Research Methods

Reconciling research and community priorities in participatory trials: application to Padres Informados/Jovenes Preparados

Michele L Allen^{a,*}, Diego Garcia-Huidobro^{b,c}, Tiana Bastian^d, G Ali Hurtado^e, Roxana Linares^f and María Veronica Svetaz^g

^aDepartment of Family Medicine and Community Health, School of Medicine, University of Minnesota, Minneapolis, USA, ^bDepartment of Pediatrics, School of Medicine, University of Minnesota, St Paul, USA, ^cDepartment of Family Medicine, School of Medicine, Pontificia Universidad Catolica de Chile, Santiago, Chile, ^dDivision of Epidemiology & Community Health, School of Public Health, University of Minnesota, Minneapolis, USA, ^eDepartment of Family Science, School of Public Health, University of Maryland, College Park, USA, ^fCentroTyrone Guzman, Minneapolis, USA and ^gAquí Para Ti/Here for You Clinic for Latino Youth, Hennepin County Medical Center; Department of Family and Community Medicine, Minneapolis, USA.

*Correspondence to Michele L Allen, Department of Family Medicine and Community Health, University of Minnesota, 717 Delaware Street S.E., Suite 166, Minneapolis, MN 55414, USA; E-mail: miallen@umn.edu

Abstract

Background. Participatory research (PR) trials aim to achieve the dual, and at times competing, demands of producing an intervention and research process that address community perspectives and priorities, while establishing intervention effectiveness.

Objective. To identify research and community priorities that must be reconciled in the areas of collaborative processes, study design and aim and study implementation quality in order to successfully conduct a participatory trial. We describe how this reconciliation was approached in the smoking prevention participatory trial Padres Informados/Jovenes Preparados (Informed Parents/Prepared Youth) and evaluate the success of our reconciled priorities.

Methods. Data sources to evaluate success of the reconciliations included a survey of all partners regarding collaborative group processes, intervention participant recruitment and attendance and surveys of enrolled study participants assessing intervention outcomes.

Results. While we successfully achieved our reconciled collaborative processes and implementation quality goals, we did not achieve our reconciled goals in study aim and design. Due in part to the randomized wait-list control group design chosen in the reconciliation process, we were not able to demonstrate overall efficacy of the intervention or offer timely services to families in need of support. **Conclusion.** Achieving the goals of participatory trials is challenging but may yield community and research benefits. Innovative research designs are needed to better support the complex goals of participatory trials.

Key words: Community based participatory research, hybrid trial, Latinos, prevention, research design, translational health research.

Introduction

Concerns with traditional approaches to generating research knowledge and translating it into meaningful improvement in health,

particularly for communities adversely affected by social determinants of health, have been well described (1). Efficacy studies are often conducted under controlled conditions that may not attend

to cultural preferences or values of local communities, may not be feasible to replicate or sustain in community settings and are fundamentally different from practice conditions in terms of participant characteristics, resource availability, competing demands and level of expertise of those implementing the intervention (2).

One means to address these concerns is participatory research (PR), which recognizes the knowledge, expertise and resources of communities, and thus engages community members as full partners in all stages of the research process (3). Within PR, communities self-define and so may include cultural, geographic, racial and ethnic communities or communities of common identity or experience such as patients or providers (4). PR principles that underlie the research process include equal partnership at all stages of research, commitment to co-learning and community capacity development, approaching health issues from an ecological perspective, building on community resources and balancing research and action (3). Participatory approaches to research build a strong community reputation for intervention integrity and may enhance intervention implementation and sustainability by increasing the usability, relevance and acceptability of programs and methods of intervention delivery (2). Despite challenges of partnership, many community members and organizations recognize the benefits of research and want to participate in studies where research questions and methods are responsive to community priorities (5).

Thus there is a need for participatory trials that bring together the grounding in community priorities and insights offered by PR with the evidence generating capabilities of formal trials to increase the applicability of research to diverse communities and community settings. Participatory trials must achieve three goals: (i) address community perspectives and priorities through a participatory research process, (ii) establish the utility of a collaboratively developed intervention, often across multiple community sites and (iii) build foundational structures that will contribute to sustainability and dissemination. PR acknowledges that community agency priorities for offering timely access to services perceived to be beneficial for their clients raises challenges in intervention design and delivery. A participatory trial therefore may combine the focus on internal validity of efficacy trials (i.e. random assignment, intervention manualization, objective outcome measures) with the application to real world scenarios of effectiveness trials (i.e. diverse intervention sites, a comparison group receiving standard care, broad eligibility criteria) (6). These goals do not represent new research methods or PR approaches, but their co-application requires attention to ensure study success.

To achieve the potentially competing demands of producing an intervention and research implementation process that addresses community perspectives and attends to community priorities, while simultaneously establishing the utility of the intervention, partners must carefully consider tradeoffs between research and community priorities. While these tradeoffs are presumed in the PR literature, means for identifying and accounting for them within randomized controlled trials (RCTs) have rarely been articulated.

The purpose of this manuscript is therefore to describe areas for reconciling community and research priorities related to the three goals of participatory trials, including collaborative processes, study aim and design, intervention implementation and partner/site roles and capacities. We describe the definition of research and community priorities within the Padres Informados/Jovenes Preparados (Informed Parents/Prepared Youth, Padres) participatory prevention trial, how we reconciled the priorities, how we evaluated whether our reconciliation was successful and lessons learned.

This evaluation process may be applied to participatory trials across a broad range of research topics and community settings.

Methods

Padres Informados/Jóvenes Preparados (Padres)

The Padres project represents a 9-year community-university collaboration. The core collaborative team including the University of Minnesota Program in Health Disparities Research, University of Minnesota Extension, Centro Tyrone Guzman (an education and family engagement organization serving Latino families) and Aquí Para Ti (a clinic-based positive youth development program for Latino youth and their families) came together over a community-identified need for a locally relevant parenting program promoting positive youth development through supporting Latino immigrant parents of adolescents. The partnership adheres to PR principles by recognizing and emphasizing the unique contributions and perspectives of all partners to the design, implementation and dissemination stages of our study.

Intervention development began with a parent advisory board (PAB) of Latino parents of youth who identified and prioritized threats to their children's health, core cultural values and key parenting concerns. The collaborative team integrated parent and community priorities, practical family education strategies and theoretical models to develop an eight-session (20 hours) family based tobacco and other substance use prevention intervention (7). The program aims to develop strong parenting practices and facilitate relationship building between parents and youth, while emphasizing Latino cultural values, navigation through multiple cultures and environmental risks families experience related to socioeconomic circumstances.

The effectiveness of the intervention at preventing tobacco and other substance use susceptibility was tested through a NIH-funded RCT including immigrant Latino parents/guardians and a child of age 10–14 years. Study planning, participant recruitment and intervention implementation including delivering the curriculum, was accomplished collaboratively. The seven site partners identified by the collaborative team as organizations that were trusted in the Latino community were diverse in terms of organization type (two clinics, three social service agencies, a school and an Extension site), location (five urban, two rural) and size (8). Trained staff from each site delivered the intervention.

Reconciling research and community priorities: evaluating the Padres experience

Participatory trials must reconcile community and research priorities in the areas of collaborative and research processes. Because study success hinges on all partners coming to a common set of goals, evaluation and documentation of the reconciled priorities becomes important to address misalignment and to enhance study implementation. Table 1 outlines research and community priorities, how priorities were reconciled in Padres and evaluations of the degree to which reconciliation was successful in achieving all partners' goals. Reconciling differences in research and community priorities occurred at each stage of the study through a governance process defined by shared power, a consensus model for decision-making, a process for conflict management and a commitment by all partners to reflect on and learn from the partnership (9). Data sources used to evaluate success of reconciliation included: a partnership evaluation survey, intervention attendance data, measures of facilitator fidelity to intervention delivery and intervention outcomes data. Padres

Table 1. Comparison of research and community priorities and evidence of reconciliation success in Padres Informados/Jovenes Preparados (Padres) for collaborative processes, study aim and design, and implementation quality

Domain	Research priorities	Community priorities	Padres reconciliation	Data source(s)	Reconciliation success
Collaborative processes					
Adherence to PR principles	Study conducted in accordance to principles of PR to maximize participation of community, organizations and	Study conducted in accordance to principles of PR in order to maximize benefit to community	Co-leadership; formalization of group processes, data sharing, publication/ presentation agreements	Collaborative survey	Priorities achieved
77.1	facilitators	26 1 1			D
Value added for community and future collaboration	Not considered in traditional research models	Must be adequate benefit to the organization & community at large	Generated opportunities for organizations to network & develop skills contributing to sustainability	Collaborative survey, social network analysis	Priorities achieved
Role of community sites	Adequate resources brought to bear on inter- vention delivery	Participate with minimal disruption to usual work flow	Involvement of or- ganizations in decision making, high levels of support	Collaborative survey	Priorities achieved
Study aim and design Defined intervention	Define replicable	Feasible, cultur-	PR development to	Participant	Priorities
Defined intervention	intervention	ally appropriate program with maximal usability	maximize feasibility and appropriateness	attendance data, cultural outcomes, fidelity data	achieved
Design	Demonstrate efficacy of intervention using RCT design	Deliver needed services to maximum number of families	Hybrid design with few exclusion criteria; minimal restriction on provision of services within organizations. Randomization with delayed control condition to include all recruited participants	Study outcomes, participant attend- ance	No, did not achieve either priority
Implementation quality Study implementation	Ethical, efficient recruitment; organized intervention implementation	Increased capacity for program delivery within context of multiple	Flexible staff qualifications. Train community facilitators for capacity and sus- tainability; training on site to accommodate	Fidelity Data, training outcomes	Priorities achieved
Intervention delivery	Skilful delivery of intervention with fidelity and minimal adaptations	demands Maximize local and immediate appropriateness	time constraints Definition of core intervention components, community training in theory and delivery of intervention. Post-delivery debriefing for spontaneous adaptations	Intervention components, fidelity data	Priorities achieved

partners reviewed relevant data and collaboratively determined the degree to which reconciliation was successful in each area.

Results

Collaborative processes goals

Strong collaborative processes that attend to community priorities across study sites benefit both community and the research process. Collaboration begins by partners co-defining group processes,

including how partners will work, make decisions and acknowledge the participatory nature of the study (3). In Padres, the core partners defined goals, communication processes, decision making and publication procedures that were detailed in signed documents.

From a research perspective, adherence to PR principles and group processes supports the goal of community sites maximizing engagement of research participants and community staff with significant roles in the project. The depth and authenticity of the collaborative process in participatory trials likely influence enthusiasm

and preparation for a research trial and thus relate to the successful implementation of the project and to its outcomes (3,10). From a community perspective, a goal of PR is to maximize benefit to the community within the current research study in terms of addressing community need and beyond the study by building internal and inter-agency capacities. Therefore, participatory trials are designed with an explicit commitment to developing capacity of community organizations to conduct research relevant to their communities, develop and sustain interventions developed through participatory research processes and collaborate in future projects.

In Padres we developed and administered a partnership evaluation survey to identify areas to improve participatory processes and strengthen the partnership and assess organizational contexts that contribute to collaboration and implementation outcomes (Table 2). The Padres team developed the 44-question survey by adapting published measures identified through a review of the CBPR and implementation science literature and adding new measures as necessary, to assess partnership strength and collaborative processes (e.g. project impact, trust, transparency), organizational characteristics/capacity (e.g. leadership support, competing priorities), community benefit from participating in a PR project (e.g. knowledge transfer, likelihood for future collaboration) and enhanced inter-agency community networks (e.g. number of connections among partners and the strength of those connections) (11). The survey was sent electronically to all Padres partners annually.

Results of the collaborative survey suggested that our reconciliation of collaborative process goals were successful. Trust, organizational capacity for research and the strength and density of social networks among project partners increased over time (12). Furthermore, even considering our small numbers of sites and consistently high perceptions of collaboration quality, we found that increased site perceptions of shared goals and project impact was positively associated with research process outcomes such as parent and youth attendance at the intervention sessions supporting the connection between strength of collaboration and success of project implementation (13).

Study aim and design

Social Network Analysis (1 item)

In participatory trials, study focus, intervention definition and study design are co-defined to be acceptable and relevant for all partners. The intervention must be specific enough that its delivery can be tested, but flexible enough that it addresses community-defined priorities and needs. Community involvement in intervention

development leads to strong cultural appropriateness and feasibility for utilization at community sites (2,3).

In Padres, to reconcile research priorities for a defined and replicable intervention with community priorities for a feasible and culturally appropriate programming, the collaborative team spent 2 years co-developing the Padres curriculum. The resulting intervention, formatted to be useful for partnering organizations in terms of length, expertise required for facilitation and infrastructure, framed evidence-based parenting practices in the local cultural and socioeconomic context for Latino families.

The PR principle calling for action in response to communityarticulated need (3) becomes important in questions of participant eligibility criteria and whether randomization is acceptable, often leading to use of the randomized wait-list control group design (14). In the Padres pilot study, we chose a non-randomized design because community partners felt that compromising trust by denying services to potential participants would not be worth methodological gains so early in the partnership (9). However, when the same conflict arose during the current study, due to trust gained through the process of working through early partnership issues, strengthened belief in the utility of the program and increased understanding of research, we reconciled this conflict by using a randomized wait-list control group design. Six months was chosen as the longest acceptable time for families in the control condition to wait to participate. In addition, we had few exclusion criteria and placed minimal restrictions on organization provision of services to study participants.

To evaluate our success in areas of intervention definition and study design, we considered study participant attendance, engagement and outcomes. In terms of intervention definition, we achieved successful reconciliation of these priorities. Appropriateness was suggested by intervention group attendance rates that were higher than many studies evaluating universal family prevention interventions with Latinos (86.2% attended one session or more; 58.0% completed 75% of the intervention) (15). The cultural framing supported study outcomes; we noted a strong moderation effect whereby smoking susceptibility decreased significantly among youth in families most estranged from traditional Latino cultural values (16).

The reconciled study design choices met neither research nor community priorities. Despite noting a strong moderation effect, our final analysis demonstrated no difference in overall program effect on youth smoking susceptibility (16). One explanation for these findings is that follow-up occurred too early to detect intervention

Table 2. Collaborative survey domains and sample items

Assessment of collaboration Impact (5 items) Our collaboration has been effective achieving its goals. Trust (6 items) Over the past year, to what extent have you felt comfortable talking openly with the Padres Informados research staff? To what extent do you feel satisfied with Padres Informados collaboration? Satisfaction (1 item) Engagement (1 item) To what extent do you feel a sense of ownership of the collaboration? To what extent do you feel you have had adequate input regarding the allocation of resources? Transparency (4 items) Partner sites capacities and barriers Organizational Factors (3 items) Organization type, number of individuals served, number of staff Organization Capacity (8 items) To what extent do you feel that your work with Padres Informados is a priority for your organization? Facilitator background (9 items) Based on what you know about Padres Informados, to what extend do you feel comfortable with your group facilitation experience? Community benefit beyond research project To what extend are you willing to work on collaborative projects similar to Padres Informados in the future? Community benefit (6 items)

How is your organization connected to other agencies involved in this project?

effects as systematic reviews of family-focused prevention trials have noted increased efficacy at 12 months follow up (17). In Padres, our experimental condition ended at 6 months post-intervention due to the randomized wait-list control design. Furthermore, while our minimal exclusion criteria allowed us to enrol most interested families, attendance records revealed that family participation was appreciably lower among participants randomized to the delayed control compared to the intervention condition (57.6% versus 86.2% attended at least one session; 28.5% versus 58.0% completed 75% of the intervention; P < 0.001 for both comparisons) (15). These findings suggest that our design did not meet the community partners' goal of delivering timely services to as many families as possible.

Implementation quality

Due to the PR commitment to community capacity generation, within participatory trials community partner staff recruit participants and deliver the intervention. Therefore partners must reconcile priorities regarding training, study implementation processes including recruitment approaches and conceptualization of fidelity to the co-defined intervention. Within this framework, evaluation of intervention implementation across sites becomes important as the success of training and support processes across partner sites directly affects study outcomes.

In Padres, to increase community capacity for supporting family-skills training and research collaboration, at least two Latino staff from each organization served as intervention facilitators and site recruiters/coordinators. We generated clear but flexible requirements for community staff including that they be bilingual and have at least 3 years experience working with Latino families; we did not require research or family education experience. At the project onset, site staff attended 3 days of group training. In addition, the facilitators participated in eight hours of individual in-depth content and delivery training prior to implementing the intervention, typically delivered at the community site. Research staff supported the site coordinators in developing formal recruitment plans which considered the number of active eligible clients at each site and new strategic partnerships that supported both recruitment and inter-agency collaboration.

We successfully trained eighteen community staff from a wide range of backgrounds as recruiters/coordinators and parent and youth facilitators. Half of the staff reported that their highest educational degrees came from high school or technical/professional school (50%). Their past work experiences included youth work (22%), parent education (22%), cultural liaison or translator (21%), health care (25%) and community health work (9%). By the end of the study period, most facilitators ranked themselves as moderately or very comfortable with group facilitation skills (88%) and intervention-related content (86%). In addition, the majority of sites met recruitment goals in a timely fashion (13). These achievements suggest successful reconciliation of research and community priorities in this area.

Traditionally, an intervention with high fidelity is one where facilitators deliver the intervention exactly as described in the program manual. However, PR acknowledges the requirement for implementation flexibility to maximize local appropriateness of the program (3). Thus, in participatory trials, fidelity to pre-conceptualized core intervention components more appropriately captures how the intervention is delivered across sites. In Padres, core components were identified by the collaborative team and aligned with theoretically driven causal mechanisms. They were operationalized as session specific (e.g. positive discipline) and broader trans-session

concepts (i.e. strengths-based framing, cultural orientation to adolescent development) and as behavioural change strategies (e.g., self-reflection, behavioural rehearsal) to reinforce each concept. Facilitators were trained to emphasize the delivery of these components, rather than to strictly adhere to the manual. In a qualitative content analysis of videotapes made of the intervention facilitators, we noted few adaptations to the core intervention components (65% of content was delivered as instructed) or to the delivery approach (92% of the time group facilitation skills were used as instructed). Furthermore, in our quantitative analysis of study outcomes we noted no significant variation in outcomes across sites. These findings suggest that our reconciliation of goals in implementation quality was successful.

Conclusions

The application of PR approaches to improve population health is increasing as it becomes apparent that inclusion of community perspectives and priorities is necessary to generate and test interventions that will be successfully taken up in community settings. However, reconciliation of research and collaboration goals and priorities must be successfully navigated to achieve the full potential of this approach.

Here we demonstrated how a participatory trial reconciled the majority of differences between research and community priorities and evaluated the success of these outcomes. As has been found in reviews of the PR literature, the benefits to communities in this project extend beyond the research outcomes to support community-desired capacity development and interagency cooperation (10). While we successfully achieved our reconciled collaborative processes and implementation quality goals, we were less successful in achieving our reconciled goals in study aim and design. Though we may have failed to show overall intervention efficacy for multiple reasons, the time limits of the experimental condition in the randomized wait-list control group design was likely a key contributor. Furthermore, this compromise did not provide timely services to families in need of support.

The failure to achieve reconciled design goals in this study speaks to known limitations of randomized controlled trials implemented within multiple real world settings (18). Randomized designs may not be sufficiently flexible to attend to ethical dilemmas in community based trials and may not readily incorporate multiple ways of knowing (19). Rigorous designs such as Sequential Multiple Assignment Randomized Trials, comparative effectiveness, steppedwedge and factorial designs, may better meet community priorities, but are relatively uncommon in grant review and implementation processes.

Participatory trials using these design innovations hold promise to fully capitalize on PR's attention to community resources, capacities and needs to produce quality evidence that contributes to intervention success, sustainability and to accelerate the dissemination of research knowledge.

Declaration

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Conflict of Interest: none.

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