USE OF MIXED METHODS IN NIH-FUNDED GRANTS

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OBJECTIVES:

* Provide examples of how qualitative analyses were incorporated into two studies of a different nature funded by NIH.

* Demonstrate how the proposed qualitative aspects were described in key areas within the grant applications (Project Summary; Specific Aims, Research Strategy; Data Analyses)

* Note how these key sections were written to highlight and justify the use of qualitative approaches within the context of the overall study.

* Concluding comments

* Q & A

Example 1. Online Intervention to Improve Stroke Care From Spouses

1 R21 NR010189 [Funded by National Institute of Nursing Research]

EXPLORATORY/DEVELOPMENTAL GRANT

Senior/Key Personnel:	*0rganization:*	*Role Category:*
Gregory Smith Ed.D	Kent State University	PD/PI
Kyle Allen MD	Summa Health System	Consultant
John Boden	Elder Issues, LLC	Consultant
Harriet Coeling PhD	Kent State University	Co-PD/PI
Mary Dellmann-Jenkins PhD	Kent State University	Co-PD/PI
Nichole Egbert PhD	Kent State University	Co-PD/PI
Roger Morrel PhD	National Minority Health Month Foundation	Consultant
Patrick Palmieri PhD	Summa Health System	Consultant

Project Summary: Our interdisciplinary research team will develop, test, and refine an innovative webbased intervention that expands family caregiving intervention research in four key ways: [redacted]

In line with an R21 award, this exploratory/ developmental project involves three phases: Development; Usability Study; and Randomized Control Pilot Study (RCPS). The Development Phase involves standardizing the intervention and assessing its perceived acceptability with a Focus Group Study of CGs, SSs, and health providers. The Usability Study is a trial run with 7 CGs to identify and remedy potential implementation problems. The RCPS is to be conducted with 32 females (age > 50) caring for husbands who have experienced a first-time ischemic stroke. Dyads will be randomly assigned to either the intervention (n=16) or to a Minimal Support Condition (n=16). [redacted]

White participants will be sampled to explore potential ethnic/ cultural differences in acceptance, perceived value, and effectiveness of treatment protocol, goals, and outcomes.

This project will be conducted in three phases, which encompass the following **Specific Aims**:

Phase 1: Development

Aim 1. To develop provisionally the proposed intervention that now exists at the conceptual level as described in this application. The specific activities of this aim are to a) produce a treatment protocol; b) operationally define intervention components; c) formulate measures of acceptance and adherence to the treatment protocol; d) train the facilitator; and e) develop or adapt relevant outcome measures.

Aim 2. To assess the perceived importance and acceptability of the recruitment plan, treatment goals, procedures and outcomes among selected experts, CGs, and CRs. This includes the identification of potential ethnic or cultural differences in acceptance and perceived value of treatment protocol, goals, and outcomes.

Phase 2: Usability Study

Aim 3. To conduct a trial run of the intervention protocol for usability with a sample of 7 spousal CGs (e.g., clarity, usefulness, ease of navigation; identify and remedy technological problems). Information derived from Aims 2 and 3 will be used to prepare a revised treatment protocol for use in Phase 3.

Phase 3: Randomized Control Pilot Study (RCPS)

Aim 4. To conduct a RCPS with 32 African American (AA) and White CGs to compare the proposed intervention (N=16) to a MSC control group (N=16). Data will be gathered to a) estimate intervention parameters (e.g., effect size, attrition rates); b) perform preliminary power analyses; c) investigate the online information seeking and communication processes used by participants; and d) evaluate the feasibility of procedures for implementing and evaluating the intervention in a subsequent full-scale R01 outcome study.

RESEARCH DESIGN and METHODS

Phase 1: Development

Aim 1 is to develop provisionally the proposed intervention that now exists at the conceptual level as described in this application. The specific activities of this aim will be to a) produce a treatment protocol; b) define intervention components operationally; c) formulate measures of acceptance and adherence to the treatment protocol; d) train the NM; and e) develop or adapt relevant outcome measures. This aim is consistent with the intent of the R21 mechanism to encourage exploratory/developmental research projects by providing support for the early and conceptual stages of development.

Procedure. The first step in this preliminary developmental stage is to hire the NM who will work with the PIs and project consultants in such tasks as producing the Video Education modules, identifying usable and credible web sites for the Web-based Information component, refining intervention procedures, and assembling the proposed outcome measures. During Phase 1, the entire team (including the NM) will also modify the existing web-based LifeLedger system (described in Section C) for its specific use in the proposed intervention.

AIMS ARE DESCRIBED WITHIN THE OVERALL CONTEXT OF THE ENTIRE PROJECT

Procedure. Six 2-hour focus groups will be conducted as follows: 2 with 8-10 spousal CGs; 2 with 8-10 SSs; and 2 with 8-10 health providers. CGs and SSs meeting the eligibility criteria of the RCPS (see below) will be recruited from local stroke support groups using purposive sampling to ensure equal representation of Whites and AAs. Focus groups with CGs and SSs from the same dyad will be run concurrently so CGs will not have to make alternate care arrangements. Health providers from such disciplines as psychology, medicine, nursing, social work, and rehabilitation therapies will be recruited from agencies serving stroke families. Participants will be paid $35 each. Our ongoing relationship with these agencies (see attached letters) instills confidence in our ability to recruit participants. All groups will occur in community settings. One PI will serve as group moderator and another as observer (assisting with logistics and taking detailed, written notes including mood, silent agreement/disagreement, and contradictory statements). To avoid amplification of the prevalent group viewpoint and suppression of divergent views, the moderator will look but not push, for consensus (178). Sessions will be taped with consent, and field notes will be discussed at a debriefing right after the group session. Taped data will be transcribed and checked for accuracy. Questions piloted before use, will progress from general to specific but allow flexibility for clarification and probing, thus encouraging diversity of opinions (179). The content of the focus groups will encompass perceived importance and acceptability of the proposed treatment goals, procedures, and outcome measures. All participants will provide informed consent and be debriefed.

DETAILS ARE SPECIFIC AND CONCRETE DOABILITY AWARENESS OF POTENTIAL PROBLEMS

REPRODUCABILITY

Aim 2 is to assess perceived importance and acceptability of recruitment methods, treatment goals, procedures, and outcomes developed under Aim 1 among selected health providers, spousal CGs, and SSs. This includes identifying ethnic or cultural differences in acceptance and perceived value of treatment protocol, goals, and outcomes. Aim 2 is critical given the claim of prominent caregiving researchers that interventions are most likely to yield significant outcomes if based on the beliefs, values, and needs of CGs, CRs, and health providers (171). Yet, Korner-Bitensky et al. (60) note that no studies in their review elicited the needs or desires of stroke families in planning interventions. Eliciting the views of families and health providers of AA descent is particularly important because stroke is highly prevalent among AAs (11); cultural diversity speaks to different caregiving needs and experiences (172); and recruitment and retention of AAs is maximized by identifying barriers that hamper successful efforts and by tailoring methods for specific ethnic groups (173, 174). Yet, since past research has virtually ignored AA stroke families (175), no prior studies support or negate the expectation of significant differences. Focus groups are an excellent method for achieving these goals (171). They permit in-depth exploration of sensitive topics; ensure that respondents' views are not precluded by the researcher; yield information that is essential in designing interventions for hard-to-reach populations; and are productive with those of historically limited power and influence, such as people of color (176,177).

AIM is CLEARLY STATED IMPORTANCE OF THE AIM IS DESCRIBED/JUSTIFIED METHOD IS JUSTIFIED

Data analysis will be ongoing, occurring during the focus group and debriefing sessions, as well as subsequent sessions involving both-within and among-group analyses. Questions will be refined as needed prior to each subsequent focus group session (179). Qualitative content analysis, as described by Patton (180, 181) and Berg (182), will be used to analyze the data. Qualitative content analysis provides an opportunity to learn the participants' perspectives on their social worlds. It considers both the literal words spoken and the manner in which these words have been offered, grounding the findings in the data. Analytical steps will include reading field notes and focus group transcripts and writing organizing comments; identifying topics; coding (independently) to label, classify, and categorize the data in each topic; and then jointly (all Co-PIs) comparing and discussing the categories. Relatively small sample sizes are acceptable in focus group research where the emphasis is on achieving a thorough understanding of the particular segments of the population selected for study rather than on generalizing the results across populations (183).

ANALYTIC PROCEDURE DESCRIBED CONCRETELY WITH APPROPRIATE CITATIONS

ADVANTAGES OF THE ANALYTIC APPROACH ARE DESCRIBED

SAMPLE SIZE JUSTIFICATION IS GIVEN

Example 2. Social Intelligence training for custodial grandmothers and their adolescent grandchildren

5R01AG054571 [Funded by National Institute on Aging]

R01

Senior/Key Personnel:	*0rganization:*	*Role Category:*
Gregory Smith Ed.D	Kent State University	PI
Frank Infurna. PhD	Arizona State University	PI
Megan Dolbin-MacNab, PhD	Virginia Tech	Co-I
Max Crowley , PhD	Penn State University	Co-I
Eva Zautra	Social Intelligence Institute	Co-I
Britney Webster, PhD	Kent State University	PD
Carol Musil, PhD	Case Western Reserve Univ	Consultant
Gregory Hancock, PhD	University of Maryland	Consultant
Nancy Eisenberg, PhD	Arizona State University	Consultant

SUMMARY:

We examine the efficacy of an online Social Intelligence Intervention (SII) at improving the health and wellbeing of custodial grandmothers (CGMs) and their adolescent custodial grandchildren (ACG) through mutual enhancement of their social competencies

…… we will conduct an online randomized clinical trial with 340 nationally-recruited CGM-ACG (ages 12-18) dyads assigned to either the SII or an attention control condition.

….. mixed-methods allow rigorous examination of four specific aims:

(1) To investigate if the SII enhances social competencies that, in turn, produce long-term changes in relationship quality, well-being, and physical health; this includes determining if increased social competence in one dyad member leads to partner effects in the other;

(2) To examine if cumulative risk, gender, and age moderate SII efficacy;

(3) To study qualitatively how CGM-ACG dyads view the SII as having changed their social competencies and yielded positive outcomes; and

(4) To assess the financial benefits of the SII to participants and their communities.

Specific Aims

Aim 1. To examine the short and long term effectiveness of the SII on CGM-ACG dyads.

Aim 2. To probe for individual differences in cumulative risk, ACG gender, and ACG age that may identify who is most responsive to the SII.

Aim 3. To probe qualitatively on how CGMs and ACG view the SII as having changed their social competencies and relations. Examination of the social awareness writings that dyads provide during each session will allow charting changes in social cognitions that transpire during the SII. To further capture how participants view changes in their mindsets and their social relations as a result of the SIII, separate qualitative interviews are planned for a randomly selected 60 CGM-ACG dyads who received the intervention. These qualitative data will also inform the refinement of future SI interventions with this target population.

Aim 4. To assess the economic impact of implementing SII with CGM-ACG dyads.

INNOVATION

Our study will be the first methodologically rigorous test of a psychosocial intervention with ACG as a specific target population.

This will be the first test of an intervention delivered simultaneously to CGM-ACG dyads.

This will be the first experimental test of the effects of parenting on the development of adolescents' social competence with any population.

This will be the first RCT intervention study with CGFs to examine a full range of short and long-term outcomes using mixed methods. Prior RCT studies with this target population have only examined mental health, such as depression and anxiety. Our comprehensive approach will also examine the impact of SII on physical functioning as well as much wider range of behavioral health outcomes for both CGMs and ACG.

This will be the first attempt to estimate the economic impacts of the SII through a rigorous cost vs financial benefit analysis.

This will be the first large scale use of online intervention with custodial grandfamilies.

APPROACH

Aim 3. ***To probe qualitatively how CGM and ACG view the SII as having changed their social competencies and relations.***

In Aims 1 and 2, we take a strict quantitative approach to examining the influence of the SII on social competencies and relationships for CGM and ACG and key indicators of well-being. For Aim 3, we add a mixed methods approach by incorporating qualitative interviews into the overall study design. This will increase our understanding of the SII and its effectiveness by clarifying how participants experience the SII and its underlying processes in ways that quantitative measures do not allow[159,160]. These interviews will also allow us to explore the complexities of treatment-related change in participants' social relations[159,160]. The narratives obtained from CGMs and ACG will add nuance and depth to our understanding of the impact of the SII and provide valuable insights regarding how the SII can be optimally delivered to CGFs in the future. The findings from the qualitative analysis will also be examined in the context of the quantitative findings as a potential means of corroborating findings, explaining unexpected findings, and identifying additional avenues for investigation[159].The following research questions will be addressed:
Research Question 1. *How does the SII influence social competence and relations in CGFs?*
Research Question 2 *How can the SII be delivered most effectively to CGFs in the future?*

Aim 3 Methods: Participants will be 60 randomly selected CGM-ACG dyads (120 total participants) that have completed the SII. The proposed sample size, which represents slightly more than a third of the total number of SII participants, will readily allow for data saturation[161]

Recruitment. During the post-test data collection session, the quantitative interviewer will provide a general overview of the qualitative interviews to a random selection of CGM-ACG dyads. Randomizing those invited to participate in the qualitative interviews will assure representation of key socio-demographic and background variables. Recruitment will occur over the course of the larger project, so that participants will be proportionately distributed across the various waves of recruitment and data collection within the larger project.

Procedures. Co-I Dolbin-MacNab will first contact the CGM by phone to review study procedures, confirm theCGM and ACG's interest in participating, and schedule the interview. Interviews will be conducted by phoneand digitally recorded between post-test and the 3-month follow-up interview. This timeframe allows for changein social interactions to develop and be observed by participants. The CGM and ACG will complete individual interviews, with their order being randomized. Individual interviews have been deemed most advantageous based on Dolbin-MacNab's prior studies with CGM-ACG dyads[160,162]. The interviews will be scheduled within the same week and conducted by the same interviewer to ensure consistency across the CGM and ACG interviews. Each interview will last about one hour, with participants receiving a $30 gift card for their participation. Dolbin-MacNab will conduct the initial interviews, in order to examine and refine the interview protocol. Two advanced family therapy PhD students will be trained to conduct remaining interviews. Data collection will be supervised by Dolbin-MacNab to ensure adherence to the interview protocol, monitor interview quality, and ensure consistency across the 120 interviews. The CGM and ACG interviews will be guided by a semi-structured interview protocol, which broadly addresses two topics – influences of the SII on social functioning and social relations; and the experience of participating in the SII. Questions focus on expectations of and reaction to the SII course, as well as recommendations for future implementation of the SII with other families. Questions related to the influence of the SII on social functioning and social relations will explore cognitive, affective, and behavioral changes participants have observed within themselves, and how those changes influenced various close relationships (e.g., the CGM-ACG relationship, other family members, peers, and friends). Special attention will be given to examining changes in the CGM-ACG relationship, and probing the systemic implications of the skills learned in the SII (See Appendix 6 for interview protocol).

DATA ANALYSES

Aim 3. To address Aim 3 questions, we will use the constant comparative method175 with both the dyad and individual as units of analysis176. Incorporating a dyadic perspective into the analysis will allow forexamination of the contrasts and overlaps in participant experiences and a more in-depth and systemic understanding of the influence of the SII on participants' social relationships, particularly with one another.

Analytic rigor will be maximized by the plan outlined here. Data analysis will begin with multiple readings of the individual interview transcripts by a team of at least two coders, including Co-I Dolbin-MacNab. After familiarizing themselves with the data, coders will inductively code the transcripts for main ideas and concepts, in relation to key elements of the SII (openness to others, social self-confidence, sensitivity to others) which serve as sensitizing concepts161. Next, the coding team will group codes together into related themes. In line with the constant comparative method175, this entails going back and forth between the data and the codes to refine themes, describe their conditions, and address overarching research questions. During this process, the team will meet regularly to build consensus and resolve discrepancies via review and discussion of the data. The team will follow a similar process when examining transcripts at the dyadic level176. The analysis will conclude with examining variation within identified themes related to early adversity (e.g., low vs. high) and a range of other socio-demographic factors. Given the mixed methods design of the larger study, findings from the qualitative analysis will be examined in light of the findings of the quantitative aspects of the study. This provides an avenue for corroborating findings, exploring unexpected findings, explaining study outcomes, and identifying areas for future investigation159,160. Trustworthiness of the qualitative analyses will be ensured via a number of strategies: 1) the use of multiple coders and peer debriefing will ensure that multiple perspectives are taken and lends credibility to the analysis177,178. 2) at least one coder will be unfamiliar with the SII, to manage researcher subjectivity, 3) triangulation of the interview data with other data collected as part of the larger project will also enhance rigor177. 4) use of an audit trail and field notes will ensure dependability and confirmability178 , 5) the coding team will continue coding and analyzing data until saturation161.

CONCLUDING REMARKS

* It takes a village. Relevant expertise is needed when any analytic approach is being proposed. Not only publications, but also evidence of training.

* Put qualitative approaches on equal footing in the application (e.g., within a Specific Aim)

* Peer reviewers tend to regard mixed methods and qualitative approaches as strengths WHEN...

- They are meaningful and appropriate within the broader scope of the overall research project.

- They are planned/described in a rigorous and reproducible manner.