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Ethical Considerations in Qualitative Study

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ABSTRACT

The protection of human subjects through the application of appropriate ethical principles is important in all research study. In a qualitative study, ethical considerations have a particular resonance due to the in-depth nature of the study process. The existing ethical guidance for undertaking qualitative research often provide general guidelines rather than focusing on how to apply it in practice, particularly when interviewing vulnerable group of women. The aim of this paper is to present my own experience of conducting 33 individual face to face interviews on the women's experience of postnatal depression across three different cultural backgrounds in Malaysia. This paper reflects on the strategies that can be adopted by a qualitative researcher to ensure that their participants' identity is protected throughout recruitment and dissemination process, to deal with participants from different cultural backgrounds, and to handle and manage distress during interview. The consideration of ethical issues is crucial throughout all stages of qualitative study to keep the balance between the potential risks of research and the likely benefits of the research.

KEYWORDS: Ethical, Principles, Qualitative

INTRODUCTION

The protection of human subjects through the application of appropriate ethical principles is important in any research study (1). In a qualitative study, ethical considerations have a particular resonance due to the in-depth nature of the study process. The concern of ethical issues becomes more salient when conducting face to face interview with vulnerable group of participants. They may potentially become stressed while expressing their feelings during the interview session.

The existing ethical guidance for undertaking qualitative research often provide general guidelines rather than focusing on how to apply it in practice, particularly when interviewing new mothers with postnatal depression (PND). The aim of this paper is to present my own experience of conducting individual face to face interview on the women experience of postnatal depression. There are six important ethical issues considered in this study, and these are discussed below.

INFORMED CONSENT AND VOLUNTARY PARTICIPATION

The process of obtaining Consent consists of the following: consent should be given freely (voluntary), subjects should understand what is being asked of them, and involved persons must be competent to consent (2). This means, to participate in a research study, participants need to be adequately informed about the research, comprehend the information and have a power of freedom of choice to allow them to decide whether to participate or decline (3). Participant's agreement to participation in this study was obtained only after a thorough explanation of the research process.

All participants were required to provide written informed consent. The potential participants were approached individually and given an explanation of the purpose of the study and data collection process. They were given an appropriate time to ask questions and address any concerns. It was explained that as their participation was voluntary, refusing to participate or withdraw from the study while it was in progress would not affect their care or job in the respective clinic in any way.

A patient/participant's information sheet was provided to further explain the study. The potential participants were given appropriate time (in this case: 24 hours up to one week) to read the information sheet and to decide whether or not they wanted to be involved in this study. They were required to sign the informed consent form before the interview to indicate their permission to be part of the study and this signature was confirmed prior to the interview session.

An explanation was clearly given to potential participants that they had a right to withdraw from the study at any time even after the informed consent had been signed. Consent to record the interview was also asked from them. The patient/participant's information sheet and informed consent was available in two languages: Malay and English.

ANONYMITY AND CONFIDENTIALITY

The anonymity and confidentiality of the participants was preserved by not revealing their names and identity in the data collection, analysis and reporting of the study findings. Privacy and confidentiality of the interview environment were managed carefully during telephone communication, interview session, data analysis and dissemination of the findings.

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TELEPHONE COMMUNICATION

Since the eligible participants (women with postnatal depressive symptoms) were contacted through phone to know their decision whether or not to participate in the interview study, proper safeguards were taken. There were a few cases where the phone call was answered by the third party (husband/ mother). In this situation, I did not expose details of the study. Instead, I explained that the purpose of the phone call was to follow up the information that had been given during the previous visit to the respective clinic. I left the contact number with that person and asked for a better time to call back.

INTERVIEW SESSION

Each interview was conducted individually in a private and quiet room in the respective clinic or participant's home without access by outsiders. I am the only one who should be able to match the identity of the participants and voice recordings.

DATA ANALYSIS AND DISSEMINATION OF THE FINDINGS

Data transcribing was conducted in a private room using earphones to avoid the possibility of recordings being heard by other people. The identities of the participants were removed during data transcription, including their names or any significant aspect of identity. In presenting the findings of the study, the participants were referred to by their pseudonym names in the verbatim quotes.

Written consent or any document which contains the participants' personal detail was kept in a locked cabinet with no access to anyone other than myself. This personal information will be destroyed in accordance with the University of Stirling research governance procedures.

Participants were however, notified that their actual age would be used for the purpose of reporting the data from the interview (4). Data were shared with the other two qualitative researchers for the purpose of reaching agreement of the interpretation without exposing the participants' details at any interim stage. The access of the supervisors to the data was explained to the participants and their consent regarding this matter was obtained.

This project adhered to the University of Stirling Code of Good Research Practice. The University of Stirling has adopted the Model Publication Scheme (MPS) for Scottish Higher Education Institutions (HEIs), which has been developed by Universities Scotland. This MPS was approved by the Scottish Information Commissioner on 25 March 2004 (5). Overall responsibility for this Publication Scheme resides with the University. No participants identifying information will be included in reports or publications arising from this project.

ETHICAL APPROVAL AND ACCESS TO PARTICIPANTS

The ethical approval was sought and granted from two main research ethics committees: The School Research Ethics Committee (SREC) in the School of Health Science, University of Stirling and the Malaysian Medical Research Ethics Committee (MREC).

Upon approval from the SREC, the ethical approval from the Malaysian National Institute of Health Research (NIHR) and MREC were applied through online registration with the Malaysian National Medical Research Register (NMRR). Prior to this application, permission from the respected authorities of the study sites was first sought. Therefore, application letters were sent to the Director of Hospital Kuala Lumpur, and the Director of Health Department of Federal Territory Kuala Lumpur.

Upon getting the permission from the respected authorities of each study site, the online application was submitted. The process of application was monitored at the NMRR website. The final decisions were notified by the MREC through email to inform the status of the application. Approval from the Economic Planning Unit, Department of Prime Minister Malaysia was also sought to obtain the research pass as this research was an application to conduct research from outside Malaysia.

Initially, only five MCH clinics were selected and approved by MREC. However, after almost three months in fieldwork, there were fewer numbers of Indian women participating in the study due to a low rate of attendance in the five selected MCH clinics. For this reason, an approval to increase the number of clinics had been made through online application at NMRR website. Three MCH clinics were added. Upon getting this approval, I started visiting the newly selected clinics and looking, mainly, for Indian participants. At the end of the fourth month of the study period, it was decided that there were no more new concepts emerging, therefore the data collection stage was ended. These experiences made me reflex that obtaining ethical approval is not always a straightforward process, instead it requires some modifications along the study period.

DATA PROTECTION

Interview Stage

Data analysis was conducted simultaneously with the data collection. I transcribed and analysed the data independently. The data was shared with two qualitative researchers.

Data were stored in encrypted devices and password protected. As for the purpose of cross checking in data analysis, the transcripts were shared with two qualitative researchers through password protected email. The information storage on the university computer, personal computer or laptop, hard disk and memory sticks were protected by using passwords that were only held by me (4). Hard copies or written materials of the data were kept in a secured cabinet in a locked room with no access to others to ensure adherence to legal requirements (6) and ethical guidelines. Both written and electronic data from this study will be stored for five years. However, the interview recordings will be disposed once they are no longer needed.

I was aware that any unexpected adverse event which was caused by this study should be reported to the MREC and the SREC, School of Health Science, University of Stirling. However, no such event occurred throughout the study period. The results of the study will be reported and disseminated through peer reviewed scientific journals, conference presentations, thesis dissertation, university library and written

feedback to research participants or relevant community groups.

All anonymised data will be securely stored for a period of 10 years in accordance with the University of Stirling Code of Good Research Practice: the safe and secure storage of the primary data will normally be for at least ten years, a safe and secure method of disposal must be used after this time, and all accordance with the requirements of the Data Protection Acts (6). Personally, identifiable data (e.g., the recruitment log) will be destroyed as soon as I am sure that they will not be needed again.

Cultural and Linguistic Barriers

It is important for researchers to be fully aware of the obstacles in their research and plan for preventative action, as this may affect the timing of the research. Since the beginning of this study, I was aware that in some cultures, women may need permission from their husband/partner to take part in this study. Therefore, I allowed adequate time for the eligible participants to discuss the decision to participate with their husband/partner. In this case, the women were allowed to contact me, or I only contacted the women with their permission. Although there was a case where a woman gave this as a reason not to participate, the majority of the participants discussed the decision to participate with their husband and were allowed to be involved in this study.

I was also aware that there were three different cultures with different mother-tongue languages involved in the interview session. Given the fact that Malay is the formal language in Malaysia, I assumed that most of Malaysian women and HCPs were able to converse and express their experiences at the optimum level using Malay language. I also included the ability to converse in either Malay or English as one of the inclusion criteria for this study. This was to optimise the understandable communications between researcher and participants. There was one case where a Chinese woman was eligible for the interview session based on the screening tools (as this was based on reading in Malay), but somehow was found not to be able to converse fluently either in Malay or English for the interview stage. Therefore, she was excluded from the study.

There were also some of the participants who preferred to be interviewed in English. This involved six interviews with women and three interviews with HCPs. Due to limited human and financial resources, there were no other versions of the questionnaire for screening and the topic guides used other than Malay and English.

Handling and Managing Distress During Interview

The face to face semi structured interview technique requires me to listen and respond to the participants' answers or speech. The act of my listening may create unintended harm to the participants (7). I was aware that working with a vulnerable group of people, the participants may potentially become stressed while expressing their feelings during the interview session. Therefore, a woman who believed herself (or was considered by the nurse in charge or by me) to be severely depressed to the extent that participation in the interview might worsen her condition, was excluded from this study. In one case, a woman was referred by a head nurse as having some level of depression after her last childbirth. After phone communication, a meeting was arranged at the woman's home. However, she was found as not being able to concentrate in the interview session, therefore the interview was stopped after ten minutes. She had not developed any adverse effects, but I felt that her descriptions on her depressive experiences were in a repetitive manner and her responses did not always relate to the questions being asked. As this woman was not able to focus, it was assumed that she had probably not fully recovered, therefore I decided not to introduce any potential harm to her and she was excluded from the study.

As applied to all participants, they were advised to withdraw from the interview at any point if they thought answering the interview questions and disclosing their feelings may impact upon their emotional health status. Ten out of 33 participants were crying when sharing some parts of their experience of PND during interview sessions. In this case, I offered them to discontinue the interview if they felt it would cause any physical or psychological harm. They were also given a choice to stop the interview and continue once they were ready to do so. In all cases, women chose to stop talking about the study topic for a few minutes and continued after they felt better. During this 'time break', I tried to distract women's attention by having conversation outside the study scope (e.g., her child's name or anything she likes to do in her spare time). Stopping the interview and searching for possible solutions for the participants' distress indicates that researchers are aware of the vulnerability of participants and their rights (1).

Women were informed that the additional support was available as quickly as they needed it especially for those who were interviewed at the MCH clinics. Offering and referring participants to counselling in case they needed it was regarded as fulfilling the moral obligation by ensuring that they have regained control of the situation by talking (1). All women were informed that the Counselling Psychology Unit Department was available in the Health Department of the Federal Territory Kuala Lumpur for further assistance. All of the women did not show any interest in contacting this unit, although this was offered.

Recommendations

This paper recommends that interviewing participants that come from different cultural backgrounds requires not only basic understanding of the participants' culture but also flexibility in the interview process. When dealing with vulnerable group of people, qualitative researcher should aware of potential harm that can be imposed to the participants. These approaches are important to ensure that these ethical principles are applied throughout all stages of the research process, thereby balancing the potential risks of research against the likely benefits.

CONCLUSION

This paper has argued that while ethical considerations are important in all research area, the concern becomes more salient in qualitative research, particularly when involving vulnerable group of participants. It is the responsibility of the qualitative researcher to ensure participants to have a power of freedom of choice to involve in the study, protect the participants' identity throughout recruitment and dissemination process, and promote clear and honest research reporting without deception to readers.

Reflecting those strategies that I have used during my research made me aware that ethical issues in qualitative research is not as general as being portrayed in the literature, instead it might require some modifications along the research process.

CONFLICT OF INTEREST

The author declares no conflict of interest.

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