Strategies Pakistani Women Use to Self-manage their Recurrent Depression:

Research Protocol

The purpose of this study is to describe Pakistani women's perspectives on strategies and their effectiveness in the self-management of their recurrent depression. Consequently, this study will describe the (1) self-management strategies of Pakistani women with recurrent depression, (2) factors which influence self-management strategies, and (3) perceived effectiveness of self-management strategies. This research protocol consists of seven sections: (a) research design, (b) sample, (c) measures, (d) procedure, (e) human subject protection, (f) minority/gender/children, and (g) data analysis.

Research Design

This qualitative study will use content analysis to describe Pakistani women's perspectives on strategies, factors influencing those strategies, and their perceived effectiveness in the self-management of their recurrent depression. Content analysis is a qualitative analysis procedure for methodically making sense of the transcriptions of open-ended interviews using three basic techniques: (a) deciding what the unit of analysis will be, (b) borrowing or developing the set of categories, and (c) developing the rationale and illustrations to guide the coding of data into categories (Wilson, 1989).

Sample

The study sample will be recruited from the outpatient psychiatric clinics of the Aga Khan University Hospital (AKUH). Data for the study will be obtained from Pakistani women with depression. Any woman can participate who meets the following inclusion criteria: (a) born in Pakistan, (b) 18 years of age or older, (c) had two or more episodes of major depression, (d) is a follow-up patient in the outpatient psychiatric clinics of the AKUH, (e) is aware that she has

depression, (f) can speak Urdu and/or English, (g) gives permission to access medical files to validate diagnosis and history of two or more depressive episodes; and validates the absence of bipolar disorder, or current substance abuse and (h) is willing to participate in the study. The exclusion criteria for a Pakistani woman with depression are: (a) has a diagnosis of bipolar disorder, (b) is currently abusing a substance, and c) is currently admitted to the in-patient psychiatric unit of the AKUH. Since there is a possibility that medical files may not have information regarding current abuse of substance; hence, each subject will be specifically asked about it.

Purposeful sampling will be used. The reason for using purposeful sampling is to achieve analytic generalizability, an aim of qualitative research. "Analytic generalizability refers to the utility of the concepts/constructs to explain a given situation" (Hutchinson, 1993, p. 190). Using purposeful sampling, a sample of 12 to 15 Pakistani women with depression will be selected. The reason for providing a sample range is that at the start of a qualitative study, it is difficult to determine the ideal extensiveness of the sample size until the study is in progress. In a qualitative study, sample size is determined when data collection achieves saturation. In short, in this proposed study, the exact sample size will depend on “saturation”.

Saturation has two important meanings in qualitative research. First, when a set of data captures the range of possible responses, data collection process achieves saturation. Second, when additional interviews do not produce information which is substantially different from that already collected, information redundancy (Lincoln & Guba, 1985), data collection achieves saturation (Safman & Sobal, 2004).

Measures

The measure that will be used in this study is an *interview* using an interview guide (Appendix A). The interview is used as a method of data collection to meet the purpose of a qualitative study. The interview is appropriate for the proposed study because the research questions require elicitation of information from the participants about the strategies they use to self-manage their recurrent depression, factors influencing those strategies, and the perceived effectiveness of those strategies. The interview will be semi-structured so as not to limit the field of inquiry i.e., self-management strategies, and will allow the investigator to word and sequence open-ended questions to respond to individual differences (Waltz, Strickland, & Lenz, 1991).

The interview guide consists of a participant information sheet and interview questions. The participant information sheet will include (a) participant code #, (b) participant interview #, (c) gender, (d) place of birth, (e) age, (f) years of formal schooling, (g) marital status, (h) numbers of years married, (i) number of and type of relation with people living in the household, (j) number of children, (k) ethnicity (l) religion, (m) employment status, (n) monthly household income, (o) age of onset of initial depressive episode, and (p) number of previous major depressive episodes.

Interview questions help the investigator generate data to understand phenomena identified in the research questions (Maxwell, 1998). In this study, the interview questions are purposefully *open-ended*. Open-ended questions permit participants to answer questions the way they want to (Patton, 1990). Before data collection, both Urdu and English versions of the interview questions will be evaluated by at least two non-depressed Pakistani women to get their feedback on clarity, understandability, meaning, usefulness, and simplicity of the interview questions.

The broad overarching interview question is "*let us talk about your experience of depression*". The specific interview question is "*what is a depressive episode like for you*?" Samples of the broad interview questions to address some of the research questions are as follows. An interview question ascertaining self-management strategies is "*what kinds of things do you do for your symptoms of depression*?" An interview question ascertaining influencing factors is "*what makes you use (name of the particular strategy) it*?" An interview question ascertaining perceived effectiveness of self-management strategies is "*how does it (name of the particular strategy) work for you*?" In addition to the broad open-ended interview questions, the investigator will develop a list of specific interview questions, probes, and clarifying questions to be used as needed during the interview.

Procedure

Following the approval of the IRB review board at the University of Michigan and the Ethical Review Committee of the Aga Khan University (AKU), permission to conduct the study will be obtained from the Director of the AKUH and the Dean of the Aga Khan University School of Nursing (AKUSON). A meeting will be arranged with the head of the psychiatric department and the psychiatric clinicians (psychiatrists and psychologists) of the AKUH to explain the study and to ask for their cooperation in identifying potential participants for the study. Next, the head nurse of the outpatient department, charge nurse and other nurses working in the psychiatric outpatient clinics of AKUH will be educated about the study and will be asked for their cooperation in facilitating contact with potential participants with the investigator and identifying an interview room where interviews can be conducted.

Two approaches have been devised to recruit potential participants for the study. First, on outpatient psychiatric clinic days at AKUH, the psychiatric clinicians will be given a two page

handout (Appendix B) that has both a checklist of inclusion and exclusion criteria (page one) and a written proof of interest (form) in participating in the study (page two). The clinician will first approach their patients and will briefly introduce the study and assess their eligibility by filling out a checklist of the inclusion and exclusion criteria provided by the investigator. The clinician will verbally provide information to potential participants who are eligible to participate in the study, as well as give them a handout. For potential participants who cannot read and write the clinician will write their names and telephone numbers on the handout; potential participants will then make a check mark at the end of the handout to demonstrate interest in participating in the study. The potential participant will submit the handout [both filled checklist and a written proof of interest (form) in participating in the study] directly to the investigator if available on site or place it in a locked box kept at the outpatient psychiatric clinic reception/information desk of the AKUH. In other words, the psychiatric clinician will refer the potential participants to the investigator. In situations where potential participants have made a check mark on page two of Appendix B to demonstrate an interest in participating in the study but the psychiatric clinician has not filled out the checklist of inclusion or exclusion criteria, page one of Appendix B, or the checklist is not completely filled out, the investigator will consider that the submission of the handout with a check mark by the potential participants represent their permission to participate in the study. The investigator will contact those potential participants either on site or by telephone and will complete the checklist to ensure that the potential participants meet all the inclusion and exclusion criteria.

Second, a flyer (both in English and Urdu) describing the study (Appendix C, page one) and copies of the proof of interest (form) in participating in the study (Appendix B, page two) will be posted in the outpatient psychiatric clinic of AKUH to recruit self-referred potential

participants. A self-referred participant can fill out the necessary information which include name, telephone number, and a check mark to give permission to be contacted for participating in the study and submit it directly to the investigator if available on site or place it in a locked box kept at the outpatient psychiatric clinic reception/information desk. The submission of a handout (Appendix B, page two) with a check mark by a potential participant will be considered to be her permission to be contacted for the study. The investigator will contact each potential participant either on site or by telephone and will assess their qualifications to be a part of the proposed study by using the inclusion and exclusion criteria on a checklist (Appendix B, page one). The limitations of this method of recruiting participants are that only those who can read and write and have telephone numbers will be able to self-refer to participate. Therefore, the use of both methods, referral by psychiatric clinician and self-referral, will be helpful in achieving the desired sample size.

Participants identified through one of the above two methods but who do not meet the criteria will be thanked and will not be included in the study. Those participants who meet the inclusion and exclusion criteria and are willing to participate, an interview date, time and venue (interview room in the outpatient psychiatric clinic at AKUH) will be arranged. Participants will have a choice of interview dates from any week day or at their next outpatient clinic appointment date. Special attention will be given to those participants who would like to be interviewed in the clinic on the day they have an appointment with their psychiatric clinicians so that the interview time does not clash with their appointment time. Moreover, enough time (1-1 1/2 hours) will be given for each interview so that the investigator and the participant do not feel rushed to complete the interview. It is possible that some participants would like to be interviewed soon after their first meeting with the investigator. For those potential participants the same study

procedures and human subject protection protocols will be used; they are explained below. It is, however, important to note that on any give day no more than two subjects will be interviewed.

On the day of the interview, the investigator will explain the study purpose and the study procedure again. In the briefing about the study procedure, the participants will be specifically informed that the interviews will be audio taped. In addition, the participants will be informed that the investigator will also take some notes during the interview. The participants will be asked to sign the consent form to participate in the study. Although all the participants will receive a written consent form, it is possible that some Pakistani women might not feel comfortable signing their name on the consent form or that some Pakistani women might not be literate. In such situations if participants say that they want to participant in the study, their verbal acceptance will be documented by the investigator on the consent form and this will be considered their consent.

The interview will be conducted using the interview guide. During the interview, participants will have a choice to speak in Urdu or English or both and to take a break at any time if they feel fatigued. Following the interview, participants' contributions to the study will be acknowledged. Since this study has a time commitment, participants will be paid Pakistani Rupees 300, approximately US $5.17 (US $1 = 58 Pakistani Rupees), at the end of the first interview for their involvement and contribution in the study. If the participant withdraws from participation before the first interview, they will not be paid 300 Pakistani Rupees.

Study participants will be requested to acknowledge the receipt of money by signing the proof of payment form and/or making a check mark on a proof of payment form (Appendix D) which will be immediately co-signed and dated by the investigator. Depending on how much is accomplished in the first interview, the participants may be asked to perhaps participate in the

second interview for completion of data collection. The third interview may be arranged if the investigator would like to seek clarification and understanding of the data so far provided by the study participant. Hence, each participant will have the total time commitment of between 3 to 41/2 hours. Those study participants with whom follow-up interview(s) will be conducted will be verbally thanked for their time both at the beginning and end of the interview(s). There will be no monetary compensation for study participants who participate in the follow-up interviews. In other words, every study participant will get a maximum of 300 Pakistani Rupees (approximately US $5.17) for their participation in the study. Data collection will take place in August, September, October, November, and December, 2005. In other words, data collection will take approximately five months to complete.

Human Subject Protection

To ensure protection of human subjects, approval of both the Institutional Review Board at the University of Michigan and the Ethical Review Committee of the AKU will be obtained before starting data collection. Participants will be informed through both written and verbal descriptions about what they can expect as participants. Participants can expect the following. First, participation in this study is voluntary and participants have a right to refuse or withdraw from the study at any time in the data collection process. The participants will be told that they can ask any questions they might have about the study or procedures related to the study.

Second, the study may not have any specific direct benefit to the participants; except for some participants, it might be a chance for them to reflect on how they manage their depression and its treatment. In addition, the participant will have a choice to ask for a one-page summary of the research findings either in Urdu or English languages which the investigator will provide after the completion of writing of the research findings. For this the participants have to provide

their complete home or work mailing address. In addition, for some the 300 Rupees may cover part of their cost of psychiatric outpatient clinic visit or travel cost. Nonetheless, results of this study will generate important information to help health care providers in Pakistan to better understand what the depression experience is like for some Pakistani women. Moreover, knowledge generated on strategies may help health care providers incorporate them to care for other Pakistani women with depression, and may help some Pakistani women self-manage their depression. This would assist Pakistani women with depression to improve their day to day functioning, minimize the effects of depression in their lives, and reduce the risks of future episodes of depression.

Third, study participants will be informed that there is minimal identified risk or harm to the participant for participating in this study, i.e., the discussion of experiences of depression and its management could be emotional. The investigator is an experienced psychiatric nurse who has worked with women with depression, and will make clinical judgments about whether or not it is appropriate to continue the interview.

Fourth, study participants will be told how their confidentiality will be maintained throughout the data collection and reporting:

1. The investigator will not inform any psychiatric clinician whether their patients opted or opted out from participating in the study.
2. The investigator will place a code number and not the name of subjects on the participant information sheets.
3. Before starting the interview, the subject will be given a choice of whether she would like the investigator to use an alias or her real name during the interview.

4. The notes taken during the interview will also be given the same code number as the information sheet.
5. The interview data will be coded so that data are not linked to subject names.
6. All study data will be stored in a secure place (i.e., locked cupboard in the investigator's home). Only the investigator will have access to the locked cupboard. For example, audio tapes will only be used for transcriptions and then kept in the locked cupboard. These audio tapes will be destroyed after the completion of writing of this research study report. Similarly, transcripts files on computers will not have any identifiers and will be password protected.
7. The study data will be shared only with the translator(s) for translating the interviews into English, and with the faculty on the investigator's dissertation committee. The translator(s) will sign a confidentiality form prior to translating the interviews into English. However, any records or data obtained as a result of subject participation in this study may be inspected by the financial sponsor, AKUSON, by the University of Michigan Institutional Review Board, Health, or by the Aga Khan University Ethical Review Committee members.
8. Both audio taped and written data collected will be destroyed once the study is completed.
9. Subjects will not be identified in any reports on this study.

Participants, however, will be informed that confidentiality will not be maintained if the participant is at risk of harming herself or others. If a participant exhibits behavior that indicates suicidal ideation or increased suicidal ideation, or suicide planning, the investigator who has experience in psychiatric nursing care will conduct a suicide assessment with the participant. If

there is: (a) increased frequency, duration or severity of suicidal ideation with no plan or imminent intent, the participant will be asked to contact her psychiatric clinician before leaving for home, (b) indication of suicidal planning, intent, and substance use, the investigator will, with the participant, contact her psychiatric clinician, family member, or friend, and (c) an imminent suicide intent, the investigator will ensure that the psychiatric clinician at the psychiatric outpatient clinic of the AKUH be informed immediately for a complete psychiatric evaluation of the participant, including suicide intent. The participant will bear the cost of psychiatric evaluation.

Fifth, the role of researcher versus clinician will be clarified. For example, as a researcher, the investigator is interested in understanding the participants perspectives of what do they do to manage their depression. Information provided by the participants in response to interview questions will not be recorded in participants' medical files; hence, it will not be used for treatment purposes. As a researcher the investigator is not responsible for changing or modifying any treatment plans such as prescribing medications or changing the dose of current medications if any.

Finally, the participant will be asked if they have any questions about the study or procedures related to the study. Data will only be collected once the participant gives either written or verbal consent including making a check mark on the consent form (Appendix E).

Minority/Gender/Children

The focus of the study is to understand Pakistani women's perspectives on strategies, factors influencing those strategies, and their perceived effectiveness in the self-management of their recurrent depression; it requires the inclusion of females, and, therefore, excludes males. After learning more about strategies women use to self-manage their recurrent depression,

research can later be extended to study strategies men use to self-manage their recurrent depression. The reason children are not included in the study is that this study focuses on strategies that are used in recurrent depression. In order to qualify as having recurrent depression, an individual has to have two or more episodes of major depression; this makes it difficult for children to qualify as study participants. In addition, the depth and the complexity of data the investigator is interested in obtaining are not likely to be provided by children. The aim of the qualitative research is to achieve analytic generalizability which can only be achieved if participants are experts about the phenomenon under investigation. So any Pakistani woman who belongs to any ethnic group and who meets the inclusion criteria will be able to participate in the study.

Data Analysis

The investigator will listen to the audio taped interviews soon after each interview. In qualitative research, data collection and data analysis occur simultaneously. Since the interview will probably be conducted in Urdu, the investigator will transcribe the interview into Urdu. The transcribed interviews will then be given to an expert (yet to be identified in Pakistan) in both Urdu and English in Pakistan to translate the interviews into English. The investigator will check the translated version of the interview to identify any discrepancies between the Urdu and English versions of the interview.

The study data will then be analyzed using content analysis (Bernard, 1988). Content analysis is a qualitative data analysis method used to make inferences from text data collected from open-ended questions asked in interviews. The goal is to understand and describe Pakistani women's perspectives on strategies, factors influencing those strategies, and their perceived

effectiveness in the self-management of their recurrent depression. The text used for content analysis will be the transcribed audio taped interviews.

Wilson (1989) established three basic elements of content analysis: (1) deciding on the unit of analysis, (2) borrowing or developing the set of categories, and (3) developing the rationale and illustrations to guide coding of data into categories. *Deciding on the unit of analysis* means that a decision needs to be made whether the whole response or a breakdown of responses into separate words, phrases, or sentences will be used (Wilson, 1989). In this study the unit of analysis will be the sentences derived by breaking down the responses to the interview questions.

Borrowing the set of categories means that a set of categories can be developed before data collection if the concepts are borrowed from existing theory; then data can be coded using the pre-identified categories. *Developing the set of categories* means that a set of categories are developed based on themes emerging in the data (Wilson, 1989). In this study, the set of categories for the content analysis will be both borrowed (Appendix F) and developed directly from the themes appearing in the responses to the open-ended interview questions. It is important to clarify that the research questions will guide the development of categories and sub-categories, and the interview questions will yield the developing of the categories. For example, the interview question is "*What makes you use (name of the particular strategy) it*?" The label for this question is “influencing factors”. Sub-categories which may emerge could be personal factors, provider factors, social factors and so forth. *Developing the rationale and illustrations to guide coding of data into categories* means that in order to code data into categories, the investigator has to “make a judgment on the right category for every response or unit of analysis” (Wilson, 1989, p. 470). The rationale to guide coding the data into specific categories is based on understanding participants’ perceptions of: (a) the factors which influence their self-management

strategies, (b) strategies they use to self-manage their depression, and (c) the perceived effectiveness of strategies in managing depression or preventing future episodes of depression. Once all the text data is represented in categories and sub-categories, a descriptive summary for each category will be written. The process of analysis will be done by hand (the decision to use particular software to aid in the process of analyzing data has not yet been decided).

Content analysis is a rigorous procedure; however, it is prone to problems of validity and reliability. In quantitative research, validity refers to what is being measured and how well it is measured (Mishel, 1998). In qualitative research, in contrast, *validity* refers to "*gaining knowledge and understanding of the true nature, essence, meanings, attributes, and characteristics of a particular phenomenon under study. Measurement is not the goal; rather, knowing and understanding the phenomenon is the* goal." (Leininger, 1985, p. 68). In other words, the validity in qualitative research refers to whether the investigator is getting what she is trying to get or what she thinks she is getting. In qualitative research there are several ways to prevent threats to *validity* such as searching for discrepant evidence and negative cases, triangulation, feedback, member checks and rich data (Maxwell, 1998). In this proposed study, the validity of the findings will derive from the data collection process and from feedback from a panel of experts to increase the credibility of the findings. "Soliciting feedback from others is an extremely useful strategy for identifying validity threats, your own biases and assumptions, and flaws in your logic or methods" (Maxwell, 1998, p. 26). Hence, in this study, feedback will be solicited and discussion of the findings will be done with a panel of experts on self-management strategies such as Dr. Bonnie Hagerty (chair, investigator's dissertation committee) and Dr. Lynch-Sauer (member, investigator's dissertation committee), faculty at the School of Nursing, University of Michigan.

In quantitative research, reliability refers to repeatedly obtaining the same results (Mishel, 1998). Since this proposed study aims at developing understanding and knowledge about the self-management strategies used by Pakistani women with recurrent depression, the issue of reliability is not a major concern. In qualitative research, *reliability* "focuses on *identifying and documenting recurrent, accurate, and consistent (homogeneous) or inconsistent (heterogeneous) features, as patterns, themes, values, world views, experiences, and other phenomenon confirmed in similar or different context*." (Leininger, 1985, p. 69). In this proposed study, the investigator will pay special attention to the reliability of the coding such as ensuring that the emergent categories are mutually exclusive, the categories are separate and independent. If responses (unit of analysis) can be reasonably coded into more than one category, the reliability of the coding is suspect (Wilson, 1989).

Besides mutual exclusiveness, the investigator will ensure that other necessary criteria of the emergent categories are met such as homogeneity, inclusiveness, usefulness, clarity and specificity (Wilson, 1989). *Homogeneity* means that the identified categories are a variation of the same phenomenon under study and have the same level of abstraction. For example, the category "types of strategies" which addresses the research question "*what types of strategies do Pakistani women use to self-manage their recurrent depression*" will have all the sub-categories as a variation of types of strategies (e.g., cognitive strategies and behavioral strategies) and are expressed at the same level of abstraction (e.g., cognitive strategies and behavioral strategies, and *not* as cognitive strategies and taking medications).

Inclusiveness means that the identified categories have every possible aspect of the phenomenon under study, and that there are no categories such as mixed or miscellaneous. *Usefulness* means that each category serves a purpose and that it relates to a specific research

question. *Clarity and specificity* means that the identified categories are stated in clear, direct and understandable terms (Wilson, 1989). Finally, the *credibility* of the findings will be established from systematic data analysis steps.

Summary

In this protocol, the methodology of this study was described. This chapter covered: (a) research design, (b) sample, (c) measures, (d) procedure, (e) human subject protection, (f) minority/gender/children, and (g) data analysis.

This qualitative study will use content analysis to describe Pakistani women's perspectives on strategies, factors influencing those strategies, and their perceived effectiveness in the self-management of their recurrent depression. Using purposeful sampling, a sample of 12 to 15 Pakistani women will be recruited from the outpatient psychiatric clinics of AKUH who meet the specified inclusion and exclusion criteria. Data will be collected through semi-structured interviews using an interview guide. The study procedure and human subjects protection protocol was described in detail. Finally, a plan for data analysis was presented with exemplars where appropriate.

Note: This proposed research is in compliance with the principles of Helsinki Declaration

Appendix A

Participant Information Sheet

Interview Guide: The English-Urdu Version of Participant Information Sheet

Date: _____

Participant code #: _____

Participant interview #: _____

Gender: _____

Direction: I will ask you some questions that will help me better understand the results of this research study:

1. What is your place of birth?
2. What is your age?
3. How many years of formal schooling did you have? _____
4. What is the highest level of school you have completed? _____
5. Marital status? ☐ Single ☐ Married ☐ Divorced ☐ Separated ☐ Widowed

   If married, for how long? _____
6. What is the total number of people who live in your household? _____
7. Who do you live with?

   □ Live alone □ Live with parents' family

   □ Live with spouse □ Live with spouse's family

   □ Live with your children □ Live with a relative

   □ Live with a roommate □ Other (please identify) _____

   Specify who lives in your household

   □ Yourself □ Your parents □ Your siblings

□ Your spouse □ Your children □ Your in-laws

□ Your relatives □ Other (please specify) _____

8. How many children do you have? _____

9. How many children are living at home? _____

10. What is your ethnicity? _____

11. What is your religion? _____

12. What is your employment status?

□ Not employed □ Employed full-time

□ Employed part-time □ Other (please specify) _____

If employed, what is your occupation? _____

13. Your household income is approximately _____ Pakistani Rupees/month

14. Age of onset of initial major depressive episode: _____

15. Number of previous major depressive episodes: _____

Appendix B (Page # 1)

Checklist of Inclusion and Exclusion Criteria

Direction: The following are the inclusion and exclusion criteria for the study, "self-management strategies Pakistani women use for recurrent depression". Please assess each criterion and check (√) the boxes that apply.

Patient's Name: _____
Telephone #: _____
Medical Record #: _____

Inclusion Criteria: The potential participant:

- □ Was born in Pakistan
- □ Is 18 years of age or older
- □ Has had at least two episodes of depression
- □ Is currently a follow-up patient in the outpatient psychiatric clinics of the AKUH
- □ Is aware that she has depression
- □ Can speak Urdu and/or English
- □ Gives permission to access her medical file

Exclusion Criteria: The potential participant

- □ Does not have a bipolar disorder
- □ Is not currently abusing any substance
- □ Is not currently admitted to the psychiatric unit of the AKUH

***Steps to follow prior to submitting this handout to the potential participant who meets all the inclusion and exclusion criteria specified above*:**

If the potential participant can write her name and telephone # on page 2 of this handout then just verbally explain to her that if she is willing to participate she will need to fill out her name and telephone # and put a check mark in the space provided on page #2 and place the completed handout (pages 1 and 2) in the box provided at the reception/information desk of the psychiatric clinic. She can also meet the investigator if available in the clinic, and submit it directly to her.

If the potential participant cannot write her name and telephone # on page 2, please write her name and telephone # on page 2 and verbally explain her that she needs to put a check mark on the space provided on page # 2 and place the completed handout (page 1 and 2) in the box provided at the reception/information desk. She can also meet the investigator if available in the clinic, and submit it directly to her. Thank you

Signature of the Psychiatric Clinician: _____ Date: _____

Appendix B (Page # 2)

The English-Urdu Written Proof of Interest in Participating in the Study

By signing my name (name of the potential participant) _____,

providing a telephone #_____, and making a check mark (√) in the box provided below I show an interest in participating in the study, “strategies Pakistani women use to self-manage their depression” conducted by ANONYMIZED, Ph.D. candidate at the University of Michigan, USA.

□ I am interested in participating in the study so please contact me

Date: _____

Appendix C

The English-Urdu Version of Flyer Describing the Study

Currently ANONYMIZED, a Ph.D. student at the University of Michigan and an Assistant Professor at the Aga Khan University School of Nursing is conducting a study in this psychiatric clinic titled “strategies Pakistani women use to self-manage their recurrent depression”. You can be a part of this study if you: (a) are a Pakistani woman, (b) are 18 years of age or older, (c) are aware that you have depression, (d) had at least two episodes of depression (e) are a follow-up patient in the outpatient psychiatric clinics of the Aga Khan University Hospital (AKUH), (f) can speak Urdu and/or English, (g) give permission to access your medical file, (h) do not have any other mental illness besides depression, (i) are not abusing any substance, (j) are not admitted to the in-patient psychiatric unit of the AKUH, and (k) are willing to be interviewed.

If you are interested in participating in this study, please fill out necessary information in the forms kept in the attached envelop and submit it to ANONYMIZED, if available in the clinic, or place it in the box provided at the clinic reception/information desk.

By participating in this study you can make a major contribution in the life of other Pakistani women with depression. You will also be paid 300 Pakistani rupees for your contribution and time in the study.

Thank you,

Appendix D

Proof of Payment Form

Direction: Please write your name in the space provided (or the investigator will write your name if you cannot write) and make a check mark (√) yourself in the box provided below:

I (name of the participant) _____ agree that I have received 300 Pakistani Rupees ☐ for participating in the research titled "Strategies Pakistani Women Use to Self-manage their Recurrent Depression".

Name of the investigator: _____

Date: _____

Appendix E

Consent Form

Title of the research project:

"Strategies Pakistani Women Use to Self-manage their Recurrent Depression"

Name of the researcher

ANONYMIZED
Ph.D. candidate, University of Michigan, United States of America
Assistant Professor, Aga Khan University School of Nursing

Description of the research

You are asked to participate in a study on what Pakistani women do for their depression, what makes them do what they do, and whether or not they find doing what they do helpful in managing their depression.

This study is important because:

(1) The findings from this study are expected to generate knowledge which will help Pakistani nurses and doctors:
   a. to better understand how Pakistani women manage their depression,
   b. to provide better care for depressed Pakistani women, and
   c. to prevent depression in Pakistani women.

(2) The findings will assist nurses and doctors to develop new and individualized treatment options for women with depression

(3) Other Pakistani women with depression who have and do not have access to health care services are expected to benefit by recognizing and learning various ways of managing depression

Description of human subject involvement

You have a choice to select an interview date from any week-day or at your next clinic appointment date at the Aga Khan University Hospital (AKUH). The interviews will be done in the clinic at the AKUH. If you choose to be interviewed on the day you have an appointment with your doctor the interview time will be set so that it does not interfere with your doctor's appointment time.

On the day of the interview, I will explain to you the study purpose and the study procedure. The study procedures include:

1. Each interview will be about 1-1 1/2 hours so that you and I do not feel rushed to complete the interview.
2. I will ask you questions to meet the study purpose which I have prepared prior to the interview.
3. I will explain to you my role as a researcher compared to a psychiatric nurse. As a researcher, I am interested in understanding your views of what do they do to manage your depression. Any information you will provide in response to interview questions will not be recorded in your medical file; hence, it will not be used for your treatment

purposes. In addition, I am not responsible for changing or modifying any of your treatment plans such as prescribing medications or changing the dose of current medications if any.

4. Each interview will be audio taped.
5. I will take some notes during the interview.
6. You have a choice to speak in Urdu or English or both and to take a break at any time during the interview.
7. You can stop before and during the interview(s) and ask me any questions you may have about the study or procedures related to the study.
8. At the end of the first interview you will be thanked and paid 300 Pakistani Rupees for your contribution and time. You will be requested to acknowledge receipt of money by signing the proof of payment form and/or making a check mark on a proof of payment form which I will immediately sign and date.
9. Depending how much is accomplished in the first interview; you may be selected for second or third follow-up interviews. At the end of follow-up interviews you will be verbally thanked for your time and contribution. There is no monetary compensation for participating in follow-up interviews. You will sign this consent form before we start the interview, if for any reason you cannot or do not want to sign your name but you say that you want to participate in the study then your verbal acceptance to participate in the study will be considered your permission to participate in this research. In this situation, I will write your name, sign my name and date of the interview on this form and you will make a check mark next to your name on the consent form.

Length of human subject participation

Each interview will be about 1-11/2 hours. Depending on how much is accomplished in the first interview, the participants may be asked to perhaps participate in the second interview for completion of data collection. The third interview may be arranged if the investigator would like to seek clarification and understanding of the data so far provided by the study participant. Hence, the total time commitment will range between 3 to 41/2 hours. Since the data collection is done during August, September, October, November, and December, 2005, the interviews are expected to be done during these months.

Risks and discomforts of participation

There are no identified risks or harms for participating in this study; however, the discussion of your experience of depression and its management may result in some emotional response.

Measures to be taken to minimize risks and discomforts

I am an experienced psychiatric nurse, have worked with women with depression, and will make clinical judgments about whether or not it is appropriate to continue the interview. If I make a judgment that we can continue the interview, I will offer you a choice to take a short break prior to restarting the interview.

Expected benefits to subjects and to others

The study may not have any specific, direct benefit to you; except that there might be a chance for you to reflect on how you manage your depression. In addition, you have a choice to

ask for a one-page summary of the research findings either in Urdu or English which I will provide to you after the completion of writing of the research findings. For this you will have to provide your complete home or work mailing address.

Your participation in the study will make a major contribution in generating important information to help health care providers in Pakistan better understand what the depression experience is for some Pakistani women. Moreover, knowledge generated on what Pakistani women do for their depression will help health care providers to incorporate the information in the care of other Pakistani women with depression and help some Pakistani women to self-manage their depression. This would assist Pakistani women with depression to improve their day to day functioning, minimize the effects of depression in their lives, and reduce the risks of future episodes of depression.

Cost to subject resulting from participation in the study

There is no cost involved in participating in the study. You have a choice to participate on the day of your clinic appointment at the AKUH. However, if you choose to be interviewed on any other day and not on your clinic appointment day, you will bear the cost of travel to AKUH.

Payments to subject for participation in the study

You will be paid 300 Pakistani Rupees for your contribution and time at the end of the first interview. If you withdraw from participation before the first interview, you will not be paid 300 Pakistani Rupees.

Confidentiality

The following steps will be taken to ensure confidentiality.

1. Your doctor will not be informed of whether you opted or opted out from participating in the study.
2. A code number and not your name will be used on the information sheets used during the interview
3. You have a choice to use an alias or your real name during the interview.
4. The notes taken during the interview will also be given the same code number as the information sheet.
5. The interview data will be coded so that data are not linked to your name.
6. All study data will be stored in a secure place (i.e., locked cupboard in the investigator's home). Only I will have access to the locked cupboard. For example, audio tapes will only be used for transcriptions and then kept in the locked cupboard. These audio tapes will be destroyed after the completion of writing of this research study report. Similarly, transcripts files on computers will not have any identifiers and will be password protected.
7. The study data will be shared only with the translator(s) for translating the interviews into English, and with the faculty on the investigator's dissertation committee. The translator(s) will sign a confidentiality form prior to translating the interviews into English. However, any records or data obtained as a result of your participation in this study may be inspected by the financial sponsor, Aga Khan University School of Nursing, by the University of Michigan Institutional Review Board, Health, or by the Aga Khan University Ethical Review Committee members.

8. Both audio taped and written materials collected will be destroyed once the study is completed.
9. You will not be identified in any reports on this study.

Situations in which confidentiality will not be maintained

1. If you are at risk of harming yourself or others, confidentiality will not be maintained.
2. If you show behavior that indicates suicidal ideation or increased suicidal ideation, or suicide planning, I, an experienced psychiatric nurse, will conduct a suicide assessment. If there is:
    a. Increased frequency, duration or severity of suicidal ideation with no plan or imminent intent, you will be asked to contact your doctor at the clinic of AKUH before leaving for home.
    b. Indication of suicidal planning, intent, and substance use, you and I will contact your doctor at the AKUH clinic, family member, or friend.
    c. An imminent suicide intent, I will make sure that the doctor at AKUH clinic be informed immediately for your complete psychiatric evaluation, including suicide intent. You will bear the cost of psychiatric evaluation.

Management of physical injury

In the unlikely event of physical injury resulting from research procedures, the Aga Khan University Hospital, Karachi, Pakistan, will provide first aid medical treatment or emergency care. Additional medical care will be provided if the Aga Khan University Hospital determines that it is responsible to provide such treatment. By signing form, you do not give up your right to seek additional compensation if you are harmed as a result of participation in this study.

Availability of further information

If significant new knowledge obtained during the course of this research which may relate to your willingness to continue participation you will be informed of this knowledge.

Contact information

Researcher Name: ANONYMIZED
Pakistan Home Telephone
Email:
Faculty Advisor Name: ANONYMIZED
Office Telephone # in USA:
Email:

Required IRB contact information

Should you have any questions regarding your rights as a research participant, please contact:

1. Institutional Review Board, ANONYMIZED, 540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210
   Telephone #:
   Fax:
   Email:
2. Aga Khan University Ethical Review Committee
   ANONYMIZED

Email:

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Telephone
Fax:
Email:

Voluntary nature of participation

Your participation in this project is voluntary. Even after you sign the informed consent document, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise be entitled.

Documentation of the consent

One copy of this document will be kept together with the research records of this study. Also you will be given a copy to keep.

Audio Recording of subjects

An audio-recoding device (tape-recorder) will be used during the interviews. Audio taped materials collected during the interview will be destroyed once the study is completed.

Please sign below if you are willing to have the interview(s) audio taped. You will not be able to participate in this study if you are not willing to have the interview recorded.

Signature/Check mark (√) **Date**

Consent of the subject

"I have read or been informed of the information given above. ANONYMIZED has offered to answer any questions I may have concerning the study. I hereby voluntarily consent to participate in the study. I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws."

Printed Name **Consenting signature/Check mark (√)** **Date**

Researcher Name **Signature** **Date**

Appendix F

Set of Borrowed Categories and Sub-categories

#	Categories	Sub-categories
1.	Depression	Personal experience
2.	Influencing Factors	Personal factors
		Illness factors
		Provider factors
		Social factors
		Interpersonal factors
		Cultural factors
		Religious/spiritual factors

3.	Self-management Strategies	Types
		• Similarities in types of strategies used for depression
		  ○ Management
		  ○ Prevention
		• Differences in types of strategies used for depression
		  ○ Management
		  ○ Prevention

		Frequency
		Strategies for specific symptoms
		Decision making • Use strategies • Do not use strategies
4.	Perceived effectiveness	Helpful strategies for depression • Management • Prevention
		Not helpful strategies for depression • Management • Prevention