



# *Successful Implementation of IM PBR*

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# 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



## CASE REPORT

# Self-directed Mindfulness Training and Improvement in Blood Pressure, Migraine Frequency, and Quality of Life

自我指导式的正念训练及改善高血压、偏头痛频率和生活质量

Formación autodirigida en la atención plena y mejora de la tensión arterial, la frecuencia de las migrañas y la calidad de vida

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ethical or financial  
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to report.

## Key Words

Mindfulness, medita-  
tion, hypertension,  
migraine, complementary  
and alternative  
medicine, case report,  
patient-centered care

## 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 her 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 ( $P = .0001$  and  $P = .0004$  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.

## 抽象

背景：在对病例研究的兴趣重现的同时，对以患者为中心的护理描述也得到进一步的重视。但是，这些报告中有关患者的实在内容仍是有限。一名医生和患者共同完成她的病例报告，在此介绍其自我指导式的正念训练及随后在高血压、偏头痛频率和生活质量上的变化。

方法：在自然疗法医生的鼓励下，该患者在接受 Kabat-Zinn 的治疗方案后，开始了一项为期 8 周的正念训练计划，并每天记录冥想前后的血压和症状，为期 11 周。

结果：病人报告的结果包括感觉压力降低、注意力更集中、并产生中心与平静感。客观结果有临床和统计上显著的变化，包括第 1 周和第 11 周之间的平均收缩压和舒张压降低（通过配对双面对  $t$  检验，收缩压和舒张压分别为  $P = .0001$  及  $P = .0004$ ）。自我报告的慢性偏头痛频率也有所降低。患者成功的关键是先以简单、易于理解的方式开始正念训练，之后再行更深层次、更久的训练。

讨论和结论：自我指导式正念训

练可对主观和客观的健康结果产生有意义的影响。患者准备采取身心治疗方式前，可能需要医疗服务提供者多年的支持；重要的是识别及使用符合患者变化与自我效能阶段的话语以进行咨询。此外，结合临床医生和患者感受的病例研究可为真正以患者为中心的护理提供有用的例证。

## SINOPSIS

**Fundamentación:** 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 colaboran 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.

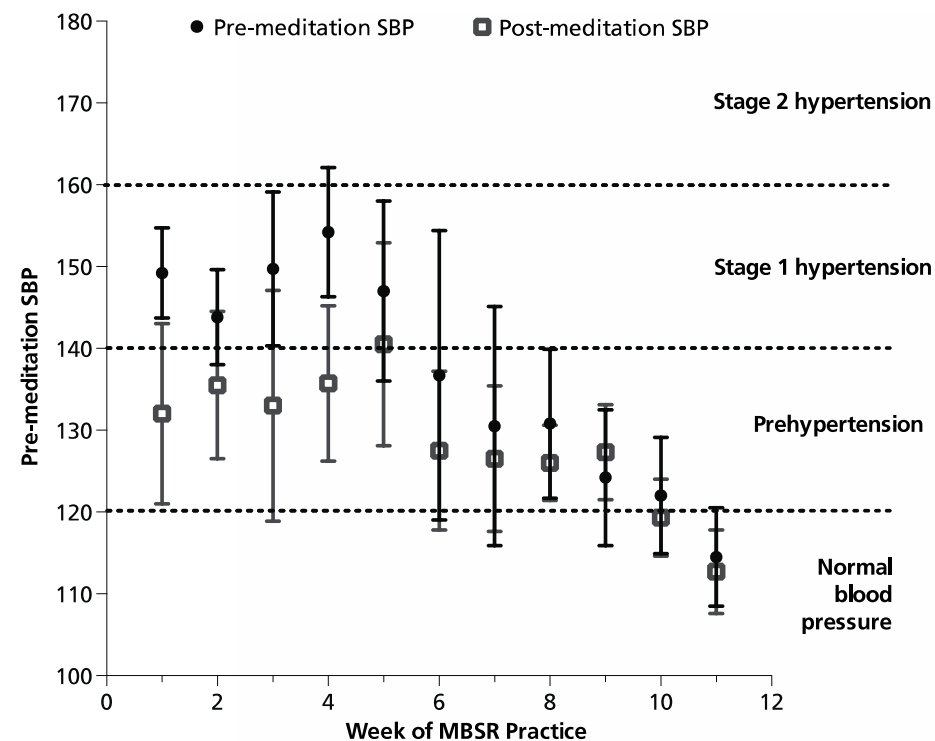
**Métodos:** Tras ser animada a ello por su médico naturista, la paciente inició un programa de 8 semanas sobre formación en la atención plena siguiendo el protocolo de Kabat-Zinn, y registró su tensión arterial diaria y sus síntomas antes y después de las sesiones de meditación durante un periodo de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



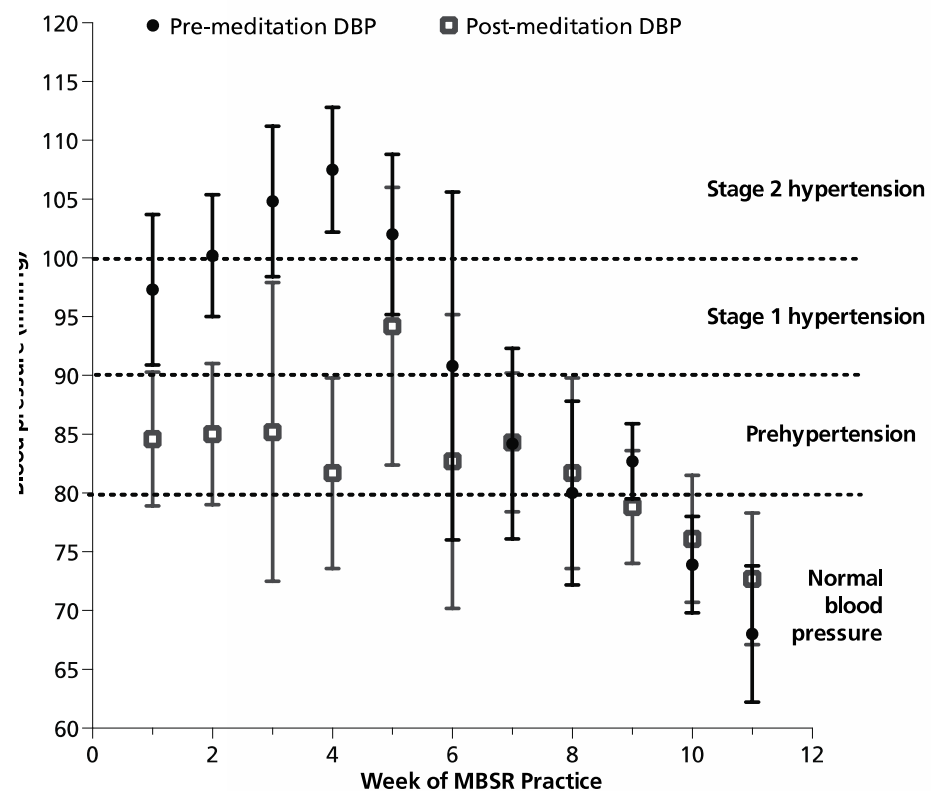
Oberg E, Bradley R. Global Adv Health Med. 2013;2(2):20-25

# 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."*

# CARE Guidelines:

## www.care-statement.org



**CARE Checklist (2013) of Information to Include when Writing a Case Report**



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

## 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<sup>o</sup> ) plus longitudinal trends for change (2<sup>o</sup> )

# Baseline Sample Characteristics

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

## Value?

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



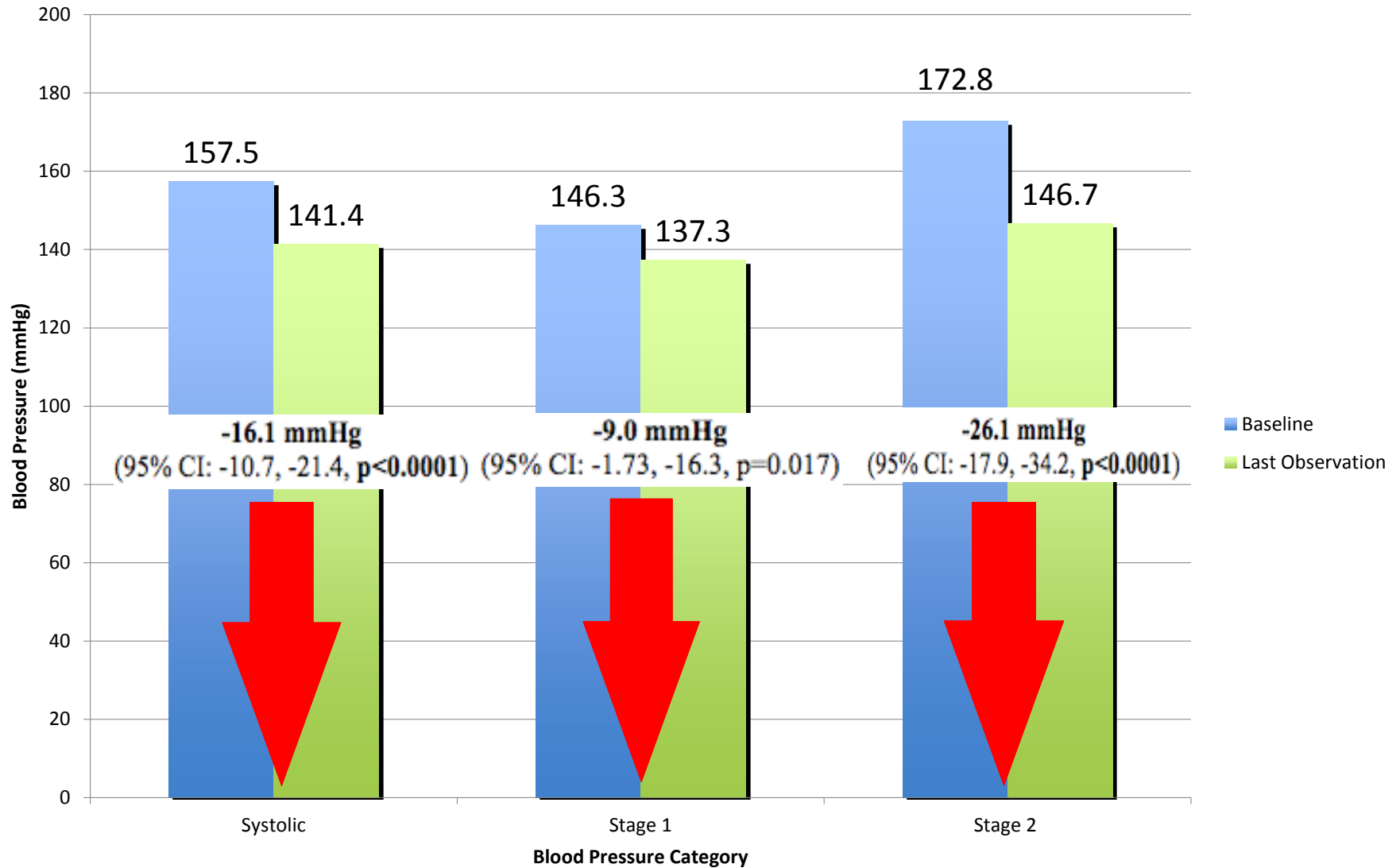
# Characteristics of ND Treatment

Specific Dietary Advice	n (%) Receiving Advice
Increase fruit & vegetable intake	71 (83.5%)
Increase legumes/beans/nuts/whole grains	43 (50.6%)
Reduce dietary sodium	36 (42.3%)
Increase dietary fiber	31 (36.5%)
Increase fish intake	17 (20%)
Adopt the “DASH” diet	16 (18.8%)
Adopt the “Mediterranean” diet	3 (3.5%)
Nutritional Supplementation	n (%) Receiving Recommendation
Omega-3 Oils from Fish	47 (55.3%)
“Combo 1”	43 (50.6%)
Magnesium	37 (43.5%)
Coenzyme Q10	33 (38.8%)
Crataegus oxyanthus (Hawthorne)	28 (32.9%)
“Combo 2”	11 (12.9%)
Potassium	7 (8.2%)

## Value?

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

## Mean Changes in Systolic Blood Pressure During ND Care for HTN



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Figure 1. GAM 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
  - Primary Outcome: Changes in patient-reported outcomes (PROs) related to diabetes self-care, self-efficacy and mood before, during and after ANC
  - 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'l 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

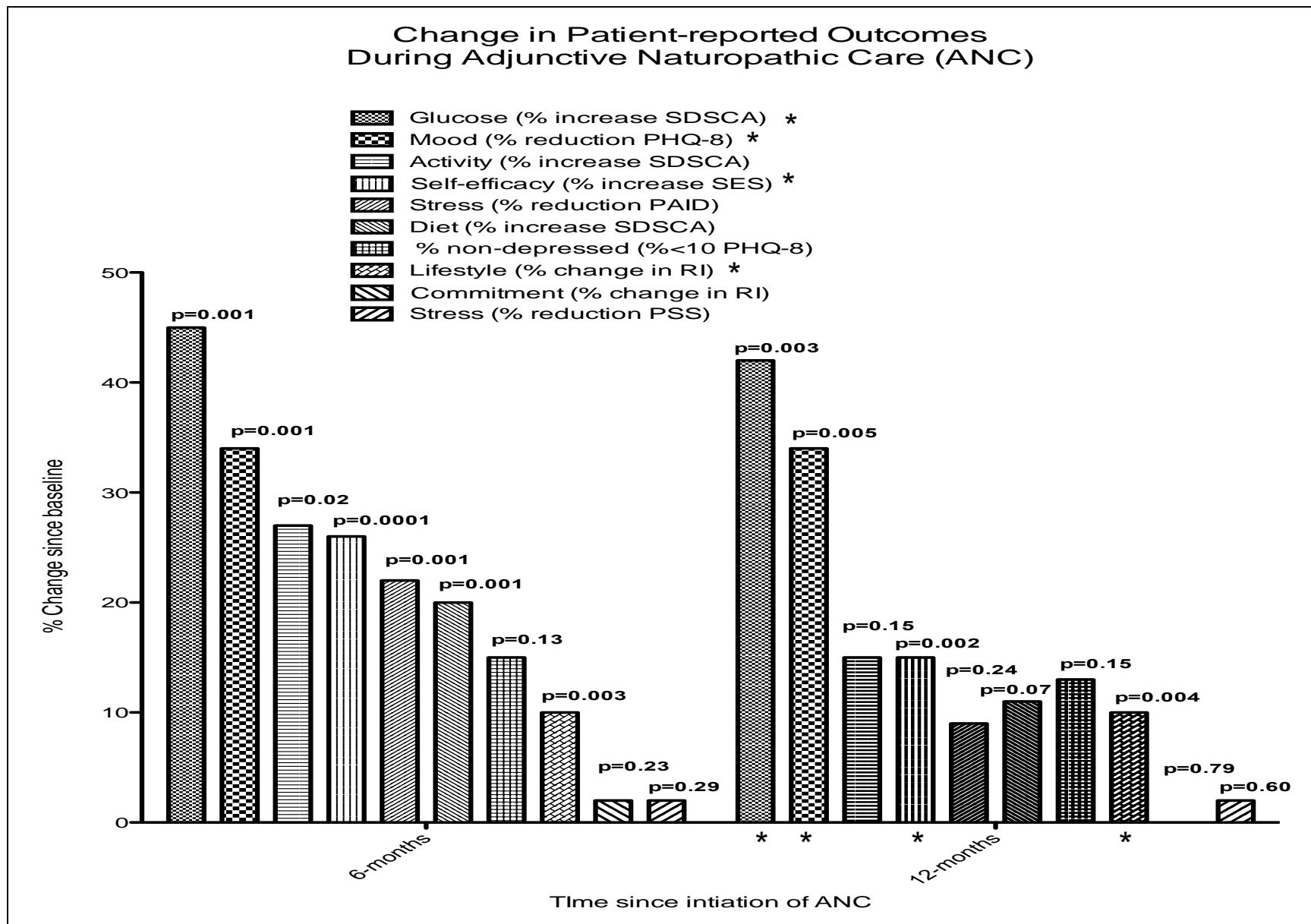
# Control

- 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

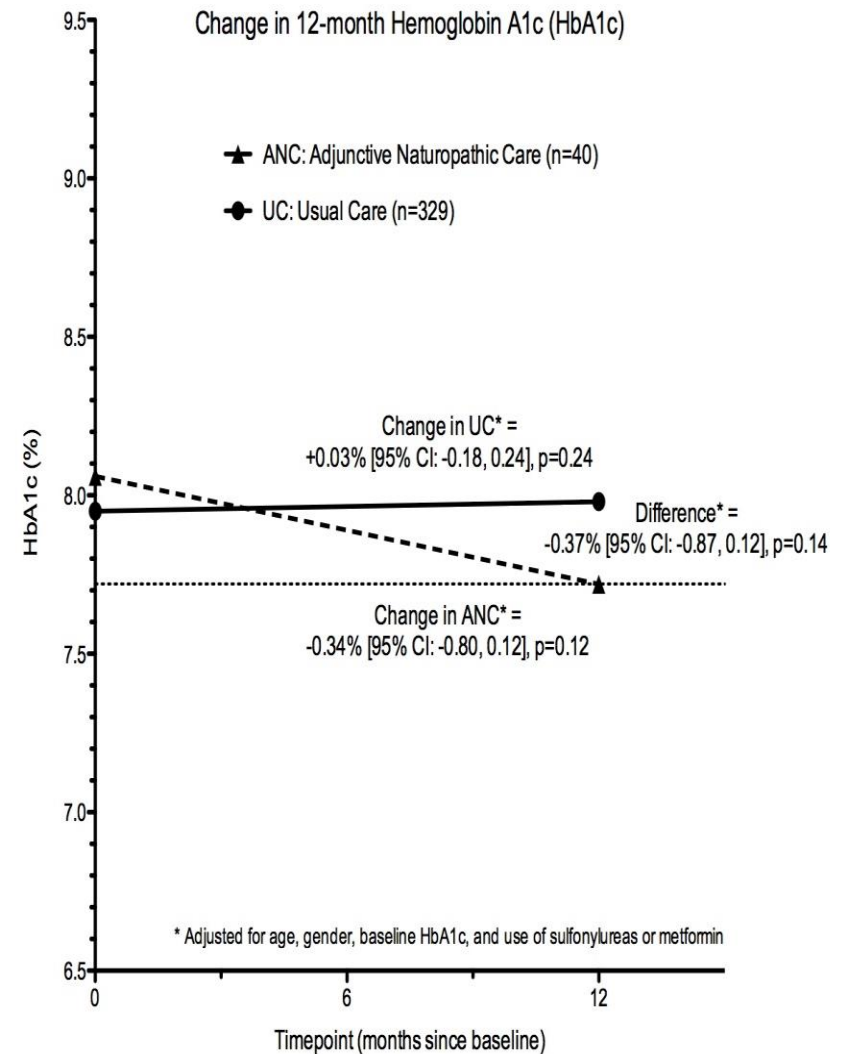
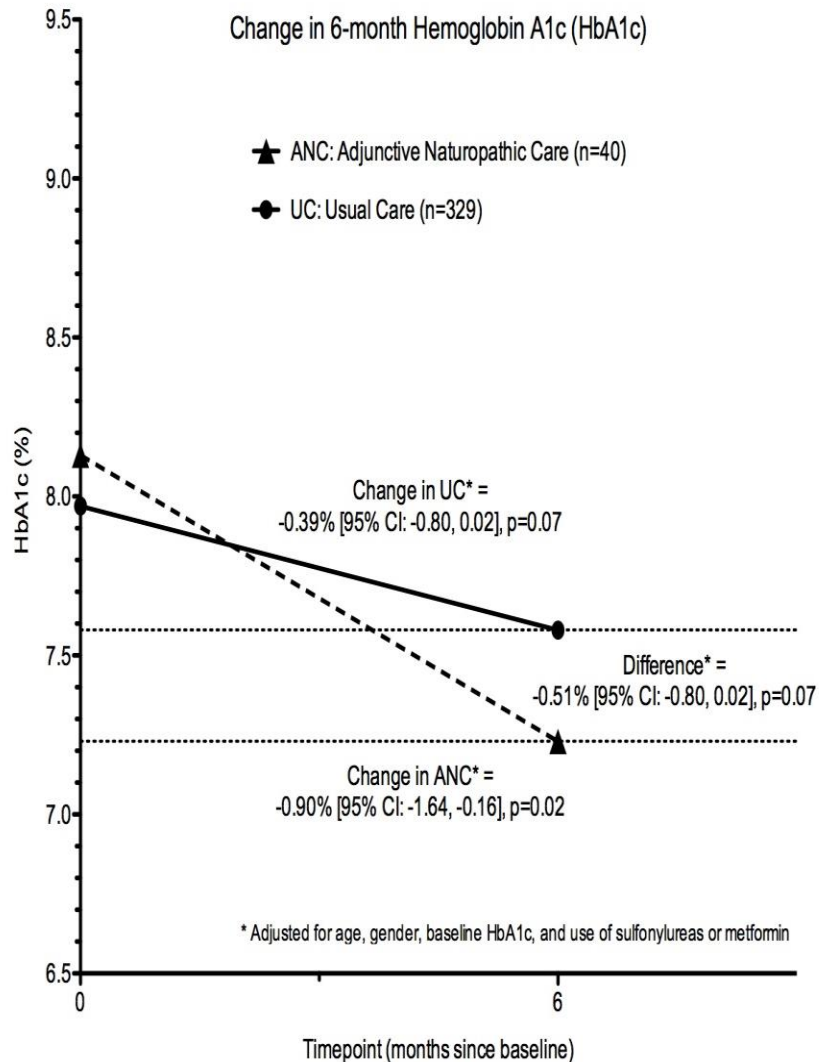
# Approach: Data Collection

- 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



# Results: Change in Clinical Glycemic Risk



# Mixed-Methods: Qualitative Components

THEMES RELATED TO THE <i>CONTENT</i> OF NATUROPATHIC CARE		
Theme	Example codes and patients' terminology	% expressing theme
<b>Health promotion counseling: detailed &amp; individualized</b>	<ul style="list-style-type: none"> <li>Naturopathic diet recommendations given</li> <li>Exercise prescriptions common and goals established with patient's input</li> <li>Stress management routinely discussed</li> <li>Other lifestyle change addressed such as promoting positive mental/emotional health</li> </ul>	100
<b>Counseling promoted patient empowerment</b>	<ul style="list-style-type: none"> <li>Learning to engage in self-reflection/self-awareness</li> <li>Increased behavioral capabilities/competence</li> <li>Strategies for prioritizing self-care</li> <li>Understanding and executing self-management activities</li> </ul>	95
<b>Recommendations were pragmatic</b>	<ul style="list-style-type: none"> <li>"Tips" about diet, exercise and other health behaviors emphasized real-world implementation</li> <li>Problem-solving (barriers to behavior change, reasons for unexpected blood sugar changes) occurred</li> <li>Learned to experiment and observe effect of different behaviors/foods on blood sugar</li> </ul>	82
<b>Novel &amp; complementary treatment options were offered</b>	<ul style="list-style-type: none"> <li>Feeling hopeful about having alternatives</li> <li>Feeling open to trying new things</li> <li>Trying dietary supplements &amp; natural products for both glycemic control and other health concerns</li> </ul>	82
<b>Information about diabetes and self-management improved health literacy</b>	<ul style="list-style-type: none"> <li>Felt better educated about diabetes as a disease and goals for self-management</li> <li>Felt better educated about the role of psychosocial, behavioral, and emotional factors in relation to blood sugar</li> <li>Received educational materials from ND</li> </ul>	77
Sums to >100% because some participants offered multiple responses		

# Limitations

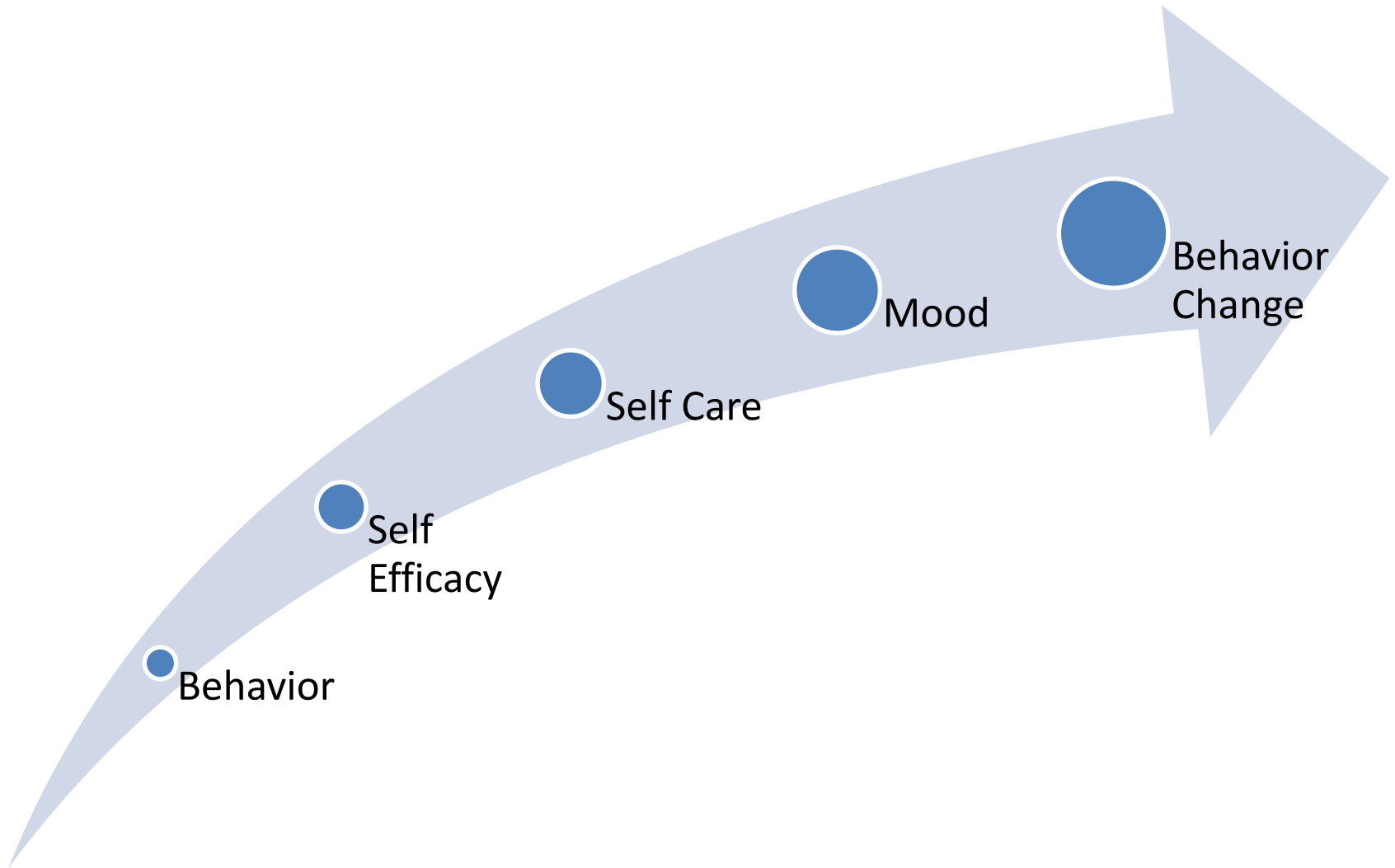
- Observational data = cannot determine causality
- Not randomized
- Patients self-select = uniquely motivated = limited generalizability
- Multiple exposures, i.e., cannot determine characteristic(s) of care responsible for observed changes

# 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

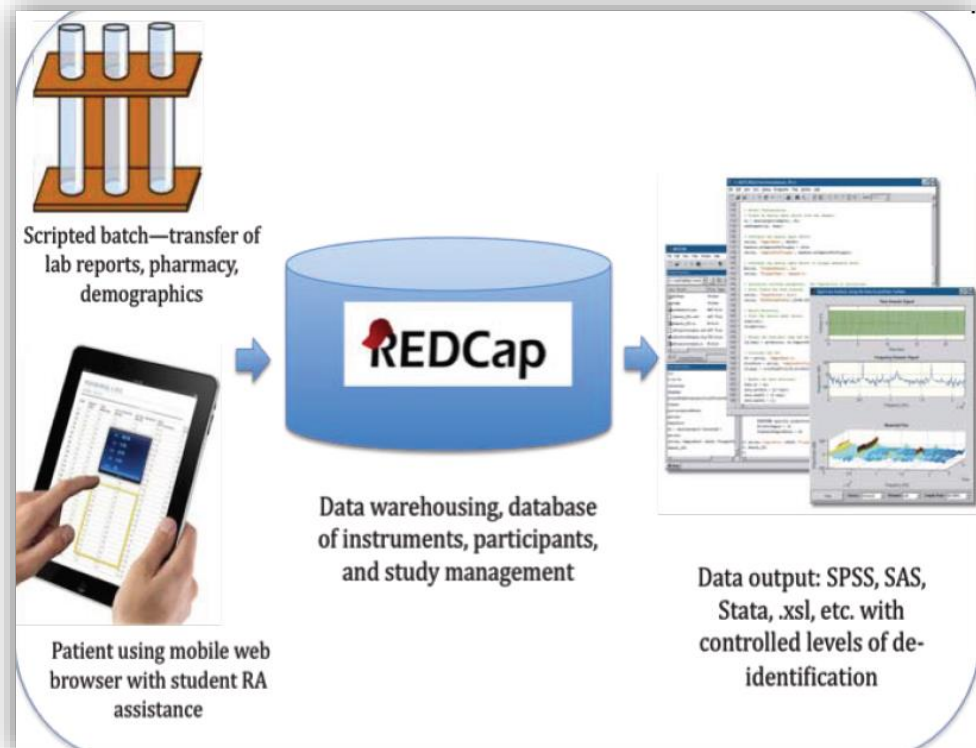


# Research question: Does Naturopathy impact Patient Behavior Change? And if so, on what timeline?



# 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

Data Collection Instrument	Events																
	Baseline (1)	First ROC (2)	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)	Q12 (16)	Year 3 Telephone Interview (17)
Enrollment and Baseline Visit	●																
Consent Form	●																
Demographics	●					●	●				●	●				●	●
Medications and Supplements	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Anthropometrics and Risk Assessment	●	●	●	●	●	●		●	●	●	●		●	●	●	●	
Baseline intake	●																
Baseline INTERHEART Psychosocial Stress	●																
Return Visits- Description		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Treatment Categories																	
SF-12	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
PHQ-8	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Summary Diabetes Self-Care Activities	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Self-efficacy Scale	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Baseline-DM Only- Information Page	●																
DM Only-Glucose Monitoring	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

# Baseline data collection

- Questionnaires embedded into baseline intake
- Data collected during student/resident/attending case consult for low impact on patient care

## Please share some information about your quality of life:

1. In general, would you say your health is? Circle:

Excellent      Very Good      Good      Fair      Poor

2. Does your health now limit you in these activities during a typical day? If so, how much?

2a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf? Circle:

Yes, a lot limited      Yes, a little limited      No, not limited at all

2b. Climbing several flights of stairs? Circle:

Yes, a lot limited      Yes, a little limited      No, not limited at all

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

3a. Accomplished less than you would like? Circle:

All of the time      Most of the time      Some of the time      A little of the time      None of the time

3b. Were limited in the kind of work or other activities? Circle:

All of the time      Most of the time      Some of the time      A little of the time      None of the time

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

4a. Accomplished less than you would like? Circle:

All of the time      Most of the time      Some of the time      A little of the time      None of the time

## Please share your current self-care:

The next questions ask about how you have taken care of yourself over the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick. Circle the number of days you engaged in the activity asked about in the question:

1. How many of the last SEVEN DAYS have you followed a healthful eating plan?

0    1    2    3    4    5    6    7

2. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

0    1    2    3    4    5    6    7

3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

0    1    2    3    4    5    6    7

4. On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

0    1    2    3    4    5    6    7

5. On how many of the last SEVEN DAYS did you limit your starchy foods, or carbohydrates during the day?

0    1    2    3    4    5    6    7

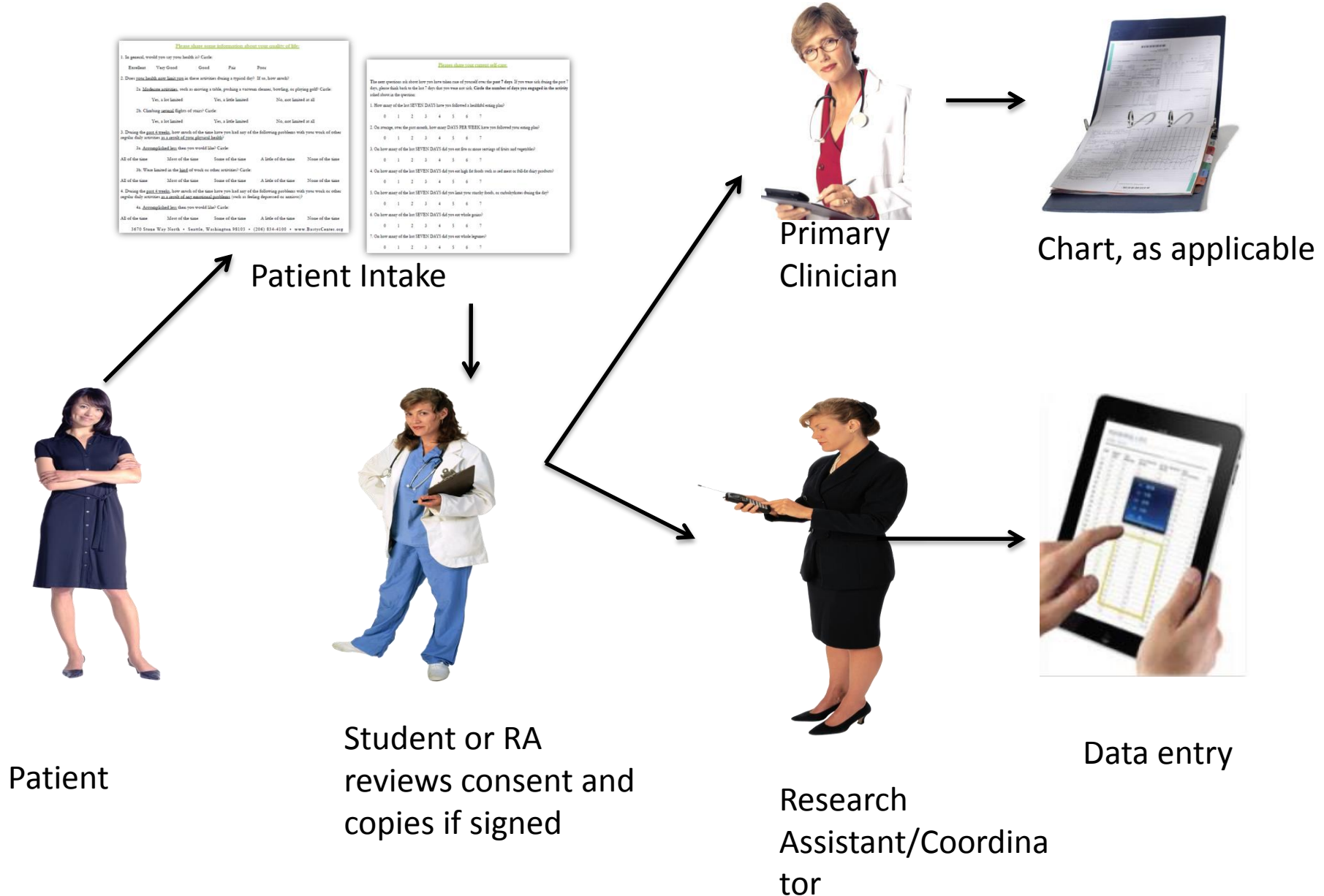
6. On how many of the last SEVEN DAYS did you eat whole grains?

0    1    2    3    4    5    6    7

7. On how many of the last SEVEN DAYS did you eat whole legumes?

0    1    2    3    4    5    6    7

# Study flow data collection thru entry: Baseline



# ND-PROHD: Study flow data collection thru entry: Return Visits

Student/resident leaves exam room for consult



Student/Resident  
Clinician



Research  
Assistant/Coordinator

\*\*Could be e-survey



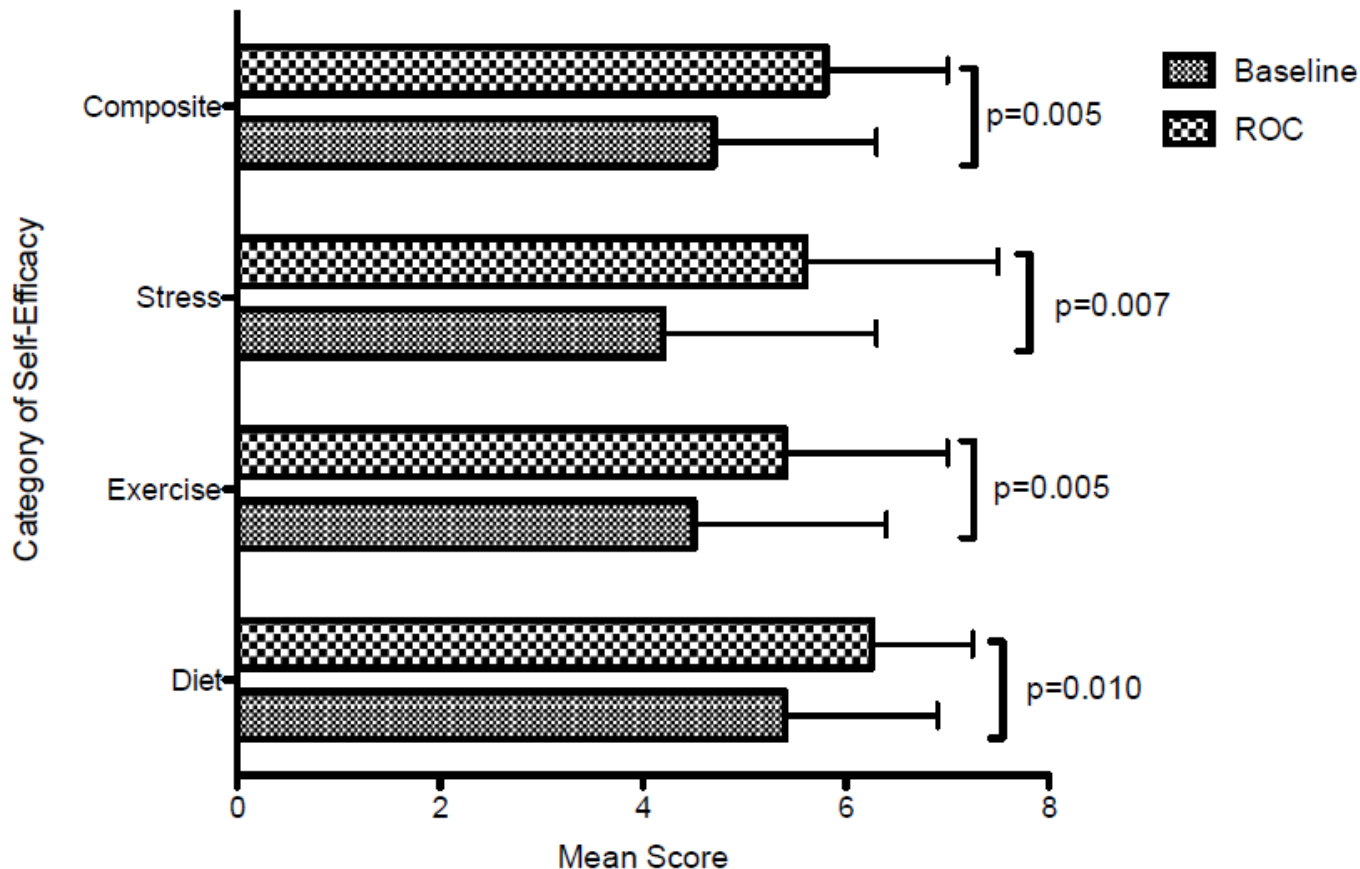
Data entry using  
iPad, i.e., SF-12,  
PHQ-8, SDSCA,  
SES only



Patient  
outcomes?

# Results to-date: Self-efficacy

Changes in Self-Efficacy:  
Baseline to First Return Visit

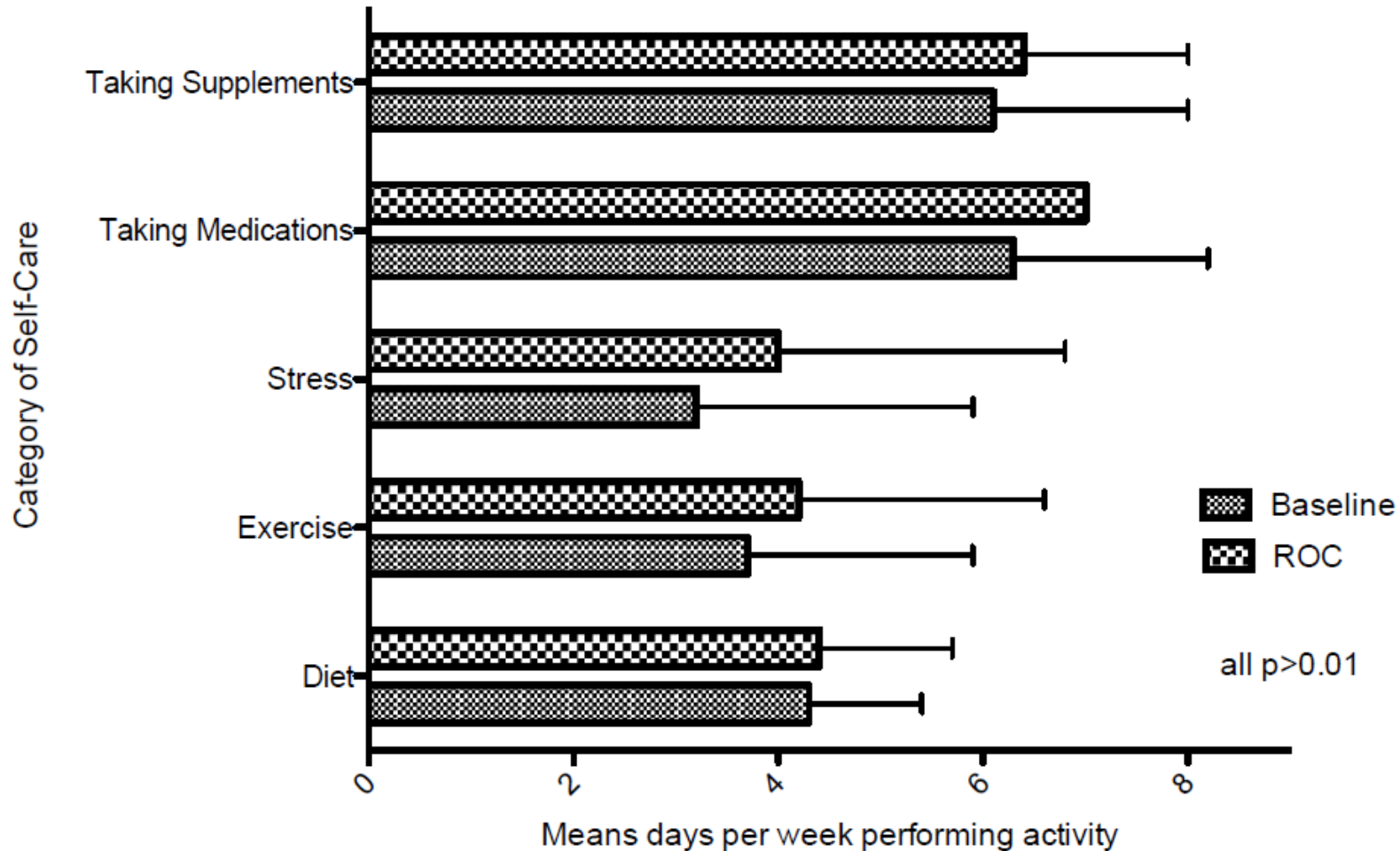


$\alpha < 0.0125$  equals Bonferroni-corrected threshold for significance




# Results to-date: Self-care Categories

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



# Semi-Pragmatic Trials: Outcomes from Integrative Practice Models



**improving  
cardio  
health:  
there is an  
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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.

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RESEARCH

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

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See related editorial at [www.cmaj.ca/lookup/doi/10.1503/cmaj.130614](http://www.cmaj.ca/lookup/doi/10.1503/cmaj.130614)

### ABSTRACT

**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 multisite randomized controlled trial of enhanced usual care (usual care plus biometric 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 work-site 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 outcomes were 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, 207 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%; risk reduction –3.07% [95% confidence interval (CI) –4.35% to –1.78%],  $p < 0.001$ ) and a lower adjusted frequency of metabolic syndrome (control group: 48.48%; naturopathic care: 31.58%; risk reduction –16.90% [95% CI –29.55% to –4.25%],  $p = 0.002$ ).

**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. NCT0071879.

**Competing interests:** See end of article.

This article has been peer reviewed.

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Cardiovascular disease is the second leading cause of death in Canada.<sup>1</sup> Observational studies, including a large international case-control study, have shown that several modifiable behavioural factors contribute to the risk of cardiovascular disease.<sup>2</sup> Metabolic syndrome, a cluster of modifiable risk factors for atherosclerotic cardiovascular disease, is strongly associated with increased risk of cardiovascular-related mortality.<sup>3,4</sup> Guidelines by the American Heart Association and the United States Preventive Services Task Force recommend lifestyle interventions as an important part of cardiovascular disease prevention.<sup>5,6</sup> Although the

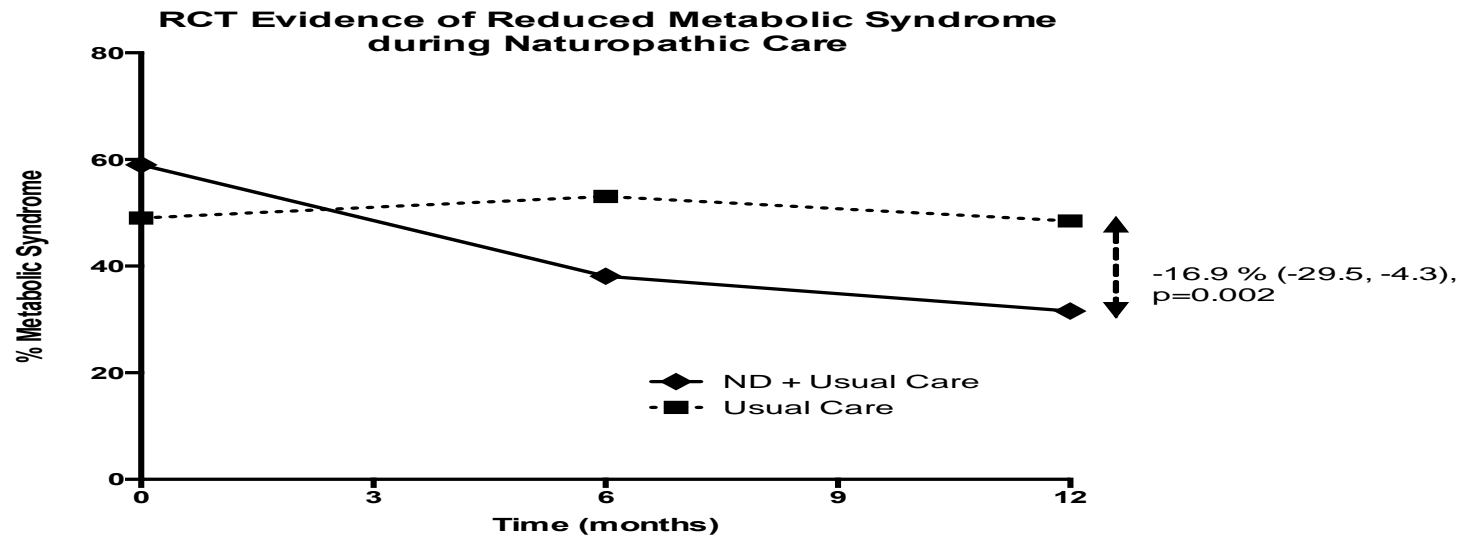
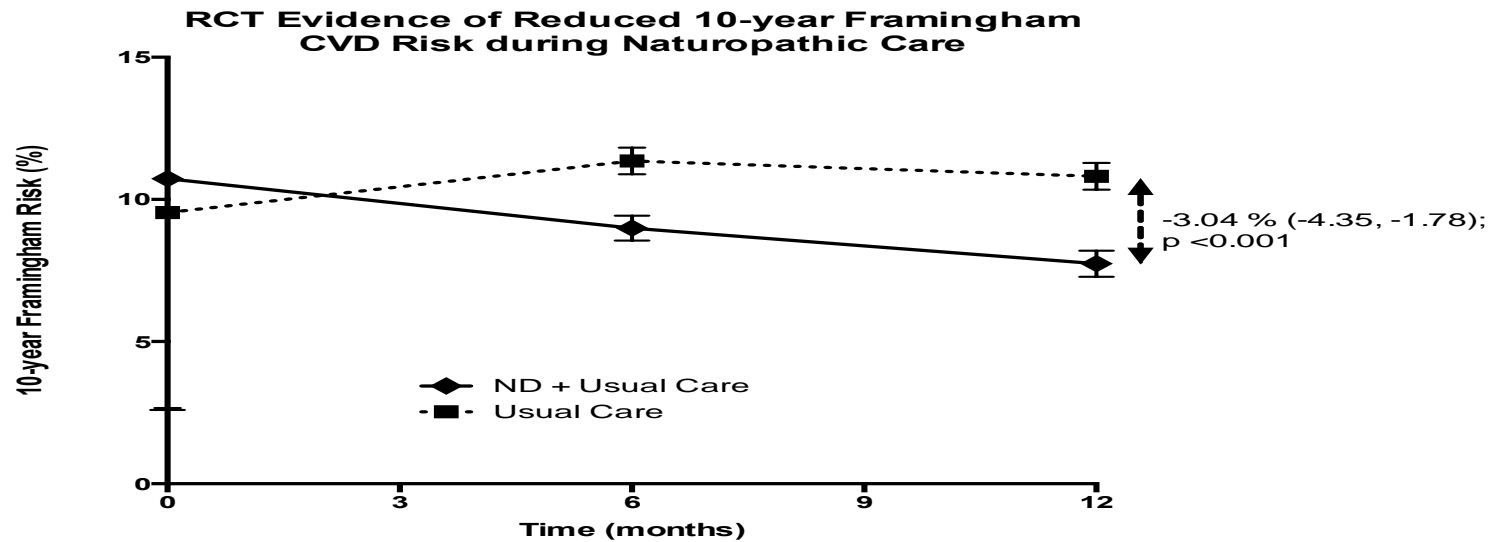
importance of lifestyle intervention is widely recognized, few individuals with, or at risk of, cardiovascular disease receive intensive dietary and lifestyle counselling.<sup>7,8</sup>

A variety of health care practitioners routinely deliver diet and health promotion advice to patients at risk of cardiovascular disease. Naturopathic doctors in North America are trained and regulated practitioners who emphasize this form of self-directed care. Several retrospective analyses have suggested that patients at risk of cardiovascular disease receive lifestyle counselling routinely as part of naturopathic care.<sup>9–11</sup> However, no rigorous studies have examined the effectiveness

# 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



Source: Seely D, Szczurko O, Cooley K, Fritz H, Aberdour S, Herrington C, Herman P, Rouchotas P, Lescheid D, Bradley R, Gignac T, Bernhardt B, Zhou Q, Guyatt G. Naturopathic medicine for the prevention of cardiovascular disease: a randomized clinical trial. CMAJ. 2013 Jun 11;185(9):E409-16

# Limitations

- Multiple exposures, i.e., cannot determine characteristic(s) of care responsible for observed changes

# Resource: Equator Network



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