SD) or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=85)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>60.6 (14.9) years</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>35 (41%)</td>
</tr>
<tr>
<td>Female</td>
<td>50 (59%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>45 (53%)</td>
</tr>
<tr>
<td>Non-White</td>
<td>12 (14%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>28 (33%)</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td></td>
</tr>
<tr>
<td>SBP</td>
<td>157.5 (20) mmHg</td>
</tr>
<tr>
<td>DBP</td>
<td>89.9 (11.8) mmHg</td>
</tr>
<tr>
<td>Blood Pressure Stage</td>
<td></td>
</tr>
<tr>
<td>Stage 1</td>
<td>30 (35%)</td>
</tr>
<tr>
<td>Stage 2</td>
<td>43 (51%)</td>
</tr>
<tr>
<td>Controlled (&lt;140/90) on Anti-HTN Medications</td>
<td>12 (14%)</td>
</tr>
<tr>
<td>Use of Anti-HTN Medications at First Visit</td>
<td>40 (47%)</td>
</tr>
<tr>
<td>New Anti-HTN Medication Added During ND Care Period</td>
<td>14 (16%)</td>
</tr>
</tbody>
</table>

Value?

- Identify care gaps
- Describe patients pursuing ND/IM care
- Clarify need for additional research, i.e., drug/herb/nutrient interactions

Bradley et al. eCAM. 2010.
Characteristics of ND Treatment

<table>
<thead>
<tr>
<th>Specific Dietary Advice</th>
<th>n (%) Receiving Advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase fruit &amp; vegetable intake</td>
<td>71 (83.5%)</td>
</tr>
<tr>
<td>Increase legumes/beans/nuts/whole grains</td>
<td>43 (50.6%)</td>
</tr>
<tr>
<td>Reduce dietary sodium</td>
<td>36 (42.3%)</td>
</tr>
<tr>
<td>Increase dietary fiber</td>
<td>31 (36.5%)</td>
</tr>
<tr>
<td>Increase fish intake</td>
<td>17 (20%)</td>
</tr>
<tr>
<td>Adopt the “DASH” diet</td>
<td>16 (18.8%)</td>
</tr>
<tr>
<td>Adopt the “Mediterranean” diet</td>
<td>3 (3.5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutritional Supplementation</th>
<th>n (%) Receiving Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3 Oils from Fish</td>
<td>47 (55.3%)</td>
</tr>
<tr>
<td>“Combo 1”</td>
<td>43 (50.6%)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>37 (43.5%)</td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td>33 (38.8%)</td>
</tr>
<tr>
<td>Crataegus oxycanthus (Hawthorne)</td>
<td>28 (32.9%)</td>
</tr>
<tr>
<td>“Combo 2”</td>
<td>11 (12.9%)</td>
</tr>
<tr>
<td>Potassium</td>
<td>7 (8.2%)</td>
</tr>
</tbody>
</table>

Value?

- Describe unknown care patterns
- Identify future research questions
- Identify needs for provider education/QI

Bradley et al. eCAM. 2010.
Mean Changes in Systolic Blood Pressure During ND Care for HTN

**Blood Pressure Category**

- **Systolic**
  - Baseline: 157.5 mmHg
  - Last Observation: 141.4 mmHg
  - Change: -16.1 mmHg
  - 95% CI: (-10.7, -21.4, p<0.0001)

- **Stage 1**
  - Baseline: 146.3 mmHg
  - Last Observation: 137.3 mmHg
  - Change: -9.0 mmHg
  - 95% CI: (-1.73, -16.3, p=0.017)

- **Stage 2**
  - Baseline: 172.8 mmHg
  - Last Observation: 146.7 mmHg
  - Change: -26.1 mmHg
  - 95% CI: (-17.9, -34.2, p<0.0001)

Bradley et al. eCAM. 2010.
Conceptual Model for Future Research

Bradley et al. eCAM. 2010.
Limitations

• Observational data = cannot determine causality
• Patients self-select = uniquely motivated ≠ generalizable findings
• No natural history, usual care or active control
• Cannot determine factors responsible for observed changes
Quasi-Experimental, Mixed-methods Research: Bringing Adjunctive Naturopathy to Diabetes (BAND)

• Specific Aim: Conduct a one-year, prospective, cohort study of Naturopathic care added to usual Care in patients with type 2 diabetes
  
  o **Primary Outcome**: Changes in patient-reported outcomes (PROs) related to diabetes self-care, self-efficacy and mood before, during and after ANC
  
  o **Secondary outcome**: Changes in HbA1c compared to a Usual Care e-comparison group
Group Health Cooperative

- Large integrated health care delivery system
  - Insurer & Care Delivery System
  - Managed care
- 549,589 covered lives in WA
- Among highest health care quality rankings in the US (NCQA/HEDIS)
- First to demonstrate success of “medical home” primary care model
Patient/Sample Population

- N=30
- Adults aged 21-65 w/ DM2 not using insulin
- Enrolled in a plan w/ ND benefit
- Recent (w/in 1 year) HbA1c=7.5-9.5%
- Presence of 1 add’ n CM risk factor:
  - LDL (>100 mg/dl),
  - HDL (< 35 mg/dl),
  - TG, (> 150 mg/dl)
  - BMI (>25),
  - HTN (>130/80)
- Those not “disallowed” by their PCP
- Exclusions: recent CA (ex. skin), NYHA Stage 3-4 CHF, MI w/in 6 months, late stage CKD (creatinine>2), bariatric surgery, PG
Recruitment

• Candidates identified using EHR by inclusion criteria & mailed letter of invitation + response card w/ opt out phone number

• Telephone screening, and then baseline A1c + lipids ordered to confirm eligibility to provides “clean” baseline data (vs. EPIC data up to 1-yr old)
Intervention

• Naturopathic care delivered by 1 of 5 licensed providers in the community
• Patients selected based on their preferences
• No restrictions on care, delivered per scope of practice
• Number and content of visits monitored, but not managed
Control

• Eligible GHC patients based on EHR screening, not contacted by study team
• Electronically abstracted clinical lab data from EHR
• No control for patient-reported outcomes (PROs) data
Approach: Data Collection

• Clinical Data:
  – Required clinical laboratory testing at BL, 6- and 12- months in ND group
  – EHR abstracted

• PROs:
  – Telephone survey at BL, 6- and 12-months in ND group

• ND Care Descriptions:
  – Standardized progress notes provided to NDs
Results: Patient-Reported Outcomes

Change in Patient-reported Outcomes During Adjunctive Naturopathic Care (ANC)

- Glucose (% increase SDSCA) *
- Mood (% reduction PHQ-8) *
- Activity (% increase SDSCA)
- Self-efficacy (% increase SES) *
- Stress (% reduction PAID)
- Diet (% increase SDSCA)
- % non-depressed (%<10 PHQ-8)
- Lifestyle (% change in RI) *
- Commitment (% change in RI)
- Stress (% reduction PSS)

Results: Change in Clinical Glycemic Risk


Change in 6-month Hemoglobin A1c (HbA1c)

- ANC: Adjunctive Naturopathic Care (n=40)
- UC: Usual Care (n=329)

Change in UC* = -0.39% [95% CI: -0.80, 0.02], p=0.07
Change in ANC* = -0.90% [95% CI: -1.64, -0.16], p=0.02

Difference* = -0.51% [95% CI: -0.80, 0.02], p=0.07

Change in 12-month Hemoglobin A1c (HbA1c)

- ANC: Adjunctive Naturopathic Care (n=40)
- UC: Usual Care (n=329)

Change in UC* = +0.03% [95% CI: -0.18, 0.24], p=0.24
Change in ANC* = -0.37% [95% CI: -0.87, 0.12], p=0.14

Difference* = -0.34% [95% CI: -0.80, 0.12], p=0.12

* Adjusted for age, gender, baseline HbA1c, and use of sulfonylureas or metformin

Timepoint (months since baseline)
# Mixed-Methods: Qualitative Components

<table>
<thead>
<tr>
<th>Themes Related to the Content of Naturopathic Care</th>
<th>Example codes and patients’ terminology</th>
<th>% expressing theme</th>
</tr>
</thead>
</table>
| **Health promotion counseling: detailed & individualized** | - Naturopathic diet recommendations given  
- Exercise prescriptions common and goals established with patient’s input  
- Stress management routinely discussed  
- Other lifestyle change addressed such as promoting positive mental/emotional health | 100 |
| **Counseling promoted patient empowerment** | - Learning to engage in self-reflection/self-awareness  
- Increased behavioral capabilities/competence  
- Strategies for prioritizing self-care  
- Understanding and executing self-management activities | 95 |
| **Recommendations were pragmatic** | - “Tips” about diet, exercise and other health behaviors emphasized real-world implementation  
- Problem-solving (barriers to behavior change, reasons for unexpected blood sugar changes) occurred  
- Learned to experiment and observe effect of different behaviors/foods on blood sugar | 82 |
| **Novel & complementary treatment options were offered** | - Feeling hopeful about having alternatives  
- Feeling open to trying new things  
- Trying dietary supplements & natural products for both glycemic control and other health concerns | 82 |
| **Information about diabetes and self-management improved health literacy** | - Felt better educated about diabetes as a disease and goals for self-management  
- Felt better educated about the role of psychosocial, behavioral, and emotional factors in relation to blood sugar  
- Received educational materials from ND | 77 |

Sums to >100% because some participants offered multiple responses

Limitations

• Observational data = cannot determine causality
• Not randomized
• Patients self-select = uniquely motivated = limited generalizability
• Multiple exposures, i.e., cannot determine characteristic(s) of care responsible for observed changes
Prospective Observational Methods in Practice: Naturopathy in Diabetes and CVD
Specific Aims

• Estimate the effectiveness of naturopathic care for eliciting beneficial changes in:
  – Self-efficacy
  – Self-care
  – Quality of Life
  – Mood/depression
Research question:
Does Naturopathy impact Patient Behavior Change? And if so, on what timeline?
Methods

• Prospective cohort design
• Mobile web browser used for data collection research electronic data capture, i.e., REDCap (Vanderbilt University)
Measures

• General Measures
  – Anthropometrics
  – Clinical labs (HbA1c)
  – Demographics

• Patient Reported Outcomes
  – Self Care: Summary of Diabetes Self-Care Activities (SDSCA)
  – Quality of Life: SF-12
  – Mood: Patient Health Questionnaire (PHQ-8)
  – Self Efficacy Scale (SES)

# Study Timeline and Procedures

<table>
<thead>
<tr>
<th>Data Collection Instrument</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment and Baseline Visit</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
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<tr>
<td>Consent Form</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
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<tr>
<td>Demographics</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Medications and Supplements</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Anthropometrics and Risk Assessment</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Baseline intake</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
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<tr>
<td>Baseline INTERHEART Psychosocial Stress</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Return Visits - Description</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Treatment Categories</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>SF-12</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>PHQ-8</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Summary Diabetes Self-Care Activities</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Self-efficacy Scale</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>Baseline-DM Only - Information Page</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
<tr>
<td>DM Only - Glucose Monitoring</td>
<td>Q1 (3) Q2 (4) Q3 (5) Q4 (6) Year 1 Telephone Interview (7) Q5 (8) Q6 (9) Q7 (10) Q8 (11) Year 2 Telephone Interview (12) Q9 (13) Q10 (14) Q11 (15) Year 3 Telephone Interview (17)</td>
</tr>
</tbody>
</table>
Baseline data collection

• Questionnaires embedded into baseline intake
• Data collected during student/resident/attending case consult for low impact on patient care
Study flow data collection thru entry: Baseline

Patient Intake

Patient

Student or RA reviews consent and copies if signed

Primary Clinician

Research Assistant/Coordinator

Data entry

Chart, as applicable

Bradley R. 2012
ND-PROHD: Study flow data collection thru entry: Return Visits

Student/resident leaves exam room for consult

Student/resident

Research Assistant/Coordinator

**Could be e-survey

Data entry using iPad, i.e., SF-12, PHQ-8, SDSCA, SES only

Patient outcomes?

Bradley R. 2012
Results to-date: Self-efficacy

Changes in Self-Efficacy: Baseline to First Return Visit

- Composite: p=0.005
- Stress: p=0.007
- Exercise: p=0.005
- Diet: p=0.010

α <0.0125 equals Bonferroni-corrected threshold for significance
Results to-date: Self-care Categories

Summary of Diabetes Self-Care Activities- Composites:
Baseline to First Return Visit

- Taking Supplements
- Taking Medications
- Stress
- Exercise
- Diet

Means days per week performing activity

all p>0.01
Semi-Pragmatic Trials: Outcomes from Integrative Practice Models

Naturopathic medicine for the prevention of cardiovascular disease: a randomized clinical trial

Dugald Seely ND MSc, Orest Szczurko ND MSc, Kieran Cooley ND, Heidi Fritz ND MA, Serenity Aberdour ND, Craig Herrington ND, Patricia Herrington ND PhD, Phillip Rouchotas MSc ND, David Leschied ND PhD, Ryan Bradley ND MPH, Tara Gignac ND, Bob Bernhardt LLM PhD, Qi Zhou PhD, Gordon Guyatt MD MSc

Background: Although cardiovascular disease may be partially preventable through dietary and lifestyle-based interventions, few individuals at risk receive intensive dietary and lifestyle counselling. We performed a randomized controlled trial to evaluate the effectiveness of naturopathic care in reducing the risk of cardiovascular disease.

Methods: We performed a multi-site randomized controlled trial of enhanced usual care (usual care plus biomarker measurement; control) compared with enhanced usual care plus naturopathic care (hereafter called naturopathic care). Postal workers aged 25-65 years in Toronto, Vancouver, and Edmonton, Canada, with an increased risk of cardiovascular disease were invited to participate. Participants in both groups received care by their family physicians. Those in the naturopathic group also received individualized care (health promotion counselling, nutritional medicine or dietary supplementation) at 7 preset times in worksite clinics by licensed naturopathic doctors. The body weight, waist circumference, lipid profile, fasting glucose levels and blood pressure of participants in both groups were measured 3 times during a 1-year period. Our primary outcome was the 10-year risk of having a cardiovascular event (based on the Framingham risk algorithm) and the prevalence of metabolic syndrome (based on the Adult Treatment Panel III diagnostic criteria).

Results: Of 246 participants randomly assigned to a study group, 203 completed the study. The characteristics of participants in both groups were similar at baseline. Compared with participants in the control group, at 52 weeks those in the naturopathic group had a reduced adjusted 10-year cardiovascular risk (control: 10.81%; naturopathic group: 7.74%; p < 0.001), a lower risk of metabolic syndrome (control group: 51.4%; naturopathic group: 31.58%; p = 0.002), a lower adjusted frequency of metabolic syndrome (control group: 48.4%; naturopathic group: 11.53%; p = 0.036), and a smaller adjusted frequency of cardiovascular disease (control group: 29.55% to 23.25%, p = 0.002).

Interpretation: Our findings support the hypothesis that the addition of naturopathic care to enhanced usual care may reduce the risk of cardiovascular disease among those at high risk. Trial registration: ClinicalTrials.gov, no. NCT00717579.

1. Naturopathic medicine will reduce the risk of developing cardiovascular disease
2. Naturopathic care has the potential to reduce overall company and societal costs of medical care.
CardioHealth: Design Considerations

• Design: RCT
• Intervention: Delivered in 1 of 3 Canadian cities in provider’s practices for 1 year
• Treatments selected from a pre-determined palette of options based on a priori Delphi process
• Outcomes: Anthropometrics, lipids, BP to evaluate:
  – Framingham Risk Score
  – Presence or absence of Metabolic Syndrome
Semi-Pragmatic Trials: 
Outcomes from Integrative Practice Models

RCT Evidence of Reduced 10-year Framingham 
CVD Risk during Naturopathic Care

```
Time (months)
```

```
10-year Framingham Risk (%)
```

```
ND + Usual Care
Usual Care
```

```
-3.04 % (-4.35, -1.78); p < 0.001
```

RCT Evidence of Reduced Metabolic Syndrome 
during Naturopathic Care

```
Time (months)
```

```
% Metabolic Syndrome
```

```
ND + Usual Care
Usual Care
```

```
-16.9 % (-29.5, -4.3), p=0.002
```

Limitations

• Multiple exposures, i.e., cannot determine characteristic(s) of care responsible for observed changes
Resource: Equator Network

Enhancing the QUALity and Transparency Of health Research

Essential resources for writing and publishing health research

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

- Search for reporting guidelines
- Not sure which reporting guideline to use?
- Reporting guidelines under development
- Visit the library for more resources

Reporting guidelines for main study types

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See all 284 reporting guidelines

http://www.equator-network.org