

Prévention de la transmission sexuelle du VIH au cours de la prise en charge des séropositifs

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Essais d'intervention et méthodes quasi-expérimentales en santé publique. Intérêts et limites pour la recherche sur le VIH/sida et les hépatites virales,

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Objective

- Taking into account the Quebec experiences (ex. Phenix program, MAΨA Project), to explore methodological issues of scenarios to develop and evaluate an intervention
 - Targeted population: HIV-Positive Men who have sex with Men (HIV+MSM)
 - Community-level goal: decreasing the incidence of HIV sexual transmission from HIV+MSM

Issues

- To develop and to implement an intervention which is :
 - Efficacious (targeting the right determinants, preventing at-risk behaviours)
 - Acceptable/ethical
 - Efficient/cost-effective
 - Replicable/transferable
 - Sustainable

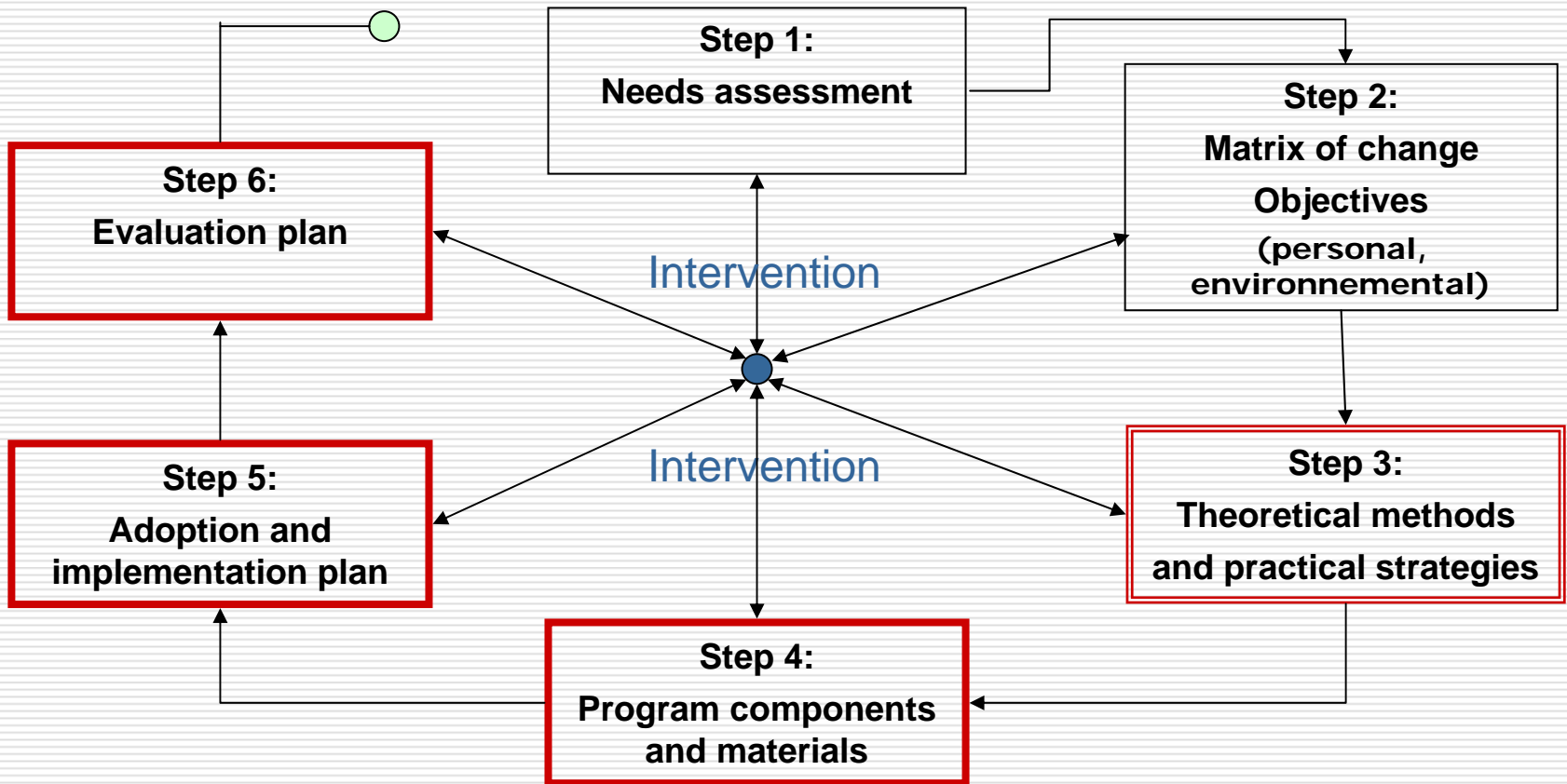
- To propose an evaluation design which takes into account these issues

Challenges and pitfalls in evaluation

Criteria	Intervention's characteristics	Implementation settings' characteristics
Efficacy of the designed intervention	An intervention design based on... <ul style="list-style-type: none"> ▪ needs assessment ▪ theory-based methods ▪ coherent practical strategies 	Degree of implementation and degree of sustainability <ul style="list-style-type: none"> ▪ Intra-setting (accessibility) ▪ Inter-settings (diversity)
Acceptability...	Point of view of the target population	Point of view of actors in each implementation setting and in the entire community
Replicability/ Transferability...	Structure and process (feasibility, complexity,...)	Contextual factors affecting the degree of implementation
Efficiency/cost effectiveness...	Structure and process (feasibility, complexity,...)	Capability of the implementation settings to support the intervention (resources, time, ...)
Sustainability...	Structure and process (feasibility, complexity,...)	Capability of the implement settings to deliver the intervention across time with the same quality standards

Intervention Mapping (IM)

IM framework (Bartholomew, Parcel & Kok, 2006)



Applications of the IM in different groups in Montreal (Quebec, Canada)

Phénix

Development of erotic, cognitive and behavioural skills
(community settings, HIV-negative MSM, 7 group-sessions)



Preventing the initiation of injection drug use among street youth

(community setting, individual strategy, 5 meetings in 3 weeks)
(Roy, Otis, Godin et al.)

Pouvoir partager/
Pouvoirs partagés
(Sharing Together for Life)

Management of HIV disclosure
(community settings, WLHIV, 6 group-sessions)

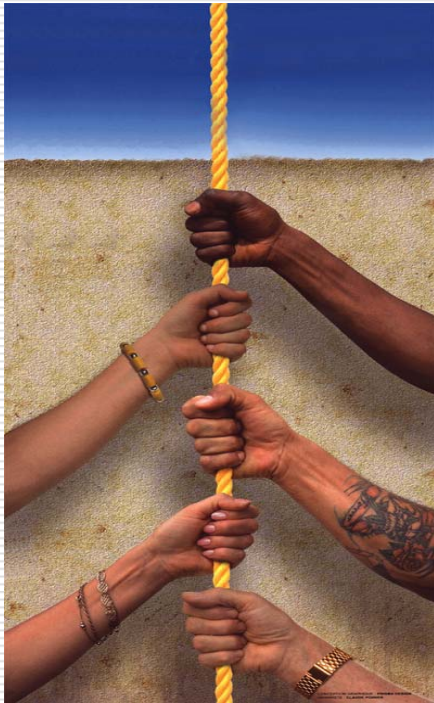


Promoting HAART observance among people living with HIV

(clinical settings, *computer tailoring*) (Côté, Godin, Otis et al.)

Phenix +*

An application of IM to HIV+MSM



- Step 1: Needs assessment based on the MAΨA project
 - MAΨA is an ongoing longitudinal study on associated psychosocial factors with quality of life and health behaviours among people living with HIV in the Montreal area (Québec, Canada)
 - Aim: Intervention planning, Implementation and Evaluation
 - Recruitment was undertaken through the 11 collaborating clinical sites and with the help of community groups
 - Participants were met at 6-month intervals (face-to-face interview)
 - Final sample obtained at the end of December 2007 (T0 N = 904; T3 N = 668)
 - 59% are MSM

* to be renamed by the community members

MAΨA was funded by the Canadian Institutes of Health Research

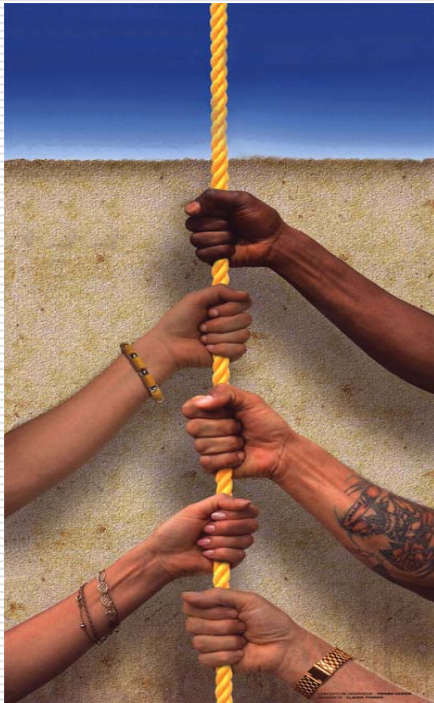


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□ Step 1 - Needs assessment



- Identification of psychosocial determinants of unprotected anal sex with HIV- or HIV+ Partners (regular and occasional) (Risky Anal Sex [RAS])
- Latent profiles analysis or Cluster Analysis based on the determinants of RAS

MAΨA's HIV+MSM - Six Profiles

Unprotected Anal Sex in each Profile

	Total sample (n=479) %	Profile 1 (4.6%) %	Profile 2 (10.9%) %	Profile 3 (7.9%) %	Profile 4 (28.9%) %	Profile 5 (36.8%) %	Profile 6 (7.9%) %
Anal sex at least 1/week	30.3	50.0	21.2	47.4	25.9	0.0	0.0
UAS ¹ all types of partners	27.3	95.5	90.4	56.8	30.2	0.0	0.0
UAS ¹ all HIV- and HIV?(RAS)	20.2	72.7	82.7	36.8	17.3	0.0	0.0
UAS ¹ HIV- and HIV? regular partners	7.1	45.5	23.1	5.3	7.2	0.0	0.0
UAS ¹ HIV+ regular partners	13.3	36.4	36.5	36.8	16.5	0.0	0.0
UAS ¹ occasional partners	17.5	59.1	76.9	31.6	13.8	0.0	0.0

1. UAS: unprotected anal sex at least once in the last six months

MAΨA's HIV+MSM – Six Profiles

Sociodemographic and psychosocial characteristics of each Profile

	Total sample	Profile 1	Profile 2	Profile 3	Profile 4	Profile 5	Profile 6
	M	M	M	M	M	M	M
Age (years) (ns)	46.2	43.3	42.9	38.9	44.6	49.9	47.2
Years since HIV diagnostic (ns)	10.5	11.0	11.3	8.6	10.4	10.5	11.7
Number of drugs last 6 months	1.0	1.3	1.6	4.6	0.7	0.3	1.0
Intention (CU)	4.58	2.14	3.83	4.85	4.91	4.93	3.95
Attitude (CU)	4.00	2.50	3.57	3.91	4.28	4.25	3.25
Self-efficacy (CU)	4.32	2.46	3.37	4.56	4.64	4.70	3.44
Anticipated regrets (CU)	4.44	2.76	3.43	4.60	4.72	4.80	3.90

CU: ...towards condom use with HIV- and HIV? partners in the next six months
(Scales varying to (1) *very low* to (5) *very high*)

MAΨA's HIV+MSM – Six Profiles

Profile	Characteristics
Profile 1 (4.6%)	<p>Frequent anal sex with each type of partners</p> <p>No risk reduction strategies</p> <p>Responsibility left to partner</p> <p>Low intention, less favourable attitude, low self-efficacy and less anticipated regrets towards condom use</p> <p>Difficulty with intimacy</p> <p>Low self-esteem</p>
Profile 2 (10.9%)	<p>Occasional anal sex, but especially with casual partners</p> <p>Strategy: favours anonymous sexuality to minimize issues related to condom negotiation</p> <p>Responsibility left to partners if casual; caution relative to regular partners</p> <p>Moderate intention, more or less favourable attitude, moderate self-efficacy and more or less anticipated regrets (similar to profile 6)</p> <p>Difficulty with intimacy</p>

MAΨA's HIV+MSM – Six profiles

Profile	Characteristics
Profile 3 (7.9%)	<p>Frequent anal sex with each type of partners, a lot of casuals Younger, he uses a large variety of drugs Strategy: very cautious with HIV- or HIV? partners; more relax with casuals High intention, rather favourable attitude, high self-efficacy and high anticipated regrets (similar to profiles 4 et 5, but lower attitude) Low quality of life (particularly mental health) Low self-esteem, high prevalence of stressful life events</p>
Profile 4 (28.9%)	<p>Occasional anal sex, principally with HIV- partners Strategy: aims condom use with any type of partners He tries to reduce his risks of co-infection Condom seems mostly his responsibility High intention, very favourable attitude, high self-efficacy and high anticipated regrets (similar to profile 5) High quality of life (physical and social functioning) High social support High self-esteem</p>

MAΨA's HIV+MSM – Six profiles

Profile	Characteristics
Profile 5 (36.8%)	No anal sex Strategy : Avoid anal sex, or use condoms High intention, very favourable attitude, high self-efficacy and high anticipated regrets (similar to profile 4) Low quality of life on physical functioning No problem with intimacy
Profile 6 (7.9%)	No anal sex Strategy: Avoid anal sex (by choice or in spite) to avoid condoms use (?) Moderate intention, more or less favourable attitude, moderate self-efficacy and more or less anticipated regrets (similar to profile 2) Low quality of life (low mental health) Low self-esteem Low social support Difficulties with intimacy

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An application of IM to HIV+MSM

Step 1: Facts and questions. Targeting? Tailoring?

- Age and number of years since diagnosis...not significant
- Heterogeneity of risk reduction strategies
- Heterogeneity of psychosocial issues
- Targeting? Tailoring?
- Individual or group intervention?
 - Refine MAYA's quantitative analyses to better understand each profile
 - Carry out focus-groups to:
 - Validate the relevance of the different profiles
 - Explore the relevance of targeting and tailoring
 - Explore the best strategies to design the intervention

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Steps 2 and 3

- Step 2: Matrix of change objectives
 - Based on personal and environmental determinants
- Step 3: Theoretical methods and practical strategies
 - Choices of theoretical methods depend only on the targeted determinants (no problem)
 - Choice of practical strategies must be related to the theoretical methods (no problem) (step 4),
 - But the choice of practical strategies...
 - Face-to-face intervention versus computer-assisted (computer tailoring or online group meetings)
 - ... still depends on the characteristics of implementation settings (step 5)

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- Step 4: program components and materials
 - Production of materials and guides (training, animation, implementation)
 - Validation of...
- Step 5: implementation plan
 - Exploration of the characteristics of the possible implementation settings and their resources, and choice of the optimal environment for implementation
 - Exploration of the recruitment strategies , production of promotional materials

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Step 5

		Clinical Settings			Community Settings
		Hospitals	Specialized Medical Clinics	Testing Centers	
Recruitment		++	+++	+++	++
Implementation	Individual	++	++	+++	+
	Group	+	?	+	+++

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- Step 6: evaluation plan
 - To develop instruments
 - To validate these instruments
 - To choose the optimal evaluation design
 - Quasi-experimental design or RCT???
 - +
 - Multiple case-study

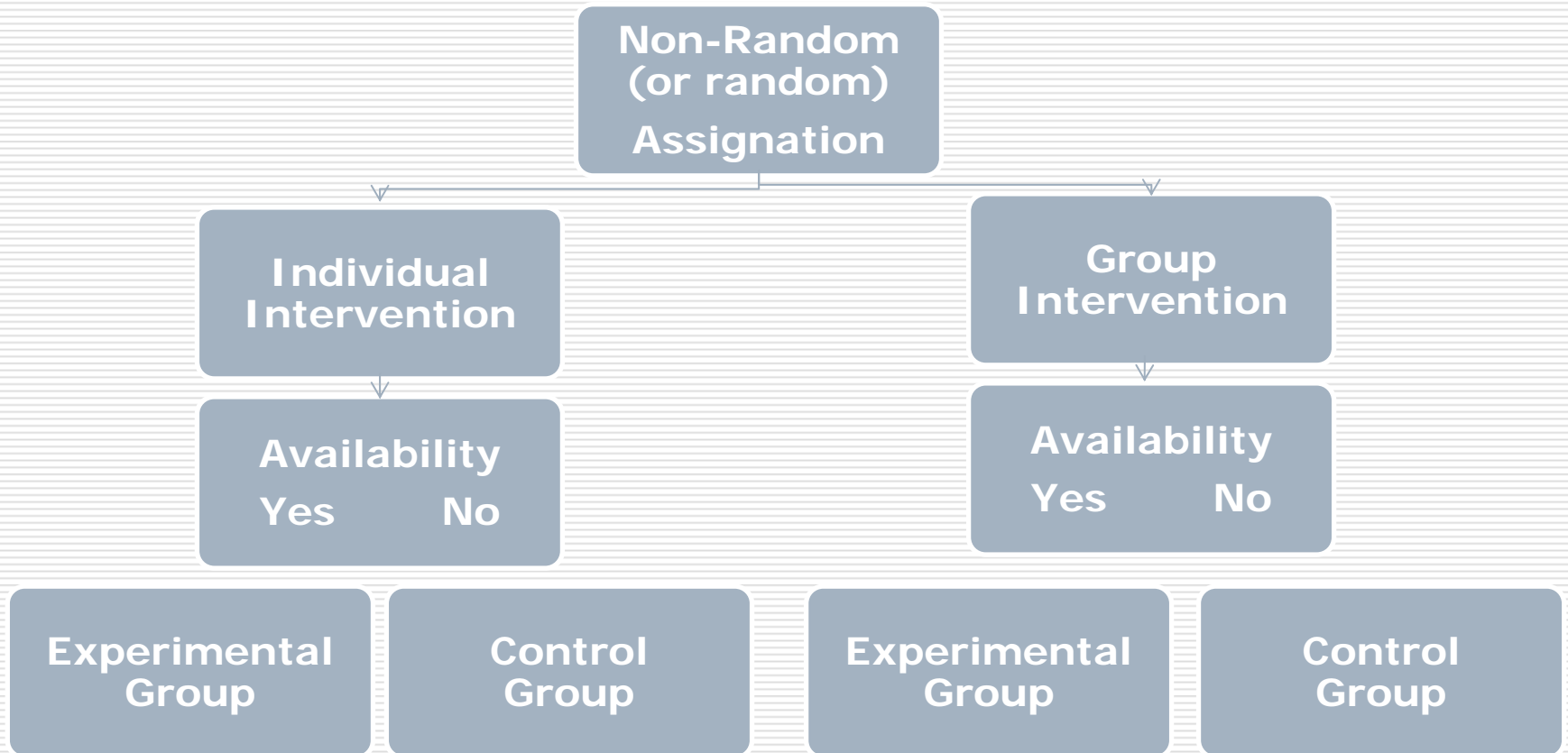
Considered Evaluation Design

Evaluation objectives	Design	Methods
Effects	Quasi-experimental design (non-equivalent control group) (or RCT ???)	Self-administered questionnaire Measures: behaviours in the last 3 months; psychosocial determinants aimed by Phenix+
Process/ Structure		In the experimental group: Appreciation questionnaire at O2 Focus-groups one week after O2
Implementation Contextual factors (CF) → Degree of implementation (DoI) → Effects	Multiple case study	Diary completed by group counsellor after each meeting (DoI) Semi-structured interviews with resources and group counsellor, mid-term and at the end (CF) Documents analysis

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Step 6 – Quasi-experimental Design



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An application of IM to HIV-positive MSM

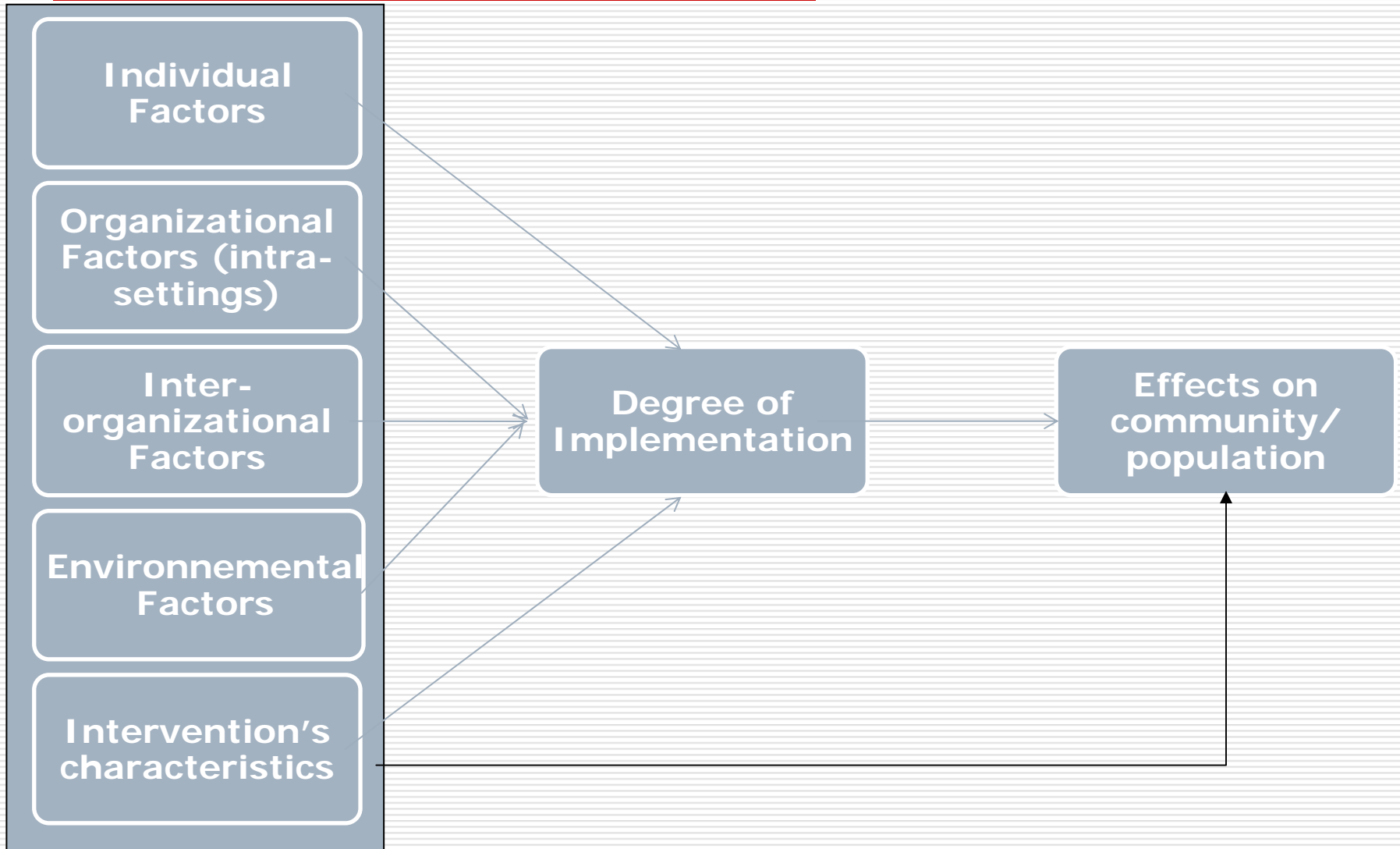
Step 6 – Quasi-experimental Design

Fall 2009	Winter 2010	Fall 2010	Winter 2011	Fall 2011	Winter 2012	Fall 2012
01 X	02	03				
01	02 X	03	04			
	01 X	02	03			
	01	02 X	03	04		
		01 X	02	03		
		01	02 X	03	04	
			01 X	02	03	
			01	02 X	03	04

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Step 6 – Implementation Analysis



Conclusions

- ❑ COMPROMISES, NEGOCIATION
- ❑ In this context, what would we have gained and lost doing RCT in terms of...
 - efficacy?
 - acceptability/ethic?
 - efficiency/cost-effectiveness?
 - replicability/transferability?
 - sustainability?