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Research ethics in behavioral interventions among special populations: Lessons from the Peer Approaches to Lupus Self-Management study

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Abstract

Background—Research involving a homogenous cohort of participants belonging to a special population must make considerations to recruit and protect the subjects. This study analyses the ethical considerations made in the Peer approaches to Lupus Self-Management project which pilot tested a peer mentoring intervention for African American women with systemic lupus erythematosus.

Methods—Considerations made at the outset of the project are described and their justifications/reasoning are given. Through analysis of feedback from a post intervention focus group and mentors' logs, implications on program outcomes and participant satisfaction are discussed.

Results—Feedback indicated the importance of recruiting and training capable mentors, consistent contact from study staff to avert adverse events and avert fear or mistrust, and careful consideration that must go into the pairing of mentors and mentees. Participant feedback also indicated that sensitive topics must be addressed carefully to prevent distress and dissatisfaction.

Conclusions—Applying the lessons learned from this work as well as the considerations that proved successful may improve the contextualization and ethical conduct of behavioral interventions in special populations resulting in improved tailoring and acceptability towards historically underserved individuals.

Keywords

Research ethics; African American; women; systemic lupus erythematosus; peer mentoring

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INTRODUCTION

History of Research Ethics in Vulnerable Populations

Ethics in biomedical research is a topic of consistent discussion amongst researchers seeking to conduct experiments which move science and medicine forward but also protect those participating. These conversations emerged after the seminal research ethics guidelines, the Nuremberg Code and The Declaration of Helsinki. Both were originally developed in the middles of the 20th century and laid the foundation for the development and refinement of ethics in research [1, 2]. However, these early general guidelines have little specific insight about research in special or vulnerable populations. Special populations can include children, the elderly, minorities, the cognitively impaired, and other vulnerable populations such as prisoners and refugees but broadly, is a term used in reference to any group of people whom are at increased risk for being exploited in research [3]. Yet there has been some debate over the need for distinct ethical considerations when working with special populations. Levine and colleagues argue that many vulnerable populations should not be considered as such and that special safeguards or techniques are not required to recruit, retain, and fairly treat them in research initiatives [4]. However Dr. Silvers breaks down this argument and separates vulnerable populations into two categories, those that are intrinsically vulnerable and those that are contingently vulnerable. She draws the distinction that the former are vulnerable due to factors inherent to individuals in that population (i.e. children or the cognitively impaired not being able to provide informed consent) and the latter are vulnerable as a result of contextual variables such as lack of education or racial minorities experiencing institutionalized racism [5]. In either case though, the population is considered vulnerable and research seeking to involve those populations must make considerations to ensure fair treatment in lieu of that context.

Special Considerations when involving Minorities in Research

Further justification for special considerations when involving minorities in research stems from the historical mistreatment minorities have experienced in the United States which can be traced back to before the Civil War. At that time, African American bodies in the South would often be exhumed soon after burial so that their bodies could be used for dissection and the training of new physicians [6]. Also prior to the Civil War, two notably atrocious experiments were carried out on African American slaves. One of which involved a slave owner inducing heatstroke in one of his slaves and testing herbal treatments to improve the slave's condition [7]. The second experiment tested surgical procedures to remediate vaginal fistulae, these procedures were repeatedly carried out on unwilling and un-anaesthetized slave women [8]. Finally the well-known Tuskegee Syphilis Study resulted in the deaths of several African American participants due to their disease purposefully being left untreated, despite the existence of available treatment options [9]. Backlash over the methods used in the study led to its termination, and as a result the Belmont Report was devised.

The Belmont Report outlines the major principles of respect for persons, beneficence, and justice and how to apply them in research [10]. In order, these are briefly defined as treating people as autonomous individuals, ensuring a likely beneficial outcome while conversely protecting from harm, and getting what is deserved/equal treatment of persons [10].

The history of mistreatment has had a lasting effect on African Americans and their trust of the medical system. A 2012 review found that this mistrust manifests in distinct barriers to minority participation in research such as doubt of physician knowledge, fear over participation (i.e. potential adverse outcomes, whether intentional or unintentional), and the burden associated with trial participation [11]. The review goes on to include facilitators to participation such as physician enthusiasm, strong communication between clinicians and participants, a strong physician-participant relationship, perceived benefit, and feelings of altruism [11]. To expand on this position, Armstrong and colleagues make several recommendations for the inclusion of African Americans in clinical research. They determine that due to attitudes of mistrust, the benefits and harms should be clearly expressed, monetary incentives should be kept within reason to avoid the appearance of patronizing, and that a diverse research team with representation of ethnic minorities may help to alleviate some of these concerns [12].

Given such residual effects of past injustices and the need to ensure ethics in research involving minority populations, this research examines the ethical considerations undertaken in a peer mentoring intervention to improve the quality of life and disease self-management of a cohort comprised entirely of chronically ill African American women, and how the resulting intervention was received by participants.

The Peer Approaches to Lupus Self-management (PALS) Project

The PALS project was a feasibility pilot of a peer mentoring intervention for African American women with systemic lupus erythematosus (SLE). SLE is a chronic autoimmune disorder characterized by periodic flare-ups of severe inflammation affecting any organ system with significantly higher morbidity and mortality in female African American populations [13-16]. The PALS program aimed to address this disparity in a culturally tailored manner by combining aspects of previously validated disease self-management programs with a culturally sensitive peer mentoring approach and incorporation of contextually relevant content [17-21]. The intervention took place over twelve weeks, during which mentors and mentees spoke weekly by phone. The twelve phone sessions were designed to take approximately one hour and included discussion of structured educational materials, problem solving exercises to apply learned skills/information, and general peer-to-peer discussion and support. While the study was a feasibility pilot primarily designed to test the intervention delivery method and acceptability, participants experienced trends towards reduced disease activity, improved quality of life, lower pain symptomology, and greater levels of perceived social support following the intervention; however these results did not reach statistically significant levels. A detailed description of the program has been reported elsewhere [22].

Considerations Specific to Population

In research involving an entirely African American female population such as the PALS project, there are specific ethical considerations and protections that must be made in order to recruit and protect this homogeneous cohort. The American College of Clinical Pharmacology outlines the importance of including women in the design of targeted interventions, so that it meets the needs of the female population [3]. In addition to this, the

peer mentoring approach employed by the PALS program was directly responsive to research indicating that African American women desire medical care and health education from individuals with whom they share cultural similarities [23]. In addition to the historical mistreatment of African Americans in biomedical research, female African American SLE patients face specific hardships and burdens that further the need for targeted ethical and methodological considerations in research projects. African American women experience SLE at notably greater incidence and severity (i.e. disease activity) as compared to men and other minorities [15]. Furthermore, mood disorders, especially depression and anxiety, are commonplace among SLE patients and are correlated with increased disease activity [16, 24, 25]. Thus it would stand to reason that while the entire SLE population experiences depression and anxiety at increased rates, the effect may be exaggerated in African American women. Finally, one study found that a cohort of women with SLE, most of whom were African American, reported facing social isolation, barriers to receiving care, and difficulty navigating the healthcare system [26]. For these reasons African American women with SLE face a unique and particularly challenging disease trajectory and thus, developing and implementing culturally and ethically sensitive interventions to address these disparities is the obligation of researchers and care providers.

METHODS

Ethical Considerations Made

In order to protect the participants of the study, many considerations were made prior to the commencement of the research (see Table 1). These concerns can be sub-divided into 4 categories: justification of the study population, institutional protections, protections for the mentors, and protections for the mentees.

Justification/tailoring toward the study population—As discussed, African American women are disproportionately affected by SLE in both occurrence and severity [13-16]. Furthermore, the PALS program is a peer mentoring behavioral intervention, an intervention approach previously shown to provide specific benefit to minority populations [27-32]. Lastly, the PALS intervention focuses on improving coping efficacy through open communication between a mentor and mentee. Due to the fact that men are more likely to internalize emotions [33, 34], this intervention approach is not tailored to their needs and they may not receive significant benefit from the program. Due to disparate impact of the disease, potential for specific benefit to African American women, and potential for differential impact between men and women, limiting the population to African American women is justified in this context.

Protection of peer mentors—As part of the mentor screening interview individual level factors from validated scales were used in order to assess competency and ability to act as a mentor and model [35-46]. This served the ethical purpose of ensuring the potential benefit of the PALS program would be delivered by individuals deemed capable of assuming the intensive role of a peer mentor. Furthermore to this end, as part of the inclusion criteria for mentors at least some college education was required due to their role in modeling, counseling, and delivering education. The next protection for mentors was achieved through

individualized weekly contact made by the PI. The ethical motivations for which include screening for adverse events and ensuring that ongoing study interactions were not overly burdensome, emotionally or in time commitment, resulting in discomfort or dissatisfaction. Finally, training the mentors prior to the initiation of the intervention acted as a mechanism to protect both mentors and mentees. Training included exercises to advance communication skills, lessons on not providing clinical/medical advice, how to respond to sensitive questions, what (adverse) events to report to study staff, and instilling the mantra of “when in doubt, contact study staff”. Due to the nature of their role as lay mentors, adequately training them to not breach ethical principles (i.e. giving medical advice and reporting adverse events) as well as how to properly deliver intervention content was paramount to the just conduct and overall success of the project.

Protection of mentored participants (mentees)—Weekly contact was made to the mentees by a study coordinator according to the same reasoning as the contact made to the mentors by the PI. After enrollment and completion of baseline assessments, study staff matched mentees with their mentors based on shared criteria. While this removed some autonomy from the participants, it served to increase compatibility among groups and protect against poor rapport among dissimilar individuals. Potential matching areas included disease symptoms, parenting, work-related concerns, similarity of life stage (including age), [32] demographics (including area of residence), similarity of personality characteristics, and peer mentor availability [47]. Careful matching of like individuals as mentor/mentee pairs served to ensure ease of communication, ability to form a relationship, and to reduce the risk of adverse outcomes by mitigating potential conflicts within the pairs.

Institutional protections—Phones were provided to participants to be used for calling their mentee/mentor according to study protocols. This provision served two ethical purposes; 1) to eliminate a barrier to program entry and 2) to eliminate the need for participants to exchange personal information. Additionally study staff was trained in relevant clinical research areas (CITI Human Subject and Core Clinical Research Training) so that individuals in contact with the participants and their sensitive information were aware of data privacy protocols and also to assist with adverse events reporting.

While this is not an exhaustive list of considerations to be made in research with a population of chronically ill African American women, it provides a starting point for the analysis of the considerations made for the PALS pilot project and where those considerations succeeded and where they fell short, indicating areas for improvement in a PALS full scale trial or consideration in similar behavioral interventions.

Evaluation

A two-tiered approach for capturing qualitative data was used. This included a focus group that included both mentees and mentors at the end of the study and data from weekly logs completed by mentors and discussed with the PI during weekly check-in interviews. Thematic areas were instructively developed at the outset of the intervention. Specifically, the intervention included topical areas that allowed for identification of thematic areas post-intervention.

Focus Group—Post-intervention, a celebration and semi-structured focus group with open ended questions was conducted debrief participants and gather feedback about the program. The questions asked can be found in Table 2. The focus group was voice recorded, transcribed, and analyzed for theme areas relating to the satisfaction or dis-satisfaction with the program and how those themes relate to the protections instituted at the outset of the study.

Weekly Logs—Weekly logs from mentors were collected and assessed at the conclusion of the study. These logs reported on the number of calls made in each intervention session week, how long the pairs spoke for, and any additional forms of contact the pairs may have used. The data from the logs provided insight into the pair's comfortability with interactions and topics based on the method of contact and length of discussion.

Qualitative data analysis—Sutanto et. al (2013) identified a mixture of grounded theory and phenomenological approaches as conceptual guides as common methods employed by qualitative studies seeking to highlight psychosocial experiences of those with SLE [48]. Similarly we implemented a combination of grounded theory and phenomenology allowing the voices of participants to be centered. Grounded theory seeks to uncover the social conditions in everyday life, while simultaneously giving voice to those under specific study [49]. Phenomenological conceptual frameworks center on understanding individualized experiences of the social world [50, 51].

RESULTS

For the PALS project ten mentors were enrolled and trained, two of which function as alternates and one was lost to follow-up. Twenty-three mentees were enrolled in the study, of which three were lost to follow due to reasons unrelated to the study. This resulted in seven quads (one mentor assigned to three mentees) and one triad (one mentor assigned to two mentees). All participants were selected from the Medical University of South Carolina SLE patient database, were African American women, and met the American College of Rheumatology criteria for SLE diagnosis. Overall, women in both groups were mostly unmarried (85.3%), well educated (64.7% graduated college), and over the age of 35 (76.5%) Results from patient feedback pertaining to the ethical conduct of the study can be separated into two categories, areas of success and areas in need of improvement/refinement. First over the course of the study, there were no major adverse events that resulted in any participants requiring medical attention, referral, or removal from the study. The primary method for detecting adverse events in this study was through weekly contact from study staff to all participants. Overall, participants reported satisfaction with interactions with study staff with one saying:

“I think the communication was good, between my mentor and [the study coordinator]. I knew [the study coordinator] from before so we kinda hit it off...it's been good. We've had more good conversations, we've learned a lot about each other”

Furthermore, all of the mentor/mentee pairs remained the same throughout the course of the study; none required adjustment to accommodate issues or disagreements within the pairs.

Finally, several mentors mentioned during the focus group that they were trained “not the cross the line” in reference to providing clinical and/or medical advice. These results indicate areas of specific success as a result of the ethical considerations made at the outset of the study and underpin the overall satisfaction of participants with the PALS program.

However, analysis and data collection was aimed towards detecting and gathering feedback on problem areas of the program primarily through the questions asked. For example, during the post study focus group the PI asked the question: “Is there anything you would change about the calls, scheduling, number...?” This question yielded rich contextual feedback about the issues many of the pairs experienced with the module on sexuality and sexual health. Selected responses related to this module (module number 11 of 12) are as follows:

“With number 11, when we had to talk about sexual activity (laughter). My mentees, they were willing to talk about it, but that one was like pulling little tooth and nail here and there, like how much can we talk about this particular subject.”

“I had a problem with the length on the sexual topic with my... with one person. Because she was an elderly lady, I don’t know it I just felt uncomfortable talking about it with her or she felt uncomfortable. It didn’t flow well”

Ostensibly both of these statements show that the sexual health module was a difficult topic to discuss for some groups and resulted in undue discomfort. Add to this the fact that the sexual health module was reported to be the most disliked, the most chosen to be removed from the study, and that two pairs reported difficulties in their weekly logs over this section (one group did not discuss at all, the other discussed over text and email) show that this module, its content, and delivery need to be revised for future work. At present this module represents an ethical concern for the PALS program as discussion of its content resulted in distress and dissatisfaction among participants which hampers the intended beneficence of the program. The second statement listed above also provides feedback on another area for improvement in the protocol. While great care and time was invested into the pairing process, some participants yet experienced troubles with their mentors or mentees with whom they were less similar. While these differences were not great enough to manifest in a significant event requiring intervention from study staff, sub-par pairing likely affected intervention effectiveness and similarly conveyed stress and anxiety to some participants.

The next area for improvement is the compensation provided to study participants. While the benefits of the large amount of information to be gathered was explained during the enrollment process, several participants expressed dissatisfaction with the length of the surveys administered during clinic visits and the compensation they were given in return. Below is a conversation taking place between the principle investigator and study participants at the post-study focus group:

PI: “Is there anything any of you would have changed about the data collection, number of times we asked you to come in, lengths of the survey, or number of questions we asked?”

Participant: “Yes, the length of the survey, MAN that was... it was just out of this world! If you could shorten it a little bit.”

PI: I know the survey is long but that's why we compensate you. And maybe that's a comment, that we're not compensating you enough for the length of it.

Several participants: "Yes yes!"

Mentees were compensated \$50 per clinic visit but this compensation was also meant to serve as payment of time and travel expenses so the frustration these mentees experienced is warranted and highlights an area for improvement. At the outset of the study, the compensation provided to participants was not considered to be of ethical relevance however this feedback would suggest that providing greater compensation may have ethical implications in improving participant satisfaction and ensuring that participants do not feel taken advantage of.

As previously noted, several mentors mentioned that they were trained on what information they could safely provide and what would be considered "crossing the line". Not all mentors shared the same line though. One mentee gave this statement below at the focus group:

"...if I was having an issue... or even as far as her taking her own time through the weekday to look up things for me"

This statement is an indication that the mentor was providing medical advice to her mentee. Despite implicit training not to do so, it would appear that the bonds formed between mentors and their mentees led some of them to cross the line and provide clinical advice. This is substantiated by the following monologue from one of the study's mentors:

"So I say it again what do you do...when you become their only resource, that's a scary place because I'm just meeting [these] people for the first time. I'm getting to know them so when we were trained, we were trained to set limitations so it's like when I'll bring it to you and set it on your back and sit with you for a little while, that was crossing lines a little bit because I was going there and doing stuff, but you know we're lucky because we have the knowledge to understand it and have the support system to understand it. Everybody doesn't have that and one of my little friends didn't have that."

This account synthesizes two ethical areas of concern; lay persons providing clinical advice and the stress inherited by the mentors. While additional training on what can and can not be done by the mentors is a feasible remedy, the stress inherited by the mentors is harder to mitigate. As mentors, these women step into a role in which they must act as a model to and in some cases help prop up the well-being of a person they have just met. While this may be seen as a potential weakness of the PALS protocol, it is more likely to be a positive influence on these women because once they leave the study, they not only have the skill set to help themselves but have the experience to help others help themselves which is a key to the success of a self-management program.

DISCUSSION

Most of the ethical considerations made for this intervention went unnoticed, which is likely a testament to their success and the lack of adverse events is a positive indicator that appropriate steps were taken to protect the subjects. Despite overall appropriateness of the

ethical considerations made, improvement and refinement is warranted in several areas. While some participants mentioned knowing when not to cross the line with providing medical advice others indicated that they may have done so. This represents a notable ethical concern due to the fact that medical advice should only be provided by a trained and certified healthcare provider. Furthermore, some mentors expressed a degree of un-comfortability with interactions that centered on providing tangible assistance to the mentees. This can be stressful situation to be in as a mentor and while handling these situations was an element of the pre-study training, this and the issue of providing medical advice shows that it may be beneficial to provide additional training and/or booster sessions to the mentors prior to and during the course of the study. Additional mentor training could mitigate these ethical missteps and prevent the transfer of additional stress to the mentors. Another option mentioned by a mentor in the focus group could be a mentor meeting at the mid-point of the study. During the course of the study, mentors were isolated from one another, but giving them an opportunity to come together and discuss the difficulties they are experiencing with each other as well as with study staff would serve to improve problem solving skills and coping abilities. This would help to address the current ethical concern that study mentors may be subject to undue stress.

While the PALS intervention was designed as a culturally tailored intervention with one aspect of that tailoring being the inclusion of a sexual health/body image module, the participants expressed overall dissatisfaction with this topic and consistently cited it as the module they found least useful or would desire to be removed. While the discomfort this module caused raises an ethical concerns over the stress its inclusion caused, it may be difficult to call for its removal entirely due to the benefit it conveys to self-worth. Thus it is vital to contemplate ways to refine the module or the way in which it was covered in the study. One such method of improvement would be to reduce the age disparity in some mentor/mentee pairs, a problem directly cited for one pair. Ensuring this with the small sample size at hand in the pilot was difficult, and would be more feasible with a larger sample size. Additionally the length of the section may need to be reduced in order to lessen the focus on this content or similarly it could be paired with another topic.

This research has yielded many salient points about the ethical conduct of behavioral research in minority population, but it is not without limitations. First, the sample size for the PALS pilot project was relatively small. Similarly, due to being a pilot study, the intervention protocol did not use randomization or a control group meaning that results may be due to a variable other than the intervention itself. This does not affect the feedback about the intervention though, as any feedback given at the conclusion of the study will be reflective of the study procedures those participants experienced. One technical error occurred on the part of the study staff that degraded or omitted a small portion of the focus group feedback data. The session was recorded using a handheld mobile device and some parts of the recording are inaudible. Thus, small portions of the transcript were left blank. While there may have been valuable contextual information in those missing portions, they make up a small percentage (<5%) of the transcript so the most salient points likely remained intact. Finally, there is a potential for bias among the focus group participants. Attendance was low for the focus group (>50% of the study cohort) and those who did

attend may have done so because they had specific grievances about the program or conversely may have been more inclined to attend due to their satisfaction.

This work confirms that of others and can act as a guide for future work due to the lessons learned in conducting a complex behavioral intervention in a minority population. As Schmotzer suggests in his 2012 review, strong communication between clinicians and participants, clearly expressing perceived benefit, and displaying feelings of altruism were key factors to the success of the PALS intervention [11]. Similarly, Armstrong and colleagues' suggestion for minority participation in clinical research, that study staff should be diverse added to the success of the program. Due to the diverse study staff taking an interest in the well-being of the participants, a strong relationship was fostered, upon which trust can be established [12]. Armstrong also suggests that monetary incentives should be kept within reason to avoid the appearance of patronizing participants [12]. While this is a valid concern with tangible consequences, our work would encourage a case-by-case assessment for what is appropriate, because what was thought to be enough at the outset of the study, turned out to be unsubstantial after assessment. Thus, increasing the monetary incentive may increase participant satisfaction without adversely affecting the trust of participants in the altruism of the study and staff.

On the other hand, there are notable lessons learned from this study. First, that great care should be taken when discussing sex, sexuality, and body image with African American women to avoid discomfort and dissatisfaction. The sexuality of African Americans is deeply interwoven with the fibers of racism and oppression faced by this group as well as their spiritual nature [52]. As a result, many older African American women are less willing to discuss the topic and studies looking to approach it should do so in a culturally sensitive manner that does not cause adverse reactions among participants. The last major lesson learned, is the need for more intensive training of mentors in order to address the ethical boundaries crossed by some mentors and to overcome the burden they undertake. In programs such as this, where intervention delivery depends heavily on the capability of the mentors, rigorous training is warranted to both provide the most benefit to those participating and also to protect mentors from the risks inherent to that role such as increased stress and boundary setting. Forthcoming interventions in similar special populations can apply the successful ethical considerations of this program while applying the lessons learned. Consistent contact from study staff, careful selection and pairing of participants, and reducing barriers to participation provided utility and ethical benefit by preventing adverse events and fostering a relationship of trust and mutual altruism. On the other hand this research would suggest the need for thorough training of lay persons involved in intervention delivery, careful consideration of how educational content may affect a particular population, and providing compensation that is reflective of the subject effort and time commitment. With additional procedural standardization interventions such as this will likely become more effective and reach a larger audience while maintaining a culturally sensitive and ethical approach towards addressing the specific health needs of special populations.

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Table 1

List of ethical considerations made for the PALS study, reasoning behind their inclusion, and the ethical concern being addressed.

Consideration Made	Reasoning	Ethical Justification
Justification of homogeneous study population	Disparate impact of SLE on African American women, programs responsiveness to population needs, potential for reduced impact in men due to differing coping styles	Medical research involving disadvantaged or vulnerable populations only justified if it is responsive to their health needs/priorities and there is reasonable likelihood of benefit [2]
Pre-screening for mentor competency	Obtain informed consent, check for preexisting conditions, need to be able to deliver educational material and act as model	Respect for persons (respecting individual autonomy) and informed consent of possible risks and benefits [1, 10]
Weekly contact from study staff to mentors and mentees	Maintain/build relationship between minority study coordinator and principle investigator with minority participants, assess workload, comfortability with interactions, check for adverse events	Overcome mistrust and fear minorities have towards medical research, address these concerns through relationship building with diverse and culturally competent research staff [3]
Mentor training	Communication skills, taught not to provide clinical advice, taught "when in doubt, contact study staff"	Protect the well-being of mentors and mentees through training to ensure accurate intervention delivery and education on how to respond to difficult and ethically concerning situations [10]
Mentee pre-screening	Informed consent and check for preexisting conditions	Respect for persons (respecting individual autonomy) and informed consent of possible risks and benefits [1, 10]
Careful paring of similar mentors and mentees	Ensure ease of communication, relationship building, commonality, reduce chance of adverse events and having to re-pair mentors/mentees	Overcome mistrust and fear through relationship building with like-peers and reduce risk of adverse interactions among dissimilar participants to secure safety and acceptability of intervention delivery [3, 10]
Phones for intervention communication provided	Lower barriers to entry and ensure confidentiality	Increase fairness of intervention accessibility to a burdened population and to protect participants' private information (phone numbers) [2, 10]
Staff training	Ensure protection of participants confidentiality and adverse event reporting	Hedge against breaches of confidentiality and ensure holistic compliance with ethical conduct of bio-medical [2, 10]

Table 2

Questionnaire used for the post intervention focus group.

Focus Group Questionnaire

- 1 Thinking about the process of the PALS study:
  - a. How easy or hard was it to schedule times to talk with your mentor/mentee?
  - b. Is there anything you would change about calls (frequency of calls, suggestions for scheduling, length of calls, etc.)?
  - c. If so, what would you change and why?
  - d. How manageable were the number of clinic visits?
  - e. For the benefit of the study, would you have been able to attend more?
  - f. Or would less have been more manageable?
  - g. Is there anything you would change about data collection (number of visits, length of survey, questions asked, etc.)?
  - h. If so, what would you change and why?
  - i. What do you think would be good measures of a successful lupus program?
- 2 Thinking about what the PALS study had to offer and what it taught you:
  - a. What lessons or skills did you learn that were most beneficial to you?
  - b. What aspect of the program did you feel provided the least benefit?
  - c. Is there anything you wished/expected to be covered in this program but was not?
  - d. If you could add one lesson to the program what would it be? Why?
  - e. If you could remove one lesson from the program what would it be? Why?
- 3 What are your opinions on communication from the research team?
  - a. Were study design, purpose, possible risks, and other factors of the study adequately explained?
  - b. Would you have benefited from more or less communication from study staff in the form of check-ins or meetings?
- 4 Was there anything else that you particularly liked about the program or felt worked really well?
- 5 Was there anything else that you think could be changed?
  - a. If so, what specific changes would you recommend and why?
- 6 We would like to ask you for other ideas. What do you think a successful program to improve the health of women with lupus should include?
- 7 Thinking about the best forms of communication to ensure your success in programs such as ours that involve mentoring:
  - a. What do you think is an appropriate amount of contact? Do you believe you would benefit more from weekly, twice weekly, daily communication, or something else?
  - b. What do you think could be the best forms of communication and why?
    - a. One-on-one phone calls with a mentor and mentee
    - b. Group meetings and/or conference calls
    - c. One-on-one face-to-face meetings with a mentor and mentee
    - d. E-mail or text messaging
    - e. A hotline with a counselor
    - f. Web based approaches (online meetings)
    - g. Something else?
- 8 What do you think we could do to keep the PALS program going?
  - a. Text reminders, web based booster sessions, other ideas?
  - b. How long do you think we would need to keep it going for women with lupus to get the maximum benefit?