Programme for improving mental health care

Inform consent

[Primary Health Care Worker version]

Introduction

Namaste! My name is…….. and along with me are my friends …….. We have come from Transcultural Psychosocial Organization (TPO)-Nepal based in Kathmandu. TPO Nepal works in the field of psychosocial and mental health of people affected by conflict, emergencies and other stressful life events. From the last six years, our organization has been providing psychosocial support to the people affected by conflict, natural disasters, human trafficking, domestic violence and HIV/AIDS. In addition, TPO Nepal has also been conducting several researches on psychosocial and mental health.

Currently, TPO Nepal is implementing **PR**ogramme for **I**mproving **M**ental health Car**E** (PRIME) project in Chitwan district of Nepal, in collaboration with the Dutch INGO HealthNet TPO, and with support of Ministry of Health. The objective of PRIME is to generate world-class research evidence on the implementation and scaling up of treatment programs for priority mental disorders in primary and maternal health care contexts in low resource settings. PRIME is a consortium of research institutions and Ministries of Health in five countries in Asia and Africa (Ethiopia, India, Nepal, South Africa & Uganda), with partners in the UK and the World Health Organization (WHO). PRIME is supported by the UK government's Department for International Development (DFID), and is a six year program which was launched in May 2011. In addition, some aspects of the study are funded by the United States' National Institute of Mental Health (NIMH) "Reducing Barriers to Mental Health Task Sharing" research project (Principal Investigator, Brandon Kohrt, MD, PhD).

Under this program, we are going to conduct a study in Chitwan to understand the psychosocial and mental services available in the health facilities, and to understand the process of identification and treatment of such cases by the health workers. The information from this study will help us to develop a strategy to provide an effective health service for those with psychosocial problems.

One of the activities included within PRIME is training healthcare workers on general psychosocial skills, "Behavior activation", "Motivational Interviewing" and skills for working with families. We would like to know if these trainings and subsequent supervision are helpful and how the training and supervision could be improved. In order to do this, we will be observing health workers participating in the training through role-plays and mock patient counseling sessions. A rating scale called TASC-R (***Task Sharing Competence Rating scale***) has been developed to do this which incorporates the skills that are being trained on and that needs to be used by psychosocial counselors. TPO counselor, you and your peers will be filling up this form for the training evaluation.

Also we will also be recording (some of them video recording) the sessions and this information will be reviewed by the PRIME supervisors, trainers and other researchers to help identify areas that are working well and areas that needs increased attention in training and supervision.

Simultaneously a pre and post test written knowledge evaluation will also be done. You will be provided with a set of questions with number of options and you have to pick up the appropriate answers and circle them. The questions are related with mental knowledge and this evaluation aims to measure the effectiveness of the overall training.

You are being asked to participate in this study because you are a primary care health worker in the study area. Approximately 200 primary care health workers are invited to participate.

Voluntary Participation: Your participation in the study completely relies on your choice. During the interview, if you feel uncomfortable or have difficulty answering any question then, you can stop the interview at any time you wish and give reason for your action, so that we too can learn from that for other interviews.

Procedures: If you agree to be in this study, you will be asked to do one or more of the following:

(1) Participate in a 9-day mental health training. This training will take place in Chitwan. The training includes pre- and post-training assessments of knowledge and attitudes. In addition, the training includes structured role plays that are recorded for research purposes. Participate in implicit association task on a laptop computer. We will periodically contact you for additional assessments. The assessments require less than two hours.
(2) Participate in focus group discussions and key informant interviews to discuss your experience with mental health training and providing mental health services. These discussions will be held in Chitwan, and last 1-2 hours each.
(3) Have your interactions with mental health patients recorded and analyzed for research purposes. This requires no additional time beyond your standard clinical care.

The outcome of all of these activities is to improve the PRIME mental health training program.

Study duration: Maximum time of participation in this research program is two years.

Location: The study will be conducted in primary care settings in Chitwan. We will meet with you in your office in Chitwan or at the training facility for the mental health trainings.

Confidentiality: We would like to assure you that your answer will be kept confidential to the extent possible by law. Your name and other things that describe you (your town name, your office name, any other persons' names you mentioned) will not appear when we discuss the interviews with others outside of TPO-Nepal or publish a summary of the interviews. You will be assigned a unique code number for records disclosed outside of TPO-Nepal, The key to the code will be kept in a locked file in the TPO-Nepal office. Your records may be reviewed in order to meet national, federal or state regulations. Reviewers may include the Nepal Health Research Council, the Duke University Health System Institutional Review Board, and the NIMH. If this information is disclosed to outside reviewers

for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Personal risk: We will discuss about "heart-mind" related issues during the interview. If you feel uncomfortable or difficulty at any time during the interview, you can stop the interview. Similarly, don't be hesitant to ask questions, if you have any. After the interview, if you have any problem please let us know so that we can provide you psychosocial support from a professional psychosocial counselor.

Benefits: You may not benefit directly from this research. This research is designed to learn more about conducting and enhancing mental health services in the health facilities and its result will be used to help such people in future. The information that we collect through this will be an important medium for improving training and supervision of health workers like you.

Ethic: It has been internationally recognized that any study or research should not pose any harm to the respondent in any way. We would like to assure you that we will abide by this value during our study.

Retaining Research Records: The study results will be retained in your research record for at least six years, and up to 10 years, after the study is completed. At that time the research information will be destroyed or information identifying you will be removed from such study results.

Costs of Study Participation: There is no financial cost to participating in this study.

Compensation: You will not be paid for taking part in this study.

What About Research Related Injuries? No injuries are anticipated in the participation of this research. Immediate necessary medical care is available at the Chitwan district hospital in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., Duke Global Health Institute, Chitwan District Hospital, the NIMH, or TPO-Nepal to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact the PRIME research coordinator Mr. Nagendra Luitel (contact information provided below). Duke University, Duke University Health System, Inc., Chitwan District Hospital, the NIMH, TPO-Nepal, the principal investigators, and study staff assume no responsibility for injuries occurring during travel to or from research or treatment activities.

What About My Rights to Decline Participation or Withdraw From The Study? Participation in this research is completely voluntary. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits

to which you are entitled, and will not affect your access to health care or treatment at TPO-Nepal. If you do decide to withdraw, we ask that you contact the research coordinator (contact information provided below) or the offices of TPO Nepal (contact information provided below). We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Whom Do I Call If I Have Questions or Problems? For questions about the study, or if you have problems, concerns, questions or suggestions about the research, contact the research coordinator (contact information provided below) or the executive manager of TPO Nepal. Suraj Koirala (contact information provided below). Dr. Brandon Kohrt, the principal investigator of the NIMH study, can be contacted at +1-919-681-7516.

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For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at +01 (919) 668-5111 or the Nepal Health Research Council.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have

been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Are you ready to participate?
Yes……..1
No……..2

If yes

_____ _____ _____
Signature of Subject Date Time

_____
Contact Phone Number for Subject

_____ _____ _____
Signature of Person Obtaining Consent Date Time

1. If interview will occur at a location other than your place of work or home, do you voluntarily consent to travel to the location?
   □ Yes □ No □ N/A

2. If the interview will occurred at a location other than your place of work or home, will you travel beyond the level of your normal daily activity?
   □ Yes □ No □ N/A