e-Counseling for Self-Care Adherence Adds Therapeutic Benefit for Hypertension: the REACH Trial

Robert P Nolan, PhD, CPsych; Ross Feldman, MD, FACP, FAHA, FRCPC; Martin Dawes, MD, PhD, DRCOG, FRCGP; Susan I. Barr, PhD; Hazel Lynn, MD, FCFP, MHSc; Carolyn MacPhail, MHSc; Janusz Kaczorowski, PhD; Scott Thomas, PhD; Jack Goodman, PhD; Sam Liu, PhD; Rika Tanaka, PhD; and Jelena Surikova, BA (Hons)

in collaboration with Heart and Stroke Foundation of Ontario.
Peter Munk Cardiac Centre, University Health Network
and University of Toronto; Toronto, Ontario, Canada
https://www.cardiacehealth.uhnresearch.ca
Introduction

• Pharmacotherapy with lifestyle counseling is recommended as the optimal strategy to reduce risk factors for CVD
  JNC8, JAMA 2014; CHEP, Can J Cardiol 2016; ESC, Eur Heart J 2016

• Context of hypertension, counseling for exercise and diet augments medical care with incremental reduction in blood pressure
  o <12 months: Systolic BP: -4.47 mmHg (95%CI, -7.91, -1.04)
    12-24 months: Systolic BP: -2.29 mmHg (95%CI, -3.82, -0.76)
  o obtained with programs of moderate-to-high intensity
  Lin et al. Agency for Healthcare Research and Quality (US) 2014
Internet-based e-counseling: evidence

• e-based interventions for hypertension decrease BP in a range comparable to conventional lifestyle programs

Burke et al. AHA Scientific Statement, Circulation 2015;132(12):1157-213

Liu et al, Can J Cardiol 2013;29(5):613-21


Beishuizen et al., JMI R 2016;18(3):e55

• However, heterogeneity of treatment effects across trials is a problem
  
  o (i) diverse technologies, (ii) variable theories of behavior change, and (iii) absence of specified models of behavioral counseling
REACH Trial: Objective

1. Assess whether e-counseling enhances BP control and CVD risk factor reduction at 12 months, for individuals with Stage 1 or 2 hypertension
   • adherence: exercise, diet, prescribed medication & smoke-free-living

2. e-Counseling protocol was “user-centered” and collaborative
   • adapted components of evidence-based models of counseling
     Miller & Rollnick. Motivational interviewing. 2nd ed. New York: Guilford Press; 2002
Methods: Trial Design and Protocol

- Double-blind, randomized controlled trial with assessments at baseline, 4 and 12 months
Primary Outcomes:
• SBP/DBP, pulse pressure: automated office protocol (BpTRU)
• Non-HDL-C and Framingham Risk Index of 10-year absolute risk for CVD

Sample: Inclusion Criteria
• Stage 1 or 2 hypertension: SBP/DBP 140-180/90-110 mmHg
• Medications: SBP ≥130 or DBP ≥85 mmHg, and unchanged for 2 months

Statistical Analysis:
• Linear Mixed Models with random effects intercept for change in BP, Non-HDL-C and Framingham Risk Index at 4- & 12-months
• Covariate adjustment for baseline values, sex and medications
CONSORT FLOW DIAGRAM

Enrollment
- Contact Information on Webpage: n=7038

Completed Telephone Screen: n=1992
- Invited to REACH Clinic Assessment: n=609
- Randomized 1:1: n=264
  - PEI: n=17
  - Toronto: n=174
  - Grey-Bruce: n=19
  - Vancouver: n=39
  - London: n=15
- Excluded at Telephone screen: n=1383
  - Not interest: n=545
  - Did not meet BP criteria: n=450
  - Distance: n=259
  - Not enough time: n=63
  - Age: n=66

Allocation
- Control + Usual Care: n=131
- eCounselling + Usual Care: n=133

Attrition at 12-months: n=33 (25.2%)
- Withdrew: n = 9
- Lost to Follow-up: n=24
- Excluded at Clinic Assessment: n=345
  - Did not meet inclusion criteria: n=260
  - Lost interest in study: n=15
  - Did not attend scheduled visit: n=70

Follow-Up
- Intention-to-Treat Analysis
  - Complete data: n=97

Attrition at 12-months: n=35 (26.3%)
- Withdrew: n = 8
- Lost to Follow-up n=27
- Complete data: n=100
# RESULTS: Background Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control + Usual Care</th>
<th>eCounseling + Usual Care</th>
<th>Pooled Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n, M</td>
<td>(%, 95%CI)</td>
<td>n, M</td>
</tr>
<tr>
<td>Sex: % female</td>
<td>80, (61)</td>
<td>74, (56)</td>
<td>154, (58)</td>
</tr>
<tr>
<td>Age: years</td>
<td>57.2, 56, 59</td>
<td>58.0, 56, 60</td>
<td>57.6, 56, 59</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>30.7, 30, 32</td>
<td>31.5, 30, 33</td>
<td>31.1, 30, 32</td>
</tr>
<tr>
<td>Current Smoking</td>
<td>11, (8.4)</td>
<td>13, (9.7)</td>
<td>24, (9.1)</td>
</tr>
<tr>
<td>4-Day Step Count*</td>
<td>7899, 7302, 8494</td>
<td>7757, 7222, 8292</td>
<td>7828, 7430, 8226</td>
</tr>
<tr>
<td>Daily Fruit-Vegetable Servings†</td>
<td>7.9, 7.0, 8.7</td>
<td>8.3, 7.2, 9.4</td>
<td>8.1, 7.4, 8.8</td>
</tr>
</tbody>
</table>

* LifeSource/A&D XL-18CN Activity Monitor  
† NCI, Diet History Questionnaire
### RESULTS: Cardiovascular Risk Factors

<table>
<thead>
<tr>
<th>Cardiovascular Indices:</th>
<th>Control + Usual Care</th>
<th>eCounseling + Usual Care</th>
<th>Pooled Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>95%CI</td>
<td>M</td>
</tr>
<tr>
<td>Systolic BP, mmHg</td>
<td>140.6</td>
<td>139, 143</td>
<td>141.5</td>
</tr>
<tr>
<td>Diastolic BP, mmHg</td>
<td>87.3</td>
<td>86, 89</td>
<td>87.3</td>
</tr>
<tr>
<td>Pulse Pressure, mmHg</td>
<td>53.3</td>
<td>51, 55</td>
<td>54.1</td>
</tr>
<tr>
<td>Total Cholesterol, mg/dl</td>
<td>195.8</td>
<td>189, 202</td>
<td>195.6</td>
</tr>
<tr>
<td>LDL Cholesterol, mg/dl</td>
<td>118.6</td>
<td>113, 125</td>
<td>116.7</td>
</tr>
<tr>
<td>Non-HDL-Cholesterol, mg/dl</td>
<td>142.1</td>
<td>136, 149</td>
<td>142.5</td>
</tr>
<tr>
<td>Framingham 10-Year Absolute CVD Risk Index, %</td>
<td>14.6</td>
<td>13, 16</td>
<td>16.5</td>
</tr>
</tbody>
</table>

**BP** = blood pressure, **LDL** = low-density lipoprotein, **HDL** = high-density lipoprotein, **CVD** = cardiovascular disease
### RESULTS: Medications

<table>
<thead>
<tr>
<th>Medications</th>
<th>Control + Usual Care</th>
<th>eCounseling + Usual Care</th>
<th>Pooled Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n, M (%)</td>
<td>n, M (%)</td>
<td>n, M (%)</td>
</tr>
<tr>
<td>≥ 1 Antihypertensives</td>
<td>107 (82)</td>
<td>113 (85)</td>
<td>220 (83)</td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>13 (10)</td>
<td>23 (17)</td>
<td>36 (14)</td>
</tr>
<tr>
<td>ARB</td>
<td>38 (29)</td>
<td>37 (28)</td>
<td>75 (28)</td>
</tr>
<tr>
<td>ACEi</td>
<td>42 (32)</td>
<td>47 (35)</td>
<td>89 (34)</td>
</tr>
<tr>
<td>Diuretic</td>
<td>33 (25)</td>
<td>37 (28)</td>
<td>70 (27)</td>
</tr>
<tr>
<td>CCB</td>
<td>24 (18)</td>
<td>42 (32)</td>
<td>66 (25)</td>
</tr>
<tr>
<td>Sum Antihypertensives</td>
<td>1.3 1.2, 1.5</td>
<td>1.6 1.4, 1.7</td>
<td>1.5 1.3, 1.6</td>
</tr>
<tr>
<td>Lipid lowering agents</td>
<td>28 (21)</td>
<td>31 (23)</td>
<td>59 (22)</td>
</tr>
<tr>
<td>Change in medications over 12 months</td>
<td>26 (20)</td>
<td>35 (26)</td>
<td>61 (23)</td>
</tr>
</tbody>
</table>

ARB = angiotensin receptor blocker, ACEi = angiotensin-converting enzyme inhibitor, CCB = calcium-channel blocker
RESULTS: Δ SBP from Baseline

4 Months.
Control: -5.6 mmHg (95%CI, -9, -2)
e-Counseling: -8.2 mmHg (95%CI, -11, -5)

12 Months.
Control: -6.0 mmHg (95%CI, -9, -3)
e-Counseling: -10.1 mmHg (95%CI, -13, -8)

*adjusted for Baseline SBP, sex, and anti-hypertensive medications
RESULTS: Δ PP from Baseline

4 Months.
Control: -1.2 mmHg (95%CI, -4, 1)
e-Counseling: -4.2 mmHg (95%CI, -6, -2)

12 Months.
Control: -1.5 mmHg (95%CI, -4, 1)
e-Counseling: -4.3 mmHg (95%CI, -7, -2)

*adjusted for Baseline PP, sex, and anti-hypertensive medications
RESULTS: Δ Framingham RI from Baseline

4 Months.
Control: -0.6% (95%CI, -1, 0.1)
e-Counseling: -2.1% (95%CI, -3, -1)

12 Months.
Control: 0.2% (95%CI, -1, 2)
e-Counseling: -1.9% (95%CI, -3, -0.6)

*adjusted for Baseline FRI, anti-hypertensive medications and lipid lowering agents
RESULTS: Δ DBP from Baseline

4 Months.
Control: -4.4 mmHg (95%CI, -7, -2)
e-Counseling: -4.1 mmHg (95%CI, -6, -2)
β = -0.21 (1.5), p = 0.89

12 Months.
Control:
m. -0.3 mmHg (95%CI, -2, 2)
f. -6.0 mmHg (95%CI, -9, -3)
e-Counseling:
m. -4.1 mmHg (95%CI, -6, -2)
f. -6.0 mmHg (95%CI, -9, -3)

*adjusted for Baseline DBP and anti-hypertensive medications
RESULTS: Δ Non-HDL-C from Baseline

4 Months.
Control: **4.5 mg/dl (95%CI, 0.4, 9)**
e-Counseling: -1.9 mg/dl (95%CI, -6, 2)
β = -6.46 (2.9), p = 0.03

12 Months.
Control:
m. **11.3 mg/dl (95%CI, 1.5, 21)**
f. -0.7 mg/dl (95%CI, -9, 7)
e-Counseling:
m. -4.3 mg/dl (95%CI, -13, 5)
f. 4.6 mg/dl (95%CI, -4, 13)

*adjusted for Baseline non-HDL-C and lipid lowering agents*
Conclusions – REACH Trial

• e-Counseling enhanced efficacy of usual care for hypertension at 12 months

• Clinically meaningful outcome: 10mmHg SBP decrease is associated with risk reduction of 20% CVD events, 17% CHD, 27% stroke, 13% all-cause mortality


• Findings provide support for a scalable phase III e-counseling trial for hypertension