

Contribution of the Pilot Study for Methodological Enrichment of the Main Study

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ABSTRACT

Introduction: A Pilot Study (PS) is useful for the assessment of the practicability of the methods and processes as well as the management of challenges before the main final study. The PS was conducted for the preparation of the mixed-method study related to nurses' and parents' perspectives regarding preterm infants' care practice in neonatal care units (NCUs) in Nepal.

Methods: Mixed method PS was conducted among nurses and mothers of preterm infants (PTIs) admitted to a NCU of an academic tertiary hospital. For data collection among nurses, a self-administered questionnaire and focus group discussion (FGD) were used in the quantitative and qualitative phases respectively. Whereas in-person interviews and in-depth interviews (IDIs) were conducted among mothers in the quantitative and qualitative phases respectively. Data were analyzed using descriptive statistics and content analysis methods.

Results: The major amendments based on PS findings were the study design from convergent parallel to exploratory sequential mixed-method design for contextual instrument development, the addition of the observation method of data collection for enhancing the validity of the findings related to care practice, and the inclusion of both parents of PTIs instead of only mothers. The PS was also useful for providing the experience of qualitative and mixed-method study for the researcher for the final study, especially for the qualitative part.

Conclusion: This article reflects the contribution of the PS to the main mixed-method study. Therefore, it is worthy to conduct the PS to enhance the methodological rigor of the study. It is commendable to discuss and disseminate the PS findings.

Keywords: *Contribution, Main study, Methodological enrichment, Pilot study*

INTRODUCTION

A pilot study (PS) is a smaller version of a study conducted in preparation for large-scale studies.¹⁻³ It is useful for assessment of the practicability of the study methods and processes and identification and management of problems and challenges before the main study.^{1,3-5} Its values are also related to the testing and refinement of the research instruments, assessment of the practicality and feasibility of the research methods and procedures, and revision as needed.^{3,4,6-8} It is beneficial also to prepare the researcher(s) for the implementation of the main study.⁹⁻¹² A well-conducted PS ensures methodological rigor high quality research.^{5,6,9} However, the publication of the pilot studies is limited due to reasons like poor reporting, and the tendency of less emphasis on feasibility findings by the journals.^{1,11,13,14} Whereas in the qualitative study, a separate PS might not be felt necessary.⁵ Considering its usefulness, the PS should be adapted in qualitative,

quantitative, and mixed-method research, discussed and disseminated.^{3,14} Literature emphasized the need for publishing the pilot study findings mentioning the actual contribution made to the study design and the research process to enhance the understanding of the PS.^{1,3} Reporting of the PS process is also important to enrich the body of knowledge in this area.⁴ Therefore, this article was prepared to discuss the practical and methodological contribution of the PS to the main final study.

PILOT STUDY PROCESS

The study was conducted to test the feasibility of the proposed study. Specific rationales were (1) to find out the relevance and quality (validity, reliability,

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of the proposed study. Specific rationales were (1) to find out the relevance and quality (validity, reliability, comprehension) of the instrument, (2) to evaluate the adequacy, appropriateness, and feasibility of the study methods, and (3) to identify the practical issues and difficulties and resolve before the main study.

The PS based on convergent parallel mixed method design was conducted from May to July 2019. The study was conducted in a neonatal care unit (NCU) of a public academic hospital having neonatal intensive care services. All nurses working in the 'NCU' for more than six months and mothers of preterm infants (PTIs) admitted to the NCU for more than four days were included in the study. Before data collection, ethical approval for the study was obtained from the Nepal Health Research Council and PS setting. Written informed consent was obtained from the participants.

The data collection instruments for nurses included the self-administered questionnaire for the quantitative phase and open-ended questions and guidelines for conducting FGDs for the qualitative phase. The self-administered questionnaire included practice items on 'PTI Care Practice in NCU' and demographic-professional information of the nurses. Participants had to rate each item considering the frequency of the practice in the clinical situation within one month on a five-point rating scale from 'never practice' to 'always practice' (score 1-5). The open-ended questions for FGD among nurses included similar components included in the self-administered questionnaire.

The quantitative data collection instruments for parents included 'Parental Need in NCU', and 'Parents' Satisfaction with PTI Care in NCU' as well as a socio-demographic information-related questionnaire. Instruments had subscales and items. Participants had to rate each item on a five-point rating scale however the basis for the rating was different for the two instruments. Rating for the parental needs was based on the importance from 'not important' to 'very important' (score 1-5), and satisfaction was rated as 'very dissatisfied' to 'very satisfied' (score 1-5). Questionnaires had a neutral response point on the scale. For qualitative data collection with parents, an IDI guide with open-ended questions was used. Instruments were developed based on available

literature and the objective of the study. The consultation was done with pediatric nursing faculties, pediatricians working in the NICU, and research experts for validation. Instruments for parents were translated into the Nepali language and back-translated by the translator blind to the original instrument. Clear instructions were given in the instruments.

To administer questionnaires among nurses (who were working in NCUs for more than six months), the first author coordinated with the unit in charge to arrange a common free time for participants (such as during lunchtime, before or after duty hours). The first author distributed a questionnaire in small groups of 3-4 participants in her presence until all the eligible participants were covered. Considering the sample size recommendation for the pretesting of the instrument, a total of 31 nurses were included.¹⁵ Similarly, for the qualitative data collection, one FGD was conducted among purposively selected nine participants (nurses who were willing to participate in the discussion) who participated in the questionnaire administration. The first author played the moderator role in conducting the FGD and was assisted by one assistant for note-taking. The discussion was audio-recorded with written informed consent from participants.

For the quantitative data collection among mothers, the researcher conducted face-to-face interviews with 31 mothers in colloquial Nepali language. For qualitative data collection, the first author conducted IDIs among purposively selected five mothers who were involved in quantitative data collection. IDI conversation was audio recorded with informed consent and necessary note-keeping was done.

The objective of the PS was not to generate an inference. Therefore, only descriptive statistics (number, percentage, mean, standard deviation) were used to analyze the quantitative data. Similarly, qualitative data were analyzed using the content analysis method, and themes were generated.

RESULTS AND CONTRIBUTION TO THE PILOT STUDY

This PS recommended some important revisions in the methods and processes of the final study, especially in population and settings, research design, instruments, and data collection.

Population and Setting

The quantitative data collection took a relatively longer duration to fulfill the targeted 31 samples of mothers whose infants are at NCU. The main reasons were related to the relatively low flow of PTIs compared to previous months, longer hospitalization of PTIs (> 2 weeks in 19 PTIs and > 1 month in six PTIs), and mortalities (two). It showed that fulfilling the sample size for the quantitative phase in the final study might be time-consuming. Therefore, it was decided to add three more hospitals (a total of six) for the quantitative data collection of the main study. It was also found that data collection involving mothers as well as available fathers would be more effective as both parents were involved in different responsibilities during the hospitalization of their PTIs. Mothers were involved in PTI care like breastfeeding, skin-to-skin contact, and other general care. Likewise, fathers were in contact with NCU personnel and responsible for dealing with the PTI's condition as well as overall management of the situation. Evidence also reported that fathers felt excluded in the care and other matters of their infants in NCUs.^{16,17} However, all the fathers may not be available because of reasons like being far from the family for the job, the responsibility of the job, having care responsibility of the elder child at home, and so forth. Therefore, it was decided to involve mothers and half a proportion of fathers in the quantitative phase and one-fifth of the sample size in the qualitative phase in the final study.

Instruments, Data Collection Method, and Research Design

One of the purposes of this PS was to identify the validity and reliability of the research instrument(s). The study significantly contributed to this matter. The study findings related to nurses' practice revealed that their rating for most of the items was in the higher site (most of the time and always practice) (extreme bias).¹⁸ It might be related to social desirability bias.¹⁹ On the other side, their rating for some items (for example minimization of light in the NCU environment, parents' involvement in pain management of PTI among others) was different from their response in FGD. Their responses were also at the higher sites for some negatively worded items. Results indicated that participants rated items inattentively (agreement acquiescence effect).²⁰ According to the literature both positively and negatively worded items were included in questionnaires to prevent response bias (answer patterns on questionnaires that do not reflect the respondents' actual state).

However, respondents may be inclined to agree with statements in general (acquiescence), to disagree (disacquiescence), or to give extreme answers, or less extreme answers.²¹ Literature further suggested that a combination of positive and negative statements in a questionnaire may be difficult for the respondents to comprehend, create confusion, and may provide a guess answer. It can pose a serious threat to the validity of self-report instruments.²¹

The internal consistency reliability score of the instrument for nurses was also < 0.8. Therefore, the instrument was modified. Among the 10 negatively worded items, five items were reversed to positive statements and five were removed. Removing the other three items with reliability score < 0.7, the total items were reduced from 60 to 47, and all items were kept in positive statements. Instruments were re-administered among nurses (a total of 31). However, extreme bias and acquiescence effect could not be minimized satisfactorily. Furthermore, among the two instruments for parents: 'Parents' need in NCU' and 'Parental Satisfaction to Care and Support in NCU', some overlap was identified. Therefore, it was decided to include parental satisfaction only in the final study.

Considering all those circumstances it was planned for a few amendments to the study methodology. One significant revision was a modification of the research design from the convergent parallel mixed method to the exploratory sequential mixed method design. The reason was to assess care practice among nurses for the second quantitative phase based on the findings of the first qualitative phase.²²⁻²³ The developed instrument to assess care practice was readministered among 30 nurses working in NCUs of two academic hospitals. The findings showed that the reliability scores of the items increased by > 0.8 (0.79- 0.88) an overall scale of 0.90 and an overall content validity index score of 0.90.²⁴

Likewise, mismatches were identified in the FGD findings and self-administered questionnaire findings of the nurses (for example minimization of light and sound in the NCU environment, pain management among others). Therefore, the need was felt for the addition of a third method of data collection among nurses for the confirmation of the findings of the self-administered questionnaire

and FGD.¹⁹ Therefore, the observation method of data collection was added to the final study.

Development of the Researcher

The study has a significant role in developing the researchers' confidence in different areas, especially for qualitative research. The study provided opportunities for practical skills in approaching, asking questions, and probing during qualitative data collection (IDI and FGD). The PS significantly helped to improve the instruments and protocol for data collection in the main study. Likewise, the researcher also got the opportunity to develop qualitative data analysis skills. However, the drawing inference was not the purpose of this PS.^{2,25} Therefore, the merging of the qualitative and quantitative data was not done in the PS findings.

DISCUSSION

Designing and conducting the pilot study with clear objectives enhances the rigor and validity of the research.^{1,3,26} The objective of the study was to assess the feasibility and practicability of the methods and processes for the final study. Study design, population, and other methodology were on a smaller scale and identical to the main study.

As recommended possible outcomes of the PS by literature,¹ this study suggested the possible need for some important amendments in the process and methodology of the main study. Previous studies also reported revisions in the methodology of the larger-scale study according to PS findings.^{4,8,27} The PS done as part of the larger mixed-method study reported the significance of the qualitative study to refine the research protocols, identify possible challenges, and increase the confidence in qualitative methodology.⁶ Similarly, the finding of PS conducted before the final research signified the usefulness of PS to develop aims and objectives, and methodological rigor.⁸

Consistent with previous studies^{27,28} the present study recommended revision and refinement of the study population in the final study. The previous study conducted in Korea indicated that the PS guided the recruitment of the participants in the final study.¹¹ Another study also reported modification of recruitment strategies after PS.²⁶ Findings also indicated the need for the addition of study sites in the quantitative phase for recruiting the required sample in the estimated time.

Literature emphasized the role of PS for confirmation of the instrument relevancy, refinement of the protocols and instruments as well as the clarification of concepts of the study.^{1,3,4} The present study suggested for revision of the study design for the development of contextual research instrument(s). In addition, data collection method was added to strengthen the findings from the existing methods. Consistent with study findings, the previous study also reported the modification of the instruments and research design after PS.⁵ Another study reported revision of the process and focus of the main study based on PS experience.²⁸ Another qualitative PS for the dissertation indicated that PS improved the interview guide with the addition of questions and rephrasing the questions.¹² Other studies reported modification and development of the contextual instrument for different types of qualitative studies.^{10,11,14,28}

CONCLUSION

This pilot study is important to the improvement of the methods and processes of the final main study. The major contributions, are in the areas like data collection settings and population, study design, research instruments, and data collection procedures which have important roles in the enhancement of the validity of the study findings. Similarly, the study helped to prepare the researcher for the final study. Therefore, it is worthwhile to have a well-planned pilot study before conducting the mixed-method study.

ACKNOWLEDGMENT

The authors express their gratitude to the study setting for providing permission to conduct the pilot study and to the participants of the study for participation in the study.

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