

Building Family Interventions for Scalability and Impact

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Citation:

DANFORD, Cynthia A, MOONEY-DOYLE, Kim, DEATRICK, Janet A, FEETHAM, Suzanne, GROSS, Deborah, KNAFL, Kathleen A, KOBAYASHI, Kyoko, MORIARTY, Helene, ØSTERGAARD, Birte and SWALLOW, Veronica (2024). Building Family Interventions for Scalability and Impact. *Journal of Family Nursing*. [Article]

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Building Family Interventions for Scalability and Impact

Background/Problem: Family nursing researchers are charged with addressing the conceptual and methodological underpinnings of family research and developing family-focused interventions. Yet, a gap in family science exists regarding how interventions are systematically developed and how investigators progress from foundational work to experimental testing to policy integration.

Purpose: To provide an overview of the trajectory of intervention development through a family research lens.

Method: The intervention development approach is presented using the first three of Sidani's five stages: 1) foundational work to understand the problem targeted for change, (2) intervention development and assessment of acceptability and feasibility, and (3) efficacy testing. Each phase of family intervention development is described in terms of process, design considerations, and policy and practice implications. Exemplars are integrated to emphasize the family lens.

Family Nursing Science Implications: The manuscript provides guidance to family scientists for intervention development and implementation to advance family nursing science.

For decades, family nursing researchers have been challenged to address the conceptual and methodological underpinnings of family research and develop family-focused interventions. Over the past 50 years, Author blinded has played a pivotal role in delineating criteria for research of families and advocating for studies that advance science and inform policy (Author blinded, 2018; Author blinded, 1984). Author blinded (1990) discussed issues and strategies related to the planning and implementation of family research, concluding that “as family nursing research evolves, intervention studies will increase” (Author blinded, 1990,p.12). She emphasized that examining both the process and outcomes of interventions is key to fully understanding how family nursing interventions work. In an early *Journal of Family Nursing* editorial, Bell (1995) urged nurse researchers to develop innovative family intervention studies and advocated for careful examination of the intervention process including nurse-client interaction involving families during delivery of the intervention (Bell, 1995). In addition, when reviewing trends in family nursing research, Ganong (2011) concluded that interest in the development and testing of family interventions was becoming a central focus for nurse researchers (Ganong, 2011).

Defined as psychosocial and behavioral interventions designed to improve health and quality of life for families and family members (Chesla, 2010; Eccleston et al., 2015; Martire et al., 2004), family interventions often focus on improving family members’ understanding of and ability to manage the health challenges confronting them, with some also seeking to improve family relationships and functioning (Shamali et al., 2019, 2021). Other family interventions are designed to systematically engage persons with chronic illness and their family members in an intervention with the goal of improving outcomes for both across the health-illness continuum and across the lifespan (Author blinded, 2016; Author blinded, 2016; Author blinded, 2016)

Family interventions vary in the problem targeted for change as well as the structure and level of family engagement (Knafl et al., 2016).

Across disciplines, progress has been made in the development and testing of family interventions. High-level reviews of family interventions provide evidence of intervention efficacy in different cultural contexts as well as in areas needing to be strengthened (Chesla, 2010; Eccleston et al., 2015; Konradsen et al., 2021; Mahrer-Imhof et al., 2022; Martire et al., 2004; J. Smith et al., 2020a). For example, in a meta-analysis of 70 family interventions addressing adult patient and family member outcomes, Martire and colleagues (2004) described positive intervention effects on patient depression and mortality and positive effects on family members' caregiving burden, depression, and anxiety. More recently, Smith and colleagues (2020) conducted a synthesis of reviews and concluded that family-focused interventions can improve the health and well-being of individuals with long-term illnesses and their families.

Despite finding evidence of efficacy, review authors have also recommended strengthening the empirical and conceptual grounding of family interventions. For instance, researchers who conducted one European scoping review found that interventions for older adults with cancer were based on limited knowledge about family health practices (Konradsen et al., 2021). The twelve studies reviewed focused on discrete components or foci of family versus broader life course perspectives. From another European scoping review of 17 studies of healthcare practices and interventions for families of older patients with cardiovascular disease (Mahrer-Imhof et al., 2022), researchers concluded that interventions and practices did not embrace a fundamental view of the family as the unit of care, but rather had a disease-centered approach and varied conceptualizations of how professionals should support families. These authors called for more extensive development of family interventions including involvement of families and clear, comprehensive descriptions of the healthcare practices related to the

interventions. Smith and colleagues (2020) concluded that although family interventions have potential to improve the health and well-being of individuals and families, a better understanding of how they accomplish this is needed to promote the implementation of family-focused care into practice. They also highlighted the need to evaluate clinical impact and cost-effectiveness of such interventions. Other authors have noted a gap exists in family intervention research in emerging areas of science, such as pediatric palliative and end-of-life care (B. Lord, 2019; S. Lord et al., 2020; K. Mooney-Doyle et al., 2021) and long-term effects of COVID-19 (Angier et al., 2021).

Evidence of the efficacy of family interventions supports their continued development and testing. The Chicago Parent Program exemplifies one efficacious program, developed in partnership with parents to ensure its relevance for families raising young children in low-resource communities (D. Gross et al., 2007), and then tested in multiple randomized trials in community settings (Breitenstein et al., 2012; Deborah Gross et al., 2009, 2018, 2019). Yet, publications of few programs such as the Chicago Parent Program exist. Thus, the importance of developing family interventions in partnership with families and ensuring the process of intervention development is carefully planned, conceptually grounded, and relevant for families from diverse backgrounds is clearly needed.

Despite advances in family research, a gap in family science exists regarding how interventions are systematically developed and how investigators progress from foundational work to experimental testing to policy integration. To address this gap, the aim of this manuscript is to provide an overview of the trajectory of intervention development through a family research lens across the first three of five phases that Sidani (2015) identified: 1)

foundational work to understand the problem targeted for change, 2) intervention development and assessment of acceptability and feasibility, and 3) efficacy testing (Sidani, 2015).

Although the intervention development trajectory is presented sequentially, the process is iterative and flexible: each phase informs the next or may clarify a previous phase. Additionally, the concept of scalability must be considered throughout the phases of family intervention development. Scaling an intervention for efficacy begins on a small scale under controlled conditions and then, while maintaining effectiveness, is expanded under real world conditions (Milat et al., 2013). To enhance rigor, it is essential to embrace scalability and the iterative nature of intervention development throughout each phase. To begin, in Phase 1, the intervention is modeled, meaning the issue of interest and the intervention are conceptualized and the intervention and its mechanism are operationalized. In Phase 2, the intervention is pilot tested, which includes examining the acceptability, feasibility, and preliminary effects of the intervention protocol and the research methods. Phase 3 involves examining the efficacy of the intervention. Phases 4 and 5 include determining the effectiveness and translation of the intervention under real world conditions, but these are beyond the scope of this manuscript. Each phase of family intervention development is described as it relates to process and design considerations and policy and practice implications (Table 1). Of note, the definition and conceptualization of family informs all aspects of the study sample, design, methods, measures, and analysis (S. Feetham, 2018). Thus, in addressing the process of family intervention development, foundational work is regularly revisited and informs subsequent stages. Exemplars are integrated throughout this paper to emphasize the family lens. The result will provide family scientists with the tools to enhance family intervention development from a small scale to real

life application, while at the same time being attentive to the complexity of the family. (Insert Table 1 here)

Phases of Family Intervention Development

Phase 1- Modeling the Intervention

Defining the Modeling Phase of the Family Intervention

The first phase, modeling the intervention, is foundational to intervention development. It includes developing the science about the research question or issue of interest, how it is conceptualized, and how its mechanism for behavior change is operationalized—in addition to proposing the optimal family outcomes. The modeling phase of the intervention includes a clear conceptualization and definition of the “family” unit, as well as a description of how family members, individually or as a unit, are engaged. In addition, the mechanisms for potential behavior change need to be conceptually and empirically identified. A discussion of relevant practice and public policy related to the context also requires attention. Consideration of what relevant policies may contribute to the family intervention issue and how the research outcomes can inform policy strengthens the family intervention during modeling.

Components of Modeling the Family Intervention

Understanding the components and steps that are needed to meet a family health goal can help family researchers chart their program of research and create realistic goals (S. Feetham & Doering, 2015). During the modeling phase, the researcher is gaining an understanding of the family health issue. The researcher may be aware of or informed about a family health issue and the possibilities for addressing it through their personal or clinical experience with families, through their own or others’ research evidence, or through discussion with stakeholders. At this point, gathering sufficient information to better understand the issue, garnering alternative

viewpoints that may challenge preconceived ideas, addressing priorities, and determining whether the problem at hand is amenable to change occur. Thus, work at this stage includes literature review, conceptualization, discussion with experts in the field, community engagement, and evidence gathering. Also, in exploring the existing evidence, determining whether any related interventions have already been tested within the selected population and setting can be helpful in identifying gaps and fine-tuning the outcome of interest.

Research during the modeling phase of intervention development may be descriptive in nature, where the family researcher is describing the nature of the family health issue and its conceptualization, or it may be inferential. After completing descriptive research, inter-relationships among outcomes are more easily uncovered. Specifically, mediators and moderators of the family health issue, potential mechanisms of change and optimal outcomes are often revealed (O’Cathain et al., 2019).

The state of the science during the modeling phase can vary. Since family researchers may approach this stage from various points in their career trajectories, the state of science may range from early conceptualization and description to advanced understandings of antecedents, consequences, mediators, moderators, family experience, stakeholder input, and intervention creation. Researchers gather evidence from multiple sources, such as the literature or their own studies that describe the family health issue, clinician insights into the issue, family insights into its impact. More nuanced understanding of relationships among family health processes, contextual variables, family health variables, and individual physical or psychosocial health variables also require consideration.

Process During Modeling of the Family Intervention

Since this first stage of intervention development can feel amorphous and complex to family researchers new to intervention development, to considering what skills and benchmarks a team needs to move forward is a good place to begin. First, the team must be able to address the “why”; they should be able to articulate their long-term intervention development goal. Second, the team must be able to articulate the “how” by describing the short-term goals and concrete steps they can take to achieve the intervention development goal.

To answer the “why” and “how” questions, the family researcher needs skills in building a team and developing partnerships across clinical, community, and academic settings. Partnerships with knowledgeable stakeholders (e.g., health professionals, family members, caregivers) and community partners (e.g., advocacy groups; clinical partners) can provide a deep and meaningful way to understand what families experience and desire and determine what matters in their family. Clinical and community partnerships provide a professional perspective that is also helpful in understanding family health issues and what could interfere with feasibility, scalability, and impact of family health interventions.

Building relevant partnerships allows for the “why” and “how” questions to be answered in the most comprehensive way possible. Family researchers in this phase should also cultivate an appreciation for different research approaches and designs. They may have expertise in one particular area of research but may need to partner with others for content or methodological expertise. For example, with a focus on understanding siblings’ perspectives when designing a study with parents and siblings of seriously ill children, Mooney-Doyle amplified her qualitative expertise by partnering with an anthropologist proficient in participatory action research and photovoice. Mooney-Doyle further collaborated with a nurse scientist with expertise as a child health services researcher to understand the impact of financial strain and caregiving burden and

as a means to leverage knowledge of family systems, social ecology, health policy, and secondary analysis of administrative data (K. Mooney-Doyle & Lindley, 2020; Kim Mooney-Doyle & Lindley, 2019) As another example, Kobayashi (2021) partnered with members from the Japanese Family Association to initiate national policy about care of the family and conducted a survey to clarify the needs of families with hospitalized children (Kobayashi, 2021). She also partnered with family members to assess whether survey items captured what Japanese families consider important and to determine what survey methods were most feasible for families to understand and complete.

An important element of addressing the “how” in the modeling phase of intervention development is assessing what resources—such as time, money, and relationships—are both needed and available. Time is an important resource necessary for conceptualizing and conducting descriptive studies, applying for funding, and publishing literature reviews. Working with a family research mentor to structure time for thinking and writing (e.g., clearly blocking writing time on a calendar to create a concrete visual) or exploring options for protected time from teaching and clinical responsibilities (Broome & Fairman, 2018) is essential during the modeling phase of family intervention development. Too little time attended to necessary foundational work could lead to a flawed intervention, while lengthy periods of time may slow advancing to subsequent phases of intervention development and risk the intervention becoming irrelevant.

Seeking funding during the modeling phase of family intervention development may be necessary to help family researchers effectively advance foundational planning by providing for sophisticated content or statistical consultation, meeting with stakeholders, and obtaining editorial services as well as software and participant incentives. Funding sources vary and may

include large grant opportunities or smaller community-focused initiatives, such as internal funding from academic or institutional workplaces or external funding from professional or specialty organizations.

Finally, relationships may be the most important resource during the modeling phase. Relationships with mentors, clinical partners, community partners, and families help the family researcher stay inspired and committed to the family intervention development journey. Such relationships expand the researchers' thinking about the family health issue and intervention design by challenging ideas, providing realistic views about what may be feasible, and determining meaningful outcomes. For example, clinical and community partners can provide evidence of the feasibility of achieving the proposed sample design. Mooney-Doyle experienced this when a funding agency suggested she increase the sample size of a proposed study during the COVID-19 pandemic. One of her community partners shared that a reduction in services and the threat of acquiring COVID-19 infection increased the vulnerability of families and left parents feeling overwhelmed and tired. This insight helped Mooney-Doyle justify the feasibility of the proposed sample size.

In creating a family research team, family researchers must assess degree of engagement, partnership, and involvement with stakeholders in decision-making processes. The family researcher may need to determine the level of family participation and whether stakeholders will help identify the family health issue to be addressed. Depending on the degree of involvement, the stakeholder may serve as a full research partner or provide guidance in a consulting role. At the modeling stage, it is important to outline the roles, rules, rights, and responsibilities of team members so that expectations are clear.

Once a deep, multifaceted understanding of the “how” and “why” of the modeling phase has been established through developing long-term goals, community partnerships, and a complementary team, family researchers should be ready to evaluate the evidence generated to understand “what” is to be addressed by a family intervention. Goals or expected outcomes of work conducted at the “what” stage include elucidating the logic model of the problem and the logic model of the intervention, a key outcome of the modeling phase of family intervention development. Logic models should be developed in partnership with team members who bring complementary skills and lived experiences, thereby adding rigor to the process.

Logic models provide a roadmap or visual depiction of the research team’s thought process. Logic models incorporate both a well-articulated description of the family health issue including assumptions (logic model of the problem) as well as actions guiding change (logic model of the intervention) (O’Cathain et al., 2019). The logic model of the *problem* provides a means to articulate relationship between parts and whole as the family health issue and its impacts are clearly understood (Fernandez et al., 2019; Milstein & Chapel, n.d.). The logic model of the *intervention* describes how a potential intervention addressing a family health issue will cause a change in the selected family outcome (Fernandez et al., 2019; Milstein & Chapel, n.d.). Collectively, the logic model of the problem and the logic model of the intervention can help a family researcher articulate the justification for the family intervention proposed and the potential direction for change anticipated. Clearly articulated justification is critical when seeking stakeholders, partnerships, and funding and is vital for identification of a relevant theory or conceptual model to guide the study.

Considering descriptive and inferential evidence, the state of the science, and community partner insights, the family research team can develop the logic model of the problem to help the

researcher highlight relevant context and assumptions, as well as potential antecedents, consequences, and contributing processes (Fernandez et al., 2019; Milstein & Chapel, n.d.) . Developing the logic model of the problem is a preliminary step in articulating the family health issue of interest to be addressed. The family research team would then choose an existing theory to identify important and relevant relationships and outcomes. Existing theory also helps formalize and inform content, recipients, and mode of delivery of a family health intervention. Mooney-Doyle captures the logic model of the problem while exploring sibling adaptation and well-being when a child in the family has a serious childhood illness. Qualitative and quantitative needs assessment, pilot data collection, and input from professional planning groups and community partnerships provided contextual considerations for intervention development and goals. (Figure 1).

Once the logic model of the problem has been articulated, the team can then begin to develop the logic model of the intervention (Figure 2). The logic model of the intervention is an explicit description of the causal pathways: the short-term, intermediate, and long-term goals. Further, it articulates factors related to the family health issue and mechanisms through which the intervention will cause an effect. The logic model of the intervention builds directly on the logic model of the problem (O’Cathain et al., 2019). Through these steps, the family researcher can map out how the family intervention will cause a change in a particular family process to create an outcome that supports family health.

Design Considerations During Modeling of the Family Intervention

Leveraging descriptive or inferential data to describe the nature of the problem and relationships among antecedent or outcome variables is foundational to assessing what outcome to target and which variables may be important mediators or moderators. The social, economic,

and historical contexts within which families exist are important to consider, whether the design is qualitative or quantitative. Considering context is also a vital component in recognizing that many family health issues have systemic upstream antecedents or causes and downstream impacts or outcomes (Butterfield, 2017; Deatruck et al., 2016; S. Feetham, 2018), which can subsequently provide insight into institutional and policy-related factors that affect the family health issue.

Policy Implications During Modeling of the Family Intervention

Because policy is a key determinant of health, policy implications of family research work from the early conceptualization of the research project require careful thought (Deatruck, 2017; S. Feetham, 2018). For example, during the modeling phase of intervention development, the impact of policy on the research to be conducted and how institutional, local, and federal health and social policy impact families is essential to consider. Regulatory and research policy regarding the primary data collection must be reviewed. Family researchers must reflect on how policy affects the context in which families live, work, and play. Addressing how policy can be an antecedent to risk or resilience or how policy enforcement can exacerbate family experiences of risk or stress are necessary considerations (Butterfield, 2017; S. Feetham, 2018). Specifically, Mooney-Doyle learned from parents that institutional policy on sibling visitation in acute care settings could exacerbate the parents' experience of distress and feelings that they could not fulfill goals in parenting the healthy siblings (Mooney-Doyle K et al., 2018; K. Mooney-Doyle & Deatruck, 2016).

During Phase 1 (modeling the intervention), the family researcher articulates the logic model of the problem and the logic model of the intervention, thereby supporting identification of a theory or conceptual framework. Successfully modeling the intervention provides the family

researcher with a solid foundation to initiate the next phase in intervention development: pilot testing the intervention.

Phase 2: Pilot Testing the Intervention

Defining Pilot Testing of the Family Intervention

The second phase of family intervention development is pilot testing the intervention to evaluate its acceptability and feasibility and the preliminary effects of the intervention protocol. Because conventions about pilot studies differ globally, it is important to clarify if a feasibility/acceptability study will be conducted first and then followed by a pilot study about the outcomes or effects of the intervention, or if they are combined. If separate studies are planned or if they are combined, the various processes involved in this phase of intervention development are systematic, iterative, and formative and together should positively inform the strength of the intervention. The criteria and measures for acceptability and feasibility as well as for measuring the intervention effects are informed by the conceptual and methodologic orientation of the study. These criteria and measures are also informed by the state of family science in the identified area of study. Data collection can involve a full range of qualitative, quantitative, and mixed methods.

Components of Pilot Testing the Family Intervention

Acceptability of an intervention is the evaluation of suitability of an intervention and related study procedures to members of the family system and other relevant stakeholders (Bowen et al., 2009). Acceptability may include the appropriateness of the content (e.g., participants' satisfaction, benefits, usefulness, recommendations to others, willingness to enter the program again, time consumed and overall length [e.g., too long, too short]). It may also include enrollment rates (e.g., were there enough family participants?) and adherence rates (e.g.,

was there enough time to complete the program? Did it fit into daily life? How many sessions were attended? How many components completed?). Safety of the protocol is also a consideration including any unexpected adverse events that resulted from the protocol.

Feasibility of an intervention is the practicality of the intervention in terms of procedures and outcomes; in other words, “Can it be done?” (Bowen et al., 2009). Feasibility includes criteria associated with the family system, such as recruitment efforts and resources needed to manage the intervention. Evaluation of recruitment efforts may include examining the overall capability of recruiting participants based upon the proportion of the participants who have been assessed as eligible and the number who have given consent, withdrawn, and attended intervention sessions. The characteristics of the successfully recruited sample may also be assessed using benchmarks discussed in the protocol (e.g., racial, or ethnic diversity of participants). Resources needed to manage the intervention can be evaluated in a pilot study using criteria related to capacity (administrative expertise, skills, space, and time); ethical conduct (study procedures and ethical standards); budget (realistic); technology and equipment (sufficient); and training (educational needs and expertise).

Processes During Pilot Testing the Family Intervention

Effects of an intervention during pilot testing are confined to preliminary consideration of their outcomes. While the small number of participants in a pilot study precludes formal hypotheses testing, calculation of descriptive scores showing trends and directions according to outcome measures can help investigators understand their utility. Descriptive scores also uncover anomalies in databases, oversights in instrument selection and research design (e.g., need for additional data points), as well as the need to re-determine power calculations.

Design Considerations During Pilot Testing of the Family Intervention

When developing the design for a feasibility/acceptability and/or a pilot study, family scientists encourage participatory designs (The National Institute of Health Research (NIHR) Centre for Engagement and Dissemination (CED), 2022). For example, the principles of co-production and co-design from the United Kingdom (UK) Centre for Engagement and Dissemination (DEC) are relevant to the development of family interventions. Co-production means that family researchers, practitioners, and community partners or participants work together and share power and responsibility from the start to the end of the project as new knowledge is disseminated. During the process of co-design, stakeholders are encouraged to identify a problem and be empowered to envision a way to solve the problem, co-design a prototype or alpha version of the solution, and then test it. Stakeholder involvement can come in many forms: advisors from research projects and organizations, research participants, members of an engaged community that are given information about the research, or, finally, members of groups to which research results are disseminated (Graffigna et al., 2021; Greenhalgh et al., 2019).

More considerations are needed about stakeholder involvement based on the exact methods and measures that are used. Qualitative methods are used to engage stakeholders to obtain their perspectives individually or in groups. In either format, data can be analyzed according to their status as a stakeholder or as a member of a sub-group of stakeholders (e.g., differentiating among parents, children, and professionals). Data can also be collected in focus groups or individual interviews, such as when co-production workshops were held with stroke survivors, caregivers, and health professionals to develop self-management interventions (Wray et al., 2021). Quantitative measures used in pilot studies of acceptability and feasibility can most easily compare metrics across stakeholders (e.g., measures built from the Unified Theory of

Acceptance and Use of Technology (UTSUT); the Acceptability of Intervention Measure (AIM); and the Feasibility of Intervention Measure [FIM]). Finally, mixed-methods approaches are optimal for use because they allow the researcher to integrate participatory assessments with evaluations based on standard metrics. With mixed methods approaches, many kinds of designs can be implemented that involve qualitative and quantitative data, which can be collected at various time points during the intervention and prioritized differently (Wu et al., 2019). Examples include using a quantitative measure to assess sessions in an intervention and simultaneously gathering qualitative explanations about what makes certain sessions most feasible and acceptable for participants. The qualitative and quantitative data can then be integrated to strengthen the results.

The Online Parent Information and Support (OPIS) study provides an exemplar of a feasibility/acceptability study (Swallow et al., 2014). Funded by the UK National Institute of Health Research, the intervention was built on a series of studies investigating families' needs and preferences for an online intervention to support parents' self-management of their child's chronic kidney disease (CKD). To conduct the feasibility/acceptability study, a three-phased exploratory mixed-methods approach was incorporated to inform design of a future randomized control trial (RCT) of OPIS. In the first phase, the OPIS content was co-designed through a combination of qualitative, semi-structured, individual interviews and focus groups with a total of 70 patients, parents, and healthcare professionals. In the second phase, the online resources to meet the needs and preferences identified in the first phase were developed through qualitative interviews and focus groups with 15 parents, eight patients, and six healthcare professionals. The resources were refined to produce an alpha version of OPIS. With these findings, researchers defined aims and objectives for the pilot RCT to assess feasibility of OPIS.

Next, the parents in the intervention group assessed the acceptability of OPIS qualitatively with interviews and quantitatively with a modified version of the Suitability Assessment of Materials (SAM). They also assessed usability via a modified version of the User Interface Satisfaction (QUIS) questionnaire. A variety of family variables were evaluated including parents' condition management ability (Condition Management Ability scale of the Family Management Measure), parents' relationships with health professionals and parents' level of comfort in asking questions and voicing their opinions (Service System Subscale of the Family Environment Scale [FES]), and father support for managing the child's CKD (Dads Active Disease Support Scale [DADS]). In summary, 20 parents accessed OPIS. Responses from the SAM, QUIS, FES, and DADS questionnaires were positive, with most respondents rating OPIS high and finding it easy to use. Qualitative suggestions from the parents included refinement of OPIS components, personalization of OPIS functionalities, and initiative-taking endorsements of OPIS by professionals. Further details of the study are reported in Swallow et al. (2014) and Swallow et al. (2016) (Swallow et al., 2016; Swallow et al., 2014).

Practice Implications When Pilot Testing the Family Intervention

Family nursing practice and research has a long history of eliciting and valuing the voices of families and communities. During pilot testing of family intervention development, these voices come alive concerning their perspectives about the feasibility and acceptability of interventions. In terms of working towards health equity, we are reminded, however, that these voices must be diverse and inclusive. In addition, we recognize that stakeholders need to include those controlling key policy and fiscal interests related to the issue in the co-production or co-design of the project (APA Council of Representatives, 2021; Ford-Gilboe et al., 2018; Loper et al., 2021; Shelton et al., 2021). Stakeholder involvement is crucial from early in intervention

development to garner this engagement and address their concerns with the proposed intervention.

Policy Implications When Pilot Testing the Family Intervention

Throughout these efforts, family researchers can determine how their project relates to local and national policy and practice/research priorities. For instance, the National Institutes of Health in the United States of America have acknowledged the importance of both family and self-management when working with populations who have chronic conditions and now stress the need for research with diverse and underserved populations (National Institute of Nursing Research, 2022).

Therefore, a family nursing researcher might want to acknowledge or incorporate family and self-management both in the content and plan for the intervention either in the background or theoretical framework, as well as assess the acceptability and feasibility of the same. While priorities established nationally or even globally could be most influential, they must make sense within the families' communities and cultures. In addition, the investigators can determine which scientific and professional standards could be used to establish criteria for acceptability and feasibility. See Table 1 for examples of such standards, which can be focal points of the evaluation and benchmarks for success.

Team Expertise When Pilot Testing the Family Intervention

The expertise needed during pilot testing of a family intervention requires family scientists. Ideally, family scientists within the study team include individuals who are not only experts in the family issue or process being studied but also the clinical context for the issue of interest (e.g., oncology). Of course, experts in intervention development, utilization, and analyses

of qualitative data and quantitative measures are valuable team members as decisions made during this phase will determine the future of the intervention.

Grants and other funding mechanisms for the pilot testing phase of intervention development may come from internal and external sources, and from public and foundation or philanthropic organizations. There may also be specific funds within these organizations for intervention development. If only a small amount of financial support can be obtained, that support may best be focused on salaries for the principal investigator and research coordinator as well as honoraria for key consultants or for participants, in recognition of their time and commitment to the study. Team members, however, may receive institutional support in the form of technology development or faculty/staff training, for example.

This second phase of intervention development requires patience, persistence, creativity, and open-mindedness by the research team. As a formative stage, it can prevent the loss of time and resources spent on subsequent testing. Refinement of the intervention, based on the evidence generated throughout this phase and with stakeholder input, creates a strong foundation for further testing in a larger sample. Family researchers who have thoughtfully reached this point are then ready to initiate Phase 3: efficacy testing of the intervention.

Phase 3: Efficacy Testing of the Intervention

Definition and Components During Efficacy Testing of the Intervention

The third phase of family intervention development involves examining the efficacy of the intervention (Sidani, 2015). Efficacy trials determine whether an intervention produces the expected result under ideal controlled conditions (Singal et al., 2014). The ideal conditions are designed to maximize the chance of showing an intervention effect by providing more control over extraneous factors that could influence intervention outcomes. Studies of efficacy aim for

high internal validity. Potential threats to internal validity are minimized by the research design and methods (Wagle, 2018). Strict inclusion and exclusion criteria are used to reduce the effect of confounding variables (Wagle, 2018) and in some studies are used to decrease risk for participants. Efficacy studies strictly follow the study protocol (Wagle, 2018). Mechanisms to reduce bias are incorporated in the design, such as random assignment to intervention groups, concealed treatment allocation, and blinding of participants, investigators, or outcome assessors to intervention assignment (Polit & Beck, 2017; Sidani, 2015). Randomized controlled trials are considered the gold standard to assess efficacy because there are more controls built into the design (Gartlehner et al., 2010). However, in some studies, random assignment of participants is not feasible and other designs are used, such as cluster randomized trials, cross-over designs, and quasi-experimental designs (Grimes & Schulz, 2002; Sidani, 2015).

While Phase 1, Modeling of Family Intervention Development, had multiple points of entry and contained multiple sources of evidence to be generated and collated and Phase 2, Pilot Testing, became more targeted in evaluating the feasibility and acceptability of the family intervention, Phase 3, Efficacy Testing, is more linear and structured and requires different decisions. In Phase 3, interventions are ready for “prime time” testing. It is based both on decisions made and evidence gathered in phases 1 and 2, yet it requires revisiting those decisions and related evidence to ensure the efficacy testing is scientifically rigorous and ethically sound. Family researchers revisit how family is defined and operationalized, how the family health issue of interest is conceptualized, and how the proposed family health intervention materializes as new evidence and literature become known. Issues such as cultural sensitivity, alignment of language and procedures, and selection of outcome variables also need to be revisited.

Issues Related to Processes During Efficacy Testing of the Intervention

When planning and conducting efficacy studies of family interventions, key decisions center on the definition of family, the conceptualization of family, the foundation for the intervention development, how and why family members are included in the intervention, characteristics of the intervention (structure, components, setting), choice of a control group, recruitment decisions, the choice of outcome measures, and the policy implications of the research. One study in the United States (Moriarty et al., 2016; Winter et al., 2016) evaluated the impact of an in-home, family-inclusive rehabilitation intervention—the Veterans’ In-home Program (VIP)—on military veterans with traumatic brain injury and their family members at the completion of the intervention (4 months after baseline) (ClinicalTrials.gov Identifier: NCT01831830) (Moriarty et al., 2016; Winter et al., 2016). Another study in Denmark, the Heart Failure Family Trial (HFF-trial) (ClinicalTrials.gov Identifier: NCT00120991), evaluated the effect of Family Nursing Therapeutic Conversations (FNTCs) on health-related quality of life and illness management (self-care, family resources, and depression) within 3, 6, and 12 months after completion of baseline data. Table 2 includes a description of key features in Phase 3 of family intervention development in the two studies.

(Insert Table 2 here)

Design Considerations During Efficacy Testing of the Intervention

There are key considerations when planning Phase 3 family intervention efficacy testing. Similar to Phase 1 modeling the intervention, it is first critical to be explicit about the “why” and “how” family members participate in the intervention, and yet, this is often missing from research reports. Regarding the “why”, inclusion of family members in the VIP was posited as leading to better veteran outcomes for two reasons: (1) insights from the family member could be used to identify strengths and problems in the veteran with TBI, and (2) family members could

reinforce intervention strategies for the veteran's application in daily life. Better outcomes for the family member were also expected because that person would receive education about TBI and how TBI was affecting the veteran and would receive support through symptom management strategies delivered in the intervention. The "how" for the family intervention, related to inclusion of family members for specific sessions, was straightforward: four sessions included both the veteran and family member, two sessions were held with just the family member, and two sessions were with only the veteran, with goals for each session being delineated.

Regarding the HHF trial, the "why" for engaging family members was that the intervention was assumed to be beneficial for both patients and their family members. The strategy of the FNTCs, with a focus on both the heart failure patient and the family members simultaneously, could be used to identify individual and shared problems, strengths and goals for illness management, and handling daily life. The "how" for the FNTCs was that the patient chose which family members should be present, but it has not been unusual for patients to exclude family members from the support offered (Lamura et al., 2008). Three sessions of FNTCs were carried out with or without family members because FNTCs can also be used to gain a family perspective when only the patient is present (Wright, 2005).

Second, it is critical to consider strategic and clear dissemination of the findings. The characteristics of the intervention (structure, setting, and components) should be explicitly described in research reports. Structure refers to the number, duration, and timing of sessions, the mode of delivery, and who is delivering it. Components are defined as "a set of interconnected activities that address one modifiable aspect of the health problem or that target a particular domain of clients' general condition" (Sidani, 2015, pg. 4) and may vary in levels of complexity from single to multiple components.

Third, questions about sampling, randomization, and type of control groups must be considered to ensure both scientific rigor and maintenance of family research ethics. For example, the United States (US) National Institutes of Health Office of Behavioral and Social Science Research developed best practice recommendations for the selection of control groups for health-related behavioral trials (Freedland et al., 2019). According to these recommendations, the choice of the control group is one that best aligns with the purpose of the study, while also considering the limitations of the group selected.

When planning for recruitment in family intervention research, efforts to learn more about the culture and language of the population of interest, along with having cultural humility (Yeager & Bauer-Wu, 2013), are imperative. Recruitment strategies in the VIP study were tailored to the veteran population to be consistent with the military culture. For example, in interactions with veterans and family members, we used the term “family member” and not “family caregiver,” as the latter could be viewed negatively by veterans within the context of the military culture. Recruitment materials, conversations, and the consent form noted the potential benefit of helping other veterans with TBI; for many eligible veterans, this was an important motivator that reflects the military value of unit cohesion. For the HFF study, recruitment of patients from three heart failure outpatient clinics was chosen because of the ability to partner with specialized heart failure nurses, patients, and families. Recruitment materials and the consent form were written in a non-professional language, and the potential benefits of improving aftercare for future heart failure patients and their family members was a motivator.

Funding needs again require strategic and thoughtful consideration by family researchers to identify funding opportunities that best align with the intervention development phase. Family researchers planning phase 3 efficacy studies typically require larger budgets to accommodate

RCT designs and attention control groups that are more than just usual care. In addition, family researchers must be strategic when planning funding for family intervention work. Since funding agencies have different priorities, family researchers may need to strategically incorporate their family research objectives within a particular clinical context to align with agency priorities. For example, the primary aim or objective may be defined as developing an intervention in a specific clinical context (e.g., asthma, dementia, diabetes, depending on the funders' stated priorities) with the family issues being defined as secondary aims/objectives.

Policy Implications During Efficacy Testing of the Intervention

The implications of a family intervention study for policy development at the local, organizational, national, and international levels should be given careful consideration – both for current policies and for envisioning policies for the future. The goal of the HFF-trial was to implement the FNTCs into nursing practice in Denmark. During the HFF- trial, the Danish government outlined guidelines for family involvement in the care of seriously ill patients to ensure that family members are involved as a resource and their needs are addressed (Sundhedsstyrelsen, 2016) . The HFF-trial supports these guidelines. Several hospitals and educational institutions in Denmark have now included family nursing in their curriculum, and two large hospitals have engaged the first professors in family nursing. The VIP study aligned with evolving VA priorities and subsequent policies planned over the next 10 years. When the study was conducted from 2011 to 2014, the VA priorities included increased attention to the needs of family members and more emphasis on the provision of family-centered care (Ford et al., 2014; Glynn, 2013). In May 2021, a report to Congress on an 11-year study by the Department of Defense (2021) concluded that there should be increased focus on TBI caregiver

and family needs, including their health and well-being, and on provision of enhanced support for veterans with TBI and their families.

As Moriarty and Østergaard moved through Phase 3 efficacy testing, they addressed the complexities of efficacy testing of family interventions using their specialized knowledge of family theory and practice and revisited how they each defined and conceptualized family. Conducting family intervention research at this phase is complicated because decisions made about sampling, randomization, control groups, and other controls can influence the study outcome and introduce ethical challenges. Ethical considerations must be deliberated thoughtfully as family investigators balance potential trade-offs.

Completion of efficacy testing allows the family researcher to understand the impact of the intervention on key outcomes within tightly controlled conditions. Through the completion of Phase 3, the family researcher will then have an understanding for subsequent phases, including effectiveness testing and translation. The family researcher's careful, collaborative, and creative work through these three stages allows for the family intervention to be as scientifically rigorous as possible, while maintaining grounding in what is meaningful to family and community partners. Some family researchers may elect to use a hybrid design that simultaneously tests effectiveness and implementation to learn what is needed for scalability in naturalistic settings. This includes consideration of factors at the local level that will affect reach, perceived benefits, implementation quality, and local interest in employing the intervention.

Discussion

This paper presents a call to action. Intervention development focused on promoting family health aligns with the heart of family nursing. Family researchers should feel empowered to consider what is possible and helpful for the families they serve and to act by developing

meaningful interventions. By articulating the phases of intervention development through a family lens, we break down the process into smaller, actionable steps that researchers can more easily implement. Like layering bricks to create a whole that is greater than the sum of its parts, foundational descriptive and inferential research in Phase 1 informs pilot testing in Phase 2 and efficacy testing in Phase 3. Yet results in phases 2 or 3 may prompt a return to review and modify evidence generated in Phase 1 or to consult further with stakeholders and collaborators during family intervention creation in order to enhance acceptability or refine key outcome(s). While recent reviews describe intervention development processes with individuals, few are known to focus on the particulars of family intervention development across the evidence trajectory (Shelton et al., 2019; J. Smith et al., 2020b). Thus, our work fills an important gap.

To be successful, family researchers need adequate support and resources to undertake intervention development with families. While Broome and Fairman (2018) call attention to the need to invest in junior faculty as they initiate their programs of research (Broome & Fairman, 2018), others have called for investment in mid-career and senior scientists (Bourgault et al., 2022; Loerzel et al., 2021). We add to this important conversation by using a family lens to highlight the resources that family researchers across various career development stages need during different phases of family intervention development. Being iterative in nature, the family intervention development process takes time to effectively evolve. The complexity and time commitment to execute family intervention research warrants attention by funding agencies and institutional promotion and tenure committees as funding and promotion decisions are being made (Bourgault et al., 2022).

Complexity, scalability, and partnerships warrant thoughtful consideration as family researchers move intervention work forward. These dynamics are vital especially as the contexts

within which family researchers try to affect change become more complex, such as in recent pandemic and natural disasters. The complexity and iterative nature of family intervention development requires expert guidance through the breadth of theoretical, methodological, ethical, and logistical challenges. Researchers new to family intervention development must think about team composition and recognize that its composition may necessarily change with new members joining to provide different family disciplinary lenses and expertise. For example, in advancing the science of family management, adding new members with varying skill sets to the team moved the work from family framework to family measure. Subsequently, new contexts and continual team reconfiguration moved the trajectory from family measurement to family partnership to family intervention (Deatrack, Knafel, Knafel, Bressler, Stevens, Ver Hoeve, et al., 2022).

Family intervention scalability and sustainability must be considered from the very beginning. Although testing interventions at full scale (phases 4 and 5) is beyond the scope of this paper, family researchers need to contemplate the extent to which the current interventions can be replicated with fidelity across different settings and contexts. Phases 1, 2, and 3 set the stage or guide successful scaling up of the intervention. For instance, family interventions that function well in a clinical trial but are too complex, costly, or resource-intensive to replicate in real world settings will have limited reach and impact on family health and well-being. Social context and determinants of health as new models of care also require investigation from a scalable perspective to enhance integration into interventions (Deatrack, Knafel, Knafel, Bressler, Stevens, ver Hoeve, et al., 2022; Kneipp et al., 2018). As another important example, policy building should not be the end point of the research agenda, but at the forefront. Integrating policy through every phase of the family research intervention process allows for the policy to

evolve simultaneously with the research plan. Thoughtful attention to policy helps in articulating the implications of family intervention research and guides family researchers' attention to feasibly implement realistic and meaningful interventions (Feetham, 2018).

Furthermore, policy as a major determinant of health can impede or facilitate family interventions to advance social justice and health equity and improve cultural sensitivity (Deatrck, 2017; Smith, 2019). These are critical values to embrace when working to build family strengths. Effective interventions consider the cultural context of the health challenge being addressed within various populations and groups. Foundational work at each phase of family intervention development, in conjunction with family advisors and research partners, can ensure alignment with relevant health care priorities. Given that the preferred end result of any intervention for the family is meaningful and sustainable change, and recognizing that policy assures sustainability, family researchers should pay initial attention to policy considerations when a research intervention plan is being formalized (Deatrck, 2017; Feetham, 2018).

Finally, although complex in nature, family intervention research is manageable and doable. The first three phases of intervention development, --modeling, pilot testing, and efficacy testing-- are seminal in moving family intervention research into the next phases. Although beyond the scope of this paper, it is important to note that family intervention development is not complete until the intervention is evaluated under real-world conditions (Phase 4) and then implemented, evaluated, and translated (Phase 5) (See Table 1) into formal guidelines to inform practice and policy and ensure sustainability (Sidani, 2015).

We challenge family researchers to embrace this 5-phase approach to family intervention development to methodically and pragmatically advance family nursing science. As mentioned previously, The Chicago Parent Program (CPP) was carefully and methodically developed in

response to a community need for evidence-based programs that are strength-based, non-stigmatizing, and replicable across community settings and diverse populations (Bettencourt et al., 2019; Breitenstein et al., 2012). The CPP initiative resulted from a family intervention that flourished as it moved through all five phases of intervention development from an idea to efficacy and comparative effectiveness trials to wide scale dissemination (Breitenstein et al., 2012; Deborah Gross et al., 2009, 2019). From a policy perspective, CPP has been recognized and can be reimbursed by Medicaid for eligible providers and families. Figure 3 depicts the complexity, iterative nature, and progression of intervention development with all phases interfacing and contributing to the CPP outcome.

(Insert Figure 3 here)

Conclusion

Family research continues to evolve with considerable growth in interventional research, yet hesitancy in developing intervention studies at any phase persists. Challenges continue around defining family, determining the family context, and identifying the unit of focus for the family research intervention, thereby emphasizing the importance of carefully constructed family intervention studies. Our manuscript aims to dispel fears about developing and implementing family intervention studies and to minimize associated challenges by presenting a methodical yet practical, step-by-step approach to developing family intervention research.

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