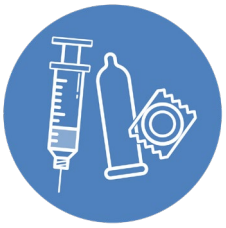
PRS Efficacy Criteria for Best-Evidence Risk Reduction (RR) Individual-Level, Group-Level, and Couple-Level Interventions (ILIs/GLIs/CPLs)



Intervention Description

- Clear description of key aspects of the intervention

Quality of Study Design

- Prospective study design
- Appropriate and concurrent comparison arm
- Random or minimally biased assignment of subjects to study arms

Quality of Study Implementation and Analysis

- Follow-up assessment ≥ 3-months post completion of intervention for each study arm with recall not referring to pre-intervention period (except for HIV testing outcomes)
- At least a 70% retention rate at a single follow-up assessment for each study arm
- Comparison between intervention arm and an appropriate comparison arm
- Analysis of participants in study arms as originally allocated regardless of contamination or logistic/implementation issues
- Analysis of participants regardless of the level of intervention exposure
- Use of appropriate cluster-level analyses if assigned to study arms by cluster or group
- Analysis must be based on post-intervention levels or on pre-post changes in measures
    - For pre-post changes used in analysis, measures must be identical, including identical recall period
- Analysis based on an α =.05 (or more stringent) and a 2-sided test
- With nonrandomized assignment, either no statistical differences in baseline levels of the outcome exist or baseline differences are controlled for in the analysis
- Analytic sample ≥ 50 participants per study arm

Strength of Evidence

Demonstrated Significant Positive Intervention Effects

- Positive and statistically significant ($p < .05$) intervention effect for ≥1 relevant outcome measure
- A positive intervention effect is defined as a greater reduction in HIV/STD incidence or risk behaviors or a greater increase in HIV protective behaviors in the intervention arm relative to the comparison arm

- A relevant outcome is defined as a behavior (e.g., abstinence, mutual monogamy, number of sex partners, consistent condom use with anal/vaginal sex, unprotected anal/vaginal sex, proportion of anal/vaginal sex acts protected, injection drug use, sharing or borrowing needles/works) - that directly impacts HIV risk, a biologic measure indicating HIV or STD infection (i.e., HIV or STD incidence) or HIV testing (if HIV test results are reported)
- Effect at the follow-up and based on the analyses that meet study implementation and analysis criteria

No Demonstrated Significant Negative Intervention Effects

- No negative and statistically significant ($p < .05$) intervention effect for any relevant outcome
- A negative intervention effect is defined as a greater increase in HIV/STD incidence or risk behaviors or a greater decrease in HIV protective behaviors in the intervention arm relative to the comparison arm.
- No other statistically significant harmful intervention effect
- For an intervention with a replication evaluation, no significant negative intervention effects in the replication study

Additional Limitations to Evaluate

- No evidence that additional limitations resulted in a fatal flaw:
    - A fatal flaw has occurred when the overall evaluation of limitations indicates they resulted in considerable bias, thus substantially reducing the confidence of the findings.
    - Examples of item limitations to check for possible fatal flaw:
        - Effects only found within a potentially biased subset analysis;
        - Substantial missing data. Missing data plus loss to attrition exceeds acceptable limits for retention alone (≥ 40%)
        - Study arm non-equivalence: statistically significant differences between arms in important baseline demographics or risk factors not controlled-for in analysis
        - Differential retention: (1) significant difference between study arms in characteristics among participants retained or lost to follow-up; OR (2) more than minimal rate of differential retention (>10%)
        - Intervention activities did not match with the intervention concepts or guiding theories intended to produce the desired outcomes
        - Did not clearly describe issues related to generalizability
        - Too many post hoc analyses (even with Bonferroni corrections)
        - Inconsistent findings

All criteria must be satisfied for an intervention to be considered as a Best-Evidence Individual-level, Group-level, or Couple-level intervention.

Source: Lyles et al., (2006) and Lyles at al., (2007).