Using community based participatory research to develop an ED violence intervention program and the use of alternative randomized control trial designs

Carolyn Snider MD, MPH
University of Manitoba
Winnipeg, MB, Canada

www.edvip.ca
WHAT ON EARTH IS A CANADIAN DOING UP HERE?
Winnipeg, MB, Canada

- Winnipeg MB – highest homicide rate in all major cities.
- 2011, ~¼ of homicide victims and ~½ accused involved youth
- Homicide rate 5.3 per 100,000
  - About the same as Denver
  - Higher than Seattle, San Diego, Portland, Austin
  - Just under New York, San Francisco
Winnipeg, MB, Canada

- Homicide
  - US: 5x more likely to be from GSW than Stab
  - Canada: GSW = Stab

- Stabbings
  - Lower fatality rate

- 20% recurrent intentional injury rate
Objectives

- Using Community Based Participatory Research
- Alternative Randomized Control Trial Designs
Community Based Participatory Research

• Integrated Knowledge Translation (iKT)

• The knowledge of those whom the problem affects are key members of a research team during the problem identification, solution identification, evaluation planning and implementation and dissemination processes.

Ensures your work is relevant and feasible within the community.
Winnipeg’s ED-VIP

- Sept 2011 – August 2012
  - Relationship building
  - Proof of concept work

- September 2012
  - Invitations to be part of co-investigator team
    - Former gang members/lived experience
    - Community Youth Workers
    - Executive Directors of Youth Violence Prevention programs
    - Clinicians – Emergency Physicians, Nurses, Trauma Surgeons, Social Workers
    - Aboriginal Elders
    - Researchers
Winnipeg’s ED-VIP

- Funded through Canadian Institute of Health Research
- 2 year pilot
  - 180 enrolled in first year
  - 90 to Intervention arm/ 90 to Waitlist Control arm
- WrapAround Care delivered by:
  - 5 support workers (with lived and work experience)
  - 1 social worker
  - 1 addictions and mental health counselor
- Very strong link with community services
  - Many EDs are co-investigators
Winnipeg’s ED-VIP

- Youth (14 – 24) met in the Emergency Department by support worker (enrollment by research assistants/coordinator prior)
- 1 Hospital – 2 sites (Children’s and Adult EDs) – combined 110,000 visits per year
Winnipeg’s ED-VIP

- Outcomes

- Pilot (starts November 2013) – 2 years
  - Recruitment, Adherence, Fidelity and Safety

- Main (goal November 2015) – 5 – 7 years
  - Administrative Health Data: Repeat Injury, Severity of Injury, Substance Use, Mental Health, Housing, Education, Justice
Do we need a randomized control trial?

SUPPORT

• Community colleagues understood and supported the role of a randomized control trial
• Acknowledged the need for rigorous evaluation method
• Recent well publicized RCT for high risk auto theft offenders demonstrated success with anklets in our city
• Fickle Funding of their own programs
• Their observational evaluations often criticized
• **Equipoise** - high risk upon leaving a gang & felt that many touted programs didn’t actually work – just good PR.
• Noted that if this doesn’t truly work – we need to use the money elsewhere to find something that does.
Do we need a randomized control trial?

**CONCERNS**

- Emotional Trauma potential with traditional design
  - offset by the obvious ethical concerns of ensuring autonomy over their information – i.e. consent to being part of a trial

- “Resentful Demoralisation” bias
  - Can make an ineffective intervention appear beneficial

- What about the control group??
  - Standard of care is not appropriate
    - Balancing the concerns of too active a control group
Repeat Injuries

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<tr>
<th>Control Group</th>
<th>Intervention</th>
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<td>Time</td>
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Effect
“Resentful Demoralization”

- Repeat Injuries
- Time

- Control Group
- Intervention
- Effect
Careful of Too Active a Control Group

![Graph showing the effect of intervention on repeat injuries over time.](graph_image)

- **Control Group**
- **Effect**
- **Intervention**

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Traditional Randomization

- All Eligible Participants
  - Consent
  - Randomization
    - Intervention Arm
    - Control Arm
Pre-Consent Randomization (Zelen’s Design)

Examples:
• Hatcher et al. *Trials* 2011
• Adamson et al. *Contemporary Clinical Trials* 2006

All Eligible Participants Screened

Randomization

- Intervention Arm
- Control Arm

Consent to be part of randomized arm
May or May not Require Consent for follow-up
Adapted pre-consent randomization

Relton et al. Rethinking pragmatic randomised controlled trials: introducing the cohort multiple randomized controlled trial” design. *BMJ* 2010
Impact of CBPR

- Intervention Design
- Outcomes
- Hiring
- Community Acceptance
- Research Design – choosing RCT design
  - Choosing “clinically-relevant” effect size for sample size calculations
Great Learning Opportunity

NIH Summer Institute on Randomized Behavioral Clinical Trials

July 20 – August 1, 2014

Applications due: January 24, 2014
Questions/Comments

csnider@mich.ca