Effect of RCT Testing on a CBPR Developed Cessation Intervention for Culturally Diverse, Low SES Women

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• Advisory Groups
  • Sister to Sister Advisory Board
  • MUSC CCHP CAB
  • MCG Health Disparities CAB
Purpose

- Describe the effect of a recently conducted, CBPR developed, multi-level cessation intervention among African American women living in subsidized housing in the Southeastern US
- Compare results with previous pilot work
- Analyze barriers and challenges of: sustaining relationships over 15 years; scaling up CBPR pilot to RCT; communities burdened with fiscal, environmental and social inequities
Background

• Partnership Formation
• 2001
• Phone call from inner city school counselor
• Mutual interest
• Need for CBPR
• 5 member Steering Committee formed
# Problem Identification

<table>
<thead>
<tr>
<th>Methods</th>
<th>Community</th>
<th>Academic</th>
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<tbody>
<tr>
<td>Windshield Tour Asset Mapping</td>
<td>- Physical Infrastructure</td>
<td>- Recognize and begin with community strengths and assets</td>
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<tr>
<td></td>
<td>- Social Infrastructure</td>
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<td></td>
<td>- Women Leaders</td>
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<tr>
<td>Neighborhood Survey (20% female head of households; n=220)</td>
<td>- 40% women current smokers</td>
<td>- 40-60% public housing residents smoke</td>
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<td>- 48% households had at least 1 smoker in residence</td>
<td>- Associated health disparities</td>
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<tr>
<td></td>
<td>- 62% who smoked interested in quitting</td>
<td>- 60-70% smokers want to quit</td>
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<tr>
<td>Grounded Theory (n=25 AA female former smokers)</td>
<td>- Transition to cessation is empowerment process</td>
<td>- AA women who have quit are empowered experts and potential CHWs</td>
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<tr>
<td></td>
<td>- Spirituality</td>
<td>- Spirituality is preferred coping strategy</td>
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</tbody>
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### Planning/Feasibility/Pilot Phase

<table>
<thead>
<tr>
<th>Methods</th>
<th>Community Preferences</th>
<th>Academic (Evidence Based Literature)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key Informant Interviews (n=30)</td>
<td>Prefer approach with multiple strategies/multiple levels of influence</td>
<td>Ecological levels of influence on behavior</td>
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<tr>
<td></td>
<td>Testimonials from AA women who had quit smoking</td>
<td>Indigenous CHWs</td>
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<td>Peer group meetings with food</td>
<td>“Sister circles”</td>
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<tr>
<td>Neighborhood Forums x 4</td>
<td>Involvement of NGHB leaders</td>
<td>NGHB governance board</td>
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<td></td>
<td>Presentation of information</td>
<td>Cultural sensitivity</td>
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<td></td>
<td>Incorporate evidence from research</td>
<td>AHRQ guidelines:</td>
</tr>
</tbody>
</table>

Pilot Study

• 2 neighborhoods (n=103 women)

• Treatment (Sister to Sister Condition)
  – Neighborhood level activities/policy
  – Peer groups – weekly x 12wks
  – CHW – Individual contact weekly x 12 wks
  – Nicotine patches

• Comparison
  – 4 group sessions (healthy eating, PA, financial management)
Pilot Outcomes

• 7-day point prevalence
  – 24 week time point
  – 39% vs. 11.5%
  – p < .0001

• CBPR partnership

• 87.4% retention at 6 months

RCT

• 14 public housing neighborhoods
• 2 metropolitan regions
• 409 women
• Entry into neighborhoods/survey
• Recruitment/information sessions
• Relationship building
• Andrews et al., 2012
Figure 2. Flow Diagram of Cluster Randomized Controlled Trial

Assessed for eligibility (34 NB in 2 southeastern US metropolitan cities)

Excluded 20 NB
Senior high rise (6)
Used previously (4)
Do not contain at least 100 women (10)

14 Neighborhoods pair-matched according to size and geographical location

Legend:
BDC = Baseline data collection* (recruit & screen women; enroll 29 eligible per NB)
NB = Neighborhood    TX = Treatment    CL = Control
NB-R = Neighborhood randomization
RCT Methods

• Group randomized controlled trial
• Neighborhood unit of randomization
• 14 neighborhoods – pair matched on size
• After baseline NGHB data collection, NGHBs randomized to intervention or delayed control
• NGHBs ranged in size from 100 – 352 households
• Recruited 27-32 women in each neighborhood
RCT Methods

• 2-3 months in neighborhood for baseline data collection; getting to know residents

• Information sessions with food

• Inclusion
  – Female
  – Over 18
  – Lives in neighborhood
  – Smoke > 100 cigs in lifetime and at least 1 cig/day
  – CO>9ppm
  – Cotinine > 15 ng/ml
RCT

- Sister to Sister neighborhoods
  - Individual Level Strategies
  - Interpersonal Level Strategies
  - Neighborhood Level Strategies
  - NRT
  - Study Specific Written Cessation Materials
RCT

• **Control Neighborhoods**
  – Pathways to Freedom (CDC) – Baseline
  – Mailouts
    • Week 6 – State sponsored quit line brochure
    • Week 12 – PHS Guideline – You Can Quit Smoking
    • Week 18 – ACS pamphlet – When Smokers Quit
    • Delayed intervention after 12 month data collection
Measures

• Primary Outcome
  – Biochemically validated smoking (abstinence)
  – Exhaled CO; saliva cotinine
  – Baseline, 6 mo, 12 mo
Hypothesis

• Women in neighborhoods receiving S2S will have higher smoking abstinence than those in delayed control

• Higher participation with coach visits, groups sessions, nicotine patch will be more likely to quit
Analyses

- Random coefficient models used to account for group randomized design
- Neighborhood unit of analyses, however individual data used to model covariates
- Logistic regression – smoking status
- Multivariate model
Attended Information Sessions/Pre-Screened for Eligibility
N=548

Consented and Screened for Eligibility
N=467

Eligible
N=409

Randomized
N=409

Not Consented
n=81

Not Eligible
n=58
Reasons:
- Does not smoke at least 1 cig/day (n=3)
- Does not live in respective neighborhood (n=4)
- Not interested in quitting smoking in next 6 months (n=6)
- Not able to provide names/phone of 3 contacts (n=3)
- Does not have CO > 8 ppm (n=25)
- Does not have saliva cotinine > 14 ng/ml (n=7)
- Pregnant or breastfeeding (n=3)
- Plans to move in the next 12 months (n=9)
- Smokes marijuana and not cigarettes (n=3)

Treatment Condition (Sister to Sister)
N=200

Completed 6 month follow-up
N=189
Reasons for not completing:
- Lost to follow-up = 8
- Moved = 1
- Withdrew Consent = 2

Completed 12 month follow-up
N=185
Reasons for not completing:
- Lost to follow-up = 4

Delayed Control Condition
N=209

Completed 6 month follow-up
N=192
Reasons for not completing:
- Lost to follow-up = 12
- Moved = 3
- Deceased = 2

Completed 12 month follow-up
N=188
Reasons for not completing:
- Lost to follow-up = 3
- Other = 1

Completed Study
N=373
<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>CONTROL N = 209</th>
<th>INTERVENTION N = 200</th>
<th>P-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes per day</td>
<td>12.8 (7.9)</td>
<td>12.6 (7.5)</td>
<td>0.7409</td>
</tr>
<tr>
<td>Nicotine Dependence Score</td>
<td>4.8 (2.2)</td>
<td>4.7 (2.2)</td>
<td>0.5237</td>
</tr>
<tr>
<td>Depression Score</td>
<td>10.6 (6.3)</td>
<td>10.2 (6.0)</td>
<td>0.5186</td>
</tr>
<tr>
<td>Perceived Stress</td>
<td>28.2 (17.6)</td>
<td>26.8 (16.5)</td>
<td>0.3846</td>
</tr>
<tr>
<td>Social Influence</td>
<td>8.4 (9.1)</td>
<td>7.7 (7.4)</td>
<td>0.3596</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>31.7 (8.9)</td>
<td>32.0 (8.5)</td>
<td>0.7577</td>
</tr>
<tr>
<td>Social Support</td>
<td>45.1 (12.8)</td>
<td>46.2 (12.3)</td>
<td>0.3982</td>
</tr>
<tr>
<td>Drug Use</td>
<td>32 (15.3%)</td>
<td>28 (14.0%)</td>
<td>0.7080</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>135 (64.6%)</td>
<td>114 (57.0%)</td>
<td>0.1157</td>
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</tbody>
</table>

Mean (SD) except where number (percentage) is noted. Percentages may not sum to 100 due to rounding.
## Smoking outcomes

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td><strong>6 MONTHS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 cigs Co&lt;8 ppm</td>
<td>8%</td>
<td>2.3%</td>
<td>0.023</td>
</tr>
<tr>
<td>Cotinine &lt;14 ng/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Cigs Co&lt;8ppm Cotinine &lt; 49 ng/ml</td>
<td>10%</td>
<td>3.4%</td>
<td>0.007</td>
</tr>
<tr>
<td><strong>12 MONTHS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 cigs Co&lt;8 ppm</td>
<td>9%</td>
<td>4.3%</td>
<td>0.058</td>
</tr>
<tr>
<td>Cotinine &lt;14 ng/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Cigs Co&lt;8ppm Cotinine &lt; 49/mg/ml</td>
<td>12%</td>
<td>5.3%</td>
<td>0.016</td>
</tr>
</tbody>
</table>
Figure 2. Changes in Mean Cigarettes Per Day from Baseline to 12 Months. *Sister to Sister Study, South Carolina, 2009-2013.*
Higher engagement with intervention, more likely to quit smoking:

– Coach contacts – more likely to quit
  OR = 1.23 (1.08 – 1.48)

– Number of group sessions – more likely to quit
  OR = 1.6 (1.14-2.24)

– Weeks on patch – more likely to quit
  OR = 1.2 (1.01 – 1.42)
Other results

• Intervention group
  – 66% made quit attempt and self reported abstinence at least one CHW visit
  – 34% self reported abstinence on at least 4 CHW visits
  – Actual CHW visits = 11.2/16
  – Average group sessions = 4/6
  – Average length of patch = 2.8 weeks
Comparison to other studies

• 20 midwestern public housing/AA received 5 MI and nicotine gum (Okuyemi et al. 2007)
  - 9.2% intervention vs. 7.6% control at 6 mo

• Low income urban AA/ nicotine gum + MI = (Ahluwalia, 2006)
  – 14.2% intervention vs. 11% control at 6 mo

• AA in urban based clinic, testing bupropion and health education (Cox, 2012)
  -13% intervention vs. 10% control at 26 weeks
Comparisons

• However – current study had 91% retention at 12 mo with CBPR model vs. 70-75% retention at 6 months in similar studies

• Outcome Results Differ from pilot 6 mo 39% intervention vs. 11.5% control
Lessons Learned

• We can easily recruit
  – With incentives/Indigenous CHWs
  – $25, $25, $50, $75 Gift Cards
  – Food

• We can retain women (challenging) – 91% retained at 12 months
  – Multiple phone contacts
  – “Hanging out” to locate
  – Flexible, flexible, flexible scheduling
Fidelity

• Challenging!!!
  – Multi-site; multi-state
  – Neighborhood context
    • High smoking prevalence (up to 60%)
    • Crime
    • Stress, Social Cohesion
  – Staff safety (day and evenings)
  – CHWs in pairs at all times
  – Depression, social norms, other priorities –
Lessons Learned - Time

- 2001 – 2002  Partnership Formation
- 2003-2004  Pilot
- 2009 – 2013  RCT
- PI relocation
- Change in administration in public housing/neighborhoods
- Advisory Board
- Funding
Lessons Learned – Context over Time

• Situational Context of Public Housing
  – Increasing Poverty
  – Recession 2008/2009
  – Crime
  – Policies in public housing/Welfare reform
  – Power imbalances between residents/administration
  – Navigation
  – Marijuana use
  – More women working; diverse work schedules
  – Smoking abstinence difficult to maintain in high stress, low cohesive environments
  – TREAT DEPRESSION
Lessons Learned - Relationships

• Pilot - Partnership for over 2 years prior to pilot testing
• RCT – 1 month relationship building, then recruitment, intervention starts within 3 months
• CAB for pilot studies later evolved to Academic Center CAB
Lessons Learned – CBPR Partnership Readiness

– Goodness of Fit
  • Shared values, compatible climate, mutual benefit, dedicated commitment

– Capacity
  • Leadership, inclusive membership, complementary competencies, adequate resources

– Operations
  • Congruent goals, transparent communication, complementary competencies, adequate resources
    – Andrews et al., 2010, 2011
Summary

• A social, culturally appropriate intervention was developed and tested in two states
• Overall, positive results
• Long term relationships
• Has led to additional partnerships/resources
  – Communities linked with resources; additional health promoting programs, students
  – Academics linked with additional partners/additional studies
Summary

• CHWs in studies continued education, new employment opportunities, broadened experiences

• We can recruit and retain participants in public housing

• Additional measures to understand context and readiness

• Behavior change and maintenance of changes difficult in complex, low SES environments
Summary

• CBPR partnerships
  – With who? Grassroots vs. organizations
  – CAB for RCT in multiple states

• Time

• Funding

• Fidelity in “real life” community settings

• Alternative designs/pragmatic trials

• Is CBPR with one community scalable to others?

• Instead of randomizing/pair matching on size – matching on readiness, cohesion, other factors?
Next steps

• New study with community based education (Diabetes Prevention Program) with linkages to Primary Care/Community Clinics
• New formative assessments/problem identification
• Process Evaluation
• Informing new intervention
References


References

Thank You

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