Checklist for Study or Intervention Planning

Reach - Extent of Representativeness of Participants

In designing your study, consider purposeful sampling from diverse groups of participants (e.g. low-income, older adults, and racially-diverse) to enhance external validity. Consider recruitment methods and intervention features that enhance the reach within populations of persons and settings. Carefully review exclusion criteria and consider whether by excluding certain types of participants you are also decreasing ability to generalize results.

Estimating Reach and Recruitment of Individuals

- Based on the available literature, your experience, and with formative evaluation, try to anticipate the primary barriers to participation of your program. How can you minimize or introduce methods to address these barriers in order to enhance participation?

- Estimate the number and percentage of people in your local population that have the targeted risk factor of interest. (e.g., number and % of smokers, sedentary adults, post-myocardial infarction cases)

- Estimate the approximate percent of this targeted population that will be eligible due to specific study inclusion/exclusionary criteria. (e.g., of all adult hypertensives, what percent are excluded due to medication, other diseases, language barriers)

- Record the actual number and percent of persons excluded from your study.

- Report the percent of eligible participants who agree to participate in your study.

- Compare differences between those participating and those not participating on illness status, sociodemographics, geography and other key variables.

- Record reasons that participants refused to participate in the study.

Estimating Attrition

Do the following for each study condition:

- Record how many _____ and when (what week of the intervention) _____ subjects dropped from the study.

- Compare differences between those completing and those not completing the study on adverse events, illness status, sociodemographics, geography, baseline scores on dependent variables, and other key variables.

Efficacy - Short-Term Impact/Outcomes for Participants

Consider including objective measures of outcome (in addition to self-report):

- Consider multiple outcome measures to triangulate an intervention effect.

- Consider specifying a theoretical framework that might explain change in behavior.

- Measure relevant theoretical constructs to assess mediational relationships between the intervention and anticipated change in the outcome variable(s).

- Record adverse outcomes and assess quality of life to judge unintended consequences.

- Track costs of all aspects of the intervention e.g., intervention materials, equipment, personnel, time, and space requirements.

Adoption - Interface between Researchers and Potential Program Settings

Conduct formative evaluations to identify what intervention features potential program adoptees (e.g., health systems, physician offices, elementary schools) would like.

- Consider the ease and feasibility of your intervention modality and staff requirements in terms of transferring the strategies to a practice setting.

- Prepare your intervention, training and materials to be easily replicated or disseminated to a practice setting.

Estimating Setting Level Participation and Adoption

If you are recruiting organizations or other intact groups to participate, consider the following elements:

- Based upon the literature, your experience, and with formative evaluation, try to anticipate primary barriers to participation in your program for settings and for potential intervention agents (e.g. teachers, physicians, peer counselors). How can you minimize or introduce methods to address these barriers in order to enhance participation?

- Estimate the number and percentage of settings or organizations in your local population that you hope to target. (e.g., "blue collar" worksites, elementary schools, HMO's)*

- Estimate the number and percentage of settings or organizations in your targeted group that meet your defined criteria. (e.g., no previous health promotion program in last 2 months, no immediate merger planned, classroom configuration to support study)*

- Record the number of settings that you exclude from participation and why.

- Record the percent of eligible settings that agree to participate in your study.

- Compare differences between those participating and those not participating on relevant characteristics such as size of organization, type of business, previous health promotion programs, number of employees/students/constituents, any policies regarding the target behaviors of interest or other key variables.

- Record reasons that settings/ organizations refused to participate in the study.

Estimating Attrition

Do the following for each study condition:

- Record how many _____ and when (what week of the intervention) _____ program adoptees dropped from the study.

- Compare differences between those settings or agents completing and not completing the study on resources, staff expertise, size, physical and social environments, and other key variables.

Implementation - Fidelity or Intervention Integrity

- Identify the potential "implementers" of your intervention and meet with them to gain an understanding of their job duties and competing demands. Conduct formative evaluation to get feedback on how your intervention will fit their usual responsibilities and will fit into the organizational environment. Ask for suggestions to improve the implementation of your program.

- Record the extent to which participants and organizational settings complete or make use of various components of your intervention.

- Measure the extent to which agents deliver the intervention as stated in the protocol (e.g., percent of scheduled phone calls completed). If possible, have multiple intervention agents from different backgrounds, levels of training, etc., and document the implementation (and outcome levels) of each agent.

- Consider in your outcome analyses and conclusions the characteristics of participants who have higher versus lower levels of program use.

Maintenance - Both Individual Participant and Program/Setting Level

- Consider long-term follow-up of at least 6 months to 1 year following your last intervention contact.

- Consider continued contact and consultation to participating organizations or settings who wish to continue the intervention after your study has ended.

- Debrief with intervention agents and organizational decision makers after the intervention and identify what they liked best and least about the program, and which aspects they would be interested in continuing or modifying.

- Collect information on whether the setting or organization continues the program after your investigation is completed to estimate the potential for sustainability. *Many estimates can be made using existing public and vital statistics data (see links)